Erin Herlihy

Attached please find additional documents submitted in support of Association of Washington Business' comment letter.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS, NORTHWEST PULP & PAPER ASSOCIATION, AMERICAN FOREST & PAPER ASSOCIATION, GREATER SPOKANE, INC., and FOOD NORTHWEST, Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, in his official capacity as Administrator of the U.S. Environmental Protection agency, Defendants.	Civil Action No. 23-cv-3605

COMPLAINT

Plaintiffs Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane, Inc., and Food Northwest hereby allege as follows:

I. Introduction

1. This is a challenge to a final rule promulgated by the U.S. Environmental Protection Agency (EPA) imposing water quality standards (WQS) on the State of Washington that are so stringent that compliance cannot even be measured, much less achieved. EPA arrived at these impossible standards by populating the variables in the relevant standards-setting formula with values that are unscientific, conflict with EPA guidance, and have no basis in real-world data. Among other errors, EPA treated a small and speculative subpopulation of tribal subsistence fishers as the "general population," even though its own guidance distinguishes between the

general population and highly exposed subpopulations when calculating these standards. To justify that assumption, EPA purported to give effect to tribal treaties that EPA has no reason—or legal authority—to interpret. EPA compounded that error by relying on an assumption about that subpopulation's rate of fish consumption that the agency *admits* is inconsistent with present-day realities. And EPA substituted its own preferences for Washington's in selecting an acceptable cancer risk level for certain chemicals—even though Washington's policy choice was fully consistent with EPA's guidance. In adopting these flawed inputs, EPA reversed its own prior determination—made just a few years earlier—that these inputs were *unlawful* and based on improper, nonscientific concerns involving tribal rights. EPA cited no new scientific evidence to justify its about face. In the end, EPA's arbitrary assumptions produced absurd standards that fall below even background levels of the relevant pollutants in many water bodies, rendering Washington's communities and businesses powerless to comply. EPA added insult to injury by justifying the rule in part using a flawed economic analysis that purported to find the standards are *cost-free*. Because reasoned decisionmaking requires far more than that, this Court should vacate the 2022 rule.

2. The Clean Water Act (CWA) "anticipates a partnership between the States and the Federal Government, animated by a shared objective: 'to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'" *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. § 1251(a)). This "program of cooperative federalism," *New York v. United States*, 505 U.S. 144, 167 (1992) (citation omitted), tasks the States with developing water quality standards and the EPA with issuing guidance and reviewing state standards for consistency with the CWA and its implementing regulations. If EPA determines that a State's

standards are inconsistent with the CWA, it must conduct its own analysis and promulgate federal standards that comply with the statute's requirements.

3. In August 2016, the State of Washington submitted a set of water quality standards to EPA after an extensive process of scientific analysis and public input. Washington used a "fish consumption rate" higher than EPA's national recommendation and pollutant-specific "cancer risk levels" within the recommended range set out in EPA's longstanding guidance. After analyzing these inputs, Washington developed target concentrations for the pollutants at issue.

4. In November 2016, EPA partially disapproved Washington's water quality standards. EPA based this decision not on reasonable interpretations of the CWA or its implementing regulations, however, but on a novel legal theory with sweeping implications: That EPA had the authority to interpret treaties between the United States and tribes located in Washington, and that "harmonizing" its interpretation of those treaties with the CWA required EPA to reject some of Washington's standards.

5. Pursuant to this theory, EPA treated "tribal subsistence fishers" as the "target general population" rather than as a highly exposed subpopulation; required a more stringent "cancer risk level" for a key pollutant than the State deemed appropriate; and imposed federal water quality standards that were as much as 25 times more stringent than the State's. In fact, EPA's standards for polychlorinated biphenyls (PCBs) were so stringent that modern technology cannot even detect the pollutant at EPA's selected level.

6. In 2019, after receiving a petition for reconsideration by a coalition of Washington businesses and others (some of which are Plaintiffs here), EPA revisited its decision and reversed course, approving the State of Washington's August 2016 proposed standards, finding them to be scientifically sound and protective of human health and the environment, and withdrawing the

November 2016 federal standards that EPA had imposed on the State. EPA acknowledged that its prior tribal rights theory had no basis in the CWA or EPA regulations, and reaffirmed its position that States have primary responsibility to make risk-management decisions in setting water quality standards.

7. In 2022, however, EPA reversed its reversal, returning to and relying on much of the same discredited rationale of the November 2016 EPA rule and re-imposing the federal standards on Washington, claiming that the State's standards were not based on sound science. In reality, EPA's 2022 decision relied on its unsupported and unlawful tribal-rights rationale. Despite commenters' identification of the serious flaws with EPA's approach in a round of notice and comment, EPA offered no further justification for its asserted tribal-rights authority, and did not explain adequately why EPA's rejection of that authority in 2019 was no longer correct. In support of its impossibly stringent 2022 standards, EPA offered an economic analysis asserting that the 2022 rule imposed *no costs* on regulated parties, including small entities, because the State's role in complying with the federal standards through the permitting process made estimating those costs "highly speculative."

8. In reality, EPA's 2022 rule imminently threatens severe injuries to regulated parties in Washington—including many of Plaintiffs' members—by imposing pollutant concentration thresholds that are unduly burdensome and, by all accounts, impossible to measure and achieve using available detection and treatment technologies. As a direct result of EPA's unlawful action, Plaintiffs' members will incur billions of dollars in additional compliance costs, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's longstanding prior policies.

9. As alleged in greater detail below, EPA's 2022 rule is unlawful for a number of independent reasons.

10. *First*, EPA's abrupt, unexplained, and complete reversal of the 2019 rule in its 2022 decision is arbitrary and capricious and violates the Administrative Procedure Act (APA). Less than three years after expressly disclaiming the tribal-rights rationale for selecting a high consumption subpopulation as a target general population, an unreasonably high fish consumption rate, and a more stringent cancer risk level, EPA's 2022 rule changed tack by finding that the 2019 standards were not based on sound science and, relying on this baseless rationale, imposed unduly stringent, and unnecessary, federal standards. In doing so, EPA failed to explain or demonstrate why the 2019 rule was not based on sound science or was not sufficiently protective of human health and the environment; despite bald assertions to the contrary, EPA's 2022 rule still relies on its groundless tribal-rights rationale. Agencies may abandon prior positions and adopt new ones so long as the change is "reasonable and reasonably explained." *Biden v. Texas*, 142 S. Ct. 2528, 2543 (2022). Because EPA's 2022 rule is neither, it violates the APA.

11. *Second*, EPA's 2022 rule violates the APA by relying on a risk analysis that departs from the agency's own longstanding guidance. Rather than analyze risk based on Washington's population, EPA considered tribal subsistence fishers as the target general population in setting the federal standards—an analytical choice with no basis in law that does not reflect population realities and has no relation to the sound science requirement that EPA purported to apply in disapproving Washington's standards. Based on this improper assumption, EPA then triple-counted the need to protect its chosen target general population by: (1) failing to consider that anadromous fish such as salmon have lower pollutant concentrations than freshwater or estuarine fish; (2) setting an unsupported and unreasonably high fish-consumption rate of 175 g/day; and

(3) choosing a more stringent cancer-risk level than even that recommended by EPA's guidance—which remains in force.

12. *Third*, EPA's 2022 rule further violates the APA by imposing a target concentration level for PCBs that is unmeasurable and unworkable. As EPA was forced to admit, its PCB limit of 7 parts per quadrillion (or 0.00007 micrograms per liter) is so low that modern technology literally cannot detect or measure the pollutant at EPA's selected concentration. Background PCB levels in many Washington waters already exceed this standard. Yet EPA expects regulated parties to comply with this limit through as-yet-unknown technologies at enormous expense. That is arbitrary and capricious, and it violates the APA.

13. *Fourth*, EPA's economic analysis in support of the 2022 rule came to the incredible and implausible conclusion that its impossible target level for PCBs imposes *no costs* on regulated parties, despite receiving ample evidence to the contrary from those parties. For an administrative agency to estimate unduly low costs is one thing; but to say a regulation imposes no costs at all is astounding. Despite proceeding to impose the federal standards for PCBs and scores of other pollutants, EPA asserted that the costs of that approach were too "speculative" to evaluate before forcing Washington and regulated parties to comply. But Washington regulators are already compelling the City of Spokane to comply, generating costs of around $19 million per gram of PCB removal. Further, contrary to EPA's view, EPA should consider costs when setting water quality standards under these circumstances. EPA's mistaken legal premise is itself reason to vacate and remand. And when an agency performs a cost-benefit analysis, that analysis must be reasonable. EPA's is not, and that violates the APA.

14. *Fifth*, EPA's 2022 rule is unreasonable in light of the Regulatory Flexibility Act (RFA) for much the same reasons. Like its decision not to assess costs at all, EPA failed to perform

any regulatory flexibility analysis. It failed to do so despite the rule's evident impact on small entities, instead certifying that costs would flow not from the 2022 rule but from Washington's permitting decisions. But it is the 2022 rule that overrode the 2019 standards, forcing regulated parties, including small entities, to comply with an impossibly low limit, and EPA was required to consider economic impacts on small entities when issuing its federal standards. That failure undermined the notice and comment process, and it is arbitrary and capricious.

15. *Sixth*, EPA's 2022 rule exceeds the agency's statutory authority under the CWA. States retain primacy in developing water quality standards, with EPA authorized to step in only when "necessary." Given Washington's protective standard and sound scientific basis for those standards under longstanding regulatory guidance, imposing federal criteria was unnecessary. Moreover, EPA's claimed authority to interpret tribal treaties with the United States and to use its own interpretation to impose more stringent requirements on the States has no basis in the CWA, its implementing regulations, or longstanding EPA policy. Recognizing this fact, EPA only *later* issued a proposed rule to codify its supposed tribal-rights authority into law. But that approach is neither required, nor authorized, by the CWA.

16. For these reasons and more, the Court should vacate EPA's unlawful 2022 rule and allow Washington's water quality standards to go into effect by operation of law.

II. Parties

17. Plaintiff Association of Washington Business (AWB) is a non-profit association headquartered in Olympia, Washington, that represents nearly 7,000 businesses with over 700,000 employees, approximately one-quarter of Washington's workforce. 90% of its members are small businesses employing fewer than 100 people, and many of its members are subject to CWA National Pollutant Discharge Elimination System (NPDES) permitting requirements administered by the Washington Department of Ecology (Ecology) under EPA supervision. AWB represents

its members' interests on state and federal policy issues, including environmental stewardship, water resources, climate change, and land use, as a key part of its mission. As relevant here, AWB and its members directly participated in the formulation of the human health criteria developed by Ecology and disapproved by EPA, and AWB commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

18. Plaintiff Northwest Pulp & Paper Association (NWPPA) is a trade association headquartered in Olympia, Washington, that represents 12 members in the paper products industry employing over 10,000 people at pulp and paper mills in Washington, Oregon, and Idaho. Many of its members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. NWPPA represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, NWPPA and its members actively participated in Ecology's development of the human health criteria disapproved by EPA, including through the Governor's Informal Advisory Group, and commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

19. Plaintiff American Forest & Paper Association (AF&PA) is a trade association headquartered in Washington, D.C., that represents member companies that make about 87% of the pulp, paper, paper-based packaging, and tissue products made in the United States, including in Washington. The forest products industry accounts for approximately 5% of the total U.S. manufacturing GDP, manufactures about $350 billion in products annually and employs about 925,000 people. AF&PA membership includes small businesses employing fewer than 100 people, and several AF&PA members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. AF&PA represents its members' interests on

legislative and regulatory issues at the federal and state level, including environmental and energy policy, as a key part of its mission. As relevant here, AF&PA and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

20. Plaintiff Greater Spokane, Inc., is a non-profit corporation headquartered in Spokane, Washington, that represents hundreds of businesses in the greater Spokane area. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Greater Spokane represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, Greater Spokane and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

21. Plaintiff Food Northwest is a trade association headquartered in Portland, Oregon, that represents over 350 members in the food-processing industry located in Washington, Oregon, and Idaho. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Food Northwest represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. Food Northwest's members will be required to expend millions of dollars in an effort to comply with the challenged rule, which sets an impossibly high standard.

22. Defendant U.S. Environmental Protection Agency is an executive department of the United States.

23. Defendant Michael S. Regan is the Administrator of the U.S. Environmental Protection Agency and the official charged by statute with administering the CWA. *See* 33 U.S.C. §§ 1313, 1361. Defendant Regan is named in his official capacity only.

III. Jurisdiction and Venue

24. This action arises under the CWA, 33 U.S.C. §§ 1311 *et seq.*, the APA, 5 U.S.C. §§ 500 *et seq.*, the RFA, 5 U.S.C. §§ 601 *et seq.*, and EPA rules and regulations.

25. This Court therefore has jurisdiction under 28 U.S.C. § 1331.

26. Plaintiffs have associational standing to bring this suit on behalf of individual members who have standing because their members' individual participation is not required and because the issues in this case are germane to Plaintiffs' organizational missions. Plaintiffs' individual members include holders of and applicants for NPDES permits issued by Ecology under EPA supervision, are subject to CWA permitting requirements and the unlawful water quality standards imposed by the challenged EPA rule, and will, as a result of the challenged EPA rule, incur additional compliance costs, bear additional fees and expenses associated with applications for permits and variance development that would otherwise have been unnecessary, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's prior policies.

27. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants EPA and Regan reside in this judicial district, and no real property is involved in this action.

IV. Allegations

A. The CWA

28. The Clean Water Act requires States to adopt water quality standards regulating discharges of pollutants into navigable waters.

29. Water quality standards incorporate the "designated uses" for the water body at issue (*e.g.*, supporting aquatic life or recreational use) and the "water quality criteria" necessary to

protect those uses, which are typically specified as the maximum concentration of a pollutant that may be present in the water. 33 U.S.C. § 1313(c)(2)(A); *see also* 40 C.F.R. §§ 131.3(b), 131.11(a).

30. Water quality criteria include human health criteria representing specific levels of chemicals or conditions in a water body that are not expected to cause adverse effects to human health. Such criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 C.F.R. § 131.11(a)(1).

31. States must periodically submit proposed water quality standards to EPA for review and approval. 33 U.S.C. § 1313(c).

32. To guide States in promulgating such standards, EPA publishes criteria recommendations for States to consider when adopting water quality criteria for particular pollutants based on "the latest scientific knowledge." 33 U.S.C. § 1314(a). Among other pollutants, EPA has published criteria recommendations for PCBs.

33. States may, but are not required to, adopt criteria recommendations identical to EPA's federal criteria. They also may adopt criteria modified to reflect site-specific conditions, or other scientifically defensible methods. 40 C.F.R. § 131.11(b)(1).

34. This case principally concerns Washington's water quality standards for PCBs—"a group of man-made organic chemicals consisting of carbon, hydrogen and chlorine atoms." EPA, Learn About Polychlorinated Biphenyls (Apr. 12, 2023), https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls. For much of the twentieth century, PCBs were used in hundreds of industrial and commercial applications, including in electrical equipment, as plasticizers in paints, plastics, and rubber products, and in pigments, dyes, and carbonless copy paper. *Id.*

35. In 1979, Congress banned PCBs in the Toxic Substances Control Act (TSCA). While no longer commercially produced in the United States, however, PCBs may still be present

in products and materials—including in common items like electrical equipment, cable insulation, caulking, and floor finish—that were produced before the 1979 PCB ban. PCBs remain present in air, water, and soil.

36. PCBs have been well studied for both their carcinogenic and non-carcinogenic effects. EPA has never recommended that States adopt a water quality criteria permitting zero PCBs, rejecting that level as "not . . . attainable." EPA, Ambient Water Quality Criteria for Polychlorinated Biphenyls vii (Oct. 1980), https://www.epa.gov/sites/default/files/2019-03/documents/ambient-wqc-polychlorinatedbiphenyls-1980.pdf.

37. In 2000, EPA published guidance—"EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000 Methodology)—that "is used in the development of EPA's recommended criteria and offered as guidance for states and tribes in developing their own criteria." EPA, Human Health Water Quality Criteria and Methods for Toxics (Oct. 2, 2023), https://epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics. The 2000 Methodology recommends specific inputs to the formulas used in determining human health criteria for particular pollutants.

38. Those inputs include the cancer risks associated with the presence of a particular pollutant in surface water. In evaluating carcinogenic effects, EPA recommends a formula with, as relevant here, two major sub-inputs: (1) cancer risk level (CRL), an excess lifetime cancer risk in the population used to derive an acceptable concentration of a pollutant in water; and (2) fish-consumption rate (FCR), a measure of the amount of fish consumed by the target general population on average per day over a lifetime. EPA also considers as other sub-inputs exposure through the ingestion of contaminated surface water and a relative source contribution—the percentage of a reference dose (the amount of a chemical that a person can ingest every day for a lifetime that is

not anticipated to cause harmful noncancer health effects) to be attributed to ambient water and freshwater and estuarine fish consumption. EPA, Water Quality Standards Handbook, Chapter 3, § 3.3.1 (2014), http://www.epa.gov/wqs-tech/water-quality-standards-handbook.

39. The 2000 Methodology provides that human health criteria "based on a 10^{-5} [cancer] risk level"—*i.e.*, the acceptable pollutant concentration should reflect a probability of no more than one additional case of cancer in a population of one hundred thousand—"are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level." 2000 Methodology 1-12.

40. The 2000 Methodology further specifies that "[t]he default fish consumption value for the general adult population . . . is 17.5 grams/day, which represents an estimate of the 90th percentile consumption rate for the U.S. adult population," and is a default value "chosen to be protective of the majority of the general population." 2000 Methodology 1-12.

41. The 2000 Methodology acknowledged, however, that these choices were not entirely scientific decisions. While "[s]ome decisions" for relevant inputs to the human health criteria formula "are more grounded in science," EPA explained, "others are more obviously *risk management* decisions (such as the determination of default fish consumption rates and cancer risk levels)." 2000 Methodology 2-4 (emphasis added).

42. States are required to propose water quality standards pursuant to 33 U.S.C. § 1313(c)(1).

43. If EPA determines that a State's proposed standards satisfy the CWA's requirements, "such standard[s] shall thereafter be the water quality standard[s] for the applicable waters of that State." 33 U.S.C. § 1313(c)(3).

44. The CWA thus gives States primary responsibility for establishing water quality standards and regulating their waters, and EPA may step in only if it determines that a State's water quality standards are inconsistent with the Act. 33 U.S.C. § 1313(c)(3).

45. If a State fails to adopt standards that meet the Clean Water Act's requirements and EPA "determines that a revised or new standard is necessary to meet the requirements" of the Act, EPA must "promptly prepare and publish proposed regulations setting forth a revised or new water quality standard." 33 U.S.C. § 1313(c)(4)(B). EPA's federal standards must be "in accordance with the applicable requirements" of the Act and, as with all agency action subject to the APA, must involve reasonable analysis, arrive at a reasonable result, and be reasonably explained. *Id.* § 1313(b)(1); *Biden*, 142 S. Ct. at 2543.

46. Whether ultimately adopted as state or federal standards, approved water quality standards are used to set effluent limits in the permits that dischargers must obtain to discharge pollutants from a point source into waters covered by the CWA. 33 U.S.C. § 1342; *see* 40 C.F.R. § 122.44(d)(1).

47. Under regulations issued by EPA, States may also seek a variance from approved water quality standards—the so-called "base" water quality standards—if compliance with such standards is shown to be infeasible. *See* 40 C.F.R. § 131.14. But EPA and States with delegated authority rarely grant variances. Indeed, Washington State has never been granted a variance. EPA may approve a variance only if the State can demonstrate that compliance with the base water quality standards is not feasible for one of several enumerated reasons. *Id.* §§ 131.10(g), 131.14(b)(2)(i)(A). Moreover, "new sources are ineligible for variances from performance standards," which are "potentially available" only "to existing sources." *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 112 (D.C. Cir. 1987). Even once granted, a variance provides only

a narrow, time-limited exemption from the base water quality standards, applicable to specific pollutants and to specific dischargers or a particular water body. 40 C.F.R. §§ 131.3(o), 131.14(a).

B. Washington's 2016 Water Quality Standards

48. In 2015, EPA determined that updated human health criteria (HHC) were "necessary" to protect Washington residents and invoked its authority to establish new federal water quality standards. 80 Fed. Reg. 55,063, 55,066 (Sept. 14, 2015). EPA proposed criteria for 99 CWA-listed toxic pollutants, including PCBs. *Id.* at 55,067. The agency calculated these standards using an FCR of 175 g/day and a CRL of 10^{-6} for all chemicals, including PCBs. *Id.* at 55,067–68. This FCR far surpassed the 2000 Methodology's FCR of 17.5 g/day; EPA adopted this higher value because it stated that 175 g/day reflected the "95th percentile consumption rate of surveyed tribal members." *Id.* at 55,067. EPA's chosen CRL of 10^{-6} was an order of magnitude more stringent than the 2000 Methodology's CRL for PCBs; EPA adopted this more stringent value only by mischaracterizing its own Methodology as requiring it. *Compare* 81 Fed. Reg. 85,417, 85,420 & n.10 (Nov. 28, 2016) ("Criteria based on a 10^{-5} risk level are acceptable . . . ."), *with id.* at 85,427 ("EPA issued its 2000 Methodology, which states that when promulgating water quality criteria for states and tribes, EPA intends to use the 10^{-6} cancer risk level, which reflects an appropriate risk for the general population.").

49. In August 2016, before EPA finalized its proposed federal standards, Washington adopted its own HHC following, in EPA's words, "an extensive public process." *Toxic Substances—WAC 173-201A-240*, Wash. State Legislature (2019), https://apps.leg.wa.gov/wac/default.aspx?cite=173-201a-240; 87 Fed. Reg. 69,183, 69,187 (Nov. 18, 2022). In all, the State's Department of Ecology promulgated 188 new criteria. The State used its discretion to make risk management decisions for its waters by incorporating several of EPA's proposed inputs, including

the unusually high FCR and CRL, while using a different CRL level of 10^{-5} for PCBs. *Toxic Substances—WAC 173-201A-240*, *supra*, at tbl. 240 & nn.B, E.

50. In 2016, EPA approved 45 and disapproved 143 of Washington's HHC, finding they were not adequately supported by sound science. 81 Fed. Reg. at 85,419. Specifically, EPA rejected the State's PCB standards because it erroneously concluded that any CRL below 10^{-6} for that chemical would be insufficiently protective. When paired with the State's inflated fish consumption rate, these inputs produced a remarkably low (and therefore stringent) PCB target level (7 parts per quadrillion, or 7 x 10^{-6} micrograms per liter). *Id.* at 85,431.

51. EPA's November 2016 rule acknowledged that its 2000 Methodology authorizes a 1.0 x 10^{-5} CRL (close to, and in reality, due to the theoretical nature of these values, indistinguishable from the value Washington had used, 2.3 x 10^{-5}), as long as "more highly exposed subgroups"—like "subsistence fishers"—were protected at a 10^{-4} CRL. 81 Fed. Reg. at 85,420 & n.10. But the agency moved the goalposts, defining "tribal subsistence fishers" as the "target general population" and combining it with a 10^{-6} CRL. To exacerbate its error, EPA not only identified the wrong group as the "general population" (it is a gross misuse of the terms of the CWA to designate an extremely small subpopulation as the "general population"), but also used an inflated estimation of that population's fish consumption rate. *Id.*; *id.* at 85,424. In promulgating the 2022 rule, EPA "appl[ied] the same rationale here as the agency articulated . . . in the 2016 federal rule." 87 Fed. Reg. 19,046, 19,054 (Apr. 1, 2022) (noting this point in connection with selection of FCR); *id.* at 19,055 (noting that selected CRL "is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels"). This definitional shift effectively protects the actual general population of Washington at a 10^{-8} risk level—one additional case of cancer in a population of *one hundred million*. Nw. Pulp & Paper

Ass'n Comment Letter on EPA Proposed Human Health Water Quality Criteria for Washington 23, Dkt. No. 2015-1089 (Apr. 1, 2022). There is absolutely no basis under the CWA for EPA to impose on a State a rule with such a risk level; the CWA gives States and tribes discretion whether to adopt such an extremely conservative (and likely unprecedented) standard. 81 Fed. Reg. at 85,420.

52. EPA's only explanation for its change in position is that the 2000 Methodology did not "speak to or envision the unique situation of setting WQS [water quality standards] that cover areas where tribes have treaty-reserved rights to practice subsistence fishing"—even though the Methodology used the phrase "subsistence fishers." 81 Fed. Reg. at 85,424–25. While purporting to disapprove Washington's standards for scientific reasons, EPA in fact predominantly relied on a tribal-rights theory that has no basis in applicable regulations or EPA's longstanding Methodology and is not a scientific consideration.

53. Both the CRL and high FCR rested on EPA's assumption of authority to "harmonize treaty-reserved fishing rights with the CWA." 81 Fed. Reg. at 85,424. The agency decided that even though "[t]he CWA generally assigns to a state the responsibility of determining the designated uses of its waters . . . , through treaties, tribes reserved specific fishing rights . . . including the right to take fish from such waters for their subsistence." *Id.* EPA then construed this "subsistence fishing" right to require that the agency treat tribes as the "target general population." *Id.*

54. According to the U.S. Census Bureau, 1.6% of Washington state's population were American Indian and Alaska Native in 2020. *Race and Ethnicity*, U.S. Census Bureau (2023), https://data.census.gov/profile/Washington?g=040XX00US53#race-and-ethnicity. Not all of these individuals are tribal members, and even fewer fish for subsistence. Moreover, a substantial

number of tribal members who do fish for subsistence likely live on tribal reservation land and fish in whole or in part in tribal reservation waters, which expressly are *not* governed by EPA's WQS or Washington's HHC. *See* 81 Fed. Reg. at 85,422 & n.27 ("This rule applies to waters under the State of Washington's jurisdiction, and not to waters within Indian country"). Thus, EPA's rule applied to all waters in the State and the entire population of Washington—even though likely less than 1% of the population consumes the amount of fish on which the fish consumption rate was based.

55. Shortly after its promulgation, a coalition of Washington businesses and others petitioned EPA to reconsider the 2016 rule. Compl. Ex. 1, Pet. for Rulemaking, *Washington v. EPA*, No. 2:19-cv-00884-RAJ (W.D. Wash. June 6, 2019). The petitioners urged that EPA change course for three reasons: (1) The CWA required EPA to approve state standards that met statutory requirements, as Washington's did, "improperly usurp[ing] the primary role of the state to make risk management decisions"; (2) EPA's new standards were arbitrary and capricious because they would "devastat[e the State's] local communities and businesses"; and (3) the federal criteria offered "no benefit to public health over the Washington-submitted standards." *Id.* at 2–3.

C. EPA's Reconsideration

56. In 2019, EPA approved all but two of Washington's HHC after determining that its partial disapproval had improperly infringed on Washington's authority under the CWA to make its own risk-management decisions based in sound science. Letter from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Wash. Dep't of Ecology 8 (May 10, 2019), https://www.epa.gov/sites/default/files/2019-05/documents/wawqsletter_td_dated_may_2019.pdf ("EPA Approval").

57. Applying the 2000 Methodology, EPA determined that Washington's cancer risk level of 2.3×10^{-5} for PCBs satisfied CWA requirements, was based on sound science, and was

protective of the general population and high-consuming subpopulations. EPA Approval at 21. EPA confirmed that the CWA does not require States to meet or exceed each of EPA's recommended criteria so long as the submission's risk-management decisions are "based on sound science and the resulting criteria protect the designated uses," consistent with the 2000 Methodology. *Id.* at 24.

58. EPA also determined that the partial disapproval had departed from longstanding EPA policy by requiring Washington as a matter of sound science to treat tribal subsistence fishers as the "target general population." EPA Approval at 21–23. As EPA explained, it was "improper and unnecessary" under the CWA and existing regulations to purportedly "harmonize" tribal treaty rights with the CWA under a new theory not found in the statute or EPA regulations. *Id.* at 22–24. EPA further explained that the partial disapproval had relied on an interpretation of treaty rights that "was not consistent with Washington's interpretation of its designed use[s]." *Id.* at 22.

59. In 2020, EPA allowed Washington's approved HHC to go into effect by finalizing its withdrawal of the relevant federal WQS for Washington through notice-and-comment rulemaking. 85 Fed. Reg. 28,494 (May 13, 2020). EPA restated its longstanding position that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." *Id.* at 28,495. EPA explained that because Washington's HHC satisfied all statutory requirements, "the cooperative federalism structure of the CWA" required the agency "to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes." *Id.* at 28,496.

60. In doing so, EPA affirmed its view that "Washington's HHC are based on sound science and are protective of Washington's designated uses." 85 Fed. Reg. at 28,496. EPA noted in response to comments that "some of Washington's HHC are less stringent than the federal HHC,

and some are more stringent." *Id.* As EPA explained, the CWA entitled Washington to make such risk-management decisions because its inputs for doing so were based on sound science. *Id.*

D. EPA's 2022 Rule

61. In 2022, following a change in administration, EPA again reversed its position and proposed to determine that Washington's HHC were not based on sound science and therefore not protective of the designated uses in Washington. 87 Fed. Reg. at 19,051. EPA finalized that determination several months later and imposed federal WQS for Washington nearly identical to those promulgated in EPA's November 2016 rule. 87 Fed. Reg. at 69,183. EPA again noted that federal WQS for Washington do not apply to "waters within Indian country." *Id.* at 69,188 & n.52.

62. In the 2022 rule, EPA purported to rely on science but in fact relied on the same rationale used in the 2016 rule to arrive at the same analytical inputs and similar federal WQS. 87 Fed. Reg. at 69,188–89. Without addressing the contrary findings in the agency's 2020 rule and 2019 approval, EPA once again determined that "tribal subsistence fishers" *must* be treated as the "target general population" when setting the fish consumption rate and cancer risk level in States with tribal reserved treaty rights. 87 Fed. Reg. at 19,054–55 (applying "same rationale" to determine fish consumption rate as 2016 Rule, and emphasizing that as "in EPA's 2016 final rule," "EPA's selection of a 10^{-6} CRL is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels"); *see also* 87 Fed. Reg. at 69,188–90. Specifically, EPA again adopted a 10^{-6} CRL for PCBs and a 175 g/day fish consumption rate. 87 Fed. Reg. at 69,188–90.

63. Relying on these inputs, EPA finalized the extraordinarily low target level for PCBs of 7 parts per quadrillion (0.000007 micrograms per liter). 87 Fed. Reg. at 69,193. Despite insisting that this target level was required by the CWA, EPA acknowledged that the existing detection limit for PCBs under EPA-approved testing methodologies is 170 parts per quadrillion

(0.00017 micrograms per liter), almost 25-times higher than EPA's target level for PCB concentrations. *Id.* at 69,195. Nevertheless, EPA asserted that "it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods." *Id.* at 69,196.

64. EPA also relied on an economic analysis that estimated the 2022 rule would impose no costs at all on permitholders and only $100,000 to $182,000 in administrative costs on the State. 87 Fed. Reg. at 69,195–96. EPA found that it would be "highly speculative to attempt to estimate potential costs" because, for example, the PCB target level is well below existing detection capabilities. *Id.* at 69,195.

65. Finally, EPA certified that the 2022 rule "will not have a significant economic impact on a substantial number of small entities under the [Regulatory Flexibility Act]." 87 Fed. Reg. at 69,196. EPA asserted that it was not required to conduct a regulatory flexibility analysis because "the State will have a number of choices associated with permit writing" while implementing the federal WQS. *Id.*

Count One (All Defendants):

EPA's Unjustified Change In Position Violates The APA.

66. Plaintiffs incorporate by reference the allegations above.

67. Abruptly reversing longstanding policy by disapproving the 2019 standards (which were based on the State of Washington's August 2016 proposed standards) and enacting the 2022 rule based in part on the purportedly scientific need to protect tribal subsistence fishers as the "target general population," EPA changed its position without adequate justification and without considering the reasonable, investment-backed reliance of regulated parties in the State. EPA again failed to offer any valid reason why the sound science standard or any applicable statutory

or regulatory requirements mandated its disapproval and imposition of infinitesimally low values for the federal standards. That unexplained departure is arbitrary and capricious and warrants vacatur of the 2022 rule.

68. The CWA and its implementing regulations enumerate specific requirements for state criteria, including the use of sound science. *See* 33 U.S.C. § 1313; 40 C.F.R. §§ 131.1 *et seq*. None requires, or even mentions, any role for tribal reserved rights in determining the "target general population," fish consumption rate, and cancer risk level in setting and reviewing WQS. EPA has since admitted in a proposed rule that "EPA's existing WQS regulation" and applicable guidance "do[] not . . . explicitly address how WQS must protect tribal reserved rights." 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022).

69. As recently as 2019, EPA has explained to States and regulated parties that "[t]he existence of tribal treaties with reserved fishing rights does not grant the EPA authority to recharacterize a state's designated uses or otherwise skew the federal-state balance of the CWA towards the federal government" and that "[n]othing in the CWA or the EPA's regulations and guidance, including the 2000 Methodology, requires a state to set a FCR based on an estimate of unsuppressed consumption." EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and Other Water Quality Standards Provisions 12, 27 (Apr. 4, 2019), https://www.epa.gov/sites/default/files/2019-04/documents/04042019_cover_letter_approval_of_deq_human_health_criteria_signed.pdf.

70. In 2019 and 2020, EPA reiterated the same view in its decisions approving Washington's August 2016 WQS and withdrawing EPA's November 2016 WQS and explained that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." 85 Fed. Reg. at 28,495.

71. EPA failed to adequately justify or explain its change in position when superseding the existing, 2019 standards with new federal standards, noting only that it was returning in part to the rationale of EPA's November 2016 WQS and that, without explaining why, the agency preferred chemical-specific cancer risk levels to be consistent across pollutants. 87 Fed. Reg. at 69,189. There is no basis in the CWA or implementing regulations to require States to adopt the same cancer risk level for all human health criteria.

72. Tellingly, EPA did not even mention the contrary policy that EPA itself adopted in 2019 and 2020 (which correctly applied EPA's longstanding approach) regarding the role of reserved tribal fishing rights in setting WQS, let alone justify its new policy based on the text, structure, and regulatory history of the CWA in light of the extensive contrary reasoning in its 2019 and 2020 decisions and many prior decisions approving water quality standards in Washington and other States without application of its novel tribal-treaty approach. Instead, EPA purported to rely on a sound-science rationale, although its reversal was based on its novel and unsupported tribal-rights rationale. And when, as here, an agency repeatedly changes its interpretation of a statute, its interpretation should receive little (if any) deference. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987).

73. Moreover, EPA completely failed to acknowledge the reliance interests of States and regulated parties. Instead, as alleged herein, EPA unreasonably asserted that costs to regulated parties would be zero and estimated an absurdly low cost to Washington in implementing the new federal WQS at between $100,000 and $182,000. 87 Fed. Reg. at 69,195–96.

Count Two (All Defendants):

EPA's Risk Analysis Violates The APA.

74. Plaintiffs incorporate by reference the allegations above.

75. EPA relied on a risk analysis to promulgate the 2022 rule that is arbitrary, capricious, and otherwise unlawful in multiple ways in violation of the APA. 5 U.S.C. § 706(2).

76. *First*, as it did in its November 2016 rule, EPA began its analysis with the insupportable conclusion that hypothetical tribal subsistence fishers consuming fish at a speculative "unsuppressed" rate must be considered the "target *general* population for protection, rather than a subpopulation," for "the purposes of setting risk levels to protect the subsistence fishing use." 81 Fed. Reg. at 85,424 (emphasis added); 87 Fed. Reg. at 69,189 ("EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule. . . . As noted in EPA's 2016 final rule for Washington, several tribes in Washington have treaty-reserved rights to fish on waters throughout the State." (footnote omitted)). EPA's choice of FCR for that population necessarily—and unjustifiably—presupposes an "unsuppressed" rate because EPA selected a value well above the 90th percentile of consumption in its survey data. And EPA failed to adequately justify that choice based on sound science, instead merely piggybacking off the "FCR . . . that Washington used in 2016 and that EPA used in its 2016 federal rule." EPA Response to Public Comments, *Restoring Protective Human Health Criteria in Washington* 50, Dkt. No. EPA-HQ-OW-2015-0174 (2022).

77. EPA's position relies on an erroneous understanding of federal duties imposed by reserved tribal rights and is based on speculation, not science or EPA's expertise as an environmental regulator. Specifically, EPA exceeded its authority under the CWA by purporting to interpret the Stevens-Palmer Treaties with the Washington Tribes to impose affirmative obligations on the United States to guarantee "water quality sufficient under the CWA to ensure that tribal members can safely eat the fish for their own subsistence." 81 Fed. Reg. at 85,423.

78. Nothing in the CWA delegates to EPA the authority to interpret treaties between the United States and Indian Tribes, much less to use such treaties to impose affirmative environmental obligations on States and regulated parties. EPA invokes its authority to make an Administrator's Determination, 33 U.S.C. § 1313(c)(4)(B), but that provision is limited to a determination that water quality standards are "not consistent with the applicable requirements *of this Act*"—not with treaties, *id.* § 1313(a)(1)–(3) (emphasis added).

79. EPA points to no other treaty text or statutory provision that is sufficiently clear to support EPA's expansive claim of authority to impose billions of dollars of costs on regulated parties. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2604 (2022) (Congress must have clearly authorized rule that would, among other things, "entail billions of dollars in compliance costs"). The provision that the CWA "not be construed as . . . affecting or impairing the provisions of any treaty of the United States," for example, is not a grant of authority at all; it is merely a rule of construction. 81 Fed. Reg. at 85,422 & n.31 (quoting 33 U.S.C. § 1371(a)). And nothing in that ancillary provision or elsewhere suggests that the treaties may be used as the basis for EPA to set impossible-to-attain water quality standards.

80. Even assuming EPA could interpret the scope of obligations imposed by treaty, it clearly erred in interpreting the Stevens-Palmer Treaties as imposing affirmative regulatory obligations under the CWA. "Whether the Government has expressly accepted such obligations 'must train on specific rights-creating or duty-imposing' language in a treaty, statute, or regulation." *Arizona v. Navajo Nation*, 143 S. Ct. 1804, 1813 (2023) (quoting *United States v. Navajo Nation*, 537 U.S. 488, 506 (2003)). By its plain terms, language in the Stevens-Palmer Treaties reserving rights "of taking fish at usual and accustomed places, in common with all citizens of the Territory" does not impose a duty on EPA to supplant state water quality standards

in order to treat tribal subsistence fishers as the "target general population." *See id.* at 1814 (similar language did not impose affirmative duties with respect to providing water to the Navajo Nation).

81. Moreover, EPA's attempt to "harmonize" its interpretation of the Stevens-Palmer Treaties with the CWA falls well outside the agency's expertise and is not entitled to deference. 81 Fed. Reg. at 85,423 & n.39. EPA cites no statutory authority or established practice authorizing the agency to interpret tribal reserved rights or to take these rights into account when evaluating WQS submitted by the States. Indeed, EPA has since admitted in a notice of proposed rulemaking that "EPA's existing WQS regulation" and relevant agency guidance on methodologies "do[] not . . . explicitly address how WQS must protect tribal reserved rights." 87 Fed. Reg. at 74,365.

82. Perhaps recognizing that this approach is unlawful, EPA contends that it "determined that a 10^{-6} CRL was appropriate independent of treaty rights," 87 Fed. Reg. at 69,189, and that it derived its new inputs based instead on a "finding that Washington's criteria are not scientifically sound," EPA 2022 Response to Public Comments, *supra*, at 50. But EPA expressly conceded "that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule," 87 Fed. Reg. at 69,189, cited no new scientific data to support its return to the rationale for EPA's November 2016 rule, and did not explain how the "science" somehow supported reaching precisely the same number it had previously adopted under a flawed legal rationale. Notwithstanding its reflexive recitation of the sound-science standard, EPA's unsupported tribal-rights rationale was critical to its decision—and it is not a scientific consideration.

83. *Second*, EPA adopted a fish consumption rate for its "target general population" of 175 g/day, that is based on an overly conservative assumption that this amount of fish is consumed every day, for seventy years, a three-fold increase from even the 90th percentile fish consumption

rate of 53 g/day. 87 Fed. Reg. at 69,188–89; 81 Fed. Reg. at 85,426–27. Because EPA arrived at this figure based on speculation rather than sound science, its use renders the 2022 rule arbitrary and capricious.

84. In selecting its fish consumption rate, EPA relied on "heritage tribal consumption reports" estimating fish consumption rates between 63 and 995 g/day under "traditional tribal practices, prior to contact with European settlers." 81 Fed. Reg. at 85,426 & n.53. These reports are inherently speculative estimates of behavior in the absence of real-world data that cannot take the place of the sound science required by the CWA and its implementing regulations.

85. Although purporting to rely on "local and regional FCR surveys," EPA actually disregarded them on the grounds that "[t]here is no local survey of contemporary fish consumption in Washington adjusted specifically to account for suppression, and no survey is a clear representation of current unsuppressed consumption for all tribes in Washington." 81 Fed. Reg. at 85,426. EPA provides no statutory, regulatory, or scientific justification for "adjust[ing]" this undisclosed data to account for "unsuppressed" rates beyond its reliance on speculative "heritage" data. Ultimately, EPA in part defers selection of its fish consumption rate to the Washington tribes, which "have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time." *Id.* That subdelegation is not authorized by statute or regulation and fails to reflect "sound science."

86. In addition, EPA points to Oregon's approved fish consumption rate of 175 g/day as supporting the same rate for the general population in Washington without explaining why one State's choice would be required for setting federal standards in another. EPA's reliance on 40 C.F.R. § 131.10(b) similarly is misplaced, as that provision does not require either EPA or up-stream States to adopt the same or even more stringent water quality standards as downstream

States. EPA also fails to mention, or take into account, that Idaho's more recently approved WQS used a fish consumption rate of 66.5 g/day for the general population. *See* EPA Idaho Approval, *supra*, at 28. And EPA's allusion to "maintaining consistency between the fish consumption values in this rule with Washington's other HHC that are not affected by the rule," EPA 2022 Response to Comments, *supra*, at 26—without any explanation for why such consistency is important enough to override EPA's obligation to base its FCR on sound science—also fails to provide an adequate basis for EPA's decision.

87. *Third*, EPA assumed without justification that anadromous fish species, including salmon, which spend most of their life cycle in non-nearshore ocean waters, have the same pollutant concentrations "as those in inland and nearshore fish." 87 Fed. Reg. at 69,190. EPA failed to consider in setting the FCR that anadromous fish have significantly lower pollutant concentrations than fish that spend the entirety of their life cycles in inland and nearshore waters. The failure to consider this aspect of the problem is material because, as repeatedly emphasized in the sources cited by EPA, salmon are the primary traditional fish food source of tribes in the Pacific Northwest. *See Washington v. Wash. State Com. Passenger Fishing Vessel Ass'n*, 443 U.S. 658, 663 (1979).

88. *Fourth*, EPA failed to explain why it did not use the National Cancer Institute (NCI) method (or EPA's simplified variant of the same method)—a sounder method than EPA's chosen approach—for estimating the FCR. EPA, *National Health and Nutrition Examination Survey* 21–22 (Apr. 2014), https://19january2017snapshot.epa.gov/sites/production/files/2015-01/documents/fish-consumption-rates-2014.pdf. These methods account for the reality that most people do not eat the same amount of fish every day over their entire lives. *Id.* If EPA chose not to adjust the numbers this way, as it has acknowledged that it should, the agency should have justified that

choice. It failed to do so. *See id.*; 87 Fed. Reg. at 69,185–86 (discussing the FCR data from 2003 through 2010 without discussing the newer NCI methodology in EPA's FCR publication in 2014); 81 Fed. Reg. at 85,426 (same); EPA Response to Public Comments, *Restoring Protective Human Health Criteria in Washington* 159–60, Dkt. No. 2015-0174-0427 (2016) (explaining the FCR calculation without mentioning the NCI method); *id.* at 145–46, 149–52 (same); *id.* at 174 (acknowledging a commenter's suggestion that EPA use the NCI method to process the fish consumption data). Using the NCI method would have lowered the FCR for the 2022 rule. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, at 21–22.

89. *Fifth*, EPA triple-counted its unwarranted assumptions by selecting an irrational chemical-specific CRL of 1×10^{-6} for PCBs based on the purported need to protect reserved tribal fishing rights, although that consideration was already reflected in the selection of subsistence fishing communities as the "target general population" and the adoption of an inflated, counterfactual FCR. 87 Fed. Reg. at 69,189; 81 Fed. Reg. at 85,427. EPA offers no scientifically defensible rationale for overriding Washington's CRL of 2.3×10^{-5} for PCBs—a level deemed sufficient in EPA's own 2000 Methodology—and instead relies on the unreasonable and erroneous tribal-reserved-rights rationale described above. EPA's efforts to disclaim reliance on this rationale are incompatible with what it actually did in the 2022 rule.

90. EPA asserted that Washington's selected CRL was not sound because it purportedly failed to account for carcinogenic health effects. But consistent with the 2000 Methodology, Washington's CRL is protective of the general population's consumption rates within a range of risk factors from 10^{-6} and 10^{-5}, while protecting tribal consumption rates at better than 10^{-4}. EPA points to no *science* mandating a 10^{-6} CRL—and it has no authority to second-guess Washington's

risk-management decision. *See* 2000 Methodology 2-4 (describing choice of CRL within range as principally a risk-management decision).

91. EPA's unscientific and *ultra vires* rationale is arbitrary and capricious.

Count Three (All Defendants):

EPA's Unreasonable PCB Standard Violates The APA.

92. Plaintiffs incorporate by reference the allegations above.

93. EPA admits that the 2022 rule's 7 parts-per-quadrillion (ppq) limit is neither measurable nor attainable with current technology.

94. *First*, EPA lacks any tools to measure whether 7 ppq of PCBs exist in a given water sample. As the agency admits, "EPA has completed a multi-laboratory validation of a new analytical method for PCBs (method 1628) that has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method, but still well above either the criterion currently in place or EPA's criterion." 87 Fed. Reg. at 69,195–96. EPA has not even hinted that its standard would be measurable with any technology lurking on the horizon, much less any existing pilot projects.

95. *Second*, the standard is unachievable, even with cost-prohibitive control technology. Washington acknowledged in a public presentation that currently installed municipal-treatment systems cannot achieve 7 ppq of PCBs, even with advanced methods like reverse osmosis, activated carbon, or advanced oxidation. *Workshop on PCB Variances for Spokane River Dischargers* 83 (Nov. 14, 2019), https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf. According to a study conducted by AWB, even the highest-performing treatment systems in Washington can reduce PCBs only to 100 ppq. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, Attach. C at 36.

96. *Third*, EPA has not justified its 7 ppq standard in the face of its own chemical regulations. EPA's rules under TSCA allow PCB concentrations of up to 50 ppm in manufactured goods, recycled fluids and used oils, and other items. 40 C.F.R. § 761.20; *id.* § 761.3 ("Excluded PCB products," subsections (1)–(4)). It is arbitrary and capricious to allow 50,000,000,000 ppq concentrations in products in commerce, while requiring other regulated entities to limit PCBs to an infinitesimal 7 ppq level. The inconsistency between these two regulations creates arbitrary and capricious burdens on CWA-regulated entities as compared to TSCA-regulated ones. EPA proffered two reasons for this discrepancy: (1) that TSCA regulations are based on the levels required for chemicals in products instead of surface water that the CWA regulates; and (2) EPA's interpretation that it cannot consider costs in setting CWA water quality standards. EPA 2016 Response Letter, *supra*, at 106; EPA 2022 Response to Public Comments, *supra*, at 109 & n.255. But those explanations do not excuse the agency's failure to grapple with TSCA's effects on PCBs in the environment and the burden that EPA shifts to CWA sources to reduce PCB concentrations below background levels. And EPA's understanding of its duty to consider costs under the CWA is mistaken: EPA *must* consider costs in setting water quality standards.

Count Four (All Defendants):

EPA's Failure To Consider Costs Violates The APA.

97. Plaintiffs incorporate by reference the allegations above.

98. EPA has broad discretion to weigh costs and benefits in implementing its regulatory statutes, and it generally must do so unless the statutory text precludes it. *See Michigan v. EPA*, 576 U.S. 743, 752 (2015). Here, nothing in the Clean Water Act's open-ended directive that the Administrator determine that a new federal standard must be "necessary" to meet the requirements of the Act forecloses consideration of costs and benefits in setting water quality standards. To the

contrary, because such costs affect whether a new standard is "necessary," ignoring compliance costs would be arbitrary and capricious.

99. EPA, however, proceeded on the mistaken legal premise that it could *not* consider such costs in setting water quality standards. EPA 2022 Response to Public Comments, *supra*, at 109 & n.255 (explaining that costs cannot be considered in the "development of water quality criteria such as HHC under the CWA"). Even if the CWA does not require it, EPA at minimum has *discretion* to consider costs. But EPA's mistaken premise led it to ignore costs altogether—or at least to arbitrarily zero them out.

100. Agency action that "stands on a faulty legal premise" is arbitrary and capricious. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985). When an agency erroneously disclaims discretion that it possesses, vacatur and remand is required so that the agency may consider whether and how to exercise that discretion.

101. EPA's standards are especially arbitrary and capricious in light of the enormous costs EPA's criteria would impose on regulated entities. EPA's failure to consider the costs involved blinded the agency to an important aspect of the problem.

Count Five (All Defendants):

EPA's Unreasonable Economic Analysis Violates The APA.

102. Plaintiffs incorporate by reference the allegations above.

103. To the extent EPA did conduct and rely upon an economic analysis, EPA's economic analysis is arbitrary and capricious under the APA. 5 U.S.C. § 706(2).

104. When an agency conducts and relies upon an economic analysis in promulgating a rule, the APA requires that the analysis be reasonable and reasonably explained.

105. EPA conducted an economic analysis in setting Washington's standards. *See* 87 Fed. Reg. at 69,194–96. To the extent EPA relied on this analysis in determining that its proposed standards are "necessary" to meet the Clean Water Act's requirements, EPA's analysis is neither reasonable nor reasonably explained.

106. EPA arbitrarily attributed *no* incremental costs to any major point sources. EPA explained that it did so not because there are no such costs, but because EPA believed it would be too "speculative" to estimate the costs of developing new technologies to measure pollutants at lower levels, even below current levels of detection, or for major facilities to change facility operations and practices to comply with EPA's new standards. The APA does not permit EPA to treat such costs as nonexistent, or to refuse to make any effort to quantify them, merely because the costs present some uncertainty or cannot be precisely quantified.

107. EPA also failed to adequately address commenters' specific cost estimates. Commenters explained that the rule would impose enormous compliance costs, providing specific estimates, and that the standards are unattainable even with cost-prohibitive control technology.

108. Available data indicates that large segments of state waters would qualify as impaired under the CWA for failing to meet the PCB criteria, based on EPA's 2022 standards, and almost every publicly owned wastewater treatment plant in Washington and other dischargers would therefore need to adopt tertiary membrane filtration treatment or other tertiary treatment technology to address PCBs. Notwithstanding this, there are no known combinations of treatments that would actually achieve EPA's PCB criteria.

109. One commenter estimated that the incremental cost for such treatment, including construction costs and operation and maintenance costs, would be between $53 and $82 million for a plant that processes 500,000 gallons of wastewater per day, with a net present value unit cost

of between $106 and $262 per gallon per day. This will amount to a range of compliance costs from nearly $6 billion to over $11 billion just for the major permits identified by EPA. Another commenter estimated costs of a similar magnitude. EPA ignored substantial record evidence by failing to explain why these cost estimates were wrong and by failing to consider the cost implications of lower analytic limits.

110. Pursuant to EPA's 2022 rule, Washington Department of Ecology is already compelling the City of Spokane to spend funds to use a more rigorous testing method to address PCB levels (Method 1668) that purports to accurately measure PCBs in the low parts per quadrillion range. An expansion of the City's wastewater treatment plants to add additional tertiary treatment to address PCBs, the City estimates, would cost $19 million per gram of additional PCB removal.

111. In the face of these crippling compliance costs, EPA's estimate of zero compliance costs is arbitrary and capricious and is evidence that the agency failed to apprehend important aspects of the problem it attempted to address.

Count Six (All Defendants):

EPA's Regulatory Flexibility Act Certification Violates The APA.

112. Plaintiffs incorporate by reference the allegations above.

113. Many of Plaintiffs' members are "small entit[ies]," including "small business[es]" as defined in the RFA and incorporated regulatory definitions promulgated by the Small Business Administration. 5 U.S.C. § 601(3), (6); *see also* 15 U.S.C. § 632(a); 13 C.F.R. § 121.201.

114. EPA was required by law to promulgate the 2022 rule through notice-and-comment rulemaking under the APA. *See* 5 U.S.C. §§ 553, 603(a), 604(a).

115. EPA is a "covered agency" under the RFA subject to additional consultation requirements for engaging in reasoned agency rulemaking. 5 U.S.C. § 609(d)(1).

116. EPA failed to ensure participation by small entities, including small businesses and small governmental jurisdictions, in the comment period for the 2022 rule by noting the potential small-entity impacts of the rule in the notice of proposed rulemaking or taking any steps to notify, directly or indirectly, small entities, including small businesses, of the potential impacts of the proposed rule. *See* 5 U.S.C. § 609(a).

117. EPA failed to comply with the RFA's requirement that "a covered agency" notify the Small Business Administration and convene a small entity impact review panel prior to publishing the proposed 2022 rule. *See* 5 U.S.C. § 609(b).

118. EPA failed to prepare, consider, and publish for comment an initial regulatory flexibility analysis of the compliance costs imposed by the 2022 rule on small businesses and other small entities or of regulatory alternatives that would minimize any significant impact on small entities while achieving the agency's objectives. *See* 5 U.S.C. § 603.

119. EPA failed to prepare, consider, or publish a final regulatory flexibility analysis responding to small-business-related and other small-entity-related comments, justifying the choice to finalize the 2022 rule as opposed to regulatory alternatives with lesser impacts on small businesses, and describing the steps the agency has taken or will take to minimize the economic impact of the 2022 rule on small businesses. *See* 5 U.S.C. § 604.

120. EPA's purported certification that the 2022 rule "will not have a significant economic impact on a substantial number of small entities" because they are "not directly regulated by this rule," 87 Fed. Reg. at 69,196, is invalid, arbitrary and capricious, contrary to the factual record, and insufficient to evade the agency's reasoned-decisionmaking duties under the APA.

121. EPA's purported certification demonstrates that the agency failed to consider the 2022 rule's economic impact on small entities, failed to consider reasonable alternatives that would

have lessened those economic impacts, and failed to explain why the 2022 rule was justified despite those economic impacts, in violation of the APA.

Count Seven (All Defendants):

EPA Exceeded Its Statutory Authority Under The CWA.

122. Plaintiffs incorporate by reference the allegations above.

123. EPA exceeded its statutory authority under the CWA when it concluded that superseding Washington state's standard was "necessary" to meet the requirements of this chapter. 33 U.S.C. § 1313(c)(4)(B). States retain primacy in developing water quality standards. Federal Water Quality Coalition Comment on EPA's Proposal "Restoring Human Health Criteria in Washington" 3 n.6, Dkt. No. EPA-HQ-OW-2015-0174 (May 31, 2022) (collecting authority).

124. The Act's requirements are both procedural and substantive. Procedurally, States must submit timely water quality standards, 33 U.S.C. § 1313(b), after public hearings, *id.* § 1313(c)(1). Substantively, the standards must "consist of the designated uses" for the waters, "water quality criteria" for such uses, and those designations must "protect the public health or welfare, enhance the quality of water . . . tak[e] into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and . . . their use and value for navigation." *Id.* § 1313(c)(2)(A).

125. EPA never raised procedural problems with Washington's standard and it acknowledged that Washington's "designated uses" for its waters "include fish and shellfish harvesting." 81 Fed. Reg. at 85,424.

126. As a substantive matter, EPA exceeded its statutory authority vis-à-vis tribal treaties. The CWA mandates only that its provisions shall not "affect[ ] or impair[ ] the provisions of any treaty of the United States." 33 U.S.C. § 1371(a). From these words, EPA presumes the power to regulate more stringently based on *its own interpretation* of tribal treaties. There are at least

two problems with this approach: EPA assumes interpretive authority over tribal treaties and, based on that, greater regulatory authority for itself. The CWA grants neither. And EPA's power-grab undermines its statutory duty to revise state criteria only when "necessary." *Id.* § 1313(c)(4)(B).

127. EPA's revisions are also not "necessary." 33 U.S.C. § 1313(c)(4)(B). EPA contends only that Washington's criteria should be "set at levels that will adequately protect Washington residents, including tribes." 81 Fed. Reg. at 85,417. But Washington's original rule was extremely protective, setting a technology-forcing 170 ppq PCB standard. *Toxic Substances—WAC 173-201A-240*, *supra*.

128. EPA used nearly the "same inputs to derive its proposed PCB HHC as Washington used, with the exception of the [CRL]." EPA 2022 Response to Public Comments, *supra*, at 116. But the CRL that EPA used in this rulemaking (10^{-6}) exceeded its 2000 Methodology (10^{-4}), which Washington followed. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, at 9. Moreover, States need not even follow every aspect of the 2000 Methodology; it is only guidance and was never promulgated as a rule. Federal Water Quality Coalition Comment, *supra*, at 4. In short, EPA has failed to show that the CWA requires its newly adopted cancer risk level, such that federal standards were "necessary" to displace state standards. EPA's new federal standards are *ultra vires* and defy the CWA's deference to state standards.

Count Eight (All Defendants):

EPA's Failure To Follow Regulations Violates The APA.

129. Plaintiffs incorporate by reference the allegations above.

130. EPA's water quality standards violate the APA's procedural requirements and well-settled principles of administrative law because they fail to follow EPA's own rules for promulgating such standards.

131. Like the Clean Water Act, EPA's implementing regulations authorize EPA to "promulgate a new or revised standard when *necessary* to meet the requirements of the Act." 40 C.F.R. § 131.5(b) (emphasis added). Because no EPA action is "necessary" if existing standards already satisfy the Act's requirements, EPA's authority to promulgate WQS is triggered only if existing state standards are unlawful.

132. As relevant here, Washington must have "adopted criteria that protect the designated water uses based on sound scientific rationale," and Washington must have "followed applicable legal procedures for revising or adopting standards." 40 C.F.R. § 131.5(a)(1)–(2), (6). As EPA itself has explained, "[i]f the EPA finds the state WQS are based on sound science and protect the state's designated uses, the CWA requires the EPA to approve those state WQS." 85 Fed. Reg. at 28,495.

133. In May 2019, EPA concluded that "Washington's HHC are based on sound science and are protective of Washington's designated uses." 85 Fed. Reg. at 28,496. That determination was based on a finding that Washington's HHC were based on already "conservative inputs," which "appropriately balanced risks and resulted in HHC that are based on sound science and are protective of Washington's designated uses, consistent with the rationale provided in Ecology's submittal." EPA Approval at 18.

134. In addition to failing to adequately explain its departure from its prior findings, EPA had no authority to promulgate new regulations. Because the state standards were sufficiently protective, EPA's own regulations forbid it from promulgating more stringent standards.

135. Plaintiffs are therefore entitled to relief under the APA and other applicable law.

Prayer for Relief

136. Plaintiffs pray for an order and judgment:

a. Declaring that EPA violated the APA in finalizing the 2022 rule because its risk analysis, economic analysis, and unattainable PCB water quality standard are arbitrary and capricious; that EPA violated the APA and the CWA by failing to consider costs, to compare the costs to the incremental benefits likely to result, and to consider reasonable alternatives; that EPA violated the APA in finalizing the 2022 rule without analyzing and accounting for its impact on small entities, including small businesses, as required by applicable law, including the APA and RFA; and that EPA exceeded its statutory authority under the CWA and failed to follow its own regulations in disapproving Washington's WQS and promulgating federal WQS based on an invalid tribal reserved rights rationale.

b. Declaring that any attempt to force Washington to implement or enforce the 2022 rule violates the APA and CWA;

c. Vacating and setting aside the 2022 rule;

d. Issuing all other process necessary and appropriate to postpone further implementation of the 2022 rule pending the conclusion of this case;

e. Awarding Plaintiffs their reasonable costs, including attorneys' fees, incurred in bringing this action under 28 U.S.C. § 2412 or other applicable law; and

f. Granting such other and further relief as this Court deems just and proper.

Dated: December 4, 2023

Respectfully submitted,

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Jeff Liu, D.C. Bar No. 1672057
(*pro hac vice* forthcoming)
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS,

1414 Cherry Street, S.E.
Olympia, Washington 98501

NORTHWEST PULP & PAPER ASSOCIATION,

212 Union Avenue, S.E.
Olympia, Washington 98501

AMERICAN FOREST & PAPER ASSOCIATION,

1101 K Street, N.W.
Washington, D.C. 20005

GREATER SPOKANE, INC.,

801 W. Riverside, Suite 200
Spokane, Washington 99201

and FOOD NORTHWEST,

8338 NE Alderwood Road, Suite 160
Portland, Oregon 97220

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

and MICHAEL S. REGAN, in his official capacity as Administrator of the U.S. Environmental Protection Agency,

1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Defendants.

Civil Action No. 23-cv-3605

COMPLAINT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS, et al., Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Civil Action No. 23-cv-3605

NOTICE OF ERRATA

Plaintiffs hereby submit this Notice of Errata relating to the caption on the Complaint (Dkt. 1) and the format of the corporate disclosure certificates (Dkts. 2–6) previously filed in the above-captioned case. Attached as Exhibit A is the corrected caption for the Complaint, which includes residential addresses for all parties as required by Local Civil Rule 5.1(c). Attached as Exhibits B through F are the corporate disclosure certificates required by Local Civil Rule 26.1 in a non-fillable PDF format. As instructed by the Court, Plaintiffs hereby substitute the first page of the Complaint and the corporate disclosure certificates previously filed.

Dated: December 5, 2023

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS, et al., Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Civil Action No. 23-cv-3605

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane, Inc., and Food Northwest hereby move for summary judgment on all claims pursuant to Federal Rule of Civil Procedure 56(a) and Local Civil Rule 7(h). In support of the motion, Plaintiffs rely on the administrative record, *see* Dkt. 38, and the memorandum of points and authorities and declarations filed concurrently with this motion. Plaintiffs respectfully request that the Court grant the motion for the reasons set out in the accompanying memorandum.

Dated: May 13, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to Local Civil Rule 5.3, I hereby certify that on May 13, 2024, I caused the foregoing Motion for Summary Judgment and supporting materials to be served on counsel of record for Defendants via this Court's CM/ECF system.

Dated: May 13, 2024

/s/ Helgi C. Walker
Helgi C. Walker

IN FIN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS, et al., Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Civil Action No. 23-cv-3605

PLAINTIFFS' MEMORANDUM IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(*continued*)

Page(s)

TABLE OF AUTHORITIES
(*continued*)

Page(s)

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Statutes

Regulations

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Other Authorities

TABLE OF AUTHORITIES
(*continued*)

Page(s)

INTRODUCTION

This is a challenge to a final rule promulgated by the U.S. Environmental Protection Agency ("EPA") imposing federal water quality standards ("WQS") on the State of Washington that are so stringent that compliance cannot even be measured, much less achieved. EPA used a permissible formula to set these standards, but it populated the variables in that formula with values that are unscientific, conflict with EPA guidance, and have no basis in real-world data—thereby producing an impossible-to-meet and irrational standard.

Among other errors with respect to the inputs, EPA treated a small subpopulation of tribal subsistence fishers as the "general population," even though its own guidance distinguishes between the general population and highly exposed subpopulations for the purpose of calculating standards. To justify that leap, EPA purported to give effect to tribal treaties that EPA has no expertise, much less authority, to interpret. EPA compounded that error by assuming a rate of fish consumption—one of the key variables in the standard-setting formula—by a subpopulation of tribal subsistence fishers that EPA has conceded is inconsistent with present day realities. EPA selected a consumption rate that amounts to about *fifteen* three-ounce filets of salmon per week, on the unsupported theory that this rate tracks the "unsuppressed" level of consumption by tribal subsistence fishers before contact with European settlers. And EPA substituted its own preferences for Washington's in selecting an acceptable cancer risk level for certain chemicals—even though Washington's choice was consistent with sound science and EPA's own guidance.

Worse still, in adopting these flawed inputs, EPA reversed its own prior determination—made only two years earlier—that these very same inputs were unlawful and based on improper, nonscientific concerns involving tribal rights. EPA cited no new scientific evidence to justify its

about-face. EPA then added insult to injury by justifying the rule in part using a flawed economic analysis that purported to find the standards are entirely cost-*free* for regulated parties.

In the end, EPA's arbitrary assumptions resulted in irrational and unlawful standards that are lower than the background pollutant levels in many receiving water bodies throughout the State, and that are impossible to achieve with available or reasonably foreseeable technologies, rendering Washington's communities and businesses powerless to comply. Because reasoned decision-making requires more, this Court should vacate the 2022 rule.

BACKGROUND

I. Statutory and Regulatory Background

In the Clean Water Act ("CWA" or "Act"), Congress adopted a "policy" of "protect[ing] the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution." 33 U.S.C. § 1251(b). To advance that policy, the Act "anticipates a partnership between the States and the Federal Government," *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992), with States bearing "primar[y] responsib[ility] for creating and revising water quality standards" that reflect "the purpose for which a particular body of water is used," *City of Dover v. EPA*, 36 F. Supp. 3d 103, 108 (D.D.C. 2014).

Water quality standards are central to the CWA's statutory framework because they "set the permissible level of pollution in a specific body of water." *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005). In turn, these standards are implemented through permits issued under the National Pollutant Discharge Elimination System ("NPDES"). The CWA prohibits the "discharge of any pollutant" by "any person" from any "point source" to navigable waters unless authorized by an NPDES permit. 33 U.S.C. §§ 1311(a), 1342. Each NPDES permit sets "specific limits that apply to individual polluters." *Arcadia*, 411 F.3d at 1105; *see also* 40 C.F.R. § 122.44(d)(1).

States bear the primary role in setting these standards, subject to circumscribed EPA oversight. States must periodically propose standards for EPA approval that identify "[1] the designated uses of the navigable waters involved and [2] the water quality criteria for such waters based upon such uses" that "protect the public health or welfare." 33 U.S.C. § 1313(c)(2)(A); *see id.* § 1251(d) (vesting oversight authority in "the Administrator of the Environmental Protection Agency"); *see also* 40 C.F.R. §§ 131.3(b), 131.11(a). Standards "shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation." 33 U.S.C. § 1313(c)(2)(A); *see id.* § 1251(a)(2). The CWA does not dictate precisely how a State must weigh each factor, so long as the resulting standards are protective.

A State's submitted standards take effect if the Administrator finds that the submission "meets the requirements" of the CWA. 33 U.S.C. § 1313(c)(3). To support States in this process, EPA issues recommended criteria for particular pollutants. *Id.* § 1314(a). States, however, are not required to follow EPA's recommendations and may adopt criteria that reflect site-specific conditions, 40 C.F.R. § 131.11(b)(1), so long as they are "based on sound scientific rationale" and "contain sufficient parameters or constituents to protect the designated use," *id.* § 131.11(a)(1).

In addition to its specific criteria recommendations, EPA has also promulgated general guidance to States in setting criteria. In 2000, EPA published its "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" ("2000 Methodology"), which "is used in the development of EPA's recommended criteria and offered as guidance for states and tribes in developing their own criteria." EPA, Human Health Water Quality Criteria and Methods for Toxics (Oct. 2, 2023), https://epa.gov/wqc/human-health-water-quality-criteria-

and-methods-toxics. EPA recommends using a formula that considers, among other things, two major inputs for each pollutant: (1) the cancer risk level ("CRL"), *i.e.*, the excess lifetime cancer risk in the population; and (2) the fish consumption rate ("FCR"), *i.e.*, the daily average measure of freshwater and ocean fish that the general target population consumes. The 2000 Methodology authorized a CRL of 10^{-5} for the general population—a probability of no more than one additional cancer case in a population of one hundred thousand—and 10^{-4} for more highly exposed subgroups like subsistence fishers or sport fishers. 2000 Methodology at 1–12. EPA determined the default FCR that was protective for the general population to be 17.5 grams/day, the 90th percentile consumption rate. *Id.* And EPA explained that while some of these input decisions were "grounded in science," others were "more obviously *risk management* decisions (such as the determination of default fish consumption rates and cancer risk levels)." *Id.* at 2–4 (emphasis added). EPA has not rescinded the 2000 Methodology and continues to rely on it in other actions.

The CWA authorizes the EPA Administrator to override state standards with federal ones only in one of two situations. The Administrator may disapprove state standards and supply federal ones if the State's submission is "not ... consistent with the applicable requirements" of the CWA. 33 U.S.C. § 1313(c)(4)(A). Or, through an "Administrator's determination," the Administrator may *sua sponte* "determin[e] that a revised or new standard is necessary to meet the requirements" of the CWA. *Id.* § 1313(c)(4)(B).

Finally, if compliance is not feasible, States may seek "variances" from EPA-approved standards, which authorize permitting authorities to establish less stringent effluent limits for the period of the variance. 40 C.F.R. § 131.14(a). But EPA and States rarely grant variances; Washington's Department of Ecology has *never* granted a variance. EPA may approve a variance only if the State can demonstrate that compliance with the water quality standards is not feasible

for one of several enumerated reasons. *Id.* §§ 131.10(g), 131.14(b)(2)(i)(A). And the variance process is only available to existing sources, not "new sources." *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 112 (D.C. Cir. 1987). Even if a variance is approved, it is time-limited and narrowly applicable to specific pollutants entering particular bodies of water. 40 C.F.R. §§ 131.3(o), 131.14(a). And variances also are subject to third-party challenges via the CWA's citizen-suit provision. 33 U.S.C. § 1365.

II. Factual Background

This case concerns the State of Washington's water quality criteria for polychlorinated biphenyls, or PCBs—a set of organic chemicals used for much of the twentieth century in common industrial and commercial applications, such as electrical equipment, plastics, and rubber products. *See* EPA, Learn About Polychlorinated Biphenyls (Apr. 2, 2024), https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls. Banned by Congress in the Toxic Substances Control Act of 1976, PCBs may still be present in the environment and found in materials that were produced before the ban.

The water quality standards at issue here arrive at the Court after a winding path before the agency. In 2016, EPA disapproved a number of Washington's water quality criteria—including for PCBs—based on EPA's erroneous premise that the State's already protective inputs were insufficient to protect tribal treaty rights. Four years later, EPA reconsidered its disapproval and permitted Washington's criteria to take effect. In a carefully reasoned decision, EPA found that Washington's standards were grounded in sound science and reflected reasonable risk management decisions. Yet in 2022, in the rule challenged here, EPA again reversed course, reinstating criteria almost identical to EPA's 2016 rule under the "same rationale" that "the agency articulated … in … 2016." 87 Fed. Reg. 69,183, 69,189 (Nov. 18, 2022) (the "2022 rule").

A. Washington's Water Quality Standards and EPA's 2016 Disapproval

Between 2012 and 2016, Washington's Department of Ecology undertook the process of revising its criteria, including for PCBs. While Washington's rulemaking process was ongoing, the EPA Administrator *sua sponte* determined in 2015 that Washington's existing criteria "no longer protect the relevant designated uses of Washington's waters" and proposed federal criteria for Washington, including for PCBs. *See* 80 Fed. Reg. 55,063, 55,066 (Sept. 14, 2015) (invoking power to make Administrator's determination under 33 U.S.C. § 1313(c)(4)(B)). Washington ultimately completed its rulemaking process in 2016 and promulgated 188 new criteria. *See* 87 Fed. Reg. at 69,187; *Toxic Substances—WAC 173-201A-240*, Wash. State Legislature (2019), https://apps.leg.wa.gov/wac/default.aspx?cite=173-201a-240. Exercising its discretion to make risk management decisions, the State used inputs to calculate its criteria that included a CRL of 2.3×10^{-5} for PCBs, and an unusually high FCR that attributed fish consumption levels for high-consuming subpopulations to the general population. *Toxic Substances—WAC 173-201A-240*, *supra*, at tbl. 240 & nn.B, E. Based on these inputs, Washington adopted a highly protective limit for PCBs of 170 parts per quadrillion (ppq) (or 170×10^{-6} micrograms per liter). 81 Fed. Reg. 85,417, 85,431 (Nov. 28, 2016) (the "2016 rule"). A part per quadrillion is 1/1,000,000,000,000,000.

Shortly after Washington promulgated its criteria, EPA finalized most of the proposed federal standards pursuant to the 2015 Administrator's determination. *See* 81 Fed. Reg. at 85,417. "Concurrent with th[e] final rule," the Administrator approved 45 and disapproved 143 of Washington's new criteria. *Id.* As a result, EPA's federal criteria took effect in place of "those [state] criteria that EPA disapproved." *Id*.

EPA's 2016 rule rejected Washington's PCB criterion on the ground that any CRL below 10^{-6} for that chemical would be insufficiently protective. *See* 81 Fed. Reg. at 85,427. EPA's

conclusion ran contrary to its own guidance—the 2000 Methodology's conclusion that a CRL of 10^{-5} would present an acceptable level of risk for PCBs when all other inputs are taken into account. *See* 2000 Methodology at 2–6 ("Adoption of a 10^{-6} *or* 10^{-5} risk level … represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes." (emphasis added)). EPA also adopted an FCR of 175 g/day, which far surpassed the 2000 Methodology's FCR of 17.5 g/day and reflected the "95th percentile consumption rate" of fish not among *the general population*, but among "surveyed tribal members." 81 Fed. Reg. at 85,426. These highly protective inputs yielded remarkable outputs, including a PCB limit of only *7 ppq*—an infinitesimally small number. *Id.* at 85,431.

The 2016 rule acknowledged that EPA's 2000 Methodology authorizes criteria "based on a 10^{-5} risk level"—just as Washington had selected—as long as "more highly exposed subgroups" like "subsistence fishers" are protected at a 10^{-4} CRL. 81 Fed. Reg. at 85,420 & n.10. But the agency moved the goalposts, reclassifying "tribal subsistence fishers" from a highly exposed subpopulation to the "target general population" solely for the purpose of the rule. This choice of "general population" was significant, because water quality criteria must be more stringent to protect specific groups exposed to higher concentrations of carcinogens at the same cancer risk level as a less exposed, broader group. By defining the tribal subsistence fisher subpopulation as the "general population," EPA effectively sought to protect the *actual* general population of Washington (as defined by the 2000 Methodology) at a 10^{-8} cancer risk level—one additional case of cancer in a population of *one hundred million*. *See* EPA-HQ-OW-2015-0174-1089 at 14 (Nw. Pulp & Paper Comment Letter May 31, 2022) ("Nw. Pulp & Paper Letter"). That is an astronomically small risk—orders of magnitude smaller than the risk of being killed by an asteroid. *See* New Scientist, *The Word: Torino Scale* (Oct. 19, 2005),

https://www.newscientist.com/article/mg18825221-900-the-word-torino-scale. EPA deployed the same sleight of hand to justify its choice of FCR. And EPA further inflated the FCR by picking a so-called "unsuppressed" rate of fish consumption based on counterfactual "heritage tribal consumption reports"—educated guesses of historical tribal consumption practices—rather than actual data about current consumption. 81 Fed. Reg. at 85,424, 85,426.

In selecting these inputs, EPA's only explanation for departing from the 2000 Methodology is that the Methodology did not "speak to or envision the unique situation of setting WQS that cover areas where tribes have treaty-reserved rights to practice subsistence fishing." 81 Fed. Reg. at 85,424–25. EPA did not attempt to square that assertion with the 2000 Methodology's express description of "subsistence fishers" as a "highly exposed subgrou[p]." 2000 Methodology at 1–12.

Ultimately, EPA's selected CRL and FCR rested on its assertion of authority to "harmonize treaty-reserved fishing rights with the CWA"—a power it had never before asserted in the five decades since the CWA's enactment. 81 Fed. Reg. at 85,424. EPA stated that even though "[t]he CWA generally assigns to a state the responsibility of determining the designated uses of its waters ... , through treaties, tribes reserved specific fishing rights ... including the right to take fish from such waters for their subsistence." *Id.* EPA then construed this "subsistence fishing" right to require the agency to treat tribes as the "target general population." *Id.* Thus, EPA concluded, "where treaty-reserved tribal fishing rights apply to particular waters, it would be unreasonable to

expose the communities exercising those rights to levels of risk above what would be reasonable for the general population of the state." *Id.* at 85,425.[1]

B. EPA's 2020 Reconsideration and Approval

In 2017, a coalition of Washington businesses and others petitioned EPA to reconsider the 2016 rule. Compl. Ex. A, Pet. for Rulemaking, *Washington v. EPA*, No. 2:19-cv-00884-RAJ (W.D. Wash. June 6, 2019). The petitioners urged EPA to change course because the rule "improperly usurped the primary role of the state to make risk management decisions," and threatened to "devastat[e the State's] local communities and businesses" while offering "no benefit to public health over the Washington-submitted standards." *Id.* at 1–2.

EPA agreed. In 2019, EPA granted the petition and, upon reconsideration, approved all but two of Washington's original criteria, reasoning that the 2016 rule had improperly infringed on the State's CWA authority to make its own risk management decisions within the limits of sound science. *See* Letter from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Wash. Dep't of Ecology 8 (May 10, 2019) ("EPA 2019 Approval"). Applying

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[1] According to the U.S. Census Bureau, 1.6 percent of Washington State's population were American Indian and Alaska Native in 2020. *Race and Ethnicity*, U.S. Census Bureau (2023), https://data.census.gov/profile/Washington?g=040XX00US53#race-and-ethnicity. Not all of these individuals are tribal members, and even fewer fish for subsistence. Moreover, a substantial number of tribal members who do fish for subsistence likely live on tribal reservation land and fish in whole or in part in tribal reservation waters, which expressly are *not* governed by EPA's or Washington's WQS. *See* 81 Fed. Reg. at 85,422 & n.27 ("This rule applies to waters under the State of Washington's jurisdiction, and not to waters within Indian country"); 87 Fed. Reg. at 69,188 & n.52 (same).

Thus, although EPA's rule is replete with legalese and scientific terms of art, its sleight of hand is simple. Fish are a source of carcinogens. If population A eats 17 grams of fish per week and subpopulation B eats 175 grams of fish per week, subpopulation B is exposed to more sources of carcinogens. To reduce cancer risk for subpopulation B to the same level that would be appropriate for population A, the level of carcinogens in the water must be reduced far more significantly. And EPA selected "subpopulation B" as the "target general population" that Washington's standards must protect, even though it is *not* the actual general population of Washington. Impossibly stringent water quality criteria were the inexorable result of that choice.

the 2000 Methodology, EPA determined that Washington's CRL of 2.3 x 10^{-5} for PCBs satisfied statutory requirements, was based on sound science, and was protective of the general population and high-consuming subpopulations. *Id.* at 21. EPA confirmed that the CWA does not require States to meet or exceed each of EPA's recommended criteria so long as the submission's risk management decisions are "based on sound science and the resulting criteria protect the designated uses." *Id.* at 24.

In a 31-page decision, EPA explained that it was "improper and unnecessary" to purportedly "harmonize" tribal treaty rights with the CWA under a "new legal theory." EPA 2019 Approval 22–24. That approach, EPA reasoned, rested on two related errors: (1) it required States "to provide the same level of protection to tribal treaty fishers as to the State's general population," identifying tribal populations as the "target general population," and (2) "interpret[ed] the State's designated uses to also mean or include subsistence fishing." *Id.* at 22. The 2016 rule thus trenched on the State's prerogative to manage risks and designate uses for its own water bodies. *Id.* Moreover, EPA explained that the 2016 rule "departed from longstanding EPA policy and the Agency's recommendations for setting [criteria], including the 2000 Methodology." *Id.* "[T]he 2000 Methodology speaks directly" to subsistence fishing protections and advises that subsistence fishers should be treated as "highly exposed subgroups." *Id.* at 23. The 2016 rule's new legal theory, in contrast, was "not ... promulgated in any nationally applicable rule or articulated in any national recommended guidance," failing to provide "adequate notice of this framework or ... the Agency's decision to apply this framework to particular state submissions in the first instance." *Id.* at 22. Simply put, tribal treaties "do not expand the EPA's authority under the CWA." *Id.* at 23.

In 2020, EPA promulgated a rule allowing Washington's approved criteria to take effect. 85 Fed. Reg. 28,494 (May 13, 2020) (the "2020 rule"). EPA restated its longstanding position that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." *Id.* at 28,495. EPA explained that because Washington's criteria satisfied all statutory requirements, "the cooperative federalism structure of the CWA" required the agency "to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes." *Id.* at 28,496. In so doing, EPA affirmed its view that "Washington's [human health criteria] are based on sound science and are protective of Washington's designated uses." *Id.* Recognizing that "some of Washington's [human health criteria] are less stringent than the federal [human health criteria], and some are more stringent," EPA concluded that the CWA authorized Washington to make these reasonable risk management decisions. *Id.*

C. EPA Proposes the 2022 Rule

In April 2022, after a change in administration, EPA again reversed course. Administrator Michael Regan determined under Section 1313(c)(4)(B) "that revised [human health criteria] are necessary" for Washington and "propos[ed] new standards for Washington waters" to replace the criteria submitted by Washington in 2016 and approved by EPA in 2019. 87 Fed. Reg. 19,046, 19,051 (Apr. 1, 2022).

The agency received a number of comments, including from Plaintiffs, arguing: (1) that the agency had taken an unjustified change in position; (2) that EPA's inputs were flawed and inconsistent with its own methodology; (3) that the resulting criteria were unworkable and unattainable; (4) that the agency had failed to consider costs as required under the APA and CWA;

and (5) that the rule's economic analysis was unreasonable.[2] Commenters, for instance, submitted data showing that the costs of treating water to EPA's PCB target concentration range from $53 to $82 million at a single facility (or $106 to $262 per gallon per day), *see* Nw. Pulp & Paper Letter 70, and between $6 billion and $11 billion for a subset of the permits identified in EPA's economic analysis, *see* Am. Forest & Paper Ass'n Letter 4. One municipality, the City of Spokane, explained that in light of the 2022 rule, the Washington Department of Ecology had already required "the City to spend additional money to control PCBs entering the river." Spokane Letter 2. And expansion of the City's wastewater treatment plants to further address PCBs, the City estimated, would cost $19 million per gram of additional PCB removal. *Id.*

D. EPA Finalizes the 2022 Rule

EPA finalized the federal standards several months later. *See* 87 Fed. Reg. at 69,183. The agency imposed federal WQS for Washington nearly identical to those promulgated in EPA's November 2016 rule, including the same PCB criterion of 7 ppq. *Id.* at 69,183.

In promulgating the 2022 rule, EPA "appl[ied] the same rationale … as the agency articulated … in the 2016 Federal rule." 87 Fed. Reg. at 69,189 (noting this point in connection with selection of FCR); *id.* at 69,198 (noting that the selected CRL "is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at the 175 g/day level"). And

[2] *See* Nw. Pulp & Paper Letter 4–13, 23 (arguing that the EPA used unreasonable inputs that were inconsistent with its own methodology and that the PCB output was unreasonable); EPA-HQ-OW-2015-0174-1092 at 2–4 (Am. Forest & Paper Ass'n Comment Letter June 1, 2022) ("Am. Forest & Paper Ass'n Letter") (arguing, *e.g.*, that the EPA's change in position was unjustified in light of the CWA's deference to States, that the agency failed to reasonably consider costs, that the economic analysis was unreasonable, and that EPA could not invoke a tribal treaty rights theory without clear statutory authorization); EPA-HQ-OW-2015-0174-1084 at 23 (Greater Spokane Comment Letter May 26, 2022) ("Spokane Letter") (arguing that the PCB standard was unreasonable); *see also, e.g.*, EPA-HQ-OW-2015-0174-1086 (City of Post Falls Comment Letter May 27, 2022) ("Post Falls Letter"); EPA-HQ-OW-2015-0174-1094 (National Mining Association Comment Letter May 31, 2022) ("National Mining Association Letter").

EPA adopted the same inputs as the 2016 rule, underscoring "that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule." *Id.* at 69,189. Thus, doubling down on its previously disavowed tribal treaty rights theory, EPA again adopted a 10^{-6} CRL for PCBs, and a 175 g/day FCR. *Id.* at 69,188–90. EPA chose these inputs purportedly because Washington had selected inputs insufficiently "protective of the State's designated uses," including "the tribal subsistence fishing portion of the fish and shellfish harvesting use *as informed by treaty-reserved fishing rights*.'" *Id.* at 69,187 & n.38 (quoting Letter from Dan Opalski, Dir. Off. Water & Watersheds to Maia Bellon, Wash. Dep't of Ecology 26 (Nov. 15, 2016) (emphasis added)). Moreover, because Washington had used a 10^{-6} CRL for other chemicals besides PCBs, EPA added that "it is important to keep these [CRL] values consistent" between specific chemicals "because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific." *Id.* at 69,189. As before, EPA's selected FCR assumed that tribal subsistence fishers consume extraordinary numbers of fish from state surface waters every day for seventy years, and that this quantity is representative of the general population. *Id.* Relying on these inputs, EPA finalized the extraordinarily low PCB criterion of 7 ppq. *Id.* at 69,193.

EPA acknowledged that the existing detection limit for PCBs under methods EPA has approved for determining NPDES permit compliance is 2000 ppq—three orders of magnitude higher than EPA's target level for PCB concentrations. 87 Fed. Reg. at 69,195–96. EPA further recognized that Washington had already set an aggressive target level below this limit—at 170 ppq, given that the highest performing treatment systems in the State can reduce PCBs to only 100 ppq (which can be measured only with highly sensitive, non-EPA approved methods). *Id.* at 69,193; Nw. Pulp & Paper Letter, Attach. C at 36. Nevertheless, EPA asserted that "it is important

that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods." 87 Fed. Reg. at 69,196.

EPA also relied on an economic analysis that estimated the 2022 rule would impose only $100,000 to $182,000 in administrative costs on the State. 87 Fed. Reg. at 69,195–96. Remarkably, EPA concluded that it "did not identify *any* incremental costs to any major point source discharges ... attributable to EPA's criteria revisions." *Id.* at 69,195 (emphasis added). EPA did not find that there would actually "be no costs to point sources over time to implement controls or modify processes to meet future permit limits." *Id.* Rather, EPA's conclusion equivocated that in the agency's judgment it would be too "speculative to attempt to estimate potential costs." *Id.* EPA asserted that it was unclear how permit limits would change as technologies for measuring PCB concentrations improved and that "advanced treatment or other substantial costs [that] arise in the future" could potentially be avoided through "variances," "alternative permit limits," and constructive engagement between EPA and stakeholders. *Id.* EPA also discounted commenters' specific cost studies on the ground that those studies did not assume a proper baseline for calculating marginal costs. The right baseline, according to EPA, is not the *real* status quo, but a counterfactual one of assumed "full compliance with existing (including not yet implemented) criteria." EPA-HQ-OW-2015-0174-1112 at 139–40 ("EPA 2022 Response to Comments").

In a separate document addressing comments, EPA made a number of additional assertions in tension with the rule's preamble. For instance, although the 2022 rule adopted the "same rationale" as the 2016 rule, 87 Fed. Reg. at 69,189, EPA's response to comments purported to disclaim "reli[ance] on tribal treaty rights" and to rest on "sound science" alone, EPA 2022 Response to Comments 24. Despite acknowledging that it had not identified any "new data or

information," 87 Fed. Reg. at 69,189, EPA did not even try to explain how it reached the same inputs and outputs as the 2016 rule *without reliance on its previously disavowed tribal rights theory*. Indeed, EPA proposed a *separate* rule just two weeks after it finalized the 2022 rule, proposing to ratify the approach it took in 2016: "WQS must protect tribal reserved rights." *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022) (discussing EPA's 2016 rule with approval).[3] Thus, while purporting to disapprove Washington's standards for scientific reasons, EPA in fact relied on a contrived tribal rights theory that has no basis in applicable regulations or EPA's longstanding 2000 Methodology.

In addition, EPA explained that "costs" cannot "be considered" in the "development of water quality criteria." EPA 2022 Response to Comments 109 & n.255. According to EPA, "compliance costs may be considered only when designating the uses to be protected by water quality standards," but not in setting criteria, which must be "based on sound scientific rationale." *Id.* (quoting *Upper Mo. Waterkeeper v. EPA*, 15 F.4th 966, 972 n.1 (9th Cir. 2021)).

III. Procedural History

On December 4, 2023, Plaintiffs brought this Administrative Procedure Act ("APA") suit. On January 25, 2024, Defendants filed a motion to transfer the case to the Western District of Washington, which remains pending. Dkt. 19. Defendants also filed a timely answer with no objection to venue. Dkt. 23. The State of Washington and five Tribes have moved to intervene, and those motions are pending. Dkts. 20, 30, 31.

LEGAL STANDARD

Summary judgment is warranted "if the moving party 'shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Toledo*

[3] EPA finalized that rule on May 2, 2024. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 89 Fed. Reg. 35,717 (May 2, 2024).

Hosp. v. Becerra, 621 F. Supp. 3d 13, 22 (D.D.C. 2021). In an APA action, "summary judgment 'serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.'" *Id.*

Courts will "hold unlawful and set aside" an agency rule that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C), (E). Agency action is arbitrary and capricious if the agency has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Agency action thus must be "reasonable and reasonably explained." *Biden v. Texas*, 142 S. Ct. 2528, 2543 (2022). And an agency may not exceed its statutory authority. *Michigan v. EPA*, 268 F.3d 1075, 1082 (D.C. Cir. 2001).

JURISDICTION

This Court has subject-matter jurisdiction under 28 U.S.C. § 1331.

Plaintiffs have Article III standing. They are associations of Washington businesses whose members operate facilities subject to CWA permitting requirements administered by Washington's Department of Ecology under EPA oversight. Plaintiffs therefore have associational standing because their members are the "object[s] of the challenged government action" who are suffering concrete injuries traceable to the 2022 rule. *New Jersey v. EPA*, 989 F.3d 1038, 1045 (D.C. Cir. 2021). EPA's human health criteria are increasing costs, undermining existing investments in facilities and regulatory compliance, and generating harmful regulatory uncertainty. *See, e.g.*, Declaration of Paul R. Noe ("AF&PA Decl.") ¶¶ 9–12; Declaration of Christian M. McCabe

("NWPPA Decl.") ¶¶ 8–11. These harms are traceable to the 2022 rule because EPA's imposition of more stringent federal criteria subjects existing NPDES permits to modification and results in new requirements for discharge permits that regulated parties must obtain on a periodic basis. *See id.* (citing NPDES Permit WA0003697); *see, e.g.*, NPDES Discharge Permit No. WA0093317, EPA-HQ-OW-2015-0174-1112 at 48, 128 n.327 ("Ecology will reopen the permit should the Human Health Criteria for PCBs be revised."). Vacating the 2022 rule would redress these ongoing and imminent harms by restoring the status quo ante, *i.e.*, EPA's prior approval of Washington's 2016 standards. *See, e.g.*, AF&PA Decl. ¶¶ 12–13.

This action is also germane to Plaintiffs' missions to advocate for reasonable environmental regulation on behalf of their members in the business community, and the participation of individual members is not required to resolve the questions presented. *See Me. Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 593 (D.C. Cir. 2023); AF&PA Decl. ¶¶ 4–8. Plaintiffs raised serious concerns about EPA's proposed rule in comments, *see* AF&PA Decl. ¶ 6, NWPPA Decl. ¶ 5, but EPA finalized the rule without material change.

ARGUMENT

The 2022 rule violates multiple precepts of administrative law. Most fundamentally, the rule is *ultra vires*: EPA overstepped its statutory authority by setting criteria based on an unfounded tribal treaty rights theory. The rule is also arbitrary and capricious. In reversing course from the 2020 rule and the 2000 Methodology, EPA departed from longstanding positions without adequate explanation. Its federal standards are based on non-factual and unreasonable inputs that unsurprisingly produced unreasonable outputs, including an unmeasurable and unattainable PCB criterion. Moreover, EPA erroneously disclaimed authority to consider costs in setting the criteria. Alternatively, to the extent EPA nonetheless relied on a cost-benefit analysis to justify the rule, its

analysis unreasonably assumed that there would be *zero* compliance costs for the regulated community.

I. EPA Exceeded Its Statutory Authority Under the CWA and Failed to Follow Its Own Regulations.

Agency action taken without statutory authority "is plainly contrary to law and cannot stand." *Michigan*, 268 F.3d at 1081. And "it is a well-settled rule that [the] agency's failure to follow its own regulations is fatal to the deviant action." *Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1524 (D.C. Cir. 1994) (cleaned up).

Here, EPA exceeded its mandate under the CWA and violated its own regulations in imposing unnecessary federal standards on Washington to protect tribal reserved rights under treaties that EPA has no power to interpret or enforce.

1. The CWA "anticipates a partnership between the States and the Federal Government, animated by a shared objective: 'to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'" *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. § 1251(a)). To advance the "policy" of "protect[ing] the primary responsibilities and rights of States" to control pollution in their waters, 33 U.S.C. § 1251(b), EPA's role in this process is "limited," *Nat. Res. Def. Council, Inc. v. EPA* ("*NRDC*"), 16 F.3d 1395, 1399, 1405 (4th Cir. 1993).

Congress evinced this intentional design through the CWA's procedural and substantive requirements. States are in the driver's seat from the start, and must submit timely water quality standards after public hearings. *See* 33 U.S.C. § 1313(b), (c)(1). EPA may supersede the States' standards and impose federal criteria only when "necessary" to meet the requirements of the statute. *Id.* § 1313(c)(4)(B). Thus, "EPA sits in a reviewing capacity of the state-implemented standards, with approval and rejection powers only." *NRDC*, 16 F.3d at 1399.

Nothing in this reticulated scheme envisions EPA invoking tribal treaties to second-guess States' reasonable risk management decisions. For treaties, the CWA provides only that its provisions shall not "affect[] or impair[] the provisions of any treaty of the United States." 33 U.S.C. § 1371(a). This provision does not compel or empower EPA to take a particular action; rather, it imposes a *limit* on EPA's authority.

Nevertheless, in the 2022 rule, EPA claims authority found nowhere in the CWA or historical practice to interpret tribal treaties for itself and to override state standards under the guise of protecting tribal rights. Treaties between the United States and tribes are not grants of authority to EPA, and EPA's action points to no treaty that would grant EPA the authority it claims. Tribal reserved rights similarly do not limit or prohibit a State or EPA from taking an otherwise lawful action under the CWA. Instead, as a general rule, "th[e] [trust] responsibility is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569, 574 (9th Cir. 1998). In prior litigation, EPA defended the same principle. *See* EPA Consolidated Br. at 40–43, *Sierra Club v. McLerran*, No. 2:11-cv-01759-BJR, Dkt. 91 (W.D. Wash. Jan. 29, 2014). Thus, as EPA itself has previously (and consistently) recognized, *see infra* at 22–23, EPA lacks statutory authority to "harmonize" tribal treaty rights with the CWA. EPA 2019 Approval 22–24.

Even assuming *arguendo* that EPA may generally construe tribal treaty rights, nothing in any relevant treaty compels *specific* water quality standards in Washington. "Whether the Government has expressly accepted [treaty] obligations must train on specific rights-creating or duty-imposing language in [the] treaty." *Arizona v. Navajo Nation*, 143 S. Ct. 1804, 1813 (2023) (cleaned up). In *Arizona*, the Supreme Court applied this principle to hold that a general treaty provision that "set apart" a reservation for the "use and occupation of the Navajo tribe" did not

impose an affirmative duty to secure water for the tribe. *Id.* at 1813–14; *see id.* at 1816 (explaining that "[t]he 1868 treaty reserved necessary water to accomplish the purpose of the Navajo Reservation" but did not obligate anyone to take "affirmative steps" to provide water).

Here, although EPA generally invoked the Stevens-Palmer Treaties with the Washington Tribes, EPA never identified a plausible textual basis for the purported treaty guarantee of "*water quality sufficient under the CWA* to ensure that tribal members can safely eat the fish for their own subsistence." 2016 Rule, 81 Fed. Reg. at 85,423 (emphasis added). In support of that asserted right, EPA cited the treaty right to "tak[e] fish at usual and accustomed places" and case law construing that right to require "fish sufficient to sustain" the right. *Id.* at 85,423 & nn.35–39 (collecting cases). But those cases at most hold that the right to take fish implies a right to access fishing grounds. The right thus imposes only a negative duty: It *constrains* States, for instance, from constructing barriers that "obstruc[t] fish passage" and barring tribes from "cross[ing] private property to access [a] traditional fishing ground." *Id.* at 85,424 n.39; *cf. Arizona*, 143 S. Ct. at 1816. No specific rights-creating language in any treaty gives EPA the *affirmative* authority to dictate water quality standards, much less to require any *specific* criterion—*e.g.*, a PCB criterion of 7 ppq, rather than 170 ppq.

Rather than justify this claim to authority in the 2022 rule, EPA denied that it was relying on treaty rights at all. *See, e.g.*, 87 Fed. Reg. at 69,189 (claiming that EPA's decision "was appropriate independent of treaty rights"); *id.* at 69,190 (asserting that the 2022 rule was predicated on EPA's conclusion that "Washington's PCB [human health criteria] are not protective of Washington's designated uses because of Washington's selected chemical-specific CRL, which is not based on a sound scientific rationale"). But EPA's backtracking is disingenuous. EPA admitted that it had no new data and characterized the 2022 rule as resting on the "same rationale"

as the 2016 rule, which indisputably relied on a treaty rights theory. *Id.* at 69,189. And EPA's assertion that Washington's standards were insufficiently protective of the State's designated uses leaves no doubt that EPA claimed authority to interpret tribal treaty provisions in the 2022 rule. EPA's *only* explanation for that conclusion was that the State's designated uses included harvesting "*as informed by treaty-reserved fishing rights*." *Id.* at 69,187 & n.38 (quoting 81 Fed. Reg. 85,426) (emphasis added). Indeed, EPA just finalized a rule "to ensure that WQS are consistent with treaties," by purportedly "build[ing] on" EPA's approach in the 2022 rule. 89 Fed. Reg. at 35,732, 35,744.

Nor can EPA rescue its atextual power-grab by resort to agency expertise or deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Where, as here, an agency repeatedly changes its interpretation of a statute, its interpretation "is entitled to considerably less deference than a consistently held agency view." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (cleaned up). EPA's discovery of a nascent tribal rights authority in the 2016 rule, decades after enactment of the CWA, is not entitled to deference—particularly since the agency later renounced the authority and has yet to reassert it in a reasoned manner. *See, e.g.*, *Chamber of Com. v. Dep't of Lab.*, 885 F.3d 360, 380–81 (5th Cir. 2018) (no deference where agency's newly discovered reading came decades after statutory enactment). EPA also never attempted to establish the "genuine ambiguity" necessary to trigger deference by "exhaust[ing] all the 'traditional tools' of construction," and cannot do so for the first time before this Court. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quoting *Chevron*, 467 U.S. at 843 n.9).[4]

[4] The Supreme Court is currently considering whether to overrule or narrow *Chevron*. *See Loper-Bright Enterprises v. Raimondo*, *cert. granted*, No. 22-451 (argued Jan. 17, 2024); *Relentless, Inc. v. Dep't of Com.*, *cert. granted*, No. 22-1219 (argued Jan. 17, 2024). Plaintiffs preserve all arguments that may arise from those decisions to the extent they limit or overrule *Chevron*.

The 2022 rule eviscerates the CWA's cooperative federalism regime with one under which EPA has freestanding authority to impose federal standards based on EPA's understanding of tribal rights. The CWA was enacted over fifty years ago. But until EPA purported to discover the power in the 2016 rule, EPA had never before asserted the authority to invoke tribal treaty rights to supercharge its authority to override state water quality standards. As the Supreme Court recently warned EPA, it must find clear authorization in the statutory text when it claims newfangled authority to regulate in an area where it has "no comparative expertise"—here, in purportedly protecting tribal treaty rights (the domain of the Department of the Interior, not EPA). *West Virginia v. EPA*, 142 S. Ct. 2587, 2612–13 (2022). Congress has not delegated—much less *clearly* delegated—tribal treaty interpretation or enforcement power to the agency, and EPA's flimsy treaty interpretation underscores its lack of expertise in construing agreements between sovereigns. Because the 2022 rule is *ultra vires*, it must be vacated.

2. Under EPA's longstanding regulations, too, Washington was entitled to set its own designated uses and water quality criteria that "are consistent with the requirements of the Clean Water Act" and "protect the designated water uses based on sound scientific rationale." 40 C.F.R. § 131.5(a)(1)–(2). EPA may disapprove state standards and impose federal criteria if, and only if, "*necessary* to meet the requirements of the Act." *Id.* § 131.5(b) (emphasis added). EPA has repeatedly acknowledged that its *current* regulations do not construe this requirement to authorize the agency to override a State's standards under a tribal rights theory. *Cf.* EPA 2019 Approval 18. That is why EPA undertook a new rulemaking during the pendency of this case in an effort to establish that very authority. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 89 Fed. Reg. 35,717, 35,718 (May 2, 2024).

EPA nonetheless invoked a tribal treaty rights theory to override state standards here, long

before it promulgated any such rule purporting to authorize it. Even if EPA could now claim the power to harmonize water quality standards with tribal treaty rights (it cannot), no EPA rule authorized it do so *before* EPA asserted that power to override Washington's standards. *See Nat'l Conservative Pol. Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980) (per curiam) (agency action unlawful when issued in a departure from agency regulations without prior notice to affected parties). On that ground alone, the rule is unlawful.

II. EPA's Unjustified Changes in Position Violate the APA.

In 2019 and 2020, EPA applied well-settled agency policy in thoroughly reasoned decisions that approved Washington's human health criteria, rescinded the federal standards imposed in 2016 that departed from this longstanding policy, and explained that EPA cannot invoke tribal treaties to expand its authority under the CWA to set water quality standards. Plaintiffs' members and others reasonably relied on those decisions to make substantial investments in Washington facilities, equipment, and personnel. *See, e.g.*, Spokane Letter 2 (stating that, as of 2022, regulators had already "compel[led] the City to spend additional money to control PCBs entering the river"). Nevertheless, in the 2022 rule, EPA abruptly reversed course without explaining the agency's own intervening findings and the reasonable reliance they engendered. Because it is "arbitrary [and] capricious to ignore such matters," the 2022 rule should be vacated. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

When an agency changes position, it must at least "display awareness" of the change and "show that there are good reasons for the new policy." *Fox*, 556 U.S. at 515. Thus, the APA's reasoned decision-making requirement "is especially important where, as here, an agency changes course." *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020). EPA violated this requirement by promulgating the 2022 rule without acknowledging or addressing the abrupt policy reversals embodied in four key features of the rule: (1) EPA's treatment of tribal subsistence

fishers as the general population, (2) EPA's demand for lockstep formula inputs across water quality criteria for all chemicals, (3) EPA's revival of a tribal treaty rights theory it had only recently repudiated, and (4) EPA's recharacterization of Washington's designated water uses to protect tribal fishing rights.

1. *First*, EPA reversed its longstanding position that States may choose criteria that protect the *general* population at a CRL of 10^{-5} and protect tribal subsistence fishers as a highly exposed subpopulation at a CRL of 10^{-4}. As EPA explained when approving Washington's criteria just two years before the 2022 rule, "longstanding EPA policy and the Agency's recommendations for setting [human health criteria], including the 2000 Methodology," authorize States to "consider tribes with reserved fishing rights to be highly exposed [sub]populations, rather than the target general population, in order to derive criteria" using appropriate CRLs and FCRs. EPA 2019 Approval 22–23. EPA further explained that the agency had been "aware" that "certain tribal populations engaged in subsistence fishing practices" for decades, and that the 2000 Methodology "speaks directly" to these populations by recommending that States protect them as "'more highly exposed subgroups.'" *Id.* (quoting 2000 Methodology at 1–12). Noting that Washington appropriately based its standards on the general population while protecting tribes as highly exposed subpopulations, EPA "determined that, looking at the record and the State's approach as a whole, [Washington's human health criteria] meet the requirements of EPA's regulations because their inputs are based on sound science and the resulting criteria protect the designated uses." *Id.* at 24; *see* 85 Fed. Reg. at 28,496 (withdrawing federal criteria for Washington to allow the State's standards to go into effect by operation of law).

That was not a standalone decision. In approving Idaho's standards in 2019, EPA similarly explained that the agency had never before used the term "target general population" and had

reviewed state submissions only for protection of the "general population" and "highly exposed subpopulations." Letter from Chris Hladick, Regional Administrator, EPA Region 10, to John Tippets, Director, Idaho Dep't of Env't Quality 15 (May 10, 2019) ("2019 Idaho Letter"). Indeed, EPA's view that States may set criteria based on the general population predates the 2000 Methodology and has survived judicial review. *See, e.g.*, *Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995) (rejecting argument that EPA effluent limits for the Columbia Basin insufficiently protected subpopulations by using an FCR for the general population); *NRDC*, 16 F.3d at 1403 (rejecting argument that EPA-approved state standards failed to "protect subpopulations with higher than average fish consumption").[5]

The 2022 rule broke from this longstanding policy without explanation. Consistent with the 2000 Methodology and decades of EPA guidance, Washington had determined its PCB criterion "based on a 10^{-5} [cancer] risk level" that is "acceptable for the general population" and "ensure[d] that the risk to more highly exposed subgroups … does not exceed the 10^{-4} level." 2000 Methodology at 1–12; *see Toxic Substances—WAC 173-201A-240*, *supra*, at tbl. 240 & nn.B, E. Nevertheless, EPA determined that Washington's standards "do not protect designated uses because the input values on which they rely are not supported by a sound scientific rationale." 87 Fed. Reg. at 19,051. The agency imposed a more stringent CRL of 10^{-6}, asserting that only this value "reflects an appropriate risk for the general population" as determined by "tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels." 87 Fed. Reg. at 69,189. Rather than acknowledge the change in policy, EPA repeatedly insisted, with

[5] The handful of agency actions taking a contrary position from 2015 to 2017—including the 2016 rule—purported to announce "new designations" that were "not established by regulation in any nationally applicable EPA rulemaking or in a guidance document or statement of policy." 2019 Idaho Letter at 15.

a flawed and circular explanation, that its 2022 rule "is consistent with EPA's 2000 Methodology." *Id.*; *see also* EPA 2022 Response to Comments 90 ("EPA's selection of a 10^{-6} CRL is consistent with EPA's 2000 Methodology, which states that EPA intends to use the 10^{-6} level[.]").

2. *Second*, EPA reversed its position that States may use chemical-specific inputs in setting water quality criteria. In 2019, EPA concluded that Washington's "chemical-specific cancer risk rate of $2.3x10^{-5}$" for PCBs "falls within the range of protective risk rates the EPA has recommended since it issued its 2000 Methodology and is protective of the State's designated uses." EPA 2019 Approval 19. As EPA explained, "[n]othing in the CWA prevents or prohibits a state from adopting a chemical-specific cancer risk rate, as long as the derived criteria are based on sound scientific rationale and protective of the designated use." *Id.* at 19–20. Again, this position was not new. For decades, EPA has authorized the use of chemical-specific values and limitations to support States' discretionary risk management decisions. *See* 2019 Idaho Letter at 28, 31–32; 2000 Methodology at 2–4 ("The choice of an acceptable cancer risk … is a risk management decision."); *cf. Am. Paper Inst., Inc. v. EPA*, 996 F.2d 346, 351 (D.C. Cir. 1993) (rejecting challenge to EPA regulation requiring "chemical-specific limitations on discharges").

EPA took exactly the opposite position in the 2022 rule, without displaying awareness or acknowledging that it was changing position, let alone weighing the benefits and tradeoffs of such a change or explaining why it believes its new position to be better. Without elaboration, EPA stated that "it is important to keep these [CRL] values consistent" between specific chemicals "because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific." 87 Fed. Reg. at 69,189. That explanation ignored that cancer risk levels used for water quality criteria vary widely for different chemicals, even though the criteria often apply to the same population. *See, e.g.*, 2019 Idaho Letter at 28, 31–32. Moreover, EPA

gave short shrift to Washington's own explanation—Washington chose a chemical-specific CRL that corresponded to a 170 ppq PCB criterion in light of Washington's other highly protective input, an FCR of 175 g/day. Wash. Dep't of Ecology, *Washington State Water Quality Standards: Human Health Criteria and Implementation Tools* 66–67 (Aug. 2016). Its choice reflected "a chemical-specific risk management decision" not to increase the PCB criterion above EPA's prior National Toxics Rule value and accorded with "EPA [human health criteria] guidance as well as with precedent from other states" permitting chemical-specific risk levels. *Id.* EPA's newfound preference for lockstep risk levels does not endow it with authority to set aside a State's differing risk management approach that accords with sound science and established EPA guidance.

3. *Third*, EPA reversed its prior position that the agency lacks statutory authority to interpret and enforce tribal rights against the States through the CWA standards-setting process, including by recharacterizing the State's designated uses for its waterways. In approving Washington's standards in 2019, EPA rejected the argument that it may require States to treat tribal subsistence fishers as the "target general population" because the State's designated uses "include subsistence fishing." EPA 2019 Approval 22. EPA further disclaimed authority to "'effectuate and harmonize' tribal reserved treaty rights with the CWA when establishing [human health criteria]," *id.* (quoting 80 Fed. Reg. at 55,067), noting that reserved rights "do not expand the EPA's authority under the CWA," *id.* at 23. But in the 2022 rule, EPA ignored the reasoning and conclusion of its 2019 Approval, adopting the treaty rights rationale with no mention of the agency's recent repudiation of that rationale. Instead, as explained above, EPA attempted to downplay reliance on a tribal rights rationale in the 2022 rule, asserting that the rule was based on "sound science" and Washington's "designated uses." *See supra* at 14–15, 20–21.

4. *Fourth*, EPA reversed its prior position that the agency lacks authority to substitute

its own designation of water uses for the State's. Until the 2022 rule, EPA consistently recognized that "States have exclusive responsibility to designate water uses," *NRDC*, 16 F.3d at 1405 (citing 40 C.F.R. § 131.10), and EPA therefore may not invoke tribal treaty rights to override or recharacterize the State's designated uses. *See Miss. Comm'n on Nat. Res. v. Costle*, 625 F.2d 1269, 1276 (5th Cir. 1980) ("[T]he specification of a waterway as one for fishing, swimming, or public water supply is closely tied to the zoning power Congress wanted left with the states."); *see also* 40 C.F.R. §§ 131.10(a) ("Each *State* must specify appropriate water uses to be achieved and protected." (emphasis added)), 131.11 (setting out requirements for criteria that protect "the designated use"). In approving Idaho's water quality standards in 2019, for instance, EPA explained that "[t]he existence of tribal treaties with reserved fishing rights does not grant the EPA authority to recharacterize a state's designated uses or otherwise skew the federal-state balance of the CWA towards the federal government" and "do[es] not expand the EPA's authority under the CWA." 2019 Idaho Letter at 30–31. And in withdrawing certain criteria for Indian lands in Maine in 2020, EPA again explained that "the CWA does not provide the Agency with statutory authority to recharacterize the State's general fishing use beyond the meaning intended by the State." Letter from Dennis Deziel, Regional Administrator, EPA Region 1, to Gerald D. Reid, Commissioner, Maine Dep't of Env't Prot., *Re: Withdrawal of Certain of EPA's February 2, 2015 Decisions Concerning Water Quality Standards for Waters in Indian Lands*, Attach. B at 20 (May 27, 2020).

Yet that is precisely what EPA did in the 2022 rule. EPA reversed its approval of Washington's standards by invoking tribal fishing rights to recharacterize Washington's designated uses: According to EPA, Washington's criteria were insufficiently protective of "the State's" designated uses, including "the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved fishing rights." 87 Fed. Reg. at 69,187 & n.38

(quoting 81 Fed. Reg. 85,426); *see also* EPA 2022 Response to Comments 36. But the phrases "tribal subsistence fishing" and "treaty-reserved fishing rights" were *EPA's* additions. As EPA previously recognized, Washington's designated uses include "Harvesting (fish harvesting)," "Shellfish Harvesting," and "Harvesting"—without specifying *subsistence* harvesting or discussing tribal fishing rights. EPA 2019 Approval 9 (citing *Toxic Substances—WAC 173-201A*, *supra*, at 600–10). EPA's blue-penciling thus trenched on the State's "*exclusive* responsibility to designate water uses." *NRDC*, 16 F.3d at 1405 (emphasis added). More to the point, EPA did not even acknowledge its prior position that the agency may not recharacterize the States designated uses, much less explain why it was changing course.

Finally, in changing position, EPA was required to consider the interests of parties (like Plaintiffs' members) that reasonably relied on EPA's prior approval of Washington's standards to "craft[] business models and invest[] significant resources" in Washington facilities, equipment, and personnel. *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1114 (D.C. Cir. 2019); *see, e.g.*, Nw. Pulp & Paper Letter 71 (explaining the time and resources involved in obtaining permits). EPA dismissed future compliance costs as too "speculative" to evaluate, 87 Fed. Reg. at 69,195, but its failure to take regulated parties' "serious reliance interests" into account is further reason to vacate the rule, *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020).

* * *

EPA is free to change its policy through appropriate means so long as it displays awareness of the change, and the new policy is "reasonable and reasonably explained." *Biden*, 142 S. Ct. at 2543. EPA violated the APA when it failed to do so here.

III. EPA Based Its Human Health Criterion for PCBs on Unreasonable Assumptions.

"[T]he presumption of agency expertise may be rebutted if its decisions, even though based on scientific expertise, are not reasoned," *Defs. of Wildlife v. Babbitt*, 958 F. Supp. 670, 679

(D.D.C. 1997), and agency action cannot survive when its stated reasons are "[un]reasonable" or "internally inconsistent," *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1024 (D.C. Cir. 2018).

Here, EPA arrived at an unreasonable standard by engaging in an unreasonable analysis under the 2000 Methodology. EPA made unreasonable scientific assumptions that resulted in double- and triple-counting risk and refused to take into account more reliable methodologies and data. These unsupported assumptions led EPA to adopt an unreasonable FCR and CRL and, ultimately, an impossible-to-meet human health criterion for PCBs. For any and all of these reasons, the 2022 rule should be vacated.

1. EPA selected an unreasonably high FCR of 175 g/day based on a series of unjustifiable assumptions about the consumption habits of hypothetical subsistence fishers consuming contaminated fish at a counterfactual "unsuppressed" rate.

Under the 2000 Methodology, the FCR is the estimated amount of fish an 80-kilogram (176-pound) adult consumes every day from his or her twenty-first birthday until death. *See* 87 Fed. Reg. at 69,186 & nn.14–15. Since 2015, EPA has used a default national FCR of 22 g/day, a protective estimate that reflects the 90th percentile of fish consumption in the United States and that amounts to about two three-ounce filets of salmon per week. And since 2000, EPA has recommended a 142 g/day rate for subsistence fishers, *i.e.*, the 99th percentile of fish consumption. *See* 2000 Methodology at 1–5. But in the 2022 rule, EPA went further—adopting a 175 g/day rate that, quite literally, is off the charts of the agency's longstanding guidance and amounts to about *fifteen* three-ounce filets of salmon per week. 87 Fed. Reg. at 69,189.

EPA's choice of FCR is unjustified on the administrative record. EPA largely piggy-backed on the FCR selected by Washington, 87 Fed. Reg. at 69,188; EPA Response to Comments 51 (purporting to use the "FCR … that Washington used in 2016"), and justified its own choice in

the 2022 rule by reference to "the same rationale" used "to support its use of those inputs in the 2016 Federal rule," 87 Fed. Reg. at 69,189. EPA's cross-references demonstrate that it arrived at its 175 g/day FCR not because the agency believes people in Washington actually eat that much fish every day for life, but rather as an approximation for the counterfactual "unsuppressed" rate of consumption by tribal subsistence fishers "prior to contact with European settlers." 81 Fed. Reg. at 85,426 & n.53. And EPA arrived at that "unsuppressed" FCR using the 95th percentile rate from a cherry-picked 1994 survey of tribal members in the Columbia River Basin that asked about fish consumption at a time in the already distant past. *Id.* at 85,426 & n.54.

This rationale cobbled together from a 30-year-old study is too thin to render EPA's choice of FCR reasonable. In EPA's chosen study, "rates of consumption represent fish obtained *from all sources*," including grocery stores—in other words, fish not even exposed to Washington waters. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* 69 (Columbia River Inter-Tribal Fish Commission 1994), tinyurl.com/53c9x9ar (emphasis added). The study concedes that other studies "reporting estimates for tribal populations" reached "consistently lower" estimates of fish consumption. *Id.* at 60. And the study's effort to determine a historical decrease in fish consumption was based on nothing more than a simple question to survey respondents over the age of 30 about whether their "current pattern of fish consumption differs from … 20 years ago." *Id.* at 20.

More fundamentally, however, EPA's rationale fails as a matter of law. EPA based its use of an "unsuppressed" FCR on the assumption that tribal members would return to subsistence levels of fish consumption but for "suppression" of those resources. But EPA's deployment of a counterfactual estimate of "unsuppressed" consumption—rather than real-world consumption data—contravenes the CWA's statutory directive to States to promulgate standards that take into

account "their use and value for" certain current uses of waterbodies. 33 U.S.C. § 1313(c)(2)(A). At no point does the Act either compel States to consider historical, prior uses that may have been decades—if not centuries—in the past or direct States to prioritize historical uses over current or reasonably anticipated future uses. Likewise, the Act does not compel States to define reasonably anticipated future uses by employing estimates of historical or "heritage" use patterns. EPA cites no authority for its theory that States must "restore" all waters to century-old uses by setting criteria based on counterfactual assumptions.

What's more, EPA's consideration of what counts as "unsuppressed" consumption is so ill-defined as to be arbitrary. Only speculation supports EPA's assumption that tribal members would return to a purported historical consumption rate from centuries ago absent "suppression" effects. And EPA fails to consider that tribal people with suburban or hybrid lifestyles and grocery-store diets consume fish largely from waters not covered by the 2022 rule, including the open ocean. It is arbitrary to base water quality criteria on conditions that are neither reflective of modern realities nor grounded in a fact-based forecast of the future.

In any event, as discussed, EPA's reliance on a tribal rights theory to justify its selected FCR also renders that choice unlawful, because EPA has no authority to invoke tribal rights to expand its authority to set water quality standards under the CWA. *See supra* at 18–22.[6]

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[6] Nor can EPA justify its choice of FCR by pointing to Oregon's approved rate of 175 g/day. *See* 87 Fed. Reg. at 69,189. EPA regulations do not require adopting equally stringent standards as downstream States, let alone using identical analytical inputs while doing so. *See* 40 C.F.R. § 131.10(b) (requiring States to "*take into consideration* the water quality standards of downstream waters" when setting designated uses (emphasis added)). A contrary conclusion would lead to absurd results—essentially allowing downstream States to dictate upstream standards—that cut against the CWA's cooperative federalism scheme and treatment of States as equal sovereigns. In any event, if other States' standards provide the relevant benchmark, then EPA faces another failure of explanation: In 2019, EPA approved Idaho water quality standards based on an FCR of 66.5

2. In picking its FCR, EPA also rejected a more reliable alternative method without adequate explanation—EPA's in-house variant of the National Cancer Institute method, which adjusts risk to account for the reality that the general population does not eat the same amount of fish every day over a lifetime. *See National Health and Nutrition Examination Survey* 21–22 (Apr. 2014), https://www.epa.gov/sites/default/files/2015-01/documents/fish-consumption-rates-2014.pdf. Commentators pointed this out to EPA, but the agency offered no justification for rejecting this alternative. Nw. Pulp & Paper Letter 21–22; EPA Response to Comments 159–60.

3. Stacking flawed assumption on top of flawed assumption, EPA unreasonably assumed in setting its FCR that anadromous fish species that spend most of their lives in ocean waters far from the shore (*e.g.*, many species of salmon) have the same degree of exposure to pollutants in inland waters as fish and shellfish found exclusively inland and that the pollutant levels are the result of such exposure. *See* 87 Fed. Reg. at 69,190 ("The pollutant concentrations in anadromous fish are the same as those in inland and nearshore fish."). Again, commenters pointed out this error in the agency's reasoning to no avail. *See* Nw. Pulp & Paper Letter 185. This unsupported assumption is material because EPA relied on it to conclude that no adjustment to its chosen FCR was needed under the 2000 Methodology to account for relative source contributions to risk—*i.e.*, exposures to a chemical from sources other than drinking water and fish from inland and nearshore waters. *See* 87 Fed. Reg. at 69,190–91.

4. EPA compounded its error by combining an unjustifiably high FCR with an unjustifiably high CRL of 1×10^{-6} for PCBs based on a purported need to protect the general population at the level of tribal subsistence fishers. *See* 87 Fed. Reg. at 69,189. Under the 2000

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g/day, nearly three times lower than the input EPA used for Washington's standards. EPA provided no explanation for its "dissimilar treatment" of these two States. *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1245 (D.C. Cir. 2023).

Methodology, these inputs together inform the criteria that are necessary to protect public health. *See, e.g.*, 2000 Methodology at 2–4. As explained, EPA failed to justify overriding Washington's CRL of 2.3 x 10^{-5} for PCBs—and did not offer a good reason to abandon its longstanding policy authorizing a similar rate for the general population, including *in Washington*. *Supra* at 23–29. But even if good reasons supported a more protective CRL, there is no basis—and EPA offered none—for using the same tribal rights rationale to require *both* an inflated FCR *and* an inflated CRL. EPA did not justify deviating from longstanding policy in one instance, much less in two.

IV. EPA's Human Health Criterion for PCBs Is Arbitrary and Capricious Because It Is Neither Measurable Nor Achievable.

"Impossible requirements imposed by an agency are perforce unreasonable." *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991); *Hughey v. JMS Dev. Corp.*, 78 F.3d 1523, 1529 (11th Cir 1996) ("In interpreting the liability provisions of the CWA we realize that Congress is presumed not to have intended absurd (impossible) results."). Thus, when a "contested regulation is unrealistic," it cannot stand. *United States v. Cartwright*, 411 U.S. 546, 550 (1973). Indeed, EPA itself has acknowledged that it "cannot impose more protective measures than can be technically feasibly implemented, as the law cannot compel the impossible." *Hazardous and Solid Waste Management System*, 84 Fed. Reg. 65,941, 65,945 (Dec. 2, 2019).

Here, EPA's 7 ppq PCB criterion is so small that modern technology cannot even reliably detect or measure the pollutant at that concentration. A part per quadrillion is one part per 1,000,000,000,000,000 parts. Try to compare roughly seventeen minutes to the entire age of the Earth (4.5 billion years). That is 7 ppq. EPA has thus imposed a criterion that is unreasonable and unworkable. Yet EPA expects regulated parties to comply with this limit through as-yet-unknown technologies at enormous expense. That is arbitrary and capricious.

1. EPA does not dispute that its PCB criterion cannot be measured. As the agency explains, EPA's most recently approved, state-of-the-art method for measuring PCBs to determine compliance with an NPDES permit "has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method," but "well above" EPA's criterion. 87 Fed. Reg. at 69,195–96 (describing Method 1628). The "current regulatory method" can reliably quantify PCB concentrations only at *500,000 ppq* and greater. *See* 40 C.F.R. § 136.3; *Puget Soundkeeper All. v. Wash. Dep't of Ecology*, 424 P.3d 1173, 1176 (Wash. 2018). Even extremely sensitive analytical methods (which are not approved by EPA to measure NPDES compliance) come nowhere close to reliably measuring 7 ppq—at best, at 1,000 ppq (Method 8082A) or 100 ppq (Method 1668C).

2. EPA's PCB criterion also cannot be attained with any existing technology even if analytical methods improve sufficiently to allow 7 ppq to be measured.

The administrative record is undisputed: 7 ppq is not achievable. As the City of Spokane explained, "[t]he City does not believe 7 ppq will ever be realistically achieved in the Spokane River or in other water bodies across the State" because "PCBs continue to be introduced into the environment under the Toxic Substances Control Act" at a concentration limit "*7 billion times less restrictive* than the proposed WQS." Spokane Letter 2 (emphasis added). The City of Post Falls, Idaho—a small municipal discharger upstream of the Spokane River—similarly highlighted that "there is no existing technology that can be employed to meet these numeric values." Post Falls Letter 1. And in a public presentation to stakeholders, Washington's Department of Ecology has effectively recognized the same: no existing technology can achieve 7 ppq PCBs. Workshop on PCB Variances for Spokane River Dischargers 83 (Nov. 14, 2019), https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf.

The available empirical evidence confirms the same conclusion. A 2013 study by the Association of Washington Business determined that the "best performing" municipal treatment facility in Washington using a microfiltration membrane could reduce PCBs to an approximate range of between 190 and 630 ppq. EPA-HQ-OW-2015-0174-0380, at 12. When AWB updated the study in 2022, it again concluded that "[t]he lowest levels achieved based on the literature review were ... two orders-of-magnitude greater than the proposed [criterion]" of 7 ppq. Nw. Pulp & Paper Letter, Attach. C at 36. EPA disputes none of this.

3. EPA's unattainable PCB criterion has caused significant uncertainty among the regulated community and may, in the long run, undercut efforts to meet the standards.

"Setting a numeric value far below where it can be measured is misleading to the public" and "leaves the regulated community uncertain as to any foreseeable path to compliance and unable to plan for the consequences" that may follow from the standards. Post Falls Letter 2. In fact, the City of Spokane underscored the "uncertainty for the City and its ratepayers" *already* engendered by the 2022 rule. Spokane Letter 2. Washington regulators have developed a draft NPDES permit that proposes a compliance schedule for additional treatment to address PCBs. *Id.* The City has applied for a variance, but it has received no indication that it will be granted, and the City has thus been put to the dilemma of undertaking costly technological developments in a futile effort to comply, or else risking non-compliance while its variance request remains pending. *Id.* ("the City is left with few options"); *see also* National Mining Association Letter 2 ("unattainable standards ... inject significant legal and regulatory uncertainty into the process").

The consequences of EPA's criteria are also significant. When regulated entities attempt to achieve the impossible through "cost-prohibitive technology," facility closures and job losses in Washington communities will follow. Nw. Pulp & Paper Letter 24. EPA's fanciful criteria thus

may prove counterproductive, because "working toward unattainable water-quality standards diminishes" EPA's and Washington's "ability to achieve widespread buy-in on pollutant load controls." K.H. Reckhow, *Unattainable Surface-Water Quality Standards May Diminish Widespread Public Support for Water Quality Improvements*, Cambridge University Press (2016).

4. EPA failed to adequately address these basic concerns. Indeed, its principal response epitomizes arbitrary and capricious decision-making: "[T]echnological feasibility," EPA declared, *does not matter* in setting human health criteria. EPA 2022 Response to Comments 20.

That can't be right. As explained above, water quality standards "set the permissible level of pollution in a specific body of water," which, in turn, are translated into an NPDES permit "that app[lies] to individual polluters." *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005). Water quality standards thus "provide the basis for specific, enforceable requirements *designed to achieve them*," as each permit "must include ... requirements sufficient to protect water quality standards." *In re ACF Basin Water Litig.*, 467 F. Supp. 3d 1323, 1337 (N.D. Ga. 2020) (emphasis added). It is arbitrary to set standards that cannot *ever* be achieved or even measured when the very purpose of the standards is to provide a basis for requirements designed to achieve them.

EPA's fallback response fares no better. EPA urged that potential "implementation concerns" could be addressed by applying for a variance or removal of a designated use for a waterbody. EPA 2022 Response to Comments 20. But these back-end remedies only amplify regulatory uncertainty, as parties are left in limbo while their applications are pending. *See* Spokane Letter 2. And neither option is realistic. Washington has *never* granted a variance, and even if granted, variances are vulnerable to challenge through citizen-suits under the CWA, 33 U.S.C. § 1365. An effort to remove a designated use is even less likely to succeed, since removing a use removes associated criteria for "all dischargers and all pollutants"—a less "targeted" solution

than a variance. *Upper Mo. Waterkeeper v. EPA*, 15 F.4th 966, 972 (9th Cir. 2021).

Thus, EPA's unmeasurable and unachievable PCB criterion is arbitrary and capricious.

V. The Rule Is Arbitrary and Capricious Because EPA Failed to Reasonably Consider Costs or, Alternatively, Conducted an Unreasonable Economic Analysis.

EPA's 2022 rule violates the APA and the CWA in two alternative respects. EPA erroneously concluded that "costs" cannot legally be "considered ... in development of water quality criteria," EPA 2022 Response to Comments 109, or alternatively, that its impossible-to-meet PCB criterion imposes *no* "incremental costs" on regulated parties at all, 87 Fed. Reg. at 69,195. If EPA disclaimed authority to consider costs, EPA misconstrued the CWA and its implementing regulations. In the alternative, if EPA relied on a cost-benefit analysis, its analysis is unreasonable because it rested on the erroneous premise that the costs of its revised criteria are too "speculative" to evaluate before they are incurred. Either way, the rule should be vacated.

A. EPA unreasonably failed to consider costs in setting water quality standards.

EPA failed to meaningfully consider the large compliance costs the rule would impose. EPA's response to comments proffered an erroneous reason as to why: EPA declared that it may *not* consider costs in establishing Washington's revised criteria. *See* EPA 2022 Response to Comments at 109 & n.255. That is wrong as a matter of law, and agency action that disclaims discretion based "on a faulty legal premise" is per se arbitrary and capricious. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985).

1. EPA has broad discretion to decide to weigh costs and benefits in implementing the CWA. As a general rule, agencies should consider costs unless the statute clearly precludes such consideration. *Michigan v. EPA*, 576 U.S. 743, 755 (2015); *see Michigan v. EPA*, 213 F.3d 663, 677–78 (D.C. Cir. 2000) (per curiam) ("[P]reclusion of cost consideration requires a rather express congressional direction"—a "clear congressional intent").

Here, nothing in the CWA precludes consideration of costs in setting water quality criteria. The Act simply provides that the EPA Administrator must deem a new federal standard "necessary" to meet the requirements of the Clean Water Act. 33 U.S.C. § 1313(c)(4)(B). It further states that water quality standards must protect "the public ... welfare" and "serve the purposes of this chapter." *Id.* § 1313(c)(2)(A). These open-ended mandates to make a necessity determination and to protect the "public ... welfare" do not express a "clear congressional intent" to preclude consideration of costs in setting criteria. *Michigan*, 213 F.3d at 678. If anything, they imply that consideration of costs is statutorily *required*.

The Supreme Court's decision in *Michigan v. EPA* is illustrative. There, the Court considered whether EPA could find regulation of hazardous air pollutants from power plants "appropriate and necessary" under the Clean Air Act without considering costs. The Court held that the directive to regulate as "appropriate and necessary" compelled consideration of costs. 576 U.S. at 755–57. Open-ended terms like "appropriate and necessary," the Court reasoned, incorporate cost as part of the relevant calculus both as a matter of common sense and longstanding practice. Regulation is neither necessary nor appropriate when it reflects "wasteful expenditure." *Id.* at 753. And "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate." *Id.* at 752–53.

Similarly, here, the CWA commands the EPA to deem a new federal standard "necessary" to supersede the State's criteria. 33 U.S.C. § 1313(c)(4)(B). The statute further provides that the standards should "protect the public health *or welfare*." *Id.* § 1313(c)(2)(A) (emphasis added). Just like the phrase "appropriate and necessary" in *Michigan*, these open-ended terms—"necessary," and "public … welfare"—embrace economic considerations.

2. EPA justified its contrary view by citing a footnote from the Ninth Circuit's decision in *Upper Missouri Waterkeeper v. EPA*, 15 F.4th 966 (9th Cir. 2021). There, the court construed EPA regulations in dicta to permit the agency to consider costs only in setting designated uses (the first component of a water quality standard), but not in setting criteria to protect those uses (the second component). *Id.* at 972 & n.1.

But *Upper Missouri Waterkeeper* misconstrued EPA's regulations, and its reasoning is not persuasive. To be sure, the relevant regulation directs EPA to base criteria on a "sound scientific rationale." 40 C.F.R. § 131.11(a)(1). But nothing in that directive *forecloses* consideration of costs. The Supreme Court has made clear that mere textual silence does not preclude such consideration. *See Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222, 225–26 (2009) (concluding that consideration of costs is permissible even when the CWA "does not expressly authorize cost-benefit analysis," and even when the CWA establishes a "best technology available" standard). Indeed, EPA itself has long understood that while the criteria are *partially* "grounded in science," they also inescapably involve "risk management decisions." 2000 Methodology at 2–4. Consideration of cost is a necessary element of risk management.

Moreover, EPA's regulation must be "construed" "in light of the statutory mandat[e] under which [it] issue[d]." *Pac. Coast Med. Enters. v. Harris*, 633 F.2d 123, 131 (9th Cir. 1980). The Act draws no distinction between designated uses and water quality criteria for cost consideration purposes. After defining a "water quality standard" as consisting both "of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses," Congress provided in the very next sentence that "*[s]uch standards* shall be such as to protect the public health *or welfare*." 33 U.S.C. § 1313(c)(2)(A) (emphases added). The collective reference to the "standards" (and not merely the "uses") suggests that *both* the uses and the criteria must

advance the "public … welfare"—a capacious term that necessarily embraces economic considerations. *Cf. Michigan*, 576 U.S. at 755; *Michigan*, 213 F.3d at 677–78.

EPA thus erroneously disclaimed authority to consider costs and ignored an important aspect of the problem. That alone is reason to vacate and remand. *Prill*, 755 F.2d at 948.

B. EPA's economic analysis rests on unreasonable assumptions.

Alternatively, to the extent EPA did rely on a cost-benefit analysis, its analysis was not reasonable. Whether or not an agency is "*require[d]*" to consider "economic effects," when "EPA in fact consider[s] economic effects at length," the Court "must review its economic reasoning" to determine "whether its overall decision was reasonable." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 525–26 (D.C. Cir. 1983); *see also Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (similar). Here, although EPA disclaimed authority to consider costs in setting the standard, the agency conducted an economic analysis of its rule. *See* 87 Fed. Reg. at 69,194–96; Economic Analysis for Restoring Protective Human Health Criteria in Washington (Nov. 2022), EPA-HQ-OW-2015-0174-1113 ("Economic Analysis").

The APA does not require "rigorous exactitude," but agencies must at least rationally weigh all relevant costs. *GTE Serv. Corp. v. FCC*, 782 F.2d 263, 273 (D.C. Cir. 1986). "The mere fact that the … effec[t] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004). Nor can an agency ignore economic impacts under the fiction that the impacts are "caused co-extensively by [another] agency action." *N.M. Cattle Growers Ass'n v. U.S. Fish & Wildlife Serv.*, 248 F.3d 1277, 1283 (10th Cir. 2001). And an agency "may not minimize" evidence that undercuts its judgment "without adequate explanation." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018). By attributing *no* incremental costs to any major point sources, EPA's economic analysis here flouts each of these principles.

1. The record shows that compliance costs will be significant. As the City of Spokane highlighted, Washington's Department of Ecology has developed a draft NPDES permit based on the 2022 rule's PCB criterion that would require the City to invest—by a highly conservative estimate—$19 million per gram of additional PCB removal in the Spokane River. Spokane Letter 2. That draft NPDES permit suggests that almost every publicly owned wastewater treatment plant in Washington and other dischargers would need to adopt tertiary membrane filtration treatment or other prohibitively costly measures to address PCBs. As noted, commenters estimated that the incremental cost of such treatment, including construction costs and operation and maintenance costs, would be between $53 and $82 million for a plant that processes 500,000 gallons of wastewater per day, with a net present value unit cost of between $106 and $262 per gallon per day. Thus, "[i]f EPA follows the same approach on Puget Sound that it has on the Spokane River, this will amount to a range of compliance costs from nearly $6 billion to over $11 billion just for the 'major' permits" alone. Nw. Pulp & Paper Letter 70. And regulated parties would do all this not actually to attain the unmeasurable 7 ppq PCB criterion, but simply to bring themselves *within two orders of magnitude* of that criterion. *See supra* at 35–36.

Despite this record evidence, "EPA did not identify any incremental costs" from the rule. 87 Fed. Reg. at 69,195. The agency explained, however, that "[t]his does not mean that EPA anticipates there would" actually be "no costs" as regulated parties "implement controls or modify processes to meet future permit limits." *Id.* Rather, according to EPA, "available data" made such costs too "speculative" to assess. *Id.* So the agency treated them as nonexistent.

EPA's explanation repeats an error the D.C. Circuit has already condemned. In *Public Citizen v. Federal Motor Vehicle Safety Administration*, the D.C. Circuit confronted an agency rule that increased the maximum permissible daily driving time for truckers from ten to eleven

hours. 374 F.3d at 1218. The agency did so based on a cost-benefit analysis that assumed that "time spent driving is equally fatiguing as time spent resting"—thus zeroing out the marginal risk of accidents due to fatigue from "time on task." *Id.* The agency did not deny that such time-on-task effects were real, but believed they were too "uncertain" to consider at all. *Id.* at 1219 (emphasis omitted). The D.C. Circuit was unpersuaded. The court vacated the rule, rejecting the agency's "implausible" assumption that the "effects are nil" merely because they are "*uncertain*." *Id.* Uncertainty, the court emphasized, "is no justification for *disregarding* the effect entirely." *Id.* *Public Citizen* squarely compels vacatur here.

2. EPA's finding of zero compliance costs was also based on unrealistic assumptions that offloaded the costs attributable to the rule to other past and future EPA actions.

a. *First*, EPA's analysis assumed a baseline of "full compliance with existing (including not yet implemented) criteria," and calculated marginal costs only above that baseline. EPA 2022 Response to Comments 139. EPA, in other words, ignored the real "status quo" in favor of its hypothetical baseline. *Id.* This unrealistic premise resulted in a vast understatement of the rule's true costs. *See* Nw. Pulp & Paper Letter 64 (EPA's analysis "assumed" as part of its baseline "that a facility in Washington has an obligation to take additional actions to comply with the existing NTR arsenic criteria" and failed to treat those as incremental costs to the rule).

The Tenth Circuit confronted an analogous issue under the Endangered Species Act in *New Mexico Cattle Growers Ass'n*, 248 F.3d 1277. There, the court considered whether the Fish and Wildlife Service could adopt an approach to determining the "economic impacts" attributable to a critical habitat designation that included only those impacts that would not have occurred "but for" the designation. *Id.* at 1283. Under that approach, such designations were often deemed to have *zero* economic impact, because the effects of a critical habitat designation overlapped entirely with

a separate agency action, the listing of an endangered species. *Id.*

The Tenth Circuit held that this approach to economic analysis was impermissible. "[T]he fact that the FWS says that no real impact flows from the [critical habitat designation]," the court explained, "does not make it so." *N.M. Cattle Growers Ass'n*, 248 F.3d at 1284. The court therefore held that "FWS must analyze all of the economic impacts of critical habitat designation (regardless of whether the impacts are co-extensive with other causes)" because FWS's contrary method had rendered its economic analysis "virtually meaningless." *Id.* at 1284–85.

So too here. Because EPA assumed an improper baseline, "the projected incremental costs in the economic impact analysis" do not track reality and are "vastly understated." Nw. Pulp & Paper Letter 65. EPA's failure to account for these costs is arbitrary and capricious.

b. *Second*, EPA discounted compliance costs by assuring regulated parties that *future* EPA action could alleviate them. Should "substantial costs arise in the future," EPA stated, "alternative permit limits may be derived" and "EPA will provide guidance for applying alternative compliance mechanisms to minimize costs." 87 Fed. Reg. at 69,195.

The APA, however, does not countenance this sort of "trust us" decision-making by federal agencies. *Am. Fed'n of Lab. & Cong. of Indus. Orgs. v. OSHA*, 965 F.2d 962, 980 & n.23 (11th Cir. 1992). As EPA acknowledges, advanced treatment technologies will almost certainly be necessary in the attempt to comply with NPDES permits as "analytical methods and quantitation limits" improve. 87 Fed. Reg. at 69,196. It is unreasonable to ignore such plainly foreseeable costs based on nothing more than EPA's say-so that it will work with regulated parties to minimize them (which would reduce, but not eliminate, the costs to regulated parties).

3. EPA's economic analysis is independently unreasonable because its "assumptio[n]" of zero compliance costs contradicts "data" and "information it had about" costs.

Leather Indus. of Am., Inc. v. EPA, 40 F.3d 392, 402–03 (D.C. Cir. 1994). The rule's costs are not speculative: Washington "regulators have already" sought "to compel the City [of Spokane] to spend additional money to control PCBs" entering the Spokane River. Spokane Letter 2. And commenters provided specific estimates of the rule's future costs.

EPA "minimize[d] [this] evidence without adequate explanation." *Genuine Parts Co.*, 890 F.3d at 312. EPA addressed commenters' cited studies and rejected their conclusions for (1) failing to "recognize baseline conditions" based on the hypothetical world of assumed compliance with current criteria; (2) "speculat[ing]" that new technologies would be required to comply with future NPDES permits; and (3) failing to "recognize the potential for WQS variances or other alternative compliance mechanisms." EPA 2022 Response to Comments 140–41. Those responses simply recite the same baseless assumptions refuted above: EPA's baseline approach misrepresents reality, and unfounded speculation regarding future technological developments or regulatory action cannot justify ignoring the real-world costs the rule would inflict on regulated parties. As EPA itself admits, its "assumption" of "[z]ero compliance costs" "[u]nderestimate[s]" "the total cost of compliance." Economic Analysis 38.

Vacatur is required in light of the "substantial doubt that the administrative agency would have reached the result it did absent [the alleged error]." *Consol. Gas Supply Corp. v. FERC*, 606 F.2d 323, 329 (D.C. Cir. 1979).

CONCLUSION

The administrative record conclusively establishes that EPA exceeded its authority under the CWA and violated the APA by reaching a result that is neither reasonable nor reasonably explained. This Court should enter summary judgment for Plaintiffs and vacate the 2022 rule.

Dated: May 13, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 13, 2024, I filed the foregoing document and all attachments with the Court's CM/ECF System, which will notify each attorney of record.

/s/ Helgi C. Walker
Helgi C. Walker

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF WASHINGTON BUSINESS, et al., Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Civil Action No. 23-cv-3605

PLAINTIFFS' COMBINED REPLY MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO EPA'S AND INTERVENOR-DEFENDANTS' CROSS-MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(*continued*)

Page(s)

TABLE OF AUTHORITIES
(*continued*)

Page(s)

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Statutes

Regulations

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Other Authorities

INTRODUCTION

Defendants' cross-motions for summary judgment are a study in doublespeak. On one hand, EPA asserts that its new PCB criterion changes nothing because the "detection limit of 65,000 pg/L exceeds" both the existing and new criterion. On the other hand, EPA claims that its new criterion affords additional "protection," so vacating it would be seriously "disruptive." Dkt. 49-1 ("Opp.") 26, 44. EPA insists that "tribal treaty-reserved rights" were not a "basis" for the 2022 rule, but it also maintains that the rule is "protective of tribal members exercising" subsistence fishing rights. Opp. 26, 35. For their part, the Tribal Intervenors mistakenly defend EPA's choice of fish consumption rate ("FCR") as based on "suppressed," "*contemporary* fish consumption," but they cannot help adding that FCRs "should reflect consumption that is *not* suppressed by fish availability." Dkt. 52-1 ("Tribes Cross-Mot.") 20 & n.16. And Washington downplays EPA's disruption of the Clean Water Act's "cooperative federalism" scheme, while admitting that the State's "criteria have been in a state of flux since 2016" due to EPA's unwarranted interventions. Dkt. 54-1 ("Wash. Cross-Mot.") 20–21.

These inconsistencies reveal that Defendants lack a coherent theory to justify the 2022 rule. Their arguments fail across the board.

First, unable to defend the 2022 rule on the merits, EPA interposes standing as a hurdle. It beggars belief that businesses, the State of Washington, Tribes, and the federal government have spent nearly a decade litigating standards that might not "ever" matter. Wash. Cross-Mot. 13; *see* Opp. 21. EPA knows better. Plaintiffs' members must comply not only with permit monitoring conditions that require using EPA-approved method *detection* limits, but also with a host of *other* permit obligations arising from or intensified by EPA's new criteria. At minimum, the 2022 rule will force Plaintiffs' members to incur costs in reopening their existing NPDES permits to reflect

the new federal criteria. As regulated parties who are the object of the regulations on review, their standing to challenge this regulation should be beyond dispute.

Second, EPA cannot now disavow its tribal reserved-rights rationale. Plaintiffs have shown that on its face, EPA's final rule necessarily rests on that rationale, and EPA offers no persuasive showing to the contrary. On the merits, EPA does not even defend that rationale, and the Tribes' effort to do so in EPA's stead fails. The Tribes offer nothing remotely suggesting that any treaty imposes affirmative duties to promulgate specific criteria, for specific chemicals, based on specific inputs, under a regulatory scheme that does not require or authorize enforcing tribal rights.

Third, EPA fails to explain its numerous flip-flops. The 2022 rule departed from the 2000 Methodology's guidance that States may protect the general population using a cancer risk level ("CRL") of 10^{-5} so long as highly exposed subpopulations are held to a CRL of 10^{-4}; reversed its position approving chemical-specific inputs in favor of lockstep CRLs for all pollutants; reversed course on EPA's rejection of a tribal-rights rationale in its 2019 approval of Washington's criteria; and abandoned its longstanding position that the CWA does not authorize EPA to reinterpret a State's designated uses. EPA insists that it has not changed position from its prior approval of Washington's criteria just three years earlier, but that stonewalling blinks reality.

Fourth, the 2022 rule is based on unreasonable inputs. EPA defends its decision to override Washington's chosen CRL by reciting the "sound science" refrain, but EPA apparently forgets that the "choice of an acceptable cancer risk level . . . is a risk management decision," not a scientific one. 2000 Methodology at 2–4. Washington's choice fell well within the limits of reasonable risk management allowed by EPA's 2000 Methodology. As to the FCR, EPA maintains that its hand-picked 1994 study of atypical populations accurately reflects contemporary fish consumption by the general population. But the record shows otherwise: "175 g/day is a *compromise* rate"—a

proxy for unsuppressed consumption in the absence of "sufficient data" of the *actual* unsuppressed rate. *Restoring Protective Human Health Criteria in Washington*, 87 Fed. Reg. 69,183, 69,188–89 & n.66 (Nov. 18, 2022) (emphasis added). That choice is arbitrary and unjustified.

Fifth, EPA does not dispute that its PCB criterion is neither achievable nor measurable. EPA's suggestion that fallback measures—including variances, mixing zones, and removal of designated uses—could make the standard achievable some day in the unforeseeable future makes it no less irrational to impose an impossible standard *today*. In any event, neither EPA nor Washington can show that any of those fallback measures are realistic options.

Sixth, EPA cannot show that the Clean Water Act forecloses consideration of costs. EPA's mistaken, contrary supposition alone mandates vacatur and remand. Alternatively, EPA at minimum acted unreasonably by attributing zero compliance costs to the 2022 rule. EPA's repeated speculation that a projection of *zero* could be an "*overestimat[e]*" is facially absurd, Opp. 41 (emphasis added), and EPA's own economists disagree with the agency: EPA's "assumption" of "[z]ero compliance costs" "*[u]nderestimate[s]*" "the total cost of compliance." Economic Analysis 38 (emphasis added).

EPA's glaring errors compel vacatur. The Court should enter summary judgment for Plaintiffs, deny the cross-motions for summary judgment, and vacate the 2022 rule.

ARGUMENT

I. Plaintiffs Have Standing.

As Plaintiffs have shown, they have standing to challenge the entirety of the 2022 rule because it imposes permitting and compliance costs on Plaintiffs' members subject to NPDES permitting in Washington. *See* Dkt. 44-2, Declaration of Paul R. Noe ("AF&PA Decl.") ¶ 9; Dkt. 44-3, Declaration of Christian M. McCabe ("NWPPA Decl.") ¶ 8. Standing is "self-evident" when the plaintiff is "an object of the challenged government action," *New Jersey v. EPA*, 989 F.3d

1038, 1045 (D.C. Cir. 2021), and where, as here, the challenged action "require[s] or forbid[s] some action by the plaintiff[s]," *FDA v. All. for Hippocratic Med.*, 144 S. Ct. 1540, 1556 (2024). EPA's new criteria will lead to the reopening of existing permits, forcing Plaintiffs' members to incur costs in modifying those permits. And EPA's unattainable 7 ppq criterion for PCBs forces Plaintiffs' members to expend significant resources to comply with criterion-based limits 24 times more stringent than limits based on Washington's current, 170 ppq criterion.

EPA does not dispute Plaintiffs' argument that if Plaintiffs' members must bear these costs, Plaintiffs have associational standing. Mot. 17. Nor does EPA dispute the argument that the 2022 rule "subjects existing NPDES permits to modification." *Id.* Because engaging in the permitting process and obtaining a modified permit cost both time and money, and because vacatur would avoid these injuries, those concessions alone suffice to establish standing.

EPA instead principally contends that Plaintiffs lack standing because its new PCB criterion will not change the compliance requirements of existing NPDES permits, which, according to EPA, turn *exclusively* on the detection limit of EPA-approved methods for measuring PCB concentrations. Opp. 21. That explanation, provided for the first time in EPA's brief, is simply incorrect.[1] The CWA and EPA's NPDES regulations tie compliance to water quality standards, not the detection limits of the EPA-approved method for measuring pollutant concentrations that is

[1] The 2022 rule mentions detection limits only in its economic analysis section, in which EPA claims that "limits are subject to change over time" and that "it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods." 87 Fed. Reg. at 69,196. In responding to comments, EPA mentioned detection limits to refute "commenters asserting that dischargers are being pressured to use an unapproved PCB test method," EPA Response to Public Comments 116, EPA-HQ-OW-2015-0174-1112 ("Final Rule RTC"), and to defend its economic analysis, *id.* at 139–40. But EPA never suggested (contrary to law) that non-detect results in monitoring are *sufficient* to comply with NPDES permit conditions and the requirements of the CWA.

applicable at the time to particular permit monitoring conditions. And the record shows that Washington's permitting authority, the Department of Ecology ("Ecology"), has imposed additional permit conditions on Plaintiffs' members that go beyond monitoring and require measurement techniques more sensitive than EPA's asserted detection limit of 65,000 pg/L.

A. "[T]he outlay of funds necessary to secure" additional or modified permits "qualifies as a concrete and particularized, actual and imminent injury." *Hydro Res., Inc. v. EPA*, 608 F.3d 1131, 1144–45 (10th Cir. 2010) (en banc) (Gorsuch, J.). Plaintiffs have standing because the 2022 rule triggers permit reopening and imposes additional out-of-pocket costs on their members.

Plaintiffs' members hold NPDES permits issued by Ecology that are valid for five years so long as the holder remains in compliance with the conditions of the permit. AF&PA Decl. ¶ 9; NWPPA Decl. ¶ 8; Dkt. 49-2, NPDES WA0003697 at 1; Dkt. 49-3, NPDES WA0000124 at 1. Pursuant to EPA regulations, however, *see* 40 C.F.R. §§ 122.44(d)(1)(vi)(C)(4), 122.62(a)(3), (7), Ecology included a reopener clause in these permits that triggers "modification" upon the "[p]romulgation of new or amended standards or regulations having a direct bearing upon permit conditions," NPDES WA0003697 at 31; NPDES WA0000124 at 84. For certain permits issued after EPA proposed the 2022 rule on April 1, 2022, Ecology included an express condition stating that "Ecology will reopen the permit should the Human Health Criteria for PCBs be revised." *E.g.*, NPDES WA0000892 at 44 (issued Apr. 11, 2022); Supplemental Declaration of Christian M. McCabe ("Supp. McCabe Decl."), Ex. 1, NPDES WA0000825 at 35 (issued June 30, 2022).

The 2022 rule forces Plaintiffs' members to incur out-of-pocket expenses to engage in the permitting process and obtain a modified permit. *See* Supp. McCabe Decl. ¶¶ 5–8. Revising permits to reflect EPA's criteria generally requires a drafting process and public-comment period, each of which requires both time and money from the permittee. *See id.* ¶ 8 (discussing "legal and

consulting support" and commitment of employee time to obtain permit modification); 40 C.F.R. §§ 124.5(c), 124.6(e). The 2022 rule also raises the costs of permit renewals by requiring applicants to collect additional data relevant to evaluating the more stringent federal criteria. *See* Supp. McCabe Decl. ¶ 9; 40 C.F.R. § 122.21(e)–(g). The "out-of-pocket costs" of "undergo[ing] the . . . permit process for a second time" are a classic injury-in-fact. *Hydro Res.*, 608 F.3d at 1144–45 (quotation omitted); *Iowa League of Cities v. EPA*, 711 F.3d 844, 870 (8th Cir. 2013) (finding standing where "[a]t least some [of plaintiffs'] members are currently operating under permits . . . inconsistent with the EPA [rule], which they must imminently rectify"); *see also City of Dover v. EPA*, 956 F. Supp. 2d 272, 277 (D.D.C. 2013) (finding standing where EPA "added restrictions to the [plaintiffs'] NPDES permits"). Indeed, even "[a] dollar of economic harm is . . . an injury-in-fact for standing purposes." *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017).

These costs are traceable to the 2022 rule because Ecology is required to modify the permits to bring its NPDES program into compliance with EPA's new criteria. *See* 33 U.S.C. § 1342(b); 40 C.F.R. §§ 122.43–44; *Me. Lobstermen's Ass'n v. NMFS*, 70 F.4th 582, 593 (D.C. Cir. 2023) (finding standing to challenge biological opinion with "virtually determinative effect" on license conditions). EPA does not dispute the point, and Washington affirmatively concedes that permits must be reopened "to incorporate the 7 pg/L human health criteria for PCBs in the 2022 Final Rule," Wash. Cross-Mot. 15. Ecology has given no indication that it intends to deviate from this practice here. These permit reopening costs alone establish standing.

B. EPA focuses its fire on the purported irrelevance of its own 7 ppq PCB criterion. Permit compliance, EPA asserts, is determined *entirely* by the applicable detection limit of 65,000 pg/L—not EPA's new 7 ppq PCB criterion. Opp. 17, 42. That is an extraordinary claim. If it were right, EPA has wasted a decade attempting to override Washington's 170 ppq standard for no reason at

all. *See* Opp. 21 ("the PCB criteria for Washington waters have never been measurable with EPA-approved methods"). EPA's own persistent regulatory efforts reveal its claim as disingenuous—and wrong.

Contrary to EPA, NPDES compliance is tied *to water quality standards*, not *the detection limit* for monitoring. NPDES permits must include "any requirements . . . necessary to . . . [a]chieve *water quality standards established under section 303 of the CWA*," including limits that "control all pollutants or pollutant parameters" that "may be discharged at a level which will cause, have the *reasonable potential* to cause, or contribute to an excursion above *any State water quality standard*." 40 C.F.R. § 122.44(d)(1)(i) (emphases added). Ecology's regulations are equally unambiguous: Permits "must be conditioned so the discharges authorized will meet *the water quality standards*," and "[n]o waste discharge permit can be issued that causes or contributes to a violation of *water quality criteria.*" WAC 173-201A-510(1) (emphases added). When a permitting authority finds a "reasonable potential" that applicable standards or criteria will be exceeded, the permit "must" include conditions to address that potential. 40 C.F.R. § 122.44(d)(1)(iii)–(iv). For example, permits may require best management practices that impose additional obligations not tied to an EPA-approved detection limit, *id.* § 122.44(k), including by mandating technologies that reduce emissions before measurement, *id.* § 122.44(a)(1); *see* WAC 173-201A-020.

EPA's discussion of monitoring is also incomplete. EPA claims that only the EPA-approved detection limit of 65,000 pg/L for PCBs matters for compliance purposes because States can only use methods that EPA has promulgated through notice-and-comment rulemaking for addition to 40 C.F.R. § 136.3. Opp. 21–22. But EPA's own regulations say otherwise. States may require permitholders to use alternative methods with approval from the relevant EPA Regional

Office, 40 C.F.R. § 136.5, and approval is not required to use alternative methods for purposes other than standard monitoring requirements in permits, *id.* § 122.44(i)(1)(iv).

Here, Ecology has already imposed permit conditions on Plaintiffs' members untethered to EPA-approved methods, including a best-management-practices requirement that aims to reduce PCB emissions below 65,000 pg/L. *See* Supp. McCabe Decl., Ex.1, NPDES WA0000825 at 27–28. The cited permit uses the more sensitive Method 1668, which has a detection limit between *40 and 60* pg/L for PCBs, to require quarterly monitoring and develop additional permit conditions to avoid potential criteria violations. *See id.* at 28; Ecology Fact Sheet for NPDES Permit WA0000825, at 52–53 ("Ecology will also use data from Method 1668" to make reasonable-potential determinations, calculate effluent limits, impose technology-based requirements, and evaluate best-management practices). Tellingly, even Washington acknowledges that its Department of Ecology uses methods other than those codified in 40 C.F.R. § 136.3 to ensure compliance with pollution-minimization requirements and notes that variance determinations "could also be made based on data showing violations of the end-of-pipe effluent limit for PCBs collected using a . . . method that is *not approved* under 40 C.F.R. Part 136." Wash. Cross-Mot. 15–16 (emphasis added). EPA mentions none of this, but it forecloses EPA's assertion that the detection limit of its nationally approved method for PCB measurement, Method 608, sets the *sole* measure of NPDES permit compliance.

C. The implications of EPA's position are also untenable. According to EPA, federally imposed water quality standards and criteria are not judicially reviewable unless EPA has already approved a method with a detection limit that is as sensitive or more sensitive than the criteria limit. So EPA's PCB criterion may *never* be reviewable. *See* Opp. 41; Wash. Cross-Mot. 14 ("it is uncertain that there will ever be a detection method . . . sensitive enough to detect a violation of

the 7 pg/L standard"). Such a result cannot be squared with "the APA's 'basic presumption'" in favor of judicial review. *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 144 S. Ct. 2440, 2459 (2024).

Moreover, EPA's theory means that any change in approved detection limits—whether through notice and comment or even Regional Office approval, which occurs entirely outside of the Federal Register—changes the effective *criteria* limit for States and permitholders. That would itself violate the CWA, which requires EPA to promulgate recommended criteria for States, impose federal criteria on noncompliant States, and promulgate criteria for federal permits through different, enumerated sets of procedures subject to different statutory standards. *See* 33 U.S.C. §§ 1314(a) (recommended criteria), 1313(c) (Administrator Determinations with respect to States), 1342 (federal permitting). EPA's position requires accepting that when Congress required EPA to "promulgate *guidelines* establishing test procedures for the *analysis* of pollutants," *id.* § 1314(h) (emphases added), it meant "promulgate guidelines establishing the compliance requirements for pollution control." That position is not credible, and EPA does not even attempt to argue that its testing-guidelines authority empowers the agency to adjust substantive controls.

Consider, too, what EPA's theory would mean when the agency proposes updated testing procedures. The stakes of such a proceeding would be a wholesale revision of nationally applicable effluent limits, applicable in one fell swoop to state permitholders, federal permitholders, and state standards—effectively obviating the CWA's careful balance between state and federal authority and delineated procedures that apply separately to each category. Congress does not "hide elephants in mouseholes" in this manner. *Sackett v. EPA*, 598 U.S. 651, 677 (2023) (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)).

Even if the Court could accept EPA's general theory that a party's standing to challenge water quality criteria depends on the availability of a sufficiently sensitive EPA-approved test method, it would fail in this instance. EPA has already announced its intent to designate Method 1628—a more sensitive test method—as an approved test method. *See* EPA Agency Rule List – Spring 2024, tinyurl.com/6wks95ws (projecting a proposed rule titled "Clean Water Act Methods Update Rule for the Analysis of Contaminants in Effluent" in 2025). So under EPA's own theory, Plaintiffs' harm is imminent.

In any event, EPA's argument at best goes to the merits of the 2022 rule, not to standing. In assessing standing, "a federal court must assume *arguendo* the merits of [the plaintiff's] legal claim." *Tanner-Brown v. Haaland*, 105 F.4th 437, 445 (D.C. Cir. 2024); *NRDC v. EPA*, 755 F.3d 1010, 1018 (D.C. Cir. 2014) (similar). On the merits, Plaintiffs contend that the 2022 rule is unlawful because it imposed unreasonably stringent criteria and failed to account for reliance interests and compliance costs. Mot. 29–38. *Assuming* Plaintiffs are correct, Plaintiffs' members are undoubtedly injured. Even EPA implicitly recognizes that its dispute goes to the merits (not standing) when it reiterates the same detection-limit theory to minimize the rule's compliance costs in an effort to show that the 2022 rule is reasonable. Opp. 42; *accord* Wash. Cross-Mot. 13–16.

It should be no surprise that EPA's standing arguments are misguided. Regulated parties, the State, the Tribes, and the federal government have not engaged in nearly a decade of litigation about criteria that might never matter. Plaintiffs have standing.

D. Finally, EPA is also incorrect that this Court "ha[s] jurisdiction to evaluate the reasonableness of *only* the Final Rule's PCB criteri[on]." Opp. 20 (emphasis added). Plaintiffs argue that EPA arrived at the PCB criterion by reversing its 2019 approval of Washington's criteria without adequate explanation, Mot. 23–29, and by adopting an unreasonable FCR for *all* federal

criteria imposed by the 2022 rule, Mot. 29–34. None of EPA's reasoning was specific to a particular criterion. *See Restoring Protective Human Health Criteria in Washington*, 87 Fed. Reg. 19,046, 19,051 (Apr. 1, 2022) (reversing 2019 approval of all relevant Washington criteria); 87 Fed. Reg. at 69,188–89 (adopting 175 g/day FCR for all federal criteria); *accord* Opp. 13 ("EPA found that the 2019 approved 141 human health criteria did not protect Washington's designated uses"). If the PCB criterion fails, so do the rest. *See Mozilla Corp. v. FCC*, 940 F.3d 1, 46–47 (D.C. Cir. 2019) (per curiam) ("When a party alleges concrete injury from promulgation of an agency rule, it has standing to challenge essential components of that rule . . . even if they are not directly linked to Petitioners' injuries; if Petitioners' objections carry the day, the rule will be struck down and their injury redressed."); *see also Sierra Club v. FERC*, 867 F.3d 1357, 1366 (D.C. Cir. 2017) ("Because they allege concrete injury from FERC's order certifying the pipeline project, and because that certification was based on an allegedly inadequate environmental impact statement, these Sierra Club members, and therefore Sierra Club itself, have standing to object to any deficiency in the environmental impact statement. The deficiency need not be directly tied to the members' specific injuries." (cleaned up)). Plaintiffs have standing to challenge the 2022 rule in its entirety.

II. EPA Exceeded Its Statutory Authority Under The CWA And Failed To Follow Its Own Regulations.

In 2016, EPA aggressively defended a tribal-treaty rights rationale to adopt a PCB criterion of 7 ppq "based on harmonizing the requirements of the CWA with the terms of the treaty-reserved subsistence fishing right." *Revision of Certain Federal Water Quality Criteria Applicable to Washington*, 81 Fed. Reg. 85,417, 85,423 n.39 (Nov. 28, 2016). EPA thus recognized that science alone could not support that impossible criterion. In 2022, EPA adopted the same criterion again, noting that it had "no new data," 87 Fed. Reg. 69,190, was "applying the same rationale" as the

2016 rule in selecting the relevant inputs, *id.* at 69,189, and that its chosen criterion was necessary to protect "tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels," *id.*

EPA now downplays those statements and insists that it arrived at the same 7 ppq criterion based on "sound science" alone. Opp. 23. The record shows otherwise. EPA's statements in the 2022 rule themselves confirm that EPA relied on a tribal-treaty rights rationale, and EPA does not even try to defend that rationale on the merits. The Tribes' effort to do so in EPA's stead fails.

A. The final rule was unequivocal: "EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule." 87 Fed. Reg. at 69,189. The 2022 rule adopted 2016 rule's inputs wholesale, including by "using the same FCR of 175 g/day . . . that EPA used in its 2016 Federal rule," *id.* at 69,188, and the same 1 x 10^{-6} CRL for PCBs, *id.* at 69,189. And the 2022 rule produced the same output. Indeed, the 2022 rule imposed the same criteria values for *all* pollutants that were also within the scope of the 2016 rule. *Compare* 81 Fed. Reg. at 85,430–31, *with* 87 Fed. Reg. at 69,192–93.

In so doing, EPA necessarily applied a tribal-treaty rights rationale. The 175 g/day FCR, for example, was a "compromise minimum consumption rate" advanced by the Tribes, which the Tribes accepted "so long as . . . coupled with a CRL of 10^{-6}." 87 Fed. Reg. at 69,189. According to EPA, the study that backed that consumption rate "provide[d] scientifically sound estimates of fish consumption . . . for the *tribal* target general population." 81 Fed. Reg. at 85,426 (emphasis added). In turn, the selection of a *tribal* target population—rather than Washington's general population—was based entirely on a tribal-treaty rights rationale. *Id.* at 85,424. Despite purporting to disavow any reliance on tribal rights in the 2022 rule, EPA incorporated the same inputs, based on the same study, and reached the same result. Without its tribal-treaty rights

rationale, there would be no support for EPA's decision to select the FCR or CRL that it did here.

EPA minimizes the "same rationale" statement in the 2022 rule, asserting that the rule "cited to narrow portions" of the 2016 rule discussing only its choice of FCR and "did not cite the portions of the 2016 rule" that concerned "tribal treaty-reserved rights." Opp. 32. That is demonstrably wrong. In the 2022 rule, EPA "specifically cited" pages 85,426 to 85,428 of the 2016 rule, in which EPA adopted both an FCR and CRL *based on a tribal-treaty rights rationale*. Opp. 32; *see* 87 Fed. Reg. at 69,189 n.56 (citing 81 Fed. Reg. at 85,426–28). On those very pages, EPA explained that its chosen FCR was "scientifically sound . . . for the *tribal* target general population," 81 Fed. Reg. at 85,426 (emphasis added), and that the CRL "ensures that the resulting human health criteria for carcinogens protect the *subsistence fishing* component of the designated use," *id.* at 85,427 (emphasis added). Washington had no such designated use; EPA invented it using its tribal-treaty rights theory. *See* Mot. 20, 26–29. In incorporating the same inputs in the 2022 rule, EPA repeated the same mistakes: It chose inputs "protective of" tribal members' right "to harvest and consume fish and shellfish at subsistence levels." 87 Fed. Reg. at 69,189. The 2022 rule's selected inputs and outputs are no mere coincidence. EPA cannot adopt the *results* of the 2016 rule's rationale without backing the rationale itself—the 2022 rule "must be measured by what the [agency] did, not by what it might have done." *SEC v. Chenery Corp.*, 318 U.S. 80, 93–94 (1943).

EPA's other responses are makeweight. The agency asks the Court not to look behind its "sound science" rationale, Opp. 17; *see* Tribes Cross-Mot. 10, 12–13, but the tribal-treaty rights rationale is not lurking behind the curtain. It is plain on the face of the 2022 rule, which expressly incorporated it by reference. *Contra* Tribes Cross-Mot. 13 (characterizing tribal-treaty rights rationale as an "unstated" reason).

EPA also quibbles that the Tribal Reserved Rights Rule—which confirms EPA's rationale in Washington and adopts that rationale nationwide—is outside the record. But EPA forfeited this argument when it failed to raise it in reply to Plaintiffs' opposition to EPA's transfer motion. *Cf.* Dkt. 25 at 5. And this Court already took judicial notice of the Tribal Reserved Rights Rule in denying EPA's transfer motion. Dkt. 48 at 20 (citing Tribal Reserved Rights Rule and noting that "*[t]he record* supports the plaintiffs' contention that the Agency intends to roll out the treaty-rights interpretation on a nationwide basis" (emphasis added)). That decision was correct: The Tribal Reserved Rights Rule is a public record of the *same agency* adopting *the same rationale* as the 2016 rule *at the same time* that the 2022 rule revived it. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022). The Court need not look beyond the record to find EPA's tribal-treaty rights rationale, but in any event, it is "not required to exhibit a naiveté from which ordinary citizens are free." *Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019); *see also Chenery*, 318 U.S. at 93–94.

B. On the merits, EPA does not even try to defend the tribal-treaty rights rationale. Even if EPA had defended it, EPA's position would not be entitled even to "due respect" given the agency's flip-flopping—embracing the tribal-treaty rights rationale in 2016, abandoning it in 2019, and reviving it in 2022. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2257–58 (2024) (courts owe "due respect to Executive Branch interpretations of federal statutes" only when "consistent over time"). The Tribes now take up the cause on EPA's behalf, Tribes Cross-Mot. 23–26, but "[a]n intervening party may join issue only on a matter that has been brought before the court by another party," *Ill. Bell. Tel. Co. v. FCC*, 911 F.2d 776, 786 (D.C. Cir. 1990); *see Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 185 n.5 (D.C. Cir. 2012) (Kavanaugh, J., dissenting) ("intervenors generally may not raise arguments not raised by the parties"). Because EPA has

abandoned its claimed statutory authority for the 2022 rule, the rule must be vacated. *See Johnson v. Copyright Royalty Bd.*, 969 F.3d 363, 389 (D.C. Cir. 2020); *Competitive Enter. Inst. v. Dep't of State*, 2022 WL 4547959, at *1 (D.D.C. Aug. 10, 2022).

C. In any event, the Tribes' defense of the tribal-treaty rights rationale fails. As Plaintiffs have shown, EPA lacks authority to override state decisions by interpreting tribal treaties. *See* Mot. 6–9, 19–23. That asserted power lacks any basis in the Clean Water Act or its implementing regulations and falls far outside of the agency's expertise.

Moreover, the Stevens Treaties impose only *negative* duties—*limits* on the federal government's power. And nothing in any treaty creates affirmative authority for EPA to impose specific human health criteria on States under the CWA, much less to require *specific* inputs in calculating those criteria. Mot. 19–20.

Rather than refute these dispositive considerations, the Tribes essentially concede them. They principally contend that the Stevens Treaties imply a "duty" to "preserve" and "avoid interference" with tribal fishing rights. Tribes Cross-Mot. 23–24, 26. That is just another way of describing a negative duty, and it does not help EPA. Under a tribal-treaty rights theory, EPA must show that a treaty *affirmatively* compels *specific* water quality standards in Washington such that it has statutory authority to reject the State's standards and promulgate federal ones. The Tribes can point to no treaty text expressing any such obligation.

The Tribes' cases confirm that the Stevens Treaties impose only negative duties. *Northwest Sea Farms, Inc. v. U.S. Army Corps of Engineers*, 931 F. Supp. 1515, 1518 (W.D. Wash. 1996), involved a permit approval for a fish farm that "would deny members of the Lummi Nation access to the site." *No Oilport! v. Carter*, 520 F. Supp. 334, 372 (W.D. Wash. 1981), concerned approval of a pipeline that would "degrade the fish habitat by destroying spawning grounds." And

Parravano v. Babbitt, 70 F.3d 539, 546 (9th Cir. 1995), held only that the government may issue regulations to limit "overharvesting" of fish that "threatened the Tribes' ability to harvest their share of the salmon." The Tribes' remaining cases fit the same pattern: a permit approval for "construction of a marina" that would occupy a fishing ground; a federal project that "would destroy salmon . . . nests"; and a federal dam that would "inundat[e] fishing grounds." Tribes Cross-Mot. 26.

Plaintiffs do not dispute that States may not affirmatively destroy fishing grounds, bar fishers from accessing them, or obstruct fish passage. Mot. 20. But those direct interferences with fishing rights are far afield from the authority EPA has asserted here. EPA claims that "tribal treaty rights" somehow require Washington to promulgate specific human health criteria that are protective of tribal populations' exercise of reserved rights; to rewrite the State's Clean Water Act designated uses; to select an FCR appropriate for tribal subsistence fishers (not Washington's general population); and to protect tribal subsistence fishers with a CRL of one case in a million persons. The Tribes do not seriously contend that any treaty affirmatively imposes such granular obligations, and their extended defense of a general duty of non-interference is irrelevant.

The Tribes likewise fail to refute *Arizona v. Navajo Nation*, 599 U.S. 555 (2023), and *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569 (9th Cir. 1998). The Tribes attempt to distinguish *Arizona* as a case involving "affirmative steps" to secure water, Tribes Cross-Mot. 27, but that is the key *similarity* here, not a difference: EPA must show that treaties require it to impose water quality standards with concomitant "affirmative" duties. And the Tribes miss *Morongo Band*'s *holding* in distinguishing its *facts* as involving a "breach of [trust]": Tribal treaties supply no affirmative obligations above generally applicable law unless they identify "a specific duty . . . with respect to Indians." 161 F.3d at 574. The Tribes do not even attempt to

show that any such "specific duty" exists here that supports EPA's power-grab.

Finally, the Court should greet with "skepticism" EPA's newfound discovery that tribal treaty obligations supercharge its authority to override state water quality standards and change the federal-state balance struck by the Clean Water Act. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); *see West Virginia v. EPA*, 597 U.S. 697, 725 (2022) (explaining that the "want of assertion of power by those who presumably would be alert to exercise it" is highly "significant in determining whether such power" exists). The Tribes suggest that harmonization of tribal-treaty rights tracks "decades of Executive Branch" practice, Tribes Cross-Mot. 28 n.20, but the cited practice involves the uncontroversial duty to avoid destroying or denying *access* to fishing grounds—not EPA's authority to force States to adopt water quality standards to protect tribal populations at particular CRLs or FCRs. There is no such power, and not even EPA believed it existed for the first 45 years after the CWA's enactment.

III. EPA's Unjustified Changes In Position Violate The APA.

EPA barely musters a defense of its unjustified changes of policy in the 2022 rule. Plaintiffs have shown that the 2022 rule abrogated longstanding policy by: (1) departing from the 2000 Methodology's guidance that States may protect the general population using a CRL of 10^{-5} so long as highly exposed subpopulations are held to a CRL of 10^{-4}; (2) reversing its position, expressed as recently as 2019, that States may use chemical-specific inputs and are not required to use blanket CRLs for all pollutants; (3) reversing the 2019 approval's robust rejection of a tribal-rights rationale; and (4) abandoning its longstanding position that, consistent with the CWA, EPA lacks authority to reinterpret a State's designated uses. Mot. 24–29. Instead of defending those decisions, EPA insists that the 2022 rule worked no change on the regulatory scheme at all. Opp. 33–35. So EPA fails even to acknowledge its changes, much less to "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

A. EPA counters that the 2022 rule did not reverse the agency's deferential approach to state selection of CRLs under the 2000 Methodology, or alternatively, that the agency adequately explained the change. Neither contention holds water.

In asserting that there was no change in position, EPA quibbles that Washington's 2.3 x 10^{-5} CRL for PCBs was "*less stringent*" than the 1 x 10^{-5} contemplated by the 2000 Methodology. Opp. 33–34. But the 2000 Methodology allowed any CRL at the "10^{-5} risk level," 2000 Methodology at 2–6, and 2.3 x 10^{-5} falls along that level. That is why EPA's 2019 approval explained that "the chemical-specific [CRL] of 2.3 x 10^{-5} falls within the range of protective risk rates the EPA has recommended since it issued its 2000 Methodology and is protective of the State's designated uses." 2019 Approval at 19; *see also id.* at 23 (explaining that the 2000 Methodology authorizes states to protect "tribes" and "other highly exposed subpopulations" to 1 x 10^{-4}). In 2019, EPA understood "that selecting an appropriate cancer risk level is a risk management decision." *Id.* at 10; 2000 Methodology at 2–6. In 2022, EPA did not.

Next, EPA changes tack to argue that the 2022 rule *did* include a reasoned explanation for the change by contending that the 2019 approval did not "engag[e] with Washington's lack of a scientific rationale for that value." Opp. 34 (citing 87 Fed. Reg. at 69,190). But the cited portion of the 2022 rule does not "acknowledge" any change in position, *Fox*, 556 U.S. at 515, much less fault the 2019 approval for failing to engage with Washington's rationale. And EPA mischaracterizes the 2019 approval. The agency there expressly found that Washington's criteria were "based on sound science" while, at the same time, acknowledging that the choice of CRL was ultimately a "risk management decision" involving non-scientific considerations. 2019 Approval at 10. EPA failed to address this rationale in the 2022 rule and simply declared the opposite conclusion. That is not reasoned decisionmaking. "EPA's final rule was not reasonably explained,"

and "it instead ignored an important aspect of the problem before it." *Ohio v. EPA*, 144 S. Ct. 2040, 2054 (2024) (cleaned up).

B. EPA similarly contends that the 2022 rule is consistent with the agency's prior policy that States may use chemical-specific CRLs, stating that the agency took issue *only* with Washington's scientific basis for its PCB value. Opp. 33. Not so. The rule asserts that "*it is important* to keep these values consistent," "because these values are associated with the population that the criteria are intended to protect and *are not pollutant-specific*." 87 Fed. Reg. at 69,189 (emphases added). *That* was EPA's sole affirmative justification for using 1×10^{-6}, rather than 1×10^{-5}, or any other value—and it is an unexplained departure from prior agency guidance leaving States discretion to manage risks on a chemical-by-chemical basis.

C. EPA's attempt to disclaim any policy change on the appropriate role of tribal reserved rights fails for the same reason as its statutory-authority arguments: EPA necessarily relied on a tribal-treaty rights theory to reinstate the results of the 2015 disapproval and 2016 rule. *Supra*, at 12–14; *contra* Opp. 35. If EPA believes the 2019 approval was wrong in this respect, it must explain why and justify its new position.

D. Finally, as noted above, EPA's only response on the rewriting of Washington's designated uses is the *ipse dixit* that EPA "did not interpret" the State's designated uses at all. Opp. 25 n.11. That is incorrect. EPA expressly reinterpreted Washington's designated uses in the 2016 rule, and as explained above, it did the same thing in the 2022 rule by readopting the conclusions reached under that reinterpretation. *Supra*, at 13. Absent such reinterpretation, EPA's decision here would lack any basis whatsoever.

IV. EPA Based Its Human Health Criterion for PCBs on Unreasonable Assumptions.

EPA fails to justify its unreasonable inputs—a 175 g/day FCR, and a 1×10^{-6} CRL.

A. ***Fish Consumption Rate.*** EPA's FCR was unjustifiably designed to approximate an unsuppressed tribal fish-consumption rate, and EPA fails to support the sole study on which that rate is based. EPA's responses do not track.

1. EPA contends that its FCR was rational because it would not have made sense to use "a different rate" for PCBs than other chemicals, and because EPA had no "new data" to justify a different rate from the 2016 rule. Opp. 28 (emphasis omitted). Neither explanation works. As to the first, EPA does not dispute that States are free to make "chemical-specific risk management decision[s]," Mot. 27, and "[t]he choice of default fish consumption rates for protection of a certain percentage . . . of the general population is clearly a risk management decision," 2000 Methodology at 1–9. Moreover, EPA cannot bootstrap the validity of its PCB criterion to its other criteria. The FCR is no more defensible for other chemicals, and EPA is wrong to assume otherwise. *See supra*, at 10–11.

EPA's no "new data" rationale also fails. It assumes that the "data" it used in the 2016 rule is supportable, but as Plaintiffs have shown, the 1994 CRITFC Study is not a valid source for extrapolating Washington's water quality standards and criteria. *See* Mot. 31.

EPA's efforts to rehabilitate the CRITFC Study's shortcomings fail. EPA resists Plaintiffs' characterization of the study as "cherry-picked," Opp. 30, but the agency fails to address the study's own statement that other studies "reporting estimates for tribal populations" reached "consistently lower" estimates of fish consumption, Mot. 31 (quoting *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* 60 (Columbia River Inter-Tribal Fish Commission 1994), tinyurl.com/53c9x9ar). EPA defends the study's inclusion of fish consumed from grocery stores by touting the importance of being able to "safely" consume fish from all potential sources, and the need to avoid producing "less stringent

water quality criteria." Opp. 30. Put aside that this reflects precisely the sort of "outcome driven" reasoning for which EPA faults Washington. Opp. 26. More importantly, those considerations miss the point: Including fish consumed from grocery stores as part of the FCR makes no sense because grocery store fish are not necessarily ever *exposed* to Washington waters. *See* Mot. 31; *id.* at 9 n.1 (explaining that the logic for including FCR as an input is that fish are exposed to carcinogens in Washington waters). EPA offers no rational explanation.

The Tribes assert (at 29) that Plaintiffs wrongly characterize the CRITFC Study as investigating an "unsuppressed" FCR. Plaintiffs said no such thing. Rather, Plaintiffs contended that EPA used the study's findings as "an approximation for the counterfactual 'unsuppressed' rate of consumption by tribal subsistence fishers." Mot. 31. And that is indeed how the 2022 rule characterizes EPA's selected rate: Absent "sufficient data regarding unsuppressed fish consumption"—which EPA said "could be necessary where tribal treaty or other reserved fishing rights apply"—EPA chose 175 g/day as a "compromise minimum consumption rate" with the Tribes—a proxy for unsuppressed consumption. 87 Fed. Reg. at 69,186, 69,189 n.66. Despite EPA's efforts to disclaim what it plainly did, even the Tribes acknowledge that "EPA explains that FCRs generally *should* reflect consumption that is not suppressed by fish availability or concerns about the safety of available fish." Tribes Cross-Mot. 20 n.16 (citing 87 Fed. Reg. at 19,049) (emphasis added). But Plaintiffs have already explained why attempting to track "'unsuppressed' consumption" is contrary to the Clean Water Act's design and reflects arbitrary decisionmaking, Mot. 31-32—and again, EPA's and the Tribes' only answer is silence.[2]

[2] EPA errs again in asserting that the "CRITFC Survey focused on *contemporary* consumption of aquatic species," Opp. 29 (emphasis added). As Plaintiffs explained, that study attempted to discern a historical decrease in fish consumption by asking survey respondents over the age of 30

EPA's "no new data" rationale is especially arbitrary because the 2016 rule reasoned only that the CRITFC Study supplied an appropriate benchmark "for the *tribal* target general population." 81 Fed. Reg. at 85,426 (emphasis added). As EPA admits, "the survey was specific to tribal members consuming fish in the Columbia River Basin." Opp. 29. Having purportedly disavowed a tribal-treaty rights rationale, EPA could no longer blindly rely on the same study to reach the same result. Doing so was arbitrary and capricious.

2. EPA and the Tribes' remaining arguments fare no better. They suggest that EPA's choice is defensible because it mirrored Washington's own choice. But that is not a justification; it only pushes the arbitrariness of EPA's choice back a step. And it underscores that EPA did not actually conduct a scientifically sound inquiry, simply piggybacking off Washington's unrealistic FCR.

The Tribes also point to Oregon's and Maine's FCR inputs as comparators. Tribes Cross-Mot. 20. Plaintiffs already explained that Oregon is an inappropriate comparison, and the Tribes offer no response. *See* Mot. 32 n.6. Maine only reinforces EPA's error: Maine has adopted an FCR of 200 g/day because it (not EPA) has designated a "*sustenance* fishing use" for its waters. Tribes Cross-Mot. 20 (emphasis added). Washington has no such use; EPA invented such a use for Washington only by invoking a tribal right to subsistence fishing. *See supra*, at 13. Comparing Washington to Maine thus highlights EPA's error—its invocation of a tribal-treaty rights theory to rewrite Washington's designated uses.

B. ***Cancer Risk Level.*** EPA's efforts to justify its CRL also lack merit.

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about whether their "current pattern of fish consumption differs *from . . . 20 years ago*." Mot. 31 (emphasis added) (quoting A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin 20 (Columbia River Inter-Tribal Fish Commission 1994), tinyurl.com/53c9x9ar).

1. As EPA's 2000 Methodology explained, a State complies with the Clean Water Act in selecting a CRL "if the State . . . has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation." 2000 Methodology at 2–6. EPA concedes that States may select a CRL at the level of 10^{-5} or lower so long as highly exposed subpopulations are protected at the 10^{-4} level. Opp. 5. Washington indisputably complied with these requirements. That should have been the end of the inquiry.

2. Nonetheless, EPA contends that it had authority to override Washington's "risk assessment" because the State's CRL "was not supported by sound scientific reasoning." Opp. 33. But that commits a category error. CRLs are not principally science-based. As EPA has explained, the "choice of an acceptable cancer risk level" is a "risk management decision," involving "social, economic, and political concerns." 2000 Methodology at 2–3 to 2–4 (comparing science, which "refer[s] to the extraction of data from toxicological or exposure studies," with risk management, which is a normative endeavor). Whether PCBs are a carcinogen is a scientific question; the acceptable population-level risk of cancer from PCB exposure is not. EPA's mistake is predictable, but it is one the 2000 Methodology warned against—failing "to separate scientific analysis from . . . risk management decisions." *Id.*

EPA derides Washington's selected 2.3×10^{-5} CRL as "outcome driven," Opp. 26, but that similarly reflects the agency's misunderstanding of the purpose of a CRL. That choice of CRL necessarily turns on the State's view of acceptable outcomes—the amount of risk it is willing to tolerate from PCBs, subject to federal minimum requirements.

In any event, EPA offers no reason for *replacing* that CRL with its choice of 1×10^{-6}. It is EPA's burden to justify that choice, and EPA has not done so. The 2022 rule attempts to justify

picking a 1 x 10^{-6} value over a 1 x 10^{-5} risk level, or any other risk level, by invoking a categorical preference for lockstep CRLs for all chemicals. *See supra*, at 19. EPA now apparently concedes that "States may use chemical-specific cancer risk levels," Opp. 33, but that concession leaves it with no affirmative rationale for its choice. In the end, therefore, EPA's chosen input reflects only arbitrary decisionmaking.[3]

V. EPA's PCB Criterion Is Arbitrary and Capricious Because It Is Neither Measurable Nor Attainable.

EPA does not dispute that impossible requirements are per se unreasonable, or that EPA cannot impose technically infeasible measures. *See* Mot. 34 (collecting authorities). Moreover, EPA does not dispute that a 7 ppq PCB criterion may *never* be achievable. And EPA does not dispute that this concentration is so small that currently available technology *cannot even reliably detect it*. *Id.*; Wash. Cross-Mot. 14 (agreeing that it is "uncertain" whether there will "ever" be a detection method "sensitive enough to detect a violation of the 7 pg/L standard"). Those concessions alone end this case in Plaintiffs' favor. EPA's responses fall flat.

A. EPA first seeks to usher its new PCB criterion off-stage by repeating its refrain that only EPA's 65,000 pg/L detection limit matters. To begin, EPA did not even *mention* the detection limit in seeking to minimize attainability concerns during the rulemaking, or in any way suggest that non-detects in monitoring are sufficient for NPDES and CWA compliance. *See generally* Final Rule RTC; *supra*, at 4 & n.1. It cannot raise the argument for the first time in litigation. *See*

[3] EPA accuses Plaintiffs of "mistakenly contend[ing]" that Washington used a *1* x 10^{-5} CRL. Opp. 32. That is incorrect; one searches Plaintiffs' brief in vain for any such reference. Plaintiffs simply explained that EPA had authorized CRLs *at the 10^{-5} risk level*—and 2.3 x 10^{-5} certainly falls along that order of magnitude. *See* Mot. 9, 10, 12, 13, 14, 25, 33, 34 (repeatedly characterizing Washington's CRL as "2.3 x 10^{-5}"). It is EPA's brief that muddies the waters on this issue, not Plaintiffs'. EPA declares that 1 x 10^{-6} "cancer risk level is a scientifically sound, risk-management decision *made by Washington*," Opp. 33 (emphasis added), but it was EPA that made that choice, not Washington.

DHS v. Regents of Univ. of Cal., 591 U.S. 1, 20 (2020) ("review of agency action is limited to the grounds that the agency invoked when it took the action" (quotation omitted)). Regardless, as explained, EPA is incorrect: Other EPA and Ecology regulations leave room for requiring the use of more sensitive analytical tools. *See supra*, at 7–8. Some regulated permitholders must undertake quarterly monitoring obligations that require measurement of PCB concentrations using a method that can detect concentrations as low as 40 ppq. *Supra*, at 8. That falls far below the current 170 ppq standard (while still exceeding EPA's impossible-to-achieve 7 ppq standard). And EPA itself is preparing to approve the more sensitive Method 1628. *See supra*, at 10.

B. EPA next suggests that human health criteria are merely aspirational goals, and that any noncompliance will be mitigated by variances, removal of designated uses, and mixing zones. But the criteria are not mere ideals. They "provide the basis for *specific, enforceable* requirements designed to achieve them." *In re ACF Basin Water Litig.*, 467 F. Supp. 3d 1323, 1337 (N.D. Ga. 2020) (emphasis added); *see* 33 U.S.C. § 1365(a) (authorizing citizen suits to enforce "a permit or condition of a permit issued under section 1342," *i.e.*, an NPDES permit). Washington's current PCB criterion is 170 pg/L, and it is no coincidence that NPDES permits impose "an end-of-pipe effluent limit of 170 pg/L." Wash. Cross-Mot. 15. When criteria change, permit limits change, too. *See supra*, at 7.

Regardless, neither EPA nor Washington claims that the State has actually adopted any of these fallback measures. *See* Opp. 44; Wash. Cross-Mot. 15–16 nn.5–6. Washington suggests that it diligently processed variance applications after 2016, but the Spokane River dischargers' variance applications have remained in limbo for nearly a decade. Wash. Cross-Mot. 15–16 nn.5–6. The State's cited source (*id.* at 16 n.6) tells the true story: "This rulemaking is permanently on hold." Wash. Dep't of Ecology, Ch. 173-201A WAC (Variances), tinyurl.com/ycy7u8sm.

EPA's other proposed mechanisms lend the government no additional support. Implicitly conceding that "removing designated uses is unrealistic," Opp. 44, EPA suggests that "mixing zones" would offer a more targeted solution, *id*. But a mixing zone permits a discharger "to exceed applicable water quality criteria within a defined area or volume of water around the discharge *as long as the WQS is met at the edge of the mixing zone*." Final Rule RTC 20 (emphasis added). EPA offers no reason to believe that this edge-of-the-zone requirement could ever be met, because its PCB criterion is *impossible* to meet.

In short, EPA demonstrates a clear lack of concern for the plight of permitholders who will be out of compliance indefinitely, and EPA's nonchalant reliance on the notion that supposed regulatory "tools" may solve the problem is misplaced.

C. Finally, EPA's rulemaking never addressed the significant uncertainty and downstream regulatory consequences the rule engenders while its proposed fixes go through the required process. *See* Mot. 36–37. Nor does the rule address the implications of EPA's new argument that the detection limit is in fact the compliance expectation, which would mean NPDES permitholders must constantly be on the lookout for detection-limit developments and EPA's review of the same in administrative proceedings that have nothing to do with substantive water quality standards and criteria. *Supra*, at 8–9. EPA's opposition again offers only silence. That is a significant aspect of the problem EPA has failed to consider, and sufficient reason to vacate and remand.

VI. The 2022 Rule Is Arbitrary And Capricious Because EPA Failed To Reasonably Consider Costs Or, Alternatively, Conducted An Unreasonable Economic Analysis.

EPA either erroneously concluded that costs cannot be considered at all in setting criteria, Final Rule RTC 109, or else unreasonably relied on an analysis showing that the 2022 rule imposes *no* compliance costs at all, 87 Fed. Reg. at 69,195. Either way, the rule cannot stand.

A. EPA Cannot Show That The Clean Water Act Authorizes It To Ignore Costs.

EPA purports to prove that the Clean Water Act *forecloses* consideration of costs in setting water quality criteria, but EPA largely ignores the interpretive arguments Plaintiffs have advanced. And EPA's proof fails.

1. ***Text.*** EPA does not dispute that "preclusion of cost consideration requires" a "clear" statement of congressional intent. *Michigan v. EPA*, 213 F.3d 663, 677–78 (D.C. Cir. 2000) (per curiam); Mot. 38. But EPA does not even try to point to any such clear statement, and none exists.

a. As Plaintiffs explained, the Clean Water Act's text *at least* permits consideration of costs in setting human health criteria. *See* Mot. 40. The Act provides that the Administrator must promulgate new criteria if "necessary" to meet the Act's requirements, 33 U.S.C. § 1313(c)(4)(B), and that water quality standards—both designated uses *and* corresponding criteria—must protect "the public . . . welfare" and "serve the purposes of this chapter," *id.* § 1313(c)(2)(A). EPA does not dispute that the Act's purposes include attainability, *id.* § 1251(a)(2), or that terms as capacious as "necessary" and "public welfare" embrace cost considerations, *see* Mot. 39–40. Indeed, EPA does not discuss these textual phrases at all.

Instead, EPA principally misdirects the Court to its own *regulations*. Opp. 36 (citing 40 C.F.R. §§ 131.10, 131.11(a)). But EPA fails to show that anything in its regulations forecloses cost consideration, and nothing in the statutory text prohibits setting human health criteria based on economic considerations. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024) ("Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority."); Mot. 40.

b. When EPA finally turns to the statute, the best it can muster (in a "*see also*" signal) is that considering costs somehow contravenes the requirement that human health criteria be "based

upon" designated uses, 33 U.S.C. § 1313(c)(2)(A). Opp. 36; *see also* Opp. 38. But EPA does not explain how considering costs contravenes that provision. It does not. The "based on designated uses" provision defines *the purposes* the criteria serve (to protect, say, fish harvesting), not *the inputs* for calculating them. And there is no contradiction in saying that human health criteria must reflect technologically feasible and cost-attainable limits in supporting a designated use. *See* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 57 (2012) (no statute pursues a single "purpose at all costs"); Mot. 37 (citing authority for the proposition that "unattainable" standards backfire in achieving their purposes because they undercut community buy-in). In fact, if EPA were right today, its 2000 Methodology would be wrong: Setting human health criteria is an irreducibly normative task, requiring consideration not only of scientific data and the designated uses, but also of "social, economic, and political concerns." 2000 Methodology at 2–4.[4]

Finding no support in Section 1313, EPA pivots to an entirely different statutory section—33 U.S.C. § 1314(a). But that section concerns the EPA Administrator's promulgation of criteria *recommendations* to assist States in setting their own criteria. It is unsurprising that those non-binding recommendations must "accurately reflec[t] the latest scientific knowledge," *id.*, because they impose no duties and involve no risk assessment or cost-balancing. But the standards that States must actually promulgate and enforce are different—and governed by different text and purposes, *see id.* § 1313(c). In the statutory provision that matters, EPA finds nothing to back its view that Congress intended to foreclose cost consideration.

[4] Moreover, the concept of a "designated use" can embrace economic considerations. Such uses can include not only environmental purposes (like "propagation of fish and wildlife") but also "industrial, and other purposes." 33 U.S.C. § 1313(c)(2)(A).

In a last gasp, EPA perplexingly suggests that Plaintiffs have "forfeited" their statutory interpretation arguments by "ma[king] no statutory-interpretation argument regarding EPA's consideration of cost" in their opening brief. Opp. 38 n.15. EPA apparently missed multiple pages in Plaintiffs' brief in support of summary judgment. *See* Mot. 38–40 (arguing that "consideration of costs is statutorily required" under the Act (emphasis altered)).

2. ***Precedent.*** Controlling Supreme Court precedent confirms that EPA's interpretation is wrong. EPA points to purportedly contrary cases, but its cases are wrong, irrelevant, or both.

a. EPA offers no persuasive answer to *Michigan v. EPA*, 576 U.S. 743 (2015). It says that the phrase "appropriate and necessary" in *Michigan* permitted cost consideration because the statute concerned a decision "whether to regulate," and regulation necessarily involves balancing costs. Opp. 39. But imposing more stringent human health criteria is also a decision "whether to regulate." Water quality standards "provide the basis for specific, enforceable requirements designed to achieve them." *In re ACF Basin Water Litig.*, 467 F. Supp. 3d at 1337; *see supra*, at 25. The fact that *other* mechanisms may mitigate a new criterion's burdens renders the decision initially to impose those burdens no less "regulatory."

EPA also cavils (at 39) that the agency was required "to study" costs in the provision at issue in *Michigan*. But that was only "further indication" of Congress's intent there. 576 U.S. at 753. EPA misses *Michigan*'s key takeaway: When Congress uses capacious language in authorizing regulation—"appropriate and necessary" in *Michigan*, "necessary" and "public . . . welfare" here—EPA errs when it disclaims authority to consider costs.

b. EPA's own cases lend it little support. Its principal authority—the Fifth Circuit's decision in *Mississippi Commission on Natural Resources v. Costle*—rested on the mistaken premise that Congress must "explicitly requir[e]" consideration of "economics and cost." 625 F.2d 1269,

1276 (5th Cir. 1980). That flips the D.C. Circuit's clear-statement rule on its head. *See supra*, at 27. *Costle* also arose in a pre-*Loper Bright* world: The Fifth Circuit undertook no serious analysis of the Act's text, and it analyzed statutory questions by asking whether it was "not unreasonable for the EPA Administrator to interpret the Act" as he did, 625 F.2d at 1276 (discussing another aspect of Act).

The Ninth Circuit's decision in *Upper Missouri Waterkeeper v. EPA*, 15 F.4th 966 (9th Cir. 2021), undercuts EPA's statutory construction. The court reasoned that the Act "*does not speak at all* to whether EPA may consider compliance costs when approving a State's proposed water quality standards," and held only that it was reasonable at *Chevron* step two for EPA to construe the Act to require States to consider costs in setting designated uses, but not in setting human health criteria. *Id.* at 973 (emphasis added). That conclusion conflicts with EPA's view that the CWA *does* speak to the issue by foreclosing consideration of costs in setting criteria. Regardless, the Ninth Circuit's reasoning—bottomed on *Chevron*'s obsolete method—should not persuade. And EPA offers no response to Plaintiffs' showing (Mot. 40–41) that *Upper Missouri Waterkeeper* misconstrued EPA's regulations even if it lawfully interpreted the statute.[5]

[5] EPA's remaining cases add nothing. *Grand Portage Band v. EPA*, 2024 WL 1345202, at *10 (D. Minn. Mar. 29, 2024), merely cited *Costle* without analysis. And *Grand Portage*, if anything, undermines EPA's position. The court upheld EPA's decision to *approve* Minnesota's removal of certain criteria because of "[c]oncerns about convenience and costs," noting that these were appropriate for at least the State to consider in setting criteria. *Id*. EPA's other two cases—*NRDC v. EPA*, 16 F.3d 1395 (4th Cir. 1993), and *El Dorado Chemical Co. v. EPA*, 763 F.3d 950 (8th Cir. 2014)—did not even present the issue whether EPA may consider costs in setting human health criteria. *See NRDC*, 16 F.3d at 1402 (refusing to review "every bit of technical evidence," and simply holding that EPA "applied the correct legal standard" in reviewing state criteria); *El Dorado*, 763 F.3d at 960 (noting that state challenged only "the scientific evidence in the record").

* * *

When a statute permits cost consideration, it is arbitrary and capricious for agencies not to consider the costs its desired regulation would impose on the public. *Michigan*, 576 U.S. at 753; *see Loper Bright*, 144 S. Ct. at 2263. And at minimum, EPA has acted under the mistaken legal premise that it may *not* consider cost considerations. Vacatur and remand are thus required. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985).

B. Alternatively, EPA Unreasonably Zeroed Out Compliance Costs.

EPA fares no better in defending the economic analysis that it actually performed. Its responses only underscore why vacatur is required.

1. EPA first asserts that its economic analysis is "outside the scope" of APA review because an economic analysis was not "require[d]" and thus is not a "basis" for the rule. Opp. 39–40. But EPA's economic analysis is plainly in the "existing administrative record" and part of EPA's "contemporaneous explanation," *Dep't of Com.*, 588 U.S. at 780; EPA points to its economic analysis *by citing the record*, Opp. 40–41 (citing Final Rule RTC 139). And EPA offers no answer to the rule that when "EPA *in fact* consider[s] economic effects at length," the Court "must review its economic reasoning" to determine "whether its overall decision was reasonable"—regardless of whether EPA was "require[d]" to consider "economic effects." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 525–26 (D.C. Cir. 1983) (emphasis added); *see* Mot. 41. EPA cannot insulate its unreasonable economic analysis from review.

2. EPA defends its erroneous baseline for analyzing costs—a hypothetical world of full compliance with existing standards—on the ground that it prevents "double count[ing]" costs attributable to existing standards. Opp. 40. On its own terms, that rationale makes little sense. When EPA replaces current standards with new ones, it wipes the existing standards from the

books; there is nothing left to "double count." And regulated parties inhabit the real world, not EPA's counterfactual one. They must incur *all* incremental costs to comply with the new standard.

EPA does not dispute that the Tenth Circuit rejected a similar approach to agency economic analysis in *New Mexico Cattle Growers Association v. Fish & Wildlife Service*, 248 F.3d 1277 (10th Cir. 2001). *See* Mot. 43–44. The agency's analysis there was "virtually meaningless," EPA agrees, but EPA greenlights its own meaningless analysis here because "the [Clean Water] Act and EPA's regulations do not even require an economic analysis." Opp. 40. But EPA overlooks that the Administrative Procedure Act always demands reasonableness. *See Loper Bright*, 144 S. Ct. at 2263 (courts must "ensur[e] the agency has engaged in 'reasoned decisionmaking'" (quoting *Michigan*, 576 U.S. at 750)). When EPA prepares a 98-page analysis and touts the benefits of public "transparency," Opp. 14, it cannot deflect scrutiny by dismissing its own analysis as an empty ritual, *cf. Small Refiner*, 705 F.2d at 525–26. Rather, when EPA undertakes such an analysis, EPA "must analyze all of the economic impacts" of its actions, "regardless of whether the impacts are co-extensive with" other agency actions. *N.M. Cattle Growers*, 248 F.3d at 1284–85.

3. EPA also fails to show that its estimate of zero compliance costs was "reasonable and reasonably explained." *Ohio*, 144 S. Ct. at 2053. EPA asserts that it made "conservative assumptions to err on the side of overestimating costs," Opp. 41 (citing Final Rule RTC 139), but the notion that *zero* compliance costs is an "overestimat[e]" is hard to take seriously. Even EPA's economists say the opposite: EPA's "assumption" of "[z]ero compliance costs" "[u]nderestimate[s]" "the total cost of compliance." Economic Analysis 38; *see* Mot. 45.

And EPA's assertion that zero is an overestimate reflects an obvious fallacy. Because "improve[d] . . . treatment technologies" could "reduce compliance costs" from the rule, the argument seems to run, compliance costs could someday be lower than they are today—and the rule,

EPA thus concludes, could impose *negative* compliance costs. Final Rule RTC 139. That is a *non sequitur*. Regulated parties' ability to reduce compliance costs through *other means* does not reduce the costs *imposed by the rule*, any more than a tenant's new income reduces the rent he owes his landlord. It simply makes the regulated industry (or the tenant) better equipped to pay. Anyway, there is no evidence in the record that an improved treatment technology that would lower compliance costs is forthcoming. And even if such a hypothetical treatment system were eventually developed, it would not offset costs incurred until such time. EPA's conclusion of negative compliance costs has no basis in reality, much less the record.

Moreover, EPA's uncertainty about the magnitude of the compliance costs did not justify zero-ing them out. EPA cannot distinguish *Public Citizen v. Federal Motor Vehicle Safety Administration*, 374 F.3d 1209, 1218–19 (D.C. Cir. 2004), which condemned this exact error. EPA asserts that in *Public Citizen* it was "implausible" and "dubious" that the cost effects there were "nil," *id.*, but it is equally implausible here. Commenters offered "a range of compliance costs from nearly $6 billion to over $11 billion just for the 'major' permits" alone. Nw. Pulp & Paper Letter 70. EPA's speculation that improvements in technology could reduce these costs did not justify discounting them altogether. *See Interstate Nat. Gas Ass'n of Am. v. Pipeline & Hazardous Materials Safety Admin.*, 2024 WL 3837458, at *7 (D.C. Cir. Aug. 16, 2024) (explaining that an agency "fails to meet the requirement of a reasoned cost-benefit analysis" when it "contradicts itself" by asserting both that the rule will "impose no costs at all" and that it will "impose some costs that cannot be calculated"). And EPA's last resort—that nothing will change because permitholders need satisfy only the EPA-approved detection limit of 65,000 pg/L—simply reruns its meritless standing arguments. *See supra*, at 6–10.

At the very least, EPA's explanation for its economic analysis was inadequate. Commenters apprised the agency of significant compliance costs, Mot. 42, yet EPA "elected not to speculate on future analytical capability." Final Rule RTC 141. That was especially unjustifiable given EPA's recent push to approve a more sensitive test method—Method 1628, which EPA could easily have considered in modeling the 2022 rule's potential costs. *See* EPA Agency Rule List – Spring 2024, tinyurl.com/6wks95ws. "EPA's own statements and actions confirm the agency appreciated" cost concerns, but "it failed to address the concern adequately." *Ohio*, 144 S. Ct. at 2055–56.

VII. The Court Should Vacate The 2022 Rule.

EPA ends with a plea for remand without vacatur. Given that remedy's hotly "disputed legality," *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring), courts reserve it only for "exceptional" circumstances, *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 519 (D.C. Cir. 2020); *see Corner Post*, 144 S. Ct. at 2463 (Kavanaugh, J., concurring) ("[T]he D.C. Circuit . . . [has] long recognized vacatur as the usual relief when a court holds that agency rules are unlawful.").[6] Courts assess (1) "the seriousness of the [rule's] deficiencies," and (2) "the disruptive consequences of vacating the [r]ule." *Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017) (cleaned up). "The burden to demonstrate such

[6] As several judges on the D.C. Circuit have explained, remand without vacatur "rests on thin air. No statute governing judicial review of agency action permits such a disposition and the controlling statute—5 U.S.C. § 706(2)(A)—flatly prohibits it." *Checkosky v. SEC*, 23 F.3d 452, 490 (D.C. Cir. 1994) (separate opinion of Randolph, J.); *see also Milk Train, Inc. v. Veneman*, 310 F.3d 747, 757 (D.C. Cir. 2002) (Sentelle, J., dissenting) (similar); *cf. In re Core Commc'ns*, 531 F.3d at 862 (Griffith, J., concurring). Scholars have backed the same view, *e.g.*, Ronald M. Levin, *"Vacation" at Sea: Judicial Remedies and Equitable Discretion in Administrative Law*, 53 Duke L.J. 291, 378–80 (2003), as have other circuits, *e.g.*, *Nat'l Ass'n of Priv. Fund Managers v. SEC*, 103 F.4th 1097, 1114 (5th Cir. 2024) ("Under section 706 of the APA, when a court holds that an agency rule violates the APA, it 'shall'—not may—'hold unlawful and set aside' [the] agency action." (citation omitted)).

extraordinary circumstances lies with the government." *Cigar Ass'n of Am. v. FDA*, 2023 WL 5094869, at *3 (D.D.C. Aug. 9, 2023).

EPA does not come close to such a demonstration. As to the "seriousness" of the rule's defects, EPA contends that it faces at most "record-based deficiencies." Opp. 45. That's wrong. Because EPA lacks statutory *authority* to harmonize state standards with tribal rights, the rule is *ultra vires*, full stop. And while EPA seemingly believes that its errors are cosmetic, they cut to the heart of the rule. EPA failed to consider compliance costs or the effects of regulatory uncertainty; attempted to revive an unlawful tribal-rights rationale; and wrongly second-guessed the State's risk-management decisions. *See SecurityPoint Holdings, Inc. v. TSA*, 867 F.3d 180, 185 (D.C. Cir. 2017) ("the court *must* vacate a decision that 'entirely failed to consider an important aspect of the problem'" (emphasis added)); *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009) (vacatur is appropriate "when the agency has not responded to empirical data or to an argument inconsistent with its conclusion"). Remand without vacatur would only reinforce EPA's apparent "indifference." *In re Core Commc'ns*, 531 F.3d at 862 (Griffith, J., concurring).

As to disruptive consequences, EPA unironically asserts that vacatur would "frustrate Washington's ability to implement CWA programs." Opp. 45. But any such frustration is of EPA's own making—its repeated override of the State's standards and risk-management decisions, dating back to 2016. More to the point, if the challenged rule is vacated, existing permits will continue to enforce the prior water quality standards. It is EPA's new standards themselves, not vacatur of those standards, that would disrupt the status quo.

CONCLUSION

The Court should enter summary judgment for Plaintiffs and vacate the 2022 rule.

Dated: September 24, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 24, 2024, I filed the foregoing document and all attachments with the Court's CM/ECF System, which will notify each attorney of record.

/s/ Helgi C. Walker
Helgi C. Walker

DEPARTMENT OF
ECOLOGY
State of Washington

Washington State Water Quality Standards: Human health criteria and implementation tools

Overview of key decisions in rule amendment

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Washington State Water Quality Standards: Human health criteria and implementation tools

Overview of key decisions in rule amendment

Water Quality Program
Washington State Department of Ecology
Olympia, Washington

00003

Table of Contents

List of Figures and Tables

Figures

Tables

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Overview

What is this rulemaking about and is it required of the state?
This state rulemaking is a revision to the Water Quality Standards (WQS) for Surface Waters of the State of Washington (Chapter 173-201A WAC; WQS). This rulemaking only addresses two specific areas of the WQS: (1) development and adoption of new human health criteria (light grey highlighted area in Figure 1), and, (2) revision and expansion of some of the tools in the standards that help in criteria implementation (darker grey highlighted area in Figure 1). This document explains the proposed changes and the rationale supporting the changes, including specific risk management input to Ecology by Governor Inslee on July 9, 2014. The preliminary proposed rule language can be seen at Ecology's Water Quality Standards website: : www.ecy.wa.gov/programs/wq/ruledev/wac173201A/1203inv.html

All states are required to adopt surface water quality standards by a federal law: the Federal Water Pollution Control Act (hereinafter called the Clean Water Act or CWA). Surface waters include (among others) streams, lakes, river, bays and marine waters. States adopt water quality standards to

- Protect public health or welfare
- Enhance the quality of water
- Serve the purposes of the Clean Water Act

Section 303(c) of the Clean Water Act provides the federal legal basis for the water quality standards program. Section 303(c)(2)(b) specifically requires states to adopt criteria for toxic priority pollutants. The federal regulatory requirements governing the water quality standards program, the Water Quality Standards Regulation, are published by the federal government in the *Code of Federal Regulations* (CFR) at 40 CFR 131.

Washington state law gives Ecology authority and responsibility to protect the quality of Washington waters and implement federal CWA programs. This authority and responsibility, with regard to WQS, can be found in the Revised Code of Washington (RCW): RCW 90.48.030, RCW 90.48.035, and RCW 90.48.260(1).

What is in Washington's Surface Water Quality Standards?
The surface water quality standards regulation (WAC 173-201A) defines the water quality goals of the surface waters in Washington. As required by federal regulation, the WQS include:

- Designated uses (also called beneficial uses) for all surface waters, such as aquatic life habitat, recreational uses, harvest, public and industrial water supply, and others.
- Water quality concentrations or levels (called criteria) necessary to protect the uses. These criteria can be numeric (such as concentrations of chemicals or maximum temperatures) or narrative (e.g., descriptions such as "…must not … offend the senses of sight, smell, touch, or taste…").
- Requirements that degradation of water quality is prevented through antidegradation provisions.

Washington's WQS also contain other provisions that aid in and direct the implementation and future changes to the standards.

The designated uses, criteria, antidegradation provisions, and other provisions are illustrated in Figure 1.

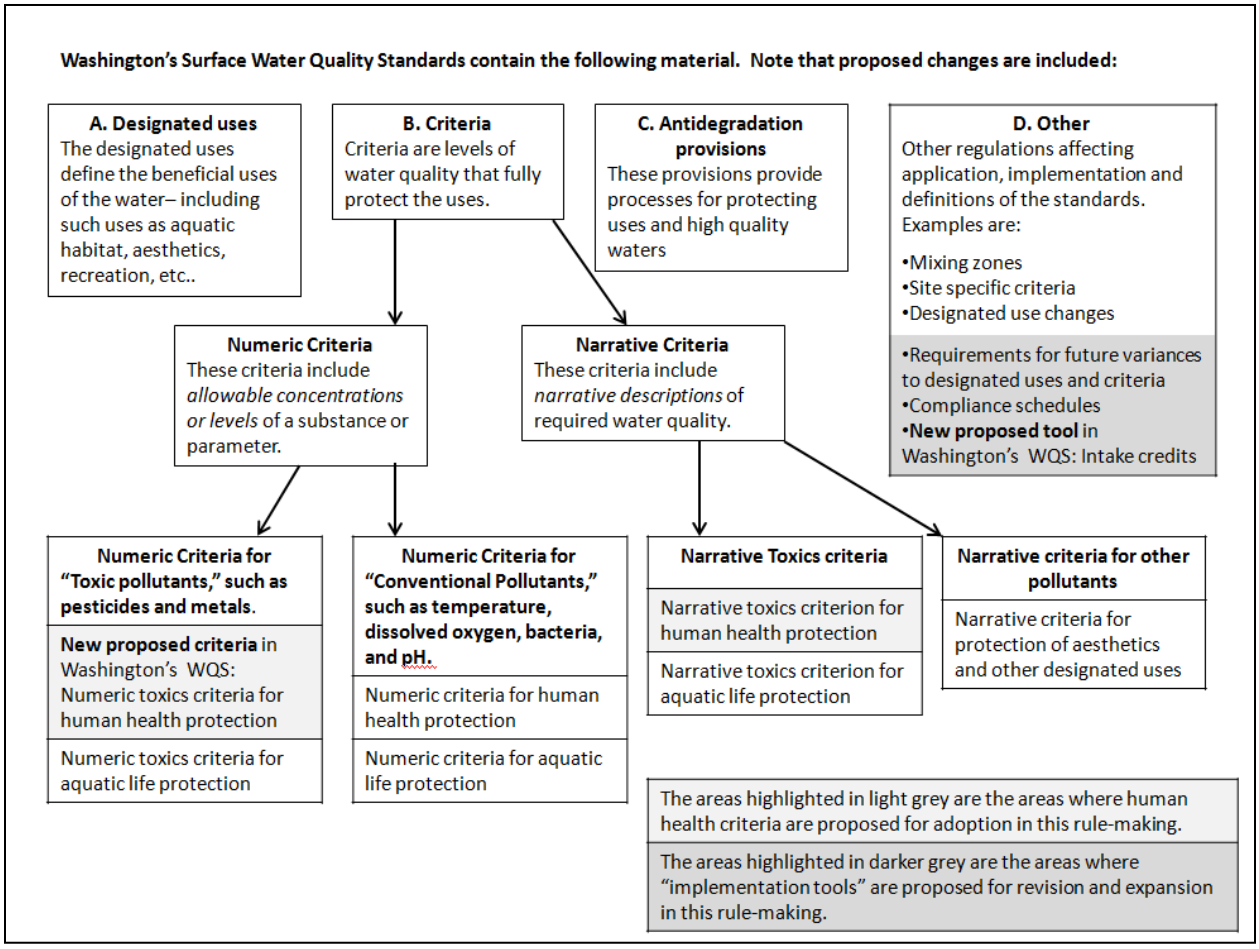

Figure 1: Water quality standards proposed changes

How are water quality standards revised?

Washington's WQS are revised periodically through a formal public rulemaking process. Revisions are made to incorporate new science, to meet new federal or state requirements, to provide additional clarity, and for many other reasons. All WQS revisions are submitted to the United States Environmental Protection Agency (USEPA or EPA) for Clean Water Act (CWA) approval prior to use. If Endangered Species Act (ESA)-listed species are affected by new WQS, then EPA is required to consult with the National Ocean and Atmospheric Administration (NOAA) and United States Fish and Wildlife Service (USFWS) regarding effects of the new WQS on the ESA-listed species prior to approval of the WQS.

An important part of the state's rule revision process, and in determining which revisions are most important to make, is public review and discussion about the water quality standards. Federal regulations require that states hold public hearings at least once every three years to

review applicable surface water quality standards and, as appropriate, adopt new or modified standards. This process is called a *triennial review*.

The triennial review provides an opportunity to discuss the priorities and commitments that Ecology makes with EPA and others regarding the surface water quality standards. Ecology then places activities (guidance development, research needs, or rulemaking) on schedules that match their complexity and importance, rather than trying to force them into a three-year cycle. The latest (2010) triennial review and the Water Quality Program's five-year plan for water quality standards can be seen at http://www.ecy.wa.gov/programs/wq/swqs/triennial_review.html.

Because the triennial review and subsequent rule making processes are an ongoing set of actions, this approach results over time in a balanced ongoing update to the WQS, with higher priority items taking precedence in rulemaking efforts (see text box below).

Selection of rulemaking topics

- Topics are selected based on the goal of getting the greatest environmental and/or administrative benefit.
- Topics are prioritized based on the expected environmental benefits, technical complexity, available staff resources, federal mandates, and need for change in the water quality standards guidance, rule, or process.
- A long-term list of prioritized topics is maintained, with commitments to implementing changes (rulemaking or otherwise). Those short-term (<1-5 years) priorities are built into the Ecology and EPA Performance Partnership Agreement (Ecology commitments to EPA), based on Ecology's ability to anticipate and commit staff resources.
- The long-term list of topics is reviewed, and modified where appropriate, during each Triennial Review.

What are the specific areas of the rule that are being considered for rule-modification?
This rulemaking addresses two specific areas of the WQS: (1) development and adoption of new human health criteria, and, (2) revision and expansion of some of the tools in the standards that help in implementation. These are discussed separately below.

New human health criteria.
Numeric criteria. The human health criteria are water concentrations for toxic substances that protect people who consume fish and shellfish from local waters and who drink untreated water from local surface waters. These criteria are calculated from a variety of different factors, including chemical-specific toxicity to humans, how chemicals move from water into fish and shellfish and then into humans, as well as other factors. The criteria calculation and these factors are discussed at more length in the section on Human Health Criteria Variables. Specific information on arsenic is found in the section on Challenging Chemicals: Arsenic. The development and adoption of new human health criteria includes consideration of new science on toxicity factors and new information on body weight and Washington-specific fish consumption. The factors that are included in the criteria calculations are a mix of average and higher percentile values, and are consistent with EPA guidance and practice. This approach results in high levels of consumer protection from pollutants that could be found in untreated surface water, fish, and shellfish from Washington. These factors were applied to 93 of 96 different chemicals in this proposed rule (see section on Criteria Chemicals). The criteria for

arsenic, copper and asbestos are not calculated values – instead they are based on the regulatory level used in the Safe Drinking Water Act (SDWA; 42 U.S.C. § 300f and as amended).

As well as incorporation of new science, this rulemaking also includes several risk management decisions that affect the final criteria values. Governor Inslee announced a proposal for the new criteria on July 9, 2014 (http://governor.wa.gov/news/releases/article.aspx?id=293). In this proposal, he included specific risk management direction that enables the calculation of criterion values. These included input to Ecology on the risk level used in the criteria calculations for carcinogens (a change from a one-in-one million additional lifetime risk of developing a cancer to one-in-one-hundred thousand), and a feedback on an updated fish consumption rate that is part of the calculations for carcinogens and non-carcinogens (a new proposed average fish consumption rate of 175 g/day).

In addition, Governor Inslee announced as an overlay to all of the calculated criteria values (except arsenic): *the new criteria values are to be no less stringent than the current criteria values found in the National Toxics Rule (NTR).* In effect, this means that if a criterion calculation results in a new criterion of a higher (less protective) concentration, the state will propose adoption of the NTR criterion instead. Thus, the preliminary rule contains a mix of (1) calculated criteria values, and (2) values based directly on the NTR as part of the overlain risk management direction described above. This does not apply to arsenic, copper, and asbestos where the preliminary proposals are values based on the Safe Drinking Water Act.

Narrative criteria. The existing water quality standards include narrative provisions that address chemicals that are not included in the list of 96 chemicals for which Ecology is developing criteria.

Revised and expanded implementation tools.
The WQS contain a number of tools that relate directly to how the criteria are met. These tools are implemented both in permits and orders, as well as specifying how the current designated uses and criteria can be changed if certain factors can be demonstrated. Ecology is proposing revisions to two of the tools (compliance schedules and variance requirements) that are already in the WQS, and the addition of a new tool (intake credits). These three tools and the proposed rule changes associated with them are fully discussed in this document under implementation tools. These tools and preliminary proposed changes are briefly summarized below:

Compliance schedules: Compliance schedules are tools used in Ecology discharge permits, orders, or other directives that allow time for discharges to make needed modifications to treatment processes in order to meet permit limits or requirements. They are commonly used for construction and treatment plant upgrades, and cannot be used for new or expanding discharges. Compliance schedules are used when there is an expectation that the discharge will meet permit limits at the end of the schedule. The current WQS contain a maximum time limit of ten years for compliance schedules. In 2009 the Washington legislature passed a law requiring Ecology to develop longer compliance schedules for certain types of discharges.

Variances: Variances are WQS changes that temporarily waive water quality standards for a specific chemical and designated use for either a single discharge or for multiple discharges, or for specified stretches of surface waters (e.g., for a specific tributary, a lake, a watershed, etc.). Variances are used in situations where it can be demonstrated that: (1) a discharge can meet the

permit limit or a water body can meet the criteria and designated use, but needs a longer time frame than allowed in a compliance schedule, or, (2) it is not known whether the discharge will ever be able to meet the permit limit or a receiving water body's criteria and designated use. Because a variance is a temporary change to a criteria and use, variances are considered changes to the WQS and must go through a rulemaking and subsequent EPA CWA approval to be effective. The current WQS give a brief list of the requirements for granting variances, including a maximum five-year time frame. The federal and state requirements for variances are brief, and demonstrating the need for a variance could be very labor intensive, depending on the specific situation. More detailed specifications in the WQS will help set clearer expectations for both discharges and the state, and will result in more predictable outcomes for dischargers.

This preliminary proposed rule-change does not grant any specific variances to WQS. Instead, this rule change gives more details on the information requirements for granting variances and on the types of actions that would be required of dischargers during variance periods. This includes a proposal to extend the duration of variances beyond five years if necessary.

Intake credits: Intake credits are a permitting tool that allows a discharge limit to be calculated in a way that does not require the discharger to "clean-up" pollutants in the discharge beyond the level of intake water when the intake and water body receiving the discharge are the same water body. This tool is currently used for technology-based limits, but Washington does not have a regulation that allows use of this tool to meet limits based on water quality criteria (a.k.a. water quality-based limits). This tool is used to meet water quality-based limits in several other states, including Oregon and the Great Lakes states.

This preliminary rule contains language describing how and when intake credits could be used.

Public Discussion

In December 2011, Ecology started public discussions around implementation tools, and in October 2012, started public discussions around state adoption of human health criteria. The agency has held many public meetings in a variety of formats to encourage participation. These meetings, and the materials used for the meetings, are at Ecology's Water Quality Standards rule website http://www.ecy.wa.gov/programs/wq/swqs/Currswqsruleactiv.html. Ecology has also met many times with various interested groups, including business, municipalities, environmental groups, counties, USEPA, and Tribes.

Governor Inslee announced his proposal on July 9, 2014. This preliminary draft rule incorporates the risk management directions made by Governor Inslee. This preliminary draft rule, along with supporting information, is being released on September 30, 2014. A formal draft rule is planned for publication in early 2015. Adoption of a final rule into the Washington Administrative Code is anticipated to occur in 2015.

After the final rule is adopted, Ecology will submit the rule to the USEPA for Clean Water Act approval. The new water quality standards do not become effective until approved by the USEPA.

The new toxics table gives a different look to the WQS
The new HHC will add several additional pages of information to the standards. In the preliminary proposed rule the aquatic life and human heath criteria for toxics are combined into one large table.

The current aquatic life criteria for toxics and the accompanying footnotes (WAC 173-201A-240(3), Table 240(3)) are in this section and table. Any references to the current aquatic life toxics table in the WQS have been modified to reference the new section. These changes have not modified the current aquatic life toxics criteria or their application in any way – this is simply a formatting change. This is considered a non-substantive change.

Specific decisions used to develop preliminary draft criteria
The following sections in this document explain the rationale for the substantive portions of this rule change.

Note to readers on other review processes currently underway:
The USEPA published draft national recommended human health surface water criteria for 94 toxics on May 13, 2014 (79 FR 27303, pages 27303 -27304). EPA's public comment period on the draft criteria closed August 13, 2014. **The public review of the EPA criteria is a different process than this rulemaking to adopt human health criteria for Washington State.** Information on the EPA process can be found at:

Federal register site: https://www.federalregister.gov/articles/2014/05/13/2014-10963/updated-national-recommended-water-quality-criteria-for-the-protection-of-human-health

EPA web site:
http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm

What Chemicals and Criteria will be included

Proposal

Ecology proposes to adopt human health criteria (HHC) for all CWA 307(a) priority toxic pollutants (except for mercury/methylmercury) for which EPA has developed national recommended numeric HHC. The existing rule language includes a narrative statement for protection from priority pollutants that do not have numeric criteria and from non-priority toxic pollutants.

The state's current human health criteria are found in federal rule (the National Toxics Rule; NTR). The NTR contains actual calculated human health criteria for 85 priority pollutants. Ecology's proposed rule contains actual calculated and Safe Drinking Water Act based human health criteria for 96 priority pollutants. The increased number of chemicals is based on EPA's development of new criteria since the NTR was issued and last revised.

Background

Current human health criteria chemicals: Washington's current HHC are found in the federal National Toxics Rule (NTR) (EPA, 1999). The NTR contains the complete listing of all 126 of the CWA 307(a) priority toxic pollutants (priority pollutants), and actual calculated human health criteria concentrations for 85 of the priority pollutants (some of the priority pollutants names are *not* accompanied by HHC concentrations). Of the 126 priority pollutants, 85 have numeric criteria for fresh water (exposure routes of drinking untreated surface waters and ingestion of fish and shellfish), and 84 have criteria for marine water (ingestion of fish and shellfish only).

EPA's recommended national criteria for chemicals: Since the 1992 NTR was published (and subsequently updated in 1999), the EPA has developed and published several additional human health criteria values for both priority pollutants and for non priority pollutants. EPA's current recommended national criteria table (EPA, 2014) includes national recommended human health criteria for 97 of the priority pollutants and approximately 18 non-priority pollutants (see Appendix A). Washington is proposing to adopt new criteria for 96 of the 97 priority pollutants. This lower number of proposed chemicals (96) is because Washington is deferring adoption of new criteria for methylmercury, and will stay under the current NTR criteria for mercury.

EPA's recommendations to states on selecting chemicals for criteria adoption: EPA's *Water Quality Standards Handbook: Second Edition* (EPA, 2012) provides guidance to states that are choosing criteria chemicals. These include recommendations for:

Priority pollutants (CWA 303(c)(2)(B) requirements). Excerpts of guidance from EPA's *Water Quality Standards Handbook: Second Edition* (EPA, 2012, Chapter 3.4.1) are copied below:

Excerpt 1

"*Section 303(c)(2)(B) addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act, which are codified at 40 CFR 131.36(b). The section 307(a) list contains 65 compounds and families of compounds, which potentially include thousands*

of specific compounds. The Agency has interpreted that list to include 126 "priority" toxic pollutants for regulatory purposes. Reference in this guidance to toxic pollutants or section 307(a) toxic pollutants refers to the 126 priority toxic pollutants unless otherwise noted."

Excerpt 2

"States may meet the requirements of CWA section 303(c)(2)(B) by choosing one of three scientifically and technically sound options (or some combination thereof):

1. *Adopt statewide numeric criteria in state water quality standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present;*
2. *Adopt specific numeric criteria in state water quality standards for section 307(a) toxic pollutants as necessary to support designated uses where such pollutants are discharged or are present in the affected waters and could reasonably be expected to interfere with designated uses;*
3. *Adopt a "translator procedure" to be applied to a narrative water quality standard provision that prohibits toxicity in receiving waters. Such a procedure is to be used by the state in calculating derived numeric criteria, which shall be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses,*

Option 1 is consistent with state authority to establish water quality standards and meets the requirements of the CWA. Option 2 most directly reflects the CWA requirements and is the option recommended by EPA, but is relatively more labor intensive to implement than Option 1. Option 3, while meeting the requirements of the CWA, is best suited to supplement numeric criteria from Option 1 or 2…"

Non-priority pollutants (see 40 CFR 131.11). Under these requirements, states must adopt criteria based on sound scientific rationale that cover sufficient parameters to protect designated uses. Both numeric and narrative criteria may be applied to meet these requirements.

Basis for Ecology's Proposal

Ecology proposes to adopt HHC for all CWA Sec. 307(a) priority toxic pollutants (except for mercury/methylmercury, for which Washington will remain under the NTR) for which EPA has developed national recommended numeric HHC, regardless of whether the pollutants are known to be present. This includes criteria for 96 different pollutants. The existing water quality standards include a narrative statement for priority pollutants that do not have numeric criteria and for non-priority toxic pollutants. This approach is consistent with Option 1 from EPA's guidance above.

Ecology is not proposing to adopt numeric criteria for non-priority pollutants at this time. Ecology will use a narrative statement to protect designated uses from effects of chemicals that

do not have numeric criteria. If monitoring or other information indicates that non-priority pollutant sources or concentrations are a concern, Ecology will use the narrative statement to protect designated uses from regulated sources. The ongoing triennial review process for the water quality standards will be used to determine whether there is a need to adopt numeric criteria for additional pollutants in future revisions to the water quality standards.

This proposal:

- Ensures that Washington will satisfy the intent of the Clean Water Act.
- Is within a state's legal authority under the CWA to adopt broad water quality standards.
- Is a comprehensive approach to satisfy the statutory requirements because it would include all of the priority toxic pollutants for which EPA has prepared section 304(a) criteria guidance (except mercury/methylmercury).
- Is fairly simple and straightforward to implement (does not require the monitoring needed to support EPA's Option 2 above).
- Contains the same chemical list (the full priority pollutant list) found in the NTR. Inserting the entire priority pollutant list in the water quality standards (even though not all priority pollutants will have accompanying criteria) makes for an easy comparison of the state's HHC with federally-required NPDES discharge permit application information.
- Relies on already existing narrative statement in the standards to protect designated uses for chemicals without adopted numeric criteria.

Additional Resources

EPA, 1992. U.S. Environmental Protection Agency. Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B). 40 CFR Part 131.36. Fed. Register, Vol. 57, No. 246, page 60848. (Also known as the National Toxics Rule.)

EPA, 1999. U.S. Environmental Protection Agency. Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B), originally published in 1992, amended in 1999 for PCBs. 40 CFR Part 131.36. Fed. Register, Vol. 64, No. 216, page 61182. http://www.ecfr.gov/cgi-bin/text-idx?SID=76816a2f92256bf94a548ed3115cee23&node=40:23.0.1.1.18.4.16.6&rgn=div8

EPA, 2012. U.S. Environmental Protection Agency. Water Quality Standards Handbook: Second Edition (EPA-823-B-12-002; March 2012); *http://water.epa.gov/scitech/swguidance/standards/handbook/index.cfm) (Note: This website was referenced 4/2014)*

EPA, 2014. U.S. Environmental Protection Agency. National Recommended Human Health Criteria list: *http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (Note: This website was referenced 4/2014)*

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Human Health Criteria Equations and Variables

Proposal

Ecology is proposing surface water human health criteria (HHC) for 96 priority toxic pollutants. 93 of the chemicals have criteria calculations associated with them that are reflected in the discussion below. Criteria for three chemicals (arsenic, copper, and asbestos) are based on Safe Drinking Water Act regulatory levels, and thus their proposed criteria do not involve calculations. The discussion below does not apply to these three chemicals

The following table provides a comparison of the explicit variables that are found in the human health equations for the federal National Toxics Rule (NTR) (currently applied in Washington), and the 2014 proposed criteria. In almost all cases, values for chemical-specific toxicity factors are taken from the United States Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS), noted in Table 1. There are also implicit variables in the equations that Ecology is not proposing to change from what was used in the NTR. They are further described in the background section of this document.

In addition, the draft criteria that were calculated using the factors and equations that are discussed below were secondarily modified by a risk management direction (http://governor.wa.gov/news/releases/article.aspx?id=293 that (except for arsenic) *no criterion concentration would become less protective than the current NTR criterion concentration.* This decision results in some draft criteria that are at a lower concentration than the calculated values. These criteria are indicated via footnote in the preliminary draft rule toxics table.

Table 1: **Comparison of equation variables for proposed rule**

Explicit variables	NTR Criteria (current)	Preliminary draft rule (2014)
Fish and shellfish consumption rate (FCR)	6.5 grams/day	175 g/day
Risk level (RL)	Additional lifetime risk of 1 in a million ($1x10^{-6}$)	Additional lifetime risk of 1 in one hundred thousand ($1x10^{-5}$)
Relative source contribution (RSC)	1	1 (no change)
Body weight (BW)	70 kilograms (154 pounds).	80 kilograms (176 pounds)
Drinking water intake (DI)	2 liters/day	2 liters/day (no change)
Reference dose (RfD) for specific chemicals	EPA IRIS values and other sources	Updated values in EPA IRIS and other values
Cancer slope factor (CSF) for specific chemicals	EPA IRIS values and other sources	Updated values in EPA IRIS and other values
Bioconcentration factor (BCF)	BCFs found in the NTR	No change from NTR; values can be found in EPA's 2002 HHC Calculation Matrix (EPA, 2002)
Additional risk management decision		If the calculated criterion concentration is greater than the NTR criterion concentration, then the preliminary draft criterion defaults to the original NTR concentration. (This does not apply to the criteria for arsenic)

Background

The human health water quality criteria (HHC) are chemical-specific concentrations applied to surface waters. The HHC are developed to protect human populations from undue risks to chemical exposures from drinking untreated surface-water and eating fish and shellfish that live in those waters.

The criteria are calculated using equations developed by EPA that incorporate information on risk and exposure, and the degree to which the pollutants accumulate in fish and shellfish tissue. EPA has developed equations for both carcinogens and noncarcinogens that apply to exposures from drinking untreated surface water and consuming fish and shellfish, or consuming fish and shellfish only. *For purposes of simplifying the discussion, these scenarios will be referred to as fresh waters or marine waters, respectively. However, some freshwaters in Washington do not have "domestic water supply" as a designated use, and for these waters the criteria that address only the consumption of organisms are applied.* This paper provides summary-only information about the equations that will be used to develop HHC for Washington; the bulk of the paper provides more detailed discussion about the individual variables that go into the equations.

References cited in the document are included at the end under the "Additional Information" section.

HHC equations and types of variables considered in the equations

In total there are four equations that are used to calculate HHC. These equations are based on chemical effects (carcinogens or noncarcinogens) and routes of exposure (fresh or marine water):

- *Chemical effects*: HHC equations are used to calculate criteria for both cancer causing chemicals, called carcinogens, and non-cancer causing chemicals, called noncarcinogens. The criteria for any one chemical are based on the acceptable level of risk (the effect that would occur at the lowest water concentration).
- *Routes of exposure*: Washington has both marine and fresh waters that are regulated under the Clean Water Act and under state jurisdiction. Therefore, separate equations are needed for each type of water to account for presence or absence of an untreated drinking water exposure route. Marine waters are assumed to include estuarine waters, and both of these do not have the drinking water use applied.

Several different factors, or variables, are included in each equation. The variables help to characterize risk and exposure, including the degree and type of toxicity attributed to specific chemicals, human body weight, human drinking water rates, fish and shellfish consumption rates, and others. These variables are assigned values which are then used in the equations to derive HHC concentrations. The exposure variables represent a combination of averages and upper percentiles. The choice of variables, and the science policy and risk management decisions that are included in the variables, act together to provide criteria that are estimates of desired levels of protection.

Why are these variables important? Each variable in the equations affects the final calculated HHC concentrations. Some variables make significant differences in the calculated values, while other variables make smaller changes. For instance, the additional lifetime cancer risk level for

carcinogens can make a large difference in some criteria concentrations. If the risk level increases, the criteria become less stringent. Fish consumption rates also affect the calculation considerably. Higher fish consumption rates result in lower criteria concentrations. An example of a variable that has much less effect on the calculated value is body weight. Higher body weight results in only slightly higher criteria concentrations.

EPA publishes CWA Sec. 304(a) national recommended HHC guidance values for approximately 120 chemicals, including priority and nonpriority pollutants. The recommended criteria are calculated using a combination of default and chemical-specific pieces of information recommended for state use by EPA. Some of the recommended criteria are based on Safe Drinking Water Act MCLs (maximum contaminant levels). Values for some variables can differ among states, based on location or regional information, science, science policy, and risk management, and can result in criteria that may be different than those recommended by EPA. For other variables, states generally use standard values, supported by national scientific research, that tend to remain constant across states even when developing state-specific criteria. The following variables are explicitly used in the HHC calculation, and are discussed later in this paper:

Values for these variables vary among states:
- Fish Consumption Rate (FCR)
- Risk level (RL)
- Relative Source Contribution (RSC)

States generally use the same values for these variables:
- Body Weight (BW)
- Drinking Water Intake (DI)
- Reference Dose (RfD)
- Cancer Slope Factor (CSF)
- Bioconcentration Factor (BCF)

The four equations for developing HHC are summarized in the Table 2 below. The equations shown in the table have been simplified for purposes of this discussion paper. Units and correction factors are not presented. The full equations with all units can be found in the EPA (2000) guidance.

Table 2: Summary of HHC equations		
Toxicity endpoint	**Water type and exposure route**	**Chemical-specific criterion equation**
Cancer	Fresh water: fish/shellfish consumption and drinking untreated surface water	$\frac{RL \times BW}{CSF \times (DI + [FCR \times BCF])}$
Non-Cancer	Fresh water: fish/shellfish consumption and drinking untreated surface water	$\frac{RfD \times RSC \times BW}{DI + (FCR \times BCF)}$
Cancer	Marine and estuarine waters: fish and shellfish consumption	$\frac{RL \times BW}{CSF \times FCR \times BCF}$
Non-Cancer	Marine and estuarine waters: fish and shellfish consumption	$\frac{RfD \times RSC \times BW}{FCR \times BCF}$

In addition to the variables described above, which are used explicitly in the equations, certain other factors are considered *implicitly* (i.e., they are not part of the written equation but are assumed during calculation). Some of these will be discussed briefly later in this paper, including lifespan, duration of exposure, and hazard quotient for non-cancer effects.

Basis for Ecology's Proposal:

Variables in the equation

A more detailed description of the variables in the equation will be presented in the following order:

Variables where the values vary among states:

1. Fish Consumption Rate (FCR)
2. Risk level (RL)
3. Relative Source Contribution (RSC)

Variables where the values generally do not vary among states:

4. Body Weight (BW)
5. Drinking Water Intake (DI)
6. Reference Dose (RfD)
7. Cancer Slope Factor (CSF)
8. Bioconcentration Factor (BCF)

Variables implicit in the HHC equations:

9. Lifespan and duration of exposure
10. Hazard quotient for non-cancer effects

1. Fish Consumption Rate (FCR)

Application: This explicit variable ***applies to all four equations****: carcinogen/fresh water; carcinogen/marine water; noncarcinogen/fresh water; and noncarcinogen/marine water.*

Ecology is proposing to use a fish consumption rate of 175 g/day in the HHC equation, based on a Washington-specific risk management decision to use a value that (1) is representative of state-specific information, and (2) was determined through a process that included consideration of EPA guidance and precedent, and input from multiple groups of stakeholders.

General information: The ***fish consumption rate*** (FCR) used in the equations usually refers to a statistic that describes a set of data from surveys of people based on the amount of fish and shellfish they eat. The data are represented as daily intake rates using the units of grams per day (g/day). The statistic used to describe the data set is a risk management decision made by states and tribes, and can be an average, a median, an upper percentile, or some other statistic. A state should also consider what target population to base the FCR on, and use survey data that represents that population of users. For example, the FCR could be based on survey data from the general population, or from high-consuming populations in the state.

The statistic used by the EPA and states has historically been an *average of a national general population data set (including consumers and non-consumers*), *freshwater and estuarine aquatic species only* (salmon excluded because of its marine life history). This is the origin of the current 6.5 g/day fish consumption rate that is incorporated into the 1992 National Toxics Rule (EPA, 1999; hereinafter called "NTR"). In 2000 EPA updated that national general population average value to 7.5 g/day, based on new science, and changed its guidance on the use of national general population data to recommend using a 90th percentile value (rather than an average) for freshwater and estuarine species only (EPA, 2000). The new 90th percentile recommended value is 17.5 g/day, and has been used by many states in criteria calculation.

EPA makes the following specific recommendation for protection of the general population for purposes of HHC development in the EPA 2000 guidance:

> *"EPA recommends a default fish intake rate of 17.5 grams/day to adequately protect the general population of fish consumers, based on the 1994 to 1996 data from the USDA's CSFII Survey. EPA will use this value when deriving or revising its national 304(a) criteria. This value represents the 90th percentile of the 1994-96 CSFII data. This value also represents the uncooked weight estimated from the CSFII data, and represents intake of freshwater and estuarine finfish and shellfish only."* (EPA, 2000, page 4-24)

EPA's use of a revised FCR in *draft* national criteria

Subsequent to development of the 2000 guidance, the USEPA developed a new recommended fish consumption rate of 22 g/day, which is currently being proposed by EPA in draft criteria updates. T**his new rate will not be addressed here because the guidance is still in draft form and not final**. The USEPA published the draft national recommended human health surface water criteria for 94 toxics on May 13, 2014 (79 FR 27303, pages 27303 -27304). EPA's public comment period on the draft criteria closed August 13, 2014. **The public review of the EPA criteria is a different process then this rulemaking to adopt new human health criteria for Washington state.** Information on the EPA process can be found at: Federal Register site: https://www.federalregister.gov/articles/2014/05/13/2014-10963/updated-national-recommended-water-quality-criteria-for-the-protection-of-human-health. EPA web site: http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm

EPA makes the following specific recommendation for protection of highly exposed populations:

> *"EPA recommends default fish intake rates for recreational and subsistence fishers of 17.5grams/day and 142.4 grams/day, respectively. These rates are also based on uncooked weights for fresh/estuarine finfish and shellfish only. However, because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy or States and authorized Tribes to follow when deriving consumption rates that encourages use of the best local, State, or regional data available. …* ***EPA strongly emphasizes that States and authorized Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s)****. The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates."* (EPA, 2000, pages 4-24 to 4-25, emphasis added)

Since Washington has a strong tradition of fish and shellfish harvest and consumption from local waters, and within-state survey information indicates that different groups of people harvest fish both recreationally and for subsistence (Ecology, 2013), *Ecology has made the risk management decision to base the fish consumption rate used in the HHC equation on "highly exposed populations,"* which include, among other groups, the following: tribes, Asian Pacific Islanders, recreational and subsistence fishers, immigrant populations, etc. Fish consumption rates developed in several surveys around the Pacific Northwest are summarized and discussed in a recent Ecology publication (Ecology, 2013).

The choice of an FCR is a risk management decision made by states: The choice of an FCR that represents a specific population, and the statistic (e.g., average, median, or other percentile) representing the distribution of individual FCRs from that specific population, is a risk management decision made by states. EPA provides language on this risk management decision in EPA 2000:

> *"Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. In this Methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision."* (Section 2.2)

As discussed above, the statistic used by the EPA and states has historically been an *average of a national general population data set.* The FCR incorporated into the NTR is an average. Ecology is continuing use of the average statistic as described above and below.

Decision for draft rule:

Ecology is proposing to use an FCR of 175 g/day for calculating the HHC, based on a state-specific risk management input made by Governor Inslee (http://governor.wa.gov/news/releases/article.aspx?id=293).

This value is representative of average FCRs ("all fish and shellfish," including all salmon, restaurant, locally caught, imported, and from other sources) for highly exposed populations that consume both fish and shellfish from Puget Sound waters. 175 g/day is considered an "endorsed" value. This numeric value was used by the Oregon Department of Environmental Quality to calculate HHC in a 2011 rulemaking. Groups endorsing the use of this numeric value include EPA and several tribes. Average FCR values for various highly exposed groups that harvest both fish and shellfish from Puget Sound waters are found in Ecology, 2013.

2. Risk level (RL)

*Application: This explicit variable applies **only to equations for carcinogens**: carcinogen/fresh water and carcinogen/marine water.*

Ecology is proposing to update the upper bound estimate of excess/additional lifetime cancer risk (the Risk Level; RL) value used in the equation from a one-in-one million additional lifetime risk of developing a cancer to one-in-one-hundred thousand**,** based on a state-specific risk management announcement made by Governor Inslee (http://governor.wa.gov/news/releases/article.aspx?id=293). This direction included considerations of engineering, social, economic and political concerns. (This does not apply to the criteria for total PCBs, which are discussed in the PCBs section of this document).

Choice of a risk level is a risk management decision made by states: The choice of an acceptable additional lifetime cancer risk level is a risk management decision made by states. EPA provides specific language on this in EPA 2000:

> *"Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. In this Methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision."* (Section 2.2)

General information: The ***risk level*** used in the HHC equations for carcinogens is defined as the "upper bound estimate of excess lifetime cancer risk" (EPA, 2000). The risk level value is only used when calculating criteria for pollutants that may cause cancer. Applying the risk level to the equation results in a HHC concentration that would hypothetically be expected to increase an individual's lifetime risk of cancer by no more than the assigned risk level, regardless of the cancer risk that may come from exposure to the chemical from sources other than surface water.

EPA 2000 guidance recommends that states and tribes set human health criteria risk levels for the general population at either one additional occurrence of cancer, after 70 years of daily exposure, in 100,000 people (1×10^{-5}) or one in 1,000,000 people (1×10^{-6}). EPA 2000 guidance also recommends that for states with high fish consuming populations, the most highly exposed populations should not exceed a risk level of one additional occurrence of cancer in 10,000 people (1×10^{-4}). Washington's current HHC from the National Toxics Rule applies a risk level of one additional occurrence of cancer in 1,000,000 (1×10^{-6}).

The choice of risk level is a policy decision by the state. Nationwide, states and tribes have typically chosen to use a risk level of one additional occurrence of cancer in 100,000 people (1×10^{-5}) or one in 1,000,000 people (1×10^{-6}) for HHC. This is demonstrated in a list of state and tribal risk levels provided to Ecology by EPA Region 10. This list was presented as part of Ecology's Policy Forum #3, held February 8, 2013. EPA guidance advises that states and tribes using these risk levels must ensure that the risk level for the most highly exposed subpopulations does not exceed one additional occurrence of cancer in 10,000 people (1×10^{-4}) (EPA, 2000). Section 303(c) of the CWA directs the requirements for setting and revising water quality standards.

It should be noted that it is not possible to assume that an equal amount of risk will be realized by the entire population of a state. All other factors being equal, people and groups who consume more fish and shellfish are inherently at greater risk from those contaminants than those who do not (given that contaminants are present in these items and that equal concentrations of contaminants are present in the consumed items). Regardless of the specific fish consumption rate used in the criteria calculations, or the final water quality criteria that are applied to waters, unequal risk among groups and individuals will always exist because of differences in fish consumption habits. This difference would exist even if criteria were not present. Therefore it is not reasonable to assume that a given risk level chosen by a state reflects actual risk across all populations or among all individuals in the entire state.

CWA regulatory programs can use a variety of excess lifetime cancer risk levels, but generally range from 1 in 10,000 ($1x10^{-4}$) to 1 in 1,000,000 ($1x10^{-6}$). See table below for two specific Clean Water Act programs with associated risk levels.

Table 3: CWA regulatory programs

Federal CWA program	Acceptable Risk Level	Other Information/State CWA program information
Clean Water Act 303(c) – requirements for states to adopt surface water criteria EPA publishes 304(a) recommended criteria to assist states – these are published at a $1x10^{-6}$ risk level	EPA 2000 guidance recommend that States and Tribes set criteria at $1x10^{-5}$ or $1x10^{-6}$ Most highly exposed populations should not exceed $1x10^{-4}$ risk level	Washington WQS contain a risk level of $1x10^{-6}$. National Toxics Rule (1992, contains Washington's current HHC) (40 CFR 131): $1x10^{-6}$. This risk level is applied in combination with average and upper percentile exposure factors in the criteria equations.
CWA Section 405 (40 CFR Part 503) Biosolids	$1x10^{-4}$	EPA risk assessment for biosolids: http://water.epa.gov/scitech/wastetech/biosolids/503rule_index.cfm See in particular Chapter 6 for rationale for use of $1x10^{-4}$ risk level for biosolids (EPA general website for biosolids: http://water.epa.gov/scitech/wastetech/biosolids/) Ecology implements 40CFR503, as directed by state law. Ecology must regulate to meet federal standards for biosolids. See: http://www.ecy.wa.gov/programs/swfa/biosolids/lawsandrules.html • State Law-Chapter 70.97J RCW • State Rule-Chapter 173-308 WAC (PDF)

How well do the criteria equations characterize risk? Even though the HHC equations appear to directly stipulate risk, other factors (those within the HHC equations and those not included in the HHC equations) complicate the ability to gauge an individual's or population's actual risk level.

Direct quantification of risk for populations is described in EPA guidance (EPA, 2000) as follows:

> *"EPA's Guidelines For Exposure Assessment (USEPA, 1992) describes the extreme difficulty in making accurate estimates of exposures and indicates that uncertainties at the more extreme ends of the distribution increase greatly. On quantifying population exposures/risks, the guidelines specifically state:*
>
> > *In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate estimates of real (or actuarial) cases of disease. The estimate's value lies in framing hypothetical risk in an understandable way rather than in any literal interpretation of the term "cases."(EPA 2000, pages 2-1 to 2-1)*

Washington's current risk level and information on changing the risk level: On December 18, 1991, in its official comments on EPA's proposed National Toxics Rule, the Department of Ecology (Ecology) urged EPA to promulgate human health criteria for the state at $1x10^{-6}$. At the time, Ecology understood that the $1x10^{-6}$ risk level would be applied with a 6.5 grams/day fish consumption rate of freshwater and estuarine fish, and that higher consumption rates would still be protective, but at a different risk level (for example, a 65 grams/day fish consumption rate will have an estimated $1x10^{-5}$ risk level) as this was clearly described by EPA in the November 19, 1991 proposed NTR. During the summer of 1992, the state formally proposed and held public hearings on revisions to its water quality standards. The standards, which were scheduled for adoption in late November 1992, include a risk level of $1x10^{-6}$.

In the 1992 NTR (EPA, 1992) the following excerpt (#3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule) provided information to states planning to adopt their own criteria in order to be removed from the NTR:

> *As discussed in prior Sections of this Preamble, the water quality standards program has been established with an emphasis on State primacy. Although this rule was developed to Federally promulgate toxics criteria for States, EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance. EPA is hopeful this rule will provide additional impetus for non-complying States to adopt the criteria for priority toxic pollutants necessary to comply with section 303(c)(2)(B).*
>
> *Removal of a State from the rule will require another rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 et seq.). EPA will withdraw the Federal rule without a notice and comment rulemaking when the State adopts standards*

no less stringent than the Federal rule (i.e., standards which provide, at least, equivalent environmental and human health protection). For example, see 51 FR 11580, April 4, 1986, which finalized EPA's removal of a Federal rule for the State of Mississippi.

However, if a State adopts standards for toxics which are less stringent than the Federal rule but, in the Agency's judgment, fully meet the requirements of the Act, EPA will propose to withdraw the rule with a Notice of proposed rulemaking and provide for public participation. This procedure would be required for partial or complete removal of a State from this rulemaking. ***An exception to this requirement would be when a State adopts a human health criterion for a carcinogen at a 10^{-5} risk level where the Agency has promulgated at a 10^{-6} risk level. In such a case, the Agency believes it would be appropriate to withdraw the Federal criterion without notice and comment because the Agency has considered in this rule that criteria based on either 10^{-5} or 10^{-6} risk levels meet the requirements of the Act.*** *A State covered by this final rule could adopt the necessary criteria using any of the three Options or combinations of those Options described in EPA's 1989 guidance." (*1992 NTR, emphasis added*)*

How risk was applied in this draft rule: The approach Ecology used to calculate the draft HHC is very similar to that used by EPA to calculate their CWA 304(a) national recommended criteria. EPA's method, however, focuses on providing protection to the general population, while the Ecology approach focuses on protection of highly exposed populations, which in Washington are assumed to include (among others) tribes, recreational, and subsistence fishers. Washington implemented this change of focus in the draft criteria equations by changing the FCR variable from a statistic (the average) that represents the general population FCR distribution to an equivalent statistic (the average) representative of FCR distributions of highly exposed populations.

Washington applied the risk framework developed by EPA for the current federal HHC rule (the 1992 NTR) to highly exposed populations in Washington in the following manner:

- Washington is currently under the federal National Toxics Rule (NTR) for HHC. Those criteria are set at a 10^{-6} risk level and the risk level is applied to the arithmetic mean (average) of the *general population.*
- For this draft rule, the risk level of 10^{-5} was applied to a FCR of 175 g/day that is representative of the arithmetic means (averages) of *highly exposed populations* (instead of the general population). (Note: the risk level used for total PCBs is different from 10^{-5} – please see section on Challenging Chemicals: PCBs.)

Most states follow EPA's approach and apply the state's default risk level to a general population, and then ensure that highly exposed populations do not exceed EPA's upper levels of allowed risk.

Decision for draft rule: Washington is making the preliminary decision to apply the risk level of 10^{-5} to highly exposed populations, which includes recreational fishers, subsistence fishers, tribes, and immigrant fishers.

3. Relative Source Contribution (RSC)

*Application: This explicit variable applies **only to equations for noncarcinogens**: noncarcinogen/fresh water and noncarcinogen/marine water.*

Ecology is proposing that the draft rule uses a relative source contribution value of one (1), which is the same as was used in the NTR.

Background: The Relative Source Contribution (RSC) is a variable in the HHC equation that represents the portion of an individual's daily exposure to a contaminant that is attributed to sources regulated by the Clean Water Act as opposed to sources of toxic chemicals that are not regulated by the Clean Water Act. The RSC only applies to the equations for noncarcinogens.

The HHC are used to regulate pollution sources that discharge to waters of the state and fall under Clean Water Act regulation, in order to control chemical exposure from untreated surface-water used for drinking water, and eating fish and shellfish that live in those waters. The RSC is intended to account for secondary sources of pollutants, such as atmospheric deposition or marine fish sources (e.g. mercury in tuna) that are not regulated by Clean Water Act authorities.

RSCs are used in the criteria equation only for non-carcinogens and non-linear carcinogens. Non-carcinogenic chemicals express their toxicity through threshold effects are more likely to express effects when a specific dose – the reference dose (RfD) – is surpassed. The RSC assumes that exposure of a particular chemical through surface water (i.e. drinking water and fish/shellfish consumption) contributes a portion of the RfD, with the remaining portion from exposure to other sources such as dietary intake other than non-local fish and shellfish. The portion of RfD exposure through surface water is the RSC, expressed as a decimal fraction. For example, a RSC of 0.4 indicates 40% of the RfD is due to exposure through surface waters and 60% is due to other sources.

The 1980 EPA guidance for HHC (EPA 1980) (used to develop the pre-2000 HHC), included the alternative of considering total exposure from all sources in the criteria calculations, but the CWA 304(a) HHC developed following these guidelines assumed an RSC of 1.0 (EPA, 2002). The 1992 National Toxics Rule HHC applied an RSC of 1.0 (100% allocation of exposure given to sources regulated by the Clean Water Act).

The EPA 2000 guidance and follow-up clarifications from EPA (2013), recommend new default values for the RSC to be used in the HHC equations for noncarcinogens:

> *"In the absence of scientific data, the application of the EPA's default value of 20 percent RSC in calculating 304(a) criteria or establishing State or Tribal water quality standards under Section 303(c) will ensure that the designated use for a water body is protected. This 20 percent default for RSC can only be replaced where sufficient data are available to develop a scientifically defensible alternative value. If appropriate scientific data demonstrating that other sources and routes of exposure besides water and freshwater/estuarine fish are not anticipated for the pollutant in question, then the RSC may be raised to the appropriate level, based on the data, but not to exceed 80 percent. The 80 percent ceiling accounts for the fact that some sources of exposure may be unknown."*

In the simplest terms, EPA's latest RSC guidance recommends two conservative default approaches:

- If sources of exposure to a chemical are not known, then a default RSC of 0.2 is included in the equation.
- If sources of exposure to a chemical are well known and documented, then a calculated RSC is included in the equation. This calculated RSC gives the HHC the remainder of the reference dose or allowable daily exposure that is not accounted for by other non-CWA sources. EPA guidance suggests that the RSC value cannot be greater than 0.8.

An inherent assumption in how the RSC for HHC is developed is that all other sources of the contaminant are required to be accounted for in the exposure scenario, and the HHC get the remainder of the reference dose or allowable daily exposure that is assumed to come from sources under the authority of the Clean Water Act. The resulting situation seems contradictory: as the contribution of a contaminant from water sources becomes smaller, the HHC becomes more stringent and in effect becomes a larger driver for more restrictive limits.

The use of an RSC affects criteria calculation results as follows:

If the RSC is 1.0, then it does not change the resulting criteria calculation.

If the RSC is 0.8, then the criterion becomes more stringent by 20%.

If the RSC is 0.5, then the criterion becomes more stringent by 50%.

If the RSC is 0.2, then the criterion becomes more stringent by 80%.

The RSC can drive, very directly, the resulting human health water quality criteria and related regulatory and permit levels. Using a RSC of 0.2, for example, means that an ambient water quality criterion that would otherwise be 10 units would be reduced by 80% to 2 units, thus becoming lower, or more stringent, in order to compensate for sources that are outside of the sources regulated by the Clean Water Act. Many other programs that address toxics, such as the Safe Drinking Water Act and the Superfund Clean-up Program, also establish similar concentration goals but then use a risk management approach that allows for consideration of other factors, such as cost and feasibility, in establishing actual compliance levels that have to be achieved. Conversely, the ambient water quality criteria under the Clean Water Act set direct regulatory levels that are enforced as both ambient concentrations in the water body (through the CWA 303(d) program with subsequent load allocation requirements (40CFR130)) as well as through NPDES permit levels (criteria applied at end-of-pipe or with use of a dilution zone, depending on the specific circumstances).

EPA's Water Quality Standards Handbook: Second Edition (EPA, 2012) provides additional guidance on this subject. This guidance is different from the EPA 2000 guidance, and indicates that in practice criteria may be based on risk from only the surface water exposure routes:

"Human Exposure Considerations

A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes. The more important of these include recreational and occupational contact, dietary intake from other than fish, intake

from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available (see 45 F.R. 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only (57 F.R. 60862-3)." (text copied from EPA web site on 3/17/2014: http://water.epa.gov/scitech/swguidance/standards/handbook/chapter03.cfm#section13,m, section 3.1.3).

The use of an RSC to compensate for sources outside the scope of the Clean Water Act when establishing HHC is a risk management decision that states need to carefully weigh. If the scope of the Clean Water Act is limited to addressing potential exposures from NPDES- or other Clean Water Act regulated discharges to surface water, it could be argued that an RSC of less than 1.0 inappropriately expands of the scope of what the CWA would be expected to control. On the other hand, if it is assumed that the scope of the Clean Water Act includes consideration and protection from other sources of toxics not regulated by the Clean Water Act, such as atmospheric deposition or marine fish sources (e.g. mercury in tuna), one could argue for an RSC of less than 1.0. The role of the RSC and how to calculate it is an issue that must be carefully considered by a state when establishing HHC.

Decision for draft rule: Because the geographic and regulatory scope of the CWA addresses contaminant discharge directly to waters of the state (not other sources or areas), Ecology is making a risk management decision that this draft rule continue to use a relative source contribution of one (RSC = 1). Given the limited ability of the Clean Water Act to control sources outside its jurisdiction, Ecology strongly believes that this is a prudent decision.

4. Body Weight (BW)

*Application: This explicit variable **applies to all four equations**: carcinogen/fresh water; carcinogen/marine water; noncarcinogen/fresh water; and noncarcinogen/marine water.*

Ecology is proposing to update the BW value used in the equation, based on new science and local data, from 70 kg to 80 kg.

Background: The BW approach included in the 1992 NTR, EPA's 2000 guidance, and EPA's published recommended national CWA 304(a) criteria values is to use an average adult BW in the HHC calculation. The BW historically used in EPA guidance and regulation is 70 kilograms (154 pounds). EPA's most recent Exposure Factors Handbook (EPA, 2011) provides an updated average BW of 80 kilograms (176 pounds), which also closely aligns with the tribal average adult BWs of the Tulalip and Suquamish tribes (EPA, 2007) of 81.8 and 79 kilograms, respectively. This newer science and local data compels Ecology to consider using the updated BW value in the HHC equations.

Table 4 provides HHC-relevant information on use of this exposure factor.

Table 4: Summary of guidance and studies on body weight

Date	Source	BW input
1992	National Toxics Rule (40CFR131.36)	70 kg = average adult body weight
2000	EPA 2000 HHC Methodology (EPA -822-B-00-004)	EPA recommends using 70 kg = average adult body weight as "a representative average value for both male and female adults:" "EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults."
2007	Tribal FCR studies – as summarized in: USEPA Reg. 10, Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia, Working Document, To Be Applied in Consultation with Tribal Governments on a Site-specific Basis, Revision 00.2007 (EPA, 2007, Tables B-1 and B-2 in Appendix B).	Tulalip Tribe = 81.8 kg average adult Suquamish Tribe = 79 kg average adult
2011	EPA Exposure Factors Handbook - 2011 edition. EPA 600/R-090/052F. (EPA, 2011)	EPA recommends 80 kg for average adult body weight

Decision for draft rule: Based on this information Ecology is making a preliminary decision to update the BW value used in the equation, based on new science and local data, from 70 kg to 80 kg.

5. Drinking Water Intake (DI)

*Application: This explicit variable **applies only to equations for fresh waters**: carcinogen/fresh water and noncarcinogen/fresh water.*

Ecology is proposing to use the EPA 2000 recommended DI value of 2 L/day to calculate criteria in the draft rule.

Background: The DI approach included in the 1992 NTR, EPA's 2000 guidance, and EPA's published recommended CWA 304(a) national criteria values is to use an approximate 90th percentile adult exposure value in the HHC calculation. The DI historically used in EPA guidance and regulation is 2 liters/day.

An excerpt from the EPA 2000 guidance that recommends using 2 liters/day states:

> *"EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and*

large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision…" (EPA, 2000, (pages 4-22 to 4-23)

EPA's most recent Exposure Factors Handbook (EPA, 2011, Tables 3-10, 3-26, and 3-27) provides examples of updated 90th percentile adult (ages 18-65) DI values between 2.1 and 3.1 liters/day, based on national data. These values are for direct and indirect (water added in the preparation of a food or beverage) consumption of water, and are further explained in the tables specified above. EPA released new *Supplemental Guidance for Superfund* on February 6, 2014 (memo from Dana Stalcup, USEPA to Superfund National Policy Managers, Regions 1-10; OSWER Directive 9200.1-120) that incorporates and adopts updates to *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A through E*, based on data in the 2011 Exposure Factors Handbook. This includes a recommended 90th percentile adult drinking water intake value of 2.5 L/day. EPA also published draft national recommended human health surface water criteria for 94 toxics on May 13, 2014 (79 FR 27303, Pages 27303 - 27304) that include use of a 90th percentile adult drinking water intake value of 3.0 L/day, based on data in the 2011 Exposure Factors Handbook. These different new 90th percentile values result from use of different data sets.

Below is information on this exposure factor:

Table 5: Exposure factor

Date	Source	DI input
1992	National Toxics Rule, 40CFR131.36 (EPA 1992)	2 L/day = approximate 90th percentile
2000	EPA 2000 HHC Methodology, EPA -822-B-00-004 (EPA, 2000)	EPA recommends using 2 L/day: "EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision…" (pages 4-22 to 4-23)
2011	EPA Exposure Factors Handbook - 2011 edition. EPA 600/R-090/052F (EPA 2011)	The Exposure Factors Handbook contains new information on DI for various ages, groups, consumer types, and water sources. It provides updated 90th percentile adult DI values, based on national data, See Chapter 3.
2014	EPA 2014; OSWER Directive 9200.1-120.	Previous default value was 2 L/day. Currently recommended value is 2.5 L/day, which is the 90th percentile of consumer-only ingestion of drinking water (≥ 21 years of age)
2014	EPA, 2014: May 13, 2014 (79 FR 27303, Pages 27303 -27304	Previous default value (EPA 2000) was 2 L/day. The draft updated drinking water intake (DI) is 3 L/day for consumer-only water ingestion at the 90th percentile for adults (≥21 years of age)

Decision for draft rule: At this time, Ecology proposes to continue to use the EPA 2000 recommended DI value of 2 liters/day to calculate criteria for the draft rule. Washington state-specific information has not been obtained, so consideration of local data in comparison with

national data has not been possible thus far in the rulemaking process. However, a different value will be considered if data or information is brought forward that compels Ecology to consider whether data from the newer *Exposure Factors Handbook* (EPA, 2011), EPA's new 2014 OSWER Directive, or the DI value used to calculate EPA's new draft national recommended human health surface water criteria should be used.

6. Reference Dose (RfD)

*Application: This explicit variable **applies only to noncarcinogens**: noncarcinogen/fresh water; and noncarcinogen/marine water.*

Background: The reference dose is an estimate of the daily exposure to the human population (including sensitive subgroups) via ingestion to a chemical that is likely to be without appreciable risk of deleterious health effects during a lifetime. The RfD applies only to non-carcinogens. EPA has developed chronic RfDs for use in regulatory programs. These can be found in EPA's Integrated Risk Information System (IRIS)(EPA, 2014).

Decision for draft rule: Ecology proposes to continue to use EPA IRIS RfDs to calculate the criteria for non-carcinogens for the draft rule. However, for some cases Ecology used non-IRIS values provided by USEPA to calculate criteria. These are indicated in the spreadsheet handout Draft –Washington Human Health Criteria Review Documents (Revised 8/8/2014) found at http://www.ecy.wa.gov/programs/wq/swqs/WAHHCrevdocs080714.pdf. New information/comment received during the rulemaking could result in use of different values.

7. Cancer Slope Factor (CSF)

*Application: This explicit variable **applies only to carcinogens**: carcinogen/fresh water and carcinogen/marine water.*

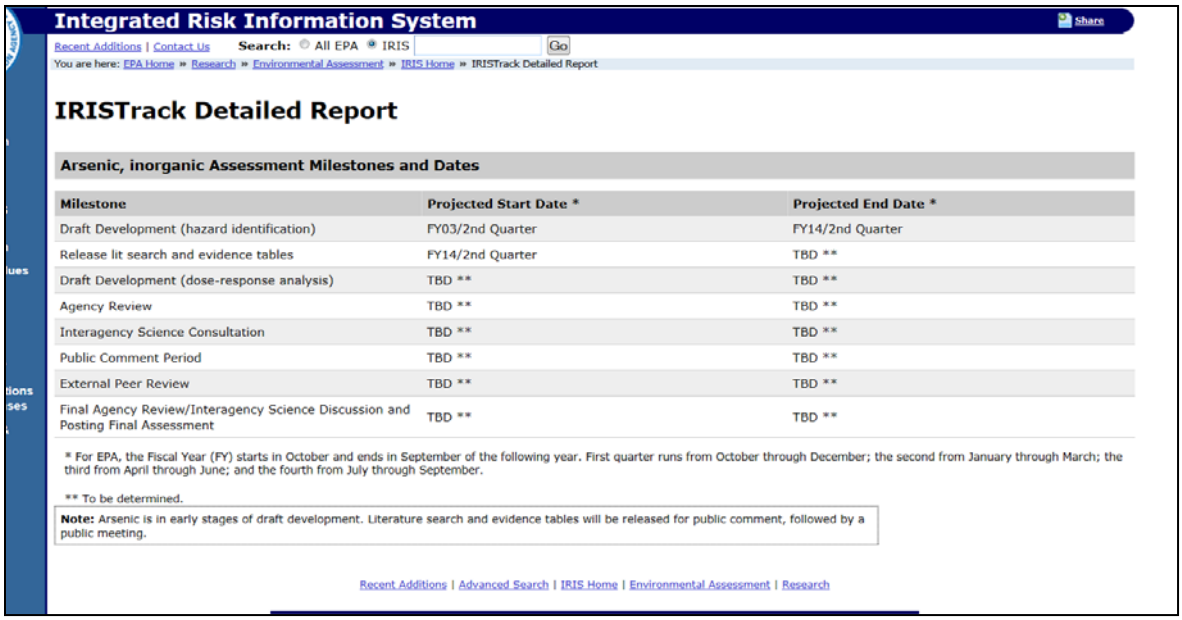
At this time, Ecology proposes to continue to use EPA IRIS CSF for carcinogens to calculate the criteria in the draft rule. However, for some cases, Ecology used non-IRIS values provided by USEPA to calculate criteria. New information/comment received during the rulemaking could result in use of different values.

Background: The ***cancer slope factor (CSF)*** provides a measure of the toxicity of an identified carcinogen. This slope factor is used for chemicals where the carcinogenic risk is assumed to decrease linearly as the chemical dose decreases. The CSF is specific to each chemical and can be found in the EPA IRIS (EPA, 2014).

Ecology is proposing to use, with few exceptions, the EPA IRIS CSF for carcinogens to calculate the criteria in the draft rule. Ecology has made the decision not to use the CSFs in HHC calculations for chloroform, inorganic arsenic and 2,3,7,8-TCDD based on recent scientific information and uncertainty surrounding assessment of carcinogenicity. Rationale for each of these chemicals varies, and is explained below.

At any given time, there will be some IRIS toxicity factors undergoing review. In these cases, EPA has a specific process that is followed to review and develop revised factors. At present, several toxicity factors are under review, two of which have been under review for many years:

the carcinogenicity reviews of inorganic arsenic and 2,3,7,8-TCDD. Information of the status of the reviews (copied from the EPA IRIS website March 2014) is below. The uncertainty around agreed-upon cancer slope factors for these chemicals is considerable, as evidenced by the long history of the review processes as well as the lack of a prospective date for completion.



Integrated Risk Information System

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IRISTrack Detailed Report

Arsenic, inorganic Assessment Milestones and Dates

Milestone	Projected Start Date *	Projected End Date *
Draft Development (hazard identification)	FY03/2nd Quarter	FY14/2nd Quarter
Release lit search and evidence tables	FY14/2nd Quarter	TBD **
Draft Development (dose-response analysis)	TBD **	TBD **
Agency Review	TBD **	TBD **
Interagency Science Consultation	TBD **	TBD **
Public Comment Period	TBD **	TBD **
External Peer Review	TBD **	TBD **
Final Agency Review/Interagency Science Discussion and Posting Final Assessment	TBD **	TBD **

* For EPA, the Fiscal Year (FY) starts in October and ends in September of the following year. First quarter runs from October through December; the second from January through March; the third from April through June; and the fourth from July through September.

** To be determined.

Note: Arsenic is in early stages of draft development. Literature search and evidence tables will be released for public comment, followed by a public meeting.

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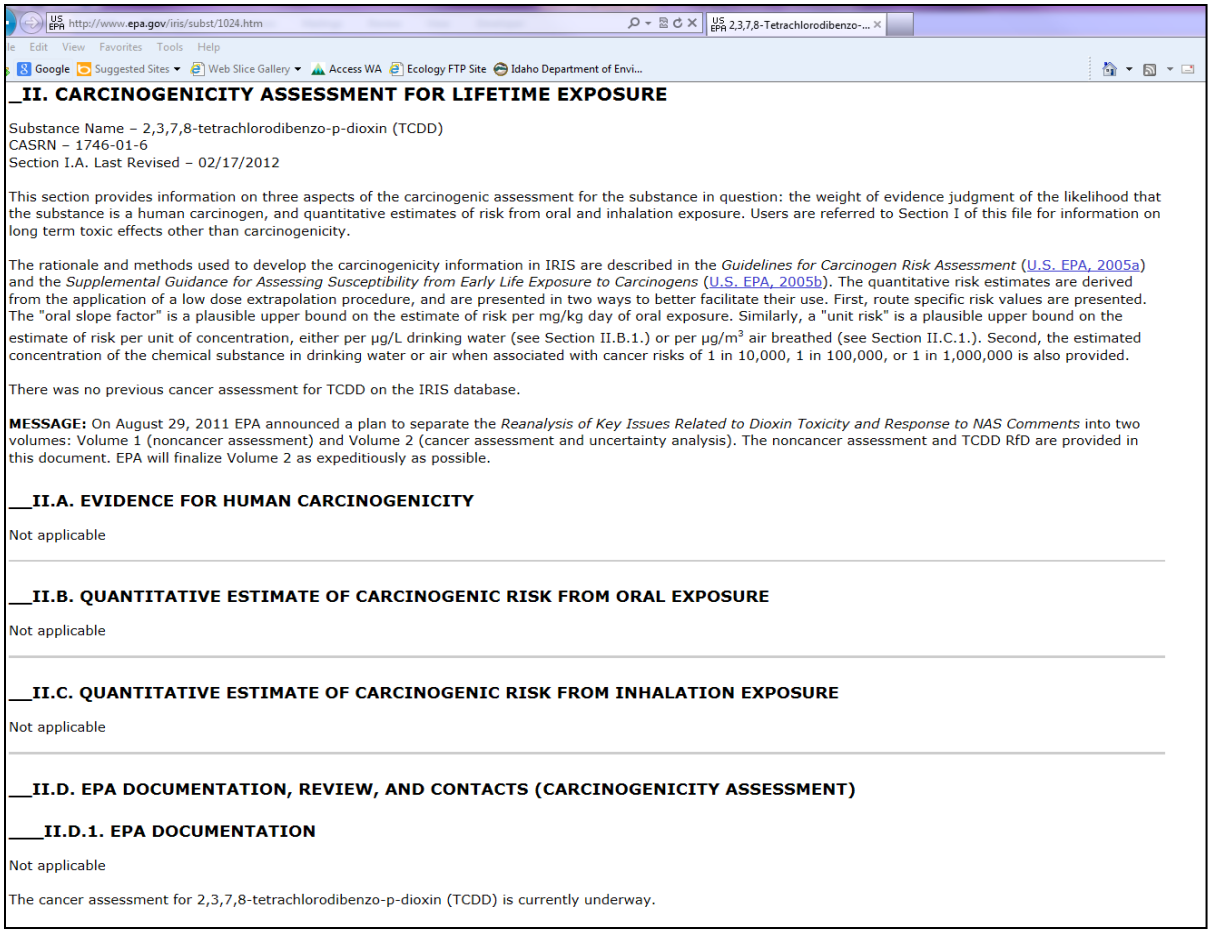
Figure 2: Integrated risk information system



_II. CARCINOGENICITY ASSESSMENT FOR LIFETIME EXPOSURE

Substance Name – 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)
CASRN – 1746-01-6
Section I.A. Last Revised – 02/17/2012

This section provides information on three aspects of the carcinogenic assessment for the substance in question: the weight of evidence judgment of the likelihood that the substance is a human carcinogen, and quantitative estimates of risk from oral and inhalation exposure. Users are referred to Section I of this file for information on long term toxic effects other than carcinogenicity.

The rationale and methods used to develop the carcinogenicity information in IRIS are described in the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a) and the *Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens* (U.S. EPA, 2005b). The quantitative risk estimates are derived from the application of a low dose extrapolation procedure, and are presented in two ways to better facilitate their use. First, route specific risk values are presented. The "oral slope factor" is a plausible upper bound on the estimate of risk per mg/kg day of oral exposure. Similarly, a "unit risk" is a plausible upper bound on the estimate of risk per unit of concentration, either per µg/L drinking water (see Section II.B.1.) or per µg/m^3 air breathed (see Section II.C.1.). Second, the estimated concentration of the chemical substance in drinking water or air when associated with cancer risks of 1 in 10,000, 1 in 100,000, or 1 in 1,000,000 is also provided.

There was no previous cancer assessment for TCDD on the IRIS database.

MESSAGE: On August 29, 2011 EPA announced a plan to separate the *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* into two volumes: Volume 1 (noncancer assessment) and Volume 2 (cancer assessment and uncertainty analysis). The noncancer assessment and TCDD RfD are provided in this document. EPA will finalize Volume 2 as expeditiously as possible.

__II.A. EVIDENCE FOR HUMAN CARCINOGENICITY

Not applicable

__II.B. QUANTITATIVE ESTIMATE OF CARCINOGENIC RISK FROM ORAL EXPOSURE

Not applicable

__II.C. QUANTITATIVE ESTIMATE OF CARCINOGENIC RISK FROM INHALATION EXPOSURE

Not applicable

__II.D. EPA DOCUMENTATION, REVIEW, AND CONTACTS (CARCINOGENICITY ASSESSMENT)

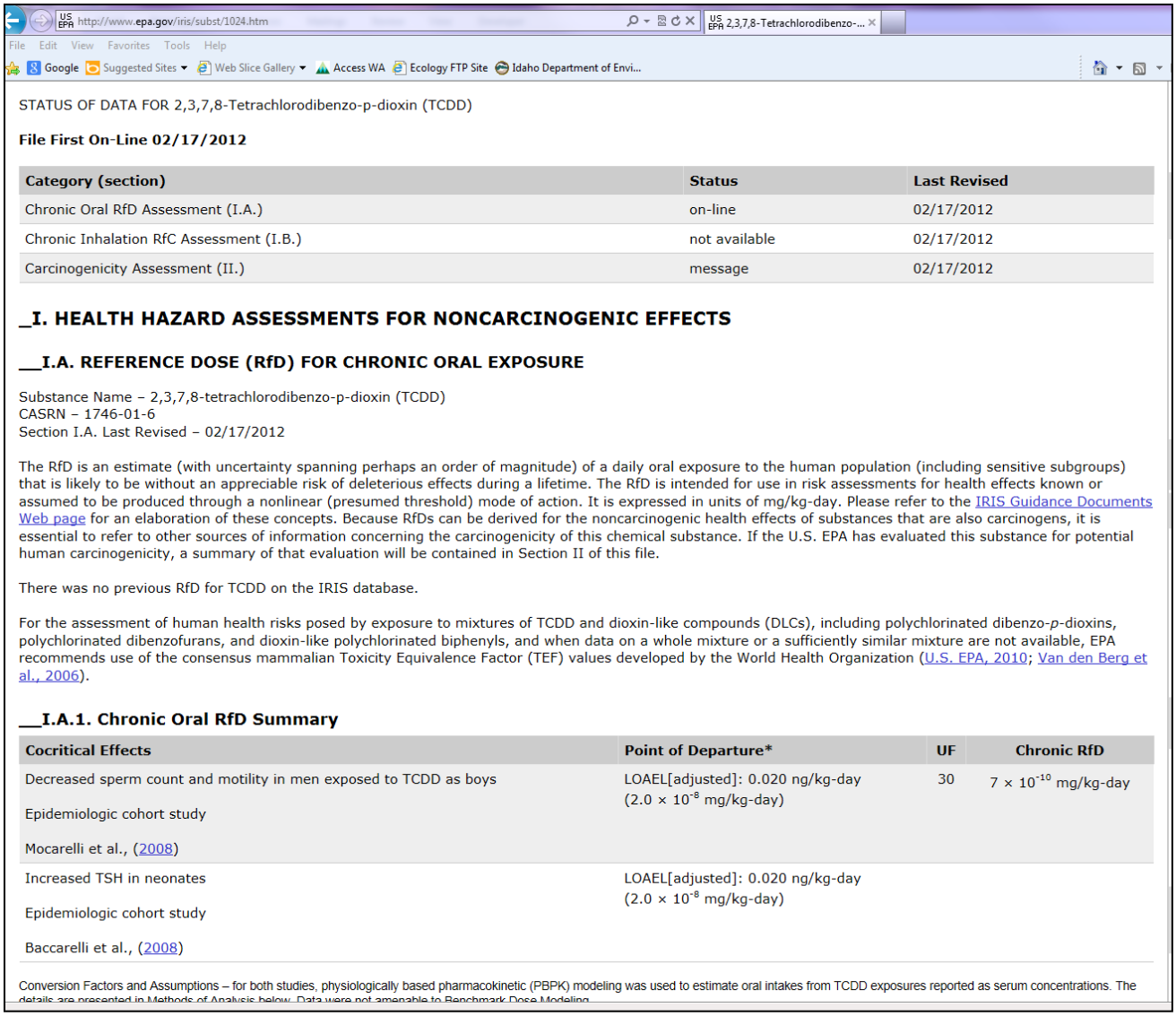
___II.D.1. EPA DOCUMENTATION

Not applicable

The cancer assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is currently underway.

Figure 3: Carcinogenicity assessment

Based on these uncertainties, Ecology has made the decision not to use CSFs in HHC calculations for these two chemicals. The approach taken for arsenic is described in the section on Challenging chemicals: Arsenic. The approach taken for 2,3,7,8-TCDD is to use the most recent IRIS non-cancer reference dose for HHC calculation. This reference dose was finalized in 2012. The IRIS information is copied below (copied from the IRIS website March 2014):



STATUS OF DATA FOR 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)

File First On-Line 02/17/2012

Category (section)	Status	Last Revised
Chronic Oral RfD Assessment (I.A.)	on-line	02/17/2012
Chronic Inhalation RfC Assessment (I.B.)	not available	02/17/2012
Carcinogenicity Assessment (II.)	message	02/17/2012

_I. HEALTH HAZARD ASSESSMENTS FOR NONCARCINOGENIC EFFECTS

__I.A. REFERENCE DOSE (RfD) FOR CHRONIC ORAL EXPOSURE

Substance Name – 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)
CASRN – 1746-01-6
Section I.A. Last Revised – 02/17/2012

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is intended for use in risk assessments for health effects known or assumed to be produced through a nonlinear (presumed threshold) mode of action. It is expressed in units of mg/kg-day. Please refer to the IRIS Guidance Documents Web page for an elaboration of these concepts. Because RfDs can be derived for the noncarcinogenic health effects of substances that are also carcinogens, it is essential to refer to other sources of information concerning the carcinogenicity of this chemical substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

There was no previous RfD for TCDD on the IRIS database.

For the assessment of human health risks posed by exposure to mixtures of TCDD and dioxin-like compounds (DLCs), including polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls, and when data on a whole mixture or a sufficiently similar mixture are not available, EPA recommends use of the consensus mammalian Toxicity Equivalence Factor (TEF) values developed by the World Health Organization (U.S. EPA, 2010; Van den Berg et al., 2006).

__I.A.1. Chronic Oral RfD Summary

Cocritical Effects	Point of Departure*	UF	Chronic RfD
Decreased sperm count and motility in men exposed to TCDD as boys Epidemiologic cohort study Mocarelli et al., (2008)	LOAEL[adjusted]: 0.020 ng/kg-day (2.0×10^{-8} mg/kg-day)	30	7×10^{-10} mg/kg-day
Increased TSH in neonates Epidemiologic cohort study Baccarelli et al., (2008)	LOAEL[adjusted]: 0.020 ng/kg-day (2.0×10^{-8} mg/kg-day)		

Conversion Factors and Assumptions – for both studies, physiologically based pharmacokinetic (PBPK) modeling was used to estimate oral intakes from TCDD exposures reported as serum concentrations. The details are presented in Methods of Analysis below. Data were not amenable to Benchmark Dose Modeling.

Figure 4 Health hazard assessments for noncarcinogenic effects

Other chemicals of interest: Chloroform criteria have historically been calculated to address cancer toxicity, and the current published EPA recommended national criteria (as of March 2014) are based on carcinogenicity. EPA is currently undergoing a major reassessment of chloroform toxicity. On 10/19/01 EPA published a new oral RfD for chloroform. IRIS provides the following statement (copied March 2014):

__II.B.1. Summary of Risk Estimates

A dose of 0.01 mg/kg/day (equal to the RfD) can be considered protective against cancer risk

_____II.B.1.1. Oral Slope Factor — Not applicable (see text).

EPA published draft national recommended human health surface water criteria for chloroform on May 13, 2014. They used a point of departure-based criteria formula based on cancer effects. This formula is virtually identical to the non-cancer criteria equation, with the RfD replaced with

a POD/uncertainty factor. The POD/uncertainty factor used by EPA in the draft criteria is equal to the reference dose of 0.01 mg/kg/day. Based on this new science and on the equivalence of the criteria calculation whether calculated for cancer or non-cancer effects, Ecology is calculating the draft criteria for chloroform, based on non-cancer effects, using the new 2001 RfD in IRIS.

Decision for draft rule: Ecology is proposing to use, with few exceptions, the EPA IRIS CSFs for carcinogens to calculate the criteria in the draft rule. For those cases where Ecology used non-IRIS values provided by USEPA to calculate criteria, new information/comment received during the rulemaking could result in use of different values.

Ecology is proposing, based on scientific information and/or uncertainty, not to use CSFs (either in IRIS or not in IRIS) in HHC calculations for chloroform, arsenic, and 2,3,7,8-TCDD.

8. Bioconcentration Factor (BCF)

Application: This explicit variable ***applies to all four equations****: carcinogen/fresh water; carcinogen/marine water; noncarcinogen/fresh water; and noncarcinogen/marine water.*

Ecology is proposing to use BCFs (not BAFs) developed by EPA and as incorporated into the 1992 NTR and the EPA recommended national criteria (as of March 17, 2014) to calculate the criteria in the draft rule.

Background: Bioconcentration is the process of absorption of chemicals into an organism only through respiratory and dermal surfaces (Arnot and Gobas, 2006). For purposes of the human health criteria equations, bioconcentration refers to the accumulation of a chemical directly from the water by fish and shellfish. Using a bioconcentration factor (BCF) accounts for any pollution uptake fish or shellfish are exposed to in their surrounding water. Because BCFs look at a specific portion of the total uptake of a chemical, the BCFs are generally laboratory-derived or modeled values. Bioaccumulation is a broader term that refers to the accumulation of chemicals from all sources, including water, food, and sediment. Bioconcentration is a subset of bioaccumulation. Use of a BCF in criteria calculation most directly addresses uptake from the water column only.

The bioaccumulation factor (BAF) reflects uptake from all sources and pathways, which can include contaminated sediments, diet, trophic transfer, and pollutants that are sourced from areas and waters outside Washington's CWA jurisdiction (e.g., mercury).

EPA and states have generally defaulted to the use of EPA's pre-existing BCFs when calculating criteria. EPA's current and prior versions of the EPA nationally recommended human health criteria depend on use of BCFs. These BCF values are in many cases older values (developed in the late 1970's), and in many cases are based on laboratory testing of only one species (EPA 2002). EPA 2000 guidance recommends the use of a BAF in criteria calculation, and recommends that states and tribes use the methodology outlined in EPA 2000 to develop locally appropriate BAFs. On March 13, 2014, EPA published 94 draft nationally recommended human health criteria that include use of model-derived BAFs.

In addition to the EPA 2000 Methodology, EPA's *Water Quality Standards Handbook: Second Edition* (EPA-823-B-12-002; as updated March 2012) provides indirect guidance on the exposure routes that should be accounted for in calculating human health criteria. Although the *Water Quality Standards Handbook* guidance is aimed at the direct exposure of humans to fish/shellfish and water, this concept may also be relevant to how sources of exposure (pathways) that supply contaminants to fish and shellfish are considered in criteria development, and could indicate that only exposure from the surface water (the BCF) should be considered:

> *"Human Exposure Considerations*
>
> *A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes. The more important of these include recreational and occupational contact, dietary intake from other than fish, intake from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available (see 45 F.R. 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only (57 F.R. 60862-3)." (emphasis added, text copied from EPA web site on 3/17/2014: http://water.epa.gov/scitech/swguidance/standards/handbook/chapter03.cfm#section13,m, section 3.1.3).*

The decision to use a BAF, a BCF, or to use a combination of the two (BAFs for some chemicals, and BCFs for others) is a risk management decision that states need to carefully weigh. Pollutants take different paths to tissue based on their chemical characteristics. If a pollutant is largely from direct CWA-regulated discharges to waters, and the food web path goes from that water concentration to the organism, without large input from other non-CWA sources that are either actively entering the water column or from other sources already sequestered in the environment from past activities, a BAF might be most reflective of the sources regulated under the CWA. In other cases a BCF might be most representative of CWA-regulated discharge sources when other greater pathways to fish lead from non-CWA sources or legacy sources already sequestered into, and then re-sourcing to organisms, from different environmental media. The use of BAF or BCF, on a chemical specific basis, could be associated with the sources and pathways of the pollutant to the water column and organisms, and the ability of CWA and different regulatory programs to address the sources.

If the scope of the Clean Water Act is limited to addressing potential exposures from NPDES- or other Clean Water Act regulated discharges to surface water, it could be argued that use of a BAF for some chemicals inappropriately expands the scope of what the CWA would be expected to control. On the other hand, if it is assumed that the scope of the Clean Water Act includes consideration and protection from other sources of toxics not regulated by the Clean Water Act, such as atmospheric deposition or marine fish sources (e.g. mercury in tuna), one could argue for use of a BAF for some chemicals. The role of the BCF and BAF is an issue that is being carefully considered by Washington in this rulemaking effort.

Decision for draft rule: Because the geographic and regulatory scope of the CWA addresses contaminant discharge directly to waters of the state (not other sources or areas), Ecology is

making a state-specific policy decision to use BCFs (not BAFs) as developed by EPA and incorporated into the 1992 NTR and the EPA recommended 304(a) national criteria (as of March 17, 2014) to calculate the criteria in the draft rule. Given the limited ability of the Clean Water Act to control sources outside its jurisdiction, Ecology thinks this is a sound and prudent decision.

9. Lifespan and duration of exposure:

*Application: These implicit variables **apply in all four equations**: carcinogen/fresh water; carcinogen/marine water; noncarcinogen/fresh water; and noncarcinogen/marine water.*

Ecology proposes to specifically acknowledge the longer term durations of exposure that are implicit in the criteria calculation in the actual draft rule.

Background: EPA 2000 guidance for HHC development assumes a lifetime exposure of 70 years, and a duration of daily exposures over 70 years. These paired assumptions result in no overall numeric change in the equation's results. However, a change in either one of these could change the calculated results of the equation. Use of the 70-year lifespan and a duration of daily exposures over 70 years is implicit in the HHC equations.

EPA also describes the duration of exposure for the HHC in the Water Quality Standards Handbook, Second Edition (EPA, 2012) as follows:

> *"Magnitude and Duration*
> *Water quality criteria for human health contain only a single expression of allowable magnitude; a criterion concentration generally to protect against long-term (chronic) human health effects. Currently, national policy and prevailing opinion in the expert community establish that the duration for human health criteria for carcinogens should be derived assuming lifetime exposure, taken to be a 70-year time period. The duration of exposure assumed in deriving criteria for noncarcinogens is more complicated owing to a wide variety of endpoints: some developmental (and thus age-specific and perhaps gender-specific), some lifetime, and some, such as organoleptic effects, not duration-related at all. Thus, appropriate durations depend on the individual noncarcinogenic pollutants and the endpoints or adverse effects being considered."*

Ecology is proposing to adopt human health criteria based on health effects, but not on organoleptic effects, thus non-duration related exposures are not applicable to the criteria being considered in this rulemaking.

EPA's Superfund Program provides specific guidance (EPA, 1989; *Risk Assessment Guidance for Superfund, Part A,* see Section 8), on interpreting the duration of exposure applicable to cancer and non-cancer effects:

> Page 8-11, guidance on exposure durations for noncarcinogenic health effects:
>
> "*Three exposure durations that will need separate consideration for the possibility of adverse noncarcinogenic health effects are chronic, subchronic, and shorter-term exposures. As guidance for Superfund, chronic exposures for humans range in duration from seven years to a lifetime; such long-term exposures are almost always of concern for*

Superfund sites (e.g., inhabitants of nearby residences, year-round users of specified drinking water sources). Subchronic human exposures typically range in duration from two weeks to seven years and are often of concern at Superfund sites. For example, children might attend a junior high school near the site for no more than two or three years. Exposures less than two weeks in duration are occasionally of concern at Superfund sites. For example, if chemicals known to be developmental toxicants are present at a site, short-term exposures of only a day or two can be of concern."

RAGSA, Pages 8-4 to 8-5, guidance on exposure durations for carcinogenic and noncarcinogenic health effects:

"Averaging period for exposure. *If the toxicity value is based on average lifetime exposure (e.g., slope factors), then the exposure duration must also be expressed in those terms. For estimating cancer risks, always use average lifetime exposure; i.e., convert less-than-lifetime exposures to equivalent lifetime values (see EPA 1986a, Guidelines for Carcinogen Risk Assessment). On the other hand, for evaluating potential noncarcinogenic effects of less-than lifetime exposures, do not compare chronic RfDs to short-term exposure estimates, and do not convert short-term exposures to equivalent lifetime values to compare with the chronic RfDs. Instead, use subchronic or shorter-term toxicity values to evaluate short-term exposures. Check that the estimated exposure duration is sufficiently similar to the duration of the exposure in the study used to identify the toxicity value to be protective of human health (particularly for subchronic and shorter-term effects). A toxicologist should review the comparisons. In the absence of short-term toxicity values, the chronic RfD may be used as an initial screening value; i.e., if the ratio of the short-term exposure value to the chronic RfD is less than one, concern for potential adverse health effects is low. If this ratio exceeds unity, however, more appropriate short-term toxicity values are needed to confirm the existence of a significant health threat. ECAO may be consulted for assistance in finding short-term toxicity values."*

The RfDs used to calculate the human health criteria are the chronic RfDs mentioned above, as opposed to the subchronic or acute toxicity values also mentioned. Toxicity values for shorter duration exposure periods have been developed (e.g., ATSDR's Minimal Risk levels (MRLs) at http://www.atsdr.cdc.gov/mrls/index.asp).

Although the duration of exposure for the HHC can be up to 70 years, the EPA recommended criteria do not contain specific durations of exposure in either a chemical-specific or overall approach. The duration of exposure is an important characteristic needed to most effectively implement the criteria to reflect the variables and assumptions in the criteria. Because the EPA criteria and equations do not *explicitly* include a lifetime value or a duration of exposure factor, and because these factors are needed to effectively implement the criteria in a manner consistent with their implicit presence in the calculation, these implicit factors are acknowledged in the draft rule language accompanying the numeric criteria values, and will be considered by Ecology in development of permit limits and water quality assessments. The preliminary draft rule includes language that explicitly states that the criteria are calculated using durations of exposure that can be up to 70 years. Ecology will draft implementation guidance to address how this information could be used in permit limit development. This information is most likely to affect discharge limits for episodic discharges where the short term nature of some discharges may

make calculation of limits that are based on the longer exposure durations that are in the HHC infeasible. In these cases discharge limits, if needed, could be based on best management practises, as per 40CFR122.44(k).

Decision for draft rule: Ecology proposes to specifically acknowledge the longer term durations of exposure that are implicit in the criteria calculation in the draft rule.

10. Hazard quotient (HQ)

Application: This implicit variable ***applies only in the noncarcinogen equations****: noncarcinogen/fresh water; and noncarcinogen/marine water.*

Ecology proposes to continue to use this implicit variable in the HHC equations.

A hazard quotient equal to one represents a risk level where non-cancer effects should not be present at specified exposure assumptions. This value is implicit in the noncarcinogen HHC equations.

Decision for draft rule: Ecology proposes to continue to use this EPA implicit variable in the HHC noncarcinogen equations.

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Challenging Chemicals: Polychlorinated Biphenyls (PCBs)

Proposal

Ecology is proposing preliminary draft human health criteria (HHC) for total polychlorinated biphenyls (PCBs) of 0.00017 µg/L for most freshwaters (drinking surface waters and ingesting fish and shellfish) and 0.00017 µg/L for marine and estuarine waters and a limited number of fresh waters (fish and shellfish ingestion only). For ease of reference, these different exposure routes are called fresh and marine for the remainder of this document. This decision on criteria concentrations is based on state risk management decisions and is in conformance with EPA historic and recent HHC development guidance.

A comparison of the current human health criteria (HHC) with the proposed criteria for PCBs is:

National Toxics Rule (NTR) HHC	2014 Proposed HHC
Freshwater: 0.00017 µg/L	Freshwater: 0.00017 µg/L
Marine: 0.00017 µg/L	Marine: 0.00017 µg/L

Background

Polychlorinated Biphenyls (PCBs) are a group of man-made chlorinated organic compounds. There are 209 individual PCB compounds, known as congeners. Aroclor is a commonly used trade name for specific PCB mixtures and is often referenced in PCB regulations. PCBs in the environment are human-caused and there are no known natural sources. Used as coolants and lubricants in electrical equipment because of their insulating properties, manufacturing of PCBs was halted in 1979 (EPA, 2014) due to evidence that PCBs accumulate and persist in the environment and can cause harmful health effects. Products made before 1979 that may contain PCBs include older fluorescent lighting fixtures and electrical devices. Even though they are "banned," PCBs are still allowed in many products manufactured and sold in the United States, including many pigments and caulking. The concentrations of PCBs in these products are regulated by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act regulations.

Health effects that have been associated with exposure to PCBs include acne-like skin conditions in adults and neurobehavioral and immunological changes in children. PCBs have been shown to cause cancer in animals (EPA 2014). Studies in exposed workers have shown changes in blood and urine that may indicate liver damage. PCB exposures in the general population are not likely to result in skin and liver effects. (ATSDR, 2001)

According to the Agency for Toxics Substances & Disease Registry, exposure routes for PCBs include:

- Leaks from old fluorescent lighting fixtures and electrical devices and appliances, such as television sets and refrigerators, that were made 30 or more years ago that may be a source of skin exposure.

- Eating contaminated food. The main dietary sources of PCBs are fish (especially sport fish caught in contaminated lakes or rivers), meat, and dairy products.
- Breathing air near hazardous waste sites and drinking contaminated well water.
- In the workplace during repair and maintenance of PCB transformers; accidents, fires or spills involving transformers, fluorescent lights, and other old electrical devices; and disposal of PCB materials.

Washington's human health criteria for PCBs: Washington's cancer-based human health criteria for PCBs are currently based on revisions to the 1992 National Toxics Rule (NTR). The 1992 rule included human health criteria for individual Aroclors that were calculated by using a cancer potency factor of 7.7 per mg/kg-day (EPA, 1992). EPA reassessed the cancer potency of PCBs in 1996 (EPA, 1996) and adopted an approach that distinguishes among PCB mixtures by using information on environmental mixtures and different exposure pathways. Based on this reassessment, EPA derived a new cancer potency factor of 2 per mg/kg-day. EPA revised the NTR human health criterion for PCBs in 1999 (EPA, 1999) to incorporate this new science. The newer NTR criterion (and current Washington standard) is 0.00017 µg/L for the protection of human health from consumption of aquatic organisms and water, and the consumption of aquatic organisms only.

PCBs in Washington's surface waters: PCBs are difficult to detect in surface waters. Commonly used analytical methods (e.g. EPA Method 608) do not detect PCBs at the low concentrations in water at which they occur. Because PCBs in waters are difficult to detect, methods that depend on concentration of PCBs in fish and shellfish tissue are frequently used to assess PCB levels across the state. Aquatic biota accumulate PCBs as part of their exposure to the food web, and the PCBs are often detected in fish and shellfish tissue. The use of fish and shellfish tissue monitoring data are used to support development of Washington Department of Health fish advisories (WDOH, 2014) and 303(d) (impaired waters) lists (Ecology, 2012). Monitoring information demonstrates that PCBs are widespread in the environment, but have in general been decreasing in concentrations since the 1979 "ban" on use of PCBs was put in place.

Regulatory issues: PCBs present regulatory challenges for CWA programs because:

- PCBs were widely used prior to the 1979 "ban".
- PCBs are widespread in the sediments and in biota.
- PCBs are long-lasting and bind readily to fats. Because of this they continue to cycle in the environment and in the food web. PCBs readily accumulate in organisms.
- PCBs are transported through the atmosphere.
- Because PCBs are transported along many pathways, and come from many sources associated with human habitation and use, they are found widely in environments that range from pristine to highly developed.
- Although PCBs can often be detected (using sensitive analytical methods) in treated effluents, treatment plants are not designed to remove these chemicals.

These PCB characteristics make them particularly difficult to control, and efforts to address PCBs are multimedia, including contaminated site clean-up, regulation of PCBs in products, and

reductions of PCBs from airborne sources. Disposal of PCBs requires specifically designed equipment. Ecology is currently developing a Chemical Action Plan for PCBs to address additional multi-media approaches to control PCBs entering the environment (Ecology, 2014).

Basis for Ecology's proposal

Ecology is proposing draft human health criteria for total PCBs based on an approach that is consistent with EPA's 2000 Human Health Criteria Guidance (EPA, 2000) and that also provides a high level of protection for Washingtonians. Ecology proposes to use a state-specific risk level exclusively for PCBs. The criteria values calculated from this risk level are then overlain by Governor Inslee's risk management direction (http://governor.wa.gov/news/releases/article.aspx?id=293) that *no new criterion concentration should be less protective than the existing NTR criterion concentration*. In cases where criteria go up in concentration, the new draft criteria would default to the NTR criterion. In the case of PCBs the draft criteria based on this default and are equal to the NTR criteria.

State-specific risk management decisions on chemical-specific risk levels are consistent with EPA HHC guidance as well as with precedent from other states. For example, EPA approved inorganic arsenic criteria adopted by the Oregon Department of Environmental Quality (ODEQ) based on $1x10^{-4}$ and $1x10^{-5}$ risk levels, even though risk levels for other chemicals were set to 10^{-6} (ODEQ, 2011). This criteria development approach combines the current cancer-based calculation with a state-specific risk level. All other variables in the HHC equations for PCBs would remain the same. The state-specific risk level being proposed is summarized as follows:

Equation variable	Risk Value	Information
Additional lifetime cancer risk level	4.0×10^{-5} (0.00004) = 4 possible additional cancer occurrences in 100,000 people after 70 years of daily exposure	Choice of a state-specific risk level is a risk management decision made by individual states. EPA 2000 guidance (EPA, 2000) specifies that the maximum risk level for highly exposed populations should not exceed $1x10^{-4}$ (1 possible additional cancer occurrence in 10,000 people after 70 years of daily exposure.) The chemical-specific risk level for PCBs was chosen to be consistent with the level of risk/hazard in the toxicity factor used by the WDOH in developing fish advisories. This is an estimated cancer risk at the corresponding safe dose (RfD) for a chemical. This value was developed as follows: Equation: RfD (mg/kg-day) x cpf $(mg/kg\text{-}day)^{-1}$ = Risk Level Equation with PCB toxicity factors: 2.0×10^{-5} mg/kg-day x 2.0 $mg/kg\text{-}day^{-1}$ = 4.0×10^{-5} This state-specific risk level is a *lower* level of risk (is *more protective*) than allowed in EPA guidance.

Since the bioconcentration factor for PCBs is very large, exposure through drinking water is negligible. The calculated criteria for exposure routes with and without drinking water are virtually the same, as are the calculated criteria values. The calculated total PCB criteria using this approach are 0.00029 µg/L. When these calculated values are compared to the NTR values, the proposed draft criteria values default downward to the NTR values of 0.00017 µg/L. These values are shown below.

Additional lifetime Cancer Risk Level	Average Fish Consumption Rate (g/day)	Calculated HHC concentration (µg/L = parts per billion)
Calculated value:		
4×10^{-5} Four–in-one hundred thousand = 0.00004	175	0.00029
Draft proposed criteria (= Current NTR Criteria)		
0.00017		

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Challenging Chemicals: Arsenic

Proposal

Ecology is proposing (1) surface water human health criteria for arsenic of 10 µg/L (total arsenic) and (2) required arsenic pollution minimization efforts.

This criteria is equivalent to the Safe Drinking Water Act (SDWA), Maximum Contaminant Level (MCL) that applies in Washington for drinking water sources. The decision to use the drinking water MCL is based on scientific information, regulatory precedent by other states and EPA, and acknowledgement of high concentrations of naturally occuring arsenic in Washington surface waters.

A comparison of the current human health criteria (HHC) with the proposed HHC for arsenic is:

National Toxics Rule (NTR) HHC	2014 Proposed HHC
Freshwater: 0.018 µg/L (inorganic)	Freshwater and Marine Water: 10 µg/L (total)
Marine: 0.14 µg/L (inorganic)	

Background

Arsenic is a naturally occurring element present in the environment in both inorganic and organic forms. Arsenic is present in rocks, soils, and the waters in contact with them, and concentrations in ground waters in the United States generally are highest in the West, with elevated levels also commonly occurring in the Midwest and Northeast. (USGS, 2000). Inorganic forms of arsenic are considered to be the most toxic, and are found in groundwater and surface water, as well as in many foods. A wide variety of adverse health effects, including skin and internal cancers, and cardiovascular and neurological effects, have been attributed to chronic arsenic exposure, primarily from drinking water (NAS, 1999; CTD, 2013).

There are also anthropogenic sources of arsenic in the environment, which include pesticides and herbicides, pressure treated lumber (this is a legacy source, as production of new pressure treated lumber treated with an arsenic compound has been phased out), fertilizers, pharmaceuticals, electronic semiconductors, automobile lead-acid batteries, lead bullets and shot, and metal smelting.

Current Standards in Washington State: Washington's current Water Quality Standards (WQS) for arsenic are contained in the state's water quality standards rule for aquatic life criteria (WAC 173-201A-240). Arsenic standards are also contained in the United States Environmental Protection Agency (EPA)-promulgated National Toxics Rule (NTR) (EPA 1992; 40 CFR 131.36). Both human health criteria (HHC) and aquatic life criteria are shown in Table 6 and are expressed as micrograms per liter (µg/L), which is equivalent to parts per billion (ppb).

Table 6: Washington's current water quality standards for arsenic					
National Toxics Rule (NTR)- Human Health Criteria (1992)		Washington State Water Quality Standards (WAC 173-201A)			
Freshwater- Organism + Water	Marine- Organism Only	Acute Marine	Chronic Marine	Acute Freshwater	Chronic Freshwater
0. 018 µg/L (inorganic)	0.14 µg/L (inorganic)	69 µg/L (dissolved)	36 µg/L (dissolved)	360 µg/L (dissolved)	190 µg/L (dissolved)

In addition to the NTR and the state WQS, EPA establishes Maximum Contaminant Levels (MCLs) for arsenic under the federal Safe Drinking Water Act. Up until 2001, the drinking water MCL for arsenic was 50 µg/L. EPA lowered the arsenic MCL to 10 µg/L in 2001 (EPA, 2001), following an extensive public process. The new standard went into effect for public supplies of drinking water nationwide in 2006. SDWA standards for arsenic in Washington are under the authority of the Washington Department of Health (WDOH).

EPA is currently in the process of reviewing the toxicity information in the Integrated Risk Information System (IRIS) related to inorganic arsenic, and plans to submit its next draft to the National Research Council for peer review (EPA, 2014). The cancer slope factor currently in IRIS is an older value developed in 1988.

HHC for arsenic in other states: Nationwide, nearly half of the states use the SDWA MCL value of 10 µg/L for their arsenic HHC (ODEQ, 2011, P. 19).

In the west, where naturally high levels of arsenic in groundwater and geology are prevalent, six states have also adopted the SDWA MCL as their HHC for arsenic. Oregon took a different approach and adopted risk-based HHC for arsenic (Table 7).

EPA promulgated HHC for the state of California in 2000, as the California Toxics Rule. However, EPA did not promulgate criteria for arsenic and acknowledged the limitations associated with using the 1988 IRIS cancer slope factor. The following is language from the EPA's 2000 promulgation of the California Toxics Rule (EPA, 2000):

> *"EPA is not promulgating human health criteria for arsenic in today's rule. EPA recognizes that it promulgated human health water quality criteria for arsenic for a number of States in 1992, in the NTR, based on EPA's 1980 section 304(a) criteria guidance for arsenic established, in part, from IRIS values current at that time. However, a number of issues and uncertainties existed at the time of the CTR proposal concerning the health effects of arsenic…."*
>
> *"…Today's rule defers promulgating arsenic criteria based on the Agency's previous risk assessment of skin cancer….."*

Table 7: Human health criteria for arsenic in Western States		
State	Arsenic criteria µg/L	Basis
Alaska	10 (total arsenic)	Same as SDWA MCL
Idaho	10 (total arsenic)	
Wyoming	10 (total arsenic)	
Nevada	10 (total arsenic)	
Utah	10 (total arsenic)	
New Mexico	10 (total arsenic)	
Oregon	2.1 (drinking surface + fish and shellfish: "fresh waters") (inorganic arsenic)	1 x 10^{-4} cancer risk level
	1.0 (fish and shellfish only: marine and estuarine)(inorganic arsenic)	1 x 10^{-5} cancer risk level
California [(1)]	5.0 Note: California uses the term "objective" , which is comparable to the term "state criteria."	Objectives are found in individual Basin Plans for the California Regional Water Quality Control Boards (see notes below for examples [(1)]– Based on Maximum Contaminant Levels as specified in Table 64431-A (Inorganic Chemicals) of Section 64431, Title 22 of the California Code of Regulations, as of June 3, 2005.

Notes:
[(1)] (California Regional Water Quality Control Board, San Francisco Bay Region, 2013), (Los Angeles Regional Water Quality Control Board, 1994), (North Coast Regional Water Quality Control Board, 2011), (Regional Water Quality Control Board, Central Coast Region, 2011)

Concentrations of arsenic in surface waters of Washington: In Washington, natural levels of inorganic arsenic in surface freshwaters are most frequently below the SDWA MCL of 10 µg/L total arsenic, but are frequently higher than the NTR HHC inorganic arsenic concentration of 0.018 ug/L. In situations where natural conditions result in ambient concentrations that are greater than the NTR criteria concentrations, Ecology uses the "natural conditions" provision in the water quality standards at WAC 173-201A-260 rather than the numeric criteria.

The following provides one example of a total maximum daily load (TMDL) study that demonstrates natural concentrations of arsenic from the Similkameen River in Okanogan County:

> The Similkameen River "TMDL Evaluation for Arsenic" (Ecology, 2002) noted that "EPA human health criteria of 0.018 and 0.14 ug/L are, however, consistently exceeded by an order of magnitude or more." Ecology's TMDL demonstrated that natural background arsenic levels in the Similkameen River are greater the NTR human health criteria. The TMDL determined that the Similkameen River naturally exceeds the EPA arsenic criteria upstream of the areas disturbed by mining. It was determined that natural conditions constitute the water quality criteria. Because arsenic levels naturally exceed criteria, the loading capacity for the river was set equal to the natural background concentration of arsenic. The TMDL was approved by EPA in 2004.

Basis for Ecology's proposal

Ecology is proposing the following two specific rule changes for arsenic:

- Surface water human health criteria for total arsenic at the SDWA MCL of 10 µg/L, based on a consideration of the continuing uncertainty around the long-term reassessment of the EPA IRIS cancer potency factor for arsenic, EPA's CWA-approval of the of the SDWA MCL for arsenic for other states, and presence of naturally occurring arsenic in Washington.
- Pollution minimization requirements to reduce anthropogenic inputs of arsenic in discharges to surface waters.

Ecology has determined that use of the EPA cancer potency factor would introduce a significant amount of uncertainty if used to develop human health criteria for arsenic:

- The inorganic arsenic cancer potency factor has been under reassessment for many years, and a date for finalization is not available (EPA, 2014).
- EPA did not use the 1998 IRIS cancer potency factor in its development of the new SDWA MCL of 10 ppb promulgated in 2001, nor did they depend on this value in their promulgation of the HHC for the state of California in 2000. In the 2000 California Toxics Rule, EPA expressed their finding of uncertainty around the effects of arsenic, and did not use the newer 1998 cancer potency factor (EPA 2000). EPA used the older cancer potency factor ((1.75 per (mg/kg)/day) derived from the drinking water unit risk (5E-5 per (ug/L)) that was used to calculate the NTR arsenic criteria in its 1998 and 2002 national recommended guidance criteria calculations, but not as the basis of new regulations in either the 2000 CTR or the new 2001 MCL for arsenic.
- Using either of these older cancer potency factors ((1) the cancer potency factor (1.75 per (mg/kg)/day) derived from the drinking water unit risk (5E-5 per (ug/L) that was used to calculate the NTR arsenic criteria, or, (2) the 1998 cancer potency factor (1.5E+0 per (mg/kg)/day)) injects a high degree of uncertainty into the criteria calculation for a regulatory level, especially given that EPA has not relied on either of these as the basis of more recent regulations.

After review of what other states have done in setting human health criteria for arsenic, with subsequent approval by EPA, and consideration of naturally high concentrations of arsenic in Washington, Ecology has determined that use of the SDWA MCL for arsenic is appropriate for Washington:

- Use of the MCL has been approved by EPA widely across the nation. In particular, several other western states that have high levels of natural arsenic in the environment have adopted the SDWA MCL and are successfully applying it for protection of human health (Table 2).

Pollution prevention requirements

Adopting new arsenic criteria that reflect both a change in the chemical form (a change from inorganic arsenic to total arsenic) and a higher concentration has prompted Ecology to address implementation to ensure that unforeseen industrial discharges of arsenic are controlled and

reduced. The following draft language was developed to address discharges of arsenic, from industrial sources, to waters with the designated use of "domestic water supply."

When Ecology determines that an indirect or direct industrial discharge to surface waters designated for domestic water supply may be adding arsenic to its wastewater, Ecology will require the discharger to develop and implement a pollution prevention plan to reduce arsenic through the use of AKART (All Known and Reasonable Treatment). Indirect discharges are industries that discharge wastewater to a privately or publicly owned wastewater treatment facility.

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Challenging Chemicals: Methylmercury

Proposal

Ecology has decided to defer state adoption of Human Health Criteria (HHC) for methylmercury at this time, and plans to schedule adoption of methylmercury criteria and develop a comprehensive implementation plan after the current rulemaking is completed and has received EPA Clean Water Act (CWA) approval. This decision means that Washington's human health criteria for total mercury will remain in the National Toxics Rule until new methylmercury criteria are adopted by the state.

The background and basis for this decision are described below.

Background

Mercury is a toxic metal that is released to the environment through natural and human processes. Most commonly, the gaseous form is released to the atmosphere, which is then deposited onto land and water from rain and snow. Once in the water, mercury can convert to its most toxic form, methylmercury, which accumulates in fish and aquatic organisms. Humans are exposed to methylmercury and its associated health problems by consuming contaminated fish. As of 2008, all 50 states had issued fish consumption advisories due to mercury contamination (EPA, 2010). Washington currently has CWA Section 303(d) listings based on the current mercury human health criteria, and the Washington Department of Health has issued statewide fish advisories for mercury for different fish species.

Washington's criteria for mercury: Washington's human health criteria (HHC) and aquatic life criteria are shown in Table 1 below. The HHC for total mercury were issued to Washington in the 1992 National Toxics Rule (NTR; 40 CFR 131.36). Washington's current aquatic life criteria for total mercury are contained in the state's water quality standards rule for aquatic life criteria (WAC 173-201A-240). The HHC are based on non-cancer effects to human health. The acute aquatic life criteria are based on aquatic life effects, and the chronic aquatic life criteria are based on human health protection. The chronic marine and freshwater numeric criteria and the chronic criteria provision of "edible tissue concentrations shall not be allowed to exceed 1.0 mg/kg of methylmercury" are all based on the federal Food and Drug Administration's action level of 1 parts per million (ppm) for methylmercury in commercial fish.

Numeric criteria for mercury: Washington's current water quality criteria are in the table below:

Table 8: **Washington's Current Water Quality Standards for mercury**

National Toxics Rule (NTR)- Human Health Criteria (1992)		Washington State water quality standards (WAC 173-201A) Aquatic Life Criteria			
Organism + Water (µg/L)	Organism Only (µg/L)	Acute Marine (µg/L)	Chronic Marine (µg/L)	Acute Freshwater (µg/L)	Chronic Freshwater (µg/L)
0. 14 (total)	0. 15 (total)	1.8 (dissolved)	[(1)] 0.025 (total)	2.1 (dissolved)	[(1)] 0.012 (total)

Footnote 1. Edible fish tissue concentrations shall not be allowed to exceed 1.0 mg/kg of methylmercury.

New EPA recommended criteria for methylmercury: Prior to 2001 the U.S. Environmental Protection Agency (EPA) recommended that states adopt mercury HHC as "total mercury" measured in surface waters. In January 2001, EPA published a new recommended CWA section 304(a) water quality criterion for methylmercury based on fish tissue residues. This new criterion replaced the prior total mercury recommended criteria. The new recommended water quality criterion, 0.3 milligram (mg) methylmercury per kilogram (kg) fish tissue wet weight, describes the concentration of methylmercury in freshwater and estuarine fish and shellfish tissue that EPA recommends not be exceeded in order to protect consumers of fish and shellfish. The new EPA 2001 recommended national criterion (0.3 mg/kg) was calculated using a fish consumption rate of 17.5 g fish/day of freshwater and estuarine fish. The older total mercury HHC (the 1992 NTR criteria) were calculated using a fish consumption rate of 18.7 g/day, as opposed to the 6.5 g/day fish consumption rate incorporated in other HHC published by EPA prior to 2001 (EPA 2001) and 2002 (USEPA 2002).

Implementation considerations:

Current implementation of mercury criteria: Washington currently implements the HHC and aquatic life criteria for total and dissolved mercury in discharge permits, in water quality assessments, and in Section 401 water quality certifications. In discharge permitting, the chronic aquatic life criteria are most likely to result in effluent limits because they are set at lower concentrations than the NTR criteria. EPA has published sensitive analytical methods for total mercury that are used in NPDES permitting as required in 40 CFR Part 136.

Implementation of EPA's 2001 recommended methylmercury criterion: The 2001 methylmercury criterion was the first EPA-developed HHC expressed as a fish and shellfish *tissue* value rather than as a water column value. EPA recognized that this approach differed from traditional water column criteria and might pose implementation challenges. Therefore, in April 2010, EPA issued *Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion* to provide direction to states and tribes on how to use the new fish tissue-based criterion recommendation in developing water quality standards for methylmercury and in implementing those standards in total maximum daily loads (TMDLs) and National Pollutant Discharge Elimination System (NPDES) permits. However, even with guidance from EPA, questions around the following exist and will require development of a Washington specific approach:

- Mixing zones
- Variances
- Field sampling recommendations
- Assessing non-attainment of fish tissue criterion
- Developing TMDLs for water bodies impaired by mercury
- Incorporating methylmercury limits into NPDES permits

Controlling sources of mercury: Controlling the sources of mercury entering the aquatic environment is a complex issue. Complications include:

- There are many sources and pathways for mercury to enter Washington's environment (atmospheric transport from local areas and from other areas of the world, direct discharges, pharmaceuticals, food supplies, contaminated sites, etc.) - see Ecology's Mercury Chemical Action Plan information at http://www.ecy.wa.gov/mercury/.)

- Many of these mercury sources cannot be addressed using CWA laws and implementing regulations.
- There are existing levels of mercury in fish sampled throughout the state that have prompted the WDOH to issue statewide fish advisories for selected species of fish.
- Developing NPDES discharge limits for permits based on a form of mercury (methylmercury criterion) that is created after mercury enters the environment is not straightforward.

Developing an implementation process that effectively addresses mercury controls and also delineates between CWA and non-CWA responsibilities will take considerable time and resources, as well as considerable public input.

Basis for Ecology's proposal

Ecology has decided to defer state adoption of HHC for methylmercury at this time, and plans to schedule adoption of methylmercury criteria and develop a comprehensive implementation plan after the current rulemaking is completed and has received CWA approval. This decision means that Washington's human health criteria for total mercury will remain in the NTR until new methylmercury criteria are adopted by the state.

Ecology based this decision on the following factors:

- Implementation and control strategies to reduce methylmercury concentrations in fish and shellfish tissue need an integrated approach that uses available CWA tools and also other non-CWA actions (Ecology 2003).
- Taking time to develop an integrated approach now would slow the progress of the adoption of the other proposed HHC and implementation tools. Ecology thinks continued progress on the main rule adoption is important to maintain.
- The state currently has criteria for mercury that address human health protection (the NTR criteria and the marine and freshwater chronic aquatic life criteria).

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Implementation Tools: Intake Credits

Proposal

Ecology proposes to add a new section to the water quality standards rule at WAC 173-201A-460 that addresses situations where facilities bring in and discharge levels of background pollutants contained in the intake water, referred to as intake credits. Intake credits have typically been allowed for technology based limits. The proposed new language is applicable to the granting of intake credits for use with water quality based effluent limits (WQBELs). Proposed language clarifies the conditions where intake credits would be allowed for determining reasonable potential and water quality-based effluent limits (WQBEL) that accounts for pollutants already present in the intake water, and would only be allowed when the mass and concentration of effluent is the same or less than intake water, and there is "no net addition" of the pollutant.

Background

An intake credit is a tool that is intended to be used in the National Pollutant Discharge Elimination System (NPDES) Permit Program, in specific circumstances where the discharger is not contributing any additional mass of the identified intake pollutant in its wastewater, thereby having a "no net addition" of the pollutant. Examples of a pollutant already found in the intake water could be from naturally-occurring or legacy pollutants that are outside of the control of the facility. This implementation tool would not impact Washington's water quality and public health because it would not be granted unless the facility met the requirements for "no net additions" of the pollutant.

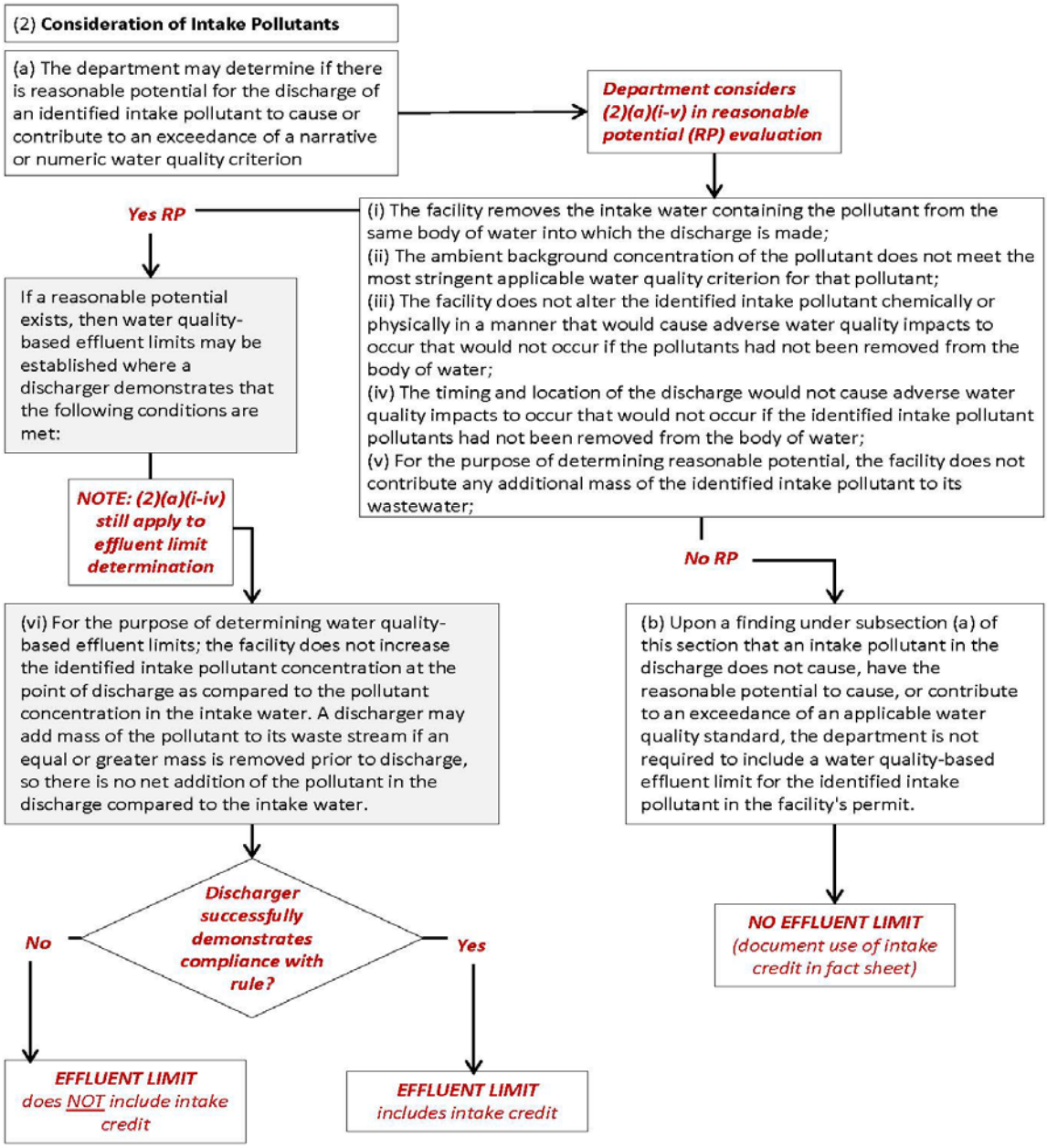
An intake credit is a procedure that allows permitting authorities to conclude that the return of unaltered intake water pollutants to the same body of water under identified circumstances does not cause, have the reasonable potential to cause, or contribute to an exceedance above water quality standards. Intake credits have been traditionally used by states to distinguish levels of pollutants already present in facility intake waters from human actions or due to naturally occurring background levels.

The following conditions typically must be met for an intake credit to apply:

- The intake pollutant must not cause, or have the reasonable potential to cause, or contribute to levels above an applicable water quality standard.
- The facility must not contribute any additional mass of the identified intake pollutant to its wastewater.
- Intake water must come from the same body of water to which the discharge is made.
- The facility must not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream.
- The facility must not increase the identified intake pollutant concentration at the point of discharge as compared to the pollutant concentration in the intake water.

The timing and location of the discharge must not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

The proposed language in Section (2) of the intake credit section would be implemented and followed as illustrated below.



Flowchart for implementation of proposed intake credit language at *WAC 173-201A-460-(2) Consideration of Intake Pollutants.*

Typically, states have used intake credits in conjunction with technology-based effluent limits (TBELs), but EPA has recently approved the use of intake credits with water quality based effluent limits in some states.

Intake credits do not alter the permitting authority obligations under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations as part of a TMDL prepared by the state department and approved by EPA as outlined in 40 CFR 130.7. They may have a limited applicability due to the requirement that pollution essentially pass through the facility unaltered.

Basis for Ecology's proposal

Proposed language in WAC 173-201A-460 closely follows the directives for allowing intake credits for determining reasonable potential and WQBELs outlined in the Great Lakes Initiative, and in the recently adopted Oregon water quality standards.

Federal regulations at 40 CFR 122.45(g) allow for adjustment of (TBELs) to reflect credit for pollutants in the discharge's intake water. Therefore, the permittee is only responsible for treating the portion of the pollutant load generated or concentrated as part of their process. The credits are commonly referred to as "intake credits." Although intake credits are commonly used by states for TBELs, states have only recently begun to use intake credits for WQBELs. The most developed of these is contained in the *Great Lakes Water Quality Guidance,* which offers a process for doing an alternative reasonable potential analysis for WQBELs that incorporate the concept of intake credits.

Intake credit language has been adopted into the water quality administrative rules of a number of states including California, Ohio, Indiana, Michigan, Wisconsin, Illinois, Minnesota, Pennsylvania and New York, although they are only included in a limited number of actual permits due to the inherent limitations of the Intake Credit procedure and the availability of other implementation procedures.

In Region 10, Oregon recently revised its intake credits provisions as part of their rulemaking for human health criteria and modeled their revisions after the language approved by the EPA for the Great Lakes Initiative. This language can be found in OAR 340-045-0105, and includes the general requirements listed above. The Oregon regulations provide facilities the ability to gain credit for pollutants in their intake water when there is "*no net addition*" of pollution, or when the facility removes any incidental concentrations of a pollutant that might have occurred during production prior to discharging.

Additional information

- EPA, 1995. Federal Register, Volume 60, Number 56, "Final Water Quality Guidance for the Great Lakes System", Appendix F, Procedure 5; Reasonable Potential to Exceed Water Quality Standards, Part D. Available online at: *http://www.epa.gov/owow/tmdl/glsprohibit.pdf#page=156*.
- ODEQ, 2011. Oregon Department of Environmental Quality. Oregon Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking (2008-2011). Available online at:

http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf.

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Implementation Tools: Compliance Schedules

Proposal

Ecology proposes to add a new definition in WAC 173-201A-020 to define "Compliance Schedule" or "Schedule of Compliance." Ecology proposes to revise language in WAC 173-201A-510(4) that deletes the specific period of time for the compliance schedule (currently ten years) and adds language to describe circumstances when a compliance schedule can go beyond the term of a permit, and ensure that compliance is achieved as soon as possible. Language has been added to authorize compliance schedules for longer periods of time in accordance with RCW 90.48.605, where a total maximum daily load (TMDL) exists. Language has also been added for circumstances when more time is needed and a TMDL does not exist.

Background

A compliance schedule is a tool that is intended to be used in the National Pollutant Discharge Elimination System (NPDES) Permit Program, in specific circumstances where an individual discharger requires additional time to comply with NPDES permit limits based on new or revised criteria in a state's water quality standards. The compliance schedule allows the particular discharger time to meet permit's limit while taking steps to eventually achieve compliance. Typically, the compliance schedule is included as part of the Terms and Conditions in an NPDES permit and includes interim requirements. A key point in a compliance schedule is that the discharger is required to achieve the final water quality-based effluent limit as soon as practicable.

A compliance schedule is an enforceable tool used as part of a permit, order, or directive to achieve compliance with applicable effluent standards and limitations, water quality standards, or other legally applicable requirements. Compliance schedules include a sequence of interim requirements such as actions, operations, or milestone events to achieve the stated goals. Compliance schedules are a broadly used tool for achieving state and federal regulations; compliance schedules under the Clean Water Act are defined federally at CWA 502(17) and 40 CFR Section 122.2.

Schedules of compliance have existed in Ecology regulations at WAC 173-220-140 for the NPDES permit program since 1974. These regulations require that compliance schedules set forth the shortest, reasonable period of time to achieve the specified requirements, and require that such period to be consistent with federal guidelines and requirements of the Clean Water Act. Compliance schedules become an enforceable part of the permit. If a permittee fails or refuses to comply with interim or final requirements of a compliance schedule in a permit, such noncompliance constitutes a violation of the permit. Compliance schedules were incorporated into the state water quality standards in 1992 to ensure continued use in the permitting program, and can be found at WAC 173-210A-510(4).

The use and limitations of compliance schedules for NPDES permits in Washington are described at WAC 173-220-140. For purposes of water quality standards, compliance schedules may be used only where there is a finding that a permittee cannot immediately comply with a

new, or newly revised, water-quality based effluent limit (WQBEL). Compliance schedules lasting longer than one year must include interim milestones, along with dates for their achievement, with no more than one year between dates. Interim milestones might relate, for example, to purchase and installation of new equipment, modification of existing facilities, construction of new facilities, and/or development of new programs. Compliance schedules also must include specific numeric or narrative effluent limits that will be met during the compliance schedule period.

Compliance schedules must require a permittee to meet the applicable WQBEL "as soon as possible." The determination of what constitutes "as soon as possible" is made on a permit-by-permit basis considering the specific steps a permittee must take to achieve compliance. A compliance schedule typically is short-term in duration that includes a schedule of actions (investigations such as source identification studies, treatment feasibility studies) to meet the final effluent limitation. A compliance schedule differs from a variance in that a discharge may need more time to meet a final effluent limitation, but it has identified specific actions that will attain water quality effluent limits. In other words, the discharger knows they can achieve the water quality standard but they need more time.

Current Washington State regulations limit compliance schedules to no more than ten years. However, Ecology has been directed by the Legislature to extend the maximum length of compliance schedules to more than ten years when a compliance schedule is appropriate, the base requirements for compliance schedules are met (i.e., compliance "as soon as possible"), and a permittee is not able to meet its TMDL waste load allocations only by controlling and treating its own effluent. Statutory language can be found at RCW 90.48.605 - Amending state water quality standards — Compliance schedules in excess of ten years authorized. Available online: http://apps.leg.wa.gov/rcw/default.aspx?cite=90.48.605.

Basis for Ecology's Proposal

The main basis for Ecology's proposal is state legislation in 2009 that recognized there are circumstances where extending a compliance schedule would be appropriate. Compliance schedules must still meet requirements in state NPDES regulations at WAC 173-220-140, which includes specific timeframes within the schedule of compliance and enforceable provisions. RCW 90.48.605 focuses on instances when a total maximum daily load (TMDL) exists on the receiving water, and describes a four part test that must be established:

1. The permittee is meeting its requirements under the total maximum daily load as soon as possible.
2. The actions proposed in the compliance schedule are sufficient to achieve water quality standards as soon as possible.
3. A compliance schedule is appropriate.
4. The permittee is not able to meet its waste load allocation solely by controlling and treating its own effluent.

Ecology has also added language that takes into consideration circumstances where a TMDL does not exist, but a compliance schedule would be the most appropriate tool to bring the permittee into compliance with the standard in the shortest timeframe possible. In this case, the

actions must be identified that will bring the discharger into compliance with the effluent limits, but more time is needed than the term of the permit.

Revised language for compliance schedules emphasizes that compliance schedules must be completed as soon as possible and should generally not exceed the term of the permit. The revisions remove the ten-year limit for compliance schedules to allow flexibility on a permit by permit basis.

In considering a longer time period than ten years under certain circumstances, the use of compliance schedules in other states was reviewed. As an example, in Idaho, the town of Smelterville wastewater treatment plant draft permit includes a compliance schedule of "twenty years plus five months" for dissolved metals. Smelterville is located within the Bunker Hill Mining and Metallurgical Complex Superfund Site that has a current clean-up schedule of thirty years. This schedule, along with the need for additional data collection to determine the source of continued elevated metal levels in the new treatment plant effluent, was part of the justification for the twenty-year compliance schedule. EPA has approved this schedule as meeting the "as soon as possible" requirement.

In summary, the following apply as a basis for the use of the proposed revisions to the general allowance for Compliance Schedules in Washington:

- They are a part of a permit and do not require a rule change.
- They are allowed when the facility can achieve water quality standards but needs more time.
- The discharger must meet water quality standards or compliance "as soon as possible."
- They must contain an enforceable sequence of actions and final limit.
- They must make progress towards the final limit or WQS by requiring interim actions with milestones if the schedule is longer than one year.
- They are not allowed for new dischargers.
- They cannot be renewed.

Additional Information

- Hanlon, 2007. U.S. EPA Office of Wastewater Management. May 27, 2007. Memorandum to Alexis Stauss, Director of Water Division EPA Region 9, on ''Compliance Schedules for Water Quality-Based Effluent Limitations on NPDES Permits.' Available at: *http://water.epa.gov/lawsregs/guidance/wetlands/upload/signed-hanlon-memo.pdf*.
- EPA, 2012. EPA Water Quality Standards Academy - Basic Course Module 5: Compliance Schedules – Discharger Grace Periods: Webpage last updated Friday, November 23, 2012. *http://water.epa.gov/learn/training/standardsacademy/mod5/page12.cfm*.
- Ecology, 2013. WA Dept. of Ecology Supplemental Material from Policy Forum #3 (Feb. 8, 2013) - Application of variances and compliance schedules to existing, new, and expanding dischargers/discharges: *http://www.ecy.wa.gov/programs/wq/swqs/SupMaterialVariancesComplianceSched.pdf*.

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Implementation Tools: Variances

Proposal

Ecology proposes to add a new definition in WAC 173-201A-020 to define "Variance." Ecology proposes to revise language in WAC 173-201A-420 that establishes minimum qualifications for granting variances for individual dischargers, stretches of waters, or application to multiple dischargers. Language is being revised to establish a process for considering a variance that includes:

- A public process, including tribal notification, rulemaking, and EPA approval.
- The time period for when a variance would be in effect, generally not to exceed the term of the permit but under certain circumstances can be longer, as long as the time is "as short as possible."
- Requirements for a pollutant reduction plan that identifies specific schedule of actions that are set forth to achieve compliance with the original criteria.
- Requirements for interim numeric and narrative requirements that reflect the highest achievable water quality, as soon as possible, during the term of the variance.
- Requirements for a mandatory five-year review if the variance extends beyond the term of a permit.
- For variances that apply more broadly than individual variances, require a watershed assessment or total maximum daily load (TMDL) to identify responsible sources.
- Conditions under which a variance would be shortened or terminated, and when renewal would be considered.

Background

A variance is a temporary change to the water quality standards for a single discharger, a group of dischargers, or stretch of waters. Variances establish a time-limited set of temporary requirements that apply instead of the otherwise applicable water quality standards and related water quality criteria. Variances may be used where attaining the designated use and criteria is not feasible immediately, but might be, or will be, feasible in the longer term (versus a compliance schedule where it is clear water quality standards can be met once specific implementation action occur). They can be targeted to specific pollutants, sources, and/or stretches of waters.

The U.S, Environmental Protection Agency (EPA) has dictated that state variance procedures, as part of state water quality standards, must be consistent with the substantive requirements of 40 CFR 131. EPA has approved state-adopted variances in the past and has indicated that it will continue to do so if:

- Each variance is included as part of the water quality standard.

- The state demonstrates that meeting the standard is unattainable based on one or more of the grounds outlined in 40 CFR 13 1.10(g) for removing a designated use.
- The justification submitted by the state includes documentation that treatment more advanced than that required by sections 303(c)(2)(A) and (B) has been carefully considered, and that alternative effluent control strategies have been evaluated.
- The more stringent state criterion is maintained and is binding upon all other dischargers on the stream or stream segment.
- The discharger who is given a variance for one particular constituent is required to meet the applicable criteria for other constituents.
- The variance is granted for a specific period of time and must be re-justified upon expiration.
- The discharger either must meet the standard upon the expiration of this time period or must make a new demonstration of "unattainability."
- Reasonable progress is being made toward meeting the standards.
- The variance was subjected to public notice, opportunity for comment, and public hearing. The public notice should contain a clear description of the impact of the variance upon achieving water quality standards in the affected stretch of waters.

The temporary requirements established through a variance are only effective for the life of the variance. Because a variance establishes a temporary set of requirements that apply instead of the otherwise applicable water quality criteria, EPA has specified that variances are appropriate only under the same circumstances required in federal rule to undertake a Use Attainability Analysis (UAA), used to change a designated use for a water body. Regulations found in 40 CFR 131.10(g) establish six circumstances under which a UAA, or a variance, might be appropriate. They are:

1. Naturally occurring pollutant concentrations prevent attainment of the use.
2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent attainment of the use, unless these conditions may be compensated for by discharge of sufficient volume of effluent discharges without violating state water conservation requirements to enable uses to be met.
3. Human caused conditions or sources of pollution prevent attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place.
4. Dams, diversions or other types of hydrologic modifications preclude attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in attainment of the use.
5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses.
6. Controls more stringent than those required by Sections 301(b) and 306 of the Clean Water Act would result in substantial and widespread economic and social impact.

Recent EPA guidance offered two examples of the circumstances under which variances may be particularly appropriate to consider:

> (1) When attaining the designated use and criteria is not feasible under current conditions (e.g., water quality-based controls required to meet the numeric nutrient criterion would result in substantial and widespread social and economic impact) but achieving the standards could be feasible in the future if circumstances related to the attainability determination change (e.g., development of less expensive pollution control technology or a change in local economic conditions).
>
> (2) When it is not known whether the designated use and criteria may ultimately be attainable, but feasible progress toward attaining the designated use and criteria can be made by implementing known controls and tracking environmental improvements (e.g., complex use attainability challenges involving legacy pollutants).

EPA has not established a specific time limit for variances. Proposed changes to the federal water quality standards rule, recently released by EPA in September 2013, include changes to address variances with a proposed timeframe not to exceed ten years. These federal rules have not been finalized and are still in draft form.

Variances have not been issued in Washington to date but are allowed under WAC 173-201A-420. The current language states that a variance is subject to a public and intergovernmental involvement process and a variance does not go into effect until it is incorporated into WAC 173-201A and approved by EPA. The current duration of a variance is for up to five years and variances may be renewed after providing another opportunity for public and intergovernmental involvement and review.

Basis for Ecology's proposal

Ecology is currently developing human health criteria for Washington's water quality standards. Changes to the variables that go into the human health criteria equation, such as an updated fish consumption rate, will generally result in more protective criteria. Ecology recognizes that these new, more protective criteria may be difficult to meet in situations where technology is not yet available or feasible to remove the pollutant, or in cases where either a persistent pollutant resides and is cycling within the aquatic ecosystem of the water body and cannot be removed without degrading the system, or when the main sources of the pollutant are not within the scope of the state's jurisdiction to control through water quality protection.

EPA has advised states that a variance should be used instead of removal of a use where the state believes the standard can ultimately be attained. By maintaining the beneficial use rather than changing it, the state will ensure that further progress is made in improving water quality and attaining the standard. With a variance, NPDES permits may be written such that reasonable progress is made toward attaining the standards without violating section 402(a)(l) of the Clean Water Act, which requires that NPDES permits must meet the applicable water quality standards.

With these factors in mind, Ecology is proposing revisions to the variance section of the water quality standards at WAC 173-201A-420, as part of the rulemaking for developing human health criteria. The key goals of these revisions are:

- **Provide accountability** that the discharger cannot feasibly meet the original criteria and that they continually strive to make reasonable progress to meet the original criteria during the life of the variance. Build in checks and balances to ensure that variance information is reviewed on a regular basis, new technology and science is taken into account, and benchmarks are required to ensure that implementation of the variance is occurring and that the variance continues to be necessary.
- **Extend timeframe** of a variance where necessary to allow time to deal with difficult, complex toxics compounds, such as legacy pollutants or those that come from sources outside of Clean Water Act jurisdiction. Include mandatory reviews to ensure that the variance is still necessary. Provide framework for renewing, shortening, and revoking a variance.
- **Efficiency of Resources**. Where possible, reduce resource intensity of regulating agencies in issuing variances.

The proposed language at WAC 173-201A-420 includes general provisions, and specific requirements that would apply for variances for individual dischargers, stretches of waters, and multiple dischargers. Requirements are intended to be consistent with federal guidance and also provide the necessary tools for implementing state water quality standards.

Besides requirements for issuing an individual variance, new language also provides requirements for issuing a variance to multiple dischargers for circumstances where multiple permittees cannot attain a designated use or criteria for the same pollutant(s) for the same reason, regardless of whether or not they are located on the same water body. In these cases, Ecology proposes to streamline the variance process by adopting one variance that applies to all the permittees. These are generally known as "multiple discharger variances." Multiple discharger variances may be considered under the same circumstances, and must meet the same standards, as single discharger variances. A permittee that could not qualify for an individual variance should not qualify for a multiple discharger variance. Ecology is following EPA guidance, which recommends that justifications for multiple discharger variances should:

> (1) Apply only to permittees experiencing the same challenges in meeting water quality based effluent limits for the same pollutant(s), criteria, and designated uses.
>
> (2) Group permittees based on specific characteristics or technical and economic scenarios that they share, and conduct a separate analysis for each group. The more homogenous a group is in terms of factors affecting attainability of the designated use and criteria, the more credible a multiple discharger variance will be. For example: type of discharger (public or private); industrial classification; permittee size and/or effluent quality; pollutant treatability; whether or not the permittee can achieve a level of effluent quality comparable to the other permittees in the group; and water body or watershed characteristics.
>
> (3) Collect sufficient information from each individual permittee to support the assignment of each individual permittee to the designated group of multiple dischargers. The justification for a multiple discharger variance should account for as much individual permittee information as possible. When a permittee does not fit with any of the group characteristics, an individual variance should instead be considered.

Ecology is also proposing new language that will allow a variance for stretches of waters, such that the variance would apply to an entire stretch of water or portions of water body segments. Other states have used water body variances where the problems in a stretch of waters are significantly impacting water quality and habitat, are widespread, and involve numerous sources of point and nonpoint pollution; that is, where waters are significantly impaired by multiple sources, not just a few point sources. For example, where historic mining practices have impaired both water quality and habitat throughout a headwater basin, states have applied temporary standards with specific expiration dates for certain pollutants related to the historic mining practices rather than downgrading these waters through a use change. In this way, states have maintained designated uses and underlying criteria for other pollutants, while recognizing that existing ambient conditions for certain pollutants are not correctable in the short-term.

The temporary standards provide a basis for permit limits in the shorter term that will in turn lead to remediation of damaged water resources to the point that they will once again provide protection for the underlying designated use and criteria. By doing a variance instead of a UAA the underlying use and criteria are preserved, allowing them to actively drive water quality improvements in the longer-term. A water body variance provides time for the state to work with both point and nonpoint sources to determine and implement adaptive management approaches on a water body or watershed scale to achieve pollutant reductions and strive toward attaining the water body's designated use and associated criteria.

Additional information

- Ecology, 2013. WA Dept. of Ecology Supplemental Material from Policy Forum #3 (Feb. 8, 2013) - Application of variances and compliance schedules to existing, new, and expanding dischargers/discharges: *http://www.ecy.wa.gov/programs/wq/swqs/SupMaterialVariancesComplianceSched.pdf*.
- EPA, 2013. Office of Water. EPA-820-F-13-012. Discharger-specific Variances on a Broader Scale: Developing Credible Rationales for Variances that Apply to Multiple Dischargers: Frequently Asked Questions. Found online at*:* *http://water.epa.gov/scitech/swguidance/standards/upload/Discharger-specific-Variances-on-a-Broader-Scale-Developing-Credible-Rationales-for-Variances-that-Apply-to-Multiple-Dischargers-Frequently-Asked-Questions.pdf*.
- EPA, 2014. Water Quality Standards Handbook - Chapter 5: General Policies (40 CFR 131.12) - Section 5.3 Variances from Water Quality Standards. Found online at: *http://water.epa.gov/scitech/swguidance/standards/handbook/chapter05.cfm#section3*.
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- IDEQ, 2009. Idaho Department of Environmental Quality. Justification for Granting of Variances from the Idaho Water Quality Standards to the Cities of Page, Mullan and Smelterville for the Discharge of Metals from their Wastewater Treatment Plant. http://www.deq.idaho.gov/media/451049-variances_justification_page_mullen_smelterville.pdf.

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Final

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NOTICE

The policies and procedures set forth in this document are intended solely to describe EPA methods for developing or revising ambient water quality criteria to protect human health, pursuant to Section 304(a) of the Clean Water Act, and to serve as guidance to States and authorized Tribes for developing their own water quality criteria. This guidance does not substitute for the Clean Water Act or EPA's regulations; nor is it a regulation itself. Thus, it does not impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances.

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

FOREWORD

This document presents EPA's recommended Methodology for developing ambient water quality criteria as required under Section 304(a) of the Clean Water Act (CWA). The Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and from time to time revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria serve States and Tribes' needs in their development of water quality standards under Section 303(c) of the CWA.

The term "water quality criteria" is used in two sections of the Clean Water Act, Section 304(a)(1) and Section 303(c)(2). The term has a different program impact in each section. In Section 304, the term represents a scientific assessment of ecological and human health effects that EPA recommends to States and authorized Tribes for establishing water quality standards that ultimately provide a basis for controlling discharges or releases of pollutants. Ambient water quality criteria associated with specific stream uses when adopted as State or Tribal water quality standards under Section 303 define the maximum levels of a pollutant necessary to protect designated uses in ambient waters. The water quality criteria adopted in the State or Tribal water quality standards could have the same numerical limits as the criteria developed under Section 304. However, in many situations States and authorized Tribes may want to adjust water quality criteria developed under Section 304 to reflect local environmental conditions and human exposure patterns before incorporation into water quality standards. When adopting their water quality criteria, States and authorized Tribes have four options: (1) adopt EPA's 304(a) recommendations; (2) adopt 304(a) criteria modified to reflect site-specific conditions; (3) develop criteria based on other scientifically defensible methods; or (4) establish narrative criteria where numeric criteria cannot be determined.

EPA will use this Methodology to develop new ambient water quality criteria and to revise existing recommended water quality criteria. It also provides States and authorized Tribes the necessary guidance to adjust water quality criteria developed under Section 304 to reflect local conditions or to develop their own water quality criteria using scientifically defensible methods consistent with this Methodology. EPA encourages States and authorized Tribes to use this Methodology to develop or revise water quality criteria to appropriately reflect local conditions. EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the State, Tribal, or regional level. Additional guidance to assist States and authorized Tribes in the modification of criteria based on the Methodology will accompany this document in the form of three companion Technical Support Documents on Risk Assessment, Exposure Assessment, and Bioaccumulation Assessment.

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Potential areas for conflict of interest were investigated via direct inquiry with the peer reviews and review of their current affiliations. No conflicts of interest were identified.

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TABLE OF CONTENTS

00087

TABLES AND FIGURES

00088

LIST OF ACRONYMS

ADI	Acceptable Daily Intake
ARAR	Applicable or Relevant and Appropriate Requirements
ASTM	American Society of Testing and Materials
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BAF_{ℓ}^{fd}	Baseline Bioaccumulation Factor
BCF	Bioconcentration Factor
BCF_{ℓ}^{fd}	Baseline Bioconcentration Factor
$BCF_{\mathbf{T}}^{\mathbf{t}}$	Bioconcentration Factor Based on Total Concentrations in Tissue and Water
BMD	Benchmark Dose
BMDL	Lower-Bound Confidence Limit on the BMD
BMF	Biomagnification Factor
BMR	Benchmark Response
BSAF	Biota-Sediment Accumulation Factors
BW	Body Weight
C_{ℓ}	Lipid-normalized Concentration
C_{soc}	Organic Carbon-normalized Concentration
C_t	Concentration of the Chemical in the Specified Wet Tissue
C_w	Concentration of the Chemical in Water
CDC	U.S. Centers for Disease Control and Prevention
CSFII	Continuing Survey of Food Intake by Individuals
CWA	Clean Water Act
DDT	1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane
DDE	1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene
DDD	1,1-dichloro-2,2-bis(p-chlorophenyl)ethane
DI	Drinking Water Intake
DNA	Deoxyribonucleic Acid
DNOC	2,4-dinitro-o-cresol
DOC	Dissolved Organic Carbon
ED_{10}	Dose Associated with a 10 Percent Extra Risk
EPA	Environmental Protection Agency
f_{fd}	Fraction Freely Dissolved
f_{ℓ}	Fraction Lipid
FCM	Food Chain Multiplier
FEL	Frank Effect Level
FI	Fish Intake
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GLI	Great Lakes Water Quality Initiative
HCBD	Hexachlorobutadiene
IARC	International Agency for Research on Cancer
II	Incidental Ingestion
ILSI	International Life Sciences Institute

00089

IRIS	Integration Risk Information System
kg	kilogram
K_{ow}	Octanol-Water Partition Coefficient
L	Liter
LAS	Linear Alkylbenzesulfonate
LED_{10}	The Lower 95 Percent Confidence Limit on a Dose Associated with a 10 Percent Extra Risk
LMS	Linear Multistage Model
LOAEL	Lowest Observed Adverse Effect Level
M_l	Mass of Lipid in Specified Tissue
M_t	Mass of Specified Tissue (Wet Weight)
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MF	Modifying Factor
mg	Milligrams
ml	Milliliters
MOA	Mode of Action
MOE	Margin of Exposure
NCHS	National Center for Health Statistics
NCI	National Cancer Institute
NFCS	Nationwide Food Consumption Survey
NHANES	National Health and Nutrition Examination Survey
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NPDES	National Pollutant Discharge Elimination System
PAH	Polycyclic Aromatic Hydrocarbon
PCB	Polychlorinated Biphenyls
POD	Point of Departure
POC	Particulate Organic Carbon
RDA	Recommended Daily Allowance
RfC	Reference Concentration
RfD	Reference Dose
RfD_{DT}	Reference Dose for Developmental Effects
RPF	Relative Potency Factor
RSC	Relative Source Contribution
RSD	Risk-Specific Dose
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SF	Safety Factor
STORET	Storage Retrieval
TEAM	Total Exposure Assessment Methodology
TEF	Toxicity Equivalency Factor
TMDL	Total Maximum Daily Load
TSD	Technical Support Document
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency

UF	Uncertainty Factor
WQBEL	Water Quality-Based Effluent Limits

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1. INTRODUCTION

1.1 WATER QUALITY CRITERIA AND STANDARDS

Pursuant to Section 304(a)(1) of the Clean Water Act (CWA), the U.S. Environmental Protection Agency (EPA) is required to publish, and from time to time thereafter revise, criteria for water quality accurately reflecting the latest scientific knowledge on the kind and extent of all identifiable effects on human health which may be expected from the presence of pollutants in any body of water.

Historically, the ambient water quality criteria (AWQC or 304(a) criteria) provided two essential types of information: (1) discussions of available scientific data on the effects of the pollutants on public health and welfare, aquatic life, and recreation; and (2) quantitative concentrations or qualitative assessments of the levels of pollutants in water which, if not exceeded, will generally ensure adequate water quality for a specified water use. Water quality criteria developed under Section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. The 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the criteria in ambient water. These 304(a) criteria may be used as guidance by States and authorized Tribes to establish water quality standards, which ultimately provide a basis for controlling discharges or releases of pollutants into ambient waters.

In 1980, AWQC were derived for 64 pollutants using guidelines developed by the Agency for calculating the impact of waterborne pollutants on aquatic organisms and on human health. Those guidelines consisted of systematic procedures for assessing valid and appropriate data concerning a pollutant's acute and chronic adverse effects on aquatic organisms, nonhuman mammals, and humans.

1.2 PURPOSE OF THIS DOCUMENT

The *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (hereafter the "2000 Human Health Methodology") addresses the development of AWQC to protect human health. The Agency intends to use the 2000 Human Health Methodology both to develop new AWQC for additional pollutants and to revise existing AWQC. Within the next several years, EPA intends to focus on deriving AWQC for chemicals of high priority (including, but not limited to, mercury, arsenic, PCBs, and dioxin). Furthermore, EPA anticipates that 304(a) criteria development in the future will be for bioaccumulative chemicals and pollutants considered highest priority by the Agency. The 2000 Human Health Methodology is also intended to provide States and authorized Tribes flexibility in establishing water quality standards by providing scientifically valid options for developing their own water quality criteria that consider local conditions. States and authorized Tribes are strongly encouraged to use this Methodology to derive their own AWQC. However, the 2000 Human Health Methodology also defines the default factors EPA intends to use in evaluating and determining consistency of State water quality standards with the requirements of the CWA. The Agency intends to use these default factors to calculate national water quality criteria under

00093

Section 304(a) of the Act. EPA will also use this Methodology as guidance when promulgating water quality standards for a State or Tribe under Section 303(c) of the CWA.

This Methodology does not substitute for the CWA or EPA's regulations; nor is it a regulation itself. Thus, the 2000 Human Health Methodology cannot impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA and State/Tribal decision-makers retain the discretion to use different, scientifically defensible, methodologies to develop human health criteria on a case-by-case basis that differ from this Methodology where appropriate. EPA may change the Methodology in the future through intermittent refinements as advances in science or changes in Agency policy occur.

The 2000 Human Health Methodology incorporates scientific advancements made over the past two decades. The use of this Methodology is an important component of the Agency's efforts to improve the quality of the Nation's waters. EPA believes the Methodology will enhance the overall scientific basis of water quality criteria. Further, the Methodology should help States and Tribes address their unique water quality issues and risk management decisions, and afford them greater flexibility in developing their water quality programs.

There are three companion Technical Support Document (TSD) volumes for the 2000 Human Health Methodology: a Risk Assessment TSD; an Exposure Assessment TSD; and a Bioaccumulation TSD. These documents are intended to further support States and Tribes in developing AWQC to reflect local conditions. The Risk Assessment TSD (USEPA, 2000) is being published concurrently with this Methodology. Publication of the Exposure Assessment and Bioaccumulation TSDs are anticipated in 2001.

1.3 HISTORY OF THE AMBIENT WATER QUALITY CRITERIA (AWQC) METHODOLOGY

In 1980, EPA published AWQC for 64 pollutants/pollutant classes identified in Section 307(a) of the CWA and provided a methodology for deriving the criteria (USEPA, 1980). These 1980 AWQC National Guidelines (or the "1980 Methodology") for developing AWQC for the protection of human health addressed three types of endpoints: noncancer, cancer, and organoleptic (taste and odor) effects. Criteria for protection against noncancer and cancer effects were estimated by using risk assessment-based procedures, including extrapolation from animal toxicity or human epidemiological studies. Basic human exposure assumptions were applied to the criterion equation.

The risk assessment-based procedures used to derive the AWQC to protect human health were specific to whether the endpoint was cancer or noncancer. When using cancer as the critical risk assessment endpoint (which had been assumed not to have a threshold), the AWQC were presented as a range of concentrations associated with specified incremental lifetime risk

levels[1]. When using noncancer effects as the critical endpoint, the AWQC reflected an assessment of a "no-effect" level, since noncancer effects were assumed to have a threshold. The key features of each procedure are described briefly in the following paragraphs.

Cancer effects. If human or animal studies on a contaminant indicated that it induced a statistically significant carcinogenic response, the 1980 AWQC National Guidelines treated the contaminant as a carcinogen and derived a low-dose cancer potency factor from available animal data using the linearized multistage model (LMS). The LMS, which uses a linear, nonthreshold assumption for low-dose risk, was used by the Agency as a science policy choice in protecting public health, and represented a plausible upper limit for low-dose risk. The cancer potency factor, which expresses incremental, lifetime risk as a function of the rate of intake of the contaminant, was then combined with exposure assumptions to express that risk in terms of an ambient water concentration. In the 1980 AWQC National Guidelines, the Agency presented a range of contaminant concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5} (that is, a risk of one additional case of cancer in a population of ten million to one additional cancer case in a population of one hundred thousand, respectively).

Noncancer effects. If the pollutant was not considered to have the potential for causing cancer in humans (later defined as a known, probable, or possible human carcinogen by the 1986 *Guidelines for Carcinogen Risk Assessment,* USEPA, 1986d), the 1980 AWQC National Guidelines treated the contaminant as a noncarcinogen; a criterion was derived using a threshold concentration for noncancer adverse effects. The criteria derived from noncancer data were based on the Acceptable Daily Intake (ADI) (now termed the reference dose [RfD]). ADI values were generally derived using a no-observed-adverse-effect level (NOAEL) from animal studies, although human data were used whenever available. The ADI was calculated by dividing the NOAEL by an uncertainty factor to account for uncertainties inherent in extrapolating limited toxicological data to humans. In accordance with the National Research Council recommendations of 1977 (NRC, 1977), safety factors (SFs) (later redefined as uncertainty factors) of 10, 100, or 1,000 were used, depending on the quality of the data.

Organoleptic effects. Organoleptic characteristics were also used in developing criteria for some contaminants to control undesirable taste and/or odor imparted by them to ambient water. In some cases, a water quality criterion based on organoleptic effects would be more stringent than a criterion based on toxicologic endpoints. The 1980 AWQC National Guidelines emphasized that criteria derived for organoleptic endpoints are not based on toxicological information, have no direct relationship to adverse human health effects and, therefore, do not necessarily represent approximations of acceptable risk levels for humans.

[1]Throughout this document, the term "risk level" regarding a cancer assessment using linear approach refers to an upper-bound estimate of excess lifetime cancer risk.

1.4 RELATIONSHIP OF WATER QUALITY STANDARDS TO AWQC

Under Section 303(c) of the CWA, States have the primary responsibility for establishing water quality standards, defined under the Act as designated beneficial uses of a water segment and the water quality criteria necessary to support those uses. Additionally, Native American Tribes authorized to administer the water quality standards program under 40 CFR 131.8 establish water quality standards for waters within their jurisdictions. This statutory framework allows States and authorized Tribes to work with local communities to adopt appropriate designated uses and to adopt criteria to protect those designated uses. Section 303(c) provides for EPA review of water quality standards and for promulgation of a superseding Federal rule in cases where State or Tribal standards are not consistent with the applicable requirements of the CWA and the implementing Federal regulations, or where the Agency determines Federal standards are necessary to meet the requirements of the Act. Section 303(c)(2)(B) specifically requires States and authorized Tribes to adopt water quality criteria for toxics for which EPA has published criteria under Section 304(a) and for which the discharge or presence could reasonably be expected to interfere with the designated use adopted by the State or Tribe. In adopting such criteria, States and authorized Tribes must establish numerical values based on one of the following: (1) 304(a) criteria; (2) 304(a) criteria modified to reflect site-specific conditions; or, (3) other scientifically defensible methods. In addition, States and authorized Tribes can establish narrative criteria where numeric criteria cannot be determined.

It must be recognized that the Act uses the term "criteria" in two different ways. In Section 303(c), the term is part of the definition of a water quality standard. Specifically, a water quality standard is composed of designated uses and the criteria necessary to protect those uses. Thus, States and authorized Tribes are required to adopt regulations which contain legally enforceable criteria. However, in Section 304(a) the term criteria is used to describe the scientific information that EPA develops to be used as guidance by States, authorized Tribes and EPA when establishing water quality standards pursuant to 303(c). Thus, two distinct purposes are served by the 304(a) criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria which will protect designated uses, and the second is as the basis for promulgation of a superseding Federal rule when such action is necessary.

1.5 NEED FOR THE AWQC METHODOLOGY REVISIONS

Since 1980, EPA risk assessment practices have evolved significantly in all of the major Methodology areas: that is, cancer and noncancer risk assessments, exposure assessments, and bioaccumulation. When the 1980 Methodology was developed, EPA had not yet developed formal cancer or noncancer risk assessment guidelines. Since then, EPA has published several risk assessment guidelines. In cancer risk assessment, there have been advances in the use of mode of action (MOA) information to support both the identification of potential human carcinogens and the selection of procedures to characterize risk at low, environmentally relevant exposure levels. EPA published *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA, 1996a, hereafter the "1996 proposed cancer guidelines"). These guidelines presented revised procedures to quantify cancer risk at low doses, replacing the current default use of the LMS model. Following review by the Agency's Science Advisory Board (SAB), EPA published the

revised *Guidelines for Carcinogen Risk Assessment–Review Draft* in July 1999 (USEPA, 1999a, hereafter the "1999 draft revised cancer guidelines"). In noncancer risk assessment, the Agency is moving toward the use of the benchmark dose (BMD) and other dose-response approaches in place of the traditional NOAEL approach to estimate an RfD or Reference Concentration (RfC). *Guidelines for Mutagenicity Risk Assessment* were published in 1986 (USEPA, 1986b). In 1991, the Agency published *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991), and it issued *Guidelines for Reproductive Toxicity Risk Assessment* in 1996 (USEPA, 1996b). In 1998, EPA published final *Guidelines for Neurotoxicity Risk Assessment* (USEPA, 1998), and in 1999 it issued the draft *Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 1999b).

In 1986, the Agency made available to the public the Integrated Risk Information System (IRIS). IRIS is a database that contains risk information on the cancer and noncancer effects of chemicals. The IRIS assessments are peer reviewed and represent EPA consensus positions across the Agency's program and regional offices.

New studies have addressed water consumption and fish tissue consumption. These studies provide a more current and comprehensive description of national, regional, and special-population consumption patterns that EPA has reflected in the 2000 Human Health Methodology. In addition, more formalized procedures are now available to account for human exposure from multiple sources when setting health goals such as AWQC that address only one exposure source. In 1986, the Agency published the *Total Exposure Assessment Methodology (TEAM) Study: Summary and Analysis, Volume I, Final Report* (USEPA, 1986c), which presents a process for conducting comprehensive evaluation of human exposures. In 1992, EPA published the revised *Guidelines for Exposure Assessment* (USEPA, 1992), which describe general concepts of exposure assessment, including definitions and associated units, and provide guidance on planning and conducting an exposure assessment. The *Exposure Factors Handbook* was updated in 1997 (USEPA, 1997a). Also in 1997, EPA developed *Guiding Principles for Monte Carlo Analysis* (USEPA, 1997b) and published its *Policy for Use of Probabilistic Analysis in Risk Assessment* (see http://www.epa.gov/ncea/mcpolicy.htm). The Monte Carlo guidance can be applied to exposure assessments and risk assessments. The Agency has recently developed the Relative Source Contribution (RSC) Policy for assessing total human exposure to a contaminant and apportioning the RfD among the media of concern, published for the first time in this Methodology.

The Agency has moved toward the use of a bioaccumulation factor (BAF) to reflect the uptake of a contaminant from all sources (e.g., ingestion, sediment) by fish and shellfish, rather than just from the water column as reflected by the use of a bioconcentration factor (BCF) in the 1980 Methodology. The Agency has also developed detailed procedures and guidelines for estimating BAF values.

Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens

under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges. Those three differences are described in the three subsections below, respectively.

1.5.1 Group C Chemicals

Chemicals were typically classified as Group C–i.e., possible human carcinogens–under the existing (1986) EPA cancer classification scheme for any of the following reasons:

1) Carcinogenicity has been documented in only one test species and/or only one cancer bioassay and the results do not meet the requirements of "sufficient evidence."

2) Tumor response is of marginal statistical significance due to inadequate design or reporting.

3) Benign, but not malignant, tumors occur with an agent showing no response in a variety of short-term tests for mutagenicity.

4) There are responses of marginal statistical significance in a tissue known to have a high or variable background rate.

The 1986 *Guidelines for Carcinogen Risk Assessment* (hereafter the "1986 cancer guidelines") specifically recognized the need for flexibility with respect to quantifying the risk of Group C, possible human carcinogens. The 1986 cancer guidelines noted that agents judged to be in Group C, possible human carcinogens, may generally be regarded as suitable for quantitative risk assessment, but that case-by-case judgments may be made in this regard.

The EPA Office of Water has historically treated Group C chemicals differently under the CWA and the SDWA. It is important to note that the 1980 AWQC National Guidelines for setting AWQC under the CWA predated EPA's carcinogen classification system, which was proposed in 1984 (USEPA, 1984) and finalized in 1986 (USEPA, 1986a). The 1980 AWQC National Guidelines did not explicitly differentiate among agents with respect to the weight of evidence for characterizing them as likely to be carcinogenic to humans. For all pollutants judged as having adequate data for quantifying carcinogenic risk–including those now classified as Group C–AWQC were derived based on data on cancer incidence. In the1980 AWQC National Guidelines, EPA emphasized that the AWQC for carcinogens should state that the recommended concentration for maximum protection of human health is zero. At the same time, the criteria published for specific carcinogens presented water concentrations for these pollutants corresponding to individual lifetime excess cancer risk levels in the range of 10^{-7} to 10^{-5}.

In the development of national primary drinking water regulations under the SDWA, EPA is required to promulgate a health-based MCLG for each contaminant. The Agency policy has been to set the MCLG at zero for chemicals with strong evidence of carcinogenicity associated with exposure from water. For chemicals with limited evidence of carcinogenicity, including many Group C agents, the MCLG was usually obtained using an RfD based on the

pollutant's noncancer effects with the application of an additional uncertainty factor of 1 to 10 to account for carcinogenic potential of the chemical. If valid noncancer data for a Group C agent were not available to establish an RfD but adequate data are available to quantify the cancer risk, then the MCLG was based upon a nominal lifetime excess cancer risk in the range of 10^{-6} to10^{-5} (ranging from one case in a population of one million to one case in a population of one hundred thousand). Even in those cases where the RfD approach has been used for the derivation of the MCLG for a Group C agent, the drinking water concentrations associated with excess cancer risks in the range of 10^{-6} to 10^{-5} were also provided for comparison.

It should also be noted that EPA's pesticides program has applied both of the previously described methods for addressing Group C chemicals in actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and finds both methods applicable on a case-by-case basis. Unlike the drinking water program, however, the pesticides program does not add an extra uncertainty factor to account for potential carcinogenicity when using the RfD approach.

In the 1999 draft revised cancer guidelines, there are no more alphanumeric categories. Instead, there will be longer narratives for hazard characterization that will use consistent descriptive terms when assessing cancer risk.

1.5.2 Consideration of Non-water Sources of Exposure

The 1980 AWQC National Guidelines recommended that contributions from non-water sources, namely air and non-fish dietary intake, be subtracted from the Acceptable Daily Intake (ADI), thus reducing the amount of the ADI "available" for water-related sources of intake. In practice, however, when calculating human health criteria, these other exposures were generally not considered because reliable data on these exposure pathways were not available. Consequently, the AWQC were usually derived such that drinking water and fish ingestion accounted for the entire ADI (now called RfD).

In the drinking water program, a similar "subtraction" method was used in the derivation of MCLGs proposed and promulgated in drinking water regulations through the mid-1980s. More recently, the drinking water program has used a "percentage" method in the derivation of MCLGs for noncarcinogens. In this approach, the percentage of total exposure typically accounted for by drinking water, referred to as the relative source contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD "apportioned" to drinking water reflected by the MCLG value. In using this percentage procedure, the drinking water program also applies a ceiling level of 80 percent of the RfD and a floor level of 20 percent of the RfD. That is, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD.

The drinking water program usually takes a conservative approach to public health by applying an RSC factor of 20 percent to the RfD when adequate exposure data do not exist, assuming that the major portion (80 percent) of the total exposure comes from other sources, such as diet.

In the 2000 Human Health Methodology, guidance for the routine consideration of non-water sources of exposure [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] is presented. The approach is called the Exposure Decision Tree. Relative source contribution estimates will be made by EPA using this approach, which allows for use of either the subtraction or percentage methods, depending on chemical-specific circumstances, within the 20 to 80 percent range described above.

1.5.3 Cancer Risk Ranges

In addition to the different risk assessment approaches discussed above for deriving AWQC and MCLGs for Group C agents, there have been different risk management approaches by the drinking water and surface water programs on lifetime excess risk values when setting health-based criteria for carcinogens. The surface water program has derived AWQC for carcinogens that generally corresponded to lifetime excess cancer risk levels of 10^{-7} to 10^{-5}. The drinking water program has set MCLGs for Group C agents based on a slightly less stringent risk range of 10^{-6} to 10^{-5}, while MCLGs for chemicals with strong evidence of carcinogenicity (that is, classified as Group A, known, or B probable, human carcinogen) are set at zero. The drinking water program is now following the principles of the 1999 draft revised cancer guidelines to determine the type of low-dose extrapolation based on mode of action.

It is also important to note that under the drinking water program, for those substances having an MCLG of zero, enforceable Maximum Contaminant Levels (MCLs) have generally been promulgated to correspond with cancer risk levels ranging from 10^{-6} to 10^{-4}. Unlike AWQC and MCLGs which are strictly health-based criteria, MCLs are developed with consideration given to the costs and technological feasibility of reducing contaminant levels in water to meet those standards.

With the 2000 Human Health Methodology, EPA will publish its national 304(a) water quality criteria at a 10^{-6} risk level, which EPA considers appropriate for the general population. EPA is increasing the degree of consistency between the drinking water and ambient water programs, given the somewhat different requirements of the CWA and SDWA.

1.6 OVERVIEW OF THE AWQC METHODOLOGY REVISIONS

The following equations for deriving AWQC include toxicological and exposure assessment parameters which are derived from scientific analysis, science policy, and risk management decisions. For example, values for parameters such as a field-measured BAF or a point of departure from an animal study [in the form of a lowest-observed-adverse-effect level (LOAEL)/no-observed -adverse-effect level (NOAEL)/lower 95 percent confidence limit on a dose associated with a 10 percent extra risk (LED_{10})] are empirically measured using scientific methods. By contrast, the decision to use animal effects as surrogates for human effects involves judgment on the part of the EPA (and similarly, by other agencies) as to the best practice to follow when human data are lacking. Such a decision is, therefore, a matter of science policy. The choice of default fish consumption rates for protection of a certain percentage (i.e., the 90th percentile) of the general population is clearly a risk management decision. In many cases, the Agency has selected parameter values using its best judgment regarding the overall protection afforded by the resulting AWQC when all parameters are combined. For a longer discussion of the differences between science, science policy, and risk management, please refer to Section 2 of this document. Section 2 also provides further details with regard to risk characterization for this Methodology, with emphasis placed on explaining the uncertainties in the overall risk assessment.

The generalized equations for deriving AWQC based on noncancer effects are:

Noncancer Effects[2]

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-1)}$$

Cancer Effects: Nonlinear Low-Dose Extrapolation

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-2)}$$

[2] Although appearing in this equation as a factor to be multiplied, the RSC can also be an amount subtracted. Refer to the explanation key below the equations.

Cancer Effects: Linear Low-Dose Extrapolation

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-3)}$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
POD	=	Point of departure for carcinogens based on a nonlinear low-dose extrapolation (mg/kg-day), usually a LOAEL, NOAEL, or LED_{10}
UF	=	Uncertainty Factor for carcinogens based on a nonlinear low-dose extrapolation (unitless)
RSD	=	Risk-specific dose for carcinogens based on a linear low-dose extrapolation (mg/kg-day) (dose associated with a target risk, such as 10^{-6})
RSC	=	Relative source contribution factor to account for non-water sources of exposure. (Not used for linear carcinogens.) May be either a percentage (multiplied) or amount subtracted, depending on whether multiple criteria are relevant to the chemical.
BW	=	Human body weight (default = 70 kg for adults)
DI	=	Drinking water intake (default = 2 L/day for adults)
FI_i	=	Fish intake at trophic level (TL) I (I = 2, 3, and 4) (defaults for total intake = 0.0175 kg/day for general adult population and sport anglers, and 0.1424 kg/day for subsistence fishers). Trophic level breakouts for the general adult population and sport anglers are: TL2 = 0.0038 kg/day; TL3 = 0.0080 kg/day; and TL4 = 0.0057 kg/day.
BAF_i	=	Bioaccumulation factor at trophic level I (I=2, 3 and 4), lipid normalized (L/kg)

For highly bioaccumulative chemicals where ingestion from water might be considered negligible, EPA is currently evaluating the feasibility of developing and implementing AWQCs that are expressed in terms of concentrations in tissues of aquatic organisms. Such tissue residue criteria might be used as an alternative to AWQCs which are expressed as concentrations in water, particularly in situations where AWQCs are at or below the practical limits for quantifying a chemical in water. Even though tissue residue criteria would not require the use of a BAF in their derivation, implementing such criteria would still require a mechanism for relating chemical loads and concentrations in water and sediment to concentrations in tissues of appropriate fish and shellfish (e.g., a BAF or bioaccumulation model). At this time, no revisions are planned to the Methodology to provide specific guidance on developing fish tissue-based water quality criteria. However, guidance may be provided in the future either as a separate document or integrated in a specific 304(a) water quality criteria document for a chemical that warrants such an approach.

AWQC for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters. The Agency is not recommending the development of additional water quality criteria similar to the "drinking water health advisories" that focus on acute or short-term effects; these are not seen as routinely having a meaningful role in the water quality criteria and standards program. However, as discussed below, there may be some instances where the consideration of acute or short-term toxicity and exposure in the derivation of AWQC is warranted.

Although the AWQC are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures. That is, through the use of conservative assumptions with respect to both toxicity and exposure parameters, the resulting AWQC should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water- or fish-intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects. The Agency recognizes that there may be some cases where the AWQC based on chronic toxicity may not provide adequate protection for a subpopulation at special risk from shorter-term exposures. The Agency encourages States, Tribes, and others employing the 2000 Human Health Methodology to give consideration to such circumstances in deriving criteria to ensure that adequate protection is afforded to all identifiable subpopulations. (See Section 4.3, Factors Used in the AWQC Computation, for additional discussion of these subpopulations.)

The EPA is in the process of revising its cancer guidelines, including its descriptions of human carcinogenic potential. Once final guidelines are published, they will be the basis for assessment under this methodology. In the meanwhile, the 1986 guidelines are used and extended with principles discussed in EPA's 1999 *Guidelines for Carcinogen Risk Assessment - Review Draft* (hereafter "1999 draft revised cancer guidelines"). These principles arise from new science about cancer discovered in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 guidelines. Until final guidelines are published, information is presented to describe risk under both the old guidelines and draft revisions. Dose-response assessment under the 1986 guidelines employs a linearized multistage model to extrapolate tumor dose-response observed in animal or human studies down to zero dose, zero extra risk. The dose-response assessment under EPA's 1999 draft revised cancer guidelines is a two-step process. In the first step, the response data are modeled in the range of empirical observation. Modeling in the observed range is done with biologically based or appropriate curve-fitting modeling. In the second step, extrapolation below the range of observation is accomplished by biologically based modeling if there are sufficient data or by a default procedure (linear, nonlinear, or both). A point of departure (POD) for extrapolation is estimated from modeling observed data. The lower 95 percent confidence limit on a dose associated with 10 percent extra risk (LED_{10}) is the standard POD for low-dose extrapolation. The linear default procedure is a straight line extrapolation to the origin (i.e., zero dose, zero extra risk) from the POD, which is the LED_{10} identified in the observable response

range. The result of this procedure is generally comparable (within 2-fold) to that of using a linearized multistage model under existing, 1986 guidelines. The linear low-dose extrapolation applies to agents that are best characterized by the assumption of linearity (e.g., direct DNA reactive mutagens) for their MOA. A linear approach would also be applied when inadequate or no information is available to explain the carcinogenic MOA; this is a science policy choice in the interest of public health. If it is determined that the MOA understanding fully supports a nonlinear extrapolation, the AWQC is derived using the nonlinear default which is based on a margin of exposure (MOE) analysis using the LED_{10} as the POD and applying uncertainty factors (UFs) to arrive at an acceptable MOE. There may be situations where it is appropriate to apply both the linear and nonlinear default procedures (e.g., for an agent that is both DNA reactive and active as a promoter at higher doses).

For substances that are carcinogenic, particularly those for which the MOA suggests nonlinearity at low doses, the Agency recommends that an integrated approach be taken in looking at cancer and noncancer effects. If one effect does not predominate, AWQC values should be determined for both carcinogenic and noncarcinogenic endpoints. The lower of the resulting values should be used for the AWQC.

When deriving AWQC for noncarcinogens and carcinogens based on a nonlinear low-dose extrapolation, a factor is included to account for other non-water exposure sources [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] so that the entire RfD, or POD/UF, is not apportioned to drinking water and fish consumption alone. Guidance is provided in the 2000 Human Health Methodology for determining the factor (i.e., the RSC) to be used for a particular chemical. The Agency is recommending the use of an Exposure Decision Tree procedure to support the determination of the appropriate RSC value for a given water contaminant. In the absence of data, the Agency intends to use 20 percent of the RfD (or POD/UF) as the default RSC in calculating 304(a) criteria or promulgating State or Tribal water quality standards under Section 303(c).

With AWQC derived for carcinogens based on a linear low-dose extrapolation, the Agency will publish recommended criteria values at a 10^{-6} risk level. States and authorized Tribes can always choose a more stringent risk level, such as 10^{-7}. EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level. Clarification on this risk management decision is provided in Section 2 of this document.

The default fish consumption value for the general adult population in the 2000 Human Health Methodology is 17.5 grams/day, which represents an estimate of the 90th percentile consumption rate for the U.S. adult population based on the U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intake by Individuals (CSFII) 1994-96 data (USDA, 1998). EPA will use this default intake rate with future national 304(a) criteria derivations or revisions. This default value is chosen to be protective of the majority of the general population. However, States and authorized Tribes are urged to use a fish intake level derived from local data on fish consumption in place of this default value when deriving AWQC, ensuring that the fish intake level chosen is protective of highly exposed individuals in the population. EPA has

provided default values for States and authorized Tribes that do not have adequate information on local or regional consumption patterns, based on numerous studies that EPA has reviewed on sport anglers and subsistence fishers. EPA's defaults for these population groups are estimates of their average consumption. EPA recommends a default of 17.5 grams/day for sport anglers as an approximation of their average consumption and 142.4 grams/day for subsistence fishers, which falls within the range of averages for this group. Consumption rates for women of childbearing age and children younger than 14 are also provided to maximize protection in those cases where these subpopulations may be at greatest risk.

In the 2000 Human Health Methodology, criteria are derived using a BAF rather than a BCF. To derive the BAF, States and authorized Tribes may use EPA's Methodology or any method consistent with this Methodology. EPA's highest preference in developing BAFs are BAFs based on field-measured data from local/regional fish.

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2. CLARIFICATIONS ON THE METHODOLOGY, RISK CHARACTERIZATION, AND OTHER ISSUES FOR DEVELOPING CRITERIA

2.1 IDENTIFYING THE POPULATION SUBGROUP THAT THE AWQC SHOULD PROTECT

Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities. For each pollutant, chronic criteria are derived to reflect long-term consumption of food and water. An important decision to make when setting AWQC is the choice of the particular population to protect. For instance, criteria could be set to protect those individuals who have average or "typical" exposures, or the criteria could be set so that they offer greater protection to those individuals who are more highly exposed. EPA has selected default parameter values that are representative of several defined populations: adults in the general population; sport (recreational) fishers; subsistence fishers; women of childbearing age (defined as ages 15-44); and children (up to the age of 14). In deciding on default parameter values, EPA is aware that multiple parameters are used in combination when calculating AWQC (e.g., intake rates and body weight). EPA describes the estimated population percentiles that are represented by each of the default exposure parameter values in Section 4.

EPA's national 304(a) criteria are usually derived to protect the majority of the general population from chronic adverse health effects. EPA has used a combination of median values, mean values, and percentile estimates for the parameter value defaults to calculate its national 304(a) criteria. EPA believes that its assumptions afford an overall level of protection targeted at the high end of the general population (i.e., the target population or the criteria-basis population). EPA also believes that this is reasonably conservative and appropriate to meet the goals of the CWA and the 304(a) criteria program. EPA considers that its target protection goal is satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water. However, associating the derived criteria with a specific population percentile is far more difficult, and such a quantitative descriptor typically requires detailed distributional exposure and dose information. EPA's *Guidelines For Exposure Assessment* (USEPA, 1992) describes the extreme difficulty in making accurate estimates of exposures and indicates that uncertainties at the more extreme ends of the distribution increase greatly. On quantifying population exposures/risks, the guidelines specifically state:

> *In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate estimates of real (or actuarial) cases of disease. The estimate's value lies in framing*

00107

hypothetical risk in an understandable way rather than in any literal interpretation of the term "cases."

Although it is not possible to subject the estimates to such a rigorous analysis (say, for example, to determine what criterion value provides protection of exactly the 90th percentile of the population), EPA believes that the combination of parameter value assumptions achieves its target goal, without being inordinately conservative. The standard assumptions made for the national 304(a) criteria are as follows. The assumed body weight value used is an arithmetic mean, as are the RSC intake estimates of other exposures (e.g., non-fish dietary), when data are available. The BAF component data (e.g., for lipid values, for particulate and dissolved organic carbon) are based on median (i.e., 50th percentile) values. The drinking water intake values are approximately 90th percentile estimates and fish intake values are 90th percentile estimates. EPA believes the use of these values will result in 304(a) criteria that are protective of a majority of the population; this is EPA's goal.

However, EPA also strongly believes that States and authorized Tribes should have the flexibility to develop criteria, on a site-specific basis, that provide additional protection appropriate for highly exposed populations. EPA is aware that exposure patterns in general, and fish consumption in particular, vary substantially. EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national 304(a) criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions.

EPA has provided recommended default intake rates for various population groups for State and Tribal consideration. EPA does not intend for these alternative default values to be prescriptive. EPA strongly emphasizes its preference that States and Tribes use local or regional data over EPA's defaults, if they so choose, as being more representative of their population groups of concern.

In the course of updating the 2000 Human Health Methodology, EPA received some questions regarding the population groups for which the criteria would be developed. EPA does not intend to derive multiple 304(a) criteria for all subpopulation groups for every chemical. As stated above, criteria that address chronic adverse health effects are most applicable to the CWA Section 304(a) criteria program and the chemicals evaluated for this program. If EPA determined that pregnant women/fetuses or young children were the target population (or criteria basis population) of a chemical's RfD or POD/UF, then the 304(a) criteria would be developed using exposure parameters for that subgroup. This would only be relevant for acute or subchronic toxicity situations. This does not conflict with the fact that chronic health effects potentially reflect a person's exposure during both childhood and adult years.

For RfD-based and POD/UF-based chemicals, EPA's policy is that, in general, the RfD (or POD/UF) should not be exceeded and the exposure assumptions used should reflect the population of concern. It is recommended that when a State or authorized Tribe sets a

waterbody-specific AWQC, they consider the populations most exposed via water and fish. EPA's policy on cancer risk management goals is discussed in Section 2.4.

Health Risks to Children

In recognition that children have a special vulnerability to many toxic substances, EPA's Administrator directed the Agency in 1995 to explicitly and consistently take into account environmental health risks to infants and children in all risk assessments, risk characterizations, and public health standards set for the United States. In April 1997, President Clinton signed Executive Order 13045 on the protection of children from environmental health risks, which assigned a high priority to addressing risks to children. In May 1997, EPA established the Office of Children's Health Protection to ensure the implementation of the President's Executive Order. EPA has increased efforts to ensure its guidance and regulations take into account risks to children. Circumstances where risks to children should be considered in the context of the 2000 Human Health Methodology are discussed in the Section 3.2, Noncancer Effects (in terms of developmental and reproductive toxicity) and in Section 4, Exposure (for appropriate exposure intake parameters).

Details on risk characterization and the guiding principles stated above are included in EPA's March 21, 1995 policy statement and the discussion of risk characterization (USEPA, 1995) and the 1999 *Guidelines for Carcinogen Risk Assessment. Review Draft* (USEPA, 1999a) and the *Reproductive and Toxicity Risk Assessment Guidelines* of 1996 (USEPA, 1996b).

2.2 SCIENCE, SCIENCE POLICY, AND RISK MANAGEMENT

An important part of risk characterization, as described later in Section 2.7, is to make risk assessments transparent. This means that conclusions drawn from the science are identified separately from policy judgments and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated. In this Methodology, EPA has attempted to separate scientific analysis from science policy and risk management decisions for clarity. This should allow States and Tribes (who are also prospective users of this Methodology) to understand the elements of the Methodology accurately and clearly, and to easily separate out the scientific decisions from the science policy and risk management decisions. This is important so that when questions are asked regarding the scientific merit, validity, or apparent stringency or leniency of AWQC, the implementer of the criteria can clearly explain what judgments were made to develop the criterion in question and to what degree these judgments were based on science, science policy, or risk management. To some extent this process will also be displayed in future AWQC documents.

When EPA speaks of science or scientific analysis, it is referring to the extraction of data from toxicological or exposure studies and surveys with a minimum of judgment being used to make inferences from the available evidence. For example, if EPA is describing a POD from an animal study (e.g., a LOAEL), this is usually determined as a lowest dose that produces an observable adverse effect. This would constitute a scientific determination. Judgments applying science policy, however, may enter this determination. For example, several scientists may differ in their opinion of what is adverse, and this in turn can influence the selection of a LOAEL

in a given study. The use of an animal study to predict effects in a human in the absence of human data is an inherent science policy decision. The selection of specific UFs when developing an RfD is another example of science policy. In any risk assessment, a number of decision points occur where risk to humans can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among several possible inferences when conducting a risk assessment.

Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. In this Methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision.

Many of the components in the 2000 Human Health Methodology are an amalgam of science, science policy, and/or risk management. For example, most of the default values chosen by EPA are based on examination of scientific data and application of either science policy or risk management. This includes the default assumption of 2 liters a day of drinking water; the assumption of 70 kilograms for an adult body weight; the use of default percent lipid and particulate organic carbon/dissolved organic carbon (POC/DOC) for developing national BAFs; the default fish consumption rates for the general population and sport and subsistence anglers; and the choice of a default cancer risk level. Some decisions are more grounded in science and science policy (such as the choice of default BAFs) and others are more obviously risk management decisions (such as the determination of default fish consumption rates and cancer risk levels). Throughout the 2000 Human Health Methodology, EPA has identified the kind of decision necessary to develop defaults and what the basis for the decision was. More details on the concepts of science analysis, science policy, risk management, and how they are introduced into risk assessments are included in *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983).

2.3 SETTING CRITERIA TO PROTECT AGAINST MULTIPLE EXPOSURES FROM MULTIPLE CHEMICALS (CUMULATIVE RISK)

EPA is very much aware of the complex issues and implications of cumulative risk and has endeavored to begin developing an overall approach at the Agency-wide level. Assuming that multiple exposures to multiple chemicals are additive is scientifically sound if they exhibit the same toxic endpoints and modes of action. There are numerous publications relevant to cumulative risk that can assist States and Tribes in understanding the complex issues associated with cumulative risk. These include the following:

- Durkin, P.R., R.C. Hertzberg, W. Stiteler, and M. Mumtaz. 1995. The identification and testing of interaction patterns. *Toxicol. Letters* 79:251-264.

- Hertzberg, R.C., G. Rice, and L.K. Teuschler. 1999. Methods for health risk assessment of combustion mixtures. In: *Hazardous Waste Incineration: Evaluating the Human*

Health and Environmental Risks. S. Roberts, C. Teaf and J. Bean, (eds). CRC Press LLC, Boca Raton, FL. Pp. 105-148.

- Rice, G., J. Swartout, E. Brady-Roberts, D. Reisman, K. Mahaffey, and B. Lyon. 1999. Characterization of risks posed by combustor emissions. *Drug and Chem. Tox.* 22:221-240.

- USEPA. 1999. *Guidance for Conducting Health Risk Assessment of Chemical Mixtures. Final Draft.* Risk Assessment Forum Technical Panel. Washington, DC. NCEA-C-0148. September. Web site: http://www.epa.gov/ncea/raf/rafpub.htm

- USEPA. 1998. *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions*. (Update to EPA/600/6-90/003 *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*). National Center for Environmental Assessment. Washington, DC. EPA-600-R-98-137. Website http://www.epa.gov/ncea/combust.htm

- USEPA. 1996. PCBs: *Cancer Dose-Response Assessment and Application to Environmental Mixtures*. National Center for Environmental Assessment. Washington, DC. EPA/600/P-96/001F.

- USEPA. 1993. *Review Draft Addendum to the Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*. Office of Health and Environmental Assessment, Office of Research and Development. Washington, DC. EPA/600/AP-93/003. November.

- USEPA. 1993. *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons*. Office of Research and Development. Washington, DC. EPA/600/R-93/089. July.

- USEPA. 1990. *Technical Support Document on Health Risk Assessment of Chemical Mixtures*. Office of Research and Development. Washington, DC. EPA/600/8/90/064. August.

- USEPA. 1989a. *Risk Assessment Guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A).* Office of Emergency and Remedial Response. Washington, DC. EPA/540/1-89/002.

- USEPA. 1989b. *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs) and 1989 Update*. Risk Assessment Forum. Washington, DC. EPA/625/3-89/016. March.

The Agency's program offices are also engaged in on-going discussions of the great complexities, methodological challenges, data adequacy needs and other information gaps, as well as the science policy and risk management decisions that will need to be made, as they pursue developing a sound strategy and, eventually, specific guidance for addressing cumulative

risks. As a matter of internal policy, EPA is committed to refining the Methodology as advances in relevant aspects of the science improve, as part of the water quality criteria program.

2.4 CANCER RISK RANGE

For deriving 304(a) criteria or promulgating water quality criteria for States and Tribes under Section 303(c) based on the 2000 Human Health Methodology, EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA's program office guidance and regulatory actions have evolved in recent years to target a 10^{-6} risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a 10^{-6} risk level is consistent with Agency-wide practice.

EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level. States or Tribes that have adopted standards based on criteria at the 10^{-5} risk level can continue to do so, if the highly exposed groups would at least be protected at the 10^{-4} risk level. However, EPA is not automatically assuming that 10^{-5} will protect "the highest consumers" at the 10^{-4} risk level. Nor is EPA advocating that States and Tribes automatically set criteria based on assumptions for highly exposed population groups at the 10^{-4} risk level. The Agency is simply endeavoring to add that a specific determination should be made to ensure that highly exposed groups do not exceed a 10^{-4} risk level. EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen. Such determinations should be made by the State or Tribal authorities and are subject to EPA's review and approval or disapproval under Section 303(c) of the CWA.

Adoption of a 10^{-6} or 10^{-5} risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation. States and authorized Tribes also have flexibility in how they demonstrate this protectiveness and obtain such information. A State or authorized Tribe may use existing information as well as collect new information in making this determination. In addition, if a State or authorized Tribe does not believe that the 10^{-6} risk level adequately protects the exposed subpopulations, water quality criteria based on a more stringent risk level may be adopted. This discretion includes combining the 10^{-6} risk level with fish consumption rates for highly exposed population groups.

It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8}. The point is that the risks for different population groups are not the same.

2.5 MICROBIOLOGICAL AMBIENT WATER QUALITY CRITERIA

Guidance for deriving microbiological AWQC is not a part of this Methodology. In 1986, EPA published *Ambient Water Quality Criteria for Bacteria - 1986* (USEPA, 1986a), which updated and revised bacteriological criteria previously published in 1976 in *Quality Criteria for Water* (USEPA, 1976). The inclusion of guidance for deriving microbiological AWQC was considered in the 1992 national workshop that initiated the effort to revise the 1980 Methodology and was recommended by the SAB in 1993. Since that time, however, efforts separate from these Methodology revisions have addressed microbiological AWQC concerns. The purpose of this section is to briefly describe EPA's current recommendations and activities.

EPA's *Ambient Water Quality Criteria for Bacteria - 1986* recommends the use of *Escherichia coli* and enterococci rather than fecal coliforms (USEPA, 1986a). EPA's criteria recommendations are:

- Fresh water: *E. coli* not to exceed 126/100 ml or enterococci not to exceed 33/100 ml; and

- Marine water: enterococci not to exceed 35/100 ml.

These criteria should be calculated as the geometric mean based on five equally spaced samples taken over a 30-day period.

In addition, EPA recommends that States adopt a single sample maximum, based on the expected frequency of use. No sample taken should exceed this value. EPA specifies appropriate single sample maximum values in the 1986 criteria document.

Current Activities and Plans for Future Work

00113

EPA has identified development of microbial water quality criteria as part of its strategy to control waterborne microbial disease, by controlling pathogens in waterbodies and by protecting designated uses, such as recreation and public water supplies. The program fosters an integrated approach to protect both ground-water and surface water sources. EPA plans to conduct additional monitoring for *Cryptosporidium parvum* and *E. coli*, and determine action plans in accordance with the results of this monitoring.

EPA recommends no change at this time in the stringency of its bacterial criteria for recreational waters; existing criteria and methodologies from 1986 will still apply. The recommended methods for *E. coli* and enterococci have been improved. As outlined in the *Action Plan for Beaches and Recreational Waters* (Beach Action Plan, see below), the Agency plans to conduct national studies on improving indicators together with epidemiology studies for new criteria development (USEPA, 1999b). The Agency is also planning to establish improved temporal and spatial monitoring protocols.

In the Beach Action Plan, EPA identifies a multi-year strategy for monitoring recreational water quality and communicating public health risks associated with potentially pathogen-contaminated recreational rivers, lakes, and ocean beaches. It articulates the Agency's rationale and goals in addressing specific problems and integrates all associated program, policy, and research needs and directions. The Beach Action Plan also provides information on timing, products and lead organization for each activity. These include activities and products in the areas of program development, risk communication, water quality indicator research, modeling and monitoring research, and exposure and health effects research.

Recently, EPA approved new 24-hour *E. coli* and enterococcus tests for recreational waters that may be used as an alternative to the 48-hour test (USEPA, 1997). EPA anticipates proposing these methods for inclusion in the 40 CRF 136 in the Fall of 2000. EPA has also published a video with accompanying manual on the original and newer methods for enterococci and *E. coli* (USEPA, 2000).

As part of the Beach Action Plan, EPA made the following recommendations for further Agency study:

- Future criteria development should consider the risk of diseases other than gastroenteritis. EPA intends to consider and evaluate such water-related exposure routes as inhalation and dermal absorption when addressing microbial health effects. The nature and significance of other than the classical waterborne pathogens are to some degree tied to the particular type of waste sources.

- A new set of indicator organisms may need to be developed for tropical water if it is proven that the current fecal indicators can maintain viable cell populations in the soil and water for significant periods of time in uniform tropical conditions. Some potential alternative indicators to be fully explored are coliphage, other bacteriophage, and *Clostridium perfringens*.

- Because animal sources of pathogens of concern for human infection such as *Giardia lamblia*, *Cryptosporidium parvum*, and *Escherichia coli* 0157:H7 may be waterborne or washed into water and thus become a potential source for infection, they should not be ignored in risk assessment. A likely approach would be phylogenetic differentiation; that is, indicators that are specific to, or can discriminate among, animal sources.

- EPA intends to develop additional data on secondary infection routes and infection rates from prospective epidemiology studies and outbreaks from various types of exposure (e.g., shellfish consumption, drinking water, recreational exposure).

- EPA needs to improve sampling strategies for recreational water monitoring including consideration of rainfall and pollution events to trigger sampling.

2.6 RISK CHARACTERIZATION CONSIDERATIONS

On March 21, 1995, EPA's Administrator issued the *EPA Risk Characterization Policy and Guidance* (USEPA, 1995). This policy and guidance is intended to ensure that characterization information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers, and from EPA to the public. The policy also provides the basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across EPA programs. The fundamental principles which form the basis for a risk characterization are as follows:

- Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.

- Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessments, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.

- Risk characterizations should be consistent in general format, but recognize the unique characteristics of each specific situation.

- Risk characterizations should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with similar risks. This may be accomplished by comparisons with other pollutants or situations on which the Agency has decided to act, or other situations with which the public may be familiar. The discussion should highlight the limitations of such comparisons.

- Risk characterization is a key component of risk communication, which is an interactive process involving exchange of information and expert opinion among individuals, groups, and institutions.

Additional guiding principles include:

- The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.

- The risk characterization includes a discussion of uncertainty and variability in the risk assessment.

- Well-balanced risk characterizations present conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.

In developing the methodology presented here, EPA has closely followed the risk characterization guiding principles listed above. As States and Tribes adopt criteria using the 2000 Human Health Methodology, they are strongly encouraged to follow EPA's risk characterization guidance. There are a number of areas within the Methodology and criteria development process where risk characterization principles apply:

- Integration of cancer and noncancer assessments with exposure assessments, including bioaccumulation potential determinations, in essence, weighing the strengths and weaknesses of the risk assessment as a whole when developing a criterion.

- Selecting a fish consumption rate, either locally derived or the national default value, within the context of a target population (e.g., sensitive subpopulations) as compared to the general population.

- Presenting cancer and/or noncancer risk assessment options.

- Describing the uncertainty and variability in the hazard identification, the dose-response, and the exposure assessment.

2.7 DISCUSSION OF UNCERTAINTY

2.7.1 Observed Range of Toxicity Versus Range of Environmental Exposure

When characterizing a risk assessment, an important distinction to make is between the observed range of adverse effects (from an epidemiology or animal study) and the environmentally observed range of exposure (or anticipated human exposure) to the contaminant. In many cases, EPA intends to apply default factors to account for uncertainties or incomplete knowledge in developing RfDs or cancer risk assessments using nonlinear low-dose extrapolation to provide a margin of protection. In reality, the actual effect level and the environmental exposure levels may be separated by several orders of magnitude. The difference between the dose causing some observed response and the anticipated human exposure should be described by risk assessors and managers, especially when comparing criteria to environmental levels of a contaminant.

2.7.2 Continuum of Preferred Data/Use of Defaults

In both toxicological and exposure assessments, EPA has defined a continuum of preferred data for toxicological assessments ranging from a highest preference for chronic human data (e.g., studies that examine a long-term exposure of humans to a chemical, usually from occupational and/or residential exposure) and actual field data for many of the exposure parameter values (e.g., locally derived fish consumption rates, waterbody-specific bioaccumulation rates), to default values which are at the lower end of the preference continuum. EPA has supplied default values for all of the risk assessment parameters in the 2000 Human Health Methodology; however, it is important to note that when default values are used, the uncertainty in the final risk assessment may be higher, and the final resulting criterion may not be as applicable to local conditions, than is a risk assessment derived from human/field data. Using defaults assumes generalized conditions and may not capture the actual variability in the population (e.g., sensitive subpopulations/high-end consumers). If defaults are chosen as the basis for criteria, these inherent uncertainties should be communicated to the risk manager and the public. While this continuum is an expression of preference on the part of EPA, it does not imply in any way that any of the choices are unacceptable or scientifically indefensible.

2.7.3 Significant Figures

The number of significant figures in a numeric value is the number of certain digits plus one estimated digit. Digits should not be confused with decimal places. For example, 15.1, 0.0151, and 0.0150 all have 3 significant figures. Decimal places may have been used to maintain the correct number of significant figures, but in themselves they do not indicate significant figures (Brinker, 1984). Since the number of significant figures must include only one estimated digit, the sources of input parameters (e.g., fish consumption and water consumption rates) should be checked to determine the number of significant figures associated with data they provide. However, the original measured values may not be available to determine the number of significant figures in the input parameters. In these situations, EPA recommends utilizing the data as presented.

When developing criteria, EPA recommends rounding the number of significant figures at the end of the criterion calculation to the same number of significant figures in the least precise parameter. This is a generally accepted practice which can be found described in greater detail in APHA (1992) and Brinker (1984). The general rule is that for multiplication or division, the resulting value should not possess any more significant figures than is associated with the factor in the calculation with the least precision. When numbers are added or subtracted, the number that has the fewest decimal places, not necessarily the fewest significant figures, puts the limit on the number of places that justifiably may be carried in the sum or difference. Rounding off a number is the process of dropping one or more digits so that the value contains only those digits that are significant or necessary in subsequent computations (Brinker, 1984). The following rounding procedures are recommended: (1) if the digit 6, 7, 8, or 9 is dropped, increase the preceding digit by one unit; (2) if the digit 0, 1, 2, 3, or 4 is dropped, do not alter the preceding digit; and (3) if the digit 5 is dropped, round off the preceding digit to the nearest even number (e.g., 2.25 becomes 2.2 and 2.35 becomes 2.4) (APHA, 1992; Brinker, 1984).

EPA recommends that calculations of water quality criteria be performed without rounding of intermediate step values. The resulting criterion may be rounded to a manageable number of decimal places. However, in no case should the number of digits presented exceed the number of significant figures implied in the data and calculations performed on them. The term "intermediate step values" refers to values of the parameters in Equations 1-1 through 1-3. The final step is considered the resulting AWQC. Although AWQC are, in turn, used for purposes of establishing water quality-based effluent limits (WQBELs) in National Pollutant Discharge Elimination System (NPDES) permits, calculating total maximum daily loads (TMDLs), and applicable or relevant and appropriate requirements (ARARs) for Superfund, they are considered the final step of this Methodology and, for the purpose of this discussion, where the rounding should occur.

The determination of appropriate significant figures inevitably involves some judgment given that some of the equation parameters are adopted default exposure values. Specifically, the default drinking water intake rate of 2 L/day is a value adopted to represent a majority of the population over the course of a lifetime. Although supported by drinking water consumption survey data, this value was adopted as a policy decision and, as such, does not have to be considered in determining the parameter with the least precision. That is, the resulting AWQC need not always be reduced to one significant digit. Similarly, the 70-kg adult body weight has been adopted Agency-wide and represents a default policy decision.

The following example with a simplified AWQC equation illustrates the rule described above. The example is for hexachlorobutadiene (HCBD), which EPA used to demonstrate the 1998 draft Methodology revisions (USEPA, 1998b). The parameters that were calculated (i.e., not policy adopted values) include values with significant figures of two (the POD and RSC), three (the UF), and four (the FI and BAF). Based on the 2000 Human Health Methodology, the final criterion should be rounded to two significant figures. The bold numbers in parentheses indicate the number of significant figures and those with asterisks also indicate Agency adopted policy values.

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + (FI \cdot BAF)} \right) \qquad \text{(Equation 2-1)}$$

Example [Refer to draft HCBD document for details on the POD/UF, RSC and BAF data (EPA 822-R-98-004). Also note that the fish intake rate in this example is the revised value.]:

$$AWQC = \left(\frac{0.054\mathbf{(2)}}{300\mathbf{(3)}} - 1.2 \times 10^{-4}\mathbf{(2)} \right) \times \left(\frac{70\mathbf{(2^*)}}{2\mathbf{(1^*)} + (0.01750\mathbf{(4)} \times 3{,}180\mathbf{(4)})} \right)$$

AWQC = 7.3×10^{-5} mg/L (0.073 µg/L, rounded from 7.285×10^{-2} µg/L)
* represents Agency adopted policy value

A number of the values used in the equation may result in intermediate step values that have more than four figures past the decimal place and may be carried throughout the calculation. However, carrying more than four figures past the decimal place (equivalent to the most precise parameter) is unnecessary as it has no effect on the resulting criterion value.

2.8 OTHER CONSIDERATIONS

2.8.1 Minimum Data Considerations

For many of the preceding technical areas, considerations have been presented for data quality in developing toxicological and exposure assessments. For greater detail and discussion of minimum data recommendations, the reader is referred to the specific sections in the Methodology on cancer and noncancer risk assessments (and especially to the referenced EPA risk assessment guidelines documents), exposure assessment, and bioaccumulation assessment, in addition to the TSD volumes for each.

2.8.2 Site-Specific Criterion Calculation

The 2000 Human Health Methodology allows for site-specific modifications by States and Tribes to reflect local environmental conditions and human exposure patterns. "Local" may refer to any appropriate geographic area where common aquatic environmental or exposure patterns exist. Thus "local" may signify Statewide, regional, a river reach, or an entire river.

Such site-specific criteria may be developed as long as the site-specific data, either toxicological or exposure-related, is justifiable. For example, when using a site-specific fish consumption rate, a State should use a value that represents at least the central tendency of the population surveyed (either sport or subsistence, or both). If a site-specific fish consumption rate for sport anglers or subsistence anglers is lower than an EPA default value, it may be used in calculating AWQC. However, to justify such a level (either higher or lower than EPA defaults), the State should assemble appropriate survey data to arrive at a defensible site-specific fish consumption rate.

Such data must also be submitted to EPA for its review when approving or disapproving State or Tribal water quality standards under Section 303(c). The same conditions apply to site-specific calculations of BAF, percent fish lipid, or the RSC. In the case of deviations from toxicological values (i.e., IRIS values: verified noncancer and cancer assessments), EPA strongly recommends that the data upon which the deviation is based be presented to and approved by the Agency before a criterion is developed.

Additional guidance on site-specific modifications to the 2000 Human Health Methodology is provided in each of the three TSD volumes.

2.8.3 Organoleptic Criteria

Organoleptic criteria define concentrations of chemicals or materials which impart undesirable taste and/or odor to water. Organoleptic effects, while significant from an aesthetic standpoint, are not a significant health concern. In developing and utilizing such criteria, two factors must be appreciated: (1) the limitations of most organoleptic data; and (2) the human health significance of organoleptic properties. In the past, EPA has developed organoleptic criteria if organoleptic data were available for a specific contaminant. The 1980 AWQC National Guidelines made a clear distinction that organoleptic criteria and toxicity-based criteria are derived from completely different endpoints, and that organoleptic criteria have no demonstrated relationship to potential adverse human health effects because there is no toxicological basis. EPA acknowledges that if organoleptic effects (i.e., objectionable taste and odor) cause people to reject the water and its designated uses, then the public is effectively deprived of the natural resource. It is also possible that intense organoleptic characteristics could result in depressed fluid intake which, in turn, might lead to an indirect human health effect via decreased fluid consumption. Although EPA has developed organoleptic criteria in the past and may potentially do so in the future, this will not be a significant part of the water quality criteria program. EPA encourages the development of organoleptic criteria when States and Tribes believe they are needed. However, EPA cautions States and Tribes that the quality of organoleptic data is often significantly less than that of toxicologic data used in establishing health-based criteria. Therefore, a comprehensive evaluation of available organoleptic data should be made, and the selection of the most appropriate database for the criterion should be based on sound scientific judgment.

In 1980, EPA provided recommended criteria summary language when both types of data are available. The following format was used and is repeated here:

> *For comparison purposes, two approaches were used to derive criterion levels for ____. Based on available toxicity data, for the protection of public health the derived level is ____. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water the estimated level is ____. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have no demonstrated relationship to potential adverse human health effects.*

Similarly, the 1980 Methodology recommended that in those instances where a level to limit toxicity cannot be derived, the following statement should be provided:

> *Sufficient data are not available for ____ to derive a level which would protect against the potential toxicity of this compound.*

2.8.4 Criteria for Chemical Classes

The 2000 Human Health Methodology also allows for the development of a criterion for classes of chemicals, as long as a justification is provided through the analysis of mechanistic data, toxicokinetic data, structure-activity relationship data, and limited acute and chronic toxicity data. When potency differences between members of a class is great (such as in the case

of chlorinated dioxins and furans), toxicity equivalency factors (TEFs) may be more appropriately developed than one class criterion.

A chemical class is defined as any group of chemical compounds which are similar in chemical structure and biological activity, and which frequently occur together in the environment usually because they are generated by the same commercial process. In criterion development, isomers should be regarded as part of a chemical class rather than as a single compound. A class criterion, therefore, is an estimate of risk/safety which applies to more than one member of a class. It involves the use of available data on one or more chemicals of a class to derive criteria for other compounds of the same class in the event that there are insufficient data available to derive compound-specific criteria. The health-based criterion may apply to the water concentration of each member of the class, or may apply to the sum of the water concentrations of the compounds within the class. Because relatively minor structural changes within the class of compounds can have pronounced effects on their biological activities, reliance on class criteria should be minimized depending on the data available.

The following guidance should also be followed when considering the development of a class criterion.

- A detailed review of the chemical and physical properties of the chemicals within the group should be made. A close relationship within the class with respect to chemical activity would suggest a similar potential to reach common biological sites within tissues. Likewise, similar lipid solubilities would suggest the possibility of comparable absorption and distribution.

- Qualitative and quantitative toxicological data for chemicals within the group should be examined. Adequate toxicological data on a number of compounds within a group provides a more reasonable basis for extrapolation to other chemicals of the same class than minimal data on one chemical or a few chemicals within the group.

- Similarities in the nature of the toxicological response to chemicals in the class provides additional support for the prediction that the response to other members of the class may be similar. In contrast, where the biological response has been shown to differ markedly on a qualitative and quantitative basis for chemicals within a class, the extrapolation of a criterion to other members is not appropriate.

- Additional support for the validity of extrapolation of a criterion to other members of a class could be provided by evidence of similar metabolic and toxicokinetic data for some members of the class.

Additional guidance is described in the *Technical Support Document on Health Risk Assessment of Chemical Mixtures* (USEPA, 1990).

2.9.5 Criteria for Essential Elements

Developing criteria for essential elements, particularly metals, must be a balancing act between toxicity and the requirement for good health. The AWQC must consider essentiality and cannot be established at levels that would result in deficiency of the element in the human population. The difference between the recommended daily allowance (RDA) and the daily doses causing a specified risk level for carcinogens or the RfDs for noncarcinogens defines the spread of daily doses within which the criterion may be derived. Because errors are inherent in defining both essential and adverse-effect levels, the criterion is derived from a dose level near the center of such dose ranges.

The process for developing criteria for essential elements should be similar to that used for any other chemical with minor modifications. The RfD represents concern for one end of the exposure spectrum (toxicity), whereas the RDA represents the other end (minimum essentiality). While the RDA and RfD values might occasionally appear to be similar in magnitude to one another, it does not imply incompatibility of the two methodological approaches, nor does it imply inaccuracy or error in either calculation.

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3. RISK ASSESSMENT

This section describes the methods used to estimate ambient water quality criteria (AWQC) for the protection of human health for carcinogenic chemicals (Section 3.1) and for noncarcinogenic chemicals (Section 3.2).

3.1 CANCER EFFECTS

3.1.1 Background on EPA Cancer Risk Assessment Guidelines

The current EPA *Guidelines for Carcinogen Risk Assessment* were published in 1986 (USEPA, 1986a, hereafter the "1986 cancer guidelines"). The 1986 cancer guidelines categorize chemicals into alpha-numerical Groups: A, known human carcinogen (sufficient evidence from epidemiological studies or other human studies); B, probable human carcinogen (sufficient evidence in animals and limited or inadequate evidence in humans); C, possible human carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); D, not classifiable (inadequate or no animal evidence of carcinogenicity); and E, evidence of noncarcinogenicity for humans (no evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiological and animal studies). Within Group B there are two subgroups, Groups B1 and B2. Group B1 is reserved for agents for which there is limited evidence of carcinogenicity from epidemiological studies. Group B2 is generally for agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiological studies (USEPA, 1986). The system was similar to that used by the International Agency for Research on Cancer (IARC).

The 1986 cancer guidelines include guidance on what constitutes sufficient, limited, or inadequate evidence. In epidemiological studies, sufficient evidence indicates a causal relationship between the agent and human cancer; limited evidence indicates that a causal relationship is credible, but that alternative explanations, such as chance, bias, or confounding, could not adequately be excluded; inadequate evidence indicates either lack of pertinent data, or a causal interpretation is not credible. In general, although a single study may be indicative of a cause-effect relationship, confidence in inferring a causal association is increased when several independent studies are concordant in showing the association. In animal studies, sufficient evidence includes an increased incidence of malignant tumors or combined malignant and benign tumors:

- In multiple species or strains;
- In multiple experiments (e.g., with different routes of administration or using different dose levels);
- To an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset;
- Additional data on dose-response, short-term tests, or structural activity relationships.

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In the 1986 cancer guidelines, hazard identification and the weight-of-evidence process focus on tumor findings. The weight-of-evidence approach for making judgments about cancer hazard analyzes human and animal tumor data separately, then combines them to make the overall conclusion about potential human carcinogenicity. The next step of the hazard analysis is an evaluation of supporting evidence (e.g., mutagenicity, cell transformation) to determine whether the overall weight-of-evidence conclusion should be modified.

For cancer risk quantification, the 1986 cancer guidelines recommend the use of linearized multistage model (LMS) as the only default approach. The 1986 cancer guidelines also mention that a low-dose extrapolation model other than the LMS might be considered more appropriate based on biological grounds. However, no guidance is given in choosing other approaches. The 1986 cancer guidelines recommended the use of body weight raised to the 2/3 power ($BW^{2/3}$) as a dose scaling factor between species.

3.1.2 EPA's Proposed Guidelines for Carcinogen Risk Assessment and the Subsequent July, 1999 Draft Revised Cancer Guidelines

In 1996, EPA published *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA, 1996a, hereafter the "1996 proposed cancer guidelines"). After the publication of the 1996 proposed cancer guidelines and a February, 1997 and January, 1999 Science Advisory Board (SAB) review, a revision was made in July, 1999 *Guidelines for Carcinogen Risk Assessment - Review Draft* (hereafter the "1999 draft revised cancer guidelines"; USEPA, 1999a), and an SAB meeting was convened to review this revised document. When final guidelines are published, they will replace the 1986 cancer guidelines. These revisions are designed to ensure that the Agency's cancer risk assessment methods reflect the most current scientific information and advances in risk assessment methodology.

In the meanwhile, the 1986 guidelines are used and extended with principles discussed in the 1999 draft revised cancer guidelines. These principles arise from scientific discoveries concerning cancer made in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 guidelines. Until final guidelines are published, information is presented to describe risk under both the 1986 guidelines and 1999 draft revisions.

The 1999 draft revised cancer guidelines call for the full use of all relevant information to convey the circumstances or conditions under which a particular hazard is expressed (e.g., route, duration, pattern, or magnitude of exposure). They emphasize understanding the mode of action (MOA) whereby the agent induces tumors. The MOA underlies the hazard assessment and provides the rationale for dose-response assessments.

The key principles in the 1999 draft revised cancer guidelines include:

a) Hazard assessment is based on the analysis of all biological information rather than just tumor findings.

b) An agent's MOA in causing tumors is emphasized to reduce the uncertainty in describing the likelihood of harm and in determining the dose-response approach(es).

c) The 1999 draft revised cancer guidelines emphasize the conditions under which the hazard may be expressed (e.g., route, pattern, duration and magnitude of exposure). Further, the guidelines call for a *hazard characterization* to integrate the data analysis of all relevant studies into a weight-of-evidence conclusion of hazard and to develop a working conclusion regarding the agent's mode of action in leading to tumor development.

d) A weight-of-evidence narrative with accompanying descriptors (listed in Section 3.1.3.1 below) would replace the current alphanumeric classification system. The narrative summarizes the key evidence for carcinogenicity, describes the agent's MOA, characterizes the conditions of hazard expression, including route of exposure, describes any disproportionate effects on subgroups of the human population (e.g., children), and recommends appropriate dose-response approach(es). Significant strengths, weaknesses, and uncertainties of contributing evidence are also highlighted.

e) Biologically based extrapolation models are the preferred approach for quantifying risk. These models integrate data and conclusions about events in the carcinogenic process throughout the dose-response range from high to low doses. It is anticipated, however, that the necessary data for the parameters used in such models will not be available for most chemicals. The 1999 draft revised cancer guidelines allow for alternative quantitative methods, including several default approaches.

f) Dose-response assessment is a two-step process. In the first step, response data are modeled in the observable range of data and a determination is made of the point of departure (POD) from the observed range to extrapolate to low doses. The second step is extrapolation from the POD to estimate dose-response at lower doses. In addition to modeling tumor data, the 1999 draft revised cancer guidelines call for the use and modeling of other kinds of responses if they are considered to be more informed measures of carcinogenic risk. Nominally, these responses reflect key events in the carcinogenic process integral to the MOA of the agent.

g) Three default approaches are provided–linear, nonlinear, or both when adequate data are unavailable to generate a biologically based model. As the first step for all approaches, curve fitting in the observed range is used to determine a POD. A standard POD is the effective dose corresponding to the lower 95 percent limit on

a dose associated with 10 percent extra risk (LED_{10}).[3] *Linear*: The linear default is a straight line extrapolation from the response at LED_{10} to the origin (zero dose, zero extra risk). *Nonlinear*: The nonlinear default begins with the identified POD and provides a margin of exposure (MOE) analysis rather than estimating the probability of effects at low doses. The MOE analysis is used to determine the appropriate margin between the POD and the exposure level of interest, in this Methodology, the AWQC. The key objective of the MOE analysis is to describe for the risk manager how rapidly responses may decline with dose. Other factors are also considered in the MOE analysis (i.e., nature of the response, slope of the dose-response curve, human sensitivity compared with experimental animals, nature and extent of human variability in sensitivity and human exposure). *Linear and nonlinear*: Section 3.1.3.4E describes the situations when both linear and nonlinear defaults are used.

h) The approach used to calculate an oral human equivalent dose when assessments are based on animal bioassays has been refined and includes a change in the default assumption for interspecies dose scaling. The 1999 draft revised cancer guidelines use body weight raised to the 3/4 power.

EPA health risk assessment practices for both cancer and noncancer endpoints are beginning to come together with recent proposals to emphasize MOA understanding in risk assessment and to model response data in the observable range to derive PODs for data sets and benchmark doses (BMDs) for individual studies. The modeling of observed response data to identify PODs in a standard way will help to harmonize cancer and noncancer dose-response approaches and permit comparisons of cancer and noncancer risk estimates.

3.1.3 Methodology for Deriving AWQC[4] by the 1999 Draft Revised Cancer Guidelines

Following the publication of the *Draft Water Quality Criteria Methodology: Human Health* (USEPA, 1998a) and the accompanying TSD (USEPA, 1998b), EPA received comments from the public. EPA also held an external peer review of the draft Methodology. Both the peer reviewers and the public recommended that EPA incorporate the new approaches into the AWQC Methodology.

Until new guidelines are published, the 1986 cancer guidelines will be used along with principles of the 1999 draft revised cancer guidelines. The 1986 guidelines are the basis for IRIS risk numbers which were used to derive the current AWQC. Each new assessment applying the principles of the 1999 draft revised cancer guidelines will be subject to peer review before being used as the basis of AWQC.

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[3] Use of the LED_{10} as the point of departure is recommended with this Methodology, as it is with the 1999 draft revised cancer guidelines.

[4] Additional information regarding the revised method for assessing carcinogens may be found in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document, Volume 1: Risk Assessment* (USEPA, 2000).

The remainder of Section 3 illustrates the methodology for deriving numerical AWQC for carcinogens applying the 1999 draft revised cancer guidelines (USEPA, 1999a). This discussion of the revised methodology for carcinogens focuses primarily on the quantitative aspects of deriving numerical AWQC values. It is important to note that the cancer risk assessment process outlined in the 1999 draft revised cancer guidelines is not limited to the quantitative aspects. A numerical AWQC value derived for a carcinogen is to be based on appropriate hazard characterization and accompanied by risk characterization information.

This section contains a discussion of the weight-of-evidence narrative, that describes all information relevant to a cancer risk evaluation, followed by a discussion of the quantitative aspects of deriving numerical AWQC values for carcinogens. It is assumed that data from an appropriately conducted animal bioassay or human epidemiological study provide the underlying basis for deriving the AWQC value. The discussion focuses on the following: (1) the weight-of-evidence narrative; (2) general considerations and framework for analysis of the MOA; (3) dose estimation; (4) characterizing dose-response relationships in the range of observation and at low, environmentally relevant doses; (5) calculating the AWQC value; (6) risk characterization; and (7) use of Toxicity Equivalent Factors (TEF) and Relative Potency Estimates. The first three topics encompass the quantitative aspects of deriving AWQC for carcinogens.

3.1.3.1 Weight-of-Evidence Narrative[5]

The 1999 draft revised cancer guidelines include a weight-of-evidence narrative that is based on an overall judgment of biological and chemical/physical considerations. Hazard assessment information accompanying an AWQC value for a carcinogen in the form of a weight-of-evidence narrative is described in the footnote. Of particular importance is that the weight-of-evidence narrative explicitly provides adequate support based on human studies, animal bioassays, and other key evidence for the conclusion whether the substance is or is likely to be carcinogenic to humans from exposures through drinking water and/or fish ingestion. The Agency emphasizes the importance of providing an explicit discussion of the MOA for the substance in the weight-of-evidence narrative if data are available, including a discussion that relates the MOA to the quantitative procedures used in the derivation of the AWQC.

3.1.3.2 Mode of Action - General Considerations and Framework for Analysis

[5] The weight-of-evidence narrative is intended for the risk manager, and thus explains in nontechnical language the key data and conclusions, as well as the conditions for hazard expression. Conclusions about potential human carcinogenicity are presented by route of exposure. Contained within this narrative are simple likelihood descriptors that essentially distinguish whether there is enough evidence to make a projection about human hazard (i.e., Carcinogenic to humans; Likely to be carcinogenic to humans; Suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential; Data are inadequate for an assessment of human carcinogenic potential; and Not likely to be carcinogenic to humans). Because one encounters a variety of data sets on agents, these descriptors are not meant to stand alone; rather, the context of the weight-of-evidence narrative is intended to provide a transparent explanation of the biological evidence and how the conclusions were derived. Moreover, these descriptors should not be viewed as classification categories (like the alphameric system), which often obscure key scientific differences among chemicals. The new weight-of-evidence narrative also presents conclusions about how the agent induces tumors and the relevance of the mode of action to humans, and recommends a dose-response approach based on the MOA understanding (USEPA, 1996a, 1999a).

An MOA is composed of key events and processes starting with the interaction of an agent with a cell, through operational and anatomical changes, resulting in cancer formation. "Mode" of action is contrasted with "mechanism" of action, which implies a more detailed, molecular description of events than is meant by MOA.

Mode of action analysis is based on physical, chemical, and biological information that helps to explain key events[6] in an agent's influence on development of tumors. Inputs to MOA analysis include tumor data in humans, animals, and among structural analogues as well as the other key data.

There are many examples of possible modes of carcinogenic action, such as mutagenicity, mitogenesis, inhibition of cell death, cytotoxicity with reparative cell proliferation, and immune suppression. All pertinent studies are reviewed in analyzing an MOA, and an overall weighing of evidence is performed, laying out the strengths, weaknesses, and uncertainties of the case as well as potential alternative positions and rationales. Identifying data gaps and research needs is also part of the assessment.

Mode of action conclusions are used to address the question of human relevance of animal tumor responses, to address differences in anticipated response among humans such as between children and adults or men and women, and as the basis of decisions about the anticipated shape of the dose-response relationship.

In reaching conclusions, the question of "general acceptance" of an MOA will be tested as part of the independent peer review that EPA obtains for its assessment and conclusions.

Framework for Evaluating a Postulated Carcinogenic Mode(s) of Action

The framework is intended to be an analytic tool for judging whether available data support a mode of carcinogenic action postulated for an agent and includes nine elements:

1. Summary description of postulated MOA
2. Identification of key events
3. Strength, consistency, specificity of association
4. Dose-response relationship
5. Temporal relationship
6. Biological plausibility and coherence
7. Other modes of action
8. Conclusion
9. Human relevance, including subpopulations

3.1.3.3 Dose Estimation

[6]A "key event" is an empirically observable, precursor step that is itself a necessary element of the mode of action, or is a marker for such an element.

A. Determining the Human Equivalent Dose by the Oral Route

An important objective in the dose-response assessment is to use a measure of internal or delivered dose at the target site where possible. This is particularly important in those cases where the carcinogenic response information is being extrapolated to humans from animal studies. Generally, by the oral exposure route, the measure of a dose provided in the underlying human studies or animal bioassays is the applied dose, typically given in terms of unit mass per unit body weight per unit time, (e.g., mg/kg-day). When animal bioassay data are used, it is necessary to make adjustments to the applied dose values to account for differences in toxicokinetics between animals and humans that affect the relationship between applied dose and delivered dose at the target organ.

In the estimation of a human equivalent dose, the 1999 draft revised cancer guidelines recommend that when adequate data are available, the doses used in animal studies can be adjusted to equivalent human doses using toxicokinetic information on the particular agent. However, in most cases, there are insufficient data available to compare dose between species. In these cases, the estimate of a human equivalent dose is based on science policy default assumptions. To derive an equivalent human oral dose from animal data, the default procedure in the 1999 draft revised cancer guidelines is to scale daily applied oral doses experienced for a lifetime in proportion to body weight raised to the 3/4 power ($BW^{3/4}$). The adjustment factor is used because metabolic rates, as well as most rates of physiological processes that determine the disposition of dose, scale this way. Thus, the rationale for this factor rests on the empirical observation that rates of physiological processes consistently tend to maintain proportionality with body weight raised to 3/4 power (USEPA, 1992a, 1999a).

The use of $BW^{3/4}$ is a departure from the scaling factor of $BW^{2/3}$ that was based on surface area adjustment and was included in the 1980 AWQC National Guidelines as well as the 1986 cancer guidelines.

B. Dose-Response Analysis

If data on the agent are sufficient to support the parameters of a biologically based model and the purpose of the assessment is such as to justify investing resources supporting its use, this is the preferred approach for both the observed tumor and related response data and for extrapolation below the range of observed data in either animal or human studies.

3.1.3.4 Characterizing Dose-Response Relationships in the Range of Observation and at Low Environmentally Relevant Doses

The first quantitative component in the derivation of AWQC for carcinogens is the dose-response assessment in the range of observation. For most agents, in the absence of adequate data to generate a biologically based model, dose-response relationships in the observed range can be addressed through curve-fitting procedures for response data. It should be noted that the 1999 draft revised cancer guidelines call for modeling of not only tumor data in the observable range, but also other responses thought to be important events preceding tumor development (e.g., DNA adducts, cellular proliferation, receptor binding, hormonal changes). The modeling of

these data is intended to better inform the dose-response assessment by providing insights into the relationships of exposure (or dose) below the observable range for tumor response. These non-tumor response data can only play a role in the dose-response assessment if the agent's carcinogenic mode of action is reasonably understood, as well as the role of that precursor event.

The 1999 draft revised cancer guidelines recommend calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or relevant non-tumor response (LED_{10}) for quantitative modeling of dose-response relationships in the observed range. The estimate of the LED_{10} is used as the POD for low-dose extrapolations discussed below. This standard point of departure (LED_{10}) is adopted as a matter of science policy to remain as consistent and comparable from case to case as possible. It is also a convenient comparison point for noncancer endpoints. The rationale supporting use of the LED_{10} is that a 10 percent response is at or just below the limit of sensitivity for discerning a statistically significant tumor response in most long-term rodent studies and is within the observed range for other toxicity studies. Use of lower limit takes experimental variability and sample size into account. The ED_{10} (central estimate) is also presented as a reference for comparison uses, especially for use in relative hazard/potency ranking among agents for priority setting.

For some data sets, a choice of the POD other than the LED_{10} may be appropriate. The objective is to determine the lowest reliable part of the dose-response curve for the beginning of the second step of the dose-response assessment—determine the extrapolation range. Therefore, if the observed response is below the LED_{10}, then a lower point may be a better choice (e.g., LED_5). Human studies more often support a lower POD than animal studies because of greater sample size.

The POD may be a NOAEL when a margin of exposure analysis is the nonlinear dose-response approach. The kinds of data available and the circumstances of the assessment both contribute to deciding to use a NOAEL or LOAEL which is not as rigorous or as ideal as curve fitting, but can be appropriate. If several data sets for key events and tumor response are available for an agent, and they are a mixture of continuous and incidence data, the most practicable way to assess them together is often through a NOAEL/LOAEL approach.

When an LED value estimated from animal data is used as the POD, it is adjusted to the human equivalent dose using an interspecies dose adjustment or a toxicokinetic analysis as described in Section 3.1.3.3.

Analysis of human studies in the observed range is designed on a case-by-case basis depending on the type of study and how dose and response are measured in the study.

A. Extrapolation to Low, Environmentally Relevant Doses

In most cases, the derivation of an AWQC will require an evaluation of carcinogenic risk at environmental exposure levels substantially lower than those used in the underlying study. Various approaches are used to extrapolate risk outside the range of observed experimental data. In the 1999 draft revised cancer guidelines, the choice of extrapolation method is largely

dependent on the mode of action. It should be noted that the term "mode of action" (MOA) is deliberately chosen in the 1999 draft revised cancer guidelines in lieu of the term "mechanism" to indicate using knowledge that is sufficient to draw a reasonable working conclusion without having to know the processes in detail as the term mechanism might imply. The 1999 draft revised cancer guidelines favor the choice of a biologically based model, if the parameters of such models can be calculated from data sources independent of tumor data. It is anticipated that the necessary data for such parameters will not be available for most chemicals. Thus, the 1999 draft revised cancer guidelines allow for several default extrapolation approaches (low-dose linear, nonlinear, or both).

B. Biologically Based Modeling Approaches

If a biologically based approach has been used to characterize the dose-response relationships in the observed range, and the confidence in the model is high, it may be used to extrapolate the dose-response relationship to environmentally relevant doses. For the purposes of deriving AWQC, the environmentally relevant dose would be the risk-specific dose (RSD) associated with incremental lifetime cancer risks in the 10^{-6} to 10^{-4} range for carcinogens for which a linear extrapolation approach is applied.[7] The use of the RSD and the POD/UF to compute the AWQC is presented in Section 3.1.3.5, below. Although biologically-based approaches are appropriate both for characterizing observed dose-response relationships and extrapolating to environmentally relevant doses, it is not expected that adequate data will be available to support the use of such approaches for most substances. In the absence of such data, the default linear approach, the nonlinear (MOE) approach, or both linear and nonlinear approaches will be used.

[7] For discussion of the cancer risk range, see Section 2.4.

C. Default Linear Extrapolation Approach

The default linear approach replaces the LMS approach that has served as the default for EPA cancer risk assessments. Any of the following conclusions leads to selection of a linear dose-response assessment approach:

- There is an absence of sufficient tumor MOA information.
- The chemical has direct DNA mutagenic reactivity or other indications of DNA effects that are consistent with linearity.
- Human exposure or body burden is high and near doses associated with key events in the carcinogenic process (e.g., 2,3,7,8-tetrachlorodibenzo-p-dioxin).
- Mode of action analysis does not support direct DNA effects, but the dose-response relationship is expected to be linear (e.g., certain receptor-mediated effects).

The procedures for implementing the default linear approach begin with the estimation of a POD as described above. The point of departure, LED_{10}, reflects the interspecies conversion to the human equivalent dose and the other adjustments for less-than-lifetime experimental duration. In most cases, the extrapolation for estimating response rates at low, environmentally relevant exposures is accomplished by drawing a straight line between the POD and the origin (i.e., zero dose, zero extra risk). This is mathematically represented as:

$$y = mx + b \qquad \text{(Equation 3-1)}$$
$$b = 0$$

where:

y	=	Response or incidence
m	=	Slope of the line (cancer potency factor) = $\Delta y/\Delta x$
x	=	Dose
b	=	Slope intercept

The slope of the line, "m" (the estimated cancer potency factor at low doses), is computed as:

$$m = \frac{0.10}{LED_{10}} \qquad \text{(Equation 3-2)}$$

The RSD is then calculated for a specific incremental targeted lifetime cancer risk (in the range of 10^{-6} to 10^{-4}) as:

00134

$$RSD = \frac{\text{Target Incremental Cancer Risk}}{m} \qquad \text{(Equation 3-3)}$$

where:

RSD	=	Risk-specific dose (mg/kg-day)
Target Incremental Cancer Risk[8]	=	Value in the range of 10^{-6} to10^{-4}
m	=	Cancer potency factor $(mg/kg\text{-}day)^{-1}$

The use of the RSD to compute the AWQC is described in Section 3.1.3.5 below.

D. Default Nonlinear Approach

As discussed in the 1999 draft revised cancer guidelines, any of the following conclusions leads to a selection of a nonlinear (MOE) approach to dose-response assessment:

- A tumor MOA supporting nonlinearity applies (e.g., some cytotoxic and hormonal agents such as disruptors of hormonal homeostasis), and the chemical does not demonstrate mutagenic effects consistent with linearity.

- An MOA supporting nonlinearity has been demonstrated, and the chemical has some indication of mutagenic activity, but it is judged not to play a significant role in tumor causation.

Thus, a default assumption of nonlinearity is appropriate when there is no evidence for linearity and sufficient evidence to support an assumption of nonlinearity. The MOA may lead to a dose-response relationship that is nonlinear, with response falling much more quickly than linearly with dose, or being most influenced by individual differences in sensitivity. Alternatively, the MOA may theoretically have a threshold (e.g., the carcinogenicity may be a secondary effect of toxicity or of an induced physiological change that is itself a threshold phenomenon).

The nonlinear approach may be used, for instance, in the case of a bladder tumor inducer, where the chemical is not mutagenic and causes only stone formation in male rat bladders at high doses. This dynamic leads to tumor formation only at the high doses. Stone and subsequent tumor formation are not expected to occur at doses lower than those that induce the physiological changes that lead to stone formation. (More detail on this chemical is provided in the cancer section of the Risk Assessment TSD; USEPA, 2000). EPA does not generally try to distinguish between modes of action that might imply a “true threshold” from others with a

[8]In 1980, the target lifetime cancer risk range was set at 10-7 to 10-5. However, both the expert panel for the AWQC workshop (USEPA, 1993) and the peer review workshop experts (USEPA,1999c) recommended that EPA change the risk range to 10-6 to 10-4, to be consistent with SDWA program decisions. See Section 2.4 for more details.

nonlinear dose-response relationship, because there is usually not sufficient information to distinguish between those possibilities empirically.

The nonlinear MOE approach in the 1986 proposed cancer guidelines compares an observed response rate such as the LED_{10}, NOAEL, or LOAEL with actual or nominal environmental exposures of interest by computing the ratio between the two. In the context of deriving AWQC, the environmentally relevant exposures are nominal targets rather than actual exposures.

If the evidence for an agent indicates nonlinearity (e.g., when carcinogenicity is secondary to another toxicity for which there is a threshold), the MOE analysis for the toxicity is similar to what is done for a noncancer endpoint, and an RfD or RfC for that toxicity may also be estimated and considered in the cancer assessment. However, a threshold of carcinogenic response is not necessarily assumed. It should be noted that for cancer assessment, the MOE analysis begins from a POD that is adjusted for toxicokinetic differences between species to give a human equivalent dose.

To support the use of the MOE approach, risk assessment information provides evaluation of the current understanding of the phenomena that may be occurring as dose (exposure) decreases substantially below the observed data. This gives information about the risk reduction that is expected to accompany a lowering of exposure. The various factors that influence the selection of the UF in an MOE approach are also discussed below.

There are two main steps in the MOE approach. The first step is the selection of a POD. The POD may be the LED_{10} for tumor incidence or a precursor, or in some cases, it may also be appropriate to use a NOAEL or LOAEL value. When animal data are used, the POD is a human equivalent dose or concentration arrived at by interspecies dose adjustment (as discussed in Section 3.1.3.3) or toxicokinetic analysis.

The second step in using MOE analysis to establish AWQC is the selection of an appropriate margin or UF to apply to the POD. This is supported by analyses in the MOE discussion in the risk assessment. The following issues should be considered when establishing the overall UF for the derivation of AWQC using the MOE approach (others may be found appropriate in specific cases):

- The nature of the response used for the dose-response assessment, for instance, whether it is a precursor effect or a tumor response. The latter may support a greater MOE.

- The slope of the observed dose-response relationship at the POD and its uncertainties and implications for risk reduction associated with exposure reduction. (A steeper slope implies a greater reduction in risk as exposure decreases. This may support a smaller MOE).

- Human sensitivity compared with that of experimental animals.

- Nature and extent of human variability and sensitivity.

- Human exposure. The MOE evaluation also takes into account the magnitude, frequency, and duration of exposure. If the population exposed in a particular scenario is wholly or largely composed of a subpopulation of special concern (e.g., children) for whom evidence indicates a special sensitivity to the agent's MOA, an adequate MOE would be larger than for general population exposure.

E. Both Linear and Nonlinear Approaches

Any of the following conclusions leads to selection of both a linear and nonlinear approach to dose-response assessment. Relative support for each dose-response method and advice on the use of that information needs to be documented for the AWQC. In some cases, evidence for one MOA is stronger than for the other, allowing emphasis to be placed on that dose-response approach. In other cases, both modes of action are equally possible, and both dose-response approaches should be emphasized.

- Modes of action for a single tumor type support both linear and nonlinear dose response in different parts of the dose-response curve (e.g., 4,4' methylene chloride).

- A tumor mode of action supports different approaches at high and low doses; e.g., at high dose, nonlinearity, but, at low dose, linearity (e.g., formaldehyde).

- The agent is not DNA-reactive and all plausible modes of action are consistent with nonlinearity, but not fully established.

- Modes of action for different tumor types support differing approaches, e.g., nonlinear for one tumor type and linear for another due to lack of MOA information (e.g., trichloroethylene).

3.1.3.5 <u>AWQC Calculation</u>

A. Linear Approach

The following equation is used for the calculation of the AWQC for carcinogens where an RSD is obtained from the linear approach:

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 3-4)}$$

AWQC	=	Ambient water quality criterion (mg/L)
RSD	=	Risk-specific dose (mg/kg-day)
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)

FI_i	=	Fish intake at trophic level I (I = 2, 3, and 4) (kg/day)
BAF_i	=	Bioaccumulation factor for trophic level I (I = 2, 3, and 4), lipid normalized (L/kg)

B. Nonlinear Approach

In those cases where the nonlinear, MOE approach is used, a similar equation is used to calculate the AWQC [9]

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 3-5)}$$

where variables are defined as for Equation 3-4 and:

POD	=	Point of departure (mg/kg-day)
UF	=	Uncertainty factor (unitless)
RSC	=	Relative source contribution (percentage or subtraction)

Differences between the AWQC values obtained using the linear and nonlinear approaches should be noted. First, the AWQC value obtained using the default linear approach corresponds to a specific estimated incremental lifetime cancer risk level in the range of 10^{-4} to 10^{-6}. In contrast, the AWQC obtained using the nonlinear approach does not describe a specific cancer risk. The AWQC calculations shown above are appropriate for waterbodies that are used as sources of drinking water.

The actual AWQC chosen for the protection of human health is based on a review of all relevant information, including cancer and noncancer data. The AWQC may, or may not, utilize the value obtained from the cancer analysis in the final AWQC value. The endpoint selected for the AWQC will be based on consideration of the weight of evidence and a complete analysis of all toxicity endpoints.

3.1.3.6 Risk Characterization

Risk assessment is an integrative process that is documented in a risk characterization summary. Risk characterization is the final step of the risk assessment process in which all preceding analyses (i.e., hazard, dose-response, and exposure assessments) are tied together to convey the overall conclusions about potential human risk. This component of the risk assessment process characterizes the data in nontechnical terms, explaining the extent and weight of evidence, major points of interpretation and rationale, and strengths and weaknesses of

[9] Although appearing in this equation as a factor to be multiplied, the RSC can also be an amount subtracted.

the evidence, and discussing alternative approaches, conclusions, uncertainties, and variability that deserve serious consideration.

Risk characterization information accompanies the numerical AWQC value and addresses the major strengths and weaknesses of the assessment arising from the availability of data and the current limits of understanding the process of cancer causation. Key issues relating to the confidence in the hazard assessment and the dose-response analysis (including the low-dose extrapolation procedure used) are discussed. Whenever more than one interpretation of the weight of evidence for carcinogenicity or the dose-response characterization can be supported, and when choosing among them is difficult, the alternative views are provided along with the rationale for the interpretation chosen in the derivation of the AWQC value. Where possible, quantitative uncertainty analyses of the data are provided; at a minimum, a qualitative discussion of the important uncertainties is presented.

3.1.3.7 Use of Toxicity Equivalence Factors and Relative Potency Estimates

The 1999 draft revised cancer guidelines state:

> *A toxicity equivalence factor (TEF) procedure is one used to derive quantitative dose-response estimates for agents that are members of a category or class of agents. TEFs are based on shared characteristics that can be used to order the class members by carcinogenic potency when cancer bioassay data are inadequate for this purpose. The ordering is by reference to the characteristics and potency of a well-studied member or members of the class. Other class members are indexed to the reference agent(s) by one or more shared characteristics to generate their TEFs.*

In addition, the 1999 draft revised cancer guidelines state that TEFs are generated and used for the limited purpose of assessment of agents or mixtures of agents in environmental media when better data are not available. When better data become available for an agent, the TEF should be replaced or revised. To date, adequate data to support use of TEFs have been found only for dibenzofurans (dioxins) and coplanar polychlorinated biphenyls (PCBs) (USEPA, 1989, 1999b).

The uncertainties associated with TEFs must be described when this approach is used. This is a default approach to be used when tumor data are not available for individual components in a mixture. Relative potency factors (RPFs) can be similarly derived and used for agents with carcinogenicity or other supporting data. The RPF is conceptually similar to TEFs, but does not have the same level of data to support it and thus has a less rigorous definition compared with the TEF. TEFs and RPFs are used only when there is no better alternative. When they are used, assumptions and uncertainties associated with them are discussed. As of today, there are only three classes of compounds for which relative potency approaches have been examined by EPA: dibenzofurans (dioxins), polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (PAHs). There are limitations to the use of TEF and RFP approaches, and caution should be exercised when using them. More guidance can be found in the draft document for conducting health risk assessment of chemical mixtures, published by the EPA Risk Assessment Forum (USEPA,1999b).

3.1.4 References for Cancer Section

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3.2 NONCANCER EFFECTS

3.2.1 1980 AWQC National Guidelines for Noncancer Effects

In the 1980 AWQC National Guidelines, the Agency evaluated noncancer human health effects from exposure to chemical contaminants using Acceptable Daily Intake (ADI) levels. ADIs were calculated by dividing NOAELs by safety factors (SFs) to obtain estimates of doses of chemicals that would not be expected to cause adverse effects over a lifetime of exposure. In accordance with the National Research Council report of 1977 (NRC, 1977), EPA used SFs of 10, 100, or 1,000, depending on the quality and quantity of the overall database. In general, a factor of 10 was suggested when good-quality data identifying a NOAEL from human studies were available. A factor of 100 was suggested if no human data were available, but the database contained valid chronic animal data. For chemicals with no human data and scant animal data, a factor of 1,000 was recommended. Intermediate SFs could also be used for databases that fell between these categories.

AWQC were calculated using the ADI levels together with standard exposure assumptions about the rates of human ingestion of water and fish, and also accounting for intake from other sources (see Equation 1-1 in the Introduction). Surface water concentrations at or below the calculated criteria concentrations would be expected to result in human exposure levels at or below the ADI. Inherent in these calculations is the assumption that, generally, adverse effects from noncarcinogens exhibit a threshold.

3.2.2 Noncancer Risk Assessment Developments Since 1980

Since 1980, the risk assessment of noncarcinogenic chemicals has changed. To remove the value judgments implied by the words “acceptable” and “safety,” the ADI and SF terms have been replaced with the terms RfD and UF/modifying factor (MF), respectively.

For the risk assessment of general systemic toxicity, the Agency currently uses the guidelines contained in the IRIS background document entitled *Reference Dose (RfD): Description and Use in Health Risk Assessments* (hereafter the “IRIS background document”. That document defines an RfD as “an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime” (USEPA,

1993a). The most common approach for deriving the RfD does not involve dose-response modeling. Instead, an RfD for a given chemical is usually derived by first identifying the NOAEL for the most sensitive known toxicity endpoint, that is, the toxic effect that occurs at the lowest dose. This effect is called the critical effect. Factors such as the study protocol, the species of experimental animal, the nature of the toxicity endpoint assessed and its relevance to human effects, the route of exposure, and exposure duration are critically evaluated in order to select the most appropriate NOAEL from among all available studies in the chemical's database. If no appropriate NOAEL can be identified from any study, then the LOAEL for the critical effect endpoint is used and an uncertainly factor for LOAEL-to-NOAEL extrapolation is applied. Using this approach, the RfD is equal to the NOAEL (or LOAEL) divided by the product of UFs and, occasionally, an MF:

$$\text{RfD (mg/kg/day)} = \frac{\text{NOAEL (or LOAEL)}}{\text{UF} \cdot \text{MF}} \qquad \text{(Equation 3-6)}$$

The definitions and guidance for use of the UFs and the MFs are provided in the IRIS background document and are repeated in Table 3-1.

The IRIS background document on the RfD (USEPA, 1993a) provides guidance for critically assessing noncarcinogenic effects of chemicals and for deriving the RfD. Another reference on this topic is Dourson (1994). Furthermore, the Agency has also published separate guidelines for assessing specific toxic endpoints, such as developmental toxicity (USEPA, 1991a), reproductive toxicity (USEPA, 1996a), and neurotoxicity risk assessment (USEPA, 1995). These endpoint-specific guidelines will be used for their respective areas in the hazard assessment step and will complement the overall toxicological assessment. It should be noted, however, that an RfD, derived using the most sensitive known endpoint, is considered protective against all noncarcinogenic effects.

TABLE 3-1. UNCERTAINTY FACTORS AND THE MODIFYING FACTOR

Uncertainty Factor	Definition
UF_H	Use a 1, 3, or 10-fold factor when extrapolating from valid data in studies using long-term exposure to average healthy humans. This factor is intended to account for the variation in sensitivity (intraspecies variation) among the members of the human population.
UF_A	Use an additional factor of 1, 3, or 10 when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans (interspecies variation).
UF_S	Use an additional factor of 1, 3, or 10 when extrapolating from less-than-chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less-than-chronic NOAELs to chronic NOAELs.
UF_L	Use an additional factor of 1, 3, or 10 when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs.
UF_D	Use an additional 3- or 10-fold factor when deriving an RfD from an "incomplete" database. This factor is meant to account for the inability of any single type of study to consider all toxic endpoints. The intermediate factor of 3 (approximately ½ $\log_{10}$ unit, i.e., the square root of 10) is often used when there is a single data gap exclusive of chronic data. It is often designated as UF_D.

Modifying Factor

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and database not explicitly treated above (e.g., the number of species tested). The default value for the MF is 1.

Note: With each UF or MF assignment, it is recognized that professional scientific judgment must be used. The total product of the uncertainty factors and modifying factor should not exceed 3,000.

Similar to the procedure used in the 1980 AWQC National Guidelines, the revised method of deriving AWQC for noncarcinogens uses the RfD together with various assumptions concerning intake of the contaminant from both water and non-water sources of exposure. The objective of an AWQC for noncarcinogens is to ensure that human exposure to a substance related to its presence in surface water, combined with exposure from other sources, does not exceed the RfD. The algorithm for deriving AWQC for noncarcinogens using the RfD is presented as Equation 1-1 in the Introduction.

3.2.3 Issues and Recommendations Concerning the Derivation of AWQC for Noncarcinogens

During a review of the 1980 AWQC National Guidelines (USEPA, 1993b), the Agency identified several issues that must be resolved in order to develop a final revised methodology for deriving AWQC based on noncancer effects. These issues, as discussed below, mainly concern the derivation of the RfD as the basis for such an AWQC. Foremost among these issues is whether the Agency should revise the present method or adopt entirely new procedures that use quantitative dose-response modeling for the derivation of the RfD. Other issues include the following:

- Presenting the RfD as a single point value or as a range to reflect the inherent imprecision of the RfD;
- Selecting specific guidance documents for derivation of noncancer health effect levels;
- Considering severity of effect in the development of the RfD;
- Using less-than-90-day studies as the basis for RfDs;
- Integrating reproductive/developmental, immunotoxicity, and neurotoxicity data into the RfD calculation;
- Applying toxicokinetic data in risk assessments; and
- Considering the possibility that some noncarcinogenic effects do not exhibit a threshold.

3.2.3.1 Using the Current NOAEL/UF-Based RfD Approach or Adopting More Quantitative Approaches for Noncancer Risk Assessment

The current NOAEL/UF-based RfD methodology, or its predecessor ADI/SF methodology, have been used since 1980. This approach assumes that there is a threshold exposure below which adverse noncancer health effects are not expected to occur. Exposures above this threshold are believed to pose some risk to exposed individuals; however, the current approach does not address the nature and magnitude of the risk above the threshold level (i.e., the shape of the dose-response curve above the threshold). The NOAEL/UF-based RfD approach is intended primarily to ensure that the RfD value derived from the available data falls below the population effects threshold. However, the NOAEL/UF-based RfD procedure has

limitations. In particular, this method requires that one of the actual experimental doses used by the researchers in the critical study be selected as the NOAEL or LOAEL value. The determination that a dose is a NOAEL or LOAEL will depend on the biological endpoints used and the statistical significance of the data. Statistical significance will depend on the number and spacing of dose groups and the numbers of animals used in each dose group. Studies using a small number of animals can limit the ability to distinguish statistically significant differences among measurable responses seen in dose groups and control groups. Furthermore, the determination of the NOAEL or LOAEL also depends on the dose spacing of the study. Doses are often widely spaced, typically differing by factors of three to ten. A study can identify a NOAEL and a LOAEL from among the doses studied, but the "true" effects threshold cannot be determined from those results. The study size and dose spacing limitations also limit the ability to characterize the nature of the expected response to exposures between the observed NOAEL and LOAEL values.

The limitations of the NOAEL/UF approach have prompted development of alternative approaches that incorporate more quantitative dose-response information. The traditional NOAEL approach for noncancer risk assessment has often been a source of controversy and has been criticized in several ways. For example, experiments involving fewer animals tend to produce higher NOAELs and, as a consequence, may produce higher RfDs. Larger sample sizes, on the other hand, should provide greater experimental sensitivity and lower NOAELs. The focus of the NOAEL approach is only on the dose that is the NOAEL, and the NOAEL must be one of the experimental doses. It also ignores the shape of the dose-response curve. Thus, the slope of the dose-response plays little role in determining acceptable exposures for human beings. Therefore, in addition to the NOAEL/UF-based RfD approach described above, EPA will accept other approaches that incorporate more quantitative dose-response information in appropriate situations for the evaluation of noncancer effects and the derivation of RfDs. However, the Agency wishes to emphasize that it still believes the NOAEL/UF RfD methodology is valid and can continue to be used to develop RfDs.

Two alternative approaches that may have relevance in assisting in the derivation of the RfD for a chemical are the BMD and the categorical regression approaches. These alternative approaches may overcome some of the inherent limitations in the NOAEL/UF approach. For example, the BMD analyses for developmental effects show that NOAELs from studies correlate well with a 5 percent response level (Allen et al., 1994). The BMD and the categorical regression approaches usually have greater data requirements than the RfD approach. Thus, it is unlikely that any one approach will apply to every circumstance; in some cases, different approaches may be needed to accommodate the varying databases for the range of chemicals for which water quality criteria must be developed. Acceptable approaches will satisfy the following criteria: (1) meet the appropriate risk assessment goal; (2) adequately describe the toxicity database and its quality; (3) characterize the endpoints properly; (4) provide a measure of the quality of the "fit" of the model when a model is used for dose-response analysis; and (5) describe the key assumptions and uncertainties.

A. The Benchmark Dose

The BMD is defined as the dose estimated to produce a predetermined level of change in response (the Benchmark Response level, or BMR) relative to control. The BMDL is defined as the statistical lower confidence limit on the BMD. In the derivation of an RfD, the BMDL is used as the dose to which uncertainty factors are applied instead of the NOAEL. The BMD approach first models a dose-response curve for the critical effect(s) using available experimental data. Several mathematical algorithms can be used to model the dose-response curve, such as polynomial or Weibull functions. To define a BMD from the modeled curve for quantal data, the assessor first selects the BMR. The choice of the BMR is critical. For quantal endpoints, a particular level of response is chosen (e.g., 1 percent, 5 percent, or 10 percent). For continuous endpoints, the BMR is the degree of change from controls and is based on what is considered a biologically significant change. The BMD is derived from the BMR dose by applying the desired confidence limit calculation. The RfD is obtained by dividing the BMD by one or more uncertainty factors, similar to the NOAEL approach. Because the BMD is used like the NOAEL to obtain the RfD, the BMR should be selected at or near the low end of the range of increased risks that can be detected in a study of typical size. Generally, this falls in the range between the ED_{01} and the ED_{10}.

The Agency will accept use of a BMD approach to derive RfDs for those agents for which there is an adequate database. There are a number of technical decisions associated with the application of the BMD technique. These include the following:

- The definition of an adverse response;
- Selection of response data to model;
- The form of the data used (continuous versus quantal);
- The choice of the measures of increased risk (extra risk versus additional risk);
- The choice of mathematical model (including use of nonstandard models for unusual data sets);
- The selection of the BMR;
- Methods for calculating the confidence interval;
- Selection of the appropriate BMD as the basis for the RfD (when multiple endpoints are modeled from a single study, when multiple models are applied to a single response, and when multiple BMDs are calculated from different studies); and
- The use of uncertainty factors with the BMD approach.

These topics are discussed in detail in Crump et al. (1995) and in the Risk Assessment TSD Volume (USEPA, 2000). The use of the BMD approach has been discussed in general terms by several authors (Gaylor, 1983; Crump, 1984; Dourson et al., 1985; Kimmel and Gaylor, 1988; Brown and Erdreich, 1989; Kimmel, 1990). The International Life Sciences Institute

(ILSI) also held a major workshop on the BMD in September 1993; the workshop proceedings are summarized in ILSI (1993) and in Barnes et al. (1995). For further information on these technical issues, the reader is referred to the publications referenced above.

The BMD approach addresses several of the quantitative or statistical criticisms of the NOAEL approach. These are discussed at greater length in Crump et al. (1995) and are summarized here. First, the BMD approach uses all the dose-response information in the selected study rather than just a single data point, such as the NOAEL or LOAEL. By using response data from all of the dose groups to model a dose-response curve, the BMD approach allows for consideration of the steepness of the slope of the curve when estimating the ED_{10}. The use of the full data set also makes the BMD approach less sensitive to small changes in data than the NOAEL approach, which relies on the statistical comparison of individual dose groups. The BMD approach also allows consistency in the consideration of the level of effect (e.g., a 10 percent response rate) across endpoints.

The BMD approach accounts more appropriately for the size of each dose group than the NOAEL approach. Laboratory tests with fewer animals per dose group tend to yield higher NOAELs, and thus higher RfDs, because statistically significant differences in response rates are harder to detect. Therefore, in the NOAEL approach, dose groups with fewer animals lead to a higher (less conservative) RfD. In contrast, with the BMD approach, smaller dose groups will tend to have the effect of extending the confidence interval around the ED_{10}; therefore, the lower confidence limit on the ED_{10} (the BMD) will be lower. With the BMD approach, greater uncertainty (smaller test groups) leads to a lower (more conservative) RfD.

There are some issues to be resolved before the BMD approach is used routinely. These were identified in a 1996 Peer Consultation Workshop (USEPA, 1996b). Methods for routine use of the BMD are currently under development by EPA. Several RfCs and RfDs based on the BMD approach are included in EPA's IRIS database. These include reference values for methylmercury based on delayed postnatal development in humans; carbon disulfide based on neurotoxicity; 1,1,1,2-tetrafluoroethane based on testicular effects in rats; and antimony trioxide based on chronic pulmonary interstitial inflammation in female rats.

Various mathematical approaches have been proposed for modeling developmental toxicity data (e.g., Crump, 1984; Kimmel and Gaylor, 1988; Rai and Van Ryzin, 1985; Faustman et al., 1989), which could be used to calculate a BMD. Similar methods can be used to model other types of toxicity data, such as neurotoxicity data (Gaylor and Slikker, 1990, 1992; Glowa and MacPhail, 1995). The choice of the mathematical model may not be critical, as long as estimation is within the observed dose range. Since the model fits a mathematical equation to the observed data, the assumptions in a particular model regarding the existence or absence of a threshold for the effect may not be pertinent (USEPA, 1997). Thus, any model that suitably fits the empirical data is likely to provide a reasonable estimate of a BMD. However, research has shown that flexible models that are nonsymmetric (e.g., the Weibull) are superior to symmetric models (e.g., the probit) in estimating the BMD because the data points at the higher doses have less influence on the shape of the curve than at low doses. In addition, models should incorporate fundamental biological factors where such factors are known (e.g., intralitter correlation for developmental toxicity data) in order to account for as much variability in the

data as possible. The Agency is currently using the BMD approach in risk assessments where the data support its use. Draft guidelines for application of the BMD approach also are being developed by the Agency.

Use of BMD methods involves fitting mathematical models to dose-response data obtained primarily from toxicology studies. When considering available models to use for a BMD analysis, it is important to select the model that fits the data the best and is the most biologically appropriate. EPA has developed software following several years of research and development, expert peer review, public comment, subsequent revision, and quality assurance testing. The software (BMDS, Version 1.2) can be downloaded from http://www.epa.gov/ncea/bmds.htm. BMDS facilitates these operations by providing simple data-management tools, a comprehensive help manual, an online help system, and an easy-to-use interface to run multiple models on the same dose-response data.

As part of this software package, EPA has included sixteen (16) different models that are appropriate for the analysis of dichotomous (quantal) data (Gamma, Logistic, Log-Logistic, Multistage, Probit, Log-Probit, Quantal-Linear, Quantal-Quadratic, Weibull), continuous data (Linear, Polynomial, Power, Hill), and nested developmental toxicology data (NLogistic, NCTR, Rai & Van Ryzin). Results from all models include a reiteration of the model formula and model run options chosen by the user, goodness-of-fit information, the BMD, and the estimate of the lower-bound confidence limit on the benchmark dose (BMDL). Model results are presented in textual and graphical output files which can be printed or saved and incorporated into other documents.

B. Categorical Regression

Categorical regression is an emerging technique that may have relevance for the derivation of RfDs or for estimating risk above the RfD (Dourson et al., 1997; Guth et al., 1997). The categorical regression approach, like the BMD approach, can be used to estimate a dose that corresponds to a given probability of adverse effects. This dose would then be divided by UFs to establish an RfD. However, unlike the BMD approach, the Categorical regression approach can incorporate information on different health endpoints in a single dose-response analysis. For those health effects for which studies exist, responses to the substance in question are grouped into severity categories; for example (1) no effect, (2) no adverse effect, (3) mild-to-moderate adverse effect, and (4) frank effect. These categories correspond to the dose categories currently used in setting the RfD, namely, the no-observed-effect level (NOEL), NOAEL, LOAEL, and frank-effect level (FEL), respectively. Logistic transformation or other applicable mathematical operations are used to model the probability of experiencing effects in a certain category as a function of dose (Harrell, 1986; Hertzberg, 1989). The "acceptability" of the fit of the model to the data can be judged using several statistical measures, including the χ^2 statistic, correlation coefficients, and the statistical significance of its model parameter estimates.

The resulting mathematical equation can be used to find a dose (or the lower confidence bound on the dose) at which the probability of experiencing adverse effects does not exceed a selected level, e.g., 10 percent. This dose (like the NOAEL or BMD) would then be divided by

relevant UFs to calculate an RfD. For more detail on how to employ the categorical regression approach, see the discussion in the Risk Assessment TSD (USEPA, 2000).

As with the BMD approach, the categorical regression approach has the advantage of using more of the available dose-response data to account for response variability as well as accounting for uncertainty due to sample size through the use of confidence intervals. Additional advantages of categorical regression include the combining of data sets prior to modeling, thus allowing the calculation of the slope of a dose-response curve for multiple adverse effects rather than only one effect at a time. Another advantage is the ability to estimate risks for different levels of severity from exposures above the RfD.

On the other hand, as with BMD, opinions differ over the amount and adequacy of data necessary to implement the method. The categorical regression approach also requires judgments regarding combining data sets, judging goodness-of-fit, and assigning severity to a particular effect. Furthermore, this approach is still in the developmental stage. It is not recommended for routine use, but may be used when data are available and justify the extensive analyses required.

C. Summary

Whether a NOAEL/UF-based methodology, a BMD, a categorical regression model, or other approach is used to develop the RfD, the dose-response-evaluation step of a risk assessment process should include additional discussion about the nature of the toxicity data and its applicability to human exposure and toxicity. The discussion should present the range of doses that are effective in producing toxicity for a given agent; the route, timing, and duration of exposure; species specificity of effects; and any toxicokinetic or other considerations relevant to extrapolation from the toxicity data to human-health-based AWQC. This information should always accompany the characterization of the adequacy of the data.

3.2.3.2 Presenting the RfD as a Single Point or as a Range for Deriving AWQC

Although the RfD has traditionally been presented and used as a single point, its definition contains the phrase ". . . an estimate (with uncertainty spanning perhaps an order of magnitude) . . ." (USEPA, 1993a). Underlying this concept is the reasoning that the selection of the critical effect and the total uncertainty factor used in the derivation of the RfD is based on the "best" scientific judgment, and that competent scientists examining the same database could derive RfDs which varied within an order of magnitude.

In one instance, IRIS presented the RfD as a point value within an accompanying range. EPA derived a single number as the RfD for arsenic (0.3 μg/kg-day), but added that "strong scientific arguments can be made for various values within a factor of 2 or 3 of the currently recommended RfD value, i.e., 0.1 to 0.8 μg/kg/day" (USEPA, 1993c). EPA noted that regulatory managers should be aware of the flexibility afforded them through this action.

There are situations in which the risk manager can select an alternative value to use in place of the RfD in the AWQC calculations. The domain from which this alternative value can

be selected is restricted to a defined range around the point estimate. As explained further below, the Agency is recommending that sometimes the use of a value other than the calculated RfD point estimate is appropriate in characterizing risk. The selection of an alternative value within an appropriate range must be determined for each individual situation, since several factors affect the selection of the alternative value. Observing similar effects in several animal species, including humans, can increase confidence in the selection of the critical effect and thereby narrow the range of uncertainty. There are other factors that can affect the precision. These include the slope of the dose-response curve, seriousness of the observed effect, dose spacing, and possibly the route for the experimental doses. Dose spacing and the number of animals in the study groups used in the experiment can also affect the confidence in the RfD.

To derive the AWQC, the calculated point estimate of the RfD is the default. Based on consideration of the available data, the use of another number within the range defined by the product of the UF(s) (and MF, if used) could be justified in some specific situations. This means that there are risk considerations which indicate that some value in the range other than the point estimate may be more appropriate, based on human health or environmental fate considerations. For example, the bioavailability of the contaminant in fish tissues is one factor to consider. If bioavailability from fish tissues is much lower than that from water and the RfD was derived from a study in which the contaminant exposure was from drinking water, the alternative to the calculated RfD could be selected from the high end of the range and justified using the quantitative difference in bioavailability.

Most inorganic contaminants, particularly divalent cations, have bioavailability values of 20 percent or less from a food matrix, but are much more available (about 80 percent or higher) from drinking water. Accordingly, the external dose necessary to produce a toxic internal dose would likely be higher for a study where the exposure occurred through the diet rather than the drinking water. As a result, the RfD from a dietary study would likely be higher than that for the drinking water study if equivalent external doses had been used. Conversely, in cases where the NOAEL that was the basis for the RfD came from a dietary study, the alternative value could be slightly lower than the calculated RfD.

Because the uncertainty around the dose-response relationship increases as extrapolation below the observed data increases, the use of an alternative point within the range may be more appropriate in characterizing the risk than the use of the calculated RfD, especially in situations when the uncertainty is high. Therefore, as a matter of policy, the 2000 Human Health Methodology permits the selection of a single point within a range about the calculated RfD to be used as the basis of the AWQC if an adequate justification of the alternative point is provided. More complete discussion of this option, including limitations on the span of the range, is provided in the Risk Assessment TSD (USEPA, 2000).

3.2.3.3 Guidelines to be Adopted for Derivation of Noncancer Health Effects Values

The Agency currently is using the IRIS background document as the general basis for the risk assessment of noncarcinogenic effects of chemicals (USEPA, 1993a). EPA recommends continued use of this document for this purpose. However, it should be noted that the process for evaluating chemicals for inclusion in IRIS is undergoing revision (USEPA, 1996c). The

revised assessments for many chemicals are now available on IRIS and can be consulted as examples of the RfD development process and required supporting documentation.

3.2.3.4 Treatment of Uncertainty Factors/Severity of Effects During the RfD Derivation and Verification Process

During the RfD derivation and toxicology review process, EPA considers the uncertainty in extrapolating between animal species and within individuals of a species, as well as specific uncertainties associated with the completeness of the database. The Agency's RfD Work Group has always considered the severity of the observed effects induced by the chemical under review when choosing the value of the UF with a LOAEL. For example, during the derivation and verification of the RfD for zinc (USEPA, 1992), an uncertainty factor less than the standard factor of 10 (UF of 3) was assigned to the relatively mild decrease in erythrocyte superoxide dismutase activity in human subjects. EPA recommends that the severity of the critical effect be assessed when deriving an RfD and that risk managers be made aware of the severity of the effect and the weight placed on this attribute of the effect when the RfD was derived.

3.2.3.5 Use of Less-Than-90-Day Studies to Derive RfDs

Generally, less-than-90-day experimental studies are not used to derive an RfD. This is based on the rationale that studies lasting for less than 90 days may be too short to detect various toxic effects. However, EPA, has in certain circumstances, derived an RfD based on a less-than-90-day study. For example, the RfD for nonradioactive effects of uranium is based on a 30-day rabbit study (USEPA, 1989). The short-term exposure period was used, because it was adequate for determining doses that cause chronic toxicity. In other cases, it may be appropriate to use a less-than-90-day study because the critical effect is expressed in less than 90 days. For example, the RfD for nitrate was derived and verified using studies that were less than 3-months in duration (USEPA, 1991b). For nitrate, the critical effect of methemoglobinemia in infants occurs in less than 90 days. When it can be demonstrated from other data in the toxicological database that the critical adverse effect is expressed within the study period and that a longer exposure duration would not exacerbate the observed effect or cause the appearance of some other adverse effect, the Agency may choose to use less-than-90-day studies as the basis of the RfD. Such values would have to be used with care because of the uncertainty in determining if other effects might be expressed if exposure was of greater duration than 90 days.

3.2.3.6 Use of Reproductive/Developmental, Immunotoxicity, and Neurotoxicity Data as the Basis for Deriving RfDs

All relevant toxicity data have some bearing on the RfD derivation and verification and are considered by EPA. The "critical" effect is the adverse effect most relevant to humans or, in the absence of an effect known to be relevant to humans, the adverse effect that occurs at the lowest dose in animal studies. If the critical effect is neurotoxicity, EPA will use that endpoint as the basis for the derivation and verification of an RfD, as it did for the RfD for acrylamide. Moreover, the Agency is continually revising its procedures for noncancer risk assessment. For example, EPA has released guidelines for deriving developmental RfDs (RfD_{DT}, USEPA, 1991a), for using reproductive toxicity (USEPA, 1996a), and neurotoxicity (USEPA, 1995) data

in risk assessments. The Agency is currently working on guidelines for using immunotoxicity data to derive RfDs. In addition, the Agency is proceeding with the process of generating acceptable emergency health levels for hazardous substances in acute exposure situations based on established guidelines (NRC, 1993).

3.2.3.7 Applicability of Toxicokinetic Data in Risk Assessment

All pertinent toxicity data should be used in the risk assessment process, including toxicokinetic and mechanistic data. The Agency has used toxicokinetic data in deriving the RfD for cadmium and other compounds and currently is using toxicokinetic data to better characterize human inhalation exposures from animal inhalation experiments during derivation/verification of RfCs. In analogy to the RfD, the RfC is considered to be an estimate of a concentration in the air that is not anticipated to cause adverse noncancer effects over a lifetime of inhalation exposure (USEPA, 1994; Jarabek, 1995a). For RfCs, different dosimetry adjustments are made to account for the differences between laboratory animals and humans in gas uptake and disposition or in particle clearance and retention. This procedure results in calculation of a "human equivalent concentration." Based on the use of these procedures, an interspecies UF of 3 (i.e., approximately $10^{0.5}$), instead of the standard factor of 10, is used in the RfC derivation (Jarabek, 1995b).

Toxicokinetics and toxicodynamics of a chemical each contribute to a chemical's observed toxicity, and specifically, to observed differences among species in sensitivity. Toxicokinetics describes the disposition (i.e., deposition, absorption, distribution, metabolism, and elimination of chemicals in the body) and can be approximated using toxicokinetic models. Toxicodynamics describes the toxic interaction of the agent with the target cell. In the absence of specific data on their relative contributions to the toxic effects observed in species, each is considered to account for approximately one-half of the difference in observed effects for humans compared with laboratory animals. The implication of this assumption is that an interspecies uncertainty factor of 3 rather than 10 could be used for deriving an RfD when valid toxicokinetic data and models can be applied to obtain an oral "human equivalent applied dose" (Jarabek, 1995b). If specific data exist on the relative contribution of either element to observed effects, that proportion will be used. The role exposure duration may play, and whether or not the chemical or its damage may accumulate over time in a particular scenario, also requires careful consideration (Jarabek, 1995c).

3.2.3.8 Consideration of Linearity (or Lack of a Threshold) for Noncarcinogenic Chemicals

It is quite possible that there are chemicals with noncarcinogenic endpoints that have no threshold for effects. For example, in the case of lead, it has not been possible to identify a threshold for effects on neurological development. Other examples could include genotoxic teratogens and germline mutagens. Genotoxic teratogens act by causing mutational events during organogenesis, histogenesis, or other stages of development. Germline mutagens interact with germ cells to produce mutations which may be transmitted to the zygote and expressed during one or more stages of development. However, there are few chemicals which currently have sufficient mechanistic information about these possible modes of action. It should be recognized that although an MOA consistent with linearity is possible (especially for agents

known to be mutagenic), this has yet to be reasonably demonstrated for most toxic endpoints other than cancer.

EPA has recognized the potential for nonthreshold noncarcinogenic endpoints and discussed this issue in the *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991a) and in the 1986 *Guidelines for Mutagenicity Risk Assessment* (USEPA, 1986). An awareness of the potential for such teratogenic/mutagenic effects should be established in order to deal with such data. However, without adequate data to support a genetic or mutational basis for developmental or reproductive effects, the default becomes a UF or MOA approach, which are procedures utilized for noncarcinogens assumed to have a threshold. Therefore, genotoxic teratogens and germline mutagens should be considered an exception while the traditional uncertainty factor approach is the general rule for calculating criteria or values for chemicals demonstrating developmental/reproductive effects. For the exceptional cases, since there is no well-established mechanism for calculating criteria protective of human health from the effects of these agents, criteria will be established on a case-by-case basis. Other types of nonthreshold noncarcinogens must also be handled on a case-by-case basis.

3.2.3.9 Minimum Data Guidance

For details on minimum data guidance for RfD development, see the Risk Assessment TSD (USEPA, 2000).

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4. EXPOSURE

The derivation of AWQC for the protection of human health requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. The two primary pathways of human exposure to pollutants present in a particular ambient waterbody that have been considered in deriving AWQC are direct ingestion of drinking water obtained from that waterbody and the consumption of fish/shellfish obtained from that waterbody. The water pathway also includes other exposures from household uses (e.g., showering). The derivation of an AWQC involves the calculation of the maximum water concentration for a pollutant (i.e., the water quality criteria level) that ensures drinking water and/or fish ingestion exposures will not result in human intake of that pollutant in amounts that exceed a specified level based upon the toxicological endpoint of concern.

The equation for noncancer effects is presented again here, in simplified form, to emphasize the exposure-related parameters (in bold). [Note: the RSC parameter also applies to nonlinear low-dose extrapolation for cancer effects and the other exposure parameters apply to all three of the equations (see Section 1.6).]

$$AWQC = RfD \bullet \boldsymbol{RSC} \bullet \frac{(\boldsymbol{BW})}{\left[\boldsymbol{DI} + (\boldsymbol{FI} \bullet BAF)\right]} \qquad \text{(Equation 4-1)}$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)
FI	=	Fish intake (kg/day)
BAF	=	Bioaccumulation factor (L/kg)

The following subsections discuss exposure issues relevant to the 2000 Human Health Methodology: exposure policy issues; consideration of non-water sources of exposure (the Relative Source Contribution approach); and the factors used in AWQC computation. In relevant sections, science policy and risk management decisions made by EPA are discussed.

4.1 EXPOSURE POLICY ISSUES

This section discusses broad policy issues related to exposure concerning the major objectives that the Agency believes should be met in setting AWQC.

An Exposure Assessment TSD provides greater detail on numerous topics discussed in this guidance: suggested sources of contaminant concentration and exposure intake information; suggestions of survey methods for obtaining and analyzing exposure data necessary for deriving AWQC; summaries of studies on fish consumption among sport fishers and subsistence fishers; more detailed presentation of parameter values (e.g., fish consumption rates, body weights); and additional guidance on the application of the RSC approach.

4.1.1 Sources of Exposure Associated With Ambient Water

4.1.1.1 Appropriateness of Including the Drinking Water Pathway in AWQC

EPA intends to continue including the drinking water exposure pathway in the derivation of its national default human health criteria (AWQC), as has been done since the 1980 AWQC National Guidelines were first published.

EPA recommends inclusion of the drinking water exposure pathway where drinking water is a designated use for the following reasons: (1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained. (2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment. (3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants. (4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

This policy decision has been supported by the States, most of the public stakeholders, and by external peer reviewers. As with the other exposure parameters, States and authorized Tribes have the flexibility to use alternative intake rates if they believe that drinking water consumption is substantively different than EPA's recommended default assumptions of 2 L/day for adults and 1 L/day for children. EPA recommends that States and authorized Tribes use an intake rate that would be protective of a majority of consumers and will consider whether an alternative assumption is adequately protective of a State's or Tribe's population based on the information or rationale provided at the time EPA reviews State and Tribal water quality standards submissions.

4.1.1.2 Setting Separate AWQC for Drinking Water and Fish Consumption

In conjunction with the issue of the appropriateness of including the drinking water pathway explicitly in the derivation of AWQC for the protection of human health, EPA intends to continue its practice of setting a single AWQC for both drinking water and fish/shellfish consumption, and a separate AWQC based on ingestion of fish/shellfish alone. This latter criterion applies in those cases where the designated uses of a waterbody include supporting fishable uses under Section 101(a) of the CWA and, thus, fish or shellfish for human consumption, but not as a drinking water supply source (e.g., non-potable estuarine waters).

EPA does not believe that national water quality criteria for protection of drinking water uses only are particularly useful for two reasons. First, State and Tribal standards for human health are set to protect Section 101(a) uses (e.g., "fishable, swimmable uses") under the CWA. Second, most waters have multiple designated uses. Additionally, the water quality standards program protects aquatic life. The 2000 Human Health Methodology revisions do not change EPA's policy to apply aquatic life criteria to protect aquatic species where they are more sensitive (i.e., when human health criteria would not be protective enough) or where human health via fish or water ingestion is not an issue.

4.1.1.3 Incidental Ingestion from Ambient Surface Waters

The 2000 Human Health Methodology does not routinely include criteria to address incidental ingestion of water from recreational uses. EPA has considered whether there are cases where water quality criteria for the protection of human health based only on fish ingestion (or only criteria for the protection of aquatic life) may not adequately protect recreational users from health effects resulting from incidental water ingestion.

EPA reviewed information that provided estimates of incidental water ingestion rates averaged over time. EPA generally believes that the averaged amount is negligible and will not have any impact on the chemical criteria values representative of both drinking water and fish ingestion. A lack of impact on the criteria values would likely also be true for chemical criteria based on fish consumption only, unless the chemical exhibits no bioaccumulation potential. However, EPA also believes that incidental/accidental water ingestion could be important for the development of microbial contaminant water quality criteria, and for either chemical or microbial criteria for States where recreational uses such as swimming and boating are substantially higher than the national average. EPA also notes that some States have indicated they already have established incidental ingestion rates for use in developing criteria. Therefore, although EPA will not use this intake parameter when deriving its national 304(a) chemical criteria, limited guidance is provided in the Exposure Assessment TSD volume in order to assist States and authorized Tribes that face situations where this intake parameter could be of significance.

4.2 CONSIDERATION OF NON-WATER SOURCES OF EXPOSURE WHEN SETTING AWQC

4.2.1 Policy Background

The 2000 Human Health Methodology uses different approaches for addressing non-water exposure pathways in setting AWQC for the protection of human health depending upon the toxicological endpoint of concern. With those substances for which the appropriate toxic endpoint is carcinogenicity based on a linear low-dose extrapolation, only the two water sources (i.e., drinking water and fish ingestion) are considered in the derivation of the AWQC. Non-water sources are not considered explicitly. In the case of carcinogens based on linear low-dose extrapolation, the AWQC is being determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure. Thus, the AWQC represents the water concentration that would be

expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

Furthermore, health-based criteria values for one medium based on linear low-dose extrapolation typically vary from values for other media in terms of the concentration value, and often the associated risk level. Therefore, the RSC concept could not even theoretically apply unless all risk assessments for a particular carcinogen based on linear low-dose extrapolation resulted in the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk value and level.

In the case of substances for which the AWQC is set on the basis of a carcinogen based on a nonlinear low-dose extrapolation or for a noncancer endpoint where a threshold is assumed to exist, non-water exposures are considered when deriving the AWQC using the RSC approach. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure does not exceed that threshold level.

There has been some discussion of whether it is, in fact, necessary in most cases to explicitly account for other sources of exposure when computing the AWQC for pollutants exhibiting threshold effects. It has been argued that because of the conservative assumptions generally incorporated in the calculation of RfDs (or POD/UF values) used as the basis for the AWQC derivation, total exposures slightly exceeding the RfD are unlikely to produce adverse effects.

EPA emphasizes that the purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD or the POD/UF. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's program office risk characterizations and criteria and standard-setting actions. Numerous EPA workgroups have evaluated the appropriateness of factoring in such exposures, and the Agency concludes that it is important for adequately protecting human health. Consequently, EPA risk management policy has evolved significantly over the last six years. Various EPA program initiatives and policy documents regarding aggregate exposure and cumulative risk have been developed, including the consideration of inhalation and dermal exposures. Additionally, accounting for other exposures has been included in recent mandates (e.g., the Food Quality Protection Act) and, thus, is becoming a requirement for the Agency. The Exposure Decision Tree approach has been shared with other EPA offices, and efforts to coordinate policies on aggregate exposure, where appropriate, have begun. EPA intends to continue developing policy guidance on the RSC issue and guidance to address the concern that human health may not be adequately protected if criteria allow for higher levels of exposure that, combined, may exceed the RfD or POD/UF. EPA also intends to refine the 2000 Human Health Methodology in the future to incorporate additional guidance on inhalation and dermal exposures. As stated previously, EPA is required to derive national water quality criteria under Section 304(a) of the CWA and does not intend to derive site-specific criteria. However, States and authorized Tribes have the flexibility to make alternative exposure and RSC estimates based on local data, and EPA strongly encourages this.

Uncertainty factors used in the derivation of the RfD (or POD/UF) to account for intra- and interspecies variability and the incompleteness of the toxicity data set(s)/animal studies are specifically relevant to the chemical's internal toxicological action, irrespective of the sources of exposure that humans may be experiencing. The Agency's policy is to consider and account for other sources of exposure in order to set protective health criteria. EPA believes that multiple route exposures may be particularly important when uncertainty factors associated with the RfD are small. Although EPA is well aware that RfDs are not all equivalent in their derivation, EPA does not believe that uncertainty in the toxicological data should result in less stringent criteria by ignoring exposure sources. However, the RSC policy approach does allow less stringent assumptions when multiple sources of exposure are not anticipated.

The AWQC are designed to be protective criteria, generally applicable to the waters of the United States. While EPA cannot quantitatively predict the actual human health risk associated with combined exposures above the RfD or POD/UF, a combination of health criteria for multiple media exceeding the RfD or POD/UF may not be sufficiently protective. Therefore, EPA's policy is to routinely account for all sources and routes of non-occupational exposure when setting AWQC for noncarcinogens and for carcinogens based on nonlinear low-dose extrapolations. EPA believes that maintaining total exposure below the RfD (or POD/UF) is a reasonable health goal and that there are circumstances where health-based criteria for a chemical should not exceed the RfD (or POD/UF), either alone (if only one criterion is relevant, along with other intake sources considered as background exposures) or in combination. EPA believes its RSC policy ensures this goal.

Also, given the inability to reasonably predict future changes in exposure patterns, the uncertainties in the exposure estimates due to typical data inadequacy, possible unknown sources of exposure, and the potential for some populations to experience greater exposures than indicated by the available data, EPA believes that utilizing the entire RfD (or POD/UF) does not ensure adequate protection.

4.2.2 The Exposure Decision Tree Approach

As indicated in Section 1, EPA has, in the past, used a "subtraction" method to account for multiple sources of exposure to pollutants. In the subtraction method, other sources of exposure (i.e., those other than the drinking water and fish exposures) are subtracted from the RfD (or POD/UF). However, EPA also previously used a "percentage" method for the same purpose. In this approach, the percentage of total exposure typically accounted for by the exposure source for which the criterion is being determined, referred to as the relative source contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD "apportioned" to that source. With both procedures, a "ceiling" level of 80 percent of the RfD and a "floor level" of 20 percent of the RfD are applied.

The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. The percentage method is recommended in the context of the above goals when multiple media criteria are at issue. The percentage method does not simply depend on the amount of a contaminant in the prospective criterion source only. It is intended to reflect health considerations, the relative portions of other sources, and the likelihood for ever-changing levels

in each of those multiple sources (due to ever-changing sources of emissions and discharges). Rather than simply defaulting in every instance, the Agency attempts to compare multiple source exposures with one another to estimate their relative contribution to the total–given that understanding the degree to which their concentrations vary, or making any distributional analysis, is often not possible. The criteria levels, when multiple criteria are at issue, are based on the actual levels, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability.

The specific RSC approach recommended by EPA, which we will use for the derivation of AWQC for noncarcinogens and carcinogens assessed using nonlinear low-dose extrapolation, is called the Exposure Decision Tree and is described below. To account for exposures from other media when setting an AWQC (i.e., non-drinking water/non-fish ingestion exposures, and inhalation or dermal exposures), the Exposure Decision Tree for determining proposed RfD or POD/UF apportionments represents a method of comprehensively assessing a chemical for water quality criteria development. This method considers the adequacy of available exposure data, levels of exposure, relevant sources/media of exposure, and regulatory agendas (i.e., whether there are multiple health-based criteria or regulatory standards for the same chemical). The Decision Tree addresses most of the disadvantages associated with the exclusive use of either the percentage or subtraction approaches, because they are not arbitrarily chosen prior to determining the following: specific population(s) of concern, whether these populations are relevant to multiple-source exposures for the chemical in question (i.e., whether the population is actually or potentially experiencing exposure from multiple sources), and whether levels of exposure, regulatory agendas, or other circumstances make apportionment of the RfD or POD/UF desirable. Both subtraction and percentage methods are potentially utilized under different circumstances with the Exposure Decision Tree approach, and the Decision Tree is recommended with the idea that there is enough flexibility to use other procedures if information on the contaminant in question suggests it is not appropriate to follow the Decision Tree. EPA recognizes that there may be other valid approaches in addition to the Exposure Decision Tree.

The Exposure Decision Tree approach allows flexibility in the RfD (or POD/UF) apportionment among sources of exposure. When adequate data are available, they are used to make protective exposure estimates for the population(s) of concern. When other sources or routes of exposure are anticipated but data are not adequate, there is an even greater need to make sure that public health protection is achieved. For these circumstances, a series of qualitative alternatives is used (with the less adequate data or default assumptions) that allow for the inadequacies of the data while protecting human health. Specifically, the Decision Tree makes use of chemical information when actual monitoring data are inadequate. It considers information on the chemical/physical properties, uses of the chemical, and environmental fate and transformation, as well as the likelihood of occurrence in various media. Review of such information, when available, and determination of a reasonable exposure characterization for the chemical will result in a water quality criterion that more accurately reflects exposures than automatically using a default value. Although the 20 percent default will still generally be used when information is not adequate, the need for using it should be reduced. There may also be some situations where EPA would consider the use of an 80 percent default (see Section 4.2.3).

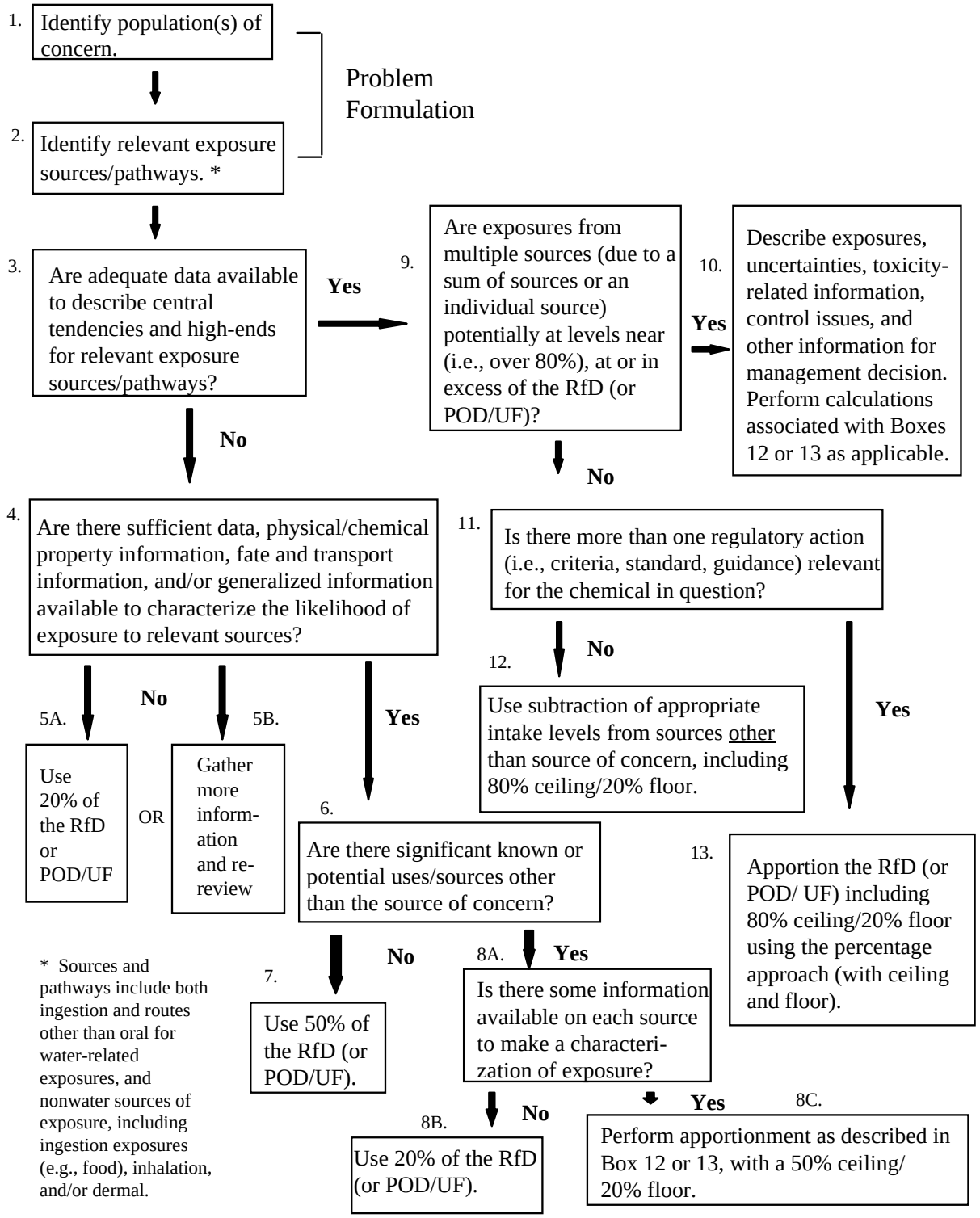
The Decision Tree also allows for use of either the subtraction or percentage method to account for other exposures, depending on whether one or more health-based criterion is relevant for the chemical in question. The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. In these cases, other sources of exposure can be considered "background" and can be subtracted from the RfD (or POD/UF).

EPA cautions States and Tribes when using the subtraction method in these circumstances. The subtraction method results in a criterion allowing the maximum possible chemical concentration in water after subtracting other sources. As such, it removes any cushion between pre-criteria levels (i.e., actual "current" levels) and the RfD, thereby setting criteria at the highest levels short of exceeding the RfD. It is somewhat counter to the goals of the CWA for maintaining and restoring the nation's waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. The subtraction method generally results in criteria levels of a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to such goals. In fact, many chemicals have pre-criteria levels in environmental media substantially lower (compared to the RfD) than the resulting criteria allow.

When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of criteria and, thus, the potential for resulting exposures do not exceed the RfD (or POD/UF). The Exposure Decision Tree (with numbered boxes) is shown in Figure 4-1. The explanation in the text on the following pages must be read in tandem with the Decision Tree figure; the text in each box of the figure only nominally identifies the process and conditions for determining the outcome for that step of the Decision Tree. The underlying objective is to maintain total exposure below the RfD (or POD/UF) while generally avoiding an extremely low limit in a single medium that represents just a nominal fraction of the total exposure. To meet this objective, all proposed numeric limits lie between 80 percent and 20 percent of the RfD (or POD/UF). Again, EPA will use the Exposure Decision Tree approach when deriving its AWQC but also recognizes that departures from the approach may be appropriate in certain cases. EPA understands that there may be situations where the Decision Tree procedure is not practicable or

Figure 4-1

Exposure Decision Tree for Defining Proposed RfD (or POD/UF) Apportionment



may be simply irrelevant after considering the properties, uses, and sources of the chemical in question. EPA endorses such flexibility by States and authorized Tribes when developing alternative water quality criteria in order to choose other procedures that are more appropriate for setting health-based criteria and, perhaps, apportioning the RfD or POD/UF, as long as reasons are given as to why it is not appropriate to follow the Exposure Decision Tree approach and as long as the steps taken to evaluate the potential sources and levels of exposure are clearly described. Often, however, the common situation of multiple exposure sources for a chemical is likely to merit a Decision Tree evaluation for the purpose of developing human health water quality criteria for a given chemical.

It is clear that this will be an interactive process; input by exposure assessors will be provided to, and received from, risk managers throughout the process, given that there may be significant implications regarding control issues (i.e., cost/feasibility), environmental justice issues, etc. In cases where the Decision Tree is not chosen, communication and concurrence about the decision rationale and the alternative water quality criteria are of great importance.

Descriptions of the boxes within the Decision Tree are separated by the following process headings to facilitate an understanding of the major considerations involved. The decision to perform, or not to perform, an apportionment could actually be made at several points during the Decision Tree process. Working through the process is most helpful for identifying possible exposure sources and the potential for exposure, determining the relevancy of the Decision Tree to developing an AWQC for a particular chemical and, possibly, determining the appropriateness of using an alternative approach to account for overall exposure. "Relevancy" here means determining whether more than one criterion, standard, or other guidance is being planned or is in existence for the chemical in question. Additional guidance for States and Tribes that wish to use the Exposure Decision Tree is provided in the Exposure Assessment TSD.

4.2.2.1 Problem Formulation

Initial Decision Tree discussion centers around the first two boxes: identification of population(s) of concern (Box 1) and identification of relevant exposure sources and pathways (Box 2). The term "problem formulation" refers to evaluating the population(s) and sources of exposure in a manner that allows determination of the potential for the population of concern to experience exposures from multiple sources for the chemical in question. Also, the data for the chemical in question must be representative of each source/medium of exposure and be relevant to the identified population(s). Evaluation includes determining whether the levels, multiple criteria or regulatory standards, or other circumstances make apportionment of the RfD or POD/UF reasonable. The initial problem formulation also determines the exposure parameters chosen, the intake assumptions chosen for each route, and any environmental justice or other social issues that aid in determining the population of concern. The term "data," as used here and discussed throughout this section, refers to ambient sampling data (whether from Federal, regional, State, or area-specific studies) and not internal human exposure measurements.

4.2.2.2 Data Adequacy

In Box 3, it is necessary that adequate data exist for the relevant sources/pathways of exposure if one is to avoid using default procedures. The adequacy of data is a professional judgment for each individual chemical of concern, but EPA recommends that the minimum acceptable data for Box 3 are exposure distributions that can be used to determine, with an acceptable 95 percent confidence interval, the central tendency and high-end exposure levels for each source. In fact, distributional data may exist for some or most of the sources of exposure.

There are numerous factors to consider in order to determine whether a dataset is adequate. These include: (1) sample size (i.e., the number of data points); (2) whether the data set is a random sample representative of the target population (if not, estimates drawn from it may be biased no matter how large the sample); (3) the magnitude of the error that can be tolerated in the estimate (estimator precision); (4) the sample size needed to achieve a given precision for a given parameter (e.g., a larger sample is needed to precisely estimate an upper percentile than a mean or median value); (5) an acceptable analytical method detection limit; and (6) the functional form and variability of the underlying distribution, which determines the estimator precision (e.g., whether the distribution is normal or lognormal and whether the standard deviation is 1 or 10). Lack of information may prevent assessment of each of these factors; monitoring study reports often fail to include background information or sufficient summary statistics (and rarely the raw data) to completely characterize data adequacy. Thus, a case-by-case determination of data adequacy may be necessary.

That being stated, there are some guidelines, as presented below, that lead to a rough rule-of-thumb on what constitutes an "adequate" sample size for exposure assessment. Again, first and foremost, the representativeness of the data for the population evaluated and the analytical quality of the data must be acceptable. If so, the primary objective then becomes estimating an upper percentile (e.g., say the 90th) and a central tendency value of some exposure distribution based on a random sample from the distribution. Assuming that the distribution of exposures is unknown, a nonparametric estimate of the 90th percentile is required. The required estimate, based on a random sample of *n* observations from a target population, is obtained by ranking the data from smallest to largest and selecting the observation whose rank is 1 greater than the largest integer in the product of 0.9 times *n*. For example, in a data set of 25 points, the nonparametric estimate of the 90th percentile is the 23rd largest observation.

In addition to this point estimate, it is useful to have an upper confidence bound on the 90th percentile. To find the rank of the order statistic that gives an upper 95 percent confidence limit on the 90th percentile, the smallest value of *r* that satisfies the following formula is determined:

$$0.95 \approx \sum_{i=0}^{r-1} \binom{n}{i} 0.9^{i}\ 0.1^{n-i} \qquad \text{(Equation 4-2)}$$

where:

r	=	the rank order of the observation
n	=	the number of observations
I	=	integer from 0 to r - 1

For relatively small data sets, the above formula will lead to selecting the largest observation as the upper confidence limit on the 90th percentile. However, the problem with using the maximum is that, in many environmental datasets, the largest observation is an outlier and would provide an unrealistic upper bound on the 90th percentile. It would, therefore, be preferable if the sample size *n* were large enough so that the formula yielded the second largest observation as the confidence limit (see for example Gibbons, 1971).

This motivates establishing the following criterion for setting an "adequate" sample size: pick the smallest *n* such that the nonparametric upper 95 percent confidence limit on the 90th percentile is the second largest value. Application of the above formula with *r* set to *n*-1 yields *n* = 45 for this minimum sample size.

For the upper 95 percent confidence limit to be a useful indicator of a high-end exposure, it must not be overly conservative (too large relative to the 90th percentile). It is, therefore, of interest to estimate the expected magnitude of the ratio of the upper 95 percent confidence limit to the 90th percentile. This quantity generally cannot be computed, since it is a function of the unknown distribution. However, to get a rough idea of its value, consider the particular case of a normal distribution. If the coefficient of variation (i.e., the standard deviation divided by the mean) is between 0.5 and 2.0, the expected value of the ratio in samples of 45 will be approximately 1.17 to 1.31; i.e., the upper 95 percent confidence limit will be only about 17 to 31 percent greater than the 90th percentile on the average.

It should be noted that the nonparametric estimate of the 95 percent upper confidence limit based on the second largest value can be obtained even if the data set has only two detects (it is assumed that the two detects are greater than the detection limit associated with all non-detects). This is an argument for using nonparametric rather than parametric estimation, since use of parametric methods would require more detected values. On the other hand, if non-detects were not a problem and the underlying distribution were known, a parametric estimate of the 90th percentile would generally be more precise.

As stated above, adequacy also depends on whether the samples are relevant to and representative of the population at risk. Data may, therefore, be adequate for some decisions and inadequate for others; this determination requires some professional judgment.

If the answer to Box 3 is no, based on the above determination of adequacy, then the decision tree moves to Box 4. As suggested by the separate boxes, the available data that will be reviewed as part of Box 4 do not meet the requirements necessary for Box 3. In Box 4, any limited data that are available (in addition to information about the chemical/physical properties, uses, and environmental fate and transformation, as well as any other information that would characterize the likelihood of exposure from various media for the chemical) are evaluated to

make a qualitative determination of the relation of one exposure source to another. Although this information should always be reviewed at the outset, it is recommended that this information also be used to estimate the health-based water quality criteria. The estimate should be rather conservative (as indicated in the Decision Tree), given that it is either not based on actual monitoring data or is based on data that has been considered to be inadequate for a more accurate quantitative estimate. Therefore, greater uncertainties exist and accounting for variability is not really possible. Whether the available data are adequate and sufficiently representative will likely vary from chemical to chemical and may depend on the population of concern. If there are some data and/or other information to make a characterization of exposure, a determination can be made as to whether there are significant known or potential uses for the chemical/sources of exposure other than the source of concern (i.e., in this case, the drinking water and fish intakes relevant to developing an AWQC) that would allow one to anticipate/quantify those exposures (Box 6). If there are not, then it is recommended that 50 percent of the RfD or POD/UF can be safely apportioned to the source of concern (Box 7). While this leaves half of the RfD or POD/UF unapportioned, it is recommended as the maximum apportionment due to the lack of data needed to more accurately quantify actual or potential exposures. If the answer to the question in Box 6 is yes (there is multiple source information available for the exposures of concern), and some information is available on each source of exposure (Box 8A), apply the procedure in either Box 12 or Box 13 (depending on whether one or more criterion is relevant to the chemical), using a 50 percent ceiling (Box 8C)–again due to the lack of adequate data. If the answer to the question in Box 8A is no (there is no available information to characterize exposure), then the 20 percent default of the RfD or POD/UF is used (Box 8B).

If the answer to the question in Box 4 is no; that is, there are not sufficient data/information to characterize exposure, EPA intends to generally use the "default" assumption of 20 percent of the RfD or POD/UF (Box 5A) when deriving or revising the AWQC. It may be better to gather more data or information and re-review when this information becomes available (Box 5B). EPA has done this on occasion when resources permit the acquisition of additional data to enable better estimates of exposure instead of the default. If this is not possible, then the assumption of 20 percent of the RfD or POD/UF (Box 5A) should be used. Box 5A is likely to be used infrequently with the Exposure Decision Tree approach, given that the information described in Box 4 should be available in most cases. However, EPA intends to use 20 percent of the RfD (or POD/UF), which has also been used in past water program regulations, as the default value.

4.2.2.3 Regulatory Actions

If there are adequate data available to describe the central tendencies and high ends from each exposure source/pathway, then the levels of exposure relative to the RfD or POD/UF are compared (Box 9). If the levels of exposure for the chemical in question are not near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF, then a subsequent determination is made (Box 11) as to whether there is more than one health-based criterion or regulatory action relevant for the given chemical (i.e., more than one medium-specific criterion,

standard or other guidance being planned, performed or in existence for the chemical). The subtraction method is considered acceptable when only one criterion (standard, etc.) is relevant for a particular chemical. In these cases, other sources of exposure can be considered "background" and can be subtracted from the RfD (or POD/UF). When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of health criteria, and thus the potential for resulting exposures, do not exceed the RfD (or POD/UF).

As indicated in Section 2, for EPA's national 304(a) criteria, the RSC intake estimates of non-water exposures (e.g., non-fish dietary exposures) will be based on arithmetic mean values when data are available. The assumed body weight used in calculating the national criteria will also be based on average values. The drinking water and fish intake values are 90th percentile estimates. EPA believes that these assumptions will be protective of a majority of the population and recommends them for State and Tribal use. However, States and authorized Tribes have the flexibility to choose alternative intake rate and exposure estimate assumptions to protect specific population groups that they have chosen.

4.2.2.4 Apportionment Decisions

If the answer to the question in Box 11 is no (there is not more than one relevant medium-specific criterion/regulatory action), then the recommended method for setting a health-based water quality criterion is to utilize a subtraction calculation (Box 12). Specifically, appropriate intake values for each exposure source other than the source of concern are subtracted out. EPA will rely on average values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values, for calculating RSC estimates to subtract. Alternatively, contaminant concentrations could be selected based on the variability associated with those concentrations for each source. This implies that a case-by-case determination of the variability and the resulting intake chosen would be made, as each chemical evaluated can be expected to have different variations in concentration associated with each source of intake. However, EPA anticipates that the available data for most contaminants will not allow this for determination (based on past experience). Guidance addressing this possibility is addressed in the Exposure Assessment TSD. EPA does not recommend that high-end intakes be subtracted for every exposure source, since the combination may not be representative of any actually exposed population or individual. The subtraction method would also include an 80 percent ceiling and a 20 percent floor.

If the answer to the question in Box 11 is yes (there is more than one medium-specific criterion/regulation relevant), then the recommended method for setting health-based water quality criteria is to apportion the RfD or POD/UF among those sources for which health-based criteria are being set (Box 13). This is done via a percentage approach (with a ceiling and floor). This simply refers to the percentage of overall exposure contributed by an individual exposure source. For example, if for a particular chemical, drinking water were to represent half of total exposure and diet were to represent the other half, then the drinking water contribution (or RSC) would be 50 percent. The health-based criteria would, in turn, be set at 50 percent of the RfD or POD/UF. This method also utilizes an appropriate combination of intake values for each

exposure source based on values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values.

Finally, if the levels of exposure for the chemical in question are near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF (i.e., the answer in Box 9 is yes), then the estimates of exposures and related uncertainties, recommended apportionment (either box 12 or 13), toxicity-related information, control issues, and other information are to be presented to managers for a decision (Box 10). The high levels referred to in Box 9 may be due to one source contributing that high level (while other sources contribute relatively little) or due to more than one source contributing levels that, in combination, approach or exceed the RfD or POD/UF. Management input may be necessary due to the control issues (i.e., cost and feasibility concerns), especially when multiple criteria are at issue. In practice, risk managers are routinely a part of decisions regarding regulatory actions and will be involved with any recommended outcome of the Exposure Decision Tree or, for that matter, any alternative to the Exposure Decision Tree. However, because exposures approach or exceed the RfD or POD/UF and because the feasibility of controlling different sources of exposure are complicated issues, risk managers will especially need to be directly involved in final decisions in these circumstances.

It is emphasized here that the procedures in these circumstances are not different than the procedures when exposures are not at or above the RfD (or POD/UF). Therefore, in these cases, estimates should be performed as with Boxes 11, 12, and 13. The recommendation should be made based on health-based considerations only, just as when the chemical in question was not a Box 10 situation. If the chemical is relevant to one health criterion or regulatory action only, the other sources of exposure could be subtracted from the RfD or POD/UF to determine if there is any leftover amount for setting the criterion. If the chemical is a multiple media criteria issue, then an apportionment should be made, even though it is possible that all sources would need to be reduced. Regardless of the outcome of Box 9, all apportionments made (via the methods of Boxes 12 or 13) should include a presentation of the uncertainty in the estimate and in the RfD or POD/UF for a more complete characterization.

The process for a Box 10 situation (versus a situation that is not) differs in that the presentations for Boxes 12 and 13 are based on apportionments (following the review of available information and a determination of appropriate exposure parameters) that must address additional control issues and may result in more selective reductions. With Box 10, one or several criteria possibilities ("scenarios") could be presented for comparison along with implications of the effects of various control options. It is appropriate to present information in this manner to risk managers given the complexity of these additional control issues.

4.2.3 Additional Points of Clarification on the Exposure Decision Tree Approach for Setting AWQC

As with Box 9, if a determination is made in Box 8A (i.e., information is available to characterize exposure) that exposures are near, at, or above the RfD (or POD/UF) based on the available information, the apportionments made need to be presented to risk managers for decision. If information is lacking on some of the multiple exposure sources, then EPA would use a default of 20 percent of the RfD or POD/UF (Box 8B).

Results of both Boxes 12 and 13 rely on the 80 percent ceiling and 20 percent floor. The 80 percent ceiling was implemented to ensure that the health-based goal will be low enough to provide adequate protection for individuals whose total exposure to a contaminant is, due to any of the exposure sources, higher than currently indicated by the available data. This also increases the margin of safety to account for possible unknown sources of exposure. The 20 percent floor has been traditionally rationalized to prevent a situation where small fractional exposures are being controlled. That is, below that point, it is more appropriate to reduce other sources of exposure, rather than promulgating standards for *de minimus* reductions in overall exposure.

If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling. EPA qualifies this policy with the understanding that as its policy on cumulative risk assessment continues to develop, the 80 percent RSC may prove to be underprotective.

In the cases of pollutants for which substantial data sets describing exposures across all anticipated pathways of exposure exist, and probabilistic analyses have been conducted based on those data, consideration will be given to the results of those assessments as part of the Exposure Decision Tree approach for setting AWQC.

For many chemicals, the rate of absorption from ingestion can differ substantially from absorption by inhalation. There is also available information for some chemicals that demonstrates appreciable differences in gastrointestinal absorption depending on whether the chemical is ingested from water, soil, or food. For some contaminants, the absorption of the contaminant from food can differ appreciably for plant compared with animal food products. Regardless of the apportionment approach used, EPA recommends using existing data on differences in bioavailability between water, air, soils, and different foods when estimating total exposure for use in apportioning the RfD or POD/UF. The Agency has developed such exposure estimates for cadmium (USEPA, 1994). In the absence of data, EPA will assume equal rates of absorption from different routes and sources of exposure.

4.2.4 Quantification of Exposure

When selecting contaminant concentration values in environmental media and exposure intake values for the RSC analysis, it is important to realize that each value selected (including those recommended as default assumptions in the AWQC equation) may be associated with a distribution of values for that parameter. Determining how various subgroups fall within the distributions of overall exposure and how the combination of exposure variables defines what population is being protected is a complicated and, perhaps, unmanageable task, depending on the amount of information available on each exposure factor included. Many times, the default assumptions used in EPA risk assessments are derived from the evaluation of numerous studies and are considered to generally represent a particular population group or a national average. Therefore, describing with certainty the exact percentile of a particular population that is protected with a resulting criteria is often not possible.

By and large, the AWQC are derived to protect the majority of the general population from chronic adverse health effects. However, as stated above in Section 4.1.1.1, States and authorized Tribes are encouraged to consider protecting population groups that they determine are at greater risk and, thus, would be better protected using alternative exposure assumptions. The ultimate choice of the contaminant concentrations used in the RSC estimate and the exposure intake rates requires the use of professional judgment. This is discussed in greater detail in the Exposure Assessment TSD.

4.2.5 Inclusion of Inhalation and Dermal Exposures

EPA intends to develop policy guidelines to apply to this Methodology for explicitly incorporating inhalation and dermal exposures. When estimating overall exposure to pollutants for AWQC development, EPA believes that the sources of inhalation and dermal exposures considered should include, on a case-by-case basis, both non-oral exposures from water and other inhalation and dermal sources (e.g., ambient or indoor air, soil). When the policy guidelines are completed, this Methodology will be refined to include that guidance.

A number of drinking water contaminants are volatile and thus diffuse from water into the air where they may be inhaled. In addition, drinking water is used for bathing and, thus, there is at least the possibility that some contaminants in water may be dermally absorbed. Volatilization may increase exposure via inhalation and decrease exposure via ingestion and dermal absorption. The net effect of volatilization and dermal absorption upon total exposure to volatile drinking water contaminants is unclear in some cases and varies from chemical to chemical. Dermal exposures are also important to consider for certain population groups, such as children and other groups with high soil contact.

With regard to additional non-water related exposures, it is clear that the type and magnitude of toxicity produced via inhalation, ingestion, and dermal contact may differ; that is, the route of exposure can affect absorption of a chemical and can otherwise modify its toxicity. For example, an inhaled chemical such as hydrogen fluoride may produce localized effects on the lung that are not observed (or only observed at much higher doses) when the chemical is administered orally. Also, the active form of a chemical (and principal toxicity) can be the parent compound and/or one or more metabolites. With this Methodology, EPA recommends that differences in absorption and toxicity by different routes of exposure be determined and accounted for in dose estimates and applied to the exposure assessment. EPA acknowledges that the issue of whether the doses received from inhalation and ingestion exposures are cumulative (i.e., toward the same threshold of toxicity) is complicated. Such a determination involves evaluating the chemical's physical characteristics, speciation, and reactivity. A chemical may also exhibit different metabolism by inhalation versus oral exposure and may not typically be metabolized by all tissues. In addition, a metabolite may be much more or much less toxic than the parent compound. Certainly with a systemic effect, if the chemical absorbed via different routes enters the bloodstream, then there is some likelihood that it will contact the same target organ. Attention also needs to be given to the fact that both the RfD and RfC are derived based on the administered level. Toxicologists generally believe that the effective concentration of the active form of a chemical(s) at the site(s) of action determines the toxicity. If specific differences between routes of exposure are not known, it may be reasonable to assume that the

internal concentration at the site from any route contributes as much to the same effect as any other route. A default of assuming equal absorption has often been used. However, for many of the chemicals that the Agency has reviewed, there is a substantial amount of information already known to determine differences in rates of absorption. For example, absorption is, in part, a function of blood solubility (i.e., Henry's Constant) and better estimations than the default can be made.

The RSC analyses that accompany the 2000 Human Health Methodology accommodate inclusion of inhalation exposures. Even if different target organs are involved between different routes of exposure, a conservative policy may be appropriate to keep all exposures below a certain level. A possible alternative is to set allowable levels (via an equation) such that the total of ingestion exposures over the ingestion RfD added to the total of inhalation exposures over the inhalation RfC is not greater than 1 (Note: the RfD is typically presented in mg/kg-day and the RfC is in mg/m^3). Again, EPA intends to develop guidance for this Methodology to explicitly incorporate inhalation and dermal exposures, and will refine the Methodology when that guidance is completed.

4.3 EXPOSURE FACTORS USED IN THE AWQC COMPUTATION

This section presents values for the specific exposure factors that EPA will use in the derivation of AWQC. These include human body weight, drinking water consumption rates, and fish ingestion rates.

When choosing exposure factor values to include in the derivation of a criterion for a given pollutant, EPA recommends considering values that are relevant to population(s) that is (are) most susceptible to that pollutant. In addition, highly exposed populations should be considered when setting criteria. In general, exposure factor values specific to adults and relevant to lifetime exposures are the most appropriate values to consider when determining criteria to protect against effects from long-term exposure which, by and large, the human health criteria are derived to protect. However, infants and children may have higher rates of water and food consumption per unit body weight compared with adults and also may be more susceptible to some pollutants than adults (USEPA, 1997a). There may be instances where acute or subchronic developmental toxicity makes children the population group of concern. In addition, exposure of pregnant women to certain toxic chemicals may cause developmental effects in the fetus (USEPA, 1997b). Exposures resulting in developmental effects may be of concern for some contaminants and should be considered along with information applicable to long-term health effects when setting AWQC. (See Section 3.2 for further discussion of this issue.) Short-term exposure may include multiple intermittent or continuous exposures occurring over a week or so. Exposure factor values relevant for considering chronic toxicity, as well as exposure factor values relevant for short-term exposure developmental concerns, that could result in adverse health effects are discussed in the sections below. In appropriate situations, EPA may consider developing criteria for developmental health effects based on exposure factor values specific to children or to women of childbearing age. EPA encourages States and Tribes to do the same when health risks are associated with short-term exposures.

EPA believes that the recommended exposure factor default intakes for adults in chronic exposure situations are adequately protective of the population over a lifetime. In providing additional exposure intake values for highly exposed subpopulations (e.g., sport anglers, subsistence fishers), EPA is providing flexibility for States and authorized Tribes to establish criteria specifically targeted to provide additional protection using adjusted values for exposure parameters for body weight, drinking water intake, and fish consumption. The exposure factor values provided for women of childbearing age and children would only be used in the circumstances indicated above.

Each of the following sections recommends exposure parameter values for use in developing AWQC. These are based on both science policy decisions that consider the best available data, as well as risk management judgments regarding the overall protection afforded by the choice in the derivation of AWQC. These will be used by EPA to derive new, or revise existing, 304(a) national criteria.

4.3.1 Human Body Weight Values for Dose Calculations

The source of data for default human body weights used in deriving the AWQC is the third *National Health and Nutrition Examination Survey* (NHANES III). NHANES III represents a very large interview and examination endeavor of the National Center for Health Statistics (NCHS) and included participation from the Centers for Disease Control (CDC). The NHANES III was conducted on a nationwide probability sample of over 30,000 persons from the civilian, non-institutionalized population of the United States. The survey began in October 1988 and was completed in October 1994 (WESTAT, 2000; McDowell, 2000). Body weight data were taken from the NHANES III Examination Data File. Sampling weights were applied to all persons examined in the Mobile Examination Centers (MECs) or at home, as was recommended by the NHANES data analysts (WESTAT, 2000).

The NHANES III survey has numerous strengths and very few weaknesses. Its primary strengths are the national representativeness, large sample size, and precise estimates due to this large sample size. Another strength is its high response rate; the examination rate was 73 percent overall, 89 percent for children under 1 year old, and approximately 85 percent for children 1 to 5 years old (McDowell, 2000). Interview response rates were even higher, but the body weight data come from the NHANES examinations; that is, all body weights were carefully measured by survey staff, rather than the use of self-reported body weights. The only significant potential weakness of the NHANES data is the fact that the data are now between 6 and 12 years old. Given that there were upward trends in body weight from NHANES II to NHANES III, and that NCHS has indicated the prevalence of overweight people increased in all age groups, the data could underestimate current body weights if that trend has continued (WESTAT, 2000).

The NHANES III collected standard body measurements of sample subjects, including height and weight, that were made at various times of the day and in different seasons of the year. This technique was used because one's weight may vary between winter and summer and may fluctuate with recency of food and water intake and other daily activities (McDowell, 2000).

As with the other exposure assumptions, States and authorized Tribes are encouraged to use alternative body weight assumptions for population groups other than the general population and to use local or regional data over default values as more representative of their target population group(s).

4.3.1.1 Rate Protective of Human Health from Chronic Exposure

EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults. As previously indicated, exposure factor values specific to adults are recommended to protect against effects from long-term exposure. The value of 70 kg is based on the following information. In the analysis of the NHANES III database, median and mean values for female adults 18-74 years old are 65.8 and 69.5 kg, respectively (WESTAT, 2000). For males in the same age range, the median and mean values are 79.9 and 82.1 kg, respectively. The mean body weight value for men and women ages 18 to 74 years old from this survey is 75.6 kg (WESTAT, 2000). This mean value is higher than the mean value for adults ages 20-64 years old of 70.5 kg from a study by the National Cancer Institute (NCI) which primarily measured drinking water intake (Ershow and Cantor, 1989). The NCI study is described in the subsection on Drinking Water Intake Rates that follows (Section 4.3.2). The value from the NHANES III database is also higher than the value given in the revised EPA *Exposure Factors Handbook* (USEPA, 1997b), which recommends 71.8 kg for adults, based on the older NHANES II data. The Handbook also acknowledges the commonly used 70 kg value and encourages risk assessors to use values which most accurately reflect the exposed population. However, the point is also made that the 70 kg value is used in the derivation of cancer slope factors and unit risks that appear in IRIS. Consistency is advocated between the dose-response relationship and exposure factors assumed. Therefore, if a value higher than 70 kg is used, the assessor needs to adjust the dose-response relationship as described in the Appendix to Chapter 1, Volume 1 of the Handbook (USEPA, 1997b).

4.3.1.2 Rates Protective of Developmental Human Health Effects

As noted above, pregnant women may represent a more appropriate population for which to assess risks from exposure to chemicals in ambient waters in some cases, because of the potential for developmental effects in fetuses. In these cases, body weights representative of women of childbearing age may be appropriate to adequately protect offspring from such health effects. To determine a mean body weight value appropriate to this population, separate body weight values for women in individual age groups within the range of 15 to 44 years old were analyzed from the NHANES III data (WESTAT, 2000). The resulting median and mean body weight values are 63.2 and 67.3 kg, respectively. Ershow and Cantor (1989) present body weight values specifically for pregnant women included in the survey; median and mean weights are 64.4 and 65.8 kilograms, respectively. Ershow and Cantor (1989), however, do not indicate the ages of these pregnant women. Based on this information for women of childbearing age and pregnant women, EPA recommends use of a body weight value of 67 kg in cases where pregnant women are the specific population of concern and the chemical of concern exhibits reproductive and/or developmental effects (i.e., the critical effect upon which the RfD or POD/UF is based). Using the 67 kg assumption would result in lower (more protective) criteria than criteria based on 70 kg.

As discussed earlier, because infants and children generally have a higher rate of water and food consumption per unit body weight compared with adults, a higher intake rate per unit body weight may be needed when comparing estimated exposure doses with critical doses when RfDs are based on health effects in children. To calculate intake rates relevant to such effects, the body weight of children should be used. As with the default body weight for pregnant women, EPA is not recommending the development of additional AWQC (i.e., similar to drinking water health advisories) that focus on acute or short-term effects, since these are not seen routinely as having a meaningful role in the water quality criteria program. However, there may be circumstances where the consideration of exposures for these groups is warranted. Although the AWQC generally are based on chronic health effects data, they are intended to also be protective with respect to adverse effects that may reasonably be expected to occur as a result of elevated shorter-term exposures. EPA acknowledges this as a potential course of action and is, therefore, recommending these default values which EPA would consider in an appropriate circumstance and for States and authorized Tribes to utilize in such situations.

EPA is recommending an assumption of 30 kg as a default child's body weight to calculate AWQC to provide additional protection for children when the chemical of concern indicates health effects in children are of predominant concern (i.e., test results show children are more susceptible due to less developed immune systems, neurological systems, and/or lower body weights). The value is based on the mean body weight value of 29.9 kg for children ages 1 to14 years old, which combines body weight values for individual age groups within this larger group. The mean value is based on body weight information from NHANES III for individual-year age groups between one and 14 years old (WESTAT, 2000). A mean body weight of 28 kg is obtained using body weight values from Ershow and Cantor (1989) for five age groups within this range of 0-14 years and applying a weighting method for different ages by population percentages from the U.S. Bureau of the Census. The 30 kg assumption is also consistent with the age range for children used with the estimated fish intake rates. Unfortunately, fish intake rates for finer age group divisions are not possible due to the limited sampling base from the fish intake survey; there is limited confidence in calculated values (e.g., the mean) for such fine age groups. Given this limitation, the broad age category of body weight for children is suitable for use with the default fish intake assumption.

Given the hierarchy of preferences regarding the use of fish intake information (see Section 4.3.3), States may have more comprehensive data and prefer to target a more narrow, younger age group. If States choose to specifically evaluate toddlers, EPA recommends using 13 kg as a default body weight assumption for children ages 1 to 3 years old. The median and mean values of body weight for children 1 to 3 years old are 13.2 and 13.1 kg, respectively, based on an analysis of the NHANES III database (WESTAT, 2000). The NHANES III median and mean values for females between 1 and 3 years old are 13.0 and 12.9 kg, respectively, and are 13.4 and 13.4 kg for males, respectively. Median and mean body weight values from the earlier Ershow and Cantor (1989) study for children ages 1 to 3 years old were 13.6 and 14.1 kg, respectively. Finally, if infants are specifically evaluated, EPA recommends a default body weight of 7 kg based on the NHANES III analysis. Median and mean body weights for both male and female infants (combined) 2 months old were 6.3 and 6.3 kg, respectively, and for infants 3 months old were 7.0 and 6.9 kg, respectively. With the broader age category of males and females 2 to 6 months old, median and mean body weights were 7.4 and 7.4 kg, respectively. The NHANES

analysis did not include infants under 2 months of age. Although EPA is not recommending body weight values for newborns, the NCHS National Vital Statistics Report indicates that, for 1997, the median birth weight ranged from 3 to 3.5 kg, according to WESTAT (2000).

Body weight values for individual ages within the larger range of 0-14 years are listed in the Exposure Assessment TSD for those States and authorized Tribes who wish to use body weight values for these individual groups. States and Tribes may wish to consider certain general developmental ages (e.g., infants, pre-adolescents, etc.), or certain specific developmental landmarks (e.g., neurological development in the first four years), depending on the chemical of concern. EPA encourages States and authorized Tribes to choose a body weight intake from the tables presented in the TSD, if they believe a particular age subgroup is more appropriate.

4.3.2 Drinking Water Intake Rates

The basis for the drinking water intake rates (also for the fish intake rates presented in Section 4.3.3) is the 1994-96 Continuing Survey of Food Intake by Individuals *(*CSFII) conducted by the U.S. Department of Agriculture (USDA, 1998). The CSFII survey collects dietary intake information from nationally representative samples of non-institutionalized persons residing in United States households. Households in these national surveys are sampled from the 50 states and the District of Columbia. Each survey collects daily consumption records for approximately 10,000 food codes across nine food groups. These food groups are (1) milk and milk products; (2) meat, poultry, and fish; (3) eggs; (4) dry beans, peas, legumes, nuts, and seeds; (5) grain products; (6) fruit; (7) vegetables; (8) fats, oils, and salad dressings; and (9) sweets, sugars, and beverages. The survey also asks each respondent how many fluid ounces of plain drinking water he or she drank during each of the survey days. In addition, the CSFII collects household information, including the source of plain drinking water, water used to prepare beverages, and water used to prepare foods. Data provide "up-to-date information on food intakes by Americans for use in policy formation, regulation, program planning and evaluation, education, and research." The survey is "the cornerstone of the National Nutritional Monitoring and Related Research Program, a set of related federal activities intended to provide regular information on the nutritional status of the United States population" (USDA, 1998).

The 1994-96 CSFII was conducted according to a stratified, multi-area probability sample organized using estimates of the 1990 United States population. Stratification accounted for geographic location, degree of urbanization, and socioeconomics. Each year of the survey consisted of one sample with oversampling for low-income households.

Survey participants provided two non-consecutive, 24-hour days of dietary data. Both days' dietary recall information was collected by an in-home interviewer. Interviewers provided participants with an instructional booklet and standard measuring cups and spoons to assist them in adequately describing the type and amount of food ingested. If the respondent referred to a cup or bowl in their own home, a 2-cup measuring cup was provided to aid in the calculation of the amount consumed. The sample person could fill their own bowl or cup with water to represent the amount eaten or drunk, and the interviewer could then measure the amount consumed by pouring it into the 2-cup measure. The Day 2 interview occurred three to 10 days

after the Day 1 interview, but not on the same day of the week. The interviews allowed participants "three passes" through the daily intake record to maximize recall (USDA, 1998). Proxy interviews were conducted for children aged six and younger and sampled individuals unable to report due to mental or physical limitations. The average questionnaire administration time for Day 1 intake was 30 minutes, while Day 2 averaged 27 minutes.

Two days of dietary recall data were provided by 15,303 individuals across the three survey years. This constitutes an overall two-day response rate of 75.9 percent. Survey weights were corrected by the USDA for nonresponse.

All three 1994-96 CSFII surveys are multistage, stratified-cluster samples. Sample weights, which project the data from a sampled individual to the population, are based on the probability of an individual being sampled at each stage of the sampling design. The sample weights associated with each individual reporting two days of consumption data were adjusted to correct for nonresponse bias.

The 1994-96 CSFII surveys have advantages and limitations for estimating per capita water (or fish) consumption. The primary advantage of the CSFII surveys is that they were designed and conducted by the USDA to support unbiased estimation of food consumption across the population in the United States and the District of Columbia. Second, the survey is designed to record daily intakes of foods and nutrients and support estimation of food consumption.

One limitation of the 1994-96 CSFII surveys is that individual food consumption data were collected for only two days–a brief period which does not necessarily depict "usual intake." Usual dietary intake is defined as "the long-run average of daily intakes by an individual." Upper percentile estimates may differ for short-term and longer-term data because short-term food consumption data tend to be inherently more variable. It is important to note, however, that variability due to duration of the survey does not result in bias of estimates of overall mean consumption levels. Also, the multistage survey design does not support interval estimates for many of the subpopulations of interest because of sparse representation in the sample. Subpopulations with sparse representation include Native Americans on reservations and certain ethnic groups. While these individuals are participants in the survey, they are not present in sufficient numbers to support consumption estimates.

Despite these limitations, the CSFII is considered one of the best sources of current information on consumption of water and fish-containing foods. The objective of estimating per capita water and fish consumption by the United States population is compatible with the statistical design and scope of the CSFII survey.

4.3.2.1 Rate Protective of Human Health from Chronic Exposure

EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with

fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision. The results of the 1994-96 CSFII analysis indicate that the arithmetic mean, 75th, and 90th percentile values for adults 20 years and older are 1.1, 1.5, and 2.2 L/day, respectively (USEPA, 2000a). The 2 L/day value represents the 86th percentile for adults. These values can also be compared to data from an older National Cancer Institute (NCI) study, which estimated intakes of tapwater in the United States based on the USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). The arithmetic mean, 75th, and 90th percentile values for adults 20 - 64 years old were 1.4, 1.7, and 2.3 L/day, respectively (Ershow and Cantor, 1989). The 2 L/day value represents the 88th percentile for adults from the NCI study.

The 2 L/day assumption was used with the original 1980 AWQC National Guidelines and has also been used in EPA's drinking water program. EPA believes that the newer studies continue to support the use of 2 L/day as a reasonable and protective consumption rate that represents the intake of most water consumers in the general population. However, individuals who work or exercise in hot climates could have water consumption rates significantly above 2 L/day, and EPA believes that States and Tribes should consider regional or occupational variations in water consumption.

4.3.2.2 Rates Protective of Developmental Human Health Effects

Based on the 1994-96 CSFII study data, EPA also recommends 2 L/day for women of childbearing age. The analysis for women of childbearing age (ages 15-44) indicate mean, 75th, and 90th percentile values of 0.9, 1.3, and 2.0 L/day, respectively. These rates compare well with those based on an analysis of tapwater intake by pregnant and lactating women by Ershow et al. (1991), based on the older USDA data, for women ages 15-49. Arithmetic mean, 75th and 90th percentile values were 1.2, 1.5, and 2.2 L/day, respectively, for pregnant women. For lactating women, the arithmetic mean, 75th and 90th percentile values were 1.3, 1.7, and 1.9 L/day, respectively.

As noted above, because infants and children have a higher daily water intake per unit body weight compared with adults, a water consumption rate measured for children is recommended for use when RfDs are based on health effects in children. Use of this water consumption rate should result in adequate protection for infants and children when setting criteria based on health effects for this target population. EPA recommends a drinking water intake of 1 L/day to, again, represent a majority of the population of children that consume drinking water. The results of the 1994-96 CSFII analysis indicate that for children from 1 to 10 years of age, the arithmetic mean, 75th, and 90th percentile values are 0.4, 0.6, and 0.9 L/day, respectively (USEPA, 2000a). The 1 L/day value represents the 93rd percentile for this group. The arithmetic mean, 75th, and 90th percentile values for smaller children, ages 1 to 3 years, are 0.3, 0.5, and 0.7 L/day, respectively. The 1 L/day value represents the 97th percentile of the group ages 1 to 3 years old. For the category of infants under 1 year of age, the arithmetic mean, 75th, and 90th percentile values are 0.3, 0.7, and 0.9 L/day, respectively. These data can similarly be compared to those of the older National Cancer Institute (NCI) study. The arithmetic mean, 75th, and 90th percentile values for children 1 to 10 years old were 0.74, 0.96, and 1.3 L/day,

respectively. The mean, 75th, and 90th percentile values for children 1 to 3 years old in the NCI study were 0.6, 0.8, and 1.2 L/day, respectively. Finally, the mean, 75th, and 90th percentile values for infants less than 6 months old were 0.3, 0.3, and 0.6 L/day, respectively (Ershow and Cantor, 1989).

4.3.2.3 Rates Based on Combining Drinking Water Intake and Body Weight

As an alternative to considering body weight and drinking water intake rates separately, EPA is providing rates based on intake per unit body weight data (in units of ml/kg) in the Exposure Assessment TSD, with additional discussion on their use. These rates are based on self-reported body weights from the CSFII survey respondents for the 1994-96 data. While EPA intends to derive or revise national default criteria on the separate intake values and body weights, in part due to the strong input received from its State stakeholders, the ml/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use. It should be noted that in their 1993 review, EPA's Science Advisory Board (SAB) felt that using drinking water intake rate assumptions on a per unit body weight basis would be more accurate, but did not believe this change would appreciably affect the criteria values (USEPA, 1993).

4.3.3 Fish Intake Rates

The basis for the fish intake rates is the 1994-96 CSFII conducted by the USDA, and described above in Section 4.3.2.

4.3.3.1 Rates Protective of Human Health from Chronic Exposure

EPA recommends a default fish intake rate of 17.5 grams/day to adequately protect the general population of fish consumers, based on the 1994 to 1996 data from the USDA's CSFII Survey. EPA will use this value when deriving or revising its national 304(a) criteria. This value represents the 90th percentile of the 1994-96 CSFII data. This value also represents the uncooked weight estimated from the CSFII data, and represents intake of freshwater and estuarine finfish and shellfish only. For deriving AWQC, EPA has also considered the States' and Tribes' needs to provide adequate protection from adverse health effects to highly exposed populations such as recreational and subsistence fishers, in addition to the general population. Based on available studies that characterize consumers of fish, recreational fishers and subsistence fishers are two distinct groups whose intake rates may be greater than the general population. It is, therefore, EPA's decision to discuss intakes for these two groups, in addition to the general population.

EPA recommends default fish intake rates for recreational and subsistence fishers of 17.5 grams/day and 142.4 grams/day, respectively. These rates are also based on uncooked weights for fresh/estuarine finfish and shellfish only. However, because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy for States and authorized Tribes to follow when deriving consumption rates that encourages use of the best local, State, or regional data available. A thorough discussion of the development of this policy method and relevant data sources is contained in the Exposure Assessment TSD. The hierarchy is also presented here because EPA strongly emphasizes that States and authorized

Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.

The recommended four preference hierarchy is intended for use in evaluating fish intake from fresh and estuarine species only. Therefore, to protect humans who additionally consume marine species of fish, the marine portion should be considered an *other source of exposure* when calculating an RSC for dietary intake. Refer to the Exposure Assessment TSD for further discussion. States and Tribes need to ensure that when evaluating overall exposure to a contaminant, marine fish intake is not double-counted with the other dietary intake estimate used. Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., fresh/estuarine and marine species) is more appropriate for protecting the population of concern may do so, provided that the marine intake component is not double-counted with the RSC estimate. Tables of fish consumption intakes based on the CSFII in the TSD provide rates for fresh/estuarine species, marine species, and total (combined) values to facilitate this option for States and Tribes. Throughout this section, the terms "fish intake" or "fish consumption" are used. These terms refer to the consumption of finfish and shellfish, and the CSFII survey includes both. States and Tribes should ensure that when selecting local or regionally-specific studies, both finfish and shellfish are included when the population exposed are consumers of both types.

EPA's first preference is that States and authorized Tribes use the results from fish intake surveys of local watersheds within the State or Tribal jurisdiction to establish fish intake rates that are representative of the defined populations being addressed for the particular waterbody. Again, EPA recommends that data indicative of fresh/estuarine species only be used which is, by and large, most appropriate for developing AWQC. EPA also recommends the use of uncooked weight intake values, which is discussed in greater detail with the fourth preference. States and authorized Tribes may use either high-end values (such as the 90^{th} or 95^{th} percentile values) or average values for an identified population that they plan to protect (e.g., subsistence fishers, sport fishers, or the general population). EPA generally recommends that arithmetic mean values should be the lowest value considered by States or Tribes when choosing intake rates for use in criteria derivation. When considering geometric mean (median) values from fish consumption studies, States and authorized Tribes need to ensure that the distribution is based on survey respondents who reported consuming fish because surveys based on both consumers and nonconsumers can often result in median values of zero. If a State or Tribe chooses values (whether the central tendency or high-end values) from studies that particularly target high-end consumers, these values should be compared to high-end fish intake rates for the general population to make sure that the high-end consumers within the general population would be protected by the chosen intake rates. EPA believes this is a reasonable procedure and is also consistent with the recent Great Lakes Water Quality Initiative (known as the "GLI") (USEPA, 1995). States and authorized Tribes may wish to conduct their own surveys of fish intake, and EPA guidance is available on methods to conduct such studies in *Guidance for Conducting Fish and Wildlife Consumption Surveys* (USEPA, 1998). Results from broader geographic regions in which the State or Tribe is located can also be used, but may not be as applicable as results from

local watersheds. Since such studies would ultimately form the basis of a State or Tribe's AWQC, EPA would review any surveys of fish intake for consistency with the principles of EPA's guidance as part of the Agency's review of water quality standards under Section 303(c).

If surveys conducted in the geographic area of the State or Tribe are not available, EPA's second preference is that States and authorized Tribes consider results from existing fish intake surveys that reflect similar geography and population groups (e.g., from a neighboring State or Tribe or a similar watershed type), and follow the method described above regarding target values to derive a fish intake rate. Again, EPA recommends the use of uncooked weight intake values and the use of fresh/estuarine species data only. Results of existing local and regional surveys are discussed in greater detail in the TSD.

If applicable consumption rates are not available from local, State, or regional surveys, EPA's third preference is that States and authorized Tribes select intake rate assumptions for different population groups from national food consumption surveys. EPA has analyzed one such national survey, the 1994-96 CSFII. As described in Section 4.3.2, this survey, conducted annually by the USDA, collects food consumption information from a probability sample of the population of all 50 states. Respondents to the survey provide two days of dietary recall data. A detailed description of the combined 1994-96 CSFII survey, the statistical methodology, and the results and uncertainties of the EPA analyses are provided in a separate EPA report (USEPA, 2000b). The Exposure Assessment TSD for this Methodology presents selected results from this report including point and interval estimates of combined finfish and shellfish consumption for the mean, 50^{th} (median), 90^{th}, 95^{th}, and 99^{th} percentiles. The estimated fish consumption rates are by fish habitat (i.e., freshwater/estuarine, marine and all habitats) for the following population groups: (1) all individuals; (2) individuals age 18 and over; (3) women ages 15-44; and (4) children age 14 and under. Three kinds of estimated fish consumption rates are provided: (1) per capita rates (i.e., rates based on consumers and nonconsumers of fish from the survey period– refer to the TSD for further discussion); (2) consumers-only rates (i.e., rates based on respondents who reported consuming finfish or shellfish during the two-day reporting period); and (3) per capita consumption by body weight (i.e., per capita rates reported as milligrams of fish per kilogram of body weight per day).

EPA's fourth preference is that States and authorized Tribes use as fish intake assumptions the following default rates, based on the 1994-96 CSFII data, that EPA believes are representative of fish intake for different population groups: 17.5 grams/day for the general adult population and sport fishers, and 142.4 grams/day for subsistence fishers. These are risk management decisions that EPA has made after evaluating numerous fish intake surveys. These values represent the uncooked weight intake of freshwater/estuarine finfish and shellfish. As with the other preferences, EPA requests that States and authorized Tribes routinely consider whether there is a substantial population of sport fishers or subsistence fishers when developing site-specific estimates, rather than automatically basing them on the typical individual. Because the combined 1994-96 CSFII survey is national in scope, EPA will use the results from this survey to estimate fish intake for deriving national criteria. EPA has recognized the data gaps and uncertainties associated with the analysis of the 1994-96 CSFII survey in the process of making its default recommendations. The estimated mean of freshwater and estuarine fish ingestion for adults is 7.50 grams/day, and the median is 0 grams/day. The estimated 90^{th}

percentile is 17.53 grams/day; the estimated 95th percentile is 49.59 grams/day; and the estimated 99th percentile is 142.41 grams/day. The median value of 0 grams/day may reflect the portion of individuals in the population who never eat fish as well as the limited reporting period (2 days) over which intake was measured. By applying as a default 17.5 grams/day for the general adult population, EPA intends to select an intake rate that is protective of a majority of the population (again, the 90th percentile of consumers and nonconsumers according to the 1994-96 CSFII survey data). Trophic level breakouts are: TL2 = 3.8 grams/day; TL3 = 8.0 grams/day; and TL4 = 5.7 grams/day. EPA further considers 17.5 grams/day to be indicative of the average consumption among sport fishers based on averages in the studies reviewed, which are presented in the Exposure Assessment TSD. Similarly, EPA believes that the assumption of 142.4 grams/day is within the range of average consumption estimates for subsistence fishers based on the studies reviewed. Experts at the 1992 National Workshop that initiated the effort to revise this Methodology acknowledged that the national survey high-end values are representative of average rates for highly exposed groups such as subsistence fishermen, specific ethnic groups, or other highly exposed people. EPA is aware that some local and regional studies indicate greater consumption among Native American, Pacific Asian American, and other subsistence consumers, and recommends the use of those studies in appropriate cases, as indicated by the first and second preferences. Again, States and authorized Tribes have the flexibility to choose intake rates higher than an average value for these population groups. If a State or authorized Tribe has not identified a separate well-defined population of high-end consumers and believes that the national data from the 1994-96 CSFII are representative, they may choose these recommended rates.

As indicated above, the default intake values are based on the uncooked weights of the fish analyzed. There has been some question regarding whether to use cooked or uncooked weights of fish intake for deriving the AWQC. Studies show that, typically, with a filet or steak of fish, the weight loss in cooking is about 20 percent; that is, the uncooked weight is approximately 20 percent higher (Jacobs et al., 1998). This obviously means that using uncooked weights results in a slightly higher intake rate and slightly more stringent AWQC. In researching consumption surveys for this proposal, EPA has found that some surveys have reported rates for cooked fish, others have reported uncooked rates, and many more are unclear as to whether cooked or uncooked rates are used. The basis of the CSFII survey was prepared or *as consumed* intakes; that is, the survey respondents estimated the weight of fish that they consumed. This was also true with the GLI (which was specifically based on studies describing consumption rates of cooked fish) and, by and large, cooked fish is what people consume. However, EPA's *Guidance For Assessing Chemical Contaminant Data For Use In Fish Advisories* recommends analysis and advisories based on uncooked fish (USEPA, 1997a). EPA considered the potential confusion over the fact that the uncooked weights are used in the fish advisory program. Further, the measures of a contaminant in fish tissue samples that are applicable to compliance monitoring and the permitting program are related to the uncooked weights. The choice of intakes is also complicated by factors such as the effect of the cooking process, the different parts of a fish where a chemical may accumulate, and the method of preparation.

After considering all of the above (in addition to public input received), EPA will derive its national default criteria based on the uncooked weight fish intakes. The Exposure

Assessment TSD provides additional guidance on site-specific modifications. Specifically, an alternate approach is described for calculating AWQC with the *as consumed* weight–which is more directly associated with human exposure and risk–and then adjusting the value by the approximate 20 percent loss to an uncooked equivalent (thereby representing the same relative risk as the *as consumed* value). This approach results in a different AWQC value (than using the uncooked weights) and represents a more direct translation of the *as consumed* risk to the uncooked equivalent. However, EPA understands that it is more scientifically rigorous and may be too intensive of a process for States and Tribes to rely on. The option is presented in the TSD to offer States and authorized Tribes greater flexibility with their water quality standards program.

The default fish intake values also reflect specific designations of species classified in accordance with information regarding the life history of the species or based on landings information form the National Marine Fisheries Service. Most significantly, salmon has been reclassified from a freshwater/estuarine species to a marine species. As marine harvested salmon represents approximately 99 percent of salmon consumption in the 1994-96 CSFII Survey, removal reduces the overall fresh/estuarine fish consumption rate by 13 percent. Although they represent a very small percentage of freshwater/estuarine intake, land-locked and farm-raised salmon consumed by 1994-96 CSFII respondents are still included. The rationale for the default intake species designations is explained in the Exposure Assessment TSD. Once again, EPA emphasizes the flexibility for States and authorized Tribes to use alternative assumptions based on local or regional data to better represent their population groups of concern.

4.3.3.2 Rates Protective of Developmental Human Health Effects

Exposures resulting in health effects in children or developmental effects in fetuses may be of primary concern. As discussed at the beginning of this section on exposure factors used, in a situation where acute or sub-chronic toxicity and exposure are the basis of an RfD (or POD/UF), EPA will consider basing its national default criteria on children or women of childbearing age, depending on the target population at greatest risk. EPA recommends that States and authorized Tribes use exposure factors for children or women of childbearing age in these situations. As stated previously, EPA is not recommending the development of additional AWQC but is acknowledging that basing a criterion on these population groups is a potential course of action and is, therefore, recommending the following default intake rates for such situations.

EPA's preferences for States and authorized Tribes in selecting values for intake rates relevant for children is the same as that discussed above for establishing values for average daily consumption rates for chronic effects; i.e., in decreasing order of preference, results from fish intake surveys of local watersheds, results from existing fish intake surveys that reflect similar geography and population groups, the distribution of intake rates from nationally based surveys (e.g., the CSFII), or lastly, the EPA default rates. When an RfD is based on health effects in children, EPA recommends a default intake rate of 156.3 grams/day for assessing those contaminants that exhibit adverse effects. This represents the 90th percentile consumption rate for actual consumers of freshwater/estuarine finfish and shellfish for children ages 14 and under using the combined 1994 to 1996 results from the CSFII survey. The value was calculated based

on data for only those children who ate fish during the 2-day survey period, and the intake was averaged over the number of days during which fish was actually consumed. EPA believes that by selecting the data for consumers only, the 90th percentile is a reasonable intake rate to approximate consumption of fresh/estuarine finfish and shellfish within a short period of time for use in assessments where adverse effects in children are of primary concern. As discussed previously, EPA will use a default body weight of 30 kg to address potential acute or subchronic effects from fish consumption by children. EPA is also providing these default intake values for States and authorized Tribes that choose to provide additional protection when developing criteria that they believe should be based on health effects in children. This is consistent with the rationale in the recent GLI (USEPA, 1995) and is an approach that EPA believes is reasonable. Distributional information on intake values relevant for assessing exposure when health effects to children are of concern is presented in the Exposure Assessment TSD.

There are also cases in which pregnant women may be the population of most concern, due to the possibility of developmental effects that may result from exposures of the mother to toxicants. In these cases, fish intake rates specific to females of childbearing age are most appropriate when assessing exposures to developmental toxicants. When an RfD is based on developmental toxicity, EPA proposes a default intake rate of 165.5 grams/day for assessing exposures for women of childbearing age from contaminants that cause developmental effects. This is equivalent to the 90th percentile consumption rate for actual consumers of freshwater/ estuarine finfish and shellfish for women ages 15 to 44 using the combined 1994 to1996 results from the CSFII survey. As with the rate for children, this value represents only those women who ate fish during the 2-day survey period. As discussed previously, EPA will use a default body weight of 67 kg for women of childbearing age.

4.3.3.3 Rates Based on Combining Fish Intake and Body Weight

As with the drinking water intake values, EPA is providing values for fish intake based on a per unit body weight basis (in units of mg/kg) in the Exposure Assessment TSD. These rates use the self-reported body weights of the 1994-96 CSFII survey. Again, while EPA intends to derive or revise national default criteria on the separate intake values and body weights, the mg/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use.

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5. BIOACCUMULATION

5.1 INTRODUCTION

Aquatic organisms can accumulate certain chemicals in their bodies when exposed to these chemicals through water, their diet, and other sources. This process is called bioaccumulation. The magnitude of bioaccumulation by aquatic organisms varies widely depending on the chemical but can be extremely high for some highly persistent and hydrophobic chemicals. For such highly bioaccumulative chemicals, concentrations in aquatic organisms may pose unacceptable human health risks from fish and shellfish consumption even when concentrations in water are too low to cause unacceptable health risks from drinking water consumption alone. These chemicals may also biomagnify in aquatic food webs, a process whereby chemical concentrations increase in aquatic organisms of each successive trophic level due to increasing dietary exposures (e.g., increasing concentrations from algae, to zooplankton, to forage fish, to predatory fish).

In order to prevent harmful exposures to waterborne chemicals through the consumption of contaminated fish and shellfish, national 304(a) water quality criteria for the protection of human health must address the process of chemical bioaccumulation in aquatic organisms. For deriving national 304(a) criteria to protect human health, EPA accounts for potential bioaccumulation of chemicals in fish and shellfish through the use of national bioaccumulation factors (BAFs). A national BAF is a ratio (in L/kg) that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms in a specified trophic level. An illustration of how national BAFs are used in the derivation of 304(a) criteria for carcinogens using linear low-dose extrapolation is shown in the following equation:

$$AWQC = RSD \bullet \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \bullet BAF_i)} \right) \qquad \text{(Equation 5-1)}$$

where:

RSD	=	Risk specific dose (mg/kg-day)
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)
FI_i	=	Fish intake at trophic level I, where I=2, 3, and 4;
BAF_i	=	National bioaccumulation factor at trophic level I, where I=2, 3, and 4

The purpose of this chapter is to present EPA's recommended methodology for deriving national bioaccumulation factors for setting national 304(a) water quality criteria to protect human health. A detailed scientific basis of the recommended national BAF methodology is provided in the Bioaccumulation TSD. While the methodology detailed in this chapter is

intended to be used by EPA for deriving national BAFs, EPA encourages States and authorized Tribes to derive BAFs that are specific to certain regions or waterbodies, where appropriate. Guidance to States and authorized Tribes for deriving site-specific BAFs is provided in the Biaccumulation TSD.

5.1.1 Important Bioaccumulation and Bioconcentration Concepts

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in setting national 304(a) criteria. First, the term "bioaccumulation" refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media (e.g., water, food, sediment). The term "bioconcentration" refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone would underestimate the extent of accumulation in aquatic biota for these chemicals. Accordingly, EPA's guidelines presented in this chapter emphasize the measurement of chemical bioaccumulation by aquatic organisms, whereas EPA's 1980 Methodology emphasized the measurement of bioconcentration.

Another noteworthy aspect of bioaccumulation process is the issue of steady-state conditions. Specifically, both bioaccumulation and bioconcentration can be viewed simply as the result of competing rates of chemical uptake and depuration (chemical loss) by an aquatic organism. The rates of chemical uptake and depuration can be affected by various factors including the properties of the chemical, the physiology of the organism in question, water quality and other environmental conditions, ecological characteristics of the waterbody (e.g., food web structure), and the concentration and loadings history of the chemical. When the rates of chemical uptake and depuration are equal, tissue concentrations remain constant over time and the distribution of the chemical between the organism and its source(s) is said to be at steady-state. For constant chemical exposures and other conditions, the steady-state concentration in the organism represents the highest accumulation potential of the chemical in that organism under those conditions. The time required for a chemical to achieve steady state has been shown to vary according to the properties of the chemical and other factors. For example, some highly hydrophobic chemicals can require long periods of time to reach steady state between environmental compartments (e.g., many months), while highly hydrophilic chemicals usually reach steady-state relatively quickly (e.g., hours to days).

Since national 304(a) criteria for the protection of human health are typically designed to protect humans from harmful lifetime or long-term exposures to waterborne contaminants, the assessment of bioaccumulation that equals or approximates steady-state accumulation is one of the principles underlying the derivation of national BAFs. For some chemicals that require relatively long periods of time to reach steady-state in tissues of aquatic organisms, changes in water column concentrations may occur on a much more rapid time scale compared to the corresponding changes in tissue concentrations. Thus, if the system departs substantially from steady-state conditions and water concentrations are not averaged over a sufficient time period, the ratio of the tissue concentration to a water concentration may have little resemblance to the steady-state ratio and have little predictive value of long-term bioaccumulation potential.

Therefore, BAF measurements should be based on water column concentrations which are averaged over a sufficient period of time (e.g., a duration comparable to the time required for the chemical to reach steady-state). In addition, BAF measurements should be based on adequate spatial averaging of both tissue and water column concentrations for use in deriving 304(a) criteria for the protection of human health.

For this reason, a BAF is defined in this Methodology as representing the ratio (in L/kg-tissue) of a concentration of a chemical in tissue to its concentration in the surrounding water in situations where the organism and its food are exposed and the ratio does not change substantially over time (i.e., the ratio which reflects bioaccumulation at or near steady-state). A bioconcentration factor (BCF) is the ratio (in L/kg-tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

5.1.2 Goal of the National BAF

The goal of EPA's national BAF is to represent the long-term, average bioaccumulation potential of a chemical in edible tissues of aquatic organisms that are commonly consumed by humans throughout the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short time periods (e.g., a few days) because 304(a) human health criteria are generally designed to protect humans from long-term exposures to waterborne chemicals. National BAFs are also intended to account for some major chemical, biological, and ecological attributes that can affect bioaccumulation in bodies of water across the United States. For example, separate procedures are provided for deriving national BAFs depending on the type of chemical (i.e., nonionic organic, ionic organic, inorganic and organometallic). In addition, EPA's national BAFs are derived separately for each trophic level to account for potential biomagnification of some chemicals in aquatic food webs and broad physiological differences between trophic levels that may influence bioaccumulation. Because lipid content of aquatic organisms and the amount of organic carbon in the water column have been shown to affect bioaccumulation of nonionic organic chemicals, EPA's national BAFs are adjusted to reflect the lipid content of commonly consumed fish and shellfish and the freely dissolved fraction of the chemical in ambient water for these chemicals.

5.1.3 Changes to the 1980 Methodology

Numerous scientific advances have occurred in the area of bioaccumulation since the publication of the 1980 Methodology for deriving AWQC for the protection of human health (USEPA, 1980). These advances have significantly increased our ability to assess and predict the bioaccumulation of chemicals in aquatic biota. As a result, EPA has revised the bioaccumulation portion of the 1980 Methodology to reflect the current state of the science and to improve accuracy in assessing bioaccumulation for setting 304(a) criteria for the protection of human health. The changes contained in the bioaccumulation portion of the 2000 Human Health Methodology are mostly designed to:

- Improve the ability to incorporate chemical exposure from sediments and aquatic food webs in assessing bioaccumulation potential,

- Expand the ability to account for site-specific factors which affect bioaccumulation, and

- Incorporate new data and assessment tools into the bioaccumulation assessment process.

A summary of the key changes that have been incorporated into the bioaccumulation portion of the 2000 Human Health Methodology and appropriate comparisons to the1980 Methodology are provided below.

5.1.3.1 Overall Approach

The 1980 Methodology for deriving 304(a) criteria for the protection of human health emphasized the assessment of bioconcentration (uptake from water only) through the use of the BCF. Based on the 1980 Methodology, measured BCFs were usually determined from laboratory data unless field data demonstrated consistently higher or lower accumulation compared with laboratory data. In these cases, "field BCFs" (currently termed field-measured BAFs) were recommended for use. For lipophilic chemicals where lab or field-measured data were unavailable, EPA recommended predicting BCFs from the octanol-water partition coefficient and the following equation from Veith et al. (1979): "log BCF = (0.85 log K_{ow}) - 0.70".

The 2000 Human Health Methodology revisions contained in this chapter emphasize the measurement of bioaccumulation (uptake from water, sediment, and diet) through the use of the BAF. Consistent with the 1980 Methodology, measured data are preferred over predictive approaches for determining the BAF (i.e., field-measured BAFs are generally preferred over predicted BAFs). However, the 2000 Human Health Methodology contains additional methods for deriving a national BAF that were not available in 1980. The preference for using the BAF methods also differs depending on the type and properties of the chemical. For example, the BAF derivation procedure differs for each of three broadly defined chemical categories: (1) nonionic organic, (2) ionic organic, and (3) inorganic and organometallic chemicals. Furthermore, within the category of nonionic organic chemicals, different procedures are used to derive the BAF depending on a chemicals' hydrophobicity and extent of chemical metabolism that would be expected to occur in aquatic biota.

5.1.3.2 Lipid Normalization

In the 1980 Methodology, BCFs for lipophilic chemicals were normalized by the lipid fraction in the tissue of fish and shellfish used to determine the BCF. Lipid normalization enabled BCFs to be averaged across tissues and organisms. Once the average lipid-normalized BCF was determined, it was adjusted by the consumption-weighted lipid content of commonly consumed aquatic organisms in the United States to obtain an overall consumption-weighted BCF. A similar procedure has been retained in the 2000 Human Health Methodology, whereby BAFs for nonionic organic chemicals are lipid normalized and adjusted by the consumption-weighted lipid content of commonly consumed organisms to obtain a BAF for criteria

calculations. However, the 2000 Human Health Methodology uses more up-to-date lipid data and consumption data for deriving the consumption-weighted BAFs.

5.1.3.3 Bioavailability

Bioconcentration factors derived according to the 1980 Methodology were based on the total concentration of the chemical in water, for both lipophilic and nonlipophilic chemicals. In the 2000 Human Health Methodology, BAFs for nonionic organic chemicals are derived using the most bioavailable fraction (i.e., the freely dissolved fraction) to account for the influence of particulate and dissolved organic carbon on a chemical's bioavailability. Such BAFs are then adjusted to reflect the expected bioavailability at the sites of interest (i.e., by adjusting for organic carbon concentrations at the sites of interest). Procedures for accounting for the effect of organic carbon on bioaccumulation were published previously by EPA under the Great Lakes Water Quality Initiative (GLWQI or GLI) rulemaking (USEPA, 1995a,b). Bioavailability is also considered in developing BAFs for the other chemical classes defined in the 2000 Human Health Methodology (e.g., ionic organics, inorganics/organometallics) but is done so on a chemical-by-chemical basis.

5.1.3.4 Trophic Level Considerations

In the 1980 Methodology, BCFs were determined and used for criteria derivation without explicit regard to the trophic level of the aquatic organism (e.g., benthic filter feeder, forage fish, predatory fish). Over the past two decades, much information has been assembled which demonstrates that an organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. In order to account for the variation in bioaccumulation that is due to trophic position of the organism, the 2000 Human Health Methodology recommends that BAFs be determined and applied on a trophic level-specific basis.

5.1.3.5 Site-Specific Adjustments

The 1980 Methodology contained little guidance for making adjustments to the national BCFs to reflect site- or region-specific conditions. The 2000 Human Health Methodology has greatly expanded the guidance to States and authorized Tribes for making adjustments to national BAFs to reflect local conditions. This guidance is contained in the Bioaccumulation TSD. In the Bioaccumulation TSD, guidance and data are provided for adjusting national BAFs to reflect the lipid content in locally consumed aquatic biota and the organic carbon content in the waterbodies of concern. This guidance also allows the use of appropriate bioaccumulation models for deriving site-specific BAFs. EPA also plans to publish detailed guidance on designing and conducting field bioaccumulation studies for measuring BAFs and biota-sediment accumulation factors (BSAFs). In general, EPA encourages States and authorized Tribes to make site-specific modifications to EPA's national BAFs provided such adjustments are scientifically defensible and adequately protect the designated use of the waterbody.

While the aforementioned revisions are new to EPA's Methodology for deriving national 304(a) criteria for the protection of human health, many of these refinements have been

incorporated in prior Agency guidance and regulations. For example, the use of food chain multipliers to account for the biomagnification of nonionic organic chemicals in aquatic food webs when measured data are unavailable was introduced by EPA in three documents*: Technical Support Document for Water Quality-Based Toxics Control* (USEPA, 1991), a draft document entitled *Assessment and Control of Bioconcentratable Contaminants in Surface Waters* (USEPA, 1993), and in the *Great Lakes Water Quality Initiative* (GLI) (USEPA, 1995b). Similarly, procedures for predicting BAFs using BSAFsand incorporating the effect of organic carbon on bioavailability were used to derive water quality criteria under the GLI.

5.1.4 Organization of This Section

The methodology for deriving national BAFs for use in deriving National 304(a) Human Health AWQC is provided in the following sections. Important terms used throughout this chapter are defined in Section 5.2. Section 5.3 provides an overview of the BAF derivation guidelines. Detailed procedures for deriving national BAFs are provided in Section 5.4 for nonionic organic chemicals, in Section 5.5 for ionic organic chemicals, and in Section 5.6 for inorganics and organometallic chemicals. Literature cited is provided in Section 5.7.

5.2 DEFINITIONS

The following terms and definitions are used throughout this chapter.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water, through gill membranes or other external body surfaces.

Bioaccumulation Factor (BAF). The ratio (in L/kg-tissue) of the concentration of a substance in tissue to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time. The BAF is calculated as:

$$BAF = \frac{C_t}{C_w} \qquad \text{(Equation 5-2)}$$

where:

C_t = Concentration of the chemical in the specified wet tissue
C_w = Concentration of chemical in water

Bioconcentration Factor (BCF). The ratio (in L/kg-tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time. The BCF is calculated as:

$$BCF = \frac{C_t}{C_w} \qquad \text{(Equation 5-3)}$$

where:

C_t = Concentration of the chemical in the specified wet tissue
C_w = Concentration of chemical in water

Baseline BAF (BAF_ℓ^{fd}). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BAF (in L/kg-lipid) that is based on the concentration of freely dissolved chemical in the ambient water and the lipid normalized concentration in tissue.

Baseline BCF (BCF_ℓ^{fd}). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BCF (in L/kg-lipid) that is based on the concentration of freely dissolved chemical in the ambient water and the lipid normalized concentration in tissue.

Biomagnification. The increase in tissue concentration of a chemical in organisms at successive trophic levels through a series of predator-prey associations, primarily through the mechanism of dietary accumulation.

Biomagnification Factor (BMF). The ratio (unitless) of the tissue concentration of a chemical in a predator at a particular trophic level to the tissue concentration in its prey at the next lower trophic level for a given waterbody and chemical exposure. For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BMF can be calculated using lipid-normalized concentrations in the tissue of organisms at two successive trophic levels as:

$$BMF_{(TL,\ n)} = \frac{C_{\ell\ (TL,\ n)}}{C_{\ell\ (TL,\ n-1)}} \qquad \text{(Equation 5-4)}$$

where:

$C_{\ell\ (TL,\ n)}$ = Lipid-normalized concentration in appropriate tissue of predator organism at a given trophic level (TL "n")

$C_{\ell\ (TL,\ n-1)}$ = Lipid-normalized concentration in appropriate tissue of prey organism at the next lower trophic level from the predator (TL "n-1")

For inorganic, organometallic, and certain ionic organic chemicals where lipid and organic carbon partitioning does not apply, a BMF can be calculated using chemical concentrations in the tissue of organisms at two successive trophic levels as:

$$BMF_{(TL,\ n)} = \frac{C_{t\ (TL,\ n)}}{C_{t\ (TL,\ n-1)}} \qquad \text{(Equation 5-5)}$$

where:

$C_{t\ (TL,\ n)}$ = Concentration in appropriate tissue of predator organism at trophic level "n" (may be either wet weight or dry weight concentration so long as both the predator and prey concentrations are expressed in the same manner)

$C_{t\ (TL,\ n-1)}$ = Concentration in appropriate tissue of prey organism at the next lower trophic level from the predator (may be either wet weight or dry weight concentration so long as both the predator and prey concentrations are expressed in the same manner)

Biota-Sediment Accumulation Factor (BSAF). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), the ratio of the lipid-normalized concentration of a substance in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment (expressed as kg of sediment organic carbon per kg of lipid), in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism. The BSAF is defined as:

$$BSAF = \frac{C_{\ell}}{C_{soc}} \qquad \text{(Equation 5-6)}$$

where:

C_{ℓ} = The lipid-normalized concentration of the chemical in tissues of the biota (µg/g lipid)

C_{soc} = The organic carbon-normalized concentration of the chemical in the surface sediment (µg/g sediment organic carbon)

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food Chain Multiplier (FCM). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), the ratio of a baseline BAF_{ℓ}^{fd} for an organism of a particular trophic level to the baseline BCF_{ℓ}^{fd} (usually determined for organisms in trophic level one). For inorganic, organometallic, and certain ionic organic chemicals where lipid and organic carbon partitioning does not apply, a FCM is based on total (wet or dry weight) concentrations of the chemical in tissue.

Freely Dissolved Concentration. For nonionic organic chemicals, the concentration of the chemical that is dissolved in ambient water, excluding the portion sorbed onto particulate or dissolved organic carbon. The freely dissolved concentration is considered to represent the most bioavailable form of an organic chemical in water and, thus, is the form that best predicts bioaccumulation. The freely dissolved concentration can be determined as:

$$C_w^{fd} = (C_w^t) \cdot (f_{fd}) \qquad \text{(Equation 5-7)}$$

where:

C_w^{fd}	=	Freely dissolved concentration of the organic chemical in ambient water
C_w^t	=	Total concentration of the organic chemical in ambient water
f_{fd}	=	Fraction of the total chemical in ambient water that is freely dissolved

Hydrophilic. A term that refers to the extent to which a chemical is attracted to partitioning into the water phase. Hydrophilic organic chemicals have a greater tendency to partition into polar phases (e.g., water) compared to chemicals of hydrophobic chemicals.

Hydrophobic. A term that refers to the extent to which a chemical avoids partitioning into the water phase. Highly hydrophobic organic chemicals have a greater tendency to partition into nonpolar phases (e.g., lipid, organic carbon) compared with chemicals of lower hydrophobicity.

Lipid-normalized Concentration (C_{ℓ}). The total concentration of a contaminant in a tissue or whole organism divided by the lipid fraction in that tissue or whole organism. The lipid-normalized concentration can be calculated as:

$$C_{\ell} = \frac{C_t}{f_{\ell}} \qquad \text{(Equation 5-8)}$$

where:

C_t	=	Concentration of the chemical in the wet tissue (either whole organism or specified tissue)

f_ℓ = Fraction lipid content in the organism or specified tissue

Octanol-water Partition Coefficient (K_{ow}). The ratio of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{ow}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Organic Carbon-normalized Concentration (C_{soc}). For sediments, the total concentration of a contaminant in sediment divided by the fraction of organic carbon in sediment. The organic carbon-normalized concentration can be calculated as:

$$C_{soc} = \frac{C_s}{f_{oc}} \qquad \text{(Equation 5-9)}$$

where:

C_s = Concentration of chemical in sediment
f_{oc} = Fraction organic carbon in sediment

Uptake. Acquisition by an organism of a substance from the environment as a result of any active or passive process.

5.3 FRAMEWORK FOR DETERMINING NATIONAL BIOACCUMULATION FACTORS

5.3.1 Four Different Methods

Bioaccumulation factors used to derive national BAFs can be measured or predicted using some or all of the following four methods, depending on the type of chemical and its properties. These methods are:

(1) a measured BAF obtained from a field study (i.e., a field-measured BAF);

(2) a BAF predicted from a field-measured BSAF;

(3) a BAF predicted from a laboratory-measured BCF (with or without adjustment by an FCM); and

(4) a BAF predicted from a chemical's octanol-water partition coefficient (K_{ow}), with or without adjustment using an FCM.

A brief summary of each of the four methods is provided below. Additional details on the use of these four methods is provided in Section 5.4 (for nonionic organics), Section 5.5 (for ionic organics) and Section 5.6 (for inorganics and organometallics).

1. **Field-Measured BAF.** Use of a field-measured BAF, which is the most direct measure of bioaccumulation, is the only method that can be used to derive a national BAF for all types of chemicals (i.e., nonionic organic, ionic organic, and inorganic and organometallic chemicals). A field-measured BAF is determined from a field study using measured chemical concentrations in the aquatic organism and its surrounding water. Because field studies are conducted in natural aquatic ecosystems, a field-measured BAF reflects an organism's exposure to a chemical through all relevant exposure pathways (i.e., water, sediment, and diet). A field-measured BAF also reflects any metabolism of a chemical that might occur in the aquatic organism or its food web. Therefore, field-measured BAFs are appropriate for all chemicals, regardless of the extent of chemical metabolism in biota.

2. **Field-measured BSAF.** For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BAF can also be predicted from BSAFs. A BSAF is similar to a field-measured BAF in that the concentration of a chemical in biota is measured in the field and reflects an organism's exposure to all relevant exposure routes. A BSAF also reflects any chemical metabolism that might occur in the aquatic organism or its food web. However, unlike a field-measured BAF which references the biota concentration to the water concentration, a BSAF references the biota concentration to the sediment concentration. Use of the BSAF procedure is restricted to organic chemicals which are classified as being moderately to highly hydrophobic.

3. **Lab-measured BCF.** A laboratory-measured BCF can also be used to estimate a BAF for organic and inorganic chemicals. However, unlike a field-measured BAF or a BAF predicted from a field-measured BSAF, a laboratory-measured BCF only reflects the accumulation of chemical through the water exposure route. Laboratory-measured BCFs may therefore under estimate BAFs for chemicals where accumulation from sediment or dietary sources is important. In these cases, laboratory-measured BCFs can be multiplied by a FCM to reflect accumulation from non-aqueous (i.e., food chain) pathways of exposure. Since a laboratory-measured BCF is determined using the measured concentration of a chemical in an aquatic organism and its surrounding water, a laboratory-measured BCF reflects any metabolism of the chemical that occurs in the organism, but not in the food web.

4. **K_{ow}.** A chemical's octanol-water partition coefficient, or K_{ow}, can also be used to predict a BAF for nonionic organic chemicals. This procedure is appropriate only for nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies). The K_{ow} has been extensively correlated with the BCF for nonionic organic chemicals that are poorly metabolized by aquatic organisms. Therefore, where substantial metabolism is known to occur in biota, the K_{ow} is not used

to predict the BAF. For nonionic organic chemicals where chemical exposure through the food web is important, use of the K_{ow} alone will under predict the BAF. In such cases, the K_{ow} is adjusted with a FCM similar to the BCF procedure above.

5.3.2 Overview of BAF Derivation Framework

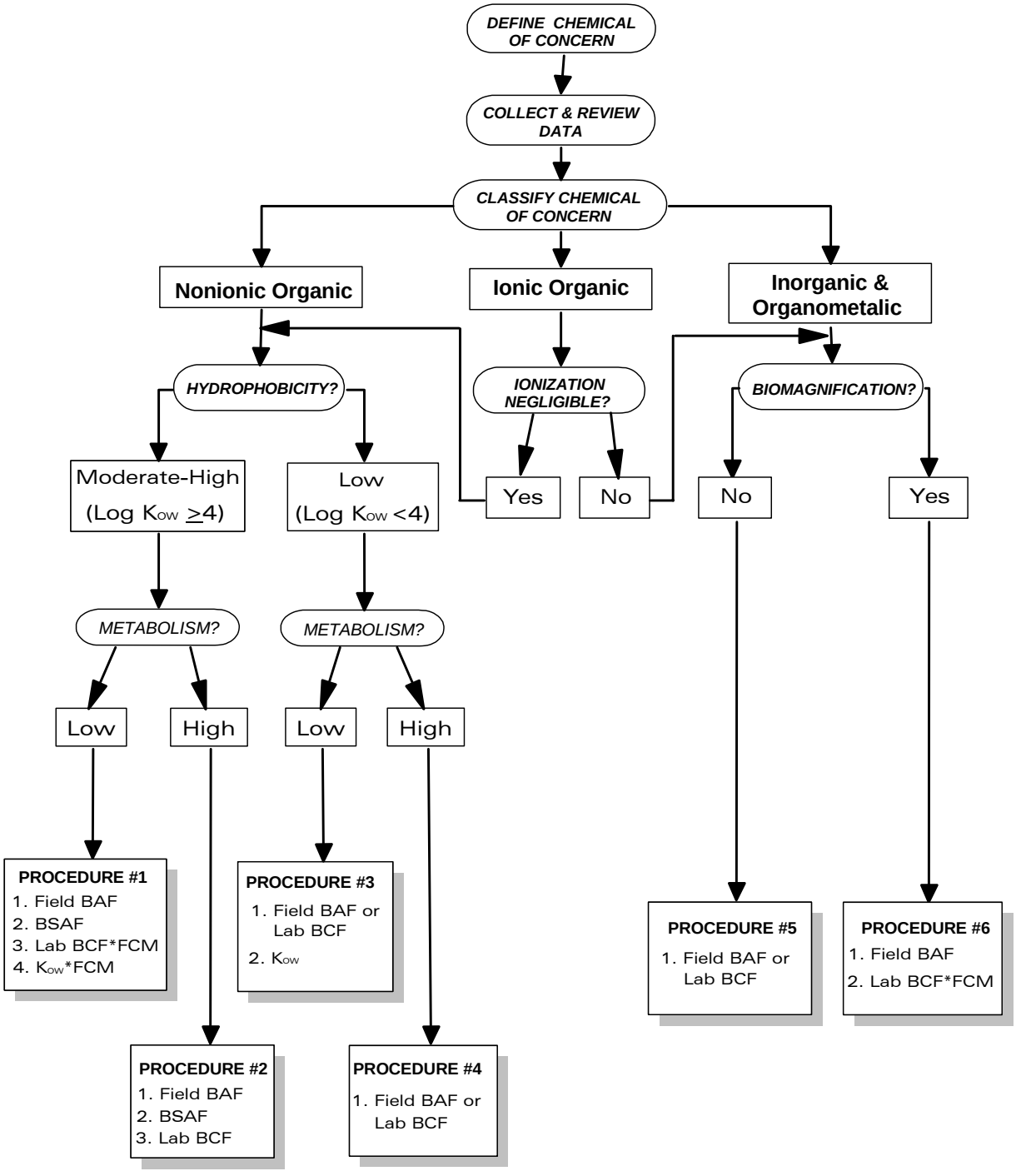
Although up to four methods can be used to derive a BAF as described in the previous section, it is evident that these methods do not apply equally to all types of chemicals. In addition, experience demonstrates that the required data will usually not be available to derive a BAF value using all of the applicable methods. As a result, EPA has developed the following guidelines to direct users in selecting the most appropriate method(s) for deriving a national BAF.

Figure 5-1 shows the overall framework of EPA's national BAF methodology. This framework illustrates the major steps and decisions that will ultimately lead to calculating a national BAF using one of six hierarchical procedures shown at the bottom of Figure 5-1. Each procedure contains a hierarchy of the BAF derivation methods discussed above, the composition of which depends on the chemical type and certain chemical properties (e.g., its degree of hydrophobicity and expected degree of metabolism and biomagnification). The number assigned to each BAF method within a procedure indicates its general order of preference for deriving a national BAF value. The goal of the framework and accompanying guidelines is to enable full use of available data and methods for deriving a national BAF value while appropriately restricting the use of certain methods to reflect their inherent limitations.

The first step in the framework is to define the chemical of concern. As described in Section 5.3.3, the chemical used to derive the national BAF should be consistent with the chemical used to derive the critical health assessment value. The second step is to collect and review all relevant data on bioconcentration and bioaccumulation of the chemical of concern (see Section 5.3.4). Once pertinent data are reviewed, the third step is to classify the chemical of concern into one of three broadly defined chemical categories: (1) nonionic organic chemicals, (2) ionic organic chemicals, and (3) and inorganic and organometallic chemicals. Guidance for classifying chemicals into these three categories is provided in Section 5.3.5.

After a chemical has been classified into one of the three categories, other information is used to select one of six hierarchical procedures to derive the national BAF. The specific procedures for deriving a BAF for each chemical group are discussed in Section 5.4 for nonionic organics, Section 5.5 for ionic organics, and Section 5.6 for inorganics and organometallics.

Figure 5-1. Framework for Deriving a National BAF



Detailed guidance concerning the first three steps of the derivation process (i.e, defining the chemical of concern, collecting and reviewing data, and classifying the chemical of concern) is provided in the following three sections.

5.3.3 Defining the Chemical of Concern

Defining the chemical of concern is the first step in deriving a national BAF. This step involves precisely defining the form(s) of the chemical upon which the national BAF value will be derived. Although this step is usually straightforward for single chemicals, complications can arise when the chemical of concern occurs as a mixture. The following guidelines should be followed for defining the chemical of concern.

1. Information for defining the chemical of concern should be obtained from the health and exposure assessment portions of the criteria derivation effort. The chemical(s) used to derive the national BAF should be consistent with the chemical(s) used to derive the reference dose (RfD), point of departure/uncertainty factor (POD/UF), or cancer potency factor.

2. In most cases, the RfD, POD/UF, or cancer potency factor will be based on a single chemical. In some cases, the RfD, POD/UF, or cancer potency factor will be based on a mixture of compounds, typically within the same chemical class (e.g., toxaphene, chlordane). In these situations, the national BAF should be derived in a manner that is consistent with the mixture used to express the health assessment.

    a. If sufficient data are available to reliably assess the bioaccumulation of each relevant compound contained in the mixture, then the national BAF(s) should be derived using the BAFs for the individual compounds of the mixture and appropriately weighted to reflect the mixture composition used to establish the RfD, POD/UF, or cancer potency factor. An example of this approach is shown in the derivation of BAFs for PCBs in the GLI Rulemaking (USEPA, 1997).

    b. If sufficient data are not available to reliably assess the bioaccumulation of individual compounds of the mixture, then the national BAF(s) should be derived using BAFs for the same or appropriately similar chemical mixture as that used to establish the RfD, POD/UF, or cancer potency value.

5.3.4 Collecting and Reviewing Data

The second step in deriving a national BAF is to collect and review all relevant bioaccumulation data for the chemical of concern. The following guidance should be followed for collecting and reviewing bioaccumulation data for deriving national BAFs.

1. All data on the occurrence and accumulation of the chemical of concern in aquatic animals and plants should be collected and reviewed for adequacy.

2. A comprehensive literature search strategy should be used for gathering bioaccumulation-related data. An example of a comprehensive literature search strategy is provided in the Bioaccumulation TSD.

3. All data that are used should contain sufficient supporting information to indicate that acceptable measurement procedures were used and that the results are probably reliable. In some cases it may be appropriate to obtain additional written information from the investigator.

4. Questionable data, whether published or unpublished, should not be used. Guidance for assessing the acceptability of bioaccumulation and bioconcentration studies is found in Sections 5.4, 5.5, and 5.6.

5.3.5 Classifying the Chemical of Concern

The next step in deriving a national BAF consists of classifying the chemical of concern into one of three categories: nonionic organic, ionic organic, and inorganic and organometallic (Figure 5-1). This step helps to determine which of the four methods described in Section 5.3.1 are appropriate for deriving BAFs. The following guidance applies for classifying the chemical of concern.

1. **Nonionic Organic Chemicals.** For the purposes of the 2000 Human Health Methodology, nonionic organic chemicals are those organic compounds that do not ionize substantially in natural bodies of water. These chemicals are also referred to as neutral or nonpolar organics in the scientific literature. Due to their neutrality, nonionic organic chemicals tend to associate with other neutral (or near neutral) compartments in aquatic ecosystems (e.g., lipid, organic carbon). Examples of nonionic organic chemicals which have been widely studied in terms of their bioaccumulation include polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and furans, many chlorinated pesticides, and polynuclear aromatic hydrocarbons (PAHs). Procedures for deriving a national BAF for nonionic organic chemicals are provided in Section 5.4.

2. **Ionic Organic Chemicals.** For the purposes of the 2000 Human Health Methodology, ionic organic chemicals are considered to include those chemicals that contain functional groups with exchangeable protons such as hydroxyl, carboxylic, and sulfonic groups and functional groups that readily accept protons such as amino and aromatic heterocyclic nitrogen (pyridine) groups. Ionic organic chemicals undergo ionization in water, the extent of which depends on pH and the pKa of the chemical. Because the ionized species of these chemicals behave differently from the neutral species, separate guidance is provided for deriving BAFs for ionic organic chemicals. Procedures for deriving national BAFs for ionic organic chemicals are provided in Section 5.5.

3. **Inorganic and Organometallic Chemicals.** The inorganic and organometallic category is considered to include inorganic minerals, other inorganic compounds and elements, metals (e.g., copper, cadmium, chromium, zinc), metalloids (selenium, arsenic) and

organometallic compounds (e.g., methylmercury, tributyltin, tetraalkyllead). Procedures for deriving BAFs for inorganic and organometallic chemicals are provided in Section 5.6.

5.4 NATIONAL BIOACCUMULATION FACTORS FOR NONIONIC ORGANIC CHEMICALS

5.4.1 Overview

This section contains the methodology for deriving national BAFs for nonionic organic chemicals as defined in Section 5.3.5. The four general steps of this methodology are:

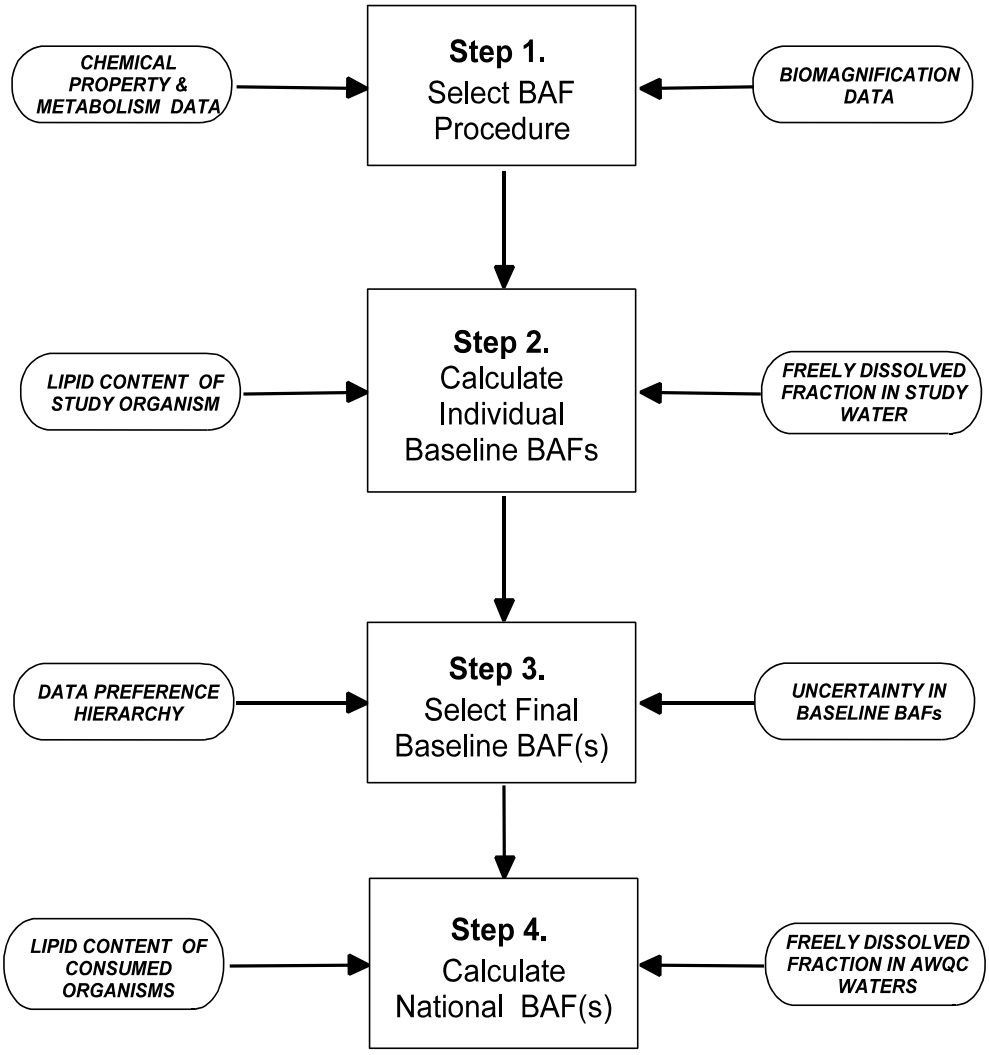
1. Selecting the BAF derivation procedure,
2. Calculating individual baseline BAF_{ℓ}^{fd}s,
3. Selecting the final baseline BAF_{ℓ}^{fd}s, and
4. Calculating the national BAFs from the final baseline BAF_{ℓ}^{fd}s.

A schematic of this four-step process is shown in Figure 5-2.

Step 1 of the methodology (selecting the BAF derivation procedure) determines which of the four BAF procedures summarized in Figure 5-1 will be appropriate for deriving the national BAF. Step 2 involves calculating individual, species-specific BAF_{ℓ}^{fd}s using all of the methods available within the selected BAF derivation procedure. Calculating the individual baseline BAF_{ℓ}^{fd}s involves using data from the field site or laboratory where the original data were collected to account for site-specific factors which affect the bioavailability of the chemical to aquatic organisms (e.g., lipid content of study organisms and freely dissolved concentration in study water). Step 3 of the methodology consists of selecting the final baseline BAF_{ℓ}^{fd}s from the individual baseline BAF_{ℓ}^{fd}s by taking into account the uncertainty in the individual BAFs and the data preference hierarchy selected in Step 1. The final step is to calculate a BAF (or BAFs) that will be used in the derivation of 304(a) criteria (i.e., referred to as the national BAF). This step involves adjusting the final baseline BAF_{ℓ}^{fd}(s) to reflect certain factors that affect bioavailablity of the chemical to aquatic organisms in waters to which the national 304(a) criteria will apply (e.g., the freely dissolved fraction expected in U.S. waters and the lipid content of consumed aquatic organisms). Baseline BAF_{ℓ}^{fd}s are not used directly in the derivation of the 304(a) criteria because they do not reflect the conditions that affect bioavailability in U.S. waters.

Section 5.4.2 below provides detailed guidance for selecting the appropriate BAF derivation procedure (Step 1 of the process). Guidance on calculating individual baseline BAF_{ℓ}^{fd}s, selecting the final baseline BAF, and calculating the national BAF (Steps 2 through 4 of the process) is provided in separate sections under each of the four BAF derivation procedures.

Figure 5-2. BAF Derivation for Nonionic Organic Chemicals



5.4.2 Selecting the BAF Derivation Procedure

This section describes the decisions that should be made to select one of the four available hierarchical procedures for deriving a national BAF for nonionic organic chemicals (Procedures #1 through #4 of Figure 5-1). As shown in Figure 5-1, two decision points exist in selecting the BAF derivation procedure. The first decision point requires knowledge of the chemical's hydrophobicity (i.e., the K_{ow} of the chemical). Guidance for selecting the K_{ow} for a chemical is provided in the Bioaccumulation TSD. The K_{ow} provides an initial basis for assessing whether biomagnification may be a concern for nonionic organic chemicals. The second decision point is based on the rate of metabolism for the chemical in the target organism. Guidance for assessing whether a high or low rate of metabolism is likely for a chemical of concern is provided below in Section 5.4.2.3. With the appropriate information for these two decision points, the BAF derivation procedure should be selected using the following guidelines.

5.4.2.1 <u>Chemicals with Moderate to High Hydrophobicity</u>

1. For the purposes of the 2000 Human Health Methodology, nonionic organic chemicals with log K_{ow} values equal to or greater than 4.0 should be classified as moderately to highly hydrophobic. For moderately to highly hydrophobic nonionic organic chemicals, available data indicate that exposure through the diet and other non-aqueous routes can become important in determining chemical residues in aquatic organisms (e.g., Russell et al., 1999; Fisk et al., 1998; Oliver and Niimi, 1983; Oliver and Niimi, 1988; Niimi, 1985; Swackhammer and Hites, 1988). Dietary and other non-aqueous exposure can become extremely important for those nonionic organic chemicals that are poorly metabolized by aquatic biota (e.g., certain PCB congeners, chlorinated pesticides, and polychlorinated dibenzo-p-dioxins and furans).

2. **Procedure #1** should be used to derive national BAFs for moderately to highly hydrophobic nonionic organic chemicals in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently low such that biomagnification is of concern, or

   (b) the rate of chemical metabolism by target aquatic organisms is not sufficiently known.

   Procedure #1 accounts for non-aqueous exposure and the potential for biomagnification in aquatic food webs through the use of field-measured values for bioaccumulation (i.e., field measured BAF or BSAF) and FCMs when appropriate field data are unavailable. Guidance on deriving national BAFs using Procedure #1 is found below in Section 5.4.3.

3. **Procedure #2** should be used to derive the national BAFs for moderately to highly hydrophobic nonionic organic chemicals in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently high such that biomagnification is not of concern.

Procedure #2 relaxes the requirement of using FCMs and eliminates the use of K_{ow}-based estimates of the BAF, two procedures that are most appropriate for poorly metabolized nonionic organic chemicals. Guidance on deriving national BAFs using Procedure #2 is found below in Section 5.4.4.

5.4.2.2 Chemicals with Low Hydrophobicity

1. For the purposes of these guidelines, nonionic organic chemicals with log K_{ow} values less than 4.0 should be classified as exhibiting low hydrophobicity. For nonionic organic chemicals that exhibit low hydrophobicity (i.e., log $K_{ow} < 4.0$), available information indicates that non-aqueous exposure to these chemicals is not likely to be important in determining chemical residues in aquatic organisms (e.g., Fisk et al., 1998; Gobas et al., 1993; Connolly and Pedersen, 1988; Thomann, 1989). For this group of chemicals, laboratory-measured BCFs and K_{ow}-predicted BCFs do not require adjustment with FCMs for determining the national BAF (Procedures #3 and #4), unless other appropriate data indicate differently.

   Other appropriate data include studies clearly indicating that non-aqueous exposure is important such that use of a BCF would substantially underestimate residues in aquatic organisms. In these cases, Procedure #1 should be used to derive the BAF for nonionic organic chemicals with log $K_{ow} < 4.0$. Furthermore, the data supporting the K_{ow} determination should be carefully reviewed for accuracy and appropriate interpretation, since the apparent discrepancy may be due to errors in determining K_{ow}.

2. **Procedure #3** should be used to derive national BAFs for nonionic organic chemicals of low hydrophobicity in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be negligible, such that tissue residues of the chemical of concern are not substantially reduced compared to an assumption of no metabolism, or

   (b) the rate of chemical metabolism by target aquatic organisms is not sufficiently known.

   Procedure #3 includes the use of K_{ow}-based estimates of the BCF to be used when lab or field data are absent. Guidance on deriving national BAFs using Procedure #3 is found below in Section 5.4.5.

3. **Procedure #4** should be used to derive national BAFs for nonionic organic chemicals of low hydrophobicity in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently high, such that tissue residues of the chemical of concern are substantially reduced compared with an assumption of no metabolism.

Procedure #4 eliminates the option of using K_{ow}-based estimates of the BAF because the K_{ow} may over-predict accumulation when a chemical is metabolized substantially by an aquatic organism. Guidance on deriving national BAFs using Procedure #4 is found below in Section 5.4.6.

5.4.2.3 Assessing Metabolism

Currently, assessing the degree to which a chemical is metabolized by aquatic organisms is confounded by a variety of factors. First, conclusive data on chemical metabolism in aquatic biota are largely lacking. Such data include whole organism studies where the metabolic rates and breakdown products are quantified in fish and other aquatic organisms relevant to human consumption. However, the majority of information on metabolism is derived from *in vitro* liver microsomal preparations in which primary and secondary metabolites may be identified and their rates of formation may or may not be quantified. Extrapolating results from *in vitro* studies to the whole organism involves considerable uncertainty. Second, there are no generally accepted procedures for reliably predicting chemical metabolism by aquatic organisms in the absence of measured data. Third, the rate at which a chemical is metabolized by aquatic organisms can be species and temperature dependent. For example, PAHs are known to be metabolized readily by vertebrate aquatic species (primarily fish), although at rates much less than those observed for mammals. However, the degree of metabolism in invertebrate species is generally much less than the degree in vertebrate species (James, 1989). One hypothesis for this difference is that the invertebrate species lack the detoxifying enzymes and pathways that are present in many vertebrate species.

Given the current limitations on assessing the degree of chemical metabolism by aquatic organisms, the assessment of metabolism should be made on a case-by-case basis using a weight-of-evidence approach. When assessing a chemical's likelihood to undergo substantial metabolism in a target aquatic organism, the following data should be carefully evaluated:

(1) *in vivo* chemical metabolism data,
(2) bioconcentration and bioaccumulation data,
(3) data on chemical occurrence in target aquatic biota, and
(4) *in vitro* chemical metabolism data.

1. ***In vivo* Data.** *In vivo* data on metabolism in aquatic organisms are from studies of chemical metabolism using whole organisms. These studies are usually conducted using large fish from which blood, bile, urine, and individual tissues can be collected for the identification and quantification of metabolites formed over time. *In vivo* studies are considered the most useful for evaluating a chemical's degree of metabolism in an organism because both oxidative (Phase I) and conjugative (Phase II) metabolism can be assessed in these studies. Mass-balance studies, in which parent compound elimination is quantified separately from biotransformation and elimination of metabolites, allow calculation of conversion rate of parent to metabolite as well as metabolite elimination. This information might be used to estimate loss due to metabolism separately from that due to elimination of the parent compound for adjustment of K_{ow}-predicted BAFs. However, due to the analytical and experimental challenges these studies pose, data of

this type are limited. Less rigorous *in vivo* metabolism studies might include the use of metabolic blockers to demonstrate the influence of metabolism on parent compound kinetics. However, caution should be used in interpretation of absolute rates from these data due to the lack of specificity of mammalian derived blockers in aquatic species (Miranda et al., 1998).

2. **Bioconcentration or Bioaccumulation Data.** Data on chemical bioconcentration or bioaccumulation in aquatic organisms can be used indirectly for assessing metabolism. This assessment involves comparing acceptable lab-measured BCFs or field-measured BAFs (after converting to baseline values using procedures below) with the chemical's predicted value based on K_{ow}. The theoretical basis of bioconcentration and bioaccumulation for nonionic organic chemicals indicates that a chemical's baseline BCF should be similar to its K_{ow}-predicted value if metabolism is not occurring or is minimal (see the Bioaccumulation TSD). This theory also indicates that baseline BAFs should be similar to or higher than the K_{ow} for poorly metabolized organic chemicals, with highly hydrophobic chemicals often exhibiting higher baseline BAFs than K_{ow} values. Thus, if a chemical's baseline BCF or BAF is substantially lower than its K_{ow}, this may be an indication that the chemical is being metabolized by the aquatic organism of concern. Note, however, that this difference may also indicate problems in the experimental design or analytical chemistry, and that it may be difficult to discern the difference.

3. **Chemical Occurrence Data.** Although by no means definitive, data on the occurrence of chemicals in aquatic biota (i.e., residue studies) may offer another useful line of evidence for evaluating a chemical's likelihood to undergo substantial metabolism. Such studies are most useful if they have been conducted repeatedly over time and over wide geographical areas. Such studies might indicate a chemical is poorly metabolized if data show that the chemical is being biomagnified in the aquatic food web (i.e., higher lipid-normalized residues in successive trophic levels). Conversely, such studies might indicate a chemical is being metabolized substantially if residue data show a decline in residues with increasing trophic level. Again, other reasons for increases or decreases in concentrations with increasing trophic level might exist and should be carefully evaluated (e.g., incorrect food web assumptions, differences in exposure concentrations).

4. ***In vitro* Data.** *In vitro* metabolism data include data from studies where specific sub-cellular fractions (e.g., microsomal, cytosolic), cells, or tissues from an organism are tested outside the body (i.e., in test-tubes, cell- or tissue-culture). Compared with *in vivo* studies of chemical metabolism in aquatic organisms, *in vitro* studies are much more plentiful in the literature, with the majority of studies characterizing oxidative (Phase I) reactions de-coupled from conjugative (Phase II) metabolism. Cell, tissue, or organ level *in vitro* studies are less common but provide a more complete assessment of metabolism. While such studies are particularly useful for identifying the pathways, rates of formation, and metabolites formed, as well as the enzymes involved and differences in the temperature dependence of metabolism across aquatic species, they suffer from uncertainty when results are extrapolated to the whole organism. This uncertainty results from the fact that dosimetry (i.e., delivery of the toxicant to, and removal of metabolite

from, the target tissue) cannot currently be adequately reproduced in the laboratory or easily modeled.

When assessing chemical metabolism using the above information, the following guidelines apply.

a. A finding of substantial metabolism should be supported by two or more lines of evidence identified using the data described above.

b. At least one of the lines of evidence should be supported by either *in vivo* metabolism data or acceptable bioconcentration or bioaccumulation data.

c. A finding of substantial metabolism in one organism should not be extrapolated to another organism or another group of organisms unless data indicate similar metabolic pathways exist (or are very likely to exist) in both organisms. *In vitro* data may be particularly useful in cross-species extrapolations.

d. Finally, in situations where sufficient data are not available to properly assess the likelihood of significant metabolism in aquatic biota of concern, the chemical should be assumed to undergo little or no metabolism. This assumptions reflects a policy decision by EPA to err on the side of public health protection when sufficient information on metabolism is lacking.

5.4.3 Deriving National BAFs Using Procedure #1

This section contains guidance for calculating national BAFs for nonionic organic chemicals using Procedure #1 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #1 is most appropriate are those that are classified as moderately to highly hydrophobic and subject to low (or unknown) rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are of concern for chemicals that are classified in this category. Some examples of nonionic organic chemicals for which Procedure #1 is considered appropriate include:

- tetra-, penta- & hexachlorobenzenes;
- PCBs;
- octachlorostyrene;
- hexachlorobutadiene;
- endrin, dieldrin, aldrin;
- mirex, photomirex;
- DDT, DDE, DDD; and
- heptachlor, chlordane, nonachlor.

Under Procedure #1, the following four methods may be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF);
- predicting a BAF from an acceptable field-measured BSAF;

- predicting a BAF from an acceptable laboratory-measured BCF and FCM; and
- predicting a BAF from an acceptable K_{ow} and FCM.

As shown in Figure 5-2, once the derivation procedure has been selected, the next steps in deriving a national BAF for a given trophic level include: calculating individual baseline BAF_{ℓ}^{fd}s (step 2), selecting the final baseline BAF_{ℓ}^{fd} (step 3), and calculating the national BAF from the final baseline BAF_{ℓ}^{fd} (step 4). Each of these three steps is discussed separately below.

5.4.3.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

Calculating an individual baseline BAF_{ℓ}^{fd} involves normalizing the field-measured BAF_{T}^{t} (or laboratory-measured BCF_{T}^{t}) which are based on total concentrations in tissue and water by the lipid content of the study organisms and the freely dissolved concentration in the study water. Both the lipid content in the organism and the freely dissolved concentration (as influenced by organic carbon in water) have been shown to be important factors that influence the bioaccumulation of nonionic organic chemicals (e.g., Mackay, 1982; Connolly and Pederson, 1988; Thomann, 1989, Suffet et al., 1994). Therefore, baseline BAF_{ℓ}^{fd}s (which are expressed on a freely dissolved and lipid-normalized basis) are considered more amenable to extrapolating between different species and bodies of water compared to BAFs expressed using the total concentration in the tissue and water. Because bioaccumulation can be strongly influenced by the trophic position of aquatic organisms (either due to biomagnification or physiological differences), extrapolation of baseline BAF_{ℓ}^{fd}s should not be performed between species of different trophic levels.

1. For each species for which acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the four methods shown above for Procedure #1.

2. Individual baseline BAF_{ℓ}^{fd}s should be calculated from field-measured BAF_{T}^{t}s, field-measured BSAFs, laboratory BCF_{T}^{t}s, and the K_{ow} according to the following procedures.

A. Baseline BAF_{ℓ}^{fd}s from Field-Measured BAFs

A baseline BAF_{ℓ}^{fd} should be calculated from each field-measured BAF_{T}^{t} using information on the lipid fraction in the tissue of concern for the study organism and the fraction of the total chemical that is freely dissolved in the study water.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable field-measured BAF_{T}^{t}, calculate a baseline BAF_{ℓ}^{fd} using the following equation:

$$\text{Baseline } BAF_{\ell}^{fd} = \left[\frac{\text{Measured } BAF_{T}^{t}}{f_{fd}} - 1 \right] \left(\frac{1}{f_{\ell}} \right) \qquad \text{(Equation 5-10)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis
Measured BAF_{T}^{t}	=	BAF based on total concentration in tissue and water
f_{ℓ}	=	Fraction of the tissue that is lipid
f_{fd}	=	Fraction of the total chemical that is freely dissolved in the ambient water

The technical basis of Equation 5-10 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-10 is provided below.

2. **Determining the Measured BAF_{T}^{t}.** The field-measured BAF_{T}^{t} shown in Equation 5-10 should be calculated based on the total concentration of the chemical in the appropriate tissue of the aquatic organism and the total concentration of the chemical in ambient water at the site of sampling. The equation to derive a measured BAF_{T}^{t} is:

$$\text{Measured } BAF_{T}^{t} = \frac{C_t}{C_w} \qquad \text{(Equation 5-11)}$$

where:

C_t	=	Total concentration of the chemical in the specified wet tissue
C_w	=	Total concentration of chemical in water

The data used to calculate a field-measured BAF_{T}^{t} should be reviewed thoroughly to assess the quality of the data and the overall uncertainty in the BAF value. The following general criteria apply in determining the acceptability of field-measured BAFs that are being considered for deriving national BAFs using Procedure #1.

a. Aquatic organisms used to calculate a field-measured BAF_{T}^{t} should be representative of aquatic organisms that are commonly consumed in the United States. An aquatic organism that is not commonly consumed in the United States can be used to calculate an acceptable field-measured BAF_{T}^{t} provided that the organism is considered to be a reasonable surrogate for a commonly consumed organism. Information on the ecology, physiology, and biology of the organism should be reviewed when assessing whether an organism is a reasonable surrogate of a commonly consumed organism.

b. The trophic level of the study organism should be determined by taking into account its life stage, diet, size, and the food web structure at the study location. Information from the study site (or similar sites) is preferred when evaluating trophic status. If such information is lacking, general information for assessing trophic status of aquatic organisms can be found in USEPA (2000a,b,c).

c. The percent lipid of the tissue used to determine the field-measured BAF_T^t should be either measured or reliably estimated to permit lipid-normalization of the chemical's tissue concentration.

d. The study from which the field-measured BAF_T^t is derived should contain sufficient supporting information from which to determine that tissue and water samples were collected and analyzed using appropriate, sensitive, accurate, and precise analytical methods.

e. The site of the field study should not be so unique that the BAF cannot be reasonably extrapolated to other locations where the BAF and resulting criteria will apply.

f. The water concentration(s) used to derive the BAF should reflect the average exposure of the aquatic organism that corresponds to the concentration measured in its tissue of concern. For nonionic organic chemicals, greater temporal and spatial averaging of chemical concentrations is required as the K_{ow} increases. In addition, as variability in water concentrations increase, greater temporal and spatial averaging is also generally required. Greater spatial averaging is also generally required for more mobile organisms.

g. The concentrations of particulate organic carbon and dissolved organic carbon in the study water should be measured or reliably estimated.

EPA is currently developing guidance for designing and conducting field studies for determining field-measured BAF_T^ts, including recommendations for minimum data requirements. A more detailed discussion of factors that should be considered when determining field-measured BAF_T^ts is provided in the Bioaccumulation TSD.

3. **Determining the Fraction Freely Dissolved (f_{fd}).** As illustrated by Equation 5-10, the fraction of the nonionic organic chemical that is freely dissolved in the study water is required for calculating a baseline BAF_ℓ^{fd} from a field-measured BAF_T^t. The freely dissolved fraction is the portion of the nonionic organic chemical that is not bound to particulate organic carbon or dissolved organic carbon. Together, the concentration of a nonionic organic chemical that is freely dissolved, bound to dissolved organic carbon, and bound to particulate organic carbon constitute its total concentration in water. As discussed further in the Bioaccumulation TSD, the freely dissolved fraction of a chemical is considered to be the best expression of the bioavailable form of nonionic organic chemicals to aquatic organisms (e.g., Suffet et al., 1994; USEPA, 1995b). Because the fraction of a nonionic organic chemical that is freely dissolved may vary among different bodies of water as a result of differences in dissolved and particulate organic carbon in the water, the bioavailability of the total chemical concentration in water is expected to vary from one body of water to another. Therefore, BAFs which are based on the freely dissolved concentration in water (rather than the total concentration in water) are considered to be more reliable for extrapolating and aggregating BAFs among different bodies of water. Currently, availability of BAFs based on measured freely dissolved

concentrations is very limited, partly because of difficulties in analytically measuring the freely dissolved concentration. Thus, if a BAF based on the total water concentration is reported in a given study, the fraction of the chemical that is freely dissolved should be predicted using information on the organic carbon content in the study water.

a. **Equation for Determining the Freely Dissolved Fraction.** If reliable measured data are unavailable to directly determine the freely dissolved fraction of the chemical in water, the freely dissolved fraction should be estimated using the following equation.

$$f_{fd} = \frac{1}{[1 + (POC \cdot K_{ow}) + (DOC \cdot 0.08 \cdot K_{ow})]} \qquad \text{(Equation 5-12)}$$

where:

POC	=	concentration of particulate organic carbon (kg/L)
DOC	=	concentration of dissolved organic carbon (kg/L)
K_{ow}	=	n-octanol water partition coefficient for the chemical

In Equation 5-12, K_{ow} is being used to estimate the partition coefficient to POC (i.e., K_{POC} in L/kg) and $0.08 \cdot K_{ow}$ is being used to estimate the partition coefficient to DOC (i.e., the K_{DOC} in L/kg). A discussion of the technical basis, assumptions, and uncertainty associated with the derivation and application of Equation 5-12 is provided in the Bioaccumulation TSD.

b. **POC and DOC Values.** When converting from the total concentration of a chemical to a freely dissolved concentration using Equation 5-12 above, the POC and DOC concentrations should be obtained from the original study from which the field-measured BAF is determined. If POC and DOC concentrations are not reported in the BAF study, reliable estimates of POC and DOC might be obtained from other studies of the same site used in the BAF study or closely related site(s) within the same water body. When using POC/DOC data from other studies of the same water body, care should be taken to ensure that environmental and hydrological conditions that might affect POC or DOC concentrations (i.e., runoff events, proximity to ground water or surface water inputs, sampling season) are reasonably similar to those in the BAF study. Additional information related to selecting POC and DOC values is provided in the Bioaccumulation TSD.

In some cases, BAFs are reported using the concentration of the chemical in filtered or centrifuged water. When converting these BAFs to a freely dissolved basis, the concentration of POC should be set equal to zero when using Equation 5-12. Particulates are removed from water samples by filtering or centrifuging the sample.

c. **Selecting K_{ow} Values.** A variety of techniques are available to measure or predict K_{ow} values. The reliability of these techniques depends to a large extent on the K_{ow} of the chemical. Because K_{ow} is an important input parameter for calculating the freely dissolved concentration of nonionic organic chemicals and for deriving BAFs using the other three methods of Procedure #1, care should be taken in selecting the most reliable K_{ow} value. The value of K_{ow} for use in estimating the freely dissolved fraction and other procedures used to derive national BAFs should be selected based on the guidance presented in the Bioaccumulation TSD.

4. **Determining the Fraction Lipid (f_ℓ).** Calculating a baseline BAF_ℓ^{fd} for a nonionic organic chemical using Equation 5-10 also requires that the total chemical concentration measured in the tissue used to determine the field-measured BAF_T^t be normalized by the lipid fraction (f_ℓ) in that same tissue. Lipid normalization of tissue concentrations reflects the assumption that BAFs (and BCFs) for nonionic organic chemicals are directly proportional to the percent lipid in the tissue upon which they are based. This assumption means that an organism with a two percent lipid content would be expected to accumulate twice the amount of a chemical at steady state compared with an organism with one percent lipid content, all else being equal. The assumption that aquatic organisms accumulate nonionic organic chemicals in proportion to their lipid content has been extensively evaluated in the literature (Mackay, 1982; Connell, 1988; Barron, 1990) and is generally accepted. Because the lipid content in aquatic organisms can vary both within and across species, BAFs that are expressed using the lipid-normalized concentration (rather than the total concentration in tissue) are considered to be the most reliable for aggregating multiple BAF values for a given species. Additional discussion of technical basis, assumptions, and uncertainties involved in lipid normalization is provided in the Bioaccumulation TSD.

a. The lipid fraction f_ℓ, is routinely reported in bioaccumulation studies involving nonionic organic chemicals. If the lipid fraction is not reported in the BAF study, it can be calculated using the following equation if the appropriate data are reported:

$$f_\ell = \frac{M_\ell}{M_t} \qquad \text{(Equation 5-13)}$$

where:

M_ℓ = Mass of lipid in specified tissue
M_t = Mass of specified tissue (wet weight)

b. Because lipid content can vary within an aquatic organism (and among tissues within that organism) due to several factors including the age and sex of the organism, changes in dietary composition, season of sampling and reproductive status, the lipid fraction used to calculate a baseline BAF_ℓ^{fd} should be measured in

the same tissue and organisms used to determine the field-measured BAF_T^t, unless comparability is demonstrated across organisms.

c. Experience has shown that different solvent systems used to extract lipids for analytical measurement can result in different quantities of lipids being extracted and measured in aquatic organisms (e.g., Randall et al.,1991, 1998). As a result, lipid measurements determined using different solvent systems might lead to apparent differences in lipid-normalized concentrations and lipid-normalized BAFs. The extent to which different solvent systems might affect lipid extractions (and lipid-normalized concentrations) is thought to vary depending on the solvent, chemical of concern, and lipid composition of the tissue being extracted. Guidance on measurement of lipid content, including the choice of solvent system and how different solvent systems may affect lipid content, is provided in the Bioaccumulation TSD.

B. Baseline BAF_ℓ^{fd} Derived from BSAFs

The second method of determining a baseline BAF_ℓ^{fd} for the chemical of concern in Procedure #1 involves the use of BSAFs. Although BSAFs may be used for measuring and predicting bioaccumulation directly from concentrations of chemicals in surface sediment, they may also be used to estimate BAFs (USEPA, 1995b; Cook and Burkhard, 1998). Since BSAFs are based on field data and incorporate effects of chemical bioavailability, food web structure, metabolism, biomagnification, growth, and other factors, BAFs estimated from BSAFs will incorporate the net effect of all these factors. The BSAF approach is particularly beneficial for developing water quality criteria for chemicals which are detectable in fish tissues and sediments, but are difficult to detect or measure precisely in the water column.

As shown by Equation 5-14 below, predicting baseline BAF_ℓ^{fd}s using BSAFs requires that certain types of data be used for the chemicals of interest (for which BAFs are to be determined) and reference chemicals (for which BAFs are measured) from a common sediment-water-organism data set. Differences between BSAFs for different organic chemicals are good measures of the relative bioaccumulation potentials of the chemicals. When calculated from a common organism-sediment sample set, chemical-specific differences in BSAFs reflect the net effect of biomagnification, metabolism, food chain, bioenergetics, and bioavailability factors on the degree of each chemical's equilibrium/disequilibrium between sediment and biota. At equilibrium, BSAFs are expected to be approximately 1.0. However, deviations from 1.0 (reflecting disequilibrium) are common due to: conditions where water is not at equilibrium with surface sediment; differences in organic carbon content of water and sediment; kinetic limitations for chemical transfer between sediments and water associated with specific biota; biomagnification; or biological processes such as growth or biotransformation. BSAFs are most useful (i.e., most predictable from one site to another) when measured under steady-state (or near steady-state) conditions. The use of non-steady-state BSAFs, such as found with new chemical loadings or rapid increases in loadings, increases uncertainty in this method for the relative degree of disequilibrium between the reference chemicals and the chemicals of interest. In general, the fact that concentrations of hydrophobic chemicals in sediment are less sensitive than concentrations in water to fluctuations in chemical loading and distribution makes the BSAF

method robust for estimating BAFs. Results from validation of the BAF procedure in Lake Ontario, the Fox River and Green Bay, Wisconsin, and the Hudson River, New York, demonstrate good agreement between observed and BSAF-predicted BAFs in the vast majority of comparisons made. Detailed results of the validation studies for the BSAF procedure are provided in the Bioaccumulation TSD.

Baseline BAF_{ℓ}^{fd}s should be calculated using acceptable BSAFs for chemicals of interest and appropriate sediment-to-water fugacity (disequilibrium) ratios $(\prod_{socw})_r/(K_{ow})_r$ for reference chemicals under the following guidelines.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each species with an acceptable field measured $(BSAF)_I$, a baseline BAF_{ℓ}^{fd} for the chemical of interest may be calculated using the following equation with an appropriate value of $(\prod_{socw})_r/(K_{ow})_r$:

$$(Baseline\ BAF_{\ell}^{fd})_i = (BSAF)_i \frac{(D_{i/r})\ (\prod_{socw})_r\ (K_{ow})_i}{(K_{ow})_r} \qquad \text{(Equation 5-14)}$$

where:

$(\text{Baseline } BAF_{\ell}^{fd})_I$	=	BAF expressed on a freely dissolved and lipid-normalized basis for chemical of interest "I"
$(BSAF)_I$	=	Biota-sediment accumulation factor for chemical of interest "I"
$(\prod_{socw})_r$	=	sediment organic carbon to water freely dissolved concentration ratio of reference chemical "r"
$(K_{ow})_I$	=	octanol-water partition coefficient for chemical of interest "I"
$(K_{ow})_r$	=	octanol-water partition coefficient for the reference chemical "r"
$D_{i/r}$	=	ratio between $\prod_{socw}/K_{ow}$ for chemicals "I" and "r" (normally chosen so that $D_{i/r} = 1$)

The technical basis, assumptions, and uncertainties associated with Equation 5-14 are provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-14 is provided below.

2. **Determining Field-Measured BSAFs.** BSAFs should be determined by relating lipid-normalized concentrations of chemicals in an organism (C_{ℓ}) to organic carbon-normalized concentrations of the chemicals in surface sediment samples (C_{soc}) using the following equation:

$$BSAF = \frac{C_{\ell}}{C_{soc}} \qquad \text{(Equation 5-15)}$$

a. **Lipid-Normalized Concentration.** The lipid-normalized concentration of a chemical in an organism should be determined by:

$$C_{\ell} = \frac{C_t}{f_{\ell}} \qquad \text{(Equation 5-16)}$$

where:

C_t = Concentration of the chemical in the wet tissue (either whole organism or specified tissue) (µg/g)
f_{ℓ} = Fraction lipid content in the tissue

b. **Organic Carbon-Normalized Concentration.** The organic carbon-normalized concentration of a chemical in sediment should be determined by:

$$C_{soc} = \frac{C_s}{f_{oc}} \qquad \text{(Equation 5-17)}$$

where:

C_s = Concentration of chemical in sediment (µg/g sediment)
f_{oc} = Fraction organic carbon in sediment

The organic carbon-normalized concentrations of the chemicals in surface sediment samples should be associated with the average exposure environment of the organism.

3. **Sediment-to-Water Partition Coefficient** $(\prod_{socw})_r$. Sediment-to-water partition coefficients for reference chemicals should be determined by:

$$(\prod_{socw})_r = \frac{(C_{soc})_r}{(C_w^{fd})_r} \qquad \text{(Equation 5-18)}$$

where:

$(C_{soc})_r$ = Concentration of a reference chemical in sediment normalized to sediment organic carbon
$(C_w^{fd})_r$ = Concentration of the reference chemical freely dissolved in water

4. **Selecting Reference Chemicals.** Reference chemicals with $(\prod_{socw}) / (K_{ow})$ similar to that of the chemical of interest are preferred for this method. Theoretically, knowledge of the

difference between sediment-to-water fugacity ratios for two chemicals, "I" and "r" ($D_{i/r}$), could be used when reliable reference chemicals that meet the fugacity equivalence condition are not available. Similarity of $(\prod_{socw}) / (K_{ow})$ for two chemicals can be indicated on the basis of similar physical-chemical behavior in water (persistence, volatilization), similar mass loading histories, and similar concentration profiles in sediment cores.

Validation studies have demonstrated that choosing reference chemicals with well quantified concentrations in water is important because the uncertainty associated with measurement of barely detected chemicals is large (see the Bioaccumulation TSD). Similarity between K_{ow} values of the reference and target chemicals is generally desirable, although recent validation studies indicate that the accuracy of the method is not substantially decreased through use of reference chemicals with large differences in K_{ow}, as long as the chemicals are structurally similar and have similar persistence behavior in water and sediments.

5. The following data, procedural, and quality assurance requirements should be met for predicting baseline BAF_{ℓ}^{fd}s using field-measured BSAFs:

   a. Data on the reference chemicals and chemicals of interest should come from a common organism-water-sediment data set at a particular site.

   b. The chemicals of interest and reference chemicals should have similar physicochemical properties and persistence in water and sediment.

   c. The loadings history of the reference chemicals and chemicals of interest should be similar such that their expected sediment-water disequilibrium ratios $(\prod_{socw}/K_{ow})$ would not be expected to be substantially different (i.e., $D_{i/r} \sim 1$).

   d. The use of multiple reference chemicals is generally preferred for determining the value of $(\prod_{socw})_r$ so long as the concentrations are well quantified and the aforementioned conditions for selecting reference chemicals are met. In some cases, use of a single reference chemical may be necessary because of limited data.

   e. Samples of surface sediments (0-1 cm is ideal) should be from locations in which sediment is regularly deposited and is representative of average surface sediment in the vicinity of the organism.

   f. The K_{ow} value for the target and reference chemicals should be selected as described in the Bioaccumulation TSD.

   g. All other data quality and procedural guidelines described earlier for determining field-measured BAFs in Section 5.4.3.1(A) should be met.

Further details on the requirements for predicting BAFs from BSAF measurements, including the data, assumptions, and limitations of this approach are provided in the Bioaccumulation TSD.

C. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF_T^t and FCM

The third method in Procedure #1 consists of using a laboratory-measured BCF_T^t (i.e., a BCF based on total concentrations in tissue and water) and FCMs to predict a baseline BAF_{ℓ}^{fd} for the chemical of concern. The BCF_T^t is used in conjunction with an FCM because non-aqueous routes of exposure and subsequent biomagnification is of concern for the types of chemicals applicable to Procedure #1. A laboratory-measured BCF inherently accounts for the effects of chemical metabolism that occurs in the organism used to calculate the BCF, but does not account for metabolism which may occur in other organisms of the aquatic food web.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable laboratory-measured BCF_T^t, calculate a baseline BAF_{ℓ}^{fd} using the following equation:

$$\text{Baseline } BAF_{\ell}^{fd} = (FCM) \cdot \left[\frac{\text{Measured } BCF_T^t}{f_{fd}} - 1 \right] \cdot \left(\frac{1}{f_{\ell}} \right) \qquad \text{(Equation 5-19)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis
Measured BCF_T^t	=	BCF based on total concentration in tissue and water
f_{ℓ}	=	Fraction of the tissue that is lipid
f_{fd}	=	Fraction of the total chemical in the test water that is freely dissolved
FCM	=	The food chain multiplier either obtained from Table 5-1 by linear interpolation for the appropriate trophic level, or from appropriate field data

The technical basis for Equation 5-19 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-19 is provided below.

2. **Determining the Measured BCF_T^t.** The laboratory-measured BCF_T^t shown in Equation 5-19 should be calculated using information on the total concentration of the chemical in the tissue of the organism and the total concentration of the chemical in the laboratory test water. The equation to derive a measured BCF_T^t is:

$$\text{Measured } BCF_T^t = \frac{C_t}{C_w} \qquad \text{(Equation 5-20)}$$

where:

C_t = Total concentration of the chemical in the specified wet tissue
C_w = Total concentration of chemical in the laboratory test water

The data used to calculate a laboratory-measured BCF_T^t should be reviewed thoroughly to assess the quality of the data and the overall uncertainty in the BCF value. The following general criteria apply in determining the acceptability of laboratory-measured BCF_T^t.

a. The test organism should not be diseased, unhealthy, or adversely affected by the concentration of the chemical because these attributes may alter accumulation of chemicals compared with healthy organisms.

b. The total concentration of the chemical in the water should be measured and should be relatively constant during the exposure period.

c. The organisms should be exposed to the chemical using a flow-through or renewal procedure.

d. The percent lipid of the tissue used to normalize the BCF_T^t should be either measured or reliably estimated to permit lipid normalization of chemical concentrations.

e. The concentrations of particulate organic carbon and dissolved organic carbon in the study water should be measured or reliably estimated.

f. Aquatic organisms used to calculate a laboratory-measured BCF_T^t should be representative of those aquatic organisms that are commonly consumed in the United States. An aquatic organism which is not commonly consumed in the United States can be used to calculate an acceptable laboratory-measured BCF_T^t provided that the organism is considered to be a reasonable surrogate for a commonly consumed organism. Information on the ecology, physiology, and biology of the organism should be reviewed when assessing whether an organism is a reasonable surrogate of a commonly consumed organism.

g. BCFs may be based on measurement of radioactivity from radiolabeled parent compounds only when the BCF is intended to include metabolites, when there is confidence that there is no interference due to metabolites of the parent compounds, or when studies are conducted to determine the extent of metabolism, thus allowing for a proper correction.

h. The calculation of the BCF_T^t should appropriately address growth dilution, which can be particularly important in affecting BCF_T^t determinations for poorly depurated chemicals.

I. Other aspects of the methodology used should be similar to those described by the American Society of Testing and Materials (ASTM, 1999) and USEPA *Ecological Effects Test Guidelines* (USEPA, 1996).

j. In addition, the magnitude of the K_{ow} and the availability of corroborating BCF data should be considered. For example, if the steady-state method is used for the BCF_T^t determination, exposure periods longer than 28 days will generally be required for highly hydrophobic chemicals to reach steady state between the water and the organism.

k. If a baseline BCF_ℓ^{fd} derived from a laboratory-measured BCF_T^t consistently increases or decreases as the chemical concentration increases in the test solutions for the test organisms, the BCF_T^t should be selected from the test concentration(s) that would most closely correspond to the 304(a) criterion. Note: a BCF_T^t should not be calculated from a control treatment.

3. **Selecting Food Chain Multipliers.** An FCM reflects a chemical's tendency to biomagnify in the aquatic food web. Values of FCMs greater than 1.0 are indicative of biomagnification and typically apply to organic chemicals with log K_{ow} values between 4.0 and 9.0. For a given chemical, FCMs tend to be greater at higher trophic levels, although FCMs for trophic level three can be higher than those for trophic level four.

Food chain multipliers used to derive baseline BAF_ℓ^{fd}s using Procedure #1 can be selected from model-derived or field-derived estimates.

a. **Model-Derived FCMs.** For nonionic organic chemicals appropriate for Procedure #1, EPA has calculated FCMs for various K_{ow} values and trophic levels using the bioaccumulation model of Gobas (1993). The FCMs shown in Table 5-1 were calculated using the Gobas model as the ratio of the baseline BAF_ℓ^{fd}s for trophic levels 2, 3, and 4 to the baseline BCF_ℓ^{fd}.

EPA recommends using the biomagnification model by Gobas (1993) to derive FCMs for nonionic organic chemicals for several reasons. First, the Gobas model includes both benthic and pelagic food chains, thereby incorporating exposure of organisms to chemicals from both the sediment and the water column. Second, the input data needed to run the model can be readily defined. Third, the predicted BAFs using the model are in agreement with field-measured BAFs for chemicals, even those with very high log K_{ow}s. Finally, the model predicts chemical residues in benthic organisms using equilibrium partitioning theory, which is consistent with EPA's equilibrium partitioning sediment guidelines (USEPA, 2000d).

The Gobas model requires input of specific data on the structure of the food chain and the water quality characteristics of the water body of interest. For calculating national BAFs, a mixed pelagic/benthic food web structure consisting of four trophic levels is assumed. Trophic level 1 is phytoplankton, trophic level 2 is

zooplankton, trophic level 3 is forage fish (e.g., sculpin and smelt), and trophic level 4 are predatory fish (e.g., salmonids). Additional assumptions are made regarding the composition of the aquatic species' diets (e.g., salmonids consume 10 percent sculpin, 50 percent alewives, and 40 percent smelt), the physical parameters of the aquatic species (e.g., lipid values), and the water quality characteristics (e.g., water temperature, sediment organic carbon).

A mixed pelagic/benthic food web structure has been assumed for the purpose of calculating FCMs because it is considered to be most representative of the types of food webs that occur in aquatic ecosystems. FCMs derived using the mixed pelagic/benthic structure are also about mid-range in magnitude between a 100% pelagic and 100% benthic driven food web (see the Bioaccumulation TSD). The validity of FCMs derived using the mixed pelagic/benthic food web structure has

Table 5-1
Food-Chain Multipliers for Trophic Levels 2, 3 and 4
(Mixed Pelagic and Benthic Food Web Structure and $\prod_{socw} / K_{OW} = 23$)

Log K_{OW}	Trophic Level 2	Trophic Level 3	Trophic Level 4	Log K_{OW}	Trophic Level 2	Trophic Level 3	Trophic Level 4
4.0	1.00	1.23	1.07	6.6	1.00	12.9	23.8
4.1	1.00	1.29	1.09	6.7	1.00	13.2	24.4
4.2	1.00	1.36	1.13	6.8	1.00	13.3	24.7
4.3	1.00	1.45	1.17	6.9	1.00	13.3	24.7
4.4	1.00	1.56	1.23	7.0	1.00	13.2	24.3
4.5	1.00	1.70	1.32	7.1	1.00	13.1	23.6
4.6	1.00	1.87	1.44	7.2	1.00	12.8	22.5
4.7	1.00	2.08	1.60	7.3	1.00	12.5	21.2
4.8	1.00	2.33	1.82	7.4	1.00	12.0	19.5
4.9	1.00	2.64	2.12	7.5	1.00	11.5	17.6
5.0	1.00	3.00	2.51	7.6	1.00	10.8	15.5
5.1	1.00	3.43	3.02	7.7	1.00	10.1	13.3
5.2	1.00	3.93	3.68	7.8	1.00	9.31	11.2
5.3	1.00	4.50	4.49	7.9	1.00	8.46	9.11
5.4	1.00	5.14	5.48	8.0	1.00	7.60	7.23
5.5	1.00	5.85	6.65	8.1	1.00	6.73	5.58
5.6	1.00	6.60	8.01	8.2	1.00	5.88	4.19
5.7	1.00	7.40	9.54	8.3	1.00	5.07	3.07
5.8	1.00	8.21	11.2	8.4	1.00	4.33	2.20
5.9	1.00	9.01	13.0	8.5	1.00	3.65	1.54
6.0	1.00	9.79	14.9	8.6	1.00	3.05	1.06
6.1	1.00	10.5	16.7	8.7	1.00	2.52	0.721
6.2	1.00	11.2	18.5	8.8	1.00	2.08	0.483
6.3	1.00	11.7	20.1	8.9	1.00	1.70	0.320
6.4	1.00	12.2	21.6	9.0	1.00	1.38	0.210
6.5	1.00	12.6	22.8				

been evaluated in several different ecosystems including Lake Ontario, the tidally influenced Bayou D'Inde in Louisiana, the Fox River and Green Bay, Wisconsin, and the Hudson River in New York. Additional details of the validation of EPA's national default FCMs and the assumptions, uncertainties, and input parameters for the model are provided in the Bioaccumulation TSD.

Although EPA uses the FCMs in Table 5-1 to derive its national 304(a) criteria, EPA recognizes that food webs of other waterbodies might differ from the assumptions used to calculate national BAFs. In these situations, States and authorized Tribes may wish to use alternate food web structures for calculating FCMs for use in setting State or Tribal water quality criteria. Additional guidance on the use of alternate food web structures for calculating State, Tribal, or site-specific criteria is provided in the Bioaccumulation TSD.

b. **Field-Derived FCMs.** In addition to model-derived estimates of FCMs, field data may also be used to derive FCMs. Currently, the use of field-derived FCMs is the only method recommended for estimating FCMs for inorganic and organometalic chemicals because appropriate model-derived estimates are not yet available (see Section 5.6). In contrast to the model-based FCMs described previously, field-derived FCMs account for any metabolism of the chemical of concern by the aquatic organisms used to calculate the FCM.

Field-derived FCMs should be calculated using lipid-normalized concentrations of the nonionic organic chemical in appropriate predator and prey species using the following equations.

$$FCM_{TL2} = BMF_{TL2} \quad \text{(Equation 5-21)}$$

$$FCM_{TL3} = (BMF_{TL3})\,(BMF_{TL2}) \quad \text{(Equation 5-22)}$$

$$FCM_{TL4} = (BMF_{TL4})\,(BMF_{TL3})\,(BMF_{TL2}) \quad \text{(Equation 5-23)}$$

where:

FCM = Food chain multiplier for designated trophic level (TL2, TL3, or TL4)
BMF = Biomagnification factor for designated trophic level (TL2, TL3, or TL4)

The basic difference between FCMs and BMFs is that FCMs relate back to trophic level one (or trophic level two as assumed by the Gobas (1993) model), whereas BMFs always relate back to the next lowest trophic level. For nonionic organic chemicals, BMFs can be calculated from tissue residue concentrations determined in biota at a site according to the following equations.

$$BMF_{TL2} = (C_{\ell, TL2}) / (C_{\ell, TL1}) \quad \text{(Equation 5-24)}$$

$$BMF_{TL3} = (C_{\ell, TL3}) / (C_{\ell, TL2}) \quad \text{(Equation 5-25)}$$

$$BMF_{TL4} = (C_{\ell, TL4}) / (C_{\ell, TL3}) \quad \text{(Equation 5-26)}$$

where:

C_ℓ = Lipid-normalized concentration of chemical in tissue of appropriate biota that occupy the specified trophic level (TL2, TL3, or TL4)

In addition to the acceptability guidelines pertaining to field-measured BAFs, the following procedural and quality assurance requirements apply to field-measured FCMs.

(1) Information should be available to identify the appropriate trophic levels for the aquatic organisms and appropriate predator-prey relationships for the site from which FCMs are being determined. General information on determining trophic levels of aquatic organisms can be found in USEPA 2000a,b,c.

(2) The aquatic organisms sampled from each trophic level should reflect the most important exposure pathways leading to human exposure via consumption of aquatic organisms. For higher trophic levels (e.g., 3 and 4), aquatic species should also reflect those that are commonly consumed by humans.

(3) The studies from which the FCMs are derived should contain sufficient supporting information from which to determine that tissue samples were collected and analyzed using appropriate, sensitive, accurate, and precise methods.

(4) The percent lipid should be either measured or reliably estimated for the tissue used to determine the FCM.

(5) The tissue concentrations should reflect average exposure over the approximate time required to achieve steady-state in the target species.

D. Baseline BAF_ℓ^{fd} from a K_{ow} and FCM

The fourth method in Procedure #1 consists of using a K_{ow} and an appropriate FCM for estimating the baseline BAF_ℓ^{fd}. In this method, the K_{ow} is assumed to be equal to the baseline BCF_ℓ^{fd}. Numerous investigations have demonstrated a linear relationship between the logarithm of the BCF and the logarithm of the octanol-water partition coefficient (K_{ow}) for organic chemicals for fish and other aquatic organisms. Isnard and Lambert (1988) list various regression equations that illustrate this linear relationship. When the regression equations are constructed using lipid-normalized BCFs, the slopes and intercepts are not significantly different from one and zero, respectively (e.g., de Wolf, et al., 1992). The underlying assumption for the linear relationship between the BCF and K_{ow} is that the bioconcentration process can be viewed as the partitioning of a chemical between the lipid of the aquatic organisms and water and that the K_{ow} is a useful surrogate for this partitioning process (Mackay, 1982). To account for biomagnification, Procedure #1 requires the K_{ow} value be used in conjunction with an appropriate FCM.

00229

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable K_{ow} value and FCM for the chemical of concern, calculate a baseline BAF_{ℓ}^{fd} using the following equation.

$$\text{Baseline } BAF_{\ell}^{fd} = (FCM) \cdot (K_{ow}) \qquad \text{(Equation 5-27)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis for a given trophic level
FCM	=	The food chain multiplier for the appropriate trophic level obtained from Table 5-1 by linear interpolation or from appropriate field data (used with Procedure #1 only)
K_{ow}	=	Octanol-water partition coefficient

The BCF-K_{ow} relationship has been developed primarily for nonionic organic chemicals that are not readily metabolized by aquatic organisms and thus is most appropriate for poorly-metabolized nonionic organic chemicals (i.e., Procedures #1 and #3 as depicted in Figure 5-1). For poorly-metabolized nonionic organic chemicals with large log K_{ow}s (i.e., > 6), reported log BCFs are often not equal to log K_{ow}. EPA believes that this nonlinearity is primarily due to not accounting for several factors which affect the BCF determination. These factors include not basing BCFs on the freely dissolved concentration in water, not accounting for growth dilution, not assessing BCFs at steady-state, inaccuracies in measurements of uptake and elimination rate constants, and complications from the use of solvent carriers in the exposure. Application of Equation 5-27 for predicting BAFs has been conducted in several different ecosystems including Lake Ontario, the tidally influenced Bayou D'Inde in Louisiana, the Fox River and Green Bay, Wisconsin, and the Hudson River in New York. Additional detail on the validation, technical basis, assumptions, and uncertainty associated with Equation 5-27 and is provided in the Bioaccumulation TSD.

2. **FCMs and K_{ow}s**. Food chain multipliers and K_{ow} values should be selected as described previously in Procedure #1.

5.4.3.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #1 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s (see Figures 5-1 and 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. The final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #1 and uncertainty in the data. The data preference hierarchy for Procedure #1 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF (method 1)

2. a baseline BAF_{ℓ}^{fd} predicted from an acceptable field-measured BSAF (method 2),
3. a baseline BAF_{ℓ}^{fd} predicted from an acceptable BCF and FCM (method 3), or
4. a baseline BAF_{ℓ}^{fd} predicted from an acceptable K_{ow} and FCM (method 4).

This data preference hierarchy reflects EPA's preference for BAFs based on field-measurements of bioaccumulation (methods 1 and 2) over those based on laboratory-measurements and/or predictions of bioaccumulation (methods 3 and 4). However, this data preference hierarchy should not be considered inflexible. Rather, it should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. The following steps and guidelines should be followed for selecting the final baseline BAF_{ℓ}^{fd}s using Procedure #1.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} as the geometric mean of all available individual baseline BAF_{ℓ}^{fd}s. When calculating a species-mean baseline BAF_{ℓ}^{fd}, individual baseline BAF_{ℓ}^{fd}s should be reviewed carefully to assess the uncertainty in the BAF values. For highly hydrophobic chemicals applicable to Procedure #1, particular attention should be paid to whether sufficient spatial and temporal averaging of water and tissue concentrations was likely achieved in the BAF, BSAF, or BCF study. Highly uncertain baseline BAF_{ℓ}^{fd}s should not be used. Large differences in individual baseline BAF_{ℓ}^{fd}s for a given species (e.g., greater than a factor of 10) should be investigated further. In such cases, some or all of the baseline BAF_{ℓ}^{fd}s for a given species might not be used. Additional discussion on evaluating acceptability of BAF values is provided in the Bioaccumulation TSD.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate a trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s in that trophic level. Trophic-level-mean baseline BAF_{ℓ}^{fd}s should be calculated for trophic levels two, three, and four because available data on U.S. consumers of fish and shellfish indicate significant consumption of organisms in these trophic levels.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy shown previously, (2) the relative uncertainty in the trophic-level-mean baseline BAF_{ℓ}^{fd}s derived using different methods, and (3) the weight of evidence among the four methods.

    a. In general, when more than one trophic-level-mean baseline BAF_{ℓ}^{fd} is available for a given trophic level, the final trophic-level-mean baseline BAF_{ℓ}^{fd} should be selected from the most preferred BAF method defined by the data preference hierarchy for Procedure #1.

    b. If uncertainty in a trophic-level-mean baseline BAF based on a higher tier (more preferred) method is judged to be substantially greater than a trophic-level-mean

baseline BAF from a lower tier method, and the weight of evidence among the various methods suggests that a BAF value from lower tier method is likely to be more accurate, then the final baseline BAF_{ℓ}^{fd} should be selected using a trophic level-mean baseline BAF_{ℓ}^{fd} from a lower tier method.

c. When considering the weight of evidence among the various BAF methods, greater confidence in the final baseline BAF_{ℓ}^{fd} is generally assigned when BAFs from a greater number of methods are in agreement for a given trophic level. However, lack of agreement among methods does not necessarily indicate less confidence if such disagreements can be adequately explained. For example, if the chemical of concern is metabolized by aquatic organisms represented by a BAF value, one would expect disagreement between a field-measured BAF (the highest priority data) and a predicted BAF using a K_{ow} and model-derived FCM. Thus, field-measured BAFs should generally be given the greatest weight among methods because they reflect direct measures of bioaccumulation and incorporate any metabolism which might occur in the organism and its food web.

d. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic levels two, three, and four.

5.4.3.3 Calculating National BAFs

The last step in deriving a national BAF for each trophic level is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflects conditions to which the national 304(a) criteria will apply (Figure 5-2). Since a baseline BAF_{ℓ}^{fd} is by definition normalized by lipid content and expressed on a freely dissolved basis, it needs to be adjusted to reflect the lipid fraction of aquatic organisms commonly consumed in the U.S. and the freely dissolved fraction expected in U.S. bodies of water. Converting a final baseline BAF_{ℓ}^{fd} to a national BAF requires information on: (1) the percent lipid of the aquatic organisms commonly consumed by humans, and (2) the freely dissolved fraction of the chemical of concern that would be expected in the ambient waters of interest. For each trophic level, a national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** For each trophic level, calculate a national BAF using the following equation.

$$\text{National BAF}_{(TL\ n)} = [(\text{Final Baseline BAF}_{\ell}^{fd})_{TL\ n} \cdot (f_{\ell})_{TL\ n} + 1] \cdot (f_{fd}) \qquad \text{(Equation 5-28)}$$

where:

Final Baseline BAF_{ℓ}^{fd} = Final trophic-level-mean baseline BAF expressed on a freely dissolved and lipid-normalized basis for trophic level "n"

$f_{\ell(TL\ n)}$	=	Lipid fraction of aquatic species consumed at trophic level "n"
f_{fd}	=	Fraction of the total chemical in water that is freely dissolved

The technical basis of Equation 5-28 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-28 is provided below.

2. **Determining the Final Baseline BAF_{ℓ}^{fd}.** The final trophic-level-mean baseline BAF_{ℓ}^{fd}s used in this equation are those which have been determined using the guidance presented in Section 5.4.3.2 for selecting the final baseline BAF_{ℓ}^{fd}s.

3. **Lipid Content of Commonly Consumed Aquatic Species.** As illustrated by Equation 5-28, the percent lipid of the aquatic species consumed by humans is needed to accurately characterize the potential exposure to a chemical from ingestion of aquatic organisms.

   a. **National Default Lipid Values.** For the purposes of calculating a national 304(a) criterion, the following national default values for lipid fraction should be used: 1.9% (for trophic level two organisms), 2.6% (for trophic level three organisms), and 3.0% (for trophic level four organisms).

      These national default values for lipid content reflect national per capita average patterns of fish consumption in the United States. Specifically, they were calculated using the consumption-weighted mean lipid content of commonly consumed fish and shellfish as identified by the USDA Continuing Survey of Food Intake by Individuals (CSFII) for 1994 through 1996. This same national survey data was used to derive national default values of fish consumption. To maintain consistency with the fish consumption assumptions, only freshwater and estuarine organisms were included in the derivation of the national default lipid values. Additional details on the technical basis, assumptions, and uncertainty in the national default values of lipid fraction are provided in the Bioaccumulation TSD.

      Although national default lipid values are used by EPA to set national 304(a) criteria, EPA encourages States and authorized Tribes to use local or regional data on lipid content of consumed aquatic species when adopting criteria into their water quality standards because local or regional consumption patterns (and lipid content) can differ from national consumption patterns. Additional guidance on developing site-specific values of lipid content, including a database of lipid content for many commonly consumed aquatic organisms, is found in the Bioaccumulation TSD.

4. **Freely Dissolved Fraction.** The third piece of information required for deriving a national BAF is the freely dissolved fraction of the chemical of concern that is expected

in waters of the United States. As noted previously, expressing BAFs on the freely dissolved concentration in water allows a common basis for averaging BAFs from several studies. However, for use in criteria development, these BAFs should be converted back to values based on the total concentration in the water to be consistent with monitored water column and effluent concentrations, which are typically based on total concentrations of chemicals in the water. This should be done by multiplying the freely dissolved baseline BAF_{ℓ}^{fd} by the fraction of the freely dissolved chemical expected in water bodies of the United States where criteria are to be applied, as shown in Equation 5-29.

$$f_{fd} = \frac{1}{[1 + (POC \cdot K_{ow}) + (DOC \cdot 0.08 \cdot K_{ow})]} \qquad \text{(Equation 5-29)}$$

where:

POC	=	national default value for the particulate organic carbon concentration (kg/L)
DOC	=	national default value for the dissolved organic carbon concentration (kg/L)
K_{ow}	=	n-octanol water partition coefficient for the chemical

Equation 5-29 is identical to Equation 5-12, which was used to determine the freely dissolved fraction for deriving baseline BAF_{ℓ}^{fd}s from field-measured BAFs. However, the POC and DOC concentrations used in Equation 5-29 reflect those values that are expected in U.S. bodies of water, not the POC and DOC values in the study water used to derive the BAF. Guidance for determining each component of Equation 5-29 follows.

a. **National Default Values of POC and DOC.** For estimating the freely dissolved fraction of the chemical of concern that is expected in U.S. water bodies, national default values of 0.5 mg/L (5×10^{-7} kg/L) for POC and 2.9 mg/L (2.9×10^{-6} kg/L) for DOC should be used. These values are 50th percentile values (medians) based on an analysis of over 110,000 DOC values and 85,000 POC values contained in EPA's STORET database from 1980 through 1999. These default values reflect a combination of values for streams, lakes and estuaries across the United States. Additional details on the technical basis, assumptions, and uncertainty in the derivation and application of the national default values of POC and DOC are provided in the Bioaccumulation TSD.

   Although national default values of POC and DOC concentrations are used by EPA to set national 304(a) criteria as described by this document, EPA encourages States and authorized Tribes to use local or regional data on POC and DOC when adopting criteria into their water quality standards. EPA encourages States and Tribes to consider local or regional data on POC and DOC because local or regional conditions may result in differences in POC or DOC

concentrations compared with the values used as national defaults. Additional guidance on developing local or regional values of POC and DOC, including a database of POC and DOC values segregated by waterbody type, is found in the Bioaccumulation TSD.

b. **K_{ow} Value.** The value selected for the K_{ow} of the chemical of concern should be the same value used in earlier calculations (e.g., for calculating baseline BAF_{ℓ}^{fd}s and FCMs). Guidance for selecting the K_{ow} value is found in the Bioaccumulation TSD.

5.4.4 Deriving National BAFs Using Procedure #2

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #2 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #2 is most appropriate are those that are classified as moderately to highly hydrophobic and subject to high rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category. As a result, FCMs are not used in this procedure. In addition, K_{ow} -based predictions of bioconcentration are not used in this procedure since the K_{ow} /BCF relationship is primarily based on poorly metabolized chemicals. Some nonionic organic chemicals for which Procedure #2 is probably appropriate include certain PAHs which are believed to be metabolized substantially by fish (e.g., benzo[a]pyrene, phenanthrene, fluoranthene, pyrene, benzo[a]anthracene and chrysene/triphenylene; USEPA, 1980; Burkhard and Lukasewycz, 2000).

According to Procedure #2, the following three methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF) (method 1),
- predicting a BAF from an acceptable BSAF (method 2), and
- predicting a BAF from an acceptable BCF (method 3).

Each of these three methods relies on measured data for assessing bioaccumulation and therefore, includes the effects of chemical metabolism by the study organism in the BAF estimate. The field-measured BAF and BSAF methods also incorporate any metabolism which occurs in the aquatic food web.

As shown in Figure 5-2, the next steps in deriving a national BAF after selecting the derivation procedure are: (1) calculating individual baseline BAF_{ℓ}^{fd}s, (2) selecting the final baseline BAF_{ℓ}^{fd}s, and (3) calculating the national BAFs. Each of these three steps is discussed separately below.

5.4.4.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

As described previously in Procedure #1, calculating individual baseline BAF_{ℓ}^{fd}s involves normalizing the measured BAF_{T}^{t} or BCF_{T}^{t} (which are based on the total chemical in water and

tissue) by the lipid content of the study organisms and the freely dissolved fraction of the chemical in the study water. Converting measured BAF_T^t (or BCF_T^t) values to baseline BAF_ℓ^{fd} (or BCF_ℓ^{fd}) values is designed to account for variation in measured BAF_T^ts that is caused by differences in lipid content of study organisms and differences in the freely dissolved fraction of chemical in study waters. Therefore, baseline BAF_ℓ^{fd}s are considered more amenable for extrapolating and averaging BAFs across different species and different study waters compared with total BAF_T^ts.

1. For each species where acceptable data are available, calculate all possible baseline BAF_ℓ^{fd}s using each of the three methods shown above for Procedure #2.

2. Individual baseline BAF_ℓ^{fd}s should be calculated from field-measured BAF_T^ts, field-measured BSAFs, and laboratory BCF_T^ts according to the following procedures.

A. Baseline BAF_ℓ^{fd} from Field-Measured BAFs

1. Except where noted below, a baseline BAF_ℓ^{fd} should be calculated from a field-measured BAF_T^t using the guidance and equations outlined in Section 5.4.3.1(A) for determining baseline BAF_ℓ^{fd}s from field-measured BAFs in Procedure #1.

2. Because nonionic organic chemicals applicable to Procedure #2 have relatively high rates of metabolism in aquatic organisms, they will tend to reach steady state more quickly than nonionic organic chemicals with similar K_{ow} values but which undergo little or no metabolism. Therefore, less temporal averaging of chemical concentrations would generally be required for determining field-measured BAF_T^ts with highly metabolizable chemicals compared with chemicals that are poorly metabolized by aquatic biota.

B. Baseline BAF_{ℓ}^{fd} Derived from Field-measured BSAFs

1. A baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BSAF using the guidance and equations outlined in Section 5.4.3.1(B) for determining baseline BAF_{ℓ}^{fd}s from field-measured BSAFs in Procedure #1.

C. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) for determining baseline BAF_{ℓ}^{fd}s from a laboratory-measured BCF and FCM in Procedure #1.

2. Because biomagnification is not an overriding concern for nonionic organic chemicals applicable to Procedure #2, food chain multipliers are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t} .

5.4.4.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual, baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #2 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s. The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. A final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #2 and uncertainty in the data. The data preference hierarchy for Procedure #2 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF (method 1),
2. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BSAF (method 2), or
3. a baseline BAF_{ℓ}^{fd} from an acceptable laboratory-measured BCF (method 3).

This data preference hierarchy reflects EPA's preference for BAFs based on field-measurements of bioaccumulation (methods 1 and 2) over those based on laboratory-measurements (method 3). However, as explained in Procedure #1, this data preference hierarchy should not be considered inflexible. Rather, it should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the underlying uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. Although biomagnification is not generally a concern for chemicals subject to Procedure #2, trophic level differences in bioaccumulation might be substantial to the extent that the rate of chemical metabolism by organisms in different trophic levels differs. For example, certain PAHs have been shown to be metabolized to a much greater extent by some fish compared with some invertebrate species (James, 1989). Therefore, final baseline BAF_{ℓ}^{fd}s for chemicals applicable to Procedure #2 should be determined on a trophic-level-specific basis according to the following guidelines.

1. The final baseline BAF_{ℓ}^{fd}s in Procedure #2 should be selected according to the same steps described in Procedure #1 but with the substitution of the data preference hierarchy described above for Procedure #2. Specifically, the species-mean baseline BAF_{ℓ}^{fd}s,

trophic-level-mean baseline BAF_{ℓ}^{fd}s, and the final baseline BAF_{ℓ}^{fd}s should be determined according to the guidelines presented in Procedure #1 (Section 5.4.3.2, Steps 1, 2, and 3).

5.4.4.3 Calculating the National BAFs

As described in Procedure #1, the last step in deriving national BAFs for nonionic organic chemicals is to convert the final baseline BAF_{ℓ}^{fd}s determined in the previous step to BAFs which reflect conditions to which the national 304(a) criteria will apply (Figure 5-2).

1. For trophic levels two, three, and four, national BAFs should be calculated from the final baseline BAF_{ℓ}^{fd}s using the same equation and procedures described previously in Procedure #1 (see Section 5.4.3.3 entitled "Calculating the National BAFs").

5.4.5 Deriving National BAFs Using Procedure #3

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #3 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #3 is most appropriate are those that are classified as low in hydrophobicity (i.e., log K_{ow} values less than 4.0) and subject to low (or unknown) rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category (Fisk et al., 1998; Gobas et al., 1993; Connolly and Pedersen, 1988; Thomann, 1989). As a result, FCMs are not used in this procedure.

According to Procedure #3, the following three methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF),
- predicting a BAF from an acceptable laboratory-measured BCF, and
- predicting a BAF from an acceptable K_{ow}.

After selecting the derivation procedure, the next steps in deriving a national BAF at a given trophic level for nonionic organic chemicals are: (1) calculating individual baseline BAF_{ℓ}^{fd}s, (2) selecting the final baseline BAF_{ℓ}^{fd}, and (3) calculating the national BAF (Figure 5-2). Each of these three steps is discussed separately below.

5.4.5.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

Calculating individual baseline BAF_{ℓ}^{fd}s involves normalizing each measured BAF_{T}^{t} or BCF_{T}^{t} (which are based on the total chemical in water and tissue) by the lipid content of the study organism and the freely dissolved fraction of the chemical in the study water. For additional discussion of the technical basis for calculating baseline BAF_{ℓ}^{fd}s, see Section 5.4.3.1 in Procedure #1.

1. For each species where acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the three methods shown above for Procedure #3.

2. An individual baseline BAF_{ℓ}^{fd} should be calculated from field-measured BAF_{T}^{t}s, laboratory-measured BCF_{T}^{t}s, and K_{ow} values according to the following procedures.

A. Baseline BAF_{ℓ}^{fd} from Field-Measured BAFs

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BAF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(A) in Procedure #1.

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals applicable to Procedure #3 are expected to remain almost entirely in the freely dissolved form in natural waters with dissolved and particulate organic carbon concentrations typical of most field BAF studies. Therefore, the freely dissolved fraction should be assumed to be equal to 1.0, unless the concentrations of DOC and POC are very high in the field BAF study. For studies with very high DOC or POC concentrations, (e.g., about 100 mg/L or higher for DOC or 10 mg/L or higher for POC), the freely dissolved fraction may be substantially lower than 1.0 and therefore should be calculated using Equation 5-12.

3. **Temporal Averaging of Concentrations.** Also due to their low hydrophobicity, nonionic organic chemicals appropriate to Procedure #3 will also tend to reach steady state quickly compared with those chemicals to which Procedure #1 applies. Therefore, the extent of temporal averaging of tissue and water concentrations is typically much less than that required for highly hydrophobic chemicals to which Procedure #1 is applied. In addition, field studies used to calculate BAFs for these chemicals should have sampled water and tissue at similar points in time because tissue concentrations respond more rapidly to changes in water concentrations. EPA will be providing additional guidance on appropriate BAF study designs for nonionic organic chemicals (including those appropriate to Procedure #3) in its forthcoming guidance document on conducting field BAF and BSAF studies.

B. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) of Procedure #1.

2. **Food Chain Multipliers.** Because biomagnification is not an overriding concern for the minimally hydrophobic chemicals applicable to Procedure #3, FCMs are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t}.

3. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals to which Procedure #3 is applied are expected to remain

almost entirely in the freely dissolved form in waters containing dissolved and particulate organic carbon concentrations typical of laboratory BCF studies. Therefore, the freely dissolved fraction should usually be assumed equal to 1.0. The freely dissolved fraction will be substantially less than 1.0 only in situations where unusually high concentrations of DOC and POC are present in the laboratory BCF study (e.g., above about 100 mg/L for DOC or about 10 mg/L for POC). In this situation, the freely dissolved fraction should be calculated according to Equation 5-12.

C. Baseline BAF_{ℓ}^{fd} from a K_{ow}

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from an acceptable K_{ow} using the guidance and equations outlined in Section 5.4.3.1(D) in Procedure #1.

2. Because biomagnification is not an overriding concern for nonionic organic chemicals with low hydrophobicity (i.e., log K_{ow} < 4.0), food chain multipliers are not used in Procedure #3 for deriving the baseline BAF_{ℓ}^{fd} from a K_{ow}.

5.4.5.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #3 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s (Figure 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. The final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #3 and uncertainty in the data. The data preference hierarchy for Procedure #3 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF or laboratory-measured BCF, or
2. a baseline BAF_{ℓ}^{fd} predicted from an acceptable K_{ow} value.

This data preference hierarchy reflects EPA's preference for BAFs that are based on measured data (field-measured BAFs and laboratory-measured BCFs) over BAFs based on predictive methods (K_{ow}). This data preference hierarchy should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. Since bioaccumulation via dietary uptake and subsequent biomagnification generally are not of concern for chemicals subject to Procedure #3, field-measured BAFs and laboratory-measured BCFs are considered equally in determining the national BAF.

Final baseline BAF_{ℓ}^{fd}s should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method (i.e., field-measured BAF, BAF from a lab-measured BCF, or BAF from a K_{ow}) where more than one

acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} according to the guidance described previously in Procedure #1.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate the trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s in that trophic level.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy, (2) the relative uncertainties among trophic-level-mean baseline BAF_{ℓ}^{fd}s derived using different methods, and (3) the weight of evidence among the three methods.

   a. In general, when more than one trophic-level-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, the final baseline BAF_{ℓ}^{fd} should be selected from the most preferred BAF method defined by the data preference hierarchy for Procedure #3. Within the first data preference tier, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final trophic-level-mean baseline BAF_{ℓ}^{fd} using Procedure #3. If a trophic-level-mean baseline BAF_{ℓ}^{fd} is available from both a field-measured BAF and a laboratory-measured BCF, the final baseline BAF_{ℓ}^{fd} should be selected using the trophic-level-mean baseline BAF_{ℓ}^{fd} or BCF_{ℓ}^{fd} with the least overall uncertainty.

   b. If uncertainty in a trophic-level-mean baseline BAF_{ℓ}^{fd} based on a higher tier (more preferred) method is judged to be substantially greater than a trophic-level-mean baseline BAF_{ℓ}^{fd} from a lower tier method, then the final baseline BAF_{ℓ}^{fd} should be selected using a trophic-level-mean baseline BAF_{ℓ}^{fd} from a lower tier method.

   c. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic level two, three, and four.

5.4.5.3 Calculating the National BAFs

As described in Procedure #1, the last step in deriving a national BAF for a given trophic level for nonionic organic chemicals is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflect conditions to which the national 304(a) criterion will apply (Figure 5-2). Each national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** Except where noted below, national BAFs for trophic levels two, three, and four should be calculated from the final, trophic-level-mean baseline BAF_{ℓ}^{fd}s using Equation 5-28 and associated guidance described in Procedure #1 (see Section 5.4.3.3).

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), a freely dissolved fraction of 1.0 should be assumed for calculating national BAFs for nonionic organic chemicals using Procedure #3. A freely dissolved fraction of 1.0 should be assumed because at a log K_{ow} of less than 4.0, nonionic organic chemicals are expected to remain over 99 percent in the freely dissolved form at POC and DOC concentrations corresponding to national default values for U.S. bodies of water (i.e., 0.5 mg/L and 2.9 mg/L, respectively).

5.4.6 Deriving National BAFs Using Procedure #4

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #4 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #4 is most appropriate are those that are classified as having low hydrophobicity and subject to high rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category. As a result, FCMs are not used in this procedure. In addition, K_{ow} -based predictions of bioconcentration are not used in this procedure since the K_{ow} /BCF relationship is primarily based on poorly metabolized chemicals. One example of a nonionic organic chemical for which Procedure #4 appears appropriate is butyl benzyl phthalate in fish. Using radiolabeling techniques with confirmation by chromatographic analysis, Carr et al. (1997) present evidence that indicates butyl benzyl phthalate is extensively metabolized in sunfish. Carr et al. (1997) also report measured BCFs (and subsequently lipid-normalized BCFs) which are substantially below predicted BCFs based on log $K_{ow.}$ In a study of chlorinated anilines (which would be essentially un-ionized at ambient pH), de Wolf et al. (1992) reported measured BCFs substantially lower than those predicted based on K_{ow}. The authors suggested that biotransformation (metabolism) involving the amine (NH_2) was responsible for the lower measured BCFs.

According to Procedure #4, the following two methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF), and
- predicting a BAF from an acceptable BCF.

After selecting the derivation procedure, the next steps in deriving a national BAF for a given trophic level for nonionic organic chemicals are: (1) calculating individual baseline BAF_{ℓ}^{fd}s, (2) selecting the final baseline BAF_{ℓ}^{fd}, and (3) calculating the national BAF (Figure 5-2). Each of these three steps is discussed separately below.

5.4.6.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

Calculating individual baseline BAF_{ℓ}^{fd}s involves normalizing the measured BAF_T^t or BCF_T^t (which are based on the total chemical in water and tissue) by the lipid content of the study organism and the freely dissolved fraction of the chemical in the study water. For additional discussion of the technical basis for calculating baseline BAF_{ℓ}^{fd}s, see Section 5.4.3.1 in Procedure #1.

1. For each species where acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the two methods shown above for Procedure #4.

2. Individual baseline BAF_{ℓ}^{fd}s should be calculated from field-measured BAF_{T}^{t}s and laboratory-measured BCF_{T}^{t}s according to the following procedures.

A. Baseline BAF_{ℓ}^{fd} from Field-Measured BAFs

1. A baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BAF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(A) in Procedure #1.

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals applicable to Procedure #4 are expected to remain almost entirely in the freely dissolved form in natural waters with dissolved and particulate organic carbon concentrations typical of most field BAF studies. Therefore, the freely dissolved fraction should be assumed equal to 1.0 unless the concentrations of DOC and POC are very high in the field BAF study. For studies with very high DOC or POC concentrations, (e.g., about 100 mg/L or higher for DOC or 10 mg/L or higher for POC), the freely dissolved fraction may be substantially lower than 1.0 and therefore should be calculated using Equation 5-12.

3. **Temporal Averaging of Concentrations.** Also due to their low hydrophobicity, nonionic organic chemicals appropriate to Procedure #4 will also tend to reach steady-state quickly compared with those chemicals to which Procedure #1 applies. Therefore, the extent of temporal averaging of tissue and water concentrations is typically much less than that required for highly hydrophobic chemicals to which Procedure #1 is applied. In addition, field studies used to calculate BAFs for these chemicals should have sampled water and tissue at similar points in time because tissue concentrations should respond rapidly to changes in water concentrations. EPA will be providing additional guidance on appropriate BAF study designs for nonionic organic chemicals (including those appropriate to Procedure #4) in its forthcoming guidance document on conducting field BAF and BSAF studies.

B. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) of Procedure #1.

2. **Food Chain Multipliers.** Because biomagnification is not an important concern for the minimally hydrophobic chemicals applicable to Procedure #4, FCMs are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t}.

3. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals to which Procedure #4 is applied are expected to remain

almost entirely in the freely dissolved form in waters containing dissolved and particulate organic carbon concentrations typical of laboratory BCF studies. Therefore, the freely dissolved fraction should usually be assumed to be equal to 1.0. The freely dissolved fraction will be substantially less than 1.0 only in situations where unusually high concentrations of DOC and POC are present in the lab BCF study (e.g., above about 100 mg/L for DOC or about 10 mg/L for POC). In this situation, the freely dissolved fraction should be calculated according to Equation 5-12.

5.4.6.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #4 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for a given trophic level from the individual baseline BAF_{ℓ}^{fd}s (Figure 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. A final baseline BAF_{ℓ}^{fd} should be determined for each trophic level from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #4 and uncertainty in the data. The data preference hierarchy for Procedure #4 is:

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF or predicted from an acceptable laboratory-measured BCF.

Since bioaccumulation via dietary uptake and subsequent biomagnification generally are not of concern for chemicals subject to Procedure #4, field-measured BAFs and laboratory-measured BCFs are considered equally in determining the national BAF.

Final baseline BAF_{ℓ}^{fd}s should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method (i.e., field-measured BAF or a BAF from a lab-measured BCF) where more than one acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} according to the guidance described previously in Procedure #1.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate the trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s for that trophic level.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy, and (2) the relative uncertainties among trophic-level-mean BAFs derived using different methods.

    a. As discussed above, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final trophic-level-mean baseline

BAF_{ℓ}^{fd} using Procedure #4. If a trophic-level-mean baseline BAF_{ℓ}^{fd} is available from both a field-measured BAF and a laboratory-measured BCF, the final baseline BAF_{ℓ}^{fd} should be selected using the trophic-level-mean baseline BAF_{ℓ}^{fd} or BCF_{ℓ}^{fd} with the least overall uncertainty.

b. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic levels two, three, and four.

5.4.6.3 Calculating National BAFs

As described in Procedure #1, the last step in deriving a national BAF for a given trophic level for nonionic organic chemicals is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflects conditions to which the national 304(a) criterion will apply (Figure 5-2). Each national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** Except where noted below, national BAFs for trophic-levels two, three, and four should be calculated from the final, trophic-level-mean baseline BAF_{ℓ}^{fd}s using the same equation and procedures described previously in Procedure #1 (see Section 5.4.3.3 in Procedure #1).

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log $K_{ow} < 4.0$), a freely dissolved fraction of 1.0 should be assumed for calculating national BAFs for nonionic organic chemicals using Procedure #4. A freely dissolved fraction of 1.0 should be assumed because at a log K_{ow} value of less than 4.0, nonionic organic chemicals are expected to remain over 99 percent in the freely dissolved form at POC and DOC concentrations corresponding to national default values for U.S. bodies of water (i.e., 0.5 mg/L and 2.9 mg/L, respectively).

5.5 NATIONAL BIOACCUMULATION FACTORS FOR IONIC ORGANIC CHEMICALS

This section contains guidelines for deriving national BAFs for ionic organic chemicals (i.e., organic chemicals which undergo significant ionization in water). As defined in Section 5.3.5, ionic organic chemicals contain functional groups which can either readily donate protons (e.g., organic acids with hydroxyl, carboxylic, and sulfonic groups) or readily accept protons (e.g., organic bases with amino and aromatic heterocyclic nitrogen groups). Some examples of ionic organic compounds include:

- chlorinated phenols (e.g., 2,4,6-trichlorophenol, pentachlorophenol),
- chlorinated phenoxyalkanoic acids (e.g., 2,4-dichlorophenoxyacetic acid [2,4-D]),
- nitrophenols (e.g., 2-nitrophenol, 2,4,6-trinitrophenol),
- cresols (e.g., 2,4-dinitro-*o*-cresol [DNOC]),
- pyridines (e.g., 2,4-dimethypyidine),
- aliphatic and aromatic amines (e.g., trimethylamine, aniline), and

- linear alkylbenzenesulfonate (LAS) surfactants.

Ionic organic chemicals are considered separately for deriving national BAFs because the anionic or cationic species of these chemicals behave much differently in the aquatic environment compared with their neutral (un-ionized) counterparts. The neutral species of ionic organic chemicals are thought to behave in a similar manner as nonionic organic compounds (e.g., partitioning to lipids and organic carbon as a function of hydrophobicity). However, the ionized (cationic, anionic) species exhibit a considerably more complex behavior involving multiple environmental partitioning mechanisms (e.g., ion exchange, electrostatic, and hydrophobic interactions) and a dependency on pH and other factors including ionic strength and ionic composition (Jafvert et al., 1990; Jafvert 1990; Schwarzenbach, et al., 1993). As a consequence, methods to predict the environmental partitioning of organic cations and anions are less developed and validated compared with methods for nonionic organic chemicals (Spacie, 1994; Suffet et al., 1994).

Given the current limitations in the state of the science for predicting the partitioning and bioaccumulation of the ionized species of ionic organic chemicals, procedures for deriving national BAFs for these chemicals differ depending on the extent to which the fraction of the total chemical is likely to be represented by the ionized (cationic, anionic) species in U.S. surface waters. When a significant fraction of the total chemical concentration is expected to be present as the ionized species in water, procedures for deriving the national BAF rely on empirical (measured) methods (i.e., Procedures #5 and 6 in Section 5.6). When an insignificant fraction of the total chemical is expected to be present as the ionized species (i.e., the chemical exists essentially in the neutral form), procedures for deriving the national BAF will follow those established for nonionic organic chemicals (e.g., Procedures #1 through #4 in Section 5.4). The following guidelines apply for assessing the occurrence of cationic and anionic forms at typical environmental pH ranges.

1. For the ionic organic chemical of concern, the dissociation constant, pK_a, should be compared to the range of pH values expected in fresh and estuarine waters of the U.S. At pH equal to the pK_a, 50% of the organic acid or base is expected to be present in the ionized species. The pH values for U.S. fresh and estuarine waters typically range between 6 and 9, although somewhat higher and lower values can occur in some bodies of water (e.g., acidic bogs and lakes, highly alkaline and eutrophic systems, etc.).

2. For organic acids, the chemical will exist almost entirely in its un-ionized form when pH is about 2 or more units below the pK_a. For organic bases, the chemical will exist almost entirely in its un-ionized form when pH is about 2 or more units above the pK_a. In these cases, the aqueous behavior of the chemical would be expected to be similar to nonionic organic chemicals. Therefore, national BAF should usually be derived using Procedures #1 through #4 in Section 5.4.

3. When pH is greater than the pK_a minus 2 for organic acids (or less than the pKa plus 2 for organic bases), the fraction of the total chemical that is expected to exist in its ionized form can become significant (i.e., $\geq$1% in the ionized). In these cases, the national BAF should usually be derived using Procedures #5 and #6 in Section 5.6.

4. In general, most organic acids (e.g., pentachlorophenol and silvex), exist primarily in the ionized form in ambient waters because their pK_a's (4.75 and 3.07, respectively) are much smaller than the pH of the ambient waters. Conversely, most organic bases, (e.g., aniline) exist mostly in the un-ionized form in ambient waters because their pK_a's (4.63 for aniline) are much smaller than the pH of the ambient waters.

5. The above guidelines are intended to be a general guide for deriving national BAFs for ionic organic chemicals, not an inflexible rule. Modifications to these guidelines should be considered on a case-by-case basis, particularly when such modifications are strongly supported by measured bioaccumulation or bioconcentration data. For example, initial models have been developed for predicting the solid and organic-phase partitioning of certain organic acids (e.g., Jafvert 1990, Jafvert et al., 1990). As these or other models become more fully developed and appropriately validated in the future, they should be considered in the development of national BAFs. In addition, since pH is a controlling factor for dissociation and subsequent partitioning of ionic organic chemicals, consideration should be given to expressing BAFs or BCFs as a function of pH (or other factors) where sufficient data exist to reliably establish such relationships.

5.6 NATIONAL BIOACCUMULATION FACTORS FOR INORGANIC AND ORGANOMETALLIC CHEMICALS

This section contains guidelines for deriving national BAFs for inorganic and organometallic chemicals as defined in Section 5.3.5. The derivation of BAFs for inorganic and organometallic chemicals differs in several ways from procedures for nonionic organic chemicals. First, lipid normalization of chemical concentrations in tissues does not generally apply for inorganic and organometallic chemicals. Thus, BAFs and BCFs cannot be extrapolated from one tissue to another based on lipid-normalized concentrations as is done for nonionic organic chemicals. Second, the bioavailability of inorganics and organometallics in water tends to be chemical-specific and thus, the techniques for expressing concentrations of nonionic organic chemicals based on the freely dissolved form do not generally apply. Third, at the present time there are no generic bioaccumulation models that can be used to predict BAFs for inorganic and organometallic chemicals as a whole, unlike the existence of K_{ow}-based models for nonionic organic chemicals. While some chemical-specific bioaccumulation models have been developed for inorganic and organometallic chemicals (e.g., Mercury Cycling Model by Hudson et. al, 1994), those models currently tend to require site-specific data for input to the model and are restricted to site-specific applications. As the models become more fully developed and validated in the future, they should be considered on a case-by-case basis in conjunction with the following procedures for deriving national BAFs.

5.6.1 Selecting the BAF Derivation Procedure

As shown in Figure 5-1, national BAFs can be derived using two procedures for inorganic and organometallic chemicals (Procedures #5 and #6). The choice of the BAF derivation procedure depends on whether or not the chemical undergoes biomagnification in aquatic food webs.

1. For many inorganic and organometallic chemicals, biomagnification does not occur and the BCF will be equal to the BAF. For these types of chemicals, Procedure #5 should be used to derive the national BAF. Procedure #5 considers BAFs and BCFs to be of equal value in determining the national BAF and does not require the use of FCMs with BCF measurements. Guidance for deriving BAFs using Procedure #5 is provided in Section 5.6.3.

2. For some inorganic and organometallic chemicals (e.g., methylmercury), biomagnification does occur and Procedure #6 should be used to determine the national BAF. Procedure #6 gives general preference to the use of field-measured BAFs over laboratory-measured BCFs and requires FCMs to be used with BCF measurements for predicting BAFs. Guidance for deriving BAFs using Procedure #6 is provided in Section 5.6.4.

3. Determining whether or not biomagnification occurs for inorganic and organometallic chemicals requires chemical-specific data on measured concentrations of the chemical in aquatic organisms and their prey. Concentrations in aquatic organisms that increase substantially at successive trophic levels of a food web suggest that biomagnification is

occurring. Concentrations in aquatic organisms that remain about the same or decrease at successive trophic levels of a food web suggest that biomagnification is not occurring. When comparing tissue concentrations for assessing biomagnification, care should be taken to ensure that the aquatic organisms chosen actually represent functional predator-prey relationships and that all major prey species are considered in the comparisons.

5.6.2 Bioavailability

The chemical-specific nature of inorganic and organometallic bioavailability is likely due in part to chemical-specific differences in several factors which affect bioavailability and bioaccumulation. These factors include differences in the mechanisms for chemical uptake by aquatic organisms (e.g., passive diffusion, facilitated transport, active transport), differences in sorption affinities to biotic and abiotic ligands, and differences in chemical speciation in water. Some inorganic and organometallic chemicals exist in multiple forms and valence states in aquatic ecosystems that can differ in their bioavailability to aquatic organisms and undergo conversions between forms. For example, selenium can exist in various forms in aquatic ecosystems, including inorganic selenite($^{+4}$) and selenate($^{+6}$) oxyanions, elemental selenium (^{0}) under reducing conditions (primarily in sediments), and organoselenium compounds of selenide ($^{-2}$). Dominant forms of mercury in natural, oxic waters include inorganic ($^{+2}$) mercury compounds and methylmercury; the latter is generally considered to be substantially more bioavailable than inorganic mercury compounds to higher trophic level organisms. Although a generic analogue to the "freely dissolved" conversion for nonionic organic chemicals does not presently exist for inorganic and organometallic chemicals as a whole, the occurrence and bioavailability of different forms of these chemicals should be carefully considered when deriving national BAFs.

1. If data indicate that: (1) a particular form (or multiple forms) of the chemical of concern largely governs its bioavailability to target aquatic organisms, and (2) BAFs are more reliable when derived using the bioavailable form(s) compared with using other form(s) of the chemical of concern, then BAFs and BCFs should be based on the appropriate bioavailable form(s).

2. Because different forms of many inorganic and organometallic chemicals may interconvert once released to the aquatic environment, regulatory and mass balance considerations typically require an accounting of the total concentration in water. In these cases, sufficient data should be available to enable conversion between total concentrations and the other (presumably more bioavailable) forms in water.

5.6.3 Deriving BAFs Using Procedure #5

This section contains guidance for calculating national BAFs for inorganic and organometallic chemicals using Procedure #5 as shown in Figure 5-1. The types of inorganic and organometallic chemicals for which Procedure #5 is appropriate are those that are not likely to biomagnify in aquatic food webs (see Section 5.1 above). In Procedure #5, two methods are available to derive the national BAF for a given trophic level:

- using a BAF from an acceptable field study (i.e., field-measured BAF), or
- predicting a BAF from an acceptable laboratory-measured BCF.

Individual BAFs should be determined from field-measured BAFs or laboratory-measured BCFs according to the following guidelines.

5.6.3.1 Determining Field-Measured BAFs

1. Except where noted below, field-measured BAFs should be determined using the guidance provided in Section 5.4.3.1(A) of Procedure #1.

2. As described previously, conversion of field-measured BAFs to baseline BAF_{ℓ}^{fd}s based on lipid-normalized and freely-dissolved concentrations does not apply for inorganic and organometallic chemicals. Therefore, the guidance and equations provided in Procedure #1 which pertain to converting field-measured BAFs to baseline BAF_{ℓ}^{fd}s and subsequently to national BAFs do not generally apply to inorganic chemicals. As discussed in Section 5.6.2 above, an analogous procedure in concept might be required for converting total BAFs to BAFs based on the most bioavailable form(s) for some inorganic and organometallic chemicals of concern. Such procedures should be applied on a chemical-specific basis.

3. BAFs should be expressed on a wet-weight basis; BAFs reported on a dry-weight basis can be used only if they are converted to a wet-weight basis using a conversion factor that is measured or reliably estimated for the tissue used in the determination of the BAF.

4. BAFs should be based on concentrations in the edible tissue(s) of the biota unless it is demonstrated that whole-body BAFs are similar to edible tissue BAFs. For some finfish and shellfish species, whole body is considered to be the edible tissue.

5. The concentrations of an inorganic or organometallic chemical in a bioaccumulation study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccumulation of an inorganic or organometallic chemical that is essential to the nutrition of aquatic organisms might be overestimated if concentrations are at or below normal background levels due to selective accumulation by the organisms to meet their nutritional requirements.

5.6.3.2 Determining Laboratory-Measured BCFs

1. Except where noted below, BAFs should be predicted from laboratory-measured BCFs using the guidance provided in Section 5.4.3.1(c) of Procedure #1.

2. As described previously, conversion of laboratory-measured BCFs to baseline BCF_{ℓ}^{fd}s based on lipid-normalized and freely dissolved concentrations does not apply for inorganic and organometallic chemicals. Therefore, the guidance and equations provided in Procedure #1 which pertain to converting laboratory-measured BCFs to baseline BCF_{ℓ}^{fd}s and subsequently to national BCFs do not generally apply to inorganic and organometallic chemicals. As discussed in Section 5.6.2 above, an analogous procedure in concept might be required for converting total BCFs to BCFs based on the most bioavailable form(s) of some inorganic and organometallic chemicals of concern. Such procedures should be applied on a chemical-specific basis. In addition, the use of FCMs with BCFs does not apply to chemicals applicable to Procedure #5.

3. BCFs should be expressed on a wet-weight basis; BCFs reported on a dry-weight basis can be used only if they are converted to a wet-weight basis using a conversion factor that is measured or reliably estimated for the tissue used in the determination of the BCF.

4. BCFs should be based on concentrations in the edible tissue(s) of the biota unless it is demonstrated that whole-body BCFs are similar to edible tissue BCFs. For some finfish and shellfish species, whole body is considered to be the edible tissue.

5. The concentrations of an inorganic or organometallic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccumulation of an inorganic or organometallic chemical that is essential to the nutrition of aquatic organisms might be overestimated if concentrations are at or below normal background levels due to selective accumulation by the organisms to meet their nutritional requirements.

5.6.3.3 Determining the National BAFs

After calculating individual BAFs using as many of the methods in Procedure #5 as possible, the next step is to determine national BAFs for each trophic level from the individual BAFs. The national BAFs will be used to determine the national 304(a) criteria. The national BAFs should be determined from the individual BAFs by considering the data preference hierarchy defined for Procedure #5 and uncertainty in the data. The data preference hierarchy for Procedure #5 is:

1. a BAF from an acceptable field-measured BAF or predicted from an acceptable laboratory-measured BCF.

Since bioaccumulation via dietary uptake and subsequent biomagnification are not of concern for chemicals subject to Procedure #5, field-measured BAFs and laboratory-measured

BCFs are considered equally in determining the national BAFs. The national BAFs should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean BAFs.** For each BAF method where more than one acceptable field-measured BAF (or a BAF predicted from a BCF) is available for a given species, calculate the species-mean BAF as the geometric mean of all acceptable individual measured or BCF-predicted BAFs. When calculating species-mean BAFs, individual measured or BCF-predicted BAFs should be reviewed carefully to assess uncertainties in the BAF values. Highly uncertain BAFs should not be used. Large differences in individual BAFs for a given species (e.g., greater than a factor of 10) should be investigated further and in such cases, some or all of the BAFs for a given species might not be used. Additional discussion on evaluating the acceptability of BAF and BCF values is provided in the Bioaccumulation TSD.

2. **Calculate Trophic-Level-Mean BAFs.** For each BAF method where more than one acceptable species-mean BAF is available within a given trophic level, calculate the trophic-level-mean BAF as the geometric mean of acceptable species-mean BAFs in that trophic level. Trophic-level-mean BAFs should be calculated for trophic levels two, three and four because available data on U.S. consumers of fish and shellfish indicate significant consumption of organisms in these trophic levels.

3. **Select a Final National BAF for Each Trophic Level.** For each trophic level, select the final national BAF using best professional judgment by considering: (1) the data preference hierarchy in Procedure #5, and (2) the relative uncertainties among trophic level-mean BAFs derived using different methods.

    a. As discussed above, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final national BAF using Procedure #5. If a trophic-level-mean BAF is available from both a field-measured BAF and a laboratory-measured BCF, the final national BAF should be selected using the trophic-level-mean BAF with the least overall uncertainty.

    b. The above steps should be performed for each trophic level until a national BAF is selected for trophic levels two, three, and four.

5.6.4 Deriving BAFs Using Procedure #6

This section contains guidance for calculating national BAFs for inorganic and organometallic chemicals using Procedure #6 as shown in Figure 5-1. The types of inorganic and organometallic chemicals for which Procedure #6 is appropriate are those that are considered likely to biomagnify in aquatic food webs (see Section 5.6.1 above). Methylmercury is an example of an organometallic chemical to which Procedure #6 applies. In Procedure #6, two methods are available to derive the national BAF:

- using a BAF from an acceptable field study (i.e., field-measured BAF), or

- predicting a BAF from an acceptable laboratory-measured BCF and a FCM.

Individual BAFs should be determined from field-measured BAFs or laboratory-measured BCFs and FCMs according to the following guidelines.

5.6.4.1 Determining Field-Measured BAFs

1. Field-measured BAFs should be determined using the guidance provided in Section 5.6.3.1 of Procedure #5.

5.6.4.2 Determining Laboratory-Measured BCFs

1. Except where noted below, BAFs should be predicted from laboratory-measured BCFs using the guidance provided in Section 5.6.3.2 of Procedure #5.

2. Because biomagnification is of concern for chemicals applicable to Procedure #6, BAFs should be predicted from laboratory-measured BCF using FCMs. Currently, there are no generic models from which to predict FCMs for inorganic or organometallic chemicals. Therefore, FCMs should be determined using field data as described in the section entitled: "Field-Derived FCMs" in Section 5.4.3.1(c) of Procedure #1. Unlike nonionic organic chemicals, field-derived FCMs for inorganic and organometallic chemicals are not based on lipid-normalized concentrations in tissues. For calculating FCMs for inorganic and organometallic chemicals, concentrations in tissues should be based on the consistent use of either wet-weight or dry-weight concentrations in edible tissues. FCMs should be derived for trophic levels two, three, and four.

5.6.4.3 Determining the National BAF

After calculating individual BAFs using as many of the methods in Procedure #6 as possible, the next step is to determine national BAFs for each trophic level from the individual BAFs. The national BAFs will be used to determine the national 304(a) criteria. The national BAFs should be determined from the individual BAFs by considering the data preference hierarchy defined for Procedure #6 and uncertainty in the data. The data preference hierarchy for Procedure #6 is (in order of preference):

1. a BAF from an acceptable field-measured BAF, or
2. a predicted BAF from an acceptable laboratory-measured BCF and FCM.

This data preference hierarchy reflects EPA's preference for field-measured BAFs over BAFs predicted from a laboratory-measured BCF and FCM, because field-measured BAFs are direct measures of bioaccumulation and biomagnification in aquatic food webs. BAFs predicted from laboratory-measured BCFs and FCMs indirectly account for biomagnification through the use of the FCM. For each trophic level, the national BAFs should be determined using the following steps and guidelines.

1. **Calculate Species-Mean BAFs.** For each BAF method where more than one acceptable field-measured BAF or BAF predicted using a BCF and FCM is available, calculate a species-mean BAF according to the guidance described previously in Procedure #5.

2. **Calculate Trophic Level-Mean BAFs.** For each BAF method where more than one acceptable species-mean BAF is available within a given trophic level, calculate the trophic level-mean BAF according to guidance described previously in Procedure #5.

3. **Select a Final National BAF for Each Trophic Level.** For each trophic level, select the final national BAF using best professional judgment by considering: (1) the data preference hierarchy in Procedure #6, and (2) the relative uncertainties among trophic level-mean BAFs derived using different methods.

    a. When a trophic-level mean BAF is available using both methods for a given trophic level (i.e., a field-measured BAF and a BAF predicted from a BCF and FCM), the national BAF should usually be selected using the field-measured BAF which is the preferred BAF method in the data preference hierarchy in Procedure #6.

    b. If uncertainty in the trophic-level mean BAF derived using field-measured BAFs is considered to be substantially greater than a trophic-level mean BAF derived using a BCF and FCM, the national BAF for that trophic level should be selected from the second tier (BCF · FCM) method.

    c. The above steps should be performed for each trophic level until a national BAF is selected for trophic levels two, three, and four.

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Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations

*A Compilation of Fish Consumption Rates (FCR) and Risk Levels for Carcinogens used by Assorted States and Tribes to Calculate Surface Water Quality Human Health Criteria**

** Data compiled from information provided to Ecology by the Environmental Protection Agency, Region 10, in January 2013.*

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Alabama	4	**30**		**10^{-6}**	Except for Arsenic, which uses 10^{-5}
Alaska	10	**6.5**	Criteria in National Toxics Rule are also applicable.	**10^{-5}**	
Arizona	9	**17.5**		**10^{-6}**	
Arkansas	6	**7.5**		**10^{-5}**	
Bad River Band of Lake Superior Tribe of Chippewa Indians of the Bad River Reservation (WI)	5	**142.4**		**None Listed**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
California	9	**6.5**	Mercury criterion is 18.7 grams/day (fresh water, enclosed bays and estuaries) and 19.5 grams/day (ocean waters). More recent site-specific mercury criteria in CA apply the methymercury tissue criterion and a rate of 32 grams/day. Criteria in the National Toxics Rule and California Toxics Rule are also applicable.	**10^{-6}**	
Colorado	8	**17.5**		**10^{-6}**	
Confederated Salish and Kootenai Tribes of the Flathead Indian Reservation	8	**17.5**		**10^{-6}**	
Confederated Tribes of the Chehalis Reservation	10	**6.5**		**10^{-6}**	
Confederated Tribes of the Colville Reservation	10	**narrative criteria**		**N/A**	
Confederated Tribes of the Umatilla Indian Reservation of Oregon	10	**389**		**10^{-6}**	
Confederated Tribes of the Warm Springs Indian Reservation of Oregon	10	**170**		**10^{-6}**	
Connecticut	1	**17.5** or **6.5**	17.5 grams/day used for most parameters.	**10^{-6}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Coeur d'Alene	10	**17.5**	Initial WQS submission - EPA has not acted on the submission.	**10^{-6}**	
Delaware	3	**17.5**		**10^{-6}**	
District of Columbia	3	**17.5**		**10^{-6}**	
Florida	4	**6.5**	Florida is proposing to update criteria with an approach that calculates the criterion level necessary to achieve the minimum risk to Florida's population. This approach is currently being reviewed as part of the public comment process.	**10^{-6}**	
Georgia	4	**17.5**		**10^{-6}**	
Grand Portage Band of the Minnesota Chippewa Tribe	5	**142.4**		**10^{-6}**	Concentrations of carcinogenic chemicals from point or non-point sources, singly or in mixtures, must not exceed risk levels of one chance in 1,000,000 in surface waters.
Hawaii	9	**19.9**		**10^{-6}**	
Idaho	10	**6.5**	Idaho proposed a rate of 17.5 grams/day in 2006, which was disapproved by EPA in 2012.	**10^{-6}**	
Illinois	5	**15** (Great Lakes Basin); **20** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Indiana	5	**15** (Great Lakes Basin); **6.5** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Iowa	7	**17.5**		**10^{-5}**	
Kalispel Indian Community of the Kalispel Reservation	10	**17.5**	Nickel, arsenic, and chloroform use a FCR of 6.5 g/day.	**10^{-6}**	
Kansas	7	**6.5** or **17.5**	Criteria in National Toxics Rule are also applicable. Kansas is proposing to adopt updated criteria based on EPA's recommended §304(a) criteria in its current revision.	**10^{-6}**	
Kentucky	4	**17.5**		**10^{-6}**	
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation	5	**32**		**10^{-6}**	
Louisiana	6	**20**	6.5 grams/day for Monte Sano Bayou.	**10^{-6}**	Except for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) and hexachlorocyclohexane (lindane, gamma BHC), in which case 10^{-5} is used.
Lummi Nation	10	**142.4**		**10^{-6}**	

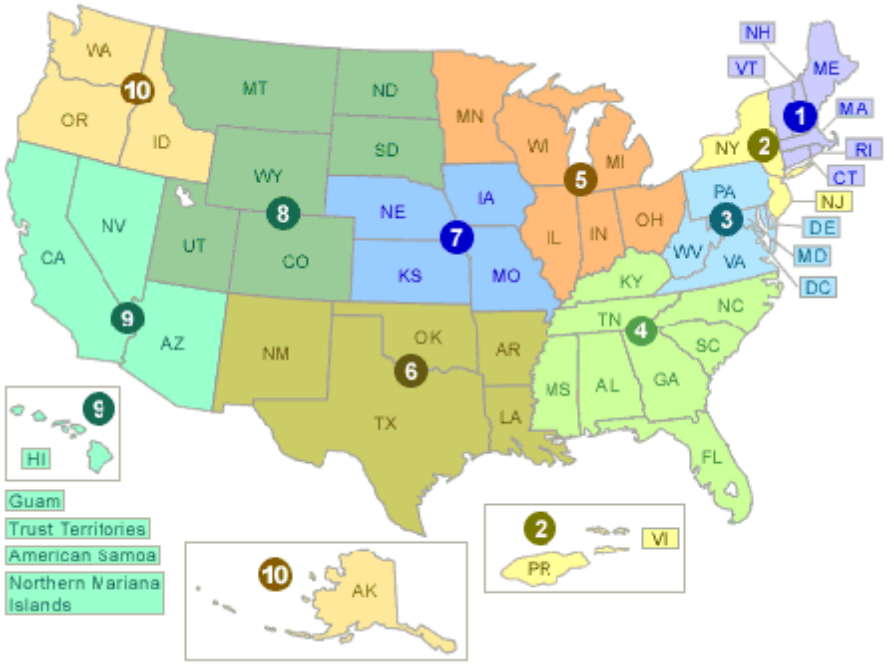
Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Maine	1	**32.2**		**10^{-6}**	Maine recently adopted new arsenic criteria based on a 10^{-4} cancer risk level and a FCR of 138 g/day.
Makah Tribe	10	**142.4**		**10^{-6}**	
Maryland	3	**17.5**		**10^{-5}**	
Massachusetts	1	**17.5** or **6.5**		**10^{-6}**	
Miccosukee Tribe Indians of Florida	4	**17.5**		**10^{-6}**	
Michigan	5	**15** (Great Lakes Basin); **15** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Minnesota	5	**30**		**10^{-5}**	Great Lakes Initiative
Mississippi	4	**6.5**	Mississippi completed a WQS revision in June 2012, with criteria based on consumption rate of 17.5 grams/day (will be submitted to EPA).	**10^{-6}**	
Missouri	7	**6.5**		**10^{-6}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Superior Tribe of the Chippewa Indians, Sokaogon Chippewa Community	5	**15**		**None Listed**	
Montana	8	**17.5**		**10^{-6}**	
Nebraska	7	**6.5**	Mercury criterion uses 32.4 grams/day	**10^{-6}**	
Nevada	9	**6.5**	Mercury criterion uses 18.7 grams/day. Criteria in National Toxics Rule are also applicable.	**10^{-5}**	
New Hampshire	1	**6.5**		**10^{-6}**	
New Jersey	2	**17.5**			
New Mexico	6	**17.5**		**10^{-5} and 10^{-6}**	
New York	2	**33**		**10^{-6}**	
North Carolina	4	**17.5**		**10^{-6}**	
North Dakota	8	**17.5**		**10^{-6}**	
Ohio	5	**15** (Great Lakes Basin); **6.5** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Oklahoma	6	**6.5**	Oklahoma intends to update criteria using 17.5 grams/day in next triennial revision.	**10^{-5}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Oregon	10	**175**		**10^{-6}**	Except for arsenic which uses 10^{-5} for organism only and 10-4 for water + organism
Pennsylvania	3	**17.5**		**10^{-6}**	
Port Gamble S'Klallam Tribe	10	**142.4**		**10^{-6}**	
Puyallup Tribe of Indians	10	**6.5**	Puyallup Tribe has proposed rate of 142.4 grams/day, but has not submitted to EPA.	**10^{-6}**	
Rhode Island	1	**17.5**		**10^{-6}**	
Saint Regis Mohawk Tribe	2	**33**		**10^{-6}**	
South Carolina	4	**17.5**		**10^{-6}**	
South Dakota	8	**17.5**		**10^{-6}**	
Spokane Tribe of Indians	10	**86.3**	Spokane Tribe submitted revised standards to EPA in 2010 using rate of 865 grams/day, but EPA has not acted on this submittal.	**10^{-6}**	
Tennessee	4	**17.5**		**10^{-6}**	
Texas	6	**17.5** (carcinogens); **5.6** (non-carcinogens, childhood exposure factors)	Mercury criteria use 10 grams/day (fresh water) and 15 grams/day (salt water).	**10^{-5}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
The Fond du Lac Band of the Minnesota Chippewa Tribe	5	**60**		**None Listed**	
Utah	8	**17.5**		**10^{-6}**	
Vermont	1	**6.5**		**10^{-6}**	
Virginia	3	**17.5**		**10^{-5}**	
Washington	10	**6.5**	Applicable human health criteria are in the National Toxics Rule.	**10^{-6}**	
West Virginia	3	**17.5**		**10^{-6}**	
Wisconsin	5	**20**		**10^{-5}**	Great Lakes Initiative
Wyoming	8	**17.5**		**10^{-6}**	

Environmental Protection Agency Regions



November 2002 (revised)

FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

A Report developed from the National Environmental Justice Advisory Council Meeting of December 3-6, 2001

A Federal Advisory Committee to the U.S. Environmental Protection Agency

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PREFACE

"[L]et everybody know that this environment belongs to all of us, and when you contaminate the water and contaminate the fish, you are contaminating all of us.

I tell you, I don't know if you know anything about Isaiah. Isaiah was a great prophet you know, and he said, "I have played, I have taught, and I have preached, and I wonder if anybody is listening." So I want to know if anybody is listening, and if you are listening I want to know what are you going to do about it?"

Remarks of Daisy Carter, Project AWAKE
Member of the NEJAC Fish Consumption Work Group
and its Air and Water Subcommittee

December 4, 2001
Meeting of the National Environmental Justice Advisory Council
Seattle, Washington

ACKNOWLEDGMENTS

The NEJAC acknowledges, with deep appreciation, the Fish Consumption Work Group and the NEJAC Report consultant, Catherine O'Neill, Associate Professor, Seattle University School of Law, for their outstanding contributions in developing this broad public policy issue report.

DISCLAIMER

This Report and recommendations have been written as part of the activities of the National Environmental Justice Advisory Council, a public advisory committee providing independent advice and recommendations on the issue of environmental justice to the Administrator and other officials of the United States Environmental Protection Agency (EPA).

This report has not been reviewed for approval by the EPA, and hence, its contents and recommendations do not necessarily represent the views and the policies of the Agency, nor of other agencies in the Executive Branch of the federal government.

INTERPRETIVE NOTES

The National Environmental Justice Advisory Council (NEJAC) is a federal advisory committee to the United States Environmental Protection Agency (EPA). This Report, therefore, focuses on those environmental justice issues raised by compromised aquatic ecosystems that EPA is empowered to address. That is to say, it examines, in the main, efforts that might be undertaken by EPA, as opposed to other agencies (whether federal, state, or tribal), and it focuses on sources of contamination and depletion within the United States, as opposed to global sources. This focus is not meant to suggest that NEJAC believes that the efforts of these other agencies and the contributions of these other sources are not important aspects of understanding and addressing compromised aquatic ecosystems; rather, it reflects NEJAC's role as a federal advisory committee to EPA.

This Report also examines the issues assuming a backdrop of the current state of the law. For example, in Chapter Two it discusses prevention, reduction, cleanup and restoration in light of existing environmental laws, and in Chapter Four it discusses the particular legal and political status of American Indian tribes and Alaska Native villages, given current interpretations of this status and the current enumeration of federally-recognized tribes. Again, this assumption is not meant to suggest that NEJAC supports in every respect these current enactments or interpretations; rather, it reflects a pragmatic choice, governed in part by considerations of scope.

Throughout, this Report discusses the impact of contaminated and depleted aquatic ecosystems on communities of color, low-income communities, tribes, and other indigenous peoples; Chapter Four, however, is devoted to those issues raised by the fact of American Indian tribes' and Alaska Native villages' unique status as sovereign governments. Thus, while the environmental justice issues posed by compromised aquatic ecosystems will often be common to each of these groups and their members, the NEJAC believes that separate treatment is warranted for tribes in their governmental capacity.

This Report uses the phrase "communities of color, low-income communities, tribes, and other indigenous peoples" in an effort to capture, in shorthand form, all of the various groups and subgroups that are affected by environmental injustice stemming from compromised aquatic ecosystems. It is meant to include all people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdictional boundaries of the United States. In an effort to avoid cumbersome repetition of this phrase, the Report also substitutes the phrases "affected communities and tribes" and "affected groups;" these shorter phrases are meant to be similarly inclusive.

Finally, this Report intends to address itself to the contamination and depletion of aquatic ecosystems and all of their components, including fish, shellfish, marine invertebrates, aquatic plants, and wildlife. This Report often refers simply to "fish" or "aquatic resources" or to some other shorthand term, but should be understood in each instance to refer to aquatic ecosystems and all of their components (unless the context suggests otherwise).

NATIONAL ENVIRONMENTAL JUSTICE ADVISORY COUNCIL

November 19, 2002

Administrator Christine Todd Whitman
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Administrator Whitman,

Please find attached a copy of the report entitled "**National Environmental Justice Advisory Council Fish Consumption and Environmental Justice,** *November 2002."*

EPA, through its Office of Environmental Justice, requested the National Environmental Justice Advisory Council (NEJAC) in its meeting of December 3-6, 2001 to provide advice and recommendations on how EPA could improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

This report reflects the advice and recommendations that resulted from pre-meeting preparation, on-site discussions, public comments and subsequent analysis. Individuals and organizations with varied backgrounds and interests offered comments, suggestions and recommendations on how EPA should address fish consumption issues.

This report proposes six overarching consensus recommendations to the EPA as follows:

(1) Require states, territories, and authorized tribes to consider specific uses, including the use of the waterbody or waterbody segment for subsistence fishing, when designating uses for a waterbody, and to set water quality criteria that support the specific designated use; *provided* that where human health criteria are established based upon consumption of toxic chemicals that bioaccumulate in fish, regulators should employ appropriate human fish consumption rates and bioaccumulation factors, including cultural practices (*e.g.*, species, fish parts used, and manner of cooking and preparation) of tribes and other indigenous and environmental justice communities using the waterbody; *provided further* that EPA should encourage and provide financial and technical support for states, territories, and authorized tribes to control effectively all sources, including both point sources and nonpoint sources, to achieve the criteria;

(2) Work expeditiously to prevent and reduce the generation and release of those contaminants to the Nation's waters and air that pose the greatest risk of harm to human health and aquatic resources, including but not limited to persistent bioaccumulative toxics (PBTs) (*e.g.*, mercury, dioxins, and polychlorinated biphenyls (PCBs)) and other toxic chemicals, and to clean up and restore aquatic ecosystems contaminated by pollutants;

(3) Protect the health of populations with high exposure to hazards from contaminated fish, aquatic organisms and plants, and wildlife, including communities of color, low income communities, tribes, and other indigenous peoples, by making full use of authorities under the federal environmental laws and accounting for the cultural, traditional, religious, historical , economic, and legal contexts in which these affected groups consume and use aquatic and terrestrial resources;

(4) Ensure that fish and other aquatic organism consumption advisories are used by regulators as a short-term, temporary strategy for informing those who consume and use fish, aquatic organisms and plants, and wildlife of risks while water quality standards are being attained and while prioritizing and pursuing the cleanup of contamination by appropriate parties; agencies must evaluate and address such risks; and require risk-producers to prevent, reduce, and clean up contamination of waters and aquatic ecosystems;

(5) Because many American Indian and Alaska Native (AI/AN) communities are particularly prone to environmental harm due to their dependence on subsistence fishing, hunting, and gathering, conduct environmental research, fish consumption surveys, and monitoring, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to determine the effects on, and ways to mitigate adverse effects on the health of AI/AN communities resulting from contaminated water sources and/or the food chain; and

(6) Consistent with the 1988 *EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations*, the federal trust responsibility to federally recognized tribes, and federal policies recognizing tribal sovereignty and promoting self-determination and self-sufficiency, provide equitable funding and technical support for tribal programs to protect AI/AN communities and tribal resources from harm caused by contaminated water and aquatic resources and, until tribes are able to assume responsibility for such programs, implement and require compliance with the federal environmental laws within Indian country; *provided* that, in consultation with tribes, EPA should promptly develop effective and appropriate regulatory strategies for setting, implementing, and attaining water quality standards within Indian country; and *provided further* that, EPA should work with Alaska Native villages to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats associated with their extensive subsistence lifeways.

The NEJAC is pleased to present this report to you for your review, consideration, response and action. In addition, the NEJAC appreciates any assistance you can provide in processing the recommendations in this report through the Office of Water with consultation as appropriate with the American Indian Environmental Office and the Office of Environmental Justice.

Sincerely,

/s/	/s/
Peggy Shepard	Jana Walker
Chair	Vice Chair

TABLE OF CONTENTS

FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

NATIONAL ENVIRONMENTAL JUSTICE ADVISORY COUNCIL (NEJAC)

Summary

This Report has been compiled after deliberation during the December, 2001 meeting of the National Environmental Justice Advisory Council (NEJAC) regarding the following overarching policy question:

> **How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?**

This Report works to identify and discuss the particular issues that this question raises when – as is often the case – those affected by contaminated and depleted aquatic ecosystems are communities of color, low-income communities, American Indian tribes/Alaskan Native villages and their members, and other indigenous peoples.

This report proposes six overarching consensus recommendations to the EPA as follows:[1]

(1) Require states, territories, and authorized tribes to consider specific uses, including the use of the waterbody or waterbody segment for subsistence fishing, when designating uses for a waterbody, and to set water quality criteria that support the specific designated use; *provided* that where human health criteria are established based upon consumption of toxic chemicals that bioaccumulate in fish, regulators should employ appropriate human fish consumption rates and bioaccumulation factors, including cultural practices (*e.g.*, species, fish parts used, and manner of cooking and preparation) of tribes and other indigenous and environmental justice communities using the waterbody; *provided further* that EPA should encourage and provide financial and technical support for states, territories, and authorized tribes to control effectively all sources, including both point sources and nonpoint sources, to achieve the criteria;

(2) Work expeditiously to prevent and reduce the generation and release of those contaminants to the Nation's waters and air that pose the greatest risk of harm to human health and aquatic resources, including but not limited to persistent bioaccumulative toxics (PBTs) (*e.g.*, mercury, dioxins, and polychlorinated biphenyls (PCBs)) and other toxic chemicals, and to clean up and restore aquatic ecosystems contaminated by pollutants;

[1]NEJAC Executive Council member Kenneth J. Warren joins in support of the Report's six Consensus Recommendations and the Report's depiction of fish consumption impacts to communities and tribes. He believes, however, that the Report should provide a more focused and well-grounded substantiation for these recommendations.

(3) Protect the health of populations with high exposure to hazards from contaminated fish, aquatic organisms and plants, and wildlife, including communities of color, low income communities, tribes, and other indigenous peoples, by making full use of authorities under the federal environmental laws and accounting for the cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic and terrestrial resources;

(4) Ensure that fish and other aquatic organism consumption advisories are used by regulators as a short-term, temporary strategy for informing those who consume and use fish, aquatic organisms and plants, and wildlife of risks while water quality standards are being attained and while prioritizing and pursuing the cleanup of contamination by appropriate parties; agencies must evaluate and address such risks; and require risk-producers to prevent, reduce, and clean up contamination of waters and aquatic ecosystems;

(5) Because many American Indian and Alaska Native (AI/AN) communities are particularly prone to environmental harm due to their dependence on subsistence fishing, hunting, and gathering, conduct environmental research, fish consumption surveys, and monitoring, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to determine the effects on, and ways to mitigate adverse effects on the health of AI/AN communities resulting from contaminated water sources and/or the food chain; and

(6) Consistent with the 1988 *EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations*, the federal trust responsibility to federally recognized tribes, and federal policies recognizing tribal sovereignty and promoting self-determination and self-sufficiency, provide equitable funding and technical support for tribal programs to protect AI/AN communities and tribal resources from harm caused by contaminated water and aquatic resources and, until tribes are able to assume responsibility for such programs, implement and require compliance with the federal environmental laws within Indian country; *provided* that, in consultation with tribes, EPA should promptly develop effective and appropriate regulatory strategies for setting, implementing, and attaining water quality standards within Indian country; and *provided further* that, EPA should work with Alaska Native villages to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats associated with their extensive subsistence lifeways.

The Report is organized into five chapters. An initial chapter provides background. The four succeeding chapters each address a more focused policy question and the issues it raises. These chapters are outlined below:

Background

This chapter explores the importance of having healthy aquatic ecosystems to address issues of environmental justice. It provides background on the perspectives of the various individuals, communities, tribes, and peoples affected by those aquatic ecosystems which are contaminated and depleted. This chapter begins with the observation that communities of color,

low-income communities, tribes, and other indigenous peoples *depend* on healthy aquatic ecosystems and the fish, aquatic plants, and wildlife that these ecosystems support. While there are important differences among these various affected groups, their members generally depend on the fish, aquatic plants, and wildlife to a greater extent and in different ways than does the general population. These resources are consumed and used to meet nutritional and economic needs. For some groups, they are also consumed or used for cultural, traditional, or religious purposes. For members of these groups, the conventional understandings of the "health benefits" or "economic benefits" of catching, harvesting, preparing, and eating fish, aquatic plants, and wildlife do not adequately capture the significant value these practices have in their lives and the life of their culture. The harms caused by degradation of aquatic habitats and depletion of fisheries, moreover, do not only affect the present generation. They take their toll on future generations and on the transfer of knowledge from one generation to the next (e.g., ecological knowledge, customs and traditions surrounding harvest, preparation and consumption of aquatic resources).

Many of the rivers, streams, bayous, bays, lakes, wetlands, and estuaries that support these resources on which communities and tribes depend have become contaminated and depleted. Contamination is causing the communities' and tribes' everyday practices – their ways of living – to serve as a source of exposure to a host of substances toxic to humans and other living things. The depletion of aquatic environments and resources also threatens these groups' subsistence, economic, cultural, traditional, and religious practices. Aquatic ecosystems are contaminated with mercury, PCBs, dioxins, DDT and other pesticides, lead and other metals, sediments, fecal coliform and other bacterial and viral contaminants – in short, a host of toxins, most of which are particularly troubling because they *persist* in the environment for great lengths of time and because they *bioaccumulate* in the tissues of fish, aquatic plants, and wildlife, existing in greater quantities higher up the food chain.

For many communities of color, low-income communities, tribes, and other indigenous peoples, there are no real alternatives to eating and using fish, aquatic plants, and wildlife. For many members of these groups it is entirely impractical to "switch" to "substitutes" when the fish and other resources on which they rely have become contaminated. There are numerous and often insurmountable obstacles to seeking alternatives (e.g., fishing "elsewhere," throwing back "undesirable" species of fish, adopting different preparation methods, or substituting beef, chicken or tofu). For some, not fishing and not eating fish are unimaginable for cultural, traditional, or religious reasons. For the fishing peoples of the Pacific Northwest, for example, fish and fishing are necessary for survival as a people – they are vital as a matter of cultural flourishing and self-determination.

When health and environmental agencies respond to contamination and its impacts, they typically employ one or both of two general strategies: *risk avoidance*, whereby risk-bearers are encouraged or required to change the practices that expose them to contamination (e.g., through fish consumption advisories, directed to those who eat fish) or *risk reduction*, whereby risk-producers are required to cleanup, reduce, or prevent contamination (e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters). In either event, agencies rely on assumptions about fish consumption rates, practices, and needs that

reflect the circumstances of the general population, but often are not reflective enough of the circumstances of affected communities and tribes. Agencies' approaches to risk assessment, risk management, and risk communication similarly fall short of taking into account that affected groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." These observations have policy implications that are taken up in the remaining chapters.

Chapter One: **Research Methods and Risk Assessment Approaches**

Chapter One focuses on the tools that agencies use to define, evaluate, and respond to the adverse health impacts from contaminated aquatic environments. It examines the research methods that agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes. It also examines the risk assessment approaches that agencies employ to evaluate and address these health impacts.

This chapter begins by noting that agencies typically focus on "adverse impacts to human health" that tend to focus narrowly on individuals and physiological harms. Some affected groups, by contrast, may view the harms from contamination more broadly: they are not only physiological, but psychological, social, and cultural; which may not only impact an individual, but a group overall.

This chapter then devotes considerable discussion to differences in various groups' circumstances of exposure. It documents the marked differences in how much fish is eaten (measured by fish consumption rates) between the general population and higher-consuming "subpopulations" such as communities of color, low-income communities, tribes, and other indigenous peoples. It canvases agencies' standard assumptions about the fish, shellfish, plant, and wildlife species that people consume and use; the parts of these species they use; and the preparation methods they employ. It points out that these assumptions often do not reflect the practices among the various affected groups. It observes the different cultural, traditional, religious, historical, economic, and legal contexts in which many affected groups consume and use aquatic resources. It takes up the issues of aggregate or multiple exposures and cumulative risks, noting that whereas agencies' current methods proceed as if humans were exposed to a single contaminant at a time, humans are actually often exposed to multiple contaminants at a time or in succession, and often by more than one route and pathway of exposure. This is especially likely to be the case for many members of communities of color, low-income communities, tribes, and other indigenous peoples. Each of the considerations raised here contributes to the observation that agencies currently underestimate the extent to which members of these groups are exposed to environmental contaminants. The result is that standards set or advisories issued based on these estimates will not be sufficiently protective of these affected groups.

This chapter next considers the different susceptibilities and "co-risk" factors that may characterize affected groups and their members, noting again that these differences are unlikely to be accounted for by current agency approaches.

This chapter then explores suppression effects and their implications. A suppression effect occurs when a fish consumption rate for a given subpopulation reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that subpopulation. The more robust baseline level of consumption is "suppressed," inasmuch as is does not get captured by the fish consumption rate. Suppression effects may arise as a result of contaminated aquatic ecosystems, depleted aquatic ecosystems and fisheries, or both. When agencies set environmental standards using a fish consumption rate based upon an artificially diminished consumption level, they may set in motion a downward spiral whereby the resulting standards permit further contamination and/or depletion of the fish and aquatic resources. This chapter discusses the policy implications of suppression effects.

This chapter then addresses research methods relevant to risk assessment, risk management, and risk communication. Much of the preceding discussion is brought to bear, as it underscores the fact that it will often be crucial to the relevance, accuracy, and acceptability of research in these areas that the affected community or tribe be central to the process throughout. This is not only a matter of community access or tribal consultation, but, importantly, a matter of scientific defensibility. There are currently sizeable gaps in the data and methods that EPA and other agencies use to assess, manage, and communicate risk, and it is often the case that these gaps can only be filled by community- and tribally-based research. As the large literature on "participatory research" documents, affected communities and tribes have expertise that is simply not going to be able to be replicated by non-member researchers. Notably, it will be important to ensure that this community participation and tribal consultation is adequately funded and supported technically. This chapter also discusses the need for research that seeks not only to describe affected groups' exposure, but also to connect exposure to sources of contaminants in aquatic environments.

Finally, this chapter examines efforts to refine current risk assessment methods in order to address issues raised by these methods for communities of color, low-income communities, tribes, and other indigenous peoples, and discusses efforts to reevaluate the use of current risk assessment approaches in light of alternative approaches, particularly those that focus on prevention and precaution.

Chapter Two: Using Existing Legal Authorities

Chapter Two discusses agencies' risk reduction efforts, that is, strategies that look to risk-producers to prevent or reduce contamination in the first place, and to cleanup and restore those environments that are already contaminated. It examines the legal authorities that might be invoked more effectively to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

This chapter begins by providing background on the contaminants of greatest concern, not only from the perspectives of health and environmental agencies, but also from the perspective of affected groups and their members. Chief among the contaminants of concern are mercury, PCBs, dioxins, DDT, and chlordane. In addition to these five contaminants, at least eight others are a source of concern, given that they are highly *toxic*; they are *persistent* once released into the

environment; and they *bioaccumulate* in the tissues of fish and wildlife. These eight are: aldrin, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, and furans. Finally, a host of other contaminants are troubling here, including: lead and other metals; numerous other pesticides; fecal coliform, marine biotoxins and various other bacterial and viral contaminants; sediment and silt loadings; and numerous others. This chapter outlines briefly the health effects of each of the major contaminants of concern, as well as its sources in the environment.

This chapter discusses how EPA might better prevent and reduce contamination in the first place, focusing primarily on efforts under the Clean Water Act (CWA) and secondarily on efforts under other legal authorities, such as the Clean Air Act (CAA). It then turns its discussion to how EPA might better clean up and restore those aquatic ecosystems that are already contaminated. Again, it looks first to the authority provided by the Clean Water Act, and then discusses other legal authorities, such as "Superfund," the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

Chapter Three: **Fish Consumption Advisories**

Chapter Three discusses agencies' risk avoidance strategies, focusing on fish and wildlife consumption advisories in particular and on risk communication in general. It asks what role fish consumption advisories should play in efforts to protect more effectively the health and safety of people consuming or using these resources. It considers how agencies can identify, acknowledge, and meet the real needs of those who are affected – how they can work to make affected groups whole once the fish, aquatic plants, and wildlife on which they depend have already become contaminated.

The chapter first takes up the question of the advisories' proper role. Drawing on the observations presented above about the impracticality and/or unimaginability of reducing fish consumption or of altering practices connected with catching, harvesting, preparing and eating fish, this chapter notes that the answer to the question of fish consumption advisories' role will likely be different for different communities or tribes. Importantly, it should be for the affected group to determine what will be appropriate from its perspective. Tribes' particular political and legal status as sovereign nations must also be taken into account here, as tribes will be in the position, in their governmental capacities, of deciding for themselves what role fish consumption advisories should play in their environmental protection efforts.

This chapter next explores fish consumption advisories' "effectiveness." It discusses briefly the potential differences in how "effective" might be defined by various agencies and by various affected communities and tribes. It reviews the current state of research regarding how those to whom advisories are directed respond to this information, observing that the available evidence suggests that low-income, people of color, those with limited English proficiency, and those with relatively little formal education are less likely to be aware of advisories.

In light of this evidence, and in view of current EPA efforts to this end, this chapter then devotes considerable attention to the matter of improving the effectiveness of risk communication and fish consumption advisories. As a general matter, it observes that if risk communication is

truly to be a "two-way street" – if *communication* is actually to occur, - affected groups must be involved as partners or co-managers at every point in the risk communication process. All of the elements of effective advisories – including "audience identification," "needs assessment," message content, media choice, implementation, and evaluation – will fall into place if agencies and affected communities or tribes consider together the questions and answers. In general, EPA and other agencies should work to reconceptualize risk communication approaches from large-scale, abstract, one-time efforts to develop and disseminate various communication "products" (e.g., developing and posting fish advisory signs) to local, contextually-supported, ongoing efforts to establish and maintain relationships with a particular affected community or tribe.

More specifically, it will be important for EPA and other agencies to recognize the diverse contexts, interests, and needs that characterize the various affected groups – including, but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refugee communities; African American communities; various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thadium communities within the larger Laotian community in West Contra County, CA); various Hispanic communities and subcommunities (e.g., Carribean-American communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaska Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people).

"Affected groups" also refers to subgroups within these larger groups, including but not limited to nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices surrounding fish consumption; and subgroups defined by geographical region. Affected group involvement in aiding identification and understanding of the diverse contexts, interests, and needs of these various groups will, perhaps unsurprisingly, be essential. The content of the message and the media selected need to be effective and appropriate from the perspective of the affected group, and this chapter examines several specific considerations to this end. Implementation efforts, too, must be effective and appropriate from the perspective of those affected, who will be particularly well-positioned to take the lead in implementing an advisory and outreach strategy that has been developed by and for their group. Evaluation will also be most usefully conducted together with members of the affected group, whose ability to help define and measure "success" will again often be unparalleled.

Additionally, this chapter observes that capacity-building or capacity-augmentation is in and of itself and environmental justice issue, for both communities and tribes. Involvement by those affected at each point in the risk communication process would go far toward enabling them to shape the process so that it is not only relevant and appropriate, but also useful and empowering from the perspective of the community or tribe.

Finally, this chapter notes that here again, as in the context of research in general, financial and technical support will be crucial to enabling communities and tribes fully to be involved.

Chapter Four: **American Indian Tribes and Alaskan Native Villages**

Chapter Four addresses issues unique to American Indian tribes, Alaskan Native villages, and their members. Although tribes and their members share many of the concerns discussed in the preceding chapters, tribes' political and legal status is unique among affected groups and so warrants separate treatment. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories, and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights. Other laws and executive commitments, too, shape the legal obligations owed to American Indian tribes and Alaska Native tribes and their members.

This chapter describes the EPA's Indian Policy for the Administration of Environmental Programs on Indian Reservations; tribes' efforts to assume responsibilities for administering environmental programs on their reservations under various federal environmental laws – notably, the Safe Drinking Water Act, the Clean Water Act, the Clean Air Act, and CERCLA; and tribes' work as co-managers of cleanup and restoration efforts and/or as Natural Resource Damage Trustees. In these and other roles, tribes will have environmental justice concerns of a different and complex nature.

The chapter then outlines the ways in which the political and legal status of Alaska Native villages has been interpreted to be both similar to and different from the status of tribes in the forty-eight contiguous states, and notes briefly some of the circumstances unique to Alaska Natives that are likely to raise particular concerns for this group.

Finally, this chapter outlines the particular circumstances of tribes and their members with respect to susceptibilities and co-risk factors; these have implications, as discussed more generally in Chapter One, for agencies' risk assessment, risk management, and risk communication approaches.

FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

BACKGROUND CHAPTER

The National Environmental Justice Advisory Council (NEJAC) is a federal advisory committee of the U.S. Environmental Protection Agency (EPA). Under its charter, the NEJAC's mission is to provide advice and recommendations to the EPA Administrator on matters related to environmental justice. In July, 2000, EPA requested that NEJAC address issues raised by the relationship between fish consumption, water quality, and environmental justice. This issue was the focus of the NEJAC's December 3-6, 2001 meeting in Seattle, Washington.

This Report focuses on the following question:

How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

This chapter provides background necessary to address adequately the above policy question. This chapter seeks to explain why contaminated and depleted aquatic ecosystems are an environmental justice issue. Importantly, this chapter seeks to present the dimensions of the problem from the perspectives of the various individuals, communities, tribes, and other peoples affected.

This chapter begins in Part A by gathering the accounts of a number of different people who suffer the ill effects of contaminated and depleted aquatic ecosystems. Although these stories do not catalogue exhaustively the harms felt by all of those who are affected, it is hoped that, taken together, they will provide a sense of the breadth and enormity of the impacts on communities of color, low-income communities, tribes, and other indigenous peoples. And it is hoped that, in their diversity, they will provide a sense of the differing dimensions of the ill effects for these different affected groups. This chapter begins with these accounts because they are properly the starting point for any discussion of environmental justice policy: they present the *real* stories – the stories told from the perspectives of those on the ground, and not as they need to be told to fit into the bins and categories created by environmental laws and regulations. These accounts should *frame* the discussion – rather than be merely "inputs" into a discussion already framed in someone else's terms.

In order to speak to government agencies that work within the boundaries of environmental laws and regulations, however, it seems useful to work to "translate" these stories so that their relevance to agencies' efforts can be appreciated. NEJAC's attempt at translation will often mean breaking things down and naming their component parts in ways that are more likely to be understood by agencies, given agencies' current categories, programs, and approaches. So, for example, in seeking to convey the importance of salmon in his life, a member of the Fourteen

Confederated Tribes and Bands of the Yakama Nation may invoke terms and concepts familiar to agencies such as "nutrition," "health," "economy," "resource," "subsistence," "culture," and "treaty-protected;" he may refer to laws and programs that separately address the "air," "water quality," "water quantity," and "sediments" that together are home to the salmon.

This attempt at translation may entail loss, however: it may fail fully to capture the multiple and interrelated dimensions of what is at stake; or it may risk misunderstanding or *mis*translation Yet an attempt at translation may be necessary for those affected to convey their recommendations to agency decision makers. Nonetheless, it is crucial that agencies also work to *hear* the stories in their original, whole form and to consider what these stories have to teach them – how they might serve to reframe agencies' approaches altogether. It is important that agencies strive to reduce the gulf that must be bridged by translation and so to minimize the loss that accompanies translation. With these considerations in mind, the remainder of this Report looks to discuss the issues in the terms used by environmental agencies and in environmental laws and regulations, while at the same time referring often to the words of those affected as touchstones for deliberation.

Part B of this chapter then raises the question that is examined in the remainder of this Report, regarding the policy implications of the accounts set forth in Part A.

A. DIVERSE IMPACTS, MULTIPLE DIMENSIONS: THE ACCOUNTS OF ENVIRONMENTAL INJUSTICE

1. Communities of Color, Low-Income Communities, Tribes, and Other Indigenous Peoples Depend on Fish,[2] Aquatic Plants, and Wildlife

Put simply, communities of color, low-income communities, tribes, and other indigenous peoples *depend* on healthy aquatic ecosystems and the fish, aquatic plants, and wildlife that these ecosystems support. While there are important differences among the various affected communities of color, low-income communities, tribes, and other indigenous peoples, members of these groups depend on fish, aquatic plants, and wildlife to a greater extent and in different ways than does the general population.

[2]The term "fish," here and throughout this Report, is meant to include shellfish and marine invertebrates, unless the particular context suggests otherwise. Please see the Interpretive Notes at the outset of this Report for elaboration.

Fish are a healthful source of dietary protein and other nutrients for humans.[3] Fish are relatively low in fat, and are a good source of selenium. Fish, aquatic plants, and wildlife are major dietary staples for some individuals, and those who subsist chiefly or solely on fish, aquatic plants, and wildlife are more likely to be people of color, low-income individuals, tribal members, or other indigenous people. Thus, for example, a recent survey revealed that whereas 60% of "non-white" (primarily African-American) fishers on the Detroit River fished there to meet their needs for food or for a combination of food and recreation, only 21.7% of white fishers indicated that they fished for reasons combining food and recreation, and none indicated that they fished only to meet their needs for food.[4] In Alaska, "[a]mong Yupiks of Gambell, over one-half of their protein, iron, vitamin B-12, and omega-3 fatty acids come from subsistence foods."[5]

Fish, aquatic plants, and wildlife are important food sources for economic reasons: it generally costs less to purchase many kinds of fish than it costs to purchase other sources of animal protein,[6] and if someone can fish, gather, harvest, or hunt nearby, he or she can bypass altogether the need to get to a store and to purchase food. For some of these fishers, fishing provides not only food for their own consumption and consumption by relatives and neighbors, but also an important source of income and livelihood. As Delbert Frank, Sr., Warm Springs, explains:

> *I used to fish at Celilo falls before The Dalles Dam was built. We used to be able to fish all year long. We caught lots of different kinds of fish – spring chinook, summer chinook, bluebacks, fall chinook, steelhead, and coho. When the fish were coming in good, I could catch one ton of salmon a day. And, it didn't take a lot of fancy gear or expensive boats to fish. For the cost of one or two balls of twine, about 6 to 12 dollars, I could make the fishing gear necessary for me to catch enough fish to supply my family and many others for a whole year.*[7]

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[3]See, e.g., Yvonne Smith and Laura Berg, *Ancient Tradition, Modern Reality: Is There a Future for a Salmon-Based Culture?*, 1 Wana Chinook Tymoo 14 (1998); Renate D. Kimbrough, *Consumption of Fish: Benefits and Perceived Risk*, 33 Journal of Toxicology & Environmental Health 82-83 (1991).

[4]Patrick C. West, *Race and the Incidence of Environmental Hazards: A Time for Discourse* "Invitation to Poison? Detroit Minorities and Toxic Fish Consumption from the Detroit River"96, 98 (Bunyan Bryant and Paul Mohai, eds. 1992).

[5]Elizabeth D. Nobmann, *Nutritional Benefits of Subsistence Foods* (1997) available at www.nativeknowledge.org/db/files/aboutnt2.htm.

[6]See, e.g., Kimbrough, *supra* at 83.

[7]**Columbia River Inter-Tribal Fish Commission, *Celilo Falls*, available at www.critfc.org/text/CELILO.HTM.**

A low-income African-American fisher on the Detroit River observes:

> *I catch to eat fish. I catch a lot of fish and bring a lot home to eat. Bring home Perch and Bass. I eat more because I like fish and it is easier to feed a family because of money.*[8]

For some groups, fish, aquatic plants, and wildlife are consumed or used for cultural, traditional, or religious purposes as well. For members of these groups, conventional dominant society understandings of the "health benefits" or "economic benefits" of catching, harvesting, preparing, and eating fish, aquatic plants and wildlife do not adequately capture the place of these practices in their lives and the life of their culture. Cultural, traditional, and religious understandings will, of course, differ among various groups; the following excerpts provide but a few accounts. Winona LaDuke, Mississippi Band of Anishinaabeg, explains:

> *There are many wild rice lakes on the White Earth reservation in northern Minnesota; my community, the Anishinaabeg, calls the rice* Manoomin*, or a gift from the Creator.*
>
> *Every year, half our people harvest the wild rice, the fortunate ones generating a large chunk of their income from it. But wild rice is not just about money and food. It's about feeding the soul.*[9]

Similarly, Horace Axtell, Nez Perce, explains:

> *According to our religion, everything is based on nature. Anything that grows or lives, like plants and animals, is part of our religion. The most important element we have in our religion is water. At all of the Nez Perce ceremonial feasts the people drink water before and after they eat. The water is a purification of our bodies before we accept the gifts from the Creator. After the feast we drink water to purify all the food we have consumed. The next most important element in our religion is the fish because fish comes from water. It doesn't matter what kind of fish. If we have suckers or eels or steelhead or salmon, we honor it next after we drink the water. Then we name whatever fish we have, and then everyone takes a small bit before we eat the rest of the food. The next element is the game meat like deer, elk, and moose. That's how we honor the food we eat, especially the fish, because it is the next element after the water. The chinook salmon is more*

[8]Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 16 (forthcoming 2002) (listing fisher's income as $5,000 - $9,999).

[9]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 115 (1999).

favored because it is the strongest fish and the most tasty. Chinook Salmon is the fish we try to bring to the long house.[10]

As Hawaii's Thousand Friends relates:

Hawaiians, the indigenous people of these islands, rely on healthy aquatic ecosystems for their life-style. The depletion and contamination of these ecosystems has drastically impacted their health, food sources, economic well-being and ability to follow cultural, traditional and religious practices.[11]

And, as Art Ivanoff, from the Alaska Native village of Unalakleet explains, their understandings of these practices – and of the very meaning of the term "subsistence" – are often quite different than the understanding of the dominant society:

We have a different definition [of subsistence]. Western society tends to look at it as something that's derogatory, before the poverty level. That's not how we define our lifestyle. It's something rich. It's spiritual. It's economic. It's social. It's getting together with your friends and your relatives going out there harvesting, and sharing with elders, sharing with widows, and that's a pride we get.[12]

The harms occasioned by the degradation of aquatic habitats and the depletion of fisheries, moreover, are not only visited on the present generation. Part of the affront to the culture and social fabric of some communities and tribes for whom fish and fishing are vital comes from the diminished opportunities for inter-generational transfer of knowledge – especially ecological knowledge about places and natural systems – and for other aspects of inter-generational socialization. The acts of inter-generational transfer of customs and traditions surrounding catching, preparing, and consuming fish are themselves important to the maintenance of social and cultural health.[13] As an African-American fisher on the Detroit River explains:

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[10]Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 55 (1999).

[11]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[12]Art Ivanoff, Alaska Native Village of Unalakleet, *Comments to the National Environmental Justice Advisory Council* Vol. III-17 (Annual meeting transcript December 4, 2001); accord, Mary Kancewick & Eric Smith, *Subsistence in Alaska: Towards a Native Priority*, 59 UMKC Law Review 645, 650 (1991) ("Alaska Natives speak of subsistence not in terms of minimalism, but in terms of wealth; not in terms of something to be risen above, but in terms of something to aspire to and hold onto: 'Subsistence living, a marginal way of life to most, has no such connotation to the Native people of southeast Alaska. The relationship between the Native population and the resources of the land and the sea is so close that an entire culture is reflected.'"(quoting testimony of Nelson Frank, Tlingit, Sitka)).

[13]See, e.g., Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 9-10, 18-21 (forthcoming 2002)

> *My stepdad taught me how to fish. He is from a little town in Mississippi. Most people around here who fish were from the South and our parents were from the South and they were used to fishing and then they taught their kids. When I was little we used to eat fish a lot but that was when the water was clean. . . . I do eat the fish that I catch.*[14]

The Columbia River Inter-Tribal Fish Commission, for example, describes the extensive tribal ecological knowledge that was "transmitted to succeeding generations as part of their inheritance," and notes that "[p]lants, animals, and especially places were . . . repositories for historical, social, and spiritual lessons."[15] The concept of "risk" then, should include "cultural risk:"

> *Cultural risk [includes] ecological impacts that reduce or impair the inter-generational transfer of ecological knowledge used for implementing traditional holistic environmental management practices.*[16]

Indeed, for many members of communities of color, low-income communities, tribes, or other indigenous peoples, there are no real alternatives to depending on fish, aquatic plants, and wildlife. In some cases, for example, it is utterly impractical to suggest that people "switch" to "substitute sources of protein" when the fish on which they rely to put food on the table have become contaminated. Such suggestions are often unrealistic, given the many obstacles to the imagined alternatives: there may be no uncontaminated bays, lakes, or rivers for miles around; even if another fishing spot can be found just a little farther away, it may be difficult or impossible to reach without a car or other transportation – and it may cost too much for the gas or the bus or train ticket to get there; or another fishing spot may traditionally be someone else's fishing spot, such that it wouldn't be appropriate simply to go there; and there may be no adequate substitutes from other food sources at the grocery store – not being able to eat fish may mean having to look to foods that are poorer quality from a nutritional and health perspective. As Mark Davis, Coalition to Restore Coastal Louisiana, Baton Rouge, explains:

> *The advisories that are issued are just not* relevant *to the people here . . . it's as if no one believes that there really are subsistence fishers. Suddenly it is* my *responsibility as a risk-bearer to figure out what the advisories mean, what my level of risk is . . . as if there*

(discussing importance of inter-generational socialization for African-American community members in Detroit, many of whom brought practices surrounding fish and fishing with them as they and their families moved from the rural south to the industrial north).

[14]Id. at 20.

[15]Columbia River Inter-Tribal Fish Commission, *Cultural Context* available at http://www.critfic.org/text/TRP_cul.htm.

[16]Columbia River Inter-Tribal Fish Commission, *Comments to EPA Administrator Carol Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* 10 (January 14, 1999).

were a choice. People here walk or bike to a drainage ditch, to a bayou, to the Mississippi River – how can these people be expected to go fish somewhere else?[17]

An African-American fisher on the Detroit River explains:

I think that mostly black people fish on the river (due to lack of money); if they have the money they can go anywhere and fish – wherever they want. A lot of us don't have the boats or the cars to get to the good fish. We settle for the fish here but it's all good. I still get the fish. Some people fish because they have to fish. Fish is good food and it is cheap but river fish is the cheapest and I don't blame people for eating it.[18]

According to Angela Wilson, Founder, Environmental Justice Action Group, Portland, Oregon:

It is unrealistic to think that the community members who fish in the Columbia Slough can simply "eat peanuts and tofu," as the agencies suggest.[19]

Hawaii's Thousand Friends explains:

Fish, raw and cooked, is a staple of the Native Hawaiian diet. In an attempt to reduce the alarmingly high percentage of Native Hawaiians with high blood pressure, diabetes, heart disease and obesity, some physicians advocate returning to a historical Hawaiian diet, of which eating fish is a major component. The EPA recommendation of only 12 ounces of fish in one week is incompatible with most Native Hawaiian diets and with all those who follow the physician-recommended diet.[20]

Yin Ling Leung, Executive Director of Asians and Pacific Islanders for Reproductive Health, California, summarizes:

To our communities, being able to fish means being able to either put food on the table, or basically eat a much less nutritious meal. I think that's a non-choice.[21]

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[17]Telephone Interview with Mark Davis, Coalition to Restore Coastal Louisiana (August 22, 2001).

[18]Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 16 (forthcoming 2002).

[19]Angela Wilson, Environmental Justice Action Group, Presentation at Public Interest Environmental Law Conference, University of Oregon (March, 2001).

[20]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[21]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 1 (1998).

In some cases, too, not fishing and not eating fish are unimaginable for cultural, traditional, or religious reasons. For the fishing peoples of the Pacific Northwest, for example, fish and fishing are necessary for survival as a people – to fish is to *be* Nez Perce.[22] Fish and fishing are vital as a matter of cultural flourishing and self-determination. The importance of fish, especially salmon, to these peoples is reflected in language, in treaties, in past and present tribal fisheries management and environmental restoration efforts, and in the ongoing political and legal struggles for the survival of the salmon and the way of life that is bound up with the salmon. Don Samson, Umatilla, Executive Director, Columbia River Inter-Tribal Fish Commission, explains:

> *The reason I've been fishing is more for my own subsistence, to bring fish home. But maybe more importantly now these days is to maintain the tradition of fishing – of going up to the mountains where my father, my elders fished before me. So it's something that we've got to carry on – that's really why I fish. We've got to pass it on to our children. We have to have that for them in order to be Indians – in order to survive and carry on the things that were placed here for us, and carry on what our elders tell us and teach us.*[23]

Billy Frank, Jr., Nisqually, Chairman, Northwest Indian Fisheries Commission, explains:

> *Fishing defines the tribes as a people. It was the one thing above all else that the tribes wished to retain during treaty negotiations with the federal government 150 years ago. Nothing was more vital to the tribal way of life then, and nothing is more important now. . . .The tribes have fought too hard for too long to let the salmon and their treaty rights to harvest salmon go extinct. This summer and fall you will see tribal fishermen doing what they have always done – fish.*[24]

Of course, for many communities of color, low-income communities, tribes, and other indigenous peoples, the nutritional, economic, and traditional or cultural aspects of fishing, preparing and eating fish are interrelated. Members of these groups thus in many cases depend on fish for a combination of the above reasons. For example, a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of

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[22]See, e.g., Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 156 (1999) (quoting Del White, Nez Perce: "People need to understand that the salmon is part of who the Nez Perce people are. It is just like a hand is a part of your body. The salmon have always been part of our religion. You can't separate the two.").

[23]Videotape: *My Strength is From the Fish* (Columbia River Inter-Tribal Fish Commission, 1994).

[24]Billy Frank, Jr., *A Statement from Billy Frank, Jr. a*vailable at www.nwifc.wa.gov/esa/start.htm.

Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups – observes:

> *[Asian and Pacific Islanders] consider seafood collection and consumption as healthy activities that reflect a homelike lifestyle and may fish for economic necessity.*[25]

Similarly, in Green Bay, Wisconsin:

> *Eating fish forms a regular part of the diet and culture for the Asians (Hmong and Laotians) living in the Green Bay area.*[26]

And, in the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

> *In G/W, some anglers consume as many as two meals per day of fish caught in the East River, which forms the western boundary of G/W. Approximately 38 percent of the G/W population lives below the poverty line, suggesting that many of the anglers fishing in this community may be urban subsistence anglers who rely on fish caught in the East River as a free source of nutrition. In addition, fishing is a way of life rooted in the cultural heritage for many of the black and Hispanic anglers observed fishing on the piers in G/W, many of whom come from Carribean fishing cultures.*[27]

Finally, the health of humans and the health of aquatic ecosystems are intimately related, such that compromised aquatic ecosystems are of concern in and of themselves, with the contamination of fish, aquatic plants, and wildlife but some of the devastating effects. Water of sufficient quality and quantity is vital to sustain all life. To allow waters to be degraded and depleted is to undermine health, traditions, cultures, and economies. To allow waters to be degraded and depleted is to neglect obligations, including the obligation to sustain tribal homelands as contemplated by federal Indian treaties and other laws. As Frank Tenorio, Governor, San Felipe Pueblo, explained:

> *There has been a lot said about the sacredness of our land which is our body; and the values of our culture which is our soul; but water is the blood of our tribes; and if its life-*

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[25]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

[26]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[27]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 3-1 (1999).

giving flow is stopped, or it is polluted, all else will die and the many thousands of years of our communal existence will come to an end.[28]

Consider in this vein, too, Langston Hughes's famous poem, "The Negro Speaks of Rivers:"

I've known rivers ancient as the
world and older than the flow of
blood in human veins.
My soul has grown deep like the rivers.
I bathed in the Euphrates when
dawns were young,
I built my hut near the Congo and
it lulled me to sleep,
I looked upon the Nile and raised
the pyramids above it,
I heard the singing of the Mississippi
when Abe Lincoln went down to
New Orleans,
And I've seen its muddy bosom turn
all golden in the sunset,
I've known rivers;
Ancient, dusky rivers;
My soul has grown deep like
the rivers.[29]

2. Contamination of Aquatic Ecosystems and the Fish, Plants, Wildlife, and People They Support

The rivers, streams, bayous, bays, lakes, wetlands, and estuaries that support the fish, aquatic plants, and wildlife on which communities and tribes depend have been allowed to become contaminated and depleted. The waters to which communities and tribes look to meet their nutritional, economic, traditional, cultural, religious and other needs also have become vectors of toxins. Contamination now renders communities' and tribes' everyday practices – their ways of living – a source of exposure to a host of substances toxic to humans and other living things. Depletion, too, threatens communities' and tribes' subsistence, traditional, cultural, and religious practices.

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[28]Elizabeth Cheechio and Bonnie G. Colby, *Indian Water Rights: Negotiating the Future* 1 (June 1993) (quoting Frank Tenorio, Governor, San Felipe Pueblo, *Indian Water Policy in a Changing Environment* 2 (1982)).

[29]Langston Hughes, *My Soul Has Grown Deep: Classics of Early African American Literature*, "The Negro Speaks of Rivers" (John Edgar Wideman ed.).

Yet toxic chemicals and other contaminants have been and continue to be permitted to be emitted, discharged, dumped, or leaked into the air, water, soils, and sediments that together make up home to all life. Once in the environment, these contaminants behave in various ways: some move – traveling over distances or cycling between air and water; some linger – persisting for months or years; some biodegrade – becoming more or less toxic chemical successors; some bioaccumulate in the tissues of aquatic organisms, fish and wildlife – existing in increasing quantities higher up the "food chain." Eventually, humans that consume and use fish, aquatic plants, and wildlife may be exposed to the toxins concentrated in their tissues.

Toxic chemicals and other contaminants also contribute to the depletion of aquatic resources. These other threats (e.g., from logging, mining, grazing, and agricultural operations; from hydropower; from development) compromise water quality and quantity, destroy habitat for fish, aquatic plants and wildlife, and otherwise contribute to the depletion of the resources on which communities and tribes depend.

As a result, aquatic ecosystems are damaged from the Penobscot River to the San Francisco Bay, from Bayou d'Inde to the Great Lakes, from the Columbia Slough to the St. James River. These aquatic ecosystems are contaminated when mercury is emitted to the air from coal-fired power plants and other sources of fossil fuel combustion or from medical waste incinerators – this mercury is then deposited to surface waters and to soils. They are contaminated when PCBs are allowed to remain in sediments without being cleaned up – these PCBs persist for long periods of time and are released to waters, air and soils. They are contaminated when dioxins are discharged to the water from the industrial production of chlorinated organic chemicals – these dioxins are often contained for long periods in sediments and may, in turn, be resuspended to surface waters. These and multiple other sources and contaminants have wreaked incalculable harms to aquatic ecosystems and the fish, aquatic plants and wildlife they support.

James Ransom, Director, Haudenosuanee Environmental Task Force, recounts the destruction of the portion of the St. Lawrence River that is Akwesasne, home to the St. Regis Mohawk:

> *Akwesasne or St. Regis is like most Native communities. We were a fishing, farming, hunting, trapping, and gathering community. These lifestyles helped to support an earth-based value system. . . . We were sustainable societies. Everything we needed was provided by the natural world. We followed the natural laws. It required that we only take from the natural world what we need and that we use all that we take. . . This all changed for the Mohawks of Akwesasne in the 1950s. . . .In 1958, the St. Lawrence-FDR Power Project was constructed on the St. Lawrence River just upriver from Akwesasne. Low-cost hydroelectric power allowed two new industries to open, Reynolds Metal company, an aluminum smelter, and General Motors Powertrain, an automobile parts manufacturer. It allowed a third industry, ALCOA, an aluminum smelter, to expand operations.*
>
> *By the early 1960s, cattle within the territories of the Mohawks began feeling the effects of flouride poisoning from the aluminum smelters. By 1981, PCB contamination of the*

General Motors site came to light. In 1983, it became a federal superfund site. By 1987, PCB problems at ALCOA and Reynolds became known as well. By 1989, a six-mile stretch of the Grasse River and a two-mile stretch of the St. Lawrence River became a federal superfund site because of PCB contamination. . . .

In 1986, a 67-inch length, 200 pound lake sturgeon was caught by Mohawk fishermen in the St. Lawrence river. Parts of it were sent for PCB analysis. The results were alarming as 3.41 parts per million (ppm) of PCBs were found in the meat, 7.95 ppm in the eggs, and 10.20 ppm in the liver. The New York State PCB fish standard for human consumption is 2.0 ppm. . . .

Contamination of the St. Lawrence River resulted in a destruction of a subsistence lifestyle for the Mohawk people. It destroyed hunting, fishing, farming, trapping, and gathering activities. . . .[30]

At a meeting of Alaskan Natives from the northwest arctic region, Herman Toolie, Savoonga, expresses his concerns and the concerns of others in his village:

They have those – what do you call it? – PCBs? A lot of those were in the village. They found gallons in the village around Northeast Cape. There were transformers that were leaking. We don't know if they took them out of the ground or not. I guess they took them out. There used to be a lot of fish right there. We had our camp there not more than a mile away from the site. There used to be lots of fish there but no more. There is a whole bunch of concerns that these elders have. I wish I had a tape recorder and could tape them.[31]

In introducing its tribally-conducted fish consumption study, the Suquamish Tribe recounts the importance of fish and shellfish, even in the face of the degraded water quality and habitat of the Puget Sound:

The Suquamish culture finds its fullest expression in the acknowledged relationship of the people with the land, air, water and all forms of life found within the natural system. River systems, lakes and numerous small creeks historically supported abundant coho, chinook, sockeye and chum runs, with other salmonids and marine fish available as well. The same forests which sustained life in the riparian zones also harbored deer, bear, and other wildlife. Vast expanses of intertidal habitat supported shellfish. By virtue of the Treaty of Point Elliott, Suquamish rights to fish and interests in their habitat were recognized to include the marine waters of Puget Sound from the northern tip of Vashon

[30]James Ransom, Director, Haudenosuanee Environmental Task Force, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish* 25 (1999).

[31]Alaska Traditional Knowledge and Native Foods Database, *Native Concerns* available at www.nativeknowledge.org/db/concerns.asp.

Island to the Fraser River in Canada, including Haro and Rosario Straits and streams draining into the western side of central Puget Sound.

Increased levels of development as well as pollutants from residential, industrial, and commercial uses have resulted in degraded habitats and harvesting restrictions. There were eleven Superfund sites within the immediate area of the Port Madison Indian Reservation at the time the fish consumption survey was conducted.

Despite degraded water quality and habitat, tribal members continue to rely on fish and shellfish as a significant part of their diet. All species of seafood are an integral component of the cultural fabric that weaves the people, the water, and the land together in an interdependent linkage which has been experienced and passed on for countless generations.[32]

And in recounting the harms of intense industrialization along the lower Mississippi River and in St. James Parish, Louisiana, the United Church of Christ Commission for Racial Justice reports:

Also presented as a negative economic impact of polluting industries by local residents was the significant loss of wildlife and vegetation, which contribute to the subsistence living of many St. James Parish residents. Fruiting trees such as pecan, fig, peach, and others have died off. Fish, crayfish and oyster beds have been poisoned. And wildlife important for subsistence hunting, such as rabbit and deer, have disappeared. Not only have important food sources disappeared, but the ability of residents to gather and sell these for cash has also gone. With the decline in the prosperity of local residents, many local businesses have also left the area. A number of residents complained that they must now commute great distances simply to buy groceries and other necessities.[33]

3. Different Exposure Circumstances and Contexts Characterize Communities of Color, Low-Income Communities, Tribes, and Other Indigenous Peoples

Consumption and use of contaminated fish, aquatic plants, and wildlife is the primary route by which humans are exposed to many toxic contaminants. For example, consumption of contaminated fish is considered to be the single greatest route of exposure to PCBs and a major route of exposure to mercury. Consumption of contaminated fish is similarly a significant route of exposure to chlordane, dioxins, DDT, toxaphene, and a litany of over 40 other contaminants. Indeed, any contaminant that *persists* in aquatic environments and *bioaccumulates* in the fish and wildlife that are supported by aquatic environments may find its way to humans when they

[32]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* 4 (2000).

[33]Charles Lee, ed., United Church of Christ Commission for Racial Justice, *From Plantations to Plants: Report of the Emergency National Commission on Environmental and Economic Justice in St. James Parish, Louisiana* (1998).

consume or use these fish and wildlife. EPA has recognized that fish and wildlife consumption, in particular, is the chief route by which all humans are exposed to many of these "persistent and bioaccumulative toxins" or PBTs.

Consumption and use of contaminated fish, aquatic plants, and wildlife is an especially pressing concern for many communities of color, low-income communities, tribes, and other indigenous peoples, whose members may (1) consume fish, aquatic plants, and wildlife in greater quantities than does the general population; (2) consume and use different fish, aquatic plants, and wildlife than does the general population; (3) employ different practices in consuming and using fish, aquatic plants, and wildlife than does the general population; (4) consume and use fish, aquatic plants, and wildlife in cultural, traditional, religious, historical, economic, and legal contexts that differ from those of the general population.

When health and environmental agencies respond to the human health impacts from contaminated aquatic environments, they typically frame the issue as one of harm to individuals' physical health: the contaminants are carcinogens, or reproductive toxins, or endocrine disrupters, or have multiple human health "endpoints." Health and environmental agencies then manage these "health risks" by employing one or both of two general strategies: *risk avoidance* (whereby risk-bearers are encouraged or required to change the practices that expose them to environmental contamination, e.g. through fish consumption advisories, directed to those people who eat fish) or *risk reduction* (whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination, e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters). In both cases, agencies' decisions for the most part reflect the exposure circumstances and the cultural, traditional, religious, historical, economic, and legal contexts that describe members of the general population – the "average American" or "the typical U.S. consumer." Importantly, these decisions often do not reflect the exposure circumstances or the traditional, religious, historical, economic, and legal contexts that describe members of communities of color, low-income communities, tribes, or other indigenous peoples.

To illustrate briefly a few of these considerations:

The EPA until quite recently based its environmental decisions on the assumption that humans eat just 6.5 grams of fish per day – *roughly one 8-ounce fish meal per month*. Yet there is abundant evidence that people of color, low-income individuals, tribal members, and other indigenous people eat far greater quantities of fish. For example, a recent study by the Columbia River Inter-Tribal Fish Commission of members of four Columbia River tribes registered a mean fish consumption rate of 58.7 grams/day and a maximum fish consumption rate of 972.0 grams/day – well over one hundred times the EPA value.[34] A recent study of ten Asian and Pacific Islander

[34]Columbia River Inter-Tribal Fish Commission, Technical Report 94-3, A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (1994); Columbia River Inter-Tribal Fish Commission, Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient water Quality Criteria for the Protection of Human Health 8 (1999).

groups in King County, Washington showed a mean fish consumption rate of 117.2 grams/day and a maximum values of 733.46 grams/day.[35] Similarly, studies of anglers in both Alabama and Michigan registered markedly higher fish consumption rates for low-income African-Americans – in Alabama, low-income African-Americans ate a mean of 63 grams/day;[36] in Michigan, low-income African-Americans (together with other "minority fishers and off-reservation Native Americans") consumed a mean of 43.1 grams/day;[37] a recent study of members of the Suquamish Tribe registered a mean fish consumption rate of 213.9 grams/day and a maximum fish consumption rate of 1,453.6 grams/day.[38] Although methodological differences in the various studies mean that these numbers cannot provide a precise basis for comparison, they nonetheless afford a sense of the large differences in the quantities of fish consumed by different groups. EPA has just revised its standard assumptions and now uses default values of 17.5 grams/day for the general population and 142.4 grams/day for subsistence populations. While these revised numbers are a marked improvement, they are still a source of concern for those groups whose members consume at the highest levels. The result is that when the fish are contaminated, those consuming at higher rates will be exposed to greater quantities of the contaminants that are present in the fish tissue.

EPA also typically makes assumptions about the species and parts consumed and about the methods of preparation that reflect that practices of the general population but often do not depict fully or accurately the practices of communities of color, low-income communities, tribes, or other indigenous peoples. For example, according to a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups:

> *[Asian and Pacific Islanders] consume a wide variety of seafood species, the most frequently consumed being shellfish. These seafood, depending on their feeding and habitat characteristics, and the tissue parts consumed pose varying chemical contaminant risks to APIs. For example, certain fat soluble chemicals, e.g., PCBs, are concentrated in the fat layer between the meat and the skin, potentially exposing such consumers to higher contaminant levels than those who simply eat the fillet. Eating the fillet with skin is clearly a common practice in the API community. . . . Overall, skin was consumed with the fillet 55% of the time. . . .*

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[35]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999) [See Table 1 in Chapter One].

[36]Alabama Department of Environmental Management (1993) [See Table 1 in Chapter One].

[37]Patrick West, et al. (1995) [See Table 1 in Chapter One].

[38]Suquamish Indian Tribe (2000) [See Table 1 in Chapter One].

API community members appear to eat shellfish parts that are thought to contain higher concentrations of chemical contamination, e.g., clam stomachs or the hepatopancreas of crabs. Bivalve shellfish were consumed whole by 24% (geoduck) to 89% (mussels) of respondents depending on the species. The "butter" as well as the meat of crabs were consumed 43% of the time . . .Finally, cooking water, both for finfish and shellfish are commonly used in cooking or directly consumed.[39]

According to a study of the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

[Hispanics and Caribbean Americans] consume considerable quantities of fresh shellfish, including parts of the fish not typically consumed (e.g., the highly contaminated hepatopancreas of blue crabs).[40]

According to Hawaii's Thousand Friends:

Hawaii's diverse ethnic population led to a mixing of traditions and foods, including many fish dishes. Japanese sashimi and Hawaiian poke, both raw fish dishes, are mainstays at most parties and traditional gatherings.[41]

According to an account of subsistence fishing on the Upper Kobuk River in Alaska:

Each summer, families from Shungnak and Kobuk move to camps to harvest salmon, whitefish, and sheefish. . . . upper Kobuk residents preferred to camp in the sheefish spawning areas because sheefish caught there had eggs, a local delicacy. . . .Although sheefish are caught throughout the summer, local residents prefer to catch them late in the season because the sheefish are fat, the eggs are ripe, and the fish can be left to age and freeze, a storage method preferable to drying.

Aged, frozen sheefish, an upper Kobuk delicacy, were eaten later in winter without further processing or preparation. By spring, these fish were known as ui.laaq *(thawed, aged sheefish) a meal savored by upper Kobuk residents.*

[39]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999)

[40]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-21 (1999).

[41]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

> *Fresh sheefish were baked, boiled, or fried. The large intestines, full of fat, were boiled. Fish oil (*qaluum uqsruq*) was separated from the boiled water with a large spoon and served with cooked sheefish.*[42]

Ron Oatman, Nez Perce, recalls:

> *We used to collect the eggs from the suckers and Mom would fry them up with the rest of the fish. We always thought this quite good.*[43]

Again, the result in many cases is that when the fish are contaminated, those consuming in accordance with different practices will be exposed to greater quantities of the contaminants.

Moreover, the approach employed by EPA and other environmental agencies proceeds as if humans were exposed to one contaminant at a time. However, members of communities of color, low-income communities, tribes, and other indigenous peoples are often exposed to multiple contaminants (and by multiple routes) at the same time; this is so to a greater extent than for the general population. For example, according to Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation:

> *[I]t is the norm, at least in the Columbia River system, for over 100 contaminants to be identified in fish tissues.*[44]

Environmental agencies also proceed as if all humans similarly enjoyed relative health and access to basic health care and nutrition. However, members of communities of color, low-income communities, and tribes often have relatively poorer background health and lesser access to health care and nutrition than is enjoyed by the general population. Other "co-risk" factors, too, affect how humans respond when they are exposed to environmental contaminants and often these co-risk factors are different for members of affected communities and tribes.

Health and environmental agencies generally assume that all humans are similarly able to turn to substitutes when fish, aquatic plants, and wildlife have become contaminated. While this substitution may pose few difficulties for members of the general population, it may be impractical or impossible for economic, cultural, religious and/or other reasons for some members of communities of color, low-income communities and tribes. For example, for some tribal peoples,

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[42]Susan Georgette and Hannah Loon, *Subsistence and Sport Fishing of Sheefish on the Upper Kobuk River, Alaska* (1990) available at www.nativeknowledge.org/db/files/tp175.htm.

[43]Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 95 (1999).

[44]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Contaminants in Fish, "*Tribal Technical Issues in Risk Reduction Through Fish Advisories*"* 19 (1999).

as Barbara Harper, Fourteen Confederated Tribes of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, explain:

> *[T]here are likely to be no acceptable 'tradeoffs.' Tribal peoples may not have an option of avoiding fish consumption for cultural or religious reasons as well as economic reasons. . . . The cultural use of fish is not a 'perceived benefit of fish consumption.' It is a baseline situation that is not an option or a choice, but an absolute requirement.*[45]

These considerations and others place in question the appropriate role of fish consumption advisories in protecting those who would consume fish, aquatic plants, and wildlife from the serious harms of exposure – harms including the risk of cancer, neurological damage, endocrine disruption, and a host of other ills. To the extent that fish consumption advisories form an appropriate part of agencies' response to contaminated aquatic environments, however, there is reason to be concerned that health and environmental agencies generally employ the language and methods of communication that are likely to reach and be understood by the members of the general population, but often fail to reach and cannot be understood by members of affected communities. This is particularly likely when agencies distribute advisories in English to those who have limited English proficiency, or when agencies post advisories on the Internet but those affected cannot afford and do not otherwise have access to a computer. There has been recent progress here, however, as EPA and other agencies in some cases have translated their advisories into the language(s) of those affected and have sought to learn which methods of communication would be most likely to reach communities likely to be among the most exposed.

4. Environmental Agencies Have Made Considerable Progress; However, Many Aspirations and Obligations Remain Unfulfilled

EPA and other agencies have made considerable progress toward addressing degraded and depleted aquatic ecosystems, and, more recently, toward attending to the needs and rights of communities of color, low-income communities, tribes, and other indigenous peoples. Aquatic ecosystems are significantly less contaminated than they were three decades ago, when the Clean Water Act was passed. According to EPA estimates, whereas in 1972 only 36% of the rivers, lakes, and estuaries within the United States were clean enough to support "fishable-swimable" uses, today roughly 60% of lakes, rivers, and estuaries are clean enough to support these uses.[46] EPA and other agencies have also made progress in attending to the different circumstances of exposure that often describe members of communities of color, low-income communities, tribes, and other indigenous peoples; in evidencing awareness of their different languages, traditions, and cultures; and in addressing their claims to participation and consultation when EPA and other agencies make decisions affecting their lives and resources.

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[45]Id. at 21 (1999).

[46]Zygmunt J.B, Plater, et al., *Environmental Law and Policy: Nature, Law, and Society* 503 (2d ed. 1998).

Yet, by EPA's own account, there is much yet to be done. EPA's Strategic Plan issued in September 2000 (2000 EPA Strategic Plan) acknowledges that much more work is needed to protect effectively American's rivers, lakes, wetlands, aquifers, and coastal and ocean waters so that they will sustain fish, plants, and wildlife as well as recreational, subsistence, and economic activities.[47] There EPA notes that "[a]s of 1998, about 40 percent of the assessed waters in the United States were degraded to the point that they did not support their designated use."[48] Additionally, more than 50% of the Nation's wetlands--some 100 million acres--have been lost since European settlement.[49] And, "polluted water and degraded aquatic ecosystems threaten the viability of all living things and vigor of the nation's economy."[50] In 2000, the number of fish consumption advisories rose by 187, representing a 7% increase over 1999, and the number of acres of lakes under advisories increased from 20.4% in 1999 to 23% in 2000, a total of 63,288 lakes.[51] All of the Great Lakes and their connecting waters and 71% of coastal waterways were under advisory in 2000.[52]

Thus, EPA has yet to fulfill the aspirations set for it in the Clean Water Act and elsewhere. The CWA, for example, aspires "to restore and maintain the chemical, physical, and biological integrity of our Nation's waters;" it aspires to do this by, among other things, eliminating the discharge of pollution into navigable waters "by 1985."

EPA also has yet to uphold fully its obligations to communities of color, low-income communities, tribes, and other indigenous peoples under various treaties, the federal trust responsibility, Title VI of the Civil Rights Act of 1964, and Executive Order 12898.

B. WHAT ARE THE POLICY IMPLICATIONS OF THE ABOVE?

Together, the chapters of this Report respond to the policy charge to NEJAC:

> How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

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[47] U.S. Environmental Protection Agency, Office of the Chief Financial Officer, *Strategic Plan* 19 (No. 190-R-00-002) (September 2000) available at www.epa.gov/ocfopage/plan/2000strategicplan.pdf.

[48] Id. Note that this figure does not include unassessed waters – some of which may not meet these standards.

[49] Id.

[50] Id.

[51] *U.S. Environmental Protection Agency Fact Sheet Update: National Listing of Fish and Wildlife Advisories* 1 (EPA-823-F-01-010) (April 2001).

[52] Id.

Chapter One focuses on the tools that environmental agencies use to define, evaluate and respond to the adverse health impacts from contaminated aquatic environments. It discuses the research methods agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes, as well as the risk assessment approaches agencies use to evaluate these impacts.

The next two chapters examine agencies' responses – the "risk management" approaches that they employ to address the health impacts of contaminated aquatic environments. Chapter Two discusses agencies' risk reduction strategies, whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination. This chapter examines the legal authorities that might be invoked more effectively to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

Chapter Three then discusses agencies' risk avoidance strategies, whereby risk-bearers are asked to change their lives and practices in order to avoid exposure to harmful contaminants. This chapter focuses on fish consumption advisories and asks what role they should play in efforts more effectively to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife. In so doing, it considers how agencies can identify, acknowledge and meet the real needs of those who are affected among communities of color, low-income communities, tribes, and other indigenous peoples. This chapter discusses means by which agencies can ensure community participation and tribal consultation. It also discusses ways agencies can work to make communities whole once the fish, aquatic plants, and wildlife on which they depend have already become contaminated. This chapter, in particular, responds to questions posed to the NEJAC by the EPA Office of Water in October, 2001, requesting advice on improving its risk communication efforts and on updating its *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication.*[53] Various aspects of these questions are also addressed throughout the Report.

Chapter Four examines issues unique to American Indian tribes, Alaskan Native villages, and their members. Although tribes and their members share many of the concerns discussed in the first three chapters, their unique political and legal status warrants separate treatment.

[53]Memorandum from James Hanlon, Acting Deputy Assistant Administrator, Office of Water, to Barry Hill, Director, Office of Environmental Justice (October 4, 2001).

CHAPTER I: RESEARCH METHODS AND RISK ASSESSMENT APPROACHES

How should EPA improve its research methods and risk assessment approaches to address degradation of aquatic ecosystems and adverse impacts to human health from consuming or using contaminated fish, aquatic plants, and wildlife for subsistence, cultural, traditional, and religious activities and purposes?

When health and environmental agencies respond to the harms from contaminated aquatic environments, they typically frame the issue as one of "human health risks" – specifically, harm to individuals' physical health: the contaminants are carcinogens, or reproductive toxins, or endocrine disrupters, or have multiple human health "endpoints."

Health and environmental agencies then manage these "health risks" by employing one or both of two general strategies: *risk avoidance* (whereby risk-bearers are encouraged or required to change the practices that expose them to environmental contamination, e.g. through fish consumption advisories, directed to those people who eat fish) or *risk reduction* (whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination, e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters).[54] Risk reduction strategies will be the focus of discussion in Chapter 2; risk avoidance strategies will be the focus of discussion in Chapter 3.

For both strategies, agencies need to get a sense of the practices that expose humans to environmental contaminants (e.g., how much fish do they eat? what kinds of fish? how is it prepared?) and the underlying health and other circumstances of those exposed (e.g., are they young or old? do they have other preexisting health conditions? do they have access to adequate health care?). In gathering this information and, more generally, in fashioning their responses to contamination, agencies' efforts have until quite recently reflected the lives, practices, and circumstances of the "average American"or "the typical U.S. consumer."[55] Importantly, they often have not reflected the lives and circumstances of communities of color, low-income communities, tribes, and other indigenous peoples. That is, agencies' efforts overall have tended to reflect the cultural, traditional, religious, historical, economic, and legal contexts that describe members of the general population. Specifically, agencies' efforts have assumed (1) the exposure circumstances of members of the general population; and (2) the susceptibilities and co-risk factors of members of the general population.

[54]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).

[55]See, e.g., U.S. Environmental Protection Agency, *Note to Correspondents: EPA Issues 1996 Fish Advisory Data* (1997) ("The typical U.S. consumer eating fish in moderation from a variety of sources and eating a variety of species is not believed to be at increased risk . . .").

This Chapter will focus on the tools environmental agencies use to define, evaluate and respond to the adverse health impacts from contaminated aquatic environments: the *research methods* agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes, and the *risk assessment approaches* agencies employ to evaluate and address these health impacts. Along the way, it will highlight issues that bear as well on agencies' approaches to *risk management* and *risk communication*, although these questions will be taken up at greater length later in the Report.

Part A of the chapter discusses briefly the prior question: what is meant by "adverse impacts to human health?" The next four parts examine exposure. Part B looks at fish consumption rates and how these differ as between the general population and higher-consuming "subpopulations" such as communities of color, low-income communities, tribes, and other indigenous peoples. Part C examines standard assumptions about the fish, plant and wildlife species people consume and use; the parts of these species they use; and the preparation methods they employ. It considers the differences in these practices among various affected groups and how this affects estimates of exposure. Part D raises the point that communities of color, low-income communities, tribes, and other indigenous peoples consume and use fish, plants and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." Part E takes up the issues of aggregate or multiple exposures and cumulative risks. Part F turns from exposure to issues of susceptibility and co-risk factors. Part G explores suppression effects and their implications. Part H addresses research methods relevant to risk assessment, management, and communication involving contaminated fish and aquatic environments. Finally, Part I considers refinements and alternatives to risk-based approaches.

A. DEFINING ADVERSE IMPACTS TO HUMAN HEALTH

How can EPA in its various functions ensure that cultural, traditional, religious practices are being considered in defining and evaluating health risks with respect to all people, including minority and low-income communities, and tribes?

When health and environmental agencies evaluate and respond to the human health risks from contaminated aquatic environments, they typically invoke a particular conception of "human health."[56] This conception tends to be that of the dominant society, for whom "human health" is taken in the narrow, individual and physiological sense of the term. So defined, agencies look to toxicological and epidemiological data that connect environmental contaminants such as mercury or PCBs to human health "endpoints" such as neurological damage or cancer. Agencies cite determinations (by legislatures, courts, or their own or other agencies) as to "acceptable" increases in the risk of occurrence of such "endpoints," and from there work backward to decide how much mercury to permit to be emitted into the air or what quantity of PCBs to allow to remain in

[56]Agencies also sometimes (although less often) respond to "ecological risks;" these are typically considered separately from human health risks, and do not include attention to social, cultural, or other related harms.

contaminated sediments after cleanup. These decisions then get incorporated into standards or permits or cleanup requirements.

This definition of the adverse impacts, however, may not reflect the perspectives of those affected. For some of those affected, the harms from contamination are not only physical, but psychological, social, and cultural. For some of those affected, the affront is not only to an individual but to a group – the threat is not only to the physical survival of a person, but to the cultural flourishing of a people. Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, International Institute for Indigenous Resource Management, explain:

> *For example, Native American communities are inseparable from their lands and resources, so evaluation of their risks from contamination must integrate human physiological and mental health, ecological health, socio-economic health, and cultural and spiritual health within a single framework. This does not mean simply adding a quality of life component and calling it cultural risk, or using an exposure scenario that reflects additional routes of exposures. Rather, it means beginning the assessment by understanding the entire eco-cultural system (people and biota interlocked in a co-adapted system of behaviors and ecologies that is sustainable over time but which is now severely strained even without the addition of contamination). . . .*
>
> *The individual and collective well-being of tribal members is often derived from membership in a healthy community that has access to ancestral lands and traditional resources and from having the ability to satisfy personal responsibility to participate in traditional community activities and to help maintain the spiritual quality of our resources.*[57]

Environmental justice means noticing and acknowledging not only the harms that are perceived by the dominant society, but also the harms that are felt by communities of color, low-income communities, tribes, and other indigenous peoples. Often, these harms will have quite different dimensions than those felt by the dominant society and reflected in agencies' definition and evaluation of the problem. EPA and other agencies need to reexamine methods and models employed in evaluating adverse health impacts from environmental contamination.[58]

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[57]Stuart G. Harris and Barbara L. Harper, *Using Eco-Cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91, 91-92 (Special Issue, 2000).

[58]Elizabeth D. Nobmann, *Nutritional Benefits of Native Foods*, available at www.nativeknowledge.org/db/files/aboutnt2.htm (describing Alaskan Native's understanding of "nutrition" in the broadest sense and recounting a call for "models that addressed social, emotional, spiritual and cultural issues as well as physical health" by attendees of the Alaska-Russia Native People's Health and Social Issues Conference in 1992).

B. EXPOSURE: FISH CONSUMPTION RATES

Several factors determine (1) whether and how an individual comes in contact with environmental contaminants and (2) to what extent that individual suffers adverse health effects as a result of this contact. The first set of factors describes one's circumstances of *exposure*. The second set of factors describes one's *susceptibilities and co-risk factors.* Although more information needs to be gathered about the differences among various "subpopulations" with respect to both exposure and susceptibilities, existing data show important differences between the general population and communities of color, low-income communities, tribes, and other indigenous peoples. Questions of exposure will be addressed in Parts B, C, D and E, below; questions of susceptibility will be addressed in Part F.

Humans are exposed to environmental contaminants through a variety of routes: they inhale toxic air contaminants; they drink contaminated groundwater; they absorb pesticides through our skin; they eat fish that swim in and bioaccumulate toxins from contaminated surface water and sediments. As noted above, fish consumption is the primary route of exposure for many toxic contaminants, including those that are now present in and permitted to be released to aquatic environments. All else being equal, the higher the level of fish one consumes, the greater one's exposure to any contaminants in the environment that the fish uptake, and the greater one's risk of adverse health effects.

EPA and other agencies use exposure data to set environmental standards for aquatic environments that support fish and other species consumed by humans: they set water quality standards to determine how much contamination will be permitted to be released now and in the future; they set cleanup standards to determine to what level surface waters and sediments must be cleaned up once they are already contaminated. They also use exposure data to estimate risk in order to determine whether to issue fish consumption advisories. When EPA and other agencies use risk assessment to set environmental standards, they start from a level of risk that has been deemed "acceptable" or a threshold level of exposure that is believed not to result in adverse health effects. They then consider the toxicity of the contaminant in question (e.g., dioxin) and the various elements of humans' exposure to that contaminant (e.g., how much fish do people consume? for how many years do people live and consume fish at these rates? to what extent does the contaminant in question bioaccumulate in the fish tissue consumed?). Working from these inputs, agencies determine how much of the contaminant to allow to be discharged to or to remain in aquatic environments. Note that when agencies set standards in this way, they typically rely on values for each of the inputs that reflect the characteristics and practices of the general population. These values often do not reflect the characteristics and practices of affected communities and tribes, which often lead to greater exposures for these groups. This is problematic in that the resulting standards will not protect these more highly-exposed groups.

1. Evidence of Different Consumption Practices

While there is considerable evidence that different groups have different fish consumption practices, these differences have until recently been demonstrated chiefly by "anecdote" rather than by empirical study. Even today, there are many more instances in which practices that include high rates of fish consumption and/or consumption from seriously contaminated waters are evidenced by local knowledge, direct observation, or "anecdote" rather than by formal study. Thus, for example, as Yalonda Sindé, Executive Director of the Community Coalition for Environmental Justice, Seattle, reports:

> *We know there are people out there fishing on the Duwamish. People in the neighborhood see them out there.*[59]

The Duwamish waterway is highly contaminated and under advisory for a host of industrial chemicals; signs are posted warning against eating all bottom fish, all shellfish, and seaweed. Similarly, as Bowden Quinn of the Grand Cal Task Force reports:

> *Although we don't have any hard data, there is anecdotal evidence of people subsistence fishing on the Calumet River. People do fish and they likely eat the fish they catch . . . despite a "Class 5" restriction on the River, which means "Do Not Eat the Fish."*[60]

The Calumet Region is home to steel manufacturing facilities, petroleum refineries, chemical manufacturing facilities and a host of other heavy industries, and has been described as "one of the nation's most polluted areas."[61] And, Ora Rawls, Executive Director, Mississippi Rural Development Council, reports:

> *Fish consumption (volume) has been underestimated. As I shared with a DEQ (EPA) official, many individuals (African American) eat fish two to three times a week – in rural areas, as often as five times a week. Where I lived on the Coast (Gulport/Biloxi), four to five times a week. This volume is from personal fishing (streams, lakes, ponds), not from retail sales data that is used to capture consumption patterns.*[62]

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[59]Personal Interview with Yalonda Sindé, Executive Director, Community Coalition for Environmental Justice, Seattle, Washington (October 16, 2001).

[60]Telephone Interview with Bowden Quinn, Executive Director, Grand Cal Task Force (October 10, 2001); accord, Telephone Interview with Alex DaSilva, Remedial Action Coordinator, Indiana Department of Environmental Management (October 10, 2001).

[61]Bill Eyring, Center for Neighborhood Technology, *The Neighborhood Works,* "Industry's Polluted Legacy: The Calumet Region" 10 (October/November 1993).

[62]National Risk Communication Conference, Proceedings Document II-17-19 (2001).

Anecdotal evidence similarly describes people fishing on and consuming fish from Lake Erie and the Cuyahoga River in Cleveland;[63] from the Mississippi River in East St. Louis;[64] from the Columbia Slough in Portland, Oregon;[65] and from the Mississippi River between New Orleans and Baton Rouge.[66]

There are, however, several formal fish consumption studies that demonstrate that members of various communities of color, low-income communities, tribes, and other indigenous peoples consume far greater quantities of fish than do members of the general population. Further, these studies show that there are differences as well *among* these various communities, groups, or peoples. They also support the observation that the intersection of poverty and identity or group membership may be an important factor in accounting for differences in fish consumption practices. Table 1 presents a sampling of the fish consumption rates gathered by recent studies, selected to illustrate these characteristics of the data in the context of various subpopulations (e.g., Native American, Alaskan Native, Asian/Pacific Islander, African-American, southern, and urban subpopulations). Note that the values presented here are not directly comparable because of design and other differences among the studies. (For example, some studies include shellfish whereas others include only finfish; some studies provide *per capita* values – which include those who do not eat fish along with those who do – whereas other studies provide values for fish-consumers only.) These values are provided only to give some sense of the relatively higher consumption rates of communities of color, low-income communities, tribes, and other indigenous peoples compared to the general population (as well as some sense of the differences among and within these groups).[67]

[63]Telephone Interview with Patrick C. West, Professor Emeritus of Natural Resources/Environmental Sociology, University of Michigan School of Natural Resources (October 23, 2001).

[64]Id.

[65]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

[66]Telephone Interview with Mary Lee Orr, Louisiana Environmental Action Network (October 17, 2001).

[67]Some of these values, moreover, were generated for this purpose only and should *not* be cited or used without consulting the studies and their authors. In some cases, these numbers were generated in reliance on assumptions that may or may not be shared by the study authors (e.g., conversion methods for values originally given in g fish/kg bodyweight/day).

Table 1: Quantified Evidence of Fish Consumption

Study Authors (Date)	Sample Population	50th Percentile (g/day)	Mean (g/day)	90th Percentile (g/day)	95th Percentile (g/day)	Max. Value (g/day)*
Duncan (2000)	Suquamish Indian tribe	132.1	213.9	489.0	796.9	1453.6
Sechena (1999)	Ten Asian & Pacific Islander groups, King Co., WA	89	117.2	242	---	733.46
Chiang (1998)	Laotian Groups (Mien, Lao, Khmu, Thadum), West Contra Costa Co., CA	9.1	18.3	42.5	85.1	182.3
Toy, et al. (1995)	Squaxin Island and Tulalip tribes	35.6 - 48.7	60.6 - 82.9	159.7 - 221.7	205.1 - 280.5	391.4
West, et al. (1995)	Michigan fishers	---	14.7	---	---	---
	Low-income African Americans and off-reservation Native Americans	---	43.1	---	---	---
CRITFC (1994)	Nez Perce, Umatilla, Yakama, and Warm Springs tribes	29.0 - 32.0	58.7	97.2 - 130.0	170.0	972.0
Alabama DEM (1993)	Alabama Fishers	---	44.8	---	50.7	---
	Black anglers with income < $15,000	---	63	---	---	---
Dellenbarger, et al. (1993)	Houma, LA consumers	65	---	---	---	---
Nobmann, et al. (1992)	Alaskan Natives from 11 communities	---	109	---	---	---
Puffer, et al. (1982)	Los Angeles Harbor fishers	37	---	225	338.8	---

* Note: In some studies, these maximum values were treated as outliers and adjusted downward.

In addition to the studies presented here, several other studies provide further formal, quantified evidence of differences in fish consumption practices among communities of color, low-income communities, tribes, other indigenous peoples, and the general population.[68]

Significantly, the fish consumption rates presented in Table 1 are markedly higher, at virtually every point of comparison, than those relied upon by agencies to set water quality standards, to set cleanup standards for surface water and sediments, and to gauge baseline consumption to estimate health risks and the need for fish consumption advisories. As elaborated below, EPA until quite recently employed a fish consumption rate of 6.5 grams/day for all populations. EPA now employs a fish consumption rate of 17.5 grams/day for the general population and recreational fishers, and 142.4 grams/day for subsistence fishers.[69] These are 90th and 99th percentile values, respectively, from a study of the general population (fish consumers and non-consumers alike). That is to say, EPA targets protection at the 90th percentile of the general population (a point discussed further below). Compare these values with the 90th percentile of Asian and Pacific Islanders in King County, at 242 g/day or the 90th percentile of the Suquamish Indian tribe, at 489 g/day, or the 90th percentile of fishers in the Los Angles Harbor, at 225 g/day. Consider, too, that whereas those Asian and Pacific Islanders in King County consuming at the average (mean) rate may be adequately protected were the relevant environmental standards to reflect EPA's default for subsistence fishers (142.4 g/day), those consuming at the maximum rate – 733.46 g/day would be grossly underprotected. They would fare even worse were the relevant environmental standards to reflect EPA's default for the general population (17.5 g/day). Those consuming at the maximum rate for the Suquamish Tribe (1453.6 g/day), the Laotian communities in West Contra Costa County (182.3 g/day), the Squaxin Island and Tulalip tribes (391.4 g/day), and the four Columbia River tribes (972 g/day) would be similarly underprotected – and, as discussed below, consumption at these rates may reflect the very practices that these affected groups would want to see perpetuated and protected for cultural, traditional, religious, economic, and other reasons.

However, as this survey of the available data reveals, there are many communities, groups, or peoples for which empirical studies have not yet been conducted. In addition, there is still relatively little data about the intersection of factors such as ethnicity or group membership and income. And, for some groups, there is the matter of acute or peak consumption rates – very high rates of consumption for shorter periods, such as during ceremonies, religious and other holidays (e.g., Lent, during which Roman Catholics may consume 2 or more fish meals per week), or

[68]Among these are studies of fish consumption in Santa Monica (CA); in the state of New York; on the Hudson River (NY); in Detroit (MI); in Lake Coeur d'Alene (ID); on Commencement Bay (WA); on the Savannah River (GA); in the state of Florida; on Lake Ontario; in American Samoa; on the Fox River (WI); among Wisconsin Chippewa Indians; among the Miccousukee Indian Tribes of South Florida; and among Native Americans living near Clear Lake, California. EPA canvassed these and other studies in preparing its AWQC Methodology. See, U.S. Environmental Protection Agency, Ambient Water Quality Criteria Derivation Methodology Human Health, Technical Support Document 89-103 (July 1998).

[69]It is not clear precisely which groups EPA means to include when it refers to "subsistence fishers."

harvest seasons (e.g. salmon runs, during which some Alaskan Natives consume 80-100 pounds of fish per month) – about which less may be known and for which, in any event, current risk assessment methods may fail to account. As Delores Garza, Alaska Native Science Commission, explains:

> *[W]e eat much more [fish, wildlife, and plants] than is listed [by EPA and other agencies], but we also eat it in a very short time period. That's when strawberries are fresh, when corn is fresh, when salmon run – you eat nothing but salmon. So you don't eat one steak per month or one filet per month. You eat salmon for breakfast, for lunch, and for dinner for a month, and then you go to your next resources and you eat that same amount of that resource.*[70]

Similarly, the Swinomish Indian Tribal Community, comments:

> *Not only should the EPA add multiple exposures and cumulative risks to health risk calculations done, but they should also publish and distribute methodology to Tribes who employ their own fish consumption rates, based on local data. Moreover, calculations and procedures to determine acute and chronic events ought to be explicitly described so that health risks can be determined from one high consumption event, for instance during a traditional ceremony, as well as over the long term.*[71]

In many cases, communities, groups, or tribes would be interested in conducting such studies, but lack the financial and/or technical resources to do so. Although anecdotal data may be plentiful, non-quantified data are difficult to incorporate into risk assessment as currently practiced; moreover, environmental agencies are unlikely to accept data that have not been quantified according to accepted norms (e.g., for statistical analysis, peer review, etc.). These are research needs that should be addressed. This point is discussed further in Part H, below.

2. EPA's Revised Fish Consumption Rates

Until recently, EPA used a standard or "default" assumption for the fish consumption rate (FCR) that would be factored into estimates of health risk: 6.5 grams/day.[72] This is about one 8-ounce fish serving *per month* – an amount that is outdated and inaccurate even for the general population. And, this amount grossly underestimates the consumption rates for many communities of color, low-income communities, tribes, and other indigenous peoples.

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[70]Delores Garza, Alaska Native Science Commission, *Testimony to National Environmental Justice Advisory Council* Vol III-89-90 (Annual Meeting Transcript) (Dec. 4, 2001).

[71]Swinomish Indian Tribal Community, *Comments on the National Environmental Justice Advisory Council's Draft Fish Consumption Report* (Feb. 5, 2002).

[72]Consent Decree Water Criteria, "Guidelines and Methodology Used in the Preparation of Health Effect Assessment" 45 Fed. Reg. 79,347, App. C (1980).

Recognizing this, EPA revised its default assumption in the fall of 2000, as part of an updated Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health ("AWQC Methodology").[73] Although in many cases federal and state water quality criteria currently in effect reflect the old 6.5 grams/day default, EPA now recommends the following default FCRs:

General population	17.5 grams/day
Recreational fishers	17.5 grams/day
Subsistence fishers	142.4 grams/day

EPA will use the 17.5 grams/day value when it derives or revises national criteria pursuant to CWA 304(a).[74] EPA will also consider these values when it reviews water quality standards set by states and authorized tribes,[75] as part of a four-part preference hierarchy:

(1) Use local data;
(2) Use data reflecting similar geography/population groups;
(3) Use data from national surveys; and
(4) Use EPA's default intake rates.

EPA "strongly emphasizes that States and authorized Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s)."[76]

EPA's default value of 17.5 grams/day for the general population and for recreational fishers reflects the 90th percentile value of 17.53 grams/day for freshwater and estuarine ingestion by adults, taken from the USDA's CSFII Survey for the years 1994 to 1996. EPA's default value of 142.4 grams/day for subsistence fishers reflects the 99th percentile value of 142.41 grams/day for freshwater and estuarine ingestion by adults, taken from the USDA's CSFII Survey for the years 1994 to 1996. EPA states that it "believes that the assumption of 142.4 grams/day is within

[73]U.S. Environmental Protection Agency, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (October 2000) ["AWQC Methodology"].

[74]Under CWA 304(a), the EPA is to develop "criteria" – scientific information and guidance for use by the states and authorized tribes and the EPA itself in establishing water quality standards pursuant to CWA 303(c). Under CWA 303(c), states and authorized tribes have primary responsibility for establishing water quality standards. EPA is charged with reviewing these standards. EPA may promulgate superceding federal standards if a state's or tribe's standards are not consistent with the CWA and its implementing regulations, or if the EPA determines that national standards are necessary. In either event, EPA relies on the criteria it developed under CWA 304(a) as it undertakes review or promulgates standards itself.

[75]See id.

[76]AWQC Methodology at 4-25.

the range of *average* consumption estimates by subsistence fishers based on the studies reviewed."[77]

For states or tribes exercising any of the first three preferences, EPA remarks: "States and authorized Tribes may use either high-end values (such as the 90th or 95th percentile values) or average values for an identified population they plan to protect (e.g., subsistence fishers, sport fishers of the general population). EPA generally recommends that arithmetic mean values should be the lowest value considered by States or Tribes when choosing intake rates for use in criteria derivation. When considering geometric mean (median) values from fish consumption studies, States and authorized Tribes need to ensure that the distribution is based on survey respondents who reported consuming fish because surveys based on both consumers and nonconsumers can often result in median values of zero. If a State or Tribe chooses values (whether central tendency or high-end values) from studies that particularly target high-end consumers, these values should be compared to high-end fish intake rates for the general population to make sure that the high-end consumers within the general population would be protected by the chosen intake rates."[78]

Several aspects of the CSFII data and EPA's AWQC Methodology are worth discussing. First, while EPA's new default values represent a vast improvement over the old 6.5 g/day default, the new default values are problematic in that they aim to protect the general population at the 90th percentile, but to protect subsistence fishers only at a level somewhere "in the range of *average* estimates." This choice provides disparate levels of protection to the general population, on the one hand, and subsistence subpopulations, on the other. Taking this view, it is unclear why EPA's default values do not set protection for subsistence subpopulations at the 90th percentile – as they do for the general population – rather than at the average. Moreover, from the perspective of some groups or tribes, it is the very highest consumers that warrant particular attention and protection, because it is these individuals who are consuming at levels and in accordance with practices that are most consonant with the group's or tribe's traditional, cultural, religious or spiritual beliefs. Taking this view, it may be appropriate in some cases for states, tribes, and the EPA to use values that target protection at the 95th or 99th percentile, or even at the maximum value, for particular subsistence subpopulations.

Second, to EPA's credit, the AWQC Methodology's four-part hierarchy recommends using local data as a first choice, data reflecting similar geography/population groups as a second choice, and relying on EPA's default values only as a fourth and last choice. That having been said, the reality is that many states still rely on EPA's default values because they (and the affected communities and tribes within their borders) simply don't have any local data on which to

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[77]AWQC Methodology at 4-27; but compare Catherine A. O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3, 59 (2000) (noting that EPA appears to offer conflicting accounts of what it means to be a "subsistence" fisher and that "EPA nowhere makes clear precisely who it views to be included in this grouping or to which studies it refers for the 'range of averages.'")

[78]AWQC Methodology at 4-26.

rely – often due to a lack of resources.[79] If using local data is to be a meaningful first choice, more resources need to be devoted to gathering this data, a point taken up at greater length below.

Third, EPA notes that the default values and the four-part preference hierarchy assume data reflecting consumption of freshwater and estuarine species only. For states or tribes exercising any of the first three preferences, EPA recommends that consumption of marine species be treated as an "other source of exposure." The effect of choosing to exclude marine species is to decrease the resulting default fish consumption rates (and, ultimately, to render any standard based on these defaults or recommendations less protective). Of note, too, EPA deemed salmon to be marine, although they are anadromous, spending a portion of their lifecycles in freshwater and/or estuarine environments. EPA estimates that the effect of this exclusion is to decrease the resulting default FCRs by approximately 13%.[80]

Fourth, the EPA's default values are based on *per capita* consumption rates from the general population – that is, "fish consumption" rates that include fish consumers and fish nonconsumers alike. The CSFII study on which the EPA's defaults are based for its Draft AWQC Methodology surveyed 11,912 individuals annually for 3-day periods.[81] Of the 11,912 participants, only 3,972 actually ate fish during the three days surveyed.[82] These were the fish consumers; their fish consumption rates were recorded. The 7,940 participants who didn't eat fish during the three-day period were the fish nonconsumers; their fish consumption rates were entered as "0." The CSFII study then generated two sets of figures: a set considering only the fish consumers and a set considering both the fish consumers and the fish nonconsumers. EPA chose to base its default values on the latter, *per capita* figures. Importantly, the effect of this choice is again to decrease the resulting default FCRs – with so many "zero" values factored in, the point estimates are decreased at every point of comparison. So, for example, whereas the mean value for fish consumers is 106.39 g/day, the mean value once fish nonconsumers are also included sinks to 18.01 g/day; similarly, whereas the 99th percentile value for fish consumers is

[79]Telephone Interviews with Denis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (Nov. 23, 1999 and March 15, 2002).

[80]Draft AWQC Methodology at 43,804.

[81]1 & 2 U.S. Department of Agriculture, Continuing Survey of Food Intake by Individuals (1998) [hereinafter 1 CSFII Study and 2 CSFII Study]. Note the caveat that the Draft AWQC Methodology references the CSFII study data for 3-day periods for the years 1989, 1990, and 1991, whereas the Final AWQC Methodology references the CSFII data for the years 1994, 1995, and 1996. The numbers in the paragraph are taken from the *Draft* AWQC Methodology, and the 1989-1991 data, which were available to the Fish Consumption Workgroup. While the numbers may be slightly different for the 1994-1996 data (on which EPA based its final AWQC Methodology, the phenomenon described here applies generally to the choice between *per capita* rates versus rates that include fish consumers only and is likely borne out by the 1994-1996 data as well.

[82]1 CSFII Study at IV-8 and IV-16. See caveat, id.

399.26 g/day, the 99th percentile value drops to 142.96 g/day.[83] It is unclear why EPA, in setting out to fashion water quality criteria that are protective of the health of humans who are exposed to contaminants through the fish ingestion route, chooses to consider the fish consumption practices of those who do not eat fish at all. People who don't eat fish aren't in any danger of being exposed via this route. And people who do eat a lot of fish will be underprotected by diluted FCRs influenced by so many "zero" values. This choice is akin to including non-smokers in a study of the direct (not indirect) exposure to nicotine, or setting occupational safety standards to protect non-workers from on-the-job hazards.

Finally, the CSFII participants were selected from the forty-eight contiguous states only. The authors of the CSFII study note that the exclusion of Alaska and Hawai'i may result in depressed fish consumption values given that Alaska and Hawai'i "could potentially contain" a larger percentage of subsistence and other higher-consuming groups than the forty-eight contiguous states. Given the available data regarding fish consumption practices in Alaska and Hawai'i, this is almost certainly the case. Moreover, as affected groups in Alaska and Hawai'i have emphasized, this exclusion is inappropriate not only as a matter of science, but also as a matter of justice.[84]

Taken together, these choices mean that EPA's default values are less protective of higher-consuming and subsistence subpopulations. Given that these subpopulations are in the main comprised of particular communities of color, low-income communities, tribes, or other indigenous peoples, these choices are deeply troubling. Even in those cases where a state or a tribe undertakes any of the first three options in the four-part hierarchy, they must demonstrate "consistency with the principles" of the guidance provided by EPA in order to satisfy EPA review under CWA 303(c). Thus, all of the choices EPA has made in setting its own default values in effect become recommendations for the states or tribes to do the same (or face having to justify departures).

3. Fish Consumption Rates Reflected in Current Water Quality Criteria and Standards[85]

As noted above, EPA has recently revised its default assumption for the fish consumption rate to capture more accurately current national consumption patterns. States and authorized tribes, moreover, have always been free, subject to EPA approval, to depart upward from EPA's

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[83] 2 CSFII Study at IV- 9 (table A-4) and IV-17 (table B-4). Note that these values are for "all fish;" recall that EPA's default values are based not on all fish, but only on freshwater and estuarine fish. See caveat, id.

[84] See, e.g., Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[85] See discussion of water quality criteria under CWA 304(a) and 303(c), at note 74. Note that the term "water quality criteria," as used in CWA 303(c), is part of the definition of a "water quality standard," which is comprised of (1) designated uses of a water quality segment, together with (2) water quality criteria necessary to support those uses. The term "water quality criteria" or "criteria" is also used to refer to the scientific information and guidance to states and tribes provided by the EPA pursuant to CWA 304(a). It is to the former usage that this section of this Report refers.

default numbers to reflect their higher-consuming populations. And under EPA's revised AWQC Methodology, states and tribes are now expressly encouraged to do so. Nonetheless, the question remains to what extent do the water quality standards *currently in effect* (whether developed by EPA, various states or tribes) reflect fish consumption rates higher than the old 6.5 grams/day default?

Although a handful of states have developed their own default fish consumption rates for use in developing water quality criteria and standards (e.g., WA, NY, MN, others), by and large, states have relied on EPA's default of 6.5 grams/day. Note that EPA, for its part, has never disapproved state water quality criteria or standards developed using the 6.5 grams/day value on the basis that this FCR did not adequately reflect higher-consuming or subsistence fishers affected by that state's standards.[86] As a result, a significant number of the state-issued water quality criteria and standards currently in effect rely on the 6.5 grams/day value.[87]

When EPA develops national water quality criteria or when it steps in to develop water quality criteria for states or tribes,[88] it looks to its own default values. Because EPA's revisions have only been in place since fall of 2000, it is perhaps not surprising that many of the criteria currently in effect still reflect EPA's old default value of 6.5 grams/day.[89]

Taken together, a significant portion of water quality criteria and standards currently in effect still rely on the 6.5 grams/day value. As has been noted, this value grossly underestimates consumption by many communities of color, low-income communities, tribes, and other indigenous peoples, and is thus no longer scientifically defensible.

C. EXPOSURE: ASSUMPTIONS ABOUT SPECIES, PARTS, PREPARATION

As noted above, the fish, aquatic plant, and wildlife consumption and use practices of communities of color, low-income communities, tribes, and other indigenous peoples differ from those of the general population. These differences in practices refer not only to the quantities of fish, plants and wildlife consumed, but also to the species consumed; the fish, animal or plant parts used; and the preparation methods employed. The studies upon which EPA and other agencies base their risk assessment and risk management decisions, however, typically make assumptions about species consumed, parts used, and preparation methods employed that reflect the practices of the general population but do not depict fully or accurately the practices of affected communities and tribes. For example, agencies typically assume that people eat or prefer certain

[86]Rich Healy, U.S. Environmental Protection Agency, Office of Water (Fish Consumption Workgroup Conference Call, June 26, 2001).

[87]Telephone Interview, Dennis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (March 15, 2002).

[88]The only example here is the case of the Confederated Tries of the Colville Reservation.

[89]Telephone Interview, Dennis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (March 15, 2002).

species, and that they refrain from eating a host of others, including "unusual" species such as sea urchin, sea cucumbers or bottom-feeding fish. Agencies typically assume that people eat only the fillet of finfish, and that they do not eat the fat, head, skin, bones, eggs, or internal organs. Agencies typically assume that people dispose of the drippings or cooking fluid. One result is that agencies set water quality standards and issue consumption advisories that are founded on an inaccurate picture of affected communities' and tribes' exposure. In most cases, the resulting standards will therefore not be sufficiently protective of members of these groups, whose different practices often expose them to additional sources of contaminants beyond those considered by the agencies. For example, lead accumulates in the bones, and most PCBs and most other persistent and bioaccumulative toxins accumulate in tissue with high lipid content, such as fat or eggs. Also, consumption advisories may include irrelevant or inappropriate information or recommendations, a point taken up in Chapter Three.

There is considerable evidence that different groups have different practices with respect to species consumed, parts used, and preparation methods employed. Much of this evidence is contained in local knowledge, direct observation, or "anecdote," rather than in formal studies, although there is a growing body of empirical work that confirms what affected communities and tribes know to be the case. For example, an African-American fisher on the Detroit River explains:

> *I keep sheephead and carp [which are bottom-feeding fish] because I have a large family to feed.*[90]

According to a study by the Squamish Tribe:

> *Children still teethe on dried clams . . .* [91]

According to a study recounting subsistence consumption practices in the Chignik Lake area, Alaska:

> *In exchange for the "red" salmon, Chignik Lake [people] received shellfish such as chitons (bidarkies), sea urchins (uduks), and butter clams from Perryville and Ivanof Bay people, resources Chignik Lake people have to travel far to get.*[92]

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[90]Patrick C. West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 5 (forthcoming).

[91]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 9 (2001).

[92]Lisa Hitchinson-Scarbrough and James A. Fall, *An Overview of Subsistence Salmon and Other Subsistence Fisheries of the Chignik Management Area, Alaska Peninsula, Southwest Alaska* (1996) available at www.nativeknowledge.org/db/files/tp230.htm.

According to a study of fishers on the Lower Fox River in the Green Bay, Wisconsin area:

> *Of those who reported eating the fish, Caucasian anglers reported that they like to eat the walleye . . . Most Asian [Hmong and Laotian] anglers reported that they prefer to eat the White Bass. White Bass is on the list of "Do Not Eat" fish in the fish advisory.*[93]

According to a study of the subsistence hooligan fishery on the Chilkat and Chilkoot Rivers in Alaska:

> *Historically, hooligan oil was used primarily for eating with other foods, but also for preserving certain berries, roots, herbs, and salmon eggs. It was commonly mixed with fresh berries. It was also consumed at feasts.*
>
> *In 1990 and 1991, processors dipped crackers, raw vegetables, dry fish, or meat into the fresh oil while it was still cooking in the vats. Pieces of hooligan meat were scooped up and eaten from cooking vats. One processing group served fresh hooligan oil accompanied by an array of other wild or fresh foods including smoked seal, smoked salmon, and raw fruits and vegetables. Throughout the year, the oil generally was eaten as a condiment with foods. It was added to boiled fish and meat, and spread or dipped with a variety of foods. Herring eggs, other fish eggs, boiled fish, and black seaweed were often eaten with hooligan oil. It was used for frying red sea ribbons in early summer. Year-old oil was whipped and mixed with cranberries, or cranberries and coho or sockeye salmon eggs. The aged oil was preferred, as it tended to whip more easily than freshly rendered oil.*[94]

Velma Veloria, Washington State Representative, observes:

> *Culturally, in the Filipino community, we eat the fin that many cut off, along with the belly fat. We love the fat. We fry it up to make soup.*[95]

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[93]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[94]Martha F. Betts, *The Subsistence Hooligan Fishery of the Chilkat and Chilkoot Rivers* (1994) available at www.nativeknowledge.org/db/files/tp213.htm.

[95]Velma Veloria, FCW Conference Call (Oct. 23, 2001).

According to a study of the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

> *[Hispanics and Caribbean Americans] consume considerable quantities of fresh shellfish, including parts of the fish not typically consumed (e.g., the highly contaminated hepatopancreas of blue crabs)*.[96]

According to a study of lead contamination in the Spokane River from the Idaho state line to the Seven Mile Bridge:

> *Russians and other immigrants said they use the whole fish, including bones and internal organs, in fish stews. The lead concentrates in bone and brains, the fish study showed.*[97]

According to a study recounting consumption practices in Bristol Bay, Alaska:

> *A variety of parts of the salmon were used for human consumption by Naknek River residents during the study period. Some parts, such as fillets, are used from every fish. Other parts, such as milt, were used on an occasional basis. . . .*
>
> *[Fillets] were frozen, salted, canned, smoked, dried, or eaten fresh. Heads, particular for those kings or large sockeyes, were used by many households. Fish head chowder was the most common method of preparation. Among those persons who used fish heads, it was ranked a favorite part of the fish, particularly of the king salmon.*
>
> *Eggs were frequently used, either as bait or eaten. If eaten, eggs were boiled or prepared as caviar. Fried milt was also used as food. . . . Milt can be frozen, but most reported using it fresh. The backbone was used two ways, either when a whole fish was canned or as 'gumchuk.' Gumchuk is the local term for a backbone that is hung until the outside layer of meat is dry, while the inside portion remains moist. It is then stored in a freezer. The dried backbone piece is boiled for eating. The backbone itself is not eaten, but sucked to extract the marrow and juices. The second method of preserving the backbone was canning. This method of processing disintegrates the backbone which is then eaten along with the meat.*
>
> *Other salmon parts were used on a less frequent basis by local Naknek River residents. Some households fixed salmon tails. These were either dried or smoked, or more*

[96]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-21 (1999).

[97]Karen Dorn Steele, *Agencies Warn of Lead in River's Fish Advisory; Targets Fish Consumption of Contaminated Fish Caught in Stretch of Spokane River*, The Spokesman Review A1 (Jun. 21, 2000).

frequently, salted, soaked out, and boiled. Tips were mainly salted and then boiled. The stomachs were cleaned and boiled by a few households. Livers and hearts were fried.[98]

According to a study by the Suquamish Tribe:

Nectar resulting from shellfish preparation methods was commonly used. Sixty-four percent of respondents reported drinking the nectar and 24% reported using it in cooking, in contrast to 19% who reported that they "threw it out."[99]

Finally, as noted above, according to a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups:

[Asian and Pacific Islanders] consume a wide variety of seafod species, the most frequently consumed being shellfish. These seafood, depending on their feeding and habitat characteristics, and the tissue parts consumed pose varying chemical contaminant risks to APIs. For example, certain fat soluble chemicals, e.g., PCBs, are concentrated in the fat layer between the meat and the skin, potentially exposing such consumer to higher contaminant levels than whose who simply eat the fillet. Eating the fillet with skin is clearly a common practice in the API community. . . . Overall, skin was consumed with the fillet 55% of the time. . . .

API community members appear to eat shellfish parts that are thought to contain higher concentrations of chemical contamination, e.g., clam stomachs or the hepatopancreas of crabs. Bivalve shellfish were consumed whole by 24% (geoduck) to 89% (mussels) of respondents depending on the species. The "butter" as well as the meat of crabs were consumed 43% of the time . . .Finally, cooking water, both for finfish and shellfish are commonly use in cooking or directly consumed.[100]

Yet, the studies upon which EPA and other agencies base their risk assessment and risk management decisions often make assumptions about species consumed, parts used, and preparation methods employed that do not reflect these practices. Consider the following description of a study of Los Angeles Harbor fishers by Puffer, et al.:

From January to December of 1980, 1059 interviews with sportfishers were conducted in several fishing areas of the Los Angeles Harbor area. No fisher was sampled more than once. Data was collected on the following: amount of fish caught on the day of the interview, the primary use of the fish (whether it was eaten by the fisher's family, given

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[98] Judith M. Morris, *The Use of Fish and Wildlife Resources by Residents of the Bristol Bay Borough, Alaska* (1985) available at www.nativeknowledge.org/db/files/tp123.htm.

[99] The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 51 (2001).

[100] Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999)

away, thrown back, etc.), frequency of fishing, and other variables. Based on this data *and assuming that only an edible portion (1/4 to ½) of the caught fish would be eaten*, median and 90th percentile consumption rates of 37 grams per day and 225 grams per day were determined.[101]

If the fishers studied were members of a group that viewed the "edible portion" of the fish to include more parts or a greater portion of the fish than assumed by the study authors, this consumption would not have been registered and the resulting consumption rates would be lower than the actual consumption rates of those studied. Although there is no way to know for exactly how many of the fishers studied this would be the case; however, given that a significant number of the fishers studied were what the authors characterized as "Orientals/Samoans," it would at least be true for some. Importantly, as noted above, it is also often the case that the different parts consumed by communities of color, low-income communities, tribes, and other indigenous peoples are the very parts that accumulate the toxins. For both of these reasons, these groups' exposure is often underestimated by agencies relying on conventional studies and methods.[102]

Of note is that the CSFII study on which the EPA bases its default fish consumption rates similarly relies on a variety of assumptions that tend to reflect the consumption practices of the general population. The CSFII study asks participants to categorize and quantify their food intake according to a list of approximately 6,600 different food codes, of which 460 relate to fish and shellfish.[103] The participants' responses are then matched with standard recipes contained in the U.S. Department of Agriculture recipe file, in order to adjust the responses to reflect the quantity of fish contained in the particular dish, assuming standard quantities and preparation methods.

The differences noted here have implications for EPA's risk assessment and risk communication decisions. When agencies set water quality standards that are founded on an inaccurate picture of affected communities' and tribes' exposure, the standards will not be sufficiently protective of members of these groups. Although the examples above provide a sense of the growing body of evidence of differences in consumption practices as between the general population and communities of color, low-income communities, tribes, and other indigenous peoples, there is still a need for systematic study for many of these groups. Further, there is no place in EPA's current risk assessment methods to account for these different practices and the higher level of exposure they entail. The fact that often extraordinary levels of exposure – e.g., exposure to the large amounts of contaminants accumulated in the hepatopancreas of crab – are

[101]U.S. Environmental Protection Agency, Office of Water, *Ambient Water Quality Criteria Derivation Methodology Human Health: Technical Support Document* 96 (1998) (emphasis added).

[102]Note that the extent to which exposure is likely to be underestimated depends in part on whether bioconcentration or bioaccumulation factors are determine using whole fish or merely "edible portions" of fish.

[103]1 U.S. Department of Agriculture, *Continuing Survey of Food Intake by Individuals* II-1-4 (1998).

simply unaccounted for by EPA and other agencies when they set environmental standards is extremely troubling to affected communities whose health is thereby relatively underprotected.

Finally, when agencies issue consumption advisories founded on a misunderstanding of affected communities' baseline practices, they may include irrelevant or inappropriate information or recommendations. This issue will be discussed at greater length in Chapter Three.

D. EXPOSURE: CONSUMPTION PRACTICES IN CONTEXT

The contamination of fish, aquatic plants, and wildlife is especially troubling to many communities of color, low-income communities, tribes, and other indigenous peoples because these groups consume and use these resources in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." Thus, it is not only that there are differences in the quantities of fish consumed or in the species, parts, and preparation methods used, but also that there differences – sometimes profound differences – in the place that these practices occupy in the lives of these people and groups. This is abundantly demonstrated by both testimonial and social scientific evidence. These practices are, in an important sense, *indispensable* to many of these communities and tribes. These differences need to be understood (as best as is possible, given that there may be difficult issues of cross-cultural translation) and accommodated in risk assessment, risk management, and risk communication approaches.

In order to gain a full sense of the circumstances of exposure for many communities of color, low-income communities, tribes, and other indigenous peoples, it is necessary to understand the cultural context in which exposure occurs. A handful of recent community- or tribally-conducted studies have demonstrated the importance of context for understanding exposure. (The necessity of community and tribal involvement in these and other studies is taken up below, in Section H.) For example, the recent consumption study conducted by the Suquamish Tribe commences with an account of "Cultural Patterns and Practices Affecting Suquamish Seafood Consumption," and notes the importance of *"[t]he stories that are woven into the statistics presented in this report."*[104]

It is not only a matter of reconsidering approaches to research, but also a matter of reevaluating approaches to risk assessment and risk management. Tradeoffs or cost-benefit analyses that may be appropriate in other contexts may thus be inappropriate where those affected engage in fishing and fish consumption for the interrelated cultural, traditional, religious, historical, and economic reasons that characterize many affected groups' practices. Additionally, such tradeoffs may run afoul of legal obligations to particular groups, e.g., civil rights-based protections or trust- and treaty- based protections.

Importantly, this discussion has implications for agencies' choices among various risk management tools. In some cases, for some affected groups, it will simply not be appropriate to

[104]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* 5-9 (2000).

ask members to avoid risks by reducing their consumption, by switching to alternative species or fishing locations, by avoiding certain fish parts, or by adopting different preparation methods. Some or all of these practices may be prescribed for cultural, traditional, religious, historical, and/or economic reasons. This issue will be discussed again in Chapter Three, but it should be recognized that its implications are broader.

E. MULTIPLE EXPOSURES AND CUMULATIVE RISKS

Agencies currently employ risk assessment methods that evaluate the risks of environmental contamination as if humans were exposed to only a single contaminant at a time, by a single route of exposure. Humans, however, are often exposed to multiple contaminants at a time or in succession, and often via more than one route of exposure. These contaminants may have synergistic (or antagonistic) effects in combination, yet very little is known about these effects and agencies do not take them into account.

It is the case, moreover, that members of communities of color, low-income communities, tribes, and other indigenous peoples are more likely to be exposed to multiple contaminants via multiple routes and pathways than are members of the general population. As Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, observe:

> *The issue of multiple contaminants is significant, and it is the norm, at least in the Columbia River system, for over 100 contaminants to be identified in fish tissues. While only a few might be at concentrations that trigger an action in any given fish, the combined risk for one fish or for the many species which comprise the native diet can be quite high. If these chemicals are in the fish, they are also in the water and/or sediment, so other routes of exposure are important. The toxicity of a mixture of dozens of carcinogens plus dozens of noncarcinogens . . . needs to be examined.*[105]

Similarly, communities along the Mississippi River Corridor between New Orleans and Baton Rouge, whose members are largely African American and/or low-income, are exposed to an unconscionable level and mix of contaminants, via several routes and pathways.[106] These multiple affronts include exposure to a host of toxic air pollutants (emitted at levels *several times* the levels elsewhere in the United States);[107] to mercury and numerous other contaminants in the fish, oysters and crayfish that are often staple foods;[108] and to vinyl chloride and other contaminants in

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[105]Barbara Harper and Stuart Harris, *Tribal Technical Issues in Risk Reduction Through Fish Advisories*, Proceedings of the American Fisheries Society, Forum on Contaminants in Fish 17,19 (1999).

[106]Charles Lee, ed., United Church of Christ Commission for Racial Justice, *From Plantations to Plants: Report of the Emergency National Commission on Environmental and Economic Justice in St. James Parish, Louisiana* (1998).

[107]Id.

[108]Telephone Interview, Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001); Louisiana Department of Environmental Quality and Louisiana Department of Health and Hospitals,

drinking water.[109] And northern Ojibwa tribes are exposed to mercury via multiple resource pathways, given its uptake by fish and its presence in and on wild rice.

EPA and other agencies have begun to look at how to address multiple exposures and cumulative risk. For example, and to its credit, EPA's Office of Policy has recently conducted a cumulative exposure project to begin to assess the total exposure of more than 100 contaminants across multiple pathways; one component of this project is a community-specific study in the Greenpoint/Williamsburg community in Brooklyn, NY, designed to assess exposures to a variety of contaminants via fish consumption, water ingestion, air inhalation, and lead exposure.[110] This urban community is one of the poorest in New York City; it is comprised of substantial African American, Hispanic (including Caribbean American), Polish, Italian, and Hasidic subpopulations.[111] It is well recognized, however, that many of the issues of multiple exposures and cumulative risks remain unaddressed for the bulk of risk assessments currently being conducted.

F. SUSCEPTIBILITY AND CO-RISK FACTORS

Even if it were the case that all individuals' exposure circumstances were the same – that they came in contact with the same environmental contaminants, by the same routes, at the same frequency, for the same duration – they might not suffer the same adverse health effects as a result of this contact due to differences in their susceptibilities and differences in the extent to which their life circumstances allowed them to be prepared for and recover from the insult of an environmental contaminant, i.e. in their "co-risk" factors.

One might be more or less susceptible to a given level or "dose" of an environmental contaminant depending on one's life stage (e.g., children or the elderly may be more susceptible); one's prior exposure to the same or other contaminants (e.g. those who have become sensitized through prior exposures and now have more severe responses); one's genetic makeup (e.g., genetic susceptibilities that occur in a small but significant percentage of the population); or one's existing conditions or diseases (e.g., asthmatics). Although very little is known about the coincidence of some of these factors – genetics, for example – and whether one is a person of

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Human Health Protection Through Fish Consumption and Swimming Advisories in Louisiana available at www.deq.state.la.us/surveillance/mercury/fishadvi.htm (listing advisories statewide, many of wide apply to the waters of the Mississippi River Corridor).

[109]See, e.g., Chris Frink, *State Knew Well was Contaminated*, The Advocate Online available at www.theadvocate.com/news/story.asp?storyid=20619; Telephone Interview, Mary Lee Orr, Louisiana Environmental Action Network (October 17, 2001).

[110]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 1-1- 1-5 (1999).

[111]Id. at 1-2.

color, a low-income person, or a Native American, it is fair to say that there is a significant correlation for others – prior exposures, or access to adequate health care, for example.[112]

One may also be more or less able to prepare for and recover from exposure to given level or "dose" of an environmental contaminant depending on the various resources an individual, community, group, or tribe can call upon and depending on other aspects of one's life circumstances. Thus, one may be more or less able to withstand and recover from a toxic insult depending on one's income, the quality of one's baseline diet, whether one is employed, whether one has access to adequate health care, whether one has adequate insurance, and whether one's community or tribe can assist to provide coping systems.

Current risk assessment, risk management and risk communication methods do not account adequately for susceptibilities and co-risk factors that affect individuals' responses to the environmental contaminants with which they come in contact. This is especially troubling to the extent that current risk estimates are made assuming the life circumstances of the general population or the affluent and fail thereby to account for the particular susceptibilities and co-risk factors that tend to be clustered in or characterize various communities of color, low-income communities, tribes, and other indigenous peoples. To take but a single co-risk factor by way of example, consider that of the respondents surveyed in a recent study of Asian and Pacific Islander communities in King County, Washington, 90% of Samoans, 62% of Vietnamese, 60% of Mien, 50% of Cambodians and 45% of Laotians live under the federal poverty line.[113] Among American Indians and Alaskan Natives, one in three lives below the federal poverty line.[114] Here again, more data need to be gathered about the particular susceptibilities and co-risk factors relevant to communities of color, low-income communities, and tribes. And here, too, EPA's and other agencies' risk assessment, management and communication methods need to be able to incorporate and address differences in susceptibilities and co-risk factors.

G. SUPPRESSION EFFECTS AND THEIR IMPLICATIONS

A "suppression effect" occurs when a fish consumption rate (FCR) for a given population, group, or tribe reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that population, group, or tribe. The more robust baseline level of consumption is suppressed, inasmuch as it does not get captured by the FCR.[115]

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[112]See e.g., Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 University of Illinois Law Review 103.

[113]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

[114]See Chapter 4 for a more complete discussion of the susceptibilities and co-risk factors of American Indians and Alaskan Natives.

[115]This effect was recognized and named in an early survey of Michigan sport anglers, and cited by the study's authors as a basis for adjusting the observed FCR upward. Patrick West, et al., *Michigan Sports Anglers Fish Consumption Survey: Supplement I, Non-Response Bias and Consumption Suppression Effect Adjustments* (School of Natural Resources, University of Michigan, Ann Arbor; Natural Resource Sociology Research Lab, Technical Report No. 2 (1989).

There are two circumstances in which suppression effects have implications for an environmental justice policy that seeks to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming fish, shellfish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes. In the first, a suppression effect may arise when an aquatic environment and the fish it supports have become contaminated to the point that humans refrain from consuming fish caught from particular waters. Were the fish not contaminated, these people would consume fish at more robust baseline levels. In the second, a suppression effect may arise when fish upon which humans rely are no longer available in historical quantities (and kinds), such that humans are unable to catch and consume as much fish as they had or would. Such depleted fisheries may result from a variety of affronts, including an aquatic environment that is contaminated, altered (due, among other things, to the presence of dams), overdrawn, and/or overfished. Were the fish not depleted, these people would consume fish at more robust baseline levels.

The implications for environmental justice policy will depend in part upon which of these two scenarios accounts for the suppression effect observed. They will also depend upon how the more robust "baseline" level is defined – an exercise that itself raises important environmental justice issues. This question of an appropriate "baseline" will in turn be related to the particular group affected. In many cases, for example, a tribe will be able to cite a historical "point of reference" that would describe an appropriate baseline in terms of environmental quality, geographic delineation, and treaty rights.[116] In each case, there would be important questions of history, culture, and aspiration that would need to be considered in determining an appropriate baseline; that is to say, an appropriate baseline might mean examination into what people *had* consumed as well as aspiration for what people *would* consume were there "fair access for all to a full range of resources,"[117] or were the conditions fulfilled for full exercise of treaty- and trust-protected rights and purposes.

When environmental agencies employ a FCR that does not capture fully the consumption that is suppressed – under either scenario in which suppression effects occur – they set in motion a sort of downward spiral whereby the resulting environmental standards permit further and further contamination or depletion of the fish and so diminished health and safety of people consuming fish, shellfish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes. These effects play out somewhat differently in each of the two scenarios, as elaborated below.

[116]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of Yakama Nation (C3G Conference Call, August 3, 2001). For the Tribes and Bands of the Yakama Nation, for example, this point of reference would be 1855. Id.

[117]Principles of Environmental Justice, Proceedings of the First National People of Color Environmental Leadership Summit (1991).

1. Contamination

Health and environmental agencies have increasingly responded to contaminated aquatic environments by issuing fish consumption advisories warning humans to limit or stop their consumption of fish from polluted waters.[118] In many cases, individuals have responded to these advisories and/or to a greater general awareness of the dangers of consuming contaminated fish by eating less fish.[119] The extent to which individuals respond to fish consumption advisories by reducing their consumption varies.[120] In some cases, this is due to the fact that advisories are more effectively communicated to some affected populations than others. Among other things, advisories may not be communicated in culturally or language-appropriate ways. In other cases, this is due to the fact that, for cultural, traditional, spiritual, economic, and/or other reasons, the individuals to whom the advisories are addressed do not respond by reducing their consumption.

When environmental agencies set or approve water quality standards that are meant to be protective of human health, agencies look to gauge humans' exposure by how much fish they are consuming, i.e. their fish consumption rate. Agencies estimate or measure this FCR, and on this basis determine how much pollution can remain in or be discharged to the relevant waters and sediments and still result in what have been deemed "acceptable" levels of contamination and risk to human health. Notably, the FCRs on which agencies rely are meant to represent *current* rates of fish consumption, rates that may reflect a suppression effect as outline above.

When environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. That is to say, agencies will set less protective standards. The downward spiral thus begins, as these aquatic environments and the fish they support will be permitted to become increasingly contaminated, and some individuals in turn might be expected to respond by reducing their fish consumption even further. The downward spiral would continue, as agencies would then register this even lower rate of consumption, set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

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[118]U.S. Environmental Protection Agency, Office of Water, Update: National Listing of Fish and Wildlife Advisories 2 (April 2001), available at www.epa.gov/ost/fish.

[119] See, e.g., Telephone interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (July 12, 2001).

[120]Studies suggest varying degrees of both (1) awareness of fish consumption advisories by members of the public and (2) "compliance" with fish consumption advisories through changed fish consumption practices even when members of the public are aware of fish consumption advisories. See e.g., John Tilden et. al, Health Advisories for Consumers of Great Lakes Sport-Fish: Is the Message Being Received?, 105 Environmental Health Perspective 1360 (Dec. 1997); Hugh F. MacDonald and Kevin J. Boyle, Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine, 17 Journal of Fisheries Management 687 (1997).

2. Depletion

Many species of fish upon which people have traditionally relied are no longer readily available, due to habitat degradation and diminishment, ecosystem alteration, overfishing, and other causes. In the Pacific Northwest, for example, compromised aquatic ecosystems mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights. These numerous affronts have resulted in 24 salmon and steelhead runs being listed as endangered or threatened under the Endangered Species Act, and other fisheries being depleted. With fewer fish available to be taken, many tribal members have been prevented from consuming fish at the level that they would have were they able to exercise their treaty rights to the fullest extent.[121]

Again, when environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. Thus, tribal members are not only left with fewer fish to take and consume, but those that remain will be permitted to become increasingly contaminated. If fish stocks continue to decline, a variation on the downward spiral described above can be expected, with lower FCRs resulting from the fact that there are simply fewer fish to be consumed. Again, agencies would then register this even lower rate of consumption, set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

It should be noted, too, that contamination is related to depletion. To take but one example, among the contaminants that have contributed to the decline and listing of salmon populations in the Pacific Northwest are numerous pesticides. Recent studies have shown that pesticides disrupt the ability of salmon to develop properly and to home to their natal streams; these harmful effects are in addition to their toxic effects on humans and other animals that consume fish.[122]

3. Evidence of Suppression Effects

There is limited evidence regarding the existence and extent of suppression effects. This is likely due in part to the fact that this term for the phenomenon hasn't been widely used – indeed, although diminished fish consumption due to contamination and/or depletion has been observed in numerous contexts, it is believed that this Report is the first document to bring these observations together under a single umbrella term. Nonetheless, there is a growing body of evidence of suppression effects due to contamination and/or to depletion. Among other sources of data are recent studies conducted to evaluate the effectiveness of fish consumption advisories for

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[121] Telephone Interview with Kelly Toy, Shellfish Biologist, Tulalip Tribes (November 9, 1999).

[122] See, e.g., Oregon Pesticide Action Network, *Diminishing Returns: Salmon Decline and Pesticides* (1999).

contaminated waters. To the extent that such studies find that people have "complied" with advisories by eliminating or lowering their consumption of fish, they provide evidence of a suppression effect – an artificially diminished level of consumption relative to a more robust baseline level. Too, community-based or tribally-conducted fish consumption studies often document broadly the subject group's fish consumption practices. Often, these studies include information about historic consumption and explore reasons for altered and diminished consumption practices.

Some of the available evidence documents suppression effects due to contamination. For example, as noted above, West, et al. recognized and named this effect in an early survey of Michigan sport anglers.[123] In a recent study of Lake Ontario anglers, Connelly, et al. cite recently altered health advisories that resulted in less Lake Ontario fishing as the reason that only 43% of anglers indicated that they had fished Lake Ontario in 1992.[124] A recent study of the Laotian communities in the San Francisco Bay area reports that 19.7% of survey respondents indicated that they had changed their fish consumption habits over the past five years, with 68.9% of these indicating that they eat less fish now.[125] Among the reasons cited for eating less fish: bay fish are "unsafe to eat."[126] Ken Jock, Director, Akwesasne Environment Program, provides an account of the effects of PCB contamination in the St. Lawrence River on the Mohawks at Akwesasne:

> *This all used to be a fishing village. That's all gone now. There's only one family that still fishes. . . . Our traditional lifestyle has been completely disrupted, and we have been forced to make choices to protect our future generations. . . . Many of the families used to eat 20-25 fish meals a month. It's now said that the traditional Mohawk diet is spaghetti.*[127]

Other available evidence documents suppression effects due to depletion or due to depletion *and* contamination. For example, as noted above, in the Pacific Northwest compromised aquatic ecosystems and depleted salmon and other fisheries mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights. According to Kelly Toy, Shellfish Biologist, Tulalip Tribes, with fewer fish available to be taken, many tribal members have been prevented from consuming fish at the level that they would

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[123]Patrick West, et al., *Michigan Sports Anglers Fish Consumption Survey: Supplement I, Non-Response Bias and Consumption Suppression Effect Adjustments* (School of Natural Resources, University of Michigan, Ann Arbor; Natural Resource Sociology Research Lab, Technical Report No. 2 (1989).

[124]U.S. Environmental Protection Agency, Office of Water, *Ambient Water Quality Criteria Derivation Methodology Human Health: Technical Support Document* 97 (1998).

[125]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra County, California* 18 (1998). Note that 31% of those who indicated that their consumption practices had changed indicated that they eat more fish now.

[126]Id.

[127]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 17 (1999) (quoting Ken Jock, Director, Akwesasne Environment Program).

have were they able to exercise their treaty rights to the fullest extent.[128] Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation, confirms similarly depleted fisheries, diminished opportunities for catching and consuming fish, and compromised treaty rights.[129] A recent study of the Suquamish Tribe reports that approximately 2/3 of respondents (67%) indicated that their consumption patterns had changed over time, with 68% of these indicating that they ate less seafood (57%) or ate a different mix of species (11%) than twenty years ago.[130] "Most explanations for changes in consumption related to changes in family composition which affected harvesting patterns, accessibility/availability of finfish and shellfish, and restricted harvesting opportunities due to 'red tides' and increased pollution."[131] As one respondent elaborated:

> *We used to eat lingcod, sole, rockfish, flounder, and I caught Grunters for my grandfather. All of my brothers used to fish; now, only one of us can because the fish are diminishing in number . . . The water is not clean. Septics are malfunctioning . . . There's pollution from the Navy, and the filling at Keyport had a big effect . . . Beaches are dug out . . . We need to reseed and enhance our beaches in order to have the number of clams we need and are used to . . . We eat more geoduck now, because more are available to us, but we used to dry oysters and clams; they're good for teething . . .*[132]

Similarly, Hawaii's Thousand Friends relates:

> *Many shellfish and limu (seaweed) staples of Native Hawaiian diets are becoming harder to find or have disappeared due to pollution and/or destruction of habitat. Thus Native Hawaiians are unable to continue eating (healthy) foods traditional to their culture and lifestyle.*[133]

There is, however, a need to understand more fully the extent and causes of suppression effects. Among other things, the evidence presented here shows that people's responses to contamination and depletion are complex and varied. Further exploration of these effects would be useful. In particular, where consumption by communities of color, low-income communities, tribes, and other indigenous peoples seems relatively low, research is needed to ascertain whether a suppression effect is at work.

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[128]Telephone Interview with Kelly Toy, Shellfish Biologist, Tulalip Tribes (November 9, 1999).

[129]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation (Conference Call, Aug. 3, 2001).

[130]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 2 (2001). Note that 31% of those who indicated that their consumption practices had changed indicated that they eat more fish now.

[131]Id.

[132]Id. at 68 (ellipses in original).

[133] Hawaii's Thousand Friends (Written Comments, March 11, 2002).

4. Implications

To the extent that people are prevented from consuming fish as they had or would due to contamination or depletion of the fish and aquatic ecosystems that support the fish, there are important implications for EPA's and other agencies' risk assessment, risk management, and risk communication approaches. As noted above, when environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. That is to say, agencies will set less protective standards. The downward spiral thus begins, as these aquatic environments and the fish they support will be permitted to become increasingly contaminated, and some individuals in turn might be expected to respond by reducing their fish consumption even further. Or some individuals in turn might find that there are fewer fish to be caught (and those that remain to be increasingly contaminated) or there are fewer places open for shellfish harvesting. In either case, studies would reflect even lower FCRs, and agencies would then set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

In order to avoid this downward spiral, EPA should identify appropriate "baselines" that reflect the more robust levels of consumption and employ these baselines in setting and approving water quality criteria. There is, of course, the difficult question of what the appropriate baseline should be, and the answer will likely differ according to the circumstances surrounding and the group affected by the observed suppression effect. For example, as noted above, a tribe will often be able to cite a historical "point of reference" that would describe an appropriate baseline in terms of environmental quality, geographic delineation, and treaty rights.[134] In each case, there would be important questions of history, culture, and aspiration that would need to be considered in determining an appropriate baseline. An appropriate baseline might mean examination into what people *had* consumed as well as aspiration for what people *would* consume were there "fair access for all to a full range of resources,"[135] or were the conditions fulfilled for full exercise of treaty- and trust-protected rights and purposes. It is recognized that the resulting baseline would surely require EPA to depart from the then-current estimates of actual fish consumption by the relevant group. In so doing, EPA would need to shift its emphasis from a descriptive assessment to a normative assessment. This shift is not without precedent, however, and, importantly, would seem to be necessary in some cases to avoid the downward spiral noted here.

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[134]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of Yakama Nation (C3G Conference Call, August 3, 2001). For the Tribes and Bands of the Yakama Nation, for example, this point of reference would be 1855. Id.

[135]Principles of Environmental Justice, Proceedings of the First National People of Color Environmental Leadership Summit (1991) available at http://www.sccs.swarthmore.edu/org/speec/ejdef.html.

H. RESEARCH METHODS AND ISSUES

This part highlights two issues respecting EPA's current research methods and priorities: the importance of facilitating community-based or tribally-conducted research, and the need for research that seeks not only to describe affected groups' exposure but also to connect exposure to the sources of contaminants in aquatic environments.

1. Community-Based and Tribally-Conducted Research

It will often be crucial to the relevance, accuracy and acceptability of research in these areas that the affected community, group or tribe be central to the process throughout. In the case of consumption studies, for example, affected groups need to be involved from the earliest stages (e.g., project conception, group/subgroup identification, survey design) through implementation (e.g., survey administration, data interpretation) to utilization (e.g., community outreach regarding results, risk assessment, management and communication incorporating results). This is not only a matter of community access or tribal consultation, but importantly, a matter of scientific defensibility. There are currently sizeable gaps in the data and methods that are being used by EPA and other agencies to assess, manage, and communicate risk, and it is often the case that these gaps can only be filled by community- and tribally-based research. *Communities and tribes have expertise that is simply not going to be able to be replicated by non-member researchers.* This point is well supported by the large literature on "participatory research." Consider the following two examples of the importance of affected group involvement:

> Asian and Pacific Islanders in King County, Washington.[136] A study of the Asian and Pacific Islander communities (including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese communities) in Seattle and King County, Washington was conducted by the Refugee Federation Service Center (the largest social aid organization for recent immigrants and refugees in King County) and the University of Washington. The study was funded by an Environmental Justice Community/University Partnership Grant through EPA Region 10. The community played a pivotal role in the study, from its initiation through the final report. A Community Steering Committee, comprised of members representing each of the ten affected ethnic groups, conducted the planning, design and development of the survey. They worked together with and received input from a Technical Committee (comprised of statisticians, toxicologists, epidemiologists, and other technical advisors) and an Advisory Committee (comprised of representatives from agencies, industry, and the medical profession). As the study authors note: "During the study period, the researchers had frequent interactions with the community because the researchers viewed the study as 'by the API community,' instead of 'for the API community.' This interaction and cooperation helped the study team in its understanding of community concerns and therefore gained the support of the community, which was vital for the completion of this

[136]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

study involving ten ethnic groups with diverse cultural backgrounds."[137] Among other things, the Community Steering Committee was instrumental to several aspects of the study design. It explained that the use of creel, mail, or telephone surveys would be culturally inappropriate, indicating that API community members would be unlikely to participate at all in a survey conducted by these methods; instead, a face-to-face questionnaire method was selected. It identified the seafood species and parts most often consumed by community members, and explained the usual preparation methods – elements crucial to questionnaire design. It also suggested interviewers that would have the requisite cultural knowledge and fluency in both English and the various native languages of the study participants. Thus, for these and other reasons, this study likely produced more accurate data by (1) avoiding the non-response bias that likely plagues other studies attempting to gauge API consumption practices; (2) including quantities consumed where the species or part consumed might have been excluded altogether from other, more generalized studies (e.g., clam stomachs or the hepatopancreas of crabs); (3) identifying consumption and preparation practices that differ from the general population and so bear on risk assessment, risk management and risk communication decisions (e.g., consuming the "butter" as well as the meat of crabs). There are also other important advantages of a community-based study, including community education and empowerment. These issues will be taken up in Chapter Three.

The Suquamish Tribe.[138] A study of Suquamish tribal members (adults and children) living on and near the Port Madison Indian Reservation was conducted upon approval by the Suquamish Tribal Council. The study was conducted by the Suquamish Tribe and funded by the Agency for Toxic Substances and Disease Registry through a grant to the Washington State Department of Health . The stated purpose of the study was to determine seafood consumption rates, patterns, and habits of members of the tribe and, secondarily, to identify "cultural practices and attributes which affect consumption rates, patterns, and habits of members of the Suquamish Tribe."[139] A Project Support Team was established, comprised of two members of the Suquamish Tribal Council, the Director of Human Services, and the Self Governance Director, all of whom are enrolled Suquamish tribal members. The study manager from the Suquamish Tribe Fisheries Department worked together with individuals from the Washington Department of Health. Suquamish Elders were consulted concerning fish and shellfish important to tribal members for commercial, subsistence, and ceremonial purposes.[140] Additionally, transcripts of the Suquamish Tribe Oral History Project of 1982, anthropological and archeological literature were consulted to document cultural practices.[141] Tribal members were integral to the study design, survey administration, and data interpretation. The study was

[137]Id.

[138]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* (2000).

[139]Id. at 1.

[140]Id.

[141]Id. at 3.

designed to determine consumption rates by individual type of finfish and shellfish – information of interest to the tribe and unavailable through other relevant fish consumption studies. Consumption data were gathered using a survey questionnaire and face-to-face interviews; these interviews were conducted by tribal members. These interviewers set up and conducted meetings with survey participants "in accordance with cultural norms."[142] The personal knowledge of those conducting the study enabled them to interpret the resulting data in a manner that ensured accuracy. For example, the data revealed some large fish consumption rates, which might be designated as "outliers" according to strictly numerical criteria. Because this designation often carries with it an assumption of error, reported consumption rates for outliers are often adjusted downward. In this case, however, "the study staff were familiar with a number of the individuals with large consumption rates and maintained that the reported rates were likely to reflect real consumption. Thus, no adjustment for potential outliers has been carried out."[143] Thus, for these and other reasons, this study likely produced more relevant, contextualized, and accurate information. Tribally-managed studies are also a manifestation of tribal self-governance and, in the case of the Washington treaty tribes, of their status as co-managers of the fish, shellfish and aquatic resources. Issues unique to tribes will be taken up at greater length in Chapter Four.

Other community-based or tribally-conducted studies have demonstrated similar advantages in terms of relevancy, accuracy, acceptability and appropriateness to the affected group. The community-based study team for the consumption survey of Laotian communities in West Contra County, for example, was able to identify and take advantage of important community festivals as a means of reaching survey participants;[144] to appreciate the existence and relevance of subgroups within the larger Laotian community;[145] and to interpret data in light of cultural, historical, social, economic and other relevant factors.[146] In the case of tribes, members have often lived their entire lives – and their families and ancestors have lived for generations – in the same place, about which they therefore have vast amounts of knowledge. In addition, many tribes today have developed extensive environment and resources management departments.

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[142]Id. at 18-19.

[143]Id. at 23. The study authors note that, in the end, this inclusion had little influence on the reported percentiles, with all but one (the 95th percentile for "all finfish") being unaffected. Id. at 70-71.

[144]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 6 (1998) (describing outreach conducted at the Laotian New Year's Festival, "one of the most well-attended community events in Richmond").

[145]Id. at 7-10 and 35-36 (discussing representation of the various ethnic groups within the Laotian community, including Mien (Christian), Mien (non-Christian), Lao, Khmu, Thaidum, Lue, Hmong, Lahu, and a Mien group from a different village in Laos than the Mien who are members of the first two groups).

[146]Id. at 36 (discussing likelihood that many respondents who fish in San Francisco Bay indicated that they did not, for fear that the survey was linked to law enforcement about fishing from the Bay, fear of losing disability benefits if they said they went fishing, or concern about "'losing the power to feed their family traditionally cooked meals'" and noting that the survey results therefore likely understated the extent of fishing in the Bay by community members).

Tribes and their members will thus be uniquely positioned to identify ecological changes,[147] suggests subjects for inquiry, and design and implement useful experiments, surveys and studies.

To the extent that research is conducted by and for communities and tribes, it can serve the additional important function of capacity building or, as Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, perhaps more appropriately terms it, "capacity augmentation."[148] This goal is important and an issue of environmental justice in and of itself, for both communities and tribes. And, to the extent that communities and tribes see that their concerns are shaping the research to be conducted, that the information gathered will be relevant from their perspective, and that their members stand to enhance their skills, knowledge and capacity in the process – as opposed to merely providing information that enables others to enhance *their* skills, knowledge and capacity – participation and trust are likely to be increased, and accuracy thereby enhanced.[149]

Indeed, those affected are likely to have a unique and heightened interest in gathering relevant and accurate data. Given that they depend on the resource in question, they have an interest in determining precisely the nature and extent of the contamination, in producing a full and accurate picture of their exposure, and in addressing any resulting problems through risk management and risk communication.[150] It may be the case as well that affected communities and tribes are less likely than other governmental entities to be subject to the competing claims of multiple stakeholders – enabling them, among other things, to devote their full time and attention to the particular problem.

Funding is crucial to the ability of affected communities and tribes to be involved in research. Although community and tribal members have considerable expertise to offer, they

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[147]See, e.g., Gerald Nicholia, Tanana, Interior Regional Meeting, Alaska Traditional Knowledge and Native Foods Database, available at www.nativeknowledge.org/db/concerns.asp ("But one thing I see is changes in the animals we live off of. The mining has affected us; mercury levels in our fish. I don't know what is in our moose. Few muskrats in our area. I don't know what happened to the whitefish in our area. It's hard to pinpoint. . . . But I know that there are a lot of changes in the Tanana area.").

[148] Moses Squeochs, *Testimony to National Environmental Justice Advisory Council* Vol III-97 (Annual Meeting Transcript) (Dec. 4, 2001) (observing "[I]n reference to a tribe, [I do not use the term capacity building,] but more so capacity augmentation. The capacity of the people that I'm from has been there for thousands of years. It's been along the Duwamish River for thousands of years. It's been in watersheds scattered across the country for thousands of years.")

[149]See, e.g., id. at 37 (noting that the survey planning team made connections with the Laotian Organizing Project's ongoing capacity building efforts regarding community health and safety, which motivated many community members to participate in the survey and explaining: "The planning team was originally hesitate about the perception commonly held by community members of outsiders taking information from the community without community people seeing the benefits of research. Linking the survey to a community based organization helped counter this perception.").

[150]Consider, e.g., the work of the Shoalwater Tribe to monitor shellfish in the Willapa Bay, described at greater length in Chapter 4. Electronic-mail Interview, Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001).

often have minimal or no funding to support their work. *To a person*, community members, tribal members, inter-tribal organization staff, and state and local agency representatives who work with affected groups stressed the importance of adequate funding. Diana Lee, a research scientist with the California Department of Health Services who has worked extensively with communities as part of the Palos Verdes Fish Contamination Outreach and Education Project and other studies in the San Francisco Bay area, is emphatic:

> *I cannot underscore enough the need to provide funding to affected communities so that they can participate fully in every aspect of the research process, from needs assessment to dissemination of the results. Funding, moreover, needs to be provided on an on-going, rather than one-time, basis.*[151]

EPA, in particular, has to date helped fund several studies and projects that have contributed enormously to the advancement of research relevant to affected communities and tribes. The EPA has helped fund such important work as the fish consumption study of and by Asian and Pacific Islanders in King County, Washington; the fish consumption study of and by the four tribes who are members of the Columbia River Inter-Tribal Fish Commission; and the community-specific cumulative risk assessment for the Greenpoint/Williamsburg community in Brooklyn, New York. In addition, the EPA, together with the ATSDR, has recently announced relevant grant initiatives, including two programs: *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment*[152] and *Superfund Minority Institutions Program: Hazardous Substance Research*.[153] Affected communities and tribes have commended EPA's past efforts to this end, and welcome EPA's new initiatives. However, those affected have noted that the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available.

2. Research Connecting Exposure to the Sources of Contamination

It is particularly important from the perspective of affected groups that research seeking to describe exposures more accurately be undertaken *as but one component of* research that presents

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[151]Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

[152]U.S. Environmental Protection Agency, Office of Research and Development, *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment* available at http://es.epa.gov/ncer/fra/02trib_risk.html (noting, importantly, that "It is expected that Tribal members and representatives will play a leading role in the planning, conduct, analysis, translation and dissemination of the research.").

[153] U.S. Environmental Protection Agency, Office of Research and Development, *Superfund Minority Institutions Program: Hazardous Substance Research* available at http://es/epa.gov/ncer/rfa/02minhazinst.html (listing as eligible program grant recipients "Minority institutions, including Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSIs), and Native American Tribal Colleges (TC) in the U.S.").

a fuller picture and seeks to connect affected groups' exposures to the sources of the contamination that gives rise to these exposures. As noted above, given their dependence on aquatic resources, communities of color, low-income communities, tribes, and other indigenous peoples have an acute interest in determining the nature, extent, and sources of such contamination, in producing a complete and accurate picture of their exposure, and in seeing that the contamination is addressed. Thus, while further research regarding various groups' exposure is important, it should not be undertaken at the expense of research that aims to identify the sources of the contamination and to understand that mechanisms by which substances that have been or are being emitted or discharged from these sources make their way to contact with humans (and other non-human components of aquatic ecosystems). Nor should research on exposure be undertaken in isolation of renewed efforts to *reduce* the resulting risks, a point echoed repeatedly by affected groups[154] and emphasized throughout this Report. As the Swinomish Indian Tribal Community stresses:

> *We urge [explicitly that EPA undertake and] support[] efforts to establish undeniable connections between contaminants found in harvested fish and shellfish and the sources of those contaminants. . . . [We believe that pinpointing the source of the pollution and mitigating it at the source will be the only successful strategy in accomplishing risk reduction.*[155]

I. REFINING AND REEVALUATING CURRENT RISK-BASED APPROACHES

Although quantitative risk assessment has increasingly, since the 1970s, been employed by environmental agencies to set health-based environmental standards, its use remains controversial.[156] Commentators have pointed out several serious concerns with quantitative risk assessment as currently practiced.[157] For example, they have taken issue with risk assessment's priorities and assumptions; they have noted that the considerable uncertainty and variability that characterizes health and environmental decisions means that risk assessment is a highly subjective process, requiring value judgments at numerous steps along the way;[158] and they have criticized the ways in which the use of risk assessment perpetuates and exacerbates the disproportionate

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[154]See, e.g., Shawna Larson, Project Coordinator, Indigenous Environmental Network and Alaska Community Action on Toxics, Panelist, "Right to Toxic-Free Traditional Foods in Our Environment," Alaska Forum on the Environment (Feb. 4-8, 2002).

[155]Swinomish Indian Tribal Community, *Comments on the National Environmental Justice Advisory Council's Draft Fish Consumption Report* (Feb. 5, 2002).

[156]See, e.g., Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 Harvard Environmental Law Review 409 (1995).

[157]See, e.g., Catherine A. O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3, 19-37 (2000).

[158]See, e.g., National Research Council, *Science and Judgment in Risk Assessment* (1994); O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal at 27-30.

burdens visited on communities of color, low-income communities, tribes, and other indigenous peoples.[159]

While quantitative risk assessment is not without attributes to recommend it, the continued presence of the concerns sketched above – and the observation that these concerns are often amplified when those who bear the risk are environmental justice communities – means that it would be inappropriate to embrace unexamined risk assessment as currently practiced. Reevaluation of the method, moreover, is particularly appropriate at this juncture in light of recent work elaborating risk assessment's limitations from the particular perspectives of various communities of color, low-income communities, tribes, and other indigenous peoples; in light of refinements developed by researchers in response to some of the limitations noted above; in light of alternatives envisioned by those whose objections are more fundamental in nature; and, more generally, in light of the lessons afforded by several decades of experience with what is, after all, a method of relatively recent origin in the environmental regulatory context. Reevaluation may also be useful given that the method is costly and time-consuming: "a single risk assessment on a single chemical might take up to five years and cost upwards of $5 million."[160]

This part identifies two categories of efforts that merit involvement by EPA and other health and environmental agencies: (1) efforts to refine current risk assessment methods; and (2) efforts to reevaluate risk assessment and employ alternative approaches, especially approaches that focus on prevention and precaution. This part does not aim to provide a complete account of the various efforts that might be undertaken in each category; rather, it discusses a few important examples and counsels further exploration by EPA and others, together with affected groups.

1. Refining Risk Assessment

As currently practiced, quantitative risk assessment focuses in the main on a finite set of adverse effects to human physical health, narrowly defined. From the perspectives of many of those affected, this understanding of the problem captures only part of what is at stake in decisions affecting the environment. Among other things, it fails to grasp the interrelated physical, psychological, social, and cultural nature of the harms that are visited on some groups when environments are contaminated. These concerns are to some extent outlined above, in Section A. The discussion here is meant to highlight current work suggesting refinements to risk assessment that may go some or all of the way to addressing these concerns, and to suggest that EPA look to these efforts and support similar work. Thus, to the extent that EPA continues to

[159]See, e.g., Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 University of Illinois Law Review 103; Daniel C. Wigley & Kristin Schrader-Frechette, *Environmental Racism and Biased Methods of Risk Assessment*, 7 Risk: Health, Safety & Environment 55 (1996); O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3.

[160]*Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Introduction: To Foresee and Forestall" 1, 4 (Carolyn Raffensperger and Joel Tickner, eds. 1999). Note that "[t]his excludes the cost of the harm that may be caused by the activity under study." Id.

employ risk assessment as a tool for making environmental decisions, it should at least consider the following and other refinements.

It is possible to refine current risk assessment practices by expanding the risk assessment framework so that, from the outset, it includes social, cultural, and economic risks as well as physical and ecological risks. Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, International Institute for Indigenous Resource Management, for example, have developed just such a framework for assessing and characterizing risks to tribal health and cultures.[161] This model not only takes a broader view of the components of risk assessment, incorporating all of the elements of an "overall eco-cultural system," including "human health (using appropriate exposure scenarios), ecological health, and socio-cultural/socio-economic health," but it does so in a way that is holistic in that it recognizes the interrelations among these components.[162] It employs the concept of "the natural-cultural resource dependency web based on cultural ecosystemic stories."[163] Among other things, it offers a risk assessment model that is more scientifically defensible in that it more completely and accurately captures the nature and extent of the risks than do conventional models.[164] A related point is that "risk" may be defined quite differently by different affected groups. It may be comprised of different components, or be differently understood. Therefore, it is important that the affected group itself be involved in determining the contours of "risk," i.e. describing what is at stake – as well as involved in the subsequent step of determining what levels of risk are acceptable, in which contexts, and under which circumstances.[165]

It is also possible to refine current risk assessment practices by selectively employing the method. Thus, for example, risk assessment may be inappropriate where the contaminants to be regulated are persistent, bioaccumulative, and/or highly toxic or where the contaminants have particularly troubling effects (including not only human physical health, narrowly defined, but also human health and well-being along multiple dimensions including psychological, social, and cultural health; and including ecological health). The Columbia River Inter-Tribal Fish Commission offers just this perspective:

> *CRITFC maintains that risk assessments have no useful purpose for making regulatory decisions for persistent, bioaccumulative toxics, known carcinogens, "probable human*

[161]Stuart G. Harris & Barbara L. Harper, *Using Eco-cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91 (Special Issue, 2000).

[162]Id. at 92.

[163]Id.

[164]Id. Note, too, that the model suggested by Harris and Harper does not inherently contain any more uncertainty than conventional risk assessment models.

[165]Note that the answer may in some cases be that only "zero increased risk" is judged acceptable by those who must bear the risk.

carcinogens," and substances known to cause reproductive, developmental or neurological effects.[166]

Finally, it is possible to refine current risk assessment practices by incorporating, to a far greater extent, the precautionary principle (this principle is discussed below). Some commentators have begun to explore how this might be accomplished.[167]

2. Alternatives to Risk-Based Approaches

Quantitative risk assessment and related analytic approaches reflect one subjective set of priorities and assumptions for environmental policy. When agencies choose these tools, they choose to privilege certain values, at the expense of others. As commentators have recognized, these methods do not – and cannot – provide the neutral, bias-free bases for environmental decisions that some proponents have suggested. As currently practiced, for example, risk assessment assumes that some amount of risk from contamination is "acceptable," and that so long as this amount is not exceeded, there is no reason or relationship that would call upon humans to prevent or limit contamination. It excludes all experience or understanding that is not readily quantified, and accepts only certain kinds of knowledge as valid. It lends a false sense of precision and accuracy to decisions about enormously uncertain and highly variable events, and operates within a regulatory framework that, for the most part, places the burden of resolving uncertainties on risk-bearers rather than risk-producers. Many people of color, low-income people, tribes, and other indigenous people do not share some or all of these assumptions, and so have questioned methods based on these premises. As Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, explains:

When I first began this work and I first learned about risk assessment, I took issue with it immediately and I still have issues with it today. That's been over 10 years now, and I have continually taken a position that risk assessment – or conventional risk assessment – is based on an American experience, not an indigenous American experience. So there is a disparity there that needs to be recognized and it needs to be addressed.[168]

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[166]Columbia River Inter-Tribal Fish Commission, *Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* 3 (1999).

[167]See, e.g., Nicholas A. Ashford, *Protecting Public Health and the Environment: Implementing the Precautionary Principle* "A Conceptual Framework for the Use of the Precautionary Principle in Law"198 (Carolyn Raffensperger and Joel Tickner, eds. 1999); see also, Stuart G. Harris & Barbara L. Harper, *Using Eco-cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91, 92 (Special Issue, 2000) (noting that "[t]he Precautionary Principle is not the antithesis of risk-based decisionmaking, but complements it by allowing decisions to be made in the face of uncertainty that is inherent in all predictive and variable situations.")

[168]Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, *Testimony to National Environmental Justice Advisory Council* Vol III-101 (Annual Meeting Transcript) (Dec. 4, 2001).

Affected groups and others have also worked to envision alternative approaches. Important among these is an approach guided by the *precautionary principle*. As Tom Goldtooth, Executive Director, Indigenous Environmental Network, observes:

> *[W]e are engaged in a clash of two competing paradigms. One is an aging model based upon quantitative risk assessment, assimilative capacities, and acceptable discharges for individual compounds, which has dominated chemical and environmental policy . . . The other is an emerging paradigm based upon prevention, precaution, and clean production processes; and this is what we've been calling precautionary action, or [the] precautionary principle.*[169]

In broad terms, the precautionary principle focuses on *preventing* environmental contamination in the first place. It views prevention as preferable to other approaches as a matter of efficiency, justice, and ethics. That is, prevention avoids the enormous monetary costs of having to cleanup contamination after it has been permitted (and, given the propensity of many pollutants to migrate, mingle and otherwise pose more severe – and more costly – problems once they are released into the environment, prevention will very often be cheaper than "cure" in this context)[170] and of having to care for the sick whose illnesses have resulted from exposure to contaminants. Prevention addresses the problem of irreversible and very long term effects, e.g., once someone has cancer, this cannot be reversed, only treated; once a species is extinct, it is gone forever; once the fishery on which the St. Regis Mohawk tribe relies is devastated, generations will come and go without being able to fish. These concerns simply cannot be addressed by after-the-fact cleanup or health care. Prevention also helps to alleviate the extraordinary burden from contamination that is currently borne by communities of color, low-income communities, tribes and other indigenous peoples. Finally, prevention does not discriminate against those whose spiritual or cultural traditions include an ethic of reciprocity.

Beyond this broad focus on prevention, what would be entailed by the precautionary principle has been more specifically elaborated. Although the precautionary principle has been defined somewhat differently in the various instruments and statements invoking it, at the heart of these definitions are several core concepts:

> a. A judgment that something of great value is at stake (usually accompanied by a recognition that what is of value includes not only human but non-human components of ecosystems, and includes not only the well-being of present generations but of future generations);
> b. An acknowledgment that the threat to what is of value is potentially serious and/or irreversible; and

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[169]Tom Goldtooth, Executive Director, Indigenous Environmental Network, *Comments to the National Environmental Justice Advisory Council*, "Public Comment" Vol III-28 (Annual Meeting Transcript) (Dec. 4, 2001).

[170]*Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Introduction: To Foresee and Forestall" 1, 4 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

c. A recognition, therefore, that action to prevent or reduce this threat is appropriate, and that uncertainty as to the existence or magnitude of the threat should not constitute a sufficient reason for refraining from action.

These concepts, in turn, have been taken to suggest further precepts, such as a shift in the burden of proof – such that those who propose to introduce or continue to produce toxic substances are required to demonstrate the non-existence of a threat; a preference for less toxic alternatives – such that laws and policies that facilitate the search for less toxic substitutes are called for; and a "proportionality of response" – such that the appropriateness of actions taken to prevent or reduce the threat from contamination depends in part upon the seriousness or irreversibility of the threat relative to the costs of the action. Although these precepts, in particular, may not be present in every conception of the precautionary principle, the outline above gives some sense of the perspectives that underlie the principle.

The precautionary principle is a component of numerous international agreements, including several to which the United States is party.[171] Perhaps most prominent among these is Section 15 of the Rio Declaration of the United Nations Conference on Environment and Development, signed in 1992 by the United States and a host of other nation-states.[172] Not only is the precautionary approach a part of United States law as a result of its international commitments, but this approach is included in domestic law, in environmental statutes and elsewhere. Thus, for example, commentators have noted that the precautionary approach is embodied in aspects of the National Environmental Protection Act (NEPA), the Clean Water Act (CWA), the Toxic Substances Control Act (ToSCA), and the Pollution Prevention Act (PPA), among other federal, state, and tribal statutes.[173] And the U.S. President's Council on Sustainable Development, a multi-stakeholder presidential board, recently issued a statement invoking the precautionary approach.[174]

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[171]For a list of these treaties and agreements, see Appendix B, in *Protecting Public Health and the Environment: Implementing the Precautionary Principle* 356 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

[172]Section 15 provides: "In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Rio Declaration on Environmental and Development, June 14, 1992, 31 International Legal Materials 874.

[173]See, e.g., *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, "Introduction: To Foresee and Forestall" 1, 4-7 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

[174]Principle number 12 provides: "We believe: even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." President's Council on Sustainable Development, *Sustainable America: A New Consensus* (1996) (cited in *Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Appendix B" 356 (Carolyn Raffensperger and Joel Tickner, eds. 1999)).

Much work remains to be done to explore and specify the contours of the precautionary principle in various contexts; to identify and make use of opportunities for precautionary approaches within the existing legal structure in the United States; and to consider and advocate appropriate changes to existing laws. There is, nonetheless, a significant and growing body of recent work on which to build. For example, recent work by Carl F. Cranor contributes to efforts along each of these fronts.[175] First, he has sought to clarify and specify several aspects of the principle. He has suggested the clarification, among others, that whereas the lack of scientific certainty may not constitute a *sufficient* reason for refraining from action, it may nonetheless count *among* the reasons for choosing among actions or for refraining from action. Second, he has identified opportunities within existing environmental laws for EPA and other agencies to revisit interpretations that discourage precaution in favor of interpretations that incorporate precaution. He has pointed out that agencies may have latitude under statutes such as TOSCA to require manufacturers to make a greater pre-market showing of safety than is currently required before introducing substances (a) that are chemically similar to those known to be highly toxic or (b) that have certain characteristics, such as a tendency to persist, to bioaccumulate, or to be mutagenic. He has also argued that agencies may have the ability under various statutes to reinterpret the burdens and standards of proof that operate to permit such persistent, bioaccumulative, highly toxic substances to continue to be manufactured or produced as byproducts. Third, he has noted instances in which changes to existing laws might be warranted in order to implement the precautionary principle, and suggested models (e.g., particular aspects of the Swedish approach) for such changes. Other commentators, too, have contributed to the efforts to elaborate the precautionary principle. And an array of local efforts – ranging from community-led efforts to eliminate consumers' contributions to contamination to small businesses' undertakings to reduce their use of toxic inputs and as a result lower their costs – have devised creative ways to implement precaution in practice. EPA should draw on this body of work and support efforts further to develop it.

[175]Carl F. Cranor, *Protecting Public Health and the Environment: Implementing the Precautionary Principle, "*Asymmetric Information, the Precautionary Principle, and Burdens of Proof" 74 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

CHAPTER II: USING EXISTING LEGAL AUTHORITIES

How might EPA's authority under federal environmental and other laws be implemented more effectively to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

RISK REDUCTION STRATEGIES AND PROBLEM POLLUTANTS

This chapter focuses on *risk reduction* strategies – that is, strategies by which agencies look to risk-producers to cleanup, limit, and prevent environmental contamination. In the case of contamination in aquatic ecosystems, these strategies have been developed under a variety of legal authorities, the Clean Water Act prominent among them. In addition to the authority provided by the Clean Water Act, this chapter considers how the authority of other relevant sources of law might be invoked more effectively to sustain healthy ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife. This chapter begins by providing background on the contaminants of greatest concern to affected communities of color, low-income communities, tribes, and other indigenous peoples. Part A considers how EPA might better prevent and reduce contamination in the first place, focusing primarily on efforts under the Clean Water Act and secondarily on efforts under other legal authorities. Part B discusses how EPA might better cleanup and restore those aquatic ecosystems that are already contaminated, again focusing primarily on efforts under the Clean Water Act and secondarily on efforts under other legal authorities.

Access to water of sufficient quality and quantity is vital to tribal, state, and local governments, as well as to environmentalists, developers, industry, and the public including minority and low-income communities. Unquestionably, degradation of water quality threatens not only the viability of aquatic ecosystems, but also human health; subsistence, traditional, cultural, and spiritual practices; economies; sustainability of tribal homelands as contemplated by

federal Indian treaties and other laws;[176] and ultimately all life itself. As Rachel Carson noted in her landmark book *Silent Spring:*

> *Water must also be thought of in terms of the chains of life it supports--from the small-as-dust green cells of the drifting plant plankton, though the minute water fleas to the fishes that strain plankton from the water and are in turn eaten by other fishes or by birds, mink, racoons--in an endless cyclic transfer of materials from life to life. We know that the necessary minerals in the water are so passed from link to link of the food chains. Can we suppose that poisons we introduce into water will not also enter into these cycles of nature?*[177]

Quite simply, poisoning the aquatic food chain ultimately poisons the Earth's entire food web.

The pollutants enumerated below are believed to result in harm to aquatic ecosystems and to pose the greatest risks to the health of people consuming or using fish, aquatic plants and wildlife for traditional, cultural and religious purposes. These pollutants have been identified by federal, tribal, state, and territorial governments as well as by affected groups and independent researchers. While numerous contaminants are potentially a basis for concern,[178] available data indicate that the following contaminants are currently the source of greatest concern.

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[176]Often, pursuant to explicit treaties, tribes bargained with the with federal government for the terms of vast land cessions and the retention of certain other lands for Indian use and occupation. Through express treaty terms or by virtue of retained aboriginal title, tribes reserved every incident of ownership not expressly relinquished to the federal government or abrogated by Congress. United States v. Winans, 198 U.S. 371, 381 (1905). These reserved rights include a recognized right to water sufficient to fulfill the purposes of the reservation. Winters v. United States, 207 U.S. 564, 577 (1908). Among other things, reserved rights have been understood to include water to maintain a permanent homeland, to preserve, produce, or sustain food and other reservation resources, and to maintain the tribe's way of life. See, e.g. Winters v. United States, 143 F. 740, 742 (1906); Colville Confederated Tribes v. Walton, 647 F.2d 42, 49 (1981 9th Cir.), *cert. denied*, 454 U.S. 1092 (1981); Felix S. Cohen, *Handbook of Federal Indian Law* 588-89 (1982 ed.). Frequently, treaties expressly retained a tribe's right to hunt, fish, and gather both on a reservation and off-reservation in all usual and accustomed places. United States v. Winans, 198 U.S. 371, 381 (1905); United States v. Adair, 723 F.2d 1394, 1410, 1417-18 (9th Cir. 1983), *cert. denied*, Oregon v. United States, 467 U.S. 1252 (1984).

[177]Rachel Carson, *Silent Spring* at 46 *(1962).*

[178]There are more than 70,000 chemicals currently in use; yet for the vast majority of these, comprehensive data about human and environmental health effects is sorely lacking. Of these chemicals, those that are highly toxic, that persist in the environment for relatively long periods, and that bioaccumulate are likely to be of particular concern here. The Washington State Department of Ecology, for example, has identified 64 highly toxic, persistent and bioaccumulative contaminants to be screened and prioritized (of these, nine have been slated for immediate action) as part of its initiative to address persistent, bioaccumlative toxins. See Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* (No. 00-03-054) (Dec. 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

Five contaminants – mercury, PCBs, dioxins, DDT, and chlordane – are responsible for the majority of fish and wildlife consumption advisories issued by federal, tribal, state, or territorial governments.[179] These five contaminants are often also among the contaminants of greatest concern according to those affected. For example, David Ludder, of the Legal Environmental Assistance Foundation in Tallahassee reports that affected communities in Florida, Alabama, and Georgia are concerned in the main with these five contaminants and toxaphene.[180] Similarly, the Asian Pacific Environmental Network cites evidence of the presence of these five chemicals and dieldrin at levels of concern for those consuming fish from San Francisco Bay, particularly members of the Laotian community in West Contra Costa County.[181] In addition to these five contaminants, there are approximately 40 different chemicals or chemical groups that give rise to at least one fish and wildlife consumption advisory.[182]

While the existence of a consumption advisory provides one useful gauge as to which contaminants are the basis for concern, there are limitations to this measure. Importantly, the absence of a consumption advisory does not necessarily mean the absence of contamination. In some cases, the necessary assessments of fish and wildlife tissues have not yet been undertaken, often for lack of resources.[183] In other cases, states or tribes might decline to issue fish consumption advisories for a variety of reasons, including economic, health and cultural

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[179]According to the EPA Office of Water, most advisories are triggered by one or more of five primary contaminants: mercury, PCBs, dioxins, DDT, and chlordane. See U.S. Environmental Protection Agency, Office of Water, *Update: National Listing of Fish and Wildlife Advisories* 5 (April 2001) available at www.epa.gov/ost/fish.

[180]Telephone Interview with David Ludder, Legal Environmental Assistance Foundation, Tallahassee, Florida (Aug. 22, 2001). Ludder noted, however, that this concern was premised primarily on the existence of fish consumption advisories and so indicated that this was a preliminary list.

[181]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community of West Contra Costa County, California* App. 1 (1998) (citing San Francisco Bay Regional Water Quality Control Board, Office of Health Hazard Assessment, *Chemical Contamination in Fish from San Francisco Bay: Study Results* (1995)).

[182] These include Arsenic, Cadmium, Chlorinated Benzene, Chlorinated Pesticides, Chromium, Copper, Creosote, Dichloroethane, Gasoline, Hexachlorobutadiene, Industrial & Municipal Discharge, Kepone, Lead, Lindane, Metals, Organo-metallics, PAHs, PBBs, Pentachlorobenzene, Pentachloroethylene, Photomirex, Phthalate Esters, Selenium, Tetrachlorobenzene, Tetrachloroethane, Tetrachloroethylene, Tributyltin, Trichloroethane, Trichloromethane, Vinyl Chloride, VOCs, Zinc.

[183]The trend to date has been for advisories to increase as assessments are completed. Thus, EPA notes that the number of advisories in 2000 represents a 7% increase over the number reported in 1999 and a 124% increase over the number reported in 1993 and observes that "[t]he increase in advisories issued by the states [territories and tribes] generally reflects an increase in the number of assessments of chemical contaminants in fish and wildlife tissues." U.S. Environmental Protection Agency, Office of Water, *Update: National Listing of Fish and Wildlife Advisories* 2 (April 2001) available at www.epa.gov/ost/fish. The need for additional funding to address a shortfall in resources for tissue and environmental assessments is particularly acute for many tribes.

reasons.[184] The Fond du Lac Environmental Program, for example, is in the process of issuing "tribal consumption guidelines."[185] Contrary to "advisories," these guidelines do not warn *against* consumption of fish or wildlife; rather, they provide guidelines for healthy consumption, consistent with tribal traditions and practices.[186] In addition, fish and wildlife advisories generally arise from one exposure scenario (consuming contaminated fish or wildlife), and so do not account for other routes or sources of exposure to those consuming or using fish, aquatic plants and wildlife for traditional, cultural and religious purposes. (e.g., consuming contaminated aquatic plants; consuming or otherwise being exposed to contaminated waters, etc.). And, fish and wildlife advisories focus on the problem of the contamination of fish and wildlife, and leave unaddressed the problem of the availability of fish, aquatic plants, and wildlife for consumption and use.

Thus, in addition to the five contaminants that have given rise to the bulk of fish and wildlife consumption advisories, there are other contaminants of concern. Chief among these are contaminants that are highly toxic, bioaccumulative, and persistent. The Convention on Persistent Organic Pollutants (POPs) initially targets twelve POPs of concern: in addition to PCBs, dioxins, DDT and chlordane, the Convention identifies aldrin, dieldrin, endrin, helptachlor, hexachlorobenzene, mirex, toxaphene, and furans as being of primary concern.[187] The EPA has also identified these same twelve contaminants as part of its Persistent Bioaccumulative Toxin

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[184]See, generally, Stuart Harris, *Impacts of Fish Contamination on Native American Culture* (talk delivered to the Annual National Forum on Contaminants in Fish, May 9, 2001) Neither Wyoming nor Alaska have issued fish or wildlife consumption advisories. Briefing by Rich Healy, U.S. Environmental Protection Agency, Office of Water to Fish Consumption Workgroup (Jun. 26, 2001). But see the recently issued *Statement from the Alaska Division of Public Health*, expressly denouncing the applicability of the general mercury advisories in Alaska and recommending "unrestricted consumption of fish from Alaskan waters" for all, given their independent review of mercury levels in Alaska fish, the known health benefits of fish consumption, and the fact that "the subsistence lifestyle and diet are of great importance to the self-determination, cultural, spiritual, social, and overall health and well being of Alaska Natives." *Mercury and National Fish Advisories Statement* from Alaska Division of Public Health: Recommendations for Fish Consumption in Alaska (Bulletin no. 6) (Jun. 15, 2001) (endorsed by the Alaska Department of Environmental Conservation, Alaska Department of Health and Social Services, Alaska Native Health Board; Alaska Native Science Commission; Alaska Native Tribal Health Consortium; Aleutian/Pribilof Islands Association, Inc.; Institute for Circumpolar Health Studies; University of Alaska Anchorage; North Slope Borough; University of Alaska Fairbanks; and Yukpm Kuskokwim Health Corporation) available at www.epi.hss.state.ak.us/bulletins/docs/b2001_06.htm

[185]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001).

[186]Id. Costa explains that the Fond du Lac Environmental Program is careful *not* to use the word "advisory," because "the last thing we want to do is discourage tribal and band members from eating their native diet, given the serious health effects that we've seen of getting away from a native diet." Id.; see also, Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000).

[187]Convention on Persistent Organic Pollutants (POPs). The United States is a signatory to this Convention, although it awaits the advice and consent of the Senate available at http://www.unece.org/env/lrtap/protocol/98pop.htm.

(PBT) Initiative. Each of these POPs or PBTs is also the source of at least one fish or wildlife consumption advisory.[188]

A variety of pesticides[189] have emerged as particular sources of concern for various affected communities, groups and tribes. The Shoalwater Bay Indian Reservation is concerned with the health of tribal members and the flourishing of the shellfish resource in Willapa Bay, on which members of the tribe depend for commercial, subsistence, and ceremonial uses. Although tribal studies are only recently underway (such that there is no evidence at this time that these pesticides are in fact harming shellfisheries), potential sources of contamination include pesticides such as diazinon, lorsban, and guthion, all of which are used by nearby commercial cranberry bog farmers; carbaryl and glyphosate, applied to the oyster beds and tideflats; and various organochlorine herbicides, sprayed in surrounding and upland areas by the U.S. Forest Service as it seeks to kill "nuisance" species, typically after clear-cut logging.[190] The Louisiana Environmental Action Network is concerned with the high levels of pesticides (among other contaminants), particularly atrazine and cyanazine, that a recent study revealed to be present in the Mississippi River between New Orleans and Baton Rouge: "As would be expected, the pesticides appeared in early spring and persisted throughout the summer, coinciding with the southern and midwestern growing seasons."[191] The study focused on the Mississippi River as a source of drinking water, noting that "[p]esticides presented the largest health hazard, where maximum levels were found to be 60 to 360 times the EPA's Maximum Contamination Level (MCL) for drinking water."[192] Various community and fishing groups have identified 48 pesticides commonly used in the Pacific Northwest that have been determined by either EPA or the United States Geological Survey (USGS) to threaten salmon and salmon habitat.[193]

Lead is a source of concern for those consuming fish from the Spokane River from the Idaho state line to the Seven Mile Bridge in Washington, given recent studies revealing elevated

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[188]See U.S. Environmental Protection Agency, Office of Water, *National Fish and Wildlife Contamination Program.* available at www.epa.gov/ost/fish.

[189]The term "pesticides", as used throughout this report, is meant to encompass all pesticides, including rodenticides, insecticides, herbicides, and fungicides, unless the context indicates a different usage.

[190]E-mail Correspondence with Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001); E-mail Correspondence with Chetana Acharya, Community Outreach and Education Program Manager, NIEHS Center for Ecogenetics and Environmental Health, University of Washington (Oct. 2, 2001); Paul Shukovsky, *Tribe Sounds Alarm Over Fetal Deaths: 13 Pregnancies in 2 years; 1 Baby Survives*, Seattle Post-Intelligencer (Feb. 22, 1999).

[191]Louisiana Environmental Action Network, *Final Report on the Riverkeeper Project* (1998) available at www.leanweb.org/rivkeep.html.

[192]Id.

[193]"Groups Uncover Government Documents Showing Pesticides Can Harm Salmon," (May 7, 2001) available at www.pesticide.org/MSJnewsrelease.html (joint press release by Washington Toxics Coalition; Northwest Coalition for Alternatives to Pesticides; Pacific Coast Federation of Fishermen's Associations; Institute for Fisheries Resources; and Earthjustice Legal Defense Fund in course of litigation against EPA for Endangered Species Act violations).

lead levels (along with elevated levels of other metals), particularly for children (given that lead causes adverse developmental effects) and for those, such as Russian immigrants, who consume the whole fish (given that lead concentrates in the bones and brains of fish).[194] Lead is also a source of concern for the Coeur d'Alene Tribe, given its presence (along with cadmium) in and on water potatoes, a staple of the Coeur d'Alene diet.[195]

Fecal coliform, marine biotoxins (e.g., saxitoxin and domoic acid released by algal blooms), and various other bacterial and viral contaminants are sources of concern for those communities, groups and tribes that rely on shellfish for commercial, subsistence, and/or ceremonial purposes. Thus, these contaminants are a source of concern for tribal resource managers in the Puget Sound and coastal regions of Washington,[196] among them the Shoalwater Tribe,[197] the Suquamish Tribe,[198] the Lower Elwha Klallam Tribe,[199] and the Tulalip Tribes.[200] These contaminants are a source of concern for various communities of color and low-income communities in Southern California.[201] And they are a source of concern for Alaskan Natives. For example, at a southeast regional meeting called to discuss Alaskan Natives' concerns with contaminants in native foods, Dangel Helen, Douglas, observes:

> *There is in North Douglas a development not served by a sewer line. A lot of the mud flats are contaminated. The shellfish aren't good to eat.*[202]

Finally, these and several additional pollutants are of particular concern to one or more affected groups or tribes. For example, the Fond du Lac Environmental Program is concerned with contamination from metals, given the negative effects of several metals (aluminum, cadmium, copper, lead, and zinc, in addition to mercury) on the growth of wild rice.[203] The Tulalip Tribes

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[194]Karen Dorn Steele, *Agencies Warn of Lead in River's Fish; Advisory Targets Consumption of Contaminated Fish Caught in Stretch of Spokane River* A1 The Spokesman Review (Jun. 21, 2000).

[195]Telephone Interview with Marc Stifelman, Environmental Protection Agency (Region X)(Oct. 30, 2001).

[196]See, generally, Northwest Indian Fisheries Commission, *Tribal Shellfish Management* available at www.nwifc.wa.gov/ctnrm/2001_shellfish.htm.

[197]E-mail Correspondence with Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001); E-mail Correspondence with Chetana Acharya, Community Outreach and Education Program Manager, NIEHS Center for Ecogenetics and Environmental Health, University of Washington (Oct. 2, 2001).

[198]Telephone Interview with Jay Zischke, Marine Fish Program Manager, Suquamish Tribe Fisheries Department (Oct. 17, 2001).

[199]Telephone Interview with Russ Busch, Attorney, Legal Counsel for the Lower Elwha Klallam Tribe. (Oct. 4, 2001).

[200]Terry Williams, Commissioner, Tulalip Tribes, Fisheries and Natural Resources (C3G Conference Call, Jul. 20, 2001).

[201]Telephone Interview with Marianne Yamaguchi, Santa Monica Bay Restoration Project.

[202]Alaska Traditional Knowledge and Native Foods Database, *Native Concerns*. Available at www.nativeknowledge.org/db/concerns/asp.

[203]Telephone Interview with Larry Schwarzkopf, Fond du Lac Resources Program (Jul. 12, 2001).

are concerned with sediment and silt loadings, given their contribution to degradation of salmon habitat and, ultimately, to the depletion of the salmon fishery.[204] The various communities that fish the Devil's Swamp, Devil's Swamp Lake, Bayou Baton Rouge, and Capitol Lake in East Baton Rouge Parish face contamination from lead and arsenic, in addition to hexachlorobenzene, hexachloro-1,3-butadiene, PCBs and mercury.[205] The Fourteen Confederated Tribes of the Yakama Indian Nation and the Confederated Tribes of the Umatilla Indian Reservation are concerned with a host of contaminants in the Columbia River, which is "heavily laden with heavy metals from mining, agricultural chemicals from intensive orchards and vineyards, radionuclides from Hanford, runoff from dairy farms, and PCBs from a variety of sources."[206] As Chief Johnny Jackson elaborates:

> *I'm from the Columbia River. I've lived there all my life. I was born and raised there. I'm a fisherman. My family have all been fishermen . . . Many of my people today are dying of cancer as well as diabetes . . . and we talk about cleaning up the area and cleaning up the water and the air, but nobody talks about what is happening up at Hanford and what's happening to the soil and the water at Hanford, and what it's doing to our river. . . We're fishing people. Fishing is our life and fish is our food, but we don't know what they're swimming through when they are going back up that river. I think it's a great injustice until somebody does something about it and cleans that river up and stops pollution at Hanford.*[207]

In addition, there is concern that the health of aquatic ecosystems is being compromised by temperature changes; changes in pH and dissolved oxygen content; introduction of exotic species; dams, diversions, and other alterations; and numerous other affronts.

The discussion below elaborates the health effects and sources of mercury, PCBs, dioxins, DDT, chlordane, and, to a lesser extent, the remaining POPs/PBTs, and other contaminants of concern.

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[204]Terry Williams, Commissioner, Tulalip Tribes, Fisheries and Natural Resources (C3G Conference Call, Jul. 20, 2001).

[205]See Louisiana Department of Health and Hospitals, under cooperative agreement with The Agency for Toxic Substance and Disease Registry, *Public Health Assessment: Petro-Processors of Louisiana Incorporate Baton Rouge, East Baton Rouge Parish, Louisiana* (Jan. 16, 1996). Available at atsdr1.atsdr.cdc.gov/HAC/PHA/petro/pet_toc.htm.

[206]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish*, "Tribal Technical Issues in Risk Reduction Through Fish Advisories" 17 (1999).

[207]Chief Johnny Jackson, *Comment to the National Environmental Justice Advisory Council* Vol III-4-6 (Annual meeting transcript) (Dec. 4, 2001).

Mercury

Background

Mercury is responsible, at least in part, for nearly 79% of all fish and shellfish advisories issued in the United States; as of December, 2000, it was the basis for 2,242 advisories issued by 41 states, territories or tribes.[208] Thirteen states have issued statewide advisories for mercury in the freshwater lakes and/or rivers within their boundaries; another nine states have issued statewide mercury advisories for their coastal marine waters.[209] Mercury is also responsible for the first ever issuance of a national fish consumption advisory: in January, 2001, the EPA (together with ATSDR) and the FDA each independently issued advisories cautioning various populations against consuming fish due to mercury contamination.[210]

Mercury has been identified as a major pollutant of concern by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) and the Fond du Lac Environmental Program, given its deleterious effects on both fish and wild rice.[211] Mercury has been identified as a pollutant of concern by the St. Regis Mohawk Tribe Environment Division (although of less significance than PCBs).[212] Hawaii's Thousand Friends observes that mercury has been identified as the major contaminant in fish eaten in Hawai'i.[213] Mercury has been identified as a major concern by the Grand Cal Task Force, given its significant contribution to the contamination of the Grand Calumet River and the Indian Harbor Ship Canal, where "virtually all fish tested in Indiana show levels of mercury and all streams are considered impaired."[214] Mercury has been identified as a source of significant concern in Louisiana, particularly in the heavily contaminated parishes along the Mississippi River between New Orleans and Baton Rouge by the Louisiana Environmental

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[208]See U.S. Environmental Protection Agency, Office of Water, *Mercury Update: Impact on Fish Advisories* 4 (June 2001) available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter "EPA. Mercury Fact Sheet"]

[209]Id.

[210]U.S. Environmental Protection Agency advisories are available at www.epa.gov/ost/fish. U.S. Food and Drug Administration advisories are available at www.cfsan.fda.gov/~dms/admehg.html. Briefing by Rich Healy, U.S. Environmental Protection Agency, Office of Water to Fish Consumption Workgroup (Jun. 26, 2001).

[211]Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org. Telephone Interview with Larry Schwarzkopf, Fond du Lac Resources Program (Jul. 12, 2001).

[212]Telephone Interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (Jul. 12, 2001).

[213]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[214]Telephone Interview with Bowden Quinn, Executive Director, Grand Cal Task Force (Oct. 10, 2001); Grand Calumet Task Force, *Mercury and the Grand Calumet River* available at www.igc.apc.org/gctf/newsletter002.htm..

Action Network and by Dr. Barry Kohl, Department of Geology, Tulane University.[215] Mercury is a source of concern for the Passamaquoddy tribe, who rely on both saltwater and freshwater fish, given that all lakes in the state of Maine are under a state-issued fish advisory for mercury.[216] At an interior regional meeting called to discuss Alaskan Natives' concerns with contaminants in native foods, Orville Huntington, Huslia, observes:

> *Around home, I think it's an accumulation. All those poisons dumped in the river are in the fish and they accumulate in your body. . . . The pike around Hog River I won't eat anymore because there's too much mercury in there.*[217]

Health Effects[218]

Methylmercury is rapidly and nearly completely absorbed by humans from the gastrointestinal tract. It readily crosses the placental and blood/brain barriers. The National Research Council (NRC) of the National Academy of Sciences observes: "[Methylmercury (MeHg)] is highly toxic. Exposure to MeHg can result in adverse effects in several organ systems throughout the life span of humans and animals. There are extensive data on the effects of MeHg on the development of the brain (neurodevelopmental effects) in humans and animals. . . . Effects [at high doses] included mental retardation, cerebral palsy, deafness, blindness, and dysarthria in individuals exposed in utero and sensory and motor impairment in exposed adults. Chronic, low-dose prenatal MeHg exposure from maternal consumption of fish has been associated with more subtle end points of neurotoxicity in children. Those end points include poor performance on neurobehavioral tests, particularly on tests of attention, fine-motor function, language, visual-spatial abilities (e.g., drawing), and verbal memory."[219] There is also evidence of adverse effects on developing and adult cardiovascular systems in both humans and animals.[220] Some studies have demonstrated an association between methylmercury and cancer, but, according to the NRC, these studies are inconclusive.[221] EPA concurs and does not regulate methylmercury as a carcinogen.

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[215]Telephone Interview with Marylee Orr, Louisiana Environmental Action Network (Oct. 17, 2001); Telephone Interview with Dr. Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001).

[216]See Paul Kuehnert, *Health Status and Needs Assessment of Native Americans in Maine: Final Report* (Jan. 15, 2000) available at www.state.me.us/dhs/boh/files/nar/nar.htm.. U.S. Environmental Protection Agency fish advisories available at www.epa.gov/ost/fish.

[217]Alaska Traditional Knowledge and Native Foods Database, *Native Concerns* available at www.nativeknowledge.org/db/concerns.asp.

[218]Unless otherwise noted, health effects information is taken from the EPA Mercury Fact Sheet.

[219]National Research Council, National Academy of Sciences, *Toxicological Effects of Methymercury* 4 (2000).

[220]Id.

[221]Id.

Sources of Mercury in the Environment[222]

Overview: Nearly 80% of the mercury contamination in surface waters comes from mercury emissions to the air. Mercury contamination also comes from direct discharges to the water, from releases to soils, and from naturally occurring mercury in the environment.

Mercury exists in the environment as elemental mercury (metallic mercury), and in inorganic and organic mercury compounds (primarily methylmercury).

Air: Mercury is released to the air by solid waste incineration and fossil fuel combustion, especially coal-fired power plants (in combination, these sources account for approximately 87% of mercury emissions in the United States); mining and smelting operations; industrial operations involving the use of mercury such as chlor-alkali production facilities; cement production; medical waste incineration (accounts for approximately 10% of mercury emissions in the United States),[223] and non-industrial combustion (e.g., wildfires and open burning).

Water/Sediments: Mercury is released to surface waters from naturally occurring mercury in rocks and from industrial processes, including pulp and paper mills, leather tanning, electroplating, and chemical manufacturing, and from some wastewater treatment facilities. Mercury emissions to the air are an important indirect source of mercury in surface waters: mercury is deposited from rain and other processes to water surfaces and to soils. Sediments contaminated with mercury also contribute mercury to surface waters upon being disturbed (e.g., by flooding or dredging).

Soils: Mercury is released to soils through the direct application of fertilizers, fungicides, and sludge or "recycled" industrial waste containing mercury to soils and crops. Mercury is also released to soils when solid waste, including batteries and thermometers, and municipal incinerator ash is disposed in landfills.

Notes

Unlike many other contaminants that are the source of fish consumption advisories, mercury does not accumulate primarily in the fatty tissue of fish but in the muscle (i.e., the portion of fish that comprises a fillet). Thus, skinning and trimming the fish do not reduce the amount of mercury in a fillet, nor is mercury removed by cooking processes.[224]

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[222]Unless otherwise noted, sources information is taken from the EPA Mercury Fact Sheet.

[223]U.S. Environmental Protection Agency, *Mercury Study Report to Congress*, "Vol. 1: Executive Summary" (No. EPA-452/R-97-003) (December 1997) available at www.epa.gov/oar/mercury.html.

[224]U.S. Environmental Protection Agency Mercury Fact Sheet; Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org.

PCBs[225]

Background

PCBs are responsible, at least in part, for nearly 27% of all fish and shellfish advisories issued in the United States; as of December, 1998, PCBs were the basis for 679 advisories issued by 37 states, territories or tribes.[226] Three states have issued statewide advisories for PCBs in the freshwater lakes and/or rivers within their boundaries; another six states have issued statewide PCBs advisories for their coastal marine waters.[227]

PCBs have been identified as a major pollutant of concern by the St. Regis Mohawk Tribe Environment Division.[228] PCBs have been cited by the Village of Savoonga and other Alaska Native villages as "[posing] special problems for Alaska Tribes who live near PCB contaminated former U.S. military sites."[229] PCBs have been identified by the Arbor Hill Environmental Justice Corporation as impacting the health of inner city communities, many of whose members subsistence fish along the Hudson River in upstate New York.[230] PCBs have been cited as a source of significant "community concern" given the number of anglers fishing along the contaminated Lower Fox River in the Green Bay area of Wisconsin (including Caucasians, Hmong, Laotian, Native American, and African-American anglers).[231] PCBs have been identified as among the issues of concern in Alabama by Project AWAKE, given that recent fish tissue monitoring by the Alabama Department of Environmental Management has revealed levels of PCBS exceeding FDA guidelines in striped bass from upper Lay Reservoir and channel catfish from upper Neely Henry Reservoir.[232]

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[225]"PCBs" is a shorthand for a group of 209 individual cogeners – members of a group of structurally similar chemicals with different configurations. PCBs generally occur as a complex mixture of some assortment of these cogeners.

[226]U.S. Environmental Protection Agency, Office of Water, *Polychlorinated Biphenyls (PCBs) Update: Impact on Fish Advisories* 3-4 (September 1999) available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter EPA PCBs Fact Sheet]

[227]Id.

[228]Telephone Interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (Jul. 12, 2001).

[229]See, e.g., Native Village of Savoonga, Resolution # 00-10.

[230]*"Fishing for Justice – May 13, 2000 Island Creek Park on the Hudson River"* available at www.ejcr.cau.edu/fishingforjust.htm (citing Arbor Hill Environmental Justice Corporation President Aaron Mair's call for increased awareness of the issue and for "GE to do the right thing and clean up the PCB's they dumped into the River").

[231]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[232]Facsimile Communication, Daisy Carter, Project AWAKE (Oct. 25, 2001); Alabama Department of Environmental Management, *ADEM Announces Results of Fiscal Year 2001 Fish Tissue Monitoring Effort* (Apr. 25, 2001) available at www.adem.state.al.us/EduInfo/PressReleases/4fish01.htm..

Health Effects[233]

PCBs have been classified by EPA as "probable human carcinogens." Studies have suggested that PCBs may play a role in inducing breast cancer. Studies have linked PCBs to increased risk of several other cancers as well, including: liver, biliary tract, gall bladder, gastrointestinal tract, pancreas, melanoma, and non-Hodgkin's lymphoma. PCBs may also cause non-carcinogenic effects, including reproductive effects and developmental effects (primarily to the nervous system). PCBs tend to accumulate in the human body in the liver, adipose tissue (fat), skin, and breast milk; PCBs have also been found in plasma, follicular fluid, and sperm fluid. Fetuses may be exposed to PCBs in utero, and babies may be exposed to PCBs during breastfeeding. According to EPA, "[s]ome human studies have suggested that PCB exposure may cause adverse effects in children and developing fetuses while other studies have not shown effects. Reported effects include lower IQ scores, low birth weight, and lower behavior assessment scores."[234]

Sources of PCBs in the Environment[235]

Overview: The manufacture of PCBs was banned in the United States in 1979. However, items containing PCBs that were still in service at the time of the ban were "grandfathered" in and not required to be removed from use; some remain in use today. For example, electrical transformers containing PCBs are still in use and have a life expectancy of 30 years. The major source of PCBs in the environment is from past releases that have not been cleaned up; most PCBs are contained in sediments and are released from sediments over long periods of time to the waters, air, and soil.

There are no naturally occurring sources of PCBs; all PCBs in the environment are therefore of human origin.

Air: PCBs from past releases to soils and surface waters evaporate or volatilize to the air over long periods of time. From the air, they are redeposited back to the land and to surface waters.

Water/Sediments: Most PCBs from past releases are contained in sediments. PCBs are extremely persistent in the environment: they have half-lives in sediments ranging from months to years; they have very low solubility in water and low volatility. Because of these characteristics, PCBs continue to be released from sediments to surface waters over long periods of time. PCBs may also be mobilized to surface waters if they are disturbed (e.g. flooding, dredging). In addition to evaporation or revolatization, PCBs may be transferred from surface waters by adsorption to sediments.

[233]Unless otherwise noted, health effects information is taken from EPA PCBs Fact Sheet.
[234]EPA PCBs Fact Sheet at 5.
[235]Unless noted, sources information is taken from EPA PCBs Fact Sheet.

Soils: PCBs from past releases may also be contained in soils. PCBs have long half-lives in soils and are released over long periods by evaporation or volatilization to air, and are in turn redeposited to soils and surface waters.

Dioxins[236]

Background

Dioxins/furans are responsible, at least in part, for approximately 2% of all fish and shellfish advisories issued in the United States; as of December, 1998, dioxins/furans were the basis for 59 advisories issued by 19 states, territories or tribes.[237] Three states, Maine, New Jersey, and New York, have issued statewide dioxins/furans advisories for their coastal marine waters.[238] Dioxins are the source of advisories on all of the Great Lakes.[239] Dioxins are also the source of advisories for the Potomac River and numerous National Estuary Program and National Estuarine Research Reserve System sites, including Casco Bay (ME), Wells (ME), Long Island Sound, Peconic Bay (NY), the Hudson River, New York/New Jersey Harbor, Barnegat Bay (NJ), Jacques Cousteau-Great Bay and Mullica River (NJ), Delware Estuary, Albemarle-Pamlico Sounds (NC), Galveston Bay (TX), Puget Sound (WA), and the Columbia River.[240]

Dioxins are a major source of concern for the Penobscot Indian Nation.[241] Although recent changes in rules affecting pulp and paper mills in Maine that use chlorine in their bleaching process (requiring a switch from the use of elemental chlorine to chlorine dioxide) may be reducing dioxin levels in the Penobscot River and sediments, the use of chlorine dioxide still leads to discharges that result in small amounts of dioxins in the water, and historical discharges, among

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[236]"Dioxins" is a shorthand for a group of synthetic organic chemicals, comprised of 210 structurally related chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs). This group of compounds ranges in toxicity, with 2,3,7,8-TCDD being the most toxic.

[237]U.S. Environmental Protection Agency, Office of Water, *Polychlorinated Dibenzo-p-dioxins and Related Compounds Update: Impact of Fish Advisories* 3 (Sept. 1999). Available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter EPA Dioxins Fact Sheet]

[238]Id.; U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[239]Id.

[240]Id.

[241]Dawn Gagnon, *Spiritual Keepers of the Penobscot*, Bangor Daily News (Oct. 6, 1995); Andrew Kekacs, *Penobscots Oppose Mill Permit; Any Discharge of Dioxin in River Detrimental, Tribal Member Says*, Bangor Daily News (Mar. 4, 1997); Mary Anne Lagasse, *Indians, People's Alliance Take Fish Advisories to Task; King Critics Say Dioxin Problem Downplayed*, Bangor Daily News (Apr. 2, 1997); Dieter Bradbury, *Contamination in Fish Weakens Cultural Link for Maine Tribe: Catching and Eating Fish is a Tradition No Longer Passed on to Many Penobscot Children*, Portland Press Herald (Sept. 30, 1997).

other sources, still likely contribute to the presence of dioxins in the sediments.[242] Given dioxins' persistence in the environment, its propensity to bioaccumulate (concentrations of dioxins in aquatic organisms may be hundreds to thousands of times higher than the concentrations found in surrounding waters or sediments), and its extreme toxicity even small amounts of discharge are reason for the Penobscot Nation Department of Natural Resources to be concerned.[243]

Health Effects[244]

Studies suggest a wide variety of adverse effects from dioxin, although there is still debate about the extent of these effects in humans. Among these are adverse effects on hepatic, gastrointestinal, hematological, dermal, endocrine, immunological, neurological, reproductive, and developmental systems. A recent report concluded more than a decade of study on dioxin's cancer-causing potential, identifying TCDD as a "human carcinogen" and the "mixture of dioxins to which people are exposed" as a "likely human carcinogen."[245] Even very small amounts of dioxins may be toxic to humans.

Sources of Dioxins in the Environment[246]

Overview: Dioxins in the environment are primarily the unintended by-products of industrial and other processes that use or burn chlorine. The major source of dioxins in the environment is incineration. Other sources of dioxins include direct discharges to water from industrial processes, resuspension of contaminated sediments, and releases from soils.

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[242]As a result of recent regulations, EPA projects considerable reductions in *discharges* of dioxins to waters; however, there is little or no data characterizing the *levels* of dioxins in the waters and sediments, resulting from historic discharges and the cycling of dioxins through the environment. See, generally, U.S. Environmental Protection Agency, *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* (Draft, 2000)[hereinafter "Draft Dioxin Reassessment"]; U.S. Environmental Protection Agency, Office of Research and Development, *Information Sheet 4, Dioxin: Summary of Major EPA Control Efforts* (June 12, 2000); Telephone Interview with Dwain Winters, U.S. Environmental Protection Agency (March 29, 2002). See, also, Andrew Kekacs, *Penobscots Oppose Mill Permit; Any Discharge of Dioxin in River Detrimental, Tribal Member Says*, Bangor Daily News (Mar. 4, 1997); Mary Anne Lagasse, *Indians, People's Alliance Take Fish Advisories to Task; King Critics Say Dioxin Problem Downplayed*, Bangor Daily News (Apr. 2, 1997).

[243]See, generally, Draft Dioxin Reassessment; accord, Dawn Gagnon, *Spiritual Keepers of the Penobscot*, Bangor Daily News (Oct. 6, 1995) (quoting Director John Banks: "Dioxin is suspected of being the most toxic compound that the EPA has ever evaluated.").

[244]Unless otherwise noted, health effects information is taken from EPA Dioxins Fact Sheet.

[245]National Institute of Health, *Ninth Report on Carcinogens*. The National Institute of Health is a part of the U.S. Department of Health and Human Services. Available at ehis.niehs.nih.gov/roc/ninth/rahc/tcddsticker.pdf. Dioxin was listed as "Known to be a Human Carcinogen in the January 2001 addendum to the Ninth Report on Carcinogens." Id. See, also, Draft Dioxin Reassessment.

[246]Unless otherwise noted, sources information is taken from EPA Dioxins Fact Sheet.

Air: Most dioxins are introduced into the environment as emissions to the air. Incineration is a major source of dioxins (including incineration of municipal solid waste, medical waste, sewage sludge, and hazardous waste), although the relative contribution of incineration is projected to decline over the next several years, as regulations require reductions.[247] Dioxins are also emitted from backyard burning, metal smelting, cement kilns, land-applied sewage sludge, residential and industrial wood burning, coal-fired utilities, diesel trucks, and pulp and paper mills.[248] Dioxins released into the air may be suspended for a long time and travel great distances before being deposited to soils and surface waters.

Water/Sediments: Dioxins are discharged directly to surface waters from pulp and paper mills that use chlorine compounds in bleaching processes.[249] Dioxins are also discharged to waters from the industrial production of chlorinated organic chemicals, such as chlorinated phenols. Most dioxins are contained in sediments, where they persist for long periods because of half-lives ranging from months to years. Particles resuspended from sediments to surface waters are an important source of dioxin in surface waters.

Soils: Dioxins enter the soils when industrial wastes and municipal sludge contaminated with dioxins are applied as fertilizer to crops or grazing lands. Dioxins that have been emitted to the air are also deposited to soils. Dioxins in the soils may in turn be released into surface waters through run-off or leaching.

Chlordane[250]

Background

Chlordane is responsible for advisories on Lake Superior, Lake Michigan, and Lake Huron.[251] It is the source of advisories for several National Estuary Program and National Estuarine Research Reserve System sites, including the Potomac, Black and Anacostia Rivers (all of which connect to Chesapeake Bay).[252] The Baltimore Harbor is under advisory for chlordane, as is the New York/New Jersey Harbor, Barnegat Bay (NJ), Jacques Cousteau-Great Bay and

[247]U.S. Environmental Protection Agency, *Inventory of Sources of Dioxin in the United States* (1998; updated 2000)(Draft); accord, Chlorine Chemistry Council (untitled and undated fact sheet)

[248]Id.

[249]Id.

[250]"Chlordane" is a manufactured mixture of more than 26 compounds. Chlordane is used here to refer to chlordane and to the multiple breakdown products of chlordane, which themselves are persistent and bioaccumulative.

[251]U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[252]Id.

Mullica River (NJ), and Delaware Estuary.[253] Chlordane is the source of a statewide advisory for lakes and rivers in New York[254].

According to a recent study of the Greenpoint/Williamsburg community in the Borough of Brooklyn in New York City, fish are a major source of chlordane exposure for African-Americans and Hasidic Jews, and shellfish are a major source of chlordane exposure for Hispanics/Caribbean Americans.[255]

Health Effects

Chlordane is associated with cancer in some but not all studies; it is classified by EPA as a probable human carcinogen.[256] Chlordane also has adverse effects on the central nervous system, the digestive system, and the liver at higher doses. Chlordane metabolites may reside in human breast milk, and may be passed on to infants through breastfeeding.

Sources of Chlordane in the Environment

Overview: The manufacture and use of chlordane has been banned in the United States since 1988. It was once used as an agricultural pesticide (on crops including corn and citrus), and on home lawns and gardens. One of chlordane's most common uses was for treatment of termites. Once chlordane is released into the environment, it may evaporate or it may bind itself to soil particles (particularly in the upper layers of soil) or to sediments in water. The breakdown of chlordane once it is bound to soil particles or sediment is very slow. According to the National Resources Defense Council, "[s]o persistent is the residue, that a recent study showed that detectable levels of chlordane are still present in some food grown in the United States, even though it has been decades since chlordane was used in agriculture."[257]

Air: Chlordane from past applications to agricultural soils, soils near houses treated for termite control, or soils near waste sites and landfills may be present in the air in small amounts.

Water/Sediments: Chlordane from past releases is contained in surface waters and especially in sediments. It is highly persistent, and may be present in sediments for years.

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[253]Id.

[254]Id.

[255]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-19 (1999).

[256]Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 44 (No. 00-03-054) (Dec. 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[257]Natural Resources Defense Council, *Healthy Milk, Healthy Baby: Chemical Pollution in Mother's Milk; Chemicals: Chlordane* available at www.nrdc.org/breastmilk/chem1.asp.

Soils: Chlordane from past releases is also contained in soils, where it is highly persistent. Chlordane has been found in some cases to be present in soil up to 20 years after application.[258]

DDT[259]

Background

DDT is the source of a statewide advisory for lakes and rivers in New York, as well as advisories in California, Texas, and Maine.[260] The total number of advisories for DDT increased from 40 in 1999 to 44 in 2000.[261]

DDT is a contaminant of concern for the Fourteen Confederated Tribes of the Yakama Nation, given that the Yakama River, which forms a reservation boundary and is a tributary to the Columbia River, is contaminated with DDT and currently under a state-issued advisory.[262]

Health Effects

DDT, together with DDD and DDE, is classified by EPA as a probable human carcinogen. DDT may cause damage to the central nervous system at high doses, leading to tremors and seizures.[263]

Sources of DDT in the Environment

Overview: DDT was one of the most widely used pesticides in the United States from 1946 to 1972. Its use has been banned in the United States, except for "public health emergencies."[264]

Other Persistent Organic Pollutants (POPs)/Persistent Bioaccumulative Toxins (PBTs)

Several other contaminants are sources of concern because they are bioaccumulative and persistent. That is, these contaminants accumulate in aquatic organisms at concentrations many times higher than the concentrations present in surrounding waters. They also persist for long

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[258]Id.

[259]"DDT' here refers not only to DDT, but also to its breakdown products, DDD and DDE.

[260]U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[261]Id.

[262]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish*, "Tribal Technical Issues in Risk Reduction Through Fish Advisories" 17 (1999).

[263]Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 44-45 (No. 00-03-054) (December 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[264]Id.

periods of time in the environment, particularly in the sediments where bottom-dwelling aquatic species can accumulate them and pass them up the food chain to fish, other predatory species, and, ultimately, humans. The contaminants are also highly toxic. In addition to the five contaminants canvassed above, the Convention on Persistent Organic Pollutants and the EPA's Persistent Bioaccumulative Toxin Initiative each include among the POPs or PBTs of concern the following seven pesticides: Aldrin, Dieldrin, Endrin, Heptachlor, Hexachlorobenzene, Mirex, and Toxaphene;[265] and the industrial chemical Hexachlorobenzene. Note that this list is likely not exhaustive; these contaminants are merely those that have been identified as being of the very highest priority. Some groups have argued, for example, the lead belongs on this list, given that it is persistent, it builds up in bone tissue, it is toxic even in minute concentrations, and its effects on exposed children are particularly troubling.[266] In some cases, governments and agencies are in the process of studying whether additions are appropriate. The Washington State Department of Ecology, for example, has identified more than 60 additional candidates for screening and prioritization, based on initial evaluations demonstrating their persistence, propensity to bioaccumulate and toxicity.[267]

Exposure to these POPs or PBTs has been linked to a wide range of toxic effects in fish, wildlife, and humans, including cancer, adverse developmental effects and adverse effects on the nervous, reproductive, immune and endocrine systems.[268] POPs or PBTs are contaminants of concern for many affected communities, groups and tribes.[269] The Indigenous Environmental Network, for example, explains some of their concerns:

> *Indigenous Peoples have special cultural and spiritual relationships to traditional foods that create increased consumption patterns compared to non-Indigenous populations.*

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[265]See U.S. Environmental Protection Agency, Office of Water, *Toxaphene Update: Impact on Fish Advisories* (September 1999) available at www.epa.gov/ost/fish/chemfacts.html.

[266]Washington Toxics Coalition, *Comments on Ecology's Draft Strategy Addressing Persistent Pollutants* available at www.watoxics.org/uaPBTcomments.htm.

[267]Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 60-61 (No. 00-03-054) (December 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[268]Id. at 5.

[269]Numerous tribes and indigenous peoples' organizations passed resolutions to this effect during the negotiating process for the International Treaty on Persistent Organic Pollutants, urging the "elimination, phase-out, or reduction wit the aim to eliminate toxic substances that are persistent and bioaccumulate in the environment and in the bodies of American Indian/Alaska Native populations." See, e.g., The National Congress of American Indians, *Resolution # PSC-99-054*; Great Lakes Indian Fish & Wildlife Commission, *Resolution No. 8-16-89-01*; Alaska Inter-tribal Council, *Resolution 99-27*; Qawalangin Tribe of Unalaska, *Resolution # 00-05*; Tanana Chiefs Conference, Inc., *Resolution No. 2000-38*; Traditional Council of Togiak, *Resolution 00-30*; Native Village of Wales, *Resolution 00-09*; Algaaciq Tribal Government, *Resolution 00-19*; Native Village of Fort Yukon, *Resolution No. 00-21*; Native Village of Elim, *Resolution 00-11*; Chickaloon Village Traditional Council, *Resolution # 000801-01*; Bill Moore's Slough Elder's Council, *Resolution # 2000-09*; Chenega I.R.A. Council, *Resolution # 00-26*; Native Village of Savoonga, *Resolution # 00-10.*

Unfortunately, the main way POPs enter our bodies is through food. POPs have been found in eagles, cormorants, ducks, geese, caribou, reindeer, raccoons, rabbits, quail, deer, moose, bison, turtles, crocodiles, sheep, cows, polar bears, seals, whales, and fish. . . . Advisories prohibiting or discouraging the consumption of traditional foods affect Indigenous Peoples' right to practice our cultural and spiritual ways.[270]

Similarly, Faith Gemmill, Arctic Village, Alaska, explains:

I speak before you today as a young Gwichin woman with an infant daughter and with a deep commitment to ensuring her future and the continuation of the Indigenous way of life. . . . One cannot separate the health of the environment from the health of our peoples. . . . As Indigenous peoples we are greatly concerned when we realize evidence which suggests that women, infants, and children are very vulnerable to POPs. This threatens the very existence of our peoples and cultures. The multigenerational impacts threaten our hope of healthy, thriving, and productive future generations.[271]

A. PREVENTION AND REDUCTION

How might EPA better prevent contamination in the first place in order to protect the aquatic ecosystems and the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes?

Efforts to prevent or reduce contamination in the first place are vital to protecting the health of communities of color, low-income communities, tribes, and other indigenous peoples. These efforts are especially important given that members of these groups are among the most highly-exposed to environmental contaminants (as discussed in Chapter One) and given that for many of these groups, risk avoidance – eating less fish, using a different preparation method, fishing in a different location – is simply not a realistic or culturally appropriate option (as will be discussed in Chapter Three). Thus, these groups will disproportionately bear the burden of sources of ongoing contamination that are not adequately addressed. Prevention and reduction efforts will need to be directed at those contaminants of concern that are still being used or produced, including mercury, dioxins, and others.

[270]Indigenous Environmental Network, *Drum Beat for Mother Earth: Persistent Organic Pollutants (POPs)* available at www.ienearth/org/pops_threat-p2.html.

[271]Faith Gemmill, Gwichin, Arctic Village, Alaska, Oral and Written Testimony at the Third Session of the United Nations Environment program Intergovernmental Negotiating Committee for and International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants (POPs) (Sept. 8, 1999).

1. Clean Water Act

Enacted in 1972, the Clean Water Act[272] (CWA) and its complex implementing regulations and guidelines focus on protecting public natural resources and welfare and improving water quality through the control of discharges of pollutants into national waters. The statutory objective of the CWA is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[273] As stated in the CWA, national goals provide that: (1) the discharge of pollution into navigable waters be eliminated by 1985; (2) an interim goal of water quality that provides for the protection and propagation of fish, shellfish, and wildlife and for recreation be achieved by July 1, 1983; (3) the discharge of toxic pollutants in toxic amounts be prohibited; (4) federal financial assistance be provided to construct publicly owned waste treatment works; (5) areawide waste treatment management planning processes be developed to assure adequate control of pollution sources in each state; (6) major research and demonstration efforts be undertaken to eliminate the discharge of pollutants into national waters; and (7) programs to control point and nonpoint discharges be developed expeditiously to meet the goals of the CWA.[274] Water quality standards are key to implementing the framework of the CWA and are necessary for regulatory and enforcement actions to protect water quality where existing controls like technology-based limitations may be insufficient to maintain or restore water quality.

Generally, the CWA requires that the U.S. Environmental Protection Agency (EPA) set standards for various sources of pollution, to enforce those standards through permitting systems, and, where a state so requests to delegate primary enforcement authority to that state. As originally enacted, the CWA, as well as many other federal environmental laws, did not mention tribes or Indian reservations or provide for direct participation by tribal governments. Because the jurisdictional rules applicable to Indian country left EPA unable to pursue its usual practice of delegating primary enforcement responsibility to states, EPA was forced to develop special rules and practices concerning environmental regulation on Indian reservations and the role to be played by tribal governments. In November 1984, EPA issued the EPA Policy for the Administration of Environmental Programs on Indian Reservations (Indian Policy) to address tribal participation and the unique circumstances presented by Indian country.[275] Each EPA Administrator, including most recently Administrator Christine Todd Whitman, has reaffirmed the principles enumerated in the Indian Policy.[276] In 1987, Congress amended the CWA to allow federally-recognized tribes to be treated as states for certain purposes under the Act. As of

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[272]33 U.S.C. §§ 1251-1387.

[273]33 U.S.C. § 1251(a).

[274]33 U.S.C. § 1251(a).

[275]U.S. Environmental Protection Agency, *Policy for the Administration of Environmental Programs on Indian Reservations* (Nov. 8, 1984).

[276]On July 11, 2001, Administrator Whitman issued a Memorandum on EPA Indian Policy to all EPA Employees recognizing the right of tribes as sovereign governments to self-determination and acknowledging the federal government's trust responsibility owed to tribes. The Administrator also reaffirmed EPA's commitment to the long-established Indian Policy and "in building a stronger partnership with tribal governments to protect the human health and environment of Indian communities."

December 2000, only eighteen tribes (of the approximately 565 total federally recognized tribes) have received treatment as a state status and adopted standards for purposes of the water quality standards effective under the CWA, and EPA has promulgated standards for one additional tribe.[277] As a result, a large gap exists in water quality standards coverage in Indian country. For example, tribal lands lacking approved water quality standards constitute an area approximating the size of all of New England plus New Jersey and as many reservation residents as the populations of Wyoming, Alaska, and Vermont combined.[278] Where tribes have not yet received treatment as a state status and assumed responsibility for CWA on their reservations and lands, EPA is responsible for implementing and enforcing the CWA within Indian country pursuant to the CWA and the federal trust responsibility owed to tribes.[279] Toward that end, EPA recently has been considering a proposal to develop core federal water quality standards for certain waters in Indian country that do not have water quality standards under the CWA.[280] The Core Standards currently call for a four-part hierarchy for selecting a fish consumption rate for use in setting water quality standards in Indian country. This hierarchy sets up a preference for using "the results of any existing fish consumption surveys of local Indian country watersheds to establish fish intake provisions that are representative of the populations being addressed."[281] While this preference for local data is appropriate, the reality, as discussed in Chapter 1, is that many tribes have not gathered this data – often for lack of resources. In the absence of such data, the proposed Core Standards would look to EPA's default fish consumption rates, and perhaps to a rate as low as 17.5 grams/day.[282] As noted in Chapter 1, this number grossly underestimates consumption for many tribes.

As discussed in Chapter One, EPA has recently updated its default values for fish consumption rates, as part of its revisions to the Ambient Water Quality Criteria Methodology for the Protection of Human Health, pursuant to CWA 304(a). The EPA has indicated that the revised values will likely guide water quality standard-setting and policy for years to come (the former values were in place for roughly 20 years). This may be problematic from the perspective of affected groups whose members consume fish at the highest levels, and whose practices are therefore not adequately accounted for or protected by even the revised AWQC Methodology. Moreover, as noted in Chapter One, to the extent that the revised AWQC Methodology

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[277] *EPA Fact Sheet: Water Quality Standards for Indian Country* (April 2001) (available online at http://www.epa.gov/ost/standards/tribal/tribalfact.html). Note, we need the Office of Water or the AIEO to verify this figure officially at the time of the report.

[278] Id.

[279] The courts have long recognized that the United States has a trust relationship with Indian tribes. See, e.g. Worcester v. Georgia, 31 U.S. 515 (1832); Cherokee Nation v. Georgia, 30 U.S. 1 (1831).

[280] On January 19, 2001, EPA's Administrator signed the proposed Federal Water Quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards, which were withdrawn from the Federal Register on January 20, 2001 to allow regulatory review by the Administrator. 66 Fed. Reg. 7701 (Jan. 24, 2001).

[281] U.S. Environmental Protection Agency, Office of Water, *Federal Water quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards* (unofficial prepublication copy, Jan.19, 2001) available at www.epa.gov/ost/standards/tribal/ .

[282] Id. at 17.

recommends that states and tribes prefer local data, EPA will need to provide funding to enable this preference to exist as a meaningful option. And, to the extent that EPA's revised AWQC Methodology proposes that "acceptable" risk for the general population be defined as an incremental cancer risk of 1 in 100,000 to 1 in 1,000,000, but deems a greater level of risk "acceptable" for "more highly exposed subgroups," including subsistence fishers, i.e., up to 1 in 10,000, this is a troubling potential source of environmental injustice.[283] EPA should decline to exercise this option to provide lower levels of protection to communities of color, low-income communities, tribes, and other indigenous peoples as it sets and approves water quality standards. Additionally, as a general matter, EPA needs to take into account the differences in fish consumption rates, practices, and context, as outlined in Chapter One, as it undertakes triennial reviews of state and tribal water quality standards under CWA 303(c)(1).

Additionally, the CWA provides some authority for addressing non-point sources of water pollution (including through TMDLs). Given that non-point sources are major contributors of numerous contaminants of concern, this authority should be interpreted broadly to enable EPA to prevent and reduce contamination from these sources. Non-point sources, moreover, are of particular concern to some affected groups. In Hawai'i, for example, there is a need for further studies on the effect of non-point sources on fish and other aquatic resources on which Native Hawaiians and other communities of color in Hawai'i depend, and for more extensive efforts to prevent and reduce pollution from these sources. As explained by Hawaii's Thousand Friends:

> *When it rains, Hawaii's short watersheds create immediate impacts to coastal areas from non-point source pollution. Studies so far have concentrated on impacts to estuaries, receiving ocean waters and coral, but not on impacts to fish and cru stations.*

Commentators have noted, moreover, the inefficiencies and unfairness, from the perspective of point sources, of failing to recognize and address as well the considerable relative contributions of non-point sources.

Neither the CWA nor its regulations alone will accomplish the objective and goals of the CWA. EPA, and authorized state and tribal governments, simply must ensure strict and widespread compliance with the CWA. Without such enforcement, polluters have absolutely no incentive to comply with the CWA as "noncompliance results in economic benefits (the free use of public waterways for waste disposal), while compliance exacts a financial cost (the construction and operation of expensive pollution removal facilities)."[284]

Water quantity is also of serious concern given, among other things, its recognized connections to and implications for water quality and integrity. For example, congressional goals and policies under the Clean Water Act direct federal agencies to "co-operate with State and local agencies to develop comprehensive solutions to prevent, reduce and eliminate pollution in concert

[283]Draft AWQC Methodology at 43,762.
[284]John Cronin and Robert F. Kennedy, Jr., *The Riverkeepers* 178 (1997).

with programs for managing water resources."[285] And the U.S. Supreme Court has recognized the connection between water quantity and quality, upholding a state's imposition of minimum instream flows as part of a Section 401 determination.[286] Wetlands, which provide essential wildlife habitats, are also recognized as an integral and natural way of removing pollutants from water bodies, and the Clean Water Act's Section 404 permitting program as well as EPA's "no net loss" strategy for wetlands preserves both the quality and quantity of these waters. Additionally, reduction in water quality affects surface flows and may increase the concentration of pollutants and other chemicals.[287]

2. Other Authorities

The Clean Air Act (CAA) is an important source of authority for addressing contamination of aquatic environments that results in part from the deposition of toxic contaminants emitted into the air. For example, it is estimated that air emissions account for some 80% of mercury contamination in water. Most dioxins released into the environment also come from emissions to air; as noted above, dioxins emitted into the air may be suspended for a long time and travel great distances before being deposited to surface waters. Among other things, the CAA Section 112 addresses certain "hazardous air pollutants;" the 1990 amendments to the CAA direct EPA to develop rules for categories of sources that emit these hazardous air pollutants, and to do so over the next ten years. EPA has promulgated many of these rules, although there are some source categories for which EPA is still in the process of rule development. Because mercury compounds and dioxin are among the hazardous air pollutants regulated under CAA Section 112, this provides an important basis for preventing and reducing these contaminants. Moreover, EPA has several upcoming opportunities under Section 112 (e.g., upcoming rule for coal-fired power plants, the single largest source of mercury emissions nationwide; upcoming rule for chlor-alkali plants, a significant source of mercury, particularly in some locales, such as Louisiana;[288] upcoming rule for industrial boilers, another important source of mercury) to address these concerns as it develops these rules. In addition, whether under CAA authority and/or other authorities, the EPA needs to attend to sources of toxic air pollutants that are currently un- or under-regulated (e.g., dioxin emissions from backyard burning). The relative contribution to dioxin emissions from these sources has increased as industrial and other sources of dioxins have been required to control their emissions; as such, addressing these un- and under-regulated sources will be a challenge for the near future.[289] Again, commentators have noted that where this

[285]33 U.S.C. § 1251(g).

[286]PUD No. 1 v. Washington Dep't of Ecology, 511 U.S. 700 (1994).

[287]See, e.g., United States v. Gila Valley Irrigation Dist., 920 F. Supp. 1444 (D. Ariz. 1996) (finding that upstream water uses reduced surface flows and increased saline levels in water reaching an Indian reservation to the extent that traditional agricultural activities were impaired and recognizing that the tribe was entitled to surface water of adequate quantity as well as quality).

[288]Telephone Interview with Dr. Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001).

[289]U.S. Environmental Protection Agency, *Inventory of Sources of Dioxin in the United States* (1998; updated 2000)(Draft); accord, Chlorine Chemistry Council (untitled and undated fact sheet).

is the case, issues of inefficiency and unfairness, from the perspective of regulated sources, mean that agencies should also look to un- and under-regulated sources for reductions. And while some community groups have recently taken it upon themselves to get community members to reduce backyard burning,[290] EPA should not rely on ad hoc, voluntary efforts but should work to coordinate, facilitate, and, where appropriate, require reduction from these and other un- and under-regulated sources.

The CAA also provides authority to address other air-related sources of contaminated waters. For example, the CAA regulates oxides of nitrogen (NOx) through a variety of provisions. NOx causes acidification and euthrophication (a process in which an overabundance of nutrients causes some algae to multiply exponentially causing oxygen depletion that limits the ability of some species to thrive and survive), a potential problem for shellfisheries and other aquatic resources. Among these, the New Source Review program, which decides controls for NOx on new or modified facilities on a case-by-case basis, is under review pursuant to the National Energy Policy. In addition, implementation of the new Ozone National Ambient Air Quality Standard (NAAQS) may affect NOx emissions as NOx is an important ozone precursor.

Other statutory and regulatory authorities similarly provide authority useful for preventing and reducing contamination of fish and aquatic environments. Several statutes and regulations pertaining to hazardous waste may provide authority to address more thoroughly the use of "recycled" wastes from various industrial processes as fertilizer – which is then applied to crops, grazing lands, and gardens, and may contribute to run-off of dioxins, lead, mercury, cadmium, and other contaminants of concern to surface waters and contamination of groundwater, including drinking water. Although current regulations address this practice, they contain a loophole exempting steel mill waste and may still permit unacceptable levels of these contaminants in fertilizer.

The Federal Insecticide, Fungicide, and Rodenticide Control Act (FIFRA) may provide authority to address the fact that "[w]ell over a billion pounds of pesticides are applied annually in the United States, at least 50 million pounds in the Great Lakes Watershed alone."[291] Also authority under FIFRA is limited, there may well be opportunities for EPA to use the available tools more aggressively, e.g., prominent advisories on pesticide labels, prohibitions on use within a specified distances from wells (well set-backs), prohibitions on use in designated geographic areas, and restricting pesticides' use to certified applicators.[292]

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[290]Shawna Larson, Project Coordinator, Indigenous Environmental Network and Alaska Community Action on Toxics, Panelist, "Food, Toxic Chemicals & Health: An Environmental Justice Forum," Anchorage, AK (Feb. 6, 2002).

[291]U.S. General Accounting Office, *Issues Concerning Pesticides Used in the Great Lakes Watershed* (1993).

[292]Zygmunt J. B. Plater, et al., *Environmental Law and Policy: Nature, Law, and Society* 728 (2d ed. 1998).

The Pollution Prevention Act (PPA), enacted in 1990, might similarly be mined for tools that EPA might employ more aggressively to prevent pollution from entering aquatic environments in the first place.

Finally, a variety of sources of authority and EPA offices have been gathered in EPA's recent Contaminated Sediment Management Strategy. Given that in terms of volume, some 10% of the sediments underlying the nation's waters are contaminated , that 96 of the watersheds tested indicate contamination at levels of serious concern, and that the contaminants that most frequently contributed to this concern were mercury, PCBs, pesticides (especially DDT), and PAHs, addressing sediment contamination should indeed be a priority.[293]

B. CLEANUP AND RESTORATION

How might EPA enhance restoration efforts in order to rehabilitate aquatic ecosystems and thereby protect the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes?

Many aquatic environments remain degraded such that they require restoration in order to ensure the viability of the ecosystem; the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes; the ability to support economies dependent on aquatic resources; and the sustainability of tribal homelands. Efforts to cleanup and restore contaminated aquatic environments are vital to protecting the health of communities of color, low-income communities, tribes, and other indigenous peoples. These efforts are especially important given that members of these groups are among the most highly-exposed to environmental contaminants (as discussed in Chapter One) and given that for many of these groups, risk avoidance – eating less fish, using a different preparation method, fishing in a different location – is simply not a realistic or culturally appropriate option (as will be discussed in Chapter Three). Thus, these groups will disproportionately bear the burden of existing contamination that is not adequately addressed. Moreover, because production (and, in many cases, use) in the United States has been banned for several of the contaminants of greatest concern – for example, PCBs, DDT, chlordane, and toxaphene – the presence of these contaminants in the environment can only be reduced through cleanup and restoration efforts.

"Restoration" has been taken by different people to mean different things.[294] Restoration has sometimes been defined somewhat narrowly, to the exclusion of the historical, cultural, legal, and social contexts within which restoration takes place. Thus, for example, the National Research Council has defined restoration of aquatic ecosystems as "the reestablishment of

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[293]U.S. Environmental Protection Agency, Office of Science and Technology, *The Incidence and Severity of Sediment Contamination in Surface Waters of the United States, Volume 1: National Contaminant Survey* (1997).

[294]For several examples relevant to the restoration of aquatic environments, see U.S. Environmental Protection Agency, Office of Water, *River Corridor and Wetland Restoration*, "What is Restoration?" at www.epa.gov/owow/wetlands/restore/defs.html.

predisturbance aquatic functions and related physical, chemical and biological characteristics."[295] Others define restoration more broadly and suggest that the ends and means of restoration can only be contemplated *in context*, i.e. in light of the particular historical, cultural, legal, and social circumstances of a place. The Society for Ecological Restoration, for example, observes that restoration should attend to "regional and historical context," and must take into account the need to sustain cultural activities, especially the cultural practices of indigenous peoples.[296] Similarly, among the Principles of Environmental Justice articulated by the First National People of Color Environmental Leadership Summit, is that "[e]nvironmental justice affirms the need for urban and rural ecological policies to clean up and rebuild our cities and rural areas in balance with nature, honoring the cultural integrity of our communities and providing fair access for all to a full range of resources."[297]

In the case of restoration affecting tribal homelands (including tribal resources and culturally-important resources whether located on- or off-reservation), tribes and commentators have noted that the ends or "point of reference" for restorative efforts cannot be considered separately from the obligations that the United States has undertaken in treaties and as part of its trust responsibility.[298] Restoration here must attend to the purposes for which tribal lands and resources have been reserved under treaties and protected in furtherance of the federal trust responsibility.[299] As noted above, arguably the primary purpose of all reservations is the creation of a permanent tribal homeland where the tribe can maintain its traditional subsistence activities including the exercise of treaty rights to hunt, fish, and gather. Water of sufficient quality and quantity for this purpose is essential.[300] Thus, for example, in introducing their plan for restoring salmon and other anadromous fish in the Columbia River Basin, *Wy-Kan-Ush-Mi Wa-Kish-Wit*,

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[295]National Research Council, *Restoration of Aquatic Ecosystems* 18 (1992).

[296]See, generally, The Society for Ecological Restoration at www.ser.org.

[297]*Proceedings of the First National People of Color Environmental Leadership Summit*, "Principles of Environmental Justice" xiii (1991).

[298]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation (Aug. 3, 2001 conference call).

[299]Jana Walker, Attorney, Law Offices of Jana L. Walker (Aug. 3, 2001 conference call); Mary Christina Wood, *Indian Land and the Promise of Native Sovereignty: The Trust Doctrine Revisited*, 1994 Utah Law Review 1471; Mary Christina Wood, *Fulfilling the Executive's Trust Responsibility Toward Native Nations on Environmental Issues: A Partial Critique of the Clinton administration's Promises and Performances*, 25 Environmental Law 733 (1995); Mary Christina Wood, *Protecting the Attributes of Native Sovereignty: A New Trust Paradigm for Federal Actions Affecting Tribal Lands and Resources*, 1995 Utah Law Review 109.

[300]See, e.g. Winters v. United States, 143 F. 740, 742 (1906); Colville Confederated Tribes v. Walton, 647 F.2d 42, 49 (9th Cir.1981), *cert. denied*, 454 U.S. 1092 (1981); Felix S. Cohen, *Handbook of Federal Indian Law*, 588-89 (1982 ed.); see also Mary Christina Wood *Indian Land and the Promise of Native Sovereignty: The Trust Doctrine Revisited*, 1994 Utah Law Review 1471; Mary Christina Wood, *Fulfilling the Executive's Trust Responsibility Toward Native Nations on Environmental Issues: A Partial Critique of the Clinton administration's Promises and Performances*, 25 Environmental Law 733 (1995); Mary Christina Wood, *Protecting the Attributes of Native Sovereignty: A New Trust Paradigm for Federal Actions Affecting Tribal Lands and Resources*, 1995 Utah Law Review 109.

the Columbia River treaty tribes explain that "[u]nlike other plans, this plan establishes a foundation for the United States and its citizens to honor their treaty and trust obligations to the four tribes. If implemented, it would at least begin to meet ceremonial, subsistence, and commercial needs of tribal members and to return fish to many of the tribes' usual and accustomed fishing places, as guaranteed in the 1855 treaties."[301] Restoration affecting tribal lands and resources, moreover, must attend to the related matters of cultural flourishing and tribal sovereignty.[302] As John LaVelle observes in the context of restoration plans for *Paha Sapa* or the Black Hills, those pursuing plans "must embrace the restoration of tribal sovereignty and cultural integrity as an indispensable remedial norm to be realized through the proposal's development and implementation."[303]

EPA's Watershed Ecology Team has set forth Principles for the Ecological Restoration of Aquatic Resources.[304] These "Guiding Principles" include (1) preserve and protect aquatic resources; (2) restore ecological integrity; (3) restore natural structure; (4) restore natural function; (5) work within the watershed and broader landscape context; (6) understand the natural potential of the watershed; (7) address ongoing causes of degradation; (8) develop clear, achievable, and measurable goals; (9) focus on feasibility; (10) use a reference site; (11) anticipate future changes; (12) involve the skills and insights of a multi-disciplinary team; (13) design for self-sustainability; (14) use passive restoration, when appropriate; (15) restore native species and avoid non-native species; (16) use natural fixes and bioengineering techniques, where possible; and (17) monitor and adopt where changes are necessary.

1. Clean Water Act

As noted above, the statutory objective of the CWA is "to *restore* and maintain the chemical, physical, and biological integrity of the Nation's waters."[305] In addition to the efforts discussed above in conjunction with prevention and reduction, EPA should read its authority under the CWA consonant with this stated objective and look creatively and aggressively for restoration opportunities.

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[301] Columbia River Inter-Tribal Fish Commission, 1 Wy-Kan-Ush-Mi Wa-Kish-Wit: Spirit of the Salmon, iv (1995).

[302] See, e.g., id. at v ("protect tribal sovereignty" among goals of restoration); *Chairman's Corner: The Exercise of Tribal Sovereignty Lies at the Heart of Healthy Ecosystems*. Fort Apache Scout 2 (May 24, 1996); see, generally, Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* (1999).

[303] John P. LaVelle, *Rescuing Paha Sapa: Achieving Environmental Justice by Restoring the Great Grasslands and Returning the Sacred Black Hills to the Great Sioux Nation*, 5 Great Plains Natural Resources Journal 40, 78 (Spr./Sum. 2001) (italics omitted).

[304] U.S. Environmental Protection Agency, *Principles for the Ecological Restoration of Aquatic Resources* (2000) available at www.epa.gov/owow/wetlands/restore/principles.html.

[305] 33 U.S.C. § 1251(a).

2. Other Authorities

Clearly, the focus of CERCLA or "Superfund" is on cleanup and restoration of contaminated environments, including aquatic environments. Under CERCLA and its implementing regulations, once contaminated sites have been identified as potential priorities for cleanup action, EPA investigates the nature and extent of the threat posed by the contamination (the "remedial investigation" or "RI") and develops alternative approaches for responding to the contamination at that site (the "feasibility study" or "FS"). EPA uses a screening process to evaluate the alternatives identified during the RI/FS, which includes, among other criteria, whether the alternatives comply with all "applicable, relevant, and appropriate requirements," whether they achieve overall protection of human health and the environment, whether they reduce the toxicity, mobility or volume of the contamination through treatment, whether they are effective in the short-term as well as the long-term, whether they are implementable and how much they cost, and whether they are acceptable to the state and to the community. Note that these criteria provide EPA with considerable latitude to choose a more or a less protective alternative as the "remedy" for the contamination. EPA's work in this regard could be improved in several ways relevant to communities of color, low-income communities, tribes, and other indigenous peoples. First, EPA needs to set cleanup levels and determine appropriate remedies in light of the considerations discussed in Chapter 1. Specifically, when EPA sets cleanup levels for contaminated sediments and surfaces waters, it needs to take into account the different fish consumption rates, practices and contexts of affected groups and set levels sufficiently protective of these groups. EPA site managers need to consider matters of aggregate or multiple exposures and cumulative risks, and delineate sites, goal, and remedies accordingly. EPA needs to refrain from falling back on "institutional controls" (e.g., put a fence around the site and post "No Fishing" signs) and undertake aggressive cleanups where the sites are past or present locations for fishing and other activities that expose communities of color, low-income communities, tribes, and other indigenous peoples to contamination. Second, EPA needs to take seriously the requirement of "community acceptance" as it chooses among alternatives. In order to do so, it needs to ensure that participation by affected communities (and co-management by affected tribes) takes place from the outset and at every point in the decision-making process. To accomplish this, EPA should be ready to provide financial and technical support. These issues of affected group involvement are also taken up in Chapter One and Chapter Three. Finally, to the extent that the Natural Resource Damage provisions of CERCLA (or other statutes) are invoked, involved agencies should work with the community to ensure that efforts are undertaken with an eye toward making the community whole. Community involvement here, of course, will be critical; tribes may well be involved in their roles as Natural Resource Damage trustees. The discussion above regarding restoration is also relevant here.

Other statutory and regulatory authorities similarly provide authority useful for cleaning up and restoring contaminated aquatic environments. Among these, as discussed above in the context of prevention and reduction, a variety of sources of authority and EPA offices have been gathered in EPA's recent Contaminated Sediment Management Strategy.

CHAPTER III: FISH CONSUMPTION ADVISORIES

What role should fish consumption advisories play in efforts to protect more effectively the health and safety of people consuming or using fish, aquatic plants, and wildlife?

Whereas Chapter Two focused on issues surrounding *risk reduction* strategies, this chapter focuses on issues surrounding a *risk avoidance* strategy: fish and wildlife consumption advisories. Rather than looking, as risk reduction strategies do, to the risk-producers to cleanup, limit, and prevent environmental contamination, risk avoidance strategies look to *risk-bearers* – those who bear the risks of contamination – to change their lives and practices in order to avoid exposure to harmful contaminants. They do this by encouraging or requiring individuals to change the way they live, specifically, to alter or refrain from certain pursuits or practices that, once a place has been allowed to become contaminated, expose them to risk.

It is important to note that with risk avoidance strategies such as fish consumption advisories, the *responsibility* for addressing environmental contamination and its harmful human health effects is allocated to those who are made to bear the risks of contamination rather than to the sources of that contamination. Furthermore, because risk avoidance strategies place this responsibility on those who are exposed to environmental contaminants, they will necessarily impose a greater burden on communities of color, low-income communities, tribes, and other indigenous peoples. As has been amply demonstrated, it is members of these groups who are among the most exposed.

In light of these and other considerations, and in view of the reality of the harmful health effects of consuming fish from seriously contaminated environments, Part A of this chapter will take up the question: what role should fish consumption advisories play in efforts to protect more effectively the health and safety of people consuming or using fish, aquatic plants, and wildlife? *It is important to note that the answer to this question is likely to be different for different communities, groups, or tribes, and should be determined by or together with the affected group.*

Parts B, C and D will examine the related matter of fish consumption advisories' "effectiveness." The concept of "effectiveness" itself raises a host of issues, the first of which is definitional: what is meant by an "effective" advisory? Again, the answer to this question may be different for different agencies and for different communities, groups, or tribes. This question will be discussed in Part B. Part C will canvas the current state of research regarding how those to whom advisories are directed respond to this information, focusing on what is known about awareness and responses among communities of color, low-income communities, tribes, and other indigenous peoples. Part D will then explore ways in which to improve the effectiveness of risk communication and fish consumption advisories. Throughout, this chapter will seek to address the question: how can EPA better meet the needs of all people, including communities of color, low-income communities, tribes, and other indigenous peoples, as it works to address degradation of aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

A. FISH CONSUMPTION ADVISORIES' ROLE

Risk avoidance strategies such as fish consumption advisories shift the responsibility for addressing environmental contamination's harmful health effects to risk-bearers, as opposed to allocating this responsibility to risk-producers. In the case of fish consumption advisories, this choice disproportionately burdens communities of color, low-income communities, tribes, and other indigenous peoples, given that these groups consume fish at higher rates and according to different practices than the general population, as discussed in Chapter One. When agencies employ fish consumption advisories, moreover, they assume that there are adequate substitutes in the lives of those to whom the advisories are directed for fishing and fish consumption. Although consumption advisories issued by federal or state agencies typically do not state as much explicitly, they rely implicitly on the assumption that there are ready substitutes for being able to fish at the same place, in the same manner, and for the same fish as one had traditionally or would today were the fish not contaminated. This assumption requires a judgment on the part of the agencies that such a substitution (1) is possible, and (2) will not occasion great loss.[306] This is a value judgment that is likely to reflect the understandings of the dominant society that fishing and fish consumption are expendable "habits," "activities," or "behaviors," for which, at the very least, substitutes can be readily obtained; and, that various groups' particular fishing and fish consumption practices can be altered without great anguish (or that this anguish and loss does not matter).[307]

However, this value judgment does not reflect the understandings of many of those who are affected – those who are being asked to change their lives and practices. First, it is often unrealistic as a practical matter to think that there are substitutes ready at hand for fishing, preparing fish, and eating fish in the manner currently practiced by affected individuals. This may be so for economic, geographic, historical, cultural, and/or other reasons. It is often difficult if not impossible to fish at a different bay, river, lake, or bayou – how would one get there if it is too far to walk, or if the bus doesn't go there, or if there isn't any money to put enough gas in the car? how would one learn what it takes to catch fish at a new place, and how would one put food on the table in the meantime? what if all of the waters nearby were also contaminated, as is likely to be the case when the sources of the contaminants are air emissions (e.g., mercury) or the entire area is heavily industrialized (e.g., the Mississippi River Corridor between New Orleans and Baton Rouge) or the entire area is plagued by pesticide runoff from farms? It is often difficult if not impossible to fish for different species or to fish for younger fish as some advisories suggest – what does one do for dinner when the only fish that are biting that day are old and the "wrong" species? It is often difficult if not impossible to stop eating fish altogether and to obtain nutrition benefits similar to fish from other sources – what if one cannot afford to pay for substitute sources of protein, such as beef, which is often more expensive? how does one account for the fact that fish are unequaled in regard to some nutrition benefits: for example, fish are an especially efficient source of protein inasmuch as fish are low in fat relative to other protein sources? Consider, for example, the obstacles and concerns identified by the following.

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[306]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).
[307]Id.

Raymond Moseley, a fisher along the Columbia Slough in Portland, Oregon, explains:

> *We have caught big fish down there, between them two posts. Plenty catfish in there. Ain't too many other places to fish – except way out of town.*[308]

A low-income, African American fisher along the Detroit River, explains:

> *Yes, income affects everything. A fishing license is expensive – or outrageous is more like it. You need money for everything. To fish is expensive and what happens when you are poor? . . . You even have to spend money on gas so that you can get to the water and if you can't get there then you can't get food.*[309]

According to an account of the response of Alaskan Natives on Nelson Island to an unusual year marked by reduced numbers of herring and a prevalence of fatty herring:

> *Several families did not fish for herring at all, resulting in the lowest overall household involvement in herring production in the years of survey. Instead, they diverted efforts to increase halibut, Pacific cod, and salmon harvests, filling drying racks and freezers with these welcome, but less preferred, alternatives. Local residents do not consider halibut and Pacific cod adequate, or even improved, substitutes for herring, as non-local people may, but these species certainly are preferred by Nelson Island families to non-local, imported foods. Herring is the traditional winter food for Nelson Island families. Changing subsistence fishing strategies often means purchasing new gear and more gasoline, adjusting processing and drying facilities, investing more time fishing for other species, and altering subsistence production roles in the family*[310]

Yin Ling Leung, Executive Director of Asians and Pacific Islanders for Reproductive Health, California, explains:

> *To our communities, being able to fish means being able to either put food on the table, or basically eat a much less nutritious meal. I think that's a non-choice.*[311]

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[308]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

[309]Patrick C. West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low-Income Afro-Americans from the Detroit River* 15 (forthcoming).

[310]Mary C. Pete, *Subsistence Herring Fishing in the Nelson Island and Nunivak Island Districts* (1991) available at www.nativeknowledge.org/db/files/tp196.htm.

[311]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 1 (1998).

As Daisy Carter, Project AWAKE, Coatopa, Alabama, summarizes,

> *When it comes to people, their health and survival, EPA must become real. It is not about formality, but reality.*[312]

Second, even if those affected in some senses could as a practical matter alter their fishing and fish consumption practices, to be asked or required to do so might be *unthinkable* in the sense of occasioning profound loss or anguish. This may be so for traditional, cultural, religious, historical, and/or other reasons. For some communities or peoples, fish and fishing are a way of life, a way to be who they are. For these groups it is *necessary* to fish in traditional places, and to catch, prepare and eat fish in accordance with traditional ways. From their perspective, these are not expendable "habits," "activities," or "behaviors;" they are crucial for survival – of the individual, the community or people, and, in some cases, the entirety of the earth.

Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, explain:

> *There are many issues relating to the evaluation of tribal health risk and, even more importantly, the health of people as they exist within their eco-cultural communities. . . . We need to think not only about human people as receptors, but about the culture itself as a receptor. We should be very uncomfortable about having to write a fish advisory in the first place. . . Really, there is just a single cultural community that is comprised of human and fish peoples and their rules for behaving and mutually surviving. It has been explained that the fish community existed first, and accepted people as community members, but only if human people follow certain rules of participating in the ecology, including a nutritionally adequate level of respectful consumption (a sacrament), and protecting the fish members from contamination and habitat degradation in return for being protected from starvation. Writing a fish advisory to protect some community members from other members is very disquieting, and causes many consequences on its own.*[313]

Similarly, the Swinomish Indian Tribal Community explains:

> *In the Swinomish Tribal Community, fish and shellfish represent vital subsistence and commercial resources for the Tribe as well as an important point of cultural association for the Tribe's identity. Employed in cultural and religious ceremonies, incorporated into the common diet, and sold to support families on the Reservation, the current ecological status and fate of these species is of utmost interest to the Tribe. . . . [We believe that risk reduction exemplifies a much more effective answer to addressing the risk [from contamination] than does risk avoidance. . . . [O]ptions such as closing*

[312]Daisy Carter, Project AWAKE (Written Comments to FCW, undated).

[313]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Contaminants in Fish, "*Tribal Technical Issues in Risk Reduction Through Fish Advisories"17 (1999).

harvesting sites, substituting with other sources of food, and posting "no fishing" signs are not viable considerations for reducing risk.[314]

And, as Hawaii's Thousand Friends emphasizes:

For the Native Hawaiian, the proposal of not eating fish because of contamination is unimaginable and unacceptable.[315]

Thus, it is often impossible to conceive of fishing at a different bay, river, lake, or stream – what if it belongs to someone else traditionally, historically and/or legally? This is an issue, in particular, for many tribes, especially the fishing tribes (e.g., of the Pacific Northwest or of the Great Lakes), whose rights to hunt, fish, and gather are tied to particular places and protected by treaties – these place-based rights are not transferable. Nor can many tribal fishers imagine going "somewhere else" to fish, even if they could. Margaret Palmer, a Yakama tribal fisher, elaborates:

I don't feel like it's within our rights, as the tribe that we are, to go to a different area and live off of something that maybe God has blessed them with. This is our blessing. This is the way we see it. This is where we should stay. I don't believe that I would leave the area. I believe I would stay where I'm at – by the water. It's our lineage.[316]

Moreover, the particularized skills and knowledge that tribal peoples have developed over centuries are place-specific and comprise a part of their intergenerational heritage, to be passed from generation to generation. It is often impossible to fish for, hunt for, or gather different species or to fish for younger fish as some advisories suggest – what if a particular species is bound up with one's cultural identity and with every aspect of who one is, as in the case of salmon and the Native peoples of the Pacific Northwest or in the case of wild rice and the Native peoples of Northern Minnesota?

Winona LaDuke, Mississippi Band of Anishinaabeg, explains:

It's mid-September in northern Minnesota. Somewhere on one of the many lakes Lennie Butcher and his wife Cleo are making wild rice. Mamoominikewag. *That is what they do.*

It's a misty morning on Big Chippewa Lake. The Anishinaabeg couple drag their canoe toward the water's edge. The woman boards in the front and sits on her haunches. The man pushes the canoe offshore and jumps in the boat behind her. As they pole toward the wild rice beds, they can feel the crisp dampness of September on their faces. The man rises to stand, his head visible just above the tall sticks of rice. The woman pulls the

[314]Swinomish Indian Tribal Community, *Comments on the NEJAC Draft Fish Consumption Report* (Feb. 5, 2002).

[315]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[316]Videotape: My Strength is From the Fish (Columbia River Inter-Tribal Fish Commission 1994).

rice over her lap with a stick and gently raps it with another one. This is a thousand-year-old scene on Big Chippewa Lake. And there is a community that intends to carry it on for another thousand years.

There are many wild rice lakes on the White Earth reservation in northern Minnesota; my community, the Anishinaabeg, calls the rice Manoomin*, or a gift from the Creator. Every year, half our people harvest the wild rice, the fortunate ones generating a large chunk of their income from it. But wild rice is not just about money and food. It's about feeding the soul.*[317]

Or what if a particular preparation method is an important component of traditional, cultural, or ceremonial use?

A majority of respondents [to the Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California] (76.1%) said they always eat the skin of the fish. Some respondents also report regularly consuming the head and organs of the fish. Many chemicals are concentrated in the fat, which is just underneath the skin, and in the organs of the fish. Consumption of these parts of the fish exposes a person to higher amounts of chemical contaminants than consumption of only the fillet.

Cooking methods often determine which parts of the fish are eaten. The California Environmental Protection Agency (Cal EPA) health advisory recommends that people eat only fillet portions of fish, and bake, broil, steam or grill fish on a rack so that juices from the fat drip off during cooking. This survey shows that frying, baking, steaming, grilling, and making "fish pudding" are the most common ways of preparing fish in the Laotian community. According to the survey staff, the whole fish, including the head, skin, and organs, is frequently cooked when frying, baking, steaming and grilling fish. . . . "Fish pudding" or lap is also made out of the whole fish, and is oftentimes made from raw fish. When making lap, the organs of the fish are commonly removed, cooked separately, chopped up and then included in the mixture. According to the survey staff, striped bass is a popular fish for lap. Sauces and pastes made from whole and raw fish, shrimp or crab are also popular traditional Laotian condiments. The health advisory's recommendations for methods of cooking fish to lower one's risk of taking in harmful chemicals clearly are at odds with traditional ways of preparing fish and other seafoods.[318]

[317]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 115 (1999).

[318]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 35 (1998).

According to a recent study of African American fishers on the Detroit River, frying is "a firmly rooted cultural tradition amongst African Americans" and is either the only method or the preferred method of preparing fish; as one fisher summarized:

> *It's cultural. Blacks fry. It's simple.*[319]

It is often simply impossible to stop eating fish altogether and to obtain nutrition benefits similar to fish from other sources. For some communities and peoples, there are simply no replacements that equal the nutritional and health benefits – in the broadest sense of these terms – of the fish, aquatic plants, and wildlife that they have traditionally consumed. Yvonne Smith and Laura Berg explain in *Wana Chinook Tymoo*, in a sidebar entitled "Declining Fish, Declining Health:"

> *The shortage of salmon and other fish has necessitated dramatic changed in the diet of the Indian people of the Columbia River Basin. They have experienced a steady decline in health as a result.*
>
> *Researchers worldwide state what Indians have known all along, that there are health benefits to consuming fish. . . .*
>
> *Ted Strong reported that when his relatives, many now deceased, spoke of those that came before them, they talked about people who lived long lives, into their 90's and beyond. "Those ancestors ate the traditional foods," he said. . . .*
>
> *Whatever other factors have contributed to the shortened lives and high death rate among the Indian people of the basin, there is little doubt dietary changes have had a significant impact.*
>
> *Joanna Meninick has watched the health of her people decline as the scarcity of salmon has increased, "diabetes, cancer, heart disease. All of these are on the increase."*
>
> *Many traditional foods are gone, or have become inaccessible. C'làу (pronounced chu-lie) is an example. Made from dried salmon, berries, and other oils and foods, the powdery preparation has multiple uses. "It is good medicine, said Bill Yal-lup, Sr. "You can mix it with certain roots, certain foods . . . very good for the heart."*
>
> *But c'làу is in short supply. It takes many pounds of dried salmon to make. Whole salmon, needed for ceremonies and subsistence, comes first.*

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[319]Katharine J. Hornbarger, et al., *Targeted Audience Analysis: Recommendations for Effectively Communicating Toxic Fish Consumption Advisories to Anglers on the Detroit River* 26 (1994) (noting that anglers described several ways of frying: "pan frying, deep fat frying, and the most often cited method, coating the fish with cornmeal and then frying.").

Pierson Mitchell noted that he had salmon for lunch at home sometimes, when it was available, but he missed the c'lày. Getting it occasionally in the Christmas basket was a treat. "If our people had remained on the diet of the salmon, our health would be better today," he said.[320]

Similarly, Silas Whitman, Nez Perce, explains:

One thing I have noticed over the years is that the Nez Perce people are highly susceptible to minute changes in diet, especially those that revolve around fish. If we supplant native foods with other foods, often times the nutritive values of that supplanted product cannot be ingested or stay in the system to the degree that our bodies as Nez Perce people can use them. From that come health problems that are eroding our mortality. So as we help the salmon and other fish to recover we help ourselves.[321]

And it is no less a source of profound loss and anguish for those whose have already been forced to give up fish because of the gross contamination of their fishing places. It is no less *necessary* for these communities or peoples to fish in traditional places, and to catch, prepare and eat fish in accordance with traditional ways. They have been made to suspend or alter their practices, but they cannot be viewed as having "chosen" to abandon these practices. The strength and resilience of these affected communities and peoples cannot now be taken to justify a claim that fish are no longer important to their survival as individuals and peoples, such that it would be permissible to allow the contamination to continue and remain. Winona LaDuke recounts:

"This is a classic environmental justice site," says Ken Jock, a director of the Akwesasene Environment Program. A slight man, with soft eyes and a quiet manner, he spends much of his time arguing with agencies about implementation of the law. His huge office is full of reports and photos documenting the extent of the [PCB contamination at Akwesasne, on the St. Lawrence River]. The reports, photos, and sheer size of the Akwesasne Environment Program dwarf the infrastructure of most Indian nations in the country. Yet it seems that even with reams of paper, the action taken by federal agencies is minimal. "This all used to be a fishing village. That's all gone now. There's only one family that still fishes," Jock says. "We can't farm here because of all of those air emissions. Industry has pretty much taken the entire traditional lifestyle away from the community here."

Today 65 percent of the Mohawks on Akwesasne reservation have diabetes, says Jock. Henry Lickers, director of the environmental health branch of the Mohawk Council of Akwesasne echoes Jock: "Our traditional lifestyle has been completely disrupted, and we have been forced to make choices to protect our future generations," says Lickers.

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[320]Yvonne Smith and Laura Berg, *Ancient Tradition, Modern Reality: Is There a Future for a Salmon-Based Culture?* 1 Wana Chinook Tymoo 14 (1998).

[321]Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 21 (1999).

"Many of the families used to eat 20-25 fish meals a month. It's now said that the traditional Mohawk diet is spaghetti."[322]

Thus, it may be impractical or impossible for those who are affected by contaminated aquatic environments to give up or alter their fish consumption practices. This may be so for economic, geographic, historical, traditional, cultural, religious, and/or legal reasons. Yet, the reality of gross contamination means that these practices may expose members of affected communities, groups and tribes to serious health risks – some of the contaminants contained in the fish, aquatic plants, and wildlife cause cancer, some wreak neurological damage, some are linked to reproductive and developmental damage, some disrupt endocrine functions, and some cause a range of these and other harms to humans. This poses a sad and dire dilemma.

What role should fish consumption advisories play in agencies' response? Broadly speaking, there are three possible policy options. These might be thought of as occupying a continuum. On the one end, agencies might rely exclusively on fish consumption advisories to address this dilemma. This option might reflect the view that it is cheaper and easier to address affected communities' and tribes' exposure by getting them to stop eating fish than it is to require risk-producers to prevent, reduce, and cleanup contamination. And, assuming the fish consumption advisories were effective (a question taken up in the next part of this chapter), affected communities would be protected from the harms of cancer and the like. There would, of course, be some losses – any substitute food sources might not be of equal nutritional quality or might not be what members of these communities would prefer to eat – but these losses would have to have been judged to be worth the benefits of not being exposed to the host of contaminants contained in the fish.

On the other end, agencies might abandon the use of fish consumption advisories altogether, and instead push aggressively for pollution prevention and cleanup. With this option, agencies' time and financial resources would be devoted entirely to preventing, reducing, and cleaning up contamination, such that aquatic environments would be returned to health and would be able to sustain fish, aquatic plants, and wildlife that were safe for humans to consume and use at the earliest possible time. This option might reflect the view that the only real way to protect health and safety of humans who consume or use these resources is to address the source of the health risk, i.e., the contamination. This option might reflect the view that it would be a misdirection of scarce agency time and money to continue to try to use and improve fish advisories – that this time and money would be better spent on prevention, reduction, and cleanup. Or it might reflect the view that even advising affected communities, groups, or tribes to alter their fish consumption practices is inappropriate, given the discrimination against and potential affront to those for whom these practices have cultural, traditional, or religious dimensions.

In the middle are a range of policy options that recognize some temporary role for fish consumption advisories but emphasize that they not become agencies' primary policy response to

[322]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 17 (1999).

the adverse health effects of contaminated aquatic environments. These middle options would grow out of a sense that neither the first nor second options actually addressed the concerns of at least some communities of color, low-income communities, tribes, and other indigenous peoples. The first option would shift the burdens of contamination entirely from those who have produced the risks to those who bear them. This is unjust and unacceptable. It would also give continued license to real and grave harms – among them nutritional deficits, other health detriments, and cultural discrimination. It would stand idly by as aquatic food sources were ultimately allowed to remain or become poisoned and forever "off limits" to those groups that formerly relied on these resources. The second option would address some of these long-term concerns, but would fail to inform affected groups in the short term. This, too, is unjust and unacceptable. The second option would, as Daisy Carter puts it, withhold from those most affected precisely what they need and are entitled to: *"the information and knowledge to help themselves."*[323] It would turn its back to the reality that fish are already contaminated – and will remain contaminated for some time, even given the most ambitious cleanup schedules – and real people will suffer when they eat or use this fish. Finally, the options that chart a middle course recognize that there may be ways to address at least some of the concerns of those affected by fashioning *appropriate* advisories (e.g., appropriate in terms of language, cultural, and other group- and place-specific considerations).

Moreover, the range of options here might enable agencies to be attentive to and respectful of the different concerns of different communities, groups, and tribes. That is to say, a particular community or tribe could choose one of the other options as most appropriate for its needs. *This brings up the crucial point that it is for the affected group to determine what will be appropriate from its perspective.*

Note that tribes' particular circumstances need to be taken into account. Tribes are sovereign nations, and in their governmental capacities are in the position of deciding for themselves what role fish consumption advisories should play in their efforts to protect the health and safety of tribal people consuming or using fish, aquatic plants, and wildlife.[324] Some tribes have decided to issue fish advisories to protect their members from contamination – often contamination that was permitted not by the tribes themselves but by state and federal agencies.[325] Some tribes or groups of tribes have opted not to issue fish consumption advisories but instead to develop "tribal consumption guidelines."[326] These guidelines tend to focus on the first and third functions of the typical advisory, i.e., providing information and suggesting alternative ways to continue consuming fish, rather than on the second function, i.e., discouraging fish consumption

[323]Daisy Carter, Project AWAKE (Written Comments to FCW, undated).

[324]See, e.g., Swinomish Indian Tribal Community, *Comments on NEJAC Draft Fish Consumption Report* (Feb. 5, 2002).

[325]See, e.g., James Ransom, Director, Haudenosuanee Environmental Task Force, *Proceedings of the American Fisheries Society: Contaminants in Fish* 25 (1999) (describing fish advisory issued by St. Regis Mohawk Health Services).

[326]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001); Great Lakes Indian Fish & Wildlife Commission, Masinaigan Supplement: How to Enjoy Fish Safely (Fall 2000).

altogether. Tribal consumption guidelines may also offer information that the typical federal- or state-issued advisory doesn't about the health benefits to tribal members of eating a "Native diet" and the health risks of turning to a "western diet."[327] Nancy Costa, of Fond du Lac Environment Program, explains:

> "*The last thing we want to do is to discourage tribal members from eating fish – given (among other things) the serious health effects we have seen for those who have gotten away from a Native diet."*[328]

Similarly, Elaine Abraham, a Tlingit elder from Yakutat, notes efforts to enhance appreciation of the cultural and nutritional value of Native foods, and cautions against focusing only on the potential health risks without acknowledging the important, multi-faceted benefits:

> *Why are you starting with talk about concerns? I have enough trouble getting my granddaughter to eat Native foods!*[329]

Tribal consumption guidelines may employ the indigenous language and artwork of those affected.[330] It is important to note that several tribes have indicated that they would like to be able to examine the question what role advisories or guidelines should play in their efforts to protect the health and safety of tribal people consuming or using fish, aquatic plants, and wildlife, and, potentially to fashion appropriate advisories or guidelines, but that they do not have sufficient technical and/or financial resources to do so. These tribes have stated that additional resources would, therefore, be crucial.

But tribes and tribal members are also affected by the environmental management decisions of federal and state agencies. In the Pacific Northwest, for example, federal and state agencies make numerous decisions that have permitted the contamination and depletion of the salmon and other culturally significant, treaty-protected tribal resources. Here, federal and state policy choices regarding the role of fish consumption advisories will have an impact on tribal members exercising their treaty-guaranteed rights to fish in all "usual and accustomed" areas, many of which are managed in whole or in part by federal and state agencies. To the extent that these agencies look to risk avoidance rather than risk reduction measures, they may risk running afoul of treaty obligations. Further, when these agencies issue fish consumption advisories that affect tribal members and resources, they have sometimes failed to communicate their actions to tribes as they should in accordance with tribes' status as sovereign nations and, for federal agencies, in compliance with the Executive Order on maintaining the appropriate "government-to-

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[327]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001).

[328]Id.

[329]Alaska Traditional Knowledge and Native Foods Database, *Resource Guide for Mini-Grants* available at www.iser.uaa.alaska.edu/projects/contam/ResourceGuide/index.htm

[330]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001); see also, Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Safely* (Fall 2000).

government" relationship with tribes. Issues particular to American Indian tribes and Alaskan Native villages are discussed further in Chapter Four.

Finally, even where agencies, together with affected groups, opt to continue to issue advisories, they need to redouble their efforts to prevent and reduce new sources of contamination and to cleanup and restore environments and fisheries that are already contaminated. *This caveat was strongly emphasized by affected groups everywhere*. Agency representatives acknowledge this need. For example, Elizabeth Southerland, Standards and Applied Science Division, Office of Science and Technology, Office of Water, opened this year's National Forum on Contaminants in Fish by describing "how water quality-based programs at both the federal and state levels seek not only to advise people on ways to minimize public health risks, but also to implement management measures to reduce the pollution problems so that measures like fish consumption advisories can be rescinded. No one wants consumption advisories in place any longer than necessary."[331] Yet, advisories have been in effect in some places since the 1970s and EPA has created a separate advisory program, which has been in place for about a decade. Furthermore, EPA appears to anticipate continued efforts to issue advisories and to ensure that those affected "comply" with them. In its Strategic Plan, for example, EPA states among its objectives: "[by 2005, consumption of contaminated fish will be reduced."[332] EPA's commitment to ensuring that advisories remain a temporary, second-best response to contamination and its effects on human health needs to be backed up by a reprioritization of goals – prevention, reduction and cleanup first and foremost – and by a redoubling of resources allocated to returning aquatic environments and fisheries to a state where it is safe for people to fish.

B. EFFECTIVENESS: BACKGROUND AND DEFINITION

1. Advisories' Components and Functions

In order to facilitate deliberation about this middle course, it seems useful to examine more closely the components and functions of a typical fish consumption advisory. A typical advisory might be thought of as comprised of three functional parts: (1) provide information about the nature and extent of the contamination and its adverse health effects (e.g., which waters are affected? which species? what are the contaminants of concern? what are the adverse health effects from these contaminants? which subgroups are affected?); (2) encourage avoidance by one or more of several means (e.g., refraining from eating fish altogether; reducing amount of fish consumed); and, sometimes, (3) suggest alternative means to continue eating fish (e.g., altering frequency of fish meals; altering preparation methods; fishing at other sites; fishing for and eating other species). These functions sometimes overlap. In addition, there are functions that advisories could usefully serve but that the typical advisory does not attempt to serve, e.g., capacity-building or empowerment in the affected group.

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[331] *Proceedings of the National Forum on Contaminants in Fish* I-10 (May 6 and 9, 2001).

[332] U.S. Environmental Protection Agency, Office of the Chief Financial Officer, *Strategic Plan* 29-30 (No. 190-R-97-002) (September 1997) available at www.epa.gov/ocfopage/plan/epastrat.pdf.

Consider this excerpt for the current advisory for organic contamination in Louisiana:

Water body	Causative pollutants	Recommendations	Approximate size affected
Devil's Swamp, Devil's Swamp Lake and Bayou Baton Rouge (Parish: East Baton Rouge)	Hexachlorobenzene, Hexachloro- 1,3-butadiene, PCBs, Lead, Mercury, Arsenic	Avoid swimming, limit fish consumption to TWO MEALS PER MONTH.	7.0 square miles
Capitol Lake (Parish: East Baton Rouge)	Priority organics (PCBs)	No fish consumption.	0.12 mile

This advisory provides information identifying the relevant contaminants, the affected waterbodies, the approximate geographical extent of the contamination, and, given that the recommendations apply to all "fish," the species covered. This information all serves the first function. Do the recommendations "limit fish consumption to two meals per month" and "no fish consumption" serve mainly to translate information about the nature and extent of the contamination and its health effects into a form that is readily usable by those who would otherwise consume these fish (an extension of the first function)? Or do they serve mainly to discourage fish consumption (the second function) – with all of the pros and cons of doing so, as discussed above in Part A? This information may serve both the first and second functions (and may be perceived to serve different functions by different communities, groups or tribes).

Note that this advisory's recommendations are not accompanied by suggestions of alternative means that would allow the continued consumption of fish, albeit of different species or according to different practices – the third function.

Finally, without more information about the process of fashioning and disseminating this advisory, it is difficult to determine to what extent it serves the additional functions of capacity-building and empowerment from the perspective of the affected groups. To highlight but one aspect of these additional functions: although this advisory identifies the "causative pollutants," it does not go on to provide information about the sources of those pollutants (e.g., particular industrial or other facilities) nor about upcoming risk assessment and risk management decisions relevant to the pollutants and sources of concern.

2. Defining "Effectiveness"

There are likely to be differences in how one defines "effective"in this context – differences among agencies and the various affected communities, groups and tribes. The first function of advisories – to provide information – is the least controversial. There is likely widespread agreement that an effective advisory is one that successfully *communicates* information about the nature and extent of the contamination and about the relevant adverse health effects. Advisories' first function is important to securing environmental justice. Although questions remain about whether current advisories actually communicate this information in understandable and appropriate ways (these will be taken up below, in Parts C and D), there seems to be little question that advisories or something akin to advisories *should* serve this function. As Ticiang Diangson, Supervising Planning and Development Specialist and Environmental Justice Advocate, Seattle Public Utilities, explains:

> *Although prevention would be the ideal solution, the essential question after contamination is, how can the harmed community be made "whole?" First and foremost, the community needs to be truly informed about the range of harm/risk it has been exposed to. . . .*

Communication, of course, requires that information be conveyed in a language, via a medium, in accordance with cultural considerations, and generally in a way that will enable it to reach and be understood by those affected – these issues are the focus of Part D.

The second function of advisories – to discourage fish consumption – is more problematic. Given the grave losses along myriad dimensions that are occasioned by not fishing and consuming fish, "success" here comes at a considerable price. To the extent that agencies judge advisories' effectiveness according to whether they elicit a decrease in fish consumption, agencies may misfocus their efforts from the perspectives of at least some affected groups. A measure of success that focuses on getting people to reduce their fish consumption may fail to appreciate the traditional, cultural, or religious reasons that make reducing consumption inappropriate, and in so doing, perpetuate cultural discrimination. In these cases, affected people may well have access to, understand, and "believe" the relevant advisories, they may simply decline to "comply" with them. As Hawaii's Thousand Friends observes:

> *A barrier to making fish consumption advisories work in Hawai'i is that no one will listen because eating fish is part of the culture.*[333]

The third function that advisories sometimes serve – to suggest alternative means (e.g., alternative fishing sites, alternative species, alternative preparation methods) to continue eating fish – is also problematic. To the extent that agencies judge advisories' effectiveness according to whether they convince people to switch to these alternative practices, agencies may again misfocus their efforts in a way that is an affront to the traditions, cultures, or religious beliefs of some of those affected. Consider, for example, the observations of the Asian Pacific Environmental Network:

> *The California Environmental Protection Agency (Cal EPA) health advisory recommends that people eat only fillet portions of fish, and bake, broil, steam or grill fish on a rack so that juices from the fat drip off during cooking. . . . The health advisory's recommendations for methods of cooking fish to lower one's risk of taking in harmful chemicals clearly are at odds with traditional ways of preparing fish and other seafoods.*[334]

To the extent that agencies judge advisories' effectiveness according to whether they convince people to switch to alternative practices that haven't been identified as appropriate *by* the affected

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[333]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[334]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 35 (1998).

group, agencies may fail to appreciate the economic, geographic, social, and other practical realities facing the affected group.

The fourth function that advisories might serve – capacity-building and empowerment – are important to securing environmental justice. It is crucial that those affected play central roles in developing and disseminating the information that they deem appropriate to their needs. Such efforts – *led* by those in the community, and *supported* by the EPA and other agencies – can contribute to the larger goals of what the Laotian Organizing Project calls "*participatory learning and culturally-appropriate organizing.*"[335] EPA and other agencies should view this as an opportunity to work with communities on the ground as they work to empower themselves. As Daisy Carter, Project AWAKE, observes:

> *The question is does the federal government (EPA) want to educate, inform, and enlighten citizens to become active in making decisions for themselves? The answer is no. Companies and the government would not be able to exploit these citizens who are at risk if this was done. Citizens would ask questions and become involved in their own destiny. However, without knowledge, communities who are at risk are prey. . . .*
>
> *One of the major roles of NEJAC is to find a way to empower local citizens who are in impacted areas to set up lines of communication and data bases to acquire information related to their needs.*

And, as noted above, advisories enhance their effectiveness in this regard when they provide information that enables affected communities and tribes to become educated about and involved in risk assessment and risk management decisions – that is, information that does not merely instruct "Do Not Eat the Fish," but that identifies the sources of contamination as well as relevant upcoming decisions about preventing, reducing, and cleaning up contamination for these sources.

Additionally, it seems that agencies' views of effectiveness are sometimes preoccupied by concerns that may bear little on effectiveness for communities of color, low-income communities, tribes, and other indigenous peoples. For example, state and federal agencies have devoted considerable effort to achieving "national consistency" in fish advisory programs. This effort was an "important objective" of the 1999 American Fisheries Society Forum on Contaminants in Fish (attended by 41 states, 7 federal agencies, and others). Yet few dividends from such efforts may accrue to communities of color, low-income communities, tribes, and other indigenous peoples: an affluent recreational fisher who lives in Ohio but vacations in Michigan might be confused by the differing approaches to fish consumption advisories taken by these two states, and so might benefit from consistency between them.[336] Fishers from environmental justice communities are

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[335]Maria Kong and Pamela Chiang, Laotian Organizing Project & Asian Pacific Environmental Network, *Fighting Fire with Fire* 5 (2001).

[336]Hugh F. MacDonald and Kevin J. Boyle, *Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine*, 17 Journal of Fisheries Management 687 (1997). Note, however, that consistency might be relevant to environmental justice communities where jurisdiction over a

less likely to be traveling about, fishing in multiple states – this may be so for historic, geographical, cultural, economic, or legal reasons, or some combination of these. These individuals are thus less likely to benefit from consistency among states.

In sum, "effectiveness" from the perspective of communities of color, low-income communities, tribes, and other indigenous peoples is likely to focus on the first and fourth functions, while for some affected groups, it is likely to include the second and third functions. However, definitions of effectiveness and appropriateness will likely vary with varying local and cultural contexts. Thus, it will be important to determine the perspective of the particular affected group on this question, and to look to this perspective to guide every aspect of any advisory process, including evaluation of its success.

C. EFFECTIVENESS: AVAILABLE EVIDENCE

Before discussing to what extent advisories are effective from the perspectives of communities of color, low-income communities, tribes, and other indigenous peoples, it is useful to canvass the available evidence on responses to the fish consumption advisories that have been issued. As a general matter, although advisories have been in effect in some places since the early 1970s, relatively little is known about how they affect humans' behavior.[337] Again, there is more evidence based on anecdote or local knowledge than based on formal study. For example, the California Department of Health Services notes that health advisories extending from Malibu to Newport Beach have been in place for many years, but that:

> *[O]utreach and education about the advisories has been difficult to accomplish. Of particular concern are the non-English speaking populations who may have difficulty obtaining and understanding health information.*[338]

To the extent that empirical data have been gathered, they tend to provide two kinds of information (1) whether people are aware of an advisory; and/or (2) whether people have altered their consumption practices as a result. "Awareness," in turn, includes (a) whether people are aware that an advisory exists, and (b) whether people are aware of an advisory's content and recommendations. Sometimes these data are gathered alongside studies of fish consumption rates and practices. These data-gathering efforts vary in the extent to which they gather socioeconomic and other data relevant to environmental justice communities.

According to one survey designed to gauge the effectiveness of Great Lakes sport fish consumption advisories, for example, "half the sport fish consumers were unaware of the fish advisory for PCBs in the Great Lakes. The lowest awareness was among women, minority

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single estuary, river or other waterway fished by these groups is shared by neighboring states.

[337]Id.

[338]California Department of Health, Environmental Health Investigations Branch, *Palos Verdes Shelf Outreach and Education Project on Fish Contamination Issues* (fact sheet available from California Department of Health Services).

groups, and persons with no high school degree."[339] Another survey of fish consumption patterns and advisory awareness among anglers on the Fox River in Wisconsin found that 95% of anglers who ate fish were unaware of Wisconsin's fish advisory pamphlet and 50% of anglers who ate fish had neither heard nor read about the health risks of eating Fox River fish. Asians (primarily Hmong and Laotians) represented 70% of the anglers who had not heard about the health risks (although they represented only 19% of the total anglers surveyed).[340] The survey found further that most of the anglers surveyed did not eat the fish they caught in the Fox River (83%)and that of these, 75% said they did not eat the fish because they were concerned about the contaminants. Of those anglers who ate the fish they caught, Asians made up the largest group, comprising 59% of fish eaters. The survey's authors observed:

> *Eating fish forms a regular part of the diet and culture for the Asians (Hmong and Laotians) living in the Green Bay area. White Bass, listed in the advisory as "Do Not Eat," appears to be their fish of choice. Although the number of Asian anglers fishing along the Fox River decreased after being informed by an interpreter that White Bass is not safe to eat, there is concern that some of these anglers still may be eating White Bass caught from other nearby contaminated waters. Many Asian anglers may not understand the fish advisory because of the language barrier or may not believe the fish advisory because no immediate physical ill effects have been observed from eating contaminated fish.*[341]

A third survey, of Maine open-water anglers, examined the effect of a 1994 statewide fish consumption advisory.[342] 63% of all anglers knew about the issuance of a mercury advisory regarding covering fish from all lakes and ponds in Maine. All socioeconomic characteristics (here: gender, age, fishing "effort") except education and income were the same for the groups who were aware of the advisory and those who were not. Of the anglers who were aware of the advisory, 22% of Maine residents and 23% of non-residents altered their fishing behavior, indicating that but for the advisory they *would* have consumed more fish, fished more days, or fished more or different waters.[343] A fourth survey, of fish consumption patterns and advisory awareness among the Laotian communities in West Contra Costa County, California, found that 48.5% of survey respondents had heard of a health advisory about eating fish and shellfish from the San Francisco Bay. Only a fraction of these (59.5%), however, could recall what the advisory

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[339]John Tilden et. al, *Health Advisories for Consumers of Great Lakes Sport-Fish: Is the Message Being Received?*, 105 Environmental Health Perspective 1360 (December 1997).

[340]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[341]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[342]Hugh F. MacDonald and Kevin J. Boyle, *Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine*, 17 Journal of Fisheries Management 687 (1997).

[343]Id.

said and none could recall an advisory more specific than "pregnant women should not eat large amounts of Bay fish," or "Bay fish are not safe to eat."[344] The survey found a statistically significant difference in awareness of the health advisory among ethnic groups within the larger Laotian community, with Khmu respondents being more likely to have heard of the advisory.[345] Of those who were aware of the health advisory, 60.3% said that it had influenced a change in their fishing or fish consumption habits. Of those whose habits were influenced, 62.7% said they no longer eat fish from the Bay or eat less fish from the Bay and 29.9% said they no longer eat fish from any source or eat less fish from all sources.[346] An account of a fifth survey, by the Environmental Health Investigations Branch of the California Department of Health, concludes:

> *Although the health advisory has been in place since 1994, outreach and education about the advisory to different fishing populations has been difficult to accomplish. The recently completed San Francisco Bay Seafood Consumption Study indicates that about two thirds of people fishing have no awareness or limited understanding of the advisory*.[347]

With this and other available evidence to go on, it appears that people of color and people with low incomes, limited English proficiency, or relatively little education are less likely to be aware of fish consumption advisories; that some portion of the people of color who are aware of advisories alters their consumption patterns as a result, but that a significant portion does not alter their consumption patterns; that there are differences among various ethnic groups in these respects; and that while contamination and advisories are not influencing all individuals to reduce their fish consumption, they are influencing individuals at sufficient rates to contribute to suppression effects (discussed in Chapter 1). Additionally, here as elsewhere, there is a need to gather further information especially about those groups and subgroups about which less is known.

D. EFFECTIVENESS: RISK COMMUNICATION AND CONSUMPTION ADVISORIES

The discussion in this Part tracks the components of risk communication as identified in the EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication*,[348] by the organizers of the 2001 National Risk Communication

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[344]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 29 (1998).

[345]Id. at 31.

[346]Id. at 30; Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org.

[347]California Department of Health, Environmental Health Investigations Branch, *San Francisco Bay Fish Consumption Outreach and Education Project* (fact sheet available from California Department of Health Services).

[348]U.S. Environmental Protection Agency, Office of Water, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication* 3 (1995).

Conference,[349] and in the risk communication literature more generally. That is, after discussing general risk communication issues in Section 1, issues of "audience identification" and "needs assessment" are examined in Section 2; issues of message content are explored in Section 3; issues of media choice are taken up in Section 4; issues of implementation are discussed in Section 5; and issues of evaluation are addressed in Section 6. In addition, the matters of funding and capacity-building are explored in Section 7.

1. Risk Communication – Overarching Issues

"Risk communication is a two-way street." This phrase is often repeated, but less often honored in practice – with the result that communication may not actually occur. How can the risk communication process be rehabilitated?

As a preliminary matter, EPA and other agencies should reexamine the terms conventionally used to describe the various participants in the risk communication process. Agencies often refer to the "public," the "community," or the "audience," on one hand, and agency and other "experts" on the other.[350] These terms set up a dichotomy that denies that members of affected groups are themselves "experts," with knowledge crucial to successful risk communication – including effective fish consumption advisories. A more appropriate terminology would recognize affected groups' expertise, and not withhold from them the appellation "expert." In a similar vein, agencies often refer to "target audiences," who are affected groups that receive messages, and distinguish these from "risk communicators," who are agencies that generate and disseminate messages.[351] These terms indicate a one-way flow of information (*from* agencies *to* affected groups) rather than a two-way process; and these terms may also carry the connotation of agencies as being active in the process whereas affected groups are passive. A more appropriate terminology might use words such as "partners" or (particularly in the case of tribes) "co-managers." While these may seem small quibbles over a few words, these words frame the relationship among the various participants in the risk communication process, and may serve to undermine successful, two-way communication before the process even gets off the ground.

Then, it is necessary to put into practice the concept of "partnership" or of "co-management." *Affected groups must be involved as partners or co-managers at every point in*

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[349]Proceedings from the National Risk Communication Conference. May 6-8, 2001. Chicago, IL. Sponsored by the Minnesota Department of Health, US. EPA and the Society Risk Analysis. EPA Cooperative Agreement Grant #X-82825101-0. August 2001. Available on line at http://www.epa.gov/ost/fish/forum/riskconf.pdf.

[350]U.S. Environmental Protection Agency, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, *Volume IV: Risk Communication* 3 and throughout (1995).

[351]Id; see also, *National Risk Communication Conference, Proceedings Document* I-5 (2001)(describing "Risk Communicator Presentation session, which described "getting to know the audience from the risk communicator's point of view.")

the risk communication process. This is the single most important lesson that EPA and other agencies should take away from this discussion of effective fish consumption advisories. All of the elements of effective fish consumption advisories will fall into place if agencies and affected communities or tribes consider together the questions and answers. That is to say, communities and tribes will articulate their needs; affected groups and agencies will each share their respective concerns; affected groups will help ensure that the content and medium of advisories are appropriate to their membership (e.g., in terms of language, literacy, culture, practice); affected groups will be able to contribute creative implementation strategies appropriate to their membership; and affected groups will have knowledge indispensable to the evaluation process. As in the case of research in general (discussed in Chapter One), communities and tribes have expertise relevant to risk communication that is simply not going to be able to be replicated by non-member researchers. This is supported by the large body of literature on "participatory research." Members of these affected groups ought to be recognized as the experts they are, and their work ought to be supported financially (whether though dispensing grants to community groups, tribes, and partnerships formed by affected groups, through hiring affected group members as expert consultants, or through other means). EPA and other agencies should recognize the difficulty of achieving full involvement – and thus actual risk communication – in the absence of financial support. This issue of funding is taken up at greater length below.

EPA and other agencies should work to reconceptualize risk communication approaches from large-scale, abstracted, one-time efforts to develop and disseminate various communication "products" (e.g, developing and posting fish consumption advisory signs) to local, contextualized, ongoing efforts to establish and maintain relationships with a particular affected community or tribe.[352] While this reconceptualization may be necessitated to a greater degree for some groups and contexts than others, the existence of an ongoing relationship will enhance communication regardless. And, while building and maintaining a relationship will likely require more time and resources than agencies have typically been able to devote to risk communication,[353] the dividends would seem to be worth it. For example, representatives of agencies and affected groups alike have suggested that a lack of familiarity or trust has been a barrier to effective fish consumption advisories in the past (resulting, e.g., in a reluctance by affected group members to participate in baseline consumption rate studies or other information-gathering efforts; or in a scepticism on the

[352]See, e.g., Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001)

[353]See, e.g., Ed Horn, Bureau of Toxic Substance Assessment, New York State Department of Health, National Risk Communication Conference II-25 (2001) ("The most effective ways of communicating with hard-to-reach populations are extremely labor intensive. They are going to require someone in the target community who has the respect of the community and an understanding of the community. It requires constant work; it's not just a matter of sending a brochure out. We can send 20,000 brochures out fairly easily and inexpensively, but if we have to travel to meet with the target population in small groups, then this requires additional staff.").

part of affected groups regarding the intent behind or the accuracy of agencies' messages).[354] To the extent this is the case, the existence of an ongoing, regular relationship would go far toward dismantling this barrier.[355] The importance of gaining trust and building a good relationship bears emphasis. Affected groups often cite agencies' lack of "follow through" as a source of mistrust. Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, elaborates:

> *After an agency has made a commitment to addressing environmental justice by committing the necessary resources, the next step perhaps is to work on gaining trust and credibility with ethnic minority, immigrant, and low-income communities. . . . Among these communities, there is a severe lack of trust that government will listen to or take care of their concerns.*
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> *Many immigrant and low-income communities place a strong emphasis on quality relationships. They need to know you care, are sincere, have* their *interests in mind (as opposed to your agency's interest) and there is follow-through on your commitments. These relationship features do not come about in a short term, but rather must be developed over time. So, if your agency's outreach staff visits a community group only when you need their help, your commitment to that community may be seen as tokenism or serving your needs. One way to develop and maintain a long-term relationship is to have regular – perhaps once a month or a quarter – meetings (these could be over coffee, breakfast or lunch) or to pay routine visits to [a community group's] office, even when there is nothing you need their help on. During these visits, once must show genuine interest in the community group's activities, and where appropriate, find out if there are ways you can help them in some of their activities, even if those activities do not directly pertain to your project's objectives.*[356]

To this end, several affected groups have recommended partnering with existing community groups and local service providers. For example, Hawaii's Thousand Friends urges:

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[354]See, e.g., Ed Horn, Bureau of Toxic Substance Assessment, New York State Department of Health, National Risk Communication Conference II-23-25 (2001); Telephone Interview, Chee Choy, Portland Bureau of Environmental Services (Oct. 26, 2001); Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 36 (1998).

[355]See, e.g., Telephone Interview, Chee Choy, Portland Bureau of Environmental Services (Oct. 26, 2001); Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

[356]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 4 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

> *To best reach Hawaii's diverse multi-ethnic and indigenous Native Hawaiian populations about the risk of fish consumption, we recommend the following: Work through existing community health centers since they have existing outreach infrastructure. This is especially true for health centers in communities with a predominantly Native Hawaiian population and Hawaiian homestead communities; . . . Form partnerships with organizations that work with the same nationality and culture as those targeted, using grants and technical assistance . . .* [357]

Again, this relationship cannot happen without the involvement of communities and tribes; to facilitate this involvement, financial support will often by critical.

In order to realize actual communication – that is, a *process* of respectful information *exchange* – agencies, in particular, need to work to enhance their skills as active, flexible, and open listeners. Relevant information may come in unexpected or non-conventional forms – in anecdote rather than empirical study, in a conversation rather than in an article in a peer-reviewed journal, in a narrative (such as the narratives gathered in this Report) rather than in a table or chart, or in an indirect or non-verbal form, rather than bluntly and directly. In many cases, these may indeed be the sources of the most valuable information.[358] Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, offers one such example:

> *In some traditional Asian cultures, and perhaps in other cultures as well, feedback may be communicated in indirect ways (e.g., reading between the lines, so to speak) because it is seen as impolite to disagree with you, or that giving you an honest but negative comment may mean a loss of face for you. This is where having built a relationship with a community will help you to identify verbal and non-verbal cues about an indirect comment and to seek an honest comment that you can understand.*[359]

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[357]Hawaii's Thousand Friends (Written Comments, March 11, 2002); accord, id. (noting that "the City of Portland has been contracting with the International Refugee Center of Oregon (IRCO) and the Hispanic Access Center to hire people who are from the Russian, Southeast Asian, and Hispanic communities to conduct fish advisory outreach to their respective communities.").

[358]See, e.g., Katharine J. Hornbarger, et al., *Targeted Audience Analysis: Recommendations for Effectively Communicating Toxic Fish Consumption Advisories to Anglers on the Detroit River* 14-18 (June, 1994) (discussing considerable benefits of "conversational interviewing" techniques).

[359]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

Often, this approach will not be easy. Not only will it take time – time to sit down and visit, time to ask further questions in order to understand – but also real work.[360] There may be language barriers to hurdle, differences in communication styles to decipher and address, large cultural differences to bridge. "Public comment periods" or "breakout sessions" may not provide useful avenues for conversation from everybody's perspective. Similarly, public meetings held in hotels or convention centers may not provide a very familiar, welcoming or accessible (e.g., by walking or using public transportation) site for many from affected groups.[361] Sometimes, where the participants in a conversation come from radically different cultures or start with radically incompatible worldviews, there may never be complete understanding. But even if there are glimpses of understanding, the process itself is important (e.g., to building good relationships). Moreover, if the conversations are ongoing, understanding is likely to increase over time. For example, Josee Cung, Program Manager, Southeast Asian Program, Minnesota Department of Natural Resources, describes a collaborative effort with the Minnesota Department of Health and community leaders to design and implement culturally appropriate education regarding consumption of contaminated fish, which includes "education delivery" methods such as:

> • *[Sessions in] anglers' homes, as a version of the storytelling tradition and often involving elders*
>
> • *Day field trips that include bus travel to fishing sites, the education component followed by a hands-on session of actual fishing and fish cutting and preparation*
>
> • *Several sessions have ended with a communal meal of the caught fish prepared jointly by instructors and students*
>
> • *All activities are planned and take place under community sponsorship. Heads of community organizations promote and publicize the educational sessions and work with [the Department of Natural Resources] to recruit and enroll participants*[362]

Agencies not only need to hear information that comes to them in unexpected forms, but also need to be open to information that provides unexpected substance. Agencies should work

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[360]See, e.g., Kerry Kirk Pflugh, Bureau Chief, Raritan Watershed, Division of Watershed Management, New Jersey Department of Environmental Protection, *National Risk Communication Conference, Proceedings Document*, "Community Outreach to At-Risk Urban Anglers: A Case Study in Risk Communication of Fish Consumption Advisories" II-36 (2001) (noting, among the "lessons learned:" "Be flexible, take time to visit, listen, and learn.").

[361]See, e.g., Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

[362]Josee N. Cung, Program Manager, Southeast Asian Program, Minnesota Department of Natural Resources, National Risk Communication Conference, Proceedings Document, II-52-53 (2001).

to accept information they don't (yet) know they need – e.g., the answer to the question that the member of an affected group *wishes* the agency had asked (because this is what is most important from her perspective), the community- or tribally- developed research agenda that frames the issues differently than the agency would. Agencies should work to take in (and redirect if necessary) information that appears to pertain to a related but different program or agency. Thus, in the context of fish consumption advisories, those in environmental agencies' fish advisory programs should work together with those in their water quality standards and clean up programs to ensure that the comments they hear – e.g., "clean up existing contamination so that advisories can be lifted" – get registered with those in relevant programs *as well as with those setting priorities among programs and efforts*. Similarly, those in health agencies should work together with those in environmental agencies to ensure that such comments get passed along and that there is a connection between relevant staff working to address the issues.[363] While it is never easy to hear information that may require one to reevaluate current priorities, methods, or approaches, this reevaluation may be the key to efforts that are defensible as a matter of science and social science, acceptable from the perspective of communities and tribes, and, ultimately, effective as a matter of risk communication.

Involvement by affected groups is necessary as well because they, ultimately, are the ones who will bear the brunt of harms from contamination not addressed and communication not achieved. They, among all "stakeholders," are the ones who face the most immediate and often irreversible losses – it is not just a matter of being out a few dollars on the profit side of the ledger but a matter of their health and the health of their children, a matter of their culture, traditions, and deeply-held beliefs. Given what is at stake for affected communities and tribes, they should be among the first to learn about contamination and its possible effects for them, and they should be among the first involved in determining how to respond. Richard Brown, Coordinator, Black United Front explains, in the context of the low-income and largely African American community in Northeast Portland, Oregon that fishes in, swims in, and is affected by the contaminated Columbia Slough:

> *The things that happen to people are devastating. You know you don't recover from a lot of these things because we don't find out about them until they've really taken its toll. Those are concerns I've always had about the way people in low-income communities have been treated as fare as environmental issues go."*[364]

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[363]Richard Greene, Delaware Department of Natural Resources and Environmental Control, for example, notes that Delaware is undertaking efforts to link fish advisories and water quality standards under the CWA's TMDL program, but comments that "state [water quality standards] program participants need to acquaint themselves with their fish advisory program counterparts and start a serious dialogue. They also need to establish common goals; improving water quality and lifting advisories can result from agency cooperation." *Proceedings of the National Forum on Contaminants in Fish* I-13 (2001).

[364]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

Ticiang Diangson, Supervising Planning and Development Specialist and Environmental Justice Advocate, Seattle Public Utilities, observes:

> *[I]t takes inordinate effort on the part of harmed communities to gain acknowledgment of the impact of the contamination and to get real-life implementation to solutions to the impact.*

To the extent that research is conducted by and for communities and tribes, it can serve the additional important function of capacity building. This goal is important and an issue of environmental justice in and of itself, for both communities and tribes. And, to the extent that communities and tribes see that their concerns are shaping the research to be conducted, that the information gathered will be relevant from their perspective, and that their members stand to enhance their skills, knowledge and capacity in the process – as opposed to merely providing information that enables others to enhance *their* skills, knowledge and capacity – participation and trust are likely to be increased, and accuracy thereby enhanced.[365]

As noted in Chapter One in the context of research in general, funding is crucial to the ability of affected communities and tribes to be involved in research, including research about risk communication. This point is elaborated below, in Section 7.

Finally, it is important to note that there are considerable resources on which EPA and other agencies interested in improving risk communication with affected groups can draw – resources that have been developed by or with the involvement of communities of color, low-income communities, tribes, and other indigenous peoples. Rather than attempt to repeat their work here, this Report refers to several of these sources: the National Environmental Justice Advisory Council Public Participation Plan; the National Environmental Justice Advisory Council Indigenous Peoples' Subcommittee, Recommendation on Environmental Health and Research Needs Within Indian Country and Alaska Native Villages; the Outreach Strategy developed as a part of EPA's Asian American and Pacific Islander Initiative; and the (Draft) Strategy on Limited English Proficiency.

2. Different Communities and Tribes, Differing Concerns and Needs

The term "affected groups" here includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected

[365] See, e.g., id. at 37 (noting that the survey planning team made connections with the Laotian Organizing Project's ongoing capacity building efforts regarding community health and safety, which motivated many community members to participate in the survey and explaining: "The planning team was originally hesitate about the perception commonly held by community members of outsiders taking information from the community without community people seeing the benefits of research. Linking the survey to a community based organization helped counter this perception.").

groups, including but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refugee communities; African-American communities, various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thaidum communities within the Laotian community in West Contra Costa, CA); various Hispanic communities and subcommunities (e.g., Caribbean-American communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaskan Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people). "Affected groups" also refers to subgroups within these larger groups, including but not limited to nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices that implicate fish consumption; and subgroups defined by geographical region.

EPA and other agencies have increasingly recognized this diversity and its relevance to fish consumption advisories and other risk communication efforts. For example, EPA, in particular, has recognized the diversity of Asian and Pacific Islander communities, and provides an "Asian American and Pacific Islander Primer" on its Asian American and Pacific Islander Initiative website.[366] This primer identifies Asian Americans as those with origins in one or more of 28 Asian nations, and Pacific Islanders as those with origins in one or more of 19 island nations.[367] EPA has undertaken a number of efforts as part of this initiative that attend to the diversity of this group.[368] Important among these efforts is an extensive Outreach Strategy.[369] Nonetheless, EPA and other agencies need to do more to attend to the myriad groups and subgroups affected by their work. Agencies' efforts, moreover, have been uneven, such that there are some groups and subgroups about which EPA and its counterparts still know relatively little. It should be noted, too, that the composition of the affected groups may be changing rapidly in some areas, such as cities that are ports of entry for immigrant and refugee groups or rural and other areas where particular groups have settled.[370] Thus ongoing and constant efforts are necessary to learn about and attend to the changing contours of affected groups and subgroups. These efforts are most usefully undertaken together with the affected groups themselves, who will often be able to alert non-members to nuances about which they would otherwise not have knowledge. Even laudable agency efforts to identify and address the needs of a non-majority group may be partial to the extent that they fail to appreciate the existence of other affected groups or subgroups. The

[366]U.S. Environmental Protection Agency, *Asian American and Pacific Islander Primer* available at www.epa.gov/aapi/primer.htm.

[367]Id.

[368]These efforts place EPA at the forefront of federal agencies in implementing Executive Order13216 (and its predecessor) on Increasing Opportunity and Improving Quality of Life of Asian Americans and Pacific Islanders.

[369]U.S. Environmental Protection Agency, Office of Administration and Resource Management, *Asian American and Pacific Islander Outreach Strategy.* (No. EPA-202-K-01-003) (September 2001) available at www.epa.gov/aapi/outreach.htm.

[370]See, e.g., Kerry Kirk Pflugh, Bureau Chief, Raritan Watershed, Division of Watershed Management, New Jersey Department of Environmental Protection, *National Risk Communication Conference, Proceedings Document,* "Community Outreach to At-Risk Urban Anglers: A Case Study in Risk Communication of Fish Consumption Advisories" II-32 (2001).

Laotian Organizing Project points, for example, to a state fish consumption warning sign at a popular fishing site in Richmond, CA written in English, Spanish, and Vietnamese and notes:

> *The Vietnamese language translation is useless to a predominantly Laotian population.*[371]

These different groups are likely to differ with respect to their concerns and needs relevant to risk communication. This is a crucial point. The risk communication literature, including Volume 4 of EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, describes "needs assessment" or determining "what the audiences want and need to know" as an initial step in the risk communication process.[372] The answer to this question is likely to differ in important respects from group to group, and even from subgroup to subgroup. *The best – if not only – way to determine the concerns and needs of a particular group is to secure the involvement of group members in the process.* This involvement is crucial at every point in the risk communication process. It is especially important at the point of needs identification, if the resulting advisories and other communication efforts are to be relevant to the group – and if they are to be perceived by the group as being relevant.

The importance of affected group involvement at the point of identifying needs and defining a research agenda has been echoed by numerous communities and tribes. For example, consider the account of recent efforts by the Alaska Native Science Commission to this end as part of the Traditional Knowledge and Contaminants Project, by Pat Cochran, Executive Director:

> *The project objectives are, first of all, to use our own native ways of knowing, learning, and teaching to gather information. We held our own talking circles in our own communities. We did not send out survey forms. We didn't have people that had focus groups. We went and sat with our people for days at a time – laughing, singing, dancing, and eating a lot of food – because this is a part of what we all do. So, we could really gain the knowledge from our communities. Our communities, we understand, are the first observers of what happens on our land, to the people, in the air, in the water, and in the environment around us. Long before a researcher or scientist or anyone else enters the community, our people are the ones who perceive what happens every day, and also generationally over centuries and beyond from information that has come down from their people. We [are] providing grant opportunities to our communities and we are looking at developing a common research agenda that answers concerns and questions about our communities and not just somebody's Ph.D. dissertation topic. And we are also developing a database. We held regional meetings all across the state of Alaska*[373]

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[371]Laotian Organizing Project, *Fighting Fire with Fire* 5 (2001).

[372]See, e.g., *National Risk Communication Conference, Proceedings Document* 14 (2001); U.S. Environmental Protection Agency, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, *Volume IV: Risk Communication* 3 (1995).

[373]Patricia Cochran, Executive Director, Alaska Native Science Foundation, *National Risk Communication Conference, Proceedings Document* II-20 (2001).

3. Message Content

What constitutes appropriate and relevant message content is likely to differ from group to group. General, "one-size-fits-all" recommendations, therefore, are likely to be unuseful. Rather, the important point is that content that is appropriate and relevant to a particular affected group cannot be determined apart from the involvement of members of that group. In addition to local knowledge, group members will often have extensive expertise in message development and community outreach for their particular community or tribe. Their involvement in every aspect of content development and advisory design is indispensable.

Several considerations are relevant. Advisory content should be culturally appropriate from the perspective of the particular affected group or subgroup. As documented in Part A., above, it may be culturally inappropriate to include various recommendations – to eliminate or reduce fish consumption, or to alter practices including procurement of fish, species and parts consumed, and preparation methods. Here, there are likely to be vast differences among affected groups as to what is and is not acceptable. Advisory content thus needs to be developed in a manner that is respectful of these differences. Involvement by members of the particular affected group is, again, crucial.

Advisory content should address the needs identified by the particular affected community. This should include the needs of any subgroups within the larger group, such as nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices that implicate fish consumption; and subgroups defined by geographical region. Other needs, too, may emerge as important to a particular group. For example, according to the summary of the important themes that emerged from the breakout group designated "Cultural Enclaves – Native American and Other Cultural and Traditional Communities:"

> *Fish advisories should contain information on the nature and sources of the contamination so that the affected community is empowered to take action to reduce pollution source and clean up existing contaminated sites or obtain financial compensation for the loss of the natural resources.*[374]

To address the needs of some affected groups, advisories should emphasize the health and cultural benefits of eating fish or of participating in particular practices.

Advisories should be provided in the language(s) of the affected communities, groups, or peoples. Many members of affected groups are limited-English proficient; some, especially recent immigrants and refugees, may have no English. For example, EPA reports that "[a]n estimated 40-50% of [Asian American and Pacific Islanders] are limited-English proficient."[375] Many agencies have recently worked to provide language-appropriate warnings (perhaps as a result of

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[374] *National Risk Communication Conference, Proceedings Document* I-11 (2001).

[375] U.S. Environmental Protection Agency, *Asian American and Pacific Islander Primer* available at www.epa.gov/aapi/primer.htm.

studies showing a particular group's lack of awareness of advisories, as was the case on the Lower Fox River, where Wisconsin recently posted signs in English and Hmong), and there has been considerable progress in this regard. For example, Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, recounts the challenges and ultimate success – in important part because of the partnership between the City and the various affected groups – of one such effort:

> *A committee comprising people from various community organizations (such as [Environmental Justice Action Group] EJAG, [International Refugee Center of Oregon] IRCO, Urban League, Coalition of Black Men, Lutheran Family Services Center, Russian Oregon Social Services, Confederated Tribes, etc.) helped the City of Portland to rewrite the technical fish advisory brochure originally written by the Oregon Health Division. This process was challenging because of the differences in opinion among the various communities regarding the usage of appropriate words in the advisory. While many committee members did not object to literally translating the word "DANGER," which was stamped across a picture of a carp, into their respective languages, the Russian community representatives strongly insisted on using "CAUTION" rather than "DANGER." After much deliberation, the committee reached a compromise to use the word "CAUTION" [and translate the advisory into six appropriate languages].*[376]

Even where agencies have made progress, however, they may have yet to identify and address the needs of all the relevant communities for language-appropriate advisories. Recall the Laotian Organizing Project's dismay when a state fish consumption warning sign at a popular fishing site in Richmond, CA was written in English, Spanish, and Vietnamese: "*The Vietnamese language translation is useless to a predominantly Laotian population."*[377] Similarly, Hawaii's Thousand Friends recommends that agencies:

> *Partner with local groups in Hawai'i to create information sheets/brochures in the Hawaiian language for distribution in immersion schools.*[378]

Advisories should be designed to account for limited literacy or illiteracy in the affected group. Some groups come from a tradition of orality.[379] They may not have a written language or may not be literate in their language to the extent it has been written down. Or they may be

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[376]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

[377]Laotian Organizing Project, *Fighting Fire with Fire* 5 (2001).

[378]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[379]See, e.g., id. ("The Native Hawaiian culture is an oral culture, so written information sheets and/or brochures will not always reach the intended audience, and more culturally sensitive methods should be developed.").

resistant to reducing communication to writing, preferring instead to give and receive information orally. Some groups have had less formal education, such that some of their members may be illiterate. In all of these cases, advisories should not rely on written words, but on devices such as spoken words, demonstration, or graphics.

Advisories should be accessible. They should use words that are understandable to the particular affected group; they should avoid jargon. To the extent possible, they should use short, manageable sentences. They should employ visual aids such as charts, pictures, models, posters, and hands-on demonstrations. Kristine Wong, the former Project Director of the Seafood Consumption Information Project, which focused on "conducting community-based research, education, outreach, and advocacy on the issue of contaminated fish consumption in San Francisco Bay," observes:

> *[M]any terms used frequently in health warnings need to be changed to reflect the common language of those who fish for food. For example, the term "sportfish" is used in the San Francisco Bay health advisory, yet those who catch and eat bay fish do not interpret the term "sportfish" as the fish that they themselves consume on a regular basis. During our regular visits to the fishing piers we conducted an informal survey to see if people actually understood that "sportfish" applied to all the fish that were being caught in the bay. Most interpreted the term "sportfish" to be the jumbo-sized fish caught on fishing boats, confirming our suspicions.*[380]

As Hawaii's Thousand Friends urges:

> *Use the local name of the fish in any outreach.*[381]

Although, in order to be sufficiently informative, advisories will need to convey complex information (e.g., about risk, contaminants' health effects, sources of contamination), there are more and less accessible ways to do this. Daisy Carter, Project AWAKE, Coatopa, Alabama, explains:

> *We believe enough books, pamphlets, policies, and manuals have been written. We have become a paper-filled society to the limit. But the question is, who is reading this material? Most people and especially the impacted communities do not take the time to read these large manuals; yet this is the method EPA and states use to get their information out. This is not the best approach to reach these communities. When asked what is being done, the reply is, "well, we have this book." What is the problem? Document upon document, volume upon volume is available, waiting to be read and complied with."*

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[380]Kristine Wong, Former Project Director, Seafood Consumption Information Project, *Comments to the National Environmental Justice Advisory Council* Vol III-65-67 (Annual Meeting Transcript) (Dec. 4, 2001).

[381]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

Finally, advisories should be designed to facilitate the two-way exchange that is the hallmark of good risk communication. *Importantly, as many affected groups have noted, advisories need to make available information about the nature, extent, and sources of the contamination that is giving rise to the advisory.* Thus, at a minimum, they should include contact information for the appropriate agencies, tribal government bodies and/or community groups, so that there is a place to lodge comments, ask questions, or obtain further information. Posted signs, for example, often leave those affected with unanswered questions.[382] Advisories should also provide additional relevant information, including information about the nature, extent, and sources of contamination that would enable those affected to participate not only in risk communication efforts but also in risk assessment and risk management decisions. Joanne Bonnar Prado, of the Washington Department of Health, emphasizes just this perspective:

> *[O]ne of the things that I've learned . . . is that we need to incorporate really thoroughly issues of source and where the sources [of contamination] are coming from . . . We understand that, [but] we do not talk about it much within our – or at all within our – health communications about source and source reduction. . . . So supplying information about sources, source reduction that individuals and communities and governments and all the various strategies that can be used on a local, statewide, and worldwide basis to reduce mercury – and this would apply to really all contaminants I would think – is really appropriate for this particular issue.*[383]

4. Medium

What constitutes an effective and appropriate medium for conveying the message will vary from group to group. Sometimes, it will be most effective to try to reach people via multiple media routes. Again, general "one-size-fits-all" recommendations are likely to be unuseful. Again, members of the affected group will possess valuable knowledge about the best medium from their perspective, and should therefore be involved in choices among media.

Several observations can be made. The medium chosen should take into account the habits and customs of the affected groups; it should take into account the access enjoyed by the affected groups. There has been some recent work identifying different media sources as more or less likely to be used or preferred by various affected groups.[384] For example, of those in the Laotian communities in West Contra Costa County who had heard of the health warning in place

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[382]See, e.g., John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-43-44 (2001).

[383]Joanne Bonnar Prado, Washington State Department of Health, *Comments to the National Environmental Justice Advisory Council* Vol III-13 (Annual Meeting Transcript) (Dec. 4, 2001).

[384]See, e.g., John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-45-49 (2001) (presenting an extensive assessment of the advantages and disadvantages of twelve different categories of media/formats for various audiences, and cataloging available community channels and potential partners).

for San Francisco Bay fish, nearly 60% had heard of it through television news, 37.8% though word of mouth from friends and family, 18.9% via signs at various piers, and 14.4% through the newspaper; others had heard of the advisory though church, a local community-based organization, school, the doctor's office, and the welfare office.[385] Many members of affected communities of color, low-income communities, tribes, and indigenous peoples do not have access to the Internet as a means of apprising themselves of current advisories posted on agencies' websites. According to John Cahill, Director, Bureau of Community Relations, New York State Department of Health:

> *Last year, 56 percent of Americans used the Internet. However, only 23 percent of African Americans had Internet access, compared to 46 percent of White households. A majority, 82 percent, of Americans earning $75,000 or more had access, compared to only 38 percent of those earning less than $30,000.*[386]

Some of those affected may not have a telephone, and so cannot readily call numbers listed on signs or in pamphlets. To the extent information is distributed by agencies or others who give out fishing licenses, Native Americans and others who are not required to obtain a license to fish will not receive information distributed in this way; neither will those who for any number of reasons simply haven't obtained a license. John Cahill points out, for example, that a recent survey of anglers along New York's Hudson River revealed that only 57.5% of them had licenses; and a series of focus groups among Latino anglers in Buffalo found that only about half of them were licensed.[387]

The medium chosen should make advisory information easy to locate and access. Some current advisories may require several steps to locate and access (e.g., the need to consult a fishery regulations book, as in Maine; the need to write to the Department of Natural Resources or to go to local offices or state parks (or on-line), as in Wisconsin; the need to sort through fairly complex information, as in Michigan), which steps impose greater hurdles for those whose educational background or financial resources do not afford them the tools to navigate governmental bureaucracies.

Here again, agencies are making strides although there is work yet to do, and agencies need to ask those affected what would work for them.

5. Implementation

Members of affected communities and tribes will often be particularly well-positioned to take the lead in implementing the advisory and outreach strategy that has been developed by and for their group. Members of affected groups will be active in or aware of community

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[385]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 30 (1998).

[386]John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-43 (2001).

[387]Id. at II-42-43.

organizations, churches and other religious organizations, clubs, schools, and other entities that could play a role in getting the message out and facilitating risk communication. Members of affected groups will likely know precisely which community festivals, ceremonies, or events are likely to be well-attended and appropriate venues for outreach. For example, Detroiters Working for Environmental Justice not only prepared a pamphlet, together with the Lake Erie Binational Public Forum, directed at those eating fish from Lake Erie, the Detroit River, and the Rouge River, but they also work to distribute the pamphlet at local health fairs.[388] Members of affected groups will often be able to put together creative ideas for outreach – a product of their knowledge of norms in the community or tribe; their on-the-ground connections; their shared experience – especially, shared practices exposing them to environmental risks; and their involvement in prior organizing efforts.

Implementation by members of affected groups may also facilitate environmental justice along multiple dimensions. In addition to capacity-building, discussed below, looking to affected groups for implementation may enable them to dovetail efforts regarding fish consumption with other health and environmental outreach efforts (e.g., regarding possible contaminants in breast milk, regarding the value of Native foods in countering diabetes, or regarding nutrition in general) and/or other community-building efforts – efforts that may already be well-established, which would in turn enhance the likelihood that data about fish consumption practices would be complete and accurate, and that advisories regarding these practices would be received. For example, the Asian Pacific Organizing Network explains, in the context of its survey of Laotian communities in West Contra Country, California:

> *Active participation by community leaders who are recognized and respected in the community brings trust and credibility to a survey that could otherwise be seen as intrusive. In this survey project, community leaders made the initial contact with people in the community, explained the goals of the survey to participants, and answered any questions and allayed any fears that people may have. Such collaborative work helped establish important relationships between community leaders and APEN's Laotian Organizing Project (LOP) as a young, emerging organization within the community.*
>
> *Organizationally, APEN is committed to working with youth, in order to foster new leadership within the community. Therefore, 'survey teams' of youth and established community leaders carried out the survey together.*[389]

Agencies, together with affected groups, should consider shifting current approaches to outreach so that it is primarily grassroots, community-based organizations and groups that do the outreach in their respective communities. Where this is appropriate, these groups should be funded to take on this responsibility. For example, they could be hired as contractors to the

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[388]Telephone Interview with Michelle Shewmaker, Detroiters for Environmental Justice (Oct. 26, 2001); Detroiters Working for Environmental Justice and Lake Erie Binational Public Forum, *A Family's Guide to Eating Fish from the Detroit Area* (pamphlet).

[389]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 8 (1998).

relevant agency. Or, they could receive grants to conduct this work. As Marianne Yamaguchi, Director, Santa Monica Bay Restoration Project, notes, some agencies and others in Southern California are already taking this approach, with benefits not only in terms of effective and appropriate implementation but also in terms of capacity building.[390] Funding and capacity-building are discussed further below, in Section 7.

6. Evaluation

Affected group involvement is critical to evaluating the success of risk communication efforts in general and consumption advisory programs in particular. This involvement is important at every point of evaluation, but is particularly necessary to evaluation in the early stages of risk communication (what *Volume IV* and the risk communication literature term "formative evaluation") and at the point of assessing whether the objectives of risk communication efforts have been met (what *Volume IV* and the risk communication literature term "summative evaluation"). Given the potential for differences in the definitions of "effectiveness" adopted by agencies and various affected groups – and the likelihood that differences in objectives would flow therefrom – it will be important for those affected to be able to ensure that *their* perspectives are being incorporated into any evaluations.

Affected groups will be able to work together with agencies to determine the extent to which it is useful to focus evaluation on particular "products" (e.g., number of radio spots, number of pamphlets distributed, numbers of health fairs visited), on outcomes indicating awareness (e.g., awareness of advisories' content and recommendations), on behavioral outcomes (e.g., extent to which consumption levels are reduced so that they fall within recommendations, extent to which species consumed changes from less safe to safer species, extent to which preparation methods change so that exposure to contaminants is avoided), or on more broadly crafted outcomes (e.g., increased knowledge within effective group of contamination, its sources, and related regulatory efforts, increased involvement by community members in decision making regarding risk from contaminated aquatic ecosystems, improved trust and enhanced relationships among agencies and affected communities and tribes, improved health in the affected group).

Agencies should ensure that "evaluation" includes assessment not only of the particular advisory program or outreach effort, but of its risk communication efforts more generally. Affected groups can usefully aid agencies in evaluating their risk communication efforts, and in evaluating connections between risk communication and risk assessment and management. For example, related to the issue of two-way communication, consider the question: How should agencies *register* the responses of those affected?[391] For example, if an affected group receives and understands the information contained in an advisory but nonetheless rejects its advice that fish consumption be reduced, how should this response be incorporated into agencies' policy choices regarding the role of fish consumption advisories? How, in the first place, should agencies ensure that they are correctly interpreting the responses of affected groups – have the

[390]E-mail Communication, Marianne Yamaguchi, Director, Santa Monica Bay Restoration Project (Oct. 23, 2001).

[391]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).

practices remained the same because those affected do not understand the advisories; because they understand but do not believe or agree with the advisories' accounts of the contamination or its health effects; because they understand and in some sense agree with the advisories' accounts of the contamination or its health effects, but nonetheless cannot for economic and/or for traditional, cultural, or religious reasons change their practices? The need for "interpreters" from within the relevant community, group or tribe seems clear. And to the extent that those who decline to "comply" with advisories should be taken to be lodging a kind of protest – that is, to the extent that noncompliance itself should be taken as an expressive act, indicating resistence to agencies' reliance on risk avoidance rather than risk reduction[392] – how will this view be taken into account when agencies decide how much to rely on advisories versus how much to focus on cleanup and prevention?

Finally, agencies should ensure that "evaluation" includes vigilant and careful re-assessment of the health of the resources that are the subject of advisory or closure, so that they are opened again for fishing and advisories are lifted as soon as is appropriate. This may be a particular issue in the case of shellfisheries closed due to the presence of acute contaminants, whose short-term life span means that re-certification may be appropriate in fairly short order.[393] This is especially important given communities' and tribes' reliance on these resources for economic, subsistence, and other reasons. Of course, agencies will need to be sure that fish are safe for consumption before doing so, and this implicates current limitations in agencies' ability to measure the presence of contaminants. For example, current methods are unable to detect below certain levels for some persistent and bioaccumulative contaminants (e.g., dioxins) – yet even very small quantities may have an effect on human and environmental health. Thus, even if it can be said that contaminant levels in a particular river stretch have been reduced to non-detectable levels, this may not mean that they have been reduced to safe levels – only that current measurement methods are at their limit. To remedy this gap in agencies' ability to determine the safety of fish for human consumption, agencies need to conduct research to improve current measurement abilities. In the meantime, agencies need to inform affected groups of the detection limit issue (and other relevant issues) if an agency chooses to alter or lift advisories under such circumstances.

7. Funding and Capacity-Building

As noted above, capacity-building or capacity-augmentation is in and of itself an environmental justice issue, for both communities and tribes. Involvement by those affected at each point in the risk communication process would go far toward enabling those affected to shape the process so that it is not only relevant and appropriate, but also useful and empowering from the perspective of the community or tribe. In addition to the aspects of capacity-building discussed above, affected groups will be able to identify other, current needs in this regard.

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[392]Id.

[393]Telephone Interview, Jay Zischke, Marine Fish Program Manager, Suquamish Tribe (Oct. 17, 2001).

Among the issues that have been identified is the need to ensure that the fruits of its work are returned to the affected group. The information gathered – e.g., as part of baseline assessment of fish consumption rates and practices, as part of evaluation processes, or otherwise – needs to get back to the affected group for them to use for their own purposes. Hopefully, the involvement of the affected group from the outset of the process means that its needs have been identified and the results meet those needs. Nonetheless, the information may be valuable to the group in the longer term, as a foundation for other projects, as historical documentation of practices at a particular point in time, or for any number of reasons. In some cases, a community or tribe may want to be custodian of the information about their group, to ensure that they have some amount of control over the ends to which it may be put in the future. Whatever the reasons, it may be important to capacity-building and empowerment that the information about a particular group be returned to that group. Daisy Carter, Project AWAKE, Coatopa, Alabama, highlights communities' lack of empowerment when information is gathered *from* them, but not necessarily for and with them:

> *EPA knows all the problems that exist in every community, state and country. EPA is aware of what is wrong. They know who is impacted by the various contaminants and to what degree citizens are unfairly treated. They know what injustices are being done. They also impose fines upon various companies. It is the policy of these companies and EPA to keep citizens who are at risk seeking and searching for answers and assistance to eliminate their problems and suffering. EPA wants to keep citizens, people of color, and impacted communities talking and asking for help so that EPA can stay informed and keep abreast of the status of the burdens and injustices in these communities.*

In addition, as noted in Chapter 1 in the context of research in general, funding is crucial to the ability of affected communities and tribes to be involved in research, including research about risk communication. Although community and tribal members have considerable expertise to offer, they often have minimal or no funding to support their work. *To a person*, community members, tribal members, inter-tribal organization staff, and state and local agency representatives who work with affected groups stressed the importance of adequate funding. Diane Lee, a research scientist with the California Department of Health Services who has worked extensively with communities as part of the Palos Verdes Fish Contamination Outreach and Education Project and other studies in the San Francisco Bay area, is emphatic:

> *I cannot underscore enough the need to provide funding to affected communities so that they can participate fully in every aspect of the research process, from needs assessment to dissemination of the results. Funding, moreover, needs to be provided on an on-going, rather than one-time, basis.*[394]

Again, EPA and other agencies have often provided much-needed support. For example, the EPA's Office of Water, together with Minnesota's Department of Health, recently sponsored the National Risk Communication Conference to bring together representatives of federal, tribal,

[394]Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

state, and local health and environmental agencies, affected communities, tribes and Alaskan Native villages, and other interested in risk communication about contaminated fish. Importantly, EPA secured funding for several community, tribal, and village representatives who otherwise likely would not have been able to attend. This was an impressive undertaking that produced a rich exchange – and a source of information and experience that should continue to advance deliberation in this area. EPA also recently gave a small grant to the California Department of Health Services "to explore and develop methods of communicating with diverse communities about fish contamination issues" in San Francisco Bay, which CDHS was able to turn around and share with community organizations working on the issue.[395] As California Department of Health Services explains:

> *Our participatory approach aims to build local partnerships through collaboration with community-based organizations (CBOs) and local agencies that serve fishing populations. A limited number of stipends will be provided to selected groups to assist them in developing and pilot testing educational materials or activities.*[396]

Affected communities and tribes have commended EPA's efforts to this end.

However, they noted that the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available. Funding needs to be regularized and allocated as a part of agencies' budgets, so that affected groups can be assured on-going support for their efforts (rather than piecemeal or one-time funding). The participation of community groups is vital to the success of agencies' risk communication efforts; agencies should not count on community groups to donate their time and expertise when others important to risk communication efforts (e.g., agency staff and contractors) are compensated and supported. Among other things, agencies should contract with grassroots community groups to undertake outreach – these groups will be uniquely positioned to provide this service to agencies and they should be compensated for doing so. Agencies should also combine financial support with technical and other in-kind support. Here again, agencies and affected groups can be creative, as some have demonstrated. For example, as part of its Palos Verdes Fish Contamination Outreach and Education Project, California Department of Health Services held a free "train the trainer" workshop for community-based organizations, agencies, and others, during which participants were trained in conducting their own educational programs for fishing populations.[397] After the

[395]California Department of Health, Environmental Investigations Branch, *San Francisco Bay Fish Consumption Outreach and Education Project* (factsheet available from California Department of Health Services).

[396]Id.

[397]California Department of Health, Environmental Investigations Branch, *Palos Verdes Shelf Outreach and Education Project on Fish Contamination Issues* (factsheet available from California Department of Health Services).

training, community-based organizations received a stipend to develop and implement a pilot educational activity for the community they serve. The type of activity was determined by the community-based organization and included a wide range of activities (e.g., organizing a table at a health fair, conducting a workshop, putting together a media kit).[398]

[398]Id.

CHAPTER IV: AMERICAN INDIAN TRIBES AND ALASKAN NATIVE VILLAGES

In determining how EPA should improve the quality, quantity, and integrity of aquatic ecosystems, what special considerations should EPA take into account when protecting the health and safety of federally recognized tribal governments and their members?

American Indian tribes and Alaskan Native villages and their members ("AI/ANs") share many of the concerns explored in the preceding chapters. However, the particular circumstances of AI/ANs also warrant separate discussion. Tribes' political and legal status is unique among affected groups. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights. Other laws and executive commitments, too, shape the legal obligations owed to AI/AN tribes and villages and their members.

There are some 556 federally recognized tribal governments in the United States, including 223 Alaska Native villages.[399] At the time of the 1990 census, about 1.9 million AI/ANs lived in the United States.[400] In 1993, the Bureau of Indian Affairs estimated that 1.2 million AI/ANs lived within Indian country on lands reserved for their tribes as permanent homelands.[401] "Indian country," which includes reservations, dependent Indian communities, and Indian allotments, comprises approximately 53 million acres of land, much of which is found in remote areas of the nation.[402] The remaining AI/ANs live in urban areas and comprise a growing segment of the Native population.

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[399]"Federally recognized" means that these tribes and groups have a special legal relationship with the United States. Additionally, a number of tribes and indigenous groups do not have federally recognized status, although some of these tribes are state-recognized or are in the process of seeking federal recognition.

[400]AI/ANs are among the fastest growing ethnic/minority populations in the nation. The 1990 census showed a 37.9% increase over the population of AI/ANs in the 1980 census. For additional facts and general information, see the Bureau of Indian Affairs' homepage at www.doi.gov/bia/aitoday/q_and_a.html.

[401]For additional facts and general information, see the Bureau of Indian Affairs' homepage at www.doi.gov/bia/aitoday/q_and_a.html.

[402]The term "Indian country" is defined by federal law as including "(a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights of way running through the reservation, (b) all dependent Indian communities . . . and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same." See 18 U.S.C. § 1151.

Part A of this chapter outlines the legal status of AI/ANs. Part B of this chapter addresses the particular issue of treaty rights. Part C of this chapter outlines issues particular to Alaska Natives. Finally, Part D examines tribes' susceptibilities and co-risk factors; while some of these will also be applicable to other affected groups, the particular combination discussed here is unique to AI/ANs.

A. LEGAL STATUS

Federally recognized Indian tribes possess a unique political and legal status that distinguishes them from all other ethnic and minority groups in the United States. Although subject to applicable federal law, tribes have long been recognized as separate sovereigns possessing broad inherent authority over their members and territories. As governments, the relationship between federally recognized tribes and the federal government is described as "government-to-government" and, in 1994 and 2000, President Clinton explicitly directed each federal agency to operate within this relationship[403] and to maintain it through meaningful consultation and coordination with tribes.[404] Among other things, the government-to-government relationship means that federal agencies may not treat Indian tribes as "interest groups" or simply as part of the general public.

The cornerstone of the government-to-government relationship is the federal government's trust responsibility to federally recognized Indian tribes to protect their status as self-governing entities and their property rights. The trust responsibility is based on treaties, statutes, executive orders, and the historical relations between the federal government and tribes. In practice, the trust responsibility gives rise to distinctive fiduciary obligations on the part of federal agencies that must be "exercised according to the strictest fiduciary standards."[405] The United States Supreme Court has stated that federal officials are "bound by every moral and equitable consideration to discharge the federal government's trust with good faith and fairness" when dealing with tribes.[406]

Also related to the trust doctrine is Congress' plenary power over Indian affairs. Under the plenary power doctrine, the federal government is vested by the Constitution with exclusive authority over relations with Indian tribes.[407] Because the power of Congress is exclusive, states

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[403]See Executive Memorandum on Government-to-Government Relations with Native American Tribal Governments (Apr. 29, 1994).

[404]See Executive Order No. 13084 (May 14, 1998). On November 6, 2000, President Clinton issued a new order strengthening the policy on tribal consultation. See Executive Order No. 13175 (Nov. 6, 2000).

[405]Nance v. Environmental Protection Agency, 645 F.2d 701, 710 (9th Cir. 1981).

[406]United States v. Payne, 264 U.S. 446, 448 (1924).

[407]See Morton v. Mancari, 417 U.S. 535 (1974).

generally lack authority over Indian tribes and tribal members within Indian country, unless Congress has expressly delegated that authority to states.

Due to the special legal status of tribes, and because the jurisdictional rules applicable to Indian country left EPA unable to pursue its usual practice of delegating primary enforcement responsibility to states that so request, EPA developed special regulations and policies concerning environmental regulation on Indian reservations and the role to be played by tribal governments. On November 8, 1984, EPA adopted a formal policy, the "EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations" ("Indian Policy"). The Indian Policy sets forth nine principles by which the EPA will pursue its objectives including, but not limited to EPA's commitment to work with tribes on a government-to-government basis, to recognize tribes as the primary decision-makers for environmental matters on reservation lands, to help tribes assume program responsibility for reservations, to remove existing legal and procedural impediments to tribal environmental programs, and to encourage tribal, state, and local government cooperation in areas of mutual concern. Following the adoption of the Indian Policy, every EPA Administrator since has reaffirmed the principles set forth therein. Most recently, on July 11, 2001, EPA Administrator Christine Todd Whitman again reaffirmed the Agency's commitment to the Indian Policy.

A major goal of the Indian Policy is to eliminate statutory and regulatory barriers to the assumption of federal environmental programs by Indian tribes. As originally enacted, most of the federal environmental laws mentioned tribes or Indian reservations and none provided for direct participation by tribal governments. To date, however, tribal amendments to four major federal environmental laws--the Safe Drinking Water Act, Clean Water Act, Clean Air Act, and Comprehensive Environmental Response, Compensation, and Liability Act--have been enacted.[408] Despite these amendments and the Indian Policy, federal funding for tribal environmental programs and environmental enforcement within Indian country has been inadequate and inequitable, particularly in light of the billions of federal dollars spent on state environmental efforts over the last three decades. While funding for tribal programs has increased substantially in recent years, inadequate funding for tribal programs is considered by many to be an environmental justice issue and also is one of the key factors impeding effective consultation with tribes due to the limited capacity of tribal environmental programs. As discussed further in Chapter 2, while some tribal governments are moving forward in participating under federal environmental programs, few tribes have actually been authorized by EPA to assume primary regulatory and enforcement responsibilities for these program on their reservations. Where tribes have not yet assumed these responsibilities, EPA remains responsible for implementing and enforcing the federal environmental laws within Indian country pursuant to these laws and the federal trust responsibility owed to tribes.

[408]See, generally, Jane Marx, Jana L. Walker, and Susan M.. Williams, *Tribal Jurisdiction Over Reservation Water Quality and Quantity*, 43 South Dakota Law Review 315 (1998).

As noted in Chapter 2, tribes may be involved as co-managers of cleanup and restoration efforts. For example, the Lower Elwha Klallam Tribe recently signed an agreement with federal and state agencies recognizing its role in overseeing cleanup of a contaminated (with dioxins and PCBs) area affecting important off-reservation resources.[409] The Menominee Indian Tribe of Wisconsin and the Oneida Tribe of Indians of Wisconsin are among the Natural Resource Trustees addressing cleanup and restoration of the Fox River and Green Bay.[410] In these roles, tribes will have environmental justice concerns of a different and often complex nature.

B. TREATY RIGHTS

Treaties preserve important tribal rights. "A treaty, including one between the United States and an Indian tribe, is essentially a contract between two sovereign nations."[411] The United States entered into more than 400 treaties with Indian tribes under which tribes typically gave up large parts of their aboriginal territories in exchange for explicit promises from the federal government. Because the United States received rights to land from the tribes, the United States Supreme Court has described a treaty as a grant of rights from the Indians with a reservation of all those rights not granted.[412] Thus, a treaty does not have to reserve expressly hunting and fishing rights within an Indian reservation for such rights to exist; rather, such on-reservation rights exist unless expressly given up by the tribe.[413] In many treaties, tribes expressly reserved certain rights in lands and waters outside their reservations. For example, today, many tribes possess treaty rights to fish, hunt, and gather at all "usual and accustomed" places. In 1871, Congress ended the practice of entering into treaties with Indian tribes, but subsequently engaged in the practice of ratifying agreements with tribes negotiated by the Executive Branch. While the United States Supreme Court has ruled that Congress has the power to break treaties with tribes, unless clear congressional intent exists to abrogate a treaty, a treaty continues in effect.[414]

C. ALASKA NATIVES

The term "tribe," and the recognition of a particular political and legal status that this term entails, applies to Alaska Native villages as well as to American Indian tribes in the forty-eight

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[409]L. Harris, *Tribe Will Oversee Pulp Mill Cleanup*, Northwest Indian Fisheries Commission News 8 (Spring, 2000).

[410]U.S. Environmental Protection Agency, *Intergovernmental Partners Negotiate Fox River Interim Agreement* (factsheet, 2001).

[411]See Washington v. Washington State Commercial Passenger Fishing Vessel Assoc., 443 U.S. 658, 675 (1979).

[412]See United States v. Winans, 198 U.S. 371 (1905) ("In other words, the treaty was not a grant of rights to the Indians, but a grant of rights from them—a reservation of those not granted.")

[413]See Menominee Tribe of Indians v. United States, 391 U.S. 404 (1968).

[414]See United States v. Dion, 476 U.S. 734 (1986).

contiguous states.[415] Indeed, as noted above, of the 556 federally recognized tribal governments within the United States, 223 of these are Alaska Native villages. While several aspects of tribes' particular political and legal status are common to American Indian tribes and Alaska Native villages, there are also important differences. This section, therefore, briefly outlines the unique circumstances of Alaska Native villages in this regard.

Consistent with their status as federally recognized tribes, Alaska Native villages have a government-to-government relationship with the federal government and its agencies, including the EPA. The rights and responsibilities that flow from this relationship are described above, in Section A, and apply equally to Alaska Native villages. Among other things, under current federal law and policy, federal agencies are directed to operate within the government-to-government framework, and to consult with tribes, including Alaska Native villages, as sovereign entities.

The federal trust responsibility is similarly applicable to Alaska Native villages.[416] The trust responsibility requires the federal government and its agencies to uphold the highest fiduciary standards when its actions affect the well-being of Alaska Native villages, their property (including subsistence rights),[417] resources, and culture. The object of the trust responsibility is the furtherance of the self-determination and cultural integrity of tribes and Alaska Native villages.

However, there are also important differences between the legal, political, historical and other circumstances of Alaska Native villages and their members and those of tribes and their members in the lower forty-eight states. For example, Alaska Native villages and the United States government did not enter into any treaties. And, while Alaska Natives have been included by Congress in legislation generally applicable to American Indians,[418] Congress has also legislated separately with respect to Alaska Native villages and their members. Alaska Native land and subsistence rights, for example, are importantly affected by the Alaska Native Claims Settlement Act (ANSCA)[419] and by the Alaska National Interest Lands Conservation Act (ANILCA).[420] In addition, special recognition of and exceptions for Alaska Native subsistence rights have been

[415]See, e.g., *Noatak v. Hoffman*, 896 F.2d 1157 (9th Cir. 1990); *Native Village of Tyonek v. Puckett*, 890 F.2d 1054 (9th Cir. 1989); see generally, Eric Smith and Mary Kancewick, *The Tribal Status of Alaska Natives* 61 University of Colorado Law Review 455 (1990).

[416]*People of Togiak v. United States*, 470 F. Supp. 423 (D.D.C. 1979).

[417]Id.

[418]See, e.g., Indian Self-Determination Act, Public Law No. 93-638, 88 Stat. 2206 (codified in scattered sections of the United States Code; see especially 43 U.S.C. §§ 1601-1624; Indian Financing Act of 1974, 25 U.S.C. § 1452(c).

[419]43 U.S.C. §§ 1601-1628.

[420]16 U.S.C. §§ 3101-3133.

included in federal statutes and treaties concerned with protection of animals, birds, and their habitat, such as the Marine Mammal Protection Act[421] and the Endangered Species Act.[422]

The special circumstances of Alaska Native villages are also relevant to their ability to choose to accept responsibility for administering federal environmental statutes. For example, because the United States Supreme Court held in *Alaska v. Native Village of Venetie*,[423] that only one Indian "reservation" -- the Annette Island Reserve -- exists in Alaska and that land conveyed by the federal government to Alaska Native villages under ANCSA was not "Indian country," and because the language of the Clean Water Act recognizes the power of tribes to establish water quality standards throughout their "reservations," Alaska Native villages are unable to assume regulatory authority or to participate in the same manner or to the same extent under the Act as tribes located in the lower forty-eight states. Alaska Native villages and their members have also identified other hurdles particular to their efforts to manage (or co-manage) and to access resources that are important for subsistence uses. Important among these has been a historical lack of attention to, funding for, and technical assistance supporting the environmental management efforts of Alaska Native villages.

Finally, it is important to recognize that the particular historical, economic, ecological, and cultural circumstances of Alaska Native villages and their members give rise to several issues that are less likely to be of concern elsewhere. These circumstances range from Alaska's unique climates, including its Arctic climate;[424] to its historical military use by the U.S. Department of Defense and the continuing legacy of contamination at the hundreds of formerly- and currently-used defense sites;[425] to the exploitation of its wealth of mineral and petroleum resources and the

[421] 16 U.S.C. § 1371(b).

[422] 16 U.S.C. § 1539(e).

[423] 118 S. Ct. 948 (1998).

[424] See, e.g., Interagency Collaborative Paper, *Contaminants in Alaska: Is America's Arctic at Risk?* (issued by the U.S. Department of the Interior, U.S. Environmental Protection Agency, Alaska Department of Environmental Conservation, Alaska Department of Health and Social Services, University of Alaska Institute for Circumpolar Health Studies, Alaska Federation of Natives, Alaska Native Science Commission, Alaska Inter-Tribal Council, Native American Fish and Wildlife Society, Alaska Native Tribal Health Consortium, Alaska Community Action on Toxics, and North Slope Borough, September 2000). This paper describes the cold, northern Arctic as a sink for numerous environmental contaminants transported from elsewhere; notes the particular persistence of these contaminants in this environment, given the slower rate of breakdown in the colder climate; and citing POPs, as well as metals as among the contaminants of concern for Arctic fish, wildlife, and people. Id.

[425] Alaska hosts approximately 700 formerly-used defense sites, five military Superfund sites, and weapons testing ranges encompassing an area equal in size to the state of Kansas. These sites are contaminated with PCBs, dioxins, radioactive waste, and a variety of other pollutants resulting from the use of solvents, fuels, and chemical munitions. See, e.g., Pamela K. Miller, Director, Alaska Community Action on Toxics, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

resulting environmental harms; to the remoteness and relative poverty of many of its rural villages, resulting, among other things, in the fact that only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best.[426] For example, Pamela K. Miller, Director, Alaska Community Action on Toxics, relates:

> *The north has become a hemispheric sink for persistent organic (POPs) . . . Many persistent pollutants originate from thousands of miles away, traveling northward via wind and ocean currents and in the bodies of migratory animals. . . . Northern ecosystems, wildlife, and people are the ultimate repositories for persistent pollutants. . . . Cold-water bodies of the Arctic are important sinks [for example] for lindane. Levels of [lindane] in seawater are an order of magnitude higher in the Arctic than in tropical and subtropical regions. . . . Lindane was among the organochlorine contaminants detected in blood samples from Alaska Native women participating in a pilot study conducted [in 1996].*[427]

June Gologergen Martin, Coordinator, National Environmental Health & Justice, St. Lawrence Island Project, explains:

> *Whanga aatqa yupiigestun Yatgawen, Sevungami allgeqawunga. Hello, my name is June Gologergen Martin. My Siberian Yupik name is Yatgawen. I was born on St. Lawrence Island in the village of Savoonga, Alaska. As a Siberian Yupik native, I grew up going to North East Cape during the summer months in the mid-1960s. . . .*
>
> *We live a subsistence lifestyle. We are rich in our culture; our Siberian Yupik language is very strong. Our families still hunt walrus, seals, bowhead whales, halibut, crabs, different species of seabirds and fish in the Bering sea, lakes, and rivers, like the Suqi River in North East Cape . . . We also gather edible plants, roots, seabird eggs, marine plants and seaweed.*
>
> *During the earlier years of my life, there were talks of not consuming fish and wildlife and edible plants around the North East Cape military site. These warnings came from our elders and leaders. We were told not to subsistence fish in the Suqi River at North East Cape. We were confused and alarmed about this warning from our elders and leaders. If we cannot consume our subsistence fish, marine mammals and other plants due to contamination by military debris left behind, our spirit slowly dies within us!*

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[426]See, e.g., Videotape: *The Forgotten America -- Alaska's Rural Sanitation Problem* (The Media Support Center for the Alaska Department of Environmental Conservation).

[427]Pamela K. Miller, Director, Alaska Community Action on Toxics, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

Our uncles and possibly our fathers and others who have spent time at North East Cape military site began dying of cancer-related illnesses. Our elders knew why this was happening. They knew that whatever contaminants the military left behind might have been the cause of these deaths. . . .

[We] urge NEJAC to review information on St. Lawrence Island regarding North East Cape and the Native Village of Gambell military clean-up project and recommend that St. Lawrence Island be considered a Superfund site so that there is complete restoration . . .[428]

Rosemary Ahtuangaruak, Native Village of Nuiqsut, explains:

I am from the Native Village of Nuiqsut on the north slope of Alaska, 60 miles west of Prudhoe bay and 130 miles southeast of barrow. We are an Inupiat village, which relies upon the subsistence resources for our survival. The land, sea, and air provide for us and we, in turn, protect them . . .

The long dark months of winter can have many starvation moons until the natural resources of subsistence return. The concerns now are not only can we put enough away but if the supply is safe to consume. . . . [O]ur attempts to harvest are coming back empty and our nets are getting few fish. . . .

The national need for energy is ignoring the need we have for subsisting. We are going without multiple subsistence resources for the benefit of our nation's energy need. There are not means for us to address the assault on our resources, which our elders have taught us to use. The recognition of our loss is belittled in the many public meetings, which come to our village as a public process without the incorporation of our concerns into the proper framework to address them. . . .

The people of Nuiqsut rely upon the fish harvesting and the last six years have seen the devastation of our fish stocks. . . . I feed three families with the harvesting I do and they go without as well as me. I eat fish or whale two times a day and 5-7 days out of the

[428]June Gologergen Martin, Coordinator, National Environmental Health & Justice, St. Lawrence Island Project, Testimony to National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony); accord, Kendra Zamzow, National Institute of Environmental Health Sciences Grant Researcher, Testimony to National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony)(noting that the U.S. Department of Health and Human Services disseminated a fish consumption advisory urging that no fish from the Suqi River be eaten, given PCB contamination in even very small (4" long) fish, and pointing out that the Suqi and its fish and wildlife are also contaminated with five PAHs (polycyclic aromatic hydrocarbons), dissolved arsenic, lead, and zinc).

week. I have to dig through the ice and in three days, I got only 1-2 fish. This cannot feed my family as well as the extended family members. We are concerned about the quality of the fish, as the meat has changed, they are yellow and not as fat as usual, and they have a bitter taste. Every fisherman in our village has faced the same hardships. We depend on the healing qualities of this resource and now it is being considered a bad thing. The social, economical, cultural, and medicinal [aspects] of our resources are needed to sustain our health . . .[429]

Dr. Delores Garza, Alaska Native Science Commission, explains:

In rural Alaska we have many communities that are still relegated to the "honey bucket." That means that there is no sewer system. The sewage goes into a five-gallon white-lined bucket that's lined with a garbage bag. It goes out to the dump and it's thrown out on the surface. In Southwestern Alaska, primarily in the Yupik area where you have communities built in areas that you might consider bogs, they have high water tables. The sewage is leaching and is contaminating the fresh water source. . . . So you have communities that now may have 70, 80 percent unemployment trying to find the gas money to take their boat upriver or to take their four-wheeler farther out to get fresh water, and while Alaska has worked to reduce the number of communities that have to rely on this honey bucket system, that is still a big issue in many communities in Southwestern Alaska.[430]

Thus, while Alaska Native villages and their members may share many of the concerns articulated by various affected groups throughout this Report, it is critical that EPA and other agencies listen and attend to the particular issues articulated by Alaska Native villages and their members. And, here as elsewhere, this will mean recognizing that there will often be differences *among* the concerns of various Alaska Native villages.

D. TRIBES' UNIQUE SUSCEPTIBILITIES AND CO-RISK FACTORS

Commonly cited statistics all seem to agree that AI/AN's economic wealth, public health, and education are the worst of any group in the nation. Poverty and unemployment rates among AI/ANs are the highest for any ethnic group in the country, and education, per capita income, and home ownership are among the lowest.[431] One out of every three AI/ANs lives

[429]Rosemary Ahtuagaruak, Native Village of Nuiqsut, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

[430]Delores Garza, Alaska Native Science Commission, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Annual Meeting Transcript, Vol III-89).

[431]See, e.g., *National Gambling Impact Study Commission Report*, "Native American Tribal Gambling" 6-5 (Jun. 18, 1999).

below the poverty line; approximately 90,000 AI/AN families are homeless or underhoused; and one out of every five AI/AN households lacks adequate plumbing.[432] The statistics are even more disheartening for Alaska Native villages. Only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best.[433] Climate poses a significant challenge to the use of conventional sanitation systems in these communities, which are typically far removed from urban areas. And, the lack of economic development in most Alaska Native villages makes it impossible for these subsistence-based families to pay the cost of bringing in appropriate and sustainable sanitation services.[434]

Health care data on AI/ANs is scarce and unreliable. Significantly, the health status of AI/ANs is far below the health status of the general population in this country, and unmet AI/AN health needs are alarmingly high. This disparity in health status is reflected clearly in the death rates for AI/ANs. For example, AI/ANs have the highest suicide rate (70% higher than the rate for the general population) and the lowest life expectancy of any population in this hemisphere except Haitians.[435] Compared to death rates for all other races in the United States, AI/ANs have a death rate for diabetes mellitus that is 249% higher; a death rate for pneumonia and influenza that is 71% higher; a death rate for tuberculosis that is 533% higher; and a death rate from alcoholism that is 627% higher.[436]

AI/ANs also have a unique set of cancer problems ranging from inadequate screening to under-diagnosis and -reporting of cancer to lack of access to quality health care and new cancer treatments. For example, the leading cause of death for AIs is lung cancer, and AN women have the highest cancer and lung cancer mortality rates of any major racial female group.[437] Recently, the Association of American Indian Physicians reported that cancer is the third leading cause of death for all AI/ANs of all ages; the second leading cause of death for all AI/ANs over age 45; and the leading cause of death for AN women. The Association also reported that, in most parts

[432]Id.

[433]See, e.g., Videotape: *The Forgotten America -- Alaska's Rural Sanitation Problem* (The Media Support Center for the Alaska Department of Environmental Conservation).

[434]Id.

[435]See, e.g., Wallwork Winik, Lyric, "There's A New Generation with a Different Attitude," Parade Magazine 6-7 (July 18, 1999).

[436]Proposed IHCA Amendments of 2000, Section 2(h), prepared by the National Steering Committee for the Reauthorization of the Indian Health Care Improvement Act, P.L. 94-437 (Oct. 6, 1999), and based on data used by the Indian Health Service for the FY 2001 budget development.

[437]See National Cancer Institute, National Institute of Health, HHS, Office of Special Populations Research Web Site, *The Cancer Burden* available at www.ospr.nci.nih.gov.burden.htm.

of the country, AI/ANs have poorer survival rates from cancer than do whites, African Americans, Hispanics, and Asians.[438]

AI/ANs are particularly susceptible to health impacts from pollution due to their traditional and cultural uses of natural resources and, in fact, AI/ANs "have greater exposure risks than the general population as a result of their dietary practices and unique cultures that embrace the environment."[439] Fishing, hunting, and gathering often are part of a spiritual, cultural, social, and economic lifestyle, and the survival of many AI/ANs depends on subsistence hunting, fishing, and gathering. In some instances, the right to engage in these activities is legally protected by treaty. Additionally, many AI/ANs also use water, plants, and animals in their traditional and religious practices and ceremonies. As a result, contamination of the water, soil, plants, and animals and the subsequent accumulation of these contaminants in the people through ingestion, inhalation, and contact not only endangers the health of AI/ANs, but also threatens the well-being of their future generations[440] and undermines the cultural survival of tribes and Alaska Native villages. For example, tribes near the Hanford Nuclear Reservation have been working with the Agency for Toxic Substances and Disease Registry to design health assessments focusing on exposure effects from food consumption and other activities. These tribes want to learn if the Hanford releases affect native food items and local materials used in tribal products like storage and cooking baskets, mats, and clothing.[441] Similarly, tribes located in coastal northern California are concerned about the pesticide exposure of some 300 traditional basketmakers who gather their own materials from the forests and roadsides. Basketweavers are exposed to pesticides as they tend and gather basketry materials; as they weave (weavers often hold one end of the grasses

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[438]K. Marie Porterfield, *American Indian Cancer Statistics Under Reported*, Indian Country Today C-1 (Jul. 26, 2000).

[439]See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 1-2.

[440]A number of studies have shown that children are uniquely susceptible to pollution and contaminants. For example, since 1992, the Agency for Toxic Substances and Disease Registry has funded research in the Great Lakes states focusing on the health effects of high risk populations, including American Indians, from persistent toxic substances found in fish. One study found that newborns born to mothers who consumed only 2.3 PCB-contaminated Great Lakes fish meals per month scored lower on the Neonatal Behavioral Assessment Scale. See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 2-3. Additionally, in Oklahoma, Indian children also suffer harm from their environment. The Tar Creek Superfund Site, a former lead and zinc mine, occupies 40 square miles within the boundaries of the former Quapaw Indian Reservation. Both the Quapaw Tribe's powwow grounds and campgrounds are contaminated from mine tailings, and the EPA Region 6 reports that approximately 25% of the Quapaw children have elevated blood lead levels compared with a statewide average of 2%. See U.S. Environmental Protection Agency, *Region 6 Environmental Justice Update* 7 (May 2000).

[441] See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 5.

or other materials in their mouths as they weave); and as they wear, cook with, and use the finished baskets. Because a disproportionate number of American Indian residents in Humboldt County, California have been diagnosed with cancer, tribes believe studies are needed to determine the exact cause of such cases.[442]

Significantly, where such traditional, cultural, and subsistence activities are involved, federal and state environmental standards used to protect the general non-Indian/non-Native population may not afford tribes and Alaska Native villages adequate protection from environmental harm.[443] Again, although several of the major federal environmental laws have been amended to allow federally recognized tribes to assume primacy for certain programs,[444] to date, only a few tribes have EPA- approved or -promulgated environmental programs.[445] Based on all of the foregoing, federally recognized tribes and AI/ANs suffer a disproportionate burden of health consequences due to their exposure to pollutants and hazardous substances in the environment. This is particularly so for AI/AN infants and children.[446]

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[442] See Chuck Striplen, Mutzun Oholone Tribe, *Native Subsistence in a Toxic Environment: A Tribal Viewpoint* 14, (EPA's OPPTS Tribal News) (Fall/Winter 1999-2000).

[443]See, e.g., City of Albuquerque v. Browner, 97 F.3d 415 (10th Cir. 1996), *cert. denied*, 118 S. Ct. 410 (1997) (upholding the EPA's approval of the Pueblo of Isleta's water quality standards that were more stringent than the state water quality standards, and which included a ceremonial use standard).

[444]Since 1986, the Safe Drinking Water Act, Clean Water Act, and Clean Air Act have been amended to afford tribes substantially the same opportunities as states to assume responsibility for certain programs or purposes.

[445]For example, as of July 13, 2000, the EPA reported that only 15 tribes have EPA-approved or -promulgated water quality standards and no tribes are authorized to administer the National Pollutant Discharge Elimination System or to establish Total Maximum Daily Loads. See 65 Fed. Reg. 43,585 (Jul. 13, 2000).

[446]For example, a New York State Department of Health study of lactating women and their infants linked breast feeding and infant exposure to hazardous substances. This study compared PCB levels in the breast milk of Mohawk women who gave birth between 1986 and 1992 with a control group. The study found that although the PCB concentrations in the breast milk of Mohawk mothers decreased over time, their infants had urine PCB levels ten times higher than that of their mothers. See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 3-4. See also Winona Laduke, *All Our Relations, Native Struggles for Land and Life* 11-23 (1999).

APPENDIX A: NEJAC EXECUTIVE COUNCIL MEMBERS

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APPENDIX C: FISH CONSUMPTION WORK GROUP PROPOSALS

The following proposals were developed by the National Environmental Justice Advisory Council (NEJAC) Fish Consumption Work Group (FCWG) for deliberation and action by the NEJAC Executive Council. While elements of these proposals were incorporated into the six Consensus Recommendations adopted by the NEJAC Executive Council, these proposals were not adopted by the NEJAC Executive Council.

The following proposals of the FCWG are set forth as "Overarching Proposals" and "Focused Proposals." Overarching proposals are intended to set forth the FCWG's proposals in broad terms. Each group of overarching proposals is in turn elaborated by one or more focused proposals. In every case, the proposals should be understood to refer to the contamination and depletion of aquatic ecosystems and all of their components, including fish, shellfish, marine invertebrates, aquatic plants, and wildlife. They should be understood to apply to efforts to address contamination wherever it may affect aquatic ecosystems, including contamination in surface waters, sediments, groundwater, soils, and air. Finally, they are meant not only to cleanup current contamination and prevent future contamination, but to do so in a manner that rectifies disproportionate impacts, so that all affected people or groups – including people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdictional boundaries of the United States – are able to live in a healthful environment, in this generation and all generations to come.

Chapter One

The contamination of fish, aquatic plants, and wildlife is an especially pressing concern for many communities of color, low-income communities, tribes, and other indigenous peoples, whose consumption and use practices differ – often profoundly so – from those of the general population. Members of these groups often consume far greater quantities of fish, aquatic plants, and wildlife; they consume fish, plants, and wildlife at different frequencies, in accordance with seasonal availability and other cultural considerations; they consume and use different species and parts; and they employ different methods in procuring and preparing the fish, aquatic plants, and wildlife that they use. Thus, communities of color, low-income communities, tribes, and other indigenous peoples are among the most highly exposed to contaminants in the fish, plants, wildlife, and aquatic environment. For example, empirical studies document 90th percentile fish consumption rates for various affected communities and tribes at 225 g/day, 242 g/day, and 489 g/day (respectively, urban fishers on Los Angeles Harbor; ten Asian and Pacific Islander communities in King County, WA; and the Suquamish Tribe). Although EPA's revised default assumptions of 17.5 g/day, representing the 90th percentile of the general population, and 142.4 g/day, representing the 99th percentile of the general population are a marked improvement over its previous assumption of 6.5 g/day, the revised defaults still considerably underestimate exposure for many affected communities and tribes.

Overarching Proposals

I-1. The FCWG proposes that EPA work with affected groups to develop and use fish consumption rates that are appropriate for various higher-consuming communities and tribes whenever EPA conducts activities that affect these higher-consuming groups, for example, when it develops water quality criteria; when it sets and approves state and tribal water quality standards; when it sets and approves cleanup levels for water and sediments; when it addresses cross-media contamination (e.g., mercury emissions to air); and when it provides other relevant guidance.

FCWG proposes that EPA work in particular with those affected groups for which few or no empirical data exist, ensuring that studies are undertaken systematically to provide a full account of all affected groups' consumption practices. FCWG notes that, among other things, an appropriate fish consumption rate must account for affected groups' different consumption frequencies or patterns due to seasonal availability and other cultural considerations, particularly those that result in acute or peak exposures.

I-2. The FCWG similarly proposes that EPA account for other aspects of communities' and tribes' different exposure circumstances when it conducts these various activities, including practices that mean different species are consumed, different parts are used (e.g., the highly contaminated hepatopancreas of crabs, often consumed by Asian and Pacific Islanders and by other island people), and/or different preparation methods are employed than those typically assumed by agencies.

I-3. The FCWG proposes that EPA remedy, in measurable and reportable ways, the disparities in the level of protection provided by water quality criteria and standards, cleanup standards, air emissions standards, and other relevant environmental standards as between the general population and "subpopulations" comprised of communities of color, low-income communities, tribes, or other indigenous peoples.

Focused Proposals

I-1 through I-3

1. FCWG proposes that EPA work with affected groups to facilitate research documenting these groups' different fish consumption and use practices, focusing on communities of color, low-income communities and tribes:

    a. FCWG proposes that EPA work with affected groups from the outset, so that research questions are framed and studies are designed to reflect accurately the needs and practices of the affected groups;

    b. FCWG proposes that, among other issues to be identified together with affected groups, studies document not only the different quantities of fish consumed by these groups, but also other aspects of these groups' different practices, including the extent to which they consume fish, plants, and wildlife at different frequencies; the extent to which they (or particular members of the relevant group, such as children or elders) consume and use different species or parts; and the extent to which they employ different methods in procuring and preparing the fish, aquatic plants, and wildlife;

    c. FCWG proposes that EPA prioritize research documenting those consumption and use practices about which relatively little is known and/or for which there are not reasonable proxies among current data, including research documenting the consumption and use of subsistence foods other than fish; research documenting consumption and use frequencies that result in acute or peak exposures (e.g., in the case of various Alaska Natives or others for whom seasonal availability or cultural considerations determine practices); and research documenting consumption and use among groups or in regions of the country for which few data exist (e.g., Native Hawaiians, among others).

2. FCWG proposes that EPA work with affected groups to ensure that EPA accurately and appropriately accounts for these groups' different fish consumption and use practices in all of its activities, including instances in which:

    a. EPA develops water quality criteria;

    b. EPA approves state or tribal water quality standards;

    c. EPA sets state or tribal water quality standards;

    d. EPA approves or sets cleanup levels for surface water and sediments;

e. EPA addresses relevant cross-media contamination (e.g., mercury emissions to air);

f. EPA undertakes relevant programs and initiatives (e.g., the Persistent Bioaccumulative and Toxic (PBT) Control Program); and

g. EPA provides other relevant guidance (e.g., its Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories).

3. FCWG also proposes that EPA act expeditiously to issue CWA § 304(a) water quality criteria that reflect affected groups' consumption and use practices; FCWG notes that EPA has sufficient data documenting the exposure circumstances of communities of color, low-income communities, tribes, and other indigenous peoples to warrant the issuance of revised criteria and emphasizes that it is unacceptable that criteria are still in effect that employ the outdated 6.5 grams/day fish consumption rate.

4. Specifically, FCWG proposes that EPA take a more active role in ensuring that state and tribal water quality standards are protective of affected groups' consumption and use practices, by assisting states, tribes, and affected groups in their data-gathering efforts; by encouraging states and tribes to employ protective assumptions (e.g., in reliance on EPA's Ambient Water Quality Criteria Methodology), even in advance of federally-mandated deadlines; and, crucially, by disapproving state and tribal standards that do not adequately account for these groups' different practices.

5. FCWG proposes that EPA work together with affected groups to revise its research methods and protocols to ensure that they result in the accurate depiction of these groups' exposure circumstances.

6. FCWG proposes that EPA should then produce and distribute a manual of methods and protocols for determining health risks for persistent and bioaccumulative toxics, for use by tribes and other affected groups who wish to employ local data in investigating and documenting human health risks in their own communities from the consumption and use of fish, shellfish, and other aquatic resources. This manual should include methods that permit analyses of both acute and chronic effects, and incorporation of multiple exposures and cumulative risks.

The contamination of fish, aquatic plants, and wildlife is also troubling to many communities of color, low-income communities, tribes, and other indigenous peoples, because these groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." For example, many tribes have treaty-guaranteed rights to take fish; the unique legal obligations entailed by these treaties are relevant to EPA's decisions affecting the health of the fish and the fisheries resource. The presence of these different contexts is abundantly demonstrated by both testimonial and social scientific evidence. For some or all of these reasons, particular fish consumption practices are in an important sense indispensable for many of these affected groups.

Overarching Proposals

I-4. FCWG strongly proposes EPA to work with affected groups to enhance its understanding of the ways in which these groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American" fish consumer and to incorporate this evidence into its risk assessment, risk management, and risk communication policies in measurable ways. FCWG proposes EPA, in collaboration with other appropriate federal agencies, to provide funding to affected groups so that they may document their particular cultural, traditional, religious, historical, economic, and legal circumstances, in a manner and for purposes they deem appropriate.

Focused Proposals

I-4

1. In each instance in which these issues are implicated, FCWG proposes that EPA work with the affected group(s) to develop a process for enhancing EPA's understanding of the particular cultural, traditional, religious, historical, economic, and legal context relevant to EPA's decisions in that case. These efforts should be among the first of EPA's fact-finding undertakings, e.g., for each cleanup of contaminated water and sediments under CERCLA. Among other things, such efforts should attend to:

    a. The existence of applicable treaties, e.g., many tribes' treaty-guaranteed rights to hunt, fish, and gather;

    b. The effects of the decision on resources, places, or sites that are culturally important to Native peoples or other affected groups, including sites protected by the National Historic Preservation Act, other sacred places, and culturally-important resources (whether located on- or off- reservation).

2. FCWG proposes that EPA and each office within EPA develop a strategy for recruitment, retention, and upward mobility for members of affected groups in order to enhance the extent to which EPA staff are familiar with and equipped to understand the particular relevant cultural, traditional, religious, historical, economic, and legal contexts in which they set priorities, undertake research and develop policies.

3. FCWG proposes that EPA increase its efforts to fund and publicize opportunities for community-based and tribally-conducted research documenting the particular cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume and use aquatic resources. FCWG welcomes EPA's recent efforts to this end; however, as noted below in Proposals I-10 through I-11(1), even greater efforts are necessary.

A "suppression effect" occurs when a fish consumption rate for a given group reflects a current level of consumption that is artificially diminished from an appropriate baseline level for that group. The more robust baseline level is suppressed, inasmuch as it does not get captured by the fish consumption rate. Suppression effects may occur because of contamination (people would consume more fish but refrain because the fish are contaminated) and/or depletion (people would consume more fish but cannot because there are fewer fish to be consumed, for a variety of reasons). Such effects have been noted, for example, at Akwesasne, home to the St. Regis Mohawk, where large-scale PCB contamination of the Grasse and St. Lawrence rivers by General Motors, ALCOA, and Reynolds has left tribal members with little choice but to reduce their consumption of fish from these waters. Similarly, the depletion and contamination of salmon and other fish in the usual and accustomed fishing areas of the Tulalip Tribes has left tribal members with fewer fish to catch and consume. When standards are set based on fish consumption rates that do not capture fully this suppressed consumption, they set in motion a sort of downward spiral whereby the further contamination or depletion is permitted, fish consumption rates are further suppressed, and so on.

Overarching Proposals

I-5. FCWG proposes EPA to work with communities of color, low-income communities, tribes, and other indigenous peoples to identify instances in which these groups believe consumption to be suppressed due to contamination and/or depletion, and to conduct research, together with the affected group, to ascertain whether a suppression effect is at work; if so, cleanup and restoration there should be a high priority.

I-6. FCWG further proposes that, wherever suppression effects are at work, EPA employ appropriate baseline levels in providing guidance for states and tribes, and in setting and approving water quality standards, cleanup standards, and other environmental standards in order to avoid the downward spiral due to suppression effects.

Focused Proposals

I-5 through I-6

1. FCWG notes that suppression effects need to be accounted for in gathering and interpreting data, and proposes that EPA work with communities of color, low-income communities, tribes and other indigenous peoples to document the existence and extent of suppression effects due to contamination and/or completion. In many cases, increased research documenting the particular cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume and use aquatic resources, proposed above in Proposal I-4(3), will go hand in hand with research documenting suppression effects.

2. FCWG proposes that wherever suppression effects are believed to be at work, EPA work together with the affected group to develop appropriate baseline levels for use when EPA provides guidance for states and tribes, and when EPA sets and approves water quality standards, cleanup standards, and other relevant environmental standards. This proposal might be applicable, for example, to EPA's current cleanup work at the Superfund Site on the Duwamish Waterway.

Current risk assessment methods do not adequately account for susceptibilities and co-risk factors that affect individuals' responses to environmental contaminants. These factors include underlying health status (including existing body burdens), baseline diet quality, genetics, socioeconomic status, access to health care, limited English proficiency, age, gender, pregnancy, lactation, and other factors.

Overarching Proposal

I-7. FCWG proposes further research into the extent to which susceptibilities and co-risk factors are clustered in certain subpopulations, including the extent to which there are disparities in current health status and body burden. To the extent that clusters emerge relevant to communities of color, low-income communities, tribes, or other indigenous peoples, FCWG proposes that EPA incorporate these factors into its risk assessment, risk management and risk communication efforts.

Focused Proposal

I-7

1. FCWG proposes that EPA undertake research to permit a more thorough understanding of these susceptibilities and co-risk factors and how they are distributed between communities.

2. FCWG proposes that, to the extent that clusters emerge relevant to affected groups, EPA develop methods to incorporate this information into its risk assessment, risk management, and risk communication efforts.

Current risk assessment methods evaluate risks as if humans were exposed to only a single contaminant at time, by a single route of exposure (e.g., consuming fish). Members of communities of color, low-income communities, tribes, and other indigenous peoples, however, are often exposed to multiple contaminants at a time or in succession, and often via more than route of exposure. For example, the Fourteen Confederated Tribes and Bands of the Yakama Nation fish in the Columbia River system, where it is the norm for over 100 contaminants to be identified in fish tissues; the northern Ojibwa Tribes are exposed to mercury via multiple natural resource pathways, given its uptake in fish and its presence in and on wild rice; and African-American and low-income communities living along the Mississippi are subject to multiple exposures, including from sources other than surface waters (e.g. consumption of contaminated fish; ingestion of polluted well water; inhalation of toxic air pollutants from surrounding incinerators, refineries, chemical manufacturers, and other industrial sources; and contact with and ingestion of particles from contaminated soils). Some of these multiple exposures and cumulative effects (and their interactions) are known; the vast majority are not well understood.

Overarching Proposals

I-8. Where the nature of cumulative effects are known, FCWG proposes their incorporation into EPA's environmental policy and specific standard setting practices. Where they are not well known, FCWG proposes this as a high priority area for research, given that the potential for cumulative effects are perhaps where the greatest danger to human health lurks.

I-9. Although EPA has made some inroads in accounting for multiple exposures and cumulative risks, it is FCWG's view that EPA simply must take a more aggressive, holistic, and integrative approach, especially where fish consumption levels are very high for communities of color, low-income communities, tribes, and other indigenous peoples and where the mix of contaminants to which these people are exposed may be highly toxic.

Focused Proposals

I-8 through I-9

1. FCWG proposes that EPA study the health impacts of chemical mixtures present in fish tissues, given that consumption and use of fish tissues represent one of the most significant and widespread instances of real life (as opposed to hypothetical) environmental exposures to chemical mixtures. FCWG further proposes that EPA incorporate the results of such studies in its risk assessment, risk management, and risk communication efforts.

2. At the same time, FCWG proposes that EPA avail itself of existing data characterizing the health risks of PCB-mercury mixtures present in fish tissues (e.g., data from the Seychelles and Faroe Islands). Given the availability of this data, and the large number of instances in which fish and wildlife consumption advisories are issued because of contamination from both PCBs and mercury, FCWG proposes that EPA not delay use of this data on the basis of the need for "further study."

Affected communities and tribes are integral to producing relevant, accurate, scientifically defensible data. Affected communities and tribes need, therefore, to be involved at every stage of the research on the issues identified above – from identifying research needs, to designing research methods, to interpreting the resulting data, to determining its importance to agencies' risk assessment, management, and communication efforts. Research should thus be a joint project reflecting and augmenting both affected communities' expertise and EPA and other agencies' expertise.

Overarching Proposals

I-10. FCWG proposes EPA to recognize the expertise of members of affected communities and tribes (including but not limited to tribal and non-governmental reservation-based organizations and organizations serving Alaska Natives), and to involve them or consult with them throughout the process of researching the various issues outlined above. FCWG proposes EPA to expand and publicize effectively the availability of financial and technical assistance for community-based organizations and tribes so that they may be directly involved in conducting research on these issues.

I-11. Importantly, FCWG proposes EPA to make available additional financial and technical resources to communities and tribes to conduct their own research (as was done for the Asian and Pacific Islander fish consumption study in King County, WA (EPA) and for the Suquamish Tribe fish consumption study (ATSDR)), and thereby to augment their expertise.

Focused Proposals

I-10 through I-11

1. FCWG proposes that EPA recognize the need for studies to be designed and administered *by and for* particular communities, groups, or peoples, and that it facilitate this process by, among other things:

a. Expanding financial and technical assistance to community-based organizations and tribes to conduct appropriate studies;

b. Taking the lead in identifying and coordinating financial and technical resources that are available through other federal agencies; and

c. Publicizing these expanded and coordinated resources to affected groups in a regular and timely fashion;

FCWG commends EPA's recent grant initiatives to this end (established together with the ATSDR), including two programs: *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment* and *Superfund Minority Institutions Program: Hazardous Substance Research.* However the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available.

2. FCWG proposes that EPA take an active role in establishing and maintaining a system enabling affected groups to share and access results from community-based and tribally conducted research, as well as other research relevant to affected groups' efforts to document and address the nature, extent, and health impacts of contamination in their own communities. Such a system would assist tribes' and communities' efforts to conduct more efficiently their own research, and to participate in or consult with EPA in a timely and informed manner.

3. FCWG emphasizes that, while further research regarding various affected groups' exposure is important, it should not be undertaken at the expense of research that aims to identify the sources of the contamination that burdens these groups and to understand the mechanisms by which substances that have been or are being emitted or discharged from these sources make their way through the environment. Thus, FCWG proposes that further research be conducted to connect the contaminants found in fish, shellfish, and other aquatic resources to the sources of those contaminants.

Current risk-based methods remain controversial as a matter of science, policy and justice.

Overarching Proposals

1-12. To the extent that EPA continues to rely on risk-based and other quantitative methods (e.g., cost-benefit analysis), FCWG proposes EPA to revisit, together with affected communities and tribes, the fundamental assumptions of these methods and to revise these methods to incorporate eco-cultural and spiritual components of risk.

I-13. FCWG strongly proposes that EPA employ the Precautionary Principle at every opportunity as an alternative to risk-based methods.

Focused Proposals

I-12 through I-13

1. FCWG proposes that EPA consider seriously alternative decision making models that permit the multiple and interrelated dimensions of the harms to be acknowledged and addressed. Among these, EPA should consider the model for enlarging current risk assessment methods suggested by Stuart G. Harris and Barbara L. Harper, *Using Eco-Cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*.

2. FCWG proposes that EPA, together with communities of color, low-income communities, tribes, and other indigenous peoples, work to explore and specify the contours of the precautionary principle. FCWG notes that there is a considerable and growing body of work to this end, and proposes that EPA draw on this body of work and support efforts further to develop it.

3. FCWG proposes that EPA actively identify and make use of opportunity for precautionary approaches within existing legislative and other authority, and that EPA consider and advocate appropriate changes to existing laws in order to facilitate precautionary approaches.

4. FCWG notes that preventive and precautionary measures will often at the same time reduce costs to regulated entities (e.g., savings through reduced use of toxic inputs, savings through reduced need to treat and dispose of toxic outputs); these cost savings will be particularly important where the particular regulated entities are an important source of jobs for communities of color, low-income communities, tribes and other indigenous peoples. FCWG proposes, therefore, that EPA make it a priority to identify and undertake prevention opportunities where this is the case.

Chapter Two

Aquatic environments remain contaminated, despite the existence of considerable environmental legal authorities designed to address contamination. About 40% of the waters assessed in the United States still do not support "fishable-swimable" uses; about 10% by volume of all sediments under U.S. waters are seriously contaminated; the list of contaminated soils, sediments, and surface waters yet to be cleaned up is long; and the number of fish consumption advisories in effect has increased steadily over the last several years. Contaminated aquatic environments are the result of releases to various environmental "receiving media" – to surface waters, groundwater, sediment, soils, and air – and movement among these interconnected media. Because people of color, low-income people, American Indians/Alaska Natives, and other indigenous people are disproportionately among the most exposed to this contamination, any lapses in agencies' efforts to prevent, reduce, clean up, and restore contaminated aquatic environments will disproportionately burden these affected groups.

Overarching Proposals

II-1. Given that five contaminants--mercury, PCBs, dioxins, DDT, and chlordane--are responsible for the majority of fish and wildlife consumption advisories, FCWG proposes that the prevention and cleanup of these pollutants in the Nation's waters and restoration of aquatic ecosystems following such contamination be a priority. FCWG further proposes that prevention, cleanup, and restoration efforts focus on all contaminants that are highly toxic, bioaccumulative, and persistent, especially those identified by the Convention on Persistent Organic Pollutants (POPs); and on other contaminants of concern, including lead and other metals, radioactive materials, pesticides, fecal coliform and other bacterial and viral contaminants, sediment and silt loading, water quantity, water temperature changes and other alterations to aquatic ecosystems, and climate change.

II-2. FCWG cannot emphasize strongly enough the need for redoubled, aggressive prevention, cleanup, and restoration efforts to address these contaminants of concern in the surface water, groundwater, sediments, soils and air. FCWG proposes EPA to ensure that efforts to cleanup and restore contaminated aquatic ecosystems are coupled with measures to prevent future contamination.

II-3. Specifically, because mercury is responsible for nearly 79% of all fish and shellfish advisories and because air emissions account for 80% of mercury depositions in water, FCWG proposes that the prevention and cleanup of mercury in the Nation's waters be a top priority for EPA, and that regulations and other efforts here address all significant sources of mercury, regardless of the initial "receiving medium" (e.g., air, soils, water, sediments). Moreover, FCWG

proposes EPA to ensure that reductions in mercury accrue equitably to all, and that mercury reduction efforts do not have the effect of creating "hot spots" or other disparate impacts.

II-4. Further, FCWG proposes that prevention and cleanup of dioxin address all significant sources, and that cleanup of PCBs, DDT, and chlordane (production of which are banned), address all significant sources. Similarly, FCWG proposes that prevention and cleanup of all Persistent Bioaccumulative Toxins(PBTs)/Persistent Organic Pollutants (POPs) address all significant sources.

II-5. Finally, because the concentrations in aquatic organisms of mercury and some other contaminants of concern, such as lead, cannot be reduced by cleaning, trimming, and or cooking, FCWG proposes that regulatory authorities should not rely on advisories suggesting these methods as a way to protect public health.

Focused Proposals

II-1 through II-5

1. FCWG proposes that EPA work expeditiously to *prevent* and *reduce* the release of contaminants of concern and to *clean up* and *restore* aquatic ecosystems contaminated by these pollutants. FCWG emphasizes that, in every instance, EPA must set the relevant environmental standards at levels that protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples. FCWG also emphasizes that, in every instance, EPA account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes:

a. With respect to mercury:

(i) EPA address these concerns and expedite the issuance of a Maximum Achievable Control Technology (MACT) standard for emissions from utilities, including coal-fired power plants (a MACT standard for utilities is not scheduled to be proposed until December, 2003; meanwhile, coal-fired power plants are the largest single source of mercury air emissions);

(ii) EPA address these concerns in issuing a Maximum Achievable Control Technology (MACT) standard for emissions from institutional, industrial, and commercial boilers;

(iii) EPA address these concerns in issuing a Maximum Achievable Control Technology (MACT) standard for emissions from chlor-alkali plants (although there are only about a dozen chlor-alkali plants in the United States, each plant is the source of large quantities of mercury. Further, chlor-alkali plants may in some cases constitute the most significant sources locally, as in Louisiana, where the two chlor-alkali plants statewide contribute more mercury than all of the coal-fired power plants statewide combined.[447]);

(iv) EPA address these concerns and expedite the (re)- issuance of its Hazardous Waste Combustor rule, and that, in the meantime, EPA not rely on an interim rule that is less protective than the original final rule – which was struck down by a court because it was insufficiently protective;

(v) EPA address these concerns in ensuring compliance with its recently-issued Maximum Achievable Control Technology (MACT) standard for emissions from medical waste incinerators, and in identifying and facilitating further efforts to reduce and eliminate the use of mercury in the first place (including, e.g., efforts similar to OPPTS' voluntary agreements with hospitals and other medical facilities to reduce mercury use; state and local governments' bans on the use of mercury-containing

[447]Telephone Interview with Barry Kohl, Department of Geology, Tulane University (October 17, 2001).

medical products;[448] and potential partnerships with private industries to develop and produce alternative, mercury-free products);

(vi) EPA's Office of Air and Radiation and its Office of Water address these concerns and redouble their efforts to address cross-media mercury contamination through various initiatives, including through the TMDL program;

(vii) EPA address these concerns in supporting the United Nations Environment Program's (UNEP) global mercury study and facilitating and participating in the resulting UNEP efforts toward negotiations on global reductions in mercury emissions;

b. With respect to PCBs:

(i) EPA give priority to these concerns in setting or approving cleanup standards under CERCLA; that EPA conduct robust cleanups and decline to employ "use-restricted" or "risk-based" methods for sites affecting communities of color, low-income communities, tribes, and other indigenous peoples; and that, in any event, EPA refuse to rely on projected or current reductions in fish, shellfish, and aquatic resource consumption and use as a justification for less protective cleanup standards or assumptions;

c. With respect to dioxin:

(i) EPA move expeditiously to release the final Dioxin Reassessment and that EPA ensure that the "need for further study and peer review" not be used as a reason to delay further its publication and use, given that dioxin has already been the subject of over a decade of study and sound scientific evidence supports the findings of the draft Dioxin Reassessment;

(ii) EPA address these concerns in ensuring compliance with its recently-issued Maximum Achievable Control Technology (MACT) standard for emissions from medical waste incinerators, and in identifying and facilitating further efforts to reduce and eliminate the use of products that, ultimately, result in releases of dioxin;

(iii) EPA address these concerns in issuing rules and undertaking initiatives to reduce further dioxin emissions to air, particularly from those sources that remain un- or under-controlled, including backyard burning;

(iv) EPA address these concerns in undertaking cleanup of sediments and soils contaminated from historical emissions and discharges of dioxin, given the increasing relative contribution of sediments and soils to dioxin contamination (as other sources are controlled);

(v) EPA work expeditiously to conduct surveys of sediments and soils likely to be contaminated with dioxin, in order to facilitate effective cleanup;

(vi) EPA, as part of its Dioxin Exposure Initiative, work systematically to characterize the exposures of communities of color, low-income communities, tribes, and their members and to link these exposures to their sources;

(vii) EPA ensure the efficacy of standards regulating dioxin, by working expeditiously to improve its ability to measure dioxin levels – because dioxin is highly toxic in even very small quantities and because current methods are not sensitive enough to detect dioxin in very small quantities, EPA cannot ensure that releases at "non-detect" levels are in fact protective of the health of communities of color, low-income communities, tribes, and other indigenous peoples;

[448]These bans have the effect not only of requiring the use of alternative, mercury-free health care products and but also of providing incentives for the development and production of improved mercury-free technology and products. Indeed, such alternative, mercury-free health care products are already becoming available. See, e.g., Sustainable Health Care Project website at: www.uml.edu/centers/LCSP/hospitals.

d. With respect to these and other contaminants of concern:

(i) EPA begin expeditiously to include additional contaminants of concern on its list of Persistent and Bioaccumulative Toxics (PBTs), including lindane, endosulfan, lead and a host of other highly toxic, persistent, and bioaccumulative substances, especially those affecting the aquatic resources on which communities of color, low-income communities, tribes, and indigenous peoples depend;

(ii) EPA, under the auspices of its PBT Initiative and otherwise, place a priority on efforts to reduce and eliminate the use of PBTs, and to clean up and restore those ecosystems already contaminated with PBTs.

2. FCWG proposes that, similarly, with respect to its efforts under the Clean Water Act and other statutes addressing water quality and quantity, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA issue guidance clarifying that water quality standards (WQS), whether issued by states, tribes or the EPA, account to the greatest extent possible under law for these affected groups' different consumption and use of aquatic resources by, among other things:

(i) requiring "designated uses" to reflect appropriate rates of consumption and use of fish, shellfish, plants and wildlife by subsistence fishers and other higher-consuming groups;

(ii) requiring that such "designated uses" be recognized not only for those water bodies where subsistence and other fishing currently occurs, but also for those water bodies where subsistence and other fishing *would* occur, but for the contamination and depletion that give rise to suppressed consumption (described in Chapter One of the Report);

(iii) requiring that designated uses support cultural, traditional, and ceremonial uses of aquatic resources, particularly where the quality of the relevant water bodies affects tribal and other culturally important resources (whether located on- or off-reservation);

(iv) requiring triennial reviews of water quality standards under CWA § 303(c)(1) to consider whether state or tribal criteria protect subsistence fishers and other higher-consuming groups where subsistence and other fishing exists, and stipulating that EPA disapprove any criteria that do not protect these groups;

b. EPA issue a Total Maximum Daily Load (TMDL) rule that protects highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and accounts for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources – especially given that the impaired waters affected by the TMDL rule occur primarily and disproportionately in locations that impact these affected groups;

c. EPA issue a rule for Large Feedlots (also called Concentrated Animal Feeding Operations (CAFOs)) that protects the health and resources of communities of color, low-income communities, tribes, and other indigenous peoples in the process of addressing the siting and regulation of new facilities and the clean up of contamination from existing and former facilities; and that incorporates the NEJAC Resolution on CAFOs;

d. EPA issue a rule for Metal Products and Machinery that protects the health and resources of communities of color, low-income communities, tribes, and other indigenous peoples while attending to issues of economic justice, particularly to the extent those small businesses affected by the rule are an important source of jobs and economic health for members of affected groups (e.g., by focusing on measures that both prevent contamination and reduce costs to regulated sources);

e. EPA make every use of its authority under the National Pollutant Discharge Elimination System (NPDES) program to protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional,

religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources, by among other things:

(i) imposing appropriate permit conditions, when EPA possesses the permitting authority;

(ii) disapproving permits that do not impose appropriate conditions, when states or tribes possess the permitting authority; and

(iii) incorporating the NEJAC proposals regarding permitting: *Environmental Justice in the Permitting Process: A Report from the Public Meeting on Environmental Permitting, Convened by the National Environmental Justice Advisory Council in Arlington, Virginia, Nov. 30-Dec. 2, 1999;*

f. EPA explore and implement additional strategies to address non-point source discharges and runoffs to waters that threaten aquatic ecosystems and human health, including but not limited to discharges from agricultural, construction, forestry, and land disposal operations; stormwater runoff; and applications of FIFRA-approved herbicides along irrigation canals and other waterways;

g. EPA make full use of its authority to ensure non-degradation of clean or "pristine" waters;

h. EPA work to protect and restore wetlands, and to oppose efforts by the Army Corps of Engineers that would relax rules designed to restrict development and degradation of streams and wetlands and to limit cumulative adverse effects on the aquatic environment and ecosystem;[449] EPA should take seriously and literally the commitment to "no net loss;"

i. EPA, in writing regulations under the CWA and in acting other authorities, consider the effect of human-controlled timing and quantity of water flows on water temperature, pollutant concentrations, the health and propagation of fish and wildlife, and the overall health of aquatic ecosystems;

j. EPA attend to urban (e.g., Oakland) and rural (e.g., towns along the U.S.-Mexico border; Alaska Native villages; elsewhere in Indian country; Hawai'i) sanitation issues and their impact on the health of humans and aquatic ecosystems.

3. FCWG also proposes that, with respect to its efforts under the Clean Air Act and other statutes addressing air emissions that affect the health of aquatic ecosystems, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA work with Congressional staff, testify before Congress, and otherwise seek to ensure that the National Energy Plan currently being debated:

(i) places stringent limits on releases of NOx, SO2, and mercury from power plants in order to protect communities of color, low income communities, tribes, and other indigenous peoples and the aquatic ecosystems on which they depend; and

(ii) in the event that it includes an emissions trading program for mercury, employs a "cap" that requires significant aggregate reductions in mercury and includes mechanisms to guarantee that disproportionate burdens from these sources on communities of color, low income communities, tribes, and other indigenous peoples are not exacerbated or newly created by trading;

b. EPA evaluate more thoroughly the impacts of air deposition on the health of fish, aquatic plants, and wildlife, and, in turn, on communities of color, low income communities, tribes, and other indigenous peoples that depend on these resources, and that EPA address these impacts, including:

[449] The Washington Post Online, "Army Corps Seeks to Relax Wetlands Rules," by Michael Grunwald, p. A01 (June 4, 2001). See also http://washingtonpost.com:80/wp-dyn/articles/A16798-2001June3.html.

(i) through expanded cross-program initiatives; and

(ii) when it considers the residual risks after the application of MACT, as part of the 10-year reviews required under CAA § 112(f);

c. EPA better control NOx to prevent acidification and eutrophication;

d. EPA make every use of its authority under the Title V Air Operating Permit program to protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources, by among other things:

(i) imposing appropriate permit conditions, when EPA possesses the permitting authority;

(ii) disapproving permits that do not impose appropriate conditions, when states or tribes possess the permitting authority; and

(iii) incorporating the NEJAC proposals regarding permitting: *Environmental Justice in the Permitting Process: A Report from the Public Meeting on Environmental Permitting, Convened by the National Environmental Justice Advisory Council in Arlington, Virginia, Nov. 30-Dec. 2, 1999.*

4. FCWG also proposes that, with respect to its efforts under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and other statutes addressing cleanup and restoration of contaminated environments, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA expand its current efforts under its Contaminated Sediment Management Strategy so that in addition to assessing the nature and extent of contamination sediments, it focuses on and prioritizes cleanup and restoration of contaminated sediments, and that in the process, EPA attend to disposal issues raised by contaminated sediments that have been removed;

b. EPA conduct robust cleanups and decline to employ "use-restricted" or "risk-based" methods for sites affecting communities of color, low-income communities, tribes, and other indigenous peoples, and that, in any event, EPA refuse to rely on projected or current reductions in fish, shellfish, and aquatic resource consumption and use as a justification for less protective cleanup standards or assumptions;

c. EPA work through every avenue possible to oppose efforts to eliminate funding for CERCLA's "Superfund;" to ensure that, to the extent these efforts are successful, EPA nonetheless continues to place a high priority on cleanup and restoration of those sites contaminated with pollutants likely to bioaccumulate in the fish, aquatic plants, and wildlife consumed or used for subsistence, traditional, cultural or religious purposes; and to ensure that any resulting delay in addressing such sites not be used to justify less protective cleanup standards;

d. EPA work to retain and effectuate the "polluter pays" principle under CERCLA, by, among other things, looking to potentially responsible parties (PRPs) to ensure funding for full restoration of those ecosystems that support fish, shellfish, aquatic plants and wildlife on which affected groups rely; ensure funding for adequate communication with affected tribes and communities and; if appropriate from the perspective of those affected, funding for alternatives that may serve as substitutes for the contaminated resources until such time as the restoration is complete (Please note, however, that such alternatives will NOT be appropriate from the perspectives of some affected groups – the provision of alternative resources, for example, is not endorsed by the Indigenous Peoples Subcommittee);

e. EPA improve cooperation among EPA offices on cleanup and restoration strategies, particularly initiatives targeted at restoring those aquatic ecosystems that are contaminated with pollutants likely to bioaccumulate in the fish, aquatic plants, and wildlife consumed or used for subsistence, traditional, cultural or religious purposes;

f. EPA revise its Principles for the Ecological Restoration of Aquatic Resources to focus not only "on scientific and technical issues"[450] but also on the historical, cultural, legal, and social contexts within which restoration takes place; that EPA revise these Principles to reflect the interrelation between "physical"structures and functions on the one hand and social and cultural structures and functions on the other hand, such that restoring and maintaining "ecological integrity" includes restoring and maintaining cultural integrity; and that EPA work with tribes and other affected groups to undertake "eco-cultural restoration."[451]

5. FCWG also proposes that, with respect to its efforts under the Toxic Substances Control Act (ToSCA), and other statutes regulating new and existing chemical substances, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA's Office of Pesticides, Prevention, and Toxic Substances (OPPTS) flag to its Office of Water (OW) those chemicals that it registers that are expected to be produced or used in high volume and that will potentially affect aquatic ecosystems; OW should then work with OPPTS to secure additional and higher level testing, and where potential contamination of fish and aquatic resources is suspected, to ensure that additional testing and rulemaking are expedited.

6. FCWG also proposes that, with respect to its efforts under other statutory authorities, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA issue a rule regulating coal combustion waste under the Resource Conservation and Recovery Act (RCRA), especially given the presence of arsenic in this waste and the fact that, in many places, this waste is still being disposed of in unlined facilities and leaching into drinking water sources;

b. EPA tighten hazardous waste rules to prohibit toxic wastes, such as dioxins, mercury, lead, cadmium, and other contaminants of concern from being "recycled" into fertilizer, and eliminate the exemption for steel mill waste;[452] and that EPA rewrite its ten-year-old treatment standard for hazardous waste, ensuring that the new rule does not create disincentives (such as those created by permissive provisions regarding recycling) for developing and implementing improved treatment technologies.

7. In undertaking compliance and enforcement efforts affecting the quality of aquatic ecosystems, FCWG proposes EPA to improve its cooperation, coordination, and collaboration with states and tribes, and, in the case of federally recognized tribes, to improve its consultation with tribal governments.

In setting or approving standards and in making other risk management decisions meant to address these contaminants, EPA aims for a level of risk to human health deemed "acceptable" or safe. That is

[450]U.S. EPA, Principles for the Ecological Restoration of Aquatic Resources (2000), available at www.epa.gov/owow/wetlands/restore/principles.html.

[451]See, e.g., Jeffrey P. Thomas, Director, Forest Resource Protection Program, Fisheries Department, Puyallup Tribe of Indians, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Comments) (describing the potential role for the Inter-Tribal Cultural Advisory Group (in Washington) to this end).

[452]Toxic wastes from pulp and paper mills, steel mills, tire incinerators and cement kilns is currently "recycled" into fertilizer and applied to crops, grazing lands and gardens. This waste has been found to contain dioxins, mercury, lead, cadmium, and other contaminants of concern. Although hazardous waste regulations address this practice, (1) they may still permit unacceptable levels of these contaminants, and (2) they contain a loophole that exempts steel mill waste. See, e.g., Washington Toxics Coalition, Visualizing Zero: Eliminating Persistent Pollution in Washington State (2000).

to say, for carcinogens or non-threshold contaminants, EPA in effect determines that it will view the increased incidence of cancer in some number of humans (e.g., 1 out of every 1,000,000 humans) to be "acceptable," and will permit environmental standards to be set accordingly. To the extent that EPA's guidance and standards deem a greater level of cancer risk to be "acceptable" for "more highly exposed subgroups" than for the general population, this is inequitable and deeply troubling as a matter of environmental justice, given that we *know* – and EPA *knows* – that it is people of color, low-income people, American Indians/Alaska Natives, and other indigenous people that comprise the "more highly exposed subgroups." Moreover, in the view of FCWG, human lives are not expendable. EPA should strive for standards that do not find "acceptable" the increased risk of cancer for *any* humans.

Overarching Proposals

II-6. FCWG proposes that as a general matter, EPA should ensure that the federal environmental laws are implemented and enforced equitably and effectively to protect the health of all people consuming fish, aquatic plants, and wildlife.

II-7. FCWG proposes that substantive environmental standards be set so as to provide equitable levels of protection to all – levels that protect not only the health of the general population, but also the health of people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdiction of the United States.

II-8. Specifically, FCWG proposes that EPA rescind any guidance setting "acceptable" risk for subsistence and other higher-consuming subgroups at levels greater than the general population (e.g., EPA's revised Ambient Water Quality Criteria Methodology, which defines "acceptable" cancer risk for higher-consuming subgroups as risk that permits up to 1 in 10,000 people to suffer from cancer whereas it defines "acceptable" cancer risk for the general population as risk that permits a fewer number of people to suffer from cancer – between 1 in 100,000 and 1 in 1,000,000, and perhaps as few as 1 in 10,000,000), and to reissue guidance that prevents such a disparity in protection. Moreover, FCWG proposes EPA to reconsider in every relevant context its determination that some greater number of human cancers due to environmental contamination is "acceptable" for more highly exposed subgroups and to strive for standards that do not find "acceptable" the increased risk of cancer for any *humans, i.e., standards that aim for zero risk.*

In setting or approving standards and in making other risk management or regulatory decisions meant to address these contaminants, EPA needs to respect and accommodate the different cultural, traditional, religious, historical, economic, and legal contexts in which affected groups consume, use, and depend on aquatic resources.

Overarching Proposal

II-9. FCWG proposes EPA to work with affected groups better to understand the various different cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume, use, and depend on aquatic resources and to develop methods to incorporate these groups' particular circumstances into the standards EPA sets or approves and into the other risk management and regulatory decisions EPA makes.

Focused Proposals

II-9

1. FCWG proposes that EPA use its authority under CWA § 101(e) and elsewhere to encourage states to improve their public participation processes in the development of water quality standards through translation for non-English speaking groups and through greater outreach.

2. FCWG proposes EPA to work together with affected communities and tribes to explore creative, culturally appropriate ways to inform its prevention and reduction efforts regarding communities' and tribes' actual practices, where these practices expose these groups to contaminants in fish, shellfish, plants, and wildlife within aquatic ecosystems.[453]

3. FCWG proposes that EPA reconceptualize its role in understanding affected groups' circumstances of exposure, so that it focuses on building longer-term relationships with affected groups. In the context of these relationships, iterative conversations and other on-going processes would then serve to better inform efforts to prevent and reduce contamination in the first place.

4. EPA's Principles for the Ecological Restoration of Aquatic Resources suggest that restoration efforts "involve the skills and insights of a multi-disciplinary team," and cite among the relevant disciplines "ecology, aquatic biology, hydrology and hydraulics, geomorphology, engineering, planning, communications and social science."[454] FCWG proposes that EPA broaden its understanding of the kinds of expertise relevant to restoration, and include among those it consults elders, anthropologists, ethnobiologists, historians, and others who can provide insight into the "eco-cultural" aspects of restoration.[455]

Prevention, cleanup, and restoration of aquatic ecosystems implicates not only EPA but also numerous other federal departments, agencies and programs (e.g., the Department of Defense, the Department of Energy, the Federal Energy Regulatory Commission, the U.S. Forest Service, the National Marine Fisheries Service, the U.S. Geological Survey, the Bureau of Indian Affairs, the Indian Health Service, the National Institute of Environmental Health Services). Prevention, cleanup, and restoration efforts would be greatly improved and hastened by coordination among these various entities.

Overarching Proposal

II-10. FCWG proposes EPA to take the lead in coordinating the various federal departments, agencies and programs in order to improve prevention, cleanup, and restoration efforts, and to ensure that the results of these efforts, as well as the process for achieving the results, are just.

[453]Communities' and tribes' knowledge here simply cannot be replicated by non-members. At the same time, agencies' familiarity with laws, regulations and guidance is crucial. In some cases, affected communities and tribes have already begun to develop relevant processes, e.g., for documenting consumption and use practices and the contexts in which these occur, or to assemble other relevant informational resources. For example, the Tulalip Tribes are gathering "cultural stories" that will help inform their natural resources and environmental management efforts.

[454]U.S. EPA, Principles for the Ecological Restoration of Aquatic Resources (2000), available at www.epa.gov/owow/wetlands/restore/principles.html.

[455]Dennis Martinez, Presentation, Indigenous Ecology and Cultural Restoration Workshop (San Francisco, Sept.21, 1999).

Focused Proposals

II-10

1. FCWG proposes EPA to improve cooperation among EPA offices, as well as among federal agencies, on pollution prevention strategies, particularly initiatives targeted at preventing the discharge or release of pollutants likely to bioaccumulate in the aquatic ecosystem and people.

2. FCWG proposes that EPA use Interagency Working Group as vehicle for disseminating information on prevention, cleanup and restoration that is attentive to the issue of contamination of aquatic ecosystems and its impact on communities of color, low-income communities, tribes, and other indigenous peoples.

3. FCWG proposes EPA to coordinate effectively with other federal agencies to ensure that *sufficient quantities* of water are maintained and protected to support a sustainable and healthy aquatic ecosystem, and to ensure that other actions are undertaken (e.g., under the Endangered Species Act (ESA) to guarantee the health of fish, shellfish, plant, and wildlife species and the habitats on which these species depend.

Tribal governments or EPA are responsible for implementing water quality standards (WQS) within Indian country and on Alaska Native lands. Yet, because only 16 of the 565 federally recognized tribes and Alaska Native villages have EPA approved and/or promulgated water quality standards, there are still considerable gaps in water quality standards coverage in Indian country.

Overarching Proposal

II-11. FCWG proposes that EPA address promptly existing gaps in water quality standards coverage in Indian country and on Alaska Native lands to protect tribal resources and treaty-protected rights as well as the health of American Indian/Alaska Native people who are heavily reliant on subsistence activities and diet. FCWG proposes EPA to make the development, adoption, implementation, and enforcement of water quality standards throughout all of Indian country a high priority. This includes support for tribal WQS in accordance with EPA's Indian Policy and promulgation of enforceable federal core WQS for reservation and other Indian country waters for which tribal WQS are not in effect. FCWG proposes that, consistent with the federal trust responsibility to the tribes, EPA use all available existing authorities under the federal environmental laws to protect tribal resources, treaty-protected rights, and the health of American Indian/Alaska Native people; provided that *EPA should cooperate with and support tribal regulatory efforts in those instances where tribes choose to carry out various responsibilities under the federal environmental laws. In the context of Alaska Native lands that are not considered Indian country, FCWG proposes EPA to engage in consultation with Alaska Native tribes and the State of Alaska on the possible revision of WQS better to protect subsistence traditions, such as the adoption of designated uses for subsistence harvesting of fish and wildlife.*

Focused Proposals

II-11

1. FCWG proposes that EPA, in consultation with tribes, proceed with rulemaking on the Core Federal Water Quality Standards for Indian Country:[456]

[456] See U.S. EPA, Office of Water, Federal Water Quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards (unofficial pre-publication copy, Jan. 19, 2001) (available at www.epa.gov/ost/standards/tribal/) [hereinafter "Proposed Core Standards"].

a. The Proposed Core Standards currently call for a four-part hierarchy for selecting a fish consumption rate for use in setting water quality standards in Indian Country. This hierarchy sets up a preference for using "the results of any existing fish consumption surveys of local Indian country watersheds to establish fish intake provisions that are representative of the population being addressed," but in the absence of such data, would look to a default fish consumption rate as low as 17.5 grams/day.[457] In FCWG's view, this default fish consumption rate does not accurately reflect the consumption practices of most tribes. FCWG proposes EPA to employ a default consumption rate that is appropriate for higher-consuming tribes and their members. EPA should select this default rate in consultation with tribes. FCWG further proposes EPA to account for other aspects of tribes' different exposure circumstances, including practices that mean different species are consumed, different parts are used, and/or different preparation methods are employed than those typically assumed by agencies. Again, EPA should consult with tribes to understand the nature and import of these practices. Finally, FCWG commends the fact that the proposed hierarchy sets up a preference for local data, but emphasizes the need for EPA to fund additional, tribally conducted fish consumption surveys in Indian country watersheds. As discussed in Chapter One, currently only a handful of such studies exist;

b. EPA should, in consultation with tribes, develop guidance for EPA permit writers charged with implementing the Proposed Core Standards in order to ensure that permit writers tailor NPDES permits to each individual tribe's circumstances, including their particular cultural practices;

c. EPA should provide adequate funding and technical assistance to enable tribes who wish to do so to develop a plan for adopting their own water quality standards under the Clean Water Act or for developing individualized federal standards together with the relevant Regional Administrator within a reasonable amount of time, as required in order to be excluded from the rule adopting Core Federal Water Quality Standards for Indian Country.[458]

The contamination of aquatic environments and the harmful effects of this contamination are matters of global concern. Pollution, of course, does not respect political boundaries and many of the contaminants of concern persist in the environment and travel great distances, cycling through the air, water, soils, and sediments and affecting people and places far from the source.

Overarching Proposals

II-12. FCWG proposes EPA to be mindful of the interconnected and international nature of contaminated aquatic ecosystems. FCWG proposes that EPA work to ensure the development, ratification, implementation, and enforcement of international law and policy addressing the contaminants of concern.

II-13. Specifically, FCWG proposes EPA to expend every effort to see that the United States ratifies the Convention on Persistent Organic Pollutants (POPs) and to develop, together with affected communities and tribes, an implementation plan for the United States that assures compliance with this treaty.

Chapter Three

Fish and wildlife consumption advisories are one component of a comprehensive health risk control strategy and can serve the useful function of aiding affected communities in determining to what extent they will take the proposed steps to avoid health risks.

[457] See Proposed Core Standards at 17.
[458] See id. at 4-6.

Overarching Proposals

III-1. However, FCWG strongly emphasizes that advisories must be coupled with ongoing and aggressive efforts to curb existing and future pollutant sources through stringent implementation and enforcement of water quality and other environmental regulations and cleanup of historic contaminant sources. FCWG proposes EPA to work with affected groups and be proactive in identifying and implementing alternatives that protect the health of disproportionately exposed groups in the meantime, that is, until prevention and cleanup are fully achieved.

Focused Proposals

III-1

1. Fish consumption advisories – which shift the burden to risk-bearers to avoid the risks they have been made to face – should never be allowed to become the primary method by which agencies address risks. Rather, FCWG proposes EPA to require risk-producers to prevent, reduce and cleanup contamination, and to view fish consumption advisories as a short-term, interim strategy to inform and to protect the health of those who consume and use fish, aquatic plants, and wildlife while cleanup is proceeding. To this end:

   a. FCWG proposes EPA to focus, during planning and priority setting, on reducing risk and addressing communities' and tribes' health and safety needs rather than on securing communities' and tribes' "compliance" with fish advisories or other risk avoidance measures;

   b. FCWG emphasizes that EPA needs to couple the use of fish consumption advisories designed to protect people's health "in the meantime" with a real, aggressive push to cleanup, reduce and prevent contamination in the first place;

   c. FCWG proposes a focus in particular on prevention now so that in the future EPA and states will not be faced with having to employ fish consumption advisories.

2. FCWG proposes that EPA develop, and help states and tribes to develop, measures to ensure that reliance on fish consumption advisories is truly a temporary strategy. Given that advisories have been in effect in some places for nearly 30 years (e.g., the Great Lakes), it seems that a renewed commitment is in order. To this end, FCWG proposes EPA to consider a wide variety of measures, including sunset provisions, periodic reevaluation, etc., that would help EPA and other agencies guard against the advisory program taking on a life of its own.

3. FCWG proposes that EPA develop, and help states and tribes to develop, mechanisms to ensure that agency risk communicators coordinate with agency risk managers so that affected groups' responses to fish consumption advisories inform future risk management decisions, including planning and priority-setting. FCWG notes that this coordination is especially important where the affected community or tribe declines to *"*comply*"* with a fish advisory: to the extent that such a response expresses a protest with current priorities (e.g., reliance on risk avoidance rather than risk reduction), EPA needs to ensure, and help states and tribes to ensure, that this protest gets registered with and taken into account by those setting priorities.

4. FCWG proposes EPA to increase financial and technical support to tribes who wish to determine for themselves what role fish consumption advisories should play in their efforts to protect the health and safety of tribal members and who may wish to fashion tribal consumption guidelines. This would include funding basic research by the tribe into the nature and extent of the contamination of concern, and its health effects for tribal members. FCWG notes that tribes are often the only ones in the position to frame the research questions in a way that reflects their unique knowledge of tribal resources and their sense of what is appropriate for tribal members. Further, FCWG proposes EPA to require states that issue advisories to notify directly all tribes whose land and resources (including resources both on- and off-reservation) are affected by the advisory.

5. FCWG proposes EPA to increase financial and technical support to affected communities to participate in decisions, including decisions at the state and local levels, about what role of fish consumption advisories should play in efforts to protect the health and safety of community members.

6. FCWG proposes that EPA consider how it might meet the immediate needs of communities of color, low-income communities, tribes, and indigenous peoples who are burdened by existing contamination.

Specifically, FCWG proposes that:

a. EPA work together with affected groups to identify useful alternatives for those who would avail themselves of alternative means of catching or consuming fish or alternative ways of meeting at least some nutritional needs;

b. EPA consider, *together with those affected*, whether there is a role for providing such things as subsidized construction of alternative fishing ponds; subsidized bus passes or other transportation vouchers to alternative fishing sites; subsidized vouchers for purchasing uncontaminated fish; subsidized vouchers for purchasing alternative sources of protein; subsidized aquaculture; or other measures to meet affected groups' immediate needs. *However, FCWG emphasizes that EPA should proceed cautiously here, working closely with the particular affected group(s) and attending to the possible negative effects of such alternatives* (e.g., government "surplus" foods are notoriously high in fat and sugar and providing such foods could exacerbate existing health conditions – such as diabetes, the incidence of which is much greater among Native American populations and some other affected subgroups). *FCWG implores EPA to recognize that the provision of alternatives will be inappropriate from the perspective of some affected groups.* (The Indigenous Peoples Subcommittee, for example, does not endorse the provision of alternatives or "substitutes" for contaminated aquatic resources.);

c. EPA make greater use of fines imposed on violators as part of CERCLA enforcement actions that result in settlement to fund studies by and for affected groups, and to otherwise meet affected groups' immediate needs.

7. FCWG proposes that EPA work with state and local environmental and health agencies to ensure that not only is initial testing of fish, shellfish, and aquatic resources undertaken expeditiously but that follow up testing is also conducted, particularly given the importance of fisheries for subsistence and economic needs. Thus, for example, a state may in some cases act to close shellfisheries due to contamination that it has confirmed by testing, but neglect to conduct further testing in order to determine at earliest possible date that the threat from contamination over and it is appropriate to reopen the fishery. FCWG notes that, as a general matter, testing is too episodic at both ends.

While advisories are useful, in order for them to be effective they must be tailored to specific locales and specific communities – there is no one-size-fits-all, and "consistency" across broad regions or population groups may not be useful. The term "affected groups" here includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected communities, including but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refuge communities; African-American communities, various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thaidum communities within the Laotian community in West Contra Costa, CA); various Hispanic communities and subcommunities (e.g., "Caribbean-American" communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaskan Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people); and subgroups such as children, pregnant women, or elders within these groups.

Overarching Proposal

III-2. FCWG proposes EPA to learn about and attend to the fact that "affected groups" includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, linguistic and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected groups.

Focused Proposals

III-2

1. FCWG proposes that EPA work with each of the large and diverse array of affected groups to determine priorities for defining, gauging, and enhancing advisories' effectiveness *from the perspectives of those affected.* FCWG emphasizes that EPA can better identify the real problems that exist in communities and tribes by listening to and consulting with those affected. FCWG commends EPA's recent efforts, together with the State of Minnesota, to bring together and fund the participation of representatives from communities and tribes in order to discuss some of these issues in the context of its *National Forum on Contaminants in Fish* in May, 2001.

2. FCWG commends the fact that EPA has dedicated resources and staff to be devoted to environmental justice issues and applauds the considerable work that has been done to identify the large and diverse array of affected groups and to attend to the particular cultural, traditional, religious, historical, economic, linguistic, and legal contexts in which these groups consume and use fish and other aquatic resources. FCWG proposes that EPA maintain and expand the resources and staff it devotes to environmental justice, and that EPA encourage states to do the same.

3. FCWG suggests that a focus on national or regional consistency among state and tribal advisory programs is misplaced from the perspective of most communities of color, low-income communities, tribes, and other indigenous peoples, whose concerns tend to be more localized; FCWG proposes, instead, that agency resources be redirected toward preventing, reducing, and cleaning up the contamination that gives rise to advisories.

Affected communities and tribes are integral to relevant, appropriate and effective risk communication. Affected communities and tribes need, therefore, to be involved as "partners" or, in the case of tribal governments, "co-managers" at every stage of the communication process – from identifying needs and priorities, to developing group-appropriate advisory content, language(s), and communication methods, to interpreting community responses and determining their import for agencies' risk assessment and management efforts.

Overarching Proposals

III-3. FCWG proposes EPA to recognize the expertise of members of affected communities and tribes, and to involve them or consult with them throughout the risk communication process. FCWG proposes EPA to follow NEJAC's Model Plan for Public Participation and NEJAC's Guide on Consultation and Collaboration with Indian Tribal Governments and the Public Participation of Indigenous Groups and Tribal Members in Environmental Decision Making.

III-4. Importantly, FCWG proposes EPA to make available additional financial and technical resources to communities and tribes to ensure that they can participate or engage in consultation effectively.

III-5. FCWG emphasizes the importance of capacity-augmentation in communities and tribes, and proposes that EPA recognize and facilitate this as a separate objective of full community and tribal involvement in risk communication.

III-6. To this end, FCWG specifically proposes that EPA, in issuing its advisories and in providing guidance to states and tribes :

(A) Ensure that affected communities and tribes are involved in the identification, design, implementation, and evaluation of culturally appropriate and effective communication of fish advisory information.

(B) Ensure that advisories present information in a form that is culturally appropriate and readily understood by the fisher and fish consumer (i.e. no jargon and in the language(s) of the affected communities, utilizing graphics as appropriate).

(C) Ensure that, where culturally appropriate and practicable, advisories suggest alternative means that would allow for the continued consumption of fish, including alternative fish species or alternative preparation and cooking methods.

(D) Ensure that affected communities and tribes are able to participate in or consult on the development of proposals about alternative or substitute food sources, and alternative preparation and cooking methods.

Focused Proposals

III-3 through III-6

1. FCWG proposes that, depending on the affected group, EPA use the NEJAC's *Model Plan for Public Participation* and/or NEJAC's *Guide on Consultation and Collaboration with Indian Tribal Governments and the Public Participation of Indigenous Groups and Tribal Members in Environmental Decisionmaking* as a guide for informing those affected not only of the fact of contamination and advisories, but also of the nature and extent of the contamination and its impacts on the health and well-being of the affected group. FCWG emphasizes the need to allow adequate time for those affected to digest and discuss the information and then to participate in or consult on relevant decisions.

2. FCWG notes that, in many cases, it will be appropriate for the regional EPA office to take the initiative to organize and collaborate with affected communities and tribes regarding contaminated fish and other aquatic resources. FCWG proposes that the regional EPA office, again using the *Model Plan* and/or the *Guide on Consultation*, as appropriate, assist affected groups to develop and communicate possibilities that would make the group whole. The regional EPA office, together with the affected group, should discuss, evaluate and negotiate which possibilities should be implemented and agree on an implementation plan and timelines; and should then be accountable to the group for "follow through," (e.g., ensuring *and communicating to the group the fact that* the measures identified are in fact implemented.

3. FCWG proposes EPA to set up data bases and other means by which affected groups may access information from and communicate with EPA, working with affected group to identify and meet their needs. FCWG emphasizes the need for EPA to provide financial and technical assistance to communities and tribes that are working to inform themselves in order to participate meaningfully in or consult meaningfully on EPA decisions affecting the aquatic ecosystems on with these groups depend. FCWG notes that this is a matter of capacity augmentation, and proposes EPA to make it a priority.

4. FCWG proposes that EPA, as it works with affected groups, be mindful of the various considerations outlined in Chapter Three, Part D of the Report, and that it encourage state and local agencies to look to the various approaches that have been cited in the Report as successful from the perspectives of those affected as potential models for their current risk communication efforts.

Chapter Four

Although American Indian tribes, Alaska Native villages, and their members share many of the concerns discussed in the preceding chapters, tribes' political and legal status is unique among affected groups and so warrants separate treatment. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories, and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights (e.g., the rights of the treaty tribes of the Pacific Northwest to take fish "at all usual and accustomed grounds and stations;" or

similar rights of treaty tribes elsewhere to fish, hunt and gather). Other laws and executive commitments, too, shape the legal obligations owed to tribes, American Indians and Alaska Natives.

Additionally, due to their special susceptibilities such as poverty, remote location, poor health and extremely high unmet health needs, subsistence-based living, and traditional and cultural uses of natural resources, tribes, American Indians, and Alaska Natives suffer a disproportionate burden of health consequences due to their exposure to pollutants and hazardous substances in the environment.

Overarching Proposals

IV-1. Where tribes and American Indians/Alaska Natives are affected by polluted aquatic ecosystems and contaminated fish, aquatic plants, and wildlife, federal agencies must respond and resolve these threats and environmental and health impacts in ways that fulfill the federal trust responsibility owed to tribes and that are respectful of and consistent with the recognition of tribal sovereignty and tribal rights under federal laws and treaties. In the context of Alaska Natives, federal agencies must respond to and resolve these threats and environmental and health impacts in ways that preserve for Alaska Natives the ability to carry on their traditional practices of providing for their subsistence needs from the lands and waters that they have used historically.

Focused Proposals

IV-1

1. FCWG proposes EPA to support legislative initiatives that will eliminate inequities in federal funding to address the alarmingly high levels of unmet environmental and health needs of AI/ANs, regardless of where they live. Although the EPA leads federal efforts in protecting the environment within Indian country and Alaska Native villages, the Indian Health Service is the principal federal health care provider and health advocate for AI/ANs. The provision of these health-related services arise from the trust responsibility and special government-to-government relationship between the federal government and federally recognized Indian tribes. However, the level of funding for Indian Health Service has long been utterly inadequate to meet the environmental and general health needs of Indian country and Alaska. In 2000, the Indian Health Service was funded and staffed at only 34% of the level of need.

2. FCWG proposes EPA to assert a leadership role among federal agencies in developing new financing mechanisms and leveraging all available resources to fund and implement environmental health-related projects and research in Indian country and Alaska Native villages.

3. FCWG proposes EPA to support regional meetings and a national summit of federal agencies, federally recognized tribes, and concerned tribal organizations to discuss the environmental health needs of AI/AN and design a comprehensive environmental health research agenda to address those needs.

4. FCWG proposes EPA to review available baseline environmental health data for Indian country and Native Alaska villages and take prompt steps to remedy all data insufficiencies, and retain and store environmental and health data on each federally recognized tribal government and provide a means for each tribe to access easily the information applicable to its members and territory. FCWG proposes EPA to request that the Indian Health Service make its annual data on health status readily available to each federally recognized tribe and other federal agencies.

5. FCWG proposes EPA, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to conduct environmental research, studies, and monitoring programs to determine the effects on, and ways to mitigate the effects on the health of AI/AN communities due to exposure to environmental hazards, including but not limited to persistent organic pollutants and persistent bioaccumulative and toxic pollutants, nuclear resource development, uranium and other mine tailing deposits, petroleum contamination, and contamination of the water source and/or food chain. *This is critical where the health of such communities is particularly susceptible to environmental harm because they are known to rely on subsistence fishing, hunting, and gathering*.

6. Because federal environmental missions and resources are divided among and in some cases overlap between various agencies, FCWG proposes that EPA take the lead in coordinating and pooling available technical and financial resources to provide environmental health-related services to federally recognized tribes equitably, efficiently, and effectively. Towards this end, the Bureau of Indian Affairs, EPA, Department of Housing and Urban Development, and the Indian Health Service should appraise the usefulness and implementation of a national Memorandum of Understanding (MOU) and take appropriate steps to enhance and better promote interagency coordination and collaboration pertaining to the protection of health and the environment within Indian country and Alaska Native villages. Additionally, interested tribes should be considered appropriate parties to similar regional MOUs addressing the protection of health and the environment on their particular reservations. FCWG proposes EPA, in consultation with federally recognized tribes, to develop a federally-funded, comprehensive, interagency program on environmental health that will address fully the environmental justice needs within Indian country and Alaska Native villages.

7. FCWG proposes EPA to make regulatory decisions and develop federal policies affecting the health of AI/AN communities in consultation with federally recognized tribes. To the greatest extent possible, such decisions should be based not only western notions of what constitutes "science, but also should address and incorporate the traditional knowledge of the AI/AN community. For example, limitations on the consumption of traditional foods such as fish, aquatic plants, and wildlife due to pollution danger may trigger unique social, economic, and health effects within AI/AN communities – effects that are most fully and appropriately understood only in consultation with affected tribes.

8. FCWG proposes EPA to ensure that agency staff and managers have a thorough understanding of federal Indian law and policies, tribal culture, and the unique governmental structure of federally recognized Indian tribes, including Alaska Native villages.

9. FCWG encourages EPA and each office within EPA to develop a strategy for recruitment, retention, and upward mobility of American Indians and Alaska Natives in order to increase the quality of planning and priority setting, standards development, and program implementation. Such diversity in hiring, retention, and promotion at EPA will help to ensure that staff is familiar with and comfortable in affected AI/AN communities.

10. FCWG proposes that EPA focus educational efforts on environmental justice and the cause, effect, and remediation of specific environmental hazards. These efforts also should strive to improve the understanding of these issues among AI/AN communities and health professionals serving these communities, including but not limited to medical, nursing, and public health practitioners.

11. FCWG proposes that EPA acknowledge and learn from the determination, creativity, and expertise possessed by tribes, tribal members, tribal scientists, and other tribal professionals in developing stewardship and restoration programs for the environment and aquatic ecosystems.

12. FCWG proposes EPA to increase the number of professionals specializing in environmental health issues confronting AI/AN communities. Because persons who have been exposed to certain hazardous substances such as lead, mercury, pesticides, TCE, and PCBs are at risk for developing permanent disabilities or diseases such as intelligence and behavioral impairments, endocrine disruptions, and cancer, the Indian Health Service, in particular, should be strongly encouraged to focus on preventing these exposures among AI/ANs, monitoring and educating AI/ANs whose health is at risk due to pollution and hazardous substance exposure, and providing equitable and fair medical treatment and long-term assistance to affected AI/ANs.

13. FCWG proposes EPA to recognize that contamination from past and ongoing mining activities are of particular concern for many AI/ANs. Abandoned mines are a concern for many tribes and Alaska Native villages. Abandoned uranium mines, for example, is a pressing issue in the four corners region and in Santa Fe.

Overarching Proposal

IV-2. Importantly, in order to facilitate tribes' efforts to address contaminated and depleted aquatic ecosystems, FCWG proposes EPA to make available additional financial and technical resources to tribes to conduct their own research, to manage (or co-manage) tribal and culturally-important natural resources whether on- or off-reservation, and to consult on environmental decisions that affect them but that are made at the federal and state levels.

Focused Proposals

IV-2

1. FCWG proposes EPA to promote the federal policy of tribal self-determination and self-sufficiency by building the environmental protection and environmental health capabilities of federally recognized tribes so that they can participate fully and effectively in the protection of the human health and environment of AI/AN communities. Equitable funding for tribal programs is critical.

2. FCWG proposes EPA to promote collaborative efforts to identify the various environmental exposures affecting each AI/AN community as an ongoing task, undertaken in consultation with federally recognized tribes. Specifically, data about the susceptibilities of AI/AN communities to various environmental agents is needed to help these communities understand and ameliorate some of their excess and disproportionate risk of exposure.

3. FCWG emphasizes EPA's obligation to consult with federally recognized tribes and involve members of AI/AN communities in designing, planning, and implementing specific environmental health research that reflects not only the traditional and cultural practices of such communities, but also their needs and concerns. FCWG proposes EPA to ensure that environmental health research data is reported back to tribal governments and AI/AN communities promptly and in an understandable manner.

4. Whenever possible and appropriate, FCWG proposes EPA to include state and local governments in collaborative efforts with tribes:

   a. to address human health and environmental justice issues within Indian country and Alaska Native villages. Because pollution does not respect jurisdictional boundaries, collaborative efforts in the human health and environmental justice arena similarly should eclipse political differences. Additionally, states must be swayed to incorporate environmental justice principles and goals into their laws, policies, and practices;

   b. to collect environmental and health data relevant to Indian country and Alaska Native villages. For example, state environmental protection agencies may have access to monitoring information on off-reservation facilities that may be causing or contributing to adverse health consequences in AI/AN communities, or the aquatic ecosystems used by these communities, located nearby, down-stream, and/or down-wind;

   c. to ensure that state and locally issues fish advisories that may affect tribal treaty fishers or tribal fish resources are communicated to tribal governments.

5. FCWG proposes EPA to be proactive in helping federally recognized tribes identify financial and technical resources throughout the federal government to address their environmental concerns and related health needs. By marshaling all available resources, federal agencies can promote "one-stop" shopping for tribal environmental and health-related programs and transcend traditional agency boundaries.

6. FCWG proposes EPA to consult with tribes on fashioning restoration approaches or remedies appropriate to the specific tribe that will address situations where tribal fisheries or treaty fishing resources have been decimated or impaired.

Overarching Proposals

IV-3. FCWG proposes EPA to respect and accommodate the particular cultural, traditional, spiritual, historical, economic, and legal contexts that characterize the various Alaska Native peoples, and to recognize the ways in which their circumstances may be different than those of American Indian tribes located within the contiguous forty-eight states.

Focused Proposals

III-3

1. Consistent with its Indian policy and the federal trust responsibility, FCWG proposes EPA to work with Alaska Native villages in developing effective and appropriate strategies to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats, particularly those threats associated with their extensive subsistence activities.

2. Consistent with its policy of promoting tribal self-determination and self-sufficiency, FCWG proposes that EPA work with Alaska Native villages to address the hurdles particular to Alaska Natives' efforts to manage (or co-manage) and to access resources that are important for subsistence uses. For example, because the United States Supreme Court has held that only one Indian "reservation" -- the Annette Island Reserve -- exists in Alaska, and because the language of the Clean Water Act recognizes the power of tribes to establish water quality standards throughout their "reservations," Alaska Native villages are unable to assume regulatory authority or to participate in the same manner or to the same extent under the Act as tribes located in the lower forty-eight states. Accordingly, FCWG further proposes EPA to cooperate with the State of Alaska in developing such strategies including, but not limited to the adoption of appropriate designated uses for water bodies that are culturally significant and essential to Alaska Native villages. Similar impediments to the participation of Alaska Native villages may also exist under other federal environmental laws.

3. FCWG proposes EPA to work closely with Alaska Native villages and to assist them in accessing relevant research, data, and studies and in applying for and obtaining grants that support efforts to address the concerns of Alaska Native villages with respect to contaminated aquatic ecosystems and impacts on the health of Alaska Natives. FCWG commends EPA's recent support, together with a host of other state and tribal agencies and groups, for the Aleutian/Probilof Islands Association's research project, *Dietary Benefits and Risks in Alaskan Villages* and proposes EPA to continue to provide and enlarge financial and technical support for this and other initiatives.

4. Because the financial resources of Alaska Native villages are severely limited, FCWG proposes EPA to fund and/or facilitate local forums or to provide other effective means wherein rural Alaska Native villages and communities may express their concerns to EPA on environmental health and environmental justice issues; EPA should contact Alaska Native villages and community groups, and others currently working toward this goal (e.g., the Alaska Native Science Commission; the Manilaq Association; Alaska Community Action on Toxics) to identify appropriate opportunities. A number of Alaska Native village representatives traveled great distances to Seattle, Washington at great expense to participate in the public comment period held during FCWG's December 2001 meeting. This burden should be borne by EPA, not Alaska Native villages. Morever, to further its environmental justice efforts, EPA should strive to ensure that at least one Alaska Native village representative is appointed to participate as member of FCWG or its various subcommittees.

5. FCWG proposes that EPA, in collaboration with other federal agencies, ensure adequate priority funding and technical assistance for the design, construction, and operation of safe drinking water, sanitation, and wastewater facilities to protect Alaska Native communities whose health and aquatic ecosystems are imminently threatened by the absence or inadequacy of such facilities. Because only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best, this effort should be given priority.

From: Don.Essig@deq.idaho.gov
Sent: Friday, April 05, 2013 2:47 PM
To: skirsch@acwa-us.org
Cc: Gildersleeve, Melissa (ECY); Niemi, Cheryl (ECY); Braley, Susan (ECY)
Subject: April 17th MSA call and EPA's Fish Consumption rate FAQ's
Attachments: Fish Consumption Water Quality.pptx; General population data and relevance to HHC development.docx

Susan,

Like WA DOE Idaho is working on updating its human health criteria as well. I have been in close communication with Cheryl and others in WA DOE as we try to figure out the best path forward and sort out EPA likes and wants from Clean Water Act mandates. Melissa forwarded me today your reply to Susan Barley and suggested I reply to you directly with some thoughts for the April 17th call in Cheryl's absence.

There is no doubt some people eat a lot more fish than the general population, but it is not at all clear what that means to water quality management. We are trying to sort out what science can tell us (fish consumption rates), from maters of science policy (such as choice of uncertainty factors in reference doses), from purely public policy decisions on risk management: What is an acceptable risk? What does it mean to be protective of a use? I see EPA tending to push things up this hierarchy, couching as science things that are not, and making decisions they say, at least in their published *guidance*, are best left to the states and tribes. See slide 6 in the attached presentation I made last week at the Spokane River Forum.

The first question I asked of EPA on the call last Tuesday was: How does EPA define high exposure or a high risk population? The answer Cheryl and I received from Beth Doyle was that EPA used the 99th percentile of the general population, as representing what they figured approximated the median consumption rate for subsistence fishers. This is what is stated in their 2000 Human Health Criteria Methodology *guidance*. While I think there is some legitimate question about their numbers, setting that aside it is interesting to me that they have in essence defined in terms of a upper percentile of the general population. I think this is good and important as we are getting pressure from EPA region 10 to ignore the general population and just focus on acknowledged high rate consumers of fish, particularly tribes. But that begs the question of which tribe, or should it be some other higher risk group, or as in the case of the recent Lummi tribe survey, male boat owning fisherman over 45 years of age, the high of the high of the high. It becomes a moving target if not grounded in the context of the general population.

EPA in their 2012 disapproval of Idaho's 2005 HH criteria update, in which we used their recommended 17.5 grams/day FCR, EPA said we did not consider, as suggested in their *guidance*, local or regional data indicating some people eat more fish than their national recommendation (maybe that's a definition of higher risk?). Anyway, we did look at other data, principally the 1994 CRITFIC study. That study reported pooled results form 4 trines in the Pacific NW and we were unable to get data for just Idaho. So although we did not use the CRITFIC data, we did consider it. In that consideration we also looked at EPA's *guidance* and the range of cancer risk they say is allowable, namely 10^{-6} to 10^{-5} for the general population, so long as the high risk consumers are protected at no less than 10^{-4} incremental increase in cancer.

Now we in Idaho are told by EPA Region 10 that they do not support a general population survey, see no value in it. And furthermore they are asserting that we must protect the high risk population (whatever that is) at 10^{-6} for a 90th, or maybe greater, for that higher risk group. That is a clear departure from published *guidance* and seems to be usurping "**risk management decisions that are, in many cases, better made at the State, Tribal, or regional level."**

At the end of the call last week Beth caught me a bit unbalanced, she asked “Are you going to base your FCR on a general consumption rate?”

My immediate answer was no. I should have proved a more considered and elaborate answer. Her question I think implied are you going to use the 90th percentile FCR from the general population. The answer to that is no, and my mind immediately went there even though it should not have.

My more considered answer, to the question she actually asked (instead of what my mind thought) is this: “No, not directly, or solely, but we will consider the general population data in putting high risk consumption data into context and choosing the FCR that is appropriate for all.”

That may be a 90th percentile from some yet undetermined high risk group, but whatever the rate chosen for basing criteria on it will also correspond to some higher percentile for the general population as well, so in the end we could state it either way. Much like EPA related the 99th percentile of the general population to the median (50th percentile) for subsistence fishers in their 2000 guidance. Only Idaho will be more sure of the relation if we have data on both a general population and some high risk sub group (s). The would seem to be a state choice and a prudent one.

So to recap a bit, I’d still like to know:

How does EPA define high exposure, or is it an undefined moving target?

What does it mean to consider, does consider equate to must use?

Has EPA backed off from the position espoused in their 2000 guidance that **“EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the State, Tribal, or regional level.”**

Has their guidance become more than guidance, what latitude does a state, or tribe, really have?

I have also attached a series of talking points Cheryl and I put together for a call we had with EPA Tuesday of last week.

Don A. Essig
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208-373-0119
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Please consider the environment before printing this email.

cont. call w/ EPA + FD

Call in: 866 299 3188

3/20/13

Niemi, Cheryl (ECY)

Meeting with a

code: 206 - 553 - 1256

Jeff Bigler, National Program Manager
Fish Advisory Program
U.S. Environmental Protection Agency
Office of Science and Technology (4305T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Also

Claudia Fabrano - WQS

Rose Graler WQS

The Beth
Lead EPA Scientist is Elizabeth Doyle, Ph.D., Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U. S. Environmental Protection Agency.

Heidi L. Bethel (bethel.heidi@epa.gov), Health and Ecological Criteria Division (4304T), U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460

Matthew Doyle's Overview

Current

- **AAAS Science and Technology Fellow** at **US EPA**

Past

- AVMA AAAS Congressional Science and Technology Fellow at U.S. House of Representatives
- Public Health Committee Member at Michigan Veterinary Medical Association
- Associate Veterinarian at Roose Animal Hospital

R10
- Lisa Macchio
- Mary Lou Soscia
- Matt Szelag
- Lan Kissinger
- Angela Chung

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
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cheryl.niemi@ecy.wa.gov

How does EPA define "high exposure"

- Both - shoot to protect 95%ile
  - 95-100%ile is usually high per capita
  - 99% per capita = high consumers

per capita includes "0"

99% = ≈ 140 g/day

To do a state survey:

- need to get all of ID population

-

Angela - "Dennis wants EPA to provide tribes & WA guidance on these things"

[redacted]

- "Dennis thinks the ARC outcome was the right outcome"
- Regionally "want to explore that position"

Tribes & Ecology, EPA
April 25

Lisa - March 29 mtg w/ ID
Kurt France
Barry Burnell

General population data and relevance to HHC development:

- General population and high-consumer population data (and the frequency distribution that represents these combined data) are both relevant to the HH criteria development process, and use of either or both are part of the EPA 2000 guidance.

- If the low end of the fish consumption distribution is poorly characterized, due to a focus solely on high end consumers, it is likely the distribution will be skewed high. This will bias high not only the value of a high end FCR, it will mean the percentile associated with it is biased low.

- Idaho has a risk level for the general population of 10^{-6}. This means that for carcinogens the FCR could be a general population value, such as EPA's national recommended 17.5 or a local general population value, and still likely confer adequate protection within EPA's acceptable risk range of 10^{-6} to no-more-than 10^{-4} for the most highly exposed populations (e.g., 17.5 at 10^{-6} = 1,750 at 10^{-4}).

- The national general population recommended value of 17.5 (for which EPA included non-consumers) was disapproved by EPA for ID use. This implies that EPA needs generation of local data in order to find a general population value that is approvable for carcinogens in Idaho. In other words, since Idaho applies their risk level to the general population it logically follows that local general population data are what are needed by EPA. So in this case EPA funding to address their Idaho disapproval seems altogether reasonable. If this was not the basis of the ID disapproval then what, specifically, was?

- Washington has not made a final science- policy decision about whether the national data set can be used to create a general population frequency distribution for Washington state, or whether new data will be needed. Ecology wants a frequency distribution that can represent the full range of consumption in Washington so we can ensure that risk management decisions are based on data representative of all Washington consumers. Washington's risk level applies to the general population, as applied in EPA's NTR. If Washington made the state risk management decision to apply the national recommended FCR of 17.5 to carcinogens, would these standards be disapproved by EPA because they were not based on local data? The answer to this question is relevant to future consideration by Ecology on FCRs and use of the national recommendations.

- General population data (if collected appropriately) could be used with the information from studies of populations with higher FC rates to better describe how all people in Idaho or Washington are protected to levels chosen by the states in their risk management processes. There could be non-surveyed people in Washington or Idaho

that consume as much or more than are shown in current FCR studies, which would affect the overall frequency distribution of consumption rates. If a state chooses to pair a specific distribution metric with a specific risk level, having a complete and representative distribution of consumers seems very relevant.

Questions to clarify EPA thoughts on risk:

Does EPA agree that WA risk level applies to the general population? - Angela: EPA can't answer that now.

If not - why?

Would EPA disapprove a standard based on 10^{-6} for general population as long as 10^{-4} is max for highly exposed? Angela: EPA can't answer that now

If not - why?

OGC opinion or guidance?

ID - disapproval Questions

"sound scientific rationale"?

"Consideration" vs "use of"?

Does epa mean "use" when they say "consider"? Angela: EPA can't answer that now

What does EPA think of the OR approach?

Angela: "Dennis thinks this is the right approach."

AQ - I told them we disagree w/ some of it - explained our scope concern - double counting imported shellfish in the RSC

From: Susewind, Kelly (ECY) [mailto:KSUS461@ECY.WA.GOV]
Sent: Tuesday, March 11, 2014 1:41 PM
To: Opalski, Dan
Cc: Bellon, Maia (ECY)
Subject: Listing and EJ Discussion

Hey Dan

Did a little looking on my own following today's discussion.

Listing:

The 2012 Oregon assessment states that:

- New and revised human health criteria apply to pollutants in the water column except for methyl mercury…..
- Category 5 listings require two or more samples not meeting the most stringent applicable criterion of a specific substance in the water, or
- A fish consumption advisory issued for a specific water body based on pollutants in fish tissue

We acknowledged that Oregon lists based on fish advisories, but that is far different than saying they do listing based on tissue. A quick perusal of Oregon's fish advisories only shows a few advisories generally based on mercury and PCBs.

We've also been contacted by DEQ staff regarding our listing policy because they are getting pressure to list based on tissue "like Washington."

Is there more information that I am missing?

EJ

I have a copy of the document: "EPA Policy on Environmental Justice for Tribes and Indigenous Peoples." It's a pre-decisional working draft dated November 14,2012.

Is that the document Dennis referred to?

The only real pertinent language I could find in that document was:

4. THE EPA ASSESSES THE POTENTIAL FOR DISPROPORTIONATELY HIGH AND ADVERSE HUMAN HEALTH OR ENVIRONMENTAL EFFECTS ON TRIBES OR INDIGENOUS COMMUNITIES.
a. The EPA considers both quantitative and qualitative information about the potential disproportionately high and adverse human health or environmental effects pertaining to, and/or provided by, tribes or indigenous stakeholders.
b. The EPA works to understand Traditional Ecological Knowledge and its role in protecting public health and the environment, and to understand community definitions of health and the environment.

As we discussed, tribal members, and anyone eating high amounts of fish, are at higher risk. They are at a risk exactly proportionate to the consumption rate and will be at the same ratio (proportion) regardless of where the rule lands. Interpreting this section of the policy to mean that they can't be at a higher risk would frustrate the entire system the HHC equations are based on and make it impossible to comply.

Is there a statement somewhere that one in a million risk rate is the baseline to establish environmental justice? Or that a higher risk rate is inherent in the approach, but establishes some criteria to define "disproportionately high and adverse effects?

I’m not trying to be argumentative, but we are getting to the end of a very contentious process, and I really need to understand these concepts in order to advise decision makers.

Thanks

Kelly

From: Fran Wilshusen [mailto:fwilshus@nwifc.org]
Sent: Tuesday, March 18, 2014 12:56 PM
To: van der Lugt, Lisa (GOV)
Cc: Brian Cladoosby; Leonard Forsman; Allen, Ron; Debra Lekanoff; Austin, JT (GOV); Bellon, Maia (ECY)
Subject: Follow-up from Friday Mar 14 Tribal FCR Mtg. with Gov. Inslee

Honorable Governor Inslee:
Thank you for meeting with us and continuing discussions on the issue of establishing revised human health criteria, including a revised fish consumption rate, as part of state water quality standards.
Following up on your request from our meeting last Friday, please find attached a copy of the white paper being developed by tribal technical staff, on compliance tools and implementation. This paper was originally drafted to be submitted to Ecology to support integration of tribal perspectives. Also attached are the tribal comments that were developed regarding the development of human health criteria. The tribal message continues to be clear, well documented and progressive. As we discussed on Friday, this issue is important to tribes and the *175 g/d fcr combined with the 10 -6 risk level represents real compromise and a meaningful step forward in protecting the health of Washington citizens.*
On Friday, we heard you questioning and considering the concept of increasing the cancer risk rate. To be clear, from a tribal perspective, adjusting the cancer risk rate and increasing exposure to known carcinogens is an unacceptable way to address discharger compliance concerns. Tribal people, and other high end fish consumers, will bear a disproportionate burden of that exposure. Flexibility should be created through compliance pathways, not by eroding the standard.
We appreciate your interest and attention on this difficult issue and are available to you for any questions or further discussion necessary as you move forward.

Thank you.

Chairman Ron Allen, Jamestown S'Klallam Tribe
Chairman Brian Cladoosby, Swinomish Tribe
Chairman Leonard Forsman, Suquamish

Northwest Indian Fisheries Commission

6730 Martin Way E., Olympia, Washington 98516-5540
Phone (360) 438-1180 www.nwifc.org FAX # 753-8659

January 31, 2014

Maia Bellon, Director
Washington Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: Follow-up from December Leadership Meeting on Water Quality Standards

Dear Director Bellon:

On behalf of the member tribes of the Northwest Indian Fisheries Commission, I would like to thank you and your staff for meeting with tribal leaders on December 12, 2013 to discuss the status of water quality standards in Washington State. The tribes recognize that this has been a very difficult issue for the state. However, the tribes remain steadfast in their request for revised standards that will protect the health of tribal people from exposure to toxic substances in Washington.

The purpose of this letter is to request an updated timeline for the completion of rule-making on the human health criteria (HHC), and to convey some initial comments on the preliminary options for the HHC. At the December meeting, tribes again asked for the timely completion of revised human health criteria in Washington State's standards that will utilize a new fish consumption rate, without lowering the protective level of other existing variables such as the cancer risk rate. As in previous meetings, tribes also asked for standards that are at least as protective as those approved in Oregon with a fish consumption rate of at least 175 grams per day and maintaining a cancer risk rate of 10^{-6}. Many tribes also stated that the Oregon standards represent a substantial compromise, since tribal studies indicate higher levels of modern and historical consumption. The rule options put forth by the Department of Ecology in November, 2013 include several options that fail to achieve the protective levels of even the Oregon standards in the HHC. The NWIFC staff has prepared a consolidated set of preliminary comments on the options, based on input from NWIFC member tribes, and have attached these for your review and consideration as you move toward preparation of rule language. The tribes also plan to continue discussions with the Department of Ecology and others on proposed implementation options.

During the last two meetings of the Leadership Oversight Group with EPA and tribal leaders, you indicated verbally that a draft rule for the revised water quality standards will be completed this winter, and a final rule will be adopted in 2014. Given that the tribes have

experienced numerous delays during the course of this work, they have asked for greater clarity as to the precise timelines for rule development and promulgation, with dates instead of seasonal time frames. The tribes also requested in December that the Department of Ecology reaffirm previous commitments, by indicating a specific timeline that incorporates no further delay.

The tribes look forward to establishing revised human health criteria, so that we may better focus on the important work of toxic reduction in Washington through all available pathways. Once again, the NWIFC thanks you for meeting with tribal leaders in December, and we look forward to continuing to work with you.

Sincerely,

Michael Grayum
Executive Director

Enclosure: Response to Preliminary Options on the Human Health Criteria by NWIFC staff

Cc: Tribal Chairs and NWIFC Commissioners
Dennis McLerran, Regional Administrator; EPA Region 10
Dan Opalski, Director - Office of Water & Watersheds; EPA Region 10
Jim Woods, Senior Tribal Policy Advisor; EPA Region 10
JT Austin, Governor's Policy Advisor for Natural Resources
Phil Rigdon, Deputy Director; Department of Natural Resources; Yakama Nation
Columbia River Intertribal Fisheries Commission

Response to Preliminary Options on the Human Health Criteria
(as presented by the Washington Department of Ecology on November 6, 2013)

Compiled by: Northwest Indian Fisheries Commission staff
January 31, 2014

A. Introduction and Summary

Washington Department of Ecology (Ecology) outlined preliminary options for rule-making for state water quality standards at a public workshop on November 6, 2013. Recognizing that these are preliminary options, and are not yet embedded into state rule-making language, staff from the Northwest Indian Fisheries Commission (NWIFC) met with staff from member tribes in November and December of 2013 to obtain initial tribal input and develop a summary of responses. These do not constitute final comments on rules and may not be representative of the perspectives of individual tribes, but are submitted to the Department of Ecology as input prior to the development of rule language.

In general, tribes agree that Ecology must update state water quality standards to incorporate human health criteria at a protective level that is much higher than what currently exists. Tribes concur that Washington State has enough data to set a fish consumption rate at this time. The tribes also concur that Washington State must use fish consumption rates reflective of tribal consumption; however, the tribes disagree that the selection of "mean" consumption levels for tribes is an adequate standard of protection. Tribes have previously indicated that the fish consumption rate of 175 grams per day adopted by Oregon and approved by EPA, using a fish consumption level at the 90th to 95th percentile of Columbia River tribal studies, is a compromise from historical levels of consumption and is lower than documented consumption by Puget Sound tribes within the last 20 years. Tribes previously indicated that the Oregon standard of 175 gpd was low, but recognized that it would significantly reduce the potential for toxic chemicals to enter state water bodies through discharges, with the assumption that the state would not relax other parameters in the risk equation.

Unfortunately, the Department of Ecology is considering an option of using 10^{-5} as the cancer risk level, and a relative source contribution of 1.0, both of which options are unacceptable to the tribes. The potential improvement in protective standards through a fish consumption rate at or above 175 gpd would be diminished by a higher risk of cancer or by failing to account for human exposure to toxins from other pathways.

The tribes support the preliminary determination by Ecology to include salmon in the fish consumption equation at 100%, i.e., using all species and all sources. The tribes continue

to evaluate the "challenging chemicals" highlighted by the Department of Ecology in their presentations, and how the state may address these through compliance tools. Comments on compliance tools, at Ecology's present stage of development of options, will be forthcoming.

B. Use of Tribal Fish Consumption Levels as a Basis for Rate-Setting

Tribes agree that the Department of Ecology must use tribal fish consumption as a basis for reasonable maximum exposure and the FCR parameter in the human health criteria. At the November workshop this decision was characterized as a "big deal" and a policy choice, because it is substantially different from existing standards, which followed a national default rule set in the early 1990's. Tribes do not believe that the Department of Ecology has any other supportable alternative than to use tribal FCR findings, since these are scientifically derived and regionally relevant. Additionally, the guidance of the National Environmental Justice Advisory Committee requires full consideration of the impact of environmental standards, and incorporation of protections, for culturally and racially distinct groups of people. Although some industrial and legislative representatives have called for a study of the fish consumption of the general population in Washington, such information would not be relevant given that Washington has appropriate and technically suitable data on tribal consumption, unless there is evidence that the general population fish consumption is higher.

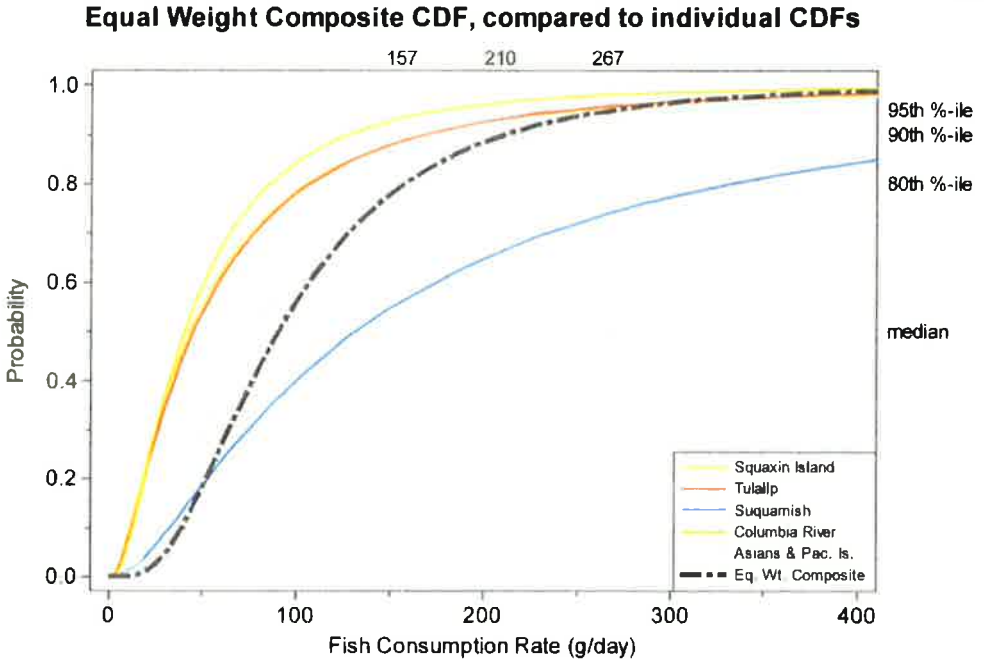
C. Fish Consumption Rate Options

The Department of Ecology presented three options for revising the FCR from the current level of 6.5 grams per day: 125, 175, and 225 grams per day. Tribes question the rationale for the selection of these options based on policy choices made by the Department of Ecology Water Quality Program. In some cases, the mean value is used, leaving a large portion of the tribal population unprotected from exposure to toxic chemicals in fish. Several tribes have commented previously that a fish consumption rate that is lower than the standard adopted by Oregon of 175 g/per day is unacceptable; tribes also note that this rate may not sufficiently protect tribes in light of suppression and other factors affecting consumption.

1. **The rationale for policy choices by the Water Quality Program in the selection of options are unclear and inadequate:** The Technical Support Document on Fish Consumption Rates, Verson 1.0 prepared by the Department of Ecology Toxics Cleanup Program and published in October 2011, used a composite analysis of regional studies of fish consumption by tribes and groups of Asian and Pacific Islander communities to recommend a FCR default range of 157-267 grams per day. (Figure 1) This was based on a logical and transparent analysis, selecting a range encompassing the 80th

to 95th percentiles of most regional studies. The University of Washington School of Public Health commented that the Technical Support Document V 1.0 "represent[ed] a robust, scientific-based assessment that is clear and transparent." The Department of Ecology's presentation on November 6, 2013 explained where the numbers came from that were used for the three proposed FCR options, but not why they were selected. Ecology will need to include a transparent rationale to express their reasoning for the selection of the final FCR option in rule language in the water quality standards, particularly if an option is selected that is less than the range recommended by the Department's own Toxic Cleanup Program in the earlier Technical Support Document.

Figure 1: Composite analysis for Pacific Northwest fish dietary surveys for tribes and Asian and Pacific Islander Communities. (From WA Department of Ecology Technical support Document, version 1.0; October 2011). A FCR range of 157 to 267 grams per day was recommended, based on the composite 80th to 95th percentile.



2. **Use of mean values for the Fish Consumption Rate is unacceptably low:** At the November 6, 2013 workshop, the Department of Ecology staff indicated that the Department is considering an option of 125 grams per day for the fish consumption rate, and that this value was based on the approximate average of averages from three

tribal dietary studies in Puget Sound.[1] Public health standards are not intended to protect only the average person; instead they are intended to set a level that reduces risk for a high percentage of the exposed population—especially where children and women of reproductive age are affected. For example, toxic cleanup programs utilize a reasonable maximum exposure at the 90th percentile. Ecology has made a preliminary determination that the standards should be based on the exposure of tribal populations, but it is unacceptable to tribes that the state would select a fish consumption rate at only an average level of tribal consumption. Tribes want to see the risk of ingesting toxics via fish consumption driven to zero or near zero. Oregon tribes advocated for an FCR at the 99th percentile of Columbia River studies in the Oregon water quality standards, but the state of Oregon ultimately decided to set a rate in the 90th - 95th percentile. The average of FCR values in Washington tribal studies at the 90th to 95th percentile would range from 254 to 385 grams per day, based on consumption surveys of Columbia River and Puget Sound tribes. For Puget Sound tribes only, the 90-95th percentile range would be 296 to 448 gpd.

3. **Additional comment on the compromise FCR in Oregon standards.** In the public workshop on November 6th, the Department of Ecology expressed no indication that the state of Washington supports consistency with the FCR option at the Oregon standard, even though the FCR of 175 gpd was based largely on studies of Columbia River tribes located in Washington. Since the state of Washington sees little need for regulatory consistency between the states, earlier comments from tribes that the Oregon standard could be an acceptable compromise, depending on other aspects of rule-making, may no longer be relevant. Some Washington tribes have informed the NWIFC that they cannot support any option that is less than the 175 grams per day FCR adopted in Oregon, and are likely to advocate for a higher rate than Oregon's to protect their citizens given the higher levels of fish consumption here. The studies of tribal consumption used for the Oregon standards are now 20 years old and occurred at a time when fish consumption was more suppressed due to habitat loss, lack of access to fishing grounds, and contamination of fish species. Tribes will want to reserve the ability to consume fish at unsuppressed levels in the future. Tribes also note that historical levels of fish consumption have been documented to be much higher—in excess of 800 grams per day at treaty times. Some tribes are using historical levels to set tribal standards, and expect the state to follow suit for downstream dischargers.

[1] See Table 33 from the Fish Consumption Rate Technical Support Document Version 2.0 for the referenced data. The average of the mean values for the Tulalip, Squaxin Island and Suquamish Tribes is 126.66 g/day.

4. **The "mean" option of 125 grams per day is inadequate to protect Puget Sound tribes.** As noted above, tribes consider the option of 125 grams per day, to be inadequate as it is based on mean values for three Puget Sound tribal studies. The combined mean (the average of the average consumption for the three Puget Sound tribes) is even lower than the median consumption rate for one of the tribes—thus the FCR would not cover consumption exhibited by over half of the tribe. Moreover, some studies indicate that tribal children have a fish consumption rate nearly three times that of adults, relative to body weight.[2] An inadequate fish consumption rate puts the health of tribal children at particular risk.

D. Cancer Risk Rate

The Department of Ecology indicated that they are considering a cancer risk rate of one-per-million (10^{-6}) or one-per-100,000 (10^{-5}) in the human health criteria. The Department currently uses a standard of 10^{-6} for the calculation of allowable limits for priority pollutants. The option of using 10^{-5} in the HHC would therefore raise the risk of cancer by ten-fold for all Washington fish consumers and is unacceptable to tribes. Tribes will suffer disproportionately from an increase in the risk rate, and the option would largely negate any protective benefit that tribes and other high fish consumers would receive from a higher FCR, if adopted and implemented. Further, the 10^{-5} option fails to consider risks to high consumers from persistent bioaccumulative toxics or exposure based on combinations of toxic chemicals (additive toxicity). Ecology has rejected a cancer risk rate of 10^{-5} in the past and should continue to do so, whether or not other states choose lesser levels of protection. The Environmental Protection Agency has not stated that a 10^{-5} risk level would be approvable given the circumstances in Washington, and the applicability of risk to tribes with treaty-reserved fishing rights.

1. **Any increased risk of cancer is a harm.** The Clean Water Act and other health-based environmental standards that govern the sources or clean-up of pollution generally express goals to reduce the risk of exposure to harmful byproducts to zero. EPA has consistently used a level of 1 per million in national standards and criteria in an effort to drive pollutant sources close to the zero goal. Many tribal leaders view <u>any</u> risk of cancer through pollution as unacceptable; a ten-fold increase in existing rates is a major step in the wrong direction.

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[2] U.S. Environmental Protection Agency (EPA). (2013) Reanalysis of fish and shellfish consumption data for the Tulalip and Squaxin Island Tribes of the Puget Sound Region: Consumption Rates for Consumers Only. National Center for Environmental Assessment, Washington, DC; EPA/600/R-06/080F.
The mean fish consumption rate for Squaxin Island Tribe adults was 1.02 g/kg-day. The mean consumption rate for children less than 6 years of age was almost three times higher at 2.89 g/kg-day.

2. **Tribes will suffer disproportionately from a ten-fold increase in the cancer risk level in Washington.** Arguments for a less protective risk level are based on a premise that everyone is equally likely to bear the higher risk of cancer. However, in Washington State the increase in risk will disproportionately affect tribes as the highest consumers and most exposed. The Department of Ecology has presented data indicating that tribes are the highest consumers of fish, and therefore is knowingly considering action that would shift a greater risk to tribal people, raising questions about ethics and environmental justice.

   Furthermore, harvesting and consuming fish is a lifeway and a right for tribal people; it is not a choice or a voluntarily assumed risk. Business has characterized the risk of getting cancer from eating fish as just one of many health risks, like cigarette smoking or getting an x-ray. In recent presentations, the Department of Ecology offered statistics, purportedly as context for the risk discussion, that the average American male has a 1 in 2 risk of cancer in his lifetime (1 in 3 for females). This discussion fuels misunderstanding by minimizing the perception of harm directed toward tribal people, especially children, from contamination that they have not caused and cannot control.

3. **The combination of a higher risk of cancer with a higher fish consumption rate negates much of the protective value of raising the FCR to a level that reflects tribal fish consumption.**
   The Department of Ecology is considering an option of a FCR of 175 grams per day, or even less, in combination with an option to raise the cancer risk rate to 10^{-5}. We note that 175 grams per day at a cancer risk rate of 10^{-5} is functionally the equivalent of a FCR of 17.5 grams per day at a risk of 10^{-6}, and that this rate has already been rejected by EPA in Oregon and Idaho. If the Department of Ecology adopts the option of a FCR at 125 grams per day and a risk rate of 10^{-5}, the level of protection would only improve to a level of 12.5 grams per day at the existing risk rate.

   In the November 6, 2013 workshop, the Department of Ecology offered a graph comparing the FCR and risk rate alternatives to a hypothetical chemical discharge at existing standards (Figure 2), purportedly to illustrate the drastic reduction in chemical concentrations that will be required of dischargers under any of the proposed options. Instead of illustrating the burden to dischargers from revised standards, the graph should be interpreted to show that existing pollutant concentrations need to be reduced. The existing standards are based on a grossly under-valued estimate of fish consumption and need to be raised to come to a realistic and protective level based on actual fish consumption and existing risk.

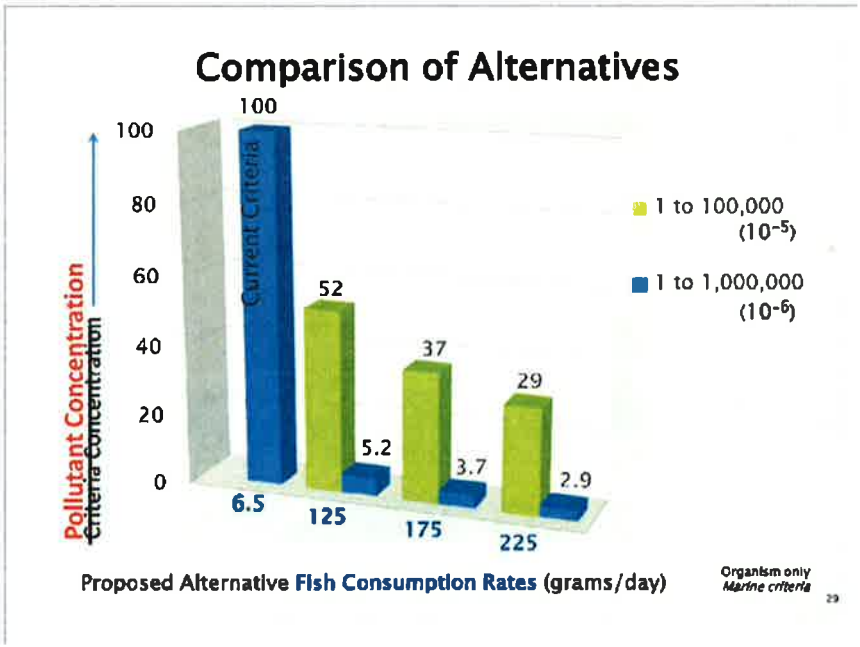

Figure 2: Comparison of FCR and risk rate alternatives to existing allowable pollutant concentration levels.

Tribes have already suffered harm from an inadequate fish consumption rate for years, and changing the risk rate to a less protective level in combination with a higher FCR will largely negate any value from potential remediation of the fish consumption criterion.

4. **Washington State should not reduce the level of protection for its people by making a comparison with the less stringent standards in other states, or assume that such reduction is approvable by EPA.**

The fact that some other states have chosen lesser protection does not answer the question whether Washington should decline to protect its people. Ecology has cited the fact that several other states have selected a less protective risk level, and used this as the basis for a preliminary option for a risk level at 1 in 100,000 (10^{-5}). However, to say that other states have selected this risk level says nothing about why they have done so, or whether it is legally, technically, or ethically appropriate to follow suit. Washington has a disproportionately high level of shorelines, streams and lakes in comparison with many other states, and is renowned for abundant and varied fish and shellfish resources. These resources, and the people who consume them, coexist with industrial users who legally discharge pollutants into Washington water bodies--thus Washington's industrial environment also varies from many other states. As noted above, a less protective cancer risk rate will disproportionately and involuntarily harm tribes and other high consumers of fish. Additionally the state has a legal obligation

to honor the treaty reserved rights held by Washington tribes, and comply with the implementation of trust responsibilities overseen by the Federal Government. These circumstances add to the legal and ethical questions that are relevant to Washington's selection of human health criteria, in contrast with those of other states, and must be considered by EPA in the exercise of their Federal Government trust responsibilities.

EPA has not stated that an increased risk level is approvable for the circumstances present in Washington. EPA has stated that it would need to consider the rigor and representativeness of the process by which a state arrived at its risk level—particularly where the risk level selected was less protective than 1 per million. Additionally the EPA has expressed concern for actual risk to affected individuals, based on a comprehensive look at parameters and circumstances. EPA guidance with respect to "sub-populations" or to diverse and unrelated subsistence fishers, cannot be equated with the risk to treaty fishing tribes and their members in Washington. Further review of the process underway in Washington will show that tribes have consistently opposed a less protective fish consumption rate and higher risk of cancer for years. Tribal members live the circumstances that contribute to compounded risks since they eat large quantities of fish, harvested from usual and accustomed fishing areas affected by Washington standards, and they consume fish from their earliest childhood through old age.

5. **The Department of Ecology has previously gone on record in support of a risk level of 10^{-6}, and should continue to support this level, particularly in light of the potential for Washington people to consume fish with bio-accumulative toxics and the potential for interaction of multiple contaminants.**
   EPA promulgated a rule for 14 states, including Washington, in 1992 to establish numeric criteria for priority toxic pollutants necessary to bring states into compliance with provisions of the Clean Water Act. In the official comments on the proposed rule, the Washington Department of Ecology urged EPA to promulgate human health criteria at 10^{-6}:

   > *"The State of Washington supports adoption of a risk level of one in one million for carcinogens. If EPA decides to promulgate a risk level below one in one million, the rule should specifically address the issue of multiple contaminants so as to better control overall site risks."*[3]

[3] 57 FR 60848 (Full description at *Federal Register*, Volume: 57, Issue: 246, Page: 60848 (Tuesday, December 22, 1992) Page 60868 contains comments by WA Department of Ecology.

The Department of Ecology should apply these comments to their own proposed rule options, specifically by rejecting the option of establishing a general risk rate of 10^{-5}. Currently there are no provisions to address the issue of multiple contaminants in Washington's existing or new rules.

During the 1992 EPA rule-making, EPA also indicated that it was appropriate to adopt a more stringent risk level (one-per-million) for those carcinogens with substantially higher bio-concentration factors. Recognizing that carcinogens that bioaccumulate are of particular concern for exposure by fishermen, EPA further stated that a more protective risk level of 10^{-6} would be appropriate for fish consumers. (ibid.)

The proposed reduction of the protective level of the cancer risk rate to 10^{-5} is inconsistent with Ecology's previous positions expressed to EPA, fails to adequately address the cancer risk from bioaccumulative toxics, and fails to account for the interactions of multiple toxic chemicals. The 10^{-5} option for a risk rate places tribes at a disproportionately higher level of risk, and negates the potential benefit of remediation to the standards that would have accrued through the adoption of a higher fish consumption rate. The option of a ten-fold increase in the risk of cancer for Washington citizens should be rejected.

E. Other Comments Related to the Proposed Options for Human Health Criteria

1. **The Tribes concur with Ecology's tentative decision to include salmon at 100% in the fish consumption rate.** This was an inevitable conclusion in the face of: the high levels of consumption of salmon by tribes and the general population in Washington; fish tissue sampling showing the presence of persistent bioaccumulative toxics in salmon in freshwater and estuarine water bodies at various life stages; and documentation that tribal consumers primarily eat salmon and other seafood that are derived from and harvested in local water bodies. Previous comments from industrial representatives on the Technical Support Document V1.0 relating to salmon attempted to discount salmon on the basis that the "oceanic" portion of their life cycle was outside of Washington's jurisdiction. However, some species of Puget Sound salmon remain resident within the marine waters of Puget Sound, and exhibit higher levels of PCBs than their counterparts in British Columbia or the Columbia River, indicating that substantial uptake of toxic chemicals occur in the estuarine portion of Washington's waters and are influenced by Washington regulatory standards. Tribal salmon harvest is comprised primarily of salmon that are natal to Washington rivers and streams, and the tribes concur with the preliminary conclusion to include all species of salmon and all geographic areas.

2. **Tribes do not concur with Ecology's decision to disregard EPA direction to consider multiple pathways of exposure to toxic chemicals. Ecology's preliminary choice of 1.0 as the relative source contribution (RSC) provides an inadequate level of protection to fish consumers.** Fish consumption is only one of the pathways by which humans absorb toxic chemicals. The EPA has issued guidance calling for states to attribute 20-80% of exposure to toxic chemicals to water-borne sources, and the rest from other sources including air and other foods. The tribes reiterate previous comments relative to carcinogenic risk--that tribes are highly exposed to toxic chemicals in fish, and will suffer disproportionately from the body burden resulting from other chemical loads as part of a human body burden. Tribes have indicated that Ecology should follow EPA guidance on this issue.

3. **The tribes recognize that pervasive chemicals are a substantial concern in Washington, and that dischargers will have difficulty meeting new standards right away for substances including PCBs, arsenic, and mercury.** Tribes are continuing to evaluate the options presented by Ecology for regulatory solutions to these chemicals of concern to facilitate the transition to new standards for dischargers. However, the tribes point out that variances, extended schedules, or other potential compliance tools must be limited, or Washington will not achieve long term goals for water quality—instead engaging in an endless and expensive cycle of pollution discharge, site and species contamination, issuance of health advisories, and site cleanup. Tribes are seeking to attain the highest water quality possible as soon as possible for the protection of tribal health. Tribes also point out that Ecology has stated that pervasive chemicals, such as PCBs, are a state-wide problem, and that some of the chemicals, such as mercury, come from air deposition. These assertions appear to contrast with Ecology's decision to use a relative source contribution of 1.0, since that option assumes 100% of toxic contaminants in the human health criteria come from consuming fish from impaired waters.

In conclusion, tribes concur with Ecology's preliminary decisions on the human health criteria to base fish consumption rates on tribal levels of consumption and to include salmon at 100%. Tribes strongly disagree with Ecology's proposal to increase the risk of cancer by ten-fold, and the use of average values in setting the fish consumption rate. Tribal populations depend on fish consumption for sustenance and livelihood and are disproportionately at risk from toxic chemicals in fish. The tribes retain treaty-reserved rights to harvest, and assume that these fish and shellfish will be healthy to eat throughout a tribal member's life span.

NWIFC and individual tribal staff will continuing to work with Ecology staff to evaluate the options presented for compliance tools. Thank you for your attention to the tribes' concerns on the preliminary options for the human health criteria.

State of Oregon Department of Environmental Quality

Human Health Criteria Issue Paper

Toxics Rulemaking

Prepared by: Andrea Matzke, Debra Sturdevant, and Jennifer Wigal

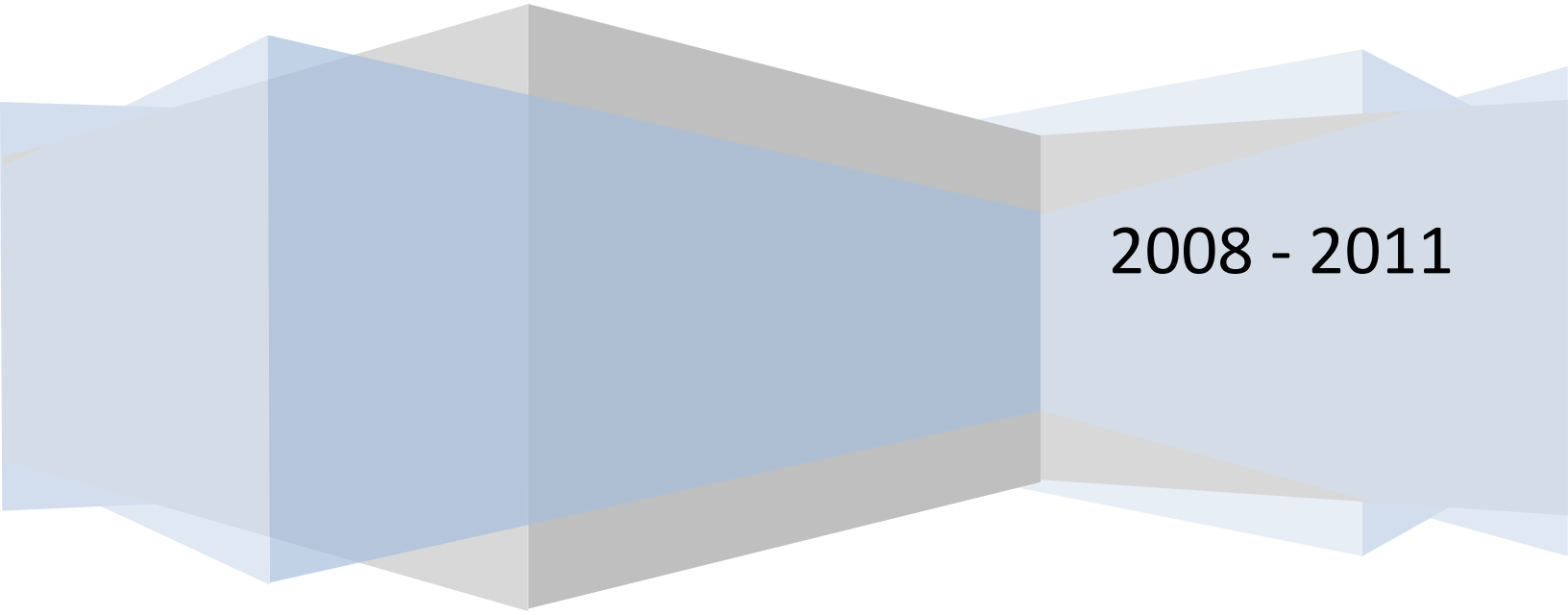

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Table of Contents

Human Health Criteria Issue Paper

Toxics Rulemaking

A. Introduction

Purpose of this issue paper

DEQ's currently effective human health toxics criteria are based on a fish consumption rate (FCR) that does not adequately protect Oregonians based on the amount of fish and shellfish they are known to consume. On June 1, 2010, EPA disapproved Oregon's human health toxics criteria that were submitted for approval in 2004 and were based on a fish consumption rate of 17.5 grams per day (g/d). EPA disapproved the human health toxics criteria because the fish consumption rate used to calculate the criteria does not protect Oregonians based on the amount of fish and shellfish they are known to consume. DEQ is addressing EPA's disapproval by proposing to use a higher, more protective fish consumption rate of 175 g/d in its calculation of revised human health toxics criteria. If DEQ does not promulgate revised standards in a timely manner addressing EPA's disapproval, EPA must conduct rulemaking to promulgate human health toxics criteria for Oregon.

This issue paper includes information relevant to DEQ's development of proposed human health toxics criteria based on a higher fish consumption rate. It also describes the human health toxics criteria methodology used to calculate criteria. Proposed changes will affect the criteria values contained in Tables 20, 33A, and 33B, as well as the narrative toxics provision in OAR 340-041-0033 (Toxic Substances).

B. Background

B.1. Brief History of EPA's Recommended Human Health Toxics Criteria

The Clean Water Act requires EPA to publish recommended water quality criteria based upon the most recent science. States typically use these values in developing their own water quality standards regulations. In 1986, EPA published a compilation of these values in the Quality Criteria for Water 1986[1], also known as the "Gold Book." In 1992, EPA promulgated water quality criteria for toxic pollutants for 14 States. These updated criteria became known as the National Toxics Rule[2] and differed substantially from the EPA Gold Book. In 1995, EPA applied the methodology and data used in the Great Lakes Water Quality Initiative[3] to derive new national aquatic life criteria for 15 toxic pollutants in freshwater. In 1999, EPA published the next major update of water quality criteria[4]. In 2000, EPA promulgated water

[1] EPA. Quality Criteria for Water, 1986 (Gold Book). EPA 440/5-86-001

[2] EPA. Federal Register, Volume: 57, Issue: 246, Page: 60848 (57 FR 60848), Tuesday, December 22, 1992.

[3] EPA. Federal Register, Volume: 60, Number 56, Page: 15365, March 23, 1995.

[4] EPA. National Recommended Water Quality Criteria—Correction. EPA 822-Z-99-001.

quality criteria for toxic pollutants for California known as the California Toxics Rule[5] and also in that same year published a revised methodology[6] for deriving human health criteria. EPA did not publish a summary criteria table to accompany the revised methodology. Since 2000, EPA has updated the human health criteria for some individual compounds as well (e.g. cadmium). In late 2002, EPA published another major update[7] of criteria values using the EPA revised human health methodology, which included more extensive criteria revisions for 15 other toxic pollutants.

B.2. Oregon 2004 Submission of Water Quality Standards

In 1999, DEQ initiated a Water Quality Standards Review (triennial review) to update DEQ toxics criteria based on the 1986 EPA Gold Book (contained in Table 20 of Oregon's water quality standards). This review was completed in 2003. During this review, DEQ made significant revisions to both the aquatic life and human health criteria based on the updated EPA methodologies and science for deriving aquatic life and human health criteria (as described above) that had occurred since the Gold Book had been published. DEQ's criteria that it adopted in 2004 reflected an increase in the fish consumption rate from 6.5 g/d to 17.5 g/d, based on the rate used EPA's national criteria recommendations. However, despite being based on this higher fish consumption rate, some of the 2004 criteria were actually less stringent than Oregon's previous criteria due to updated scientific information affecting other factors that go into calculating human health criteria. To be consistent with the federal requirements, DEQ specified that the criteria that were less stringent than the older Table 20 criteria were not effective for Clean Water Act purposes until after EPA approval.

The Environmental Quality Commission (commission) adopted these new and revised water quality standards on May 20, 2004. Upon adoption, DEQ submitted these criteria changes along with revisions to the narrative toxics provision to EPA on July 8, 2004.

EPA did not act on these revised water quality standards, and a lawsuit was filed on April 7, 2006 noting EPA's failure to act on Oregon's revised human health water quality criteria among other revisions. On May 29, 2008, a U.S. District Court in the District of Oregon issued a consent decree setting forth deadlines by which EPA must take action on Oregon's 2004 water quality standards submission, under Section 303(c) of the CWA (*Northwest Environmental Advocates v. U.S. EPA,* No. 06-479-HA (D. Or. 2006)). The court subsequently issued several extensions of the applicable deadlines for action. The consent decree's applicable deadline for EPA action on the human health criteria was ultimately extended to June 1, 2010.

[5] EPA. Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California. Federal Register, Volume: 65, Number 97, Page: 31682, May 18, 2000.
[6] EPA. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). EPA-822-B-00-004, October 2000.
[7] EPA. Revision of National Recommended Water Quality Criteria. Federal Register, Volume: 67, Number 249, Page 79091-79095, December 27, 2002.

B.3. EPA Action on Oregon's 2004 Submission of Human Health Toxics Criteria

B.3.1. Disapproved Human Health Criteria

On June 1, 2010, EPA concluded that human health criteria based on a fish consumption rate of 17.5 g/d were not protective of Oregon's designated use of fishing, and thus, did not protect Oregonians who consume higher levels of fish. Consequently, EPA disapproved the majority of the human health criteria that were based on 17.5 g/d (i.e. 48 non-carcinogens and 55 carcinogens). Accompanying footnotes to the disapproved criteria were subsequently disapproved as well. For specific details on EPA's actions, refer to EPA's Technical Support Document[8] accompanying its action.

Oregon's water quality standards included a provision specifying that if a value in Table 33A was disapproved by EPA, the corresponding value in Table 20 would become effective immediately. Values that were the same in Tables 20 and 33A would remain in effect. Consequently, as a result of EPA's disapproval, DEQ's human health toxics criteria reverted back to Table 20 values which are largely based on a fish consumption rate of 6.5 g/d. The few exceptions where EPA did approve criteria from DEQ's 2004 adoption are noted below in the "Approved Human Health Criteria" section.

Under CWA Section 303(c)(3) and EPA's regulations at 40 CFR Parts 131.21 and 131.22, if EPA disapproves a state's new or revised water quality standards, it must "specify the changes" necessary to meet the applicable requirements of the Act and EPA's regulations. If the state does not adopt necessary changes, EPA must propose and promulgate appropriate changes. In the EPA letter[9] disapproving DEQ's 2004 submission, EPA indicated that revising the human health toxics criteria based on a higher fish consumption rate of 175 g/d will address the EPA's disapproval. This rate represents the value that DEQ recommended to the commissioners at the October 23, 2008 Environmental Quality Commission meeting and that they subsequently directed DEQ to use in its revisions. For more information on DEQ's recommended fish consumption rate, see section C.

B.3.2. Approved Human Health Criteria

The human health criteria identified in this section that EPA approved on June 1, 2010, will be included in the new Table 40 along with the proposed human health criteria.

1. **Human health criteria for copper and asbestos**

   Copper

   The "water + organism" criterion of 1300 ug/L is consistent with EPA's 304(a) recommendation and was therefore approved by EPA. Since human health risks from copper are primarily from

[8] EPA. Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions Submitted on July 8, 2004. June 1, 2010.
[9] EPA. Mike Bussell, EPA Region 10 Division Director to Neil Mullane, DEQ Water Quality Division Administrator. EPA's Action on New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions in Oregon's Water Quality Standards. June 1, 2010

drinking water and not fish consumption, the lower fish consumption rate of 17.5 g/d was not relevant to EPA's decision.

Asbestos
The "water + organism" criterion of 7,000,000 fibers/L is consistent with EPA's 304(a) recommendation and was therefore approved by EPA. Since human health risks from copper are primarily from drinking water and not fish consumption, the lower fish consumption rate of 17.5 g/d was not relevant to EPA's decision.

2. Footnote K insofar as it applies to the "water + organism" human health criteria for iron and manganese

Footnote K states: "Human Health criterion is for "dissolved" concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic." EPA approved this footnote for the "water + organism" criteria for both iron and manganese, but disapproved the footnote for the manganese "organism only" criterion because EPA could not ensure the protectiveness of using the dissolved form of manganese. In a separate rulemaking for manganese, DEQ therefore, expressed the criterion as an "organism only" total manganese criterion for marine waters. The criterion is based on human health toxicity endpoints related to the consumption of marine mollusks.

In same rulemaking, DEQ withdrew the "water + organism" iron and manganese human health criteria and the "organism only" manganese criterion for fresh waters. The criteria were not based on levels needed to protect human health. Rather, the primary effects considered were aesthetic (e.g., taste and laundry staining). Iron and manganese are a naturally occurring earth metals that sometimes exceeded the previous criteria due to natural background levels.

The Environmental Quality Commission adopted the revisions to the iron and manganese criteria on December 9, 2010. The revisions are reflected in the new Table 40 and will become applicable upon EPA approval.

3. Withdrawal of the human health criteria for eight toxic pollutants

Consistent with EPA's action under the National Toxics Rule, Oregon withdrew its human health criteria for the following toxic pollutants and was approved by EPA:

- Beryllium
- Cadmium
- Chromium III
- Chromium VI
- Lead
- Mercury
- Silver

- Trichloroethane 1, 1, 1

4. Revisions to the narrative toxic provisions at OAR 340-041-0033(1) and (2).

Revisions to OAR 340-041-0033(1) were approved by EPA as minor editorial changes. Revisions to (2) describe effective dates for human health and aquatic life toxics criteria in Tables 20, 33A and 33B.

B.4. Applicability of EPA's June 2010 Action to 2011 Proposed Human Health Criteria Revisions

In the current effort to develop the human health criteria proposed revisions, DEQ generally relied on the scientific information, policy decisions, and subsequent recommendations from the 1999 triennial review and 2004 submission as the basis for these human health criteria revisions. The major difference between criteria that were submitted in 2004 and the proposed 2011 criteria is the fish consumption rate (i.e. 175 g/d versus 17.5 g/d). In addition, DEQ is not proposing any revisions to the aquatic life criteria. These criteria were adopted and submitted to EPA in 2004 and are still undergoing Endangered Species Act consultation by EPA, the U.S. Fish and Wildlife Service, and NOAA's National Marine Fisheries Service and are not the subject of this review.

C. Development of a Fish Consumption Rate

C.1. Background

DEQ's water quality standards play an important role in maintaining and restoring the environmental quality and quality of life that Oregonians value. Human health criteria are used to limit the amount of toxic pollutants that enter Oregon's waterways and accumulate in the fish and shellfish consumed by many Oregonians as a traditional and/or healthful lifestyle. Human health criteria help to ensure that people may eat fish and shellfish (from here forward referred to as "fish") from local waters without incurring unacceptable health risks.

In 2004, the commission, at DEQ's recommendation, adopted water quality criteria based on EPA's 2002 recommended toxic pollutants criteria for aquatic life and for human health. The human health criteria were based on a fish consumption rate of 17.5 g/d, which represents the 90th percentile of consumption among consumers and non-consumers of fish nationwide. Prior to adopting the 2004 revisions, DEQ's human health criteria were based on EPA's 1986 recommended criteria and a fish consumption rate of 6.5 g/d. A fish consumption rate of 17.5 g/d equals about 0.6 ounces per day or three 6-ounce meals per month. Based on concerns that the fish consumption rate used in the EPA criteria may not accurately represent Oregonian's consumption patterns, the commission requested that DEQ seek resources to conduct a fish consumption rates study in Oregon.

Following DEQ's 2004 adoption of EPA's recommended criteria, concerns about Oregon's human health criteria heightened. Native American tribal governments objected to the criteria, stating that the criteria

did not protect tribal members who eat much greater amounts of fish and for whom fish consumption is a critical part of their cultural tradition and religion. Tribes have rights to catch fish in Oregon waters and EPA has a trust responsibility to protect the interests of the tribes. The Oregon tribes who were most involved in the fish consumption rate workshops and discussions and the subsequent rulemaking process include the Umatilla, Warm Springs, Klamath, Siletz and Grand Ronde tribes.

Although DEQ's 2004 human health criteria reflected EPA's guidance contained in the Human Health Methodology including use of 17.5 g/d as a default value, the guidance also recommends using local fish consumption data when it is available. In this circumstance, local data was available from a study conducted by the Columbia River Inter-Tribal Fish Commission [10] or "CRITFC Study", which included surveys of four Columbia River Tribes, two of whom reside in Oregon, the Confederated Tribes of the Umatilla Indian Reservation (CTUIR) and the Confederated Tribes of the Warms Springs Reservation.

C.2. Fish Consumption Rate Review Project

For the above reasons and with the recognition that many Oregonians eat more than 17.5 g/d of fish and shellfish, DEQ embarked on a project to review the fish consumption rate and subsequently revise the human health water quality criteria for Oregon. DEQ was not able to obtain funding for a study of Oregon fish consumption rates, so the review was based on available literature and data.

DEQ launched the fish consumption rate review project in the fall of 2006 and conducted seven workshops in cooperation with the EPA and the Confederated Tribes of the Umatilla Indian Reservation. The objective for these workshops was to allow any member of the public to receive and provide input on the information being gathered and evaluated, and express views on the policy issues inherent in choosing a fish consumption rate.

DEQ also formed two workgroups, the Human Health Focus Group (HHFG), to assist with gathering and evaluating relevant information. The Human Health Focus Group, made up of public health professionals and toxicologists, reviewed the available data on fish consumption patterns in the Pacific Northwest and elsewhere. The group wrote a report[11] summarizing the science and made recommendations about the quality and appropriate use of the available information. DEQ considered the HHFG's analysis in its selection of a fish consumption rate. The report, materials and agendas from the HHFG process, are contained on DEQ's website.

C.3. Choosing an Appropriate Fish Consumption Rate

Oregon's existing human health criteria are based either on a defined acceptable level of cancer risk (1 in 1,000,000 additional incidents of cancer) or a reference dose beyond which effects in test populations begin to be observed. People who eat more fish have a greater probability of incurring a health effect

[10] Columbia River Inter-Tribal Fish Commission. October 1994. A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin. Technical Report 94.3.
[11] Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project. June 2008.

from this exposure to contaminants and those who eat less fish will have less risk. As the fish consumption rate increases, the water quality criteria values will decrease and the costs to meet requirements associated with the revised criteria may rise. How much the criterion for any given pollutant will change with a change in the fish consumption rate also depends on the degree to which that pollutant accumulates in fish tissue. Therefore, a ten-fold increase in the fish consumption rate will not necessarily result in a ten-fold decrease for all criteria; the change in the criteria will vary by pollutant.

A major policy decision inherent in developing human health criteria is whether to base the criteria on a fish consumption rate that includes Oregonians who eat large amounts of fish and shellfish for cultural, economic, health or other reasons, or whether to use a fish consumption rate reflective of Oregon's total population, including people who do not eat fish or eat it rarely. A related decision is what proportion or percentile of the population(s) to base the fish consumption rate on. Within any group, whether Native-Americans, Asian-Americans or commercial fishermen, there will be some individuals who eat more than any chosen rate and some who eat less than that rate.

An additional issue discussed during this process was whether to include salmon (an anadromous fish) and/or marine fish in the consumption rate. The Human Health Focus Group recommended that DEQ include salmon and marine fish in the fish consumption rate because these fish are an important part of the fish diet in the Northwest and represent a potential source of exposure to contaminants. In addition, they found that for non-carcinogens, given the status of the relative source contribution (RSC) approach and values, it would be more accurate to account for the consumption of marine fish in the consumption rate than to use the RSCs in deriving criteria for non-carcinogens. Counter arguments to including (or fully counting) salmon and marine fish in the fish consumption rate assert that these fish accumulate most of their contaminant body burden in ocean waters, outside the influence of Oregon's water quality standards and pollution controls. In addition, salmon tend to contain lower levels of contaminants than resident fish. DEQ ultimately recommended that salmon be included in the rate given the large number of Oregonians who traditionally consume large amounts of salmon and noted that they represent a potential path of exposure to toxic pollutants. Consequently, the recommended rate reflects consumption of salmon and lamprey relative to rates documented in the CRITFC study (to protect at least 95% of fish consumers in Oregon), as well as marine fish and shellfish relative to the rates documented in the Puget Sound studies (to protect at least 90% of fish consumers in Oregon).

C.4. DEQ Recommendation on Selecting a Fish Consumption Rate

DEQ determined that a fish consumption rate of 175 g/d is a reasonable and protective fish consumption rate to use as the basis for Oregon's human health criteria. A fish consumption rate of 175 g/d equals approximately 6.2 ounces per day (or approximately 23 8-oz fish or shellfish meals per month). This rate represents the 95th percentile value from the Columbia River Inter-Tribal Fish Commission study and is within the range of the 90th percentile values from various studies from the Northwest assembled by the HHFG. The 175 g/d rate is consistent with the HHFG recommendation to use 90th or 95th percentile values to represent the proportion of the population the criteria should be

designed to protect. It is also consistent with HHFG recommendations to use a fish consumption rate that represents fish consumers only, rather than a rate derived from the overall population including both consumers and non-consumers of fish, and to include salmon and other marine species in the rate.

Another question raised during the 2004 water quality standards review was whether Oregon should use different fish consumption rates for basins or water bodies that reflect consumption patterns in those areas. Although the Technical Advisory Committee proposed applying different consumption rates for different geographic areas within the state, DEQ did not recommend this option based on the following considerations:

- While there is data only for the Umatilla and Warm Springs Tribes in Oregon, studies from the Pacific Northwest and elsewhere show that many Tribes and other groups (e.g. Asian Americans) eat moderate to large amounts of fish. Input at public workshops indicates that there may be other groups that eat large amounts of fish as well, such as commercial or sport fishermen.
- Nearly all the major river basins in Oregon are usual and accustomed fishing areas for an Oregon Tribe.
- People may catch fish in many locations around the state, not just in the river basin in which they live.
- Having different criteria in different basins would create complexities in the regulations and their implementation.

The EPA, CTUIR, and DEQ collaborated on this project throughout the process and issued a joint recommendation[12] to the Environmental Quality Commission on October 23, 2008, to revise Oregon's toxics criteria for human health based on a FCR of 175 g/d. The commission agreed with this recommendation and directed DEQ to proceed with this fish consumption rate as a basis for revising human health criteria.

D. New and Revised Human Health Water Quality Criteria

D.1. Technical Review Process for 2004 Submission

During the development of the 2004 water quality standards revisions, the Technical Advisory Committee (TAC) reviewed EPA's 2000 Methodology in comparison to the 1980 methodology used to derive Table 20 toxics criteria.

The formulae in the 2000 EPA Methodology used to calculate the criteria values differed from those in the 1980 EPA methodology by:

[12] DEQ. October 6, 2008 Memo from Dick Peterson, Director DEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 commission Meeting.

1) the addition of a new formula to calculate criteria for compounds where the mode of carcinogenicity shows a non-linear relationship between dose and effect;
2) the use of a bioaccumulation factor rather than bioconcentration factor (bioconcentration refers to the uptake and retention of a chemical from the water only; bioaccumulation refers to the uptake and retention of a chemical from all the surrounding environment, e.g. water, food, and sediment); and
3) the use of a new fish consumption rate.

Unless otherwise specified, DEQ relied on the review and decisions made during the development of the 2004 water quality standards to form the technical basis of revising criteria for this rulemaking. The major difference is the use of a higher fish consumption rate of 175 g/d.

D.2. Applicability of "water + organism" and "organism only" Criteria

The criteria calculations for both carcinogens and non-carcinogens differ depending upon the exposure scenario for which the criteria are derived. Oregon's criteria were developed to protect human health from long term exposure to toxic pollutants in drinking water and through eating fish and shellfish contaminated with toxics. The "water + organism" criteria refer to values that if met, ensure exposure through the consumption of drinking water and fish, including shellfish does not result in adverse health effects. The "organism only" criteria refer to values that if met, ensure exposure through the consumption of fish and shellfish only does not result in adverse health effects. These criteria apply where Oregon has designated waters as either a public or private domestic water supply, or as a fishing beneficial use. Generally, the majority of Oregon's waterbodies have been designated as both a domestic or private domestic water supply and as a fishing beneficial use. Therefore, human health toxics criteria will be widely applicable across the state. Table 1 indicates where the "organism only" criteria are the only human health criteria applicable, since a drinking water use has not been designated in these waters (e.g. non-potable estuarine waters).

TABLE 1: Waters Where "Organism Only" Criteria are Solely Applicable: Waters designated as having a fishing use, but not a domestic or private water supply

Table Reference Number	Basin	Segment Name
140A	Goose and Summer Lakes Basin	Goose Lake; and Highly Alkaline and Saline Lakes
190A	Malheur Lake Basin	Natural Lakes
220A	Mid Coast Basin	Estuaries and Adjacent Marine Waters
230A	North Coast Basin	Estuaries and Adjacent Marine Waters
271A	Rogue Basin	Rogue River Estuary and Adjacent Marine Waters; and Bear Creek Main Stem
286A	Sandy Basin	Streams Forming Waterfalls Near Columbia River Highway
300A	South Coast Basin	Estuaries and Adjacent Marine Waters
320A	Umpqua Basin	Umpqua River Estuary to Head of Tidewater and Adjacent Marine Waters

D.3. Criteria Derivation

The methodology for calculating human health toxics criteria takes into consideration three major factors: risk assessment, exposure, and to what degree the pollutant accumulates in fish tissue. Risk assessment includes the potency of the compound to cause a toxic effect that is either cancerous or noncancerous, and for cancer causing compounds, the level of risk that is acceptable for society (e.g. one additional cancer per million people). Exposure includes consideration of body weight, water intake, and fish intake. Bioconcentration is the degree to which an organism accumulates the contaminant from water only, while bioaccumulation describes the net accumulation of a contaminant from all sources.

D.3.1. Non-Carcinogens

DEQ utilized the 2000 Methodology to derive ambient water quality criteria for pollutants. This section describes how DEQ used the methodology as it applies to non-carcinogens.

Equation for Non-Carcinogens:

$$AWQC = RfD \times RSC \times \frac{(BW)}{[DI + (FCR \times BAF)]}$$

where:

AWQC = Ambient Water Quality Criterion (mg/L)

RfD = Reference dose for noncancer effects (mg/kg-day)

RSC = Relative source contribution factor to account for non-water sources of exposure

BW = Human body weight (kg) =70 kg

DI = Drinking water intake (L/day) = 2 L/day

FCR = Fish consumption rate (kg/d) = 175 g/d

BAF = Bioaccumulation factor (L/kg)

Body Weight and Drinking Water Intake

DEQ used EPA's national default values for body weight (70 kilograms or 154 lbs) and drinking water intake (2 L/day). DEQ also relied on EPA's reference doses used as part of its nationally recommended criteria[13]. A reference dose is defined[14] as an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime.

[13] EPA. 2002. Nationally Recommended Water Quality Criteria 2002 – Human Health Criteria Calculation Matrix. USEPA, Office of Water, Washington, DC. EPA 822-R-02012.

[14] EPA. 1993. Reference Dose (RfD): Description and Use in Health Risk Assessments. Integrated Risk Information System (IRIS). Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, USEPA, Cincinnati, OH.

Bioconcentration Factors (BCF) Versus Bioaccumulation Factors (BAF)

Water quality criteria for the protection of human health are derived, in part, by considering human exposure to pollutants that have been stored within fish after that fish has been exposed to a toxic pollutant. A BCF accounts for the uptake of a pollutant by a fish from the surrounding water, while a BAF accounts for the uptake of a pollutant from all sources (including the surrounding water, food, and sediment). While the consideration of a BAF in EPA's 2000 Methodology was considered an improvement over BCFs, developing BAFs is a complex process and can vary from site to site. EPA has not yet developed a national list of BAFs for its nationally recommended criteria. Consequently, EPA recommends criteria be developed using BCFs until such time local or regional BAFs that would be applicable to Oregon are developed. As a result, proposed criteria for this rulemaking reflect EPA recommended BCF values.

Reference Dose (RfD)

A reference dose is an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime[15]. Proposed criteria for this rulemaking reflect EPA recommended RfD values. Reference Dose values are based on real studies that reflect health effects from these pollutants at specific levels.

Relative Source Contribution

Criteria for pollutants that are non-carcinogens are based on a total cumulative dose over time that causes an observable effect. Because the human health water quality criteria address exposure only through drinking water and eating fish, a relative source contribution (RSC) factor is used to calculate the criteria. The RSC identifies or estimates the portion of total exposure attributed to water and fish consumption, and therefore, accounts for potential exposure from other sources, such as skin absorption, inhalation, other foods and occupational exposures. The RSC value is either multiplied by the reference dose or subtracted from the reference dose, depending on the chemical and known exposure sources of contaminants. Table 2 identifies the pollutants for which DEQ applied RSC values to the revised human health water quality criteria. For all of the pollutants but Endrin, DEQ used EPA's recommended RSC value. The other non-carcinogen pollutants used a RSC of 1, which indicates that all of the exposure to that pollutant is assumed to come from water and fish ingestion. In some cases, EPA does not have enough data to establish RSC values for other chemicals.

TABLE 2: Criteria Where Relative Source Contribution Values Were Applied

1) Antimony (40%)	9) Thallium (20%)
2) Chlorobenzene (20%)	10) Toluene (20%)
3) Chlorodibromomethane (80%)	11) 1,1,2-Trichloroethane (20%)

[15] EPA. Reference dose (RfD): Description and use in health risk assessments. Integrated Risk Information System (IRIS). Online. Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. Cincinnati, OH. March 15, 1993.

4) Cyanide (20%)	12) 1,1-Dichloroethylene (20%)
5) Endrin (80%)	13) 1,2,4-Trichlorobenzene (20%)
6) Ethylbenzene (20%)	14) 1,2-Dichlorobenzene(o) (20%)
7) gamma-BHC (Lindane) (20%)	15) 1,2-trans-Dichloroethylene (20%)
8) Hexachlorocyclopentadiene (20%)	16) 1,4-Dichlorobenzene(p) (20%)

RSC for Methylmercury

EPA established a RSC value that is subtracted from the reference dose to derive the tissue based methyl mercury criterion. EPA's recommended criterion uses a RSC because EPA's national default fish consumption rate does not include the consumption of marine species of fish (including Pacific salmon), which are a significant potential exposure route for methylmercury. Because the primary human route of exposure to methylmercury comes from ingestion of fish and shellfish, and because DEQ included marine species in the development of its fish consumption rate, it would be "double counting" the exposure if DEQ incorporated the same RSC value used in EPA's recommended methylmercury criterion. Methylmercury is unique in that it is a fish tissue criterion and the primary route of exposure to humans is through the consumption of fish and shellfish. The other criteria where RSC values have been established have other contributing sources of pollutant (e.g., consumption of food or other exposure routes), so removing the RSC would not be appropriate in those circumstances.

RSC for Endrin

EPA used a default RSC value of 20% for Endrin based on a recommendation from EPA's drinking water program. DEQ's final proposed criteria for Endrin use a RSC value of 80%. The primary reason DEQ proposes using an alternate default value is because DEQ does not anticipate exposure to this chemical outside of water and fish ingestion. This is consistent with EPA guidance for use of default RSC values:

> Default RSC Percentage Values: Floor of 20%, Ceiling of 80% (65 FR 66472)
> - EPA has recommended using the 20% RSC default when routes of water exposures other than oral or sources of exposure other than fish and water are anticipated, but adequate data are lacking to quantify those exposures.
> - Utilize local data to quantify exposures from other routes where available: When data are adequate to quantify exposures to other sources (oral or exposure to fish and water), EPA recommends that they be used instead of the default 20% RSC value.
> - If it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), then the 80% ceiling is recommended. This 80% ceiling is a way to provide adequate protection for those who experience exposures (from any or several sources) higher than available data may indicate.

Due to the properties of this chemical and the fact that it has not been in use for about 25 years, it is highly unlikely that people in Oregon would gain only 20% of their exposure to Endrin from water and fish and 80% of their exposure from other sources. Endrin bioconcentrates in aquatic organisms, but is not very soluble in water. The bioconcentration factor used to derive the human health criteria is 3970,

resulting in the same criteria value (when rounded to significant digits) for water + organism and for organism only ingestion.

The following information from the US Department of Health and Human Services Toxicological Profile for Endrin (1996, Chapter 5) supports DEQ's decision to use an RSC of 80% rather than 20% to derive Oregon's water quality criteria:

- The use of Endrin ended in the mid-1980s and "consequently, there are no longer any significant releases of Endrin to the environment in the United States."
- "Information on current levels of Endrin in the environment is limited; however, the available data indicate that concentrations in all environmental media are generally negligible or below levels of concern. "
- "The FDA has concluded that Endrin is no longer present in the environment to the extent that it may be contaminating food or feed at levels of regulatory concern (USDA 1995)."
- Endrin tends to persist in the environment mainly in forms sorbed to sediments and soil particles. A conservative estimate of its half-disappearance time in sandy loam soils is approximately 14 years. "Therefore, the exposure risks from Endrin to the general population of the United States are likely to steadily decrease over time."
- Limited information on the physical and/or chemical properties of Endrin aldehyde indicates that it is highly insoluble in water (EPA 1981a), highly immobile in soil, and will not volatilize significantly from water or soil.
- Endrin has been found to volatilize significantly (20-30%) from soils within days after application (Nash 1983). Because Endrin has not been in use for many years, this exposure route no longer occurs in Oregon.
- The main sources for potential human exposure to Endrin are residues on imported food items, unused stocks, unregistered use, inappropriate disposal, and hazardous waste sites; however, there is no current evidence of significant exposures from any of these sources. Furthermore, it should be noted that in environmental media, especially in contaminated soils and sediments, the amount of Endrin chemically identified by analysis is not necessarily the amount that is toxicologically available.
- Endrin was identified at 102 and Endrin ketone was identified at 37 of 1430 current or former hazardous waste sites in the United States. None of these sites were in Oregon (Figures 5-1 and 5-2).

D.3.2. Carcinogens

DEQ utilized the 2000 Methodology to derive ambient water quality criteria for pollutants that are carcinogens.

Equation for linear dose-response carcinogens:

$$AWQC = \frac{(Risk\ Level \times BW)}{[CSF \times (DI + (FCR \times BAF))]}$$

where:

AWQC = Ambient Water Quality Criterion (mg/L)

Risk Level = Risk Level (unitless)

CSF = Cancer slope factor (mg/kg-day)

BW = Human body weight (kg) =70 kg

DI = Drinking water intake (L/day) = 2 L/day

FCR = Fish consumption rate (kg/d) = 175 g/d

BAF = Bioaccumulation factor (L/kg)

The equation to derive ambient water quality criteria for pollutants that are carcinogens (i.e. cancer-causing pollutants) uses many of the same variables as the equation for non-carcinogens (i.e. body weight, drinking water intake, fish consumption rate, and bioaccumulation factor). The main difference is that a risk level and a cancer slope factor are used, and a relative source concentration is not used.

Cancer Slope Factor and Risk Level

The cancer slope factor is a measure of chemical potency. For most cancer-causing chemicals there is no toxicity threshold or reference dose. Because carcinogenic chemicals are thought to initiate the cancer process at almost any concentration, a dose-response parameter referred to as the cancer slope factor is used for chemicals that display toxic behavior such that the carcinogenic risk increases linearly as the chemical dose increases. Cancer slope factors are specific to individual pollutants. DEQ utilized EPA's nationally recommended slope factors to calculate criteria for carcinogens. Cancer slope factors are based on real studies that reflect health effects from carcinogenic pollutants at specific levels.

Risk estimates for carcinogens are expressed as the incremental probability of developing cancer (e.g., an additional one in one million chance of developing cancer) over a lifetime of exposure to potential carcinogens. EPA has identified a risk level range of 1×10^{-6} (1 in 1,000,000) to 1×10^{-5} (1 in 100,000) to be an appropriate risk management goal for the general population, as long as the most sensitive population is protected at 1×10^{-4} (1 in 10,000). As a matter of policy, DEQ has historically chosen to protect Oregonians at a risk level of 1×10^{-6} and will continue with this recommendation for the proposed human health toxics criteria. As a result, the proposed criteria will protect highly exposed populations in Oregon consuming up to 175 g/d of fish at a risk level of 1×10^{-6}.

D.3.3. Criteria Not Dependent on a Fish Consumption Rate

Although the majority of DEQ's proposed human health criteria are affected by the fish consumption rate, several of Oregon's existing criteria are not based on a fish consumption rate. For these criteria,

human health risks are primarily from drinking water and the existing criteria are based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act. Therefore, DEQ has not developed any "organism only" criteria. As a result, DEQ is not proposing to change the existing human health criteria identified in Table 3.

TABLE 3: Human health toxics criteria not dependent on a fish consumption rate

Asbestos	Methoxychlor
Barium	Nitrates
Chlorophenoxy Herbicide (2,4,5,-TP)	Copper
Chlorophenoxy Herbicide (2,4,-D)	Manganese

D.3.4. Toxics Criteria DEQ is Proposing to Withdraw

The following toxics pollutants have currently effective human health criteria, however, there are no longer EPA criteria for these pollutants. In some cases, like PAHs, the revised criteria include individual species of the more toxic forms of PAH, rather than a single criterion for a chemical family. Therefore, DEQ's proposed final rule withdraws the human health criteria for these pollutants.

TABLE 4: Pollutants for which DEQ Proposes to Withdraw Criteria

Dinitrotoluene
Dinitro-o-Cresol 2,4
Diphenylhydrazine
Halomethanes
Monochlorobenzene
Polynuclear Aromatic Hydrocarbons (PAHs)
Endosulfan

Based on information gathered during the public comment period, DEQ learned it had inadvertently included a "benzene range" as part of Table 40. In addition, DEQ included revisions to the "benzene" criteria that are single values. In investigating the basis for the "benzene range" DEQ identified that EPA does not have any recommended criteria for a "benzene range" and noted that DEQ has no precedent for expressing criteria as a range of values. Further investigations show there is a range of values presented in EPA's IRIS database for the cancer slope factor associated with benzene associated with the use of different modeling methods for the data. The cancer slope factor used for the development of the benzene criteria is consistent with the factor EPA used in deriving the national benzene criterion. Given this information, including both the "benzene range" criteria in addition to the benzene criteria is duplicative. As a result, DEQ removed the benzene range criteria from Table 40.

D.3.5. Proposed Toxics Criteria Additions

DEQ's final proposed rules add criteria for 39 toxic pollutants to the human health criteria table. DEQ included criteria for these pollutants in its 2004 water quality standards based on updated EPA criteria,

but EPA subsequently disapproved those criteria on June 1, 2010, because of an inadequate fish consumption rate. Revised criteria for these pollutants now reflect a fish consumption rate of 175 g/d.

TABLE 5: Pollutants for Which DEQ Proposes to Add Criteria

Acenapthene	Dimethyl phenol 2,4
Anthracene	Dinitrophenol 2,4
Benzene [represents range]	Dinitrophenols
Benz(a)anthracene	Diphenylhydrazine 1,2
Benzo(a)pyrene	Endosulfan alpha
Benzo(b)fluoranthene 3,4	Endosulfan beta
Benzo(k)fluoranthene	Endosulfan sulfate
Bromoform	Endrin aldehyde
Butylbenzyl phthalate	Fluorene
Chlorodibromomethane	Heptachlor epoxide
Chloronaphthalene 2	Indeno(1,2,3-cd)pyrene
Chlorophenol 2	Methyl bromide
Chrysene	Methyl-4,6-dinitrophenol 2
DDD 4, 4'	Methylene chloride
DDE 4, 4'	Methylmercury (mg/kg)
Dibenz(a,h)anthracene	Nitrosodi-n-propylamine, n
Dichlorobenzene(p) 1,4	Pyrene
Dichlorobromomethane	Trichlorobenzene 1,2,4
Dichloroethylene trans 1,2	Zinc
Dichloropropane	

D.3.6. Less Stringent Toxics Criteria

Although the majority of proposed toxics criteria are more stringent than the currently effective values based on a higher fish consumption rate, several of the criteria values became less stringent. As new risk-based data and studies become available, EPA updates risk values (e.g. cancer slopes, reference doses, bioconcentration factors) associated with exposure to environmental contaminants in EPA's IRIS (Integrated Risk Information System) database. DEQ, unless otherwise specified, used EPA's default values in IRIS as the basis for revising criteria. For the pollutants identified in Table 6, changes to values other than the fish consumption rate resulted in proposed criteria that were less stringent than current criteria despite utilizing a higher fish consumption rate.

TABLE 6: Less Stringent Toxics Criteria

Chloroform
Nickel
Phenol
Selenium

E. New, Revised, and Removed Footnotes

DEQ included new or removed footnotes for some human health criteria in Table 40. The majority of these footnotes clarify the source of information upon which the proposed criteria are based. Several of these footnotes with similar language were proposed as part of the 2004 water quality standards submittal, but were subsequently disapproved in conjunction with EPA's disapproval of the associated criteria.

TABLE 7: New Footnotes

Toxic Pollutant	New Footnote
1. Arsenic	This footnote was not included as part of the separate rulemaking for arsenic which was adopted by the EQC on April 21, 2011. A new footnote is now proposed to clarify how arsenic is expressed, as well as the associated risk level the criteria are based upon. *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately of 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1 x 10^{-4}*
2. Asbestos	*The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
3. Barium	*The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
4. Chlorophenoxy Herbicide (2,4,5,-TP)	*The Chlorophenoxy Herbicide (2,4,5,-TP) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
5. Chlorophenoxy Herbicide (2,4-D)	*The Chlorophenoxy Herbicide (2,4-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also*

Toxic Pollutant	New Footnote
	published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.
6. Cyanide	*The cyanide criterion is expressed as total cyanide (CN)/L.*
7. Di-2-ethylhexyl Phthalate	*Di-2-ethylhexyl Phthalate was previously known as Bis-2-ethylhexyl phthalate*
8. Methoxychlor	*The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
9. Methylmercury	*This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury*
10. PCBs	*This criterion applies to total PCBs (e.g. determined by Aroclors or congeners)*

TABLE 5: Revised Footnotes

Toxic Pollutant	Current Footnote	Revised Footnote
1. Copper	*This value is based on a Drinking Water regulation.*	*Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*

Toxic Pollutant	Current Footnote	Revised Footnote
2. Nitrates	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*

TABLE 6: Footnotes Removed

Bioconcentration factors for the three toxic pollutants in Table 6 are now available and were used to calculate criteria. For this reason, DEQ removed the footnotes because they are no longer applicable.

Toxic Pollutant	Current Footnote To Be Removed
1. Hexachlorocyclo-hexane-Technical	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*
2. Nitrosamines	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*
3. N-Nitrosodiethylamine	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*

F. Proposed Redline/Strikethrough Revisions to the Toxic Substances Rule

DEQ proposed several changes to 340-041-0033 in the rules DEQ published for public comment. The proposed revisions addressed the separation of the aquatic life criteria and the human health criteria in different tables. In addition, DEQ proposed a "Background Pollutant Allowance" for public comment.

In the revisions shown below, DEQ reorganized provisions relating to the aquatic life criteria and the human health criteria as separate sections. In addition, DEQ added a new section (1) specifying that the 112 toxics human health criteria revised by this rule are not applicable for purposes of the Clean Water Act until they are approved by EPA. This section also applies to the revised iron, manganese, and arsenic criteria the commission adopted in December 2010 and April 2011, respectively.

The provisions addressing background pollutants (now termed "Site-Specific Background Pollutant Criteria") remain in OAR 340-041-0033(6). These revisions are discussed in the *Implementing Water*

Quality Standards in NPDES Permits issue paper, and therefore, are not included in the revisions shown below.

In April 2011, EQC also adopted the arsenic reduction policy as OAR 340-041-0033(3). To accommodate revisions associated with this rulemaking, DEQ reorganized the rule to move the arsenic reduction policy section further back in this rule to OAR 340-041-0033(7), but did not revise any of the rule as adopted by the commission.

340-041-0033

Toxic Substances

(1) Amendments to sections (4) and (6) of this rule (OAR 340-041-0033) and associated revisions to Tables 20, 33A, 33B and 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

(~~1~~2) Toxic substances may not be introduced above natural background levels in waters of the state in amounts, concentrations, or combinations that may be harmful, may chemically change to harmful forms in the environment, or may accumulate in sediments or bioaccumulate in aquatic life or wildlife to levels that adversely affect public health, safety, or welfare or aquatic life, wildlife, or other designated beneficial uses.

(~~2~~3) Aquatic Life Criteria. Levels of toxic substances in waters of the state may not exceed the applicable aquatic life criteria listed in Tables 20, 33A, and 33B. Tables 33A and 33B, adopted on May 20, 2004, update Table 20 as described in this section.

(a) Each value for criteria in Table 20 is effective until the corresponding value in Tables 33A or 33B becomes effective.

(A) Each value in Table 33A is effective on February 15, 2005, unless EPA has disapproved the value before that date. If a value is subsequently disapproved, any corresponding value in Table 20 becomes effective immediately. Values that are the same in Tables 20 and 33A remain in effect.

(B) Each value in Table 33B is effective upon EPA approval.

~~(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).~~

(~~c~~b) The department will note the effective date for each value in Tables 20, 33A, and 33B as described in this section.

~~(3) To establish permit or other regulatory limits for toxic substances for which criteria are not included in Tables 20, 33A, or 33B, the department may use the guidance values in Table 33C, public health advisories, and other published scientific literature. The department may also require or conduct bio-~~

assessment studies to monitor the toxicity to aquatic life of complex effluents, other suspected discharges, or chemical substances without numeric criteria.

(4) Arsenic Reduction Policy: The inorganic arsenic criterion for the protection of human health from the combined consumption of organisms and drinking water is 2.1 micrograms per liter. While this criterion is protective of human health and more stringent than the federal maximum contaminant level (MCL) for arsenic in drinking water, which is 10 micrograms per liter, it nonetheless is based on a higher risk level than the Commission has used to establish other human health criteria. This higher risk level recognizes that much of the risk is due to naturally high levels of inorganic arsenic in Oregon's waterbodies. In order to maintain the lowest human health risk from inorganic arsenic in drinking water, the Commission has determined that it is appropriate to adopt the following policy to limit the human contribution to that risk.

(a) The arsenic reduction policy established by this rule section does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until the numeric arsenic criteria established by this rule are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

(b) It is the policy of the Commission that the addition of inorganic arsenic from new or existing anthropogenic sources to waters of the state within a surface water drinking water protection area be reduced the maximum amount feasible. The requirements of this rule section [OAR 340-041-0033(4)] apply to sources that discharge to surface waters of the state with an ambient inorganic arsenic concentration equal to or lower than the applicable numeric inorganic arsenic criteria for the protection of human health.

(c) The following definitions apply to this section [OAR 340-041-0033(4)]:

(A) "Add inorganic arsenic" means to discharge a net mass of inorganic arsenic from a point source (the mass of inorganic arsenic discharged minus the mass of inorganic arsenic taken into the facility from a surface water source).

(B) A "surface water drinking water protection area," for the purpose of this section, means an area delineated as such by DEQ under the source water assessment program of the federal Safe Drinking Water Act, 42 U.S.C. § 300j-13. The areas are delineated for the purpose of protecting public or community drinking water supplies that use surface water sources. These delineations can be found at DEQ's drinking water program website.

(C) "Potential to significantly increase inorganic arsenic concentrations in the public drinking water supply source water" means:

(i) to increase the concentration of inorganic arsenic in the receiving water for a discharge by 10 percent or more after mixing with the harmonic mean flow of the receiving water; or

(ii) as an alternative, if sufficient data are available, the discharge will increase the concentration of inorganic arsenic in the surface water intake water of a public water system by 0.021 micrograms per liter or more based on a mass balance calculation.

(d) Following the effective date of this rule, applications for an individual NPDES permit or permit renewal received from industrial dischargers located in a surface water drinking water protection area and identified by DEQ as likely to add inorganic arsenic to the receiving water must include sufficient data to enable DEQ to determine whether:

(A) The discharge in fact adds inorganic arsenic; and

(B) The discharge has the potential to significantly increase inorganic arsenic concentrations in the public drinking water supply source water.

(e) Where DEQ determines that both conditions in subsection (d) of this section (4) are true, the industrial discharger must develop an inorganic arsenic reduction plan and propose all feasible measures to reduce its inorganic arsenic loading to the receiving water. The proposed plan, including proposed measures, monitoring and reporting requirements, and a schedule for those actions, will be described in the fact sheet and incorporated into the source's NPDES permit after public comment and DEQ review and approval. In developing the plan, the source must:

(A) Identify how much it can minimize its inorganic arsenic discharge through pollution prevention measures, process changes, wastewater treatment, alternative water supply (for groundwater users) or other possible pollution prevention and/or control measures;

(B) Evaluate the costs, feasibility and environmental impacts of the potential inorganic arsenic reduction and control measures;

(C) Estimate the predicted reduction in inorganic arsenic and the reduced human health risk expected to result from the control measures;

(D) Propose specific inorganic arsenic reduction or control measures, if feasible, and an implementation schedule; and

(E) Propose monitoring and reporting requirements to document progress in plan implementation and the inorganic arsenic load reductions.

(f) In order to implement this section, DEQ will develop the following information and guidance within 120 days of the effective date of this rule and periodically update it as warranted by new information:

(A) A list of industrial sources or source categories, including industrial stormwater and sources covered by general permits, that are likely to add inorganic arsenic to surface waters of the State.

(i) For industrial sources or source categories permitted under a general permit that have been identified by DEQ as likely sources of inorganic arsenic, DEQ will evaluate options for reducing inorganic arsenic during permit renewal or evaluation of Stormwater Pollution Control Plans.

(B) Quantitation limits for monitoring inorganic arsenic concentrations.

(C) Information and guidance to assist sources in estimating, pursuant to paragraph (d) (C) of this section, the reduced human health risk expected to result from inorganic arsenic control measures based on the most current EPA risk assessment.

~~(g) It is the policy of the Commission that landowners engaged in agricultural or development practices on land where pesticides, fertilizers, or soil amendments containing arsenic are currently being or have previously been applied, implement conservation practices to minimize the erosion and runoff of inorganic arsenic to waters of the State or to a location where such material could readily migrate into waters of the State.~~

(4) Human Health Criteria. The criteria for waters of the state listed in Table 40 are established to protect Oregonians from potential adverse health effects associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water.

(~~3~~5) To establish permit or other regulatory limits for toxic substances for which criteria are not included in Tables 20, 33A, or 33B, the department may use the guidance values in Table 33C, public health advisories, and other published scientific literature. The department may also require or conduct bio-assessment studies to monitor the toxicity to aquatic life of complex effluents, other suspected discharges, or chemical substances without numeric criteria.

(6) Establishing Site-Specific Background Pollutant Criteria: ….

(4~~7~~) Arsenic Reduction Policy: …

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 468.020, 468B.030, 468B.035 & 468B.048
Stats. Implemented: ORS 468B.030, 468B.035 & 468B.048
Hist.: DEQ 17-2003, f. & cert. ef. 12-9-03; DEQ 3-2004, f. & cert. ef. 5-28-04; DEQ 17-2010, f. & cert. ef. 12-21-10

G. Implementation

G.1. Effective Dates

DEQ is proposing that the human health criteria revisions established by OAR 340-041-0033 and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

In contrast, for DEQ's 2004 water quality standards submission, the revised toxics criteria became effective for NPDES purposes nine months following the date of commission adoption. DEQ also specified that if the values were subsequently disapproved after that date, any corresponding value in Table 20 would become effective. EPA disapproved the majority of DEQ's 2004 human health criteria on June 1, 2010, nearly six years after the effective date. As a result, many of the criteria adopted in 2004 that had become effective subsequently reverted back to human health criteria based on a FCR of 6.5 g/day. Given the potential ramifications of criteria becoming effective in advance of EPA's action, DEQ is proposing that the human health criteria only become applicable for CWA programs upon EPA approval, rather than at the time of commission adoption.

G.2. NPDES Compliance

Dischargers will not need to modify existing permits to immediately incorporate new limits or requirements associated with the revised criteria at the time of EPA approval if that approval occurs during their permit cycle. However, at the time of permit renewal, permits will be evaluated and water quality-based effluent limitations (WQBELs) will be developed or revised in the renewed permit, if needed, to meet revised water quality criteria.

G.3. Methylmercury

In January 2001, EPA published a new water quality criterion for methylmercury that, for the first time, expresses a human health criterion as a concentration in fish and shellfish tissue rather than in the water. In 2004, the EQC adopted a tissue-based methylmercury criterion to replace its previous mercury water column criteria, but it was subsequently disapproved by EPA based on a fish consumption rate that was too low (i.e. 17.5 g/day). DEQ's final proposed rules includes a revised methylmercury fish tissue criterion based on a fish consumption rate of 175 g/day. Because the adoption of tissue-based criteria can pose challenges in implementing the criteria, DEQ has begun exploring options for incorporating the new criteria into various DEQ programs. Generally, DEQ intends to develop implementation procedures similar to EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion*.

G.3.1. NPDES Permitting

DEQ intends to develop implementation procedures based on EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion*. A variety of situations exist throughout Oregon that are addressed in EPA's implementation guidance, including waterbodies with mercury TMDLs, waters listed as impaired without TMDLs, and other waters with insufficient methylmercury data. DEQ will use the options as described in EPA's guidance to develop additional detail regarding how DEQ will implement the new criterion in various circumstances, once adopted by the Environmental Quality Commission and approved by EPA.

G.3.1.2. TMDLs

DEQ intends to make use of EPA's guidance in developing TMDLs and notes that it is fairly flexible and provides DEQ with several options. However, the guidance is written to address waterbodies that are dominated by direct air deposition of mercury, as found in the mid-west and east coast states. In contrast, Oregon is not dominated by direct air deposition of mercury.

In addition to EPA's Guidance, DEQ may also utilize EPA Region 10's Mercury Reduction Strategy in implementing a methylmercury criterion of which DEQ was a key stakeholder in the development of this strategy. Additionally, implementation may include the results of Region 10's *"Development of a Monitoring Guide to Support Water-Resource Assessments for Mercury within EPA Region X"*. This work may help answer questions related to mercury methylation and bioaccumulation in fish tissue.

Oregon's methylmercury criterion implementation strategy from a TMDL perspective would:

- Utilize an environmentally relevant analytical approach that could be conducted on a seasonal basis and include general water and sediment quality parameters that are known to methylate mercury, which could allow for a spatially appropriate bioaccumulation factor to be calculated.
- Focus either on a regional or grouped (likely basin scale) spatial approach that would evaluate both mercury loading and methylmercury methylation.
- Spatially detailed models could be used that are dynamic for modeling fate and transport of both mercury and methylmercury, or a simplified regression model depending on the amount of data available for the analytical area.
- A linked model approach may be likely, especially in data rich areas such as the Willamette Basin. This method would include the use of EPA models: GBMM, WASP, and / or BASS
- Fish tissue could be monitored at a frequency of every 5 years at a minimum(DEQ is already developing a statewide baseline with the Toxics Monitoring Program).
- Relative source contribution analysis would include REMSAD air modeling from EPA for both far field (Asia) and near-field (in-basin sources) analysis.

Further discussion with EPA and DEQ staff in implementing the methylmercury criterion will occur following the commission's adoption of the rules.

G.4. Quantitation Limits

Approximately 48 percent of the proposed human health criteria have Quantification Limits (QLs) that are higher than the criterion. For that reason, pollutants may occur in Oregon's waterbodies at concentrations greater than the proposed criteria that cannot be measured given limitations in analytical methods. As a point of reference, approximately 40 percent of the currently effective criteria have QLs that are higher than the criterion. For permitting purposes, the QL becomes the compliance point for dischargers. Consequently, if the criterion for a particular pollutant becomes more stringent, but the QL remains higher than the criterion, there would be no effective change in the point of compliance until and unless analytical methods improve. Historically, the pace of change in laboratory methods has not been rapid. However, when methods do improve, there will likely be additional toxics impairment listings and more stringent water quality based effluent limits (WQBELs) for permit holders.

G.5. Effective Toxics Criteria Tables

DEQ is proposing a new Table 40 which will only contain criteria applicable to human health. Human health criteria will be deleted from Table 20, Table 33A, and Table 33B. These tables will remain a part of Oregon's water quality standards and only contain the aquatic life criteria. Once EPA takes action on the aquatic life criteria, DEQ will take action to combine the aquatic life criteria in Tables 20, 33A, and Table 33B into one table containing all of the aquatic life criteria.

Appendix A. Table 20 Redline/Strikethrough

TABLE 20

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[1]

The concentration for each compound listed in Table 20 is a criterion not to be exceeded in waters of the state in order to protect aquatic life ~~and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding designations as to whether EPA has identified it as a priority pollutant and a carcinogen, aquatic life freshwater acute and chronic criteria, and aquatic life marine acute and chronic criteria, ~~human health water & organism and fish consumption only criteria, and Drinking Water Maximum Contaminant Level (MCL)~~. The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
ACENAPTHENE	Y	~~N~~							
ACROLEIN	Y	~~N~~					~~320ug~~	~~780ug~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
ACRYLONITRILE	Y	~~Y~~					~~0.058ug**~~	~~0.65ug**~~	
ALDRIN	Y	~~Y~~	3		1.3		~~0.074ng**~~	~~0.079ng**~~	
ALKALINITY	N	~~N~~		20,000					
AMMONIA	N	~~N~~	CRITERIA ARE pH AND TEMPERATURE DEPENDENT—SEE DOCUMENT USEPA JANUARY 1985 (Fresh Water) CRITERIA ARE pH AND TEMPERATURE DEPENDENT—SEE DOCUMENT USEPA APRIL 1989 (Marine Water)						
ANTIMONY	Y	~~N~~					~~146ug~~	~~45,000ug~~	
ARSENIC	Y	~~Y~~					~~2.2ng**~~	~~17.5ng**~~	~~0.05mg~~
ARSENIC (PENT)	Y	~~Y~~							
ARSENIC (TRI)	Y	~~Y~~	360	190	69	36			
ASBESTOS	Y	~~Y~~					~~30K f/L**~~		
BARIUM	N	~~N~~					~~1mg~~		~~1.0mg~~
BENZENE	Y	~~Y~~					~~0.66ug**~~	~~40 ug**~~	
BENZIDINE	Y	~~Y~~					~~0.12ng~~	~~0.53ng**~~	
BERYLLIUM	Y	~~Y~~					~~6.8ng**~~	~~117ng**~~	
BHC	Y	~~N~~							

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
CADMIUM	Y	~~N~~	3.9+	1.1+	43	9.3	~~10ug~~		~~0.010mg~~
CARBON TETRACHLORIDE	Y	~~Y~~					~~0.4ug**~~	~~6.94ug**~~	
CHLORDANE	Y	~~Y~~	2.4	0.0043	0.09	0.004	~~0.46ng**~~	~~0.48ng**~~	
CHLORIDE	N	~~N~~	860 mg/L	230 mg/L					
CHLORINATED BENZENES	Y	~~Y~~					~~488 ug~~		
CHLORINATED NAPHTHALENES	Y	~~N~~							
CHLORINE	N	~~N~~	19	11	13	7.5			
CHLOROALKYL ETHERS	Y	~~N~~							
CHLOROETHYL ETHER (BIS-2)	Y	~~Y~~					~~0.03 ug~~	~~1.36 ug**~~	
CHLOROFORM	Y	~~Y~~					~~0.19ug**~~	~~15.7ug**~~	
CHLOROISOPROPYL ETHER (BIS-2)	Y	~~N~~					~~34.7ug~~	~~4.36mg~~	
CHLOROMETHYL ETHER (BIS)	N	~~Y~~					~~0.00000376ng**~~	~~0.00184ug**~~	
CHLOROPHENOL 2	Y	~~N~~							
CHLOROPHENOL 4	N	~~N~~							

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
CHLOROPHENOXY HERBICIDES (2,4,5,-TP)	N	~~N~~					~~10ug~~		
CHLOROPHENOXY HERBICIDES (2,4-D)	N	~~N~~					~~100ug~~		
CHLORPYRIFOS	N	~~N~~	0.083	0.041	0.011	0.0056			
CHLORO-4 METHYL-3 PHENOL	N	~~N~~							
CHROMIUM (HEX)	Y	~~N~~	16	11	1,100	50	~~50ug~~		~~0.05mg~~
CHROMIUM (TRI)	N	~~N~~	1,700.+	210.+			~~170mg~~	~~3,433mg~~	~~0.05mg~~
COPPER	Y	~~N~~	18.+	12.+	2.9	2.9			
CYANIDE	Y	~~N~~	22	5.2	1	1	~~200ug~~		
DDT	Y	~~Y~~	1.1	0.001	0.13	0.001	~~0.024ng**~~	~~0.024ng**~~	
(TDE) DDT METABOLITE	Y	~~Y~~							
(DDE) DDT METABOLITE	Y	~~Y~~							
DEMETON	Y	~~N~~		0.1		0.1			
DIBUTYLPHTHALATE	Y	~~N~~					~~35mg~~	~~154mg~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
DICHLOROBENZENES	Y	~~N~~					~~400ug~~	~~2.6mg~~	
DICHLOROBENZIDINE	Y	~~Y~~					~~0.01ug**~~	~~0.020ug**~~	
DICHLOROETHANE 1,2	Y	~~Y~~					~~0.94ug**~~	~~243ug**~~	
DICHLOROETHYLENES	Y	~~Y~~					~~0.033ug**~~	~~1.85ug**~~	
DICHLOROPHENOL 2,4	N	~~N~~					~~3.09mg~~		
DICHLOROPROPANE	Y	~~N~~							
DICHLOROPROPENE	Y	~~N~~					~~87ug~~	~~14.1mg~~	
DIELDRIN	Y	~~Y~~	2.5	0.0019	0.71	0.0019	~~0.071ng**~~	~~0.076ng**~~	
DIETHYLPHTHALATE	Y	~~N~~					~~350mg~~	~~1.8g~~	
DIMETHYL PHENOL 2,4	Y	~~N~~							
DIMETHYL PHTHALATE	Y	~~N~~					~~313mg~~	~~2.9g~~	
DINITROTOLUENE 2,4	N	~~Y~~					~~0.11ug**~~	~~9.1ug**~~	
DINITROTOLUENE	Y	~~N~~					~~70ug~~	~~14.3mg~~	
DINITROTOLUENE	N	~~Y~~							
DINITRO-O-CRESOL 2,4	Y	~~N~~					~~13.4~~	~~765ug~~	
DIOXIN (2,3,7,8-TCDD)	Y	~~Y~~					~~0.000013ng**~~	~~0.000014ng**~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
DIPHENYLHYDRAZINE	Y	~~N~~					~~42ng**~~	~~0.56ug**~~	
DIPHENYLHYDRAZINE 1,2	Y	~~N~~							
DI-2-ETHYLHEXYL PHTHALATE	Y	~~N~~					~~15mg~~	~~50mg~~	
ENDOSULFAN	Y	~~N~~	0.22	0.056	0.034	0.0087	~~74ug~~	~~159ug~~	
ENDRIN	Y	~~N~~	0.18	0.0023	0.037	0.0023	~~1ug~~		~~0.0002mg~~
ETHYLBENZENE	Y	~~N~~					~~1.4mg~~	~~3.28mg~~	
FLUORANTHENE	Y	~~N~~					~~42ug~~	~~54ug~~	
GUTHION	N	~~N~~		0.01		0.01			
HALOETHERS	Y	~~N~~							
HALOMETHANES	Y	~~Y~~					~~0.19ug**~~	~~15.7ug**~~	
HEPTACHLOR	Y	~~Y~~	0.52	0.0038	0.053	0.0036	~~0.28ng**~~	~~0.29ng**~~	
HEXACHLOROETHANE	N	~~Y~~					~~1.9ug~~	~~8.74ug~~	
HEXACHLOROBENZENE	Y	~~N~~					~~0.72ng**~~	~~0.74ng**~~	
HEXACHLOROBUTADIENE	Y	~~Y~~					~~0.45ug**~~	~~50ug**~~	
HEXACHLOROCYCLOHEXANE (LINDANE)	Y	~~Y~~	2	0.08	0.16				~~0.004mg~~

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
HEXACHLOROCYCLOHEXANE-ALPHA	Y	~~Y~~					~~9.2ng**~~	~~31ng**~~	
HEXACHLOROCYCLOHEXANE-BETA	Y	~~Y~~					~~16.3ng**~~	~~54.7ng**~~	
HEXACHLOROCYCLOHEXANE-GAMA	Y	~~Y~~					~~18.6ng**~~	~~62.5ng**~~	
HEXACHLOROCYCLOHEXANE-TECHNICAL	Y	~~Y~~					~~12.3ng**~~	~~41.4ng**~~	
HEXACHLOROCYCLOPENTADIENE	Y	~~N~~					~~206ug~~		
IRON	N	~~N~~		1,000			~~0.3mg~~		
ISOPHORONE	Y	~~N~~					~~5.2mg~~	~~520mg~~	
LEAD	Y	~~N~~	82.+	3.2+	140	5.6	~~50ug~~		~~0.05mg~~
MALATHION	N	~~N~~		0.1		0.1			
MANGANESE	N	~~N~~					~~50ug~~	~~100ug~~	
MERCURY	Y	~~N~~	2.4	0.012	2.1	0.025	~~144ng~~	~~146ng~~	~~0.002mg~~
METHOXYCHLOR	N	~~N~~		0.03		0.03	~~100ug~~		~~0.1mg~~
MIREX	N	~~N~~		0.001		0.001			
MONOCHLOROBENZENE	Y	~~N~~					~~488ug~~		
NAPHTHALENE	Y	~~N~~							

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
NICKEL	Y	~~N~~	1,400.+	160+	75	8.3	~~13.4ug~~	~~100ug~~	
NITRATES	N	~~N~~					~~10mg~~		~~10mg~~
NITROBENZENE	Y	~~N~~					~~19.8mg~~		
NITROPHENOLS	Y	~~N~~							
NITROSAMINES	Y	~~Y~~					~~0.8ng**~~	~~1,240ng**~~	
NITROSODIBUTYLAMINE N	Y	~~Y~~					~~6.4ng**~~	~~587ng**~~	
NITROSODIETHYLAMINE N	Y	~~Y~~					~~0.8ng**~~	~~1,240ng**~~	
NITROSODIMETHYLAMINE N	Y	~~Y~~					~~1.4ng**~~	~~16,000ng**~~	
NITROSODIPHENYLAMINE N	Y	~~Y~~					~~4,900ng**~~	~~16,100ng**~~	
NITROSOPYRROLIDINE N	Y	~~Y~~					~~16ng**~~	~~91,900ng**~~	
PARATHION	N	~~N~~	0.065	0.013					
PCB's	Y	~~Y~~	2	0.014	10	0.03	~~0.079ng**~~	~~0.079ng**~~	
PENTACHLORINATED ETHANES	N	~~N~~							
PENTACHLOROBENZENE	N	~~N~~					~~74ug~~	~~85ug~~	
PENTACHLOROPHENOL	Y	~~N~~	***20	***13	13		~~1.01mg~~		

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
PHENOL	Y	~~N~~					~~3.5mg~~		
PHOSPHORUS ELEMENTAL	N	~~N~~				0.1			
PHTHALATE ESTERS	Y	~~N~~							
POLYNUCLEAR AROMATIC HYDROCARBONS	Y	~~Y~~					~~2.8ng**~~	~~31.1ng**~~	
SELENIUM	Y	~~N~~	260	35	410	54	~~10ug~~		~~0.01mg~~
SILVER	Y	~~N~~	4.1+	0.12	2.3		~~50ug~~		~~0.05mg~~
SULFIDE HYDROGEN SULFIDE	N	~~N~~		2		2			
TETRACHLORINATED ETHANES	Y	~~N~~							
TETRACHLOROBENZENE 1,2,4,5	Y	~~N~~					~~38ug~~	~~48ug~~	
TETRACHLOROETHANE 1,1,2,2	Y	~~Y~~					~~0.17ug**~~	~~10.7ug**~~	
TETRACHLOROETHANES	Y	~~N~~							
TETRACHLOROETHYLENE	Y	~~Y~~					~~0.8ug**~~	~~8.85ug**~~	
TETRACHLOROPHENOL 2,3,5,6	Y	~~N~~							
THALLIUM	Y	~~N~~					~~13ug~~	~~48ug~~	
TOLUENE	Y	~~N~~					~~14.3mg~~	~~424mg~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
TOXAPHENE	Y	~~Y~~	0.73	0.0002	0.21	0.0002	~~0.71ng**~~	~~0.73ng**~~	~~0.005mg~~
TRICHLORINATED EtHANES	Y	~~Y~~							
TRICHLOROETHANE 1,1,1	Y	~~N~~					~~18.4mg~~	~~1.03g~~	
TRICHLOROETHANE 1,1,2	Y	~~Y~~					~~0.6ug**~~	~~41.8ug**~~	
TRICHLOROETHYLENE	Y	~~Y~~					~~2.7ug**~~	~~80.7ug**~~	
TRICHLOROPHENOL 2,4,5	N	~~N~~					~~2,600ug~~		
TRICHLOROPHENOL 2,4,6	Y	~~Y~~					~~1.2ug**~~	~~3.6ug**~~	
VINYL CHLORIDE	Y	~~Y~~					~~2ug**~~	~~525ug**~~	
ZINC	Y	~~N~~	120+	110+	95	86			

MEANING OF SYMBOLS:

g = grams ~~M.C.L = Maximum Contaminant Level~~

mg = milligrams + = Hardness Dependent Criteria (100 mg/L used).

The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

$CMC = (\exp(m_A*[\ln(hardness)] + b_A))*CF$

$CCC = (\exp(m_C*[\ln(hardness)] + b_C))*CF$

Chemical	m_A	b_A	m_C	b_C
Cadmium	1.128	-3.828	0.7852	-3.49
Chromium III	0.819	3.688	0.819	1.561
Copper	0.9422	-1.464	0.8545	-1.465
Lead	1.273	-1.46	1.273	-4.705
Nickel	0.846	3.3612	0.846	1.1645
Silver	1.72	-6.52		
Zinc	0.8473	0.8604	0.8473	0.7614

ug = micrograms

* = Insufficient data to develop criteria; value presented is the L.O.E.L – Lower Observed Effect Level.

ng = nanograms

pg = picograms

f = fibers

Y = Yes

N = No

** = Human health criteria for carcinogens reported for three risk levels. Value presented is the 10-6 risk level, which means the probability of one concern case per million people at the stated concentration.

*** = pH Dependent Criteria (7.8 pH used).

1 = Values in Table 20 are applicable to all basins.

Water and Fish Ingestion

Values represent the maximum ambient water concentration for consumption of both contaminated water and fish or other aquatic organisms.

Fish Ingestion

Values represent the maximum ambient water concentrations for consumption of fish or other aquatic organisms

Appendix B. Table 33A Redline/Strikethrough

TABLE 33A

Note: The Environmental Quality Commission adopted the following criteria on May 20, 2004 to become effective February 15, 2005. However, EPA has not yet (as of June 2006) approved the criteria. Thus, Table 33A criteria may be used in NPDES permits, but not for the section 303(d) list of impaired waters.

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[A]

The concentration for each compound listed in Table 33A is a criterion not to be exceeded in waters of the state in order to protect aquatic life ~~and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding EPA number (from National Recommended Water Quality Criteria: 2002, EPA-822-R-02-047), the Chemical Abstract Service (CAS) number, aquatic life freshwater acute and chronic criteria, aquatic life saltwater acute and chronic criteria~~, human health water & organism and organism only criteria~~, and Drinking Water Maximum Contaminant Level (MCL). The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only[B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
56	Acenaphthene			83329									~~670~~		~~990~~		
57	Acenaphthylene			208968													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
17	Acrolein			107028									~~190~~		~~290~~		
18	Acrylonitrile			107131									~~0.051~~		~~0.250~~		
102	Aldrin			309002	3 O	X			1.3 O	X			~~0.00004 9~~		~~0.00005 0~~		
1 N	Alkalinity						20,000 P										
2 N	Aluminum (pH 6.5 - 9.0)			7429905													
3 N	Ammonia			7664417					D	X	D	X					
58	Anthracene			120127									~~8300~~		~~40000~~		
1	Antimony			7440360									~~5.6~~		~~640~~		
2	Arsenic			7440382													~~0.05mg~~
15	Asbestos			1332214													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
6 N	Barium			7440393									~~1000~~				~~1.0mg~~
19	Benzene			71432													
59	Benzidine			92875									~~0.00008 6~~		~~0.00020~~		
60	Benzo(a)Anthracene			56553									~~0.0038~~		~~0.018~~		
61	Benzo(a)Pyrene			50328									~~0.0038~~		~~0.018~~		
62	Benzo(b)Fluoranthene			205992									~~0.0038~~		~~0.018~~		
63	Benzo(g,h,i)Perylene			191242													
64	Benzo(k)Fluoranthene			207089									~~0.0038~~		~~0.018~~		
3	Beryllium			7440417													
103	BHC alpha-			319846									~~0.0026~~		~~0.0049~~		
104	BHC beta-			319857									~~0.0091~~		~~0.017~~		
106	BHC delta-			319868													
105	BHC gamma- (Lindane)			58899	0.95		0.08	X	0.16 O								~~0.004mg~~
7 N	Boron			7440428													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
20	Bromoform			75252									~~4.3~~		~~140~~		
69	Bromophenyl Phenyl Ether 4-																
70	Butylbenzyl Phthalate			85687									~~1500~~		~~1900~~		
4	Cadmium			7440439													~~0.010mg~~
21	Carbon Tetrachloride			56235									~~0.23~~		~~1.6~~		
107	Chlordane			57749	2.4 O	X	0.0043 O	X	0.09 O	X	0.004 O	X					
8 N	Chloride			16887006	860000		230000										
9 N	Chlorine			7782505	19	X	11	X	13	X	7.5	X					
22	Chlorobenzene			108907									~~130~~		~~1600~~		
23	Chlorodibromomethane			124481									~~0.40~~		~~13~~		
24	Chloroethane			75003													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	~~Drinking Water M.C.L.~~
65	ChloroethoxyMethane Bis2-			111911													
66	ChloroethylEther Bis2-			111444									~~0.030~~		~~0.53~~		
25	Chloroethylvinyl Ether 2-			110758													
26	Chloroform			67663													
67	ChloroisopropylEther Bis2-			108601													
15 N	ChloromethylEther, Bis			542881											~~0.00029~~		
71	Chloronaphthalene 2-			91587									~~1000~~		~~1600~~		
45	Chlorophenol 2-			95578									~~81~~		~~150~~		
10 N	Chlorophenoxy Herbicide (2,4,5,-TP)			93721									~~10 H~~				
11 N	Chlorophenoxy Herbicide (2,4-D)			94757									~~100 H~~				
72	Chlorophenyl Phenyl Ether 4-			7005723													
12 N	Chloropyrifos			2921882	0.083	X	0.041	X	0.011	X	0.0056	X					

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
																	~~0.05mg~~
5a	Chromium (III)																~~0.05mg~~
5b	Chromium (VI)			18540299													~~0.05mg~~
73	Chrysene			218019									~~0.0038~~		~~0.018~~		
6	Copper			7440508									~~1300 H~~				
14	Cyanide			57125	22 S	X	5.2 S	X	1 S	X	1 S	X	~~140~~		~~140~~		
108	DDT 4,4'-			50293	1.1 O,T	X	0.001 O,T	X	0.13 O,T	X	0.001 O,T	X					
109	DDE 4,4'-			72559									~~0.00022~~		~~0.00022~~		
110	DDD 4,4'-			72548									~~0.00031~~		~~0.00031~~		
14 N	Demeton			8065483			0.1	X			0.1	X					
74	Dibenzo(a,h)Anthracene			53703									~~0.0038~~		~~0.018~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
75	Dichlorobenzene 1,2-			95501									~~420~~		~~1300~~		
76	Dichlorobenzene 1,3-			541731									~~320~~		~~960~~		
77	Dichlorobenzene 1,4-			106467									~~63~~		~~190~~		
78	Dichlorobenzidine 3,3'-			91941									~~0.021~~		~~0.028~~		
27	Dichlorobromomethane			75274									~~0.55~~		~~17~~		
28	Dichloroethane 1,1-			75343													
29	Dichloroethane 1,2-			107062									~~0.38~~		~~37~~		
30	Dichloroethylene 1,1-			75354									~~330~~		~~7100~~		
46	Dichlorophenol 2,4-			120832									~~77~~		~~290~~		
31	Dichloropropane 1,2-			78875									~~0.50~~		~~15~~		
32	Dichloropropene 1,3-			542756									~~0.34~~		~~21~~		
111	Dieldrin			60571	0.24				0.71 O	X	0.0019 O	X	~~0.000052~~		~~0.000054~~		
79	DiethylPhthalate			84662									~~17000~~		~~44000~~		
47	Dimethylphenol 2,4-			105679									~~380~~		~~850~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	Water + Organism [B]	Effective	Organism only [B]	Effective	Drinking Water M.C.L.
80	DimethylPhthalate			131113									270000		1100000		
81	Di-n-Butyl Phthalate			84742									2000		4500		
49	Dinitrophenol 2,4-			51285									69		5300		
27 N	Dinitrophenols			2555058 7									69		5300		
82	Dinitrotoluene 2,4-			121142									0.11		3.4		
83	Dinitrotoluene 2,6-			606202													
84	Di-n-Octyl Phthalate			117840													
16	Dioxin (2,3,7,8-TCDD)			1746016									5.0E-09		5.1E-09		
85	Diphenylhydrazine 1,2-			122667									0.036		0.20		
68	EthylhexylPhthalate Bis2-			117817									1.2		2.2		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
	Endosulfan				0.22 I,P	X	0.056 I,P	X	0.034 I,P	X	0.0087 I,P	X	~~62 I~~		~~89 I~~		
112	Endosulfan alpha-			959988	0.22 O		0.056 O		0.034 O		0.0087 O		~~62~~		~~89~~		
113	Endosulfan beta-			33213659	0.22 O		0.056 O		0.034 O		0.0087 O		~~62~~		~~89~~		
114	Endosulfan Sulfate			1031078									~~62~~		~~89~~		
115	Endrin			72208	0.086				0.037 O		0.0023 O		~~0.059~~		~~0.060~~		~~0.0002 mg~~
116	Endrin Aldehyde			7421934									~~0.29~~		~~0.30~~		
33	Ethylbenzene			100414									~~530~~		~~2100~~		
86	Fluoranthene			206440													
87	Fluorene			86737									~~1100~~		~~5300~~		
17N	Guthion			86500			0.01	X			0.01	X					

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
117	Heptachlor			76448	0.52 O	X	0.0038 O	X	0.053 O	X	0.0036 O	X	~~0.00007 9~~		~~0.00007 9~~		
118	Heptachlor Epoxide			1024573	0.52 O		0.0038 O		0.053 O		0.0036 O		~~0.00003 9~~		~~0.00003 9~~		
88	Hexachlorobenzene			118741									~~0.00028~~		~~0.00029~~		
89	Hexachlorobutadiene			87683									~~0.44~~		~~18~~		
91	Hexachloroethane			67721									~~1.4~~		~~3.3~~		
19 N	Hexachlorocyclo-hexane-Technical			319868									~~0.0123 J~~		~~0.0414 J~~		
90	Hexachlorocyclopentadiene			77474									~~40~~		~~1100~~		
92	Ideno1,2,3-(cd)Pyrene			193395									~~0.0038~~		~~0.018~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only[B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
20 N	Iron			7439896			1,000	X									
93	Isophorone			78591									~~35~~		~~960~~		
7	Lead			7439921													~~0.05mg~~
21 N	Malathion			121755			0.1	X			0.1	X					
22 N	Manganese			7439965													
8a	Mercury			7439976	2.4	X	0.012	X	2.1	X	0.025	X					~~0.002mg~~
23 N	Methoxychlor			72435			0.03	X			0.03	X	~~100 J~~				~~0.1mg~~
34	Methyl Bromide			74839									~~47~~		~~1500~~		
35	Methyl Chloride			74873													
48	Methyl-4,6-Dinitrophenol 2-			534521									~~13~~		~~280~~		
52	Methyl-4-Chlorophenol 3-			59507													
36	Methylene Chloride			75092									~~4.6~~		~~590~~		
8b	Methylmercury			22967926											~~300ug/kg L~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
24 N	Mirex			2385855			0.001	X			0.001	X					
94	Naphthalene			91203													
9	Nickel			7440020													
25 N	Nitrates			14797558									~~10000 J~~				~~10mg~~
95	Nitrobenzene			98953									~~17~~		~~690~~		
50	Nitrophenol 2-			88755													
51	Nitrophenol 4-			100027													
26 N	Nitrosamines			35576911									~~0.0008 J~~		~~1.24 J~~		
28 N	Nitrosodibutylamine,N			924163									~~0.0063~~		~~0.22~~		
29 N	Nitrosodiethylamine,N			55185									~~0.0008 J~~		~~1.24 J~~		
96	N-Nitrosodimethylamine			62759									~~0.00069~~		~~3.0~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	Water + Organism [B]	Effective	Organism only [B]	Effective	Drinking Water M.C.L.
98	N-Nitrosodiphenylamine			86306									3.3		6.0		
30 N	Nitrosopyrrolidine,N			930552									0.016		34		
97	N-Nitrosodi-n-Propylamine			621647									0.0050		0.51		
32 N	Oxygen, Dissolved			7782447													
33 N	Parathion			56382	0.065	X	0.013	X									
119	Polychlorinated Biphenyls PCBs:			1336363	2 U	X	0.014 U	X	10 U	X	0.03 U	X	0.000064 U		0.000064 U		
34 N	Pentachlorobenzene			608935									1.4		1.5		
53	Pentachlorophenol			87865	M				13		7.9		0.27		3.0		
99	Phenanthrene			85018													
54	Phenol			108952											1700000		
36 N	Phosphorus Elemental			7723140							0.1						

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
100	Pyrene			129000									~~830~~		~~4000~~		
10	Selenium			7782492											~~4200~~		~~0.01mg~~
11	Silver			7440224													~~0.05mg~~
40 N	Sulfide-Hydrogen Sulfide			7783064			2	X			2	X					
43 N	Tetrachlorobenzene,1,2,4,5			95943									~~0.97~~		~~1.1~~		
37	Tetrachloroethane 1,1,2,2-			79345									~~0.17~~		~~4.0~~		
38	Tetrachloroethylene			127184									~~0.69~~		~~3.3~~		
12	Thallium			7440280									~~0.24~~		~~0.47~~		
39	Toluene			108883									~~1300~~		~~15000~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
120	Toxaphene			8001352	0.73	X	0.0002	X	0.21	X	0.0002	X	~~0.00028~~		~~0.00028~~		~~0.005mg~~
40	Trans-Dichloroethylene 1,2-			156605									~~140~~		~~10000~~		
44 N	Tributyltin (TBT)			688733													
101	Trichlorobenzene 1,2,4-			120821									~~35~~		~~70~~		
41	Trichloroethane 1,1,1-			71556													
42	Trichloroethane 1,1,2-			79005									~~0.59~~		~~16~~		
43	Trichloroethylene			79016									~~2.5~~		~~30~~		
45 N	Trichlorophenol 2,4,5			95954									~~1800~~		~~3600~~		
55	Trichlorophenol 2,4,6-			88062											~~2.4~~		
44	Vinyl Chloride			75014									~~0.025~~		~~2.4~~		
13	Zinc			7440666									~~7400~~		~~26000~~		

Footnotes for Tables 33A and 33B:

A Values in Table 20 are applicable to all basins.

~~B Human Health criteria values were calculated using a fish consumption rate of 17.5 grams per day (0.6 ounces/day) unless otherwise noted.~~

C Ammonia criteria for freshwater may depend on pH, temperature, and the presence of salmonids or other fish with ammonia-sensitive early life stages. Values for freshwater criteria (of total ammonia nitrogen in mg N/L) can be calculated using the formulae specified in *1999 Update of Ambient Water Quality Criteria for Ammonia* (EPA-822-R-99-014; http://www.epa.gov/ost/standards/ammonia/99update.pdf):

Freshwater Acute:

salmonids present….CMC = $\frac{0.275}{1+10^{7.204-pH}}+\frac{39.0}{1+10^{pH-7.204}}$

salmonids not present…CMC= $\frac{0.411}{1+10^{7.204-pH}}+\frac{58.4}{1+10^{pH-7.204}}$

Freshwater Chronic:

fish early life stages present

CCC = $\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}$ * $MIN(2.85, 1.45*10^{0.028*(25-T)})$

fish early life stages not present

CCC= $\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}$ * $1.45*10^{0.028*(25-MAX(T,7))}$

Note: these chronic criteria formulae would be applied to calculate the 30-day average concentration limit; in addition, the highest 4-day average within the 30-day period should not exceed 2.5 times the CCC.

D Ammonia criteria for saltwater may depend on pH and temperature. Values for saltwater criteria (total ammonia) can be calculated from the tables specified in *Ambient Water Quality Criteria for Ammonia (Saltwater)--1989* (EPA 440/5-88-004; http://www.epa.gov/ost/pc/ambientwqc/ammoniasalt1989.pdf).

E Freshwater and saltwater criteria for metals are expressed in terms of "dissolved" concentrations in the water column, except where otherwise noted (e.g. aluminum).

F The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

$$CMC = (\exp(m_A*[\ln(hardness)] + b_A))*CF$$

$$CCC = (\exp(m_C*[\ln(hardness)] + b_C))*CF$$

where CF is the conversion factor used for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column.

Chemical	m_A	b_A	m_C	b_C
Cadmium	1.0166	-3.924	0.7409	-4.719
Chromium III	0.8190	3.7256	0.8190	0.6848
Copper	0.9422	-1.700	0.8545	-1.702
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	-6.59		
Zinc	0.8473	0.884	0.8473	0.884

Conversion factors (CF) for dissolved metals (the values for total recoverable metals criteria were multiplied by the appropriate conversion factors shown below to calculate the dissolved metals criteria):

Chemical	Freshwater		Saltwater	
	Acute	Chronic	Acute	Chronic
Arsenic	1.000	1.000	1.000	1.000
Cadmium	1.136672-[(ln hardness)(0.041838)]	1.101672-[(ln hardness)(0.041838)]	0.994	0.994
Chromium III	0.316	0.860	--	--
Chromium VI	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	1.46203-[(ln hardness)(0.145712)]	1.46203-[(ln hardness)(0.145712)]	0.951	0.951
Nickel	0.998	0.997	0.990	0.990
Selenium	0.996	0.922	0.998	0.998
Silver	0.85	0.85	0.85	--
Zinc	0.978	0.986	0.946	0.946

~~G Human Health criterion is the same as originally published in the 1976 EPA Red Book (Quality Criteria for Water, EPA-440/9-76-023) which predates the 1980 methodology and did not use the fish ingestion BCF approach.~~

~~H This value is based on a Drinking Water regulation.~~

I This value is based on criterion published in Ambient Water Quality Criteria for Endosulfan (EPA 440/5-80-046) and should be applied as the sum of alpha- and beta-endosulfan.

~~J No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.~~

~~K Human Health criterion is for "dissolved" concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic.~~

~~L This value is expressed as the fish tissue concentration of methylmercury.~~

M Freshwater aquatic life values for pentachlorophenol are expressed as a function of pH, and are calculated as follows: CMC=(exp(1.005(pH)-4.869); CCC=exp(1.005(pH)-5.134).

N This number was assigned to the list of non-priority pollutants in National Recommended Water Quality Criteria: 2002 (EPA-822-R-02-047).

O This criterion is based on EPA recommendations issued in 1980 that were derived using guidelines that differed from EPA's 1985 Guidelines for minimum data requirements and derivation procedures. For example, a "CMC" derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

P Criterion shown is the minimum (i.e. CCC in water should not be below this value in order to protect aquatic life).

Q Criterion is applied as total arsenic (i.e. arsenic (III) + arsenic (V)).

R Arsenic criterion refers to the inorganic form only.

S This criterion is expressed as µg free cyanide (CN)/L.

T This criterion applies to DDT and its metabolites (i.e. the total concentration of DDT and its metabolites should not exceed this value).

U This criterion applies to total PCBs (e.g. the sum of all congener or all isomer or homolog or Arochlor analyses).

V The CMC=1/[(f1/CMC1)+(f2/CMC2)] where f1 and f2 are the fractions of total selenium that are treated as selenite and selenate, respectively, and CMC1 and CMC2 are 185.9 µg/L and 12.82 µg/L, respectively.

W The acute and chronic criteria for aluminum are 750 µg/L and 87 µg/L, respectively. These values for aluminum are expressed in terms of "total recoverable" concentration of metal in the water column. The criterion applies at pH<6.6 and hardness<12 mg/L (as $CaCO_3$).

X The effective date for the criterion in the column immediately to the left is 1991.

Y No criterion.

Appendix C. Table 33B Redline/Strikethrough

TABLE 33B

Note: The Environmental Quality Commission adopted the following criteria on May 20, 2004 to become effective on EPA approval. EPA has not yet (as of June 2006) approved these criteria. The Table 33B criteria may not be used until they are approved by EPA.

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[A]

The concentration for each compound listed in Table 33A is a criterion not to be exceeded in waters of the state in order to protect aquatic life ~~and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding EPA number (from National Recommended Water Quality Criteria: 2002, EPA-822-R-02-047), the Chemical Abstract Service (CAS) number, aquatic life freshwater acute and chronic criteria, aquatic life saltwater acute and chronic criteria, ~~human health water & organism and organism only criteria~~, and Drinking Water Maximum Contaminant Level (MCL). The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	
2 N	Aluminum (pH 6.5 - 9.0)			7429905	W		W										
3 N	Ammonia			7664417	C		C										
2	Arsenic			7440382									~~0.018 R~~		~~0.14 R~~		
15	Asbestos			1332214									~~7.0E+06 fibers/Liter~~				

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	
19	Benzene			71432									~~2.2~~		~~51~~		
3	Beryllium			7440417									~~¥~~		~~¥~~		
105	BHC gamma- (Lindane)			58899									~~0.98~~		~~1.8~~		
4	Cadmium			7440439	E,F		E,F		40 E		8.8 E		~~¥~~				
107	Chlordane			57749									~~0.00080~~		~~0.00081~~		
	CHLORINATED BENZENES												~~¥~~		~~¥~~		
26	Chloroform			67663									~~5.7~~		~~470~~		
67	ChloroisopropylEther Bis2-			108601									~~1400~~		~~65000~~		
15 N	ChloromethylEther, Bis			542881									~~0.00010~~				
5a	Chromium (III)				E,F		E,F						~~¥~~				
5b	Chromium (VI)			18540299	16 E		11 E						~~¥~~		~~¥~~		
6	Copper			7440508	E,F		E,F		4.8 E		3.1 E						
108	DDT 4,4'-			50293									~~0.00022~~		~~0.00022~~		
	DIBUTYLPHTHALATE												~~¥~~		~~¥~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	Water + Organism [B]	Effective	Organism only [B]	Effective	
	DICHLOROBENZENES												¥		¥		
	DICHLOROBENZIDINE												¥		¥		
	DICHLOROETHYLENES												¥		¥		
	DICHLOROPROPENE												¥		¥		
111	Dieldrin			60571			0.056										
	DINITROTOLUENE												¥		¥		
	DIPHENYLHYDRAZINE												¥		¥		
115	Endrin			72208			0.036										
86	Fluoranthene			206440									130		140		
	HALOMETHANES												¥		¥		
20 N	Iron			7439896									300 K				
7	Lead			7439921	E,F		E,F		210 E		8.1 E		¥				
22 N	Manganese			7439965									50 K		100 K		
8a	Mercury			7439976									¥		¥		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				Human Health For Consumption of:				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	Water + Organism [B]	Effective	Organism only [B]	Effective	
	MONOCHLOROBENZENE												¥		¥		
9	Nickel			7440020	E,F		E,F		74 E		8.2 E		610		4600		
53	Pentachlorophenol			87865			M										
54	Phenol			108952									21000				
	POLYNUCLEAR AROMATIC HYRDOCARBONS												¥		¥		
10	Selenium			7782492	E,V		5 E		290 E		71 E		170				
11	Silver			7440224	E,F,P		0.10 E		1.9 E,P				¥				
44 N	Tributyltin (TBT)			688733	0.46		0.063		0.37		0.01						
41	Trichloroethane 1,1,1-			71556									¥		¥		
55	Trichlorophenol 2,4,6-			88062									1.4				
13	Zinc			7440666	E,F		E,F		90 E		81 E						

Footnotes for Tables 33A and 33B:

A Values in Table 20 are applicable to all basins.

~~B Human Health criteria values were calculated using a fish consumption rate of 17.5 grams per day (0.6 ounces/day) unless otherwise noted.~~

C Ammonia criteria for freshwater may depend on pH, temperature, and the presence of salmonids or other fish with ammonia-sensitive early life stages. Values for freshwater criteria (of total ammonia nitrogen in mg N/L) can be calculated using the formulae specified in *1999 Update of Ambient Water Quality Criteria for Ammonia* (EPA-822-R-99-014; http://www.epa.gov/ost/standards/ammonia/99update.pdf):

Freshwater Acute:

salmonids present….CMC = $\frac{0.275}{1+10^{7.204-pH}}+\frac{39.0}{1+10^{pH-7.204}}$

salmonids not present…CMC= $\frac{0.411}{1+10^{7.204-pH}}+\frac{58.4}{1+10^{pH-7.204}}$

Freshwater Chronic:

fish early life stages present

CCC = $\left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right)*MIN(2.85, 1.45*10^{0.028*(25-T)})$

fish early life stages not present

CCC= $\left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right)*1.45*10^{0.028*(25-MAX(T,7))}$

Note: these chronic criteria formulae would be applied to calculate the 30-day average concentration limit; in addition, the highest 4-day average within the 30-day period should not exceed 2.5 times the CCC.

D Ammonia criteria for saltwater may depend on pH and temperature. Values for saltwater criteria (total ammonia) can be calculated from the tables specified in *Ambient Water Quality Criteria for Ammonia (Saltwater)--1989* (EPA 440/5-88-004; http://www.epa.gov/ost/pc/ambientwqc/ammoniasalt1989.pdf).

E Freshwater and saltwater criteria for metals are expressed in terms of "dissolved" concentrations in the water column, except where otherwise noted (e.g. aluminum).

F The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

$$CMC = (\exp(m_A*[\ln(hardness)] + b_A))*CF$$

$$CCC = (\exp(m_C*[\ln(hardness)] + b_C))*CF$$

where CF is the conversion factor used for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column.

Chemical	**m_A**	**b_A**	**m_C**	**b_C**
Cadmium	1.0166	-3.924	0.7409	-4.719
Chromium III	0.8190	3.7256	0.8190	0.6848
Copper	0.9422	-1.700	0.8545	-1.702
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	-6.59		
Zinc	0.8473	0.884	0.8473	0.884

Conversion factors (CF) for dissolved metals (the values for total recoverable metals criteria were multiplied by the appropriate conversion factors shown below to calculate the dissolved metals criteria):

Chemical	Freshwater		Saltwater	
	Acute	Chronic	Acute	Chronic
Arsenic	1.000	1.000	1.000	1.000
Cadmium	1.136672-[(ln hardness)(0.041838)]	1.101672-[(ln hardness)(0.041838)]	0.994	0.994
Chromium III	0.316	0.860	--	--
Chromium VI	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	1.46203-[(ln hardness)(0.145712)]	1.46203-[(ln hardness)(0.145712)]	0.951	0.951
Nickel	0.998	0.997	0.990	0.990
Selenium	0.996	0.922	0.998	0.998
Silver	0.85	0.85	0.85	--
Zinc	0.978	0.986	0.946	0.946

~~G Human Health criterion is the same as originally published in the 1976 EPA Red Book (Quality Criteria for Water, EPA-440/9-76-023) which predates the 1980 methodology and did not use the fish ingestion BCF approach.~~

~~H This value is based on a Drinking Water regulation.~~

I This value is based on criterion published in Ambient Water Quality Criteria for Endosulfan (EPA 440/5-80-046) and should be applied as the sum of alpha- and beta-endosulfan.

~~J No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.~~

~~K Human Health criterion is for "dissolved" concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic.~~

~~L This value is expressed as the fish tissue concentration of methylmercury.~~

M Freshwater aquatic life values for pentachlorophenol are expressed as a function of pH, and are calculated as follows: CMC=(exp(1.005(pH)-4.869); CCC=exp(1.005(pH)-5.134).

N This number was assigned to the list of non-priority pollutants in National Recommended Water Quality Criteria: 2002 (EPA-822-R-02-047).

O This criterion is based on EPA recommendations issued in 1980 that were derived using guidelines that differed from EPA's 1985 Guidelines for minimum data requirements and derivation procedures. For example, a "CMC" derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

P Criterion shown is the minimum (i.e. CCC in water should not be below this value in order to protect aquatic life).

Q Criterion is applied as total arsenic (i.e. arsenic (III) + arsenic (V)).

R Arsenic criterion refers to the inorganic form only.

S This criterion is expressed as µg free cyanide (CN)/L.

T This criterion applies to DDT and its metabolites (i.e. the total concentration of DDT and its metabolites should not exceed this value).

U This criterion applies to total PCBs (e.g. the sum of all congener or all isomer or homolog or Arochlor analyses).

V The CMC=1/[(f1/CMC1)+(f2/CMC2)] where f1 and f2 are the fractions of total selenium that are treated as selenite and selenate, respectively, and CMC1 and CMC2 are 185.9 µg/L and 12.82 µg/L, respectively.

W The acute and chronic criteria for aluminum are 750 µg/L and 87 µg/L, respectively. These values for aluminum are expressed in terms of "total recoverable" concentration of metal in the water column. The criterion applies at pH<6.6 and hardness<12 mg/L (as $CaCO_3$).

X The effective date for the criterion in the column immediately to the left is 1991.

Y No criterion.

Appendix D. Crosswalk Between Effective Human Health Criteria and Proposed Criteria

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
ACENAPTHENE	Y	N	--	--	95	99
ACROLEIN	Y	N	320	780	0.88	0.93
ACRYLONITRILE	Y	Y	0.058	0.65	0.018	0.025
ALDRIN	Y	Y	0.000074	0.000079	0.0000050	0.0000050
ANTHRACENE	N	N	--	--	2900	4000
ANTIMONY	Y	N	146	45,000	5.1	64
ARSENIC	Y	Y	2.1	2.1 (freshwater) 1.0 (saltwater)	2.1	2.1 (freshwater) 1.0 (saltwater)
ASBESTOS	Y	Y	7,000,000 fibers/L	--	7,000,000 fibers/L	--
BARIUM	N	N	1000	--	1000	--
BENZENE	N	Y	0.66	40	0.44	1.4
BENZIDINE	N	Y	0.00012	0.00053	0.000018	0.000020

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
BENZ(A) ANTHRACENE	N	Y	--	--	0.0013	0.0018
BENZO(A)PYRENE	N	Y	--	--	0.0013	0.0018
BENZO(B)FLUORANTHENE 3,4	N	Y	--	--	0.0013	0.0018
BENZO(K)FLUORANTHENE	N	Y	--	--	0.0013	0.0018
BROMOFORM	N	Y	--	--	3.3	14
BUTYLBENZYL PHTHALATE	N	N	--	--	190	190
CARBON TETRACHLORIDE	Y	Y	0.4	6.94	0.10	0.16
CHLORDANE	Y	Y	0.00046	0.00048	0.000081	0.000081
CHLORINATED BENZENES [CHLOROBENZENE]	Y	Y	488	--	74	160
CHLORODIBROMOMETHANE	N	Y	--	--	0.31	1.3
CHLOROETHYL ETHER (BIS-2)	Y	Y	0.03	1.36	0.020	0.05
CHLOROFORM	Y	Y	0.19	15.7	260	1100
CHLOROISOPROPYL ETHER (BIS-2)	Y	N	34.7	4360	1200	6500
CHLOROMETHYL ETHER (BIS)	N	Y	0.00000376	0.00184	0.000024	0.000029

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
CHLORONAPHTHALENE 2	N	N	--	--	150	160
CHLOROPHENOL 2	Y	N	--	--	14	15
CHLOROPHENOXY HERBICIDES (2,4,5,-TP)	N	N	10	--	10	--
CHLOROPHENOXY HERBICIDES (2,4-D)	N	N	100	--	100	--
CHRYSENE	N	Y	--	--	0.0013	0.0018
COPPER	Y	N	1300	--	1300	--
CYANIDE	Y	N	200	--	130	130
DDT [DDT 4,4']	Y	Y	0.000024	0.000024	0.000022	0.000022
DDD 4, 4'	Y	Y	--	--	0.000031	0.000031
DDE 4, 4'	Y	Y	--	--	0.000022	0.000022
DIBENZO(A,H)ANTHRACENE	N	Y	--	--	0.0013	0.0018
DIBUTYLPHTHALATE [DI-N-BUTYL PHTHALATE]	Y	N	35,000	154,000	400	450

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
DICHLOROBENZENES [DICHLOROBENZENE(O)1,2]	Y	N	400	2,600	110	130
DICHLOROBENZENE(P) 1,4	N	N	--	--	16	19
DICHLOROBENZIDINE [DICHLOROBENZIDINE 3,3']	Y	Y	0.01	0.020	0.0027	0.0028
DICHLOROBROMOMETHANE	N	Y	--	--	0.42	1.7
DICHLOROETHANE 1,2	Y	Y	0.94	243	0.35	3.7
DICHLOROETHYLENES [DICHLOROETHYLENE 1,1]	Y	Y	0.033	1.85	230	710
DICHLOROETHYLENE TRANS 1,2	N	N	--	--	120	1000
DICHLOROPHENOL 2,4	N	N	3,090	--	23	29
DICHLOROPROPANE [DICHLOROPROPANE 1,2]	Y	N	--	--	0.38	1.5
DICHLOROPROPENE [DICHLOROPROPENE 1,3]	Y	N	87	14,100	0.30	2.1
DIELDRIN	Y	Y	0.000071	0.000076	0.0000053	0.0000054

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
DIETHYLPHTHALATE	Y	N	350,000	1,800,000	3800	4400
DIMETHYL PHENOL 2,4	Y	N	--	--	76	85
DIMETHYL PHTHALATE	Y	N	313,000	2,900,000	84,000	110,000
DINITROPHENOL 2,4	Y	N	--	--	62	530
DINITROPHENOLS	Y	N	--	--	62	530
DINITROTOLUENE 2,4	N	Y	0.11	9.1	0.084	0.34
DINITROTOLUENE	Y	N	70	14,300	No criteria	No criteria
DINITRO-O-CRESOL 2,4	Y	N	13.4	765	No criteria	No criteria
DIOXIN (2,3,7,8-TCDD)	Y	Y	0.000000013	0.000000014	0.00000000051	0.00000000051
DIPHENYLHYDRAZINE	Y	N	0.042	0.56	No criteria	No criteria
DIPHENYLHYDRAZINE 1,2	Y	N	--	--	0.014	0.02
DI-2-ETHYLHEXYL PHTHALATE [BIS-2-ETHYLHEXYL PHTHALATE]	Y	N	15,000	50,000	0.20	0.22
ENDOSULFAN	Y	N	74	159	--	--
ENDOSULFAN ALPHA	Y	N	--	--	8.5	8.9

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
ENDOSULFAN BETA	Y	N	--	--	8.5	8.9
ENDOSULFAN SULFATE	Y	N	--	--	8.5	8.9
ENDRIN	Y	N	1	--	0.024	0.024
ENDRIN ALDEHYDE	Y	N	--	--	0.03	0.03
ETHYLBENZENE	Y	N	1,400	3,280	160	210
FLUORANTHENE	Y	N	42	54	14	14
FLUORENE	Y	N	--	--	390	530
HALOMETHANES	Y	Y	0.19	15.7	No criteria	No criteria
HEPTACHLOR	Y	Y	0.00028	0.00029	0.0000079	0.0000079
HEPTACHLOR EPOXIDE	Y	Y	--	--	0.0000039	0.0000039
HEXACHLOROETHANE	N	Y	1.9	8.74	0.29	0.33
HEXACHLOROBENZENE	Y	N	0.00072	0.00074	0.000029	0.000029
HEXACHLOROBUTADIENE	Y	Y	0.45	50	0.36	1.8

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
HEXACHLOROCYCLOHEXANE-ALPHA [BHC ALPHA]	Y	Y	0.0092	0.031	0.00045	0.00049
HEXACHLOROCYCLOHEXANE-BETA [BHC BETA]	Y	Y	0.0163	0.0547	0.0016	0.0017
HEXACHLOROCYCLOHEXANE-GAMA [BHC GAMMA (LINDANE)]	Y	Y	0.0186	0.0625	0.17	0.18
HEXACHLOROCYCLOHEXANE-TECHNICAL	Y	Y	0.0123	0.0414	0.0014	0.0015
HEXACHLOROCYCLOPENTADIENE	Y	N	206	--	30	110
INDENO(1,2,3-CD)PYRENE	Y	Y	--	--	0.0013	0.0018
ISOPHORONE	Y	N	5,200	520,000	27	96
MANGANESE	N	N	--	100	--	100
METHOXYCHLOR	N	N	100	--	100	--
METHYL BROMIDE	Y	N	--	--	37	150

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
METHYL-4,6-DINITROPHENOL 2	Y	N	--	--	9.2	28
METHYLENE CHLORIDE	Y	Y	--	--	4.3	59
METHYLMERCURY (MG/KG)	Y	N	--	--	--	0.040
MONOCHLOROBENZENE	Y	N	488	--	No criteria	No criteria
NICKEL	Y	N	13.4	100	140	170
NITRATES	N	N	10,000	--	10,000	--
NITROBENZENE	Y	N	19,800	--	14	69
NITROSAMINES	Y	Y	0.0008	1.24	0.00079	0.046
NITROSODIBUTYLAMINE N	Y	Y	0.0064	0.587	0.0050	0.02
NITROSODIETHYLAMINE N	Y	Y	0.0008	1.24	0.00079	0.046
NITROSODIMETHYLAMINE N	Y	Y	0.0014	16	0.00068	0.30
NITROSODI-N-PROPYLAMINE, N	Y	Y	--	--	0.0046	0.051
NITROSODIPHENYLAMINE N	Y	Y	4.9	16.1	0.55	0.60
NITROSOPYRROLIDINE N	Y	Y	0.016	91.9	0.016	3.4

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
PCBS	Y	Y	0.000079	0.000079	0.0000064	0.0000064
PENTACHLOROBENZENE	N	N	74	85	0.15	0.15
PENTACHLOROPHENOL	Y	N	1,010	--	0.15	0.30
PHENOL	Y	N	3,500	--	9,400	86,000
POLYNUCLEAR AROMATIC HYDROCARBONS	Y	Y	0.0028	0.0311	No criteria	No criteria
PYRENE	Y	N	--	--	290	400
SELENIUM	Y	N	10	--	120	420
TETRACHLOROBENZENE 1,2,4,5	Y	N	38	48	0.11	0.11
TETRACHLOROETHANE 1,1,2,2	Y	Y	0.17	10.7	0.12	0.40
TETRACHLOROETHYLENE	Y	Y	0.8	8.85	0.24	0.33
THALLIUM	Y	N	13	48	0.043	0.047
TOLUENE	Y	N	14,300	424,000	720	1500
TOXAPHENE	Y	Y	0.00071	0.00073	0.000028	0.000028
TRICHLOROBENZENE 1,2,4	Y	N	--	--	6.4	7.0

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
TRICHLOROETHANE 1,1,2	Y	Y	0.6	41.8	0.44	1.6
TRICHLOROETHYLENE	Y	Y	2.7	80.7	1.4	3.0
TRICHLOROPHENOL 2,4,5	N	N	2,600	--	330	360
TRICHLOROPHENOL 2,4,6	Y	Y	1.2	3.6	0.23	0.24
VINYL CHLORIDE	Y	Y	2	525	0.02	0.24
ZINC	Y	N	--	--	2100	2600

Appendix E. TABLE 40: Human Health Water Quality Criteria for Toxic Pollutants

DRAFT

Human Health Criteria Summary

The concentration for each pollutant listed in Table 40 was derived to protect Oregonians from potential adverse health impacts associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water. The "organism only" criteria are established to protect fish and shellfish consumption and apply to waters of the state designated for fishing. The "water + organism" criteria are established to protect the consumption of drinking water, fish, and shellfish, and apply where both fishing and domestic water supply (public and private) are designated uses. All criteria are expressed as micrograms per liter (µg/L), unless otherwise noted. Pollutants are listed in alphabetical order. Additional information includes the Chemical Abstract Service (CAS) number, whether the criterion is based on carcinogenic effects (can cause cancer in humans), and whether there is an aquatic life criterion for the pollutant (i.e. "y"= yes, "n" = no). All the human health criteria were calculated using a fish consumption rate of 175 grams per day unless otherwise noted. A fish consumption rate of 175 grams per day is approximately equal to 23 8-ounce fish meals per month. For pollutants categorized as carcinogens, values represent a cancer risk of one additional case of cancer in one million people (i.e. 10^{-6}), unless otherwise noted. All metals criteria are for total metal concentration, unless otherwise noted. Italicized pollutants represent non-priority pollutants. The human health criteria revisions established by OAR 340-041-0033 and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of:	
					Water + Organism (µg/L)	Organism Only (µg/L)
1	Acenaphthene	83329	n	n	95	99
2	Acrolein	107028	n	n	0.88	0.93
3	Acrylonitrile	107131	y	n	0.018	0.025
4	Aldrin	309002	y	y	0.0000050	0.0000050
5	Anthracene	120127	n	n	2900	4000
6	Antimony	7440360	n	n	5.1	64
7	Arsenic (inorganic)[A]	7440382	y	n	2.1	2.1(freshwater) 1.0 (saltwater)
	[A] The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately of 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1 x 10^{-4}					
8	Asbestos[B]	1332214	y	n	7,000,000 fibers/L	--
	[B] The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
9	*Barium*[C]	7440393	n	n	1000	--
	[C] The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
10	Benzene	71432	y	n	0.44	1.4
11	Benzidine	92875	y	n	0.000018	0.000020
12	Benz(a)anthracene	56553	y	n	0.0013	0.0018
13	Benzo(a)pyrene	50328	y	n	0.0013	0.0018
14	Benzo(b)fluoranthene 3,4	205992	y	n	0.0013	0.0018
15	Benzo(k)fluoranthene	207089	y	n	0.0013	0.0018
16	BHC Alpha	319846	y	n	0.00045	0.00049
17	BHC Beta	319857	y	n	0.0016	0.0017
18	BHC Gamma (Lindane)	58899	n	y	0.17	0.18
19	Bromoform	75252	y	n	3.3	14
20	Butylbenzyl Phthalate	85687	n	n	190	190
21	Carbon Tetrachloride	56235	y	n	0.10	0.16
22	Chlordane	57749	y	y	0.000081	0.000081
23	Chlorobenzene	108907	n	n	74	160
24	Chlorodibromomethane	124481	y	n	0.31	1.3
25	Chloroethyl Ether bis 2	111444	y	n	0.020	0.05
26	Chloroform	67663	n	n	260	1100
27	Chloroisopropyl Ether bis 2	108601	n	n	1200	6500
28	*Chloromethyl ether, bis*	542881	y	n	0.000024	0.000029
29	Chloronaphthalene 2	91587	n	n	150	160
30	Chlorophenol 2	95578	n	n	14	15
31	*Chlorophenoxy Herbicide (2,4,5,-TP)*[D]	93721	n	n	10	--
	[D] The Chlorophenoxy Herbicide (2,4,5,-TP) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established					

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of:	
					Water + Organism (µg/L)	Organism Only (µg/L)
	under the Safe Drinking Water Act.					
32	*Chlorophenoxy Herbicide (2,4-D)* [E]	94757	n	n	100	--
	[E] *The Chlorophenoxy Herbicide (2,4-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*					
33	Chrysene	218019	y	n	0.0013	0.0018
34	Copper [F]	7440508	n	y	1300	--
	[F] *Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*					
35	Cyanide [G]	57125	n	y	130	130
	[G] *The cyanide criterion is expressed as total cyanide (CN)/L.*					
36	DDD 4,4'	72548	y	n	0.000031	0.000031
37	DDE 4,4'	72559	y	n	0.000022	0.000022
38	DDT 4,4'	50293	y	y	0.000022	0.000022
39	Dibenz(a,h)anthracene	53703	y	n	0.0013	0.0018
40	Dichlorobenzene(m) 1,3	541731	n	n	80	96
41	Dichlorobenzene(o) 1,2	95501	n	n	110	130
42	Dichlorobenzene(p) 1,4	106467	n	n	16	19
43	Dichlorobenzidine 3,3'	91941	y	n	0.0027	0.0028
44	Dichlorobromomethane	75274	y	n	0.42	1.7
45	Dichloroethane 1,2	107062	y	n	0.35	3.7
46	Dichloroethylene 1,1	75354	n	n	230	710
47	Dichloroethylene trans 1,2	156605	n	n	120	1000
48	Dichlorophenol 2,4	120832	n	n	23	29
49	Dichloropropane 1,2	78875	y	n	0.38	1.5
50	Dichloropropene 1,3	542756	y	n	0.30	2.1
51	Dieldrin	60571	y	y	0.0000053	0.0000054
52	Diethyl Phthalate	84662	n	n	3800	4400
53	Dimethyl Phthalate	131113	n	n	84000	110000
54	Dimethylphenol 2,4	105679	n	n	76	85
55	Di-n-butyl Phthalate	84742	n	n	400	450
56	Dinitrophenol 2,4	51285	n	n	62	530
57	*Dinitrophenols*	25550587	n	n	62	530
58	Dinitrotoluene 2,4	121142	y	n	0.084	0.34
59	Dioxin (2,3,7,8-TCDD)	1746016	y	n	0.00000000051	0.00000000051
60	Diphenylhydrazine 1,2	122667	y	n	0.014	0.020
61	Endosulfan Alpha	959988	n	y	8.5	8.9
62	Endosulfan Beta	33213659	n	y	8.5	8.9
63	Endosulfan Sulfate	1031078	n	n	8.5	8.9
64	Endrin	72208	n	y	0.024	0.024
65	Endrin Aldehyde	7421934	n	n	0.030	0.030

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of:	
					Water + Organism (µg/L)	Organism Only (µg/L)
66	Ethylbenzene	100414	n	n	160	210
67	Ethylhexyl Phthalate bis 2	117817	y	n	0.20	0.22
68	Fluoranthene	206440	n	n	14	14
69	Fluorene	86737	n	n	390	530
70	Heptachlor	76448	y	y	0.0000079	0.0000079
71	Heptachlor Epoxide	1024573	y	y	0.0000039	0.0000039
72	Hexachlorobenzene	118741	y	n	0.000029	0.000029
73	Hexachlorobutadiene	87683	y	n	0.36	1.8
74	*Hexachlorocyclo-hexane-Technical*	608731	y	n	0.0014	0.0015
75	Hexachlorocyclopentadiene	77474	n	n	30	110
76	Hexachloroethane	67721	y	n	0.29	0.33
77	Indeno(1,2,3-cd)pyrene	193395	y	n	0.0013	0.0018
78	Isophorone	78591	y	n	27	96
79	*Manganese* [H]	7439965	n	n	--	100
	[H] *The "fish consumption only" criterion for manganese applies only to salt water and is for total manganese. This EPA recommended criterion predates the 1980 human health methodology and does not utilize the fish ingestion BCF calculation method or a fish consumption rate.*					
80	*Methoxychlor* [I]	72435	n	y	100	--
	[I] *The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*					
81	Methyl Bromide	74839	n	n	37	150
82	Methyl-4,6-dinitrophenol 2	534521	n	n	9.2	28
83	Methylene Chloride	75092	y	n	4.3	59
84	Methylmercury (mg/kg) [J]	22967926	n	n	--	0.040 mg/kg
	[J] *This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury*					
85	Nickel	7440020	n	n	140	170
86	*Nitrates* [K]	14797558	n	n	10000	--
	[K] *The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*					
87	Nitrobenzene	98953	n	n	14	69
88	*Nitrosamines*	35576911	y	n	0.00079	0.046
89	*Nitrosodibutylamine, N*	924163	y	n	0.0050	0.022
90	*Nitrosodiethylamine, N*	55185	y	n	0.00079	0.046
91	Nitrosodimethylamine, N	62759	y	n	0.00068	0.30
92	Nitrosodi-n-propylamine, N	621647	y	n	0.0046	0.051
93	Nitrosodiphenylamine, N	86306	y	n	0.55	0.60
94	*Nitrosopyrrolidine, N*	930552	y	n	0.016	3.4
95	*Pentachlorobenzene*	608935	n	n	0.15	0.15
96	Pentachlorophenol	87865	y	y	0.15	0.30

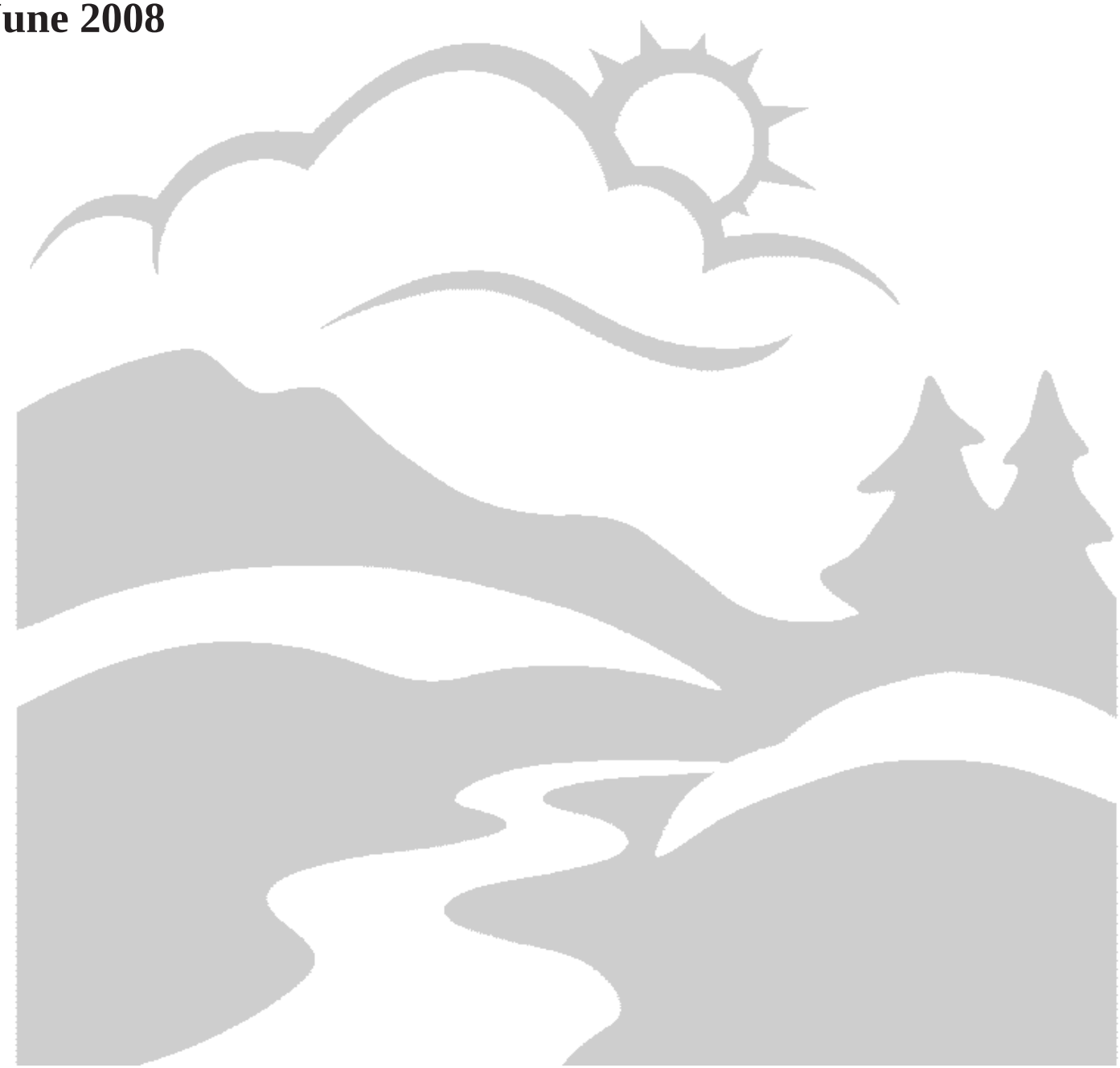
No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	*Human Health Criteria for the Consumption of:*	
					Water + Organism (µg/L)	Organism Only (µg/L)
97	Phenol	108952	n	n	9400	86000
98	Polychlorinated Biphenyls (PCBs)[L]	NA	y	y	0.0000064	0.0000064
	[L] *This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).*					
99	Pyrene	129000	n	n	290	400
100	Selenium	7782492	n	n	120	420
101	*Tetrachlorobenzene, 1,2,4,5-*	95943	n	n	0.11	0.11
102	Tetrachloroethane 1,1,2,2	79345	y	n	0.12	0.40
103	Tetrachloroethylene	127184	y	n	0.24	0.33
104	Thallium	7440280	n	n	0.043	0.047
105	Toluene	108883	n	n	720	1500
106	Toxaphene	8001352	y	y	0.000028	0.000028
107	Trichlorobenzene 1,2,4	120821	n	n	6.4	7.0
108	Trichloroethane 1,1,2	79005	y	y	0.44	1.6
109	Trichloroethylene	79016	y	n	1.4	3.0
110	Trichlorophenol 2,4,6	88062	y	n	0.23	0.24
111	*Trichlorophenol, 2, 4, 5-*	95954	n	n	330	360
112	Vinyl Chloride	75014	y	n	0.023	0.24
113	Zinc	7440666	n	n	2100	2600

DEQ Water Quality Division - Standards and Assessments

State of Oregon
Department of
Environmental
Quality

Human Health Focus Group Report
Oregon Fish and Shellfish Consumption Rate Project

June 2008



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Questions or comments about this document should be directed to:

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This document can be found on the Department's web site at:

(http://www.deq.state.or.us/wq/standards/fishfocus.htm)

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TABLE OF CONTENTS

APPENDICES

LIST OF TABLES

1. INTRODUCTION

Oregon has over 110,000 miles of rivers and streams, more than 6,000 lakes and ponds, and 362 miles of coastal waters (ODEQ 2000). These waters support fish and shellfish species that are consumed by a broad range of Oregonians. Potentially toxic chemicals are found in some Oregon waters (ODEQ 2008). Over time, fish and shellfish may accumulate these pollutants, resulting in a potential risk to the health of people who consume them. The magnitude of health risks depends on the amount of fish or shellfish consumed, the level of contamination in the fish and shellfish, and a person's susceptibility to a particular contaminant. The Oregon Department of Human Services (ODHS) has issued numerous fish advisories throughout the state's rivers and reservoirs (ODHS 2007) to protect the health of people who may consume contaminated fish.

For purposes of its regulatory programs, the Oregon Department of Environmental Quality (ODEQ) is responsible for establishing the level of human health protection for Oregonians who consume fish and shellfish from state water bodies. In order to provide adequate protection for Oregonians, ODEQ needs to accurately assess how much fish Oregonians consume and adopt an appropriate fish consumption rate. This fish consumption rate is used with other factors such as chemical toxicity to develop human health-based water quality criteria. These criteria are codified into Oregon law as human health water quality standards (OAR 340-41). These human health water quality standards are used in ODEQ's regulatory programs to establish water quality permit limits, etc.

The purpose of this report is to document the discussion and conclusions of the Human Health Focus Group. The Human Health Focus Group includes Pacific Northwest scientists who were convened to advise the Oregon Fish and Shellfish Consumption Rate Project on technical issues surrounding the selection of fish consumption rates in Oregon. The Fish Consumption Rate Project is a collaborative effort of ODEQ, the U.S. Environmental Protection Agency (EPA), and the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). The purpose of this collaborative effort is to revise ODEQ's current fish consumption rate of 17.5 grams per day (g/day). In addition to the three cooperating agencies the Fish Consumption Rate Project includes a Core Team of about 40 individuals and organizations that are either directly affected by or interested in the outcome of this project.

The Human Health Focus Group members are regional experts with experience in the areas of toxicology, risk assessment, public health, biostatistics, and/or epidemiology. The members of the Human Health Focus Group were selected from nominations received from the Fish Consumption Rate Project's Core Team as well as ODEQ, EPA, and CTUIR. A total of 26 nominations were received and the six members were selected by ODEQ, EPA, and the CTUIR.

1.1 MEMBERS OF THE HUMAN HEALTH FOCUS GROUP

- Patricia Cirone, PhD, Retired Federal Scientist – Affiliate of University of Washington

- Elaine M. Faustman, Ph.D. DABT, Professor and Director, Institute for Risk Analysis and Risk Communication – Department of Environmental and Occupational Health Sciences, University of Washington

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1.2 OBJECTIVES FOR THE HUMAN HEALTH FOCUS GROUP

In their advisory role to the Fish Consumption Rate Project, the Human Health Focus Group was asked to address the following three questions:

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?
2) How should salmon be considered in selecting a fish consumption rate and/or setting criteria?
3) To what extent are populations who consume more than the current fish consumption rate of 17.5 g/day at a greater risk for adverse health impacts?

The Human Health Focus Group was asked to review the available scientific evidence that would inform the Fish Consumption Rate Project. The scientific evidence was gathered from existing literature and the expertise of the Human Health Focus Group. Many different fish consumption rate studies are available in the literature. The Human Health Focus Group chose a subset of relevant studies to assess more comprehensively as well as provide a manageable summary of information.

The Human Health Focus Group was asked to provide a range of fish consumption rates that the group deems to be credible and representative of various Oregon fish-consuming populations. The Oregon Environmental Quality Commission, ODEQ's governing body, is responsible for choosing a fish consumption rate(s), or alternatively, a range of consumption rates. This risk management decision will specifically consider the people that will be protected by the human health-based water quality criteria (e.g. the general population, tribal populations, children and other sensitive populations), and what percentage of those populations to protect. The Environmental Quality Commission will be responsible for considering whether to include Pacific salmon in the rate, if there should be a single statewide fish consumption rate or various rates for different regions, and how revised human health criteria will be implemented. Overall, the Fish Consumption Rate Project encompasses a complicated mix of science and policy considerations.

The discussion and conclusions presented in this report were generated in one year (May 2007 – May 2008), a relatively short time considering the scope of the questions addressed. This report should be used in conjunction with the wide range of literature on fish consumption data that already exists. Some of this literature can be found in the report's cited references (Chapter VIII), and in the attached bibliography of related literature sources (Chapter IX). This report is not a comprehensive review of all fish consumption surveys. It is a focused review of the fish consumption surveys most relevant to fish consumers in Oregon, a review which was subject to the time constraints of the overall Fish Consumption Rate Project schedule. EPA ambient water quality criteria guidance (USEPA 2000a) recommends that "states use regional or local consumption studies and consumption rates to adequately protect the most highly exposed population when developing state water quality criteria". Other relevant national and world studies on fish consumption patterns were also reviewed by the Human Health Focus Group members during this process, but time constraints prevented in-depth analysis of all of these studies. Additionally, this report represents a brief review and recommendations for how Pacific salmon should be considered in selecting a fish consumption rate, but does not provide a comprehensive review of the life histories or potential sources of contamination for Pacific salmon.

This report is a summary of the Human Health Focus Group discussions, recommendations, and conclusions for each of the three questions posed by ODEQ, EPA, and CTUIR. There are seven chapters in this report. The historical and regulatory background regarding selection of a fish consumption rate(s) for human health-based water quality criteria in Oregon are described in Chapter 2. The results and discussion of the Human Health Focus Group's review of fish consumption surveys relevant to Oregon are presented in Chapter 3. The Human Health Focus Group's discussion of the inclusion of Pacific salmon in the fish consumption rate is given in Chapter 4. The rationale and recommendations of the Human Health Focus Group for fish consumption rate(s) for Oregon are described in Chapter 5. A brief description of human health risk assessment and its application to human health-based water quality criteria is presented in Chapter 6. Finally, the conclusions and recommendations of the Human Health Focus Group for the Fish Consumption Rate Project are presented in Chapter 7.

Detailed Human Health Focus Group meeting minutes and information on the Human Health Focus Group meeting schedule can be obtained from ODEQ or online at (http://www.deq.state.or.us/wq/standards/fishfocus.htm)

2. BACKGROUND

Water quality standards are the foundation of ODEQ's water quality program and influence a variety of other programs within ODEQ. Standards are established to protect the designated uses of Oregon waters, such as fishing, swimming, irrigation, drinking water, and industrial use. Water quality standards consist of three basic elements: 1) designated uses; 2) numeric and narrative water quality criteria; and 3) an anti-degradation policy. In order to restore and maintain the chemical, physical and biological integrity of Oregon waters, ODEQ works with a wide range of public and private entities to administer the regulatory programs of the Clean Water Act (CWA) that are based on water quality standards.

Water quality criteria can be both numeric and narrative and are derived for the protection of aquatic life and human health. Both aquatic life and human health criteria are used to assess water quality monitoring data and identify impaired waters, establish waste load allocations for Total Maximum Daily Loads (TMDLs), evaluate projects seeking a CWA Section 401 water quality certification, control non-point source pollution, establish cleanup targets at hazardous waste sites, and establish permit limits through the National Pollution Discharge Elimination System water quality permits. Any change in water quality criteria would affect all ODEQ programs using those criteria.

The Fish Consumption Rate Project is focused on reviewing and revising the fish consumption rate, which is one variable used to calculate human health-based water quality criteria. These criteria are intended to protect the quality of state waters so that fish and shellfish can be consumed by all Oregonians without unacceptable risk to human health. All of Oregon's waters (except the Bull Run River[1]) are designated for fishing, which makes the importance of protecting those waters relevant to all Oregonians.

Oregon's water quality standards (beneficial uses and criteria) are adopted by the Oregon Environmental Quality Commission through an administrative rule development process. The Fish Consumption Rate Project will provide fish consumption rates that will be used to establish water quality criteria for protection of human health. The application of human health-based water quality criteria in the CWA regulatory programs mentioned previously occurs in all waters of the state. According to Oregon Administrative Rule (OAR) 340-041-0001, *"Waters of the State" means lakes, bays, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Pacific Ocean within the territorial limits of the State of Oregon, and all other bodies of surface or underground waters, natural or artificial, inland or coastal, fresh or salt, public or private (except those private waters that do not combine or effect a junction with natural surface or underground waters) that are located wholly or partially within or bordering the state or within its jurisdiction.*

EPA's nationally recommended fish consumption rates are based on data from United States Department of Agriculture's (USDA) 1994-1996, 1998 Continuing Survey of Food Intake by Individuals (CSFII) and reported in USEPA 2002b.

Implementing and enforcing human health-based water quality criteria in waters of the state will only have an effect on those fish and shellfish species residing in and exposed to those waters. Thus, the selection of a fish consumption rate to be used in Oregon human health-based water quality criteria may only include those fish and shellfish species directly influenced by waters of the state. The territorial limits of Oregon extend three nautical miles from shore into the Pacific Ocean.

Oregon's current numeric human health criteria are based on EPA's 2002 recommended CWA Section 304(a) water quality criteria (USEPA 2002a). EPA derived these criteria by considering

[1] The Bull Run River is located inside a watershed that is closed to public access and is therefore not accessible for fishing.

the known toxicity of the regulated chemicals and the likely exposure people have to these chemicals. These criteria are based on a specific set of variables for estimating exposure including fish consumption rate and human body weight. EPA's current recommended CWA Section 304(a) human health-based water quality criteria are calculated using the national fish consumption rate of 17.5 g/day (USEPA 2000a). This nationally recommended rate is roughly equivalent to two, eight-ounce fish meals per month. This rate represents the 90th percentile of all people (fish consumers and non-consumers) who were interviewed from across United States.

ODEQ is considering which fish consumption rates are most appropriate to use in calculating water quality criteria that are protective of human health. These criteria will apply to Oregon waters and will be implemented through CWA regulatory programs such as National Pollution Discharge Elimination System water quality permits, water quality assessments, and Total Maximum Daily Loads. ODEQ is considering raising the fish consumption rate in part because a local study shows that the Columbia River Tribes (CRITFC 1994) eat substantially more fish than the current EPA default rate of 17.5 g/day (USEPA 2000a). EPA, in an August 15, 2005 letter to the Environmental Quality Commission (ODEQ's rulemaking body), suggested that, "Current information indicates that a fish consumption rate in the range of 105 to 113 g/day may be appropriate for some waters in Oregon, Washington, and Idaho including a number of reaches of the Columbia River (based on studies prepared by EPA and the Columbia River Inter-Tribal Fish Commission)" (Kreizenbeck 2005). Other studies identified in this report demonstrate the existence of other high-volume fish consumers in Oregon, in the United States generally and in the world. An increase in the fish consumption rate in Oregon would result in more stringent human health-based water quality criteria.

Until 2003, Oregon's water quality standards were based on a fish consumption rate of 6.5 g/day, consistent with EPA's default fish consumption rate (USEPA 2000a). EPA increased its recommended rates to a nationally-based per capita default level of 17.5 g/day while urging states to rely on local consumption data wherever possible (USEPA 2000a).

From 1999 to 2003, two separate teams reviewed Oregon's water quality standards and considered potential revisions: the ODEQ's Technical Advisory Committee (TAC) and the Policy Advisory Committee (PAC). When reviewing the appropriate fish consumption rates to calculate the human health-based criteria, the TAC proposed a tiered approach for the Oregon criteria:

1) EPA's (USEPA 2000a) default fish consumption rate (17.5 g/day) for low intensity fish consumption,
2) EPA's (USEPA 2000a) recommended subsistence fish consumption rate (142.4 g/day), for medium intensity fish consumption
3) The ninety-ninth percentile of the Columbia River Basin Tribal fish consumption rates (389 g/day, from CRITFC 1994) for high intensity fish consumption.

The PAC, upon reviewing the TAC's recommendations, had concerns about how this tiered system would be implemented, and could not come to consensus on what the appropriate fish consumption rate should be for calculating the human health-based water quality criteria.

Subsequently, ODEQ recommended to the Environmental Quality Commission that it adopt EPA's 2002 recommended CWA Section 304(a) water quality criteria for toxic pollutants, including the human health criteria (USEPA 2002a), with a few exceptions. The Environmental Quality Commission adopted these criteria, and the revised water quality criteria were submitted to the EPA on July 8, 2004 for its review and approval.

The CWA directs EPA to review and either approve or disapprove water quality standards submitted by states and authorized tribes (40CFR Part 131.5). EPA has not yet taken any action on Oregon's revised human health-based water quality criteria that were submitted on July 8, 2004, but has recommended that Oregon consider adopting a rate of 105-113 g/day for some waters in Oregon in order to be more protective of people who eat fish (Kreizenbeck 2005).

3. EVALUATION OF FISH CONSUMPTION SURVEYS

3.1 FISH CONSUMPTION SURVEYS REVIEWED

The purpose of the Human Health Focus Group review of fish consumption surveys was to establish a body of literature that documents the range of fish consumption rates practiced by fish consuming groups in the Pacific Northwest; and from which Oregon can choose a fish consumption rate.

With the help of ODEQ and EPA, the Human Health Focus Group compiled a list of national and international surveys for review. National and international studies (Table 1, located at the end of this document) demonstrate that there are a wide range of populations with diverse cultures, traditions, and practices that result in a very broad range of fish consumption patterns. This variability can be expected in any population of statewide scale and in some cases, similar variability can be seen in much smaller populations.

3.1.1 SELECTION OF RELEVANT FISH CONSUMPTION SURVEYS

Current EPA (USEPA 2000a) ambient water quality criteria guidance for adopting state fish consumption rates recommends the use of local and regional fish consumption data first, the use of national studies second, and recommends reliance on EPA default rates only if no specific regional data are available.

The Human Health Focus Group established an informal set of procedures for determining which surveys were the most relevant for Oregon and the most useful for estimating fish consumption rates. These procedures included but were not limited to the following considerations:

1) Survey design,
2) Survey questionnaire,
3) Population surveyed,
4) Statistical analysis, and
5) Type of fish and shellfish consumed

Of the national and international studies listed in Table 1, eight regional surveys and one national fish consumption survey reviewed by the Human Health Focus Group were found to be relevant for developing fish consumption rate(s) for Oregon Water Quality Criteria. With this guidance

and Oregon's population in mind, nine fish consumption surveys (Table 1) were chosen for detailed review. A survey was determined relevant if the people surveyed were from Oregon or their fish consumption patterns are what one might expect from the people of Oregon.

The nine relevant surveys are:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- Fish Consumption, Nutrition, and Potential Exposure to Contaminants Among Columbia River Basin Tribes. – A Masters thesis by Neil A. Sun Rhodes, Oregon Heath Sciences University (Rhodes 2006)
- Columbia Slough and Sauvie Island Fish Consumption Survey, Technical Memorandum on the Results of the 1995 Fish Consumption and Recreational Use Surveys, Amendment No. 1 (Adolfson Associates 1996)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Lake Whatcom Residential and Angler Fish Consumption Survey (WDOH 2001)
- Consumption Patterns of Anglers Who Frequently Fish Lake Roosevelt (WDOH 1997)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b)

3.1.2 Selection of Surveys Most Useful for Recommending Fish Consumption Rates

In this review, a survey was determined useful if the quantitative results can be relied upon as good estimates of fish consumption rates for the population surveyed. Of the nine fish consumption surveys considered to be relevant by the Human Health Focus Group, the following five surveys were determined to have the most useful data for estimating quantitative fish consumption rates:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b)

Four of the original nine studies were eliminated for further consideration for various reasons. The Lake Whatcom, Lake Roosevelt, Sauvie Island and the Columbia Slough are good studies, but the reported values in each of these studies were not adequate for calculating accurate fish consumption rates. The re-evaluation of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribal (CRITFC 1994) data by Rhodes did not provide any new quantitative data that would change the results of the original survey of the Columbia River Basin Tribes (CRITFC 1994).

3.1.3 RESULTS OF REVIEW OF NINE SURVEYS

The result of the Human Health Focus Group's evaluation of the nine surveys is provided in the following section.

A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN (CRITFC 1994)

Relevance

The survey of Columbia River Basin Tribes (CRITFC 1994) is regarded as the study most relevant to Oregon fish consumers. The Confederated Tribes of the Umatilla Indian Reservation and the Warm Springs Tribe, two of the four tribes surveyed, are both located in Oregon, which makes the survey a direct measure of an Oregon population. The Yakama Tribe (Washington) and Nez Perce Tribe (Idaho) both fish in parts of the Columbia River Basin in Oregon

The survey reported that 97 percent of the people interviewed eat fish. Other surveys reviewed by the Human Health Focus Group demonstrated that Asian and Pacific Islanders and Eastern European communities also consume fish at levels similar to Oregon Tribes.

The fish species consumed by Columbia Basin Tribes (CRITFC 1994), either spend their entire life in Oregon waters or part of their life in Oregon waters (Appendix A-1). The fish reported as consumed in this survey include trout, northern pike-minnow, sturgeon, suckers, walleye, and whitefish. The study also reported consumption of Pacific salmon, steelhead, lamprey, shad, smelt, and sturgeon. This is significant because all of these fish are affected by the quality of Oregon waters for all or part of their life cycle. Furthermore, 88 percent of the fish consumed by the Columbia Basin River Tribes originated from the Columbia River Basin (CRITFC 1994).

No consumption of any shellfish or open ocean finfish species was reported. The questionnaire used in the interviews did not include specific questions about marine species or shellfish. Since these questions were not asked in the interview, it is not clear how this may have affected the fish consumption rates reported by the Columbia River Tribes. Since the people of Oregon are likely to eat coastal marine seafood, the Columbia River Tribal data may not be relevant with respect to the marine and shellfish consumption patterns of Oregonians.

In summary, with the exception of the marine fish and shellfish component, the survey of Columbia River Basin Tribes (CRITFC 1994) is relevant to Oregon fish consumers because it offers a reliable and direct measurement of fish consumption by an Oregon population.

Utility

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study was peer-reviewed and represented a random selection of 513 adult survey participants ages 18 and older from four Columbia River Basin Tribes (CRITFC 1994). Survey participants also provided information for 204 children ages five and younger from adult participant's households. The adult participants were interviewed by trained tribal representatives and asked to report 24-hour recall, weekly, monthly, seasonal, and 20-year average fish intake. The weekly estimates of fish consumption and data on serving size

were used to determine the grams per day of fish consumed by each respondent. The survey's overall average and distributed rate of consumption were calculated from the individual rates. The survey did not include body weights for individual participants. This did not affect the overall usefulness of these data, since most consumption patterns are based on a measurement of grams per person per day. However, the accuracy of this measurement for individuals is reduced.

Although the raw data were not available for re-analysis, there was good documentation of the summary statistics conducted. The highest fish consumption rates were not categorized using any statistical methods, but rather considered "unreasonably high" and not included in the statistical analysis.

FISH CONSUMPTION, NUTRITION, AND POTENTIAL EXPOSURE TO CONTAMINANTS AMONG COLUMBIA RIVER BASIN TRIBES (RHODES 2006)

Relevance

This study is a re-evaluation of the original survey of the Columbia River Basin Tribes by CRITFC (1994). Thus it is relevant for developing a fish consumption rate for Oregon. There are no changes (no corrections) in the rate of consumption for the Columbia River Basin Tribes.

Utility

This report provides additional multivariate analysis on the correlation between fish consumption rates and factors including breast feeding after most recent births, percent of fish obtained non-commercially for women who recently gave birth, living off the reservation, and fish consumption rates for children and the elderly. This re-evaluation resulted in no changes or corrections to the consumption rates presented in the original Columbia River Basin Tribal survey (CRITFC 1994). Therefore, the data reported in this survey, were not included in the Human Health Focus Group's deliberations.

COLUMBIA SLOUGH AND SAUVIE ISLAND FISH CONSUMPTION SURVEY, TECHNICAL MEMORANDUM ON THE RESULTS OF THE 1995 FISH CONSUMPTION AND RECREATIONAL USE SURVEYS, AMENDMENT NO. 1 (ADOLFSON ASSOCIATES 1996)

Relevance

This study is regarded as being relevant to fish consumers in Oregon as it provides a description of the race, ethnicity, age and gender of the people fishing and the types of fish species caught and consumed in the Portland, Oregon metropolitan area. The study also provides information on various methods of fish preparation by local populations, other fishing frequencies and local fishing locations.

Utility

The data reported in this creel survey are not useful for quantitative assessment of fish consumption rates but provide regional information of subsistence fishers in the Portland metropolitan area. This study was conducted primarily on land and one day on water for 20 randomly selected days over a one month period. Both the days and times selected to conduct the survey utilized a stratified random sampling methodology. The survey team was trained and

multi-lingual. A total of 91 interviews were conducted in the Columbia Slough and 55 interviews on Sauvie Island. The species, weight and length of the fish caught on the day of the interview was reported in addition the number of people consuming the catch. This survey has significant limitations for calculating individual fish consumption rates.

The quantitative fish consumption rates were limited by the inconsistencies in how individuals reported their fish consumption. The survey interviewers noted that individuals had difficulties in reporting the quantity of fish they consumed. Additionally, only fish weighed by the surveyors were counted in consumption estimates and of those fish, only 30 percent of the total weight of fish was regarded as edible despite the preparation method reported by the individual. Finally, if the participant reported that other people in the household ate fish, the individual consumption was simply divided by the number of people and individual portion size was disregarded. Overall, there was not sufficient information to calculate reliable fish consumption estimates.

A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION (TOY ET AL. 1996)

Relevance

The Tulalip and Squaxin Island Tribes survey is regarded as being relevant to Oregon fish-consuming populations; although some of the fish and shellfish they consumed may not be found in Oregon waters (Appendix A-2). Oregon does not have a marine body of water comparable to the size and complexity of Puget Sound, which is the fishing ground for the Tulalip and Squaxin Island Tribes. Places in Oregon such as Coos, Tillamook, and Nehalem Bays may provide a proportionally smaller habitat for comparable finfish and shellfish species that are found in Puget Sound. The life histories or habitat classifications of finfish or shellfish species were not included in the report, although they did identify those species that are found in Puget Sound.

Toy *et al.* (1996) states, "if the fish consumption rates in this report are to be used to represent fish consumption in other tribal populations, information should be collected about their species consumption, preparation methods and other relevant factors". The origin of fish consumed in the Tulalip and Squaxin Island Tribes survey was divided into five categories: a) those caught in Puget Sound, b) those caught outside Puget Sound, c) those eaten in restaurants, d) those purchased from grocery stores, and e) other. Anadromous fish (e.g. Pacific salmon) were the most heavily consumed fish group, of which 72-80 percent was caught in Puget Sound. Seventy-five percent of the shellfish consumed came from Puget Sound. Less than 50 percent of the open ocean fish (e.g. cod, Pollock) consumed by The Tulalip and Squaxin Island Tribes were collected from the Puget Sound.

The rates in this report are specifically relevant to Oregon fish-consuming populations, especially the coastal communities. Since the results are comparable to the fish consumption rates of members of the Columbia River Basin Tribes (CRITFC 1994), it demonstrates a simple relationship between tribal fish-consuming populations in the Pacific Northwest: people eat what's available to them and what's culturally preferred. Additionally, there are patterns of high consumption rates in Pacific Northwest Tribes regardless of species consumed or origin of the fish.

Utility

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represented a random selection of 190 adult survey participants from the Tulalip and Squaxin Island Tribes in Washington State. Additionally, survey participants provided information on 69 children of age six years and younger. The participants were interviewed by trained tribal representatives and asked to report on the number of fish meals eaten per day, per week, per month or per year over a one-year period and the portion size of each meal. Individual consumption rates were calculated using the portion size reported and the frequency of consumption, which depended upon how the participant reported it (daily, weekly, monthly, yearly). Any participant that did not eat any fish at all (non-consumer) was not included in the survey or data analysis since the survey objective was to ascertain the consumption rates of people who did eat fish.

The participants also reported their own body weight, which allowed for the calculation of consumption rates in grams per kilogram per day (g/kg/day). Including human body weights enhances the accuracy of estimating risk to any given individual. This study presented varied and useful analyses and summary statistics. There were a number of large consumption rates reported for this study. These high rates were considered outliers (an observation that is numerically distant from the rest of the data). The outliers were re-coded "…to the largest reported consumption rate within three standard deviations of the arithmetic mean" (Toy *et al.* 1996). Toy *et al.* 1996 acknowledged that, when calculating central tendencies, there is the potential that excluding outliers in such a manner may add bias in studies specially designed to examine variation and range of fish consumption and such biases would underestimate true fish consumption.

FISH CONSUMPTION SURVEY OF THE SUQUAMISH INDIAN TRIBE OF THE PORT MADISON INDIAN RESERVATION, PUGET SOUND REGION (SUQUAMISH 2000)

Relevance

The Suquamish Tribe survey is regarded as being relevant to Oregon fish-consuming populations. The type of fish caught in Puget Sound varies from those found in Oregon waters (Appendix A-3). While there is not a one hundred percent correlation between Puget Sound and Oregon waters this limitation does not affect the relevance of this study to Oregon populations.

The origin of fish consumed was divided into five categories: a) those caught in Puget Sound, b) those caught outside Puget Sound, c) those eaten in restaurants, d) those purchased from grocery stores, and e) other. The most heavily consumed fish groups in this survey were Pacific salmon (including steelhead) and shellfish. For both of these groups, 80-90 percent of the fish or shellfish consumed was harvested, of which the vast majority was harvested in Puget Sound. All other fish groups exhibited much lower harvest rates (less than 50 percent) and had higher percentages of restaurant or grocery origin. These data show that for certain groups of fish (Pacific salmon and shellfish) the local (Puget Sound) harvest comprises the vast majority of fish consumed.

This study of the Suquamish Tribe follows the same methodology within the same basin (Puget Sound) as the study of the Tulalip and Squaxin Island Tribes. Thus, the rates in this report are specifically relevant to Oregon fish-consuming populations, especially the coastal communities.

Utility

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represents a random selection of 92 adult survey participants from the Suquamish Tribe. Additionally, survey participants provided information on 31 children ages six years and younger. The participants were interviewed by trained tribal representatives and asked to report on the number of fish meals eaten per day, per week, per month or per year over a one-year period and the portion size of each meal. Individual consumption rates were calculated using the portion size reported and the frequency of consumption, which depended on how the participant reported it (daily, weekly, monthly, yearly). All 92 survey respondents reported eating some type of fish which meant there were no "non-consumers" among the respondents. The participants also reported respondent body weight, which allowed for the calculation of consumption rates in g/kg/day. Including body weight enhances the accuracy of estimating risk to any given individual or population. Good summary statistics were presented in the report with useful and varied analyses of the data. The analysis did not exclude any data.

The Suquamish staff chose to include high consumption rates because they were familiar with the individuals eating those large quantities and that the consumption rates reported were likely to reflect real consumption (Suquamish 2000). With no adjustments made for the high consumption rates, it was noted that the reported means may be highly influenced by the consumption of just a few individuals.

ASIAN AND PACIFIC ISLANDER SEAFOOD CONSUMPTION STUDY (SECHENA ET AL. 1999)

Relevance

The Asian and Pacific Islander survey is regarded as being relevant to Oregon fish-consuming populations (with some limitations), as there were a significant number of marine finfish and shellfish species consumed by people interviewed in this study that may or may not be found in certain Oregon waters (see Appendix A-4).

The origin of fish consumed was divided into four categories: a) those harvested in King County, b) those caught outside King County, c) those eaten in restaurants, and d) those purchased from grocery stores or street vendors. The most heavily consumed fish group in this survey was shellfish. For all fish groups, 79-97 percent of the seafood consumed came from either groceries/street vendors or restaurants. Seafood known to be harvested locally comprised from three percent to twenty-one percent of their diet. These data show that the vast majority of fish and shellfish consumed by Asian and Pacific Islanders is obtained through groceries/street vendors and restaurants.

The rates in this report are potentially relevant to Oregon fish-consuming populations such as the Asian and Pacific Islander communities in Oregon. The vast majority of seafood consumed was purchased, but it is not known what proportion of purchased fish was locally caught. Despite

this limitation, the study is still relevant to the Asian and Pacific Islanders of Oregon as an indicator of their fish consumption patterns.

Utility

The data on fish consumption rates reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represented a selection of 202 adult survey participants from 10 different ethnic communities that comprise the Asian and Pacific Islander community of King County, Washington. The participants were interviewed by trained representatives from each of the ethnic communities represented and asked to report on the number of annual servings and the portion size of the servings. Individual consumption rates were calculated using the portion size reported multiplied by the number of annual servings and then divided by 365 days times the respondent's body weight. Any participant that did not eat any fish was not included in the survey or data analysis since the survey objective was to ascertain the consumption rates of people who did eat fish.

The participants also reported their own body weights, which allowed for the calculation of consumption rates in g/kg/day. Including human body weights enhances the accuracy of estimating risk to any given individual or population.

Summary statistics were presented in the report with useful and varied analyses of the data. The authors (Sechena *et al*. 1999) reported that there were an usually large number of high fish consumption rates. The values that were identified as outliers were those observed values greater than three standard deviations above the mean. These outliers were then given a smaller value equal to the mean plus three standard deviations.

CONSUMPTION PATTERNS OF ANGLERS WHO FREQUENTLY FISH LAKE ROOSEVELT (WDOH 1997)

Relevance

This survey is regarded as being relevant to Oregon fish consumers. The populations surveyed in this study are likely to exist on a comparable lake in Oregon. The species reported in the survey included kokanee, rainbow trout, walleye and bass. Some or all of these species are likely to be found in Oregon lakes as well. Survey participates were primarily vacationing boat anglers returning from fishing trips. No tribal members were surveyed.

Utility

The data reported in this survey are not useful for quantitative assessment of fish consumption rates. This survey was conducted to determine the consumption patterns of anglers who repeatedly fish in Lake Roosevelt. Creel and fish consumption surveys were conducted at boat launches with people returning from their fishing trips at randomly selected locations. The survey was pilot tested and administered by creel clerks over a four to five month period during 1994 and 1995. The survey protocol was slightly altered from one year to the next to collect more accurate and meaningful consumption data. A total of 448 interviews were conducted. Anglers who did not consume fish (total of 57) were not included in the data analysis. Data collected showed that 84 percent of all respondents were members of two adult households.

The fish consumption rates derived from this survey were not useful because of inconsistencies in how the consumption information was reported. Although the frequency of consumption was obtained, there were difficulties in obtaining the portion size consumed at each meal, which led to further difficulties in calculating individual consumption rates. Therefore, actual consumption rates were not reported, but frequency of consumption and number of fillets eaten per meal was reported.

LAKE WHATCOM RESIDENTIAL AND ANGLER FISH CONSUMPTION SURVEY (WDOH 2001)

Relevance

This survey is regarded as being relevant to Oregon fish consumers as populations similar to those surveyed in this study are likely to exist on a comparable lake in Oregon. The species reported in the survey included smallmouth bass, yellow perch, kokanee, cutthroat trout, and signal crayfish. Some or all of these species are likely to be found in Oregon lakes as well. The source of the fish consumed was Lake Whatcom. There was no indication through the survey protocol if those interviewed consumed harvested fish from any other lake, river, or bay. There was, however, a question about the consumption of canned tuna fish since the study was driven originally by concerns of mercury exposure. Nineteen of the 242 respondents consumed tuna an average of 4.2 times over the previous four weeks. This fact may indicate that these respondents are frequent "fish eaters" and may supplement their diets with fish from other sources such as restaurants or grocers stores.

Utility

This study was designed to collect fish consumption information from residents who live on or near the lake or in developments with direct access to the lake, boat anglers accessing the lake at public boat launch facilities, and shore anglers. Although, the data reported in this survey are not useful for quantitative assessment of fish consumption rates, the study provides some information on types of fish collected and eaten, even in the presence of fish advisories. Only average meal sizes were calculated, and an accurate frequency of meals per week or month was not clearly presented. Due to elevated mercury levels in some fish species reported in a screening survey from Lake Whatcom, Washington, fishing was already influenced by perceived contamination as reported in local media. This study also gathered information regarding the respondents' perceptions and likely reactions to a fish consumption advisory. There were trained interviewers who went door-to-door at randomly selected residencies and approached anglers during specified times on the boat launches and the shore. There interviewees included residents (194), boat anglers (38), and shore anglers (10).

The participants were asked to report on how many times over the previous four weeks they had eaten fish from Lake Whatcom, how many fish were eaten per meal, and how many months per year they consumed Lake Whatcom fish. They were also asked to report typical meal size based on a picture of a Pacific salmon fillet. Fish consumption rates were calculated using the number of reported fish eaten per meal multiplied by the average fillet weight of that species, which was obtained from a previous Lake Whatcom fish sampling effort.

The fish consumption rates from this survey were not useful because of inconsistencies on how the interviewees reported their fish consumption. The four-week recall diet limited the ability to

fully quantify fish consumption due to the low number of people that consumed fish during that period. Although some limitations exist for the data, they do provide an indication of the amount of fish consumed exclusively from Lake Whatcom, Washington following the media coverage of potential contamination issues.

ESTIMATED PER CAPITA FISH CONSUMPTION IN THE UNITED STATES (USEPA 2002B

Relevance

This large national study is relevant to Oregon and provides context upon which specific, regional data can be based. The methodology used to conduct the survey and analyze the data is useful for analyzing fish consumption trends of the U.S. population via per-capita consumption rates. The study does not report state-specific fish consumer survey results from Oregon alone but was designed as a national study.

There was a wide variety of fish consumed in this survey, some of which may be found in Oregon waters.

Utility

The EPA national estimates of fish consumption (USEPA 2002b) are considered useful for the purposes of establishing water quality criteria for Oregon. The EPA national estimates (USEPA 2002b) were based on combined data from the USDA 1994-1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII). The survey of 20,607 people (adults and children) was well designed to be statistically representative of the overall per-capita consumption rates of the U.S. population. The 24-hour dietary recall was administered by an interviewer and was conducted on two non-consecutive days. Data collection from these surveys spanned a period of four years. For this national survey individuals were interviewed in-person on their food intake on two non-consecutive days. Advantages of the survey methodology are that is that it is statistically representative of all 50 states, it has a good design for per-capita consumption estimates, the interviewer administration enhances its accuracy, and it was administered on non-consecutive days, which avoids correlated consumption data.

Because of the extraordinarily large survey population and the fact that individuals were chosen to statistically represent overall US populations this data set provides a valuable context for Pacific Northwest surveys.

Short-term data collection (two day - 24 hour recall) may not be representative of long-term consumption rates that have been averaged over time. However, since large numbers (20,607) of individuals were included in the EPA estimated per capita survey (USEPA 2002b and the survey includes more than one time period and season, there is a greater likelihood of capturing the distribution of consumption rates when compared to smaller surveys.

Since the goal of the USDA CSFII surveys was to represent the diet of all people (per capita) in the United States, the data included people who eat fish (consumers) and those who don't eat fish (non-consumers). Including non-consumer data in a fish consumption rate can result in misleadingly low fish consumption rates. In addition to reporting the per capita fish

consumption rates, EPA (2002) considered it appropriate to report the data for consumers only as well as the combined consumer and non-consumer data.

The Human Health Focus Group agreed that exposure assessments and the evaluation of potential risks to fish consumers must consider the consumption rates appropriate for actual consumers. Thus, EPA (USEPA 2002b) "consumer-only" data were examined for their usefulness. The statistical certainty of the USDA CSII Study was quite high because of the large number of participants (20,607). This certainty is reduced when "consumer-only" data for only adults are extracted because of the decrease in the number of people from 20,607 to 2,585. However, the Human Health Focus Group considered these rates to be useful for Oregon with the acknowledgement of decrease in statistical certainty.

3.1.4 General Discussion of Fish Consumption Survey Methodologies

The survey methodologies in the studies reviewed by the Human Health Focus Group include interview questionnaire (CRITFC 1994, Toy *et al.* 1996, Suquamish 2000, Sechena *et al.* 1999, dietary recall (USEPA 2002b) and creel surveys (Adolfson 1996, WDOH 1997, WDOH 2001). Each of these methodologies has individual advantages and disadvantages.

Fish consumption surveys are designed to estimate the fish consumption patterns of a target population. A number of potential biases can influence survey results. Response rates, literacy, and language barriers may affect the quality of data collected in surveys. Other sources of bias in a survey include interviewer bias, differential effort by interviewers or respondents, cultural differences in interpretation, recall bias or memory problems, and over- or under-reporting (OEHHA 2001). Finally, different methods of data analysis can yield very different estimates of consumption from the same dataset.

The four personal interview surveys reviewed by the Human Health Focus Group utilized local interviewers to conduct the interviews for their own groups, to ensure that the people being interviewed felt comfortable answering the survey questions. This approach helps enhance the trust of the interviewee and the effectiveness of communication during the interview. Personal interviews are often pilot-tested to enhance the relevance of the questionnaire.

Personnel interview surveys may suffer from recall bias as individuals lose accuracy as time from an activity increases. This becomes a challenging issue when individuals are asked to recall consumption rates over prior twelve months. An individual may remember that they ate fish a certain number of times but they may not remember the exact amount in each instance.

The Human Health Focus Group reviewed three creel surveys for this report. Creel surveys are field interviews of anglers at the site they are fishing. Many creel surveys include inspection of the angler's catch, which can increase survey accuracy. Creel survey results are limited by the locations, seasons, dates, and times of the interview. Language and literacy may present difficulties during an interview (USEPA 1998). Since interviews are based upon when the interviewer chooses to visit the angling site, interviewees are not prepared for the interview and may be less likely to participate. The interviewee also may not trust the stranger conducting the interview.

The Human Health Focus Group reviewed only one dietary recall survey for this report. Short-term data collection (two day - 24 hour recall) is a well accepted methodology for dietary studies because individuals more accurately recall recent events, such as the food they consumed within the last day). Recall surveys that are administered by a trained interviewer allow for consistency between participants and reduce the errors in reporting that are possible in self reported surveys. Correlated consumption data can occur if a participant cooks and eats fish on one day and then eats that same fish as leftovers the next day. This can be avoided by conducting the survey on non-consecutive days.

Although estimates of consumption from dietary recalls may be reported as g/day, the values may not be representative of long-term consumption rates that have been averaged over time and presented as a daily rate. Other fish consumption study methodologies consider fish consumption over a much longer period of time and are therefore more likely to more closely represent the fish consumption patterns of the population studied.

3.2 CONSUMERS-ONLY DATA

Fish consumption surveys typically include people who eat fish and people who don't eat fish. People who don't eat fish are termed "non-consumers". Those that do eat fish are considered "consumers". The proportion of non-consumers included in the survey will vary depending on the population being interviewed. For instance, of the 500 respondents in *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994), 93 percent were fish consumers. It is common among the tribal populations reviewed in this report to have a high percentage of fish consumers in their population. In contrast, EPA (USEPA 2002b) evaluated national data from approximately 20,000 individuals (3 years and older). Approximately 28 percent were fish consumers.

In EPA's *Estimated Per Capita Fish Consumption in the United States* (USEPA 2002b), fish consumption data were collected using a non-consecutive two-day dietary recall. Anyone who didn't eat fish on either of the two recall days was considered a non-consumer. This methodology has the potential to underestimate the number of consumers in a population. Furthermore, anyone who did eat fish on either of the two days would be considered a consumer. The data for an individual consumer were then assumed to be that person's rate of consumption for every day of the year. In this case, a reported value for short-term consumption on two survey days was used to estimate long-term or "usual" intake of fish and shellfish.

Oregon's current fish consumption rate of 17.5 g/day was determined on a per-capita basis for the entire U.S. population (USEPA 2002b) including fish consumers and non-consumers. All non-consumers are recorded as having a consumption rate of zero g/day. When averaging in the zero consumption rates of the non-consumers with the actual rates of the consumers, the resulting rates represent the averages across an entire population, and do not represent the actual fish consumption rate for people who eat fish.

Oregon's human health-based water quality criteria are developed to specifically protect individuals who consume fish, which would make the consumer-only rates most representative

of a fish-consuming population. Oregon should base its regulatory consumption rate on data specifically derived from consumers of fish.

3.3 SUPPRESSED RATES

The Human Health Focus Group also discussed some of the factors that may contribute to the suppression of fish consumption rates. Current reported fish consumption rates may be depressed compared to historic rates due to several factors: 1) significant reductions in fish populations, 2) the belief that fish that reside in polluted waters will bio-concentrate pollutants, 3) contaminated fish, and 4) the intended impact of local fish advisories or the unintended consequences of national fish advisories of commercial fish species that are not applicable to local waters

The Human Health Focus Group also noted that three of the five studies presented in Table 3 (in Section 5.2) excluded or discounted high fish consumers by identifying statistical outliers. This would have the effect of underestimating the true range in fish consumption rates. If the rates are already suppressed the elimination of the highest values may be reporting an artificially low fish consumption rate.

3.4 FISH SPECIES CONSUMED

There are a variety of fish and shellfish species represented in the studies reviewed. Fish and shellfish species can be classified as marine, estuarine, or freshwater based upon the habitat in which they are born/hatched, reproduce, grow, and die. Some species of fish or shellfish can spend portions of their life in multiple aquatic environments. Pacific salmon hatch in freshwater, migrate to the ocean and then return to freshwater to spawn and die. Other migratory species commonly consumed in Oregon include sturgeon, lamprey, smelt, and shad. Note that the white sturgeon is landlocked because of dams on the Columbia River.

The seafood species consumed by recreational and subsistence fishers are dependent upon where these people live and fish. The availability of fish and shellfish is a major factor influencing the types of seafood consumed by populations who harvest for consumption purposes. For example, tribal members interviewed in the survey of Columbia River Basin Tribes (CRITFC 1994) reported eating resident trout, northern pike-minnow, sturgeon, suckers, walleye, and whitefish. They also consumed Pacific salmon, lamprey, shad, smelt, and sturgeon. They did not report eating any shellfish or open ocean finfish species. This may be influenced by the fact that the Columbia River Basin Tribes (CRITFC 1994) questionnaire did not include questions about consumption of specific marine fish or shellfish species.

In contrast, the Puget Sound Tribes (Tulalip and Squaxin Island) reported eating a variety of marine and migratory fish species (e.g. cod, sole, Pacific salmon) and shellfish (e.g. clams) (See Appendix A-2). All of these tribes were consuming fish and shellfish that were available to them in their given harvest locations. Although direct comparisons of the fish and shellfish species consumed between the Columbia River Tribes and the Puget Sound Tribes are difficult, an overall comparison of consumption patterns among tribal fishers is relevant.

The surveys reviewed by the Human Health Focus Group (Table 1, located at the end of this document) suggest that fish consumers generally eat a variety of species that are most readily

available geographically and seasonally. Additionally, the ranges of consumption rates among fish consumers tend to be comparable regardless of the species that are available at a given location. Thus, it is reasonable to assume that persons who eat fish will change or substitute species based on availability, cost and accessibility.

4. PACIFIC SALMON IN THE FISH CONSUMPTION RATE

EPA's national default fish consumption rates are derived for specific fish habitats (freshwater, estuarine, marine 65 FR 66469, 2000a). The choice of a fish consumption rate to use in calculating water quality criteria can be influenced by what types of fish and shellfish are included in the rate.

Human health water quality criteria are applied to "waters of the state" (as previously defined) and are used to maintain and improve water quality through numerous CWA regulatory programs administered by ODEQ. Implementing and enforcing human health criteria in waters of the state will only affect those fish and shellfish species residing in and exposed to those waters. Since water quality criteria are only protective of Oregon waters, it is important to understand which fish and shellfish species are found in Oregon waters. This is not a simple task since Oregon waters technically extend three nautical miles off the Oregon coast. There are a wide variety of fish and shellfish that live within that nautical boundary for all or part of their life cycle. Complicating matters even further is the presence of migratory fish (e.g., Pacific salmon), which spend part of their life cycle in the freshwaters of Oregon and part of their life cycle in deep ocean waters that are outside Oregon's jurisdiction.

4.1 EPA CLASSIFICATION OF PACIFIC SALMON

For some species their life history involves multiple habitats (e.g. anadromous). EPA designated their habitat as fresh water/estuarine and marine on a case-by-case basis (Table 2 excerpt from USEPA 2002b). EPA classified the habitat of salmon based on commercial-landings data provided by the National Marine Fisheries Service for the period of 1989-1991 (65 FR 66469, 2000b). All landings of Pacific salmon, including Chum, Coho, King, Pink, or Sockeye were assigned to marine habitat. All landlocked Great Lakes salmon and farmed salmon received the classification of freshwater.

Migratory
Fish that move between multiple habitats (freshwater, estuarine, and marine).
Anadromous
Migratory fish that spend most of their lives in the sea and migrate to fresh water to breed (Myers, 1949 as reported in Bond, 1979)

As the landings of Pacific salmon were reported from the marine environment, Pacific salmon were classified as marine (USEPA 2002b) and excluded from the national default fish consumption rates for calculating water quality standards. However, states and authorized tribes can make alternative assumptions to specifically account for the dietary preferences of the specific population (Oregon) of concern.

TABLE 2 EPA HABITAT APPORTIONMENTS (EXCERPT FROM TABLE 2-1 HABITAT APPORTIONMENTS, EPA 2002B)

		USDA CSFII food survey database	
Species	**Habitat**	**1994-1996**	**1998**
Flatfish	Estuarine (Flounder)	90	84
	Marine (Halibut)	10	16
Clams	Estuarine (softshell)	2	3
	Marine (Ocean Quahog, Quahog, Atlantic Surf, and remaining hardshell species)	98	97
Crab	Estuarine (Blue, Soft, Hard, Peeler, Dungeness)	66	47
	Marine (King, Snow, Jonah, and Other	34	53
Scallop	Estuarine (Bay)	0.6	0.7
	Marine (Calico and Sea)	99	99
Salmon	Freshwater (Great Lakes)	0.06	0.05
	Estuarine (Aquaculture)_	3	5
	Marine (Pacific)	97	95

4.2 PACIFIC SALMON IN OREGON WATERS

Pacific salmon and other migratory species present a rather complicated life history for establishing habitat preferences. Pacific salmon reside and pass through waters of the state. They are spawned and develop in waters of the state, and, after spending time in the ocean, return to Oregon freshwaters to spawn and die. Additionally, local data reviewed by the Human Health Focus Group (CRITFC 1994) indicate that Pacific salmon are caught in waters of the state in addition to the deep marine water landing data that EPA relied upon to classify Pacific salmon.

Different Pacific salmon species have different life histories, and therefore use fresh and estuarine waters for different lengths of time, and at different intensities. For example, Fall Chinook may be more at risk for uptake of toxic contaminants because of their greater use of shallow-water habitats in the estuary, where toxic sediments are most likely to accumulate (Fresh 2005). Spring Chinook enter fresh waters early in the year and do not spawn until late fall or early winter. These varying life histories also affect the exposure patterns in the marine portion of the Pacific salmon life history, where some stocks may spend more time in coastal waters within the regulatory boundaries of Oregon's water quality standards.

The source of the pollutants found in Pacific salmon tissue is not well understood. The Human Health Focus Group did not conduct a comprehensive review of the life histories or potential sources of contamination for Pacific salmon. Johnson *et al.* (2007a, b) studied the tissue residue levels of chemicals in juvenile Chinook salmon in the Columbia River. They detected the following fish tissue chemical residues: PCBs, DDT, and, to a small extent, aromatic hydrocarbons, chlordanes, aldrin, dieldrin and mirex. These data demonstrate exposure to toxic chemicals occurs during the freshwater portion of the Pacific salmon life cycle.

4.3 RELATIVE SOURCE CONTRIBUTION

If Pacific salmon are not included in the fish consumption rate, utilizing the concept of Relative Source Contribution (RSC) is another way to account for some of the potential risk from consuming Pacific salmon in addition to all other marine fish and shellfish. The purpose of the RSC concept is to account for all other sources of exposure other than those associated with consumption of freshwater and estuarine finfish and shellfish, such as skin absorption, inhalation, drinking water, marine fish, other foods, and occupational exposures.

EPA applies the concept of RSC to chemicals with a reference dose to account for exposure through consumption of marine fish, Pacific salmon and other non-fish sources. The RSC value is not applied to carcinogens. EPA's ambient water quality criteria guidance (USEPA 2000a) states that the concept of the RSC does not apply to carcinogens because regulatory agencies are only responsible for assessing incremental risk from exposure to contaminants in fish tissue and water and no other exposures. In addition EPA states that:

> "...health-based criteria values for one medium [water] based on linear low-dose extrapolation [cancer] typically vary from values for other media in terms of the concentration value, and often the associated risk level. …Therefore, the RSC concept could not … apply unless all risk assessments for a particular carcinogen … resulted in the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk value and level." (USEPA 2000a)

The RSC value is applied to chemicals with a reference dose to ensure that exposure to these chemicals, when combined with all other sources will not exceed the reference dose (65 FR 66473, 2000). Details of how the RSC values are incorporated into the equation to calculate human health-based water quality criteria can be found in EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection for Human Health* (USEPA 2000a).

The RSC value could be applied to the 47 chemicals with a references dose within the current list of priority pollutants. Oregon currently applies the RSC values developed by EPA to human health-based water quality criteria for the following pollutants (more details are available in Appendix B):

- Antimony
- Methylmercury
- Thallium
- Cyanide
- Chlorobenzene
- 1,1, Dichloroethylene
- Ethylbenzene
- Toluene
- 1,2 Trans Dichloroethylene
- 1,2 Dichlorobenzene
- 1,4 Dichlorobenzene
- Hexachlorocyclo-pentadiene
- 1,2,4 Trichlorobenzene
- Gamma-BHC
- Endrin

The concept of the RSC is not applied to the other 32 toxicity reference dose-based criteria. This does not necessarily mean that other reference dose-based criteria do not have other routes of

exposure. It simply means that there may not be enough data for EPA to establish RSC values for these other 32 chemicals.

At this time the only pollutant whose exposure pathway is known to be primarily from marine fish and Pacific salmon is methylmercury. The primary source of methylmercury is through consumption of marine fish. Oregon's current criterion for methylmercury incorporates an RSC value of 2.7×10^{-5} milligrams per kilogram (mg/kg) of body weight per day that accounts for the consumption of marine fish shellfish and salmon (Appendices B and C). All other water quality criteria for which RSC values have not been developed do not encompass protection of humans through exposure via consumption of marine fish or Pacific salmon.

EPA provides guidance for calculating RSC values outside of its own default values (Appendix D). This process requires robust datasets on sources of exposure for individual chemicals. Data on other sources of exposure do not exist for Oregon. It would be difficult for ODEQ to develop Oregon-specific RSC values without assistance from EPA.

If Oregon-specific RSC values cannot be derived, then states and tribes have the option to rely upon the EPA default RSC value of 20 percent (of the reference dose). In this approach states and tribes could apply an RSC value of 20 percent to the remaining 32 chemicals that have a reference dose. Since there are no data to evaluate whether the 20 percent default option for the remaining criteria satisfactorily accounts for exposure through Pacific salmon consumption and all other non-fish exposures, the Human Health Focus Group cannot evaluate the use of the RSC concept on its technical merits. Therefore, the use of a default RSC value of 20 percent remains a policy decision.

Double Counting
To prevent double counting, exposures considered through the relative source contribution factor should not be included in the fish consumption rate.

4.4 INCLUDING PACIFIC SALMON IN THE FISH CONSUMPTION RATE

Since Pacific salmon are a known part of the diet for fish-consuming populations in Oregon, the human health-based water quality criteria should account for the potential risk incurred from consuming Pacific salmon. The surveys reviewed by the Human Health Focus Group not only reveal that Pacific salmon is being eaten, but also indicate with varying degrees of accuracy how much Pacific salmon is being consumed. Knowing the amount of consumed Pacific salmon allows for measurable and scientifically defensible inclusion of Pacific salmon in the fish consumption rate. Including Pacific salmon in the fish consumption rate can provide more scientific certainty that Pacific salmon consumption is being accurately accounted for when calculating risk-based water quality criteria.

The alternative to including Pacific salmon in the fish consumption rate is using the concept of the RSC to account for Pacific salmon exposure. The concept of the RSC falls short of full protection because of insufficient data to calculate accurate RSC values, and the RSC process does not account for carcinogenic risk. However, there are reliable data available from studies on the consumption of Pacific salmon. Therefore, it is more accurate to account for the total

human health risk by including Pacific salmon directly in the fish consumption rate rather than trying to address it through an estimated RSC value.

4.5 INCLUDING MARINE FISH IN THE FISH CONSUMPTION RATE

During discussions about inclusion of Pacific salmon in the fish consumption rate, the Human Health Focus Group also discussed the possibility of including all marine fish in the fish consumption rate. If a deep ocean fish such as tuna is consumed by an Oregonian, there is a potential that the fish may contain contaminants that would add to the health risk of the consumer. So, regardless of the source of the fish, fish consumers face potential risks. Although this is true, Oregon's fish consumption rate and its associated human health-based water quality criteria can only be applied to waters within the regulatory jurisdiction of the State of Oregon (OAR 340-041-0001(1)). The jurisdiction in marine waters is confined to Oregon's waters of the state, which extend three nautical miles into the Pacific Ocean from the Oregon coast.

5. SELECTING FISH CONSUMPTION RATES

5.1 PROCESS FOR SELECTING FISH CONSUMPTION RATES

A variety of quantitative fish consumption estimates were selected from the five surveys considered relevant and useful by the Human Health Focus Group:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b).

The following process was used by the Human Health Focus Group to refine the recommended fish consumption rates:

1) Eliminate fish consumption rates that include non-fish-consuming populations
2) Include all fish consumption estimates regardless of the source of the fish (harvested or purchased)
3) Include fish consumption estimates for all types of seafood (fish and shellfish species) from marine, freshwater, and estuarine habitats.

1) Eliminate fish consumption rates that include people who don't eat fish.
Oregon's human health-based water quality criteria are developed to specifically protect individuals who eat fish. Therefore it seems most appropriate to select those fish consumption estimates for people who eat fish and exclude estimates that include people who don't eat fish. The inclusion of the non-fish consuming population lowers the consumption rate and thus reduces the level of protection for the people who do eat fish.

2) *Include all fish consumption estimates regardless of the source of the fish (harvested or purchased).*

In some surveys, the respondents report on the source of the fish they consume. Sources of fish and shellfish can include self-harvested, or purchased from stores or restaurants. The fish and shellfish that are purchased may be locally caught. The Human Health Focus Group decided that it is more important to capture the fish consumption rate for all fish consumed rather than excluding those estimates for fish that was purchased.

3) *Include fish consumption estimates for all types of seafood (fish and shellfish species) from marine, freshwater, and estuarine habitats.*

Deep ocean fish that are found beyond three nautical miles off the Oregon coast (tuna, shark, halibut, etc) are not included in the current fish consumption rate in Oregon. ODEQ was not able to provide a list of the exact species that would be considered near-shore marine fish that live within three nautical miles of the coast. Therefore these particular species could not be isolated from the deep ocean fish in the surveys.

In addition to marine species, EPA's national guidance recommends that Pacific salmon and other migratory species be excluded from the fish consumption rates for water quality criteria.

Exposure to chemicals in marine fish and migratory fish including Pacific salmon is accounted for through the concept of the RSC. Thus, people who eat these fish may be protected through an indirect measure of exposure. However, there is only one chemical (methylmercury) where marine species (Pacific salmon and other migratory species), are accounted for using the concept of RSC. Due to EPA's policy regarding the lack of data that prevents the application of the concept of RSC across all other chemicals and endpoints such as carcinogenesis, the Human Health Focus Group chose not to recommend use of the RSC approach.

Oregonians eat a variety of fish species that may be harvested from fresh water, estuarine, or marine habitats. All types of fish and shellfish are included in the fish consumption rates recommended by the Human Health Focus Group. In particular, Pacific salmon is a major component of fish consumption in Oregon. Including Pacific salmon and other migratory species in the fish consumption rate can provide more scientific certainty that these species are accurately accounted for when calculating water quality criteria.

The alternative to including salmon in the fish consumption rate, as explained in the report, is using the concept of the RSC to account for salmon exposure. This will fall short of full protection because sufficient data are not available to calculate accurate RSC values, and the RSC process does not account for carcinogenic risk. Therefore, it is more accurate to account for the total human health risk by including salmon directly in the fish consumption rate itself.

5.2 RECOMMENDED FISH CONSUMPTION RATES

The final fish consumption rates identified by the Human Health Focus Group are presented in Table 3. The range of fish consumption rates presented in Table 3 provides a scientific basis for choosing a fish consumption rate and establishing water quality criteria that are protective of Oregonians that eat fish. A range of statistical values from each of the five studies: the mean, the median, and the 75th, 90th, 95th, and 99th percentiles are listed in Table 3. Note that there are

six surveys reported in five studies. The Toy *et al.* report includes surveys of two tribes (Squaxin Island Tribe and Tulalip Tribes).

TABLE 3. ADULT FISH CONSUMPTION RATES (GRAMS PER DAY) RECOMMENDED BY THE HUMAN HEALTH FOCUS GROUP FOR OREGON HUMAN HEALTH-BASED WATER QUALITY CRITERIA.

Group	Species included in consumption rate evaluation		Statistic					
					Percentile			
		N	Mean	Median	75th	90th	95th	99th
Tulalip Tribe	Anadromous and estuarine finfish and shellfish	73	72	45	85	186	244	312
Suquamish Tribe	Anadromous and estuarine finfish and shellfish	284	214	132	NA	489	NA	NA
Squaxin Island Tribe	Anadromous and estuarine finfish and shellfish	117	73	43	NA	193	247	NA
Columbia River Tribes	Freshwater and anadromous finfish	512	63	40	60	113	176	389
Asians & Pacific Islanders	Anadromous and estuarine finfish and shellfish	202	117	78	139	236	306	NA
U.S. General Population	Freshwater, anadromous, estuarine, and marine finfish and shellfish	2585	127	99	NA	248	334	519

N = Number of adults in survey
NA= Statistical value not available.
Adults are 18 years or older for all surveys except Suquamish; Suquamish adults were 16 years or older
All values reported in this table are described in Table 1 (located at the end of this document)
Tulalip Tribes and Squaxin Island Tribe from Toy *et al.* 1996.
Suquamish Tribe from Suquamish. 2000.
Columbia River Treaty Tribes from CRITFC. 1994.
The Columbia River Tribes did not report marine fish consumption;
The 75, 90, 95 and, 99th percentiles are interpolated from percentiles reported in CRITFC 1994
Asian Pacific Islanders from Sechena *et al.* 1999.
US General Population from US EPA. 2002b.

The Human Health Focus Group only included fish consumption rates (Table 3) for adults in their recommended list of fish consumption rates. When fish consumption rates from these surveys are reported as grams per person per day, the consumption for children is lower than that of the adults and thus when expressed as an exposure value of grams per day, the adult levels may be protective of children. At this time the USEPA recommended water quality criteria are derived for adults with an average body weight of 70 kg (USEPA 2000a). With respect to exposure, children are particularly vulnerable compared to adults due to their lower body weight, differing metabolism, and behaviors. Thus it may be appropriate for the State of Oregon to develop water quality criteria for children.

Table 3 does not include the fish consumption rate of 17.5 g/day which is the basis for current Oregon water quality criteria. This number is considerably lower than the estimates recommended by the Human Health Focus Group because it was calculated in part by including people who don't eat fish and excluding Pacific salmon as well as other migratory and marine species. It is not an accurate estimate of long-term fish consumption rates for people who eat fish. For example, the fish consumption rate of 248 g/day for the general population (USEPA 2002b) shown in Table 3 is more than 14 times greater than the current EPA default fish consumption rate (17.5 g/day) and more than double the 90th percentile (113 g/day) fish consumption rate for the Columbia River Basin Tribes (CRITFC 1994). For the U.S. general population, the mean seafood consumption rate for adults who consume fish is 127 g/day (+/- 6 g/day), while five percent of the adult population consumes 334 grams per day or more (+/- 15 g/day). These fish consumption rates are based on a sample of 2,634 adult consumers 18 years and older (USEPA 2002b, Section 5.2.1.1.Table 4.).

All the fish consumption rates in Table 3 are higher than the current 17.5 g/day fish consumption rate used in the current Oregon water quality criteria. The reason for this is that the Human Health Focus Group included only fish consumption rates for people who eat fish; and included all marine and migratory species described in the regional studies. The 90^{th} and 95^{th} percentile consumption rates for US fish consumers shown in Table 3 are consistent with, and are in fact greater than, the corresponding consumption levels documented in the Pacific Northwest regional studies identified by the Human Health Focus Group.

The Human Health Focus Group recommends selecting an Oregon fish consumption rate from a range of values that includes only those data for fish consumers (since this is about people who eat fish) and all types of fish (fresh water, estuarine, marine, and migratory finfish and shellfish). The national survey fish consumption survey (USEPA 2002b), is important to Oregon because the fish consumption rates from the national survey reflect the general U.S. population. Since there is no similar state-wide survey of all fish-consuming populations in Oregon, the national survey remains a relevant contextual piece of information for determining a change in the Oregon fish consumption rate.

The Human Health Focus Group discussed how recommendations for a fish consumption rate should be presented for use by Oregon. Scientists frequently present their scientific results in two ways, one to represent uncertainty and one to represent variability. Scientists present uncertainty information as 95 percent confidence levels around the mean which is based on a standard error calculation.

For the types of issues the Human Health Focus Group considered in this report, variability in fish consumption rates, scientists usually present the 95^{th} percentile which represents the variability of the population at two standard deviations from the mean (Kavloch *et al.* 1995). The majority of scientists on the Human Health Focus Group referred to this value when they discussed approaches for communicating how the fish consumption values could range for the Oregonian populations. One member used the 90^{th} percentile as the point of reference. Both values are presented in Table 3.

Although the survey (cited here) of Japanese and Korean communities was not reviewed by the Human Health Focus Group because the results were not yet published, the results of the survey add to the conclusions made by the Human Health Focus Group about relevant fish consumption rates to recommend for the Oregon population.

> *Mercury Exposure from Fish Consumption within the Japanese and Korean Communities*. Ami Tsuchiya, Thomas A. Hinners, Thomas M. Burbacher, Elaine M. Faustman, Koenraad Mariën. Journal of Toxicology and Environmental Health 2008 (in press).
>
> *Fish intake guidelines: Incorporating n-3 fatty acid intake and contaminant exposure in the Korean and Japanese communities*. Ami Tsuchiya, Joan Hardy, Thomas M. Burbacher, Elaine M. Faustman, Koenraad Mariën. American Journal of Clinical Nutrition. 2008 (in press).

The survey, conducted by scientists at the Washington State Department of Health and University of Washington, assessed fish consumption in woman in Asian populations, Japanese and Korean, living in Western Washington. The results indicate fish consumption rates higher than the national average. The mean fish consumption rates for the Japanese and Korean populations (73 and 82 grams/day, respectively) fall within the range of mean rates of the surveys assessed by the Human Health Focus Group (shown in Table 3). The 95th percentile of the rates was 188 grams/day for the Japanese population and 230 grams/day for the Korean population. Both of these values also fall within the range of 95th percentiles of surveys assessed by the Human Health Focus Group (shown in Table 3) and thus provide additional support for Pacific Northwest fish consumption values of relevance for Oregon populations.

5.3 OREGON POPULATION-BASED FISH CONSUMPTION RATES

It is important to consider the number of Oregonians who are high consumers of seafood based upon the fish consumption rates shown in Table 3 of this report. In order to do this we have used estimates of the population based upon the 2003 Oregon Population Report of the Population Research Center at Portland State University. In these calculations, we assume that the Oregon population's dietary patterns are similar to the general U.S. population reported in Table 3. The data for the U.S. general population in Table 3 of this report, which comes from Section 5.2.1.1, Table 4, in USEPA Estimated Per Capita Fish Consumption in the United States August 2002b, is for adult consumers of seafood 18 years of age or older (n=2,634). Here, seafood is defined as finfish and shellfish from fresh, estuarine, and marine environments. The population of Oregon in 2003 was 2,655,700 adults, 18 years and older (see Table 9 of 2003 Oregon Population Report).

In the US EPA 2002 survey used to generate the general population fish consumption rates in Table 1 (located at the end of this document), 28 percent of the population interviewed were consumers (see Section 5.1.1.1 Figure 4 in USEPA Estimated Per Capita Fish Consumption in the United States August 2002b). In the study, participants were asked to recall their seafood consumption on two non-consecutive days and consumers were participants who ate seafood on at least one of the two days. Assuming the Oregon population is similar to the U.S. general population's diet, we estimate that there are:

2,665,700 X 28% = 746,400 adult Oregonians consuming fish.

If we consider high consumers of fish as being those at the 90th percentile and above (consuming at or above 248 grams of fish per day in Table 3 of this report) this would include:

746,400 X 10% = 74,640 adult Oregonians who are high consumers.

248 grams per day is equivalent to consuming 8.6 oz. of seafood per day, which is a plausible daily intake fish consumption rate for high consumers. This calculation only considers adult consumers and does not consider children who consume fish.

In 2003, the population of Oregonians under the age of 14 years old was 722,885. Applying the same calculation as that used for adults, children with a fish consumption rate of 191 grams of fish per day (USEPA 2002b, Section 5.2.1.1.Table 4)), would result in:

772,885 x 28% x 10%= 21,640 young Oregonians (under 15 years old) who are high consumers.

6. HUMAN HEALTH RISK AND WATER QUALITY CRITERIA

6.1 HUMAN HEALTH RISK

Risk assessment is the determination of the likelihood of adverse human health effects due to exposure to toxic chemicals. This determination is made by combining estimates of exposure through ingestion, inhalation, or skin absorption of a chemical with an estimate of toxic effects of that chemical. Exposure includes measures of duration and frequency of contact as well as body weight. Quantitative and qualitative estimates of exposure and toxicity are combined to estimate risk.

The lifetime probability of developing cancer for the American male is 1 in 2; for the American female it is 1 in 3 based on data from 2002-2004 (American Cancer Society 2008).

Toxicology provides information on the nature of the adverse effects that can be caused by the pollutant under consideration and the doses that cause the effect. Adverse health effects can range from immunological diseases to birth defects or cancer. The type of health effect caused by exposure to toxic chemicals has historically been divided into two categories based on the biological endpoints observed: 1) cancer and 2) non-cancer effects (e.g. neurological, cardiovascular, reproductive, developmental and immunological effects and blood and metabolic disorders). Toxicity information is usually obtained from animal experiments. Such studies can provide important dose-response information for identifying a reference dose for individual chemicals. The level of effect relates directly to the amount and duration of exposure. Studies of human populations can provide important information about sensitivity and variability of humans and can also provide information about exposure and the absorption, distribution, metabolism and excretion of chemicals in humans.

Non-cancer chemicals affect the function of various organ systems. The measure of effect for these chemicals is the reference dose. The reference dose is defined as an estimate of a daily oral exposure to a chemical by humans, including sensitive subpopulations, which are likely to be without an appreciable risk of causing adverse effects over a lifetime. Exposure below the reference dose is considered to be without statistically or biologically significant adverse effects. Once the reference dose is exceeded an individual is at increased risk of adverse health effects.

For most cancer-causing chemicals there is no toxicity threshold or reference dose. Because carcinogenic chemicals are thought to initiate the cancer process at almost any concentration, a dose-response parameter referred to as the cancer slope factor is used for chemicals that display toxic behavior such that the carcinogenic risk increases linearly as the chemical dose increases. The cancer slope factor is a measure of chemical potency.

Risk estimates for carcinogens are expressed as the incremental probability of developing cancer (e.g., an additional one in one million chance of developing cancer) over a lifetime of exposure to potential carcinogens. Risk estimates for non-cancer causing chemicals are expressed as a hazard index or the ratio of the dose to the individual or population divided by a reference dose.

EPA records the most current scientific judgment on chemical toxicity in the Risk Integrated Information System (IRIS). IRIS is an electronic online data base maintained by EPA that provides chemical-specific risk information on the relationship between chemical exposures and estimated human health effects. The IRIS chemical files contain information on factors that are used in estimating risk or developing water quality such as oral Reference Doses (RfDs) and inhalation Reference Concentrations (RfCs) for chronic noncarcinogenic health effects; oral and inhalation cancer slope factors (CSF) and unit risks for chronic exposures to carcinogens; Drinking Water Health Advisories (HAs); EPA regulatory action summaries; and, supplementary data on acute health hazards and physical/chemical properties. More information on individual pollutants can be found online at: http://www.epa.gov/iriswebp/iris/index.html.

6.2 HUMAN HEALTH WATER QUALITY CRITERIA

A human health water quality criterion is the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health. Human consumption of contaminated aquatic life is of primary concern because the presence of even extremely low ambient concentrations of bioaccumulative pollutants in surface waters can result in chemical residue concentrations in fish tissue that may pose a human health risk.

EPA's recommended procedures for developing human health criteria are provided in the revised *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (USEPA 2000a)*.

ODEQ has numeric human health-based water quality criteria for 130 toxic pollutants. Human health-based water quality criteria regulatory limits are derived for: 1) cancer and 2) non-cancer effects. In the case of carcinogens:

> "the [ambient water quality criterion] represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one

> million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources." (USEPA 2000a)

The acceptable level of cancer risk is usually expressed as an incremental cancer risk or an additional cancer risk.

The mathematical estimation of risk is different for carcinogenic and non-carcinogenic biological endpoints (Equations 1 and 2). When developing water quality criteria, the regulatory agency establishes the acceptable risk level and then determines the concentration in water and fish tissue that will not exceed the acceptable risk levels.

Exposure scenarios for the derivation of human health-based water quality criteria address two types of exposure: 1) combining ingestion of fish and surface water, and 2) ingestion of fish alone. Exposure factors include: bioconcentration, body weight, drinking water ingestion rate, and fish ingestion rates. Other exposure route information (skin absorption, other dietary sources, inhalation, etc) should be considered and incorporated into human exposure evaluations as the RSC values.

EPA generally assigns a mix of central tendency values (e.g., average for the population) and high end values (e.g., 90th or 95th percentiles) for exposure factors such as ingestion rates and body weight. For the purposes of developing water quality criteria EPA uses an average adult body weight of 70 kg. The water quality criteria equations (Equations 1 and 2) for chemical exposure are defined as body weight divided by the drinking water intake rate added to the fish ingestion rate, multiplied by the bioconcentration of the chemical from water into fish tissue.

For carcinogens, the water quality criteria are calculated by dividing the acceptable risk level by the rate of tumor production (cancer slope factor). This estimate of toxicity is then multiplied by the chemical exposure to estimate risk (Equation 1). The regulatory agency or other decision makers prescribe the acceptable risk level. ODEQ established an acceptable cancer risk level of an additional one in one million chance of developing cancer.

> The bioconcentration factor (BCF accounts for the uptake by fish or shellfish of a pollutant from the surrounding water. Units of liters/kg (L/kg)

The following description of the estimation of the water quality criteria for dioxin and DDT illustrates the relationship of toxicity, the fish consumption rate, and the bioconcentration factor with the ambient water quality criterion. Dioxin (cancer slope factor 156,000 per mg/kg-day) is much more potent than DDT (cancer slope factor 0.34 per mg/kg-day). DDT has a higher bioconcentration factor (53,600 L/kg) than dioxin (5,000 L/kg). Using the current ODEQ fish consumption rate of 17.5 grams per day the water quality criterion for dioxin will be 0.00000000513 µg/L; DDT will be 0.000219 µg/L. Even though the uptake of DDT into fish tissue is greater than the uptake of dioxin the high toxicity of dioxin results in a lower ambient water quality criterion.

If the fish consumption rate were increased by ten-fold to 175 grams per day the water quality criterion for dioxin would be 0.000000000513 µg/L; 0.0000219 µg/L for DDT. Thus, if someone eats ten times more fish than the current ODEQ rate of 17.5 grams/day they would exceed the Oregon acceptable cancer risk level of an additional one in one million chance of developing cancer. Their risk of developing cancer from exposure to dioxin or DDT would be one in one hundred thousand.

Equation 1 ***Cancer***

$$AWQC = Risk/CSF \cdot \left(\frac{BW}{DI + [FCR \cdot BCF]} \right)$$

Equation 1 ***Cancer Dioxin***

$$0.00000000513\ \mu g/L = 156{,}000/mg/kg/day \cdot \left(\frac{70\ kg}{2\ L/day + [17.5\ g/day \cdot 5{,}000\ L/kg]} \right)$$

Equation 1 ***Cancer DDT***

$$0.000219\ \mu g/L = 0.34/mg/kg/day \cdot \left(\frac{70\ kg}{2\ L/day + [17.5\ g/day \cdot 53{,}600\ L/kg]} \right)$$

AWQC = Ambient Water Quality Criteria (µg/L)
BW = Body Weight (kg)
DI = Drinking Water Intake (L/day)
FCR = Fish Consumption Rate (kg/day)
BCF = Bioconcentration Factor of chemical from water to fish tissue (L/kg)
Risk = Acceptable Cancer Risk Level (Oregon = an additional one in one million chance of developing cancer)
CSF = Cancer Slope Factor

For chemicals with a reference dose, the water quality criteria are calculated by multiplying the reference dose times the chemical exposure (Equation 2). The RSC is either subtracted from the reference dose if the concentration of the chemical in other media is known (methylmercury Appendix C) or a percentage of the exposure is attributed to freshwater and estuarine fish and shellfish consumption (20 percent). The effect of toxicity, the fish consumption rate, the bioconcentration factor, and the RSC on the determination of water quality criteria for chemicals with a reference dose is illustrated by the following examples for endrin and pyrene.

The reference dose for the pesticide endrin is 0.0003 mg/kg/day. In addition only a fraction (20 percent) of the exposure to endrin is attributed to freshwater and estuarine fish and shellfish. The

primary source of endrin is from its presence in air, water, sediment, soil, fish, and other aquatic organisms (Appendix C). The bioconcentration factor for endrin is 3,970 L/kg. The reference dose for pyrene is 0.03 mg/kg/day. The bioconcentration factor for pyrene is 30 L/kg. With the current ODEQ fish consumption rate of 17.5 grams per day, the water quality criterion for endrin is 0.0605 µg/L; the water quality criterion for pyrene is 4,000 µg/L. Endrin's higher toxicity and bioconcentration factor result in a lower water quality criterion for endrin than pyrene. If the fish consumption rate were increased 10 times to 175 grams per day the water quality criterion for endrin would be 0.00605 µg/L; for pyrene it would be 400 µg/L. The people who eat ten times more fish than the current fish consumption rate would exceed the reference dose by ten.

ODEQ established the level of protection from exposure to chemicals with a reference dose as equal to or less than the reference dose for a specific chemical. The reference dose for endrin is based on adverse effects to the liver; for pyrene its adverse health effects to the kidney. Thus people who eat more than 17.5 grams per day would be at risk to adverse effects to their kidney or liver.

Equation 2 ***Non - Cancer***

$$AWQC = RFD \bullet RSC \bullet \left[\frac{BW}{DI + [FCR \bullet BCF]} \right]$$

Equation 2 ***Non - Cancer Endrin***

$$0.0605\ \mu g/L = 0.0003\ mg/kg/day \bullet 0.2 \bullet \left[\frac{70\ kg}{2L/day + [17.5\ g/day \bullet 3{,}970\ L/kg]} \right]$$

Equation 2 ***Non - Cancer Pyrene***

$$4000\ \mu g/L = 0.03\ mg/kg/day \bullet \left[\frac{70\ kg}{2L/day + [17.5\ g/day \bullet 30\ L/kg]} \right]$$

AWQC = Ambient Water Quality Criteria (µg/L)
BW = Body Weight (kg)
DI = Drinking Water Intake (L/day)
FCR = Fish Consumption Rate (kg/day)
BCF = Bioconcentration Factor of chemical from water to fish tissue (L/kg)
RFD = Reference Dose (mg/kg/day)
RSC = Relative Source Contribution

6.3 SENSITIVE POPULATIONS AND TOXICITY

The Human Health Focus Group discussed populations that may be more susceptible to environmental toxicants due to special exposure circumstances or sensitivity to the toxicity of certain pollutants. Of importance is early *in utero* and post-natal exposure of infants and children, and the elderly. There are critical periods of fetal development and the effects of prenatal chemical exposures will differ depending on the dose and the timing of the exposure (Needham *et al.* 2008). These populations include fetuses, children, and the elderly. With respect to exposure, children are particularly vulnerable as compared to adults due to their lower body weight, differing metabolism, and behaviors.

The human health-based water quality criteria are calculated using a default adult male body weight of 70 kilograms. For chemical exposure you need to know not only the amount and rate of chemical intake but also body weight. Chemical exposure is expressed relative to body weight and is calculated from the concentration of chemical in fish tissue and the frequency and duration of fish consumption. In the case of adult males (18-74 years of age), mean body weight is 78 kg (172 lbs), with 5th and 95th percentile weights of 59kg (130 lbs) to 103 kg (227 lbs), respectively. Mean adult female body weight for the same age range is 65 kg (143 lbs), with 5th and 95th percentiles of 48 kg (106 lbs) and 93 kg (205 lbs), respectively (USEPA 1997).

The variation of weight between children and adults is significant, considering that newborns typically weigh 4 kg (8 lbs) while adults can reach weights of 113 kg (250 lbs). Thus, risk estimates for children versus adults can vary considerably. In the current water quality criteria guidance EPA recommends using an average adult body weight of 70 kg (154 lbs) as a default body weight value in the water quality criteria calculations. While use of water quality criteria based on the adult default weight provides adequate protection for adults, it may not provide adequate protection for children.

As discussed in USEPA 2000a, the EPA encourages states and authorized tribes to use alternative body weight assumptions for population groups other than the general population and to use local or regional data for its calculations. In the case of children, EPA's water quality guidance (USEPA 2000a) recommends using 30 kg (66 lbs)as a default children's body weight to provide additional protection for children when chemicals of concern indicate that health effects (i.e developmental neurotoxicity, immunotoxicity, etc.) may be of particulate concern for these early ages. As this would potentially be the case for chemicals to be considered under Oregon's water quality standards, we have included Table 4 which lists fish consumption per body weight per children.

In the surveys reviewed for this report, the consumption rate for children was quite variable. In all cases the consumption rate for children was less than that for adults on a gram-per-day basis (Table 1, located at the end of this document). However, when the rates were computed with individual body weight, the children's levels included levels greater than the adults (Table 4). Note that in Tables 4 a, b, c and d, the grams of fish consumed per kg body weight per day for children at ages 6 and under all had 90th or 95th percentile values approximately 2-fold higher than those listed for the adult 90th and 95th percentile values except for the Tulalip and Squaxin Island tribes. Thus, these figures suggest the need to consider greater fish consumption rates than adult rates to ensure full protection of children specific exposure factors.

The potential for toxicity and adverse health outcomes varies with life stage and/or health status. Toxicity values should incorporate consideration of developmental life stages that might be particularly vulnerable. The information is then incorporated into a risk assessment. For humans, early life stages (e.g. fetus, infant) may be vulnerable to toxic chemical effects due to immature or developing metabolic and organ systems. Effects that are reversible in adults may not be reversible during the developmental stage. The concern for women of child bearing age is risk to offspring during development. There is also concern for the elderly who may be more susceptible than younger adults because of their reduced capacity for recovery due to illness, age, or ability to eliminate or metabolize chemicals. There are also people whose existing health condition (e.g. immune suppression, asthma) may exacerbate the harmful affects of toxic chemicals.

The term "children" in this document refers to birth through adolescence (16-18 years).

In many cases, the toxicity of chemicals is derived from laboratory studies of animals. Depending on the pollutant of interest, some of these studies consider sensitive populations, and other studies may not. Many of the toxicity values are in fact based on doses for adults so there is no direct correlation between toxicity and life stage. EPA's Integrated Risk Information System database provides information on how the toxicity of each pollutant was derived.

TABLE 4. FISH CONSUMPTION RATES (PER BODY WEIGHT) FOR CHILDREN

Table 4a. All fish g/kg-body weight/day (excerpt from Section 4.1.1.2, Table 3 and Table 5 USEPA 2002b)

Consumers and non consumers

Age (years)	N	Mean	Median	90%	95%
3 to 5	4112	0.29		1.10	2.00
6 to 10	1553	0.21		0.78	1.40
11 to 15	975	0.16		0.57	1.10
15 to 44	4644	0.19		0.71	1.10
>44	5333	0.24		0.84	1.30

Table 4b. All fish g/kg- body weight/day (excerpt from Tables T-3 and T-14 Suquamish 2000)

Children's rate varied from zero consumption of certain shellfish to 100% consumption for salmon

Age (years)	N	Mean	Median	90%	95%
0 to 6	31	1.5		3.4	
16 to >55	92	2.7		6.2	

TABLE 4. FISH CONSUMPTION RATES (PER BODY WEIGHT) FOR CHILDREN (CONTINUED)

Table 4c.All fish g/kg-body weight/ day (excerpt from Table 3 and Table 8, Toy *et al.* 1996)

Non-consumers for children was 29% for Tulalip Tribes and 25% for Squaxin Island Tribe

Tulalip Tribes

Age (years)	N	Mean	Median	90%	95%

0 to 5	21		0.08	0.74	
18 to >65	73	0.89	0.55		2.88
Squaxin Island Tribe					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
0 to 5	48		0.51	2.06	
18 to >65	117	0.89	0.52		3.01
Table 4d. All fish mg/kg-body weight/day (excerpt from Section 5.2.1.2., Table 3 and Table 5 (USEPA 2002b)					
Consumers only					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
3 to 5	779	4.20	3.60	8.00	10.00
6 to 10	250	3.20	2.50	6.50	8.70
11 to 15	164	2.20	1.60	4.40	6.20
15 to 44	1102	1.80	1.40	3.50	4.80
>44	1567	1.70	1.40	3.40	4.30
N=Number of people in survey					

NOTE: As with all studies, when measured body weight values are not available for individual study/survey participants, caution must be taken as evaluations of retrospectively added default body weight values can be shown to have potential to both over as well as under estimate relative exposures (Marien *et al.* 2005).

6.4 CHEMICAL INTERACTIONS

Exposure to mixtures of chemicals poses a special circumstance for toxicologists. Individual chemicals may interact in a variety of ways. The impact of multiple chemicals on toxicological response can be additive (e.g., toxicity by the same mode of action), less-than-additive (e.g., zinc inhibits cadmium toxicity by reducing the amount of cadmium absorbed), or greater-than additive (e.g., enhanced carcinogenicity for asbestos and tobacco smoke) (USEPA, 2000b). Chemical interactions may also include antagonistic interactions as well as no influence (USEPA 2000b).

Human health-based water quality criteria are calculated for individual chemicals. The calculated risk of any single chemical does not take into account the interaction of chemical mixtures that may occur when people are exposed to multiple chemicals simultaneously. Thus, human health-based water quality criteria do not take potential exposure to multiple chemicals into account.

The number of complex mixtures that may be found in the environment and concomitantly in fish tissue is difficult to predict. Thus, development of an interactive scheme for all possible chemical combinations is impossible. While the Human Health Focus Group recognizes this limitation, the lack of accounting for chemical interactions is a shortfall in the overall protectiveness of the human health-based water quality criteria. The Human Health Focus Group recommends that there be an accounting for this interaction when criteria are used to establish limits for specific regulatory actions (e.g. Total Maximum Daily Loads, water quality permits, hazardous waste cleanup) where the chemical regime is known.

In addition to concerns with potential exposure regarding the unknown interaction of multiple pollutants in fish tissue that is ingested there are the potential benefits that may occur through the concurrent ingestion of nutrients present in certain fish tissue, such as omega-3-fatty acids (e.g. docosahexaenoic acid and eicosapentaenoic acid) (Oken *et al.* 2005).

7. CONCLUSIONS

The following conclusions are based on the review of the fish consumption surveys discussed in this report as well as the expertise of the Human Health Focus Group.

The Human Health Focus Group was asked to respond to three questions posed by ODEQ, The Confederated Tribes of the Umatilla Reservation and EPA as part of the Fish Consumption Rate Project. The three questions were:

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?
2) How should Pacific salmon be considered in selecting a fish consumption rate and/or setting criteria?
3) To what extent are populations who consume more than the current fish consumption rate of 17.5 g/day at a greater risk for adverse health impacts?

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?

The Human Health Focus Group was able to identify multiple regionally relevant studies of high quality for selecting a fish consumption rate. Indeed, these studies cover not only the Pacific Northwest but the United States and the globe. Each of these studies provides a fresh view of the amount of fish that people consume over their lifetime. The national and international studies, provided as additional references, confirm the view that the level of fish consumption is quite similar across different cultures and countries. The specific types of fish consumed varies across populations.

The Human Health Focus Group reduced its list of nine relevant studies to five that are most useful for recommending fish consumption rate(s) to ODEQ, EPA, and CTUIR. Within these studies there is definitely enough information to provide the State of Oregon with reliable estimates of risk. While these surveys were not specifically done for the people of Oregon, they provide a relevant and reliable range of rates that may be considered by the state.

The Human Health Focus Group also agreed that:

- The current fish consumption rates may be suppressed due to pollution and/or decreased fish abundance
- The current rate of 17.5 grams per day does not reflect Oregon or US population fish consumption rates
- The fish consumption rate should include fish consumers only

- All types of fish should be included in the fish consumption rate regardless of whether they were bought or locally harvested
- An upper-bound fish consumption rate(s) (90 percent or 95 percent, Table 3) should be adopted by ODEQ for Oregon fish consumers

2) *How should Pacific salmon be considered in selecting a fish consumption rate and/or setting criteria?*

The Human Health Focus Group unanimously agreed Pacific salmon should be included in the fish consumption rate. They generally are the primary choice of fish for most fish consumers in the Pacific Northwest.

The RSC factor is not sufficiently defined to allow accounting for contaminant exposure through consumption of Pacific salmon or marine species. All members of the Human Health Focus Group agreed that data available in the surveys reviewed by the Human Health Focus Group did not distinguish between near shore marine species and deep ocean species. Therefore, the recommended fish consumption rate should include all types of marine species since the open ocean and near shore species typically found in Oregon could not be differentiated in the studies reviewed.

3) *To what extent are populations who consume more than the current fish consumption rate of 17.5 grams per day (g/day) at a greater risk for health impacts?*

The Human Health Focus Group finds that the current fish consumption rate would leave a proportion of the population of Oregon without protection. People who eat more than 17.5 grams per day are at an increased risk of heart, kidney or liver disease, neurological and developmental effects, cancer, and other health effects. This is a particular concern for vulnerable populations based on age, gender, or health status. The level of concern increases with higher fish consumption rates and for children since the relative consumption per body weight may be greater than these body weight-based values in adults.

In summary, people who eat more than 17.5 g/day of fish and shellfish will exceed the reference dose, or the level which is considered acceptable by EPA and at which there are no expected adverse health effects. The extent and specificity of that risk is dependent upon the toxicity of the individual chemical and cannot be easily quantified without specific pollutant considerations. People consuming more than 17.5 g/day of fish will also exceed the Oregon acceptable cancer risk level of an additional one in one million chance of developing cancer established by the ODEQ.

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
								Percentile				
						Mean	Median	75th	90th	95th	99th	
	Surveys reviewed by the HHFG											
1	Tulalip Tribes[a]	Children (0-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	3.6	1.2	4.5	11.2			Toy et al 1996
2	Squaxin Island Tribe[v]	Children (0-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	12.5	7.7	18.2	31.3			Toy et al 1996
3	Suquamish Tribe[u]	Children (9 months to 6 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	24	12		57			Toy et al. 1996
4	Columbia River Tribes[p]	Children (0-5 years old)	Consumer only	All	Anadromous & resident fish	19.6		~22	~40	~68	~129	CRITFC 1994
5	Columbia River Tribes - Reevaluation of data[aa]	Children (0-5 years old)	Consumer only	All	Anadromous & resident fish	26.7	16.2		64.8	81	162	CRITFC 1994

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
6	U.S. General Population[q]	Children (3-5 years old)	Consumer + Non-consumer	All	Resident finfish & shellfish from fresh and estuarine environments	2.19		NA	0.05	12.2	52.46	USEPA 2002
7	U.S. General Population[q]	Children (3-5 years old)	Consumer + Non-consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	7.7		NA	32.56	51	100	USEPA 2002
8	U.S. General Population[r]	Children (3-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	74	64	NA	149	184	363	USEPA 2002
9	U.S. General Population[r]	Children (3-5 years old)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	40	23	NA	95	129	205	USEPA 2002
10	Lake Whatcom (WA) Fisherman[x]	Children	Consumer only	Lake Whatcom (WA)	Resident fish		3.6					WDOH 1997

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
								Percentile				
						Mean	Median	75th	90th	95th	99th	
11	Columbia River Tribes[o]	Women who have breastfed (36% of survey respondents)	Consumer only	All	Anadromous & resident fish	59.1		~58.5	~112	~174	~278	CRITFC 1994
12	U.S. General Population[s]	Women (15-44 years old)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	108	77	NA	221	315	494	USEPA 2002
13	U.S. General Population[t]	Women (15-44 years old)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	75	36	NA	172	273	502	USEPA 2002
14	Tulalip Tribes[a]	Adults	Consumer only	All	Anadromous & resident finfish & shellfish	72	45	85	186	244	312	Toy et al 1996
15	Tulalip Tribes[a]	Adults	Consumer only	Harvested anywhere	Anadromous & resident finfish & shellfish	63	37	80	159	236	311	Toy et al 1996
16	Tulalip Tribes[a]	Adults	Consumer only	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	54	30	74	139	194	273	Toy et al 1996

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
								Percentile				
						Mean	Median	75th	90th	95th	99th	
17	Tulalip Tribes[a]	Adults	Consumer only	All	Resident finfish & shellfish	36	18	41	116	132	168	Toy et al 1996
18	Tulalip Tribes[a]	Adults	Consumer only	Harvested anywhere	Resident finfish & shellfish	32	14	40	103	116	157	Toy et al 1996
19	Tulalip Tribes[a]	Adults	Consumer only	Harvested from Puget Sound	Resident finfish & shellfish	31	14	39	90	113	157	Toy et al 1996
20	Squaxin Island Tribe[v]	Adult males	Consumer only	All	All Fish and shellfish	73	NA	NA	165	249	NA	Toy et al 1996
2	Squaxin Island Tribe[v]	Adult females	Consumer only	All	All Fish and shellfish	70	NA	NA	220	274	NA	Toy et al 1996
22	Suquamish Island Tribe[b]	Adults (16 or older)	Consumer only	All	Anadromous & resident finfish & shellfish	214	132		489	NA	NA	Suquamish 2000
23	Suquamish Tribe[c]	Adults (16 or older)	Consumer only	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	165	58	221	397	767	NA	Suquamish 2000
24	Suquamish Tribe[c]	Adults (16 or older)	Consumer only	Harvested from Puget Sound	Resident finfish & shellfish	126	49	116	380	674	NA	Suquamish 2000

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
								Percentile				
						Mean	Median	75th	90th	95th	99th	
25	Columbia River Tribes[d]	Adults	Consumer only	All	Anadromous & resident fish	63	40	60[e]	113[f]	176[g]	389	CRITFC 1994
26	Columbia River Tribes[m]	Adults	Consumer + Non-consumer	All	Anadromous & resident fish	58.7	~40	~57	~113	170	389	CRITFC 1994
27	Columbia River Tribes[n]	Adults	Consumer only	All	Resident fish	~43		~41	~82	~124	~284	CRITFC 1994
28	Asians & Pacific Islanders[h]	Adults	Consumer only	All	Anadromous & resident finfish & shellfish	117	78	139	236	306	NA	Sechena et al 1999
29	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested anywhere	Anadromous & resident finfish & shellfish	16	7	16	49	76	NA	Sechena et al 1999
30	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested from King County	Anadromous & resident finfish & shellfish	14	6	15	26	57	NA	Sechena et al 1999

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
								Percentile				
						Mean	Median	75th	90th	95th	99th	
31	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested anywhere	Resident finfish & shellfish	16	7	18	54	72	NA	Sechena et al 1999
32	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested from King County	Resident finfish & shellfish	14	7	16	33	57	NA	Sechena et al 1999
33	U.S. General Population[i]	Adults (18 or older)	Consumer + Non-consumer	All	Resident freshwater/estuarine finfish & shellfish[j]	8	0	NA	17	50	143	USEPA 2002
34	U.S. General Population[k]	Adults (18 or older)	Consumer + Non-consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	20	0	NA	75	111	216	USEPA 2002
35	U.S. General Population[l]	Adults (18 or older)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	127	99	NA	248	334	519	USEPA 2002
36	U.S. General Population[l]	Adults (18 or older)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	81	47	NA	199	278	505	USEPA 2002

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
37	Columbia Slough Fisherman[w]	Adults	Consumer only	Columbia Slough	Resident finfish & shellfish from fresh and estuarine environments		24	36				Adolfson Associates 1996
38	Sauvie Island Fisherman[w]	Adults	Consumer only	Sauvie Island	Anadromous & resident finfish & shellfish from fresh and estuarine environments		4	6				Adolfson Associates 1996
39	Lake Whatcom (WA) Fisherman[x]	Adults	Consumer only	Lake Whatcom (WA)	Resident fish	6						WDOH 1997
40	Lake Roosevelt (WA) Fisherman[y]	Adults	Consumer only	Lake Roosevelt (WA)	Resident fish	42					90[z]	WDOH 1997
Angler surveys in the U.S. - useful references - surveys not reviewed by the HHFG												
41	Michigan licensed anglers	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	27		35	73	102		West, 93

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						Mean	Median	Percentile				
								75th	90th	95th	99th	
42	Michigan licensed anglers	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	17		20	61	82	489	West, 93
43	S. Carolina	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	48						[ab]jurer et al 1999
44	Michigan	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	27						Chan et al 1999 Having et al 1992 reported in Chan et al 1999
45	Great Lakes	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	21						Chan et al 199 Health Canada 1995 reported in Chan et al 1999
46	Santa Monica Bay (CA) Seafood consumers	anglers who ate fish from Santa Monica Bay	consumer only	harvested locally	All self caught species	50	21		107			SCCWRP and MBC (1994)
	Native American - useful references											
47	Lakes Huron, Michigan, Superior	Adults	subsistence-recall	harvested locally	fresh water fish	62						[ac]Dellinger 2004

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
48	Lake superior	Adults	subsistence-recall	harvested locally	fresh water fish	60						[ad]Dellinger 2004
49	Inland Lakes	Adults	subsistence-recall	harvested locally	fresh water fish	46						[ad]Dellinger 2004
50	Menominee	Adults	subsistence-recall	harvested locally	fresh water fish	34						[ad]Dellinger 2004
51	Other Res	Adults	subsistence-recall	harvested locally	fresh water fish	87						[ad]Dellinger 2004
52	All tribes	Adults	subsistence-recall	harvested locally	fresh water fish	60						[ad]Dellinger 2004
53	Lakes Huron, Michigan, Superior	Adults	subsistence-actual	harvested locally	fresh water fish	4						[ad]Dellinger 2004
54	Lake superior	Adults	subsistence-actual	harvested locally	fresh water fish	11						[ad]Dellinger 2004
55	Inland Lakes	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
56	Menominee	Adults	subsistence-actual	harvested locally	fresh water fish	34						[ad]Dellinger 2004

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
57	Other Res	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
58	All tribes	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
59	Mohawk, Montreal	Adults	consumers	harvested locally	fresh water fish	33						[ae]Chan et al, 1999
60	Mohawk, Montreal	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	23						[ae]Chan et al, 1999
61	Akwasasne	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	25						Chan et al 1999 Forti et al 1995 reported in Chan et al 1999
62	Wisconsin Chippewa	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	26						Chan et al Peterson et al 1994 reported in Chan et al 1999
63	Ojibwa	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	23						Burger et al 1999; Dellinger et al 1997 reported in Burger et al 1999

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile 75th	Percentile 90th	Percentile 95th	Percentile 99th	
64	Canadian First Nation	All ages	consumers	harvested locally	salmon only	28						[am]Mos et al, 2004
65	Canadian First Nation	All ages	consumers	harvested locally	salmon only	48						[af]Mos et al, 2004
66	Canadian First Nation	All ages	consumers	harvested locally	all marine species including salmon	44						[af]Mos et al, 2004
World												
67	Japan	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	96						[ag]Nakagawa et al, 1997 (1976 data from Kitamura et al 1976)
68	Japan	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	163						[ag]Nakagawa et al, 1997
69	Hong Kong	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	52						[ah]Dickman and Leung, 1998

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
70	Hong Kong	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	164						[ah]Dickman and Leung, 1998 extracted from Euromonitor 1997

Footnotes:

[a] Values computed from Toy et al. 1996 study data (Kissinger 2003).
[b] Values g/kg/day for "all seafood" taken from Table T-3 of the Suquamish Survey (Suquamish 2000) and converted to g/day by multiplying by the average body weight for men and women of 79 kg
[c] Values computed by ShiQuan Liao and Nayak Polissar of the Mountain Whisper Light Statistical Consulting company for the Suquamish Tribe (Liao and Polissar 2007)
[d] Values compiled from Table 10 "Number of Grams per Day Consumed by Adult Fish Consumers" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)
[a] A value of 60 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 75th percentile (48.6 g/day, 65.1%) and (64.8 g/day, 79.1%)
[f] A value of 113 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 90th percentile (97.2 g/day, 88.5%) and (130 g/day, 91.6%)
[g] A value of 176 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 95th percentile (170 g/day, 94.4%) and (194 g/day, 97%)
[h] Values computed from 1999 EPA Asian Pacific Islander seafood consumption survey data (Kissinger 2005). Kissinger (2005) converted mixed cooked and raw wet weight consumption rate information from the 1999 publication into a wet weight consumption rate.
[i] Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "freshwater/estuarine" section of the table are used.
[j] Pacific salmon were assigned to consumption of marine species rather than estuarine species (SEE Section 2.1.1 of EPA 2002 for an explanation).
[k] Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used.
[l] Values taken from EPA 2002 Section 5.2.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used.
[m] Values compiled from Table 7 "Number of Grams per Day of Fish Consumed by Adult Respondents (Fish consumers and non-fish consumers) combined - Throughout the year" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)
[n] Values compiled from Tables 10, 18 and 19 from CRITFC 1994. The average consumption rate for Pacific Northwest Salmon was estimated to be 20 grams/day. That was subtracted from the average for all fish for consumers only to result in 43 grams/day as the average fish consumption for adult consumers only for resident fish. The ratio of .73% (all fish/resident) was then applied to the other percentiles. All values are estimates.
[o] The mean values were taken from Table 16 and all other percentiles were estimated from Table 15 in CRITFC 1994. All calculated values are estimates.
[p] The mean values were taken from Table 24 and all other percentiles were estimated from Table 24 in CRITFC 1994. All calculated values are estimates.

[q] All values taken from EPA 2002 Section 5.1.1.1, Table 5
[r] All values taken from EPA 2002 Section 5.2.1.1, Table 5
[s] All values taken from EPA 2002 Section 5.2.1.1, Table 3
[t] All values taken from EPA 2002 Section 5.2.1.1, Table 1
[u] All values calculated using 16.8 as the average body weight of children and applying that body weight to values in Table T-14 in Suquamish 2000
[v] All values were calculated using an average child BW of 15.2 kg (from Table A1) and the consumption rates Toy et al., 1996, Table A9
[v] All values were calculated using an average adult female BW of 76 kg and adult male body weight of 86 kg (from Table A1) and the consumption rates Toy et al., 1996, Table A4
[w] All values taken from Adolphson 1996, Table 4, page 20. Values were converted to grams/day from kg/person/year.
[x] All values taken from Dave McBride's summary of the Lake Whatcom 2001 study. Adult average consumption of 225 g/meal was used along with a median children rate of 131 g/meal. 10 meals were assumed per year
[y] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study.
[z] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study. 90g/day was labeled as "high end consumers" and placed in the 99th percentile column for that reason.
[aa] All values taken from Rhodes 2006, Table 32.
[ab] Burger et al 1999; interview of Savannah R fisherman; n=258; mean serving size 376 g; mean fish/month 1.46 kg; mean fish per year 17.6 kg; mean age 43; 48 g/day
[ac] Chan et al 1999 questionnaire of consumption over the past 12 months; n= 42, average age 39 years; 474 to 766 grams per meal
[ad] Dellinger, 2004 questionnaire fish consumption for 12 months; estimated grams per meal = 280 grams, GLIFWC 2003 summarized in Dellinger 2003 147 tribal members from 1999 to 2002
Lake Huron Michigan, Superior male & female adults (n=271 age 40)
Lake Superior male & female adults (n= 346; 41 years)
Inland Lakes male & female adults (n=63; age=40)
Menominee male & female adults (n=66; age=39)
Other Res male & female adults (n=76; age=43)
All tribes male & female adults (n=822; age=41)
[ae] Moss et al 2004, interview of 4 Sencoten villages during summer of 2001; n=76 ages 13-75; individuals selected at random; focused on marine species; estimate monthly or yearly number of meals;
estimate grams per day (1 portion = 180 grams); 36 meals of salmon per year= 10.3 kg per person per year; 86 meals of all marine food per person per year;
Note adults over 40 years consume more fish than youth or young adults (13-40 years)
44 g/day 86 meals x 186 grams/meal divided by 365
28 g/day 10.3 kg x 100 g/kg divided by 365
48 g/day 17.5 kg x 100 g/kg divided by 365
[af] Nagakawa et al 1997 study of mercury in fish; fish rates are mean consumption of eatable fish per capita per day. Methodology for consumption survey was not reported.
1976 data are extracted from Kitamura, s. Kondo, m. Takizawa, t. Fuji, m. Mercury Kodansha Japan 267-273 1976
[ag] Dickman and Leung 1998; study of mercury and PCBs in fish tissue; Hong Kong Asians consume fish 3 to 4 times per week; Hong Kong average person 4 or more times per week average 60 kg per year; Finland and Europe fish consumption is lower; assuming 1/2 of what is imported is consumed = 18.9 kg fresh fish per person or 52 grams per day.
164 g/day 60 kg/year extracted from Consumer Asia Euromonitor plc 60-61 Britton St. London ECIM 5NA 1997
52 g/day 234500 tonnes of fish imported 1/2 consumed = 117245 tonnes by 6.2 million people 18.9 kg fresh fish per person or 52 grams per day
[ah] Values computed using a weighted average of body weight for males and females from Table A1, which was calculated as 82kg. Body weight was multiplied by "total fish" values in Table A2 to obtain final values listed.

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10. GLOSSARY OF ACRONYMS AND UNITS OF MEASURE

10.1 ACRONYMS

AWQC	Ambient Water Quality Criteria.
BCF	Bioconcentration factor (generally expressed in liters per kilogram)
BW	Body weight (generally expressed in kilograms)
CRITFC	Columbia River Inter-Tribal Fish Commission, including the Warm Springs, Yakama, Umatilla, and Nez Perce Tribes
CROET	Center for Research on Occupational and Environmental Toxicology (CROET), Oregon Health & Science University
CSFII	Continuing Survey of Food Intakes by Individuals. A survey conducted by the United States Department of Agriculture (USDA) 1994-1996 and 1998
CTUIR	Confederated Tribes of the Umatilla Indian Reservation, including the Cayuse, Umatilla and Walla Walla Tribes
CWA	Clean Water Act.
DABT	Diplomat of the American Board of Toxicology
DEQ	Oregon Department of Environmental Quality
DHS	Oregon Department of Human Services
DI	Drinking water intake (generally expressed in liters per day)
EPA	United States Environmental Protection Agency
EQC	Environmental Quality Commission
FCR Project	Oregon Fish and Shellfish Consumption Rate Project
FCR	Fish Consumption Rate
HHFG	Human Health Focus Group
HQ	Hazard Quotient

NMFS	National Marine Fisheries Service
NPDES	National Pollutant Discharge Elimination System program
OAR	Oregon Administrative Rules
OEHHA	Office of Environmental Health Hazard Assessment; a division of the California Environmental Protection Agency
PAC	Policy Advisory Committee
PCB	Polychlorinated biphenyl
RfD	Reference dose
RSC	Relative Source Contribution
TAC	Technical Advisory Committee
TMDL	Total Maximum Daily Load
URL	Uniform Resource Locator, the global address of documents and other resources on the World Wide Web
USDA	United States Department of Agriculture
WQC	Water quality criteria.
WQS	Water quality standards
WSDOH	Washington State Department of Health.

10.2 UNITS OF MEASURE

g/day	grams per day
g/kg/day	grams per kilogram per day
kg	kilogram
kg/day	kilogram per day
L/day	liter per day
L/kg	liter per kilogram
µg/L	micrograms per liter
mg/kg	milligrams per kilogram
mg/kg/day	milligrams per kilogram per day

APPENDIX A: FISH SPECIES IDENTIFIED AS CONSUMED IN SELECT SURVEYS

APPENDIX A – 1. SPECIES GROUPS LISTED IN A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN (CRITFC, 1994)

Anadromous	Resident
Salmon	Trout
Steelhead	Whitefish
Lamprey	Sturgeon
Smelt	Walleye
Shad	Squawfish
	Sucker

APPENDIX A – 2. SPECIES GROUPS LISTED IN A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION (TOY ET AL. 1996)

Group A	Group B	Group C	Group D	Group E	Group F
Anadromous	**Pelagic**	**Bottom**	**Shellfish**	**Other**	**Other 2**
Chinook salmon	Cod	Halibut	Clams (Manila/Littleneck)	Canned Tuna	Trout
Pink salmon	Pollock	Sole/Flounder	Horse clam		
Sockeye salmon	Sablefish	Sturgeon	Butter clam		
Coho salmon	Rockfish	Skate	Cockles		
Chum salmon	Greenling	Eel	Mussels		
unidentified salmon	Herring	Grunters	Oysters		
Steelhead	Spiny		Shrimp		
Smelt	Dogfish		Dungeness Crab		
	Perch		Red Rock Crab		
	Mackeral		Moon Snail		
	Shark		Scallops		
			Squid		
			Sea Urchin		
			Sea Cucumber		
			Sea Urchin		
			Geoduck		
			Limpets		
			Lobster		
			Bullhead		
			Manta Ray		
			Razor clam		
			Chitons		
			Octopus		
			Abalone		
			Chitons		
			Barnacles		
			Crayfish		

Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish, 2000)

APPENDIX A-3. SPECIES GROUPS LISTED IN FISH CONSUMPTION SURVEY OF THE SUQUAMISH TRIBES OF THE PORT MADISON INDIAN RESERVATION, PUGET SOUND REGION (SUQUAMISH, 2000)

Group A	Group B	Group C	Group D	Group E	Group F	Group G
King salmon	Smelt	Cod	Halibut	Manila/Littleneck clams	Cabezon	Abalone
Sockeye salmon	Herring	Perch	Sole/Flounder	Horse clams	Blue Back (sockeye)	Lobster
Coho salmon		Pollock	Rockfish	Butter clams	Trout/cutthroat	Octopus
Chum salmon		Sturgeon		Geoduck	Tuna (fresh/canned)	Limpets
Pink salmon		Sable fish		Cockles	Groupers	Miscellaneous
unidentified salmon		Spiny dogfish		Oysters	Sardine	
Steelhead		Greenling		Mussels	Grunter	
Salmon (gatherings)		Bull Cod		Moon snails	Mackerel	
				Shrimp	Shark	
				Dungeness crab		
				Red rock crab		
				Scallops		
				Squid		
				Sea urchin		
				Sea cucumber		
				Oysters (gatherings)		
				Clams (gatherings)		
				Crab (gatherings)		
				Clams (razor, unspecified)		
				Crab (king/snow)		

APPENDIX A-4 SPECIES GROUPS IN ASIAN AND PACIFIC ISLANDER SEAFOOD CONSUMPTION STUDY (SECHENA ET AL. 1999).

Anadromous Fish	%	Pelagic Fish	%	Freshwater Fish	%	Bottom Fish	%	Shellfish	%	Seaweed /Kelp	%
Salmon	93	tuna	86	catfish	58	halibut	65	shrimp	98	seaweed	57
Trout	61	cod	66	tilapia	45	sole/flounder	42	crab	96	kelp	29
Smelt	45	mackerel	62	perch	39	sturgeon	13	squid	82		
Salmon eggs	27	snapper	50	bass	28	suckers	4	oysters	71		
		rockfish	34	carp	22			manila/ littleneck clams	72		
		herring	21	crappie	17			lobster	65		
		dogfish	7					mussel	62		
		snowfish	6					scallops	57		
								butter clams	39		
								geoduck	34		
								cockles	21		
								abalone	15		
								razor clams	16		
								sea cucumber	51		
								sea urchin	14		
								horse clams	13		
								macoma clams	9		
								moonsnail	4		

APPENDIX B: RELATIVE SOURCE CONTRIBUTION FACTOR FOR METHYLMERCURY

Excerpt from EPA Criterion document for Methylmercury Table 5-14, Average Mercury Concentrations in Marine Fish and Shellfish Species (EPA 2001).

Species	Concentration [a] (µg Hg/g Wet Wt.)	Species	Concentration [a] (µg Hg/g Wet Wt.)
Finfish			
Anchovy	0.047	Pompano*	0.104
Barracuda, Pacific	0.177	Porgy*	0.522[b]
Cod*	0.121	Ray	0.176
Croaker, Atlantic	0.125	***Salmon****	***0.035***
Eel, American	0.213	Sardines*	0.1
Flounder*,[e]	0.092	Sea Bass*	0.135
Haddock*	0.089	Shark*	1.327
Hake	0.145	Skate	0.176
Halibut*	0.25	Smelt, Rainbow*	0.1
Herring	0.013	Snapper*	0.25
Kingfish	0.10	Sturgeon	0.235
Mackerel*	0.081	Swordfish*	0.95[c]
Mullet	0.009	Tuna*	0.206
Ocean Perch*	0.116	Whiting (silver hake)*	0.041
Pollock*	0.15	Whitefish*	0.054[d]
Shellfish			
Abalone	0.016	Oysters	0.023
Clam*	0.023	Scallop*	0.042
Crab*	0.117	Shrimp	0.047
Lobster*	0.232	Other shellfish*	0.012b
Molluscan Cephalopods			
Octopus*	0.029	Squid*	0.026

Source: U.S. EPA (1997c).

*Denotes species used in calculation of methylmercury intake from marine fish for one or more populations of concern, based on existence of data for consumption in the CSFII (U.S. EPA, 2000b).

[a] Mercury concentrations are from NMFS (1978) as reported in U.S. EPA (1997d) unless otherwise noted, measured as ug of total mercury per gram wet weight of fish tissue.

[b] Mercury concentration data are from Stern et al. (1996) as cited in U.S. EPA (1997c).

[c] Mercury concentration data are from U.S. FDA Compliance Testing as cited in U.S. EPA (1997c).

[d] Mercury concentration data are from U.S. FDA (1978) as cited in U.S. EPA (1997c).

[e] Mercury data for flounder were used as an estimate of mercury concentration in marine flatfish in marine intake calculations.

U.S. EPA. 1997c. Mercury study report to Congress. Vol. IV. An assessment of exposure to mercury in the United States. U.S. EPA, Office of Air Quality Planning and Standards and Office of Research and Development. EPA/452/R-97-006.

U.S. EPA. 2000b. Estimated per capita fish consumption in the united states: based on data collected by the United States Department of Agriculture's 1994-1996 continuing survey of food intake by individuals. Office of Science and Technology, Office of Water, Washington, DC. March.

U.S. FDA (United States Food and Drug Administration). 1978. As cited in text *Mercury Study Report to Congress*. Vol. IV. Reference information not listed in bibliography.

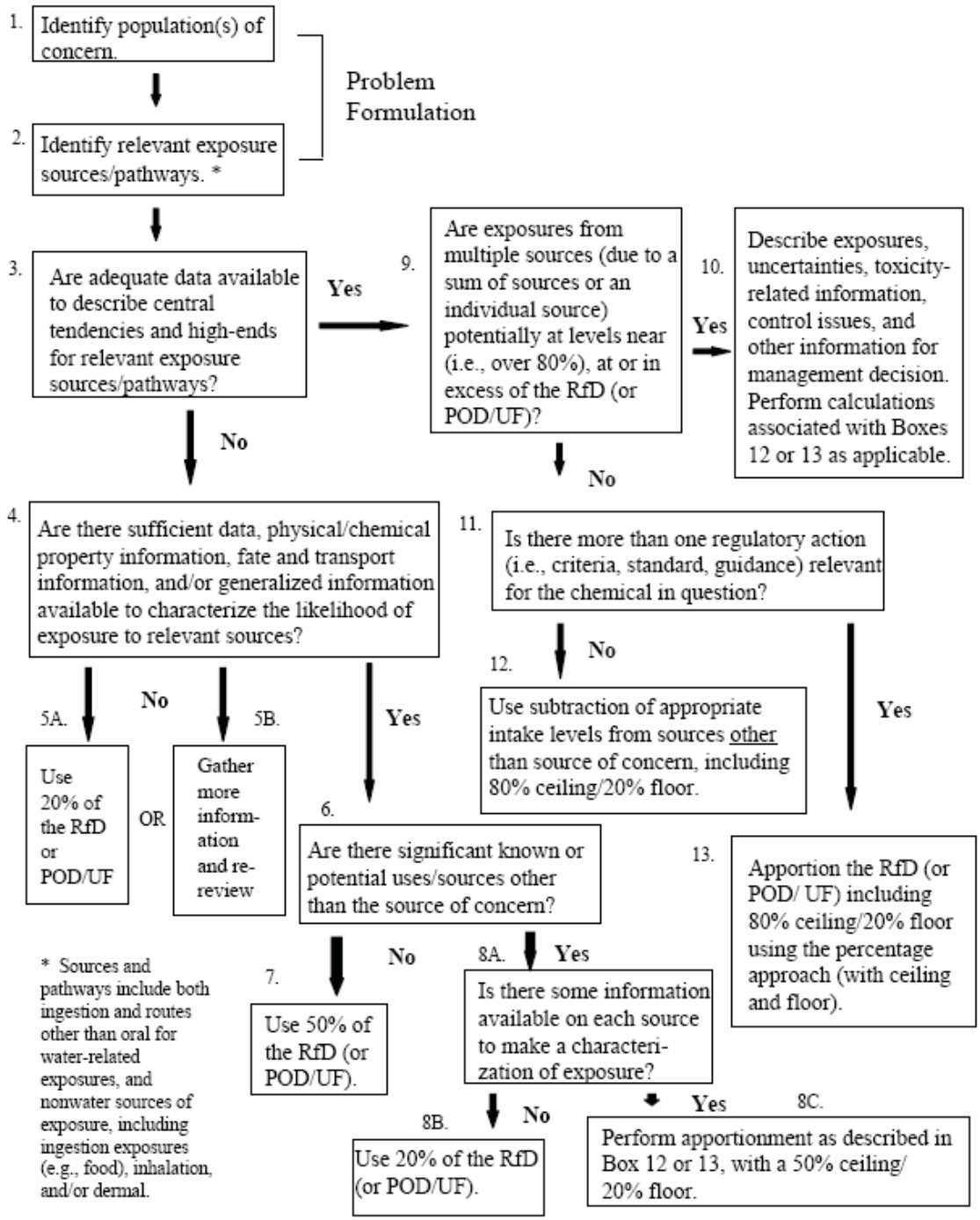
APPENDIX C: BASIS FOR RELATIVE SOURCE CONTRIBUTION VARIABLES

Compound	EPA's Recommended RSC[1, 2]	Sources of Exposure	Citation
Antimony	40%	Drinking Water Contribution= 40% Diet Contribution=50%, Inhalation Contribution=10%	Drinking Water: National Primary Drinking Water Regulations (7/17/1992) 57 FR 31784
Methylmercury	2.7×10^{-5} mg/kg BW/day (subtracted from RfD)	Accounts for marine fish consumption	EPA Methylmercury Criterion Document (1/2001) EPA 823-R-01-001
Thallium	20%		
Cyanide	20%	Available data on dietary exposure are inadequate, so apply the default value of 20% RSC.	Drinking Water: National Primary Drinking Water Regulations (7/17/1992) 57 FR 31784
Chlorobenzene	20%		
1,1 Dichloroethylene	20%	Detected in several sources (i.e. air, and wells contaminated with other solvents).	EPA Health Advisory for 1,1-Dichloroethylene of Office of Drinking Water (3/31/1987)
Ethylbenzene	20%	Primary source of exposure is from the air, although contaminants in drinking water can be quite high for wells near leaking gasoline storage tanks and drinking waters taken from surface waters.	Technical Fact Sheet on Ethylbenzene for the National Primary Drinking Water Regulations. http://www.epa.gov/safewater/dwh/t-voc/ethylben.html
Toluene	20%	Based on available data, the major source of toluene exposure is from air; occurs in low levels in drinking water, food and air. Where actual exposure data are not available, 20% RSC is assumed.	EPA Health Advisory for Toluene of Office of Drinking Water (3/31/1987)
1,2 Transdichloroethylene	20%		
1,2 Dichlorobenzene	20%	Detected in multiple sources (i.e. ground water, surface water, air), however there are insufficient data to determine where the major route of environmental exposure.	EPA Health Advisory for Ortho-, Meta-, and Para-Dichlorobenzenes of Office of Drinking Water (3/31/1987)

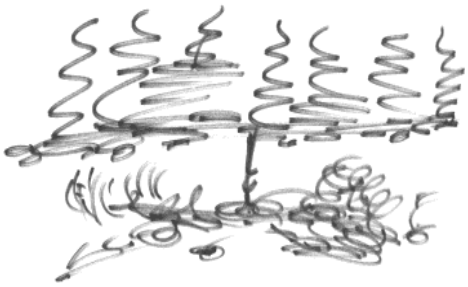
Compound	EPA's Recommended RSC[1, 2]	Sources of Exposure	Citation
1,4 Dichlorobenzene	20%	Detected in multiple sources (i.e. ground water, surface water, air), however there are insufficient data to determine where the major route of environmental exposure.	EPA Health Advisory for Ortho-, Meta-, and Para-Dichlorobenzenes of Office of Drinking Water (3/31/1987)
Heachlorocyclo-pentadiene	20%		
1,2,4 Trichlorobenzene	20%		
Gamma BHC	20%		
Endrin	20%	Human exposure appears to most come from food or an occupational source. Monitoring data demonstrates it continues to be a contaminant from air, water, sediment, soil, fish, and other aquatic organisms.	Technical Fact Sheet on Endrin for the National Primary Drinking Water Regulations. http://www.epa.gov/safewater/dwh/t-soc/endrin.html

[1] EPA, 2002. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012.
[2] EPA, 2003. National Recommended Water Quality Criteria for the protection of Human Health. 68 FR 75507-75515.

APPENDIX D: EPA's DECISION TREE FOR DEVELOPING A RELATIVE SOURCE CONTRIBUTION [2]



[2] EPA, 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. EPA 822-B-00-0004. P. 4-8.



The Mountain-Whisper-Light Statistics

1827 23rd Ave. East, Seattle, WA 98112-2913

Date: 10/31/13

To: Cheryl Niemi, Becca Conklin

From: Nayak Polissar, Dan Hippe

Re: Fish consumption rates for a hypothetical combination of Puget Sound tribes.

Here is our report on consumption rates for a hypothetical population of pooled Native American Tribes, pooling fish consumption rates from the Squaxin Island Tribe, Squamish Tribe and Tulalip Tribes.

Background and Objectives

We were asked by the Washington Department of Ecology (Ecology) to provide estimates of fish consumption rates for a hypothetical population. The composition of that population would consist of an equal proportions of members drawn from three Native American Tribes residing in the Puget Sound region: the Squaxin Island Tribe, the Squamish Tribe and the Tulalip Tribes[1]. The fish consumption rates for these three Tribes were to be drawn from publicly available sources. Our objective was to provide estimates of the mean consumption rate and selected percentiles of the consumption rate distribution for the combined population. Further, the rates were to derived under three scenarios: 1) including all fish and shellfish consumption; 2) the same, but excluding anadromous fish consumption; 3) the same as #1 but including only part (58.8%) of anadromous fish consumption (see *Methods*.)

Summary of findings

A selection of the derived rates for the combined population are presented in Table A and additional rates are provided later. The scenario of reduced anadromous consumption (scenario 2) decreases the mean consumption rate about 15% compared to the rate for all seafood without reduction (scenario 1.) Complete elimination of anadromous consumption (scenario 3) reduces the mean rate by 37% compared to scenario 1. A rough estimate of the margin of error of these rates is also presented later and indicates moderate uncertainty.

[1] Throughout this document, all consumption rates refer to adults and all rates are for consumers.

The percentiles of consumption rates for the hypothetical combined population can differ substantially from the percentiles for the three individual tribes. For example, the 90th percentile value for all seafood consumption, 302.9 g/day from Table A, indicates that 90% of the hypothetical combined population consumes at a rate of 302.9 g/day or less and 10% of the combined population consumes at a higher rate. For the underlying tribal populations, 22% of the Suquamish Tribe consumes at a higher rate than 302.9 g/day along with 3.2%% of the Tulalip Tribes and 1.5% of the Squaxin Island Tribe. Similarly, for the three consumption scenarios and for the higher percentiles, a larger percentage of the Suquamish Tribe and smaller percentages of the Tulalip and Squaxin Island Tribes consume more than the given rate than in the combined population.

Table A. Fish consumption rates (grams/day) for a combined population: mean and selected percentiles for three scenarios.

Statistic	All seafood (g/day)	All, incl. part of anadromous (g/day)	All except anadromous (g/day)
Mean	127.2	108.0	80.4
50th percentile (median)	60.9	49.0	32.2
90th percentile	*302.9	*265.7	*208.5
95th percentile	*466.5	*407.6	**

*Estimation involved extrapolation beyond published rates for at least one of the three tribes.
**Percentile not provided because extrapolation beyond the 99th percentile for at least one tribe would be needed.

Methods

A percentile of a population's consumption rates is a value calculated to include the stated percentage of the population consuming at or below the consumption rate. For example, if 302.9 g/day is the 90th percentile rate, then 90% of the population consumes at or below that rate per day. A collection of percentiles of consumption for a population is usually referred to as a distribution.

The mean (average) and selected percentiles of seafood consumption rates were extracted from published reports for three tribes (Squamish Tribe: Suquamish 2000 and Liao 2002; Tulalip and Squaxin Island Tribes: Polissar 2006). Intermediate percentiles that were not available were estimated using interpolation between pairs of percentiles. Extrapolation of rates to percentiles beyond the 95th percentile (the largest available percentile from previous reports) up to the 99th percentile were calculated for each Tribe[2]. These estimated seafood consumption distributions were combined using formal statistical methods, giving each Tribe equal

[2] Interpolation and extrapolation of percentiles were based on the lognormal distribution. See the technical appendix.

weight, i.e., 1/3 weight for each Tribe, summing to 1.0. For example, if 100 g/day corresponded to the 40th, 50th and 60th percentiles of the three Tribes, respectively, then 100 g/day would correspond to the 50th percentile of the combined distribution (i.e., [40+50+60]/3). This operation corresponds to pooling three tribes into a hypothetical population which has equal numbers of members from each tribe.

Three scenarios of fish consumption were considered, The scenarios differ only in the amount of anadromous fish consumption that is included, as follows: 1) include all seafood; 2) all seafood except reduced anadromous consumption; 3) all seafood except no anadromous consumption. The source reports provided estimates for all-seafood consumption rates (used directly for scenario 1) and for anadromous species consumption rates. The previous reports were used to statistically estimate an overall proportion of anadromous seafood consumed per tribe, which was removed from the all-seafood consumption estimates to generate scenario 3. An adjustment to the proportion of anadromous seafood to be removed was made to generate scenario 2—partial removal of anadromous consumption from all-seafood consumption rates. The Washington Department of Ecology provided the adjustment factors that were the basis for partial removal of anadromous consumption from all-seafood consumption. The adjustment retained 58.8% of each tribe's anadromous fish consumption prior to pooling consumption to yield rates for the hypothetical combined of tribes. The value of 58.8% retained has been based on the following assumptions and values supplied by Ecology[3].

1. Anadromous consumption is composed of 50% Chinook and 50% Coho consumption.

2. Among the consumed Chinook species, 70% are migratory and 30% are non-migratory (resident in Puget Sound.)

3. Among the non-migratory Puget Sound Chinook (the 30% component) 100% of contaminants are from Washington. Retain 100% of this component in the adjusted consumption rate.

4. Among the Puget Sound migratory Chinook (the 70% component) 78% of contaminants are from Washington. Retain 78% of this component in the adjusted consumption rate.

5. Among the Puget Sound migratory Coho salmon 33% of the contaminants are from Washington. Retain 33% of this component in the adjusted consumption rate.

These values lead to the following calculation of the proportion of anadromous consumption to be retained in the adjusted rate. Percentages have been converted to proportions.

Proportion retained = 0.5*0.3*1.0 + 0.5*0.7*0.78 + 0.5*0.33 = 0.588.

[3] Email message from Ecology, 10/14/13.

Approximate uncertainty bounds were computed for selected rates (see technical appendix.) They indicate "margin of error" for the selected percentile rates. These bounds should be viewed as a rough guide and should only be used qualitatively, e.g., narrow or wide[4].

RESULTS AND DISCUSSION.

Key summaries of the combined consumption rates under the three scenarios are shown in tabular form in Table 1 and graphically in Figures 1.S1, 1.S2 and 1.S3. For example, under scenario 1 (all seafood consumption), the 50th percentile (also known as the median) was estimated as 60.9 g/day. The interpretation is that 50% of individuals in the hypothetical combined population consume seafood at this daily rate or less and that 50% consume at a higher rate. The 90th percentile for scenario 1 was estimated as 302.9 g/day, so 90% of individuals would consume at or below this rate and 10% would consume at a higher rate. The margin of error, or uncertainty bounds on the rate of 302.9 g/day is 237.3 g/day up to 386.6 g/day, as shown in Table 1. Thus, it is plausible that the true 90th percentile consumption rate for this combined population is between 237 and 387 g/day, a moderately wide interval of uncertainty. The uncertainty bounds for selected percentiles of each scenario are shown in Figures 1.S1-1.S4. For example, the 90th percentile rate of 302.9 g/day for scenario 1 (all seafood) is shown as a vertical bar in figure 1.S1, and the "whiskers" extending above and below the bar indicate the uncertainty interval, extending down to 237 g/day and up to 387 g/day.

The 95th percentile of each individual tribe was available in published reports, but in some cases higher percentiles were needed for at least one of the tribes in order to compute the combined population's 95th percentile rate. When needed, these higher percentiles (beyond the 95th percentile) were calculated by extrapolation[5]. However, we do not present any combined population rates that would require extrapolation to a 99th percentile rate or higher from one of the individual tribes.

All rates which involved extrapolation are noted in the tables and figures with asterisks (*). More caution is needed in using these rates. Tables 4.S1-4.S3 show which percentiles were needed from each Tribe, with values >95% bolded. For example, from Table 1.S1, to compute the scenario 1 (all seafood) 90th percentile of 302.9 g/day, the 78th Suquamish percentile, 96.8th Tulalip percentile and 95.5th Squaxin percentile were needed. The latter two percentile rates were calculated by extrapolation.

[4] The bounds are calculated in the methodologic spirit of 95% confidence intervals, but they are quite approximate and should not be taken as formal 95% confidence intervals. See the technical appendix.
[5] The extrapolation was carried out assuming that each Tribe's consumption followed a log-normal distribution (which appeared reasonable between the 5th and 95th percentiles for each Tribe—see Technical Appendix.) Without additional data the quality of these extrapolations is unknown.

The consumption rates of the combined population are different than those of the three individual tribes. The preceding paragraph shows that diverse percentiles from the individual tribes were needed to calculate a given percentile of consumption rates for the combined population. In the example given in the preceding paragraph 10% of the combined population would have consumption rates higher than the 90th percentile consumption rate of 302.9 g/day. That is simply the definition of a 90th percentile—10% of the consumers lie beyond the 90th percentile. In constructing that combined percentile rate the individual tribes had quite diverse percentages of their members consuming more than 302.9 g/day. The value of 302.9 g/day was the 78th percentile consumption rate of the Suquamish Tribe, which means that the tribe had 22% of adult members consuming more than 302.9 g/day. Stated differently, the tribe had more than twice as many people consuming above the noted rate compared to what would be expected from the combined population. On the other hand, the Tulalip and Squaxin Island Tribes had, respectively, less than half or about half as many of their members consuming above the noted rate compared to the combined tribe. This shows that the combined population is its own population that its percentiles of consumption may differ quite substantially from the percentiles of the individual tribes.

Figures 2 and 3 are provided as technical illustrations of the consumption rate distributions. Figure 2 illustrates how estimated consumption distributions were combined. The dotted blue (Tulalip) and green (Squaxin Island) curves start at the 95th percentile (see y-axis) and show the extrapolation for the corresponding Tribes. These curves end at the extrapolated 99th percentile. Note that the black curve corresponding to the combined distribution, which is in between the other three curves, starts to become dotted at the same point on the x-axis as the blue curve (Tulalip), because that is when the extrapolation for the Tulalip was needed. The black curve ends at the same point on the x-axis as the blue curve ends.

Figure 3 illustrates combined consumption distributions under the three scenarios. Note, in particular, where scenario 2 falls between scenario 1 and 3. The scenario 1 curve (red) is the same as the black curve in Figure 2.

Tables

Figures

Table 1. Selected consumption rate estimates with uncertainty estimates for the combined population, adult consumers, under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Combined Estimates, g/day								
	Scenario 1			Scenario 2			Scenario 3		
Statistic	**Estimate**	**LB**	**UB**	**Estimate**	**LB**	**UB**	**Estimate**	**LB**	**UB**
Mean	127.2	100.4	161.3	108.0	84.7	137.6	80.4	62.0	104.3
p10	9.8	7.2	12.4	7.7	5.6	9.7	**	-	-
p25	26.0	21.1	32.1	20.7	16.8	25.6	12.3	9.9	15.3
p50 (median)	60.9	50.8	72.9	49.0	40.8	58.9	32.2	26.6	39.0
p75	145.8	120.0	177.2	124.0	101.6	151.4	85.2	68.9	105.3
p80	179.4	145.8	220.6	151.5	122.5	187.3	*109.8	88.0	137.0
p85	216.8	174.3	269.6	*180.5	144.8	225.1	*135.6	107.4	171.1
p90	*302.9	237.3	386.6	*265.7	207.3	340.7	*208.5	163.3	266.4
p95	*466.5	354.2	614.6	*407.6	311.9	532.7	**	-	-

LB=lower approximate uncertainty bound; UB=upper approximate uncertainty bound; pXX is the XXth percentile;

*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption;

**Percentile not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed.

Table 2. Consumption rate estimates for the combined population, adult consumers, under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Combined Estimate, g/day		
	Scenario 1	**Scenario 2**	**Scenario 3**
Mean	127.2	108.0	80.4
p10	9.8	7.7	**
p15	15.1	11.8	6.7
p20	20.8	16.5	9.3
p25	26.0	20.7	12.3
p30	31.9	25.4	15.4
p35	38.7	30.9	18.7
p40	45.2	36.9	22.6
p45	52.0	42.4	27.3
p50 (median)	60.9	49.0	32.2
p55	70.9	57.7	37.7
p60	79.1	67.5	45.1
p65	96.5	77.6	54.8
p70	120.9	99.1	64.4
p75	145.8	124.0	85.2
p80	179.4	151.5	*109.8
p85	216.8	*180.5	*135.6
p90	*302.9	*265.7	*208.5
p95	*466.5	*407.6	**

pXX is the XXth percentile;

*Percentiles were extrapolated beyond the 95th percentile for some individual Tribes using a log-normal assumption;

**Percentile not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed.

Table 3. Mean consumption for individual Tribes and combined under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Mean, g/day		
	Scenario 1	**Scenario 2**	**Scenario 3**
Suquamish	213.9	193.7	165.0
Tulalip	84.1	69.1	47.7
Squaxin	83.7	61.0	28.6
Combined	127.2	108.0	80.4

Table 4.S1. Select percentiles from the combined consumption distribution from scenario 1 (all seafood) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	9.8	2	15	13
p25	26.0	9	33	33
p50 (Median)	60.9	28	61	61
p75	145.8	55	85	84
p80	179.4	63	89	88
p85	216.8	69	95.0	91
p90	*302.9	78	**96.8**	**95.5**
p95	*466.5	89	**98.2**	**97.7**

pXX is the XXth percentile; extrapolated percentiles (i.e. > 95th percentile) are bolded;

*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

Table 4.S2. Select percentiles from the combined consumption distribution from scenario 2 (all seafood minus adjusted anadromous consumption) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	7.7	2	14	14
p25	20.7	7	32	36
p50 (Median)	49.0	26	60	64
p75	124.0	52	86	87
p80	151.5	61	89	90
p85	*180.5	67	**95.1**	93
p90	*265.7	76	**97.0**	**96.6**
p95	*407.6	88	**98.4**	**98.3**

pXX is the XXth percentile; extrapolated percentiles (i.e. > 95th percentile) are bolded;

*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

Table 4.S3. Select percentiles from the combined consumption distribution from scenario 3 (all seafood minus all anadromous consumption) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	**	-	-	-
p25	12.3	4	28	43
p50 (Median)	32.2	17	58	75
p75	85.2	46	86	93
p80	*109.8	54	90	**95.9**
p85	*135.6	62	**95.6**	**97.0**
p90	*208.5	74	**97.5**	**98.5**
p95	**	87	**98.8**	**99.4**

pXX is the XXth percentile; extrapolated percentiles (i.e. > 95th percentile) are bolded;

*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

**Percentile not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed.

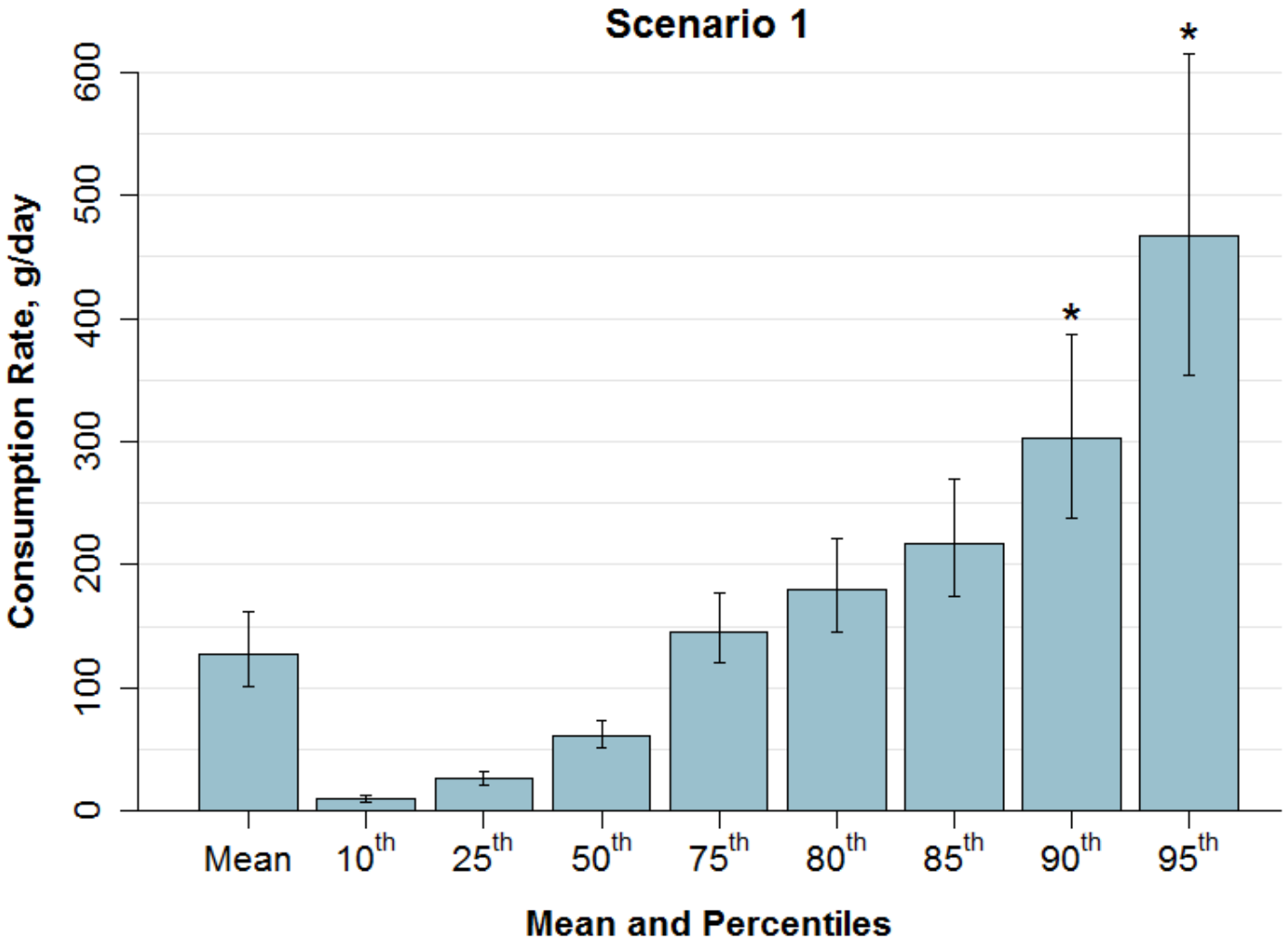


Figure 1.S1. Mean and percentiles of the combined consumption distribution in scenario 1 (all seafood). The error bars indicate approximate uncertainty bounds. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

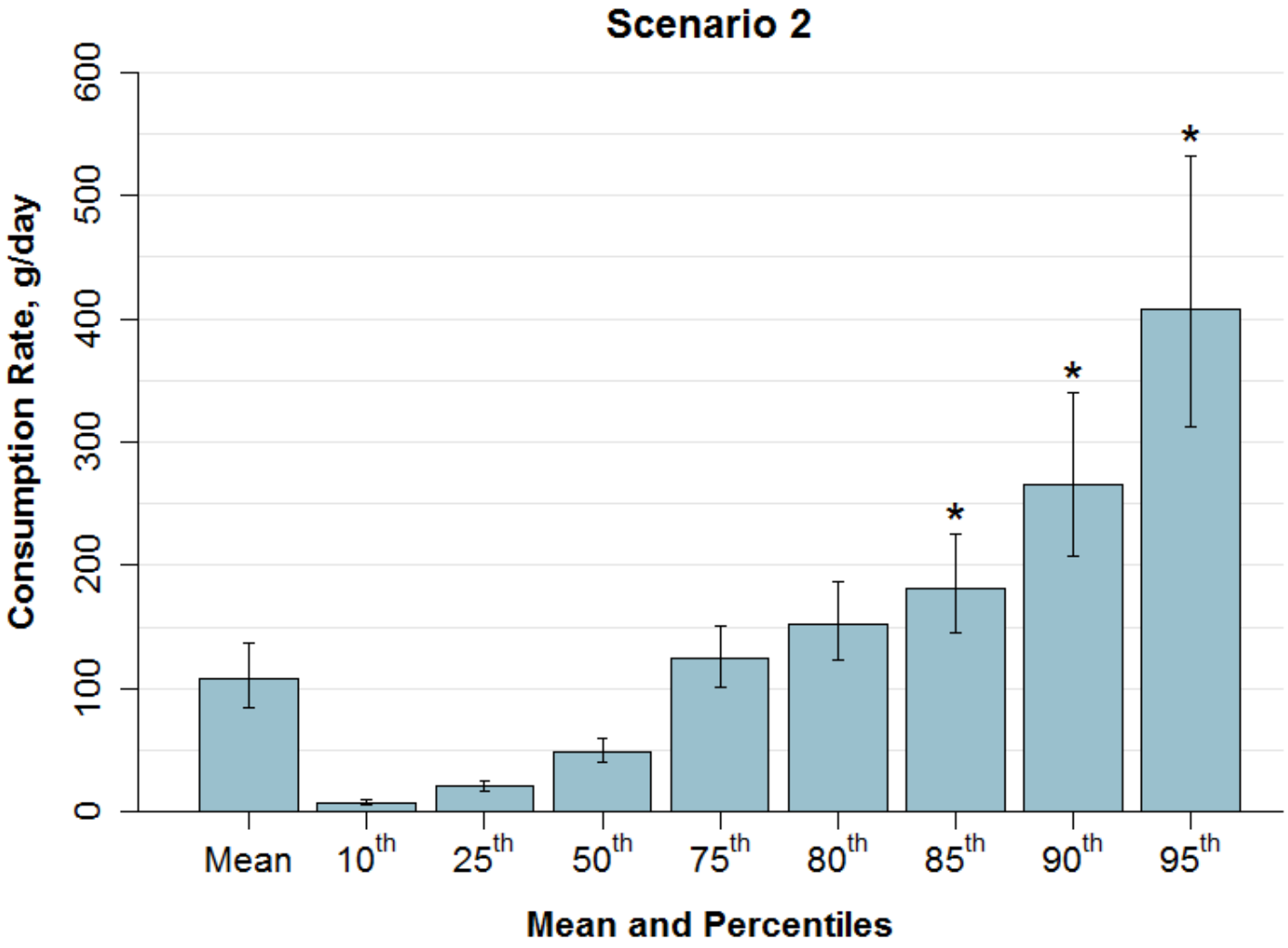


Figure 1.S2. Mean and percentiles of the combined consumption distribution in scenario 2 (all seafood minus adjusted anadromous consumption). The error bars indicate approximate uncertainty bounds. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

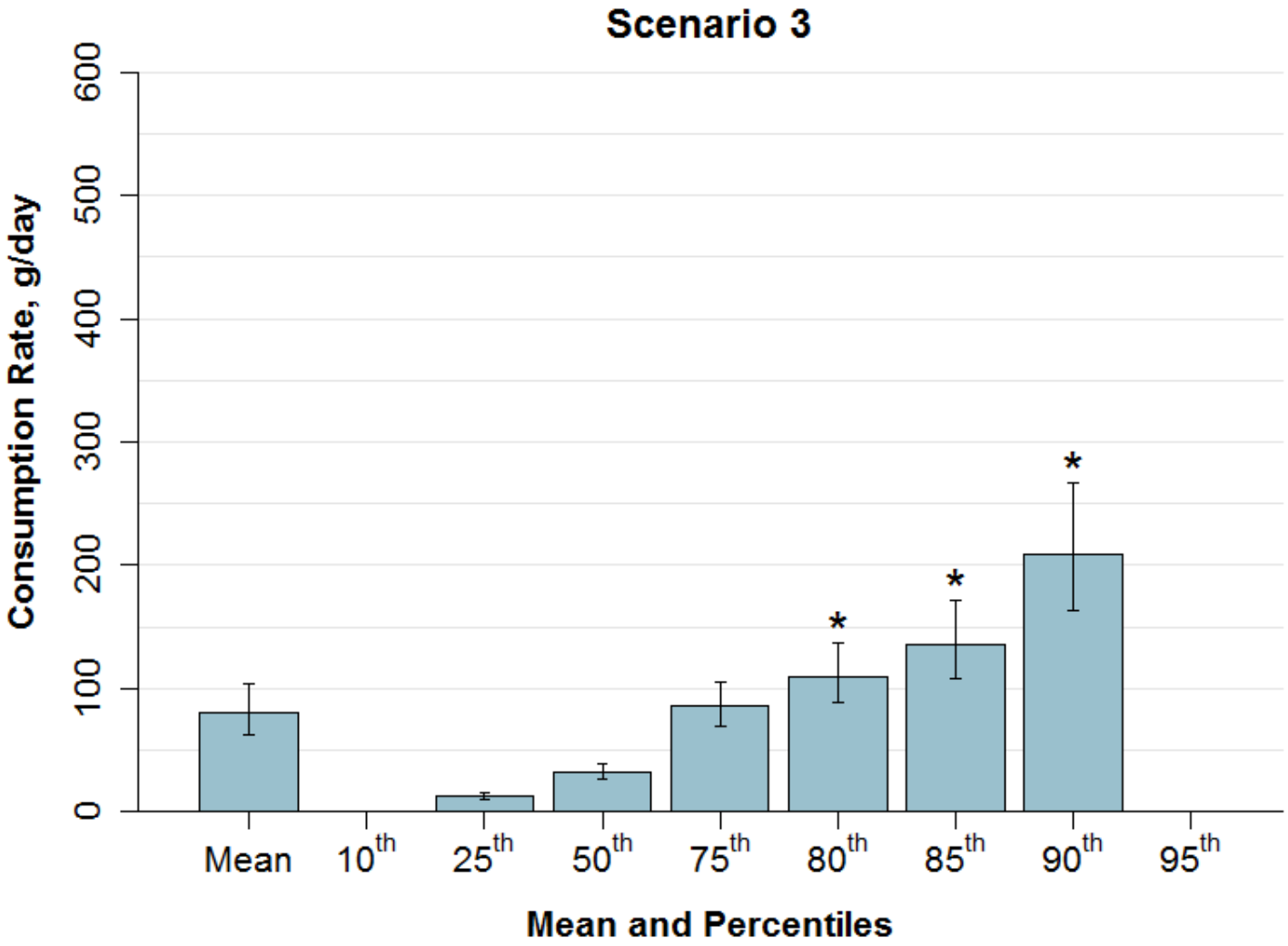


Figure 1.S3. Mean and percentiles of the combined consumption distribution in scenario 2 (all seafood minus all anadromous consumption). The error bars indicate approximate uncertainty bounds. Missing bars correspond to percentiles not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

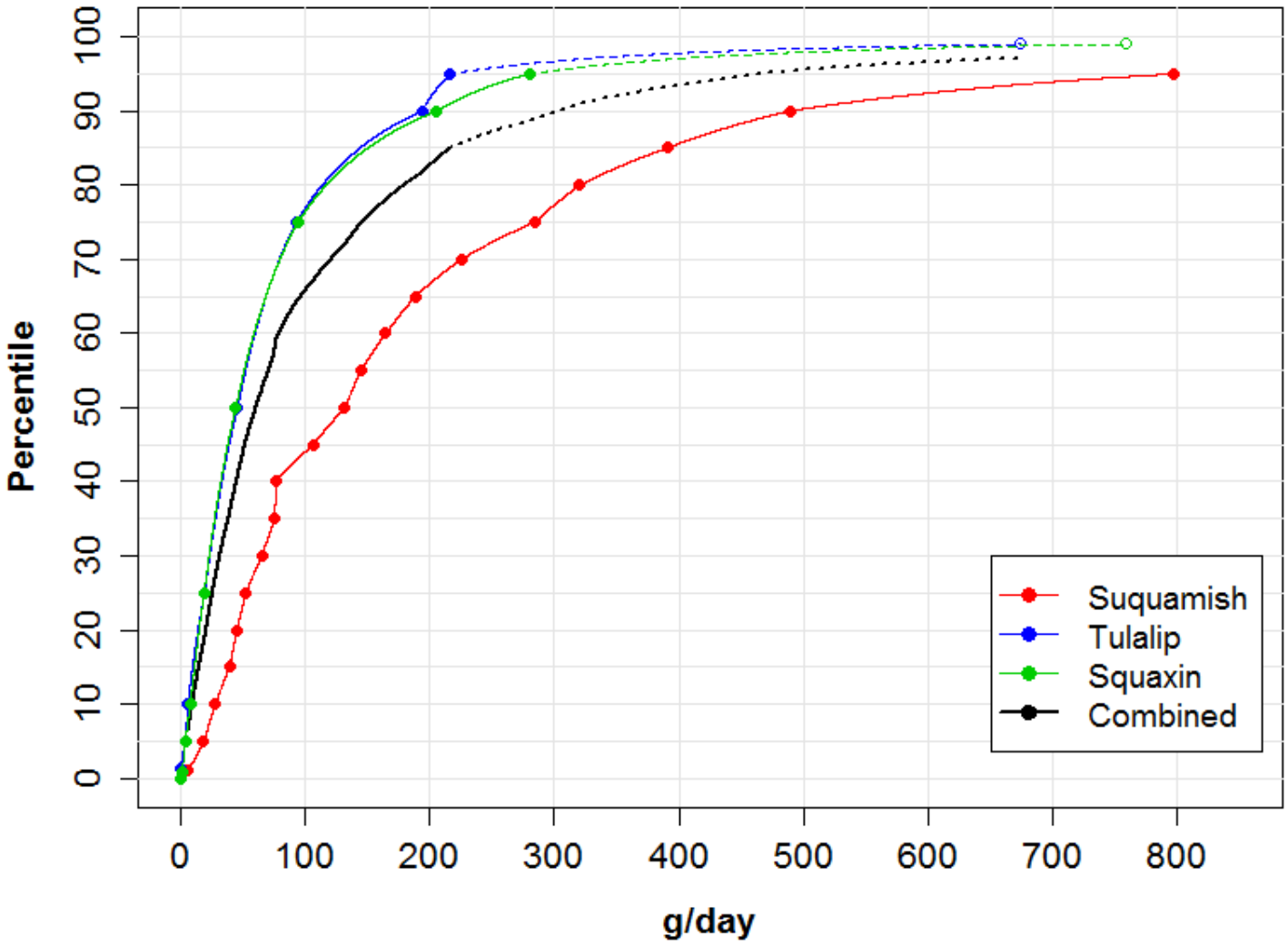


Figure 2. Each Tribe's estimated cumulative consumption distribution and the combined population consumption distribution giving each tribe equal weight (scenario 1). Closed points correspond to original estimates and the open points correspond to extrapolated 99th percentiles. Dotted and dashed lines indicate where extrapolation beyond the 95th percentile for at least one Tribe was needed (see Tables 4.S1-4.S3). Note that fewer intermediate percentiles were available from the Squaxin and Tulalip Tribes. Intermediate percentiles were based on log-normal interpolation.

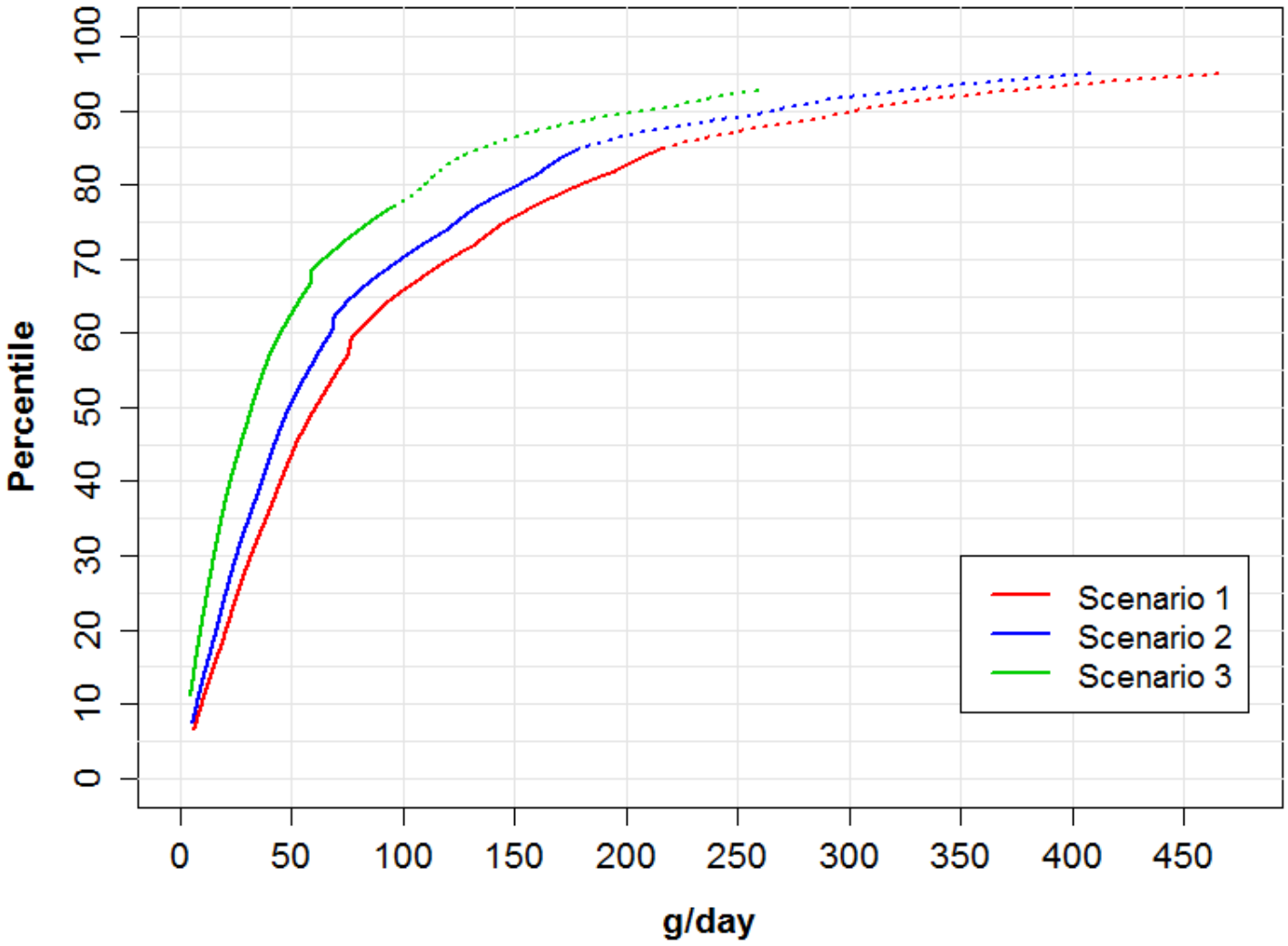


Figure 3. Combined population distributions for the three scenarios: 1) all seafood; 2) all seafood with reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption. The dotted lines indicate where extrapolation beyond the 95th percentile for at least one Tribe was needed (see Tables 4.S1-S3).

References

Liao S. 2002. Excel spreadsheets of percentiles of consumer-only rates (g/kg-day) for the Suquamish Tribe—various species groups.

Polissar, Nayak L.; Stanford, Derek; Liao, Shiquan; Neradilek, Blazej; Mittelstaedt, Gillian D.; Toy, Kelly A. A fish Consumption Survey Of The Tulalip and Squaxin Island Tribes of the Puget Sound Region—Consumption Rates For Fish Consumers Only. Report by The Mountain-Whisper-Light Statistics[6], 2006. *This was designated as an EPA contractor report. A final report which is an extension of this work is expected to be released by EPA.*

The Suquamish Tribe. 2000. "Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation." Puget Sound Region. August 2000. Report writing group: Duncan M, Polissar NL, Liao S, LaFlamme D.

[6] Know then as 'The Mountain-Whisper-Light Statistical Consulting.'

Date: 10/31/13

This technical appendix, prepared by Nayak Polissar and Dan Hippe, is intended to accompany our memo of 10/31/13, "Fish consumption rates for a hypothetical combination of Puget Sound tribes."

Technical Appendix: Methodology

Mathematically, the cumulative distribution function (CDF) of consumption rates from each tribe can be combined into a pooled CDF by a simple weighted sum, where the weights are between 0 and 1 and sum to 1. The cumulative percent in the combined population corresponding to a given consumption rate is calculated as the weighted sum of cumulative percentages for the three tribes. The inverse of this combined function would return percentiles of pooled consumption as a function of the desired percentage, e.g. the input of 75% would return as output the level of consumption that meets or exceeds the consumption of 75% of (weighted) consumers. The following procedure was performed:

1. Mean, available percentiles and the minimum consumption rates were tabulated from published reports—Suquamish 2000, Liao 2002 and Polissar 2006—and the original g/kg/day estimates were converted to g/day by multiplying by the mean body weight specific to each tribe's survey sample
    a. Tables A1 and A2 show the original data used
    b. All rates correspond to adult consumers only

2. The minimum consumption rate reported for each tribe was used as the 100 x 1/(N+1) percentile, where N is the sample size of the reported survey. This was typically around 1% for each tribe. No extrapolation was performed below this percentile.

3. The maximum consumption rate was not previously reported for the Tulalip and Squaxin Island tribes. As an alternative approach to estimating percentiles beyond the 95^{th}, the 99^{th} percentile was extrapolated for each of the three tribes using a log-normal assumption (described below.)

4. Estimated CDFs were formed as piecewise continuous interpolations of the available estimates and the extrapolated 99^{th} percentile (termed the base percentiles), where the original estimates were always retained
    a. Percentiles were interpolated between adjacent base percentiles using a log-normal assumption.
    b. This procedure amounts to linearly interpolating between points after 1) log transforming the consumption rate percentile and 2) transforming the percentile number (between 0 and 1) using the inverse of standard normal CDF $\Phi(\cdot)$
    c. Figure 2 illustrates the interpolation

5. The combined CDF was formed as a weighted sum of each tribe's CDF, where each tribe was given equal weight, i.e. (1/3, 1/3, 1/3)
    a. Example: if the input was 100 g/day, and this corresponded to the 40^{th}, 50^{th} and 60^{th} percentiles of the three tribes, respectively, then it would correspond to the 50^{th} percentile of the combined CDF (i.e., [40+50+60]/3).

6. The desired parameters were computed as follows
    a. Mean consumption: weighted sum of each tribe's mean consumption using the same weights as for the combined CDF
    b. Percentiles: combined CDF inverted numerically

Table A1. Summary of reports of adult consumer consumption rates from all sources (including from and outside Puget Sound.)

Tribe	Consumption group	N	Mean body weight, kg	Mean consumption in g/kg/day	Source Report
Suquamish	All seafood	92	79	2.707	Suquamish 2000 (Table C1); Liao 2002
Suquamish	Anadromous	92	79	0.618	Suquamish 2000 (Table C1); Liao 2002
Tulalip	All seafood	73	82	1.026	Polissar 2006 (Table A1.T)
Tulalip	Anadromous	72	82	0.451	Polissar 2006 (Table A1.T)
Squaxin	All seafood	117	82	1.021	Polissar 2006 (Table A1.S)
Squaxin	Anadromous	117	82	0.672	Polissar 2006 (Table A1.S)

Table A2. Source percentiles for all seafood consumption. Blank cells indicate that the percentile was not previously reported.

	Consumption rate percentiles in g/kg/day		
	Suquamish	**Tulalip**	**Squaxin**
Min	0.080	0.006	0.017
p5	0.236	0.049	0.05
p10	0.354	0.074	0.097
p15	0.498		
p20	0.574		
p25	0.665	0.238	0.233
p30	0.826		
p35	0.960		
p40	0.969		
p45	1.352		
p50	1.672	0.560	0.543
p55	1.831		
p60	2.087		
p65	2.385		
p70	2.851		
p75	3.598	1.134	1.151
p80	4.058		
p85	4.942		
p90	6.190	2.363	2.51
p95	10.087	2.641	3.417

pXX is the XX^{th} percentile;

Scenarios

Three scenarios were considered: 1) all seafood (no adjustment); 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption. The source reports provided estimates for all seafood consumption rates (used directly for scenario 1) and for total anadromous rates (used to derived scenario 2 and 3 rates.)

The Washington Department of Ecology provided an adjustment factor (AF) where only a portion of the anadromous fish consumption was retained in the rates. The adjustment factor was derived as follows:

1. It was assumed that all anadromous fish consumed were coho or Chinook salmon

2. Coho were assumed to constitute 50% of the anadromous fish consumed, of which 33% of contaminants were from Puget Sound and should be retained
3. Chinook were assumed to constitute the other 50% of anadromous fish consumed
    a. 70% of Chinook were migratory with 78% of contaminants from Puget Sound and so retained
    b. 30% of Chinook were resident with all contaminants from Puget Sound, so all would be retained
4. Thus 0.5*0.33 + 0.5*(0.7*0.78 + 0.3*1.0)=0.588 of anadromous fish should be retained in the rates
5. The AF=1-0.588 represents the proportion of anadromous fish that should be excluded from the rates

It was assumed that anadromous fish represented a fixed proportion (which differs per tribe) of the total seafood consumption. This proportion (pAna) was estimated as the proportion of anadromous biomass consumed out of the total biomass consumed. Biomass consumed was computed as the number of consumers (in the survey sample) times the mean consumption rate.

The mean and percentiles of non-anadromous consumption (scenario 3) were then estimated as (1-pAna) times the corresponding total seafood consumption statistics. The adjusted anadromous consumption statistics (scenario 2) were estimated analogously but with the factor (1-pAna*AF.) Table A3 shows the calculations.

Table A3. Illustration of scaling factors applied to generate the consumption scenarios. See text for more details.

	Suquamish	Tulalip	Squaxin
Anadromous biomass consumed, g/day	4492	2663	6447
All seafood biomass consumed, g/day	19674	6142	9795
pAna	0.2283	0.4335	0.6582
1-pAna	0.7717	0.5665	0.3418
1-pAna*AF	0.9059	0.8214	0.7288

Log-Normal Assumption

Some calculations assumed that the consumption rates from each tribe were log-normally distributed or that the distribution resembled a particular log-normal over a particular range. The QQ-plots shown in Figures A1 - A3 show that the observed data do resemble a log-normal distribution over the range of percentiles available.

Extrapolation to 99th Percentile

The highest percentile available for all tribes was the 95th, but due to differences between tribes, individual percentiles greater than the 95th were needed for some percentiles of the combined CDF. The 99th percentile was

extrapolated for each tribe by first estimating log-normal parameters (mean and SD of consumption on the log-scale) using a least-squares regression of the log of the observed percentiles (all available between the 5th and 95th) onto the standard normal percentiles. Then those estimates were plugged into the theoretical CDF, from which the 99th percentile was derived.

Approximate Uncertainty Bounds

The parametric bootstrap was used to compute approximate uncertainty bounds based on an underlying log-normal assumption. As this model may not be fully correct and not all sources of variability could be simulated, these bounds should be interpreted as a rough guide to the level of precision available rather than as formal 95% confidence intervals.

For each tribe, the log-normal parameters (mean and SD of consumption on the log-scale) were estimated using a least-squares regression of the log of the consumption percentiles (all available between the 5th and 95th) onto the standard normal percentiles. This is the same method as used for the extrapolation approach described above. A total of 999 replicate data sets of tribal consumption rates were generated by randomly drawing from the corresponding log-normal distributions using the same sample sizes as in the original surveys. For each replicate, the same sequence of computations was applied as was used to compute the results from the original data. These computations include estimating the mean and percentiles as found in the previous reports (e.g. minimum, 5%, 10%, 25%, etc.), interpolating between those percentiles, extrapolating to the 99th percentile, combining the three tribes and calculating the summary statistics of the combined distribution (mean and percentiles.)

Because each replicate came from a different random sample, the values of the final statistics computed varied. The collection of these values formed estimates of the bootstrap distribution for each statistic (mean and percentiles.) The log transform was applied to these statistics to reduce right skewness, except for the 10th percentile which was not skewed on the original scale. The standard error (SE) was estimated as the standard deviation of the transformed estimates generated from each replicate. Uncertainty bounds were then computed on the log-scale as log(original estimate) ± 1.96 x SE. The antilog was applied to produce bounds on the original scale. For the 10th percentile, the calculation was (original estimate) ± 1.96 x SE without any transformations, as none were needed in this case.

Any bias between the original estimates and the replicates was ignored as this could be due to the lognormal model being incorrect. Thus, these uncertainty bounds primarily capture variability. For some replicates particular percentiles were not available in some scenarios (most often the 10th or 95th.) These replicates were ignored for the calculations of the uncertainty bounds for the missing percentiles.

The ratio between mean seafood consumption and mean anadromous finfish consumption was kept constant per tribe as the dependence between the total consumption and anadromous consumption could not be simulated. The anadromous adjustment factor provided by Washington Department of Ecology was also kept constant. Thus these two sources of variable were not accounted for in the uncertainty bounds. The uncertainty bounds may also tend to under-estimate uncertainty, because in the simulation the log-normal assumption used throughout the calculations was assumed to be true, while this assumption may not be true for the originally observed data.

Figures

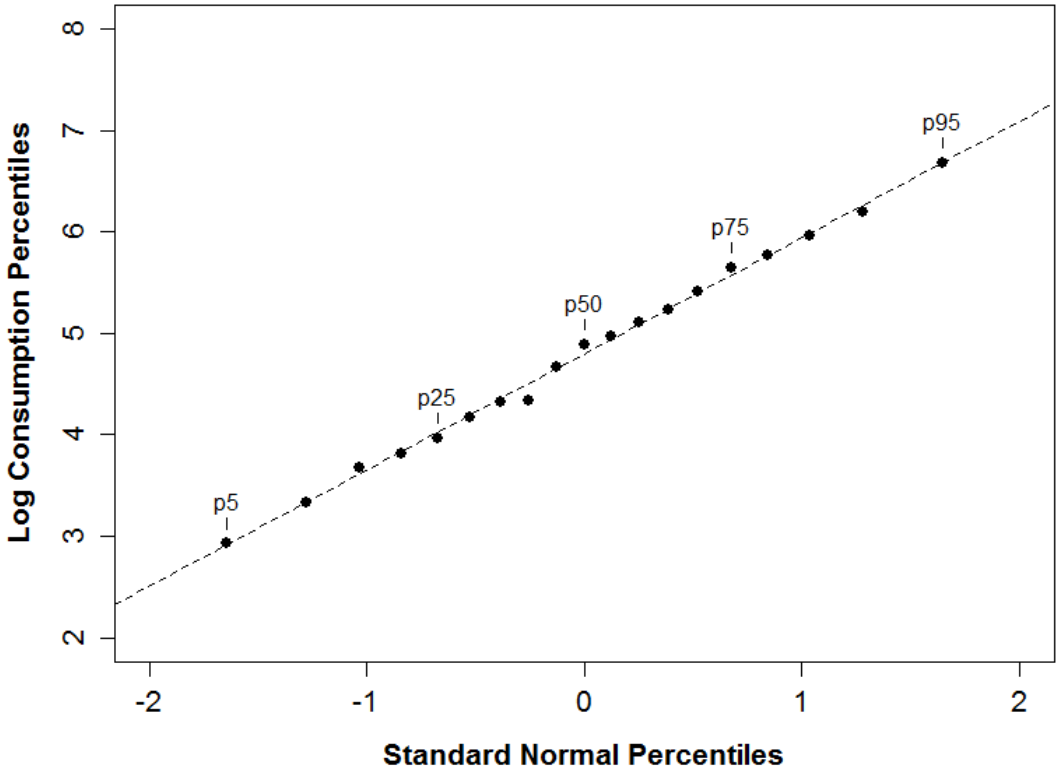


Figure A1. QQ-plot of log consumption for the Suquamish Tribe. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

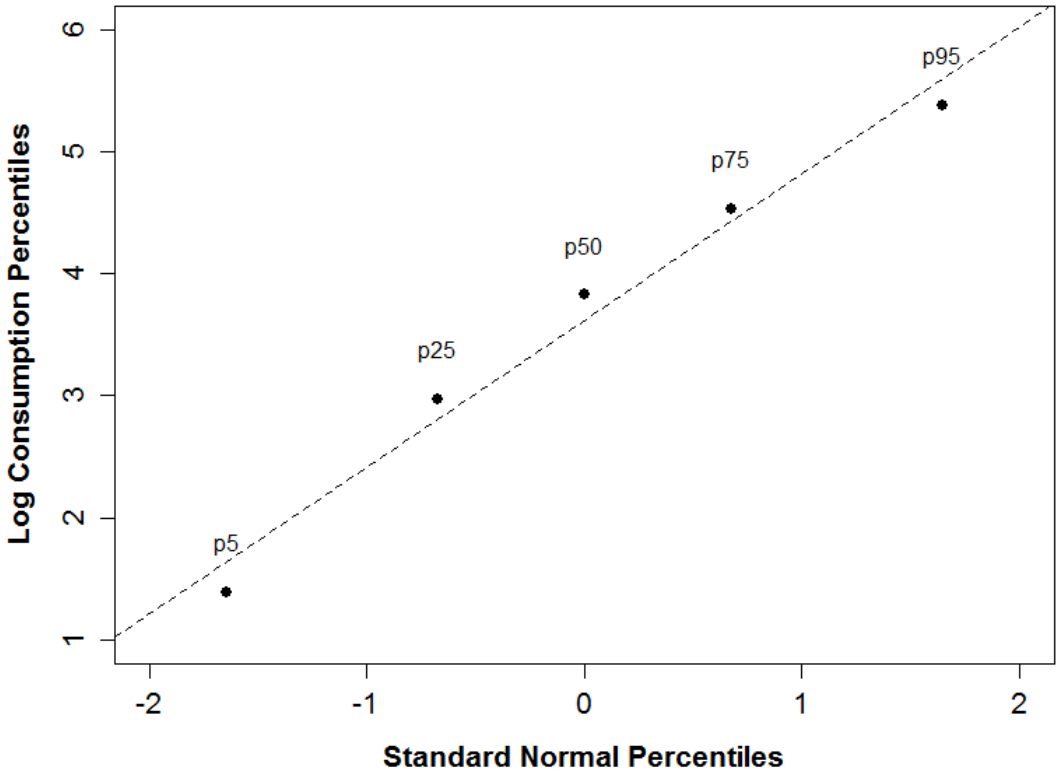


Figure A2. QQ-plot of log consumption for the Tulalip Tribes. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

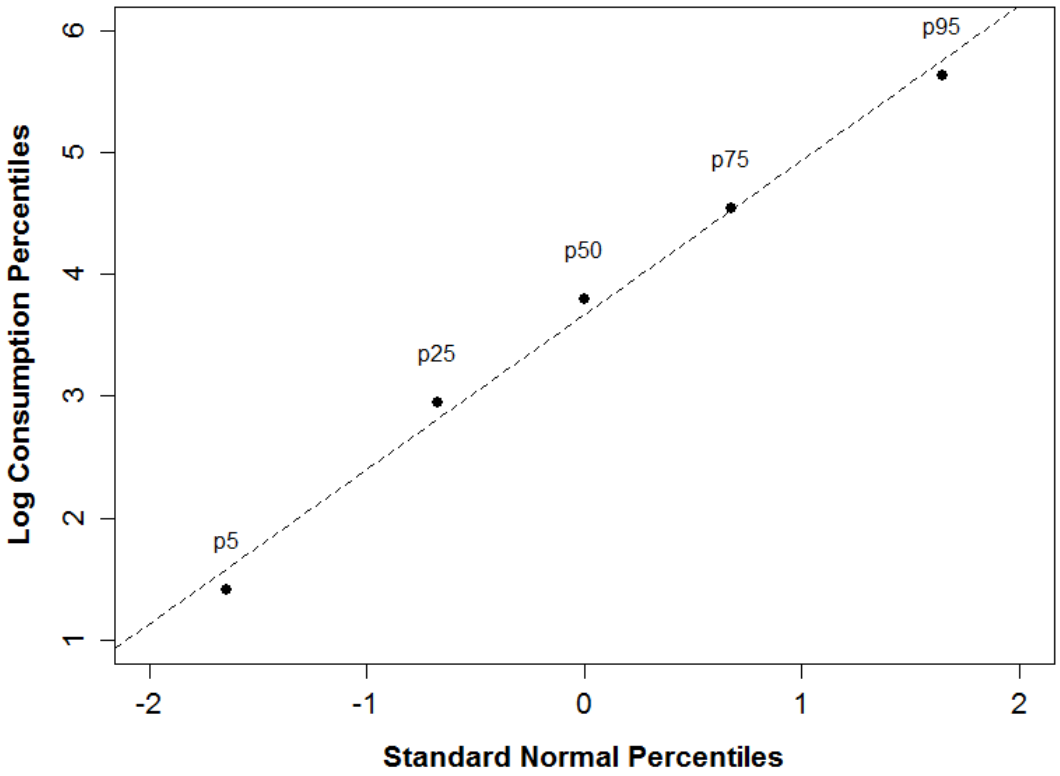


Figure A3. QQ-plot of log consumption for the Squaxin Island Tribe. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

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Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington

February 4, 2014

00658

Attachments

Acronyms and Abbreviations

aAWQC	alternative ambient water quality criteria
AT_c	averaging time for carcinogenic effects
AT_{nc}	averaging time for noncarcinogenic effects
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	ambient water quality criteria
BCF_{lipid}	lipid-based bioconcentration factor
BCF_{tissue}	tissue-based bioconcentration factor
BW	body weight
C_w	concentration in water
CL	cooking loss
CLF	catch location factor
CSF	cancer slope factor
CSFII	Continuing Survey of Food Intakes by Individuals
DI	drinking water intake
ED	exposure duration
ELCR	excess lifetime cancer risk
FCR	fish consumption rate
FDEP	Florida Department of Environmental Protection
HEAST	Health Effects Assessment Summary Tables
HQ	hazard quotient
IRIS	Integrated Risk Information System
LHF	life history factor
NHANES	National Health and Nutrition Examination Survey

NWPPA	Northwest Pulp & Paper Association
PAWQCC	Probabilistic Ambient Water Quality Criteria Calculator
PCB	polychlorinated biphenyl
PPRTV	Provisional Peer Reviewed Toxicity Values
RBA_w	relative bioavailability, water
RBA_f	relative bioavailability, fish
RfD	reference dose
RSC	relative source contribution
TSD	Technical Support Document
USEPA	United States Environmental Protection Agency
WDOE	Washington Department of Ecology

1. Introduction

On behalf of the Northwest Pulp & Paper Association (NWPPA), ARCADIS used probabilistic risk assessment methods to derive alternative ambient water quality criteria (also referred to as aAWQC in the report) for 114 chemicals listed in the United States Environmental Protection Agency's (USEPA's) 2013 Human Health Criteria Table (USEPA 2013a). The input assumptions used to derive the alternative AWQC were developed to be representative of residents of the State of Washington and, thus, the alternative AWQC represent criteria that are protective of Washington residents.

When using the traditional deterministic approach to deriving AWQC, point estimates are selected to represent exposure parameters such as body weight, drinking water intake, and fish consumption rate. Typically, high-end or maximum values are chosen to represent most of these parameters, which, when combined, lead to unlikely exposure scenarios and overestimates of potential risk. The phenomenon of a combination of high-end assumptions leading to an overestimate of risk is known as "compounded conservatism."

In contrast to the deterministic approach, the probabilistic approach accounts for variability within populations by allowing one or more of the exposure parameters to be defined as distributions of potential values (i.e., probability density functions). The result is a distribution of potential risk representing a range of possible exposures. The probabilistic approach therefore provides explicit estimates of potential risk for different segments of the population, including both the general population (e.g., arithmetic mean or 50th percentile) and individuals with high-end exposures (e.g., the 90th, 95th or 99th percentiles). In this report, for example, fish consumption rates representative of both the general and tribal populations of Washington State are accounted for, with total fish consumption rates as high as 291 grams per day (g/day) at the 99th percentile of the tribal population included in the development of the fish consumption rate distribution. As long as one or more of the exposure parameters used to estimate risk are defined as distributions of values, the outcome will be a distribution of estimated risks. To derive AWQC using the information developed by the probabilistic approach, regulators must make risk management decisions to determine what level of protection will be afforded to a given segment of the population, recognizing that different segments of the population by definition will always have varying levels of potential risk.

The concept of probabilistic assessment is not a new one; USEPA has issued formal guidance for conducting probabilistic risk assessments (USEPA 2001). However, most agencies, including USEPA, have continued to use the traditional deterministic approach to deriving AWQC, despite criticism that the deterministic approach is overly conservative and can lead to unrealistic estimates of risk. Recently, the benefits of using the probabilistic approach to derive AWQC have been recognized. For example, the Florida Department of Environmental Protection (FDEP) is currently revising its state criteria using probabilistic methods that allow the State to demonstrate all segments of the population, including high end consumers, are protected, albeit at varying acceptable risk levels. While USEPA has not yet formally

accepted FDEP's revised criteria, they have reviewed the derivation methods and have indicated a probabilistic approach is acceptable.

2. Methods

The general AWQC derivation process uses equations that account for the key exposure pathways (i.e., consumption of water and fish). Deterministic AWQC are derived using equations that include both exposure and toxicity parameters combined with a risk management threshold (i.e., an acceptable risk level). Probabilistic AWQC are derived by using these same equations, combined with distributions for one or more parameters representing the inherent variability in a population's physical characteristics and behaviors, to generate a distribution of risk. The AWQC derived using probabilistic methods is the water concentration that has associated with it a distribution of potential risk that meets (i.e., does not exceed) the risk management threshold(s) selected by the regulatory agency. In some cases, a regulatory agency may select a single risk management threshold. For example, a regulatory agency might require that the Hazard Quotient (HQ) for the 90th percentile of the population be equal to or less than 1.0. Alternatively, a regulatory agency may select multiple risk management thresholds that need to be met by an AWQC. For example, that the 50th percentile of the population (the median) must have an excess lifetime cancer risk (ELCR) equal to or less than 1x10^{-5} and that the 99th percentile of the population must have an ELCR equal to or less than 1x10^{-4}. Both of these risk management thresholds must be met by the AWQC and are used in this report to derive alternate AWQC.

2.1 Risk Characterization

Risks were estimated using the fundamental equations employed by USEPA to derive AWQC (USEPA 2000). The USEPA equation for chemicals with noncarcinogenic endpoints is:

$$HQ = \frac{C_w \; x \; [DI + (FCR \; x \; BCF_{tissue})]}{BW \; x \; RSC \; x \; RfD} \qquad \textbf{(Equation 1)}$$

The USEPA equation for chemicals with noncarcinogenic endpoints is:

$$ELCR = \frac{C_w \; x \; [DI + (FCR \; x \; BCF_{tissue})] \; x \; CSF}{BW} \qquad \textbf{(Equation 2)}$$

Where:

HQ = hazard quotient (unitless);
ELCR = excess lifetime cancer risk (unitless);
C_w = concentration in water (mg/L);
DI = drinking water intake (L/day);

FCR = fish consumption rate (kg/day);
BCF_{tissue} = tissue-based bioconcentration factor (L/kg tissue);
BW = body weight (kg);
RSC = relative source contribution (unitless);
RfD = reference dose (mg/kg-day); and
CSF = cancer slope factor $(mg/kg\text{-}day)^{-1}$.

In addition to the parameters explicitly listed in the USEPA equations, additional implicit parameters (e.g., cooking loss, relative bioavailability, life history factor) also affect the characterization of risk and can be included in the risk characterization equations. The expanded equation for chemicals with noncarcinogenic health endpoints is:

$$HQ = \frac{C_w \, x \left[(RBA_w \, x \, DI) + \left(RBA_f \, x \, FCR \, x \, CLF \, x \, LHF \, x \, BCF_{lipid} \, x \, lipid \, x \, (1 - CL) \right) \right] x \, ED}{BW \, x \, AT_{nc} \, x \, RSC \, x \, RfD} \quad \textbf{(Equation 3)}$$

The expanded equation for chemicals with carcinogenic health endpoints is:

$$ELCR = \frac{C_w \, x \left[(RBA_w \, x \, DI) + \left(RBA_f \, x \, FCR \, x \, CLF \, x \, LHF \, x \, BCF_{tissue} \, x \, lipid \, x \, (1 - CL) \right) \right] x \, ED \, x \, CSF}{BW \, x \, AT_c} \quad \textbf{(Equation 4)}$$

Where the additional implicit parameters include:

RBA_w = relative bioavailability, water (unitless);
RBA_f = relative bioavailability, fish (unitless);
CLF = catch location factor (unitless);
LHF = life history factor (unitless);
BCF_{lipid} = bioconcentration factor (L/kg lipid)
Lipid = proportion of lipid in fish tissue (kg lipid/kg tissue);
CL = cooking loss (unitless);
ED = exposure duration (years);
AT_{nc} = averaging time for noncarcinogenic effects (years); and
AT_c = averaging time for carcinogenic effects (years).

2.2 Probabilistic Approach

The equations presented in Section 2.1 are referred to as "forward" risk equations; that is, the equations estimate risk from a chemical concentration, exposure dose, and toxicity. When deriving AWQC using a deterministic approach, USEPA rearranges the equations such that they predict an allowable water concentration (i.e., the AWQC) based on an allowable risk and the same exposure and toxicity factors

used by the forward equation to estimate risk. These rearranged equations are sometimes referred to as "backward" equations and are typically used for deterministic calculation of risk-based acceptable media concentrations (e.g., AWQC or preliminary remediation goals at waste sites).

Deriving AWQC using probabilistic methods requires forward equations. The reasons for using the forward equations for probabilistic assessments are mathematically complex and are described in greater detail elsewhere (e.g., Burmaster et al. 1995, Ferson 1996). In essence, the forward equation will yield a distribution of risks dependent on several inputs that are also distributions. If the equation is "flipped" to solve for one of the inputs, the resulting distribution and the original input distribution may have similar means, but the spread of the distributions will be different. Because it is the tails of a distribution that are typically of interest when setting acceptable risk or acceptable media concentrations, this disparity has marked effects on the outcome of the calculation. Therefore, USEPA recommends using forward equations when conducting probabilistic assessments to avoid the mathematical limitations associated with backcalculation (USEPA 2001).

For probabilistic derivation of AWQC, the process of estimating risk by selecting from the input point estimates or distributions is repeated until the number of desired iterations (e.g., 100,000 iterations in the case of the alternative AWQC presented herein) is complete. One complete set of iterations is called a simulation. As long as one or more of the input parameters are distributions, the final output of a simulation will be a distribution of risks associated with a particular concentration of a chemical in water. If the estimate of risk at a specific percentile meets the risk management requirements selected by the regulatory agency, the chemical concentration that was used to generate the output is the AWQC.

Typically, multiple simulations are required to derive probabilistic AWQC. Two methods can be used to develop the AWQC.

- **Trial and Error** – Select a water concentration, run a simulation, and compare the resulting risk distribution to risk management thresholds. If one or more thresholds is not met, repeat the process inserting alternative chemical concentrations until a concentration is identified that results in a risk distribution that meets risk management thresholds. That concentration is the AWQC.
- **Systematic Linear Derivation** – Run simulations at three or more alternative chemical concentrations. Plot the estimated risk at the percentile of the risk distribution corresponding to the risk management threshold versus the chemical concentration used for each simulation. Generate a least-squares linear regression line based on the plot of paired ELCRs and concentrations. Use that equation to solve for the chemical concentration that corresponds to the allowable risk level for the percentile of the population specified by the risk management threshold. That concentration is the AWQC. This process is recommended by USEPA (2001) as a "shortcut" for the trial-and-error method when using probabilistic methods to calculate risk-based acceptable media concentrations.

The systematic linear derivation method was used to derive the alternative AWQC presented in this report. Simulations using 100,000 iterations each were run using the Probabilistic Ambient Water Quality Criteria Calculator (PAWQCC) developed by ARCADIS. PAWQCC is an Excel-based calculator tool that employs @Risk software (Palisade Corporation 2013) to develop probabilistically based estimates of risk. The calculator, along with the inputs used to derive the AWQC presented in this report, will be provided under separate cover.

2.3 Risk Management Thresholds

For chemicals with noncarcinogenic health endpoints, the alternative AWQC are based on a target HQ of 1.0 at the 90th percentile of the risk distribution. For chemicals with carcinogenic health endpoints, the alternative AWQC are based on a target ELCR of one in one hundred thousand ($1x10^{-5}$) at the 50th percentile (i.e., median) of the risk distribution and one in ten thousand ($1x10^{-4}$) at the 99th percentile of the risk distribution. This is consistent with USEPA methodology, which states "EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level" (USEPA 2000).

2.4 Input Assumptions

To derive alternative AWQC using a probabilistic approach, distributions were selected to represent a number of the input parameters. Washington-specific data were used to incorporate information about fish consumption rate and the life history factor into the fish consumption rate distribution. The other distributions were based on data representing the general United States population.

2.4.1 Toxicity

The toxicity values used to derive AWQC were obtained from the USEPA National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix (USEPA 2002a). To determine whether the toxicity values listed in USEPA (2002a) still reflect the current understanding of each chemical's health effects, the following sources were consulted, in accordance with the recommended hierarchy presented in USEPA guidance (2003), in order of priority:

- USEPA's Integrated Risk Information System (IRIS) (USEPA 2014a);
- USEPA's Provisional Peer Reviewed Toxicity Values (PPRTVs) (USEPA 2014b);
- Additional USEPA and non-USEPA sources of toxicity information, including but not limited to the California Environmental Protection Agency toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimum risk levels, and toxicity values published in the USEPA Health Effects Assessment Summary Tables (HEAST) (USEPA 1997).

In cases where the toxicity values listed in USEPA (2002a) have been superseded by newer data (e.g., a toxicity value had been withdrawn or updated in IRIS), the current toxicity values were used, in accordance with the hierarchy listed above.

In some cases, USEPA (2002a) was not able to identify toxicity values for a given chemical. In these cases, USEPA (2002a) chose surrogate toxicity values from a chemical that is considered structurally and toxicologically similar to the chemical that did not have toxicity values from the above sources (e.g., the toxicity value for endosulfan was selected to represent both alpha- and beta-endosulfan, for which toxicity values are not available). The same chemical surrogates used by USEPA (2002a) were used in this report. A summary of toxicity values used to derive alternative AWQC is presented in **Table 1**.

The derivation of probabilistic alternative AWQC presented in this report treats all toxicity values as point estimates.

2.4.2 Relative Source Contribution

Relative source contribution (RSC) refers to the portion of an individual's daily exposure to a chemical that is allocated to exposure from the regulated surface water (i.e., the consumption of water and fish). The RSC accounts for the possibility that individuals can be exposed to a chemical through sources other than surface water (e.g., food or air). The RSC applies only to AWQC with noncarcinogenc health endpoints.

USEPA (2000) describes a decision process to select an RSC. That process leads to RSCs of no greater than 0.8 and as low as 0.2. However, for the majority of chemicals, national AWQC are based on an RSC of 1.0, though USEPA has indicated that in the future, the decision process described in USEPA (2000) for selecting an RSC will need to be followed when revising AWQC. In response to comments from USEPA regarding Florida's proposed AWQC, Florida is currently deriving RSCs for several chemicals.

Because RSCs can have a substantial effect on AWQC (a five-fold difference between AWQC based on an RSC of 1.0 versus an RSC of 0.2), alternative AWQC protective of noncarcinogenic endpoints were derived in two ways.

- First, AWQC were derived assuming an RSC of 1.0 for all chemicals (i.e., all of a person's exposure to a chemical is assumed to come from the regulated surface water). This approach is consistent with most of the existing national AWQC derived by USEPA.
- Second, USEPA has derived RSCs of less than 1.0 for 19 of the 114 chemicals addressed in this report (USEPA 2013b). Alternative AWQC were also derived for these 19 chemicals using the RSCs recommended by USEPA (**Table 2**).

The derivation of probabilistic alternative AWQC presented in this report treats all RSCs as point estimates.

2.4.3 Bioconcentration and Percent Lipid

Bioconcentration refers to the process by which a chemical present in ambient water accumulates in fish tissue. The lipid-based bioconcentration factor (BCF) used in Equations 1 and 2, expressed in units of liters per kilogram lipid, is defined as the ratio of the concentration of the chemical in fish lipid to its concentration in the surrounding water. The lipid-based BCF is multiplied by the proportion of lipid in fish tissue to ultimately express bioconcentration on a fish tissue basis (i.e., units of liters per kilogram tissue). USEPA (2002a) provides default BCFs expressed on a fish tissue basis and normalized to a default lipid content of 3%. The default USEPA BCFs and 3% lipid were used to derive the alternative AWQC presented in this report. Where a default BCF was unavailable, AWQC were derived based on the consumption of water only. A summary of bioconcentration factors used to derive AWQC for the State of Washington is presented in **Table 3**.

The derivation of probabilistic alternative AWQC presented in this report treats all BCFs and lipid content as point estimates.

2.4.4 Cooking Loss

Cooking loss refers to the proportion of the chemical present in fish tissue that is lost as part of the cooking process. The AWQC presented in this report conservatively assume no cooking loss and that all of the chemical in raw fish remains in cooked fish. This assumption is consistent with the approach USEPA has used to derive national AWQC. For lipophilic chemicals (e.g., polychlorinated biphenyls [PCBs]) this is likely to lead to conservative AWQC because concentrations of such chemicals tend to be reduced by cooking. The amount of loss depends upon cooking method and the frequency at which various methods are used. Sufficient data are available for some chemicals (e.g., PCBs) to develop an input distribution for cooking loss. Thus, cooking loss could be incorporated in AWQC in the future.

2.4.5 Exposure Duration

As a matter of default and to be consistent with USEPA's approach to derivation of AWQC, exposure duration was assumed to occur over an entire lifetime (equal to 70 years). This conservative approach assumes that every member of the population lives in the same place and is exposed to the same chemical concentration in water and/or fish tissue each day over the duration of their 70-year lifetime. In reality, this is unlikely to be the case; the mean residential occupancy period according to USEPA is 12 years, and the 95th percentile is only 33 years (USEPA 2011). Even if an individual lives in the same state

their entire life, it is highly unlikely that they will live only near (and thus be exposed only to) contaminated waters over the course of their lifetime.

2.4.6 Body Weight

The 2011 Exposure Factors Handbook (USEPA 2011) provides age-specific distributions of body weight computed by Portier et al. (2007) using National Health and Nutrition Examination Survey (NHANES) II, III, and IV data. USEPA recommends using the Portier et al. (2007) data when body weight distributions are required, because the data are based on a large sample size and are representative of the general United States population. The body weight distribution derived from the NHANES IV survey for ages 18-65, males and females combined, was used to develop the alternative AWQC presented in this report (USEPA 2011; Table 8-25). Body weight was truncated at a lower limit of 44 kilograms (97 pounds), corresponding to the 1st percentile of the distribution. This approach is consistent with the approach used by the State of Florida to derive AWQC (FDEP 2013). Summary statistics for the body weight distribution are provided in **Table 4**.

2.4.7 Drinking Water Intake

In 2010, USEPA analyzed the 2003-2006 NHANES survey data to assess water ingestion rates across the general United States population. The results of the USEPA analysis are presented in the 2011 Exposure Factors Handbook (USEPA 2011). The consumer-only direct and indirect water intake distribution for ages 21 and above was used to derive the alternative AWQC presented in this report (USEPA 2011; Table 3-36). Using @Risk, a distribution was fit to the data using the range of reported percentiles as fit parameters. The resulting distribution was truncated at a lower limit of 0 liters per day. Summary statistics for the drinking water intake distribution are provided in **Table 4**.

2.4.8 Catch Location Factor

Catch location factor refers to the proportion of fish consumed that are caught in state or local waters. The alternative AWQC presented in this report assume that all fish consumed are caught locally (i.e., catch location factor [CLF] equals 1.0). This approach leads to conservative AWQC because it assumes that no one consumes either fresh or pre-packaged fish products that may have been produced in other states or outside of the United States.

2.4.9 Life History Factor

In this report, life history factor (LHF) refers to the portion of the fish life cycle that is spent in state or local waters. For true freshwater fish, the LHF will be 1. For anadromous species that spend the majority of their life cycle in marine waters, including many species and populations of salmon, the LHF will be some value less than 1. If it is assumed that bioaccumulation of chemicals by aquatic organisms is a linear function of

time, a life history factor reflecting time spent in waters of the state is equivalent to the fraction of the chemical body burden in adult salmon acquired in waters of the state. Thus, life history factors based on residence time were developed for five species of Pacific Northwest salmon to account for the fraction of salmon chemical body burden acquired in state or local waters (**Appendix A in Attachment A**). An alternative and perhaps more accurate approach would consider when and where chemical body burden is accumulated as a function of relative growth. Deriving life history factors based on residence time is a simplifying assumption and one that is likely to overstate the importance of bioaccumulation during early life stages, when salmon are not accruing a significant portion of their body mass. In other words, the residence time-based life history factors derived for salmon are believed to serve as a conservative approximation. Ultimately, a composite life history factor for all Pacific Northwest salmon species was derived using weighting factors reflecting the species-specific consumption patterns of the Suquamish Tribe. The final composite life history factor (i.e., 0.318) was then incorporated directly into the derivation of a Washington State fish consumption rate, as summarized below in Section 2.4.10 and detailed in **Appendix A in Attachment A**.

2.4.10 Fish Consumption Rate

The Washington Department of Ecology (WDOE) released two Technical Support Documents (TSDs) reviewing fish consumption rates for both the general and tribal populations of Washington State (WDOE 2011, 2013). Using the data presented in these WDOE TSDs, a composite fish consumption rate distribution was developed to represent both general population and tribal consumption of freshwater species, estuarine species, and salmon (**Attachment A**).

The general population distribution provided in the WDOE TSD (2013) for consumption of all fish species has a mean of 19 g/day, ranging up to 91 g/day at the 99th percentile. Several steps were taken to refine the fish consumption rate distribution to make sure it is representative of Washington residents. First, the general population distribution was adjusted to reflect only freshwater and estuarine species (i.e., off-shore marine species were removed from the distribution) using data from USEPA's Continuing Survey of Food Intakes by Individuals (CSFII) survey (USEPA 2002b). Next, the distribution was adjusted upward to add back the portion of overall fish consumption that is salmon (because USEPA's CSFII survey classifies salmon as a marine species and marine species were excluded in the first step of the fish consumption rate [FCR] distribution derivation process). This salmon component was multiplied by the composite salmon life history factor before being added to the final distribution; thus, only the consumption of salmon associated with waters of the State based on salmon life history was included in the distribution.

The tribal population distribution provided in the WDOE TSD (2011; Appendix C) for consumption of all fish species has a mean of 71 g/day, ranging up to 291 g/day at the 99th percentile. It was assumed that the only marine species consumed by the tribal population is salmon. Therefore, the only adjustment made to the tribal fish consumption rate distribution was to incorporate the salmon life history factor. It was

assumed that 46% of tribal fish consumption is comprised of salmon, based on data provided in the WDOE TSD. The salmon life history factor was applied to this portion of the overall tribal fish consumption rate.

Once the general and tribal fish consumption rate distributions were adjusted to reflect only freshwater species, estuarine species, and salmon associated with waters of the State, the two distributions were combined to reflect the entire population of Washington State. A single, composite fish consumption rate distribution was derived using weighting factors based on relative population size. Using data provided in the WDOE TSD, weighting factors of 98% and 2% were used for the general and tribal portions of the population, respectively. Using @Risk, a distribution was fit to the data using the range of percentiles as fit parameters. The resulting distribution was truncated at a lower limit of 0 g/day. An upper truncation limit for the fish consumption rate distribution was not defined, meaning that the fitted distribution can theoretically extend to any positive value. The actual maximum values achieved by the distribution ranged from 135 to 250 g/day, with a mean of 150 g/day, after 500 simulations of 100,000 iterations each. Summary statistics for the fish consumption rate distribution are provided in **Table 4**, and a detailed description of the complete derivation process is provided in **Attachment A**.

3. Results and Discussion

ARCADIS developed alternative AWQC (abbreviated aAWQC in the supporting tables) for 114 chemicals using a probabilistic approach. Alternative AWQC were developed for the consumption of water and organisms as well as for the consumption of organisms only (**Table 5**). All alternative AWQC were developed using an RSC of 1.0. Alternate AWQC were also derived for the 19 chemicals having USEPA-recommended RSCs lower than 1.0, (**Table 6**).

All alternative AWQC were compared to the corresponding national AWQC listed in USEPA's 2013 Human Health Criteria Table (USEPA 2013a) (**Table 7**). Differences between existing national AWQC and the probabilistically derived alternative AWQC arise due to the fundamental differences in derivation approach; the current national criteria were derived using deterministic methods assuming single point estimates for all inputs, while the alternative criteria were derived using a probabilistic approach that incorporates distributions for several of the inputs that determine exposure. Differences also arise due to changes in the understanding of the health effects associated with select chemicals (i.e., changes in the USEPA toxicity factors).

The alternative AWQC presented in this report were derived using probabilistic methods to be protective of Washington residents. The exposure assumptions used to derive these alternate criteria were developed to represent the full range of potential exposures as they are understood today, including both the general population as well as highly exposed individuals, such as tribal members who consume large amounts of fish (i.e., greater than 200 g/day).

National data were used to develop distributions for drinking water intake and body weight. Both national and Washington-specific data were used to develop a distribution of fish consumption rates representative of the entire population of Washington State. The national data were used to represent general fish consumption rates and tribal rate data published by Washington State Department of Ecology (WDOE 2011, 2013) were used to represent tribal consumption rates.

Even with the inclusion of probabilistic methods to better represent the range of fish consumption expected among residents of Washington State as well as distributions for body weight and drinking water consumption, the alternative AWQC retain several conservative elements and are more protective than implied by the risk management thresholds employed in this report. For example, point estimates equal to the maximum value were used for several implicit parameters (e.g., cooking loss, catch location factor, relative bioavailability) leading to an overestimate of potential risk and alternative AWQC that are more stringent than necessary to meet the specified level of protection. Additionally, point estimates were used for toxicity factors and those too are upper bounds (in the case of cancer slope factors) or are derived using several uncertainty factors (in the case of reference doses) as well as other conservative assumptions designed to overstate the potential toxicity of a chemical to protect public health.

Combined the assumptions and approach used in this report lead to alternative AWQC that are protective of public health but are based on a more complete representation of the range of risks associated with consumption of fish and drinking water than is possible with a deterministic approach, leading to improved risk management decision-making.

4. References

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ARCADIS

Tables

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg-day)^{-1}$	source
71-55-6	1,1,1-Trichloroethane	2.0E+00	IRIS	NA	
79-34-5	1,1,2,2-Tetrachloroethane	2.0E-02	IRIS	2.0E-01	IRIS
79-00-5	1,1,2-Trichloroethane	4.0E-03	IRIS	5.7E-02	IRIS
75-35-4	1,1-Dichloroethene	5.0E-02	IRIS	NA	
95-94-3	1,2,4,5-Tetrachlorobenzene	3.0E-04	IRIS	NA	
120-82-1	1,2,4-Trichlorobenzene	1.0E-02	IRIS	2.9E-02	PPRTV
95-50-1	1,2-Dichlorobenzene	9.0E-02	IRIS	NA	
107-06-2	1,2-Dichloroethane	NA		9.1E-02	IRIS
78-87-5	1,2-Dichloropropane	9.0E-02	ATSDR	3.6E-02	CalEPA
122-66-7	1,2-Diphenylhydrazine	NA		8.0E-01	IRIS
541-73-1	1,3-Dichlorobenzene	9.0E-02	IRIS [1]	NA	
542-75-6	1,3-Dichloropropene	3.0E-02	IRIS	1.0E-01	IRIS
106-46-7	1,4-Dichlorobenzene	7.0E-02	ATSDR	5.4E-03	CalEPA
1746-01-6	2,3,7,8-TCDD	7.0E-10	IRIS	1.3E+05	CalEPA
95-95-4	2,4,5-Trichlorophenol	1.0E-01	IRIS	NA	
88-06-2	2,4,6-Trichlorophenol	1.0E-03	PPRTV	1.1E-02	IRIS
120-83-2	2,4-Dichlorophenol	3.0E-03	IRIS	NA	
105-67-9	2,4-Dimethylphenol	2.0E-02	IRIS	NA	
51-28-5	2,4-Dinitrophenol	2.0E-03	IRIS	NA	
121-14-2	2,4-Dinitrotoluene	2.0E-03	IRIS	3.1E-01	CalEPA
91-58-7	2-Chloronaphthalene	8.0E-02	IRIS	NA	
95-57-8	2-Chlorophenol	5.0E-03	IRIS	NA	
534-52-1	2-Methyl-4,6-Dinitrophenol	8.0E-05	PPRTV	NA	
91-94-1	3,3-Dichlorobenzidine	NA		4.5E-01	IRIS
72-54-8	4,4-DDD	NA		2.4E-01	IRIS
72-55-9	4,4-DDE	NA		3.4E-01	IRIS
50-29-3	4,4-DDT	5.0E-04	IRIS	3.4E-01	IRIS
83-32-9	Acenaphthene	6.0E-02	IRIS	NA	
107-02-8	Acrolein	5.0E-04	IRIS	NA	
107-13-1	Acrylonitrile	4.0E-02	ATSDR	5.4E-01	IRIS
309-00-2	Aldrin	3.0E-05	IRIS	1.7E+01	IRIS
319-84-6	alpha-BHC	8.0E-03	ATSDR	6.3E+00	IRIS
959-98-8	alpha-Endosulfan	6.0E-03	IRIS [2]	NA	
120-12-7	Anthracene	3.0E-01	IRIS	NA	
7440-36-0	Antimony	4.0E-04	IRIS	NA	
7440-38-2	Arsenic (Inorganic)	3.0E-04	IRIS	1.5E+00	IRIS
7440-39-3	Barium	2.0E-01	IRIS	NA	
56-55-3	Benz[a]anthracene	NA		7.3E-01	ECAO
71-43-2	Benzene	4.0E-03	IRIS	1.5E-02	IRIS [3]
92-87-5	Benzidine	3.0E-03	IRIS	2.3E+02	IRIS
50-32-8	Benzo[a]pyrene	NA		7.3E+00	IRIS
205-99-2	Benzo[b]fluoranthene	NA		7.3E-01	ECAO
207-08-9	Benzo[k]fluoranthene	NA		7.3E-02	ECAO
7440-41-7	Beryllium	2.0E-03	IRIS	NA	
319-85-7	beta-BHC	NA		1.8E+00	IRIS
33213-65-9	beta-Endosulfan	6.0E-03	IRIS [2]	NA	
111-44-4	Bis(2-Chloroethyl)ether	NA		1.1E+00	IRIS
108-60-1	Bis(2-Chloroisopropyl)ether	4.0E-02	IRIS	7.0E-02	HEAST
117-81-7	Bis(2-Ethylhexyl) Phthalate	2.0E-02	IRIS	1.4E-02	IRIS
542-88-1	Bis(Chloromethyl)ether	NA		2.2E+02	IRIS
75-25-2	Bromoform	2.0E-02	IRIS	7.9E-03	IRIS
85-68-7	Butylbenzyl phthalate	2.0E-01	IRIS	1.9E-03	PPRTV
7440-43-9	Cadmium	5.0E-04	IRIS [4]	NA	
56-23-5	Carbon Tetrachloride	4.0E-03	IRIS	7.0E-02	IRIS
12789-03-6	Chlordane	5.0E-04	IRIS	3.5E-01	IRIS
108-90-7	Chlorobenzene	2.0E-02	IRIS	NA	
124-48-1	Chlorodibromomethane	2.0E-02	IRIS	8.4E-02	IRIS

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg-day)^{-1}$	source
67-66-3	Chloroform	1.0E-02	IRIS	3.1E-02	CalEPA
94-75-7	Chlorophenoxy Herbicide (2,4-D)	1.0E-02	IRIS	NA	
16065-83-1	Chromium III	1.5E+00	IRIS	NA	
18540-29-9	Chromium VI	3.0E-03	IRIS	5.0E-01	NJDEP
218-01-9	Chrysene	NA		7.3E-03	ECAO
7440-50-8	Copper	4.0E-02	HEAST	NA	
57-12-5	Cyanide	6.0E-04	IRIS	NA	
53-70-3	Dibenz[a,h]anthracene	NA		7.3E+00	ECAO
75-27-4	Dichlorobromomethane	2.0E-02	IRIS	6.2E-02	IRIS
75-09-2	Dichloromethane	6.0E-03	IRIS	2.0E-03	IRIS
60-57-1	Dieldrin	5.0E-05	IRIS	1.6E+01	IRIS
84-66-2	Diethyl phthalate	8.0E-01	IRIS	NA	
131-11-3	Dimethyl Phthalate	1.0E+01	[5]	NA	
25550-58-7	Dinitrophenols	2.0E-03	IRIS [6]	NA	
84-74-2	Di-n-Butyl phthalate	1.0E-01	IRIS	NA	
1031-07-8	Endosulfan Sulfate	6.0E-03	IRIS [2]	NA	
72-20-8	Endrin	3.0E-04	IRIS	NA	
7421-93-4	Endrin Aldehyde	3.0E-04	IRIS [7]	NA	
100-41-4	Ethylbenzene	1.0E-01	IRIS	1.1E-02	CalEPA
206-44-0	Fluoranthene	4.0E-02	IRIS	NA	
86-73-7	Fluorene	4.0E-02	IRIS	NA	
76-44-8	Heptachlor	5.0E-04	IRIS	4.5E+00	IRIS
1024-57-3	Heptachlor Epoxide	1.3E-05	IRIS	9.1E+00	IRIS
118-74-1	Hexachlorobenzene	8.0E-04	IRIS	1.6E+00	IRIS
87-68-3	Hexachlorobutadiene	1.0E-03	PPRTV	7.8E-02	IRIS
608-73-1	Hexachlorocyclohexane (Technical)	NA		1.8E+00	IRIS
77-47-4	Hexachlorocyclopentadiene	6.0E-03	IRIS	NA	
67-72-1	Hexachloroethane	7.0E-04	IRIS	4.0E-02	IRIS
193-39-5	Indeno[1,2,3-cd]pyrene	NA		7.3E-01	ECAO
78-59-1	Isophorone	2.0E-01	IRIS	9.5E-04	IRIS
58-89-9	Lindane (gamma-BHC)	3.0E-04	IRIS	1.1E+00	CalEPA
7439-96-5	Manganese	1.4E-01	IRIS	NA	
72-43-5	Methoxychlor	5.0E-02	IRIS	NA	
74-83-9	Methyl bromide	1.4E-03	IRIS	NA	
7440-02-0	Nickel	2.0E-02	IRIS	NA	
14797-55-8	Nitrates	1.6E+00	IRIS	NA	
98-95-3	Nitrobenzene	2.0E-03	IRIS	NA	
—	Nitrosamines	NA		1.5E+02	IRIS [8]
924-16-3	N-Nitrosodibutylamine	NA		5.4E+00	IRIS
55-18-5	N-Nitrosodiethylamine	NA		1.5E+02	IRIS
62-75-9	N-Nitrosodimethylamine	8.0E-06	PPRTV	5.1E+01	IRIS
621-64-7	N-Nitrosodi-n-propylamine	NA		7.0E+00	IRIS
86-30-6	N-Nitrosodiphenylamine	NA		4.9E-03	IRIS
930-55-2	N-Nitrosopyrrolidine	NA		2.1E+00	IRIS
1336-36-3	PCBs	NA		2.0E+00	IRIS
608-93-5	Pentachlorobenzene	8.0E-04	IRIS	NA	
87-86-5	Pentachlorophenol	5.0E-03	IRIS	4.0E-01	IRIS
108-95-2	Phenol	3.0E-01	IRIS	NA	
129-00-0	Pyrene	3.0E-02	IRIS	NA	
7782-49-2	Selenium	5.0E-03	IRIS	NA	
127-18-4	Tetrachloroethene	6.0E-03	IRIS	2.1E-03	IRIS
7440-28-0	Thallium	6.8E-05	IRIS [9]	NA	
108-88-3	Toluene	8.0E-02	IRIS	NA	
8001-35-2	Toxaphene	NA		1.1E+00	IRIS
156-60-5	trans-1,2-Dichloroethylene	2.0E-02	IRIS	NA	
79-01-6	Trichloroethene	5.0E-04	IRIS	4.6E-02	IRIS

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg-day)^{-1}$	source
75-01-4	Vinyl Chloride	3.0E-03	IRIS	1.4E+00	IRIS [10]
7440-66-6	Zinc	3.0E-01	IRIS	NA	

Sources:

IRIS = USEPA Integrated Risk Information System
PPRTV = Provisional Peer-Reviewed Toxicity Values
HEAST = Health Effects Assessment Summary Tables
CalEPA = California Environmental Protection Agency
ECAO = Environmental Criteria and Assessment Office
NJDEP = New Jersey Department of Environmental Protection
ATSDR = Agency for Toxic Substances and Disease Registry

USEPA. 2002a. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012. Washington, DC: United States Environmental Protection Agency Office of Water Office of Science and Technology.

USEPA. 2013a. National Recommended Water Quality Criteria: Human Health Criteria Table. Accessible via: http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm. Last updated: August 22.

Notes:

CAS = Chemical Abstracts Service
mg/kg-day = milligrams per kilogram per day
NA = not available
USEPA = United States Environmental Protection Agency

[1] 1,2-Dichlorobenzene was used as a surrogate, consistent with the USEPA (2002a) approach.
[2] Endosulfan was used as a surrogate, consistent with the USEPA (2002a) approach.
[3] The CSF for benzene ranges from $1.5x10^{-2}$ to $5.5x10^{-2}$ per mg/kg-day. The lower value was used ($1.5x10^{-2}$), consistent with the USEPA (2013a) approach.
[4] Reference dose for cadmium in water.
[5] An average daily intake (ADI) of 10 mg/kg-day was used by USEPA (2002a) to derive the national criterion for dimethyl phthalate.
[6] 2,4-Dinitrophenol was used as a surrogate, consistent with the USEPA (2002a) approach.
[7] Endrin was used as a surrogate, consistent with the USEPA (2002a) approach.
[8] N-Nitrosodiethylamine was used as a surrogate, consistent with the USEPA (2002a) approach.
[9] In 2009, USEPA withdrew the oral RfD for thallium noting the available toxicity database contains studies that are generally of poor quality.
[10] The CSF for vinyl chloride assumes continuous lifetime exposure from birth.

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Table 2. USEPA-Recommended Relative Source Contribution Factors (RSCs)

Chemical	USEPA-Recommended RSC
1,1-Dichloroethene	0.2
1,2,4-Trichlorobenzene	0.2
1,2-Dichlorobenzene	0.2
1,4-Dichlorobenzene	0.2
Antimony	0.4
Cadmium	0.25 [1]
Chlorobenzene	0.2
Chromium III	0.2
Chromium VI	0.2
Copper	0.2
Cyanide	0.2
Endrin	0.2
Ethylbenzene	0.2
Hexachlorocyclopentadiene	0.2
Lindane (gamma-BHC)	0.2 – 0.8
Methoxychlor	0.2
Thallium	0.2
Toluene	0.2
trans-1,2-Dichloroethylene	0.2

Source:

USEPA. 2013b. Technical Support Document for Action on the Revised Surface Water Quality Standards of the Spokane Tribe of Indians Submitted April 2010. U.S. Environmental Protection Agency, Region 10, Seattle, Washington. December.

Notes:

RSC = relative source contribution

USEPA = United Stated Environmental Protection Agency

[1] Based on the RSC used to develop the cadmium drinking water Maximum Contaminant Level Goal (MCLG).

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
71-55-6	1,1,1-Trichloroethane	5.6
79-34-5	1,1,2,2-Tetrachloroethane	5
79-00-5	1,1,2-Trichloroethane	4.5
75-35-4	1,1-Dichloroethene	5.6
95-94-3	1,2,4,5-Tetrachlorobenzene	1125
120-82-1	1,2,4-Trichlorobenzene	114
95-50-1	1,2-Dichlorobenzene	55.6
107-06-2	1,2-Dichloroethane	1.2
78-87-5	1,2-Dichloropropane	4.1
122-66-7	1,2-Diphenylhydrazine	24.9
541-73-1	1,3-Dichlorobenzene	55.6
542-75-6	1,3-Dichloropropene	1.9
106-46-7	1,4-Dichlorobenzene	55.6
1746-01-6	2,3,7,8-TCDD	5000
95-95-4	2,4,5-Trichlorophenol	110
88-06-2	2,4,6-Trichlorophenol	150
120-83-2	2,4-Dichlorophenol	40.7
105-67-9	2,4-Dimethylphenol	93.8
51-28-5	2,4-Dinitrophenol	1.5
121-14-2	2,4-Dinitrotoluene	3.8
91-58-7	2-Chloronaphthalene	202
95-57-8	2-Chlorophenol	134
534-52-1	2-Methyl-4,6-Dinitrophenol	5.5
91-94-1	3,3-Dichlorobenzidine	312
72-54-8	4,4-DDD	53600
72-55-9	4,4-DDE	53600
50-29-3	4,4-DDT	53600
83-32-9	Acenaphthene	242
107-02-8	Acrolein	215
107-13-1	Acrylonitrile	30
309-00-2	Aldrin	4670
319-84-6	alpha-BHC	130
959-98-8	alpha-Endosulfan	270
120-12-7	Anthracene	30
7440-36-0	Antimony	1
7440-38-2	Arsenic (Inorganic)	44
7440-39-3	Barium	NA [1]
56-55-3	Benz[a]anthracene	30
71-43-2	Benzene	5.2
92-87-5	Benzidine	87.5
50-32-8	Benzo[a]pyrene	30
205-99-2	Benzo[b]fluoranthene	30
207-08-9	Benzo[k]fluoranthene	30
7440-41-7	Beryllium	19
319-85-7	beta-BHC	130
33213-65-9	beta-Endosulfan	270
111-44-4	Bis(2-Chloroethyl)ether	6.9
108-60-1	Bis(2-Chloroisopropyl)ether	2.47
117-81-7	Bis(2-Ethylhexyl) Phthalate	130
542-88-1	Bis(Chloromethyl)ether	63
75-25-2	Bromoform	3.75
85-68-7	Butylbenzyl phthalate	414
7440-43-9	Cadmium	NA [2]
56-23-5	Carbon Tetrachloride	18.75

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
12789-03-6	Chlordane	14100
108-90-7	Chlorobenzene	10.3
124-48-1	Chlorodibromomethane	3.75
67-66-3	Chloroform	3.75
94-75-7	Chlorophenoxy Herbicide (2,4-D)	NA [1]
16065-83-1	Chromium III	16
18540-29-9	Chromium VI	16
218-01-9	Chrysene	30
7440-50-8	Copper	36
57-12-5	Cyanide	1
53-70-3	Dibenz[a,h]anthracene	30
75-27-4	Dichlorobromomethane	3.75
75-09-2	Dichloromethane	0.9
60-57-1	Dieldrin	4670
84-66-2	Diethyl phthalate	73
131-11-3	Dimethyl Phthalate	36
84-74-2	Di-n-Butyl phthalate	89
25550-58-7	Dinitrophenols	1.51
1031-07-8	Endosulfan Sulfate	270
72-20-8	Endrin	3970
7421-93-4	Endrin Aldehyde	3970
100-41-4	Ethylbenzene	37.5
206-44-0	Fluoranthene	1150
86-73-7	Fluorene	30
76-44-8	Heptachlor	11200
1024-57-3	Heptachlor Epoxide	11200
118-74-1	Hexachlorobenzene	8690
87-68-3	Hexachlorobutadiene	2.78
608-73-1	Hexachlorocyclohexane (Technical)	130
77-47-4	Hexachlorocyclopentadiene	4.34
67-72-1	Hexachloroethane	86.9
193-39-5	Indeno[1,2,3-cd]pyrene	30
78-59-1	Isophorone	4.38
58-89-9	Lindane (gamma-BHC)	130
7439-96-5	Manganese	NA [1]
72-43-5	Methoxychlor	NA [1]
74-83-9	Methyl bromide	3.75
7440-02-0	Nickel	47
14797-55-8	Nitrates	NA [1]
98-95-3	Nitrobenzene	2.89
—	Nitrosamines	0.2
924-16-3	N-Nitrosodibutylamine	3.38
55-18-5	N-Nitrosodiethylamine	0.2
62-75-9	N-Nitrosodimethylamine	0.026
621-64-7	N-Nitrosodi-n-propylamine	1.13
86-30-6	N-Nitrosodiphenylamine	136
930-55-2	N-Nitrosopyrrolidine	0.055
1336-36-3	PCBs	31200
608-93-5	Pentachlorobenzene	2125
87-86-5	Pentachlorophenol	11
108-95-2	Phenol	1.4
129-00-0	Pyrene	30
7782-49-2	Selenium	4.8
127-18-4	Tetrachloroethene	30.6

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
7440-28-0	Thallium	116
108-88-3	Toluene	10.7
8001-35-2	Toxaphene	13100
156-60-5	trans-1,2-Dichloroethylene	1.58
79-01-6	Trichloroethene	10.6
75-01-4	Vinyl Chloride	1.17
7440-66-6	Zinc	47

Source:

USEPA. 2002a. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012. Washington, DC: United States Environmental Protection Agency Office of Water Office of Science and Technology.

Notes:

CAS = Chemical Abstracts Service

L/kg tissue = liters per kilogram tissue

NA = not available

USEPA = United States Environmental Protection Agency

[1] The national criterion for this chemical was originally published in the 1976 USEPA Red Book, which did not utilize the fish ingestion BCF approach. No default USEPA BCF is provided.

[2] The national criterion for cadmium is based on the Maximum Contaminant Level (MCL) issued by USEPA. No default USEPA BCF is provided.

Table 4. Input Distribution Summary Statistics

Input Parameter	Drinking Water Intake	Body Weight	Fish Consumption Rate
Units	liters per day (L/day)	kilograms (g)	grams per day (g/day)
Distribution Type	Pearson Type V	Lognormal	Inverse Gaussian
Minimum	0	44	0
Maximum	∞	∞	∞
Mean	1.72	80.5	8.59
Mode	1.20	72.5	2.29
Median	1.53	77.7	5.79
Std Dev	1.07	20.3	8.86
1%	0.110	46.6	0.385
5%	0.358	52.4	1.02
10%	0.552	56.8	1.56
15%	0.703	60.1	2.03
20%	0.835	63.1	2.49
25%	0.957	65.7	2.96
30%	1.07	68.2	3.44
35%	1.19	70.6	3.96
40%	1.30	72.9	4.51
45%	1.41	75.3	5.12
50%	1.53	77.7	5.79
55%	1.66	80.2	6.54
60%	1.79	82.9	7.39
65%	1.93	85.7	8.39
70%	2.09	88.7	9.56
75%	2.27	92.2	11.0
80%	2.48	96.2	12.8
85%	2.75	101	15.3
90%	3.12	108	19.0
95%	3.73	118	25.7
99%	5.15	140	43.3

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical	Water + Organism				Organism Only			
	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
1,1,1-Trichloroethane	4.61E+04	1.0	NA	NA	1.42E+06	1.0	NA	NA
1,1,2,2-Tetrachloroethane	2.50E+00	0.0054	1.0E-05	3.8E-05	1.35E+02	0.0085	1.0E-05	8.2E-05
1,1,2-Trichloroethane	8.78E+00	0.095	1.0E-05	3.8E-05	5.29E+02	0.15	1.0E-05	8.1E-05
1,1-Dichloroethene	1.16E+03	1.0	NA	NA	3.54E+04	1.0	NA	NA
1,2,4,5-Tetrachlorobenzene	9.71E-01	1.0	NA	NA	1.06E+00	1.0	NA	NA
1,2,4-Trichlorobenzene	1.11E+01	0.070	1.0E-05	3.5E-05	4.09E+01	0.12	1.0E-05	8.2E-05
1,2-Dichlorobenzene	1.74E+03	1.0	NA	NA	6.39E+03	1.0	NA	NA
1,2-Dichloroethane	5.62E+00	NA	1.0E-05	3.8E-05	1.24E+03	NA	1.0E-05	8.2E-05
1,2-Dichloropropane	1.40E+01	0.0067	1.0E-05	3.8E-05	9.17E+02	0.011	1.0E-05	8.2E-05
1,2-Diphenylhydrazine	5.63E-01	NA	1.0E-05	3.6E-05	6.80E+00	NA	1.0E-05	8.1E-05
1,3-Dichlorobenzene	1.74E+03	1.0	NA	NA	6.39E+03	1.0	NA	NA
1,3-Dichloropropene	5.11E+00	0.0073	1.0E-05	3.9E-05	7.11E+02	0.011	1.0E-05	8.1E-05
1,4-Dichlorobenzene	7.29E+01	0.054	1.0E-05	3.4E-05	4.50E+02	0.090	1.0E-05	8.1E-05
2,3,7,8-TCDD	1.96E-07	0.36	1.0E-05	7.8E-05	2.09E-07	0.38	1.0E-05	8.2E-05
2,4,5-Trichlorophenol	1.61E+03	1.0	NA	NA	3.59E+03	1.0	NA	NA
2,4,6-Trichlorophenol	1.41E+01	1.0	5.3E-06	2.0E-05	2.64E+01	1.0	3.2E-06	2.6E-05
2,4-Dichlorophenol	6.13E+01	1.0	NA	NA	2.92E+02	1.0	NA	NA
2,4-Dimethylphenol	3.39E+02	1.0	NA	NA	8.45E+02	1.0	NA	NA
2,4-Dinitrophenol	4.67E+01	1.0	NA	NA	5.26E+03	0.99	NA	NA
2,4-Dinitrotoluene	1.63E+00	0.035	1.0E-05	3.8E-05	1.15E+02	0.055	1.0E-05	8.2E-05
2-Chloronaphthalene	9.71E+02	1.0	NA	NA	1.57E+03	1.0	NA	NA
2-Chlorophenol	7.40E+01	1.0	NA	NA	1.47E+02	1.0	NA	NA
2-Methyl-4,6-Dinitrophenol	1.85E+00	1.0	NA	NA	5.78E+01	1.0	NA	NA
3,3-Dichlorobenzidine	4.73E-01	NA	1.0E-05	4.6E-05	9.61E-01	NA	1.0E-05	8.2E-05
4,4-DDD	1.04E-02	NA	9.9E-06	8.1E-05	1.05E-02	NA	1.0E-05	8.2E-05
4,4-DDE	7.39E-03	NA	1.0E-05	8.1E-05	7.43E-03	NA	1.0E-05	8.2E-05
4,4-DDT	7.38E-03	0.2	1.0E-05	8.2E-05	7.44E-03	0.20	1.0E-05	8.2E-05
Acenaphthene	6.56E+02	1.0	NA	NA	9.84E+02	1.0	NA	NA
Acrolein	5.89E+00	1.0	NA	NA	9.21E+00	1.0	NA	NA
Acrylonitrile	8.13E-01	0.00096	1.0E-05	3.5E-05	8.36E+00	0.0016	1.0E-05	8.2E-05
Aldrin	1.59E-03	0.064	1.0E-05	7.7E-05	1.70E-03	0.067	1.0E-05	8.2E-05
alpha-BHC	4.90E-02	0.00041	1.0E-05	3.6E-05	1.65E-01	0.00068	1.0E-05	8.2E-05
alpha-Endosulfan	6.10E+01	1.0	NA	NA	8.79E+01	1.0	NA	NA
Anthracene	6.37E+03	1.0	NA	NA	3.97E+04	1.0	NA	NA
Antimony	9.35E+00	1.0	NA	NA	1.58E+03	0.99	NA	NA
Arsenic (Inorganic) [3]	NA	NA	NA	NA	NA	NA	NA	NA
Barium [4]	4.70E+03	1.0	NA	NA	NA	NA	NA	NA
Benz[a]anthracene	6.02E-01	NA	1.0E-05	3.5E-05	6.18E+00	NA	1.0E-05	8.1E-05
Benzene	3.34E+01	0.36	1.0E-05	3.8E-05	1.73E+03	0.57	1.0E-05	8.1E-05
Benzidine	1.52E-03	0.000029	1.0E-05	3.5E-05	6.72E-03	0.000049	1.0E-05	8.2E-05
Benzo[a]pyrene	6.02E-02	NA	1.0E-05	3.5E-05	6.17E-01	NA	1.0E-05	8.2E-05
Benzo[b]fluoranthene	6.02E-01	NA	1.0E-05	3.5E-05	6.19E+00	NA	1.0E-05	8.2E-05
Benzo[k]fluoranthene	6.01E+00	NA	1.0E-05	3.5E-05	6.17E+01	NA	1.0E-05	8.1E-05

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical	Water + Organism				Organism Only			
	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
Beryllium	4.42E+01	1.0	NA	NA	4.16E+02	1.0	NA	NA
beta-BHC	1.72E-01	NA	1.0E-05	3.6E-05	5.80E-01	NA	1.0E-05	8.2E-05
beta-Endosulfan	6.13E+01	1.0	NA	NA	8.78E+01	0.99	NA	NA
Bis(2-Chloroethyl)ether	4.50E-01	NA	1.0E-05	3.8E-05	1.78E+01	NA	1.0E-05	8.1E-05
Bis(2-Chloroisopropyl)ether	7.24E+00	0.0078	1.0E-05	3.8E-05	7.82E+02	0.012	1.0E-05	8.1E-05
Bis(2-Ethylhexyl) Phthalate	2.21E+01	0.074	1.0E-05	3.6E-05	7.44E+01	0.12	1.0E-05	8.2E-05
Bis(Chloromethyl)ether	1.74E-03	NA	1.0E-05	3.4E-05	9.74E-03	NA	1.0E-05	8.2E-05
Bromoform	6.38E+01	0.14	1.0E-05	3.8E-05	4.55E+03	0.22	1.0E-05	8.1E-05
Butylbenzyl phthalate	9.62E+01	0.064	1.0E-05	5.1E-05	1.72E+02	0.090	1.0E-05	8.1E-05
Cadmium [4]	1.17E+01	1.0	NA	NA	NA	NA	NA	NA
Carbon Tetrachloride	6.63E+00	0.075	1.0E-05	3.6E-05	1.03E+02	0.12	1.0E-05	8.1E-05
Chlordane	2.68E-02	0.19	1.0E-05	8.0E-05	2.75E-02	0.20	1.0E-05	8.0E-05
Chlorobenzene	4.55E+02	1.0	NA	NA	7.70E+03	1.0	NA	NA
Chlorodibromomethane	5.99E+00	0.013	1.0E-05	3.8E-05	4.30E+02	0.020	1.0E-05	8.2E-05
Chloroform	1.62E+01	0.070	1.0E-05	3.8E-05	1.16E+03	0.11	1.0E-05	8.1E-05
Chlorophenoxy Herbicide (2,4-D) [4]	2.34E+02	1.0	NA	NA	NA	NA	NA	NA
Chromium III	3.34E+04	1.0	NA	NA	3.72E+05	1.0	NA	NA
Chromium VI	9.41E-01	0.014	1.0E-05	3.6E-05	1.69E+01	0.023	1.0E-05	8.1E-05
Chrysene	6.02E+01	NA	1.0E-05	3.5E-05	6.16E+02	NA	1.0E-05	8.1E-05
Copper	8.34E+02	1.0	NA	NA	4.40E+03	1.0	NA	NA
Cyanide	1.40E+01	1.0	NA	NA	2.37E+03	0.99	NA	NA
Dibenz[a,h]anthracene	6.01E-02	NA	1.0E-05	3.5E-05	6.19E-01	NA	1.0E-05	8.1E-05
Dichlorobromomethane	8.13E+00	0.018	1.0E-05	3.8E-05	5.81E+02	0.028	1.0E-05	8.1E-05
Dichloromethane	1.40E+02	1.0	5.5E-06	2.1E-05	2.65E+04	1.0	3.5E-06	2.8E-05
Dieldrin	1.70E-03	0.041	1.0E-05	7.7E-05	1.81E-03	0.043	1.0E-05	8.1E-05
Diethyl phthalate	1.46E+04	1.0	NA	NA	4.32E+04	0.99	NA	NA
Dimethyl Phthalate	2.08E+05	1.0	NA	NA	1.10E+06	1.0	NA	NA
Di-n-Butyl phthalate	1.73E+03	1.0	NA	NA	4.45E+03	1.0	NA	NA
Dinitrophenols	4.68E+01	1.0	NA	NA	5.25E+03	1.0	NA	NA
Endosulfan Sulfate	6.13E+01	1.0	NA	NA	8.79E+01	1.0	NA	NA
Endrin	2.92E-01	1.0	NA	NA	2.99E-01	1.0	NA	NA
Endrin Aldehyde	2.93E-01	1.0	NA	NA	3.00E-01	1.0	NA	NA
Ethylbenzene	3.86E+01	0.019	1.0E-05	3.5E-05	3.27E+02	0.031	9.9E-06	8.1E-05
Fluoranthene	1.26E+02	1.0	NA	NA	1.38E+02	1.0	NA	NA
Fluorene	8.50E+02	1.0	NA	NA	5.29E+03	1.0	NA	NA
Heptachlor	2.62E-03	0.015	1.0E-05	8.1E-05	2.69E-03	0.015	1.0E-05	8.2E-05
Heptachlor Epoxide	1.29E-03	0.28	1.0E-05	8.0E-05	1.33E-03	0.29	1.0E-05	8.1E-05
Hexachlorobenzene	9.36E-03	0.026	9.9E-06	7.9E-05	9.73E-03	0.027	1.0E-05	8.2E-05
Hexachlorobutadiene	6.49E+00	0.28	1.0E-05	3.8E-05	6.23E+02	0.44	1.0E-05	8.1E-05
Hexachlorocyclohexane (Technical)	1.72E-01	NA	1.0E-05	3.6E-05	5.79E-01	NA	1.0E-05	8.1E-05
Hexachlorocyclopentadiene	1.39E+02	1.0	NA	NA	5.46E+03	1.0	NA	NA
Hexachloroethane	8.79E+00	0.73	1.0E-05	3.4E-05	3.20E+01	1.0	8.2E-06	6.8E-05
Indeno[1,2,3-cd]pyrene	6.03E-01	NA	1.0E-05	3.5E-05	6.18E+00	NA	1.0E-05	8.2E-05

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical	Water + Organism				Organism Only			
	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
Isophorone	5.29E+02	0.11	1.0E-05	3.8E-05	3.24E+04	0.18	1.0E-05	8.1E-05
Lindane (gamma-BHC)	2.80E-01	0.062	1.0E-05	3.6E-05	9.46E-01	0.10	1.0E-05	8.1E-05
Manganese [4]	3.29E+03	1.0	NA	NA	NA	NA	NA	NA
Methoxychlor [4]	1.17E+03	1.0	NA	NA	NA	NA	NA	NA
Methyl bromide	3.25E+01	1.0	NA	NA	1.47E+03	1.0	NA	NA
Nickel	3.99E+02	1.0	NA	NA	1.69E+03	1.0	NA	NA
Nitrates [4]	3.74E+04	1.0	NA	NA	NA	NA	NA	NA
Nitrobenzene	4.66E+01	1.0	NA	NA	2.74E+03	1.0	NA	NA
Nitrosamines	3.45E-03	NA	1.0E-05	3.9E-05	4.52E+00	NA	1.0E-05	8.2E-05
N-Nitrosodibutylamine	9.36E-02	NA	1.0E-05	3.9E-05	7.41E+00	NA	1.0E-05	8.1E-05
N-Nitrosodiethylamine	3.42E-03	NA	1.0E-05	3.9E-05	4.51E+00	NA	1.0E-05	8.1E-05
N-Nitrosodimethylamine	1.01E-02	0.054	1.0E-05	3.9E-05	1.02E+02	0.084	1.0E-05	8.1E-05
N-Nitrosodi-n-propylamine	7.31E-02	NA	1.0E-05	3.9E-05	1.71E+01	NA	1.0E-05	8.2E-05
N-Nitrosodiphenylamine	6.21E+01	NA	1.0E-05	3.7E-05	2.03E+02	NA	1.0E-05	8.1E-05
N-Nitrosopyrrolidine	2.45E-01	NA	1.0E-05	3.9E-05	1.17E+03	NA	1.0E-05	8.2E-05
PCBs	2.15E-03	NA	1.0E-05	8.0E-05	2.17E-03	NA	1.0E-05	8.2E-05
Pentachlorobenzene	1.42E+00	1.0	NA	NA	1.49E+00	1.0	NA	NA
Pentachlorophenol	1.21E+00	0.011	1.0E-05	3.7E-05	3.07E+01	0.017	1.0E-05	8.2E-05
Phenol	7.01E+03	1.0	NA	NA	8.48E+05	1.0	NA	NA
Pyrene	6.38E+02	1.0	NA	NA	3.96E+03	1.0	NA	NA
Selenium	1.15E+02	1.0	NA	NA	4.11E+03	1.0	NA	NA
Tetrachloroethene	1.27E+02	1.0	6.1E-06	2.1E-05	7.76E+02	1.0	3.7E-06	3.0E-05
Thallium	1.07E+00	1.0	NA	NA	2.32E+00	1.0	NA	NA
Toluene	1.82E+03	1.0	NA	NA	2.97E+04	1.0	NA	NA
Toxaphene	9.14E-03	NA	1.0E-05	8.1E-05	9.37E-03	NA	1.0E-05	8.1E-05
trans-1,2-Dichloroethylene	4.66E+02	1.0	NA	NA	5.04E+04	1.0	NA	NA
Trichloroethene	1.06E+01	0.93	1.0E-05	3.7E-05	1.87E+02	1.0	6.7E-06	5.5E-05
Vinyl Chloride	3.66E-01	0.0052	1.0E-05	3.8E-05	8.24E+01	0.0081	1.0E-05	8.1E-05
Zinc	5.98E+03	1.0	NA	NA	2.52E+04	1.0	NA	NA

Notes:

aAWQC = alternate ambient water quality criterion
ELCR = excess lifetime cancer risk
HQ = hazard quotient
NA = not available/not applicable
ug/L = micrograms per liter

[1] Hazard quotient calculated only for chemicals for which a reference dose (RfD) is available.
[2] Excess lifetime cancer risk calculated only for chemcials for which a cancer slope factor (CSF) is available.
[3] Arsenic criteria is blank because in public forums the Washington Department of Ecology has stated they may consider an alternative approach for arsenic criteria.
[4] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.

Table 6. Alternate AWQC Derived Using USEPA-Recommended Relative Source Contribution Factors

Chemical		USEPA RSC	Water + Organism aAWQC (ug/L)		Organism Only aAWQC (ug/L)	
			RSC = 1	USEPA RSC	RSC = 1	USEPA RSC
1,1-Dichloroethene		0.2	1.16E+03	2.31E+02	3.54E+04	7.07E+03
1,2,4-Trichlorobenzene	[1]	0.2	1.11E+01	1.11E+01	4.09E+01	4.09E+01
1,2-Dichlorobenzene		0.2	1.74E+03	3.49E+02	6.39E+03	1.28E+03
1,4-Dichlorobenzene	[1]	0.2	7.29E+01	7.29E+01	4.50E+02	4.50E+02
Antimony		0.4	9.35E+00	3.74E+00	1.58E+03	6.34E+02
Cadmium	[2]	0.25	1.17E+01	2.93E+00	NA	NA
Chlorobenzene		0.2	4.55E+02	9.10E+01	7.70E+03	1.54E+03
Chromium III		0.2	3.34E+04	6.69E+03	3.72E+05	7.43E+04
Chromium VI	[1]	0.2	9.41E-01	9.41E-01	1.69E+01	1.69E+01
Copper		0.2	8.34E+02	1.67E+02	4.40E+03	8.79E+02
Cyanide		0.2	1.40E+01	2.80E+00	2.37E+03	4.74E+02
Endrin		0.2	2.92E-01	5.84E-02	2.99E-01	5.97E-02
Ethylbenzene	[1]	0.2	3.86E+01	3.86E+01	3.27E+02	3.27E+02
Hexachlorocyclopentadiene		0.2	1.39E+02	2.78E+01	5.46E+03	1.09E+03
Lindane (gamma-BHC)	[1,3]	0.5	2.80E-01	2.80E-01	9.46E-01	9.46E-01
Methoxychlor	[2]	0.2	1.17E+03	2.34E+02	NA	NA
Thallium		0.2	1.07E+00	2.14E-01	2.32E+00	4.63E-01
Toluene		0.2	1.82E+03	3.63E+02	2.97E+04	5.94E+03
trans-1,2-Dichloroethylene		0.2	4.66E+02	9.32E+01	5.04E+04	1.01E+04

Notes:

aAWQC = alternate ambient water quality criterion
NA = not available/not applicable
RSC = relative source contribution
ug/L = micrograms per liter
USEPA = United States Environmental Protection Agency

[1] AWQC is based on carcinogenic health endpoint; RSC adjustment does not affect the AWQC because the AWQC is driven by the carcinogenic endpoint.
[2] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.
[3] Average of USEPA-recommended range of RSCs.

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical		Water + Organism		Organism Only	
		aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
1,1,1-Trichloroethane	[1]	4.61E+04	NA	1.42E+06	NA
1,1,2,2-Tetrachloroethane		2.50E+00	1.70E-01	1.35E+02	4.00E+00
1,1,2-Trichloroethane		8.78E+00	5.90E-01	5.29E+02	1.60E+01
1,1-Dichloroethene		1.16E+03	3.30E+02	3.54E+04	7.10E+03
1,2,4,5-Tetrachlorobenzene		9.71E-01	9.70E-01	1.06E+00	1.10E+00
1,2,4-Trichlorobenzene		1.11E+01	3.50E+01	4.09E+01	7.00E+01
1,2-Dichlorobenzene		1.74E+03	4.20E+02	6.39E+03	1.30E+03
1,2-Dichloroethane		5.62E+00	3.80E-01	1.24E+03	3.70E+01
1,2-Dichloropropane		1.40E+01	5.00E-01	9.17E+02	1.50E+01
1,2-Diphenylhydrazine		5.63E-01	3.60E-02	6.80E+00	2.00E-01
1,3-Dichlorobenzene		1.74E+03	3.20E+02	6.39E+03	9.60E+02
1,3-Dichloropropene		5.11E+00	3.40E-01	7.11E+02	2.10E+01
1,4-Dichlorobenzene		7.29E+01	6.30E+01	4.50E+02	1.90E+02
2,3,7,8-TCDD		1.96E-07	5.00E-09	2.09E-07	5.10E-09
2,4,5-Trichlorophenol		1.61E+03	1.80E+03	3.59E+03	3.60E+03
2,4,6-Trichlorophenol		1.41E+01	1.40E+00	2.64E+01	2.40E+00
2,4-Dichlorophenol		6.13E+01	7.70E+01	2.92E+02	2.90E+02
2,4-Dimethylphenol		3.39E+02	3.80E+02	8.45E+02	8.50E+02
2,4-Dinitrophenol		4.67E+01	6.90E+01	5.26E+03	5.30E+03
2,4-Dinitrotoluene		1.63E+00	1.10E-01	1.15E+02	3.40E+00
2-Chloronaphthalene		9.71E+02	1.00E+03	1.57E+03	1.60E+03
2-Chlorophenol		7.40E+01	8.10E+01	1.47E+02	1.50E+02
2-Methyl-4,6-Dinitrophenol		1.85E+00	1.30E+01	5.78E+01	2.80E+02
3,3-Dichlorobenzidine		4.73E-01	2.10E-02	9.61E-01	2.80E-02
4,4-DDD		1.04E-02	3.10E-04	1.05E-02	3.10E-04
4,4-DDE		7.39E-03	2.20E-04	7.43E-03	2.20E-04
4,4-DDT		7.38E-03	2.20E-04	7.44E-03	2.20E-04
Acenaphthene		6.56E+02	6.70E+02	9.84E+02	9.90E+02
Acrolein		5.89E+00	6.00E+00	9.21E+00	9.00E+00
Acrylonitrile		8.13E-01	5.10E-02	8.36E+00	2.50E-01
Aldrin		1.59E-03	4.90E-05	1.70E-03	5.00E-05
alpha-BHC		4.90E-02	2.60E-03	1.65E-01	4.90E-03
alpha-Endosulfan		6.10E+01	6.20E+01	8.79E+01	8.90E+01
Anthracene		6.37E+03	8.30E+03	3.97E+04	4.00E+04
Antimony		9.35E+00	5.60E+00	1.58E+03	6.40E+02
Arsenic (Inorganic)	[2]	NA	NA	NA	NA
Barium	[3]	4.70E+03	1.00E+03	NA	NA
Benz[a]anthracene		6.02E-01	3.80E-03	6.18E+00	1.80E-02
Benzene		3.34E+01	2.20E+00	1.73E+03	5.10E+01
Benzidine		1.52E-03	8.60E-05	6.72E-03	2.00E-04
Benzo[a]pyrene		6.02E-02	3.80E-03	6.17E-01	1.80E-02
Benzo[b]fluoranthene		6.02E-01	3.80E-03	6.19E+00	1.80E-02
Benzo[k]fluoranthene		6.01E+00	3.80E-03	6.17E+01	1.80E-02
Beryllium	[1]	4.42E+01	NA	4.16E+02	NA
beta-BHC		1.72E-01	9.10E-03	5.80E-01	1.70E-02
beta-Endosulfan		6.13E+01	6.20E+01	8.78E+01	8.90E+01
Bis(2-Chloroethyl)ether		4.50E-01	3.00E-02	1.78E+01	5.30E-01
Bis(2-Chloroisopropyl)ether		7.24E+00	1.40E+03	7.82E+02	6.50E+04
Bis(2-Ethylhexyl) Phthalate		2.21E+01	1.20E+00	7.44E+01	2.20E+00
Bis(Chloromethyl)ether		1.74E-03	1.00E-04	9.74E-03	2.90E-04
Bromoform		6.38E+01	4.30E+00	4.55E+03	1.40E+02
Butylbenzyl phthalate		9.62E+01	1.50E+03	1.72E+02	1.90E+03
Cadmium	[1,3]	1.17E+01	NA	NA	NA
Carbon Tetrachloride		6.63E+00	2.30E-01	1.03E+02	1.60E+00

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical	Water + Organism		Organism Only	
	aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
Chlordane	2.68E-02	8.00E-04	2.75E-02	8.10E-04
Chlorobenzene	4.55E+02	1.30E+02	7.70E+03	1.60E+03
Chlorodibromomethane	5.99E+00	4.00E-01	4.30E+02	1.30E+01
Chloroform	1.62E+01	5.70E+00	1.16E+03	4.70E+02
Chlorophenoxy Herbicide (2,4-D) [3]	2.34E+02	1.00E+02	NA	NA
Chromium III [1]	3.34E+04	NA	3.72E+05	NA
Chromium VI [1]	9.41E-01	NA	1.69E+01	NA
Chrysene	6.02E+01	3.80E-03	6.16E+02	1.80E-02
Copper	8.34E+02	1.30E+03	4.40E+03	1.30E+03
Cyanide	1.40E+01	1.40E+02	2.37E+03	1.40E+02
Dibenz[a,h]anthracene	6.01E-02	3.80E-03	6.19E-01	1.80E-02
Dichlorobromomethane	8.13E+00	5.50E-01	5.81E+02	1.70E+01
Dichloromethane	1.40E+02	4.60E+00	2.65E+04	5.90E+02
Dieldrin	1.70E-03	5.20E-05	1.81E-03	5.40E-05
Diethyl phthalate	1.46E+04	1.70E+04	4.32E+04	4.40E+04
Dimethyl Phthalate	2.08E+05	2.70E+05	1.10E+06	1.10E+06
Di-n-Butyl phthalate	1.73E+03	2.00E+03	4.45E+03	4.50E+03
Dinitrophenols	4.68E+01	6.90E+01	5.25E+03	5.30E+03
Endosulfan Sulfate	6.13E+01	6.20E+01	8.79E+01	8.90E+01
Endrin	2.92E-01	5.90E-02	2.99E-01	6.00E-02
Endrin Aldehyde	2.93E-01	2.90E-01	3.00E-01	3.00E-01
Ethylbenzene	3.86E+01	5.30E+02	3.27E+02	2.10E+03
Fluoranthene	1.26E+02	1.30E+02	1.38E+02	1.40E+02
Fluorene	8.50E+02	1.10E+03	5.29E+03	5.30E+03
Heptachlor	2.62E-03	7.90E-05	2.69E-03	7.90E-05
Heptachlor Epoxide	1.29E-03	3.90E-05	1.33E-03	3.90E-05
Hexachlorobenzene	9.36E-03	2.80E-04	9.73E-03	2.90E-04
Hexachlorobutadiene	6.49E+00	4.40E-01	6.23E+02	1.80E+01
Hexachlorocyclohexane (Technical)	1.72E-01	1.23E-02	5.79E-01	4.14E-02
Hexachlorocyclopentadiene	1.39E+02	4.00E+01	5.46E+03	1.10E+03
Hexachloroethane	8.79E+00	1.40E+00	3.20E+01	3.30E+00
Indeno[1,2,3-cd]pyrene	6.03E-01	3.80E-03	6.18E+00	1.80E-02
Isophorone	5.29E+02	3.50E+01	3.24E+04	9.60E+02
Lindane (gamma-BHC)	2.80E-01	9.80E-01	9.46E-01	1.80E+00
Manganese [3]	3.29E+03	5.00E+01	NA	NA
Methoxychlor [3]	1.17E+03	1.00E+02	NA	NA
Methyl bromide	3.25E+01	4.70E+01	1.47E+03	1.50E+03
Nickel	3.99E+02	6.10E+02	1.69E+03	4.60E+03
Nitrates [3]	3.74E+04	1.00E+04	NA	NA
Nitrobenzene	4.66E+01	1.70E+01	2.74E+03	6.90E+02
Nitrosamines	3.45E-03	8.00E-04	4.52E+00	1.24E+00
N-Nitrosodibutylamine	9.36E-02	6.30E-03	7.41E+00	2.20E-01
N-Nitrosodiethylamine	3.42E-03	8.00E-04	4.51E+00	1.24E+00
N-Nitrosodimethylamine	1.01E-02	6.90E-04	1.02E+02	3.00E+00
N-Nitrosodi-n-propylamine	7.31E-02	5.00E-03	1.71E+01	5.10E-01
N-Nitrosodiphenylamine	6.21E+01	3.30E+00	2.03E+02	6.00E+00
N-Nitrosopyrrolidine	2.45E-01	1.60E-02	1.17E+03	3.40E+01
PCBs	2.15E-03	6.40E-05	2.17E-03	6.40E-05
Pentachlorobenzene	1.42E+00	1.40E+00	1.49E+00	1.50E+00
Pentachlorophenol	1.21E+00	2.70E-01	3.07E+01	3.00E+00
Phenol	7.01E+03	1.00E+04	8.48E+05	8.60E+05
Pyrene	6.38E+02	8.30E+02	3.96E+03	4.00E+03
Selenium	1.15E+02	1.70E+02	4.11E+03	4.20E+03
Tetrachloroethene	1.27E+02	6.90E-01	7.76E+02	3.30E+00

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical	Water + Organism		Organism Only	
	aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
Thallium	1.07E+00	2.40E-01	2.32E+00	4.70E-01
Toluene	1.82E+03	1.30E+03	2.97E+04	1.50E+04
Toxaphene	9.14E-03	2.80E-04	9.37E-03	2.80E-04
trans-1,2-Dichloroethylene	4.66E+02	1.40E+02	5.04E+04	1.00E+04
Trichloroethene	1.06E+01	2.50E+00	1.87E+02	3.00E+01
Vinyl Chloride	3.66E-01	2.50E-02	8.24E+01	2.40E+00
Zinc	5.98E+03	7.40E+03	2.52E+04	2.60E+04

Source:

USEPA. 2013a. National Recommended Water Quality Criteria: Human Health Criteria Table. Accessible via: http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm. Last updated: August 22.

Notes:

aAWQC = alternate ambient water quality criterion
MCL = Maximum Contaminant Level
NA = not available/not applicable
ug/L = micrograms per liter

[1] This chemical is regulated based on the MCL.
[2] Arsenic criteria is blank because in public forums the Washington Department of Ecology has stated they may consider an alternative approach for arsenic criteria.
[3] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.

ARCADIS

Attachment A

Development of a Fish Consumption Rate Distribution for Residents of the State of Washington

DEVELOPMENT OF A FISH CONSUMPTION RATE DISTRIBUTION FOR RESIDENTS OF THE STATE OF WASHINGTON

A fish consumption rate distribution representative of the entire population of Washington State residents was developed for use in calculating water quality criteria for the protection of human health using either probabilistic or deterministic methods. National fish consumption rate (FCR) data published by EPA (USEPA 2002, 2011) were used as the basis for estimating FCRs for the general population and tribal rate data published by Washington State Department of Ecology (WDOE 2011, 2013) were used to estimate tribal consumption rates. The general population distribution was adjusted to reflect: (1) consumption of fish and shellfish from freshwater and near-shore marine habitats only; and (2) the portion of salmon consumption accounting for contaminants acquired by salmon in waters of the state. The tribal distribution was only adjusted to account for contaminants acquired by salmon in waters of the state. The two distributions were then combined using weighting factors representing the relative populations of each group.

1. Development of a General Population Fish Consumption Rate

a. Use NCI-adjusted data from the 2003 to 2006 National Health and Nutrition Examination Survey (NHANES) to represent fish consumption rates of the general population of Washington State residents. EPA (USEPA 2011) analyzed these data and generated per capita and consumer-only intake rates for finfish, shellfish, and total fish and shellfish combined. These rates represent intake of all forms of seafood (e.g., purchased, self caught, marine, freshwater, estuarine) for individuals who provided data for two days of the survey.

The "consumers only" data were used for this analysis. Two day average fish intake rates were calculated for all individuals in the database for each of the food items/groups. If a person reported consuming fish on only one day of the survey, their two day average would be half the amount reported for the one day of consumption.

The short-term nature of the NHANES survey methodology has been found to overestimate long-term consumption rates of infrequently consumed foods such as fish (Polissar 2012). To address this problem, researchers at the National Cancer Institute (NCI) developed methodology for estimating the intake of such foods that better represents long-term consumption rates. This methodology addresses biases associated with the day-to-day variation in reported consumption as well as exclusion of fish consumers who did not report eating fish on either day of the survey. Table 1 shows the NCI-adjusted NHANES data as reported by Polissar et al. (2012).

Table 1. Summary of NCI-adjusted NHANES Whole Population Fish Consumption Distribution

Statistic	All Consumers Consumption Rate, All Fish (g/d)	Statistic	All Consumers Consumption Rate, All Fish (g/d)
Mean	18.8	75%	24.8
1%	0.9	80%	28.9
5%	2	85%	34.5
10%	3	90%	42.5
25%	6.2	95%	56.6
50%	12.7	99%	90.8

b. Adjust general population fish consumption data to reflect only freshwater and near-shore marine (estuarine) species. Because the NHANES data are based on total fish consumption, including offshore marine species such as tuna, and because EPA specifically recommends that data used to

represent fish consumption for the purpose of developing human health water quality criteria be based on fish from freshwater and near-shore (estuarine) marine environments only, some means of adjusting the distribution in Table 1 is needed. To make this adjustment, data from US Department of Agriculture's (USDA) Continuing Survey of Food Intake by Individuals (CSFII) 1994 to 1996 were used. Adjustment of the NCI-adjusted NHANES distribution in this manner is based on the assumption that the relative proportions of fresh, near-shore marine, and off-shore marine fish in the American diet have not shifted dramatically in the period of time (about ten years) between the two surveys.

USDA's CSFII survey data (USEPA 2002, Section 5.1.1.1 Table 4) provide estimates of consumption rates of uncooked finfish and shellfish for the US population age 18 and older and were the basis of EPA's current national recommended default fish consumption rate of 17.5 g/day. The data are reproduced herein as Table 2. The reported mean consumption rates of freshwater/estuarine, marine, and all fish were 7.50, 12.41, and 19.91 g/day, respectively. The ratio between the mean freshwater and estuarine (F/E) rate and the all FCR was calculated (0.377) and used as an adjustment factor for the NCI-adjusted NHANES distribution. This ratio represents the average percentage (37.7%) of F/E fish in Americans' total fish diet. It also indicates that on average 62.3% of the fish consumed are from off-shore marine waters.

Table 2. Summary of EPA's Analysis of Uncooked Finfish and Shellfish Consumption Rates (g/person/day) for the CSFII Survey[a]

			90% Interval	
Habitat	Statistic	Estimate	Lower Bound	Upper Bound
Freshwater/Estuarine	Mean	7.50	6.75	8.25
	50th %	0.00	0.00	0.00
	90th %	17.37	14.32	21.58
	95th %	49.59	46.87	55.41
	99th %	143.35	125.27	156.84
Marine	Mean	12.41	11.46	13.37
	50th %	0.00	0.00	0.00
	90th %	48.92	47.10	51.17
	95th %	80.68	77.77	83.45
	99th %	150.77	139.66	164.34
All Fish	Mean	19.91	18.69	21.13
	50th %	0.00	0.00	0.00
	90th %	74.79	71.72	75.71
	95th %	111.35	110.03	114.02
	99th %	215.70	197.09	228.53

[a] USEPA 2002, Section 5.1.1.1 Table 4

Adjustment of the NCI-adjusted NHANES distribution was accomplished by multiplying the mean and each percentile by the F/E adjustment factor (0.377), based on the assumption that the average rate of fresh and estuarine fish consumption can be applied across the entire distribution. Note that ratios between F/E and total fish consumption in Table 2 are 0.232 and 0.445 at the 90th and 95th percentiles, respectively, suggesting that application of the mean ratio is in fact conservative for the majority of consumers (>90%). Table 3 summarizes the "all fish" NCI-adjusted NHANES data and the "fresh and estuarine adjusted" NCI-adjusted NHANES consumption rates.

Table 3. NCI-adjusted NHANES Data Adjusted to Reflect Freshwater and Estuarine Species Consumption Only

Distribution Statistic	All Fish (g/d)[a]	Fresh and Estuarine Species Only (g/d)[b]
Mean	18.8	7.09
1%	0.9	0.34
5%	2	0.75
10%	3	1.13
25%	6.2	2.34
50%	12.7	4.79
75%	24.8	9.35
80%	28.9	10.90
85%	34.5	13.01
90%	42.5	16.02
95%	56.6	21.34
99%	90.8	34.23

[a] from Polissar et al. 2012, Table 4
[b] component of all fish that are freshwater or estuarine fish [all fish x 0.377]

c. Adjust general population distribution to include salmon in proportion to their general population consumption rate and life history spent in fresh and estuarine waters. Scientific studies (e.g., Hope 2012) provide information indicating that some portion of highly bioaccumulative chemicals (e.g., PCBs) found in salmon consumed by Washington residents may be acquired in F/E environments. Thus, the distributions shown in Table 3 were adjusted upward to reflect this information. This was accomplished by adjusting the total salmon consumption rate to reflect only that portion of salmon life history that is spent in F/E waters and the fraction of salmon in the general population total fish diet, and then adding the adjusted salmon consumption rate to the NCI-adjusted NHANES "fresh and estuarine" rates shown in Table 3.

Life history factors (LHFs) were developed for each species of salmon based on information in the technical literature. Derivation of these LHFs is discussed in Appendix A, and Table 4 summarizes the final species-specific LHFs relevant to different waters of the state. As suggested by WDOE (2013), the species-specific LHFs used in this analysis were based on the amounts of time these fish spend in waters of the state from emergence to migration off-shore. For multiple reasons (see Appendix A), this approach probably overstates the accumulation of chemicals from waters of the state. For example, it assumes that accumulation occurs at a constant rate unrelated to growth or trophic level, and it ignores depuration of chemicals acquired in F/E waters.

Table 4. Life History Factors for Different Salmon Species and Different Waters Based on Residence Times in Waters of the State

	Life History Factors (LHFs)		
Species	Non-Puget Sound Waters	Puget Sound Waters Only	Statewide Composite
Chinook/King	0.15	0.40	0.30
Sockeye	0.50	0.60	0.56
Coho	NA	NA	0.19
Chum	0.13	0.28	0.22
Pink	NA	NA	0.24

A single composite salmon LHF for all waters of the state is computed by summing the species-specific (statewide composite) LHFs weighted by the relative amounts of each species consumed as given in EPA's *Exposure Factors Handbook* (USEPA 2011), Table 10-104, Adult Consumption Rate (g/kg-day) for Consumers Only. The information in the table is from an FCR survey conducted by the Suquamish Tribe. It was assumed that the relative amounts of salmon species consumed by the Suquamish tribe are representative of Washington consumers generally. The data from EPA's table are reproduced in part as Table 5 herein, which also shows generation of the final composite LHF for salmon (0.318). Salmon LHFs could be developed based on other information, as discussed in Appendix A.

Table 5. Relative Proportions of Salmon Species Consumed by the Suquamish Tribe and Derivation of Composite Life History Factor for All Salmon

	EPA Consumption Data				LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Fraction at Mean	From Table 4	Consumption Weighted
Chinook/King	63	0.200	12.600	0.294	0.30	0.088
Sockeye	59	0.169	9.971	0.232	0.56	0.130
Coho	50	0.191	9.550	0.223	0.19	0.043
Chum	42	0.242	10.164	0.237	0.22	0.053
Pink	17	0.035	0.595	0.014	0.24	0.003
Final Composite LHF						0.318

An adjustment for salmon to the general population FCR distribution also requires an estimate of the fraction of the general population's total fish diet that is comprised of salmon. Information provided by EPA (USEPA 2002) and reproduced in EPA's *Exposure Factors Handbook* as Table 10-28 (USEPA 2011) was used for this purpose. The table, reproduced herein as Table 6, lists mean consumption rates for 64 species of fish from the 1994 to 1996 and 1998 combined CSFII survey data from USDA. Based on these data the fraction of total fish consumption that is comprised of salmon is 0.094 (9.4%).

Table 6. Uncooked Fish Consumption Estimates, US Population – Mean Consumption by Species within Habitat, Individuals of Age 18 and Older

Habitat	Species	Estimated Mean (g/person/day)	Habitat	Species	Estimated Mean (g/person/day)
Estuarine			Marine		
	Shrimp	2.64686		Tuna	4.18375
	Flounder	0.69946		Salmon (marine)	1.77537
	Catfish (estuarine)	0.57463		Cod	1.65997
	Flatfish (estuarine)	0.40395		Clam (marine)	0.87021
	Crab (estuarine)	0.29953		Porgy	0.49466
	Perch (estuarine)	0.21256		Haddock	0.37374
	Herring	0.17937		Crab (marine)	0.34008
	Oyster	0.17395		Pollock	0.3321
	Croaker	0.16936		Whiting	0.30583
	Trout, mixed spp.	0.14568		Lobster	0.25919
	Salmon (estuarine)	0.08819		Scallop (marine)	0.23749
	Anchovy	0.05544		Squid	0.20948
	Rockfish	0.05162		Ocean perch	0.15663
	Mullet	0.04295		Mackerel	0.1456
	Clam (estuarine)	0.02332		Sardine	0.14375
	Smelts (estuarine)	0.00838		Swordfish	0.12595
	Eel	0.00444		Sea Bass	0.12543
	Scallop (estuarine)	0.0016		Pompano	0.11198
	Smelts, rainbow	0.00072		Mussels	0.09969
	Sturgeon (estuarine)	0.00017		Octopus	0.08819
Freshwater				Flatfish (marine)	0.07563
	Catfish (freshwater)	0.57463		Halibut	0.04224
	Trout	0.2414		Snapper	0.03624
	Perch (freshwater)	0.21256		Whitefish (marine)	0.01246
	Carp	0.18153		Smelts (marine)	0.00838
	Trout, mixed spp.	0.14568		Shark	0.00581
	Pike	0.03827		Conch	0.00284
	Whitefish (freshwater)	0.01246		Snails (marine)	0.00206
	Crayfish	0.01024		Roe	0.0014
	Snails (freshwater)	0.00206	Unknown		
	Cisco	0.0017		Fish	0.47575
	Salmon (freshwater)	0.00093		Seafood	0.00394
	Smelts, rainbow	0.00072			
	Sturgeon (freshwater)	0.00017			
All Fish		19.91037			
All Salmon		1.86449			
All Salmon as % of All Fish		9.4%			

[Source: USEPA 2002]

The portion of salmon to be added to the F/E NCI-adjusted NHANES distribution is determined by multiplying the salmon fraction in the total fish diet (.094) by the NCI-adjusted NHANES distribution for all fish and by the composite salmon LHF (0.318). The final general population FCR distribution is shown in column 5 of Table 7.

Table 7. General Population Fish Consumption Rate Distribution Adjusted for Fresh and Estuarine Species and for Salmon Life History

	(1)	(2) (1) * 0.377	(3) (1) * 0.094	(4) (3) * 0.318	(5) (2) + (4)
	NCI-Adjusted NHANES Consumption, All Fish (g/d)[a]	Fresh/ Estuarine Fish Only (g/d)[b]	Salmon Only (g/d)[c]	Fresh/Estuarine Life History Apportioned Salmon (g/d)[d]	Final General Population FCR (g/d)[e]
Mean	18.8	7.09	1.77	0.56	7.65
1%	0.9	0.34	0.08	0.03	0.37
5%	2	0.75	0.19	0.06	0.81
10%	3	1.13	0.28	0.09	1.22
25%	6.2	2.34	0.58	0.19	2.52
50%	12.7	4.79	1.19	0.38	5.17
75%	24.8	9.35	2.33	0.74	10.09
80%	28.9	10.90	2.72	0.86	11.76
85%	34.5	13.01	3.24	1.03	14.04
90%	42.5	16.02	4.00	1.27	17.29
95%	56.6	21.34	5.32	1.69	23.03
99%	90.8	34.23	8.54	2.71	36.95

[a] from Polissar et al. 2012, Table 4
[b] component of all fish that are freshwater or estuarine [all fish x 0.377]
[c] component of all fish that is salmon [all fish x 0.094]
[d] consumption of salmon associated with waters of state based on composite residence time LHF [salmon x 0.318]
[e] final general population FCR [F/E + apportioned salmon fraction]

2. Development of a Tribal Population Fish Consumption Rate

a. Use data from Washington tribal population surveys to represent fish consumption rates of the total tribal population of Washington State. Data from four tribal fish consumption surveys were used by WDOE to develop composite tribal distributions using different weighting schemes. Scheme No. 6 from *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, version 1.0 (WDOE 2011), Table C-4 (tribal-specific distributions weighted according to relative population) was chosen to represent the fish consumption rates of Washington tribal members. The data are shown in Table 8, column 1.

b. Adjust tribal population distribution to include salmon in proportion to their tribal population consumption rate and life history spent in fresh and estuarine waters. The composite tribal distribution is adjusted to exclude the time salmon spend in the off-shore marine environment. To estimate the fraction of salmon consumed by these tribes, data provided in WDOE's *Fish Consumption Rate Technical Support Document*, version 2 (WDOE 2013) were used, reproduced here as Table 9. The amount of anadromous fish as a percentage of the total fish and shellfish diet for these tribes ranges from 23% for the Suquamish Tribe to about 66% for the Squaxin Island Tribe. The Tulalip Tribe seafood diet is about 46% anadromous fish. Data for the Columbia River Inter-Tribal Fish Commission (CRITFC) tribes are not directly comparable to the other tribal data because the survey did not reflect any consumption of shellfish. Nonetheless, CRITFC tribes ate anadromous fish equivalent to about 48% of all harvested fish from all sources. If one assumes that the CRITFC tribes consume only small amounts of shellfish relative to finfish, then 48% represents an approximate maximum value for the CRITFC tribes. A simple average of these percentage values for each of the four tribes (46% anadromous fish) was used to make this adjustment.

Table 8 shows adjustments to the composite tribal FCR distribution. Briefly, the total tribal fish consumption distribution was multiplied by the fraction of salmon in the tribal fish diet (0.46) and the composite salmon LHF (0.318). This "waters of the state" adjusted salmon consumption rate was then added to the non-salmon consumption rate to generate the final tribal FCR distribution.

Table 8. Composite Distribution of Washington Tribal Fish Consumption Rates Weighted Based on Relative Population

	(1)	(2) (1) * 0.46	(3) (1) * (1 - 0.46)	(4) (2) * 0.318	(5) (3) + (4)
	All Fish (g/d)[a]	Salmon (g/d)[b]	Non-Salmon (g/d)[c]	Fresh/Estuarine Apportioned Salmon (g/d)[d]	Final Washington Tribal Population FCR (g/d)[e]
mu	4.0083				
sigma	0.7158				
Mean	71.12	32.72	38.40	10.40	48.81
1%	10.41	4.79	5.62	1.52	7.14
5%	16.96	7.80	9.16	2.48	11.64
10%	22	10.12	11.88	3.22	15.10
25%	33.97	15.63	18.34	4.97	23.31
50%	55.05	25.32	29.73	8.05	37.78
75%	89.22	41.04	48.18	13.05	61.23
80%	100.55	46.25	54.30	14.71	69.01
85%	115.6	53.18	62.42	16.91	79.33
90%	137.77	63.37	74.40	20.15	94.55
95%	178.69	82.20	96.49	26.14	122.63
99%	291.03	133.87	157.16	42.57	199.73

[a] composite tribal distribution No. 6 from WDOE 2011, Table C-4, (tribal-specific distributions weighted according to relative population); assume 100% of tribal populations are consumers and all fish are from waters of the state
[b] component of all fish that is salmon [all fish x 0.46]
[c] component of all fish that is not salmon [all fish - salmon]
[d] consumption of salmon associated with waters of state based on composite residence time LHF [salmon x 0.318]
[e] final FCR [non-salmon + salmon fraction]

Table 9. Summary of Washington Tribal Fish Consumption Survey Data (g/day)

	Fish Source	50th %tile	Mean	75th %tile	90th %tile	95th %tile	% of All Fish at Mean
Tulalip Tribe							
All fish	All sources	44.5	82.2	94.2	193	268	100.0
Finfish	All sources	22.3	44.1	49.1	110	204	53.6
Shellfish	All sources	15.4	42.6	40.1	113	141	51.8
Non-anadromous	All sources	20.1	45.9	52.4	118	151	55.8
Anadromous	All sources	16.8	38.1	43.3	92.1	191	46.4
Squaxin Island Tribe							
All fish	All sources	44.5	83.7	94.4	206	280	100.0
Finfish	All sources	31.4	65.5	82.3	150	208	78.3
Shellfish	All sources	10.3	23.1	23.9	54	83.6	27.6
Non-anadromous	All sources	15.2	28.7	32.3	70.5	95.9	34.3
Anadromous	All sources	25.3	55.1	65.8	128	171	65.8
Suquamish Tribe							
All fish	All sources	132	214	284	489	797	100
Shellfish	All sources	64.7	134	145	363	615	63
Non-anadromous	All sources	102	169	219	377	615	79
Anadromous	All sources	27.6	48.8	79.1	133	172	23
CRITFC Tribes							
All finfish	All harvested	40.5	63.2	64.8	130	194	100
Non-anadromous	All harvested	20.9	32.6	33.4	67	99.9	52
Anadromous	All harvested	19.6	30.6	31.4	63.1	94.1	48

3. Development of an Overall Fish Consumption Rate Reflecting General Population and Tribal Fish Consumption

The general population and tribal population composite FCR distributions are combined to produce a single distribution for Washington. This is accomplished by weighting the two distributions according to the sizes of their respective populations. Population statistics reported in *Fish Consumption Rate Technical Support Document*, version 2 (WDOE 2013) were used for this purpose. The data are shown in Table 10, along with tribal and non-tribal weighting factors.

The final overall FCR distribution is shown in Table 11.

Table 10. Washington State Population Statistics (WDOE 2013)

Population	Numbers	Weighting Factors
Current total	6724540	
Adults	5143186	
Fish consuming adults	3805958	
Tribal	103869	
Adults (est. as 70%; assume 100% consumers)	73523	
Fish consuming non-tribal adults	3732435	0.981
Fish consuming tribal adults	73523	0.0193

Table 11. Final Overall Fish Consumption Rate Distribution for Washington State Including Consumption of Salmon Weighted to Reflect Bioaccumulation of Chemicals in Waters of the State Only Based on Salmon Life History Factors

Statistic	Tribal Population Composite FCR (g/d)[a]	General Population Composite FCR (g/d)[b]	Final Overall Washington FCR (g/d)[c]
mu			
sigma			
Mean	48.81	7.65	8.44
1%	7.14	0.37	0.50
5%	11.64	0.81	1.02
10%	15.10	1.22	1.49
25%	23.31	2.52	2.92
50%	37.78	5.17	5.80
75%	61.23	10.09	11.08
80%	69.01	11.76	12.87
90%	94.55	17.29	18.79
95%	122.63	23.03	24.95
99%	199.73	36.95	40.09

[a] final composite tribal distribution
[b] final general population distribution
[c] final composite distribution [(tribal x 0.019)+(gen pop x 0.981)]

Summary

A fish consumption rate distribution representative of the entire population of Washington State residents was developed. National FCR data published by EPA (USEPA 2002, 2011) were used as the basis for estimating FCRs for the general population, and tribal rate data published by WDOE (2011, 2013) were used for tribal consumption rates. The general population distribution was adjusted to reflect: (1) consumption of fish and shellfish from freshwater and near-shore marine habitats only; and (2) the portion of salmon consumed reflecting contaminants acquired by salmon in waters of the state. The tribal distribution was only adjusted to account for contaminants acquired by salmon in waters of the state. The two distributions were then combined using weighting factors representing the relative populations of each group. Table 12 provides a summary of the data and rationale used in developing this overall fish consumption rate distribution for Washington residents.

Table 12. Summary of Data and Rationale Used in Developing a Fish Consumption Rate Distribution for Residents of the State of Washington

	Fish Consumption Aspect	Data Source	Rationale	Comments
1a	Starting dataset for developing Washington-tailored general population FCR distribution	NHANES data from EPA's 2011 *Exposure Factors Handbook*, Table 10-12, Consumer-Only Intake of Total Finfish and Shellfish Combined (g/kg-day), Edible Portion, Uncooked Fish Weight, adjusted using NCI methodology	Used by EPA to establish default FCR rate, used by Florida to develop Florida-tailored FCR distribution; NCI methodology adjusts for short-term recall bias and bias associated with exclusion of fish consumers who did not report fish consumption on either of two survey events	There are no Washington-specific fish consumption data representing the entire population; this dataset reflects fish consumption rates nationally, consumers only, entire population
1b	Adjustment to exclude off-shore marine fish from NCI- NHANES distribution	USDA Continuing Survey of Food Intake by Individuals (CSFII)	Used by Florida to develop Florida-tailored FCR distribution	This adjustment is applied to entire NCI-NHANES distribution; adjusts distribution to reflect consumption of fish from freshwater and estuarine (near-shore marine) habitats only, per EPA guidance
1c	Adjustment to include portion of salmon consumed to account for contaminants acquired in waters of the state	See items 1c (i), (ii), and (iii) below	NHANES and CSFII survey data classify salmon as marine species; this adjustment 'adds back' a portion of salmon consumed based on (i) LHFs for each of five major species, (ii) relative fractions of each species consumed, and (iii) estimated fraction of salmon in total fish and shellfish diet of Washington residents	Adjustment is species-weighted composite salmon LHF multiplied by fraction of salmon in total fish and shellfish diet; value is multiplied by each percentile of the NCI-NHANES total fish consumption distribution; values are then added to NCI-NHANES freshwater and estuarine only distribution

	Fish Consumption Aspect	Data Source	Rationale	Comments
1c(i)	Salmon life history factor	Technical literature on species-specific behavior and life history	Development of LHFs for five major salmon species based on estimated time salmon spend in waters of the state as a fraction of total lifetime prior to return as adults for spawning	Approach may overestimate contaminant body burden acquired in waters of the state (e.g., salmon gain more than 95% of body mass in marine environment), so is believed to be conservative approach
1c(ii)	Salmon species relative consumption fractions	Suquamish tribal data as given in EPA's 2011 *Exposure Factors Handbook*, Table 10-104.	The only Washington-specific data on salmon species consumption rates; may not be representative of total state population	Relative rates for each salmon species used to weight LHFs to develop single composite LHF for all salmon
1c(iii)	Fraction of salmon in total general population fish and shellfish diet	EPA's 2011 *Exposure Factors Handbook*, Table 10-28, mean consumption rates for 64 species of fish from the 1994 to 1996; 1998 combined USDA CSFII survey data	Assumes data are representative of fish consumption for general population of Washington State	Based on these data, salmon fraction for general population consumer is 0.094 (9.4% of total fish and shellfish consumed)
2a	Starting dataset for developing Washington-tailored tribal population FCR distribution	*Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, Ver. 1.0 (WDOE 2011), Table C-4, (tribal-specific distributions weighted according to relative population)	Represents all tribal fish consumption survey results	Individual tribal survey distributions were weighted according to relative populations of each surveyed tribe

	Fish Consumption Aspect	Data Source	Rationale	Comments
2b	Adjustment to include portion of salmon consumed to account for contaminants acquired in waters of the state	See items 1c (i), (ii) above and 2b(i) below	NHANES and CSFII survey data classify salmon as marine species; this adjustment 'adds back' a portion of salmon consumed based on (i) LHFs for each of five major species, (ii) relative fractions of each species consumed, and (iii) estimated fraction of salmon in total fish and shellfish diet of surveyed Washington tribes	Adjustment is species-weighted composite salmon LHF multiplied by fraction of salmon in total fish and shellfish diet; value is multiplied by each percentile of composite tribal total fish consumption distribution; values then added to composite tribal non-salmon consumption rate distribution
2b(i)	Fraction of salmon in total tribal fish and shellfish diet	Tribal data presented in *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, Public Review Draft, ver. 2.0, August 27, 2012	The only Washington-specific tribal data on salmon consumption rates as a fraction of total fish and shellfish consumption	Simple average of four tribal FCR surveys used to represent whole tribal population of state; value is 0.46, meaning that 46% of average tribal fish consumption consists of salmon and other anadromous fish
3	Develop population-weighted overall Washington FCR based on general population and tribal composite FCR distributions and Washington population data	General population and tribal composite FCR distributions as described in 1 and 2 above; Washington population data from *Fish Consumption Rates Technical Support Document, A Review of Data and Information About Fish Consumption in Washington*, ver. 2 (WDOE 2013)	Population-based weighting schemes provide a way to combine general population and tribal FCR data into a single distribution that represents all fish consumers	

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APPENDIX A

LIFE HISTORY FACTORS FOR PACIFIC SALMON (01-13-2014)

1.0 INTRODUCTION

One of the primary factors to consider in deciding whether to include salmon in a fish consumption rate (FCR) used in deriving Clean Water Act (CWA) human health water quality criteria is when/where salmon accumulate their ultimate body burden of the relevant chemical(s). Traditionally, EPA has recommended against including salmon in these FCRs because it was accepted that, for bioaccumulative chemicals, the majority of a chemical-specific body burden in a returning adult salmon is acquired in the Pacific Ocean (in the case of Pacific Northwest salmon), and not in the fresh and/or estuarine waters under jurisdictional control of a state. However, this assumption has been challenged as part of the ongoing process in Washington State, and various stakeholders have argued that salmon must be included in the FCR for various reasons, including the cultural importance of salmon to tribal and other residents of the state.

A review of the technical literature shows that there are sufficient (albeit limited) data to conclude that the vast majority of the body burden of bioaccumulative chemicals in adult Chinook salmon is acquired during the marine phase of that species' life history. The data were developed by various researchers who measured chemical-specific body burdens in both out-migrating juvenile fish and returning adults belonging to the same runs. In all cases where these kinds of data have been developed, the researchers have concluded that >95% of the body burdens were acquired in the marine phase of the Chinook life history (Cullon et al. 2009; O'Neill and West 2009). However, these data are specific to Chinook salmon, and because each species of salmon has a unique life history it may not be appropriate to assume that what holds for Chinook also holds for coho, sockeye, chum, or pink salmon. Thus, there is some uncertainty regarding where these other species acquire their ultimate body burdens of bioaccumulative chemicals.

In response to this uncertainty, the Washington Department of Ecology (WDOE) has proposed use of what this report will call life history factors (LHFs) as a means of apportioning total body burden in adult salmon between different phases of a salmon's life history. As proposed, these LHFs reflect the relative amount of time salmon spend in different environments or geographic locations, and would be used to apportion the ultimate body burden in returning adults between these environments or geographic locations. Subsequently, the fraction of the burden acquired in waters of the state could be used to adjust the actual consumption rate for salmon included in the FCR.

The assumption inherent in this model is that the body burden of bioaccumulative chemicals in returning adult salmon is a linear function of time. This is the basis for the site-use factors WDOE has proposed as a means of accounting for salmon consumption when developing human health benchmarks for sediment cleanups (WDOE 2012). Thus, there is precedent in Washington for this kind of apportionment, and WDOE has prepared a Technical Issue Paper (TIP) summarizing information on the life-histories of Chinook, coho, sockeye, chum, and pink salmon as part of developing this concept (WDOE 2013). However, WDOE did not identify specific numeric LHFs for each species. This paper takes this next step using WDOE's TIP as the primary information resource; other sources of information were used only in instances where there were clear gaps in the TIP.

For the purposes of this exercise, consistent with scope of the CWA, LHFs were developed for waters of the state. In this context, waters of the state include all fresh and estuarine waters, Puget Sound, and all marine waters within three miles of the Washington coastline.

Section 2 addresses development of species-specific LHFs for Pacific Northwest salmon based on residence time. Section 3 offers some discussion supporting the position that LHFs based on residence time overstate the significance of bioaccumulation during the early stages of salmon life history. LHFs based on where body mass is acquired (i.e., where salmon grow) are likely to provide a more accurate measure of where salmon acquire their ultimate cumulative body burdens of bioaccumulative chemicals, and Section 4 addresses development of these alternative mass-based LHFs.

2.0 LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

2.1 Chinook Salmon

Table A1 summarizes LHFs for stream- and ocean-type Chinook salmon and resulting composite LHFs for all Chinook.

2.1.1 *Stream-Type Chinook Salmon Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs listed in Table A1.

Page 5. "After emergence, stream-type Chinook spend a year or more in the river before migrating downstream."

Different LHFs were calculated using one and two years residence in freshwater.

Page 5. "Once entering the marine environment, stream-type Chinook spend very little time in the estuaries before migrating towards coastal waters."

In this analysis, residence in estuarine waters prior to migration to coastal waters is approximated as 15 days. This decision was informed by the residence time of ocean-type Chinook, which WDOE cites as being a few weeks (which we interpret to mean three weeks); i.e., stream-type Chinook spend <21 days in estuarine environments, and 15 days was assumed.

Page 6. "Further, juvenile salmonids do not limit their use of estuarine habitats to their natal estuaries, as juvenile salmonids have also been found to enter and utilize non-natal estuaries during their marine near shore migration."

WDOE provided no indication of how much time juvenile Chinook salmon spend in these near-shore environments, so LHFs were calculated ignoring this behavior.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

LHFs were calculated using two, three, and four years.

2.1.2 *Ocean-Type Chinook Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs listed in Table A1.

Table A1. Life History Factors for Chinook Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawing (days)	(years)	LHFs FW+Est.[c]	Marine	Notes[d]
Stream-Type	365	15	730	1110	3.0	0.342	0.658	"a year or more in the river before migrating downstream"; "spend very little time in the estuaries"; "2 to 4 years is more typical"
	730	15	730	1475	4.0	0.505	0.495	
	365	15	1095	1475	4.0	0.258	0.742	
	730	15	1095	1840	5.0	0.405	0.595	
	365	15	1460	1840	5.0	0.207	0.793	
	730	15	1460	2205	6.0	0.338	0.662	
Ocean-Type (immediate)	50	21	730	801	2.2	0.089	0.911	"migrates to ocean soon after yolk resorption"; "a few weeks in the estuary"
	50	21	1095	1166	3.2	0.061	0.939	
	50	21	1460	1531	4.2	0.046	0.954	
Ocean-Type (most common)	105	21	730	856	2.3	0.147	0.853	"migrate to marine habitats at 60 to 150 days post hatching"; "a few weeks in the estuary"
	105	21	1095	1221	3.3	0.103	0.897	
	105	21	1460	1586	4.3	0.079	0.921	
Ocean-Type (poor conditions)	365	21	730	1116	3.1	0.346	0.654	"juveniles remain in fresh water for a year"
	365	21	1095	1481	4.1	0.261	0.739	
	365	21	1460	1846	5.1	0.209	0.791	
Average Stream-Type	547.5	15	1095	1657.5	4.5	0.339	0.661	average freshwater residence assuming 3 y in marine habitat
Average Ocean-Type	105	21	1095	1221	3.3	0.103	0.897	"most common" life history assuming 3 y in marine habitat
LHFs for non-Puget Sound waters →						0.15	0.85	LHFs assuming 80% of Chinook are ocean-type fish; Puget Sound residency not incorporated (Sec 2.3)
LHFs for Puget Sound Waters only →						0.40	0.60	LHFs for Puget Sound only Chinook incorporating residency and assuming 80% are ocean-type fish (Sec 2.3)
Composite LHFs for all waters of the state →						0.30	0.70	state-wide composite LHFs incorporating residency of Puget Sound Chinook assuming 60% Puget Sound fish (Sec 2.3)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 5. WDOE (2012) describes three distinct behaviors (phases) for ocean-type Chinook fry:

1. The "immediate" phase – fish that migrate to the ocean "…soon after yolk resorption…"
2. The "most common" phase – the most common life history for ocean-type fry "…is to migrate to marine habitats at 60 to 150 days post hatching…"
3. The "poor conditions" phase – "During years of poor environmental conditions…ocean-type juveniles remaining in fresh water for a year, although this is relatively uncommon."

In this analysis, we assumed that the "immediate phase" spend 50 days in freshwater (an arbitrary number meant to include migration to the natal estuary), the "most common" phase spend 105 days (the average of the reported range) in freshwater, and the "poor conditions" phase spend 365 days in freshwater.

Page 5. "Once reaching the marine environment, they then spend a few weeks or longer rearing in the estuary."

An estuarine residence time of 21 days was used for all phases of ocean-type Chinook.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

LHFs were calculated using two, three, and four years.

2.1.3 *Discussion and Final LHF for Chinook Salmon*

As shown in Table A1, the LHFs for stream- and ocean-type Chinook differ. As a consequence, consumption of Chinook would, ideally, be broken out based on life history and the appropriate LHF applied to each type. Alternatively, if all Chinook are lumped together, composite LHFs are required. However, information on the relative fraction of the overall Chinook population that belong to each life history type are required to generate LHFs for lumped Chinook, and this information was not provided in the TIP.

According to Healey (1991), the ocean-type life history is "typical" of Pacific North American Chinook populations south of 56°N, which includes all of Washington and Oregon. More specifically, stream-type runs represent only 0 to 12% of Chinook runs in smaller rivers, and 14 to 48% of Chinook runs in larger rivers. However, Table 1 in Healey (1991) also indicates that 78% of Columbia River spawning runs and 88% of Sixes River (southern Oregon coast) runs are ocean-type. This information suggests that about 80% of Chinook salmon caught and consumed in Washington are ocean-type fishes. Thus, using the average stream- and ocean-type LHFs extracted from WDOE's TIP (Table 1), composite LHFs for Chinook salmon would be nominally 0.85 and 0.15 for marine and fresh plus estuarine waters, respectively, meaning that the LHF for waters of the state would be 0.15. However, this LHF does not account for a third life history not addressed by the TIP, which is Puget Sound residency throughout the full marine-phase of Chinook life history.

Puget Sound is known to support populations of resident Chinook and coho salmon (Chamberlin 2009; Rohde 2013). These fish spend the marine-phase of their life history in Puget Sound proper, meaning the LHF for waters of the state would be 1 for these specific fish. Based on information presented by WDOE (2013), 60% of the salmon harvested in Washington were caught in marine waters, and WDOE identified 60% of these as Puget Sound salmon. Of the 40% of salmon caught in freshwaters, WDOE estimated that 57% were harvested in Puget Sound streams. Thus, overall, approximately 60% ([0.6 x 0.6]+[0.4 x 0.57]) of the salmon harvested in Washington are estimated to originate from Puget Sound. Although not all these fish are Chinook, in this analysis we assume that this proportion applies to all salmon except pink salmon (100% of which are assumed to be Puget Sound fish); that is, we assume that 60% of the Chinook

caught and consumed in Washington are from runs originating in Puget Sound. Regardless, not all Puget Sound Chinook exhibit full residency in Puget Sound.

Although full residency is a well known phenomenon, there is very little information indicating what fraction of Puget Sound Chinook exhibit this life history. Chamberlin (2009) studied the role of multiple factors on the tendency of Puget Sound Chinook to exhibit full residency (in Puget Sound) and concluded that 30% of Puget Sound Chinook salmon display this behavior (i.e., 30% of Puget Sound Chinook have a waters of the state LHF of 1). Chamberlin's conclusion is generally consistent with that of O'Neill and West (2009), who estimated that full residency was exhibited by between 29 and 45% of Puget Sound Chinook. Here, Chamberlin's estimate is used to calculate a composite waters of the state LHF of 0.40 ([0.7 x 0.15]+[0.3 x 1]) specific to Puget Sound Chinook.

This value is notably larger than the waters of the state LHF for non-Puget Sound Chinook (0.15) but is only applicable to Puget Sound Chinook. For other Chinook (e.g., Columbia River runs), the appropriate waters of the state LHF remains 0.15. Based on the same information, a composite waters of the state LHF for all Chinook would be 0.3 ([0.4 x 0.15]+[0.6 x 0.4]). This final value is the appropriate waters of the state LHF for use when considering Chinook on a statewide basis.

2.2 Coho Salmon

Table A2 summarizes LHFs for coho salmon.

2.2.1 *Coho Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A2.

Page 7. "For populations in and around Washington State, returning adult Coho salmon are generally 3-year-olds, and spend approximately 18 months in fresh water and 18 months in marine habitats."

Page 7. "After emerging, the fry generally remain within freshwater streams for a year or two before migrating downstream."

LHFs were calculated assuming one and two year periods.

Page 8. "Emergence has been detected from March to July."

In this analysis we assume emergence in mid-April.

Page 8. "Although some fry migrate to marine waters soon after emergence, the majority disperse both up- and downstream, remaining in streams to rear as juveniles for one to two years before migrating downstream."

LHFs were calculated assuming one and two year periods.

Page 8. "Within this region, Coho smolts typically leave fresh water and migrate to marine habitats to enter the smolting process in the spring (April to June). Once entering marine waters, Coho smelts spend little time rearing in estuaries, instead migrating toward coastal waters."

Migration was assumed to begin in mid-May.

Page 8. "Although some Coho salmon move to offshore waters, typically subadults continue to feed and mature in these coastal waters of the northeast Pacific."

Page 8. "The majority of Coho originating from Washington streams migrate to coastal waters off Oregon and Washington, with low numbers occurring in Oregon and British Columbia waters."

Table A2. Life History Factors for Coho Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
547.5		547.5	1095	3.0	0.500	0.500	"18 months in fresh water and 18 months in marine habitats"
395		471	866	2.4	0.456	0.544	"1y" in FW (mid-April emergence and mid-May migration to saltwater = 13 months) followed by 1, 2, or 3 "summers" in marine water (15.5 months = 2 summers)
395		836	1231	3.4	0.321	0.679	
395		1201	1596	4.4	0.247	0.753	
760		471	1231	3.4	0.617	0.383	"2y" in FW (mid-April emergence and mid-May migration to saltwater = 25 months) followed by 1, 2, or 3 "summers" in marine water (15.5 months = 2 summers)
760		836	1596	4.4	0.476	0.524	
760		1201	1961	5.4	0.388	0.612	
					0.47	0.53	average LHFs for 3.4 year old fish excluding Puget Sound residency (Sec 3.2)
LHFs for non-Puget Sound waters →					0.50	0.50	LHFs based on 18 months in marine water, a 3 y life span, and excluding Puget Sound residency (Sec 3.2)
LHFs for Puget Sound Waters only →					0.60	0.40	LHFs for Puget Sound only coho incorporating residency (Sec 3.2)
Composite LHFs for all waters of the state →					0.56	0.44	state-wide composite LHFs incorporating residency of Puget Sound coho assuming 60% Puget Sound fish (Sec 3.2)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 9. "While some adult male Coho salmon return after spending only one summer at sea, the majority of Coho return after spending two, and sometimes three, summers at sea. There are some run timing differences between coastal and inland Washington stocks of Coho salmon, but adults begin returning to estuaries and outlets of their natal streams from July to September."

In this analysis, we assume return in September, and LHFs were calculated assuming two and three summers at sea.

2.2.2 *Discussion and Final LHF for Coho Salmon*

The timing of specific events in the life history of coho is variable at the scale of months. This level of variability is significant if it is accepted that the majority of returning adults are around three years old. This variability is reflected in the various LHFs shown in Table A2, which shows LHFs for marine residency ranging from 0.383 to 0.679 for 3.4 year old fish, depending on whether it is assumed they spent one or two years in freshwater. However, the average of these two marine LHFs is 0.53, which is essentially the same as obtained by assuming that coho split their life between fresh and estuarine waters, or near-shore waters vs. marine waters. Thus, the final LHFs for coho salmon are taken as 0.5 and 0.5 for marine and fresh plus estuarine waters, respectively, meaning that the final LHF for waters of the state would be 0.5.

However, similar to Chinook, some fraction of Puget Sound coho salmon also exhibit full residency in Puget Sound proper (e.g., Rohde 2013), and for these fish the waters of the state LHF would be 1. Following the work of Chamberlin (2009) on Chinook salmon, Rohde (2013) attempted to characterize the relative fraction of Puget Sound coho exhibiting this life history, and estimated that 3.4% are true residents, 61.3% migrate outside Puget Sound, and the behavior of the remaining 35.3% is ambiguous. Assuming 50% of the ambiguous fish are in fact residents means that approximately 21% of Puget Sound coho exhibit full residency, and the waters of the state LHF for these fish is 1. The associated composite waters of the state LHF for all Puget Sound coho is 0.6 ([0.79 x 0.5]+[0.21 x 1]). For other coho (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.5. Following the analysis for Chinook (i.e., assuming that 60% of the coho caught in Washington are from Puget Sound runs), the composite statewide waters of the state LHF for coho salmon is 0.56 ([0.4 x .5]+[0.6 x 0.6]).

2.3 Sockeye Salmon

Table A3 summarizes LHFs for sockeye salmon.

2.3.1 *Sockeye Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A3.

Page 9. "Sockeye salmon have one of the most diverse patterns of life history among Pacific Northwest salmon species. For example, age at out-migration to marine systems from their natal streams not only varies between systems, and within systems, but can vary among related individuals."

Page 10. "The hatched alevin then take an additional 24 to 60 days to emerge from the gravel as fry, with warmer temperatures reducing the time for emergence. Sockeye salmon emerge as fry generally in April or May, with some variability associated with temperature."

In this analysis we assume emergence on May 1 (approximately 42 days post-hatch, meaning hatch in mid-March).

Table A3. Life History Factors for Sockeye Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawing (days)	(years)	LHFs FW+Est.[c]	Marine	Notes[d]
Stream-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1; assume hatch mid-March, emergence by May 1 (42 days post-hatch), 1 y residence, and then out-migration (50 days); "limited" use of estuary
Stream-Type	457		1095	1552	4.3	0.294	0.706	
Stream-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
Ocean-Type	92		730	822	2.3	0.112	0.888	to marine water first year (assume hatch mid-March, emergence by May 1 (42 days), and immediate out-migration (50 days); "limited" use of estuary
Ocean-Type	92		1095	1187	3.3	0.078	0.922	
Ocean-Type	92		1460	1552	4.3	0.059	0.941	
						0.083	0.917	average of all age fish
Ocean-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1
Ocean-Type	457		1095	1552	4.3	0.294	0.706	
Ocean-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
Composite LHFs for all waters of the state →						0.19	0.81	composite LHFs assuming 50:50 split between stream- and ocean-type (92 days FW residence) (Sec 4.2)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 10. "Regarding their entry into marine waters, two types of sockeye salmon occur: the ocean-type (or sea-type) that migrates to marine waters in the first year of their life, and the stream-type that may rear in rivers and lakes for a year or more before migrating to marine habitats."

LHFs were calculated for both scenarios. In all cases, it was assumed that out-migration peaks on May 1.

Page 10. "Juvenile sockeye in Washington generally migrate from their nursery lakes to marine habitats in March and continuing through June, with peak out-migration occurring in April and May. Upon entering marine waters, estuarine use by juvenile sockeye salmon (smolts at this point) is limited, although some ocean-type sockeye may use these habitats before migrating toward coastal waters."

Here we assume peak migration occurs on May 1 for both ocean- and stream-type, and we assume this migration takes 50 days.

Page 10. "Sockeye spend 2 to 4 years at sea before returning to their natal systems to spawn."

In this analysis, LHFs were calculated using two, three, and four years.

2.3.2 *Discussion and Final LHF for Sockeye Salmon*

LHFs for stream-type and ocean-type sockeye differ only if it is assumed that ocean-type fish out-migrate immediately following emergence. If these ocean-type fish rear in freshwater for a full year after emergence, they effectively become stream-type fish with respect to their LHF. However, WDOE gives no information indicating what fraction of these ocean-type fish exhibit this life history. As a consequence, this life history for ocean-type fish is ignored.

WDOE's TIP is also mute on what fraction of sockeye salmon exhibit stream- vs. ocean-type life histories. Likewise, no information regarding what fraction of each type spends two, three, or four years at sea was provided in the TIP. As a consequence, LHFs for each life history type were calculated as the average of the LHFs for fish spending two, three, and four years at sea. Subsequently, composite LHFs were calculated assuming a 50:50 split between stream- and ocean-type fish. The resulting composite LHFs are 0.81 and 0.19 for marine and fresh plus estuarine waters, respectively, meaning that the final statewide composite waters of the state LHF is 0.19.

2.4 Chum Salmon

Table A4 summarizes LHFs for chum salmon.

2.4.1 *Chum Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A4.

Page 11. "Similar to pink salmon or ocean-type Chinook, juvenile chum migrate from their freshwater redds to marine waters almost immediately after emergence."

Page 11. "The alevins remain in the gravel another 30 to 50 days, until their yolk sac is absorbed."

Here we assume 40 days.

Table A4. Life History Factors for Chum Salmon[a]

Residence Time (days)			Age at Spawing		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
121	42	932	1095	3.0	0.149	0.851	fish migrate to ocean after minimal residence in estuarine waters
121	42	1297	1460	4.0	0.112	0.888	
					0.130	0.870	average of 3 and 4 year old fish
121	426.5	547.5	1095	3.0	0.500	0.500	fish stay in Hood Canal/Puget Sound until age 1.5 y (this time in coastal marine water assigned to "Est")
121	426.5	912.5	1460	4.0	0.375	0.625	
					0.438	0.563	average of 3 and 4 year old fish
LHFs for non-Puget Sound waters →					0.13	0.87	LHFs for non-Puget Sound chum based on average age fish (Sec 5.2)
LHFs for Puget Sound waters only →					0.28	0.72	LHFs for Puget Sound only chum using average age fish and assuming 50:50 split between two life histories (Sec 5.2)
Composite LHFs for all waters of the state →					0.22	0.78	statewide composite LHFs assuming 60% Puget Sound fish (Sec 5.2)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 11. "Most chum salmon fry spend only a few days to a few weeks rearing in fresh water before migrating toward marine habitats from March to May. A much smaller number of fry may rear in freshwater streams but migrate to marine waters by the end of their first summer."

This "much smaller number" of fry is excluded from this analysis, and the post-hatch time in freshwater prior to out-migration is assumed to be 21 days ("a few weeks"). Out-migration is assumed to peak on April 1.

Page 11. "Chum salmon utilize estuarine habitats for a few more weeks before migrating to coastal, then offshore waters."

This suggests estuarine residence is ≈21 days.

Page 12. "Most chum fry enter estuaries by June and leave them by mid to late summer."

This appears to conflict with the statement (page 11) that chum utilize estuarine habitats for a "few more weeks." Thus, this analysis assumes arrival in June and a six week (42 days) residence in estuarine waters (i.e., fish leave natal estuaries in mid-July). This means that migration time to the natal estuary is assumed to be two months (60 days).

Page 12. "The Hood Canal shoreline is said to serve as a nursery and rearing habitat for a significant portion of all chum salmon originating from Washington State rivers."

WDOE gives no information on the amount of time these fish spend in this habitat. However, the indication that a significant portion of chum salmon manifest this life history means they should be accounted for in any LHFs, and our analysis assumes that 50% of Puget Sound chum exhibit this behavior.

Page 12. "A number of age 2 chum salmon do occur within Puget Sound waters, although the absence of age 3 chum suggests that all chum salmon spend some time rearing in the Pacific Ocean."

It is not clear what age 2 means (e.g., in the second year of life, i.e., 1.01 years; over 2 years old, i.e., in the third year of life). In this analysis, it is assumed that these fish move out of Puget Sound at age 1.5 years (547.5 days old). This assumption concerning residence time is also meant to encompass Puget Sound fish that utilize Hood Canal for rearing.

Page 12. "In general, chum salmon originating from Washington streams and rivers, and rearing in the open ocean, do not return as mature adults until age 3 or 4."

LHFs were calculated assuming both three and four years.

2.4.2 *Discussion and Final LHF for Chum Salmon*

Table A4 gives LHFs for three and four year old chum assumed to migrate to marine waters after minimal residence in estuarine waters (assumed as 42 days) following 121 days in freshwater. These LHFs are relevant to chum originating outside of Puget Sound/Hood Canal. For these fish, the waters of the state LHF is estimated to be 0.13 (average of three and four year old fish).

For Puget Sound/Hood Canal chum, one important unknown is the fraction of the total population spending "additional" time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean proper, and just exactly how much time they spend in these waters prior to this final out-migration. As noted, we assume these fish migrate to the Pacific Ocean at age 1.5 years (547.5 days). This corresponds to 121 days in freshwater followed by 426.5 days in estuarine waters and Hood Canal/Puget Sound combined, and Table A4 gives LHFs for age three and four year old Puget Sound chum according to these assumptions. However, not all Puget Sound chum exhibit this life history. Because the TIP gives no information indicating what fraction of Puget Sound fish follow this life history, we have arbitrarily

assumed 50%. Thus, the final LHF for Puget Sound chum is a composite of the two life histories equally weighted. The resulting LHFs are 0.72 and 0.28 for marine and fresh plus estuarine waters, respectively, meaning that the waters of the state LHF for Puget Sound chum is 0.28 ([0.5 x 0.13]+[0.5 x 0.438]).

Composite LHFs for statewide use were calculated assuming that 60% of the chum salmon harvested in Washington are Puget Sound fishes. The resulting values are 0.78 and 0.22 for marine and fresh plus estuarine waters, respectively, meaning that the statewide composite waters of the state LHF for chum salmon is 0.22 ([0.4 x 0.13]+[0.6 x 0.28]).

2.5 Pink Salmon

Table A5 summarizes LHFs for pink salmon derived from the information provided by WDOE (2013).

2.5.1 *Pink Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A5.

Page 13. "Pink salmon only live for 2 years, with very little variability."

Page 13. "As pink salmon adults spawn near river mouths, and fry migrate downstream immediately after emergence, this salmon species spends the least amount of time in fresh water."

The fact that pink salmon spawn near the mouth of their natal river suggests that the time required for migration to estuarine waters is minimal. This analysis assumes migration takes 10 days.

Page 13. "Although some smaller coastal and Columbia River runs occur, within Washington State two of the rivers supporting the largest pink salmon runs are the Snohomish and Puyallup."

This statement is consistent with essentially all pink salmon in Washington State originating from Puget Sound.

Page 14. "Once the yolk sac is depleted, the alevins emerge as fry some 41 to 64 days (average 52 days) post hatching."

The 52 day average is used herein.

Page 14. "There is little or no fresh water rearing as pink salmon fry migrate seaward upon emergence from the gravel, and so their downstream migration also occurs in March and April."

Based on this and other statements in WDOE's TIP, migration was assumed to begin immediately following emergence.

Page 14. "Pink salmon originating from Puget Sound and Hood Canal streams and rivers appear to use near shore areas extensively for early rearing during their first few weeks of entry into marine habitats."

This suggests nominally 21 days (a "few weeks") in estuarine waters.

Page 14. "While little is known about their behavior as the fry are exiting Puget Sound proper, Hiss (1994, as cited in Hard et al 1996) found that fry occurrence in Dungeness Bay (near Sequim) peaked in April and they were gone by late May."

Assuming that peak migration manifests on April 1, the observation that fry are no longer present in Dungeness Bay by late May suggests two months (60 days) residence in near-shore waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean.

Table A5. Life History Factors for Pink Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
62	106.5	561.5	730	2	0.231	0.769	fry emerge 52 days post-hatch; estimate 10 days to migrate to estuary for a total of 62 days in FW; 3.5 months in estuary/near-shore waters prior to migration to marine waters; 2 y total life span
183		547	730	2	0.251	0.749	based on 18 months rearing in marine water and 24 month life span
LHFs for all waters of the state[e]					0.24	0.76	average LHFs

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] all pink salmon assumed to be Puget Sound fish

Page 14. "Findings suggest that most out-migrating pink salmon enter the open ocean by late summer or early fall."

This suggests residence in estuarine waters for more than two months.

Page 14. "However, like some Chinook, and Coho, a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle."

WDOE gives no information on what fraction of pink salmon exhibit this behavior.

Page 14. "Once reaching estuarine and marine habitats, pink salmon migrate towards the open ocean within the first couple of months. By September the majority of pink salmon migrate hundreds of miles out in the open sea to grow and mature."

Assuming migration from freshwater to estuarine water peaks on April 1 suggests that pink salmon spend anywhere from two to five months in estuarine (near-shore) waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean. In this analysis, we assume an average of 3.5 months (106.5 days).

Page 14. "They spend approximately eighteen months rearing in the open ocean before their eastward migration to their natal streams and rivers."

LHFs were calculated assuming 18 months in marine waters and a 24 month total life span.

2.5.2 *Discussion and Final LHF for Pink Salmon*

Table A5 gives two sets of LHFs based on the information presented by WDOE (2013). The difference between these two estimates is minimal, and the final LHFs are taken as the mean of the two. Thus, the resulting LHFs for pink salmon are 0.76 and 0.24 for marine and fresh plus estuarine waters, respectively. The final LHF for pink salmon reflecting time spent in waters of the state is 0.24.

For pink salmon that spend their marine phase in Puget Sound, the resulting LHF reflecting time in waters of the state would be 1. However, no information on what fraction of pink salmon manifest this life history was found, while WDOE (2013) noted that only a "small portion" of the overall pink salmon population exhibit Puget Sound residency. As a consequence, this full residency life history is not accounted for in the final waters of the state LHF.

2.6 Composite Residency-Based LHF for all Washington Salmon

Sections 2.1 through 2.5 address development of LHFs for individual salmon species based on residence times. However, there may be circumstances in which a single composite LHF for all Washington salmon will be required. One approach to developing such a composite LHF is to sum the species-specific LHFs after weighting each by a factor reflecting species-specific consumption rates of Washington consumers. One source of these consumption rates is EPA's Exposure Factor Handbook (USEPA 2011), which gives species-specific consumption rates for adult members (consumers only) of the Suquamish Tribe in Table 10-104. Although this tribe consumes more shellfish than other tribal data would suggest, it was assumed that the relative amounts of the different salmon species consumed are representative of Washington consumers generally, including high-end tribal consumers. The data from EPA's table is reproduced in part as Table A6 herein, which also shows generation of a single composite LHF for salmon in general (0.32) based on the species-specific LHFs.

A composite salmon LHF could be developed based on other information such as commercial landings, but such data do not necessarily reflect consumption habits of Washington residents.

Table A6. Derivation of Composite Residency-Based Life History Factor for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	N	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.300	0.088
Sockeye	59	0.169	9.971	0.233	0.560	0.130
Coho	50	0.191	9.55	0.223	0.194	0.043
Chum	42	0.242	10.164	0.237	0.222	0.053
Pink	17	0.035	0.595	0.014	0.241	0.003
			composite LHF for salmon		→	0.318

[a] consumption data for Suquamish Tribe from Table 10-104 in USEPA 2011
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 2.1 to 2.5, Tables A1 to A5

3.0 DISCUSSION OF LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

As seen in Section 2, LHFs for Washington salmon can be developed based on residence time. However, in addition to uncertainty regarding residence times of different salmon species (or specific runs) in different environments or geographic locations, the available data also manifest a high degree of variability. Thus, the resulting LHFs must be considered gross approximations. Despite this, there are factors that inform the potential for bias in the residence time LHFs presented in Section 2, and these factors suggest that, in general, residence time LHFs overstate the magnitude of bioaccumulation in early life stages of salmon life history.

One such factor is, ironically, time. This results because bioaccumulation is a reversible process, meaning that organisms are accumulating and depurating bioaccumulative chemicals simultaneously. Indeed, it is the ratio (accumulation rate/depuration rate) that underpins chemical- and organism-specific bioaccumulation factors. Once an organism moves from one environment (geographic location) to another, the probability that the specific molecules of a chemical acquired in the first environment/location will depurate increases with the time spent in the second environment/location. This probability increases when the first environment/location is more contaminated than the second, which is the exact scenario relevant to Puget Sound salmon that spend time in the Pacific Ocean proper. Apportioning body burdens based on residence time thus tend to overstate the contribution of accumulation during the early life stages to the ultimate body burden in returning adult Puget Sound salmon.

Beyond this, the assumption that an organism acquires bioaccumulative chemicals at a constant rate is analogous to assuming a fixed bioaccumulation factor. This assumption might hold for an organism that is static, that is, an organism that is not undergoing any physiological changes, feeds at a fixed trophic level, and exhibits either no growth or a constant rate of growth, but it is clearly a gross oversimplification for salmon, which exhibit extremely complex life histories. Thus, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired might be relative growth, that is, when/where salmon acquire body mass. Section 4 describes an initial attempt to develop such LHFs.

4.0 LIFE HISTORY FACTORS BASED ON GROWTH

The literature contains many statements (e.g., Quinn 2005) to the effect that salmon acquire the majority of their body mass during the marine phase of their life cycle; that is, while feeding in the ocean (or Puget Sound for true resident fish). For this analysis, the generalized summary of body mass presented by Quinn (2005) is taken as representative; these data are summarized in Table A7, which also gives nominal mass-based LHFs reflecting the relative body masses of out-migrating smolt and returning adult salmon.

Table A7. Generalized Weights of Salmon as they Enter the Ocean and as Returning Adults[a]

	Chinook	Coho	Sockeye	Chum	Pink
Smolt weight (g)	5-18	18	10	0.4	0.22
Adult weight (kg)	7.22	3.02	2.69	3.73	1.63
LHF[b]	0.00249	0.00596	0.00372	0.00011	0.00013

[a] from Quinn 2005, Table 16.3
[b] calculated as simple ration (smolt/adult)

By definition (Quinn 2005), smolts are the final stage in salmon development prior to migration to true marine waters. This means the difference in body mass between smolt and adult fish reflects growth in marine waters, and the information provided in Table A7 indicates that all five species of Pacific Northwest salmon acquire >99% of their adult body mass during the marine phase of their life history. Thus, if it is assumed that these fish spend this portion (the marine phase) of their life outside waters of the state, the mass-based LHFs given in Table A7 are the relevant waters of the state LHF. However, some salmon spend a portion of their marine life history in waters of the state. Unfortunately, as noted (Section 3), residence time cannot be used to apportion growth among different habitats or geographic locations. Thus, without higher resolution mass data (i.e., measured mass of fish at multiple ages corresponding to species-specific shifts in habitat usage), the only distinction that can be made is between those fish that exhibit nominally full residency in waters of the state (i.e., Puget Sound) during their marine phase and those that exhibit full residency in the Pacific Ocean during this phase. Adjustments to the mass-based LHF given in Table A7 reflecting this life history (full residency in Puget Sound) are discussed on a species-specific basis.

4.1 Chinook Salmon

Based on the analysis presented in Section 2.1.3, approximately 60% of the salmon, including Chinook, are caught and consumed in Washington are Puget Sound fish. Of these Puget Sound Chinook, about 30% are resident fish. Thus, 18% of all Chinook (0.6 x 0.3) are Puget Sound residents which, by definition, have an LHF equal to 1. For the remaining 82%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for Chinook salmon reflecting waters of the state is 0.182 ([0.82 x 0.00249]+[0.18 x 1]).

4.2 Coho Salmon

Following the analysis for Chinook, 60%of coho salmon are considered to be Puget Sound fish, and 21% of these are assumed to be full time residents of Puget Sound (Section 2.2.2). Thus, 13% (0.6 x 0.21) of all coho are Puget Sound residents which, by definition, have a waters of the state LHF equal to 1. For the remaining 87%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for coho reflecting waters of the state is 0.135 ([0.87 x 0.00596]+[0.13 x 1]).

4.3 Sockeye Salmon

WDOE's TIP gives no information on what fraction of Puget Sound sockeye salmon exhibit full residency in Puget Sound, so there is no basis for parsing sockeye as Puget Sound or non-Puget Sound fish. This means that the only mass-based LHF for sockeye is that given in Table A7. Thus, the single mass-based LHF for Sockeye salmon reflecting waters of the state is 0.00372.

4.4 Chum Salmon

As discussed in Section 2.4.2, some chum spend some time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean. However, as also discussed (Section 4.0), without data there is no way to identify the fraction of ultimate adult body mass chum acquire during this period. Beyond this, the TIP provides no information suggesting any chum salmon take up full residency in Puget Sound. Thus, there

is no basis for modifying the mass-based LHF for chum given in Table A7, meaning that the final mass-based LHF for chum salmon reflecting waters of the state is 0.00011.

4.5 Pink Salmon

As noted in WDOE's TIP (Section 2.5.1 herein), some pink salmon spend some time in near-shore marine waters rearing prior to completing migration to the Pacific Ocean. However, as discussed (Section 4.0), without data there is no way to identify the fraction of ultimate adult body mass these fish acquire during this period. Beyond this, the TIP states that only "a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle." Thus, there is no basis for modifying the mass-based LHF for pink salmon given in Table A7, meaning that the final mass-based LHF for pink salmon reflecting waters of the state is 0.00013.

4.6 Composite Mass-Based LHF for all Washington Salmon

Table A8 summarizes calculation of a single composite mass-based LHF for all Washington Salmon according to Section 2.6.

Table A8. Derivation of Composite Mass-Based Life History Factor for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	N	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.182	0.053
Sockeye	59	0.169	9.971	0.233	0.135	0.031
Coho	50	0.191	9.55	0.223	3.72×10^{-3}	8.28×10^{-4}
Chum	42	0.242	10.164	0.237	1.10×10^{-4}	2.61×10^{-5}
Pink	17	0.035	0.595	0.014	1.30×10^{-4}	1.80×10^{-6}
			composite mass-based LHF for salmon		→	0.086

[a] consumption data for Suquamish Tribe from Table 10-104 in USEPA 2011
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 4.1 to 4.5

5.0 REFERENCES

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From: Niemi, Cheryl (ECY)
Sent: Wednesday, November 20, 2013 11:30 AM
To: Susewind, Kelly (ECY); Gildersleeve, Melissa (ECY)
Subject: FW: Slide: Fish Consumption Alternatives for Consideration

Kelly and Melissa,

I think the summary slide below is important, and will probably be referenced by many people. I am concerned that in the process of making the alternative simpler to understand, the descriptions have picked up inaccuracies.

Below are recommendations for your consideration regarding the summary slide:

1. 225 g/day.

The description of the 225 g/day alternative in the slide below is inaccurate: 225 is not the" Mean of highest highly exposed fish consumption study and recreation fish consumption."

My recommendation is that the text be modified to improve accuracy as follows: "Representative of highly exposed populations. Encompasses the means and most 90th percentiles of tribal and recreational fish consumption surveys in Washington."

2. 175 g/day.

The description of the 175 g/day currently reads: Negotiated value used in Oregon's updated Human Health Criteria. Based on 90-95th percentile of Oregon Fish Consuming populations.*

ODEQ characterizes the 175 g/day as: *"...This rate matches the 95th percentile value from the CRITFC study..."* (ODEQ 5/24/2011). The CRITFIC study includes the Umatilla (Oregon), Nez Perce (Idaho), Yakima (Washington), and Warm Springs (Oregon) tribes.

My recommendation is that the text be modified to improve accuracy to read as follows: "Representative of highly exposed populations. Value with written endorsement by many tribes and EPA. Basis is the FCR chosen by Oregon for CWA human health criteria rule-making (2011).

Thanks,

Cheryl

Cheryl A. Niemi
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From: Conklin, Becca (ECY)
Sent: Wednesday, November 20, 2013 10:03 AM
To: Niemi, Cheryl (ECY)
Subject: Slide: Fish Consumption Alternatives for Consideration

Hi Cheryl,

Here is the table you requested. Please email any edits to Kelly and Melissa.

Thanks,
Becca

	Current	Alternative 1	Alternative 2
Fish Consumption Rate	**6.5** grams/day	**125** grams/day	**175** grams/day
Approximate conversion to standard units	¼ ounce per day	¼ pound per day	**1/3** pound per day
	½ pound per month	8 pounds per month	**12** pounds per month
	5 pounds per year	**100** pounds per year	**140** pounds per year
Basis	Mean of the per capita national data set.	Mean of the fish consumption rate surveys of 3 Puget Sound tribes	Negotiated value used in Oregon's updated Human Health Criteria. Based on 9(95th percentile of Oregon Fi Consuming populations.*

Deliberative Process Draft Document

Decision Factors in development of Human Health Criteria

Deterministic or probabilistic approach- This approach relies on choosing one value (usually average or high end) to use in the human health criteria equation.	
Advantages – can be done quickly using default values (plug and play). This is the traditional approach that has been used by most states and EPA	Disadvantages – does not use all the variability in the data sets, so the certainty of the level of protection is not as representative of the data accurate
Probabilistic approach - This approach relies on using a range of values (distribution) in the human health criteria equation and then modeling for criteria based on the population to protect and the statistic (mean, 90th percentile, etc.)	
Advantages – uses all information including variability and uncertainty, provides a complete assessment of risk	Disadvantages – more complex calculations, difficult to explain to public and will require us to change out outreach strategy... does not clearly define 1 fish consumption rate.

How salmon are treated. Current federal guidelines do not use salmon in the fish consumption rate because most do not reside for their full life in water regulated by the Clean water Act. Salmon are an iconic fish species for Washingtonians and most spend time in the state waters (regulated under CWA) and part of their life outside state waters. Human health criteria development options center around how to address this situation. Ecology is looking at scientific data to determine if there is support for using a multiplier to determine salmon percentage of toxics picked up in Washington's regulated waters.
Geographic Area The data sets and distribution of fish consumption in Washington are variable. This is especially true where marine shellfish are so prevalent in Washingtonian diets. The fish consumption studies performed for Washington might be better aligned by fish consumption patterns. Those patterns, such as consumption of shellfish, might better support a different HHC for the Puget Sound vs. non-Puget Sound areas. Fish consumption studies that represent the Puget Sound could be used to develop Puget Sound HHC while the non-Puget Sound studies could be used to develop HHC the rest of the state.
Whether to use the same population to protect assumptions for cancerous vs. noncancerous chemicals. Washington currently protects the mean of the general population at 10^{-6} cancer risk rate. We protect a mean of the general population at a hazard quotient of 1 for the noncarcinogens. Some options recommend a different level of protection for these different chemicals. EPA does not provide guidelines for the risk acceptable for noncarcinogens
Risk level for cancerous chemicals. The EPA has said that each state can decide their cancerous risk rates but are required to provide a risk

level no less protective than 10^{-4} for all high consumers. Washington currently protects for a 10^{-6} cancer risk rate for a mean of the general population. Should that rate be retained for cancer causing chemicals?
Target population. Identifies the population of consumers that the criteria are designed to protect. The current NTR protects the mean of the general population. Other options could be the mean of the highly exposed population (HEP), the 90th or 95th percentile of the HEP, the mean of the HEP, etc....
Hazard Quotient for noncarcinogens – the ratio of potential exposure to the substance and the level at which no adverse effects are expected. If the hazard quotient is equal to or less than 1 then no adverse health effects are expected.
Relative Source Contribution for noncarcinogens This is the percentage of the pollutant that comes from other sources than fish/shellfish. EPA has just written guidance on what they think states should use for this part of the equation. Currently, the National Toxics rule uses a value of 1. The new EPA guidance articulates a lower range to be used for development of new criteria. EPA itself has only used a value different than 1 for 17 of the national recommended criteria.

All other parts of the equation remain constant for the following parts of the human health equation:

Body weight	70 kg
Duration of exposure	70 years
Drinking water intake	2 L/day

Pre-decisional document

ncasi

NATIONAL COUNCIL FOR AIR AND STREAM IMPROVEMENT, INC.
West Coast Regional Center
***Mailing address*: PO Box 458, Corvallis OR 97339**
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Steve Stratton
Regional Manager
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January 11, 2012

Washington State Department of Ecology
PO Box 47600
Olympia, Washington 98504-7600

RE: Comments on Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*

The National Council for Air and Stream Improvement, Inc. (NCASI) is an independent, nonprofit membership organization that provides technical support to the forest products industry on a wide range of environmental issues. An important part of our mission is to ensure that regulatory decision making is based on sound science. In this capacity, NCASI reviewed the September 2011 document titled: *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington* (Publication No. 11-09-050), and offers the attached comments.

Overall, NCASI finds that Ecology has not made a compelling case for increasing statewide default fish consumption rates (FCRs). Ecology should clearly explain the level of protection afforded by existing environmental standards for protection of human health, and the incremental benefit to public health that would result from making these standards up to 41 times more stringent. We also have serious concerns that the fish consumption data used to develop the proposal are not representative of the general population, and that these data have been interpreted in an arbitrary manner that leads to an extreme conclusion.

Sincerely,

Jeffrey Louch, PhD.
Senior Scientist, NCASI

Steve Stratton
West Coast Regional Manager, NCASI

ec: Christian McCabe, Northwest Pulp & Paper Association
Paul Wiegand, NCASI

NCASI COMMENTS ON WASHINGTON'S PROPOSAL TO REVISE STATEWIDE DEFAULT FISH CONSUMPTION RATES

In September 2011 Washington State Department of Ecology (Ecology) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) summarizes available fish consumption studies and proposes that the state adopt default fish consumption rates (FCR) of between 157 and 267 grams per day (g/day). One or more default rates would be used to establish regulatory requirements under the following programs:

- Sediment Management Standards (SMS) rule, which establishes standards for cleanup of contaminated sediments in fresh and marine waters; this rule is currently being revised and a default FCR will be part of the revisions
- Model Toxics Control Act (MTCA), which regulates cleanup of contaminated soils and sediments
- Clean Water Act water quality standards (WQS) established by states and tribes to limit the effects of contaminants ingested with fish and water on human health.

Current default FCRs are 6.5 g/day for WQS and 54 g/day for MTCA cleanup standards. Thus, Ecology is proposing to make human health WQS more stringent by a factor of between 24 and 41, and to make MTCA cleanup standards more stringent by a factor of between 2.9 and 4.9. Ecology is currently working to revise the SMS rule and anticipates establishing a default FCR for sediment cleanups. Ecology also intends to update Washington's WQS and has stated that the information contained in the TSD and the SMS rule revision "will likely strongly influence the rates included in future human health-based water quality criteria."

Ecology has requested comments on the TSD and the proposed range of default FCRs. NCASI offers the following general comments and answers to questions posed in the TSD.

General Comments

1. <u>Any decision to change the current default FCRs should be justified in terms of overall benefit to public health</u>. The underlying premise of the report is that use of the current default FCRs result in water quality or sediment management standards that are not sufficiently protective. However, the TSD provides no perspective on the degree to which public health is protected under the existing FCRs. More importantly, the TSD provides no basis for gauging the overall benefit to public health that might result from changing these FCRs. Ecology should present a coherent assessment of health risks to the general population of the state represented by the current default FCRs and contrast them with the health risks that would result if the default FCRs were increased as recommended in the TSD. This assessment is imperative as there is currently no viable comparator for the costs that would be borne by both Ecology and the regulated community in responding to lowered sediment and water quality criteria as a result of increased FCRs. Without knowledge of what the benefit might be, it is impossible to determine if these costs would be justified.

Understanding what benefit to public health might result from increasing the FCRs is critically important in this context because the current risk assessment paradigm already results in highly protective environmental standards as a result of multiple conservative assumptions. For example, the calculation of risks resulting from consuming contaminants in fish generally assumes that fish are consumed at the default rate for 70 years, that all fish consumed are contaminated to the same degree (which is functionally equivalent to assuming all fish are from the same body of water), and that there are no losses of contaminants during preparation. Beyond this, the maximum dose of a chemical considered to be safe is always adjusted downward from the level indicated by the toxicological data. In the case of non-cancer endpoints, the product of the multiple safety factors (termed uncertainty or modifying factors) used to develop a reference dose (RfD) can approach well over 1000, meaning that the dose used in a risk assessment could be 1000 times lower than the dose directly indicated by the toxicological data. For carcinogens, this safety factor is typically 10, and the acceptable risk level is typically set at one hypothetical additional cancer case per million lifetimes. This is an exceedingly small incremental risk in light of a current lifetime cancer incident rate due to all causes of about 40% (400,000 in one million)[1]. Finally, the paradigm completely discounts any health benefits attributable to consuming fish.

All this supports the current water and sediment quality standards as being highly protective of the residents of Washington, and any proposal to revise these standards should be based on an analysis of the public health benefit to be gained.

2. <u>The proposed range of default FCRs overstates the fish consumption rates for the vast majority of residents of the state.</u> The proposed range is based on high-end statistical consumption rates (e.g., 80th to 95th percentile values) developed from five fish consumption rate studies of known high fish consuming subpopulations. Four of the studies are of tribal groups and the fifth is a study of the King County Asian and Pacific Islander (API) subpopulation. Notwithstanding the methodological concerns we have about Ecology's interpretation of some of these studies (see general comment no. 3), the FCRs recommended in the TSD have the effect of establishing protections for the general population of Washington residents using consumption rates derived from a total surveyed population of 996 individuals reflecting the behaviors of an estimated 0.2-0.9% of the total population of the state.

   Studies that apply to general populations suggest that fish consumption rates are considerably lower than Ecology's proposed range. For example, EPA[2] indicates that for US adults, the 90th and 95th percentile consumption rates of freshwater and estuarine finfish and shellfish are 17.4 and 49.6 g/day, respectively. These values suggest that Ecology's proposed FCR range is not representative of fish consumption rates for the general population statewide.

3. <u>Ecology's analysis of the data from the fish consumption studies used to develop the proposed FCRs is significantly flawed.</u> First, the API study is dominated by first-generation residents (89% of respondents), who are known to consume more fish than later generations.

[1] See, for example, the American Chemical Society at http://www.cancer.org/Cancer/CancerBasics/lifetime-probability-of-developing-or-dying-from-cancer

[2] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

This known bias in the results casts considerable doubt on the representativeness of the results to describe the fish consumption rates of the broader API population.

Another significant issue with the API study is that the consumption rates used in the TSD to generate a proposed range of FCRs for adoption are not corrected for cooking losses, non-local harvest, or API population demographics. EPA Region 10 reanalyzed these data[3], adjusted for these biases, and determined the reasonable maximum exposure (RME, the 95th percentile value) to be 51.1 g/day not including anadromous fish, or 57 g/d including anadromous fish (see table on pg. 61 of TSD). Contrast this with the unadjusted data in the TSD, where the 95th percentile value is shown as 306 g/day (e.g., Table A-1 in TSD). It is unclear why Ecology believes that consumption data biased high by inclusion of non-locally harvested fish should be the basis of its FCR proposal when more scientifically defensible estimates are available. To be clear, any default FCRs should reflect consumption of locally harvested fish only.

It appears that the data from the Tulalip and Suquamish Island tribes also need to be adjusted to remove non-locally harvested fish, as EPA Region 10 did in developing its guidance for site-specific cleanup levels[4]. In addition, Pacific salmon comprised a significant fraction of the fish diet for all the Native American fish consumption studies. For reasons discussed in Appendix A, inclusion of salmon in a statewide default FCR is clearly not appropriate.

Because the actual data from most of the fish consumption surveys are not publically available, Ecology used descriptive statistics to develop composite log-normal distributions based on seven different weighting schemes. (As noted above, these datasets should be adjusted (per EPA Region 10 guidance) to eliminate fish that are not locally harvested before developing composite distributions). Ecology ultimately chose to use a scheme in which each of the five surveys was given equal weight to develop a composite distribution from which the proposed range (80th to 95th percentiles) of FCRs was developed. Given that these data represent only known high fish consuming subpopulations, the use of statistics that characterize the upper extremes (e.g., 80th to 95th percentile values) of a composite distribution that intentionally excludes the vast majority of fish consumers and, more importantly, the vast majority of the general population, would be inappropriate for establishing default FCRs for statewide application. Beyond this, assigning equal weights to each of the five surveys is arbitrary, giving a proposed FCR that is driven by survey results from as few as 50 people (95th percentile of 996 surveyed adults). It would be more defensible to weigh each of these studies according to the estimated total adult populations represented by the underlying data (e.g., per weighing scheme #2 in Appendix C of the TSD), and this process should include the total population of Washington State (with consumption rates taken from EPA[5,6] or other appropriate studies).

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[3] Kissinger, L. 2005. *Application of data from an Asian and Pacific Islander (API) seafood consumption study to derive fish and shellfish consumption rates for risk assessment*.

[4] USEPA. 2007. *Framework for selecting and using tribal fish and shellfish consumption rates for risk-based decision making at CERCLA and RCRA cleanup sites in Puget Sound and the Strait of Georgia*.

[5] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

[6] USEPA. 2011. *Exposure Factors Handbook: 2011 Edition*.

In addition to these general comments, responses to specific questions posed by Ecology in the TSD are provided below. Note that some of these responses draw on information presented in Appendix A, which provides a brief review of what is known about the accumulation of persistent, bioaccumulative, and toxic (PBT) chemicals by salmon.

Responses to Questions Posed by Ecology in the TSD

1. How should default rates take into account the consumption of fish species like salmon that spend much of their life outside of Washington waters?

The consumption of salmon should be excluded from any statewide default FCR. This conclusion is based on review of the scientific literature (Appendix A), which indicates that different species of salmon and different runs of the same species of salmon will accumulate PBT chemicals to differing degrees. In addition, the literature supports the contention that the major fraction of any PBT burden carried by returning adult salmon (i.e., salmon that will be harvested and consumed) is acquired in the open ocean. The fact that resident Puget Sound salmon generally exhibit higher burdens than true open ocean salmon is not inconsistent with this, and simply points out that Puget Sound is a unique habitat (i.e., Puget Sound is not the open ocean).

Because of this, it might be appropriate to assess risk to select Puget Sound residents as a separate activity, and inclusion of salmon in an FCR used in such a risk assessment may well be warranted. However, given that Chinook, Coho, sockeye, pink, and chum salmon are predicted to accumulate different body burdens of PBT chemicals even when they share a common migration corridor, salmon consumption should be apportioned between species, and not simply lumped together as "salmon." In addition, only salmon harvested directly from Puget Sound should be included in an FCR used for this purpose: ideally, only truly resident salmon (i.e., "blackmouth" salmon) would be included.

2. How should the complex life cycle and biology of the different salmon species be considered when making regulatory decisions?

As noted above, the complexities of salmon biology and/or ecology require that:

- salmon be excluded from any default FCR,
- a site-specific FCR include only "resident" salmon, and only when there are data showing that these salmon are impacted by local sources of chemical contaminants,
- whenever salmon are included in a site-specific FCR, consumption must be broken out on a species-specific basis, and the associated risk assessment must use species-specific chemical concentrations and, when necessary, bioaccumulation factors (BAFs).

3. What is the status of resources pertaining to the harvest of fish and shellfish in Washington?

This question seems irrelevant to the issue at hand.

4. How many people in Washington consume fish? How many people in Washington can be considered high-end fish consumers?

NCASI suggests that assigning individuals to a "consumer" or "non-consumer" category is a false dichotomy, and that it would be more correct to consider fish consumption on a continuum having, essentially, no non-consumers (there are likely to be very few individuals that consume no fish over the course of a lifetime). Thus, according to the TSD, there are 5,143,186 adult consumers of fish in Washington State currently. Beyond this, any categorization of what constitutes "high-end" consumption is unavoidably arbitrary in the sense that it will always be a matter of subjective opinion. This is, and will remain true regardless of statistical categorizations or the overall accuracy or completeness of associated fish consumption data.

5. What are scientifically defensible methods for characterizing fish consumption rates?

A variety of survey methods have been used to generate fish consumption data, as the TSD discusses; each method has both strengths and weaknesses. Regardless, the more important issue is whether the method used accurately captures the consumption habits of the targeted population which, for purposes of establishing default statewide FCRs, should be the population of the entire State of Washington.

Clearly, Ecology has a large body of data characterizing the fish consumption habits of four Puget Sound tribal communities, certain Columbia Basin tribes and the API population residing in King County. Ecology apparently does not have data sufficient to characterize fish consumption by the general population of Washington State to anywhere near the same level of confidence as it has for these very specific subpopulations. This is a critical information gap that must be filled in order to fully understand the risks to public health resulting from the consumption of fish.

6. What is currently known about the fish consumption habits and rates for different fish-consuming populations in Washington?

What is known are the consumption patterns of a few Native American tribes and the API population residing in King County. As a whole, the sampled population represents approximately 311,300 adults (from Table C-2 in the TSD). This number is equivalent to approximately 11% of the adult consumers of purchased fresh fish (as estimated by Washington's Department of Health, Table 5 in the TSD), approximately 8% of the adult consumers of store-bought fish, and approximately 6% of the general adult population. The TSD provides no details relevant to the consumption habits of the remaining population besides that taken from DOH (e.g., 74% of the general adult population consumes store-bought fish).

7. Would establishing a statewide default fish consumption rate (or rates) be a useful step toward consistency among regulatory programs (for example, MTCA cleanups and water quality-based permitting)?

NCASI notes that statewide default fish consumption rates are already in place for the development of water quality standards (6.5 g/d) and for MTCA cleanups (54 g/d), and Ecology has stated that it intends to adopt a default FCR for sediment management standards (SMS). Thus, any questions regarding the utility of intra-program default FCRs appear to be moot, and

the real question is whether there is a benefit to be had from adopting a single default FCR applicable to all programs. NCASI suggests that the answer to that question is no.

Given the distinctly different scopes and missions of Ecology's different programs (e.g., the MCTA program focuses on cleanup of geographically limited sites posing risk to very specific populations and known to be contaminated with specific chemicals, while the Clean Water Act applies to the whole state regardless of any known source of contamination by any single chemical), it is hard to image that adopting a single default FCR for all programs would actually provide any benefit beyond conceptual simplicity. The validity of this conclusion is best illustrated by the range of FCRs exhibited across different subpopulations and the degree to which these FCRs clearly reflect geographic location. With this last point in mind, the only defensible statewide default FCR for any regulatory program is an FCR reflecting mean consumption by the statewide general population. In situations where subpopulations are believed to be subject to significantly greater risks than the general population (e.g., a subpopulation taking fish from near a MCTA site), an appropriate, risk-based response would be to conduct a population- or site-specific risk assessment[7] to determine if actual risk (in this case due to a greater than average FCR) for that subpopulation exceeds target values considering all aspects of exposure including, in this case, the health benefits of eating fish[8].

8. What is an appropriate statewide default fish consumption rate (or rates) given available data, uncertainties and variability in fish consumption habits, and current statutes, regulations, and policies?

As noted, the only defensible statewide default FCR is one that reflects consumption by the general population as a whole (i.e., without attempting to discriminate "consumers" from "non-consumers").

Consistent with this, if Ecology is driven to adopt a single default FCR for use statewide and has no data characterizing fish consumption by the general population of Washington State, it should draw from EPA's data for the general US population[6]. Based on these data, EPA[9] has concluded that the mean consumption rate of freshwater and estuarine finfish and shellfish by adults (18 and older) is 7.50 g/day. The associated 90th and 95th percentile consumption rates are 17.4 and 49.6 g/d, respectively. Although these FCRs are almost certainly high-biased (i.e., conservative) estimates for the general US population, they provide a much better measure of fish consumption by the general population of Washington State than the range of FCRs proposed by Ecology, which clearly reflects high-end consumers exclusively, and so are preferable for use as default values meant to apply statewide. Using the flexibility afforded under different regulatory programs (MTCA, etc.), adjustments to a "general population" default FCR can then be made using site-specific information, meaning that Ecology can decide to make site-specific standards more protective when circumstances clearly warrant.

[7] USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).*
[8] Washington Department of Health. 2006. *Human Health Evaluation of Contaminants in Puget Sound Fish.*
[9] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

APPENDIX A

A BRIEF REVIEW OF ISSUES RELEVANT TO THE ACCUMULATION OF PERSISTANT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS BY SALMON

INTRODUCTION

In September 2011 Washington State Department of Ecology (WDOE) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) was generated to support decision making regarding how to obtain an appropriate fish consumption rate (FCR) for use in calculating water quality standards for protecting human health (HHWQS). One of the issues WDOE raised in this TSD was whether consumption of salmon should be included in whatever FCR is ultimately used in these calculations, and if it is concluded that salmon should be included in an FCR, how to do so.

The driver behind this is human exposure to toxic chemicals, specifically via consumption of fish (or aquatic tissue in general). The greatest risk to human health from consumption of fish is generally understood to result from the presence of persistent, bioaccumulative, and toxic (PBT) chemicals. Thus the primary factor in determining the appropriateness of including consumption of salmon in an FCR is where salmon actually pick up these contaminants. A brief review of what is known about this subject is presented herein.

WHERE SALMON ACCUMULATE PBT CHEMICALS

As discussed by NOAA (2005), different runs of salmon exhibit different life histories. More specifically, NOAA described stream-type and ocean-type life histories. Behavioral attributes of these two general types of salmon are summarized in Table 1.

Table 1. A Summary of the Juvenile Characteristics of Stream and Ocean Life History Types

Stream-Type Fish	Ocean-Type Fish
Species	
Coho salmon	Coho salmon
Some Chinook populations	Some Chinook populations
Steelhead	Chum
Sockeye	Pink
Attributes	
Long period of freshwater rearing (>1 yr)	Short period of freshwater rearing
Shorter ocean residence	Longer ocean residence
Short period of estuarine residence	Longer period of estuarine residence
Larger size at time of estuarine entry	Smaller size at time of estuarine entry
Mostly use deeper, main channel estuarine habitats	Mostly use shallow water estuarine habitats, especially vegetated ones

[SOURCE: NOAA 2005]

From Table 1, different species of salmon and different runs of the same species can exhibit distinctly different life histories, including how much time is spent in freshwater and where in

freshwater systems this time is spent. These differences are potentially significant in that they may lead to differences in the mass (burden) of chemical contaminants (e.g., PBT chemicals) ultimately accumulated by the salmon, and in the fraction of this ultimate burden accumulated in freshwater vs. saltwater. Although the latter may not be relevant when assessing the risk to human health resulting from eating contaminated fish in general, it is relevant when considering what fraction of this overall risk results from accumulation of contaminants in freshwater systems vs. saltwater systems.

This last point is directly relevant to the question of whether there is any utility in including consumption of salmon in an FCR that will be used to drive remedial action(s) on the geographically limited scale of a single state. If a significant fraction of the contaminant burden found in salmon is accumulated in true freshwater systems it makes sense that the consumption of salmon be included in an FCR. However, if accumulation in the open ocean dominates, inclusion of salmon in an FCR makes no sense because there is no action the state can take that will have a significant effect on the contaminant burden found in returning adult salmon.

Exclusion of salmon from an FCR does not imply that human exposure to contaminants due to consumption of salmon should not be accounted for when assessing overall risks to human health. Instead, these issues should be weighed when deciding whether salmon are accounted for when assessing the risks resulting from consumption of freshwater fish (by including consumption of salmon in an FCR) or when assessing the risks resulting from consumption of saltwater or marine fish (salmon would be backed out of the risk assessment for deriving a freshwater HHWQS via the relative source contribution or RSC). Ultimately, the issue of where the risks from consumption of salmon are counted appears to be an academic question. The more important factor (from the perspective of characterizing risk) is to ensure that consumption of salmon is not double counted by including it in both an FCR **and** as a component of the RSC.

In any case, the issue of salmon (or anadromous fish in general) is unique in that it is quite likely that a generic salmon will accumulate contaminants in both freshwater and saltwater habitats, and that the relative fraction accumulated in one habitat vs. the other will vary with species, run, and even individual. Taken to the extreme, this implies that each run needs to be evaluated independently to determine where contaminants are accumulated. However, much of the scientific literature supports accumulation in the open ocean as the dominant pathway for uptake of PBT chemicals by salmon, with the work of O'Neill, West, and Hoeman (1998), West and O'Neill (2007), and O'Neill and West (2009) providing perhaps the most through examination of the issue.

Figure 1 is taken from O'Neill and West (2009) and shows that levels of polychlorinated biphenyls (PCBs) in adult Chinook salmon (fillets) collected from a wide range of geographic locations are relatively uniform except for fish taken from Puget Sound, which show three to five times higher levels of PCBs than fish taken from other locations. As discussed by the authors, these data can be interpreted as indicating accumulation of PCBs in Puget Sound and/or along the migratory routes of these fish, which, depending on the specific runs, can pass through some highly contaminated Superfund sites (e.g., Duwamish Waterway). However, O'Neill and West (2009) concluded that, on average, >96% of the total body burden (mass) of PCBs in these Puget Sound Chinook was accumulated in the Sound and not in natal river(s).

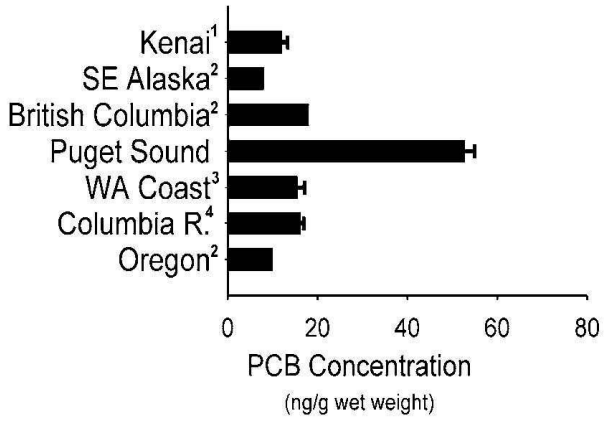

Figure 1. Average (±SE) PCB Concentration in Chinook Salmon Fillets
Data for Puget Sound were based on 204 samples collected by the Washington Department of Fish and Wildlife from 1992 to 1996; data for other locations were taken from the following (indicated by superscript numbers): [1]Rice and Moles (2006), [2]Hites et al. (2004; estimated from publication), [3]Missildine et al. (2005), and [4]United States Environmental Protection Agency (USEPA 2002)
[SOURCE: O'Neill and West 2009]

The basis for this conclusion is presented in Table 2, which compares PCB concentrations and body burdens in out migrating Chinook smolts collected from the Duwamish River and adults returning to the Duwamish.

TABLE 2.—Concentration of PCBs (ng/g) and body burden of PCBs (total ng/fish) in out-migrating Chinook salmon smolts and returning adults from the contaminated Duwamish River, Washington.

Variable	Smolts	Adults
Number of samples	80	34
Mean fish weight (g)	10	6,000
Whole body PCB concentration (ng/g)[a]		
Mean	170	57
95th percentile	860	88
PCB body burden (ng/fish)[a]		
Mean	2,100	350,000
95th percentile	9,200	800,000
Mean % of PCB body burden from the most contaminated smolts[b]	—	3.8

[a] Values for smolts are from J. P. Meador (National Oceanic and Atmospheric Administration Fisheries, Northwest Fisheries Science Center, personal communication); values for adults were estimated from measured muscle tissue concentration using the fillet–whole-body regression (see Methods) for PCBs.
[b] Contaminant data were only available for out-migrating subyearling smolts, so only samples with adults that went to sea as subyearlings were included in the analysis.

[SOURCE: O'Neill and West 2009]

These data show that even the most contaminated out migrating smolts contained no more than 4% of the body burden (mass) of PCBs found in returning adults. Thus, >96% of the PCB mass (burden) found in the returning adults was accumulated in Puget Sound. Even allowing for an order of magnitude underestimate in the body burden of out migrating smolts, O'Neill and West (2009) concluded that accumulation in freshwater would account for <10% of the average PCB burden ultimately found in adults returning to the Duwamish. By extension, this analysis supports the conclusion that Chinook salmon passing through uncontaminated estuaries during out migration accumulate a dominant fraction of their ultimate PCB body burdens in the open ocean. Other researchers have also reached this conclusion using their own data (e.g., Johnson et al. 2007; Cullon et al. 2009).

However, this analysis does not explain why Chinook salmon collected in Puget Sound exhibit higher concentrations of PCBs than Chinook salmon collected from other locations (Figure 1). Ultimately, O'Neill and West (2009) attributed this to a combination of factors, specifically PCB contamination of the Puget Sound food web (e.g., West, O'Neill, and Ylitalo 2008) combined with a high percentage of Chinook displaying resident behavior. That is, a large fraction of out migrating Chinook smolts take up permanent residence in the Sound, where they feed from a more contaminated food web than found in the open ocean. These factors would not affect Chinook runs or runs of any other species associated with natal rivers that discharge to saltwater outside Puget Sound.

Overall, these data support the position that, as a general rule, the predominant fraction of the ultimate PCB burden found in harvested adult fish is accumulated while in the ocean-phase of their life cycle (e.g., Cullon et al. 2009; Johnson et al. 2007; O'Neill and West 2009). Although this conclusion is specific to PCBs, there is no reason to suppose that it would not also hold for other legacy PBTs (e.g., DDT, dioxins) or globally ubiquitous PBTs (e.g., PBDEs, methylmercury) in general (e.g., Cullon et al. 2009). Because concerns about human consumption of fish are driven by risks from exposure to PBTs, driving the FCR higher by including salmon would thus appear to be of limited utility from the perspective of protecting human health simply because these contaminants are accumulated in the ocean.

With that said, there are sufficient data to conclude that the food web in Puget Sound is contaminated with PCBs to a greater degree than the food web in the open ocean. To the extent that this is a result of true local sources (e.g., sediment hotspots), there may in fact be some "local" action that can be taken to reduce PCBs, or potentially other PBTs, in Puget Sound salmon. However, this is totally dependent on identification of localized sources amenable to remediation, and not simply a conclusion that the food web is contaminated (e.g., West and O'Neill 2007).

Again, simply increasing the FCR by including salmon will have essentially no positive effect on human health given that the dominant fraction of PBT body burdens in salmon appears to be accumulated in the open ocean, and not in waters immediately subject to in-state loadings.

PBT ACCUMULATION BY DIFFERENT SALMON SPECIES

As discussed, there is ample evidence that the body burdens of PBTs found in returning adult Chinook salmon depend to a significant extent on the life history of the specific run. Beyond this, there are interspecies differences in migratory and feeding behavior that suggest Coho, sockeye, pink, and chum salmon will not accumulate PBTs to the same extent as Chinook

salmon under similar exposure scenarios (Groot and Margolis 1991; Higgs et al. 1995). Perhaps the most significant factor differentiating Chinook from the other salmon species is that Chinook tend to eat more fish (Higgs et al. 1995). Thus they effectively feed at a higher trophic level than the other species of salmon, and would be expected to accumulate greater burdens of PBT chemicals even when sharing the same habitat. This is in fact observable. For example, when looking at adult Chinook and Coho returning to the same rivers, O'Neill, West, and Hoeman (1998) found that Chinook muscle contained, on average, almost twice the total PCB concentrations found in Coho muscle. This was also true for adults collected in Puget Sound proper (O'Neill, West, and Hoeman 1998).

Differences between species can also manifest in sub-adults. For example, Johnson et al. (2007) reported ΣPCB concentrations in juvenile wild Coho collected from five different estuaries ranging from 5.9 to 27 ng/g (wet weight; whole body minus stomach contents). The corresponding range for wild Chinook juveniles collected from the same estuaries was 11 to 46 ng/g (wet weight; whole body minus stomach contents). Overall, PCB concentrations in juvenile Coho were, on average, equivalent to nominally 50% of those found in the paired Chinook juveniles. This is essentially the same ratio observed by O'Neill, West, and Hoeman (1998) in adult fish.

All this indicates that PBT residues in salmon will vary within species depending on the specific run, and between species regardless (i.e., even when different species share the same general habitat). Thus, grouping all salmon together does not provide an accurate assessment of PBT doses delivered to human consumers due to consumption of salmon. This suggests that human health risk assessments should, as a general rule, incorporate salmon on a species-specific basis, if not a run-specific basis.

Certainly, none of this is supportive of adopting a single default value for the dose of any contaminant received by humans via consumption of salmon. Thus adoption of a single default FCR for salmon is also not supported.

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ncasi

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March 4, 2015

D R A F T

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RE: Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal dated January 12, 2015

The National Council for Air and Stream Improvement, Inc. (NCASI) is an independent, nonprofit membership organization that provides technical support to the forest products industry on a wide range of environmental issues. An important part of our mission is to help ensure that regulatory decision making is based on sound science. In this capacity, NCASI reviewed the January 2015 Proposed Human Health Criteria and Implementation Tools Rule Proposal, and offers the following comments.

After review of Ecology's proposal, we find that while the decision to select a fish consumption rate (FCR) is a policy choice, the value selected (175 g/day) grossly overstates consumption by the general population as well as the vast majority of Washington tribal members. NCASI's analysis of publically available tribal fish consumption summary data indicates that Ecology's claim that 175 g/day is "*representative of average FCRs*" for highly exposed populations is incorrect as it pertains to tribal populations specifically. Rather, as discussed below, it represents approximately the 95th percentile of tribal fish consumption based on Washington-specific tribal studies. Thus, Ecology is proposing criteria based on the consumption patterns of a few of the highest consuming individuals in the state. Coupled with Ecology's selected values for other risk management factors (1×10^{-5} excess lifetime cancer risk for carcinogens and a hazard quotient equal to 1.0 for non-carcinogens) that are intended to apply to general populations (per EPA guidance), an FCR of 175 g/day yields water quality criteria that are protective in the extreme. Consequently, we believe that Ecology needs to provide technical justification for its FCR selection.

The attached analysis performed by NCASI using data provided by Ecology (Table 1 in Attachment A) shows that the mean consumption rate based on Washington tribal studies is approximately 71 g/day and that 175 g/day is approximately equivalent to the 95th percentile tribal consumption rate. These rates are based on tribal data only and include consumption of all fish, including salmon. Thus, if Ecology intended to select an FCR reflecting "average"

consumption of all fish (including salmon and store-bought fish) by tribal populations, 71 g/day would be the appropriate statistic.

However, as NCASI has noted previously, we believe it is not appropriate to include all salmon in the FCR because the vast majority of the contaminants found in these fish are accumulated in marine waters outside of state jurisdiction. NCASI has developed an alternative tribal FCR distribution including salmon at a rate nominally reflecting accumulation of pollutants by salmon in waters of the state only (Table 1 in Attachment A). The resulting distribution has a mean of approximately 49 g/day. As discussed in the attachment (Sections 3 and 4), we believe that this value still overstates human exposure to accumulation of contaminants sourced within Washington State, but believe it is at least scientifically defensible. It is also worth noting that 49 g/day is very conservative compared to EPA's default recommendation for the general population of 17.5 g/day, which is a 90th percentile statistic.

NCASI also notes that Ecology's use of deterministic calculations using such extreme (conservative) values for the FCR and other exposure factors yields water quality criteria whose actual level of protection greatly exceeds that needed to adequately protect all residents of the state. Use of probabilistic risk assessment (PRA) using data representing the entire population avoids this problem, which is known as compounded conservatism. Compounded conservatism results when single point estimates for fish consumption, drinking water consumption, and other risk management and exposure factors, each of which represents a conservative selection, are multiplied together to calculate water quality criteria. The resulting criteria can be so stringent that they protect against human exposure scenarios that would never occur. In contrast, PRA uses data distributions that represent the exposure behaviors of all residents. Given that the computational tools needed to perform a PRA analysis are readily available and easy to use, and that data for fish consumption rates and other human exposure factors representing all Washington residents have already been compiled, Ecology should use a probabilistic approach to develop its water quality criteria. Attachment B is a peer-reviewed article approved for publication in *Integrated Environmental Assessment and Management* that expounds on the problem of compounded conservatism.

Finally, despite the concerns outlined herein, we would like to express our appreciation to Ecology for its sustained efforts to carry out this rule making in a thorough and transparent manner.

Sincerely,

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ATTACHMENT A

DEVELOPMENT OF A FISH CONSUMPTION RATE DISTRIBUTION FOR WASHINGTON'S GENERAL TRIBAL POPULATION

Washington State Department of Ecology (WDOE) has presented results from surveys characterizing fish consumption by the Tulalip, Squaxin, Suquamish, and Columbia River (Nez Perce, Umatilla, Warm Springs, and Yakama) tribes. WDOE used these data to develop a composite fish consumption rate (FCR) distribution by weighting the individual (tribal-specific) distributions based on relative populations. The resulting composite distribution was presented as Scheme 6 in Table C-4 of *Fish Consumption Rates Technical Support Document: A Review of Data and Information about Fish Consumption in Washington*, ver. 1.0 (WDOE 2011). This distribution, shown in Column 1 in Table 1, represents all fish consumption by the general tribal population of Washington State.

Table 1. Derivation of Fish Consumption Rate (FCR) Distribution for the General Tribal Population of Washington State (g/d)

	[1]	[2] [1] * 0.46	[3] [1] * (1 - 0.46)	[4] [2] * 0.314	[5] [3] + [4]
	All Fish[a]	Salmon[b]	Non-Salmon[c]	Fresh/Estuarine Apportioned Salmon[d]	Final Washington Tribal Population FCR[e]
mu	4.0083				
sigma	0.7158				
Mean	71.12	32.72	38.40	10.27	48.68
1%	10.41	4.79	5.62	1.50	7.13
5%	16.96	7.80	9.16	2.45	11.61
10%	22	10.12	11.88	3.18	15.06
25%	33.97	15.63	18.34	4.91	23.25
50%	55.05	25.32	29.73	7.95	37.68
75%	89.22	41.04	48.18	12.89	61.07
80%	100.55	46.25	54.30	14.52	68.82
85%	115.6	53.18	62.42	16.70	79.12
90%	137.77	63.37	74.40	19.90	94.30
95%	178.69	82.20	96.49	25.81	122.30
99%	291.03	133.87	157.16	42.04	199.19

[a] composite tribal distribution No. 6 from WDOE 2011, Table C-4 (tribal-specific distributions weighted according to relative population); assumes 100% of tribal populations are consumers and all fish are from waters of the state

[b] component of all fish that is salmon (all fish x 0.46)

[c] component of all fish that is not salmon (all fish – salmon)

[d] consumption of salmon associated with waters of state based on composite residence time life history factor (salmon x 0.314)

[e] final FCR (non-salmon + salmon fraction)

The distribution in Column 1 of Table 1 reflects consumption of all fish (including salmon) and seafood reported by the surveyed populations regardless of source. Under these conditions, the mean tribal FCR specific to Washington's tribal population is 71 g/d and the 95th percentile FCR is 179 g/d (Table 1). However, even though all surveyed tribal populations reported that a high

percentage (62-96%) of total consumption was of locally harvested organisms (e.g., WDOE 2013), these consumption rates may include store-bought fish and so may overstate consumption of organisms harvested from waters of the state.

Inclusion of salmon in this FCR distribution (Table 1, column 1) is controversial because the majority of the body burden of bioaccumulative chemicals found in returning (adult) salmon is accumulated in the oceans, not in freshwater. Thus inclusion of salmon in any FCR overstates exposure to pollutants sourced within Washington State, and the effect of including salmon in an FCR used to calculate human health water quality criteria represent goals that are unattainable by actions that Washington State can take on its own.

WDOE (2013) has provided data sufficient to estimate the fraction of tribal-specific FCRs contributed by consumption of salmon (summarized in Table 2). The amount of salmon (anadromous fish) as a percentage of the total fish and shellfish diet for these tribes ranges from 23% for the Suquamish Tribe to about 66% for the Squaxin Island Tribe, with an arithmetic mean of 46%. As summarized in Columns 2 and 3 of Table 1, this mean value was used to back out consumption of salmon from the general FCR distribution given in Column 1 of that table; that is, Column 3 in Table 1 gives the general tribal FCR distribution excluding all salmon.

Table 2. Summary of Washington Tribal Fish Consumption Survey Data (g/day)

	Fish Source	50th %tile	Mean	75th %tile	90th %tile	95th %tile	% of All Fish at Mean
Tulalip Tribe[a]							
All fish	All sources	44.5	82.2	94.2	193	268	100.0
Finfish	All sources	22.3	44.1	49.1	110	204	53.6
Shellfish	All sources	15.4	42.6	40.1	113	141	51.8
Non-anadromous	All sources	20.1	45.9	52.4	118	151	55.8
Anadromous	All sources	16.8	38.1	43.3	92.1	191	46.4
Squaxin Island Tribe[b]							
All fish	All sources	44.5	83.7	94.4	206	280	100.0
Finfish	All sources	31.4	65.5	82.3	150	208	78.3
Shellfish	All sources	10.3	23.1	23.9	54	83.6	27.6
Non-anadromous	All sources	15.2	28.7	32.3	70.5	95.9	34.3
Anadromous	All sources	25.3	55.1	65.8	128	171	65.8
Suquamish Tribe[c]							
All fish	All sources	132	214	284	489	797	100
Shellfish	All sources	64.7	134	145	363	615	63
Non-anadromous	All sources	102	169	219	377	615	79
Anadromous	All sources	27.6	48.8	79.1	133	172	23
CRITFC Tribes[d]							
All finfish	All harvested	40.5	63.2	64.8	130	194	100
Non-anadromous	All harvested	20.9	32.6	33.4	67	99.9	52
Anadromous	All harvested	19.6	30.6	31.4	63.1	94.1	48

[a] WDOE 2013 Table 23
[b] WDOE 2013 Table 24
[c] WDOE 2013 Table 26
[d] WDOE 2013 Table 21

The FCR distribution in Column 3 of Table 1 does not include consumption of any salmon, and so does not account for tribal exposure to whatever fraction of the ultimate pollutant body burden in returning adult fish might have been acquired as juveniles in fresh and/or estuarine (F/E) waters of the state (e.g., Hope 2012). WDOE anticipated this issue and proposed use of site-use factors based on residence time as a means of apportioning the fraction that might be accumulated in F/E vs. offshore waters (WDOE 2011, 2013). To this end, NCASI undertook a detailed analysis of salmon life histories (Appendix A), which resulted in species-specific life-history factors (LHFs, Table 3) representing the fraction of total pollutant body burden in returning adult fish acquired in F/E waters of Washington State.

Table 3. Life History Factors for Different Salmon Species and Different Waters Based on Residence Times in Waters of the State[a]

Species	Non-Puget Sound Waters	Puget Sound Waters Only	Statewide Composite
Chinook/King	0.15	0.40	0.30
Coho	0.50	0.60	0.56
Sockeye	NA	NA	0.19
Chum	0.13	0.28	0.22
Pink	NA	NA	0.24

[a] see Appendix A

To obtain a single composite LHF for salmon in general, the species-specific statewide composite LHFs in Table 3 were combined after weighting based on the amounts of each species consumed by members of the Suquamish Tribe (USEPA 2011). This derivation is summarized in Table 4, and resulted in a single statewide LHF of 0.314. The composite LHF was then used to estimate the fraction of the pollutant body burden present in returning (adult) salmon that might have been acquired during time spent in waters of the state. This fraction was added back to the non-salmon FCRs to obtain a final FCR distribution for the general tribal population of Washington State (Column 5 in Table 1) reflecting exposure to contaminants acquired by fish from waters of the state.

Table 4. Relative Proportions of Salmon Species Consumed by the Suquamish Tribe and Derivation of Composite Life History Factor for All Salmon

	EPA Consumption Data[a]				LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Fraction at Mean	From Table 4	Consumption Weighted
Chinook/King	63	0.200	12.600	0.294	0.30	0.088
Coho	50	0.191	9.550	0.223	0.56	0.125
Sockeye	59	0.169	9.971	0.233	0.19	0.045
Chum	42	0.242	10.164	0.237	0.22	0.053
Pink	17	0.035	0.595	0.014	0.24	0.003
Final composite LHF						0.314

[a] EPA 2011

As discussed in Appendix A, Section 3, LHFs based on residence time almost certainly overstate the relative magnitude of bioaccumulation during the early life stages of salmon life history. That is, LHFs based on residence time almost certainly overstate human exposure to pollutants acquired from waters of the state. As discussed in Appendix A, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired by salmon might be relative growth; that is, when/where salmon acquire body mass. Appendix A, Section 4, describes derivation of a single composite, consumption-weighted, LHF for salmon based on where salmon acquire biomass. The result was 0.086 (Appendix A, Table A8), which is ≈3.5 times smaller than the single composite (consumption-weighted) LHF based on residence time. Thus, use of LHFs based on residence times should be considered conservative.

Summary

An FCR distribution representative of the general tribal population of Washington State residents was developed. An initial composite distribution was taken from WDOE (2011), and was adjusted to reflect the portion of salmon consumed by tribal members reflecting contaminants acquired by salmon in waters of the state. Table 5 provides a summary of the data and rationale used in developing the final FCR distribution for Washington tribal members, which is given in Column 5 of Table 1. Ultimately, this final distribution should be considered conservative in that it almost certainly overstates human exposure to pollutants sourced from waters of the state because 1) it potentially includes consumption of organisms not sourced from waters of the state and 2) it relies on residence time LHFs instead of growth rate-based LHFs to apportion bioaccumulation of pollutants by salmon in waters of the state.

References

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Table 5. Summary of Data and Rationale Used in Developing Fish Consumption Rate Distribution for Tribal Residents of the State of Washington (presented in Table 1)

Table 1 Column	Description/Purpose	Data Source	Rationale	Comments
[1]	Starting dataset for developing Washington-specific tribal population FCR distribution	WDOE 2011, Table C-4; tribal-specific distributions weighted according to relative population	Represents all tribal fish consumption survey results reflecting Washington tribes	Individual tribal survey distributions weighted according to relative populations of each surveyed tribe
[2] and [3]	Adjustment to exclude all salmon	WDOE 2013, Tables 21, 23, 24, and 26; tribal-specific consumption rates of salmon as relative percent of total consumption	Same dataset used to develop composite FCR distribution	Adjustment applied to entire tribal distribution; adjusts distribution to reflect consumption of all fish except salmon
[4]	Adjustment to add back portion of salmon reflecting bioaccumulation from waters of the state	See items [4](i), [4](ii) below	Consistent with WDOE 2013 proposal	Adjustment is species-weighted composite salmon LHF multiplied by salmon-specific consumption rate (added back to consumption rate excluding salmon)
[4](i)	Salmon LHF	Technical literature on species-specific behavior and life history (primarily from WDOE 2013); see Appendix A	Development of LHFs for five major salmon species based on time salmon spend in waters of the state as a fraction of total lifetime prior to return as adults for spawning (residence time as proxy for bioaccumulation)	Approach may overestimate contaminant body burden acquired in waters of the state (e.g., salmon gain more than 95% of body mass in marine environment), so is believed to be conservative approach
[4](ii)	Relative consumption of different salmon species	Suquamish tribal data from USEPA 2011, Table 10-104	Washington-specific data on tribal consumption of different salmon species	Relative consumption rates for each salmon species used to weight LHFs to develop single composite LHF for all salmon

(Continued on next page.)

Table 1 Column	Description/Purpose	Data Source	Rationale	Comments
[5]	Final tribal-specific FCR distribution including fraction of total salmon consumption reflecting bioaccumulation from waters of the state	Table 1 columns [3] and [4] summed		Final distribution includes consumption of all fish but only the fraction of salmon reflecting bioaccumulation in waters of the state

APPENDIX A

LIFE HISTORY FACTORS FOR PACIFIC SALMON (02-13-2015)

1.0 INTRODUCTION

One of the primary factors to consider in deciding whether to include salmon in a fish consumption rate (FCR) used in deriving Clean Water Act human health water quality criteria is when/where salmon accumulate their ultimate body burden of relevant chemicals. Traditionally, EPA has recommended against including salmon in these FCRs because it was accepted that for bioaccumulative chemicals a majority of the chemical-specific body burden in a returning adult salmon is acquired in the Pacific Ocean (in the case of Pacific Northwest salmon), and not in the fresh and/or estuarine (F/E) waters under jurisdictional control of a state. However, this assumption has been challenged as part of the ongoing process in Washington State, and various stakeholders have argued that salmon must be included in the FCR for various reasons, including the cultural importance of salmon to tribal and other residents of the state.

A review of the technical literature shows that there are sufficient (albeit limited) data to conclude that the vast majority of the body burden of bioaccumulative chemicals in adult Chinook salmon is acquired during the marine phase of that species' life history. The data were developed by various researchers who measured chemical-specific body burdens in both out-migrating juvenile fish and returning adults belonging to the same runs. In all cases where these kinds of data have been developed, the researchers have concluded that >95% of the body burdens were acquired in the marine phase of the Chinook life history (Cullon et al. 2009; O'Neill and West 2009). However, these data are specific to Chinook salmon, and because each species of salmon has a unique life history it may not be appropriate to assume that what holds for Chinook also holds for coho, sockeye, chum, or pink salmon. Thus, there is some uncertainty regarding where these other species acquire their ultimate body burdens of bioaccumulative chemicals.

In response to this uncertainty, the Washington State Department of Ecology (WDOE) has proposed use of what this report will call life history factors (LHFs) as a means of apportioning total body burden in adult salmon between different phases of a salmon's life history. As proposed, these LHFs reflect the relative amount of time salmon spend in different environments or geographic locations, and would be used to apportion the ultimate body burden in returning adults between these environments or geographic locations. Subsequently, the fraction of the burden acquired in waters of the state could be used to adjust the actual consumption rate for salmon included in the FCR.

The assumption inherent in this model is that the body burden of bioaccumulative chemicals in returning adult salmon is a linear function of time. This is the basis for the site-use factors WDOE has proposed as a means of accounting for salmon consumption when developing human health benchmarks for sediment cleanups (WDOE 2012). Thus, there is precedent in Washington for this kind of apportionment, and WDOE has prepared a technical issue paper (TIP) summarizing information on the life histories of Chinook, coho, sockeye, chum, and pink salmon as part of developing this concept (WDOE 2013).

However, WDOE did not identify specific numeric LHFs for each species. This paper takes the next step using WDOE's TIP as the primary information resource; other sources of information were used only in instances where there were clear gaps in the TIP.

For the purposes of this exercise and consistent with scope of the Clean Water Act, LHFs were developed for waters of the state. In this context, waters of the state include all F/E waters, Puget Sound, and all marine waters within three miles of the Washington coastline.

Section 2 addresses development of species-specific LHFs for Pacific Northwest salmon based on residence time. Section 3 offers some discussion supporting the position that LHFs based on residence time overstate the significance of bioaccumulation during the early stages of salmon life history. LHFs based on where body mass is acquired (i.e., where salmon grow) are likely to provide a more accurate measure of where salmon acquire their ultimate cumulative body burdens of bioaccumulative chemicals, and Section 4 addresses development of these alternative mass-based LHFs.

2.0 LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

2.1 Chinook Salmon

Table A1 summarizes LHFs for stream- and ocean-type Chinook salmon and resulting composite LHFs for all Chinook (all tables are in Section 6 herein).

2.1.1 *Stream-Type Chinook Salmon Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs in Table A1.

Page 5. "After emergence, stream-type Chinook spend a year or more in the river before migrating downstream."

- Different LHFs were calculated using one and two years residence in freshwater.

Page 5. "Once entering the marine environment, stream-type Chinook spend very little time in the estuaries before migrating towards coastal waters."

- In this analysis, residence in estuarine waters prior to migration to coastal waters is approximated as 15 days. This was informed by the residence time of ocean-type Chinook, which WDOE cites as being a few weeks (we interpret this to mean three weeks); i.e., stream-type Chinook spend <21 days in estuarine environments, and 15 days was assumed.

Page 6. "Further, juvenile salmonids do not limit their use of estuarine habitats to their natal estuaries, as juvenile salmonids have also been found to enter and utilize non-natal estuaries during their marine near shore migration."

- WDOE provided no indication of how much time juvenile Chinook salmon spend in these near-shore environments, so LHFs were calculated ignoring this behavior.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

- LHFs were calculated using two, three, and four years.

2.1.2 *Ocean-Type Chinook Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs in Table A1.

Page 5. WDOE (2012) describes three distinct behaviors (phases) for ocean-type Chinook fry:

1. The "immediate" phase – fish that migrate to the ocean "…soon after yolk resorption…"
2. The "most common" phase – the most common life history for ocean-type fry "…is to migrate to marine habitats at 60 to 150 days post hatching…"
3. The "poor conditions" phase – "During years of poor environmental conditions…ocean-type juveniles remaining in fresh water for a year, although this is relatively uncommon."

- In this analysis, we assumed that the "immediate phase" spend 50 days in freshwater (an arbitrary number meant to include migration to the natal estuary), the "most common" phase spend 105 days (average of the reported range) in freshwater, and the "poor conditions" phase spend 365 days in freshwater.

Page 5. "Once reaching the marine environment, they then spend a few weeks or longer rearing in the estuary."

- An estuarine residence time of 21 days was used for all phases of ocean-type Chinook.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

- LHFs were calculated using two, three, and four years.

2.1.3 *Discussion and Final LHF for Chinook Salmon*

As shown in Table A1, LHFs for stream- and ocean-type Chinook differ. As a consequence, consumption of Chinook would, ideally, be broken out based on life history and the appropriate LHF would be applied to each type. Alternatively, if all Chinook are lumped together composite LHFs are required. However, information on the relative fraction of the overall Chinook population that belong to each life history type are required to generate LHFs for lumped Chinook, and this information was not provided in the TIP.

According to Healey (1991), the ocean-type life history is "typical" of Pacific North American Chinook populations south of 56°N, which includes all of Washington and Oregon. More specifically, stream-type runs represent only 0 to 12% of Chinook runs in smaller rivers and 14 to 48% of Chinook runs in larger rivers. However, Table 1 in Healey (1991) also indicates that 78% of Columbia River spawning runs and 88% of Sixes River (southern Oregon coast) runs are ocean-type. This suggests that about 80% of Chinook salmon caught and consumed in Washington are ocean-type fishes. Using the average stream- and ocean-type LHFs extracted from WDOE's TIP (Table 1), composite LHFs for Chinook salmon would be nominally 0.85 and 0.15 for marine and F/E waters, respectively, so the LHF for waters of the state would be 0.15. However, this does not account for a third life history not addressed by the TIP, which is Puget Sound residency throughout the full marine phase of Chinook life history.

Puget Sound is known to support populations of resident Chinook and coho salmon (Chamberlin 2009; Rohde 2013). These fish spend the marine phase of their life history in Puget Sound proper, so the LHF for waters of the state would be 1 for these fish. Based on information presented by WDOE (2013), 60% of the salmon harvested in Washington were caught in marine waters, and WDOE identified 60% of these as Puget Sound salmon. Of the 40% of salmon caught in freshwaters, WDOE estimated that 57% were harvested in Puget Sound streams. Thus, overall, approximately 60% ([0.6 x 0.6]+[0.4 x 0.57]) of the salmon harvested in Washington are estimated to originate from Puget Sound. Although not all these fish are Chinook, in this analysis we assume that this proportion applies to all salmon except pink salmon (100% of which are assumed to be Puget Sound fish); that is, we assume that 60% of the Chinook caught and consumed in Washington are from runs originating in Puget Sound. Regardless, not all Puget Sound Chinook exhibit full residency in Puget Sound.

Although full residency is a well known phenomenon, there is very little information indicating what fraction of Puget Sound Chinook exhibit this life history. Chamberlin (2009) studied the role of multiple factors in the tendency of Puget Sound Chinook to exhibit full residency and concluded that 30% of Puget Sound Chinook salmon display this behavior (i.e., 30% of Puget Sound Chinook have a waters of the state LHF of 1). Chamberlin's conclusion is generally consistent with that of O'Neill and West (2009), who estimated that full residency was exhibited by between 29 and 45% of Puget Sound Chinook. Here, Chamberlin's estimate is used to calculate a composite waters of the state LHF of 0.40 ([0.7 x 0.15]+[0.3 x 1]) specific to Puget Sound Chinook salmon.

This value is notably larger than the waters of the state LHF for non-Puget Sound Chinook (0.15) but is only applicable to Puget Sound Chinook. For other Chinook (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.15. Based on the same information, a composite waters of the state LHF for all Chinook would be 0.3 ([0.4 x 0.15]+[0.6 x 0.4]). This is the appropriate waters of the state LHF for use when considering Chinook on a statewide basis.

2.2 Coho Salmon

Table A2 summarizes LHFs for coho salmon.

2.2.1 *Coho Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A2.

Page 7. "For populations in and around Washington State, returning adult Coho salmon are generally 3-year-olds, and spend approximately 18 months in fresh water and 18 months in marine habitats."

Page 7. "After emerging, the fry generally remain within freshwater streams for a year or two before migrating downstream."

- LHFs were calculated assuming one and two year periods.

Page 8. "Emergence has been detected from March to July." In this analysis we assume emergence in mid-April.

Page 8. "Although some fry migrate to marine waters soon after emergence, the majority disperse both up- and downstream, remaining in streams to rear as juveniles for one to two years before migrating downstream."

- LHFs were calculated assuming one and two year periods.

Page 8. "Within this region, Coho smolts typically leave fresh water and migrate to marine habitats to enter the smolting process in the spring (April to June). Once entering marine waters, Coho smelts spend little time rearing in estuaries, instead migrating toward coastal waters."

- Migration was assumed to begin in mid-May.

Page 8. "Although some Coho salmon move to offshore waters, typically subadults continue to feed and mature in these coastal waters of the northeast Pacific."

Page 8. "The majority of Coho originating from Washington streams migrate to coastal waters off Oregon and Washington, with low numbers occurring in Oregon and British Columbia waters."

Page 9. "While some adult male Coho salmon return after spending only one summer at sea, the majority of Coho return after spending two, and sometimes three, summers at sea. There are some run timing differences between coastal and inland Washington stocks of Coho salmon, but adults begin returning to estuaries and outlets of their natal streams from July to September."

- In this analysis we assume return in September, and LHFs were calculated assuming two and three summers at sea.

2.2.2 *Discussion and Final LHF for Coho Salmon*

The timing of specific events in the life history of coho is variable at the scale of months. This is significant if it is accepted that the majority of returning adults are around three years old. This variability is reflected in the various LHFs shown in Table A2, which shows LHFs for marine residency ranging from 0.383 to 0.679 for 3.4 year old fish, depending on whether it is assumed they spent one or

two years in freshwater. However, the average of these two marine LHFs is 0.53, which is essentially the same as obtained by assuming that coho split their life between fresh and estuarine waters, or near-shore waters vs. marine waters. Thus, the final LHFs for coho salmon are taken as 0.5 and 0.5 for marine and F/E waters, respectively, meaning that the final LHF for waters of the state would be 0.5.

However, as with Chinook salmon, some fraction of Puget Sound coho salmon exhibit full residency in Puget Sound proper (e.g., Rohde 2013), and for these fish the waters of the state LHF would be 1. Following the work of Chamberlin (2009) on Chinook salmon, Rohde (2013) attempted to characterize the relative fraction of Puget Sound coho exhibiting this life history, and estimated that 3.4% are true residents, 61.3% migrate outside Puget Sound, and the behavior of the remaining 35.3% is ambiguous. Assuming 50% of the ambiguous fish are in fact residents means that approximately 21% of Puget Sound coho exhibit full residency, and the waters of the state LHF for these fish is 1. The associated composite waters of the state LHF for all Puget Sound coho is 0.6 ([0.79 x 0.5]+[0.21 x 1]). For other coho (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.5. Following the analysis for Chinook (i.e., assuming that 60% of coho caught in Washington are from Puget Sound runs), the composite statewide waters of the state LHF for coho salmon is 0.56 ([0.4 x 0.5]+[0.6 x 0.6]).

2.3 Sockeye Salmon

Table A3 summarizes LHFs for sockeye salmon.

2.3.1 *Sockeye Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A3.

Page 9. "Sockeye salmon have one of the most diverse patterns of life history among Pacific Northwest salmon species. For example, age at out-migration to marine systems from their natal streams not only varies between systems, and within systems, but can vary among related individuals."

Page 10. "The hatched alevin then take an additional 24 to 60 days to emerge from the gravel as fry, with warmer temperatures reducing the time for emergence. Sockeye salmon emerge as fry generally in April or May, with some variability associated with temperature."

- In this analysis we assume emergence on May 1 (approximately 42 days post-hatch, hatch in mid-March).

Page 10. "Regarding their entry into marine waters, two types of sockeye salmon occur: the ocean-type (or sea-type) that migrates to marine waters in the first year of their life, and the stream-type that may rear in rivers and lakes for a year or more before migrating to marine habitats."

- LHFs were calculated for both scenarios. In all cases, it was assumed that out-migration peaks on May 1.

Page 10. "Juvenile sockeye in Washington generally migrate from their nursery lakes to marine habitats in March and continuing through June, with peak out-migration occurring in April and May. Upon entering marine waters, estuarine use by juvenile sockeye salmon (smolts at this point) is limited, although some ocean-type sockeye may use these habitats before migrating toward coastal waters."

- Here we assume peak migration occurs on May 1 for both ocean- and stream-type, and we assume migration takes 50 days.

Page 10. "Sockeye spend 2 to 4 years at sea before returning to their natal systems to spawn."

- In this analysis, LHFs were calculated using two, three, and four years.

2.3.2 *Discussion and Final LHF for Sockeye Salmon*

LHFs for stream-type and ocean-type sockeye differ only if it is assumed that ocean-type fish out-migrate immediately following emergence. If these ocean-type fish rear in freshwater for a full year after emergence, they effectively become stream-type fish with respect to their LHF. However, WDOE gives no information indicating what fraction of these ocean-type fish exhibit this life history. As a consequence, this life history for ocean-type fish is ignored.

WDOE's TIP is also mute on what fraction of sockeye salmon exhibit stream- vs. ocean-type life histories. Likewise, no information regarding what fraction of each type spends two, three, or four years at sea was provided in the TIP. As a consequence, LHFs for each life history type were calculated as the average of the LHFs for fish spending two, three, and four years at sea. Composite LHFs were then calculated assuming a 50:50 split between stream- and ocean-type fish. The resulting composite LHFs are 0.81 and 0.19 for marine and F/E waters, respectively; the final statewide composite waters of the state LHF is 0.19.

2.4 Chum Salmon

Table A4 summarizes LHFs for chum salmon.

2.4.1 *Chum Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A4.

Page 11. "Similar to pink salmon or ocean-type Chinook, juvenile chum migrate from their freshwater redds to marine waters almost immediately after emergence."

Page 11. "The alevins remain in the gravel another 30 to 50 days, until their yolk sac is absorbed."

- Here we assume 40 days.

Page 11. "Most chum salmon fry spend only a few days to a few weeks rearing in fresh water before migrating toward marine habitats from March to May. A much smaller number of fry may rear in freshwater streams but migrate to marine waters by the end of their first summer."

- This "much smaller number" of fry is excluded from this analysis, and the post-hatch time in freshwater prior to out-migration is assumed to be 21 days ("a few weeks"). Out-migration is assumed to peak on April 1.

Page 11. "Chum salmon utilize estuarine habitats for a few more weeks before migrating to coastal, then offshore waters."

- This suggests estuarine residence is ≈21 days.

Page 12. "Most chum fry enter estuaries by June and leave them by mid to late summer."

- This appears to conflict with the statement (page 11) that chum utilize estuarine habitats for a "few more weeks." Thus, this analysis assumes arrival in June and a six week (42 days) residence in estuarine waters (i.e., fish leave natal estuaries in mid-July). Migration time to the natal estuary is assumed to be two months (60 days).

Page 12. "The Hood Canal shoreline is said to serve as a nursery and rearing habitat for a significant portion of all chum salmon originating from Washington State rivers."

- WDOE gives no information on the amount of time these fish spend in this habitat. However, the indication that a significant portion of chum salmon manifest this life history means they should be

accounted for in any LHFs, and our analysis assumes that 50% of Puget Sound chum exhibit this behavior.

Page 12. "A number of age 2 chum salmon do occur within Puget Sound waters, although the absence of age 3 chum suggests that all chum salmon spend some time rearing in the Pacific Ocean."

- It is not clear what age 2 means (e.g., in the second year of life, i.e., 1.01 years; over 2 years old, i.e., in the third year of life). In this analysis, it is assumed that these fish move out of Puget Sound at age 1.5 years (547.5 days). This assumption concerning residence time also includes Puget Sound fish that utilize Hood Canal for rearing.

Page 12. "In general, chum salmon originating from Washington streams and rivers, and rearing in the open ocean, do not return as mature adults until age 3 or 4."

- LHFs were calculated assuming both three and four years.

2.4.2 *Discussion and Final LHF for Chum Salmon*

Table A4 gives LHFs for three and four year old chum assumed to migrate to marine waters after minimal residence in estuarine waters (assumed as 42 days) following 121 days in freshwater. These LHFs are relevant to chum originating outside of Puget Sound/Hood Canal. For these fish, the waters of the state LHF is estimated to be 0.13 (average of three and four year old fish).

For Puget Sound/Hood Canal chum, one important unknown is the fraction of the total population spending "additional" time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean proper, and just exactly how much time they spend in these waters prior to this final out-migration. As noted, we assume these fish migrate to the Pacific Ocean at age 1.5 years (547.5 days). This corresponds to 121 days in freshwater followed by 426.5 days in estuarine waters and Hood Canal/Puget Sound combined, and Table A4 gives LHFs for three and four year old Puget Sound chum according to these assumptions. However, not all Puget Sound chum exhibit this life history. Because the TIP gives no information indicating what fraction of Puget Sound fish follow this life history, we have arbitrarily assumed 50%. Thus, the final LHF for Puget Sound chum is a composite of the two life histories equally weighted. The resulting LHFs are 0.72 and 0.28 for marine and F/E waters, respectively, meaning that the waters of the state LHF for Puget Sound chum is 0.28 ([0.5 x 0.13]+[0.5 x 0.438]).

Composite LHFs for statewide use were calculated assuming that 60% of the chum salmon harvested in Washington are Puget Sound fishes. The resulting values are 0.78 and 0.22 for marine and F/E waters, respectively, meaning that the statewide composite waters of the state LHF for chum salmon is 0.22 ([0.4 x 0.13]+[0.6 x 0.28]).

2.5 Pink Salmon

Table A5 summarizes LHFs for pink salmon derived from the information provided by WDOE (2013).

2.5.1 *Pink Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A5.

Page 13. "Pink salmon only live for 2 years, with very little variability."

Page 13. "As pink salmon adults spawn near river mouths, and fry migrate downstream immediately after emergence, this salmon species spends the least amount of time in fresh water."

- The fact that pink salmon spawn near the mouth of their natal rivers suggests that the time required for migration to estuarine waters is minimal. This analysis assumes migration takes 10 days.

Page 13. "Although some smaller coastal and Columbia River runs occur, within Washington State two of the rivers supporting the largest pink salmon runs are the Snohomish and Puyallup."

- This statement is consistent with essentially all pink salmon in Washington State originating from Puget Sound.

Page 14. "Once the yolk sac is depleted, the alevins emerge as fry some 41 to 64 days (average 52 days) post hatching."

- The 52 day average is used herein.

Page 14. "There is little or no fresh water rearing as pink salmon fry migrate seaward upon emergence from the gravel, and so their downstream migration also occurs in March and April."

- Based on this and other statements in WDOE's TIP, migration was assumed to begin immediately following emergence.

Page 14. "Pink salmon originating from Puget Sound and Hood Canal streams and rivers appear to use near shore areas extensively for early rearing during their first few weeks of entry into marine habitats."

- This suggests nominally 21 days (a "few weeks") in estuarine waters.

Page 14. "While little is known about their behavior as the fry are exiting Puget Sound proper, Hiss (1994, as cited in Hard et al 1996) found that fry occurrence in Dungeness Bay (near Sequim) peaked in April and they were gone by late May."

- Assuming that peak migration manifests on April 1, the observation that fry are no longer present in Dungeness Bay by late May suggests two months (60 days) residence in near-shore waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean.

Page 14. "Findings suggest that most out-migrating pink salmon enter the open ocean by late summer or early fall."

- This suggests residence in estuarine waters for more than two months.

Page 14. "However, like some Chinook, and Coho, a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle."

- WDOE gives no information on what fraction of pink salmon exhibit this behavior.

Page 14. "Once reaching estuarine and marine habitats, pink salmon migrate towards the open ocean within the first couple of months. By September the majority of pink salmon migrate hundreds of miles out in the open sea to grow and mature."

- Assuming that migration from freshwater to estuarine water peaks on April 1 suggests that pink salmon spend anywhere from two to five months in estuarine (near-shore) waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean. In this analysis, we assume an average of 3.5 months (106.5 days).

Page 14. "They spend approximately eighteen months rearing in the open ocean before their eastward migration to their natal streams and rivers."

- LHFs were calculated assuming 18 months in marine waters and a 24 month total life span.

2.5.2 *Discussion and Final LHF for Pink Salmon*

Table A5 gives two sets of LHFs based on the information presented by WDOE (2013). The difference between these estimates is minimal, and the final LHFs are taken as the mean of the two. Thus, the resulting LHFs for pink salmon are 0.76 and 0.24 for marine and F/E waters, respectively. The final LHF for pink salmon reflecting time spent in waters of the state is 0.24.

For pink salmon that spend their marine phase in Puget Sound, the LHF reflecting time in waters of the state would be 1. However, no information on what fraction of pink salmon manifest this life history was found, while WDOE (2013) noted that only a "small portion" of the overall pink salmon population exhibit Puget Sound residency. As a consequence, this full residency life history is not accounted for in the final waters of the state LHF.

2.6 Composite Residency-Based LHF for all Washington Salmon

Sections 2.1 through 2.5 address development of LHFs for individual salmon species based on residence times. However, there may be circumstances in which a single composite LHF for all Washington salmon will be required. One approach to developing such a composite LHF is to sum the species-specific LHFs after weighting each by a factor reflecting species-specific consumption rates of Washington consumers. One source of these consumption rates is EPA's *Exposure Factor Handbook* (USEPA 2011), which gives species-specific consumption rates for adult members (consumers only) of the Suquamish Tribe in Table 10-104. Although this tribe consumes more shellfish than other tribal data would suggest, it was assumed that the relative amounts of the different salmon species consumed are representative of Washington consumers generally, including high-end tribal consumers. The data from EPA's table is reproduced in part as Table A6 herein, which also shows generation of a single composite LHF for salmon in general (0.32) based on the species-specific LHFs.

A composite salmon LHF could be developed based on other information such as commercial landings, but such data do not necessarily reflect consumption habits of Washington residents.

3.0 DISCUSSION OF LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

As seen in Section 2, LHFs for Washington salmon can be developed based on residence time. However, in addition to uncertainty regarding residence times of different salmon species (or specific runs) in different environments or geographic locations, the available data also manifest a high degree of variability. Thus, the resulting LHFs must be considered gross approximations. Despite this, there are factors that inform the potential for bias in the residence time LHFs presented in Section 2, and these factors suggest that, in general, residence time LHFs overstate the magnitude of bioaccumulation in early life stages of salmon life history.

One such factor is, ironically, time. This is because bioaccumulation is a reversible process, such that organisms are accumulating and depurating bioaccumulative chemicals simultaneously. Indeed, it is the ratio (accumulation rate/depuration rate) that underpins chemical- and organism-specific bioaccumulation factors. Once an organism moves from one environment (geographic location) to another, the probability that the specific molecules of a chemical acquired in the first environment/location will depurate increases with the time spent in the second environment/location.

This probability increases when the first environment/location is more contaminated than the second, which is the exact scenario relevant to Puget Sound salmon that spend time in the Pacific Ocean proper. Apportioning body burdens based on residence time thus tend to overstate the contribution of accumulation during the early life stages to the ultimate body burden in returning adult Puget Sound salmon.

Beyond this, the assumption that an organism acquires bioaccumulative chemicals at a constant rate is analogous to assuming a fixed bioaccumulation factor. This assumption might hold for an organism that is static, that is, an organism that is not undergoing any physiological changes, feeds at a fixed trophic level, and exhibits either no growth or a constant rate of growth, but it is clearly a gross oversimplification for salmon, which exhibit extremely complex life histories. Thus, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired might be relative growth, that is, when/where salmon acquire body mass. Section 4 describes an initial attempt to develop such LHFs.

4.0 LIFE HISTORY FACTORS BASED ON GROWTH

The literature contains many statements (e.g., Quinn 2005) to the effect that salmon acquire the majority of their body mass during the marine phase of their life cycle; that is, while feeding in the ocean (or Puget Sound for true resident fish). For this analysis, the generalized summary of body mass presented by Quinn (2005) is taken as representative. These data are summarized in Table A7, which also gives nominal mass-based LHFs reflecting the relative body masses of out-migrating smolt and returning adult salmon.

By definition (Quinn 2005), smolts are the final stage in salmon development prior to migration to true marine waters. This means the difference in body mass between smolt and adult fish reflects growth in marine waters, and the information provided in Table A7 indicates that all five species of Pacific Northwest salmon acquire >99% of their adult body mass during the marine phase of their life history. Thus, if it is assumed that these fish spend this portion (the marine phase) of their life outside waters of the state, the mass-based LHFs given in Table A7 are the relevant waters of the state LHF. However, some salmon spend a portion of their marine life history in waters of the state. Unfortunately, as noted in Section 3, residence time cannot be used to apportion growth among different habitats or geographic locations. Thus, without higher resolution mass data (i.e., measured mass of fish at multiple ages corresponding to species-specific shifts in habitat usage), the only distinction that can be made is between those fish that exhibit nominally full residency in waters of the state (i.e., Puget Sound) during their marine phase and those that exhibit full residency in the Pacific Ocean during this phase. Adjustments to the mass-based LHFs given in Table A7 reflecting this life history (full residency in Puget Sound) are discussed on a species-specific basis.

4.1 Chinook Salmon

Based on the analysis presented in Section 2.1.3, approximately 60% of the salmon, including Chinook, caught and consumed in Washington are Puget Sound fish. Of these Puget Sound Chinook, about 30% are resident fish. Thus, 18% of all Chinook (0.6 x 0.3) are Puget Sound residents which, by definition, have an LHF equal to 1. For the remaining 82%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for Chinook salmon reflecting waters of the state is 0.182 ([0.82 x 0.00249]+[0.18 x 1]).

4.2 Coho Salmon

Following the analysis for Chinook, 60%of coho salmon are considered to be Puget Sound fish, and 21% of these are assumed to be full time residents of Puget Sound (Section 2.2.2). Thus, 13% (0.6 x 0.21) of all coho are Puget Sound residents which, by definition, have a waters of the state LHF equal to 1. For the remaining 87%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for coho reflecting waters of the state is 0.135 ([0.87 x 0.00596]+[0.13 x 1]).

4.3 Sockeye Salmon

WDOE's TIP gives no information on what fraction of Puget Sound sockeye salmon exhibit full residency in Puget Sound, so there is no basis for parsing sockeye as Puget Sound or non-Puget Sound

fish. This means that the only mass-based LHF for sockeye is that given in Table A7. Thus, the single mass-based LHF for Sockeye salmon reflecting waters of the state is 0.00372.

4.4 Chum Salmon

As discussed in Section 2.4.2, some chum spend some time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean. However, as discussed in Section 4.0, without data there is no way to identify the fraction of ultimate adult body mass chum acquire during this period. Beyond this, the TIP provides no information suggesting that any chum salmon take up full residency in Puget Sound. Thus, there is no basis for modifying the mass-based LHF for chum given in Table A7, so the final mass-based LHF for chum salmon reflecting waters of the state is 0.00011.

4.5 Pink Salmon

As noted in WDOE's TIP (Section 2.5.1 herein), some pink salmon spend time in near-shore marine waters rearing prior to completing migration to the Pacific Ocean. However, as discussed in Section 4.0, without data there is no way to identify the fraction of ultimate adult body mass these fish acquire during this period. Beyond this, the TIP states that only "a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle." Thus, there is no basis for modifying the mass-based LHF for pink salmon given in Table A7, so the final mass-based LHF for pink salmon reflecting waters of the state is 0.00013.

4.6 Composite Mass-Based LHF for all Washington Salmon

Table A8 summarizes calculation of a single composite mass-based LHF for all Washington salmon according to Section 2.6.

5.0 REFERENCES

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6.0 TABLES

Table A1. Life History Factors (LHFs) for Chinook Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawning (days)	(years)	LHFs F/E[c]	Marine	Notes[d]
Stream-Type	365	15	730	1110	30.	0.342	0.658	"a year or more in the river before migrating downstream"; "spend very little time in the estuaries"; "2 to 4 years is more typical"
	730	15	730	1475	4.0	0.505	0.495	
	365	15	1095	1475	4.0	0.258	0.742	
	730	15	1095	1840	5.0	0.405	0.595	
	365	15	1460	1840	5.0	0.207	0.793	
	730	15	1460	2205	6.0	0.338	0.662	
Ocean-Type (immediate)	50	21	730	801	2.2	0.089	0.911	"migrates to ocean soon after yolk resorption"; "a few weeks in the estuary"
	50	21	1095	1166	3.2	0.061	0.939	
	50	21	1460	1531	4.2	0.046	0.954	
Ocean-Type (most common)	105	21	730	856	2.3	0.147	0.853	"migrate to marine habitats at 60 to 150 days post hatching"; "a few weeks in the estuary"
	105	21	1095	1221	3.3	0.103	0.897	
	105	21	1460	1586	4.3	0.079	0.921	
Ocean-Type (poor conditions)	365	21	730	1116	3.1	0.346	0.654	"juveniles remain in fresh water for a year"
	365	21	1095	1481	4.1	0.261	0.739	
	365	21	1460	1846	5.1	0.209	0.791	
Stream-Type average	547.5	15	1095	1657.5	4.5	0.339	0.661	average freshwater residence assuming 3 y in marine habitat
Ocean-Type average	105	21	1095	1221	3.3	0.103	0.897	"most common" life history assuming 3 y in marine habitat
LHFs for non-Puget Sound waters →						0.15	0.85	LHFs assuming 80% of Chinook are ocean-type fish; Puget Sound residency not incorporated[e]
LHFs for Puget Sound waters only →						0.40	0.60	LHFs for Puget Sound only Chinook incorporating residency and assuming 80% are ocean-type fish[e]
Composite LHFs for all waters of the state →						0.30	0.70	statewide composite LHFs incorporating residency of Puget Sound Chinook assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.1.3

Table A2. Life History Factors (LHFs) for Coho Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
547.5		547.5	1095	3.0	0.500	0.500	"18 months in fresh water and 18 months in marine habitats"
395		471	866	2.4	0.456	0.544	"1y" in FW (mid-April emergence and mid-May migration to
395		836	1231	3.4	0.321	0.679	saltwater = 13 mon) followed by 1, 2, or 3 "summers" in marine
395		1201	1596	4.4	0.247	0.753	water (15.5 mon = 2 summers)
760		471	1231	3.4	0.617	0.383	"2y" in FW (mid-April emergence and mid-May migration to
760		836	1596	4.4	0.476	0.524	saltwater = 25 mon) followed by 1, 2, or 3 "summers" in marine
760		1201	1961	5.4	0.388	0.612	water (15.5 mon = 2 summers)
					0.47	0.53	average LHFs for 3.4 y old fish excluding Puget Sound residency[e]
LHFs for non-Puget Sound waters →					0.50	0.50	LHFs based on 18 mon in marine water, a 3 y life span, and excluding Puget Sound residency[e]
LHFs for Puget Sound waters only →					0.60	0.40	LHFs for Puget Sound only coho incorporating residency[e]
Composite LHFs for all waters of the state →					0.56	0.44	statewide composite LHFs incorporating residency of Puget Sound coho assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.2.2

Table A3. Life History Factors (LHFs) for Sockeye Salmon[a]

	Residence Time (days)			Age at Spawning		LHFs		
Type	FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
Stream-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1; assume hatch mid-March,
Stream-Type	457		1095	1552	4.3	0.294	0.706	emergence by May 1 (42 d post-hatch), 1 y
Stream-Type	457		1460	1917	5.3	0.238	0.762	residence, then out-migration (50 d); "limited" use of estuary
						0.306	0.694	average of all age fish
Ocean-Type	92		730	822	2.3	0.112	0.888	to marine water first year; assume hatch mid-March,
Ocean-Type	92		1095	1187	3.3	0.078	0.922	emergence by May 1 (42 d), and immediate out-
Ocean-Type	92		1460	1552	4.3	0.059	0.941	migration (50 d); "limited" use of estuary
						0.083	0.917	average of all age fish
Ocean-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1
Ocean-Type	457		1095	1552	4.3	0.294	0.706	
Ocean-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
	Composite LHFs for all waters of the state ⇒					0.19	0.81	statewide composite LHFs assuming 50:50 split between stream- and ocean-type (92 days FW residence[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.3.2

Table A4. Life History Factors (LHFs) for Chum Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
121	42	932	1095	3.0	0.149	0.851	fish migrate to ocean after minimal residence in estuarine waters
121	42	1297	1460	4.0	0.112	0.888	
					0.130	0.870	average of 3 and 4 y old fish
121	426.5	547.5	1095	3.0	0.500	0.500	fish stay in Hood Canal/Puget Sound until age 1.5 y (this time is in
121	426.5	912.5	1460	4.0	0.375	0.625	coastal marine water assigned to 'Est.')
					0.438	0.563	average of 3 and 4 y old fish
LHFs for non-Puget Sound waters ⇒					0.13	0.87	LHFs for non-Puget Sound chum based on average age fish[e]
LHFs for Puget Sound waters only ⇒					0.28	0.72	LHFs for Puget Sound only chum using average age fish and assuming 50:50 split between two life histories[e]
Composite LHFs for all waters of the state ⇒					0.22	0.78	statewide composite LHFs assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.4.2

Table A5. Life History Factors (LHFs) for Chum Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
62	106.5	561.5	730	2	0.231	0.769	fry emerge 52 d post-hatch; estimate 10 d to migrate to estuary, total of 62 d in FW; 3.5 mon in estuary/near-shore waters prior to migration to marine waters; 2 y total life span
	183	547	730	2	0.251	0.749	based on 18 mon rearing in marine water and 24 mon life span
LHFs for all waters of the state[e] ⇒					0.24	0.76	average LHFs

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] all pink salmon assumed to be Puget Sound fish

Table A6. Derivation of Composite Residency-Based Life History Factor (LHF) for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.300	0.088
Coho	50	0.191	9.55	0.223	0.560	0.125
Sockeye	59	0.169	9.971	0.233	0.194	0.045
Chum	42	0.242	10.164	0.237	0.222	0.053
Pink	17	0.035	0.595	0.014	0.241	0.003
			Composite residency-based LHF for salmon		→	0.314

[a] consumption data for Suquamish Tribe from USEPA 2011, Table 10-104
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 2.1 to 2.5, Tables A1 to A5

Table A7. Generalized Weights of Salmon as they Enter the Ocean and as Returning Adults[a]

	Chinook	Coho	Sockeye	Chum	Pink
Smolt weight (g)	5 – 18	18	10	0.4	0.22
Adult weight (kg)	7.22	3.02	2.69	3.73	1.63
LHF[b]	0.00249	0.00596	0.00372	0.00011	0.00013

[a] from Quinn 2005, Table 16.3
[b] calculated as simple ratio (smolt/adult)

Table A8. Derivation of Composite Mass-Based Life History Factor (LHF) for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.182	0.053
Coho	50	0.191	9.55	0.223	0.135	0.030
Sockeye	59	0.169	9.971	0.233	3.72×10^{-3}	8.65×10^{-4}
Chum	42	0.242	10.164	0.237	1.10×10^{-4}	2.61×10^{-5}
Pink	17	0.035	0.595	0.014	1.30×10^{-4}	1.80×10^{-6}
			Composite mass-based LHF for salmon		→	0.084

[a] consumption data for Suquamish Tribe from USEPA 2011, Table 10-104
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 4.1 to 4.5

ATTACHMENT B

823/Z-92-001

Federal Register

Tuesday
December 22, 1992

Part II

Environmental Protection Agency

40 CFR Part 131
Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance; Final Rule

00768

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4660-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Correction notice; final rule.

SUMMARY: EPA is correcting typographical errors in the final rule for water quality standards for priority toxic pollutants which appeared in the Federal Register on December 22, 1992, 57 FR 60848.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401-M Street, SW, Washington, DC 20460. Telephone number is 202-260-1318.

SUPPLEMENTARY INFORMATION: EPA promulgated a final rule to establish numeric water quality criteria for priority toxic pollutants applicable to State water quality standards under section 303(c) of the Clean Water Act on December 22, 1992 (57 FR 60848). These criteria became the enforceable criteria for all purposes under the Clean Water Act for the 12 States and 2 territories listed in the rule on February 5, 1993.

Description of Errors and Corrections

On Page 60911, EPA has been advised that the legibility of the matrix on some of the printed notices is such that it is not clear that Arsenic is identified as number 2 on the table and Silver is number 11. In addition, pollutant number 12 is Thallium.

On page 60917, middle column, line 49, the phrase "• • • the lethal concentration of • • •" is incorrect. It should read "• • • the concentration lethal to • • •."

On page 60919, in the middle column dealing with paragraph (6) Florida, in subparagraph (ii), the applicable criteria for Class II and Class III (marine) were inadvertently omitted from the text. The applicable criteria for both Class II and Class III (marine) should read: "This classification is assigned the criteria in: Column D2-#16."

On page 60920, dealing with paragraph (10) California, in subparagraph (ii), the applicable criteria for "Waters of the Sacramento-San Joaquin Delta" should also include pollutant #67 in Column D1; this pollutant was inadvertently omitted from the list.

On page 60921 dealing with paragraph (10) California, in subparagraph (ii), the fifth paragraph beginning "All enclosed bays and estuaries" under the heading "Water and Use Classification", the words "that do not include an MUN designation" were omitted from the first line. The correct wording is: "All enclosed bays and estuaries that are waters of the United States *that do not include an MUN designation* and that the State has. . ."

On page 60922, dealing with paragraph (12) Alaska, in subparagraph (ii), the applicable criteria assigned to use classification (1)(A)(ii) is incorrectly printed as Column D1. The correct reference should be to Column D2.

Dated: May 25, 1993.

Tudor Davies,

Acting Assistant Administrator for Water.

[FR Doc. 93-12845 Filed 5-28-93; 8:45 am]

BILLING CODE 6560-50-M

Corrections

Federal Register
Vol. 58, No. 121
Friday, June 25, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4660-6]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

Correction

In rule document 93-12845 beginning on page 31177 in the issue of Tuesday, June 1, 1993, make the following correction:

On page 31178, in the first column, in the fifth full paragraph, in the fourth line, "(1)(A)(ii)" should read "(1)(A)(iii)".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-930-4210-06; WYW 128871]

Proposed Withdrawal and Opportunity for Public Meeting; Wyoming

Correction

In notice document 93-13009, appearing on page 31538 in the issue of Thursday, June 3, 1993 in land description T.41 N., R. 117 W., "34 and 25" should read "34 and 35".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4658-1]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is amending a rule issued on December 22, 1992, to withdraw a portion of that rule as it applies to the State of Washington. The aquatic life criteria for arsenic and selenium adopted by Washington and approved by EPA make the Federally promulgated criteria for these pollutants unnecessary.

EFFECTIVE DATE: This amendment is effective July 6, 1993.

ADDRESSES: The administrative record for the consideration of Washington's revised standards is available for public inspection from the Environmental Protection Agency, Region X Office, Water Division, 1200 Sixth Avenue, Seattle, WA, 98101, during normal business hours of 8 a.m. until 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The telephone number is 202-260-1315.

SUPPLEMENTARY INFORMATION: A final rule to establish numeric water quality criteria for those States and Territories that failed to comply fully with section 303(c)(2)(B) of the Clean Water Act was published in the Federal Register on December 22, 1992 (57 FR 60848). Federal criteria were promulgated for 12 States and 2 Territories, and these criteria became the legally enforceable water quality standards in the named States and Territories for all purposes and programs under the Clean Water Act on February 5, 1993.

As indicated in the preamble to the final rule, EPA would amend the rule to withdraw criteria from the rule when a State adopted and EPA approved criteria that met the requirements of the Clean Water Act (see 57 FR 60860). On November 25, 1992, the State of Washington adopted revisions to the State's surface water quality standards, Chapter 173-201A of the Washington Administrative Code, regarding aquatic life criteria for arsenic and selenium. The State adopted criteria identical to those promulgated by EPA for both fresh and marine waters. These criteria were approved by EPA on March 25, 1993.

EPA's promulgated criteria for arsenic and selenium are now duplicative of EPA-approved State criteria and are no longer needed to meet the requirements of the Act. It is EPA's policy to withdraw promulgated water quality standards when the State adopts new or revised standards which meet the requirements of the Act (57 FR 60848). Accordingly, EPA is amending its rule promulgated December 22, 1992, to withdraw the criteria for arsenic and selenium for the protection of aquatic life for Washington. Other criteria promulgated by EPA for Washington remain in force.

Washington complied with the public participation requirements in its adoption of State standards. Additionally, because Washington adopted, and EPA approved, water quality criteria for arsenic and selenium for the protection of fresh and marine aquatic life identical to those being withdrawn in today's rule, EPA has determined that additional public participation in this action is unnecessary and constitutes good cause for issuing this final rule without notice and comment. For the same reasons, the Agency has determined that good cause exists to waive the requirement for a 30-day period before the amendment becomes effective and therefore the amendments will be immediately effective.

This action imposes no new regulatory requirements but merely withdraws a Federal regulation. Therefore, this rule imposes no costs and does not require a regulatory impact analysis under Executive Order 12291. The Agency has determined that this action will have no significant impact on a substantial number of small entities. The rule also does not impose any requirements subject to the Paperwork Reduction Act.

List of Subjects in 40 CFR Part 131

Water pollution control, Water quality standards, Toxic pollutants.

Dated: June 8, 1993.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, Chapter I, part 131 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

§ 131.36 [Amended]

2. Section 131.36(d)(14)(ii) is amended in "Fish and Shellfish; Fish" use classification, under the listing of applicable criteria, by removing the entries "Column B1 and B(2)—#2, 10" and "Column C1—#2, 10" in their entirety and by removing "#2" and "#10" from the entry for Column C2.

[FR Doc. 93-15862 Filed 7-2-93; 8:45 am]
BILLING CODE 6560-60-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4543-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rule promulgates for 14 States, the chemical-specific, numeric criteria for priority toxic pollutants necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act (CWA). States determined by EPA to fully comply with section 303(c)(2)(B) requirements are not affected by this rule.

The rule addresses two situations. For a few States, EPA is promulgating a limited number of criteria which were previously identified as necessary in disapproval letters to such States, and which the State has failed to address. For other States, Federal criteria are necessary for all priority toxic pollutants for which EPA has issued section 304(a) water quality criteria guidance and that are not the subject of approved State criteria.

When these standards take effect, they will be the legally enforceable standards in the named States for all purposes and programs under the Clean Water Act, including planning, monitoring, NPDES permitting, enforcement and compliance.

EPA is also withdrawing today the human health criteria published in the 1980 Ambient Water Quality Criteria documents for: Beryllium, Cadmium, Chromium, Lead, Methyl Chloride, Selenium, Silver, and 1,1,1 Trichloroethane. A summary of the criteria recommendation and the notice of availability of each criteria document were published at 45 FR 79318, November 28, 1980.

EFFECTIVE DATE: This rule shall be effective February 5, 1993.

ADDRESSES: The public may inspect the administrative record for this rulemaking, including documentation supporting the aquatic life and human health criteria, and all public comments received on the proposed rule at the Environmental Protection Agency, Standards and Applied Science Division, Office of Science and Technology, room 919 East Tower, Waterside Mall, 401 M Street, SW., Washington, DC 20460 (Telephone: 202–260–1315) on weekdays during the Agency's normal business hours of 8 a.m. to 4:30 p.m. A reasonable fee will be charged for photocopies. Inquiries can be made by calling 202–260–1315.

FOR FURTHER INFORMATION CONTACT: David K. Sabock or R. Kent Ballentine, Telephone 202–260–1315.

SUPPLEMENTARY INFORMATION:

This preamble is organized according to the following outline:

A. Introduction and Overview

1. Introduction

This section of the Preamble introduces the topics which are addressed subsequently and provides a brief overview of EPA's basis and rationale for promulgating Federal criteria for priority toxic pollutants. Section B of this Preamble presents a description of the evolution of the Federal Government's efforts to control toxic pollutants beginning with a discussion of the authorities in the Federal Water Pollution Control Act Amendments of 1972. Also described in some detail is the development of the water quality standards review and revision process which provides for establishing both narrative goals and enforceable numeric requirements for controlling toxic pollutants. This discussion includes the changes enacted in the 1987 Clean Water Act Amendments which are the basis for this rule. Section C summarizes State efforts since 1987 to comply with the requirements of section 303(c)(2)(B). Section D describes EPA's procedure for determining whether a State has fully complied with section 303(c)(2)(B). Section E sets out the rationale and approach for developing the final rule, including a discussion of EPA's legal basis. Section F describes the development of the criteria included in this rule. Section G summarizes the provisions of the final rule. (Section H is reserved.) Section I contains the response to major public comments received on the proposal. Sections J, K, and L address the requirements of Executive Order 12291, the Regulatory Flexibility Act, and the Paperwork Reduction Act, respectively. Section M provides a list of subjects covered in this rule.

A public hearing on the proposed rule was held on December 19, 1991, in Washington, DC. A total of 26 non-EPA people registered at the hearing. The public comment period closed on December 19, 1991. EPA received a total of 153 written comments on the proposed rule.

2. Overview

This rule, which establishes Federal criteria for certain priority toxic pollutants in a number of States, is important for several environmental, programmatic and legal reasons.

First, control of toxic pollutants in surface waters is an important priority to achieve the Clean Water Act's goals and objectives. The most recent National Water Quality Inventory indicates that one-third of monitored river miles, lake acres, and coastal waters have elevated levels of toxics. Forty-seven States and Territories have reported elevated levels of toxic pollutants in fish tissues. States have issued a total of 586 fishing advisories and 135 bans, attributed mostly to industrial discharges and land disposal.

The absence of State water quality standards for toxic pollutants undermines State and EPA toxic control efforts to address these problems. Without clearly established water quality goals, the effectiveness of many of EPA's water programs is jeopardized. Permitting, enforcement, coastal water quality improvement, fish tissue quality protection, certain nonpoint source controls, drinking water quality protection, and ecological protection all depend to a significant extent on complete and adequate water quality standards. Numeric criteria for toxics are essential to the process of controlling toxics because they allow States and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Formally adopted standards are the legal basis for including water quality-based effluent limitations in NPDES permits to control toxic pollutant discharges. The critical importance of controlling toxic pollutants has been recognized by Congress and is reflected, in part, by the addition of section 303(c)(2)(B) to the Act. Congressional impatience with the pace of State toxics control programs is well documented in the legislative history of the 1987 CWA amendments. In order to protect human health, aquatic ecosystems, and successfully implement toxics controls, EPA believes that all actions which are available to the Agency must be taken to ensure that all necessary numeric criteria for priority toxic pollutants are established in a timely manner.

Second, as States and EPA continue the transition from an era of primarily technology-based controls to an era in which technology-based controls are integrated with water quality-based controls, it is important that EPA ensures timely compliance with CWA requirements. An active Federal role is essential to assist States in getting in place complete toxics criteria as part of their pollution control programs. While most States recognize the need for enforceable water quality standards for toxic pollutants, their recent adoption efforts have often been stymied by a variety of factors including limited resources, competing environmental priorities, and difficult scientific, policy and legal challenges. Most water quality criteria for toxic pollutants have been available since 1980. Section 303 of the CWA requires States to review, revise, and adopt updated water quality standards every three years as part of a continuing triennial review process. The water quality standards regulation has required State adoption of numeric criteria for toxic pollutants since 1983 (see 40 CFR 131.11). Despite the availability of scientific guidance documents and clear statutory and regulatory requirements, a preliminary assessment of the water quality standards for all States in February of 1990 showed that only six States had established fully acceptable criteria for toxic pollutants. This rate of toxics criteria adoption is contrary to the CWA requirements and is a reflection of the difficulties faced by States. In such circumstances, it is EPA's responsibility to exercise its CWA authorities to move forward the toxic control program in concert with the statutory scheme.

EPA's action will also help restore equity among the States. The CWA is designed to ensure all waters are sufficiently clean to protect public health and the environment. The CWA allows some flexibility and differences among States in their adopted and approved water quality standards, but it was not designed to reward inaction and inability to meet statutory requirements.

Although most States have made important progress toward satisfying CWA requirements, some have still failed to fully comply with section 303(c)(2)(B). The CWA authorizes EPA to promulgate standards where necessary to meet the requirements of the Act. Where States have not satisfied the CWA requirement to adopt water quality standards for toxic pollutants, which was reemphasized by Congress in 1987, it is imperative that EPA take action.

EPA's ability to oversee State standards-setting activities and to correct deficiencies in State water quality standards is critical to the effective implementation of section 303(c)(2)(B). This rule is a necessary and important component of EPA's implementation of section 303(c)(2)(B) as well as EPA's overall efforts to control toxic pollutants in surface waters.

On February 26, 1992, EPA's Deputy Administrator issued "Guidance on Risk Characterization for Risk Managers and Risk Assessors" which addresses a problem that affects public perception regarding the reliability of EPA's scientific assessments and related regulatory decisions. The guidance noted that "when risk information is presented to the * * * public, the results have been boiled down to a point estimate of risk * * * which do not fully convey the range of information considered and used in developing the assessment." The guidance lays out principles and implementation procedures to address risk assessments in future EPA presentations, reports and decision packages. The guidance specifically notes, *"However, we do not* expect risk assessment documents that are close to completion to be rewritten."

The proposal for this final rule was published in November, 1991, three months prior to the risk assessment guidance being issued. Since the Agency was striving to meet a mid-February statutory deadline for final publication, when the risk guidance was issued the rulemaking package was essentially complete. The specifics of the aquatic life and human health guidelines are discussed in the preamble and in the response to public comments. The actual methodology and criteria documents describe in detail the risk assessment process involved in deriving a water quality criteria and the water quality standards contained in this rule and the resulting risk characterization. The water quality criteria methodology and individual criteria documents are part of the record for this rule. Therefore, while all the specifics of the new risk characterization guidance were not followed in this preamble, the spirit of the guidance is reflected.

Moreover, EPA has initiated a review and update of these criteria methodologies. These updates will be conducted in conformance with the risk characterization guidance and include public involvement and review.

B. Statutory and Regulatory Background

1. Pre-Water Quality Act Amendments of 1987 (Pub. L. 100-4)

Section 303(c) of the 1972 Federal Water Pollution Control Act Amendments (FWPCA) (33 U.S.C. 1313(c)) established the statutory basis for the current water quality standards program. It completed the transition from the previously established program of water quality standards for interstate waters to one requiring standards for all surface waters of the United States.

Although the major innovation of the 1972 FWPCA was technology-based controls, Congress maintained the concept of water quality standards both as a mechanism to establish goals for the Nation's waters and as a regulatory requirement when standardized technology controls for point source discharges and/or nonpoint source controls were inadequate. In recent years, these so-called water quality-based controls have received new emphasis by Congress and EPA in the continuing quest to enhance and maintain water quality to protect the public health and welfare.

Briefly stated, the key elements of section 303(c) are:

(a) A water quality standard is defined as the designated beneficial uses of a water segment and the water quality criteria necessary to support those uses;

(b) The minimum beneficial uses to be considered by States in establishing water quality standards are specified as public water supplies, propagation of fish and wildlife, recreation, agricultural uses, industrial uses and navigation;

(c) A requirement that State standards must protect public health or welfare, enhance the quality of water and serve the purposes of the Clean Water Act;

(d) A requirement that States must review their standards at least once each three year period using a process that includes public participation;

(e) The process for EPA review of State standards which may ultimately result in the promulgation of a superseding Federal rule in cases where a State's standards are not consistent with the applicable requirements of the CWA, or in situations where the Agency determines Federal standards are necessary to meet the requirements of the Act.

Another major innovation in the 1972 FWPCA was the establishment of the National Pollutant Discharge Elimination System (NPDES) which requires point source discharges to obtain a permit before legally discharging to the waters of the United States. In addition to the permit limits established on the basis of technology (e.g. effluent limitations guidelines), the Act requires discharges to meet instream water quality standards. (See section 301(b)(1)(C), 33 U.S.C. 1311(b)(1)(C)).

The water quality standards serve a dual function under the Clean Water Act regulatory scheme. Standards establish narrative and numeric definitions and quantification of the Act's goals and policies (see section 101, 33 U.S.C. 1251) which provide a basis for identifying impaired waters. Water quality standards also establish regulatory requirements which are translated into specific discharge requirements. In order to fulfill this critical function, adopted State criteria must contain sufficient parametric coverage to protect both human health and aquatic life.

In its initial efforts to control toxic pollutants, the FWPCA, pursuant to section 307, required EPA to designate a list of toxic pollutants and to establish toxic pollutant effluent standards based on a formal rulemaking record. Such rulemaking required formal hearings, including cross-examination of witnesses. EPA struggled with this unwieldy process and ultimately promulgated effluent standards for six toxic pollutants, pollutant families or mixtures. (See 40 CFR part 129.) Congress amended section 307 in the 1977 Clean Water Act Amendments by endorsing the Agency's alternative procedure of regulating toxic pollutants by use of effluent limitations guidelines, by amending the procedure for establishing toxic pollutant effluent standards to provide for more flexibility in the hearing process for establishing a record, and by directing the Agency to include sixty-five specific pollutants or classes of pollutants on the toxic pollutant list. EPA published the required list on January 31, 1978 (43 FR 4109). This toxic pollutant list was the basis on which EPA's efforts on criteria development for toxics was focused.

During planning efforts to develop effluent limitations guidelines and water quality criteria, the list of sixty-five toxic pollutants was judged too broad as some of the pollutants were, in fact, general families or classes of organic compounds consisting of many individual chemicals. EPA selected key chemicals of concern within the 65 families of pollutants and identified a more specific list of 129 priority toxic pollutants. Two volatile chemicals and one water unstable chemical were removed from the list (see 46 FR 2266, January 8, 1981; 46 FR 10723, February 4, 1981) so that at present there are 126 priority toxic pollutants. This list is published as appendix A to 40 CFR part 423.

Another critical section of the 1972 FWPCA was section 304(a) (33 U.S.C. 1314(a)). Section 304(a)(1) provides, in pertinent part, that EPA

> * * * shall develop and publish * * * criteria for water quality accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, * * * and (C) on the effects of pollutants on biological community diversity, productivity, and stability, * * *

In order to avoid confusion, it must be recognized that the Clean Water Act uses the term "criteria" in two separate ways. In section 303(c), which is discussed above, the term is part of the definition of a water quality standard. That is, a water quality standard is comprised of designated uses and the criteria necessary to protect those uses. Thus, States are required to adopt regulations or statutes which contain legally achievable criteria. However, in section 304(a), the term criteria is used in a scientific sense and EPA develops recommendations which States consider in adopting regulatory criteria.

In response to this legislative mandate and an earlier similar statutory requirement, EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were Water Quality Criteria (1968 "Green Book") and Quality Criteria for Water (1976 "Red Book"). EPA also sponsored a contract effort with the National Academy of Science—National Academy of Engineering which resulted in Water Quality Criteria, 1972 (1973 "Blue Book"). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the list of 65 toxic pollutants and the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate, since for many pollutants essential information was not available. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants. (See 45 FR 79318.) Since that initial publication, the aquatic life methodology was slightly amended (50 FR 30784, July 29, 1985) and additional criteria was proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in Quality Criteria for Water 1986 (1986 "Gold Book") which is updated from time-to-time. However, the individual criteria documents, as updated, are the official guidance documents.

EPA's criteria documents provide a comprehensive toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) which the Agency recommends to protect aquatic life resources. For human health criteria, the document provides the appropriate reference doses, and if appropriate, the carcinogenic slope factors, and derives recommend criteria. The details of this process are described more fully in a later part of this Preamble.

Programmatically, EPA's initial efforts were aimed at converting a program focused on interstate waters into one addressing all interstate and intrastate surface waters of the United States. Guidance was aimed at the inclusion of traditional water quality parameters to protect aquatic life (e.g., pH, temperature, dissolved oxygen and a narrative "free from toxicity" provision), recreation (e.g., bacteriological criteria) and general aesthetics (e.g., narrative "free from nuisance" provisions). EPA also required State adoption of an antidegradation policy to maintain existing high quality or ecologically unique waters as well as maintain improvements in water quality as they occur.

The initial water quality standards regulation was actually a part of EPA's water quality management regulations implementing section 303(e) (33 U.S.C. 1313(e)) of the Act. It was not comprehensive and did not address toxics or any other criteria specifically. Rather, it simply required States to adopt appropriate water quality criteria necessary to support designated uses. (See 40 CFR 130.17 as promulgated in 40 FR 55334, November 28, 1975).

After several years of effort and faced with increasing public and Congressional concerns about toxic pollutants, EPA realized that proceeding under section 307 of the Act would not comprehensively address in a timely manner the control of toxics through either toxic pollutant effluent standards or effluent limitations guidelines because these controls are only applicable to specific types of discharges. EPA sought a broader, more generally applicable mechanism and decided to vigorously pursue the alternative approach of EPA issuance of scientific water quality criteria documents which States could use to adopt enforceable water quality standards. These in turn could be used as the basis for establishing State and EPA permit discharge limits pursuant to section 301(b)(1)(C) which requires NPDES permits to contain

> * * * any more stringent limitation, including those necessary to meet water quality standards * * *, or required to implement any applicable water quality standard established pursuant to this Act.

Thus, the adoption by States of appropriate toxics criteria applicable to their surface waters, such as those recommended by EPA in its criteria documents, would be translated by regulatory agencies into point source permit limits. Through the use of water quality standards, all discharges of toxics are subject to permit limits and not just those discharged by particular industrial categories. In order to facilitate this process, the Agency amended the water quality standards regulation to explicitly address toxic criteria requirements in State standards. The culmination of this effort was the promulgation of the present water quality standards regulation on November 8, 1983 (40 CFR part 131, 48 FR 51400).

The current water quality standards regulation (40 CFR part 131) is much more comprehensive than its predecessor. The regulation addresses in detail both the beneficial use component and the criteria component of a water quality standard. Section 131.11 of the regulation requires States to review available information and,

> * * * to identify specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.

The regulation provided that either or both numeric and narrative criteria may be appropriately used in water quality standards.

EPA's water quality standards emphasis since the early 1980's reflected the increasing importance placed on controlling toxic pollutants. States were strongly encouraged to adopt criteria in their standards for the priority toxic pollutants, especially where EPA had published criteria guidance under section 304(a) of the Act.

Under the statutory scheme, during the 3-year triennial review period following EPA's 1980 publication of water quality criteria for the protection of human health and aquatic life, States should have reviewed those criteria and adopted standards for many priority toxic pollutants. In fact, State response to EPA's criteria publication and toxics initiative was disappointing. A few States adopted large numbers of numeric toxics criteria, although primarily for the protection of aquatic life. Most other States adopted few or no water quality criteria for priority toxic pollutants. Some relied on a narrative "free from toxicity" criterion, and so-called "action levels" for toxic pollutants or occasionally calculated site-specific criteria. Few States addressed the protection of human health by adopting numeric human health criteria.

In support of the November, 1983, water quality standards rulemaking, EPA issued program guidance entitled, Water Quality Standards Handbook (December 1983) simultaneously with the publication of the final rule. The foreword to that guidance noted EPA's two-fold water quality based approach to controlling toxics: chemical specific numeric criteria and biological testing in whole effluent or ambient waters to comply with narrative "no toxics in toxic amounts" standards. More detailed programmatic guidance on the application of biological testing was provided in the Technical Support Document for Water Quality Based Toxics Control (TSD) (EPA 440/4–85–032, September 1985). This document provided the needed information to convert chemical specific and biologically based criteria into water quality standards for ambient receiving waters and permit limits for discharges to those waters. The TSD focused on the use of bioassay testing of effluent (so-called whole effluent testing or WET methods) to develop effluent limitations within discharge permits. Such effluent limits were designed to implement the "free from toxicity" narrative standards in State water quality standards. The TSD also focused on water quality standards. Procedures and policy were presented for appropriate design flows for EPA's section 304(a) acute and chronic criteria. In 1991, EPA revised and expanded the TSD. (Technical Support Document for Water Quality-based Toxics Control, EPA 505/2–90–001, March 1991.) A Notice of Availability was published in the **Federal Register** on April 4, 1991 (56 FR 13827). All references in this Preamble are to the revised TSD.

The Water Quality Standards Handbook and the TSD are examples of EPA's efforts and assistance that were intended to help, encourage and support the States in adopting appropriate water quality standards for the protection of their waters against the deleterious effects of toxic pollutants. In some States, more and more numeric criteria for toxics were being adopted as well as more aggressive use of the "free from toxics" narratives in setting protective NPDES permit limits. However, by the time of Congressional consideration and action on the CWA reauthorization, most States had adopted few, if any, water quality standards for priority toxic pollutants.

State practices of developing case-by-case effluent limits using procedures that were not standardized in State regulations made it difficult to ascertain whether such procedures were consistently applied. The use of approaches to control toxicity that did not rely on the statewide adoption of numeric criteria for the priority toxic

pollutants generated frustration in Congress. Senator Robert T. Stafford, first chairman and then ranking minority member of the authorizing committee, noted during the Senate debate:

> An important problem in this regard is that few States have numeric ambient criteria for toxic pollutants. The lack of ambient criteria [for toxic pollutants] make it impossible to calculate additional discharge limitations for toxics * * *. It is vitally important that the water quality standards program operate in such a way that it supports the objectives of the Clean Water Act to restore and maintain the integrity of the Nation's Waters. (bracketed material added). A Legislative History of the Water Quality Act of 1987 (Pub. L. 100-4), Senate Print 100-144, USGPO, November 1988 at page 1324.

Other comments in the legislative history similarly note the Congressional perception that the States were failing to aggressively address toxics and that EPA was not using its oversight role to push the States to move more quickly and comprehensively. Thus Congress developed the water quality standards amendments to the Clean Water Act for reasons similar to those strongly stated during the Senate debate by a chief sponsor, Senator John H. Chafee,

> A cornerstone of the bill's new toxic pollution control requirements is the so called beyond-BAT program * * *. Adopting the beyond BAT provisions will assure that EPA continues to move forward rapidly on the program * * *. If we are going to repair the damage to those water bodies that have become highly degraded as a result of toxic substances, we are going to have to move forward expeditiously on this beyond-BAT program. The Nation cannot tolerate endless delays and negotiations between EPA and States on this program. Both entities must move aggressively in taking the necessary steps to make this program work within the time frame established by this Bill * * *. Ibid, at page 1309.

This Congressional impatience with the pace of State and EPA progress and an appreciation that the lack of State standards for toxics undermined the effectiveness of the entire CWA-based scheme, resulted in the 1987 adoption of stringent new water quality standard provisions in the Water Quality Act amendments.

2. The Water Quality Act Amendments of 1987 (Pub. L. 100-4)

a. Description of the New Requirements

The 1987 Amendments to the Clean Water Act added Section 303(c)(2)(B) which provides:

> Whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection, or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria for all toxic pollutants listed pursuant to section 307(a)(1) of this Act for which criteria have been published under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses. Such criteria shall be specific numerical criteria for such toxic pollutants. Where such numerical criteria are not available, whenever a State reviews water quality standards pursuant to paragraph (1), or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria based on biological monitoring or assessment methods consistent with information published pursuant to section 304(a)(8). Nothing in this section shall be construed to limit or delay the use of effluent limitations or other permit conditions based on or involving biological monitoring or assessment methods or previously adopted numerical criteria.

b. EPA's Initial Implementing Actions for Sections 303(c) and 304(l)

The addition of this new requirement to the existing water quality standards review and revision process of section 303(c) did not change the existing procedural or timing provisions. For example, section 303(c)(1) still requires that States review their water quality standards at least once each 3 year period and transmit the results to EPA for review. EPA's oversight and promulgation authorities and statutory schedules in section 303(c)(4) were likewise unchanged. Rather, the provision required the States to place heavy emphasis on adopting numeric chemical-specific criteria for toxic pollutants (i.e., rather than just narrative approaches) during the next triennial review cycle. As discussed in the previous section, Congress was frustrated that States were not using the numerous section 304(a) criteria that EPA had developed, and was continuing to develop, to assist States in controlling the discharge of priority toxic pollutants. Therefore, for the first time in the history of the Clean Water Act, Congress took the unusual action of explicitly mandating that States adopt numeric criteria for specific toxic pollutants.

In response to this new Congressional mandate, EPA redoubled its efforts to promote and assist State adoption of water quality standards for priority toxic pollutants. EPA's efforts included the development and issuance of guidance to the States on acceptable implementation procedures for several new sections of the Act, including sections 303(c)(2)(B) and 304(l).

The 1987 CWA Amendments added to, or amended, other CWA Sections related to toxics control. Section 304(l) (33 U.S.C. 1314(l)) was an important corollary amendment because it required States to take actions to identify waters adversely affected by toxic pollutants, particularly those waters entirely or substantially impaired by point sources. Section 304(l) entitled "Individual Control Strategies for Toxic Pollutants," requires in part, that States identify and list waterbodies where the designated uses specified in the applicable water quality standards cannot reasonably be expected to be achieved because of point source discharge of toxic pollutants. For each segment so identified, the State is required to develop individual control strategies to reduce the discharge of toxics from point sources so that in conjunction with existing controls on point and nonpoint sources, water quality standards will be attained. To assist the States in identifying waters under section 304(l), EPA's guidance listed a number of potential sources of available data for States to review. States generally assembled data for a broad spectrum of pollutants, including the priority toxic pollutants, which could be useful in complying with sections 304(l) and 303(c)(2)(B). In fact, between February 1988 and October 1988, EPA assembled pollutant candidate lists for section 304(l) which were then transmitted to each jurisdiction. Thus, each State had a preliminary list of pollutants that had been identified as present in, or discharged to, surface waters. Such lists were limited by the quantity and distribution of available effluent and ambient monitoring data for priority toxic pollutants. This listing exercise further emphasized the need for water quality standards for toxic pollutants. Lack of standards increased the difficulty of identifying impaired waters. On the positive side, the data gathered in support of the 304(l) activity proved helpful in identifying those pollutants most obviously in need of water quality standards.

EPA, in devising guidance for section 303(c)(2)(B), attempted to provide States the maximum flexibility that complied with the express statutory language but also with the overriding congressional objective: Prompt adoption and implementation of numeric toxics criteria. EPA believed that flexibility was important so that each State could comply with section 303(c)(2)(B) and to the extent possible, accommodate its existing water quality standards regulatory approach. The options EPA identified are described in the next Section of this Preamble. EPA's program guidance was issued in final form on December 12, 1988 but was not

substantially different from earlier drafts available for review by the States. The availability of the guidance was published in a Federal Register Notice on January 5, 1989 (54 FR 346).

3. EPA's Program Guidance for Section 303(c)(2)(B)

EPA's section 303(c)(2)(B) program guidance identified three options that could be used by a State to meet the requirement that the State adopt toxic pollutant criteria "* * * the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses."

Option 1. Adopt statewide numeric criteria in State Water Quality Standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

This option is the most comprehensive approach to satisfy the statutory requirements because it would include all of the priority toxic pollutants for which EPA has prepared section 304(a) criteria guidance for either or both aquatic life protection and human health protection. In addition to a simple adoption of EPA's section 304(a) guidance as standards, a State must select a risk level for those toxic pollutants which are carcinogens (i.e., that cause, or may cause cancer in humans).

Many States found this Option attractive because it ensured comprehensive coverage of the priority toxic pollutants with scientifically defensible criteria without the need to conduct a resource-intensive evaluation of the particular segments and pollutants requiring criteria. This option would also not be more costly to dischargers than other options because permit limits would only be based on the regulation of the particular toxic pollutants in their discharges and not on the total listing in the water quality standards. Thus, actual permit limits should be the same under any of the options.

Option 2. Adopt chemical-specific numeric criteria for priority toxic pollutants that are the subject of EPA section 304(a) criteria guidance, where the State determines based on available information that the pollutants are present or discharged and can reasonably be expected to interfere with designated uses.

This option results in the adoption of numeric water quality standards for some subset of those pollutants for which EPA has issued section 304(a) criteria guidance based on a review of current information. To satisfy this Option, the guidance recommended that States use the data gathered during the section 304(l) water quality assessments as a starting point to identify those water segments that need water quality standards for priority toxic pollutants. That data would be supplemented by a State and public review of other data sources to ensure sufficient breadth of coverage to meet the statutory objective. Among the data available to be reviewed were: (1) Ambient water monitoring information, including those for the water column, sediment, and aquatic life (e.g., fish tissue data); (2) NPDES permit applications and permittee self-monitoring reports; (3) effluent guideline development documents, many of which contain priority toxic pollutant scans; (4) pesticide and herbicide application information and other records of pesticide or herbicide inventories; (5) public water supply source monitoring data noting pollutants with maximum contaminant levels (MCLs); and (6) any other relevant information on toxic pollutants collected by Federal, State, industry, agencies, academic groups, or scientific organizations. EPA also recommended that States selecting this option adopt a translator provision similar to that described in Option 3 but applicable to all chemicals causing toxicity, and not just priority toxic pollutants.

This Option 2 review resulted in a State proposing new or revised water quality standards and providing an opportunity for public review and comment on the pollutants, criteria, and water bodies included. Throughout this process, EPA's Regional Offices were available to assist States by providing additional guidance and technical assistance on applying EPA's recommended criteria to particular situations in the States.

Option 3. Adopt a procedure to be applied to a narrative water quality standard provision prohibiting toxicity in receiving waters. Such procedures would be used by the State in calculating derived numeric criteria which must be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses.

The combination of a narrative standard (e.g., "free from toxics in toxic amounts") and an approved translator mechanism as part of a State's water quality standards satisfies the requirements of section 303(c)(2)(B). As noted above, such a procedure is also a valuable supplement to either option 1 or 2. There are several regulatory and scientific requirements EPA's guidance specifies are essential to ensure acceptable scientific quality and full involvement of the public and EPA in this approach. Briefly stated these are:

- The procedure (i.e., narrative criterion and translator) must be used to calculate numeric water quality criteria;
- The State must demonstrate to EPA that the procedure results in numeric criteria that are sufficiently protective to meet the goals of the Act;
- The State must provide for full opportunity for public participation during the adoption of the procedure;
- The procedure must be formally adopted as a State rule and be mandatory in application; and
- The procedure must be submitted for review and approval by EPA as part of the State's water quality standards regulation.

The scientific elements of a translator are similar to EPA's 304(a) criteria methodologies when applied on a site-specific basis. For example, aquatic criteria are developed using a sufficient number and diversity of aquatic species representative of the biological assemblage of a particular water body. Human health criteria focus on determining appropriate exposure conditions (e.g. amount of aquatic life consumed per person per day) rather than underlying pollutant toxicity. The results of the procedures are scientifically defensible criteria that are protective for the site's particular conditions. EPA's review of translator procedures includes an evaluation of the scientific merit of the procedure using the section 304(a) methodology as a guide.

Ideally, States adopting option 3 translator procedures should prepare a preliminary list of criteria and specify the waters the criteria apply to at the time of adoption. Although under option 3 the State retains flexibility to derive new criteria without revising the adopted standards, establishing this preliminary list of derived criteria at the time of the triennial review will assist the public in determining the scope of the adopted standards, and help ensure that the State ultimately complies with the requirement to establish criteria for all pollutants that can "reasonably be expected" to interfere with uses. EPA believes that States selecting solely option 3 should prepare an analysis (similar to that required of option 2 States) at the time of the triennial review identifying pollutants needing criteria.

EPA's December 1988 guidance also addressed the timing issue for State compliance with section 303(c)(2)(B). The statutory directive was clear: All State standards triennial reviews initiated after passage of the Act must include a consideration of numeric toxic criteria.

The structure of section 303(c) is to require States to review their water quality standards at least once each three year period. Section 303(c)(2)(B) instructs States to include reviews for toxics criteria whenever they initiate a triennial review. EPA initially looked at February 4, 1990, the 3-year anniversary of the 1987 CWA amendments, as a convenient point to index State compliance. The April 1990 Federal Register Notice used this index point for the preliminary assessment. However, some States were very nearly completing their State administrative processes for ongoing reviews when the 1987 amendments were enacted and could not legally amend those proceedings to address additional toxics criteria. Therefore, in the interest of fairness, and to provide such States a full 3-year review period, EPA's FY 1990 Agency Operating Guidance provided that "By the end of the FY 88–90 triennium, States should have completed adoption of numeric criteria to meet the section 303(c)(2)(B) requirements." (p.48.) The FY 88–90 triennium ended on September 30, 1990.

Clean Water Act section 303(c) does not provide penalties for States that do not complete timely water quality standards reviews. In no previous case has the EPA Administrator found that State failure to complete a review within three years jeopardized the public health or welfare to such an extent that promulgation of Federal standards pursuant to section 303(c)(4)(B) was justified. The pre-1987 CWA never mandated State adoption of priority toxic pollutants or other specific criteria. EPA generally relied on its water quality standards regulation (40 CFR 131.11) and its criteria and program guidance to the States on appropriate parametric coverage in State water quality standards to encourage State adoption of water quality standards. However, since the 1987 statutory amendments, the programmatic environment has changed. Beyond the increased Congressional and public concern, about the relative importance of toxic pollutant controls, there is increased evidence of toxic pollution problems in our Nation's waters. In response, the Agency in this rulemaking is proceeding pursuant to section 303(c)(4)(B) and 40 CFR 131.22(b) to rectify a longstanding program deficiency.

The current regulation at 40 CFR Part 131 in conjunction with the statutory language provides a clear and unambiguous basis and process for today's Federal promulgation.

C. State Actions Pursuant to Section 303(c)(2)(B)

In recent years, there has been substantial progress by many States in the adoption, and EPA approval, of water quality standards for toxic pollutants. Virtually all States have at least proposed new toxics criteria for priority toxic pollutants since section 303(c)(2)(B) was added to the CWA in February of 1987. Unfortunately, not all such State proposals address, in a comprehensive manner, the requirements of section 303(c)(2)(B). For example, some States have proposed to adopt criteria to protect aquatic life, but not human health; other States have proposed human health criteria which do not address major human exposure pathways. In addition, in some cases final adoption of proposed State toxics criteria which would be approvable by EPA has been substantially delayed due to controversial and difficult issues associated with the toxics criteria adoption process. For purposes of today's rulemaking, it is EPA's judgment that 43 States completed actions which fully satisfy the requirements of section 303(c)(2)(B).

In sum, States have devoted substantial resources, and have made substantial progress, in adopting new or revised numeric criteria for priority pollutants. In so doing, they have addressed a number of significant and difficult issues. These efforts have generated extensive examination by dischargers, States, environmental groups and the public on all aspects of the CWA water quality criteria and related issues. It amounts to a multi-year consideration of the issues that are central to this proposed and final rulemaking.

D. Determining State Compliance With Section 303(c)(2)(B)

1. EPA's Review of State Water Quality Standards for Toxics

The EPA Administrator has delegated the responsibility and authority for review and approval or disapproval of all State water quality standards actions to the 10 EPA Regional Administrators (see 40 CFR 131.21). State section 303(c)(2)(B) actions are thus submitted to the appropriate EPA Regional Administrator for review and approval. This de-centralized EPA system for State water quality standards review and approval is guided by EPA Headquarters Office of Water, which issues national policies and guidance to the States and Regions such as the annual Office of Water Operating Guidance and various technical manuals.

For purposes of evaluating State compliance with CWA section 303(c)(2)(B), EPA relied on the statutory language, the existing water quality standards regulation, and section 303(c)(2)(B) national guidance to provide the basis for EPA review. In some cases, individual Regions also used Regional policies and procedures in reviewing State section 303(c)(2)(B) actions. The flexibility provided by the national guidance, coupled with subtle differences in Regional policies and procedures, contributed to some differences in the approaches taken by States to satisfy section 303(c)(2)(B) requirements.

As discussed previously, EPA's final guidance on compliance with section 303(c)(2)(B) was developed to provide States with the necessary flexibility to allow State standards revisions that would complement the State's existing water quality standards program and still comply with section 303(c)(2)(B). As guidance, it described the range of acceptable approaches and EPA's recommendations. Some innovative State approaches were expected as well as differences in terms of criteria coverage, stringency and application procedures.

Although the guidance provided for State flexibility, it was also consistent with existing water quality standards regulation requirements of 40 CFR 131.11 that explicitly require State criteria to be sufficient to protect designated uses. Such water quality criteria also must be based on sound scientific rationale and support the most sensitive use designated for a water body.

The most complicated EPA compliance determinations involve States that selected EPA Options 2 or 3. Since most States use EPA's section 304(a) criteria guidance, where States select Option 1, EPA normally is able to focus Agency efforts on verifying that all available EPA criteria are included, appropriate cancer risk levels are selected, and that sufficient application procedures are in place (e.g. laboratory analytical methods, mixing zones, flow condition, etc.).

However, for States using EPA's Option 2 or 3, substantially more EPA evaluation and judgment was required because the Agency must evaluate which priority pollutants and, in some

cases, segments or designated uses, require numeric criteria. Under these options, the State must adopt or derive numeric criteria for priority toxic pollutants for which EPA has section 304(a) criteria, "* * * the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State * * *." The necessary justification and the ultimate coverage and acceptability of a State's actions vary State-to-State because of differences in the adequacy of available monitoring information, local waterbody use designations, the effluent and nonpoint source controls in place, and different approaches to the scientific basis for criteria.

In submitting criteria for the protection of human health, States were not limited to a 1 in 1 million risk level (10^{-6}). EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations. If a State selects a criterion that represents an upper bound risk level less protective than 1 in 100,000 (i.e., 10^{-5}), however, the State needed to have substantial support in the record for this level. This support focused on two distinct issues. First, the record must include documentation that the decision maker considered the public interest of the State in selecting the risk level, including documentation of public participation in the decision making process as required by the water quality standards regulation at 40 CFR 131.20(b). Second, the record must include an analysis showing that the risk level selected, when combined with other risk assessment variables, is a balanced and reasonable estimate of actual risk posed, based on the best and most representative information available. The importance of the estimated actual risk increases as the degree of conservatism in the selected risk level diminishes. EPA carefully evaluated all assumptions used by a State if the State chose to alter any one of the standard EPA assumption values.

Where States selected Option 3, EPA reviews must also include an evaluation of the scientific defensibility of the translator procedure. EPA must also verify that a requirement to apply the translator whenever toxics may reasonably be expected to interfere with designated uses (e.g., where such toxics exist or are discharged) is included in the State's water quality standards. Satisfactory application procedures must also be developed by States selecting Option 3.

In general, each EPA Region made compliance decisions based on whatever information was available at the time of the triennial review. For some States, information on the presence and discharge of priority toxic pollutants is extremely limited. Nevertheless, during the period of February 1988 to October 1990, to supplement State efforts, EPA assembled the available information and provided each State with various pollutant candidate lists in support of the section 304(l) and section 303(c)(2)(B) activities. These were based in part on computerized searches of existing Agency data bases.

Beginning in 1988, EPA provided States with candidate lists of priority toxic pollutants and water bodies in support of CWA Section 304(l) implementation. These lists were developed because States were required to evaluate existing and readily available water-related data in order to comply with Section 304(l). 40 CFR 130.10(d). A similar "strawman" analysis of priority pollutants potentially requiring adoption of numeric criteria under Section 303(c)(2)(B) was furnished to most States in September or October of 1990 for their use in on-going and subsequent triennial reviews. The primary differences between the "strawman" analysis and the section 304(l) candidate lists were that the "strawman" analysis: (1) Organized the results by chemical rather than by water body, (2) included data for certain STORET monitoring stations that were not used in constructing the candidate lists, (3) included data from the Toxics Release Inventory database, and (4) did not include a number of data sources used in preparing the candidate lists (e.g. those, such as fish kill information, that did not provide chemical specific information).

In its 1988 section 303(c)(2)(B) guidance, EPA urged States, at a minimum, to use the information gathered in support of section 304(l) requirements as a starting point for identifying which priority toxic pollutants require adoption of numeric criteria. EPA also encouraged States to consider the presence or potential construction of facilities that manufacture or use priority toxic pollutants as a strong indication of the need for toxics criteria. Similarly, EPA indicated to States that the presence of priority pollutants in ambient waters (including those in sediments or in aquatic life tissue) or in discharges from point or nonpoint sources also be considered as an indication that toxics criteria should be adopted. A limited amount of data on the effluent characteristics of NPDES discharges was readily available to States. States were also expected to take into account newer information as it became available, such as information in annual reports from the Toxic Chemical Release Inventory requirements of the Emergency Planning and Community Right-To-Know Act of 1986. (Title III, Pub. L. 99–499.)

In summary, EPA and the States had access to a variety of information gathered in support of section 304(l), section 303(c)(2)(B), and section 305(b) activities. For some States, as noted above, such information for priority toxic pollutants is extremely limited. In the final analysis, the Regional Administrator made a judgment on a duly submitted State standards triennial review based on the State's record and the Region's independent knowledge of the facts and circumstances surrounding the State's actions. These actions, taken in consultation with the Office of Water, determined which State actions were sufficiently consistent with the coverage contemplated in the statute to justify approval. These approval actions include allowable variations among State water quality standards. EPA approval indicates that, based on the record, the State water quality standards met the requirements of the Act.

2. Determining Current Compliance Status

The following summarizes the process generally followed by the Agency in assessing compliance with section 303(c)(2)(B).

A State was determined to be in full compliance with the requirements of section 303(c)(2)(B) if,

a. The State had submitted a water quality standards package for EPA review since enactment of the 1987 Clean Water Act amendments or was determined to be already in compliance, and,

b. The State adopted water quality standards are effective under State law and consistent with the CWA and EPA's implementing regulations (EPA's December 1988 guidance described three Options, any one, or a combination of which EPA suggested States could adopt for compliance with the CWA and EPA regulations), and

c. EPA has issued a formal approval determination to the State.

States meeting these criteria are not included in this final rulemaking.

States which adopted standards following Option 1 generally have been found to satisfy section 303(c)(2)(B). An exception exists for selected States which attempted to follow Option 1 by adopting all EPA section 304(a) criteria by reference. EPA has withheld

approval for one State which has adopted such a reference into their standards because the adopted standards did not specify application factors necessary to implement the criteria (e.g., a risk level for carcinogens). Other States have achieved full compliance following options 1, 2, 3, or some combination of these options.

As of the date of signature of today's rule, the Agency has determined that 43 States and Territories are in full compliance with the requirements of section 303(c)(2)(B). Compliance status for all States and Territories is set forth in Table 1.

TABLE 1.—ASSESSMENT OF STATE COMPLIANCE WITH CWA SECTION 303(c)(2)(B)

State	Is State in compliance with section 303(c)(2)(B)?
Alabama	Yes.
Alaska	No.
Arizona	Yes.
Arkansas	No.
California	No.
Colorado	Yes.
Connecticut	Yes.
Delaware	Yes.
Florida	No.
Georgia	Yes.
Hawaii	Yes.
Idaho	No.
Illinois	Yes.
Indiana	Yes.
Iowa	Yes.
Kansas	No.
Kentucky	Yes (1).
Louisiana	Yes.
Maine	Yes.
Maryland	Yes.
Massachusetts	Yes.
Michigan	No.
Minnesota	Yes.
Mississippi	Yes.
Missouri	Yes.
Montana	Yes.
Nebraska	Yes.
Nevada	No.
New Hampshire	Yes.
New Jersey	No.
New Mexico	Yes (2).
New York	Yes.
North Carolina	Yes.
North Dakota	Yes.
Ohio	Yes.
Oklahoma	Yes.
Oregon	Yes.
Pennsylvania	Yes.
Rhode Island	No.
South Carolina	Yes.
South Dakota	Yes.
Tennessee	Yes.
Texas	Yes.
Utah	Yes.
Vermont	No.
Virginia	Yes.
Washington	No.
West Virginia	Yes.
Wisconsin	Yes.
Wyoming	Yes.
American Samoa	Yes.
Commonwealth of the Northern Mariana Islands.	Yes.
District of Columbia	No.
Guam	Yes.
Puerto Rico	No.
Tr. Territories	Yes.
Virgin Islands	Yes.

Notes to Table 1

(1) At the initiation of this rulemaking, Kentucky was determined to be in compliance with the Act. On January 27, 1992, the Commonwealth of Kentucky deleted the water quality criteria for dioxin from the Kentucky water quality standards. Although EPA has not formally acted to disapprove Kentucky's action to delete the criteria, information is available which documents the need for dioxin criteria for the Commonwealth of Kentucky. Any potential EPA promulgation arising from a future EPA action to disapprove the deletion of the dioxin criteria for Kentucky will be through a rulemaking independent of today's rule.

(2) At the initiation of this rulemaking, New Mexico was determined to be in compliance with the Act. On October 8, 1991, New Mexico adopted revisions to its standards which affected compliance with acute toxicity criteria. On January 13, 1992, EPA disapproved the State's action, thus initiating the possibility of Federal promulgation should the State fail to adopt acceptable standards within 90 days from the EPA notice. Any potential EPA promulgation arising from this disapproval will be through a rulemaking independent of today's rule. EPA policy has been and continues to be that we prefer States and Territories to adopt their own standards consistent with the requirements of the Clean Water Act.

(3) EPA has become aware that several of the State water quality standards approved as complying with section 303(c)(2)(B) have been challenged in State courts for various reasons. Additional such challenges may occur in the future. In cases where such State rules are remanded or otherwise set aside, or intentionally withdrawn by the State for any reason, and the State does not pursue in good faith correcting such defects in a timely manner, it is EPA's intention to initiate appropriate rulemaking to put in place appropriate criteria for priority toxic pollutants to bring State water quality standards into compliance with the Clean Water Act.

E. Rationale and Approach for Developing the Final Rule

The addition of section 303(c)(2)(B) to the Clean Water Act was an unequivocal signal to the States that Congress wanted toxics criteria in the State's water quality standards. The legislative history notes that the "beyond BAT" program (i.e., controls necessary to comply with water quality standards that are more stringent than technology-based controls) was the cornerstone to the Act's toxic pollution control requirements.

The major innovation of the 1972 Clean Water Act Amendments was the concept of effluent limitation guidelines which were to be incorporated into NPDES permits. In many cases, this strategy has succeeded in halting the decline in the quality of the Nation's waters and, often, has provided improvements. However, the effluent limitation guidelines for industrial discharges and the similar technology-based secondary treatment requirements for municipal discharges are not capable, by themselves, of ensuring that the fishable-swimmable goals of the Clean Water Act will be met for all waters.

The basic mechanism to accomplish this in the Act is water quality standards. States are required to periodically review and revise these standards to achieve the goals of the Act. In the 1987 CWA amendments, Congress focused on addressing toxics in several sections of the Act, but special attention was placed on the section 303 water quality standards program requirements. Congress intended that the adoption of numeric criteria for toxics would result in direct improvements in water quality by forcing, where necessary, effluent limits more stringent than those resulting from technology-based effluent limitations guidelines.

As the legislative history demonstrates, Congress was dissatisfied with the piecemeal, slow progress being made by States in setting standards for toxics. Congress reacted by legislating new requirements and deadlines directing the States to establish toxics criteria for pollutants addressed in EPA section 304(a) criteria guidance, especially for those priority toxic pollutants that could reasonably be expected to interfere with designated uses. In today's action, EPA is exercising its authority under section 303(c)(4) to promulgate criteria where States have failed to act in a timely manner.

The previous section of this preamble explains EPA's approach to evaluating the adequacy of State actions in response to section 303(c)(2)(B). This section explains EPA's legal basis for issuing today's rule, and discusses EPA's general approach for developing the State-specific requirements in Section 131.36(d).

In addition to the Congressional directive and the legal basis for this action, there are a number of environmental and programmatic reasons why further delay in

establishing water quality standards for toxic pollutants is no longer acceptable.

Prompt control of toxic pollutants in surface waters is critical to the success of a number of Clean Water Act programs and objectives, including permitting, enforcement, fish tissue quality protection, coastal water quality improvement, sediment contamination control, certain nonpoint source controls, pollution prevention planning, and ecological protection. The decade long delay in State adoption of water quality standards for toxic pollutants has had a ripple effect throughout EPA's water programs. Without clearly established water quality goals, the effectiveness of many water programs is jeopardized. For too long, the absence of water quality standards has had a chilling effect on toxic control progress in many State and Federal programs.

Failure to take prompt action at this juncture would also undermine the continued viability of the current statutory scheme to establish standards. Excessive delay subverts the entire concept of the triennial review cycle which is intended to combine current scientific information with the results of previous environmental control programs to direct continuing progress in enhancing water quality.

Finally, another reason to proceed expeditiously is to bring closure to this long-term effort and allow State attention and resources to be directed towards important, new national program initiatives. Until standards for toxic pollutants are in place, neither EPA nor the States can fully focus on the emerging, ecologically-based water quality activities such as wetlands criteria, biological criteria and sediment criteria.

1. Legal Basis

Clean Water Act Section 303(c) specifies that adoption of water quality standards is primarily the responsibility of the States. However, Section 303(c) also describes a role for EPA of overseeing State actions to ensure compliance with CWA requirements. If the Agency's review of the State's standards finds flaws or omissions, then the Act authorizes EPA to initiate promulgation to correct the deficiencies (see section 303(c)(4)). The water quality standards promulgation authority has been used by EPA to issue final rules on nine separate occasions. These actions have addressed both insufficiently protective State criteria and/or designated uses and failure to adopt needed criteria. Thus, today's action is not unique, although it would affect more States and pollutants than previous actions taken by the Agency.

The Clean Water Act in section 303(c)(4) provides two bases for promulgation of Federal water quality standards. The first basis, in paragraph (A), applies when a State submits new or revised standards that EPA determines are not consistent with the applicable requirements of the Act. If, after EPA's disapproval, the State does not promptly amend its rules so as to be consistent with the Act, EPA must promulgate appropriate Federal water quality standards for that State. The second basis for EPA's action is paragraph (B), which provides that EPA shall promptly initiate promulgation "* * * in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this Act." EPA is relying on both section 303(c)(4)(A) and section 303(c)(4)(B) as the legal basis for this rule.

Section 303(c)(4)(A) supports today's action for several States. These States have submitted criteria for some number of priority toxic pollutants and EPA has disapproved the State's adopted standards. The basis for EPA's disapproval generally has been the lack of sufficient criteria or particular criteria that were insufficiently stringent. In these cases, EPA has, by letter to the State, noted the deficiencies and specified the need for corrective action. Not having received an appropriate correction within the statutory time frame, EPA is today promulgating the needed criteria. The action in today's rule pursuant to section 303(c)(4)(A) may differ from those taken pursuant to section 303(c)(4)(B) by being limited to criteria for specific priority toxic pollutants, particular geographic areas, or particular designated uses.

Section 303(c)(4)(B) is the basis for EPA's requirements for most States. For these States, the Administrator has determined that promulgating criteria is necessary to bring the States into compliance with the requirements of the CWA. In these cases, EPA is promulgating, at a minimum, criteria for all priority toxic pollutants not addressed by approved State criteria. EPA is also promulgating criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human exposure pathways, or where such previously-approved State criteria are not applicable to all appropriate designated uses. EPA's action pursuant to section 304(c)(4)(B) may include several situations.

In some cases, the State has failed to adopt and submit for approval any criteria for those priority toxic pollutants for which EPA has published criteria. This includes those States that have not submitted triennial reviews. In other cases, the State has adopted and EPA has approved criteria for either aquatic life or human health, but not both. In yet a third situation, States have submitted some criteria but not all necessary criteria. Lastly, one State has submitted criteria that do not apply to all appropriate geographic sections of the waters of the State.

The use of section 303(c)(4)(B) requires a determination by the Administrator "* * * that a revised or new standard is necessary to meet the requirements of * * *" the Act. The Administrator's determination could be supported in different ways.

One approach would be for EPA to undertake a time-consuming effort to research and marshall data to demonstrate the need for promulgation for each criteria for each stream segment or waterbody in each State. This would include evidence for each Section 307(a) priority toxic pollutant for which EPA has Section 304(a) criteria and that there is a "discharge or presence" which could reasonably "be expected to interfere with" the designated use. This approach would not only impose an enormous administrative burden, but would be contrary to the statutory scheme and the compelling Congressional directive for swift action reflected in the 1987 addition of section 303(c)(2)(B) to the Act.

An approach that is more reasonable and consistent with Congressional intent focuses on the State's failure to complete the timely review and adoption of the necessary standards required by section 303(c)(2)(B) despite information that priority toxic pollutants may interfere with designated uses of the State's waters. This approach is consistent with the fact that in enacting section 303(c)(2)(B) Congress expressed its determination of the necessity for prompt adoption and implementation of water quality standards for toxic pollutants. Therefore, a State's failure to meet this fundamental 303(c)(2)(B) requirement of adopting appropriate standards constitutes a failure "to meet the requirements of the Act." That failure to act can be a basis for the Administrator's determination under section 303(c)(4)(B) that new or revised criteria are necessary to ensure designated uses are adequately protected. Here, this determination is buttressed by the existence of evidence of the discharge or presence of priority toxic pollutants in

a State's waters for which the State has not adopted numeric water quality criteria. The Agency has compiled an impressive volume of information in the record for this rulemaking on the discharge or presence of toxic pollutants in State waters. This data supports the Administrator's determination pursuant to section 303(c)(4)(B). The record was available to the public for review during this rulemaking period and continues to be on file.

The Agency's choice to base the determination on the second approach is supported by both the explicit language of the statutory provision and by the legislative history. Congress added subsection 303(c)(2)(B) to section 303 with full knowledge of the existing requirements in section 303(c)(1) for triennial water quality standards review and submission to EPA and in section 303(c)(4)(B) for EPA promulgation. There was a clear expectation that these provisions be used in concert to overcome the programmatic delay that many legislators criticized and achieve the Congressional objective of the rapid availability of enforceable water quality standards for toxic pollutants. As quoted earlier, chief Senate sponsors, including Senators Stafford, Chaffee and others, wanted the provision to eliminate State and EPA delays and force aggressive action.

In normal circumstances, it might be argued that to exercise section 303(c)(4)(B) the Administrator might have the burden of marshalling conclusive evidence of "necessity" for Federally promulgated water quality standards. However, in adopting section 303(c)(2)(B), Congress made clear that the "normal" procedure had become inadequate. The specificity and deadline in section 303(c)(2)(B) were layered on top of a statutory scheme already designed to achieve the adoption of toxic water quality standards. Congressional action to adopt a partially redundant provision was driven by their impatience with the lack of State progress. The new provision was essentially a Congressional "determination" of the necessity for new or revised comprehensive toxic water quality standards by States. In deference to the principle of State primacy, Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. However, this Congressional indulgence does not alter the fact that section 303(c)(2)(B) changed the nature of the CWA State/EPA water quality standard relationship. The new provision and its legislative background indicate that the Administrator's determination to invoke his section 303(c)(4)(B) authority in this circumstance can be met by a generic finding of inaction on the part of a State and without the need to develop data for individual stream segments. Otherwise, the Agency could face a heavy data gathering burden of justifying the need for each Federal criterion and the process could stretch for years and never be realized. To interpret the combination of subsections (c)(2)(B) and (c)(4) as an effective bar to prompt achievement of statutory objectives would be a perverse conclusion and render section 303(c)(2)(B) essentially meaningless.

A second strong argument against requiring EPA to shoulder a heavy burden to exercise section 303(c)(4)(B) authority is that it would invert the traditional statutory scheme of EPA as national overseer and States as the entity with the greatest local expertise. The CWA provides States the flexibility to tailor water quality standards to local conditions and needs based upon their wealth of first-hand experience, knowledge and data. However, this allowance for flexibility is based on an assumption of reasoned and timely State action, not an abdication of State responsibility by failure to act. EPA does not possess the local expertise or resources necessary to successfully tailor State water quality standards. Therefore, the fact that the CWA allows States flexibility in standards development does not impose an inappropriate burden on EPA in the exercise of its oversight promulgation responsibilities. A broad Federal promulgation based on a showing of State inaction coupled with basic information on the discharge and presence of toxic pollutants meets the statutory objective of having criteria in places that are protective of public health and the environment. Without local expertise to help accurately narrow this list of pollutants and segments requiring criteria, there is no assurance of comparable protection. Nothing in the overall statutory water quality standards scheme anticipates EPA would develop this expertise in lieu of the States. EPA's lack of familiarity with local conditions argues strongly for a simple "determination" test to trigger section 303(c)(4)(B) promulgations. It also supports the concept of an across-the-board rulemaking for all priority toxic pollutants with section 304(a) criteria.

A final major reason supporting a simple determination to trigger 303(c)(4)(B) action is that comprehensive Federal promulgation imposes no undue or inappropriate burden on States or dischargers. It merely puts in place standards for toxic pollutants that are utilized in implementing Clean Water Act programs. Under this rulemaking, a State still retains the ability to adopt alternative water quality standards simply by completing its standards adoption process. Upon EPA approval of those standards, EPA will take actions to withdraw the Federally-promulgated criteria.

Federal promulgation of State water quality standards should be a course of last resort. It is symptomatic of something awry with the basic statutory scheme. Yet, when it is necessary to exercise this authority, as the compelling evidence suggests in this case, there should be no undue impediments to its use. Section 303(c)(4) is replete with deadlines and Congressional directives for the Administrator to act "promptly" in these cases. The statute indicates that the Administrator of EPA, is to "* * * promptly prepare and publish proposed regulations setting forth a revised or new water quality standard * * *" and "* * * shall promulgate any revised or new standard * * * not later than 90 days after he published such proposed standards, unless prior to such promulgation, such State has adopted a revised or new standard which the Administrator determines to be in accordance with the Act." The adoption of section 303(c)(2)(B) reinforced this emphasis on expeditious actions. EPA has demonstrated extensive deference to State primacy and a willingness to provide broad flexibility in their adoption of State standards for toxics. However, to fulfill its statutory obligation requires that EPA's deference and flexibility cannot be unlimited.

For the reasons just discussed, EPA does not believe it is necessary to support the criteria promulgated today on a pollutant specific, State-by-State, waterbody-by-waterbody basis. Nonetheless, over the course of the past several years in working with and assisting the States, the Agency has reviewed the readily-available data on the discharge and presence of priority toxic pollutants. While this data is not necessarily complete, it constitutes a substantial record to support a strong *prima facie* case for the need for numeric criteria for most priority toxic pollutants with section 304(a) criteria guidance in most States. In the absence of final State actions to adopt criteria pursuant to either Option 2 or 3 which meet the requirements for EPA approval, this evidence strongly supports EPA's decision to promulgate, pursuant to section 303(c)(4)(B), criteria

for all priority toxic pollutants not fully addressed by State criteria. The EPA data supporting this assertion is discussed more fully in the next section.

2. Approach for Developing the Final Rule

The State-specific requirements in § 131.36(d) were developed using one of two approaches. In the formal review of the adopted standards for certain States, EPA determined that specific numeric toxics criteria are lacking. For some, criteria were omitted from the State standards, even though in EPA's judgment, the pollutants can reasonably be expected to interfere with designated uses. In these cases where EPA specifically identified deficiencies in a State submission, this rule establishes Federal criteria for that limited number of priority toxic pollutants necessary to correct the deficiency.

For the balance of the States, EPA applies, to all appropriate State waters, the section 304(a) criteria for all priority toxic pollutants which are not the subject of approved State criteria. EPA also is promulgating Federal criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human health exposure pathways, where such previously-approved State criteria do not protect against both acute and chronic aquatic life effects, or where such previously-approved State criteria are not applicable to all appropriate State designated uses.

Absent a State-by-State pollutant specific analysis to narrow the list, existing data sources strongly support a comprehensive rulemaking approach. Information in the rulemaking record from a number of sources indicates the discharge, potential discharge or presence of virtually all priority toxic pollutants in all States. The data available to EPA was assembled into a "strawman" analysis designed to identify priority toxic pollutants that potentially require the adoption of numeric criteria. Information on pollutants discharged or present was identified by accessing various national data sources:

—Final section 304(l) short lists identifying toxic pollutants likely to impair designated uses;
—Water column, fish tissue and sediment observations in the Storage Retrieval (STORET) data base (i.e., where the pollutant was *detected*);
—The National Pollutant Discharge Elimination System's (NPDES) Permit Compliance System data base to identify those pollutants limited in direct dischargers' permits;
—Pollutants included on Form 2(c) permit applications which have been submitted by wastewater dischargers;
—Information on discharges to surface waters or POTWs from the Toxics Release Inventory required by the Emergency Planning and Community Right-To-Know Act of 1986 (Title III, P.L. 99–499);
—Pollutants predicted to be in the effluent of NPDES dischargers based on industry-specific analyses conducted for the Clean Water Act effluent guideline program.

The extent of this data supports a conclusion that promulgation of Federal criteria for all priority toxic pollutants with section 304(a) criteria guidance documents is appropriate for those States that have not completed their standards adoption process. This conclusion is supported by several other factors.

First, many of the available data sources have limitations which argue against relying on them solely to identify all needed water quality criteria. For example, the section 304(l) short lists only identified water bodies where uses were impaired by point source discharges; State 304(l) long lists did not generally identify pollutants causing use impairment by nonpoint sources. Other available data sources (i.e., NPDES permit limits) have a similar narrow scope because of their particular purposes. Even the value of those data bases designed to identify ambient water problems is restricted by the availability of monitoring data. In many States, the quantity, spatial and temporal distribution, and pollutant coverage of monitoring data is severely limited. For example, the most recent Water Quality Inventory Report to Congress included an evaluation of use attainment for only one-third of all river miles and less than one-half of lake acres. Even for those waters where use attainment status was reported, many assessments were based on data which did not include the chemical-specific information necessary to identify the priority toxic pollutants which pose a threat to designated uses. After evaluating this data, EPA concluded that it most likely understates the adverse presence or discharge of priority toxic pollutants.

Further evidence justifying a broad promulgation rulemaking can be found in the State actions to date in their standards adoption process. While many have not come to completion, the initial steps have led many States to develop or propose rulemaking packages with extensive pollutant coverage. The nature of these preliminary State determinations argues for a Federal promulgation of all section 304(a) criteria pollutants to ensure adequate public health and environmental protection against priority toxic pollutant insults.

The detailed assumptions and approach followed by EPA in writing the § 131.36(d) requirements for all jurisdictions are described below. In the following discussions, EPA refers to these assumptions and approach as "rules."

(1) No criteria are promulgated for States which have been fully approved by EPA as complying with the section 303(c)(2)(B) requirements.

(2) For States which have not been fully approved, if EPA has not previously determined which specific pollutants criteria/waterbodies are lacking from a State's standards (i.e., as part of an approval/disapproval action only), all of the criteria in Columns B, C, and D of the § 131.36(b) matrix are promulgated for statewide application to all appropriate designated uses, except as provided for elsewhere in these rules. That is, EPA brought the State into compliance with section 303(c)(2)(B) via an approach which is comparable to option 1 of the December 1988 national guidance for section 303(c)(2)(B).

(3) If EPA has previously determined which specific pollutants/criteria/waterbodies are needed to comply with CWA section 303(c)(2)(B) (i.e., as part of an approval/disapproval action only), the criteria in § 131.36(b) are promulgated for only those specific pollutants/criteria/waterbodies (i.e., EPA brought the State into compliance via an approach which is comparable to option 2 of the December 1988 national guidance for section 303(c)(2)(B)).

(4) For aquatic life, except as provided for elsewhere in these rules, all waters with designated aquatic life uses providing even minimal support to aquatic life are included in the rule (i.e., fish survival, marginal aquatic life, etc.).

(5a) For human health, except as provided for elsewhere in these rules, all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route) or minimal aquatic life protection (and therefore a potential fish consumption exposure route) are included in the rule.

(5b) Where a State has determined the specific aquatic life segments which provide a fish consumption exposure route (i.e., fish or other aquatic life are being caught and consumed) and EPA approved this determination as part of

a standards approval/disapproval action, the rule includes the fish consumption (Column D2) criteria for only those aquatic life segments, except as provided for elsewhere in these rules. In making a determination that certain segments do not support a fish consumption exposure route, a State must have completed, and EPA approved, a use attainability analysis consistent with the provisions of 40 CFR 131.10(j). In the absence of such an approved State determination, EPA promulgated fish consumption criteria for all aquatic life segments.

(6) Uses/Classes other than those which support aquatic life or human health are not included in the rule (e.g., livestock watering, industrial water supply), unless they are defined in the State standards as also providing protection to aquatic life or human health (i.e., unless they are described as protecting multiple uses including aquatic life or human health). For example, if the State standards include a use such as industrial water supply, and in the narrative description of the use the State standards indicate that the use includes protection for resident aquatic life, then this use is included in this rule.

(7) For human health, the "water + fish" criteria in Column D1 of § 131.36(b) are promulgated for all waterbodies where public water supply and aquatic life uses are designated, except as provided for elsewhere in these rules (e.g., rule 9).

(8) If the State has public water supplies where aquatic life uses have not been designated, or public water supplies that have been determined not to provide a potential fish consumption exposure pathway, the "water + organisms only" criteria in Column D1 of § 131.36(b) are promulgated for such waterbodies, except as provided for elsewhere in these rules (e.g., rule 9).

(9) EPA is generally not promulgating criteria for priority toxic pollutants for which a State has adopted criteria and received EPA approval. The exceptions to this general rule are described in rules 10 and 11:

(10) For priority toxic pollutants where the State has adopted human health criteria and received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes human health criteria for such pollutants. For example, consider a case where a State has a water supply segment that poses an exposure risk to human health from both water and fish consumption. If the State has adopted, and received approval for, human health criteria based on water consumption only (e.g., Safe Drinking Water Act Maximum Contaminant Levels (MCLs)) which are less stringent than the "water + fish" criteria in Column D1 of § 131.36(b), the Column D1 criteria are promulgated for those water supply segments. The rationale for this is to ensure that both water and fish consumption exposure pathways are adequately addressed and human health is fully protected. If the State has adopted water consumption only criteria which are more stringent or equal to the Column D1 criteria, the "water + fish" criteria in Column D1 criteria are not promulgated.

(11) For priority toxic pollutants where the State has adopted aquatic life criteria and previous to the 1987 CWA Amendments received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes aquatic life criteria for such pollutants. For example, if the State has adopted not-to-be-exceeded aquatic life criteria which are less stringent than the 4-day average chronic aquatic life criteria in § 131.36(b) (i.e., in Columns B2 and C2), the acute and chronic aquatic life criteria in § 131.36(b) are promulgated for those pollutants. The rationale for this is that the State-adopted criteria do not protect resident aquatic life from both acute and chronic effects, and that Federal criteria are necessary to fully protect aquatic life designated uses. If the State has adopted not-to-be-exceeded aquatic life criteria which are more stringent or equal to the chronic aquatic life criteria in § 131.36(b), the acute and chronic aquatic life criteria in § 131.36(b) are not promulgated for those pollutants.

(12) Under certain conditions discussed in rules, 9, 10, and 11, criteria listed in § 131.36(b) are not promulgated for specific pollutants; however, EPA made such exceptions only for pollutants for which criteria have been adopted by the State and approved by EPA, where such criteria are currently effective under State law the appropriate EPA Region concluded that the State's criteria fully satisfy section 303(c)(2)(B) requirements.

3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule

As discussed in prior Sections of this Preamble, the water quality standards program has been established with an emphasis on State primacy. Although this rule was developed to Federally promulgate toxics criteria for States, EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance. EPA is hopeful this rule will provide additional impetus for non-complying States to adopt the criteria for priority toxic pollutants necessary to comply with section 303(c)(2)(B).

Removal of a State from the rule will require another rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). EPA will withdraw the Federal rule without a notice and comment rulemaking when the State adopts standards no less stringent than the Federal rule (i.e., standards which provide, at least, equivalent environmental and human health protection). For example, see 51 FR 11580, April 4, 1986, which finalized EPA's removal of a Federal rule for the State of Mississippi.

However, if a State adopts standards for toxics which are less stringent than the Federal rule but, in the Agency's judgment, fully meet the requirements of the Act, EPA will propose to withdraw the rule with a Notice of proposed rulemaking and provide for public participation. This procedure would be required for partial or complete removal of a State from this rulemaking. An exception to this requirement would be when a State adopts a human health criterion for a carcinogen at a 10^{-5} risk level where the Agency has promulgated at a 10^{-6} risk level. In such a case, the Agency believes it would be appropriate to withdraw the Federal criterion without notice and comment because the Agency has considered in this rule that criteria based on either 10^{-5} or 10^{-6} risk levels meet the requirements of the Act. A State covered by this final rule could adopt the necessary criteria using any of the three Options or combinations of those Options described in EPA's 1989 guidance.

EPA cautions States and the public that promulgation of this Federal rule removes most of the flexibility available to States for modifying their standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by the States. These are optional policies under terms of the Federal water quality standards regulation. Except for the water-effect ratio for certain metals, EPA has not incorporated either optional policy, in general, in this rulemaking; that is, EPA has not generally authorized State modification of Federal water quality standards. Each of these types of modifications will, in general, require Federal rulemaking on a case-by-case basis to change the Federal rule. Because of the time consuming nature of reviewing such requests, limited Federal resources, and the need for the Agency to move into other priority programs

areas in establishing environmental controls, EPA alerts the States and the public that a prompt Agency response to requests for variances and site-specific modifications to the Federal criteria is unlikely. The best course of action, if such provisions are desired in a State, is for a State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions.

The Federal criteria published today are effective in 45 days. However, this action does not change existing applicable State and EPA provisions related to permit issuance or reissuance as they affect schedules of compliance. EPA and the States may continue issuing permits containing enforceable compliance schedules for these Federally established water quality standards if it is consistent with State policy.

F. Derivation of Criteria

1. Section 304(a) Criteria Process

Under the authority of CWA section 304(a), EPA has developed methodologies and specific criteria to protect aquatic life and human health. These methodologies are intended to provide protection for all surface water on a national basis. As described below, there are site-specific procedures for more precisely addressing site-specific conditions for an individual water body. However, the water quality criteria are scientifically sound and will achieve the statutory objective of protecting designated uses even in the absence of these modification procedures. Although the site-specific procedures may allow for more precise criteria for certain waterbodies, these procedures are infrequently used because the Section 304(a) criteria recommendations are designed to protect all waterbodies and have proven themselves to be appropriate. The methodologies have been subject to public review, as have the individual criteria documents. Additionally, the methodologies have been reviewed and approved by EPA's Science Advisory Board of external experts. Additional comments on the methodologies were taken as part of this action and have been considered and responded to in developing this final rule. In addition, these comments will be considered in the Agency's ongoing effort to propose revised methodologies for public review and comment in fiscal year 1993.

EPA incorporated by reference into the record of this rule the aquatic life methodology as described in "Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses" (45 FR 79341, November 28, 1980) as amended by "Summary of Revisions to Guildlines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30792, July 29, 1985).

Note: Throughout the remainder of this rule, this reference is described as the 1985 Guidelines. Any page number references are to the actual guidance document, not the notice of availability in the **Federal Register**. The actual guidelines document was available through the National Technical Information Service (PB85–227049), is in the record of this rulemaking, and is abstracted in Appendix A of Quality Criteria for Water, 1986.

EPA also incorporated by reference into the record of this rule the human health methodology as described in "Appendix C—Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents" (45 FR 79347, November 28, 1980).

Note: Throughout the remainder of this Preamble, this reference is described as the Human Health Guidelines or the 1980 Guidelines.

EPA also recommends that the following be reviewed: "Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses," (45 FR 79357, November 28, 1980); "Appendix E—Responses to Public Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria" (45 FR 79368, November 28, 1980); and "Appendix B—Response to Comments on Guidelines for Deriving Numerical National Water quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30793, July 29, 1985). EPA also placed into the record the most current individual criteria documents for the priority toxic pollutants included in today's rule.

The primary focus of this rule is the inclusions of the water quality criteria for pollutant(s) in State standards as necessary to support water quality-based control programs. The Agency accepted comment on the criteria proposed for inclusion in this rule. However, Congress established a very ambitious schedule for the promulgation of the final criteria. The statutory deadline in section 303(c)(4) clearly indicates that Congress intended the Agency to move very expeditiously when Federal action is warranted.

The methodology used to develop the criteria and the criteria themselves (to the extent not updated through IRIS) have previously undergone scientific peer review and public review and comment, and have been revised as appropriate. For the most part, this review occurred before Congress amended the Act in 1987, to require the inclusion of numeric criteria for certain toxic pollutants in State standards. Congress acted with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely in large part on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. Accordingly, the Agency stands by its prior decisions regarding its published methodology and criteria even after review of the comments received. It is the Agency's belief that this approach will best achieve the purpose of moving forward in promulgating criteria for States not in compliance with section 303(c)(2)(B) so that environmental controls intended by Congress can be put into place to protect public health and welfare and enhance water quality.

It should be noted that the Agency is initiating a review of the basic guidelines for developing criteria and that comments received during this rulemaking will be considered in that effort. Future revisions to the criteria guidelines will be reviewed by the Agency's Science Advisory Board and submitted to the public for review and comment following the same process that was used in issuing the existing methodological guidelines. Subsequent revisions of criteria documents and the issuance of any new criteria documents will also be subject to the public review.

2. Aquatic Life Criteria

Aquatic life criteria may be expressed in numeric or narrative forms. EPA's 1985 Guidelines describe an objective, internally consistent and appropriate way of deriving chemical-specific, numeric water quality criteria for the protection of the presence of, as well as the uses of, both fresh and marine water aquatic organisms.

An aquatic life criterion derived using EPA's section 304(a) method "might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses." (45 FR 79341.) The term "their uses" refers to consumption by humans and wildlife (1985 Guidelines, page 48). EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time, but not necessarily all of the species all of the time (1985 Guidelines, page 1). Aquatic communities can tolerate some

stress and occasional adverse effects on a few species so that total protection of all species all of the time is not necessary. EPA's 1985 Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of substantial overprotection or underprotection. As discussed in detail below, there are several individual factors which may make the criteria somewhat overprotective or underprotective. The approach EPA is using is believed to be as well balanced as possible, given the state of the science.

Numerical aquatic life criteria derived using EPA's 1985 Guidelines are expressed as short-term and long-term numbers, rather than one number, in order that the criteria more accurately reflect toxicological and practical realities. The combination of a criteria maximum concentration (CMC), a one-hour average acute limit, and a criteria continuous concentration (CCC), a four-day average concentration chronic limit, provide protection of aquatic life and its uses from acute and chronic toxicity to animals and plants, and from bioconcentration by aquatic organisms, without being as restrictive as a one-number criterion would have to be. (1985 Guidelines, pages 4–5.)

The two-number criteria are intended to identify average pollutant concentrations which will produce water quality generally suited to maintenance of aquatic life and their uses while restricting the duration of excursions over the average so that total exposures will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient unless the time period is short, because excursions higher than the average can kill or cause substantial damage in short periods.

A minimum data set of eight specified families is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented by the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available.

EPA's application of guidelines to develop the criteria matrix in the final rule is judged by the Agency to be applicable to all waters of the United States, and to all ecosystems (1985 Guidelines, page 4). There are waters and ecosystems where site-specific criteria could be developed, as discussed below, but it is up to States to identify those waters and develop the appropriate site-specific criteria.

Fresh water and salt water (including both estuarine and marine waters) have different chemical compositions, and freshwater and saltwater species rarely inhabit the same water simultaneously. To provide additional accuracy, criteria developed recently are developed for fresh water and for salt water.

Assumptions which may make the criteria underprotective include the fact that not all species are protected, the use of criteria on an individual basis, with no consideration of additive or synergistic effects, and the general lack of consideration of impacts on wildlife, due principally to a lack of data. Chemical toxicity is often related to certain receiving water characteristics, (pH, hardness, etc.) of a waterbody. Adoption of some criteria without consideration of these parameters could result in the criteria being overprotective.

3. Criteria for Human Health

EPA's section 304(a) human health guidelines attempt to provide criteria which minimize or specify the potential risk of adverse human effects due to substances in ambient water (45 FR 79347). EPA's section 304(a) criteria for human health are based on two types of biological endpoints: (1) Carcinogenicity and (2) systemic toxicity (i.e., all other adverse effects other than cancer). Thus, there are two procedures for assessing these health effects: one for carcinogens and one for non-carcinogens.

EPA's human health guidelines assume that carcinogenicity is a "non-threshold phenomenon," that is, there are no "safe" or "no-effect levels" because even extremely small doses are assumed to cause a finite increase in the incidence of the response (i.e., cancer). Therefore, EPA's water quality criteria for carcinogens are presented as pollutant concentrations corresponding to increases in the risk of developing cancer.

For pollutants that do not manifest any apparent carcinogenic effects in animal studies (i.e., systemic toxicants), EPA assumes that the pollutant has a threshold below which no effects will be observed. This assumption is based on the premise that a physiological mechanism exists within living organisms to avoid or overcome the adverse effects of the pollutant below the threshold concentration.

The human health risks of a substance cannot be determined with any degree of confidence unless dose-response relationships are quantified. Therefore, a dose-response assessment is required before a criterion can be calculated. The dose-response assessment determines the quantitative relationships between the amount of exposure to a substance and the onset of toxic injury or disease. Data for determining dose-response relationships are typically derived from animal studies, or less frequently, from epidemiological studies in exposed populations.

The dose-response information needed for carcinogens is an estimate of the carcinogenic potency of the compound. Carcinogenic potency is defined here as a general term for a chemical's human cancer-causing potential. This term is often used loosely to refer to the more specific carcinogenic or cancer slope factor which is defined as an estimate of carcinogenic potency derived from animal studies or epidemiological data of human exposure. It is based on extrapolation from test exposures of high dose levels over relatively short periods of time to more realistic low dose levels over a lifetime exposure period by use of linear extrapolation models. The cancer slope factor, $q1^*$, is EPA's estimate of carcinogenic potency and is intended to be a conservative upper bound estimate (e.g. 95% upper bound confidence limit).

For non-carcinogens, EPA uses the reference dose (RfD) as the dose response parameter in calculating the criteria. The RfD was formerly referred to as an "Acceptable Daily Intake" or ADI. The RfD is useful as a reference point for gauging the potential effects of other doses. Doses that are less than the RfD are not likely to be associated with any health risks, and are therefore less likely to be of regulatory concern. As the frequency of exposures exceeding the RfD increases and as the size of the excess increases, the probability increases that adverse effects may be observed in a human population. Nonetheless, a clear conclusion cannot be categorically drawn that all doses below the RfD are "acceptable" and that all doses in excess of the RfD are "unacceptable." In extrapolating non-carcinogen animal test data to humans to derive an RfD, EPA divides a no-observed-effect dose observed in animal studies by an "uncertainty factor" which is based on profession judgment of toxicologists and typically ranges from 10 to 10,000.

For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is

the exposure default assumption although the human health guidelines provide for considering other sources where data are available (see 45 FR 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only.

The assumed exposure pathways in calculating the criteria are the consumption of 2 liters per day at the criteria concentration and the consumption of 6.5 grams per day of fish/shellfish contaminated at a level equal to the criteria concentration but multiplied by a "bioconcentration factor." The use of fish consumption as an exposure factor requires the quantification of pollutant residues in the edible portions of the ingested species. Bioconcentration factors (BCFs) are used to related pollutant residues in aquatic organisms to the pollutant concentration in ambient waters. BCFs are quantified by various procedures depending on the lipid solubility of the pollutant. For lipid soluble pollutants, the average BCF is calculated from the weighted average percent lipids in the edible portions of fish/shellfish, which is about 3%; or it is calculated from theoretical considerations using the octanol/water partition coefficient. For non-lipid soluble compounds, the BCF is determined empirically. The assumed water consumption is taken from the National Academy of Sciences publication "Drinking Water and Health" (1977). (Referenced in Human Health Guidelines, 45 FR 79356). The 6.5 grams per day contaminated fish consumption value is equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish for the U.S. population. (See Human Health Guidelines, 45 FR 79348.)

EPA also assumes in calculating water quality criteria that the exposed individual is an average adult with body weight of 70 kilograms. The issue of concern is dose per kilogram of body weight. EPA assumes 6.5 grams per day of contaminated fish consumption and 2 liters per day of contaminated drinking water consumption for a 70 kilogram person in calculating the criteria. Persons of smaller body weight are expected to ingest less contaminated fish and water, so the dose per kilogram of body weight is generally expected to be roughly comparable. There may be subpopulations within a State, such as subsistence fishermen, who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2 liters per day of maximally contaminated drinking water.

For example, individuals that ingest ten times more of a pollutant than is assumed in derivation of the criteria at a 10^{-6} risk level will be protected to a 10^{-5} level, which EPA has historically considered to be adequately protective. There may, nevertheless, be circumstances where site-specific numeric criteria that are more stringent than the State-wide criteria are necessary to adequately protect highly exposed subpopulations. Although EPA intends to focus on promulgation of appropriate State-wide criteria that will reduce risks to all exposed individuals, including highly exposed subpopulations, site-specific criteria may be developed subsequently by EPA or the States where warranted to provide necessary additional protection. (See Human Health Guidelines, Issue 8, 45 FR 79369.)

For non-carcinogens, oral RfD assessments (hereinafter simply "RfDs") are developed based on pollutant concentrations that cause threshold effects. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. (See Human Health Guidelines, 45 FR 79348.)

Criteria are calculated for individual chemicals with no consideration of additive, synergistic or antagonistic effects in mixtures. If the conditions within a State differ from the assumptions EPA used within the constraints of the Federal rule, the States have the option to perform the analyses for their conditions.

EPA has a process to develop a scientific consensus on oral reference dose assessments and carcinogenicity assessments (hereinafter simply cancer slope factors or slope factors). Reference doses and slope factors are validated by two Agency work groups (i.e., one work group for each) which are composed of senior Agency scientists from all of the program offices and the Office of Research and Development. These work groups develop a consensus of Agency opinion for RfDs and slope factors which are then used throughout the Agency for consistent regulation and guidance development. EPA maintains an electronic data base which contains the official Agency consensus for oral RfD assessments and carcinogenicity assessments which is known as the Integrated Risk Information System (IRIS). It is available for use by the public on the National Institutes of Health's National Library of Medicine's TOXNET system, and through diskettes from the National Technical Information Service (NTIS). (NTIS access number is PB 90–591330).

For the criteria included in today's rule, EPA used the criteria recommendation from the appropriate Section 304(a) criteria document. (The availability of EPA's criteria documents has been announced in various Federal Register Notices. These documents are also placed in the record for today's rule.) However, if the Agency has changed any parameters in IRIS used in criteria derivation since issuance of the criteria guidance document, EPA recalculated the criteria recommendation with the latest information, invited comment on the updating procedure and the numbers that would be derived from it. (This information is included in the record.) Thus, there may be differences between the original criteria guidance document recommendation, and those in this rule, but this rule presents the Agency's most current section 304(a) criteria recommendation. The recalculated human health numbers are denoted by an "a" in the criteria matrix in subsection 131.36(b) of today's rule.

A difficult and controversial problem facing both the States and EPA in attempting to comply with the requirements of section 303(c)(2)(B) involved selecting a criterion for 2,3,7,8–TCDD (dioxin). EPA, the States, dischargers, environmental groups and the public at large have been involved in discussions concerning the ambient level of protection that is protective of public health. At issue during the State debates on selecting criterion for dioxin and in comments to this rulemaking are scientific questions specific to dioxin such as determining the carcinogenic potency of the pollutant and the extent to which the pollutant tends to accumulate in fish tissues. Other issues are raised that are more generic to EPA's human health criteria. Most of these issues relate, directly or indirectly, to concerns expressed by dischargers regarding the cost of complying with water quality-based effluent limits for dioxin.

In order to base its regulatory decisions on the best available science, EPA continuously updates its assessment of the risk from exposure to contaminants. On September 11, 1991, EPA's Office of Research and Development (ORD) began reassessing the scientific models and exposure scenarios used to predict the risks of biological effects from exposure to low levels of dioxin. This reassessment has the potential to alter the risk assessment for dioxin and accordingly the Agency's

regulatory decisions related to dioxin. At this time, EPA is unable to say with any certainty what the degree or directions of any changes in risk estimates might be. Moreover, the results of the assessment and any potential impact on the criteria limit will not be known for quite some time.

Considerable comment was received that the Agency not include dioxin in the rule pending the results of the dioxin reassessment. However, no additional data was submitted by the commenters that adds to the information available upon which to make a decision. Based on information currently available to the Agency and in the face of known uncertainties, the limit promulgated today is within the range of scientific defensibility.

A State may adopt a different limit subsequent to this rule, following the normal procedures for adopting or revising water quality standards (40 FR 131). The adoption by a State of a new or revised criterion for dioxin, whether more or less stringent than the existing section 304(a) guidance, will be accepted by the Agency based on the results of the Agency's reassessment without any further justification. Once a State adopts a new dioxin criterion, the permitting authority, either EPA or the State (if authorized to administer a permit program), may change the effluent limitation for dioxin in a permit subject to the antibacksliding requirements of sections 402(o) and 303(d)(4) of the CWA and the antidegradation policy of the State.

This final rule includes criteria for dioxin. This action encourages and supports the ongoing efforts of fourteen States actively considering adopting criteria for dioxin. Most of these States are relying on the same data used by EPA in deriving its criterion for dioxin. In addition, dioxin limits are included as appropriate in Individual Control Strategies (ICS's) developed under section 304(l), so there should be no immediate regulatory action that will be based upon the promulgation of Federal criteria.

Moreover, as discussed in more detail in Section J, Executive Order 12291, example 5, it is unlikely that the practical impact of including dioxin at the 0.013 ppq level in this rule will affect the need for treatment and thus, is unlikely to be the basis for any incremental costs for pulp and paper mills to reduce dioxin discharges.

4. Section 304(a) Human Health Criteria Excluded

Today's rule does not contain certain of the section 304(a) criteria for priority toxic pollutants because those criteria were not based on toxicity. The basis for these particular criteria are organoleptic effects (e.g., taste and odor) which would make water and edible aquatic life unpalatable but not toxic. Because the basis for this rule is to protect the public health and aquatic life from toxicity consistent with the language and intent in section 303(c)(2)(B), EPA is promulgating criteria only for those priority toxic pollutants whose criteria recommendations are based on toxicity. The Section 304(a) human health criteria based on organoleptic effects for copper, zinc, 2,4-dimethylphenol, and 3-methyl-4-chlorophenol are excluded for this reason.

5. Cancer Risk Level

EPA's section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer per 100,000 people (10^{-5}), per 1,000,000 people (10^{-6}), and per 10,000,000 people (10^{-7}). However, the criteria documents do not recommend a particular risk level as EPA policy.

In the April, 1990, Federal Register notice of preliminary assessment of State compliance, EPA announced its intention to propose this rule with an incremental cancer risk level of one in a million (10^{-6}) for all priority toxic pollutants regulated as carcinogens (55 FR 14351). This risk level was in fact proposed in the November 19, 1991 Federal Register Notice of proposed rulemaking. However, EPA's Office of Water's guidance to the States has consistently reflected the Agency's policy of accepting cancer risk policies from the States in the range of 10^{-6} to 10^{-4} (see 45 FR 79323, November 28, 1980; Guidance for State Implementation of Water Quality Standards for CWA section 303(c)(2)(B), November 12, 1988 (54 FR 346); see also document described in footnote 3 of this preamble). EPA reviews individual State policies as part of its water quality standards oversight function and determines if States have appropriately consulted their citizenry and applied good science in adopting water quality criteria.

In the proposal, EPA not only sought public comment on its decision to propose criteria based on a 10^{-6} risk level, but also specifically solicited comment on an alternate risk level of 10^{-5}. EPA received extensive comments that the proposed application of the criteria at the 10^{-6} risk level was contrary to Agency policy, contradicted other risk levels accepted by EPA in States included in the proposal, oversteps EPA authority by failing to recognize that such a decision more properly should be a State decision, given their primary authority to establish water quality standards, and that EPA should not include a risk level in the final rule.

Upon consideration of these comments, EPA agrees that establishing a single risk level for all States departs from Agency policy in the standards program. The application of the human health criteria in today's rule, on a State-by-State basis, therefore, has been changed. In today's rule, the risk level for each State is based on the best information available to the Agency as to each State's policy or practice regarding what risk level is, or should be, used in regulating carcinogens in surface waters. In most cases the risk levels were based on a State-adopted or formally proposed risk level, or in the case of Idaho, Rhode Island, and Nevada on an expression of State policy preference. EPA is therefore promulgating criteria at either the 10^{-5} or 10^{-6} risk level, either of which is consistent with EPA policy and with the requirements of the Clean Water Act.

The Agency recognizes that it made some of its decisions regarding the appropriate risk level on limited data. However, in the time available to the Agency, we relied on the best available information. The Agency believes it is important to move forward with this rule based on available information. To ensure that the Agency has selected the appropriate risk level for each State, the Agency is providing a final opportunity for the Governor of each State (or other official with authority to determine risk levels with respect to water quality criteria) to inform EPA if they believe a different risk level should be selected for their State.

Today's regulation will become effective 45 days from publication in the Federal Register. However, if within 30 days of publication of this rule in the Federal Register, the Governor or other appropriate official determines that the final rule is not based on the correct State policy or practice with regard to risk levels, the Governor (or other appropriate official) may request the Administrator in writing to adopt a different risk level for the State.

Note: The Governor is not constrained to requesting the Administrator to adopt a single risk level for all carcinogenic compounds. It is also acceptable for a State to select more than one risk level. For example, New Jersey is proposing to adopt 10^{-6} for Class A and B carcinogens, and 10^{-5} for Class C carcinogens. In this rule, EPA is promulgating the two risk level concept for New Jersey. The Governor must explain the basis for the request to change the risk level.

If EPA determines, after receipt of such a letter from the Governor or other appropriate State official, the State's preference is consistent with EPA policy, as set out in this rulemaking, and the requirements of the Clean Water Act, EPA will amend the rule accordingly.

As noted above, in this rulemaking EPA is adopting risk levels that it believes best reflects the expressed preferences of the covered States (10^{-6} or 10^{-5} for all carcinogens). If there were, however, no clear expression of preference by a State, EPA also believes it is reasonable for States to adopt a risk level of 10^{-5} for many of the covered carcinogens and a more stringent risk level of 10^{-6} for those carcinogens with substantially higher bioconcentration factors. Recognizing the current limitations of the scientific data available for this rulemaking, EPA believes it would be reasonable to conclude that carcinogens that bioaccumulate, particularly given the exposure of fishermen to such carcinogens, may justify a more protective risk level of 10^{-6} for the average fish consumer, but for other carcinogens a less conservative level (10^{-5}) may be appropriate.

6. Applying EPA's Nationally Derived Criteria to State Waters

To assist States in modifying EPA's water quality criteria, the Agency has provided guidance on developing site specific-criteria for aquatic life and human health (see Chapter 4, Water Quality Standards Handbook, Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses, and the Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents). This guidance can be used by the appropriate regulatory authority to develop alternative criteria. Where such criteria are more stringent than the criteria promulgated today, Section 510 of the Clean Water Act (33 U.S.C. 1370) allows their implementation and enforcement in lieu of today's promulgated criteria.

EPA's experience with such site-specific criteria has verified that the national criteria are generally protective and appropriate for direct use by the States. (See Response to Comments on the 1985 Aquatic Life Guidelines, Comment 57, 50 FR 30796, July 29, 1985.)

7. Application of Metals Criteria

A substantial number of comments were received requesting Agency guidance on the implementation of metals criteria for aquatic life. In response, the Agency has prepared guidance on this issue, which is described in general terms below, and which is being applied to the metals criteria being promulgated today. Responses to individual comments may be found in section I, comments 19 to 53.

In selecting an approach for implementing the metals criteria, the principal issue is the correlation between metals that are measured and metals that are biologically available and toxic, as discussed more fully in EPA's Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, U.S. EPA, 1992, Office of Science and Technology, May 1992. (Notice of availability published at 57 FR 24041, June 5, 1992.

In order to assure that the metals criteria are appropriate for the chemical conditions under which they are applied, EPA is promulgating the criteria in terms of total recoverable metal and providing for adjustment of the criteria through application of the "water-effect ratio" procedure as described and recommended in the above Guidance document. This procedure was developed in the early 1980's, and was originally set forth, along with several case study applications, as the Indicator Species procedure in Chapter 4 of the Water Quality Standards Handbook (U.S. EPA 1983 at page 4–12). EPA notes that performing the testing to use site-specific water-effect ratios is optional on the part of the States.

In natural waters metals may exist in a variety of dissolved and particulate forms. The bioavailability and toxicity of metals depend strongly on the exact physical and chemical form of the metal. Generally, dissolved metal has greater toxicity than particulate metal, and for some metals, such as copper, certain dissolved forms have greater toxicity than other dissolved forms. Because the speciation among the various forms of a particular metal may vary from place to place, the same metal concentration may cause different toxicity from place to place.

With one exception (selenium), EPA's metals criteria for aquatic life protection are developed from laboratory toxicity data. Use of laboratory toxicity testing is usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species, and (2) the effect of various water quality characteristics on toxicity. (See 1980 Aquatic Life guidelines, comment 21, 45 FR 79360. See also responses to comments 17, 18, 19, 20.) The dilution water used in laboratory toxicity tests is ordinarily low in particulate matter (i.e. suspended solids), and low in organic matter compared to many ambient waters. As a result, laboratory toxicity tests are ordinarily more likely to overestimate the toxicity than underestimate the toxicity of metals in some ambient waters, particularly fresh waters.

Because of the complexity of metals speciation and its effect on toxicity, the relationship between measured concentrations and toxicity is not precise. Consequently, any method that could be recommended would not guarantee precise comparability between concentrations measured in the field and concentrations employed in the toxicity tests underlying the criteria.

For metals criteria derived from laboratory toxicity tests, the best approach is to use a biological method to compare bioavailability and toxicity in receiving waters versus laboratory test waters (the water-effect ratio) and to adjust the criteria values accordingly. This involves running toxicity tests for at least two species, each preferably from a different family, measuring acute (and possibly chronic) toxicity values for the pollutant using (a) the local receiving water, and (b) standard laboratory toxicity testing water, which is also the source of toxicity test dilution water. A water-effect ratio is the acute (or chronic) value in site water divided by the acute (or chronic) value in standard laboratory water. An acute value is an LC50 from a 48–96 hour test, as appropriate for the species. A chronic value is a concentration resulting from hypothesis testing or regression analysis of measurements of survival, growth, or reproduction in life cycle, partial life cycle, or early life stage tests on aquatic species.

Chemical approaches for defining and comparing bioavailable metal are subject to greater uncertainty than the above biological approach.

Chemical approaches, such as dissolved and total recoverable metals are easier to apply than biological approaches. One approach that EPA has approved in State standards is to measure metals in ambient waters in terms of dissolved metal, and to compare such measurements to criteria appropriate for dissolved metal. Since effluent limits, for both technical and legal (see NPDES permits regulation, 40 CFR 122.45) reasons, should be expressed in terms of total recoverable metal, it is necessary to translate between the dissolved and total recoverable concentrations. EPA has not incorporated the alternative of dissolved

metals criteria into this rule, because the use of the water-effect ratio accomplishes the same ends but is technically superior and subject to fewer uncertainties than implementation of the criteria as dissolved concentrations.

The simplest approach for ambient metals standards is the use of the total recoverable analytical method without a water-effect ratio adjustment. This is a reasonable, albeit environmentally conservative strategy, for applying EPA's aquatic life criteria. Where the toxicity testing necessary to develop an alternative water-effect ratio has not been performed, this rule will apply the total recoverable analytical method without a water-effect ratio adjustment. This occurs because EPA assigns the water-effect ratio a value of 1.0, subject to being rebutted by toxicity testing results.

Because of the comments received, and because of the desire to achieve the greatest possible degree of accuracy, EPA has chosen to apply the total recoverable metals criteria unadjusted for site-specific water chemistry, unless the State adjusts the criteria through the use of a water-effect ratio as provided for in this rule. Allowance for water-effect ratio adjustment also satisfies the concerns of comments requesting consideration of dissolved criteria.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species an appropriate number of times, as determined by the States, ordinarily on samples collected in at least two seasons (or more where large metal loadings are involved). As with other site-specific procedures, the basic analysis or testing may be performed by the State, a permittee, or any other interested party. Acute or chronic toxicity for the pollutant are measured using (a) the local receiving water where the criterion is being implemented, and (b) standard laboratory toxicity testing water, as the sources of toxicity test dilution water. The water-effect ratio is calculated as the acute or chronic value in site water divided by respective acute or chronic values in standard laboratory water. Ordinarily, the geometric mean water-effect ratio from the valid tests is used for calculation of the criterion, except where protection of sensitive species requires a more stringent value. Because the metal's toxicity in standard laboratory water is the basis for EPA's criterion, this comparison is used to adjust the national criterion to a site-specific value. Because the procedure is a biological measure of differences in water chemistry, the water-effect ratio, even when derived from acute tests, usually may be assumed to also apply to chronic criteria.

For criteria that do not vary with hardness, the criterion for a specific site equals the acute or chronic value tabulated in the rule (i.e., the matrix in 40 CFR 131.36(b)) multiplied by the site-specific water-effect ratio for that pollutant. The result may either reduce or increase the stringency of the criteria.

For criteria whose toxicity varies with hardness, the criterion for a specific site equals the criterion calculated at the design hardness (see 40 CFR 131.36(c)(4)), multiplied by the site-specific water-effect ratio.

The water-effect ratio is assigned a value of 1.0, unless scientifically defensible data clearly demonstrate that a value less than 1.0 is necessary or a value greater than 1.0 is sufficient to fully protect the designated uses of the water body from the toxic effects of the pollutant. Any data accepted for calculation of the water-effect ratio is to be generated through standard toxicity testing protocols (EPA recommends the methodology in Annual Book of ASTM Stds. 1991, Vol.11.04, ASTM, Philadelphia, PA.), using sampled ambient water representative of conditions in the affected water body, and using laboratory dilution water comparable to that used in toxicity tests underlying the criteria. The guidance documents cited at the beginning of this section provides more guidance on generating the information necessary to determine the correct value of the water-effect ratio. However, EPA intends within the next few months to provide additional guidance or performing the analyses necessary to develop scientifically defensible water-effect ratios for metals. As envisioned at this time, EPA will expand Chapter 4 in the Handbook to apply the appropriate procedures described there specifically to metals. EPA will look at the chemical characteristics of the laboratory water used in the toxicity tests included in the metals criteria data base, appropriate test organisms, analytical methods, safeguards against unintended metals contamination during toxicity testing, and appropriate data handling and statistics. While EPA believes the current guidance is adequate for application of the water-effect ratio, the additional guidance should help standardize procedures and make results more comparable and defensible.

The rule as promulgated is constructed as a rebuttable presumption. The water-effect ratio is assigned a value of 1.0 but provides that a State may assign a different value derived from suitable tests. As EPA has noted elsewhere, the actual decision as to the numeric value assigned to a water-effect ratio may be made during a State or EPA NPDES permit proceeding provided that adequate notice and opportunity for public participation is provided. It is the responsibility of the permit writing authority to determine whether to apply the water-effect ratio in an NPDES permit. However, EPA believes use of the ratio will lead to more appropriate permit limits. States may wish to allow permittees to fund State-administered studies necessary to develop the ratio for particular waterbodies.

EPA reviews State issued NPDES permits. To facilitate EPA consideration of a State-developed water-effect ratio, a State should specify in documentation supporting that action what decisions were made for critical parameters such as toxicity testing protocols used, frequency of testing, critical periods for sampling and testing, and analytical quality control and assurance. Each of the factors must be articulated in a record as a basis for a determination that the water-effect ratio is scientifically defensible.

The procedure applies only to aquatic life criteria derived from laboratory toxicity data. That is, it applies to the acute and chronic criteria (Columns B and C in 40 CFR 131.36(b)) for arsenic, cadmium, chromium, copper, lead, nickel, and zinc. It also applies to the acute criteria for mercury and silver, and the saltwater acute and chronic criteria for selenium. It does not apply to the chronic criteria for mercury, because they are residue based, or to the freshwater acute and chronic criteria for selenium, because they are field based.

The water-effect ratio is affected not only by speciation among the various dissolved and particulate forms, but also by additive, synergistic, and antagonistic effects of other materials in the affected site waters. As such, the water-effect ratio is a rather comprehensive measure of the effect of water chemistry on the toxicity of a pollutant. Because the procedure accounts for any reduction in bioavailability resulting from binding of the metal to particulate matter, all metals criteria have been appropriately expressed as total recoverable metal in this rule.

Where measured water-effect ratios are used in deriving NPDES permit limits, data from appropriate testing during the term of the permit should be accumulated so that the value of the water-effect ratio can be reevaluated each time the permit is reissued. Thus, were measured water-effect ratios are

involved, EPA recommends that NPDES permits establish monitoring requirements that include periodic determinations of water-effect ratios.

G. Description of the Final Rule and Changes From Proposal

1. Changes From Proposal

Several changes were made in the final rule from the proposal both as a result of Agency and State action with respect to the ongoing adoption of water quality standards by the States and because of the Agency's consideration of issues raised in specific public comments.

The States of Arizona, Colorado, Connecticut, Louisiana, New Hampshire, Virginia, the Commonwealth of the Northern Mariana Islands, and Hawaii are not included in the final rule as their standards were duly adopted and approved by EPA as fully meeting the requirements of section 303(c)(2)(B). Arizona's water quality standards were approved on March 2, 1992; Colorado's standards were approved by EPA on December 10, 1991; Connecticut on May 15, 1992; Louisiana on January 24, 1992; New Hampshire on June 25, 1992; Virginia on June 30, 1992; CNMI on January 13, 1992; and Hawaii on November 4, 1992. Copies of the approval letters are included in the record to this final rulemaking.

In addition, human health criteria adopted by the State of Arkansas were approved by EPA on January 24, 1992, and such criteria were removed from today's rule as it affects Arkansas. EPA is not promulgating and aquatic life criterion in Arkansas for arsenic because a review of monitoring data from 1985 to the present reveals no reason to conclude that arsenic will interfere with designated aquatic life uses. Additional details on EPA's action with respect to Arkansas may be found in Section I—Response to Public Comments, subsection 6.

Except for dioxin, criteria for the State of Florida for both human health and protection of aquatic life were approved by EPA on February 25, 1992. Florida is included in the rule only for the purposes of establishing a criterion for dioxin. More details on Florida's action are included in the Florida section of subsection 6 of the Response to Comments section of this preamble.

The criteria applicable to California have been revised to reflect a partial approval of the State's water quality standards on November 6, 1991. Additional comments with respect to California may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to the State of Washington was revised after discussion with the State as to EPA's interpretation of the uses designated by the State. The rule is now based on use categories rather than use classes. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Alaska was modified to delete the assignment of criteria to a seafood processing use. This use falls under the standards program. However, because it applies to food preparation only, it is not appropriate to apply to it aquatic life or human health criteria. Additional aquatic life and human health criteria were added to several use classifications after discussions with the State clarified the State's use classifications. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Idaho was modified to add additional criteria for the protection of primary contact recreation after discussions with the State concerning that use. Additional details may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Kansas was changed by removing the promulgation of silver for sections (2) (A), (B), (C), and (6)(C) as the State has an EPA approved aquatic life criterion more stringent than the EPA criterion. The human health criterion for silver was removed because EPA has withdrawn its silver human health criterion.

The rule as it applies to New Jersey was revised to reflect comments received from the New Jersey Department of Environmental Protection and Energy to add waters classified as Pinelands and to extend coverage of the criteria to the mainstem Delaware River and Delaware Bay (zones 1C–6). Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

Clarifications on several aspects of the rule with respect to implementation procedures are addressed in the response to public comments section of this preamble (section I).

Language was added in § 131.36(c)(4) dealing with the application of metals criteria as discussed in section F–7 of this preamble. We also added requirements to clarify how hardness should be handled in doing water-effect ratio determinations (see 131.36(c)(4)(iii), footnotes "e" and "m" to 131.36(b)).

The criteria for carcinogenic compounds included in this rule are applied at a risk level based on State preference as reflected by adopted or proposed standards, or in the case of Idaho, Nevada, and Rhode Island, on expression of State policy preference, rather than at an across-the-board 10^{-6} risk level as was proposed by the Agency. The rationale for this change is discussed in detail in section F–5 and there is additional discussion in the Response to Public Comment Section. The basis for EPA's selection of a risk level for an individual State is described in the following paragraphs:

Alaska: Risk Level: 10^{-5}

In July 1992, the State proposed human health water quality based on achieving a 10^{-5} risk level for two carcinogens: Dioxin and chloroform. Also, on November 16, 1992, the Commissioner of the Alaska Department of Environmental Conservation wrote the Director, Water Division, in EPA Region X, and indicated that ". . . I also had this matter reviewed by our Attorney General's Office, and hereby confirm the appropriateness of utilizing a 10^{-5} risk level for Alaska in the National Toxics Rule."

California: Risk Level: 10^{-6}

Standards adopted by the State contained in the Enclosed Bays and Estuaries Plan, and the Inland Surface Waters Plan, approved by EPA on November 6, 1991, and the Ocean Plan approved by EPA on June 28, 1990, contain a risk level of 10^{-6} for carcinogens. The total number of toxic pollutants differs in each plan but approximately 60–65 pollutants are covered.

District of Columbia: Risk Level: 10^{-6}

In 1985 the District adopted water quality criteria for human health, based solely on exposure through water consumption. The criteria were based on a 10^{-6} risk level. See D.C.M.R. title 21, chapter 1102.8(I).

Florida: Risk Level: 10^{-6}

The State adopted human health criteria for all toxic pollutants, except dioxin, and received EPA approval on February 25, 1992, at a risk level of 10^{-6}.

Idaho: Risk Level: 10^{-6}

On November 12, 1992, the Administrator of the Division of Environmental Quality, Idaho Department of Health and Welfare, indicated in a letter to the EPA Assistant Administrator for Water that while Idaho would be publishing proposed standards for public review and

comment in the next several months. . . . "Until we know what standard the public in Idaho prefers, we believe it is prudent to adopt the more protected standards of ten to the minus six."

EPA Region X is the permit issuing authority for the State and applies 10^{-6} for water quality based human health requirements. These permits have been certified by the State under section 401 as meeting water quality standards.

Kansas: Risk Level: 10^{-6}

The State completed a series of public hearings in August 1992 on proposed water quality standards revisions and is now processing public comments leading to the final, formal adoption hearing scheduled for January 1993. Formal adoption is scheduled for February 1993. The risk level in the current proposed standards is 10^{-6}. See proposed K.A.R. 28–16–28e(c)(4)(B).

Michigan: Risk Level: 10^{-5}

For several years Michigan has been controlling toxics through application of the Guidelines for Rule 57. These guidelines are applied at a 10^{-5} risk level. See R 323, 1057(2)(d).

Nevada: Risk Level: 10^{-5}

On November 3, 1992, EPA received a letter from the Administrator of the Division of Environmental Protection, Department of Conservation and Natural Resources, ". . . that the public health risk level that DEP would prefer to see in federal regulations is 10^{-5} (one in one hundred thousand), unless a state can provide substantial support in the record that a risk level of 10^{-4} (one in ten thousand) is appropriate and protective. This gives states the flexibility to use a more conservative 10^{-6} risk level if they see fit, but without requiring it when it is not necessary."

New Jersey: Risk Level: 10^{-6} For Class A and B Carcinogens, 10^{-5} For Class C Carcinogens

New Jersey, on October 20, 1992, solicited public comment on proposed surface water quality standards. The comment period is to close on December 18, 1992. The proposed human health criteria for carcinogens are established on a two-tiered system for risk levels. See proposed N.J.A.C. 7:9B–1.5(a)4. The State previously had indicated their intention to do this in a letter to EPA on December 19, 1991.

Puerto Rico: Risk Level: 10^{-5}

In 1990, the State proposed and held public hearings on criteria for human health using a 10^{-5} risk level. Subsequently, the proposed standards were revised. Just recently the State completed public hearings on the most recent revision to standards. The standards are under review by the Environmental Quality Board. The risk level remains at 10^{-5}.

Rhode Island: Risk Level: 10^{-5}

On November 2, 1992, the EPA Regional Administrator received a letter from the Director, Department of Environmental Management, that, along with the Department of Health, the State's "* * * policy choice on the promulgation of the human health criteria is for the adoption of a cancer risk level of 10^{-5}." The Director also indicated that "* * * future modifications of this risk level, whether it be to 10^{-4} or 10^{-6}, could be considered on a pollutant and subpopulation basis to produce a site specific risk assessment and protection of human health."

Vermont: Risk Level: 10^{-6}

On May 27, 1991, State submitted to EPA final water quality standards which reference the EPA section 304(a) criteria to be applied at a 10^{-6} risk level. However, the effective date of these standards is not until January 1, 1995. This delayed effective date was the reason Region I advised the State that the State did not comply with section 303(c)(2)(B).

Washington: Risk Level: 10^{-6}

During the summer of 1992, the State formally proposed and held public hearings on revisions to its water quality standards. The standards, scheduled for adoption in late November 1992, include a risk level of 10^{-6}.

On December 18, 1991, in its official comments on the proposed rule, the Department of Ecology urged EPA to promulgate human health criteria at 10^{-6}. Specifically, "The State of Washington supports adoption of a risk level of one in one million for carcinogens. If EPA decides to promulgate a risk level below one in one million, the rule should specifically address the issue of multiple contaminants so as to better control overall site risks."

The final phrase in § 131.36(c)(2) relating to the applicability of the rule was amended by deleting the text beginning "but only * * *" EPA received numerous comments that the Federal criteria should be implemented consistently with current State practices. EPA amended the language because the Agency had not intended to be inconsistent with the provisions of the water quality standards regulation (40 CFR 131.21(c)), which provides that a State water quality standard remains in effect even though disapproved by EPA, until the State revises it or EPA promulgates a rule that supersedes the State water quality standards.

Although not directly resulting in a change to the rule, this preamble clarifies, at the public's request, whether schedules of compliance were applicable to this rule. In Section E–3 EPA clarifies that schedules of compliance for these criteria are not provided for in these rules, but that such schedules of compliance are available in NPDES permits if authorized by State regulations. See *In the Matter of Star-Kist Caribe, Inc.*, NPDES Appeal No. 88–5, Before the Environmental Appeals Board, EPA. May 26, 1992.

Several deletions were made to the proposed human health criteria as a result of the Agency's review of data submitted in public comments and to reflect the pertinent impact of other relevant Agency actions. The revisions are as follows:

(1) Criteria for three pollutants included in the matrix of the proposed rule are not included in the final rule for (A) acenaphthylene, (B) benzo(ghi)perylene, and (C) phenanthrene. The criteria for these pollutants were removed because they are not recognized by the Agency as carcinogenic compounds nor do they have a reference dose that would allow the Agency to calculate a criterion level.

(2) Silver: The human health criteria for silver were deleted from this final rule because the criteria were developed based on a cosmetic effect impact and not a toxicity endpoint.

(3) Cadmium, Chromium, Selenium and Beryllium: As described below, the Agency has determined that the proposed criteria for these contaminants are no longer scientifically defensible and accordingly has withdrawn these criteria pending evaluation of relevant data regarding their toxicity. EPA notes that the criteria promulgated for aquatic life will provide adequate protection for human health in most instances.

(4) Methyl Chloride, Lead and 1,1,1, Trichloroethane: As described below, the Agency has determined that there is currently an insufficient basis for calculating human health criteria for these three contaminants. Accordingly, EPA has withdrawn the proposed criteria for these contaminants pending further analysis.

In addition to the above changes, the Agency is today withdrawing the human health criteria recommendations previously published in the 1980 Ambient Water Quality Criteria Documents for silver, cadmium, chromium, selenium, beryllium, lead,

methyl chloride, and 1,1,1, Trichloroethane. Summaries of the human health criteria were also published in Quality Criteria for Water, 1986. These summaries are also being officially withdrawn today.

EPA's final rule establishes a new § 131.36 in 40 CFR part 131 entitled, "Toxics Criteria for Those States Not Fully Complying with Clean Water Act, section 303(c)(2)(B)."

2. Scope

Subsection (a), entitled "Scope", clarifies that this Section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

3. EPA Criteria for Priority Toxic Pollutants

As proposed, subsection (b) presents a matrix of the applicable EPA criteria for priority toxic pollutants. Section 303(c)(2)(B) of the Act addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act. As discussed earlier in this preamble, the section 307(a) list of toxics contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency uses the list of 126 "priority toxic pollutants" for administrative purposes (see 40 CFR 131.36(b) herein). Reference in this rule to priority toxic pollutants, toxic pollutants, or toxics refers to the 126 priority toxic pollutants.

However, EPA has not developed both aquatic life and human health section 304(a) criteria for all of the 126 priority toxic pollutants. The matrix in paragraph (b) contains human health criteria in Column D for 91 priority toxic pollutants which are divided into criteria (Column 1) for water consumption (i.e., 2 liters per day) and aquatic life consumption (i.e., 6.5 grams per day of aquatic organisms), and Column 2 for aquatic life consumption only. The term aquatic life includes fish and shellfish such as shrimp, clams, oysters and mussels. The total number of priority toxic pollutants with criteria promulgated today differs from the total number of priority toxic pollutants with section 304(a) criteria because EPA has developed and is promulgating chromium criteria for two valence states with respect to aquatic life criteria. Thus, although chromium is a single priority toxic pollutant, there are two criteria for chromium for aquatic life. However, the human criterion is based on total chromium consistent with Agency policy. See pollutant 5 in § 131.36(b).

The matrix contains aquatic life criteria for 30 priority pollutants. These are divided into freshwater criteria (column B) and saltwater criteria (Column C). These columns are further divided into acute and chronic criteria. The aquatic life criteria are considered by EPA to be protective when applied under the conditions described in the section 304(a) criteria documents and in the "Technical Support Document for Water Quality-based Toxics Control." For example, waterbody uses should be protected if the criteria are not exceeded, on average, once every three year period. It should be noted that the criteria maximum concentrations (the acute criteria) are one-hour average concentrations and that the criteria continuous concentrations (the chronic criteria) are four-day averages. It should also be noted that for certain of the metals, the actual criteria are equations which are included as footnotes to the matrix. The toxicity of these metals are water hardness dependent and may be adjusted by determining appropriate water-effect ratios. The values shown in the table are based on a hardness expressed as calcium carbonate of 100 mg/l and a water-effect ratio of 1.0. Finally, the criterion for pentachlorophenol is pH dependent. The equation is the actual criterion and is included as a footnote. The value shown in the matrix is for a pH of 7.8 units.

Several of the freshwater aquatic life criteria are incorporated into the matrix in the format used in the 1980 criteria methodology which uses a final acute value instead of a continuous maximum concentration. This distinction is noted in footnote (g) to the table.

4. Applicability

Section 131.36(c) establishes the applicability of the criteria for each included State. It provides that the criteria promulgated for each State supersede and/or complement any State criteria for that toxic pollutant. EPA believes it has not superseded any State criteria for priority toxic pollutants unless the State-adopted criteria are disapproved or otherwise insufficient. The approach followed by the Agency in preparing § 131.36(d) is described in section E.2, and further rationale is provided in section E.3 of this preamble.

EPA's principal purpose today is to promulgate the toxics criteria necessary to comply with section 303(c)(2)(B). However, in order for such criteria to achieve their intended purpose the implementation scheme must be such that the final results protect the public health and welfare. In section F of this preamble a discussion focused on the factors in EPA's assessment of criteria for carcinogens. For example, fish consumption rates, bioaccumulation factors, and cancer potency slopes were discussed. When any one of these factors is changed, the others must also be evaluated so that, on balance, resulting criteria are adequately protective.

Once an appropriate criterion is selected for either aquatic life or human health protection, then appropriate conditions for calculating water quality-based effluent limits for that chemical must be established in order to maintain the intended stringency and achieve the necessary toxics control. EPA has included in this rule appropriate implementation factors necessary to maintain the level of protection intended. These factors are included in subsection (c).

For example, in order to do steady state waste load allocation analyses, most States have low flow values for streams and rivers which establish flow rates below which numeric criteria may be exceeded. These low flow values became design flows for sizing treatment plants and developing water quality-based effluent limits. Historically, these so-called "design" flows were selected for the purposes of waste load allocation analyses which focused on instream dissolved oxygen concentrations and protection of aquatic life. With the publication of the 1985 Technical Support Document for Water Quality Based Toxics Control (TSD), EPA introduced hydrologically and biologically based analyses for the protection of aquatic life and human health.[1] EPA recommended either of two methods for calculating acceptable low flows, the traditional hydrologic method developed by the U.S. Geological Survey and a biological based method developed by EPA. The results of either of these two methods may be used.

Some States have adopted specific low flow requirements for streams and rivers to protect designated uses against the effects of toxics. Generally these have followed the guidance in the TSD. However, EPA believes it is essential to include design flows for steady state analyses in today's rule so that, where

[1] These concepts have been expanded subsequently in guidance entitled "Technical Guidance Manual for Performing Wasteload Allocations, Book 6, Design Conditions," USEPA, Office of Water Regulations and Standards, Washington, DC. (1986). These new developments are included in Appendix D of the revised TSD. The discussion here is greatly simplified and is provided to support EPA's decision to promulgate baseline application values for instream flows and thereby maintain the intended stringency of the criteria for priority toxic pollutants.

States have not yet adopted such design flows, the criteria promulgated today would be implemented appropriately. The TSD also recommends the use of three dynamic models to perform wasteload allocations. Dynamic wasteload models do not generally use specific steady state design flows but accomplish the same effect by factoring in the probability of occurrence of stream flows based on the historical flow record. For simplicity, only steady state conditions will be discussed here. Clearly, if the criteria were implemented using inadequate design flows, the resulting toxics controls would not be fully effective, because the resulting ambient concentrations would exceed EPA's criteria.

In the case of aquatic life, more frequent violations than the once in 3 years assumed exceedences would result in diminished vitality of stream ecosystems characteristics by the loss of desired species such as sport fish. Numeric water quality criteria should apply at all flows that are equal to or greater than flows specified below. The low flow values are:

Aquatic Life
acute criteria (CMC) 1 Q 10 or 1 B 3
chronic criteria (CCC) 7 Q 10 or 4 B 3
Human Health
non-carcinogens 30 Q 5
carcinogens harmonic mean flow

Where:

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years deteremined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low-flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and

the harmonic mean flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

EPA is promulgating the harmonic mean flow to be applied with human health criteria for carcinogens. The concept of a harmonic mean is a standard statistical data analysis technique. EPA's model for human health effects assumes that such effects occur because of a long-term exposure to low concentration of a toxic pollutant. For example, two liters of water per day for seventy years. To estimate the concentrations of the toxic pollutant in those two liters per day by withdrawal from streams with a high daily variation in flow, EPA believes the harmonic mean flow is the correct statistic to use in computing such design flows rather than other averaging techniques.[2]

All waters, whether or not suitable for such hydrologic calculations but included in this rule (including lakes, estuaries, and marine waters), must attain the criteria promulgated today. Such attainment must occur at the end of the discharge pipe, unless the State has a mixing zone regulation. If the State has a mixing zone regulation, then the criteria would apply at the locations stated in that regulation. For example, the chronic criteria (CCC) must apply at the geographically defined boundary of the mixing zone. Discussion of and guidance on these factors are included in the revised TSD in chapter 4.

EPA is aware that the criteria promulgated today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting standards since they are not related to actual environmental impacts. The environmental impact of a pollutant is based on a scientific determination, not a measuring technique which is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. (See 1985 Guidelines, page 21.) As the methods improve, limits closer to the actual criteria necessary to protect aquatic life and human health became measurable. The Agency does not believe it is appropriate to promulgate criteria that are not sufficiently protective.

EPA does believe, however, that the use of analytical detection limits are appropriate for determining compliance with NPDES permit limits. This view of the role of detection limits was recently articulated in guidance for translating dioxin criteria into NPDES permit limits which is the principal method used for water quality standards enforcement.[3] This guidance presents a model for addressing toxic pollutants which have criteria recommendations less than current detection limits. This guidance is equally applicable to other priority toxic pollutants with criteria recommendations less than current detection limits. The guidance explains that standard analytical methods may be used for purposes of determining compliance with permit limits, but not for purposes of establishing water quality criteria or permit limits. Under the Clean Water Act analytical methods are appropriately used in connection with NPDES permit limit compliance determinations. Because of the function of water quality criteria, EPA has not considered the sensitivity of analytical methods in deriving the criteria promulgated today.

EPA has added provisions in paragraph (c)(3) to determine when fresh water or saltwater aquatic life criteria apply. In response to comments, this provision was expanded to incorporate a time parameter to better define the critical condition. The structure of the paragraph is to establish presumptively applicable rules and to allow for site-specific exceptions where the rules are not consistent with actual field conditions. Because a distinct separation generally does not exist between fresh water and marine water aquatic communities, EPA is establishing the following: (1) The fresh water criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) marine water criteria apply at salinities of 10 parts per thousand and above at locations where this occurs 95% more of the time; and (3) at salinities between 1 and 10 parts per thousand the more stringent of the two apply unless EPA approves the application of the freshwater or saltwater criteria based on a biological assessment. The percentiles included here were selected to minimize the chance of overlap, that is, one site meeting both criteria. Determination of these percentiles can be done by any reasonable means such as interpolation between points with measured data or by the application of calibrated and verified mathematical models (or hydraulic models). It is not EPA's intent

[2] For a description of harmonic means see "Design Stream Flows Based on Harmonic Means," Lewis A. Rossman, J. of Hydraulics Engineering, Vol. 116, No. 7, July, 1990. This article is contained in the record for this proposal.

[3] Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States, memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors and NPDES State Directors, May 21, 1990.

to require actual data collection at particular locations.

In the brackish water transition zones of estuaries with varying salinities, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply. In evaluating appropriate data supporting the alternative set of criteria, EPA will focus on the species composition as its preferred method.

This assignment of criteria for fresh, brackish and marine waters was developed in consultation with EPA's research laboratories at Duluth, Minnesota and Narragansett, Rhode Island. The Agency believes such an approach is consistent with field experience.

In paragraph (c)(4)(i) EPA included a limitation on the amount of hardness that EPA can allow to antagonize the toxicity of certain metals (see footnote (e) in the criteria matrix in paragraph (b) of the rule). The data base used for the Section 304(a) criteria documents for metals do not include data supporting the extrapolation of the hardness effects on metal toxicity beyond a range of hardness of 25 mg/l to 400 mg/l (expressed as calcium carbonate). Thus, the aquatic life values for the CMC (acute) and CCC (chronic) criteria for these metals in waters with a hardness less than 25 mg/l, must nevertheless use 25 mg/l when calculating the criteria; and in waters with a hardness greater than 400 mg/l, must nevertheless use 400 mg/l when calculating the criteria.

In paragraph (c)(4), subparagraphs (i) and (ii) are the same as proposed. Subparagraph (iii) was added to incorporate the water-effect ratio guidance described in Section F–7 of this preamble.

Subsection (d) lists the States for which rules are being promulgated. For each identified State, the designated water uses impacted (and in some cases the specific waters covered) and the criteria are identified. In all cases, the criteria are applied to use designations adopted by the States; EPA has not promulgated any new use classifications in this rule although the Agency has the authority to do so.

H. [Reserved]

I. Response to Public Comments

The Response to Public Comment Section is organized into several subsections, as follows:

1. Legal Authority
2. Science
3. Economics
4. Implementation
5. Timing and Process
6. State Issues

1. Legal Authority

1. *Comment:* Several comments were received that in various ways suggested that EPA exceeded its authority in proposing to establish Federal water quality standards for States because it was alleged standards are to be developed by the States. These comments tended to emphasize the primary role attributed to States under the Clean Water Act in establishing standards with some going so far as to indicate that States should have full and unrestrained authority to act. In this mode, a comment was offered that all the Clean Water Act requires is a good faith effort on the part of a State to meet the statutory requirement. A related comment suggested that EPA can promulgate standards only after specifically disapproving a State's standard. There were opposing views offered suggesting that EPA not only has the authority to act, it is obliged to act.

Response: The Clean Water Act assigns States the primary role in establishing water quality standards and EPA has continually supported that role before Congress in reauthorization hearings on the Clean Water Act. The Act, however, also defines a role for EPA in terms of reviewing and either approving or disapproving State-adopted standards and of promulgating Federal standards. Sections 303(c) (3) and (4) of the Act clearly indicate that Congress did not intend States to have full and unrestrained authority to set standards. EPA's action in developing this rulemaking is not to be taken as a change in EPA policy in dealing with the States. Our policy continues to be that we prefer States to adopt their own standards but we will use our promulgation authority when warranted. EPA believes that the need to control the discharge of toxic pollutants to protect human health and the environment, the establishment of the statutory requirement for addressing toxic pollutants, and the responsibility for EPA review of State water quality standards for consistency with the Clean Water Act coupled with the inclusion of a process for Federal promulgation in the Act strongly supports EPA's promulgation authority. Moreover, this elaborate process also makes clear that Congress intended that States do more than just evidence a good faith effort.

As described in detail in section E of this Preamble, the Clean Water Act authorizes and establishes a timetable for Federal promulgation action. Under the Clean Water Act, States must adopt water quality standards to protect public health and welfare and enhance the quality of water. Section 303(c)(4) of the Clean Water Act authorizes the Administrator of EPA to promulgate Federal standards applicable to a State when: (1) The State submits standards for EPA approval and EPA determines that the State standards fail to meet the requirements of the Act, or (2) in any case where the Administrator determines a new or revised standard is necessary to meet the requirements of the Act. EPA's implementing regulations also make clear that the Administrator may take action to promulgate either when a State fails to adopt changes specified in a disapproval or in any case where the Administrator determines a new or revised standard is necessary (40 CFR 131.22). Both these provisions are used to support this action. Although in fact EPA did notify the States in a Federal Register notice of April 19, 1990, and in a letter to the Administrator of the responsible State agency of each potentially affected State on April 9, 1990, the Administrator is not required in exercising the authority of section 303(c)(4) to specifically disapprove a State's standard when exercising the authority to promulgate Federal standards. Historically, in eight of the nine Federal promulgation actions completed, the Agency based its action on disapproval of State standards but in the ninth instance, a criterion for chloride in the Commonwealth of Kentucky, there was no disapproval involved (see 52 FR 9102, March 20, 1987).

2. *Comment:* Closely related to the above comments were others that asserted that EPA is empowered to promulgate Federal standards only on a State-by-State, waterbody-by-waterbody, pollutant-by-pollutant approach, and that Congress did not intend that national standards be developed. In the same vein, it was suggested that it would be easier for the public to respond if each State were proposed in a separate rule.

Response: Neither EPA nor the States are directed by either the statute or the implementing water quality standards regulation to establish standards in the manner suggested by the first comment. EPA's implementing regulation and policies certainly allow EPA to act in this way but it is not required to do so. Section 131.22(b) of the water quality standards regulation specifically indicates that the Administrator "* * * may propose and promulgate a regulation applicable to one or more states * * *."

We do not see this action as establishing national standards as it

expressly limits the application of the criteria in the final rule to the States named in the rule. (40 CFR 131.36(a))

As explained more fully in the preamble, water quality standards consist of designated beneficial uses of a State's waters and the criteria necessary to protect those uses. The comment urges a waterbody-by-waterbody approach. For purposes of this rulemaking, EPA is presuming that the States have adequately made such designated use determinations for its waters. EPA is merely adding criteria for priority toxic pollutants on a State-by-State basis sufficient to protect the State's designated uses. EPA believes its approach accomplishes the commenters objectives but in a more comprehensive manner. Moreover, EPA doesn't believe this approach is more burdensome on dischargers in affected States. Because permit limits are incorporated into NPDES permits only for constituents having a reasonable potential to exceed State water quality standards, a discharger does not receive a limit in its permit unless its discharge contains the pollutant. Thus, comprehensive criteria coverage in water quality standards does not translate into unnecessary permit limits.

EPA is unpersuaded that somehow it would have been easier or more efficient for the public to comment on twenty-two separate rules covering the same issues than to deal with the issues in a single rulemaking. It would most likely result in EPA receiving the same type comments on each separate rule which would do nothing other than increase the administrative burden to EPA and further delay getting water quality standards in place.

3. *Comment:* A comment was made that several proposals for reauthorizing the Clean Water Act considered by Congress in 1991 contemplated giving EPA authority to promulgate Federal standards thus indicating that EPA does not have such authority now.

Response: A response to a comment above describes EPA's current authority to act under terms of the Clean Water Act. The principal CWA reauthorization bills considered by Congress in 1991 would neither question nor limit this existing authority. Rather they would alter the water quality standards program as it now exists by providing specific deadlines for States to act in adopting standards based on recommendations published by EPA and then mandating Federal promulgation by a date certain. Rather than suggesting that EPA does not now have such authority, these proposals support EPA's view that Congress is becoming increasingly impatient with the slow pace at which States adopt new criteria recommendations issued by EPA under section 304(a) and is willing to consider supplementing EPA's current discretionary promulgation authority.

4. *Comment:* Several comments suggested that EPA's promulgation action should be limited to the waterbodies and pollutants reported on the section 304(l) lists or information contained in section 305(b) Water Quality Inventory Reports. The basic thrust of these comments were that such lists, prepared by the States, contain sufficient information necessary to identify all potential toxic problem areas within the State. Some of these commenters also suggested these limited sources were more accurate than the broader approach relied on in EPA's proposal.

Response: A detailed description of the approach the Agency followed in developing this final rule is included in section E–2 of this preamble. As indicated in that section, EPA used information from a variety of sources in determining which criteria to include in the rule for each State. The Agency did not rely on a single source, such as 304(l), 305(b), or any other set of information.

Each of the data sources suggested by the commenters are valuable tools which serve specific purposes under the Clean Water Act. However, as described in section E–2, each source has limitations either as to coverage of waterbodies or sources of pollution, extent of information included, or a narrow focus because of their particular purpose. Even when information from a variety of sources is used as described as the Agency's "strawman", there remain inherent weaknesses in the underlying data.

EPA believes there is a greater possibility of achieving the statutory purpose of protecting water uses by relying on a range of available data sources rather than selecting one or two narrow databases. EPA believes that by not directing the Agency to use the results of the other statutory sections the commenters identified, and by use of the "could reasonably be expected to interfere" language, Congress directed the Agency to be more inclusive rather than less inclusive in the applicable criteria coverage. Thus, EPA urged a low threshold for inclusion of priority toxic pollutants in the guidance transmitted to the States.

5. *Comment:* One commenter argued that EPA's strawman systematically overestimates the presence of priority toxic pollutants because of its use of industry wide default assumptions for particular SIC codes. The commenter further argues that comparisons between the number of toxics adopted in States who evaluated available data for toxics and established criteria based on that data to the results of the strawman predictions show that a substantially smaller number of pollutants resulted. The commenter urged that only section 304(l) short list pollutants should be used for this rule.

Response: EPA's strawman analysis was designed to use all of the Agency's data bases to develop candidate lists of toxics on a State specific basis. States were urged to use this information as a starting point in evaluating the need for particular priority toxic pollutants.

EPA intentionally designed the analysis to yield a list of suspected priority toxic pollutants that would not understate the potential presence of such pollutants. As noted in the preamble, State monitoring information, for example, as used in the section 305(b) water quality reports, is not comprehensive in either geographic or parametric coverage. That is the reason EPA used the industry profile data—to maximize the data base.

Thus, EPA was providing the States with a listing that identified potential toxics and where those were potentially located. The State was encouraged to verify the lists. EPA has not used the list to identify pollutants for States included in this rulemaking. Rather EPA has viewed the analysis as supporting its contention that priority toxics exist in State waters and therefore, a broad promulgation for priority toxic pollutants is justified.

In arguing for limiting the promulgation to the section 304(l) short list pollutants, the commenter failed to compare the criteria the example State adopted in its water quality standards versus the pollutants identified in its section 304(l) short list. The State used as an example placed substantially more criteria in their standards than in their section 304(l) short list. The reason for this disparity is because the threshold for inclusion in water quality standards is much lower than for inclusion in the section 304(l) short list.

6. *Comment:* EPA solicited comment concerning the acceptability of the review process used by EPA to determine compliance with the Act—this process is described in section D of this preamble. EPA received few public comments in response to this request, beyond the general comment that EPA exceeded its authority to promulgate Federal standards, an issue addressed earlier in this section. One view offered was that the review process used by the Agency makes it difficult to evaluate whether adequate consistency was

applied by the Regions in evaluating acceptability of State standards.

Response: Each State's water quality standards submission is different. They require case specific review for adequacy and consistency with environmental and human health requirements and statutory and regulatory provisions. The statute allows for State flexibility. Given these factors, EPA established broad guidance parameters and Regional Offices reviewed each submission for consistency. EPA Headquarters staff exercised oversight on this process to assure appropriate inter-Regional consistency. This process did not produce identical standards in each State but that is not required. All State standards that were approved were judged by EPA to meet the twin tests of protection of water body uses and scientific defensibility.

Both the criteria development and the standards programs are iterative programs and EPA expects to request States to continue to focus on adopting criteria for additional toxic pollutants and revising existing criteria in future triennial reviews which new information indicates is appropriate. In no sense should States or the regulated community assume that the task of addressing pollution from toxics is completed by what the States have adopted or EPA is promulgating in the way of criteria for toxic pollutants.

7. *Comment:* EPA did not propose criteria for inclusion in State standards when the criteria were based on organoleptic effects. The Agency specifically solicited comment on this issue. Most of the comments received indicated that EPA was correct in not including such criteria in the rule. There were several comments to the contrary indicating that such criteria should be included because the pollutants are on the section 307(a) list and EPA did issue a criteria recommendation for the pollutant under section 304(a). Therefore, they argue that the requirements of section 303(c)(2)(B) apply.

Response: In the final rule, EPA has not included criteria for pollutants where the section 304(a) criteria recommendation was based on organoleptic effects. Such effects cause taste and odor problems which may increase treatment costs in drinking water or the selection by the public of alternative but less protective sources of drinking water and may cause tainting of or off flavors in fish flesh and other edible aquatic life reducing their marketability and resource value. EPA is also aware that some States have adopted such criteria in their standards. Nonetheless, because section 303(c)(2)(B) focuses on toxicity of the priority toxic pollutants, EPA believes its rule should likewise focus on toxicity. The 304(a) criteria documents for these pollutants do not recommend a criteria based on toxicity and therefore such criteria are outside the intent of a rulemaking for section 303(c)(2)(B).

This decision notwithstanding, it should be noted that the criteria based on organoleptic effects still represent the Agency's best scientific recommendations at this time and are within the range of scientific acceptability for a State's use.

8. *Comment:* One commenter asserted that EPA's Option 3 (i.e. adoption of a narrative standard coupled with a translator mechanism to compute a derived numeric limit) of its December 1988 guidance on complying with the Act does not meet the legal requirements of section 303(c)(2)(B). It is argued that EPA should therefore disapprove all State water quality standards which rely solely on a narrative "free from" toxics water quality standard and a translator mechanism. A related comment is that this translator procedure may be appropriate as a supplement to adopting specific numeric criteria.

Response: The legality of Option 3 is not an issue in this rulemaking. We are not promulgating any water quality standards based on Option 3. Option 3 is only a potential issue in the subsequent approval of standards for those States which are not included in this rule.

Nevertheless, as noted in the December 1988 guidance, EPA believes the combination of a narrative standard along with a translator mechanism as a part of a State's water quality standards can satisfy the substantive requirements of the Clean Water Act. Such translators would need to be subject to all the State's legal and administrative requirements for adoption of standards plus review and either approval or disapproval by EPA, and result in the development of derived numeric criteria for specific section 307(a) toxic pollutants.

EPA's guidance presented several factors that EPA expected to be incorporated into a translator process in order to comply with the Act. In essence, EPA expected that the technical mechanism used would need to be equivalent to a criteria development protocol. That is, it would need to include an appropriate number of sensitive species using suitable testing and analytical methodologies. If established and applied correctly, EPA has indicated that it could meet the legal requirements of section 303(c)(2)(B). *The central objective of* section 303(c)(2)(B)—establishing chemical specific numeric limits—is achieved by this approach. There is no statutory bar to it and the Agency sees no reason not to continue to support this approach by States.

Ultimately, EPA believes all State toxic control programs will be strengthened by adoption of both chemical specific standards and a translator mechanism for those pollutants where water quality criteria have yet to be developed.

9. *Comment:* EPA invited comment on whether to promulgate a translator mechanism for the States in this final rule. A translator mechanism would enable the States to derive numeric limits for pollutants beyond those in this promulgation based on a State's general narrative criterion. The Agency received comments both supporting and opposing this approach.

Response: While a translator mechanism could be a valuable supplement to State standards to deal with toxics for which no section 304(a) criteria recommendation is available, it is not necessary for EPA to promulgate a translator at this time to meet the objectives of section 303(c)(2)(B). Today's promulgation of chemical specific criteria fulfills that obligation. For that reason a translator mechanism is not included in today's final action. However, EPA believes that such a mechanism should be available in all States. Therefore, in revisions to the basic water quality standards regulation, EPA may propose a requirement for a translator mechanism which would be applicable to all jurisdictions included in the standards program.

10. *Comment:* Comments were received that EPA is attempting to establish use classifications in this rule and that such action is a right belonging to a State.

Response: The use classifications to which Federal criteria are applied in this rule are the classifications established and defined by each State affected by the rule. EPA is not creating State use classifications nor assigning use classifications to any water bodies in this rule. In the few instances described in Section G of this preamble, appropriate adjustments to uses and criteria were made as necessary to accurately reflect State use classifications. Further, EPA believes the regulated community is fully aware of the uses adopted by a State and to which water bodies the uses apply. Specific revisions in the rule pertaining to State use classifications are discussed

in subsection 6 of the Response to Public Comments Section.

11. *Comment:* During the pendency of this rulemaking, several States asked if adopting an emergency rule would be sufficient to allow removal of the State from the final promulgation. Several States also indicated they should be removed from the rule because they had plans to adopt standards.

Response: Emergency rulemaking actions by States are not judged by EPA as sufficient basis for removal from this rulemaking. In most cases, State emergency rules have a limited duration and expire at a date certain. There is no assurance that enforceable permanent water quality standards would be in-place at that time. If EPA were to allow emergency rulemakings to be the basis for removal from this package, given the long delays to date by these States, there is the strong possibility promulgation action would have to be commenced again by EPA in the near future. The delays and related program disruptions experienced by EPA have already been too great. There has to be closure on the standards adoption portion of our toxic control efforts. Reliance on temporary emergency State actions would not produce that closure.

There is also the question of legal vulnerability to the adoption of emergency rules and whether the State emergency rule procedures allow for sufficient public review. Moreover, the emergency rules adopted would have to fully comply with the Act. States which contend they should be dropped from this rule because they now plan to adopt standards remain in this rule because EPA has no reasonable means of being assured standards will be adopted as planned. Since passage of the amendments in 1987, many State plans for standards adoption have not been completed as anticipated. When States complete approvable adoptions, EPA will take timely action to remove the promulgation as applicable to that State.

12. *Comment.* One commenter asserted that States do not have the necessary legal authority under State law to use national water quality standards in State permits.

Response. Without more information, we cannot determine the precise concerns of this commenter. However, section 402(b) of the Clean Water Act requires that States approved to administer the National Pollutant Discharge Elimination System (NPDES) program must have adequate authority to issue permits which comply with any applicable requirements of section 301 of the Act. Among those requirements are limitations to meet water quality standards, and the criteria promulgated today are "* * * applicable water quality standard(s) established pursuant to this Act." Section 301(b)(1)(C).

Once promulgated, Federal standards will be the basis of all environmental control programs designed to meet water quality standards. States which had inadequate criteria for toxics will have a much more complete basis for determining if there are toxic contamination problems in their waters. If problems are identified, the State and EPA will need to work together to see if the sources of these problems can be identified and controlled. The most direct impact will be on NPDES permits for individual point source discharges. The permitting agency, whether it be the State or EPA will have to determine on a case-by-case basis whether to re-open an individual permit or wait until a permit expires before introducing new limits.

13. *Comment.* One commenter described ongoing judicial and administrative proceedings to establish the authority of the state to set permit limits for dioxin by interpreting the state's narrative criterion using EPA's section 304(a) dioxin guidance. The commenter indicated that the state has consistently implemented its narrative water quality criterion to control dioxin discharges by interpreting that criterion using EPA's guidance. It is the commenter's view that if the state prevails in the ongoing litigation, it will effectively have a numeric criterion for dioxin.

Response The critical flaw in the commenter's argument is that the State does not have in-place an EPA-approved numeric criterion for dioxin, or an approved translator to generate a numeric criteria for dioxin. Moreover, conclusion of the litigation would not establish an approved numeric criterion, even if the State were to prevail. EPA understands that States often implement their narrative criteria by interpreting those criteria using EPA guidance. EPA supports this process by the States. However, section 303(c)(2)(B) is clear that States are to adopt numeric water quality criteria for toxic pollutants. The purpose of this rulemaking is to finally establish the necessary numeric toxic criteria in all States, and only those states with the necessary approved numeric criteria are excluded from the rule.

2. Science

The response to comments in this subsection are included under the following headings: (A) General Comment, (B) Aquatic Life Criteria, and (C) Human Health Criteria.

A. General Comments

14. *Comment:* Numerous comments were received that EPA's water quality criteria were published as scientific guidance and were never intended to be used as regulatory provisions without modification to reflect local environmental conditions. Related comments indicated that because the criteria were published as guidance, the public comment received on the draft water quality criteria documents were restricted since reviewers did not anticipate their use as enforceable limits.

Response: Water quality criteria are published as scientific information or guidance under section 304(a) of the Act because that is what the Clean Water Act specifies. EPA's implementing water quality standards regulation recognizes that the section 304(a) criteria may be used as a basis for States to establish enforceable standards. See 40 CFR 131.11(b). To imply that the section 304(a) criteria are merely informational and not directly related to establishing water quality standards under section 303(c) is not only reading the Act in an crabbed manner, it also ignores 26 years of program history which demonstrates that States generally rely on the criteria recommended by EPA in establishing standards. Moreover, this rulemaking is the process which transforms these recommendations into enforceable regulatory requirements for specific States. Any specific issues related to establishing these criteria as applicable to State standards could have been raised during this rulemaking even if the issues were raised or considered in the earlier publication of criteria documents.

Furthermore, although the EPA water quality standards regulation allows State modification of water quality criteria to reflect local, site-specific conditions, it is not a requirement to do so. EPA is also not obligated to modify criteria to reflect local environmental conditions although ideally EPA would consider any data submitted in support of establishing a site-specific criterion in determining whether site-specific criteria would be appropriate. In addition, EPA believes the methodology and the extensive data base used by the Agency results in deriving national criteria that will be protective for most species in virtually all waterbodies throughout the country. (See 1985 Guidelines, page 4.)

Congress has given substantial credibility to the section 304(a) criteria as well. For example, in section 301(h)(9) applicants must meet the

section 304(a) criteria as if they were regulatory.

Finally, it should be noted that when announcing the availability of draft and final criteria documents, it is stated in the EPA announcement that such criteria may form the basis for enforceable standards. EPA believes that adequate notice of the uses of the section 304(a) criteria has been provided to the public.

15. *Comment:* Commenters suggested in general that the EPA criteria are outdated and need to be revised extensively to reflect the latest scientific information available before they can be appropriately used in rulemaking. For a few pollutants data were submitted to substantiate this claim. (See response to comments on specific pollutants below.)

Response: EPA does not agree with these comments for several scientific, programmatic, and statutory reasons. Scientific information is constantly evolving. Additional research is always being done, test methods and theories improve, and more precise analytical methods become available. There can be a long lag time between conducting the research, analyzing the data, issuing the criteria documents for review, revising the documents, and working through the State or Federal administrative processes to adopt standards. There comes a point in this process, where the administering agencies, both EPA and the States, have to act using the existing criteria recommendations based on the methodology by which they are derived, and put standards into place so that control programs can be implemented to protect the health of the public and the environment. One basic reason why criteria and standards is an iterative process is to continuously evaluate and incorporate new information. Through this process, many of EPA's criteria have been updated since issuance of the formal criteria documents.

Moreover, once standards are in place, applications can be made through the mathematical models used to derive total maximum daily loads and wasteload allocations. These determinations are associated with the NPDES permits process and result in permit limits being established that have sufficient latitude to adequately account for other than major adjustments to individual criteria recommendations.

Finally, it must be recognized that Federal promulgation is the end of the process to establish water quality standards, not the beginning. In this case, the beginning was in 1980 when most of the criteria and the first generation criteria development methodologies were issued. By 1983, due to lack of response by the States, EPA revised its basic water quality standards regulation to put primary emphasis on the adoption of water quality criteria and control of toxic pollutants. This too failed to engender adequate State response which in turn led to the directive from Congress contained in section 303(c)(2)(B). Now, five years later, and two years after the States should have taken action, this final rule completes the process of establishing the first set of comprehensive standards for toxic pollutants. This final Federal promulgation ends this current effort but the revision of criteria based on new research, the revision of applicable standards, alterations in analytical methods, and the evolution of control technologies will continue.

EPA asserts, as we have elsewhere in this preamble, that the promulgation process established under the Clean Water Act is a process designed to bring to closure the act of putting enforceable standards into place as basis for environmental control programs designed to protect public health and the environment. The promulgation process is not designed or intended to be the vehicle for a reevaluation of the scientific underpinnings of water quality criteria. It is also not the process for protracting the debates about the scientific merits of various pollutants. That debate is essential, necessary, and is constantly ongoing but as a separate activity. The promulgation process envisioned must go forward and the Agency must make decisions based on the available data. It is clearly a means to end such debates and to get environmental controls started based on available information.

EPA believes the criteria promulgated today are scientifically sound as they are based upon a technically and scientifically acceptable methodology. Detailed descriptions of the formulation of aquatic life criteria and human health criteria are included in section F (1,2, and 3). As discussed below, we have made some revisions to the criteria based on public comments. Our criteria for both human health and aquatic life provide a reasonable amount of protection with only a small possibility of substantial overprotection or underprotection.

To completely review all the criteria as some suggested would take a minimum of several years during which time the human health and environmental problems associated with the continued discharge of toxic pollutants would worsen. There is no predetermined result from an extended review—some criteria might become more stringent, some less, some might remain the same. In the meantime, the States that failed to comply with the Act are rewarded for their failure. These States have delayed while 43 of the jurisdictions included in the program have adopted water quality standards for the most part relying on EPA's section 304(a) criteria guidance.

As indicated in this preamble, we are currently re-examining our basic criteria development methodology, which is a normal course of action for the Agency. We anticipate some changes will be made and we assume some changes in the criteria will be made over the years. This, however, is no reason to suspend action now.

16. *Comment:* The use of information contained in the Agency's Integrated Risk Information System (IRIS) to update human health criteria was questioned by several commenters. The central concerns were that the information contained in the system was not subject to external peer and public review, the background information contained in IRIS is not readily available for review, and the public had little chance to review the results of the recalculations.

Response. A detailed discussion of the IRIS may be found in Section F–3 of this preamble. To summarize the salient points: (1) Reference doses and cancer classifications are validated by two Agency work groups composed of senior Agency scientists from all other program offices (i.e., internal peer review), (2) the consensus opinion for reference doses and slope factors are then used throughout EPA for consistent regulation and guidance development, (3) the data are available through the TOXNET System maintained by NIH and through diskettes available from the National Technical Information Service (NTIS), (4) the information used to recalculate the section 304(a) criteria in today's rule was included in the record of this rulemaking, and (5) through the proposal of this rule, the public had an opportunity to review and comment on the revised criteria. In addition, some of the RfD values and the cancer potency slope factors undergo public review during rulemaking for other Agency programs such as drinking water, pesticides, and Superfund. Thus, EPA believes that adequate notice about IRIS and its use in Agency programs has been provided to the public, at least as it concerns its use in this rulemaking.

17. *Comment:* Several commenters indicated that the criteria should be subjected to a peer and public review process similar to that followed by the Agency in issuing proposed criteria

under section 405 of the Act concerning the disposal of wastewater solids.

Response: The proposed regulations for the disposal of wastewater solids represented the first time EPA proposed such standards, and was the first time a methodology and specific criteria were proposed by EPA for wastewater solids. Therefore, the extensive review for that proposed regulation was appropriate. The situation is not the same for the criteria promulgated in today's rule. EPA and the States have been regulating the discharge of pollutants into surface waters for many years. The methodologies for deriving criteria for the protection of both human health and aquatic life were peer and publicly reviewed in 1980. The aquatic life guidelines were revised with peer and public review in 1985. Both methodologies are currently being reviewed for possible revisions. As discussed elsewhere in this section, this rulemaking makes use of the existing criteria and therefore is not the most effective vehicle for revising either the methodologies or the actual criteria.

18. *Comment:* Several commenters objected that applying criteria as standards when the criteria are below analytical detection limits is unreasonable because this may force the imposition of unreasonable permit limits and "false positive" indications of non-compliance. Others suggested that it was not clear how detection limits affect permit limits and compliance. There were also comments supporting EPA's position as described in the proposal.

Response: In consideration of statutory requirements that water quality standards are to be protective of designated stream uses, EPA has determined that consideration of analytical detectability would not be an appropriate factor to consider when calculating the water quality criteria component of water quality standards. This has been the Agency's position since the inception of the water quality standards program in 1965.

Although the sensitivity of analytical methods are not appropriate for setting water quality criteria, they may be appropriate in determining compliance with permit limits based water quality standards. It should also be noted that by the time standards are converted into permit limitations after calculating total maximum daily load and wasteload allocations, the actual permit limit may be in the range of standard analytical methods cited by EPA in 40 CFR part 136.

EPA's criteria development methods for aquatic life are generally based on laboratory bioassays with sensitive aquatic life. The results from these tests are analyzed by mathematical procedures outlined in EPA's criteria methodology guidelines. EPA human health criteria are developed from protocols generally using toxicity studies on laboratory animals such as mice and rats. Thus, EPA's criteria are effect-based without regard to chemical analytical methods or techniques.

Because water quality standards developed pursuant to section 303(c) of the Clean Water Act are not self-enforcing, the measurement of these chemicals in a regulatory sense is generally in the context of an NPDES permit limitation. The permit issuing authority, either a State or EPA, in conjunction with the permittee establishes the analytical methodology to be used in determining compliance with the permit limit.

As noted in footnote 3 of this preamble, EPA has issued guidance on how constituents with water quality criteria specified at less than the sensitivity of official analytical methods (i.e., those listed in 40 CFR part 136) are established in permits.

EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by States at concentrations necessary to protect designated uses. The criteria promulgated today meet that requirement while EPA's policy with respect to regulatory compliance takes analytical sensitivity and precision into consideration.

B. Aquatic Life

19. *Comment:* A few comments questioned the role of biological criteria in the standards program with one commenter suggesting that establishing numeric limits is contrary to achieving the biological goals of the Clean Water Act.

Response: Together, chemical and physical characteristics and biological integrity define the overall ecological integrity of an aquatic ecosystem. State regulatory agencies should strive to fully integrate all three approaches since each has its respective capabilities and limitations. EPA's position is that each approach as represented by whole effluent toxicity testing, chemical specific criteria, and bioassessment approaches is independently applicable (see Policy on Use of Biological Assessments and Criteria in the Water Quality Program, U.S. EPA, May 1991). A description of the integration of these approaches along with a detailed analysis of the capabilities and limitations of each approach may be found in the Technical Support Document for Water Quality-based Toxics Control, March 1991. See TSD Section 1.5 beginning on page 20, and references cited therein.

20. *Comment:* A commenter argued that EPA's proposed national aquatic life criteria will be overprotective for many surface waters because they do not account for site-specific conditions. At a minimum, any federal water quality criteria must take into account broad aquatic life categories.

Response: The development of EPA's criteria is based on a broad aquatic life data set. The 1985 guidelines recommend that eight species from eight separate families be used in the development of the freshwater and saltwater criteria. While it is always beneficial to have more data, EPA's peer reviewed guidelines establish that criteria developed from this minimum data set adequately protect aquatic communities (1985 Guidelines, see section III, p. 22). The apparent level of protection is different for each kind of effect (acute or chronic toxicity to animals, toxicity to plants, etc.) because of the quality and quantity of information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. The present approach to aquatic toxicity allows conclusions to be made about the ability of a substance to adversely affect aquatic organisms and their uses whenever the minimum data set are satisfied. See also the discussion on metals speciation in Section F-7 and the response to comment below.

21. *Comment:* One commenter asserted that EPA has incorrectly concluded that the Section 304(a) criteria are appropriate for most waters because there have been few occasions where site-specific water quality criteria have been applied.

Response: EPA's determination that Section 304(a) criteria are generally applicable is not based on a lack of site-specific criteria modification studies as asserted by the commenter. EPA has conducted a series of field applicability studies to determine the correlation between chemical specific criteria and receiving water impacts. (Technical Support Document for Water Quality-based Toxics Control, March, 1991 at p. 2). These test results indicate a good correlation between the laboratory concentrations and expected field results. The water quality criteria are not threshold values. One should not expect that once these values are exceeded, the result is a measurable impact on aquatic life. The aquatic life criteria embody conservative assumptions so that small excursions

above the criteria will not result in adverse impacts. The data indicate that if ambient water quality criteria are met, organisms in the receiving water are protected from adverse impacts.

22. *Comment:* Comment was received that EPA should clarify that the aquatic life water quality criteria for arsenic are based on the trivalent form of arsenic.

Response: The arsenic criteria promulgated today are applied on total recoverable inorganic arsenic. The 1985 arsenic criteria document is derived from data on Arsenic (III). However, because there is no readily available or practical analytical method to quantify the various forms of arsenic in monitoring applications for aquatic life, EPA has concluded that it is reasonable to quantify environmental arsenic concentrations as total recoverable inorganic arsenic. (EPA Methods 206.2, 206.3, 206.4, 206.5.)

In addition, EPA reevaluated the acute and chronic toxicity data on the two most prevalent forms of arsenic in aquatic systems (trivalent and pentavalent arsenic) in the Arsenic criteria document. These data show that arsenic (III) and arsenic (V) toxicity is similar for both sensitive freshwater and saltwater species. For five of the six freshwater species and all of the saltwater species used in the arsenic calculation where there was comparable information on acute and chronic toxicity, values were within a factor of two or three. Certain plants, for example *Selenastrum capricornutum* (alga), are 45 times more sensitive to arsenic (V) than to arsenic (III). Therefore, it is reasonable to combine forms of arsenic to specify the criteria. The measurement of total recoverable arsenic has both toxicological and practical advantages and appropriately represents the aquatic life toxicities of arsenic compounds.

23. *Comment:* Several commenters asserted that criteria based on laboratory tests are overprotective when applied in the field. Another commenter quoted laboratory study reports stating that the results are applicable only to the particular water tested.

Response: EPA agrees that waters used for laboratory toxicity testing are generally cleaner than many natural systems. In cases where ambient waters contain constituents which alter the toxicity of chemicals, an increase in accuracy may be provided by rerunning the toxicity tests in site water. (For example, the water-effect ratio approach for metals promulgated today.) In most instances, this correction will be small. (TSD, March 1991, p.2). Therefore, applying the criteria values developed from laboratory testing provides an acceptable level of accuracy, and this approach is used by most States. In the context of this rule it represents a technically acceptable approach to cover a variety of waters, and the only feasible one. (See also the response to comments for the 1980 Guidelines, Nos. 17 and 19, 45 FR 79359, November 28, 1980.)

In response to the second comment, the scientist running the specific toxicity test referenced by the comment noted that its accuracy is only guaranteed for the specific water tested. However, applying these tests to other waters is an acceptable approximation. (See response to public comments for the 1980 Guidelines, 45 FR 79359–79360, comment #20 and #21.) Additionally, laboratory toxicity testing is the most reasonable and practical way to develop a database which is large enough to develop criteria, and diverse enough in species, which generally represent a larger source of variability.

While most States have not chosen to perform site-specific toxicity tests, any State may develop site specific-criteria. These criteria will be more appropriate and tailored to the site for setting NPDES permit limits than EPA's national criteria. Because they are amended water quality standards, site specific criteria are subject to EPA review. Other than the water-effect ratio for metals which is promulgated today, State-developed site specific-criteria do not replace the criteria promulgated in today's rule unless the site specific-criteria are approved by EPA as meeting the requirements of the Act and EPA amends the rule adopted today.

24. *Comment:* Comment was received that the proposed rule includes some aquatic life criteria computed using the 1980 guidelines methodology and others were computed using the 1985 guidelines methodology. It was asserted that the simplistic approach of the 1980 methodology ignores the scientific improvements of the 1985 guidelines. The commenter urged that these criteria should be updated to provide consistent methodology and adherence to the statutory requirement of section 304(a).

Response: As the commenter noted, some of the aquatic life criteria in this rule are based on 1980 guidelines. EPA reviewed the data base for these criteria and determined that in general they could not be recalculated by the 1985 guidelines because of differences in data base requirements between the two guidelines used species specific requirements whereas the 1985 guidelines expanded this to broader taxonomic categories.) EPA believes that the data used in the 1980 criteria document are sound. As a practical matter, a reasonable approximation to a criteria maximum concentration can be obtained by simply dividing the final acute values in the matrix by 2. The criteria in the matrix in today's rule were not changed from the results of the respective 1980 and 1985 methodologies. Therefore, EPA has reconsidered these aquatic life criteria at the commenter's request and considers them to be within the acceptable range based on uncertainties associated with computing water quality criteria. These criteria are protective of aquatic life and are scientifically sound.

The development of aquatic life criteria is a dynamic process which responds to the influence of improved science. It is expected that this science will be constantly evolving as new analytical techniques become available and new studies are evaluated. To this end, EPA is also reviewing the current methodology for developing aquatic life criteria. The current methodology will be reviewed, and if needed, revised to incorporate the latest concepts of aquatic toxicology.

25. *Comment:* A commenter asserted that the proposed aquatic life criteria may be underprotective since they fail to account for synergism and additivity and fail to consider wildlife impacts.

Response: EPA agrees that the aquatic life criteria do not deal with simultaneous exposure to more than one pollutant. This is largely because few data are available, the data which are available do not allow for development of useful principles and there are so many possible combinations of pollutants present to prevent development of appropriate guidance. EPA has considered the effects of multiple toxics discharged into receiving waters. (Technical Support Document for Water Quality-based Toxics Control; March 1991.) The studies cited in the TSD indicate that the median combined effect of a mixture of acutely toxic pollutants in receiving water is additive. EPA recommends, that in the absence of site-specific data, regulatory authorities consider combined acute toxicity to be additive. Thus, the combined acutely lethal toxicity to fish and other aquatic organisms is approximately the simple addition of the proportional contribution from each toxicant.

However, available data do not indicate additivity for chronic toxicity. EPA further recommends that chronic toxicity not be considered additive, and that each toxic be considered individually.

Synergism has not been demonstrated to be an important factor in the toxicity of effluents. Field studies or effluent toxicity and laboratory tests with

specific chemicals support an inference that synergism is a rare phenomenon. (See TSD, page 24.) (See also response to comments in the 1980 Guidelines, Comment #9, 45 FR 79358, November 28, 1980.) Theoretically, antagonism is just as likely to occur, which might suggest that the criteria are overly protective in an environment exposed to contaminant mixtures.

EPA considers the criteria, when applied with the appropriate frequency and duration of exposure, to adequately protect wildlife. Three of the aquatic life criteria in this rulemaking are based on wildlife toxicity and exposure, (Selenium, DDT and Polychlorinated Biphenyls). EPA is in the process of developing a wildlife criteria development methodology to provide further guidance for wildlife concerns. Once this tool is developed, EPA will have a method of focusing criteria on wildlife issues.

26. *Comment:* Several commenters argue that the criteria do not apply to semi-arid ecosystems. None of the guidance issued to date expressly address the means to apply those criteria to semi-arid ecosystems found in Arizona. Ephemeral streams and effluent-dominated waters are distinct classes of waters that should be regulated to protect the aquatic species that typically inhabit them.

Response: Water quality criteria are toxicity based values, usually chemical specific. The criteria are based on toxic effects to a broad taxonomic group and do not consider the types of water bodies, such as semi-arid ecosystems, they may be applied to. Aquatic life criteria, when implemented as part of water quality standards, are meant to be protective of aquatic life. These standards are applied to specific waterbodies through designated uses. For this rulemaking, EPA assumes that States correctly define designated uses and the specific waterbodies to which those uses apply. EPA agrees that ephemeral streams and effluent dominated waters are distinct classes of waters. If a State feels an aquatic life use designation is appropriate for these waterbodies, then the aquatic life criteria will apply to protect that use. If not, then they will not apply. EPA is not promulgating designated uses for State waters. EPA is only applying appropriate aquatic life criteria to waters that States designated for aquatic life protection.

27. *Comment:* Comment was made that EPA should allow an alternate methodology for calculating the Final Acute Value when dealing with small data sets.

Response: EPA has considered alternate methods for calculating the Final Acute Value (FAV). The present methodology was developed by the Agency's guidelines committee, subjected to outside peer and public review, and is a reasonable technique. EPA develops a Final Acute Value on as large a data set as available. The guidelines generally require eight separate families for derivation of acute values (1985 Guidelines, p. 23). EPA considers this to be an adequate data set for calculation of the FAV. As the data set grows it only provides additional confidence of the scientific basis for calculating the Final Acute Value. The present methodology has been reviewed both within and outside the EPA for scientific merit. EPA considers the present methodology to be sound. The guidelines are presently under review. The method suggested by the commenter is relatively new, and it and other statistical bases for criteria development are being reviewed in the Agency's current effort in reviewing the criteria development guidelines. It is intended that the guidelines reflect the best science and to that end EPA will consider all aspects to continue to provide a sound and scientifically based methodology.

28. *Comment:* Comment was received that the aquatic life criteria and guideline methodology, contrary to EPA's assertions, have not undergone sufficient scientific peer review.

Response: EPA does not agree. The criteria and underlying methodology guidelines were widely distributed to interested parties. These drafts were made available to and thoroughly discussed with experts within EPA, industry, and academia. These interactions have provided many useful comments and information which greatly improved the scientific basis of the criteria and methodologies. The methodologies were further reviewed by an independent Science Advisory Board which EPA considers to constitute external peer review. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985). The SAB noted that since EPA's initial efforts in developing water quality criteria, the process has undergone considerable evolution. The SAB felt that each revision represented a more sophisticated and realistic approach. EPA encourages and makes every reasonable attempt to include as much of the scientific community as practical in carrying out its responsibility under the Clean Water Act.

29. *Comment:* Comment was received that EPA states in the proposal that the methodology for developing aquatic life criteria have been approved by the Science Advisory Board (SAB); however this approval was not unqualified.

Response: In its comments on EPA's 1985 guidelines, the SAB committee noted that EPA had developed a more scientifically sophisticated and realistic set of guidelines. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985.) It noted approvingly that EPA considers such issues as mode of exposure, level of protectiveness and ecosystem protection. It further noted that the guidelines took advantage of advances in recent scientific research. The report, being a critique, did note areas where the guidelines could be improved and areas where additional research might be helpful. Overall the SAB report was supportive of the Agency's aquatic life criteria development guidelines.

30. *Comment:* Numerous comments were received with regard to the metals criteria. It was noted that the draft rule did not make clear what analytical method was to be used for implementation and that metals criteria should not be interpreted in terms of total recoverable or acid soluble metal. It was asserted that dissolved criteria would be more appropriate, and in many cases effluent limits based on dissolved metals only would be more appropriate. Many commenters urged that the rule should implement the metals criteria using the site-specific water-effect ratio, in order to target the bioavailable fraction of pollutant.

Moreover, it was asserted that the copper criteria document states that organic carbon has a strong effect in reducing copper toxicity, and that the copper criterion should be recalculated for waters having TOC greater than 2–3 mg/L. Furthermore, it was argued, the toxicity of several metals are related to pH, total organic carbon (TOC), speciation, as well as the hardness.

The commenters asserted that the criteria are overly protective when applied to the field, and are overly protective because they are not site-specific.

Another commenter argued that the criteria are underprotective because they do not account for synergism or additive effects.

Response: These diverse and recurring comments have been aggregated above because they deal in large measure with the phenomenon that the same metal concentration may cause different toxicity from place to place due to chemical differences from place to place. In natural waters metals may exist in a variety of dissolved and particulate forms. As discussed

elsewhere in the preamble, the bioavailability and toxicity of a metal depends strongly on its exact physical and chemical form. See Section F.7. It also depends on the site-specific chemistry of the water, and on the other materials contained in the water.

Because of (a) the complexity of metals speciation, (b) the varying degrees of bioavailability and toxicity of the many forms and complexes, and (c) the additive, synergistic, and antagonistic influences of other materials in the water, there is no one chemical method that can assure that a unit of concentration measured in the field would always be toxicologically equivalent to a unit of concentration occurring in the laboratory toxicity tests underlying the criteria. Consequently, simply choosing a particular chemical method (such as total recoverable metal or dissolved metal) to measure attainment of the metals criteria would not assure the appropriateness of the criterion for the water chemistry of the various sites at which the criteria apply.

In response to comments, EPA is implementing the criteria in terms of total recoverable metal while calculating the criteria value using the water chemistry adjustment provided by the "water-effect ratio" procedure for certain metals as described and reocmmended in its current Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, May 1992. This approach takes into account, directly, water characteristics such as total organic carbon, pH, metals speciation and hardness, as suggested by the commenter.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species, measuring LC50s for the pollutant using (a) the local receiving water collected from the site where the criterion is being implemented, and (b) laboratory toxicity testing water made comparable to the site water in terms of chemical hardness. Because the water-effect ratio procedure, described in the above referenced guidance, provides a biological measure of differences in water chemistry, the ratio between site water and lab water LC50s is used to adjust the national acute and chronic criteria to site-specific values.

Because the water-effect ratio is a comprehensive measure of differences in bioavailability and toxicity, including the differences between dissolved and particulate bioavailability, it will produce a more appropriate criterion than simply expressing the criteria as dissolved metal. Some metals, such as copper and silver, can exist in a variety of dissolved forms that differ greatly in toxicity. The water-effect ratio is the best procedure EPA currently has for measuring such differences.

The water-effect ratio is also a reasonable method now available for accounting for synergistic and additive effects of pollutants. Regardless of whether a value less than or greater than one is measured for the water-effect ratio, synergistic and additive effects of other pollutants in the site water are working against the antagonistic effects of any metal binding agents present.

EPA recognizes that the comprehensive qualities of the water-effect ratio do come at a cost. The procedure will yield results that are locally the most appropriate, but it is more difficult and expensive than a purely chemical approach. Consequently, performing such an analysis is not mandatory. In the absence of acceptable data, the rule assigns the ratio a value of 1.0, which yields no change in the national criteria. The rule also stipulates that the water-effect ratio cannot be set at a value different than 1.0 unless such value protects the water body from the toxic effects of the pollutant, and is derived from suitable tests on samples appropriately representative of the water body. Consequently, inadequacies, uncertainties, or ambiguities in the data will also result in the water-effect ratio being set at 1.0.

The type of specific data needed to implement the method is described in guidance: The 1992 Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, and the 1983 Water Quality Standards Handbook. As discussed in Section 7 of the preamble, EPA is currently developing more specific procedures and methods to assist States in implementing the water-effect ratio approach.

31. *Comment:* A commenter asserted that laboratory tests using artificial testing conditions have little or no direct applicability to actual discharges and receiving water situations, therefore the criteria are overprotective.

Response: Laboratory tests are not conducted in pure water and pollutants are not solely in a free ionic form (complexed by nothing but water). (For example, laboratory waters are described in some detail in various standard protocols for doing toxicity testing, e.g., American Society for Testing Materials (ASTM), Standard E729, "Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.") Laboratory waters have low, but still significant, levels of organic carbon and suspended particles that are in the range of a significant number of receiving waters. In the case of heavy metals, for example, certain particulate forms may be partially bioavailable and particulate forms in effluents may become dissolved after discharge into receiving waters. It is not appropriate to attribute toxicity solely to a particular form of metal: This has never been clearly demonstrated for any metal, being only questionably inferred under very restrictive conditions. (See response to public comment for the 1980 Guidelines, comment nos. 17, 19 & 20; 45 FR 79359.)

Because water quality criteria are derived to be protective in almost all situations, they may be overprotective in some situations. Moreover, site water effects may be most prevalent for heavy metals, this rule thus provides for site-specific determination of criteria values for metals based on local water-effect ratios.

32. *Comment:* EPA's aquatic life criteria for metals do not take into account the effect that water chemistry and metals speciation has on toxicity. EPA should withdraw criteria (such as zinc and copper), and provide criteria that vary with pH, total organic carbon (TOC), and other factors that affect speciation and toxicity.

Response: While it is true that speciation and site water chemistry can modulate toxicity and that the national criteria do not account for most of these factors, we do not agree with the comment that we should withdraw the criteria. There is inadequate data on enough species and conditions to adjust for all important factors in the national criteria, although current work is trying to address this situation. However, this uncertainty is insufficient reason to not issue and apply criteria; criteria are sufficiently applicable without modification to most receiving waters and can be appropriately adjusted for other waters by the water-effect ratio approach. The purpose of water effect calculation is to provide a means for setting the value appropriate for the site-specific water chemistry, where sufficient data are available. By providing for such a calculation in the rule, the criteria thereby appropriately incorporate such factors.

33. *Comment:* EPA's aquatic life criteria do not take into account acclimation. As a result, the criteria are overly protective.

Response: Acclimation is the ability of organisms to tolerate higher concentrations or pollutants or other conditions, developed through an exposure to such chemical or condition

without apparent adverse effects. Studies with fish have not documented large changes in sensitivity because of acclimation effects, the typical factor being about two. Furthermore, significant changes have usually been reported under very restrictive and unusual exposure conditions—a prolonged exposure in a narrow concentration range near chronic toxicity values followed by a sharp rise to acutely toxic concentrations. Acclimation of individuals under most exposure conditions would be less and does not persist for long once exposures drop significantly below toxic levels. To try to account for such conditions in nationally applicable criteria is not feasible. Adaptation of populations can occur due to natural selection, but is not well described; in any event, it cannot be accounted for in any generally applied presumptive standard but only documented on a site specific basis.

34. *Comment:* Several commenters asserted that the metals criteria are below natural background levels, as shown by EPA's own studies. Thus, such criteria are overprotective and invalid.

Response: EPA studies which examine USGS data, appear to indicate that the natural background concentrations in undisturbed watersheds at times exceed the criteria for copper, lead, zinc, iron, and aluminum. However, recent work by USGS and by others (for example, Windom et al. in Environ. Sci. Technol. Vol. 25, 1137) indicates that much of this data, that is the copper, lead, and zinc data, are not valid. The measured concentrations of these metals are largely artifacts of external contamination of the sample during collection and processing. At this time USGS has suspended collecting data on these metals nationwide, until improved methods can be implemented in their central laboratories.

EPA notes that USGS generates a large portion of the data available for the nation's ambient waters, and that the federally approved protocols are used by a variety of other agencies that collect ambient data. Consequently, it appears likely that many waters may be improperly determined not to be attaining the metals criteria.

Based on USGS results, the data for the metals on the priority toxic pollutant list most likely to be affected by external contamination are arsenic, beryllium, cadmium, copper, mercury, lead, and zinc. The nickel data is unlikely to be affected. USGS suspects that filtering artifacts, rather than contamination, may produce anomalies in dissolved data for other metals not in today's rule. USGS has not yet ascertained quality of its selenium and silver data. Moreover, EPA has reviewed the data used in establishing the EPA metals criteria and does not believe these criteria are affected by the analytical problems noted by USGS. (Erickson, 1992, personal communication, in EPA's record).

To assure the reliability of the data in the lower microgram per liter range, priority toxic pollutant metals should be sampled and analyzed using protocols that involve ultra-clean reagents, ultra-clean Teflon or polyethylene labware, and ultra-clean laboratory environments.

EPA is not aware of reliable analytical data showing excursion of aquatic life criteria by natural background concentrations of the metals covered by this rule.

35. *Comment:* Commenters asserted that the acute and chronic averaging periods are unnecessarily restrictive, and were set in an arbitrary manner. As the acute criteria are derived from 48–96 hour tests, the EPA's one-hour averaging period for acute criteria cannot be correct. As the chronic criteria are derived from 30–360 day tests, the EPA's four-day period for chronic criteria cannot be correct. Pollutant specific averaging periods should be used, based on the latest scientific information, including the 1983 work of Mancini (Water Res. 17: 1355), which dealt with the effects of time varying concentrations.

Response: The quality of ambient water typically varies in response to variations in effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing essentially constant exposure as in laboratory bioassays, but fluctuating exposures which may include short periods of high concentrations potentially causing adverse effects. EPA's criteria formulations therefore include an exposure period for concentration averaging which must be sufficiently short to limit elevated concentrations that might cause harm to aquatic life.

The 1-hour average exposure for the criteria maximum concentration (CMC) was derived to protect against the effects of fast acting toxicants like ammonia and cyanide. Thus, short-term spike increases in certain of these toxicants have been observed to cause toxic effects. (See 1991 Technical Support Document, appendix D.)

The 4-day averaging period for the criteria continuous concentration (CCC) is based on the shortest duration in which chronic effects are sometimes observed for certain species and toxicants. The most important consideration in establishing duration criteria is how long the exposure concentrations can exceed the criterion without affecting the endpoint of the test (e.g., survival, growth or reproduction). EPA believes 4 days should be fully protective even for the fastest acting toxicants.

The approach of Mancini (or similar modeling cited in Chapter 2 of EPA's Technical Support Document) is certainly a promising one for establishing averaging periods. It and similar methods are being evaluated for incorporation as options into new water quality criteria guidelines. However, the validity and applicability of these methods are still not completely resolved. Applying Mancini's model to available toxicity data forces an analyst to immediately deal with problems of delayed mortality and limitations on observation times. The fit of the model to data is also only approximate and requires professional judgment in appropriately applying it.

Because of such considerations, EPA's current approach remains reasonably protective and is therefore appropriate.

36. *Comment:* Commenters asserted that the three-year return interval is too stringent for marginal excursions of water quality criteria. As a result the criteria are overpretective. It is argued that: EPA's Technical Support Document has cited information on recovery from severe or catastrophic acute stresses as the basis for its recommended return interval for both acute and chronic criteria; EPA's criteria, however, are intended to avoid even slight stresses; and cites on EPA draft staff analysis showing that a three-year return interval for slight excursions results in a billion-year return interval for a severe stress.

Response: EPA is promulgating its proposed general rules of applicability (40 CFR 131.36(c)(2)) for the return interval based on guidance contained in chapter 2 and appendix D of the TSD. As discussed in the TSD, EPA expects the three-year return interval to provide "a very high degree of protection" (TSD at page 36). The three-year return interval approximates the same degree of protection as a once-in-ten-year seven-day average low flow design condition (7Q10), the use of which has historical precedent and is in many State water quality standards. (*Id.*)

Given the state of the science, and the limitations of available data, EPA as a matter of policy, takes the position that it should assure adequate protection and takes a conservative approach. This policy is also consistent with and recognizes historic program practices

and procedures used by both the Agency and the States in implementing the water quality standards and related implementation programs. (Guidelines for Developing or Revising Water Quality Standards, April 1973, p.7.)

The draft EPA staff analysis referred to by the commenter was prepared solely as background information for discussions by the committee reviewing the methodological guidelines. EPA neither confirms or rejects the calculations.

37. *Comment:* The Guidelines indicate that criteria may be derived using data that have not undergone formal peer review, but the Guidelines do not offer meaningful guidance to determine the acceptability of test results. Inappropriate data are used to derive criteria.

Response: Toxicity tests methods have changed over time to improve precision and accuracy. This requires use of judgment in evaluation of test acceptability and results. EPA utilizes the Guidelines and professional judgment to reject unacceptable data (see Unused Data sections of Criteria Documents). Reservations about data are considered when judging acceptability of results in the context of criteria development. EPA also receives public comments on the criteria documents.

EPA's criteria for accepting or rejecting data do not depend on whether the data were published in peer-reviewed journals. The guidance provided in the 1985 Guidelines is predicated on more explicit review considerations than may be provided by most publishers of peer-reviewed journals addressing toxicity tests with aquatic organisms. EPA has observed that the public comments have also raised specific technical issues regarding the validity of peer-reviewed results.

Occasionally values in publications are not used because they are not biologically important or statistically different. In addition, recalculation of authors raw data may occur. This is part of the judgment required by criteria document preparers.

All published and unpublished references cited in aquatic life criteria documents are on file at EPA's Duluth or Narragansett laboratories.

38. *Comment:* A commenter asserted that analysis indicates that databases that have few genus mean acute valves (GMAVs) produce significantly more restrictive final acute valves (FAVs). The commenter asserts that EPA needs to increase the size of such databases to avoid promulgation of excessively restrictive water quality criteria.

Response: This comment summarizes hypothetical calculations in which the effect of the number of tested genera on the FAV were examined. It concludes that because the FAV changes as this number changes, the database size is insufficient.

EPA disagrees with the commenter's interpretation of the analysis. The commenter studied the effect of database size by changing the insensitive species while keeping the four most sensitive species the same (Commenter number 133, Appendix A., page 26). It is therefore quite expected and proper that the FAV would change as indicated. The FAV is designed to protect the fifth percentile in the sensitivity of organisms (see 1985 Guidelines, section IV, p. 26) (also 50 FR 30784, at pg. 30794; July 29, 1985). Using available suitable tests as representative of the species that are to be protected is the most reasonable feasible approach to establishing criteria values. If the sample size is 8, the four most sensitive values must be considered representative of half of the species that are to be protected and the fifth percentile would be expected to be somewhat below the lowest value. If the sample size is 32, the four most sensitive values are representative of the lowest 12.5% of the species and the fifth percentile would be expected to be near the middle of these values. And it is not just the fifth percentile that is expected to change but the entire distribution—for a sample size of 8 the mean will be near the highest of the four most sensitive values; for a sample size of 32 the mean would be far above the four most sensitive values (near the sixteenth most sensitive value).

Therefore, the response of the FAV cited in this comment is fully expected and appropriate; it in no way indicates a deficiency in the procedure or the database requirements. Similarly, the response of the FAV cited in site-specific calculations is also reasonable. If site calculations are based on fewer species and if these species tend to be more sensitive on average than the total dataset, the FAV should be lower.

39. *Comment:* A comment was received that most of the data used to derive the criteria were not developed for that purpose.

Response: The reason a toxicity test was originally conducted is not important. If the data are considered to be pertinent, of acceptable quality, and meet our protocols and other data requirements in the 1985 Guidelines, they should be used in the derivation of water quality criteria. Moreover, as stated in the 1985 Guidlines, p. 26, "confidence in a criterion usually increases as the amount of pertinent data increases."

40. *Comment:* A commenter asserted that since EPA has acknowledged that species can exhibit a significant substance tolerance range and inter-laboratory variability, the databases for many of the criteria must be significantly improved before they can be considered suitable for use in the promulgation of water quality standards. The commenter cited. Schimmel, S.C., 1981. Results: Interlaboratory Comparison—Acute Toxicity Tests Using Estuarine Organisms (EPA–600/4–81–001).

Response: Inter- and intra-laboratory variation is expected and unavoidable. Variation that causes imprecision is undesirable, but is not nearly as undesirable as is error that causes bias (Lemke, A.E.; 1981; Inter-Laboratory Acute Testing; EPA 600/3–87–005). More data are always desirable, and EPA welcomes the submission of additional high quality pertinent data, whether or not they have been peer-reviewed. The guidelines for deriving water quality criteria for aquatic life specify minimum data requirements that are intended to ensure reasonable confidence in the appropriateness of the resulting criteria.

The Science Advisory Board review referenced earlier at comment 29 accepted the EPA aquatic life 1985 Guidelines which permit the use of a single test to fulfill the minimum data base requirement. The results cited by the commenter when referring to a study conducted by Schimmel, 1981, were used by the Agency in developing the revised aquatic life guidelines in 1985. The guidelines specifically allow the use of a single-species test to fulfill the requirement for a species mean acute value. (1985 Guidelines, p. 29.)

41. *Comment:* A commenter asserted that very few of the studies used to develop the criteria cited any assessment of precision or accuracy and there was no standardization of testing protocols. Consequently, the commenter believes that the data are inadequate for the promulgation of water quality standards; and that only data from current testing protocols should be used.

Response: There is no way to fully assess the accuracy of a toxicity test because the "real" toxicity of the test material cannot be known. Various lines of evidence including results of toxicity tests and correlations between species and between test materials can help increase confidence in an estimate of toxicity. Studies of inter- and intra-laboratory variation are conducted to allow assessments of precision. Very

few, if any, studies are perfect, even if they exactly followed a "current testing protocol"; the acceptability of each study must be judged individually. Studies that follow approved methodology are more likely to be high quality, but some are not; some studies that deviate from approved methodology do provide useful information.

42. *Comment:* A commenter suggested that EPA provided no data to support its contention that acute-chronic ratios are similar in fresh and salt water.

Response: As quoted by the commenter, the 1985 Guidelines, p. 15, states that "When data are available to indicate that these ratios and factors are probably similar, they are used interchangeably." The guidelines do not contend that acute-chronic ratios are similar; the guidelines state that the ratios should be considered similar only when data are available to support the decision of similarity. Ratios are usually considered to be dissimilar if the range is greater than a factor of 10 (1985 Guidelines, p. 45).

43. *Comment:* A commenter asserted that EPA should establish a separate warm-water cadmium criterion, because the national criterion is set based on rainbow trout, a cold-water fish.

Response: The commenter misconstrues EPA's criteria development protocol. EPA's aquatic life guidelines require data for the family Salmonidae as one of the minimum eight species required to calculate a water quality criterion (1985 Guidelines, Section III, p. 23). EPA did not base its criteria for cadmium solely on rainbow trout data. (Rainbow trout is a member of the family Salmonidae.) EPA used this data to meet one of the requirements for tested species required by the guidelines (Ambient Water Quality Criteria for Cadmium-1984, Table 2, p. 6). Moreover, a review of toxicity data in EPA's criteria document does not indicate that the sensitivities of so-called coldwater for warmwater species differ significantly (Ambient Water Quality Criteria for Cadmium-1984, Table 2, pp. 46–47). EPA had no scientific basis to develop separate cadmium criteria based on the division of aquatic species into coldwater or warmwater types.

44. *Comment:* A commenter argued that because EPA did not follow its own Guidelines, EPA should withdraw the lead criteria document, update and complete the species database, and recalculate an appropriate freshwater lead criterion.

Response: EPA recognizes that the lead criterion is based on seven rather than eight freshwater acute tests as recommended in the aquatic life guidelines. EPA has determined that the criteria are valid and that an additional test would not cause a sufficiently large change in the criteria (in the computation formula [see page 97, appendix 2 of the Aquatic Life Guidelines] increasing N, the number of species tested, by one with an LC50 value that is higher than the four most sensitive values only increases the acute criterion from 34 to 37 µg/l, at a hardness of 50). (See Memorandum to the Record, Kennard Potts, March 12, 1992.) This change does not warrant withdrawing the current criteria. This decision to establish the criterion based on seven tests is consistent with Section 12—Final Review, paragraph B, page 57 of the Guidelines, which allow "On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of these Guidelines."

45. *Comment:* A commenter asserted that there is a significant error in the lead saltwater acute database, and it has implications on the validity (or lack thereof) of the saltwater acute-chronic ratio for lead.

Response: EPA recognized the error in the ambient water quality criteria document for lead in the genus mean acute value (GMAV) for *Fundulus* and corrected that error in the criteria matrix included in the proposed rule. The result of this correction was to increase the criteria maximum concentration (CMC) to 220 µg/l and criteria continuous concentration (CCC) to 8.5 µg/l.

The use of the acute-chronic ratio (ACR) of 51.29 for lead is reasonable, given the available information (see p. 9, Ambient Water Quality Criteria for Lead). The GMAV for *Mysidopsis* included in the criteria document for lead (p. 26), is ranked 7th of the 11 genera tested for lead toxicity. Therefore, *Mysidopsis* might be considered among the less sensitive genera as suggested by the commenter. However, the GMAV for *Mysidopsis* is less than 10 times the value for *Mytilus* suggesting the acute sensitivities of two genera are not greatly different. (*Ibid.*)

Other factors are more important than species sensitivity in selecting the final acute to chronic ratio (FACR) for lead. EPA did not believe that the data from chronic tests with freshwater species clearly demonstrated that acute-chronic ratios changed with acute sensitivity for the following reason. Acute values for the copepod (*Acartia*), amphipod (*Ampelisca*) and dungeness crab (*Cancer*) are within a factor of less than 2 times the value for *Mytilus*. EPA then assumed that the ratio was not related to acute sensitivity. Even if an ACR of 2.0 could be justified for larval molluscs and lead, this value should not be applied to crustaceans when an experimentally derived value for *Mysidopsis* and *Daphnia* are available. See Table 3, Ambient Water Quality Criteria for Lead.

The commenter felt EPA was inconsistent in its use of ACR values from toxicity tests and the ACR of 2.0, when the most acutely sensitive organism is larval molluscs. EPA used acute-chronic ratios from toxicity tests for lead and silver and the value of 2.0 for copper (see ambient water quality criteria documents for lead and copper, and the draft water quality criteria document for silver, 55 FR 19988, May 14, 1990. The reason experimental ACR values were selected for lead instead of the value of 2.0 are described above.

46. *Comment:* A commenter suggested that the saltwater silver criterion is not valid and submitted test results to support this claim.

Response: Some of the data presented by the commenter (Number 80) to show problems in the silver data base actually supports its validity. Acute and chronic values for *Mysidopsis* are within the range reported by others. Silver's acute toxicity to sheepshead minnows is at silver's solubility. This probably accounts for the large range in reported silver toxicity. For these species only flow-through tests with measured silver concentrations were used. The data submitted in the public comment did not include information on the test conditions, and would not be used in criteria derivation without that information. See Ambient Water Quality Criteria Document for Silver, 1980; see also draft criteria document referenced in 55 FR 19988, May 14, 1990.

Results from silver tests from Cardin (1986) where control mortalities exceeded 10% were not used. In tests with copepods and larval silversides and flounder, control mortality of <20% is judged acceptable by those who conduct tests with fragile life stages of these species. Control survival requirements for chronic tests (ASTM protocol) are more liberal than those for acute tests.

EPA's rapid chronic toxicity protocols are not appropriate test methods for deriving chronic values for water quality criteria derivation because they are not true chronic tests. Only early life-stage tests with fish and partial and entire life-cycle tests with fishes and invertebrates are acceptable as provided

for in the 1985 Guidelines, section VI, part E, pages 37–39.

47. *Comment:* Comment was received that the proposed silver numeric standards should be revised to apply to the free silver ion. The commenter asserted that available information demonstrates that only the free silver ion is highly toxic to aquatic organisms while most other common forms of silver, whether soluble or insoluble, are several orders of magnitude less toxic.

Response: It would be appropriate to interpret the criterion in terms of the free silver ion only if all the silver that was included in the measured or nominal concentrations of silver in the pertinent toxicity tests would have been measured as free silver ion. Some silver would be complexed by such things as chloride, hydroxide, or carbonate in acute toxicity tests. Moreover, the feeding of the organisms in the chronic tests would result in complexation of at least some silver. This has been postulated as the explanation as to why (a) the addition of food to an acute toxicity test raises the EC50 for daphnids and (b) silver has appeared to be more toxic to daphnids in some acute toxicity tests than in comparable chronic tests. Absent a criterion that correctly applies to the free silver ion, the water-effect ratio procedure incorporated into today's rule is an appropriate means to deal with differences in toxicity caused by silver speciation.

48. *Comment:* A comment was made that the numeric silver standards should not be proposed until EPA's May 14, 1990 proposed revisions to the current ambient silver water quality criteria are finalized to reflect comments about the current science as submitted for the record of that proposal.

Response: EPA agrees with some of the comments on the May 14, 1990 proposed silver criteria. As a result, additional testing is planned and a revised document for silver will be prepared, but this is not anticipated in the near future. With this rule, EPA is promulgating its 1980 criteria for silver, because the Agency believes the criteria is protective and within the acceptable range based on uncertainties associated with deriving water quality criteria. In addition, the water-effect ratio promulgated in this rule offers development of appropriate site-specific criteria.

49. *Comment:* A commenter asserted that in the studies of Calabrese and Nelson 1974, Calabrese et al. 1973, and Coglianese 1982, the properties of the dilution water significantly affected the metals toxicity.

Response: EPA agrees that there may be differences in metals toxicity between laboratory test waters and ambient waters. For this reason, EPA has incorporated use of water-effect ratios in this rule (see Section F–7 of this preamble and an earlier response to public comment).

50. *Comment:* A comment was made that EPA should not use the metals toxicity data from Dinnel et al. 1983, who were evaluating alternative conditions in order to refine the testing protocol.

Reponse: EPA disagrees. Valid toxicity data can come from tests used to develop test methodologies and EPA determined that the Dinnel, et al. toxicity data was valid toxicity data. For example, see draft Ambient Water Quality Criteria for Silver, September 24, 1987.

51. *Comment:* A commenter argued that the metals toxicity data from Eisler 1977 are not valid because they involve 168-hour static tests. The currently recommended maximum duration for such tests is 48 hours.

Reponse: EPA disagrees. Most values reported in criteria documents are 96-hour LC50s for adult clams. EPA considers the Eisler data to be from valid and reliable tests even though they were based on other than 96-hour tests.

52. *Comment:* Comment was received that the 20–25 degree Celsius temperatures and 12:12 hour light cycle used to obtain the metals toxicity data of Lussier 1985, do not match current mysid protocol's 26–27 degree Celsius temperature and 16 hour light:8 hour dark light cycle.

Response: The submitted comments provided no data to show the effect of temperature or lighting on the chronic value. EPA does not consider Lussier's results to be artifacts because test conditions duplicate conditions found in nature.

53. *Comment:* The zinc and chromium toxicity data of Nelson 1972 should not be used because it involves an endpoint not recognized by EPA approved protocols.

Reponse: EPA disagrees. The test endpoint (the development of a hinge after 48 hours) is the same as that of the American Society for Testing Materials (ASTM), which is a standard, recognized protocol.

C. Human Health Criteria

The guideline references in the sub-section refer to Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Quality Criteria Documents, 45 FR 79347, November 28, 1980. The short reference in this sub-section is "the 1980 *Guidelines.*"

54. *Comment:* A comment was received that use of the harmonic mean flow is a new technique and is not consistent with the way sampling is in fact done.

Response. Harmonic mean flow determinations have been adopted because the underlying hydrology support this analytical procedure. Such flows are applied only to human health criteria where human exposure is expected over a long period of time. It is derived by analyzing the pollutant mass a consumer would received by, for example, consuming a uniform amount of water everyday from a natural waterbody receiving a uniform mass loading of a pollutant.

Theoretical development as shown in the reference cited in footnote 2 of the preamble of the proposed rule (56 FR 58438) demonstrates that actual human exposure is best ascertained by using harmonic mean flow to account for concentration variation in computing the actual exposure to a pollutant.

55. *Comment:* The exposure assumptions used by EPA in developing human health criteria do not account for the variability of the population nor the consideration of exposure to more than one chemical and more than one exposure route.

Response: The EPA assumed exposure model was based on estimates or measures of national norms (see preamble discussion on human health criteria, Section F–3 and 1980 Guidelines, 45 FR 79347, Nov. 28, 1980). EPA has suggested in these and other documents that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so.

EPA's risk calculations aim to protect individuals exposed at an average level (*Ibid*). Thus, EPA does the calculation for average daily consumption of 2 liters of water and 6.5 grams of aquatic life for a 70 kg size individual over a 70-year lifetime. Then the Agency selects a conservative risk level (e.g., 10^{-6} or 10^{-5}) for such an average person.

People who do not fit this norm are subjected to more or less exposure to the pollutants of concern. For example, assuming a criterion based on a 10^{-6} risk level, a person who consumes 65 grams of contaminated aquatic life per day from ambient water at the criterion level would be protected at the 10^{-5} risk level, still well within EPA's desired risk range.

The effects of multiple toxicants is a more difficult problem. The science of toxicology has not developed generic ways to combine multiple risks. For

specific chemicals, analysis would focus on whether the same organ and mode of toxicity were implicated. For example, it may be more significant if two chemicals both caused liver cancer as compared with a situation where one chemical was carcinogenic and the other caused other systemic effects. Thus, a case-by-case approach is currently the only feasible approach available.

EPA has clearly delineated the human health models it uses. That is, one for systemic toxicity and one for carcinogenicity. The Agency's accepted factors are available in the Integrated Risk Information System (IRIS) and in the section 304(a) water quality criteria documents, and in the 1980 Guidelines, page 79353. Locally specific risk can be estimated using the readily available information based on monitoring data for local public water supplies or fish tissue analysis for specific chemicals.

However, in a rule affecting large areas of the country, EPA's view is that it should focus on the average exposure, as a protective basis for this rule. States may take subsequent action to provide the means to account for specific cases. This rule attains that goal.

56. *Comment:* Since EPA is undertaking a dioxin reassessment, it should not be included in this rule.

Response: We believe there are sound reasons for proceeding to promulgate dioxin criteria. First, the dioxin criteria are within the range of scientific defensibility. EPA's action will also encourage and support the fourteen States now considering adopting a dioxin criterion to complete their action. Most of those States are relying on the same data used by EPA to derive its criterion. Individual Control Strategies developed under section 304(l) of the Act contain limits on dioxin as appropriate, so there will be no immediate impact from this promulgation. It is too early in the process of scientific reassessment to support major changes in either the substance or timing of regulatory decisions related to dioxin.

It should also be pointed out that 42 states and territories have adopted criteria or translator procedures for dioxin; EPA approved 40 of those actions.

57. *Comment:* Several commenters raised questions concerning the methodology used to develop the human health criteria. Some stated that the CWA methodology did not reflect changes in risk assessment and therefore was obsolete. Some commenters noted the differences between the risk ranges under the CWA and the SDWA and argued that the acceptable range of cancer risk should be the same under both statutes. Several commenters discussed specific contaminants and argued that the regulatory levels under the CWA and SDWA should be the same. One commenter provided a list of contaminants where drinking water standards were more stringent than the proposed criteria and urged that criteria should be established equal to drinking water MCLs.

Response: EPA has developed risk assessment methodologies to protect human health from contaminants in drinking water and ambient waters. Although there are some differences in the methodologies, both are scientifically defensible. Both methodologies stem from Agency risk assessment values for noncancer effects (the Reference Dose or Rfd) and for cancer effects (the cancer potency factor, q1*). See Water Quality Criteria documents (the 1980 Guidelines), 45 FR 793180 (November 28, 1980) and 56 FR 3526 (January 30, 1991) (SDWA Phase II regulations).

Both methodologies follow the Agency's Guidelines for Carcinogen Risk Assessment (the Cancer Guidelines). 51 FR 33992 (September 24, 1986). Under both programs, the Agency takes the position that there is no threshold for carcinogenic effect unless there is convincing evidence to the contrary. Both programs therefore recommend that contaminant concentration for carcinogens should be zero based on this "no threshold" presumption. See SDWA Phase II regulations at 56 FR 3533 and the 1980 Guidelines at 45 FR 79324.

The nature of the human exposure to contaminants is somewhat different in the two programs, and the assumptions used in the methodologies reflect those differences. Under the SDWA, it is protection from exposure to contaminants in drinking water that is the concern. The maximum contaminant level goals (MCLGs) reflect the level of contamination where "no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." 42 U.S.C. 300g–1(b)(4). For those contaminants that are not suspected of posing carcinogenic risk for drinking water, the Agency bases the MCLG on noncancer effects and adjusts the RfD to reflect drinking water consumption of an average of two liters of tap water per day by a 70 kg adult. This value is further adjusted by exposure assumptions; the key assumption in the drinking water program is that significant exposure to a contaminant comes from sources other than drinking water (*e.g.*, ingestion of food, inhalation), and it is prudent to allow for the contingency that other exposure may occur. While EPA uses actual exposure data where they are available, the Agency assumes, as a default position, that drinking water contributes 20%–80% of the total exposure to a contaminant. 56 FR 3532. MCLs can also be adjusted for non-health reasons, such as treatability and detectability.

Under CWA section 304(a), EPA developed human health criteria to protect for exposure to ambient water contaminants. In this case, exposure comes from ingestion of surface water and consumption of aquatic organisms which are assumed to have bioconcentrated pollutants from the water in which they live. Accordingly, the 1980 Guidelines assumes the consumption of two liters of water and the ingestion of 6.5 grams of fish per day, and the bioconcentration potential of a contaminant in fish tissue may be a significant factor in the human health criteria value. The exposure assumption in the 1980 Guidelines differs from that in the drinking water program. If data were available on exposure to a contaminant from other media such as air or non-aquatic diet, such data could be used in setting criteria. Absent such data, EPA assumes, as a default position, that ambient water (i.e., aquatic exposure and organism ingestion) contributes 100% of the exposure to a contaminant. 1980 Guidelines, 45 FR 79323. EPA considers both methods to be protective of human health for their respective exposure scenarios.

EPA agrees with commenters that the Agency has chosen somewhat different risk levels in the two programs for determining MCLs and criteria for carcinogens, but does not agree that the different levels indicate major scientific differences. Under the SDWA, it is EPA policy to establish MCLs at a range associated with excess risks of one in ten thousand (10^{-4}) to one in one million (10^{-6}). In the CWA water quality criteria documents, the Agency presents a range of concentrations corresponding to incremental cancer risks of one in one hundred thousand (10^{-5}) to one in ten million (10^{-7}); the risk ranges are presented only as information. Under the usual process in which States develop water quality criteria, the risk management decision on an appropriate risk level is made by each State. In these circumstances, States have the flexibility to choose a risk level as long as the decision is well documented, was subject to public notice and comment, and protects water uses. In this rulemaking, EPA proposed criteria with an incremental cancer risk level of one

in a million (10^{-6}) for carcinogens. Today's action promulgates a risk level for each State to reflect the State's risk management decision where such a decision is discernable. See discussion in section F–5 of the preamble. In the Agency's view, the considerable overlap between the risk ranges in the two programs indicates that they are not significantly different.

Accordingly, EPA does not agree with commenters' arguments that the Agency must have identical risk assessments under the CWA and SDWA. At the same time, the Agency is studying the extent to which both methodologies might start with the same presumptions. If any changes to the methodologies seem appropriate, the changes would be proposed for public comment. In the meantime, because both methodologies stem from the same Agency risk assessment values, RfD and $q1^*$, they are considered appropriate for deriving human health criteria for water contaminants. Therefore, as a general matter, EPA does not intend to revise the human health criteria unless and until there are changes in the 304(a) methodology.

One commenter urged the Agency to establish human health criteria equal to MCLs when the 304(a) methodology resulted in less stringent criteria. The commenter provided a list of contaminants for which the proposed criteria are less stringent than proposed or promulgated drinking water regulations for the contaminants (MCLs), and recommended that EPA promulgate water quality criteria equal to the MCLs for antimony, cadmium, nickel, selenium, silver, thallium, cyanide, ethylbenzene, toluene, 1,1,1-trichloroethane, benzylbutylphthalate, hexachlorocyclopentadiene, and 1,2,4-trichlorobenzene. EPA notes that there are five other contaminants in this proposed rulemaking for which the SDWA regulatory levels (either final or proposed) are more stringent than the proposed human health criteria; these are chromium, lead, chlorobenzene, trans-1, 2-dichloroethylene, and o-dichlorobenzene.

The fact that the numeric standards for these contaminants are different under the two programs is not a sufficient basis for replacing the proposed human health criteria with criteria equal to the MCLs. As discussed above, the methods used to derive the human health values under both the SDWA and the CWA are generally considered protective of human health. The differences that occur in the regulatory standards under the two statutes result from the assumptions used in their respective methodologies, particularly the default values chosen to estimate exposure. These assumptions are reasonable policy choices for implementing the statutory directives of the two programs. Since the CWA section 1980 Guidelines are adequately protective of human health, EPA does not consider it necessary to undertake a large scale revision of the proposed criteria in this rule to make them correspond to the SDWA standards. Moreover, EPA does not agree that MCLs are an appropriate value for a human health criterion since MCLs are partially based on feasibility considerations, including the availability of technology to achieve the regulatory level and the cost of such treatment. It is the MCLG that reflects solely health considerations. Accordingly, the Agency will not promulgate criteria equal to MCLs in lieu of less stringent proposed human health criteria. Except as noted below, the human health criteria are promulgated as proposed.

The Agency does find it necessary to withdraw the proposed human health criteria for seven contaminants pending further consideration. In the case of three contaminants—1,1,1-trichloroethane, methyl chloride, and lead—there is currently an insufficient basis for calculating human health criteria. For cadmium, chromium, selenium, and beryllium, the proposed criteria are no longer scientifically defensible. EPA is withdrawing the criteria while it evaluates all relevant data regarding the toxicity of these contaminants. The Agency's basis for deferring action on the human health criteria for these contaminants is discussed further below. For several of these contaminants, the Agency is today promulgating aquatic life criteria that are more stringent than the proposed human health criteria. However, the Agency recognizes that in limited circumstances, there might be regulatory voids in the absence of promulgated human health criteria. To minimize this potential problem, the Agency has added a footnote, footnote n, to the table setting out the criteria in § 131.36(b) that directs permit authorities to specifically address these contaminants in NPDES permit actions using the States' existing narrative "free from toxicity" criteria.

(A). 1,1,1-Trichloroethane

No public comments were received on the proposed human health criteria for this contaminant. However, in response to other comments, EPA evaluated the proposed criteria and has decided not to promulgate human health criteria. EPA proposed the human health criteria using an RfD based on inhalation data. However, the Agency has withdrawn that RfD from the IRIS database since it is generally not appropriate to use inhalation data to estimate oral risk. As noted above, EPA bases the proposed criteria on Agency-wide RfDs in IRIS. Since no such RfD currently exists, there is no basis to support the proposed values.

(B). Methyl Chloride

58. *Comment:* A commenter stated that the criteria should not be based on carcinogenicity but on systemic toxicity. Another commenter stated that it is inappropriate to establish criteria for methyl chloride based on the carcinogenicity for chloroform.

Response: EPA agrees there are now data available on methyl chloride itself, and it is no longer scientifically defensible to rely on surrogate data for chloroform. EPA is currently evaluating a $q1^*$ and RfD for methyl chloride for developing an RfD. In view of the availability of chemical specific data and the ongoing risk assessment process, EPA does not believe it is appropriate to promulgate human health criteria for methyl chloride at this time.

(C). Selenium

59. *Comment:* One commenter noted that in the case of selenium, EPA proposed a human health criterion of 100 ug/l even though the current MCL for selenium if 50 ug/l (the same as the MCLG). The commenter believes the numbers should be the same and urged EPA to set the human health criterion at the MCL.

Response: As discussed above, EPA does not intend to replace proposed criteria with criteria equal to the MCL solely because the latter is the more stringent level. However, in the case of selenium, the Agency has determined that further consideration should be given to recent data on selenium before setting the human health criteria. Selenium is an essential nutrient in humans and plays a vital role in cell metabolism. See Health Criteria Document for Selenium, (May 1989). In such instances, the Agency must evaluate evidence of the compound's essentiality as well as evidence of toxicological effects. The Agency's Science Advisory Board has noted that synergistic effects—the interaction between selenium and other inorganic chemicals—are an important consideration in determining regulatory standards. Moreover, there are individuals who, whether from diet or supplements, consume significantly more selenium than EPA estimates of average consumption levels.

During the development of drinking water regulations for selenium, the Agency discussed new epidemiological data that were becoming available. See 56 FR 3526 at 3538–39 (January 30, 1991). In view of these new data, the numerous complex issues concerning essentiality, the consumption of elevated levels by some members of the population, and the need to ensure a protective level, EPA is unable to determine the scientific defensibility of the human health criteria, and therefore will not promulgate human health criteria for selenium at this time.

(D). Beryllium

60. *Comment:* One commenter stated that EPA's beryllium criterion is too low (i.e., 0.0077 ug/l). The commenter alleged three serious flaws in the proposed criterion for beryllium. These are: (1) Beryllium does not pose a carcinogenic risk by ingestion; (2) EPA's use of animal inhalation and injection data to support a cancer risk by human ingestion is arbitrary and capricious and is not consistent with EPA's methodology in setting human health criteria for other metals; and (3) the proposed criteria are less than natural ambient levels as well as EPA's proposed drinking water standards and would have very significant and unwarranted economic impacts.

The commenter further argued the defects in the data upon which EPA relies are so fundamental that the classification of beryllium as a Group B2 substance is unreasonable; and the EPA should classify beryllium in Group D for purposes of its potential ingestion carcinoganicity, and should adopt a human health criterion for beryllium of 1.6 mg/l, based upon a no-observed adverse effects calculation for a non-carcinogenic substance. Information on the Agency's classification system for carcinogens is included in U.S. Environmental Protection Agency (EPA), 1986, Guidelines for Carcinogen Risk Assessment. 51 FR 33992, September 24, 1986.

Response: EPA does not agree with the commenter's argument that the Agency's weight of evidence classification of beryllium as a B2 carcinogen is incorrect. There is clear evidence of carcinogenicity through inhalation or injection in monkeys, rats and rabbits, and animal studies showing tumors at sites different from the route of exposure. On this basis, the Agency has concluded that the overall weight of evidence in beryllium studies proves sufficient evidence of carcinogenicity to support a B2 classification. Drinking Water Criteria Document for Beryllium, September 1991. However, the Agency has determined that it is necessary to give further consideration to the toxicity and carcinogenicity of beryllium through ingestion before promulgating human health criteria. In the final drinking water rulemaking regarding beryllium (see 57 FR 31776, July 17, 1992), Agency analysis of the ingestion route of exposure failed to provide definitive evidence that correlates ingestion with tumor appearance. Drinking Water Criteria Document at I–7. The Agency has determined that these ingestion analyses are relevant in this rulemaking and therefore the proposed criteria are not scientifically defensible. The Agency will give additional consideration to the question of whether beryllium in water could pose a carcinogenic risk to humans before issuing criteria and accordingly, will not promulgate criteria for beryllium.

(E). Lead

61. *Comment:* A commenter noted that EPA proposed a 50 ppb-lead human health criteria for consumption of water and organisms. The commenter argued that a 50 ppb criteria is not compatible with EPA's overall lead control strategy reflected under the drinking water standards, and recommended a 5 ppb lead health criteria.

Response: As noted above, differences in the proposed human health criteria and regulatory levels under the SDWA methodology are not, in themselves sufficient basis for revising the criteria. In this case, the original basis for the 1980 Guidelines and, in turn, the proposed criteria was however the MCL. In 1991, EPA promulgated a zero MCLG and treatment technique for lead in drinking water, which will, when effective, replace the current MCL. The treatment technique includes a 15 ppb lead action level at the tap.

In view of drinking water regulatory action, EPA has determined that it is not appropriate to promulgate a human health criteria based on a drinking water MCL that no longer reflects the Agency's position. The Agency has given preliminary consideration to other numeric values but has not yet reached a consensus on an appropriate human health criteria. Accordingly, EPA is not promulgating human health criteria for lead at this time.

(F). Cadmium

62. *Comment:* A commenter noted that EPA had proposed criteria for cadmium that were less stringent than the MCLs. The commenter urged EPA to set the criteria at the MCL level.

Response: As noted above, differences in the two regulatory levels is not a sufficient basis for using the more stringent MCL. However, the Agency has determined that it is necessary to give further consideration to the toxicity of cadmium from exposure to water in terms of the bioconcentration potential of this contaminant. As discussed earlier, one of the factors used to calculate the human health criteria is consumption of aquatic organisms. It is, therefore, particularly important that the Agency ensure that the criteria adequately reflect the bioconcentration of cadmium. EPA is currently addressing this issue in other regulatory actions (*e.g.*, sewage sludge and the Great Lakes initiative) and expects that the data and analyses being developed in these efforts will be of value in further examination of the human health criteria. Accordingly, the proposed criteria are not scientifically defensible and EPA will not promulgate human health criteria for cadmium.

(G). Chromium

63. *Comment:* A commenter noted that in the case of chromium with valences of plus VI and III, EPA proposed human health criteria of 170 and 33,000 µg/l, but that the Agency had promulgated a total chromium MCL of 100 µg/l. The commenter urged the Agency to take a similar position here.

Response: As noted above, the fact that the numeric values for CWA and SDWA regulatory actions are different is not a sufficient basis for revising the CWA criteria. However, in this instance, EPA has determined that the proposed criteria are not scientifically defensible. New information concerning the conversion of chromium III to a more toxic chromium VI during the chlorination process should be considered in setting the criteria as well. (See 56 FR 3526 at 3737, January 30, 1991). Accordingly, EPA will not promulgate the proposed human health criteria for chromium.

For other reasons, proposed human health criteria were withdrawn for four pollutants.

(H). Silver

64. *Comment:* Several commenters stated that silver should no longer be classified as a toxic pollutant for human health concerns and that no further regulation for silver is appropriate. Commenters also addressed the issue that the proposed silver criteria should be revised to delete human health as a toxicity-based criterion to be consistent with the recent deletion of the MCL for silver under the Safe Drinking Water Act. (56 FR 3526, January 30, 1991.)

Response: EPA deleted the human health criteria for silver, because the

only potential adverse effect from exposure to silver in drinking water is argyria (a discoloration of the skin). EPA considers argyria a cosmetic effect since it does not impair body function. However, free silver ion is highly toxic to fish. Therefore, to protect aquatic life, silver will be regulated with aquatic life criteria as promulgated in today's rule.

(I). Acenaphthylene, Phenanthrene, Benzo(g,h,i)Perylene

65. *Comment:* Several comments were received which stated that (1) the EPA has expanded the list of polynuclear aromatic hydrocarbon (PAH) compounds to be regulated as carcinogens. Specifically, the commenters do not agree with the Agency that acenaphthylene, phenanthrene, benzo(g,h,i)perylene, and chrysene should be treated as carcinogens, and (2) the proposed rule establishes human health criteria for a diverse class of compounds (such as polynuclear aromatic hydrocarbons) based solely on structural similarity, and the assumption that all of the compounds are of equal toxicity to the most potent compound within the "class."

Response: The Agency agrees with the several comments that the water quality criteria for acenaphthylene, phenanthrene, and benzo(g,h,i)perylene should be based on non-carcinogenic effects of these chemicals since inadequate toxicity data are available to assess carcinogenic potential of these chemicals. However, there are insufficient toxicity data available to provide risk assessment for these three compounds at this time. Therefore, they have been deleted from this rule.

The Agency does not agree with the comment regarding chrysene. Chrysene has shown carcinogenicity in several animal studies. (U.S. EPA, 1991. Drinking Water Criteria Document for Polynuclear Aromatic Hydrocarbons (PAH's) Office of Water.) Chrysene produced tumors (as did other PAHs included in this rule) in several mouse strains when applied topically in assays for complete skin carcinogenicity or in initiation/promotion protocols. Several early studies employing intramuscular or subcutaneous injection of mice and rats produced negative or equivocal results. Three studies wherein neonatal mice of two strains were exposed intraperitoneally reported increased tumor incidence in liver and other sites (*Ibid*). Chrysene produced mutations in *Salmonella* and chromosome aberrations and morphologic transformation in mammalian cells.

The Agency recognizes that carcinogenicity of various PAHs vary with each PAH, however, Benzo(a)pyrene being the most potent carcinogen of this class, was used to develop criteria for all the PAHs.

(J). Other Pollutants

66. *Comment:* A commenter requested that EPA explain the origin of the use of safety (uncertainty) factors.

Response: The safety factors (now referred to as uncertainty factors [UF]) used in calculation of the Acceptable Daily Intake (how referred to as the Reference Dose [RfD]) were developed from the National Academy of Science guidelines (1977) with modification by the EPA. These factors are similar to those used by the World Health Organization (Food Chemistry Toxicology, Vol. 27, No. 4, pp. 273–274, 1989). The EPA is presently working on new approaches to calculation (estimation) of a RfD (ADI).

The term "safety factor" (now UF) was initially used by the Food and Drug Administration (FDA). They used no-effect levels (in mg/kg of diet) from chronic animal feeding studies and divided by 100 to get an Acceptable Daily Intake (ADI) level. For less-than-lifetime (or sub-chronic) studies, they divided the no-effect level by 1000. The National Academy of Science recommended that EPA use a similar approach and outlined the use of 10-fold UFs for intra- and interspecies variation. An additional 10-fold UF is also included to calculate a lifetime number from a less-than-lifetime study. The term "RfD (Reference Dose)" is now used by the EPA instead of the ADI. The above referenced information is included in the Agency's Risk Assessment Guidelines published at 51 FR 33992, September 24, 1986.

67. *Comment:* A commenter stated that EPA should not use Structure-Activity Relationships (SAR) techniques to regulate chemicals, such as methyl chloride, when data on the specific chemical are available.

Response: The EPA uses SAR only when data on specific chemicals of a chemical group are lacking (see 1980 Guidelines, Section D, page 79355). SAR is a technique used to compare the toxicity of individual chemical in the group with the known toxicity of one member of the group based on chemical structural similarities. For example, SAR was used in criteria development for polynuclear aromatic hydrocarbons (PAHs), polychlorinated bi-phenyls (PCBs), and tri-halomethanes (THMs) because the EPA does not have adequate health data on most of the chemicals in the class under review. For a detailed discussion on methyl chloride, see previous comment.

68. *Comment:* A commenter stated that the toxicities of inorganic arsenic (As) and the organic arsenic derivatives present in fish may be quite different.

Response: EPA agrees with the commenter—the organic arsenic forms are known to be less acutely toxic then inorganic arsenic forms ("Threshold Carcinogenicity Using Arsenic as an Example," Advances In Modern Environmental Toxicology, 15:133–158, 1988). In addition, since the organic forms found in fish appear to be excreted as the parent molecules, they are likely to have less long-term toxicity. A footnote has been added to section 131.36(b) stating that the criteria for arsenic refers to the inorganic form only.

69. *Comment:* A commenter stated that the arsenic standard is based on an IRIS recalculation that has never been open for public inspection.

Response: The 0.018 µg/l (water and aquatic life consumption) and 0.14 µg/l (aquatic life consumption) criteria were calculated from the unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$. The unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$ is on IRIS and available for public inspection. Although EPA incorrectly indicated in the proposal that the criterion was calculated using an addendum to the prior criteria document and not IRIS, in fact the addendum included the IRIS information and this information was in the record. There is an IRIS submission desk for public comments. Moreover, this rulemaking provided an opportunity for public comment.

70. *Comment:* A commenter claims that the EPA's Science Advisory Board (SAB) is critical of EPA's criteria for arsenic.

Response: The SAB stated that "at doses below 200 to 250 µg As^{+3}/person/day there is a possible detoxication mechanism" and recommended that EPA "develop a revised risk assessment based on estimates of the delivered dose on non-detoxified arsenic." (EPA–SAB–EHC–89–038. Letter from SAB to William Reilly, September 28, 1989.)

Since it is not known exactly when and how arsenic can be considered to be detoxified, EPA cannot, at present, calculate this "delivered non-detoxified" dose. It has been postulated by Marcus and Rispin ("Threshold carcinogenicity using arsenic as an example" Adv. Modern Environ. Toxicol. 15:133–158, 1988) that methylation is a detoxification process. While methylation certainly decreases the acute lethality of arsenic, we do not have enough toxicity data to regard the mono- and dimethylated methobolites as "non-toxic".

71. *Comment:* A commenter noted that no significant health effects from

arsenic exposure has been found in the U.S., as compared to the effects seen in Taiwan.

Response: The cancer potency for arsenic is calculated using standard Agency methods. The available U.S. epidemiology studies are small and do not have the statistical power to state whether the effects and risks in the U.S. are dissimilar to those that have been reported in Taiwan.

72. *Comment:* A commenter questioned the effects of arsenic at low dose and states that a threshold for arsenic may exist. The Marcus and Rispin paper is cited as justification. (Threshold Carcinogenicity Using Arsenic as an Example", "Advances in Modern Toxicology, 15:133–158, 1988.)

Response: There are no adequate data on whether arsenic exerts the same effects at low doses that it does at higher doses. To extrapolate to low dose effects, the EPA uses the linearized multistage model. At the present time, there is no substantial database which demonstrates that arsenic has a threshold for adverse effects. Marcus and Rispin theorized that there is a threshold for arsenic. However, there is no adequate proof that such a threshold exists. In addition, it should be noted that there is not an adequate epidemiology study on U.S. populations. Accordingly, at the present time, there is no way to establish the presence or absence of a threshold level for arsenic.

73. *Comment:* Arsenic causes skin cancer, and not all forms of skin cancer are equally lethal.

Response: The EPA knows that the form of skin cancer induced by Arsenic is treatable and agrees with the commenter that not all forms of cancer are equally lethal. However, the EPA is aware of data showing that arsenic can cause internal cancer and is reluctant to change the risk assessment based on skin cancer until the recent data can be evaluated (the Taiwan data).

74. *Comment:* EPA assumes that all forms of arsenic are equally carcinogenic and therefore the proposed criteria are overly conservative.

Response: The Agency does not consider all forms of arsenic to be equally cancinogenic and has clarified this issue by adding footnote "b" to the matrix in this rule.

75. *Comment:* Several commenters stated that the exposure assumptions or models used to generate ambient water quality criteria are extremely conservative for the following reasons: (1) 6.5 g/d reflects consumption of both contaminated and non-contaminated fish, (2) given the mobility of the population, drinking water from the same source over an average lifetime is extremely remote, (3) the supposition that a person will be drinking water from a surface stream in the first place is questionable, and (4) criteria assume that the same person would actually be consuming "contaminated" water which should have been prohibited under the Safe Drinking Water Act.

Response: The EPA exposure model was based on estimates or measures of national averages (Seafood consumption data analysis, U.S. EPA, 1980—see Guidelines, page 79356). Data indicate that fish consumption rates for recreational and subsistence anglers can exceed 6.5 g/day. EPA has suggested that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so. (See TSD, p.37.) The commenter is correct that the 6.5 grams data reflects consumption of both contaminated and non-contaminated fish. The 6.5 grams is the quantitative daily aquatic life consumption used by EPA. However, EPA's methodology assumes that the 6.5 grams per day of aquatic life were taken from waters meeting the criteria level (see 1980 Guidelines, Section A, page 79343).

In EPA's view, the assumption that an individual may drink from the same surface water for their lifetime is reasonable and meets the goal of the CWA. Drinking water directly from surface supplies is not always regulated under the SDWA: There are many circumstances which are not regulated by the SDWA. SDWA regulations are only applicable to public water supplies serving populations of 25 people or more or in which there are 15 or more service connections.

76. *Comment:* Several commenters questioned the fish and water consumption rates of humans as related to the dioxin criteria.

Response: The Agency is reviewing the scientific basis for the human fish consumption factor used in the derivation of dioxin criteria. (56 FR 50983; October 9, 1991.) When these reviews are completed and the findings critically evaluated, the Agency will initiate a process to determine whether the criteria for dioxin should be revised.

77. *Comment:* Bioconcentration factors (BCFs) should be based on the proportion and type of organisms that would be non-migratory and likely to be caught and consumed by recreational fishermen.

Commenters disagreed with the way the BCF's were derived for 8 chemicals:

Antimony
Arsenic
Beryllium
Cadmium
Chromium
Mercury
Selenium
Thallium

Response: BCFs for all of the criteria, including the above cited metals were supplied by EPA's Duluth laboratory and were used to calculate the promulgated criteria (i.e., from the list above, antimony, arsenic, mercury and thallium which are still in today's rule. The other four metals have been deleted. See comment number 57). (See 1980 Guidelines, pp. 79340–49.) EPA has suggested that States may select more appropriate fish species such as non-migratory and recreational species in developing BCF values which would more appropriately reflect local conditions and aquatic species (see response to comment earlier regarding BCFs and the Technical Support Document for Water Quality-based Toxics Control, EPA/505/2–90–001; March, 1991 at pp. 36–41.) Some States have chosen to do so.

78. *Comment:* A commenter stated that EPA utilized a high degree of overprotection in developing criteria for antimony. The commenter requested EPA to update the IRIS and Health Effects Assessment Summary Tables by using available data to provide toxicity information for various antimony compounds that more appropriately reflects such factors as differences in gastrointestinal absorption rates.

Response: In developing a criteria for antimony the Agency relied upon the available data which is very limited for antimony compounds. The greatest volume of information in terms of chronic exposures to antimony salts was for potassium antimony tartrate. This compound is also the most toxic antimony compound tested. In order to be protective of antimony in all its possible forms, organic and inorganic, the Agency relied upon data from potassium antimony tartrate. Therefore, the IRIS-listed reference dose (RfD) for antimony tartrate is used in the criteria development.

It is true that this criterion may be conservative in some cases. EPA is promulgating this antimony criterion because the criteria must protect human health and it has not been established which antimony compounds may be produced under natural conditions in ambient waters.

79. *Comment:* A commenter stated that EPA should establish seperate criteria for the less soluble and commercially more important antimony oxides. The IRIS database indicates a much higher NOAEL for antimony trioxide than for antimony tartrate.

Response: As stated above, the Agency is setting criteria which would result in protection from all soluble forms of antimony, not just the most common forms. It is true that antimony oxide is much less toxic than potassium antimony tartrate. However, the Agency is taking a conservative approach and assuming that there is the potential for toxic organic antimony compounds, such as the tartrate compound, to form under ambient water conditions. For this reason, the Agency chose the more stringent of the two RfDs listed on IRIS for antimony compounds. (See 1980 Guidelines discussion, p. 79355.)

80. *Comment*: A commenter stated that EPA should use a less conservative application of uncertainty factors in developing the RfD for antimony.

Response: The RfD for antimony, based on the lifetime rat study by Schroeder et al. cited in IRIS (1992), includes an uncertainty factor of 1000 since the study resulted in a Lowest Observed Adverse Effect Level (LOAEL). A No Observed Adverse Effect Level (NOAEL) could not be determined from this study. It is Agency policy to assign an uncertainty factor of 1000 to a LOAEL from an animal study of lifetime duration. If there had been a higher degree of certainty that this LOAEL was indeed close to an observed NOAEL, then the uncertainty factor assigned may have been reduced. However, given the paucity of data on antimony, the Agency assigned the full 1000 uncertainty factor in developing an RfD. (See discussion in the 1980 Guidelines, pp. 79353–54.)

81. *Comment*: A commenter stated that EPA should use the revised bioconcentration factor (BCF) of 0.5 recently developed by EPA for antimony instead of the outdated BCF (1.0) used in calculating the criteria.

Response: It is not true that the BCF for antimony has been officially revised since the 1980 ambient water quality criteria (AWQC) was developed. There are draft updated BCFs under development by the Agency. However, the Agency has not provided the public an opportunity for comment on the new BCF as it has for the revised RfD values which were derived from IRIS. Information on IRIS is considered public information, easily accessed and open to public review. The Agency decided it would be unfair to include revised BCF values into this rulemaking without giving all interested parties a chance to comment on them. For this reason the Agency has presented criteria with 1980 BCF values. EPA will revise the criteria for human health once a revised methodology is developed. At that time we will also include all updated BCF values.

82. *Comment*: Several commenters stated that the polychlorinated biphenyls (PCBs) criteria needed revisions. These included: (1) Revising the cancer potency factor estimated by EPA, (2) setting criteria for each of the Aroclor mixtures separately rather than for a single Aroclor mixture, (3) translating the animal evidence of carcinogenicity into human risk values.

In support of their argument concerning the cancer potency of PCBs, the commenters cited from the report, "Reassessment of Liver Findings in PCB Studies in Rats by Pathology Working Group" prepared by the Institute for Evaluating Health Risk (IEHR). The report reviewed five chronic studies in rats using Aroclor 1260, Aroclor 1254, Clophen A–60 and Clophen A–30. PCBs with chlorine content of less than 60% i.e., Aroclor 1254 and Clophen A–30 had little or no evidence of carcinogenicity. With respect to Aroclor 1260 study, the commenter recommended that the EPA should use a cancer potency factor of either 5.1 or 1.8 $(mg/kg/day)^{-1}$. The EPA potency factor of Aroclor 1260 is 7.7 $(mg/kg/day)^{-1}$. The cancer potency factor of 5.1 $(mg/kg/day)^{-1}$ was calculated from the same study (Norback and Wellman) as used by the EPA. Use of geometric means of all the studies with chlorine content of 60% resulted in the cancer potency factor of 1.9 $(mg/kg/day)^{-1}$.

The commenter argues since there is no evidence that the PCBs with chlorine content of less than 60%, are carcinogenic, the Agency should set a separate criterion for each of the mixtures i.e., Aroclor 1242, Aroclor 1254, etc.

Response: EPA disagrees with the commenter concerning the cancer potency calculations using geometric means of several studies resulting in value of 1.9 $(mg/kg/day)^{-1}$. Utilization of a geometric means approach for the calculation of potency estimates from the available studies is not reasonable because different animal strains and age levels were used in these studies. In addition, the study of Norback and Wellman, cited in IRIS (1992), from which EPA calculated its potency factor of 7.7 $(mg/kg/day)^{-1}$, was much superior in its design and conduct than the other studies. Therefore, the Norback and Wellman study is expected to provide a more precise criterion. The re-examination of slides from the Norback and Wellman study by a group of private pathologists and the use of the revised data is alleged to a yield cancer potency factor of 5.1 $(mg/kg/day)^{-1}$. This potency factor is not very different from that calculated by the Agency.

The Agency believes that it is not reasonable to develop a criterion for each of the PCB Aroclor mixtures. PCBs are mixtures of chlorinated biphenyls. Each mixture may contain up to 209 possible individual compounds. These mixtures are prepared by treating biphenyls and chlorine under alkaline conditions and are characterized by the chlorine contents of the mixtures. For example Aroclor 1242, 1254 and 1260 contain 42, 54 and 60 percent chlorine contents respectively. These mixtures are not characterized by the occurrence of each possible compound in the mixture. Each of the mixtures would be expected to contain all combinations of chlorinated compounds even though some of them in small or trace amounts. In summation, all the Aroclors are expected to contain chlorinated carcinogenic PCB isomers. Besides expecting carcinogenic compounds in each mixture, these mixtures cannot adequately be analyzed with commonly available methods.

The Agency believes that the evidence of carcinogenicity observed in animals can be used to estimate risk values. The Agency has used this approach in this regulation based on the existing Agency 1980 Guidelines (51 FR 33992).

83. *Comment:* One commenter noted that there is a marked range of carcinogenic potencies between the various nitrosamines with some nitrosamines exhibiting no carcinogenic activity. The commenter argued that reliance on structural similarity methodology could therefore result in misclassification errors as to whether specific compounds should be treated as carcinogens.

Response: EPA agrees that there is a marked range of carcinogenic potencies between the various nitrosoamines with some nitrosoamines exhibiting no carcinogenic activity. If there are adequate data available for a specific nitrosoamine, EPA uses such data in evaluating the health risks that such a chemical may present. However, such data are often not available. As a consequence, EPA must, as a practical matter, infer the toxicity of one compound from the toxicity of a chemically similar analogue.

84. *Comment:* A commenter submitted a document entitled, "Biological Risk Assessment of N-Nitrosodimethylamine." While this document does not recommend a specific human health criteria for N-nitrosodimethylamine (NDMA), it does conclude that: 0.0044 µg NDMA/kg/day will present the public with a lifetime 10^{-5} risk level of cancer.

Response: It is not at all clear how the author(s) of "Biological Risk Assessment

of N-Nitrosodimethylamine" arrived at the 0.0044 µg NDMA/kg/day with 10^{-5} risk level. Assuming the ingestion of 2 L of water/day by a 70 kg adult, 0.0044 µg NDMA/kg/day is equivalent to a level of NDMA in drinking water of 0.28 µg NDMA/L. Based on the same data, IRIS concluded that the 10^{-5} risk level for NDMA in drinking water is 0.007 µg/L (i.e., 1/40 the value of "Biological Risk Assessment of N-Nitrosodimethylamine"). Thus, EPA disagrees with the comment since inadequate data and analysis were provided.

85. *Comment:* A commenter noted that the human health criteria presented in the table (in parentheses) are for pollutants which had no health based criteria in the 1980 criteria documents (45 FR 79318). The commenter urged EPA to not include these criteria in the final rulemaking.

Response: The proposed rule indicated these values presented with parentheses in the matrix were *not* being proposed as regulatory criteria but were presented as notice for inclusion in future State triennial reviews. So as not to confuse these values with the criteria being promulgated today, those values were deleted from the matrix and presented below.

Compound	Water and organisms (µg/L)	Organisms only (µg/L)
Copper	1300	
1,2-Dichloropropane	0.52	39
1,2-Trans-Dichloroethylene	700	
2-Chlorophenol	120	400
2,4-Dimethylphenol	540	2300
Acenaphthene	1200	2700
Butyl Benzene Phthalate	3000	5200
2-Chloronaphthalene	1700	4300
n-Nitrosodi-n-Propylamine	0.005	1.4

3. Economics

86. *Comment:* Many commenters objected to the Agency's decisions not to develop detailed cost estimates and not to conduct a comprehensive Regulatory Impact Analysis. The objections were presented in terms of (a) EPA's obligation pursuant to Executive Order 12291 to conduct an analysis; (b) the need to use benefit-cost analysis to make effective public policy decisions, and (c) EPA's error in relying on the difficulty of the task as a reason for not conducting the analysis.

Response: EPA's decision not to provide detailed cost estimates was based on the unusually complex characteristics of this rule with respect to projecting the burden on dischargers. Section J of this preamble includes a discussion of EPA's effort to estimate costs for the rule. As a very brief summary, cost estimates for compliance with water quality-based permits would be based on numerous assumptions; results are sensitive to these assumptions; and consequently, the results would not provide meaningful information to the rulemaking process.

For the final rule, the Agency has undertaken a cost assessment to express a range of compliance costs for several combinations of industries and pollutants. The Agency has also estimated and/or described a range of health and ecological benefits for the rule. While this information about costs and benefits does not constitute a comprehensive Regulatory Impact Analysis, the assessment provides descriptive information about the types of costs that might be incurred as new water quality standards are translated into specific NPDES permits. Also, the ranges illustrate the uncertainties inherent in any estimate of costs.

In addition to the compliance costs to dischargers, other types of cost impacts may occur as a result of EPA-imposed numeric criteria in State water quality standards. For example, nonpoint sources of pollution may incur costs to the extent that best management practices need to be modified to meet water quality standards. In addition, States may incur increased monitoring costs, but only if there is some reasonable expectation that the pollutants are manufactured or actually used in the State.

Several commenters, representing the interests of industrial and municipal dischargers, provided cost estimates; others provided cost data for various compliance strategies. These cost estimates cannot form the basis of an economic impact analysis. Insufficient information is presented in the comments to determine whether these costs reflect the most cost-effective means of achieving the required pollutant reductions. Similarly, EPA cannot confirm whether the cost estimates reflect the incremental cost to comply with water quality-based standards beyond the cost to comply with technology-based regulations. It is the incremental costs that are relevant to this assessment. In addition, the information supplied in the comments is not sufficient to measure the impact of these costs on the financial condition of the dischargers (whether industrial or households).

Due to the uncertainties, a Regulatory Impact Analysis would not alter the Agency's decision to fulfill its statutory responsibilities and promulgate numeric criteria for toxic pollutants. The same conclusion applies to detailed compliance cost estimates.

U.S. Government Standard Form 83, Request for OMB Review, includes a section for OMB to waive the requirements to conduct a Regulatory Impact Analysis, so OMB does have such authority.

87. *Comment:* Several commenters asserted that EPA has not demonstrated that the costs and operating inefficiencies of complying with federal criteria are commensurate with environmental benefits.

Response: The provisions in the Clean Water Act covering water quality standards and specifically, establishing numeric water quality criteria for toxic pollutants, do not include consideration of costs or benefit-cost comparisons. As explained above in section J, economic factors are considered at some points in the process (such as establishing water body use classifications), but not as a component of adopting water quality criteria. The statutory requirements covering water quality criteria focus instead of protection of human health and the environment.

EPA has considered the ability and value of estimating the benefits associated with revised water quality criteria. A summary of the human health and ecological benefits is included in Section J of this preamble.

Briefly, the Agency finds that reduced pollutant discharges are feasible at reasonable costs for several examples. In addition, the national toxics rule has the potential to reduce excess cancer cases. Other ecological benefits, such as protection of wildlife and aquatic organisms, are also projected as an outcome of States adopting numeric pollutant criteria in their water quality standards.

88. *Comment:* Several commenters argued that EPA should conduct a Regulatory Flexibility Analysis because not to do so is a violation of the Regulatory Flexibility Act, and an agency cannot abrogate its statutory duty by pleading hardships.

Response: EPA finds that meaningful results from extensive cost and regulatory impact analyses for this rule are unlikely to be achieved. The same conclusion applies to a detailed analysis conducted in response to the Regulatory Flexibility Act. Briefly, the numerous assumptions and analytical difficulties that are inherent to this rulemaking yield information about the scope of costs, but not detailed cost estimates for specific groups of dischargers, such as small entities. Nonetheless, as described above, EPA's evaluation does not find that there will be a significant impact on a substantial number of small entities; therefore, a final Regulatory Flexibility Analysis is not required.

89. *Comment:* Several commenters asserted that EPA should consider current economic conditions in determining whether to promulgate Federal criteria.

Response: While EPA acknowledges that prevailing economic conditions affect individual business decisions concerning investment in pollution control, Congress clearly intended the Agency to move expeditiously when Federal action is warranted. In compliance with congressional intent, EPA is promulgating these criteria at this time.

In addition, it is not clear which "current economic conditions" should be taken into account in establishing federal criteria. The limitation of toxic discharges is intended to be a continuing process, with this rule a part of the on-going control process. Since the criteria will be in effect during all phases of business cycles, current conditions cannot be the sole determinant of economic conditions when analyzing the economic impact of a regulation. Likewise, the impact of this rule will not be incurred immediately because the criteria will be written into new discharge permits as the current permits expire.

90. *Comment:* Several commenters, representing industrial and municipal dischargers, asserted that the economic impacts of complying with EPA-imposed criteria will be substantial and will be burdensome.

Response: While it is likely that some dischargers will incur compliance costs when the EPA-imposed numeric toxic pollutant criteria are translated into specific NPDES permits, it is not certain that such costs or their impacts will be unreasonable. For several industries, as described in the Agency's cost assessment, large segments of the discharging community will not be affected by this rule because, for example, costs to comply are very small, or technology-based limitations are a sufficient basis for effluent control that will also control pollutants to the level needed to comply with in-stream water quality criteria.

91. *Comment:* Commenters representing municipal interests stated that EPA is incorrect in the assumption that industrial sources are the primary source of toxics discharges by POTWs.

Response: EPA recognizes that there are several sources of toxic pollutant contributions to POTWs. Industrial indirect dischargers, while not the only source, are often the primary source, and the toxic influent from these sources can often be controlled through pretreatment programs.

92. *Comment:* Several commenters stated that promulgation of Federal criteria removes the flexibility to reduce impacts that States would have had by adopting their own standards. Further, they argue, EPA is incorrect in its assumption that impacts are no different than what would occur if States had acted to adopt their own standards.

Response: States continue to have the opportunity to adopt their own standards that include numeric criteria for toxic pollutants. As they adopt and EPA approves their water quality standards, the flexibility provided in the standards-implementation and permit-writing phases of the standards process will return to the States. For a discussion of the effect of this promulgation on various implementation questions, including flexibility, see subsection 4 of this section.

In the cost assessment, EPA has investigated the potential incremental effects of EPA setting standards instead of States. Briefly, EPA finds that for certain dischargers, incremental costs may be incurred in States where toxic pollutant criteria are adopted at EPA's levels. If a State were to adopt less stringent criteria, it is possible that the impacts would be reduced. It is important to consider that in some of the examples, EPA's criteria did not result in incremental costs.

As discussed elsewhere in this preamble, EPA encourages States to adopt their own standards and make use of site-specific criteria as appropriate.

4. Implementation

93. *Comment:* The Agency received substantial comment on 40 CFR 131.36(c) which described the proposed implementation procedures for priority toxic pollutant criteria. Comments divided on whether such factors should be included or left to the discretion of the States.

Response: For reasons stated in the preamble to the proposed rule (56 FR 58437, section 3, Applicability), EPA believes that baseline application conditions must be included in order to provide the intended environmental and human health protection of the criteria. These criteria consist of more than quantitative concentrations. EPA's section 304(a) criteria methodology clearly presents the criteria as criteria maximum concentrations (CMC) and criteria continuous concentrations (CCC) which contain averaging periods and return frequencies. The implementing hydrological conditions merely provide minimum conditions to meet these definitions. The salinity conditions delineating when and where the freshwater and saltwater criteria apply are also necessary. EPA must specify where each of these sets of criteria apply. Likewise the hardness limitations for applying the metals criteria. Each of these paragraphs will be discussed in more detail below but are mentioned here to demonstrate their necessity for implementation of the criteria. Without these generic application conditions NPDES permit writers, the principal users of the criteria, would be unable to develop conditions and limits for inclusion in NPDES permits within the requisite ranges of consistency and predictability.

94. *Comment:* The ability of States to develop site-specific criteria and to grant variances and exceptions to standards received several comments generally indicating that EPA should not constrain the ability of States to use such implementation procedures.

Response: The development of site-specific criteria and the use of variances to standards are optional procedures made available to States that adopt State criteria (40 CFR 131.11(b)(ii) and 131.13). It is neither a statutory nor a regulatory requirement to develop site-specific criteria or to issue variances.

The preamble language to this final rule clarifies EPA's statement on this subject in the proposal. Since the criteria in this rule are Federal criteria applicable to the State, a State cannot unilaterally establish site-specific criteria or grant variances to the Federal rule. That is what EPA meant in the proposal when we indicated that actions pursuant to State law for Federally promulgated criteria are precluded. Such procedures are still available to the State, but are much more cumbersome as it requires the State to meet all the regulatory requirements for developing such procedures, but then EPA would need to undertake a Federal rulemaking process in order to effectuate changes to the Federal rule in accordance with the requirements of the Administrative Procedures Act. EPA continues to emphasize that this is another strong reason for States to act to adopt their own standards even after Federal promulgation action is taken.

95. *Comment:* One EPA Region questioned whether the specification of the applicable hydrological baseline mandated the use of steady state models and eliminated the use of dynamic models for wasteload allocations.

Response: The proposed rule did *not* intend to eliminate the use of dynamic models for wasteload allocations and total maximum daily load determinations. Generally the low flows specified explicitly contain duration and frequency of occurrence which

represent certain probabilities of occurrence. Likewise the criteria for the priority toxic pollutants are defined with duration and frequency components. Dynamic modeling techniques explicitly predict the effects of variability in receiving water, effluent flow, and pollutant concentration. EPA has recommended and described three dynamic modeling techniques for performing waste load allocations in section 4.5 of the 1991 Technical Support Document: Continuous simulation, Monte Carlo simulation and lognormal probability modeling. These procedures allow for calculating wasteload allocations that meet the criteria for priority toxic pollutants without using a single, worst-case concentration based on a critical condition.

Thus, EPA believes that either dynamic modeling or steady State modeling can be used to implement the criteria adopted today.

96. *Comment:* Several commenters in addressing implementation conditions argued that EPA should defer entirely to State discretion including the applicable design flows. Other commenters urged removal of design flows from the rule and rely on the guidance in the TSD and/or other EPA guidance. Another commenter agreed that flow requirements were necessary but that the harmonic mean flow requirement was flawed.

Response. As noted in the preamble to the proposed rule, implementation requirements that include limitations on flow values are required in order to achieve the intended environmental and human health protection. The applicable discussion of this issue is found in the preamble to the proposed rule on pages 58437–58438 and footnotes 1 and 2. The hydrological or biological basis for the proposed low flows were taken directly from EPA's Technical Support Document for Water Quality-based Toxics Control. (See TSD, Appendix D for aquatic life and section 4.6 for human health.)

The argument by the commenter on the harmonic mean flow was in reality a disagreement on EPA's assumed long-term dose assumption for toxics. The commenter believes short-term effects are more relevant, and therefore requires a different flow, especially for bioaccumulative pollutants. However, EPA continues to support the human health protocol used in the proposed rulemaking and notes that it explicitly accounts for bioaccumulation in the criteria development protocols. For such long-term human assumed consumption of water and aquatic life from such waters containing a pollutant, EPA's best scientific judgment is that the harmonic mean flow is the correct flow to apply in order to correctly estimate the exposure dosage of the average exposed individual.

97. *Comment:* One commenter questioned the applicability of the specified design flows in waters downstream from impoundments which have minimum release rates specified, as for example hydroelectric dams.

Response: EPA's proposed rule in § 131.36(c)(2)(ii) specifies that the low flows are applicable to "waters suitable for the establishment of low flow return frequencies." Thus, free flowing streams and rivers were the types of receiving waters contemplated. In cases where legally specified low flows exist, as for example under FERC licenses, these become the applicable minimum flows. In future State water quality standards reviews, EPA encourages the States to take into account these specified flows and adjust the criteria appropriately to provide equivalent protection of human health and the environment to that applied in today's rule.

98. *Comment:* One commenter noted that "rules" 5(a) and (b) are inconsistent with "rule" 8 in the "Assumptions and Rules Followed by EPA in Writing the proposed § 131.36(d) Requirements for All Jurisdictions." (See the appendix at page 58451 in the proposed rulemaking package.)

Response: "Rules 5(a), 5(b) and rule 8" as stated in the appendix are correct. An incorrect statement of "rule 8" is contained in the preamble to the proposed rule at page 58432. Briefly stated, these rules provide:

—Rule 5(a) applies appropriate human health criteria to all waters in a State classified for either public water supply or for minimal aquatic life protection;

—Rule 5(b) provides that where a State has determined the specific segments where aquatic life are caught and consumed, the human health fish consumption only criteria (Column D2) are being applied to those specific segments;

—Rule 8 provides that where drinking water uses are designated, and even though the State has determined that no potential fish consumption uses exist, the human health criteria for "water + fish" in column D1 are applied. EPA applies these criteria because no "water only" column is available in the section 304(a) criteria methodology and drinking water uses must be protected.

99. *Comment:* Several commenters claimed that EPA was applying the criteria too broadly; that is, to waters where aquatic life propagation or public water supply uses were either not designated or did not constitute existing uses. In contrast, another commenter urged EPA to apply the criteria to all waters of the State where an EPA-approved use attainability analysis did not exist.

Response: Water quality standards contain both a designated use and the criteria necessary to support those designated uses. In this rulemaking EPA is not addressing the designated use component at all, but only the criteria component for the priority toxic pollutants. EPA has relied entirely on the existing State water quality standards to determine the waters to which the criteria apply. In § 131.36(d) EPA refers to all waters within particular designated use classifications.

Because EPA is not addressing the State designated uses here, EPA has not attempted to review State application of designated use classification through use attainability analyses or the other requirements of 40 CFR 131.10. Any identified deficiencies will be handled during the State triennial water quality standard review process with any necessary Federal actions being taken on a State by State basis.

100. *Comment:* One commenter objected to EPA specifying that EPA-approved State mixing zone regulations could be applied to the priority toxic pollutant criteria promulgated today. Others stated that EPA should include procedures to define appropriate mixing zones, that EPA should allow mixing zones in all States and that EPA should require mixing zones in all States.

Response: Mixing zones are one of the general discretionary policies specifically authorized for State adoption by EPA's water quality standards regulation at 40 CFR 131.13. Mixing zones have most recently been defined by EPA in the revised TSD (see page "xx") as "an area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where water quality criteria can be exceeded as long as acutely toxic conditions are prevented." Although mixing zones are discretionary for the States, they are part of the State's water quality standards and therefore subject to EPA review and approval pursuant to CWA section 303(c) and 40 CFR 131.

Mixing zones recognize ambient water dilution and therefore larger mixing zones generally would reduce the stringency of discharge permit limits established to meet ambient water quality criteria. It would be inconsistent with CWA section 501 (33 U.S.C. 1370)

for EPA to impose a less stringent mixing zone policy in a State than is currently authorized. Therefore, in this rulemaking EPA recognizes State mixing zones and provides for their application in implementing the criteria promulgated by this rule. However it does not impose mixing zone requirements on States which do not have such policies.

101. *Comment:* Comments were received that the Federal toxics criteria are not viable because they have never been subject to public comment and review and that the criteria should be subject to continuing peer review and study in order to ensure technical viability. Commenters stated that it is improper to require development of permit limitations on the basis of technically flawed criteria which may not be relaxed in the future due to the anti-backsliding requirements of the CWA and regulations, and that EPA must find that criteria changes which result from peer reviews constitute new information which qualify as an exemption from the anti-backsliding requirements.

Response: We disagree with the premise of this comment that provision for public review and comment on the federal toxics criteria has been inadequate. The criteria methodology and documents were the subject of public review when issued. See the discussion of this issue in the preamble to the proposed rule as well as discussion of EPA's plans to revise criteria guidelines in the future and solicit public comment, 56 FR at 58433. (See also Section F of this preamble.) To the extent we received specific information concerning the criteria in this rulemaking, we have reviewed and responded to that information. Indeed, certain of the promulgated criteria have been changed to reflect public comments. EPA rejects the assertion that the criteria are "technically flawed." EPA believes the criteria are scientifically defensible and would not promulgate criteria that were technically flawed regardless of the anti-backsliding implications. With respect to the comment that revised criteria resulting from peer reviews should constitute "new information" which is exempt from the anti-backsliding requirements, that is not an issue to be decided in this rulemaking. EPA is developing proposed amendments to the NPDES regulations that will interpret and implement the provisions of section 402(o). The commenter's concerns can be addressed in that rulemaking or possibly in a prior permit proceeding if the issue is relevant.

102. *Comment:* One commenter argued that the rule will adversely affect implementation of the NPDES program by diverting resources to deal with permitting and enforcement issues arising from the use of unscientific water quality criteria. It is argued further that no discharger will accept permit conditions that are unreasonable, have no scientific basis, and do not reflect the naturally occurring environmental conditions in the receiving water.

Response: Federally promulgated water quality criteria will be implemented in NPDES permits issued by EPA Regional Offices or authorized States. Dischargers are free to challenge requirements implementing federally promulgated criteria contained in modified, reopened, or reissued permits according to established NPDES permit appeal procedures and as permitted by law. EPA, however, disagrees that the federally promulgated criteria lack a scientific basis and has explained in the preamble to this rule and elsewhere in response to comments why promulgation of the criteria as provided in this rule is necessary to meet the requirements of section 303(c)(2)(B). We anticipate that many dischargers will accept permit requirements based upon the federally promulgated criteria. Dischargers may be permitted to backslide from water-quality based permit limitations where revised criteria are developed if they meet the requirements of CWA sections 402(o) or 303(d)(4) for allowing backsliding in attained and non-attained waters.

103. *Comment:* Comments were received that either the proposed Federal or State standards should provide for a schedule of compliance so that permittees affected by the new federal criteria could have sufficient time to come into compliance.

Response: The proposed rule did not directly provide for a schedule of compliance, however, it also did not change existing applicable State and EPA provisions related to permit issuance or reissuance. EPA agrees with the commenters that some compliance implementation time may, in certain situations, be necessary and appropriate for permittees to meet new permit limits based on the new standards. EPA has not removed this flexibility in the permitting process by this rulemaking. Under the Administrator's April 16, 1990 decision in an NPDES appeal (Star-Kist Caribe Inc., NPDES Appeal No. 88-5), the Administrator stated that the only basis in which a permittee may delay compliance after July 1, 1977 (for a post July 1977 standard), is pursuant to a schedule of compliance established in the permit which is authorized by the State in the water quality standard itself or in other State implementing regulations. (This decision did not affect compliance schedules in individual control strategies issued under section 304(e) of the CWA.)

Standards are made applicable to individual dischargers through NPDES permits which reflect the applicable Federal or State water quality standards. When a permit is issued, a schedule of compliance for water quality-based limitations may be included, as necessary, and EPA assumes this is the case for permits issued to meet these new Federal criteria where States do not have existing statutes, regulations or policy prohibiting compliance schedules. EPA notes that some permits contain a "reopener" clause which may be exercised by the permitting agency on a case-by-case basis to control toxics earlier than the normal re-issuance cycle. However, EPA does not generally contemplate nor does it intend to ask States to undertake permit reissuance related to these new criteria for toxics through anything other than the normal permit reissuance cycle, except in rare instances.

104. *Comment:* EPA's section 304(a) criteria may not be appropriate when applied to non-conventional discharge situations such as stormwater discharges and discharge to ephemeral streams.

Response: EPA's criteria for priority toxic pollutants were developed to protect beneficial designated uses. The criteria are independent of considerations about kinds of dischargers whether point or nonpoint sources. If a State finds that the criteria for the current ambient water designated uses are inappropriate, then EPA's water quality standards regulations provide for a use attainability analysis and establishment of appropriate designated uses. Thus the commenter's concerns are misplaced and focus on the wrong part of the water quality standard.

105. *Comment:* Two comments addressed the salinity and effects on determining which criteria apply at particular locations in estuaries. One commenter, a State agency, supported the concept of clarifying the salinity ranges within which the various freshwater and marine water criteria apply. The State was concerned because the salinity ranges selected by EPA were different from those the State had recently placed in sediment standards. The second commenter asserted that the proposed rule created an untenable situation where fresh and salt waters mix. This commenter suggested that rather than using the more stringent of

the fresh or saltwater criteria, EPA should interpolate between the two on the basis of salinity.

Response: The range of salinities incorporated into this rule at 40 CFR 131.36(c)(3) are appropriate, especially in light of the guidance for the applications of the metals criteria addressed elsewhere in this package.

EPA's proposed rulemaking on salinity, however, was silent on the percentage of the time that the proposed salinity limits could be exceeded but the respective fresh or saltwater criteria still apply. It could be inferred that EPA intended 100% of the time as the appropriate limit. It is EPA's position that a reasonable exceedence should be specified or otherwise the intermediate brackish water zone becomes unnecessarily large. It is EPA's judgment that a factor of 95% of the time provides reasonable cut off points. Thus, for the freshwater criteria to apply, the salinity should be less than 1 ppt 95% of the time. Likewise for the marine water criteria to apply the salinity should be greater than 10 ppt 95% of the time.

EPA recognizes that judgment is required in providing guidance on the appropriateness of freshwater and saltwater water quality criteria across a salinity gradient. This is because a fundamental understanding is lacking of metals form, bioavailability and toxicity along with the relative sensitivities at appropriate salinities of species that occupy this gradient. EPA's recommendations are reasonable given that (1) the database for most metals includes tests with saltwater and freshwater species that tolerate these salinities; (2) that salinities at a particular location change daily with tide and wind and seasonally; and (3) that at low salinities, freshwater and saltwater species mix. It is reasonable that the presence of both types of species in this transition zone require application of both freshwater and saltwater water quality criteria. Given the temporal variability of salinity in both the short and long term and the judgmental basis for EPA's recommendations, knowledge of the kinds of organisms at a site of concern will be particularly helpful in being confident that the appropriate criterion has been applied to the site.

The second commenter's suggestion is not supported by data or professional experience of EPA's scientists. For many metals, toxicity to saltwater species increases at low salinities. Therefore, underprotection would result from the use of an interpolation approach that would result in higher criteria at low or intermediate salinities.

5. Timing and Process

106. *Comment:* EPA should delay Federal promulgation until current State efforts to adopt water quality standards have been completed.

Response: Without sufficiently protective and defensible water quality standards, EPA and the States cannot effectively control discharges of toxic pollutants. While the Clean Water Act clearly gives primary authority for adopting water quality standards to the States, Congress clearly signaled its frustration with State delays in adopting criteria for toxics in the 1987 Clean Water Act amendments. Since the 1987 amendments, the States have had over five years to meet the statute's requirements for adopting water quality standards for toxic pollutants. Further delay is unacceptable. It is now time for EPA to exercise its oversight authority to ensure that human health and the environment are adequately protected.

107. *Comment:* Several comments were received relating to the general subject of State action during or subsequent to this rulemaking and on the processes EPA would use to withdraw Federal criteria applicable to a State. A related comment was that EPA should clarify that partial withdrawals are possible. Another comment questioned which criteria would apply in a situation where EPA approves State standards subsequent to the Federal promulgation.

Response: EPA is fully aware that several States are actively involved in reviewing and possibly revising their standards to meet the requirements of the Act simultaneously with the Agency's action to promulgate Federal standards. It is an objective of the Federal action to spur State action to complete their own administrative procedures so as to obviate the need for Federal promulgation. However, for the reasons stated earlier in the preamble as the basis for this rulemaking, EPA believes States have already had more than adequate time to respond to the statutory requirement and that EPA has a responsibility to act to put standards in place to serve as a basis for environmental control programs. Nevertheless, EPA encourages States to continue to adopt their own standards and thereby enabling themselves to make use of the flexibility inherent in the program through use of the various implementation processes even if such action will not be completed until after promulgation of this rule. EPA is committed to timely withdrawal of the Federal standards after State adoption and EPA approval of State standards.

The assertion that upon adoption of standards by the State, EPA's Federal criteria are no longer applicable within the State is not correct. The Federal criteria will continue to be the applicable water quality standards until withdrawn. Where the State standards are less stringent than the Federal standards, the Federal standards will be controlling until final action is taken to withdraw the Federal standards. In this situation, the permitting agency must use the more stringent standards in issuing permits. As a practical matter, it is assumed that permit holders would seek a stay of permit requirements pending the final decision of the Federal standards. While there may be a period in which there are both State and Federal standards in effect, the most stringent standards (either the State's or EPA's) would be controlling.

As described earlier in the preamble, EPA will act to withdraw this rule as applicable to a State, if the State completes action on adopting standards that adequately protect their waterbodies from toxic contamination and EPA approves those standards. The standards do not necessarily have to be exactly as those promulgated by EPA but they must meet the requirements of the Act and 40 CFR 131.11.

Many comments were received that EPA should not be required to receive comment and execute a rulemaking in order to withdraw State-adopted and EPA-approved standards that are less stringent than those promulgated by EPA. As described in Section E–3 of this preamble, EPA withdrawal action differs depending upon whether the State standards are equal to or more or less stringent than those promulgated in this rule.

While it would be administratively less cumbersome not to provide notice and comment in withdrawing a more stringent Federal water quality standard, EPA, however, is constrained by the provisions of the Administrative Procedures Act, 5 U.S.C. Section 551 (4) and (5) which we believe preclude the Agency from withdrawing a rule as suggested by the commenters. EPA will take timely action to withdraw the Federal rule in these cases. EPA has had experience in withdrawing the Federal rule covering each situation, i.e. standards equal to or more or less stringent than the Federal rule (51 FR 11581, April 4, 1986; 47 FR 53372, November 26, 1982; 56 FR 13592, April 3, 1991). It has not proven to be a practical problem. Consistent with the water quality standards guidance and historical operating policies, EPA confirms that partial approval of State standards and partial withdrawal of the

Federal rule is allowable. (See generally, Chapter 2, Water Quality Standards Handbook, December 1983)

There is an exception to this process. If a State adopts a 10^{-5} risk level when EPA promulgated 10^{-6}, the rule can be withdrawn without notice and comment because we raised the possibility of different risk levels in the proposal and we have accepted both risk levels as meeting the requirements of the Act.

108. *Comment:* EPA received comment that there is no procedural necessity for this rule because Congress did not set a specific deadline for State action to comply with section 303(c)(2)(B).

Response: For the reasons set forth elsewhere in this preamble, EPA has the requisite statutory authority to promulgate these criteria and that such criteria are necessary as a basis for water quality-based control programs designed to protect the public health and the environment.

Section 303(c)(2)(B) of the Act requires States action to address toxic pollutants "whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection * * *". Paragraph (1) refers to the requirements to review and revise, if necessary, standards at least once each three year period—the triennial review cycle for standards.

Notwithstanding arguments concerning timeliness of EPA and State actions, the Agency has made a decision that toxics criteria for priority toxic pollutants should be in place. The Administrator's action has started the process described in CWA section 303(c)(4) for Federal promulgation. Thus, because of the Agency's action, the comment at this point is moot.

109. *Comment:* EPA received numerous comments concerning the 30-day public comment period. Some industries and municipalities expressed concern that the rulemaking was too extensive to allow meaningful comment within 30 days. Some commenters requested extensions up to six additional months. Several commenters noted that EPA had never before promulgated a final water quality standards rule within 90 days of proposal.

Response: EPA appreciates that 30 days is a short comment period but believes that it is fully consistent with section 303(c)(4) (33 U.S.C. 1313(c)(4)) which requires EPA to promulgate a final regulation within 90 days of proposal. The fact that EPA only met this requirement once in its nine final promulgation actions does not change the statutory requirement.

In most of those previous cases (and in 2 cases today) the Agency was in fact superseding a State rule. Pursuant to the Agency's regulation at 40 CFR 131.21(c) the State rule stayed in effect until EPA's final rule took effect. Today's action is different. Here, by and large, there are no State criteria for priority toxic pollutant in place and EPA is acting to fill that void. This EPA action has a greater sense of urgency and justifies the Agency's effort to meet the 90 day statutory time schedule in CWA section 303(c)(4).

The addition of section 303(c)(2)(B) to the Clean Water Act was a clear and unequivocal signal from Congress that it was dissatisfied with the slow pace at which States were adopting numeric criteria for toxic pollutants. This intent is made clear in the legislative history of that provision. It is the only time in the 26-year history of the program that Congress explicitly directed the States to address certain pollutants in their standards. Moreover, section 303(c)(4), which authorizes Federal promulgation has explicit deadlines and Congressional directives to act promptly. The intent of the Federal promulgation section of the Act is to accelerate human health and ecological protection by establishing water quality standards as a basis for pollution control programs. To achieve these objectives and meet the statutory deadline, we need sufficient time to review public comments and make any necessary revisions.

Although the State and pollutant coverage of this final rule is large, the issues involved are neither new nor numerous. The primary focus of this rule is the narrow issue of whether a State has adopted sufficient water quality criteria for toxic pollutants in State standards as necessary to support water quality-based control programs.

EPA alerted the public to its intentions and the planned contents of the proposal on April 19, 1990, in an announcement in the Federal Register. In addition, we notified the administrators of the State agencies responsible for the water quality standards program of each potentially affected State of our plans on April 9, 1990. In the April 19, 1990, notice, EPA described what would be in the proposal, including: Which pollutants, which States, the cancer risk level, and EPA's intention to update criteria using publicly available information in the Integrated Risk Information System. Since that notice, EPA has apprised the public of its intentions and status of its action through State and Regional meetings and quarterly newsletters on the criteria and standards program. EPA, through both its Headquarters and Regional Offices have met with the States, and the regulated community individual and public meetings and public hearings to discuss EPA's plans and progress. This lengthy lead time has allowed potential commenters to prepare for the proposal and should have facilitated preparation and submission of meaningful comments within the 30-day public comment period.

As discussed previously in this preamble and the preamble to the proposed rule, the methodology used to develop the criteria and the criteria themselves have previously undergone scientific peer and public review and comment and were revised as appropriate. Some human health criteria were updated by recalculating the criteria using revised reference dose information contained and publicly available in the Agency's Integrated Risk Information System. Information in this system was peer reviewed within EPA and, as a matter of policy, is the information which was recommended to the States for their use. Most of these reviews occurred before 1987. Congress acted to amend the Act with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. At some point in the standards setting process the States and EPA must act recognizing that scientific research leading to improved water quality information is an ongoing process. In the case of this rulemaking, EPA affirms that in addition to all the environmental, programmatic, and statutory factors supporting the rule, the basic criteria methodologies are scientifically sound as are the resulting criteria.

In the five years since the February 1987 enactment of section 303(c)(2)(B), most States have worked extensively to adopt water quality standards for toxics pollutants. The issues in this proposal are the same ones that States, dischargers, public interest groups, and EPA have discussed and debated in-depth during those deliberations. The comments prepared for State and EPA meetings and hearings are to a great extent the same as those to be made on this Federal action and made it easier for the commenters to prepare submissions on this rule. The arguments presented in the public comments that EPA's action is new or that the States are not in compliance because they are

carefully reviewing their standards all tend to ignore the fact that many of the criteria were available as early as 1980. Because of a lack of State action, EPA made it a priority emphasis in the revision to the water quality standards regulation in 1983 and, most importantly of all, that section 303(c)(2)(B) was not the start of the process but the signal from Congress that delays had to cease. It is now eleven years after the criteria were first made available to the States, five years after Congress specifically directed the States to Act. Given this background, 30 days was sufficient for commenters to prepare and submit meaningful comments. The extensive nature of the comments submitted support this position. Further delay in the process is totally unwarranted for all of the above programmatic, health, ecological, and statutory reasons.

110. *Comment:* EPA should promulgate criteria only for those pollutants clearly shown to be interfering with designated uses.

Response: The record supporting this proposal contains extensive data on the toxic pollutant problem in each State. It shows the presence of numerous toxics in State waterbodies and it also contains information on impaired waterbodies. Earlier in this preamble, in section E–2 of this preamble, we described that rationale for why EPA could not undertake extensive studies in each State.

In responses to previous comments earlier in this section, we described EPA's legal authority to undertake this promulgation action including why it is not necessary for EPA to promulgate standards pollutant-by-pollutant, waterbody-by-waterbody. In summary: (1) EPA has sufficient data to indicate the widespread presence of toxic pollutants, (2) administratively, given the statutory schedule for promulgation, Congress clearly never intended EPA to conduct in-depth State analysis, (3) EPA, in its December 1983 guidance on options to meet the statutory requirement of section 303(c)(2)(B) indicated a policy position that "* * * the presence or potential construction of facilities that manufacture or use priority toxic pollutants or other information indicating that such pollutants are or may be discharged strongly suggests that States should set standards since such pollutants have the potential to or could be interfering with attaining designated uses", (4) neither the Act nor EPA's regulation limits the establishment of standards to a waterbody-by-waterbody, pollutant-by-pollutant approach, (5) as a matter of public policy to protect human health and the environment, it is the Agency's position that a more conservative approach is warranted, and (6) actual dischargers of such pollutants should expect to have control limits placed in their permits for such pollutants while other dischargers will not be affected.

111. *Comment:* Since EPA published a range of risk levels in its water quality criteria documents, it should allow a range in this rule or allow States to select the appropriate risk level.

Response: EPA's publication of a range of risk levels in individual water quality criteria documents was simply an illustration of how the criteria recommendations would be affected by adopting various risk levels. It was not intended to nor did it, in fact, establish a policy on risk levels.

Consistent with recognizing the primary authority of States to adopt water quality standards and that Agency policy allows States to select an appropriate risk level within the general range of 10^{-4} to 10^{-6}, EPA modified this final rule to apply the human health criteria at the risk level adopted or proposed by the State for all or a majority of toxic pollutants under applicable State water quality standards regulations, or in the case of Idaho, Nevada, and Rhode Island, on an expression of State preference. EPA notes that in a majority of cases, the 10^{-6} risk level is the one adopted by the States. In order for the human health criteria to be implemented in water quality programs, a single risk level must be chosen so that a specific numeric limit is established for a pollutant. The rationale for EPA's choice of a risk level for each State in this rule is contained in section G–1 of this preamble.

Any State adopting its own standards that meet the requirements of the Act may adopt a risk level other than that used by EPA in this rule. The ability of a State to select an alternative risk level is one of the reasons EPA encourages each State to adopt its own water quality standards rather than rely on Federal promulgation.

6. State Issues

Alaska, Washington, and Idaho

112. *Comment:* Alaska, Washington and Idaho have noted errors in the proposed rules. In some cases these errors were improper citations, or the inclusion of, or failure to include, certain criteria.

Response: EPA sought comments on the interpretation it had made of the various State water quality standards that were potentially affected by the proposed rulemaking. EPA expected and received comments on the appropriateness of the individual criteria groups applied to the State beneficial use designations.

In deciding which changes it can make to the proposed rules EPA notes that the preamble to the proposed rule laid out the intent and purposes of this action extensively. Beginning on page 58431 of the preamble to the proposed rule, EPA described the 12 "rules" or logic used to derive the criteria applicable to States judged not in compliance with CWA section 303(c)(2)(B). The gist of this rationale was for EPA to apply aquatic life criteria to State-defined designated uses providing even minimal support to aquatic life survival; and human health criteria to State-defined designated uses providing for public water supply and/or aquatic life consumption. Moreover, EPA provided in the matrix in proposed 40 CFR 131.36(h) all of the numeric levels that it proposed for application to the designated uses. Thus, EPA believes that sufficient notice was provided as to the purpose of the proposed rule, the types of affected State designated uses and the identification and stringency of the section 304(a) criteria to provide the Agency some latitude in deleting and adding criteria, especially when these changes are made because of comments made by the affected States and are necessary to correct unintended mistakes.

After discussing this comment with the State of Alaska, it was agreed that the following changes to the rule were necessary. These changes occur in 40 CFR 131.36(d)(16)(ii).

The State's current water quality standards (WQS) reference "Gold Book" criteria for all uses included in the rule except secondary contact recreation. Because the promulgated numbers are, in essence, revised Gold Book criteria, to be consistent with State WQS, EPA applied aquatic life and human health numbers to all uses except secondary contact. Secondary contact recreation is included because it is defined in the State's standards as including fishing. D1 criteria are applied to the drinking water use. D2 criteria are applied to all uses except drinking water for both fresh and marine waters. All acute aquatic life criteria are included in this rule. (See correspondence between the State and EPA in the record.) Also, all human health criteria for carcinogens based on the fact that the State has not adopted a risk level and therefore, cannot calculate or apply appropriate criteria for carcinogens. The chronic aquatic life criterion for selenium as it has been updated since publication of the Gold Book and made more stringent.

The seafood processing use (2)(A)(ii) was deleted from rule because it is an industrial use category to which the criteria promulgated today do not appropriately apply.

Additionally, in 40 CFR 131.36(13)(iii), the risk level for carcinogens was changed to 10^{-5} to reflect the State's July 1992, proposal to amend its water quality standards and to reflect an indication of State policy preference received on November 16, 1992.

The following changes were made with respect to the State of Washington. After discussion with the State, EPA has assigned appropriate criteria to use categories rather than to classes. The rule was revised as follows (see 40 CFR 131.36(d)(17)):

(22)(i) Fish and Shellfish
Fish
Water Supply (domestic)
Recreation
(22)(ii) Fish and Shellfish; Fish
B1 and B2—#2, 10
C1—#2, 10
C2—#2, 6, 10, 14
Water supply (domestic)
D1—All
Recreation
D2—All marine waters
D2—freshwaters not protected for domestic water supply

The following changes were made with respect to the State of Idaho. After discussion with the State, EPA renumbered the use classifications to reflect the reorganization of the State standards and made the following changes in the criteria assigned (see 40 CFR 131.36(d)(18)):

1.b Domestic Water Supplies
Remove cyanide and asbestos
3.a Primary Contact Recreation
Remove B1—All
Remove B2—All
Add D1—All
3.b Secondary Contact Recreation
Remove B1—All
Remove B2—All

Alaska

113. *Comment:* EPA has incorrectly included CMC (acute) aquatic life criteria for freshwater and saltwater for Alaska in the proposed rule.

Response: EPA's inclusion of CMC aquatic life criteria in the rule is appropriate. Alaska's water quality standards state that, "Substances shall not * * * exceed criteria cited in EPA, Quality Criteria for Water." Whether or not the State has adopted both acute and chronic criteria by reference is ambiguous and requires clarification through this rulemaking, especially in light of language included in the following three documents issued by the State:

1. The State's Water Quality Standards Workbook, published in July 1991, and widely distributed in order to "understand what water quality standards and criteria are, how to interpret the Alaska water quality standards regulation * * *", states that, "* * * EPA has developed a two-number criterion for acute and chronic conditions. The state adopts only the chronic criterion."

In the same state WQS workbook, Table 1, "Alaska's Water Quality Criteria for Toxic Substances in Freshwater and Saltwater", is said to "represent the toxic substances criteria adopted by reference in the AWQS." This table does not include any acute values for the priority toxic pollutants.

2. An August 30, 1991 letter from John A. Sandor, Commissioner of ADEC, to Harold Geren, Chief of EPA Region 10's Water Permits and Compliance Branch, states, "The Department affirms its decision to continue to use "Gold Book" *chronic* criteria to establish receiving water criteria and effluent limits in NPDES permits." (emphasis added)

114. *Comment:* Alaska was not informed of EPA's intention to include acute criteria in this rulemaking.

Response: On November 4, 1991, EPA Region 10's Water Division Director sent via fax and hard copy, a letter to ADEC's Chief of Water Quality Management, notifying the State of EPA's intention to include acute criteria in this rulemaking. The letter stated, "These letters affirm Alaska's use of "Gold Book" chronic criteria for freshwater and marine systems and have convinced us that Alaska is in compliance * * * with the following exceptions: * * * Acute aquatic life criteria for all pollutants * * *."

115. *Comment:* The statement included in the rule that, "Alaska is included in today's proposal because although the State had previously adopted all section 304(a) criteria by reference, the State Attorney General has decided that the adoption by reference is invalid", is in error and should be deleted from the final rule.

Response: EPA concurs that the statement was in error and no such statement is included in this final rule.

Arkansas

116. *Comment:* Any promulgation of human health criteria for the State of Arkansas should be withdrawn from the rulemaking because the state has adopted such criteria.

Response: A State's standard must be reviewed and approved by EPA before the State can be removed from the rule. Arkansas formally submitted their water quality standards containing human health criteria to EPA on December 17, 1991. EPA's review found that the human health criteria were supportive of designated uses and therefore no human health criteria are promulgated in this rule. The State's criteria to protect human health were approved by EPA on January 24, 1992. EPA also disapproved Arkansas' water quality standards for failing to adopt the criteria for priority pollutants to protect aquatic life as required by section 303(c)(2)(B). Necessary aquatic life criteria are promulgated today and include the following: Cadmium, chromium, copper, lead, mercury, nickel, selenium, silver, zinc, and cyanide.

117. *Comment:* Arkansas is not required by the Act to adopt numeric criteria for metals because it has not been established that the metals listed "could reasonably be expected to interfere with those designated uses adopted by the State."

Response: EPA's policy is that the presence of any Section 307(a) pollutants raises an issue as whether they could reasonably be expected to interfere with designated uses. The presence in ambient waters and the discharge of metals is documented in several databases, including the Toxic Release Inventory, STORET, and discharge monitoring reports. The State could have submitted supporting documentation that demonstrates that the presence or discharge of these metals is not expected to interfere with designated uses. The State submitted no such information. In the absence of any demonstration to the contrary, EPA must conclude that the metals can reasonably be expected to interfere with designated uses.

118. *Comment:* The documentation on which EPA based its assertion that designated uses "could reasonably be expected to be interfered with" should be provided under this rulemaking process.

Response: The documentation that showed the widespread occurrence of metals in Arkansas' waters in concentrations exceeding EPA's recommended levels was part of the record for this rulemaking and was available for review at the Region 6 office as well as at EPA headquarters.

119. *Comment:* All pertinent data developed by EPA under the 304(1) process should be made available without special request to ensure its availability to potentially affected parties.

Response: The material developed by the States with respect to section 304(l)

was publicly available at the time the list was compiled. A complete discussion of the relationship between the 304(l) list and today's rule is included earlier in this section. Moreover, because EPA did not rely on the State's section 304(l) materials for this rulemaking, it was unnecessary to place such materials in the record.

California

120. *Comment:* A commenter urged that the national rule should clarify that no criterion continuous concentration for selenium less stringent than 5 µg/l will be allowed in California's San Francisco Bay. Commenters suggested that the National Rule should direct Region IX to develop site-specific criteria for selenium in San Francisco Bay. It was further suggested that the National Rule should state that the 5 µg/l selenium criterion (B2) applies only to fish and aquatic invertebrates, not to more sensitive uses such as wildlife. The narrative standards should govern for the more sensitive uses.

Response: This rule promulgates EPA's freshwater criteria for selenium of a CCC of 5 µg/l (4 day average) and a CMC of 20 µg/l (1 hour average) for San Francisco Bay and Delta. In EPA's November 6, 1991 approval letter on California's Enclosed Bays and Estuaries Plan, EPA approved California's decision to allow regional water quality control boards (Regional Boards) to determine where in an estuary it is appropriate to apply freshwater or saltwater criteria. Although most Regional Boards have not yet specified the appropriate standard, EPA generally agrees with this process. However, the EPA standards approval letter specifically found that utilization of the saltwater criteria for selenium in the San Francisco Bay/Delta would be inappropriate. This finding is based on substantial scientific evidence that there are high levels of selenium bioaccumulation in San Francisco Bay and the saltwater criteria fails to account for food chain effects. Accordingly, in the absence of Regional Board action consistent with EPA's approval letter, EPA is promulgating the freshwater criteria for selenium for the San Francisco Bay/Delta. EPA's criteria for selenium in freshwater are derived from laboratory and field data on the effects of selenium on aquatic vertebrates, invertebrates and plants and should be protective of aquatic organisms under most conditions. The selenium criteria were not developed with the intent to address protection of wildlife such as waterfowl. EPA is in the process of developing wildlife criteria for selenium. Recent studies and analyses have enhanced our understanding of avian exposure to selenium in the field and have clarified the importance of food chain biomagnification and low level toxic effects on avian reproduction. Such information is, for the most part, new information available after the Water Quality Criteria for Selenium was published in 1987. EPA supports the efforts of the State to develop selenium criteria based upon food chain biomagnification. However, in the absence of a final wildlife criteria document, or other sufficient information, EPA is unable to promulgate a criterion more stringent than 5 µg/l as part of this rulemaking. The purpose of this rule is to establish Federal criteria for all waters that do not have EPA-approved state criteria. It is not appropriate to use this Federal rule as a mechanism for directing promulgation efforts of a region. Further, EPA's regulations, guidance documents, and the Preamble to the Federal rule clearly specify the steps to be taken when a state wishes to adopt site specific criteria. EPA believes that it is already clear that both the numeric and the narrative standards apply in all cases. This information is contained in EPA's guidance documents and does need not be reiterated in this rulemaking.

121. *Comment:* EPA should promulgate freshwater selenium criteria in California for the Sacramento-San Joaquin Delta, the inland surface waters including the San Joaquin River, and the Central Valley Wildlife refuges.

Response: The draft rulemaking proposed the national selenium criteria for all water bodies in California and included those listed above. On November 6, 1991, EPA approved California's Inland Surface Waters Plan which adopted EPA's selenium criteria for freshwater bodies with the exception of Salt Slough, Mud Slough, and the upper San Joaquin River. EPA approved the State's selenium criteria but did not approve these exceptions. Accordingly, the final national rule promulgates the EPA freshwater criteria for selenium for Salt Slough, Mud Slough, and the upper San Joaquin River. The State's freshwater selenium criteria will apply elsewhere in the Sacramento-San Joaquin Delta and San Joaquin River. The California Inland Surface Waters Plan also included a selenium criterion of 2 ppb for the inflow to Grasslands Area Wildlife Refuge in the Central Valley that is more protective than EPA's criteria. This selenium criterion was approved by EPA and, therefore, today's promulgation will not apply to the inflow to Grasslands Valley Wildlife Refuge.

122. *Comment:* Several commenters asserted that: (1) Past efforts to develop site specific objectives for San Francisco Bay demonstrate the technical difficulties, costs, and uncertainty of developing site specific criteria and; (2) those difficulties make site-specific criteria ineffective in amending inappropriate national criteria.

Response: EPA approved the water quality criteria adopted by California in the Enclosed Bays and Estuaries Plan on November 6, 1991. EPA has revised today's rule so that it does not include pollutants covered by those state-adopted, EPA-approved criteria, except for selenium as described in the previous comment and response. The San Francisco Bay is a highly complex estuarine system. In such cases, developing site specific criteria may be difficult. In October 1991, EPA made technical comments on the site specific objectives proposed for San Francisco Bay. The site specific criteria for San Francisco Bay have not yet been adopted by the State and, therefore, it is premature to evaluate their effectiveness. EPA has approved site specific criteria in several States and recommends that site specific criteria be developed where physical or chemical characteristics of the site alter the biological availability of the chemical or where species at the site are more or less sensitive than those species used in the development of national criteria. Please see Science and Implementation under general comments.

123. *Comment:* A commenter indicated that Region IX has placed impediments on the adoption of site-specific criteria which make future adoption of site-specific criteria an unrealistic alternative.

Response: There is no indication what "impediments" the commenter refers to, or the action by which Region 9 allegedly created such impediments. Please see Implementation under general comments about requirements for site-specific criteria.

124. *Comment:* EPA also received comments that the proposed rule would establish inappropriate and technically unsupported criteria for copper, nickel, lead, and mercury for South San Francisco Bay.

Response: The final rule has been amended to reflect EPA's November 6, 1991 action on California's Enclosed Bays and Estuaries Plan and does not include criteria for copper, nickel, mercury or lead for San Francisco Bay. EPA generally approved California's approach directing regional boards to choose between two sets of criteria

(freshwater or saltwater) in an estuary. California's saltwater and freshwater criteria are approved by EPA. At this point, EPA does not have sufficient information to conclude that this approach of allowing Regional Boards to choose between the two sets of criteria is inappropriate for copper, nickel, lead, and mercury in the South Bay. Therefore, criteria for these metals are not included in this final rule.

125. *Comment:* Several commenters questioned the appropriateness of promulgating EPA criteria for special water bodies such as ephemeral streams, constructed agricultural drains, effluent-dominated streams, irrigation-flow dominated streams, or evaporation ponds.

Response: The criteria contained in this rule apply to all "waters of the United States" as defined in the Clean Water Act and implementing regulations except where State-adopted/EPA-approved criteria apply. Waters of the U.S. may include human-constructed water bodies. Waters of the U.S. does not include waters that fall under EPA's waste treatment system exemption. California deferred adopting water quality standards for certain effluent-dominated streams and irrigation-flow dominated streams. This deferral was disapproved by EPA in its letter dated November 6, 1991 on the basis that it did not protect the water bodies from toxics that are reasonably expected to interfere with designated uses. EPA Region IX agrees with California that site specific criteria would be appropriate for many waters in these categories. If California adopts and EPA approves site-specific criteria that protect the designated uses, criteria for those waters will be removed from this final rule.

126. *Comment:* Several commenters found it impossible to comment on the proposed rule in the short comment period provided. Specifically, commenters noted that the thirty-day comment period is unreasonable and unfair for California given Region IX's delay in acting on California's own water quality standards.

Response: Commenters had more than five weeks to review Region IX's November 6, 1991 action, including thirty days to compare it to the proposed Federal rule. Also, please see general comments under Timing and Process.

127. *Comment:* EPA was not mandated to propose standards for California at this time, especially in light of Region IX's November 6, 1991 action on California's standards. The Clean Water Act contains no specific deadline for EPA to propose standards and does not require standards to be proposed for the entire nation at once. California could be separated from other states in order to allow reasonable time to evaluate both actions.

Response: On November 6, 1991, Region IX disapproved California's failure to adopt numerical criteria for all 307(a) pollutants for all "waters of the U.S." in California. According to EPA's water quality standards regulations (40 CFR part 131), the State has a 90-day opportunity to correct any deficiencies and EPA may then approve adequate corrections. If the State does not adopt the necessary corrections (or additions) within that period, then EPA must "promptly" propose and promulgate Federal standards in place of those deficient State standards. (Clean Water Act, section 303(c)(4)(A); 40 CFR 131.22.) In this instance, Federal promulgation occurred more than 90 days after November 6, 1991, and took into account any and all changes adopted by the State during those ninety days. To further delay promulgation for California when EPA is prepared to act on California's standards concurrent with other States is unnecessary. As to the adequacy of time to evaluate both actions, see response to preceding comment.

128. *Comment:* California commenters stated that it is unclear whether Federal or State criteria would apply to waters which California exempted, since EPA disapproved this exemption.

Response: California, by exempting certain waters from its 303(c)(2)(B) criteria, failed to adopt such criteria for those waters. EPA's disapproval of the exemptions did not bring about an adoption which the State never made. With this rulemaking, EPA adopts criteria for all 307(a) priority pollutants for those exempted waters which are Waters of the U.S. See additional comments below.

129. *Comment:* It is unclear which of California's use classifications are considered aquatic life or human health classifications. The proposed rule equates aquatic life protection with aquatic life consumption and states that waters with any aquatic life designation must meet human health criteria. A commenter indicated that assigning fish consumption for any aquatic life segment is equivalent to Federal promulgation of new designated uses and should not be done in this rulemaking.

Response: California's basin plans identify specific aquatic life and human health uses that are to be protected in a particular waterbody. EPA has no intention of changing designated uses in this rulemaking. As stated in the proposed rulemaking, States may remove the human health use classification for waters which have aquatic life but no existing aquatic life consumption uses. California, however, applies human health protection for fish consumption statewide to all navigable waters through the Inland Surface Waters Plan, Enclosed Bays and Estuaries Plan, and Ocean Plan. Therefore, the Federal rule is based on the presumption that, for all navigable waters of the State, aquatic life is present, fish or other aquatic life are being caught and consumed, and human health protection for fish consumption is necessary. It is consistent with EPA's established water quality standard regulations to require States to include all uses identified in Section 101(a) of the Act for all waters unless removed through an approved use attainability analysis. (See 40 CFR 131.10(j)). In this rulemaking EPA has not included the human health criteria (based on fish consumption) for any segments for which a State has conducted, and EPA has approved, a use attainability analysis to remove fish consumption as a use. Please see Legal Authority under general comments.

130. *Comment:* EPA's claim on 56 FR 58422 at p. 58431 that comprehensive Federal promulgation of standards place "no undue or inappropriate burden on States or dischargers" is unsubstantiated and believed to be untrue in California. The economic impacts of complying with Federal criteria are believed to be enormous particularly for publicly owned treatment works (POTWs) and are likely to discourage water reclamation projects.

Response: The commenter provides no explanation as to why complying with Federal criteria will discourage water reclamation projects. EPA is unconvinced that this would be the case. Please see Economics under general comments in response to economic impact concerns.

131. *Comment:* The commenter is concerned about the use of 10^{-6} risk level criteria as opposed to MCLs for protection of drinking water.

Response: California does not have any water bodies where drinking water is the sole exposure pathway. Therefore, MCLs may not be sufficient to protect human health from exposure to toxics from combined drinking water and fish consumption pathways. See section F–5 for a more detailed discussion of risk levels included in this rule.

132. *Comment:* The commenter is concerned that State schedules of compliance will not apply to Federal criteria.

Response: Federal criteria will be implemented in accordance with existing state adopted compliance schedules. For a detailed discussion of this subject see a response to comment in subsection 4 of this section.

133. *Comment:* A commenter asserted that EPA did not do enough to educate the State early on of the 303(c)(2)(B) requirements and that EPA's final 303(c)(2)(B) guidance was not transmitted to the States until December 12, 1988, almost two years after the 1987 amendments. This delay left California with inadequate time to adopt criteria on a pollutant-by-pollutant and water body-specific basis, and consider the scientific uncertainties relating to the Federal data and methodologies.

Response: As stated in the Preamble to the proposed rule, the December, 1988 guidance was not substantially different from earlier drafts which were available for review by the states. That guidance proposed a pollutant-by pollutant and waterbody specific approach as an acceptable option. While recommending certain approaches, the guidance also made it clear that States retained flexibility to implement their own preferred approaches. Please see Science and Timing and Process under general comments.

134. *Comment:* One commenter stated that Region IX's requirement that California adopt criteria for all priority pollutants is erroneously based on statements in California's Functional Equivalent Documents and is inconsistent with national guidance. Another commenter stated that this requirement was unfounded.

Response: Region IX has consistently advised California that it must adopt criteria for all pollutants for which EPA has section 304(a) criteria recommendations, with the exception of any pollutants which cannot reasonably be expected to interfere with designated uses. Omission of any such pollutant must be based on evidence concerning the presence and effect of that pollutant in any given waterbody. This policy is consistent with national guidance, the history of which is set forth in Part B2 of the Preamble of November 19, 1991. None of the guidance options has ever allowed the exclusion of any such pollutant from the requirements of section 303(c)(2)(B) without a factual scientific basis. In the absence of such scientific basis, EPA relied on California's draft Functional Equivalent Document which stated that "it is likely that priority pollutants not covered in this plan will be found [in the State] in a more extensive analytical survey." This statement is sufficient basis for EPA to have determined that all priority pollutants would reasonably be expected to interfere with designated uses in all waters of the State.

135. *Comment:* The Federal criteria are more stringent than necessary for some water bodies in California.

Response: Without specific information about which pollutants and which water bodies the commenter is referencing, EPA has difficulty responding to this comment. In the absence of such specific information, EPA determined that it was appropriate to adopt EPA's section 304(a) criteria for all "waters of the U.S." that lack State-adopted, EPA-approved criteria. If, based on further scientific information, the State adopts site-specific criteria which are less stringent than the Federal criteria but, in EPA's judgment, fully meet the requirements of the Act, EPA will undertake a rulemaking to remove the affected pollutants from the Federal rule. For additional information, please see Science under general comments.

136. *Comment:* Major wastewater dischargers in California have filed a petition in State court to restrain the State from utilizing its section 303(c)(2)(B) standards for inland waters, bays, and estuaries. They filed the petition out of concern over significant economic impacts caused by blanket imposition of the [EPA] criteria. The filing of the petition illustrates the concerns of many public agencies over use of EPA criteria as national standards.

Response: The petition referred to in this comment is a challenge to section 304(a) criteria which have been adopted by the State. It is a pending proceeding in State court and does not affect today's rulemaking. The commenter states that this matter reflects a widespread concern over adoption of section 304(a) criteria as national standards. That concern is apparent in the comments received from several entities, particularly in California, and they are addressed in the Economics under general comments.

137. *Comment:* A commenter stated that "only marine criteria should be selected for enclosed bays in California since these are, by definition, indentations along the coast which enclose an area of oceanic water. It is not appropriate to apply freshwater criteria to these water bodies." The commenter also indicated that States should be given the discretion to determine when freshwater or salt water criteria should apply in an estuary.

Response: State standards in California's Inland Surface Waters and Enclosed Bays and Estuaries Plans have been approved for most of the priority toxic pollutants. These standards include both freshwater and saltwater uses and leave the selection of appropriate criteria to the regional boards. EPA approved the two sets of criteria on November 6, 1991. The Federal rule has been amended to reflect this approval. The final Federal rule applies to those parameters and also to water bodies where State standards are lacking or not protective. The regional boards shall determine for both State and Federal criteria whether freshwater or saltwater criteria are appropriate at the confluence of the water bodies with different water quality objectives.

District of Columbia

138. *Comment:* The adequacy of new human health criteria has not been proven to be germane to the District of Columbia.

Response: As a general proposition, EPA is applying criteria for all priority toxic pollutants not addressed by approved State criteria for those States not in full compliance with section 303(c) of CWA. EPA's reasoning behind this approach (and the exceptions) are discussed fully in the preamble. However, two reasons deserve repeating here. First, existing data sources indicate the discharge, potential discharge or presence of substantial numbers of priority toxic pollutants in most States. With the failure of some States to adopt toxic criteria in a timely fashion, coupled with the evidence of the discharge or potential presence of priority toxic pollutants for which the State has failed to adopt criteria, the Agency believes there is a need for numeric criteria for most priority toxic pollutants in most States. Second, the support of each criterion on a state-by-state and waterbody-by-waterbody basis by EPA would be an enormous administrative burden on EPA and would be contrary to the statutory scheme and Congressional directive for swift action. Congress directed EPA to accomplish the promulgation within 90 days and EPA has made every effort to expedite this rulemaking. Providing the adequacy for all criteria for all States would take years and would be counter to the directive of swift action.

Florida

139. *Comment:* One commenter stated that, since the State of Florida adopted numeric criteria on December 7, 1990 based on Option II of EPA's section 303(c)(2)(B) guidance, the Federal rule should not include criteria for all priority toxic pollutants.

Response: Since the time that the proposed rulemaking was published, Florida formally requested EPA's review of the criteria adopted by the State on

December 7, 1990. EPA approved these criteria, with the exception of the absence of criteria for 2,3,7,8 TCDD (i.e., dioxin) on February 25, 1992. Therefore, EPA has only included criteria for 2,3,7,8 TCDD for the State of Florida in the final rulemaking.

Kentucky

140. *Comment:* One commenter stated that Kentucky has proposed and adopted a revision to 401 KAR 5:031 which deletes the previously adopted numeric human health criteria for dioxin. A request was made by the commenter that EPA's determination of full compliance for Kentucky for the section 303(c)(2)(B) requirement be considered and a Federal water quality criteria be promulgated through this Federal rulemaking. Alternatively, a request was made that such criteria be established as an interim final rule in a separate rulemaking.

Response: At the time EPA published the proposed rulemaking, the State-adopted criteria for 2,3,7,8, TCDD for the State of Kentucky was in effect as part of 401 KAR 5:031 (Surface water standards). EPA is aware that the proposed deletion of 2,3,7,8 TCDD criteria was put into effect on January 29, 1992. EPA's position on Kentucky's proposed deletion of the State-adopted dioxin criteria was transmitted to Kentucky by letter dated November 21, 1991. In that letter, EPA's Region IV Water Management Division Director stated, "Should the State complete adoption of the proposed amendment without replacing the adopted dioxin criteria with approvable criteria values, I will recommend to the Regional Administrator that the dioxin criteria, or absence of dioxin criteria, be disapproved by EPA. If the State does not adopt criteria within 90 days of EPA's disapproval action, EPA will initiate a promulgation of Federal water quality criteria for dioxin for the State." This continues to be EPA's position on this issue.

Louisiana

141. *Comment:* EPA should not promulgate dioxin standards for Louisiana.

Response: Louisiana submitted to EPA criteria to protect human health for dioxin on December 18, 1991. EPA's review found that the criteria adopted by the State were scientifically defensible and supported the designated uses. EPA approved the State standard on January 24, 1992. Therefore, Louisiana is not included in today's rule.

Nevada

142. *Comment:* A Nevada commenter suggested that Column D1 criteria should apply only at the point of intake of any municipal or domestic supply.

Response: Column D1 criteria are to apply to all waters designated by the State of Nevada for municipal or domestic supply. In the case of Lake Mead, that is the entire lake except for the segment at the end of Las Vegas Bay recognizing that Las Vegas Wash enters there. All of Lake Mead is subject to human consumption of water either directly from the lake or downstream.

143. *Comment:* It was stated that the State of Nevada has already considered and rejected criteria similar to the proposed amendments, and Nevada's decision is not contrary to the requirements of the Clean Water Act.

Response: The State excluded criteria similar to those in the proposed rulemaking from the water quality standard amendments considered for adoption by the Nevada State Environmental Commission (SEC). The State did not provide an adequate justification for this exclusion; therefore, on January 16, 1991, EPA disapproved this portion of the SEC action as being inconsistent with section 303(c)(2)(B). Without substantive justification (such as evidence of lack of presence of particular pollutants in waters of the State) for excluding any of the priority pollutants from State standards, all of them must be added.

144. *Comment:* A Nevada commenter stated that Las Vegas Wash should be excluded from any human health protection for consumption of aquatic organisms under the Federal rule.

Response: The general issue of the applicability of column D2 (consumption of aquatic organisms) criteria is discussed in the preamble and in the Science portion of general comments. Human health protection is required where a fishery, or other aquatic life that can be consumed, is present. Las Vegas Wash has been designed by the State for the use of "Propagation of aquatic life, excluding fish." State regulations clarify that this designation does not preclude the establishment of a fishery. Although the commenter offers anecdotal information that no one fishes in (or eats any kind of aquatic organism from) Las Vegas Wash, no evidence is provided supporting that anecdotal information. No use attainability analysis has been conducted to justify removal or amendment of this use. Also, the State has already adopted (and EPA approved) standards for protection of aquatic life in Las Vegas Wash. Because of the existing aquatic life use and the potential for consumption of aquatic organisms, EPA has applied column D2 criteria to Las Vegas Wash.

145. *Comment:* A Nevada commenter stated that the proposed rule does not provide sufficient notice as to why certain criteria were included and others excluded from the proposed rulemaking for Nevada.

Response: The rulemaking includes criteria only for parameters that Nevada did not adopt, or, if the State did adopt criteria for a parameter, for parameters that were specifically disapproved. This information was all part of the administrative record associated with Nevada's adoption of numeric standards for toxics in May 1990 and EPA's approval/disapproval on January 16, 1991 and was available to the public prior to the notice of EPA's proposed rule, and during the public comment period for the proposed rule.

New Jersey

146. *Comment:* A commenter argues that New Jersey is in compliance with section 303(c)(2)(B) of the Clean Water Act because the State incorporates section 304(a) criteria, by reference, in their Water Quality Standards Regulation for actions involving the development of water quality based effluent limitations for point sources.

Response: While the State Water Quality Standards Regulation does incorporate section 304(a) criteria by reference, the standards do not specify the application factors necessary to implement criteria (e.g., a risk level for carcinogens). Further, the reference in the water quality standards regulation limits application of these criteria to actions involving the development of water quality-based controls for point sources while water quality standards must serve as the basis for controls on all sources, point and nonpoint.

147. *Comment:* A commenter noted that water quality criteria were not proposed in the promulgation for New Jersey waters classified as PL (Pinelands), or as mainstem Delaware River and Delaware Bay (zones 1C-6).

Response: EPA agrees that, due to EPA oversight, criteria were not proposed in the promulgation for New Jersey waters classified as PL (Pinelands) or as mainstem Delaware River and Delaware Bay (zones 1C-6).

Appropriate criteria for New Jersey waters classified as PL (Pinelands), and as mainstem Delaware River and Delaware Bay (zones 1C-6) are now included in this final rule.

Puerto Rico

148. *Comment:* A commenter stated that EPA's proposed rule presents serious problems regarding its implementation, specifically in determining the waters to which such criteria would be applicable in the Commonwealth of Puerto Rico.

Response: The Puerto Rico Water Quality Standards Regulations is clear regarding the designated uses of all waters of the Commonwealth of Puerto Rico. EPA is assigning necessary and appropriate criteria to support those uses in order to satisfy the requirements of section 303(c)(2)(B) of the Clean Water Act.

149. *Comment:* A commenter stated that the Puerto Rico Water Quality Standards Regulation, which establishes the classifications and designated uses, does not comply with the Federal Water Quality Standards Regulation in terms of the adoption of subcategories of uses, the need to conduct use attainability analyses when standards are exceeded, the adoption of a variety of uses for a single waterbody, and in considering the social and economic needs of the Commonwealth.

Response: While the Federal Water Quality Standards Regulation authorizes the adoption of subcategories of uses, States are not required to adopt subcategories of uses in the establishment of standards. States are not required to complete use attainability analyses (UAAs) when designated uses are not met. Section 131.10(j) of the water quality standards regulation requires that States must complete UAAs when removing designated uses that are not existing uses, or when specifying uses inconsistent with the goals of the Clean Water Act. States may not remove designated uses if they are existing uses. In the establishment of water quality standards and water body classifications, including requisite public participation, Puerto Rico has taken social and economic needs of the Commonwealth into consideration, as well as the inherent differences in levels of protection and water quality required by the various designated uses. Notwithstanding this discussion, the rule only addresses appropriate criteria for priority toxic pollutants. Other elements of State water quality standards are not addressed.

150. *Comment:* It was commented that the Puerto Rico Water Quality Standards Regulation does not recognize the uses of waterbodies that are actually attained.

Response: Designated uses of waterbodies are not required to only reflect those uses that are actually attained. While the Puerto Rico Water Quality Standards Regulation defines Class SD waters as surface waters intended for use as a raw water source for public water supply and the preservation and propagation of desirable species, not all Class SD waters presently meet these goals. Designated uses need not be existing uses. Consolidation of various uses (i.e., fishing and swimming) into one classification is an acceptable approach for designating uses of waterbodies, and a necessary one in order to meet the goal of the Clean Water Act. Federal regulations require that waters have designated uses that provide for fishable/swimmable water quality where attainable. When establishing criteria to protect these various designated uses, criteria may be specified to protect each use.

Washington

151. *Comment:* The term "water supplies" should be deleted from the Class AA listing in (22)(i) because it is incorrect.

Response: EPA concurs, it was a misprint.

152. *Comment:* Comments were received that EPA should not promulgate criteria for dioxin in the State of Washington. The commenters expressed concerns that EPA's actions would be disruptive and unnecessarily interfere with ongoing State administrative and judicial actions involving Department of Ecology's decisions in establishing effluent limitations in permits issued to numerous pulp and paper mills. The Department of Ecology had established the permit effluent limitations based on the State's existing narrative water quality criterion. The commenters urged EPA to defer action pending the conclusion of the ongoing State actions challenging the State's authority to establish permit limitations based on its narrative criterion. In addition commenters said that the current State regulations met the requirements of section 303(c)(2)(B) and that the State's regulations were equivalent to another State's water quality standards that an EPA region had approved as being in compliance with section 303(c)(2)(B).

Response: EPA carefully considered the comments on this issue and has decided to exercise its discretionary authority under section 303(c)(4)(B) to promulgate human health criteria for dioxin and the other toxic pollutants to be applicable to waters in the State of Washington. This action will ensure that there are numeric water quality criteria applicable in the State as required by section 303(c)(2)(B).

EPA's review of the current Washington water quality standards for toxic pollutants indicates that those standards do not include the necessary water quality criteria to satisfy the requirements of section 303(c)(2)(B). While WAC 173-201-047(1) includes numeric aquatic life criteria, protection of human health is only addressed through a narrative criterion that provides that toxic substances not be introduced at levels which "adversely affect public health, as determined by the department * * *." WAC 173-201-047(4). EPA believes that this limited narrative criterion does not satisfy the requirements of section 303(c)(2)(B).

EPA acknowledges that the Department of Ecology relied upon its narrative criterion to establish effluent limitations for dioxin in State NPDES permits. EPA supported the Department's reliance in its narrative criterion in developing necessary effluent limitations for the control of discharge of dioxin. EPA encourages all States to have narrative criteria for protection of aquatic life, wildlife and human health in instances when the State does not have an applicable numeric criterion. However, section 303(c)(2)(B) is clear in its directive that States adopt numeric criteria for toxic pollutants if EPA has issued section 304(a) guidance and the discharge or presence of such pollutants could reasonably be expected to interfere with designated uses in the State.

In the notice of proposed rulemaking, EPA discussed the basis for its decision to include Washington in the rule. 56 FR at 58477. The absence of any numeric criteria for human health and the acknowledged discharge and presence of toxic pollutants being expected to interfere with designated used supported inclusion of Washington in the rule. With respect to dioxin, the issuance of permits with discharge limitations was further evidence that the discharge or presence of dioxin could reasonably be expected to interfere with designated basis.

EPA does not believe that promulgation of numeric criteria for the State of Washington should be delayed pending resolution of the ongoing litigation challenging the Department of Ecology's authority to establish effluent limitations based on the State's narrative criterion. The State's narrative criterion, while it may be the basis for deriving effluent limitations, is not adequate to satisfy the requirements of Section 303(c)(2)(B). Some commenters argued that Washington had in effect incorporated by reference EPA's Section 304(a) water quality criteria guidance as the basis for interpreting and

implementing the State's narrative criterion. The Washington water quality standards, however, merely provide that for toxic substances not listed in the standards, concentrations shall be determined "in consideration of USEPA's Quality Criteria for Water, 1986, and as revised, and other relevant information." WAC 173–201–047(3). The State standards neither require use of EPA's criteria nor limit the State's decision to use of such criteria. Therefore, even a decision by the Washington Supreme Court that the Department of Ecology is authorized to use its narrative criterion to develop permit effluent limitations would not address the specific requirement of section 303(c)(2)(B) that the State adopt numeric criteria.

In response to the comments that the current Washington regulations are equivalent to regulations adopted by the Commonwealth of Massachusetts which is not included in today's rulemaking, EPA believes there is a important difference between the two State regulations. The Massachusetts regulations provide that in deriving criteria for unlisted pollutants, the State "shall use the recommended limit published by EPA pursuant to section 304(a) * * *." Code of Massachusetts Regulations, Title 314, section 4.05(5)(e). Pursuant to an Implementation Policy adopted on February 23, 1990, Massachusetts stated that it would use a risk management goal of 10^{-6} for individual chemicals and 10^{-5} for mixtures of chemicals in deriving criteria for carcinogens. The regulations contain a specificity regarding what the applicable criteria will be that is not present in the Washington regulations. EPA's Region I determined that the Massachusetts regulations complied with section 303(c)(2)(B) and approved those regulations on December 20, 1990. See 56 FR 58452.

EPA's decision to promulgate appropriate human health criteria for the State of Washington is consistent with the Agency's prior statements regarding the status of Washington's compliance with Section 303(c)(2)(B). In the Federal Register notice of April 17, 1990, EPA identified Washington as not being in compliance with section 303(c)(2)(B). 55 FR 14350. By letter dated March 27, 1990, from the Department of Ecology to EPA, the Department listed the adoption of human health criteria as an action for its triennial review that had been requested by EPA. By letter dated March 21, 1991, from EPA to the Department of Ecology, EPA explained that the State would remain in noncompliance under section 303(c)(2)(B) for human health criteria even if the State proceeded to adopt aquatic life criteria and a human health risk level. These documents are in the record of this rulemaking.

Executive Order 12291

1. Introduction and Rationale for Estimating Costs

Executive Order 12291 requires EPA to prepare a Regulatory Impact Analysis for major regulations, which are defined by certain levels of costs or impacts. For example, the Executive Order specifies that a regulation imposing an annual cost to the economy of $100 million or more is considered major. According to the Executive Order, the Regulatory Impact Analysis should contain descriptions of both potential costs and benefits. While the Executive Order calls for an estimate of costs, the Statute mandating today's rule does not allow cost to be a consideration in setting water quality criteria. The following discussion describes the Agency's consideration of costs in the rulemaking and decision process even though cost considerations are not included in the development of numeric criteria for toxic pollutants.

In developing the proposed rule, EPA considered various perspectives regarding the potential incremental costs that might be incurred as a result of the Agency promulgating numeric criteria for individual States. The Agency concluded that the costs incurred by individual dischargers as a result of complying with water quality-based permits might be large enough to designate the rule as "major," according to the definitions included in Executive Order 12291. The Agency did not include a quantitative estimate of the costs due to the uncertainties of such an estimate, but instead, described the types of costs that were expected.

There are certain characteristics of the rule that make the estimation of costs particularly complicated and difficult. Since the rule imposes requirements only until the State submits, and EPA approves, the State's own numeric standards, the cost estimates should be calculated on a per State and per pollutant basis, so that State/pollutant combinations can be removed as numeric standards are approved. Additionally, an analysis of the incremental costs attributed to the rule should reflect information on specific impaired stream segments and the dischargers on those segments.

Because a detailed analysis of all affected stream segments is not practical given the available resources, the development of compliance cost estimates for this rule would require numerous assumptions about pollutant loadings, impacts of technology-based regulations on loadings, combinations of pollutants handled by a given treatment approach, and the costs of each treatment train. The many sources of uncertainty associated with estimating the costs would produce an estimate with limited value for evaluating the merits of the rule. In addition, the rule does not remove the responsibility of States to adopt numeric criteria for toxic pollutants. As the remaining States submit their own standards and EPA approves those standards, the costs attributed to the rule will decline. Hence, EPA, with the concurrence of OMB, proceeded with the proposed rulemaking without a quantitative estimate of compliance costs.

2. Overview of Projected Costs

EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits. The addition of Federally promulgated criteria for toxic pollutants could affect the wasteload allocations developed for each waterbody segment in affected States to the extent the pollutant is discharged into the stream. Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry.

Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW. The POTW may incur costs for expansion, operational changes, additional treatment, modified pretreatment programs, and increased operator training.

Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges.

Monitoring programs are another source of potential incremental costs to dischargers and States. Monitoring programs to generate information on the existing quality of water and the types and amount of pollutants being discharged are potentially affected by the imposition of EPA criteria. The addition of Federal criteria for toxic pollutants does not require the State to engage in a program to monitor ambient waters for such pollutants. Unless there is some reasonable expectation that the pollutants are manufactured or actually used in the State with the likelihood that those pollutants will be discharged into surface waters, NPDES permittees also would not have to monitor for these pollutants.

3. Comments and EPA's Response

EPA received numerous comments regarding the potential cost impacts of the rule; most of these comments contend that a Regulatory Impact Analysis is required. Specifically, many commenters asserted that EPA should estimate the costs that dischargers would incur and include such cost estimates in all decision-making aspects of the rule. Some of these comments argued the qualitative discussion of costs did not fulfill the requirements of E.O. 12291.

EPA does not concede that its rationale for *not* estimating costs was flawed. Rather than appear nonresponsive, however, the Agency recognizes that further discussion is warranted and has undertaken an assessment of potential costs that might be incurred for several types of dischargers.

This cost assessment is not a Regulatory Impact Analysis, nor is it a comprehensive cost analysis. The following discussion is intended to describe the scope and range of costs that might occur. Many analytical assumptions were necessary to conduct this cost assessment, which is presented in the form of four examples. Each example was conducted independently with no common data sources. The examples are not intended to represent an estimate of the total costs of the rule.

The Agency maintains that a comprehensive analysis of costs would not provide enough additional information to assist Agency management with decisions concerning the rule. A complete analysis of costs for this rule would likely include differential costs to comply with various levels of regulatory control. Similarly, an RIA would likely evaluate alternative options for structuring the rule, where the options might reflect various level of stringency. Due to the complexities of analyzing the impacts of this rule, however, a meaningful cost estimate would be extremely difficult and costly, and it is uncertain whether an RIA would lend reliable information to the decision-making process.

4. Scope of Cost Impacts

Since this rule directly affects only those States that have not adopted their own numeric criteria for toxic pollutants, the cost impacts are limited to dischargers in those States. The cost impacts are further limited by several other factors. First, the potential impact of the rule is limited to treating discharges of only those pollutants included in the rulemaking for each State. In other words, if today's rule imposes criteria for only one pollutant (assuming criteria were adopted and approved for all other pollutants—a situation which occurs for several States), the number of dischargers in that State that might incur compliance costs are limited to dischargers for which that single pollutant drives the treatment needed to comply with their NPDES permit. This situation significantly reduces the number of dischargers with a cost impact. The number of pollutants that could be the basis for additional treatment may be reduced from the number actually included in the rule due to the overlap of controls for groups of pollutants. For example, discharges of several of the metals can be reduced by a single treatment system (generally lime precipitation and clarification) without additional treatment for each additional pollutant in that group.

In some cases, the controls in place—whether installed to comply with technology-based limitations or to comply with a discharge permit issued pursuant to section 304(l) of the Clean Water Act—may be sufficient to provide compliance with water quality criteria. In other cases, controls implemented to meet whole effluent toxicity permit requirements may preclude the need to implement additional controls to reduce a toxic pollutant discharge covered by the rule.

Finally, flow levels, receiving stream conditions, and wasteload allocations are likely to cause variation in the need to install additional treatment technology. For all of these reasons, the Agency believes that the number of dischargers with potential incremental costs is significantly lower than the total number of dischargers in the controlled States.

An estimate of the number of point sources that could be affected begins with the major dischargers from the 14 States included in today's rule.[8] The focus on major dischargers (where the term "major" refers to the distinction used in the NPDES program for facilities with the potential for a significant impact on water quality) is consistent with the rulemaking's focus on toxic pollutants. Any point source with a significant discharge of toxic pollutants is likely to be included in this category.

The number of major facilities for the 18 States is 2,055. (See Footnote 5.) This is a subset of the approximately 7,000 major dischargers in the entire country (3,000 industrial, 4,000 municipal). Of these, 229 facilities already have Individual Control Strategies (ICS) that were established in response to section 304(l) of the Clean Water Act. These facilities have effluent limitations for toxic pollutants sufficient to achieve water quality standards in the receiving water. Thus, the number of major facilities that potentially could be subject to incremental requirements is 1,826. The exact number is likely to be lower because of the number of regulated pollutants in each State and the current discharges of the facilities.

All of the analytical difficulties described above, such as estimating pollutant loadings and compliance costs, would need resolution to accurately estimate the cost impacts for this group of dischargers. In place of attempting to estimate total costs, the following four examples illustrate the range of costs likely to be incurred in specific situations, and some of the problems involved in developing potential compliance costs for this rule.

5. Example: Regulating Dioxin for the Pulp and Paper Industry

As an example of the range of costs that could be associated with the imposition of EPA's numeric criteria, we considered the pulp and paper industry and the pollutant dioxin.

Dioxin (i.e., 2,3,7,8–TCDD, listed as Compound #16 at § 131.35(b) of the proposed rule) is a likely by-product from chlorine bleaching of chemically-pulped wood. Chlorine bleaching is used by approximately 100 pulp mills in the United States. Of those bleach mills, 22 are located in States that had not adopted human health criteria for dioxin as of the date of the proposed

[8] When this assessment was prepared, the Agency contemplated that 18 States would be included in the rule. Thus, the estimated costs described in this preamble are based on a "universe" of 18 States. Since then, four States have adopted and EPA has approved priority toxic pollutant criteria. In the examples that follow, the assessment has not been revised from 18 States to 14 States because the objective of the assessment—to describe the scope and range of impacts—is met even with the higher number of States.

rule. (See Footnote 5.) Thus, this rule could potentially serve as the basis for establishing dioxin limitations in the NPDES permits for those facilities. Of the 22 bleach mills in "unapproved" States, however, 13 already have dioxin limitations in their discharge permits, established in response to section 304(l) of the Clean Water Act. Only for the remaining nine facilities, then, will this rule be a potential reason for establishing dioxin limitations in the discharge permits.

For those nine facilities, however, the effluent levels of dioxin, as reported by the facilities, are all equal to or less than 10 parts per quadrillion (ppq).[6] This effluent data has important implications for projecting costs and impacts. Today's rule will result in water quality standards that contain EPA's human health criteria of 0.013 ppq for dioxin at a 10^{-6} incremental risk level (or 0.13 ppq for States that have expressed a preference for a 10^{-5} incremental risk level). This value would then be reflected in the permits for the facilities that discharge dioxin, after conducting a wasteload allocation and accounting for stream dilution. If the resulting permit limitation is less than 10 ppq, compliance with the permit is likely to be determined at 10 ppq, because that is level of detection for dioxin for the EPA analytical method.

The practical interpretation of the effluent data for these nine facilities is that promulgation of this rule is unlikely to affect the need for treatment and thus, the costs of compliance for water quality-based permits.

These conclusions are very much a function of the laboratory analytical methods and their levels of detection for dioxin. If more precise and reliable measurement becomes available and is incorporated into the monitoring requirements in the permits for these facilities, the small differences between their effluent levels and the more stringent water quality-based limitations could present the need for additional treatment or revised production processes.

The Agency has collected extensive information about the pulp industry's efforts to reduce dioxin discharges from chlorine-bleaching facilities. The industry has responded to the need to reduce dioxin (and related chemicals) discharges with a variety of technological advancements. These include process refinements, such as changing input chemicals or altering the bleaching process. These types of changes are not necessarily prohibitive in terms of investment cost or operating costs. Substantial dioxin reductions have been achieved at little or no incremental compliance costs by changing certain process chemicals. For example, a change to dioxin precursor-free brownstock defoamers has been successful in reducing dioxin discharges at virtually no change in chemical cost and with no additional equipment. Other process chemical changes, however, can result in increased costs. For example, increased chlorine dioxide substitution, which is often accompanied by increased chlorine dioxide generation on-site, has been adopted by various facilities at on investment cost of approximately $20 million each. At the costly extreme, dioxin discharge reductions at other facilities reflect major renovations, not only to reduce dioxin discharges, but to modernize or otherwise restructure the facility. For example, a facility might choose to rebuild its bleach plant and adopt an entirely new bleaching process. Costs for this type of rebuilding may reach $100 million.

In summary, the costs associated with meeting an EPA-imposed dioxin limit can be estimated only with information on the bleaching process currently used at each facility, its wastewater characteristics, the characteristics of the receiving stream, and the level of control mandated by a new water quality-based permit. Based on reported effluent levels, however, this rule is unlikely to be the basis for any incremental compliance costs for Pulp and Paper mills to reduce dioxin discharges.

6. Example: Regulating Copper in the Metal Finishing Industry

As a second example of the range of costs that might be incurred as a result of complying with water quality-based permits issued in response to the imposition of EPA's criteria for toxic pollutants, we considered the metal finishing category for the control of the pollutant copper.

Effluent guidelines limitations and standards, which are technology-based regulations developed by the Agency pursuant to section 304 of the Clean Water Act, were promulgated for this industry in July 1983. Briefly, the effluent guidelines for the metal finishing industry set national standards for all dischargers to surface waters and to wastewater treatment plants (sometimes called publicly-owned treatment works, or POTW). The effluent guidelines for the metal finishing industry include numeric limitations for copper, based on the Best Available Technology Economically Achievable (BAT), for direct dischargers. The limitations for copper, as promulgated, are a daily maximum of 3.38 mg/l and a monthly average of 2.07 mg/l. The technology basis for these limitations is generally lime precipitation and clarification.

When the Agency promulgated effluent guidelines for this industry, the estimated number of direct dischargers subject to the regulation was approximately 2,900. In the Agency's permit compliance database, which reflects a more recent assessment, there are approximately 4,000 metal finishing direct dischargers. The higher, and more conservative number (in terms of projecting the number of affected facilities) is used in this assessment.

Of the 18 States included in this assessment, only six will receive EPA's aquatic criteria for copper; the remainder have already adopted aquatic criteria for copper in their standards.[7] (See Footnote 5.) Approximately 530 of the direct dischargers are located in these six States (where two States account for 93 percent of the facilities).

The number of potentially affected facilities is further reduced for several reasons. First, the number of facilities that would actually be considered for water quality-based permits could be lower, after subtracting any facilities that have individual control strategies (ICSs) to control the discharge of copper. In addition, the Agency has provided a formula in today's rule to allow the permitting authority to determine a water-effect ratio to account for metals speciation. The practical result is that, where determined, the water quality criteria for copper in certain waterbodies is likely to increase. This adjustment will have the effect of bringing the water quality-based limitation closer to the BAT limitation; for some facilities, this water-effect adjustment could eliminate the need for incremental treatment.

Finally, depending on site-specific conditions at each facility, such as the actual discharge concentration of copper, treatment-in-place, and the dilution provided by the receiving stream, complying with the in-stream concentration specified in the rule could be achieved by merely complying with BAT limitations. Alternatively,

[6] U.S. Environmental Protection Agency, Engineering and Analysis Division, "1990 National Census of Pulp, Paper, and Paperboard Manufacturing Facilities—Preliminary Summary Report of Questionnaire Responses for Mills Which Bleach Chemical Pulps," October 31, 1991.

[7] For metal pollutants, such as copper, the aquatic criteria tend to be more stringent than the criteria based on protecting human health. For purposes of this assessment, EPA is estimating impacts related to the aquatic life protection criteria because those criteria are more relevant for establishing water quality standards.

since the in-stream water quality criteria is more stringent than the discharge limitation established by BAT, it is possible that a facility complying with BAT would need additional treatment to comply with a water quality-based limitation.

For purposes of this assessment, EPA investigated whether BAT would be sufficient to meet water quality criteria. Many simplifying assumptions are incorporated into the following discussion. The investigation focused on metal finishing facilities with water releases of the metal pollutants (including, but not limited to copper) as reported in the Toxic Release Inventory.[8] The facilities included in this assessment were limited to those for which plant and stream flow data were readily accessible. While the number of facilities meeting all of these criteria was small, the results were indicative of both scenarios described above. In Connecticut (which is used for illustrative purposes only because it is not included in the final rule), EPA has identified a facility for which BAT will be sufficient for controlling discharges of copper to the level needed to comply with a water quality-based limitation for copper, assuming EPA's criteria level. At that site, the stream dilution is such that meeting the BAT limitation at the discharge point will also likely meet the water quality criteria within the stream. We have also identified another facility in Connecticut for which BAT will not be sufficient—that is, the effluent levels needed to comply with the water quality criteria in the stream are lower than the level that BAT will provide. Thus, additional treatment controls, and incremental compliance costs, are potentially needed for the second facility.

Without a detailed water quality and stream dilution analysis for all dischargers, the number of facilities where BAT will be sufficient to also meet water quality criteria is unknown. For purposes of this assessment, the distribution of facilities where additional treatment may be necessary is assumed to be between 25 and 75 percent. Additionally, the distribution of facility and stream characteristics for metal finishers in Connecticut is assumed to be representative of the distribution of characteristics in the other States. Using these simplifying assumptions, EPA estimates that 130 to 400 facilities are potentially subject to additional treatment requirements.

During the development of the effluent guidelines for this industry, EPA considered several treatment technologies that control pollutant discharges. In addition to the precipitation and clarification technology that was used as the basis for effluent limitations, EPA investigated and published information about effluent filtration, which provides more stringent control of copper discharges.[9] Filtration was not selected as the basis for BAT because of its high cost when considered on a nationwide basis.[10] The removal efficiency for filtration is substantially higher than that for precipitation and clarification. Based on engineering judgment, if filtration were installed at a facility in addition to the technology used as the basis for BAT, meeting the in-stream water quality criteria for copper would be technologically feasible. Hence, the incremental costs for filtration are used here to estimate the range of costs that might be attributable to this rule.

During development of BAT, the Agency estimated total annual costs to add filtration to precipitation and clarification for various sizes of facilities. The incremental cost estimates used here reflect one of several combinations of manufacturing processes and conditions. The costs are likely to be an overestimate because they reflect the upper bound of each flow size range. The potential incremental total annual costs used to estimate the compliance burden for meeting a water quality-based permit are approximately $20,000 for small plants, $43,000 for medium plants, and $146,000 for large plants. To estimate the costs that might be incurred by the dischargers potentially affected by the rule, we assume that the distribution of facility sizes for those dischargers is the same as the distribution used for BAT development. While specific cost estimates depend on many site-specific factors, the range of costs that could be expected for 130 to 400 facilities are approximately $7 million to $20 million.

It is likely that the assessment presented here for copper will include meeting aquatic criteria for other metals due to the similarity in treatment technology. Thus, the cost impacts estimated here will likely provide sufficient treatment to comply with the aquatic criteria for most of the metals.

Another means of considering the potential costs is to evaluate the cost-effectiveness of the additional treatment, where cost-effectiveness is defined by the ratio of incremental cost to incremental pollutant removal. The cost-effectiveness of filtration for those facilities projected to need additional treatment is based on the cost estimates shown above and the pollutant removals for not only copper, but five additional metals that will be removed by filtration. Cost-effectiveness ratios are expressed as "dollars per pound-equivalent removed," where a pound-equivalent is a pound of pollutant weighted by the relative toxicity of that pollutant. The cost-effectiveness of filtration for these facilities is $22 per pound-equivalent removed. This result suggests that filtration is a cost-effective technology.

In summary, the actual burden to dischargers in the metal finishing industry ranges from no impact, where BAT is sufficient to protect the receiving stream, to an incremental cost impact of 5 to 13 percent above the cost of BAT, where filtration is needed. In addition, treatment to comply with more stringent standards appears to be cost-effective.

7. Example: Regulating Priority Pollutants in the Organic Chemicals, Synthetic Fibers, and Plastics Industry

A third example of the range of costs that might be incurred as a result of complying with EPA's criteria for toxic pollutants is based on several segments of the organic chemicals manufacturing industry, where EPA considered the control of all priority pollutant discharges.

Technology-base effluent limitations guidelines and standards were promulgated for this industry in November 1987. The Agency is still engaged in rulemaking activities for this industry in response to litigation and court remands. The following discussion is based on the regulation and supporting documentation from the 1987 final rulemaking.[11]

[8] U.S. Environmental Protection Agency, Toxic Release Inventory, 1989. A search of the inventory for direct dischargers in the metal finishing industry in the six States yielded 41 facilities. Two of the six States have zero facilities matching that description. The comparisons of BAT and water quality criteria are drawn from that subset of the inventory.

[9] U.S. Environmental Protection Agency, Effluent Guidelines Division, Development Document for Effluent Limitations Guidelines and Standards for the Metal Finishing Point Source Category, June 1983.

[10] When establishing BAT, the Clean Water Act requires specific consideration of cost and economic achievability; such consideration is not required when establishing water quality standards. This is not to say that economic considerations are completely outside of the water quality standards process, but that such factors are considered at other points in the process, such as establishing waterbody use classifications. Here, the focus is adopting water quality criteria that are protective of human health and the environment.

[11] U.S. Environmental Protection Agency, Industrial Technology Division, Development Document for Effluent Guidelines and Standards for the Organic Chemicals, Plastics and Synthetic Fibers Point Source Category, Volume I, EPA 440/1-87-009, October 1987.

During development of the effluent guidelines for the organic chemicals industry, the Agency considered the potential for pollutant discharges from all of the priority pollutants. Approximately half of the priority pollutants were detected in effluents from chemical manufacturing facilities, and the effluent guidelines for this industry include limitations for most of these pollutants. The technology basis for establishing BAT varies by pollutant and by industry subcategory, but for many subcategory/pollutant combinations is steam stripping and/or biological treatment.

The promulgated effluent guidelines for the organic chemicals industry were expected to control discharges from more than 700 facilities. Of these, 275 are located in the 18 States used in this assessment to analyze the economic impacts of EPA's human health criteria. (See Footnote 5.) The human health criteria are likely to be the more significant values (compared to aquatic life criteria) for purposes of controlling organic pollutant discharges. The number of direct dischargers in the 18 States is estimated to be 90, based on the total industry proportion of direct dischargers. These dischargers are potentially subject to incremental requirements as a result of today's rule.

The key question for estimating the effect of the rule is whether BAT is sufficient to protect water quality to the levels that would be mandated by imposition of the criteria promulgated today. Water quality modelling results suggest very few exceedances of the water quality criteria, after the imposition of BAT requirements.

The level of control provided by the effluent guideline reflects the analytical laboratory level of detection for nearly half of the regulated pollutants. While the maximum monthly average expressed in the effluent guidelines may be higher than the detection limit (to account for variability), the level of detection corresponds to the long-term average of the treatment's removal efficiency. No water quality exceedances were projected among the pollutants that are regulated at levels higher than the detection limit.

The practical effect of the BAT limitations, combined with levels of detection and water quality assessments, is that this rule is unlikely to affect the behavior of chemical manufacturers in terms of pollution control investments. By complying with BAT limitations, the facilities are likely to also comply with more stringent, water quality-based limitations. Even though EPA's human health criteria suggest that permit requirements for some dischargers will be lower than the level of detection, a facility that cannot demonstrate compliance with the lower permit value is unlikely to add treatment or change processes in response to the revised permit.

In summary, BAT requirements for this industry control nearly half of the regulated pollutants to the level of detection for each pollutant. It is unlikely that the rule will result in incremental economic impacts for direct dischargers in the organic chemicals, plastics, and synthetic fibers industry.

8. Example: Regulating Priority Pollutant for POTWs

The final example of the range of costs that might be incurred as a result of EPA-imposed numeric criteria is for POTWs. An important aspect of regulatory impact for sewage treatment plants is that increases in investment and operating costs are often passed on to consumers in the form of user fees or taxes. For purposes of this assessment, however, we have not extended the cost impacts to household burden.

For POTWs, the choice of treatment technology is dependent on many factors; one of the most important is the pollutant (or group of pollutants) of concern and the source of that pollutant. For example, different technologies are recommended if the pollutants of concern are dissolved organic compounds as opposed to suspended solids. For this assessment, we relied on summary cost information presented in comments the Agency received during development of the Great Lakes Water Quality Initiative and on summary information from a rulemaking that focused on the incremental cost for POTWs to upgrade wastewater treatment.[12] The pollutants of concern and levels of control in those sources are similar to the additional controls that might be imposed by compliance with water quality standards following adoption of EPA's numeric criteria for priority toxic pollutants.

Several comments to the proposed rule contended that reverse osmosis is needed to comply with EPA's criteria for metals. According to commenters, this technology is likely to be very expensive when applied to the high flows found at many POTWs. EPA believes that POTWs often have alternatives to installing this type of treatment technology. These alternatives may be attractive from an overall water quality perspective because they prevent pollution at the source. For example, it may be less expensive for a small number of indirect dischargers to reduce their metals contribution to the POTW's wastestream than for the POTW to treat all of its effluent.

Copper discharges are another potential source of difficulty for POTWs in meeting water quality criteria. Many drinking water systems use copper to control algae growth. The copper is then discharged to the POTW and then to the receiving stream. Other algae controls, such as potassium permanganate, may be effective for some drinking water systems. This example of an alternative would reduce the copper loading to the POTW's receiving stream without requiring expensive treatment such as reverse osmosis at the POTW. Reverse osmosis was not used in either of the cost sources noted above; nor is it used here. The pollution control technology selected for a POTW depends on various engineering judgments and site-specific conditions. The incremental costs used in this assessment are based on activated carbon for some POTWs and on polymer addition for others. Engineering judgment suggests that many of the organic and metal compounds of concern will be removed in the final effluent with these types of treatment technologies.

The following cost assessment is likely to be an overestimate due to the simplifying assumptions used in this procedure. The number of POTWs that possibly could be subject to incremental costs that are attributable to this rule is first limited to POTWs in those States that had not adopted their own numeric criteria by the time of the proposed rulemaking. A total of 18 States was used to project the number of POTWs (See Footnote 5.) Of the approximately 15,000 POTWs in the U.S., 3,942 are identified as "majors" in the Permit Compliance System. Of these, 952 are located in the 18 States. Even as of the proposed rule, however, this number of POTWs is an overestimate of the number that might incur increased costs because it includes *all* States projected to receive *any* pollutant criteria. In fact, many of the 18 states need only a limited number of pollutant criteria (for some States, as few as one).

The number of POTWs that might be subject to new or more stringent permit requirements is further reduced because some portion of those permits already include limitations for some of the pollutants of concern. Such permit limitations and the ICSs were established in response to section 304(l) of the Clean Water Act. Another factor that may eliminate the need for additional treatment by the POTW is the use of whole effluent toxicity limits.

[12] Best Conventional Pollutant Control Technology; Effluent Limitations Guidelines; Final Rule, 51 FR 24974, July 9, 1986.

which are possibly already controlling toxic discharges. In addition, existing treatment and pretreatment may obviate the need for more stringent permit requirements. Other site-specific analyses, such as wasteload allocations and dilution studies are likely to affect the reasonable expectation that a pollutant is discharged. Also, as mentioned earlier, the water-effect ratio calculation is likely to eliminate the need for incremental treatment in certain waterbodies.

For purposes of this assessment, the number of POTWs that will need additional treatment has been estimated by focusing on the results of section 304(l) reviews. During each State's review of dischargers to identify sources that were discharging toxic pollutants at a level that could potentially cause water quality impairments, less than 5 percent of the major municipal dischargers were listed. Applying this proportion to the number of municipal dischargers covered by today's rule yields an estimated 46 POTWs that could potentially cause water quality criteria violations. The provisions of section 304(l) required States to respond to these projected violations by developing Individual Compliance Strategies and permit limitations for toxic pollutants.

The Agency acknowledges that the discharger reviews conducted in response to section 304(l) were not comprehensive and probably undercounted the number of dischargers, including POTWs, that were discharging toxic pollutants. Some of the reasons for undercounting include the lack of monitoring information, quickly-conducted reviews, varying methodologies among States, and out-of-date discharge information. For purposes of this assessment, the number of sources that potentially cause water quality criteria problems is assumed to be three times the number actually listed; in other words, the number of POTWs subject to additional controls is conservatively estimated to be triple the 46 actually identified, or 138 POTWs.

As mentioned, there are various alternatives that an individual POTW might undertake to comply with more stringent permit requirements. While the most costly alternatives involve additional pollution control equipment to the POTW, there are other mechanisms to improve the quality of the POTW's effluent. For example, a pretreatment program could require an industrial discharger to reduce or eliminate its contribution of toxic pollutants to the POTW's wastestream. Alternatively, nonpoint sources could undertake better management practices to reduce runoff. Many of these alternatives have little or no incremental cost impact to the POTW. While some of the alternatives involve a shift in costs, the overall effect is likely to be a lower cost than if incurred solely by the POTW. Even with the availability of alternatives for compliance, this assessment assumes that half of the POTWs will install additional treatment. Hence, 50 percent, or 69, of the potentially affected POTWs are assumed to incur additional compliance costs.

The costs of additional pollution controls are derived from the two sources mentioned above. The cost calculations for activated carbon include capital costs, O&M costs, source controls, and studies (such as mixing zone demonstrations, toxicity testing, monitoring, and fish bio-uptake tests). For purposes of this assessment, simplifying assumptions were then applied to those cost calculations to estimate total annual costs for various sizes of POTWs. The incremental total annual costs for activated carbon are estimated to be $0.4 million for a small POTW, $1.4 million for a medium POTW, and $12.8 million for a large POTW. The cost estimates for improved secondary treatment by polymer addition include annualized capital costs and O&M expenses. The incremental total annual costs for this technology are estimated to be less than $0.1 million for a small POTW, $0.4 million for a medium POTW, and $1.5 million for a large POTW.

Based on engineering judgment, 75 percent of the POTWs are assumed to rely on chemical addition to meet permit limits. The remaining 25 percent are assumed to rely on activated carbon adsorption. To estimate costs for each group of POTWs, the facilities are categorized according to flow groups, assuming that the size distribution of the POTWs in the affected States is the same as those used in each cost source. Then, the incremental costs for each type of treatment are applied to the number of POTWs in each size category. This procedure results in an incremental cost estimate of approximately $30 million.

To summarize, some POTWs may be subject to additional treatment requirements as a result of this rule. The number of POTWs and the types of treatment are dependent on many site-specific conditions and on the pollutants included in today's rule. For many of the POTWs that are major discharges in the States that will need to adopt new water quality standards, there is likely to be no incremental cost. Using a conservative estimate of the remaining POTWs, the upper bound of an incremental cost estimate is approximately $30 million for POTWs to comply with new discharge permit requirements.

9. Conclusions of EPA's Cost Assessment

Today's rule establishes a legal minimum standard where States have failed to comply with the statutory mandate to adopt numeric criteria for toxic pollutants. The impacts to dischargers are difficult to estimate because of the numerous assumptions and unknowns. While the Agency acknowledges that some dischargers may incur compliance costs due to new water quality standards, a meaningful cost estimate that covers the entire rule is not feasible.

In the absence of a cost estimate, per se, the Agency has described the types of costs that may be incurred by various types of dischargers. In addition, this cost assessment includes four examples of potential compliance cost scenarios: reducing dioxin discharges from pulp mills, reducing copper discharges for metal finishing, controlling priority pollutant discharges for organic chemical manufacturing, and reducing discharges from POTWs.

EPA finds that the costs to comply with toxic pollutant criteria may be less than anticipated at the time the rule was proposed. Many States have adopted their own numeric criteria and are therefore excluded from today's rulemaking. In addition, for some point source categories, where technology-based controls have been established, more stringent water quality-based controls will result in no incremental compliance costs. Further, EPA concludes that additional analysis is not warranted because the uncertainty of such an analyses would not provide enough reliable information to assist decision-makers in evaluating the regulatory strategy for this statutorily-mandated rule.

10. Introduction to Benefits Assessment

The numeric criteria for toxic pollutants promulgated in today's rule are essential in implementing toxics controls and protecting human health and aquatic ecosystems. Under this Rule, a total of 15 States and Territories will receive criteria for human health and aquatic life (14 for human health and 13 for aquatic life). The adopted standards will result in decreased toxic pollutant loading discharges which will result in improved protection of human health and aquatic life.

The Agency did not include a quantitative estimate of the benefits in the proposed rule for reasons similar to those cited above for not including a detailed cost estimate. The environmental benefits associated with this promulgation are difficult to assess and quantify. A comprehensive analysis of human health and ecological benefits is not practical given the available resources and inherent limitations such as (1) assuming a linear relationship between pollutant loading reductions and benefits attributed to the clean-up of surface waters; (2) underestimating the benefits or reducing toxics due to the complexity of assessing impacts on aquatic ecosystems; and (3) the uncertainty in estimating the magnitude of intermedia transfers of pollutants. Such uncertainties limit the value of using such estimates to evaluate the net benefits of this rule. However, the Agency has undertaken a preliminary assessment of potential human health and ecological benefits that might be accrued through promulgation of the rule.

11. Human Health Assessment Scope

The potential benefits to human health of establishing toxic criteria include: (1) Reducing the potential health risks to persons eating fish contaminated with toxic pollutants, (2) reducing the potential health risks to persons drinking contaminated drinking water, and (3) reducing the potential health risks to swimmers from dermal exposure to contaminated surface waters. EPA's qualitative assessment is limited to assessing (1) potential benefits from reducing pollutant levels in fish that may be caught by sport and subsistence fishermen and subsequently consumed by them and their families; and (2) potential benefits that may also result from lowering pollutant levels in commercially caught fish consumed by the general population. This assessment is limited to assessing only the potential reduction in cancer risk; no attempt has been made to assess potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects.

12. Ecological Assessment Scope

Some of the ecological benefits are difficult to assess due to the complexity of ecological interactions, the limited amount of ecological risk information available, and the lack of an established methodology for evaluating ecological benefits. In addition, difficulties arise in estimating the exposure of aquatic ecosystems due to the large size of ecosystems, wide geographical distribution, heterogeneous characteristics and the wide range of populations with differing sensitivities to impacts. While the benefits of promulgating this rule were not quantified due to such uncertainties and limitations, the potential benefits of establishing toxic criteria for the protection of aquatic life can be described qualitatively.

The most recent National Water Quality Inventory indicates that one-third of monitored river miles, lake acres, and coastal waters have elevated levels of toxic pollutants. After evaluating these data, the Agency concluded that the data most likely understate the presence or discharge of toxic pollutants because of the limited amount of monitoring data for some States and inconsistencies among the States in how the data were generated. Thus, it is likely that significant portions of water bodies in some States exceed water quality criteria for the protection of aquatic life. These criteria were developed to protect most aquatic organisms, as well as wildlife that consume aquatic organisms, from acute and chronic toxic effects that adversely affect survival, growth or reproduction. These effects will vary due to the diversity of species with differing sensitivities to impacts. For example, lead exposure can cause spinal deformities in rainbow trout. Nickel exposure can affect spawning behavior of shrimp. Nickel, mercury, and copper exposure can affect the growth activity of algae. In addition, copper, mercury, and cadmium can be acutely toxic to aquatic life including finfish. These types of ecological effects are expected to be reduced because this rule should reduce ambient pollutant levels. In addition, this rule will reduce continuous discharges of toxics which will allow for a natural recovery of the ecosystems.

13. Qualitative Benefits Assessment

Human health benefits that can be attributed to this rule are expressed in terms of the reduction in cancer risk. The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxicity.

The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms. Today's rule will result in a reduction in the presence and discharge of toxic pollutants in the water bodies of these States thereby protecting those aquatic ecosystems currently under stress, providing the opportunity for the reestablishment of productive ecosystems in damaged water bodies, and protection of resident endangered species.

In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with the maintenance of an aesthetically pleasing environment. Both recreational and commercial activities contribute, in turn, to the support of local and State economies.

K. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq., Pub. L. 96-354) requires EPA to assess whether its regulations create a disproportionate effect on small entities. Among its provisions, the Act directs EPA to prepare and publish an initial regulatory flexibility analysis at the time a rule is proposed if the rule will have a significant impact on a substantial number of small entities. In the preamble to the proposed rule, EPA discussed the possibility that the rule could result in treatment costs to some dischargers to comply with water quality standards that incorporate new criteria for toxic pollutants. The Agency did not conclude, however, that the rule would have a significant impact on a substantial number of small entities due to the uncertainties associated with estimating total costs and impacts. The difficulties of cost estimation for specific groups of dischargers (such as small businesses or governments) were described in the preamble section that outlined EPA's response to Executive Order 12291. Similarly, in today's final rulemaking, the details of EPA's findings concerning the costs and impacts of this rule are presented in section J, above.

Briefly, the complexities and difficulties associated with estimating costs for purposes of economic or regulatory analysis similarly apply to estimating impacts to small entities. For purposes of this rulemaking, small entities are small dischargers, whether industrial or municipal. Regardless of

the parameters used to define small dischargers (for example, discharge flow, number of employees, population served), EPA's expression of costs and impacts for this rulemaking is limited to the descriptions in section J. EPA does not find that there will be a significant impact on a substantial number of small entities because impacts on specific dischargers cannot be predicted with certainty, and based on several examples in the cost assessment, it appears that potential impacts will not be concentrated among small dischargers.

In addition, EPA again finds that the impacts on small entities are best considered during standards development and implementation when site-specific costs can be estimated, and any resulting impacts can be minimized or alleviated as part of writing the discharge permit. It is not the Agency's intent to ignore the consequences of incorporating toxic pollutant criteria, but instead, that these consequences are more appropriately defined and accounted for in the permit-writing context. The water quality standards regulation provides several means (such as adjusting designated uses, setting site-specific criteria, or granting variances) to consider costs and adjust standards to account for the impacts on small dischargers.

While the imposition of EPA's numeric criteria for toxic pollutants may limit the flexibility that States will have to use these procedures to modify standards, EPA's expectation is that impacts will not be concentrated on small dischargers. Although there can be site-specific cases of water quality violations due to toxic discharges from low-flow point sources, EPA generally finds that priorities for NPDES permits focus on major dischargers. Small entities are less likely to be included in this group.

Other requirements of the Regulatory Flexibility Act are fulfilled in other sections of this preamble. Specifically, the Agency's explanation for taking this action and the legal basis for the rule are found in section E. The number of small entities that will be affected by the rule is not estimated for the reasons expressed above. The projected reporting and recordkeeping requirements are discussed in Section L. There is no anticipated duplication, overlap, or conflict with other Federal rules, except to the extent that technology-based standards (such as BAT) are sufficient to also meet water quality standards. Alternatives to the final rule include any of the opportunities that States had to adopt their own standards, incorporating any of the procedures to limit the compliance burden; these alternatives are discussed in Sections B and C.

The Agency concludes that this rulemaking, *per se*, will not result in a significant impact on a substantial number of small entities, and a final regulatory flexibility analysis is not required.

L. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. These requirements will not be effective until OMB approves them and a technical amendment to that effect is published in the Federal Register. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0988.04) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 or by calling (202) 260–2740.

Public reporting burden for this collection of information is estimated to average 725 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223Y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs; Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." Comments must be submitted by January 21, 1993.

List of Subjects in 40 CFR Part 131

Water pollution control, Water quality standards, Toxic pollutants.

Dated: December 1, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble title 40, chapter I, part 131 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 is revised to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart D—[Amended]

2. Section 131.36 is added to subpart D to read as follows:

§ 131.36 Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B).

(a) *Scope.* This section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

(b)(1) *EPA's Section 304(a) Criteria for Priority Toxic Pollutants.*

BILLING CODE 6560-50-M

(#) COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
1 Antimony	7440360					14 a	4300 a
2 Arsenic	7440382	360 m	190 m	69 m	36 m	0.018 a,b,c	0.14 a,b,c
3 Beryllium	7440417					n	n
4 Cadmium	7440439	3.9 e,m	1.1 e,m	43 m	9.3 m	n	n
5a Chromium (III)	16065831	1700 e,m	210 e,m			n	n
b Chromium (VI)	18540299	16 m	11 m	1100 m	50 m	n	n
6 Copper	7440508	18 e,m	12 e,m	2.9 m	2.9 m		
7 Lead	7439921	82 e,m	3.2 e,m	220 m	8.5 m	n	n
8 Mercury	7439976	2.4 m	0.012 i	2.1 m	0.025 i	0.14	0.15
9 Nickel	7440020	1400 e,m	160 e,m	75 m	8.3 m	610 a	4600 a
10 Selenium	7782492	20	5	300 m	71 m	n	n
11 Silver	7440224	4.1 e,m		2.3 m			
12 Thallium	7440280					1.7 a	6.3 a
13 Zinc	7440666	120 e,m	110 e,m	95 m	86 m		
14 Cyanide	57125	22	5.2	1	1	700 a	220000 a,j
15 Asbestos	1332214					7,000,000 fibers/L k	
16 2,3,7,8-TCDD (Dioxin)	1746016					0.000000013 c	0.000000014 c
17 Acrolein	107028					320	780
18 Acrylonitrile	107131					0.059 a,c	0.66 a,c
19 Benzene	71432					1.2 a,c	71 a,c
20 Bromoform	75252					4.3 a,c	360 a,c
21 Carbon Tetrachloride	56235					0.25 a,c	4.4 a,c
22 Chlorobenzene	108907					680 a	21000 a,j
23 Chlorodibromomethane	124481					0.41 a,c	34 a,c
24 Chloroethane	75003						
25 2-Chloroethylvinyl Ether	110758						
26 Chloroform	67663					5.7 a,c	470 a,c
27 Dichlorobromomethane	75274					0.27 a,c	22 a,c

(#) COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
28 1,1-Dichloroethane	75343						
29 1,2-Dichloroethane	107062					0.38 a,c	99 a,c
30 1,1-Dichloroethylene	75354					0.057 a,c	3.2 a,c
31 1,2-Dichloropropane	78875						
32 1,3-Dichloropropylene	542756					10 a	1700 a
33 Ethylbenzene	100414					3100 a	29000 a
34 Methyl Bromide	74839					48 a	4000 a
35 Methyl Chloride	74873					n	n
36 Methylene Chloride	75092					4.7 a,c	1600 a,c
37 1,1,2,2-Tetrachloroethane	79345					0.17 a,c	11 a,c
38 Tetrachloroethylene	127184					0.8 c	8.85 c
39 Toluene	108883					6800 a	200000 a
40 1,2-Trans-Dichloroethylene	156605						
41 1,1,1-Trichloroethane	71556					n	n
42 1,1,2-Trichloroethane	79005					0.60 a,c	42 a,c
43 Trichloroethylene	79016					2.7 c	81 c
44 Vinyl Chloride	75014					2 c	525 c
45 2-Chlorophenol	95578						
46 2,4-Dichlorophenol	120832					93 a	790 a,j
47 2,4-Dimethylphenol	105679						
48 2-Methyl-4,6-Dinitrophenol	534521					13.4	765
49 2,4-Dinitrophenol	51285					70 a	14000 a
50 2-Nitrophenol	88755						
51 4-Nitrophenol	100027						
52 3-Methyl-4-Chlorophenol	59507						
53 Pentachlorophenol	87865	20 f	13 f	13	7.9	0.28 a,c	8.2 a,c,j
54 Phenol	108952					21000 a	4600000 a,j
55 2,4,6-Trichlorophenol	88062					2.1 a,c	6.5 a,c
56 Acenaphthene	83329						

#)	A COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
57	Acenaphthylene	208968						
58	Anthracene	120127					9600 a	110000 a
59	Benzidine	92875					0.00012 a,c	0.00054 a,c
60	Benzo(a)Anthracene	56553					0.0028 c	0.031 c
61	Benzo(a)Pyrene	50328					0.0028 c	0.031 c
62	Benzo(b)Fluoranthene	205992					0.0028 c	0.031 c
63	Benzo(ghi)Perylene	191242						
64	Benzo(k)Fluoranthene	207089					0.0028 c	0.031 c
65	Bis(2-Chloroethoxy)Methane	111911						
66	Bis(2-Chloroethyl)Ether	111444					0.031 a,c	1.4 a,c
67	Bis(2-Chloroisopropyl)Ether	108601					1400 a	170000 a
68	Bis(2-Ethylhexyl)Phthalate	117817					1.8 a,c	5.9 a,c
69	4-Bromophenyl Phenyl Ether	101553						
70	Butylbenzyl Phthalate	85687						
71	2-Chloronaphthalene	91587						
72	4-Chlorophenyl Phenyl Ether	7005723						
73	Chrysene	218019					0.0028 c	0.031 c
74	Dibenzo(a,h)Anthracene	53703					0.0028 c	0.031 c
75	1,2-Dichlorobenzene	95501					2700 a	17000 a
76	1,3-Dichlorobenzene	541731					400	2600
77	1,4-Dichlorobenzene	106467					400	2600
78	3,3'-Dichlorobenzidine	91941					0.04 a,c	0.077 a,c
79	Diethyl Phthalate	84662					23000 a	120000 a
80	Dimethyl Phthalate	131113					313000	2900000
81	Di-n-Butyl Phthalate	84742					2700 a	12000 a
82	2,4-Dinitrotoluene	121142					0.11 c	9.1 c
83	2,6-Dinitrotoluene	606202						
84	Di-n-Octyl Phthalate	117840						
85	1,2-Diphenylhydrazine	122667					0.040 a,c	0.54 a,c

(#)	A COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
86	Fluoranthene	206440					300 a	370 a
87	Fluorene	86737					1300 a	14000 a
88	Hexachlorobenzene	118741					0.00075 a,c	0.00077 a,c
89	Hexachlorobutadiene	87683					0.44 a,c	50 a,c
90	Hexachlorocyclopentadiene	77474					240 a	17000 a,j
91	Hexachloroethane	67721					1.9 a,c	8.9 a,c
92	Indeno(1,2,3-cd)Pyrene	193395					0.0028 c	0.031 c
93	Isophorone	78591					8.4 a,c	600 a,c
94	Naphthalene	91203						
95	Nitrobenzene	98953					17 a	1900 a,j
96	N-Nitrosodimethylamine	62759					0.00069 a,c	8.1 a,c
97	N-Nitrosodi-n-Propylamine	621647						
98	N-Nitrosodiphenylamine	86306					5.0 a,c	16 a,c
99	Phenanthrene	85018						
100	Pyrene	129000					960 a	11000 a
101	1,2,4-Trichlorobenzene	120821						
102	Aldrin	309002	3 g		1.3 g		0.00013 a,c	0.00014 a,c
103	alpha-BHC	319846					0.0039 a,c	0.013 a,c
104	beta-BHC	319857					0.014 a,c	0.046 a,c
105	gamma-BHC	58899	2 g	0.08 g	0.16 g		0.019 c	0.063 c
106	delta-BHC	319868						
107	Chlordane	57749	2.4 g	0.0043 g	0.09 g	0.004 g	0.00057 a,c	0.00059 a,c
108	4-4'-DDT	50293	1.1 g	0.001 g	0.13 g	0.001 g	0.00059 a,c	0.00059 a,c
109	4,4'-DDE	72559					0.00059 a,c	0.00059 a,c
110	4,4'-DDD	72548					0.00083 a,c	0.00084 a,c
111	Dieldrin	60571	2.5 g	0.0019 g	0.71 g	0.0019 g	0.00014 a,c	0.00014 a,c
112	alpha-Endosulfan	959988	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
113	beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a

(#)	A COMPOUND	CAS Number	B FRESHWATER Criterion Maximum Conc. d (ug/L) B1	B FRESHWATER Criterion Continuous Conc. d (ug/L) B2	C SALTWATER Criterion Maximum Conc. d (ug/L) C1	C SALTWATER Criterion Continuous Conc. d (ug/L) C2	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organisms Only (ug/L) D2
114	Endosulfan Sulfate	1031078					0.93 a	2.0 a
115	Endrin	72208	0.18 g	0.0023 g	0.037 g	0.0023 g	0.76 a	0.81 a,i
116	Endrin Aldehyde	7421934					0.76 a	0.81 a,i
117	Heptachlor	76448	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00021 a,c	0.00021 a,c
118	Heptachlor Epoxide	1024573	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00010 a,c	0.00011 a,c
119	PCB-1242	53469219		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
120	PCB-1254	11097691		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
121	PCB-1221	11104282		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
122	PCB-1232	11141165		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
123	PCB-1248	12672296		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
124	PCB-1260	11096825		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
125	PCB-1016	12674112		0.014 g		0.03 g	0.000044 a,c	0.000045 a,c
126	Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 a,c	0.00075 a,c
Total No. of Criteria (h) =			24	29	23	27	91	98

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Footnotes:

a. Criteria revised to reflect current agency q_1^* or RfD, as contained in the Integrated Risk Information System (IRIS). The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained in all cases.

b. The criteria refers to the inorganic form only.

c. Criteria in the matrix based on carcinogenicity (10^{-6} risk). For a risk level of 10^{-5}, move the decimal point in the matrix value one place to the right.

d. Criteria Maximum Concentration (CMC) = the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time (1-hour average) without deleterious effects. Criteria Continuous Concentration (CCC) = the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. ug/L = micrograms per liter

e. Freshwater aquatic life criteria for these metals are expressed as a function of total hardness (mg/L), and as a function of the pollutant's water effect ratio, WER, as defined in § 131.36(c). The equations are provided in matrix at § 131.36(b)(2). Values displayed above in the matrix correspond to a total hardness of 100 mg/L and a water effect ratio of 1.0.

f. Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows. Values displayed above in the matrix correspond to a pH of 7.8.

$CMC = \exp\{1.005(pH) - 4.830\}$ $CCC = \exp\{1.005(pH) - 5.290\}$

g. Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (FAV) which by the 1980 Guidelines are instantaneous values as contrasted with a CMC which is a one-hour average.

h. These totals simply sum the criteria in each column. For aquatic life, there are 30 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 91 priority toxic pollutants with either "water + fish" or "fish only" criteria. Note that these totals count chromium as one pollutant even though EPA has developed criteria based on two valence states. In the matrix, EPA has assigned numbers 5a and 5b to the criteria for chromium to reflect the fact that the list of 126 priority toxic pollutants includes only a single listing for chromium.

i. If the CCC for total mercury exceeds 0.012 ug/L more than once in a 3-year period in the ambient water, the edible portion of aquatic species of concern must be analyzed to determine whether the concentration of methyl mercury exceeds the FDA action level (1.0 mg/kg). If the FDA action level is exceeded, the State must notify the appropriate EPA Regional Administrator, initiate a revision of its mercury criterion in its water quality standards so as to protect designated uses, and take other appropriate action such as issuance of a fish consumption advisory for the affected area.

j. No criteria for protection of human health from consumption of aquatic organisms (excluding water) was presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.

k. The criterion for asbestos is the MCL (56 FR 3526, January 30, 1991).

l. This letter not used as a footnote.

m. Criteria for these metals are expressed as a function of the water effect ratio, WER, as defined in 40 CFR 131.36(c).

CMC = column B1 or C1 value × WER
CCC = column B2 or C2 value × WER

n. EPA is not promulgating human health criteria for this contaminant. However, permit authorities should address this contaminant in NPDES permit actions using the State's existing narrative criteria for toxics.

General Notes:

1. This chart lists all of EPA's priority toxic pollutants whether or not criteria recommendations are available. Blank spaces indicate the absence of criteria recommendations. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A of 40 CFR Part 423. EPA has added the Chemical Abstracts Service (CAS) registry numbers, which provide a unique identification for each chemical.

2. The following chemicals have organoleptic based criteria recommendations that are not included on this chart (for reasons which are discussed in the preamble): copper, zinc, chlorobenzene, 2-chlorophenol, 2,4-dichlorophenol, acenaphthene, 2,4-dimethylphenol, 3-methyl-4-chlorophenol, hexachlorocyclopentadiene, pentachlorophenol, phenol

3. For purposes of this rulemaking, freshwater criteria and saltwater criteria apply as specified in 40 CFR 131.36(c).

(2) *Factors for Calculating Metals Criteria*

$CMC = WER \exp\{m_A[\ln(\text{hardness})] + b_A\}$ $CCC = WER \exp\{m_C[\ln(\text{hardness})] + b_C\}$

	m_A	b_A	m_C	b_C
Cadmium	1.128	-3.828	0.7852	-3.490
Copper	0.9422	-1.464	0.8545	-1.465
Chromium (III)	0.8190	3.688	0.8190	1.561
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	3.3612	0.8460	1.1645
Silver	1.72	-6.52	.....	.....
Zinc	0.8473	0.8604	0.8473	0.7614

Note: The term "exp" represents the base e exponential function.

(c) *Applicability.* (1) The criteria in paragraph (b) of this section apply to the States' designated uses cited in paragraph (d) of this section and supersede any criteria adopted by the State, except when State regulations contain criteria which are more stringent for a particular use in which case the State's criteria will continue to apply.

(2) The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are the other numeric toxics criteria when applied to the same use classifications including mixing zones, and low flow values below which numeric standards can be exceeded in flowing fresh waters.

(i) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones; otherwise the criteria apply throughout the waterbody including at the end of any discharge pipe, canal or other discharge point.

(ii) A State shall not use a low flow value below which numeric standards can be exceeded that is less stringent than the following for waters suitable for the establishment of low flow return frequencies (i.e., streams and rivers):

Aquatic Life	
Acute criteria (CMC)	1 Q 10 or 1 B 3
Chronic criteria (CCC)	7 Q 10 or 4 B 3

Human Health	
Non-carcinogens	30 Q 5
Carcinogens	Harmonic mean flow

Where:

CMC—criteria maximum concentration—the water quality criteria to protect against acute effects in aquatic life and is the highest instream concentration of a priority toxic pollutant consisting of a one-hour average

not to be exceeded more than once every three years on the average;

CCC—criteria continuous concentration—the water quality criteria to protect against chronic effects in aquatic life is the highest instream concentration of a priority toxic pollutant consisting of a 4-day average not to be exceeded more than once every three years on the average;

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and the harmonic mean flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

(iii) If a State does not have such a low flow value for numeric standards compliance, then none shall apply and the criteria included in paragraph (d) of this section herein apply at all flows.

(3) The aquatic life criteria in the matrix in paragraph (b) of this section apply as follows:

(i) For waters in which the salinity is equal to or less than 1 part per thousand 95% or more of the time, the applicable criteria are the freshwater criteria in Column B;

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in Column C; and

(iii) For waters in which the salinity is between 1 and 10 parts per thousand as defined in paragraphs (c)(3) (i) and (ii) of this section, the applicable criteria are the more stringent of the freshwater or saltwater criteria. However, the Regional Administrator may approve the use of the alternative freshwater or saltwater criteria if scientifically defensible information and data demonstrate that on a site-specific basis the biology of the waterbody is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the waterbody is dominated by saltwater aquatic life and that saltwater criteria are more appropriate.

(4) *Application of metals criteria.* (i) For purposes of calculating freshwater aquatic life criteria for metals from the equations in paragraph (b)(2) of this section, the minimum hardness allowed for use in those equations shall not be less than 25 mg/l, as calcium carbonate, even if the actual ambient hardness is less than 25 mg/l as calcium carbonate. The maximum hardness value for use in those equations shall not exceed 400 mg/l as calcium carbonate, even if the actual ambient hardness is greater than 400 mg/l as calcium carbonate. The same provisions apply for calculating the metals criteria for the comparisons provided for in paragraph (c)(3)(iii) of this section.

(ii) The hardness values used shall be consistent with the design discharge conditions established in paragraph (c)(2) of this section for flows and mixing zones.

(iii) The criteria for metals (compounds #1–#13 in paragraph (b) of this section) are expressed as total recoverable. For purposes of calculating aquatic life criteria for metals from the equations in footnote M. in the criteria matrix in paragraph (b)(1) of this section and the equations in paragraph (b)(2) of this section, the water-effect ratio is computed as a specific pollutant's acute or chronic toxicity values measured in water from the site covered by the standard, divided by the respective acute or chronic toxicity value in laboratory dilution water. The water-effect ratio shall be assigned a value of 1.0, except where the permitting authority assigns a different value that protects the designated uses of the water body from the toxic effects of the pollutant, and is derived from suitable tests on sampled water representative of conditions in the affected water body, consistent with the design discharge conditions established in paragraph (c)(2) of this section. For purposes of this paragraph, the term acute toxicity value is the toxicity test results, such as the lethal concentration of one-half of the test organisms (i.e., LC50) after 96 hours of exposure (e.g., fish toxicity tests) or the effect concentration to one-half of the test organisms, (i.e., EC50) after 48 hours of exposure (e.g., daphnia toxicity tests). For purposes of this paragraph, the term chronic value is the result from appropriate hypothesis testing or regression analysis of measurements of growth, reproduction, or survival from life cycle, partial life cycle, or early life stage tests. The determination of acute and chronic values shall be according to current standard protocols (e.g., those published by the American Society for Testing Materials (ASTM)) or other comparable methods. For calculation of criteria using site-specific values for both the hardness and the water effect ratio, the hardness used in the equations in paragraph (b)(2) of this section shall be as required in paragraph (c)(4)(ii) of this section. Water hardness shall be calculated from the measured calcium and magnesium ions present, and the ratio of calcium to magnesium shall be approximately the same in standard laboratory toxicity testing water as in the site water.

(d) *Criteria for Specific Jurisdictions*—(1) *Rhode Island, EPA Region 1.* (i) All waters assigned to the following use classifications in the Water Quality Regulations for Water Pollution Control adopted under Chapters 46–12, 42–17.1, and 42–35 of the General Laws of Rhode Island are subject to the criteria in paragraph (d)(1)(ii) of this section, without exception:

6.21 Freshwater	6.22 Saltwater:
Class A	Class SA
Class B	Class SB
Class C	Class SC

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(1)(i) of this section:

Use classification	Applicable criteria
Class A Class B waters where water supply use is designated	These classifications are assigned the criteria in: Column D1—all
Class B waters where water supply use is not designated; Class C; Class SA; Class SB; Class SC	Each of these classifications is assigned the criteria in: Column D2—all

(iii) The human health criteria shall be applied at the 10^{-5} risk level, consistent with the State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(2) *Vermont, EPA Region 1.* (i) All waters assigned to the following use classifications in the Vermont Water Quality Standards adopted under the authority of the Vermont Water Pollution Control Act (10 V.S.A., Chapter 47) are subject to the criteria in paragraph (d)(2)(ii) of this section, without exception:

Class A
Class B
Class C

(ii) The following criteria from the matrix in paragraph (b)(1) of this section

apply to the use classifications identified in paragraph (d)(2)(i) of this section:

Use classification	Applicable criteria
Class A	
Class B waters where water supply use is designated	This classification is assigned the criteria in: Column B1—all Column B2—all Column D1—all
Class B waters where water supply use is not designated	
Class C	These classifications are assigned the criteria in: Column B1—all Column B2—all Column D2—all

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level.

(3) *New Jersey, EPA Region 2.* (i) All waters assigned to the following use classifications in the New Jersey Administrative Code (N.J.A.C.) 7:9–4.1 et seq., Surface Water Quality Standards, are subject to the criteria in paragraph (d)(3)(ii) of this section, without exception.

N.J.A.C. 7:9–4.12(b): Class PL
N.J.A.C. 7:9–4.12(c): Class FW2
N.J.A.C. 7:9–4.12(d): Class SE1
N.J.A.C. 7:9–4.12(e): Class SE2
N.J.A.C. 7:9–4.12(f): Class SE3
N.J.A.C. 7:9–4.12(g): Class SC
N.J.A.C. 7:9–4.13(a): Delaware River Zones 1C, 1D, and 1E
N.J.A.C. 7:9–4.13(b): Delaware River Zone 2
N.J.A.C. 7:9–4.13(c): Delaware River Zone 3
N.J.A.C. 7:9–4.13(d): Delaware River Zone 4
N.J.A.C. 7:9–4.13(e): Delaware River Zone 5
N.J.A.C. 7:9–4.13(f): Delaware River Zone 6

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(3)(i) of this section:

Use classification	Applicable criteria
PL (Freshwater Pinelands), FW2	These classifications are assigned the criteria in: Column B1—all except #102, 105, 107, 108, 111, 112, 113, 115, 117, and 118. Column B2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125.
PL (Saline Water Pinelands), SE1, SE2, SE3, SC	These classifications are each assigned the criteria in: Column C1—all except #102, 105, 107, 108, 111, 112, 113, 115, 117, and 118. Column C2—all except #105, 107, 108, 111, 112, 113, 115, 117, 118, 119, 120, 121, 122, 123, 124, and 125. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.
Delaware River zones 1C, 1D, 1E, 2, 3, 4, 5 and Delaware Bay zone 6	These classifications are each assigned the criteria in: Column B1—all. Column B2—all. Column D1—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.
Delaware River zones 3, 4, and 5, and Delaware Bay zone 6	These classifications are each assigned the criteria in: Column C1—all. Column C2—all. Column D2—all at a 10^{-6} risk level except #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105; #23, 30, 37, 38, 42, 68, 89, 91, 93, 104, 105, at a 10^{-5} risk level.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level for EPA rated Class A, B_1, and B_2 carcinogens; EPA rated Class C carcinogens shall be applied at 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c. in the matrix in paragraph (b)(1) of this section.

(4) *Puerto Rico, EPA Region 2.* (i) All waters assigned to the following use classifications in the Puerto Rico Water Quality Standards (promulgated by Resolution Number R–83–5–2) are subject to the criteria in paragraph (d)(4)(ii) of this section, without exception:

Article 2.2.2—Class SB
Article 2.2.3—Class SC
Article 2.2.4—Class SD

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(4)(i) of this section:

Use classification	Applicable criteria
Class SD	This Classification is assigned criteria in: Column B1—all, except: 10, 102, 105, 107, 108, 111, 112, 113, 115, 117, and 126. Column B2—all, except: 105, 107, 108, 112, 113, 115, and 117. Column D1—all, except: 6, 14, 105, 112, 113, and 115. Column D2—all, except: 14, 105, 112, 113, and 115.
Class SB, Class SC	These Classifications are assigned criteria in:

Use classification	Applicable criteria
	Column C1—all, except: 4, 5b, 7, 8, 10, 11, 13, 102, 105, 107, 108, 111, 112, 113, 115, 117, and 126.
	Column C2—all, except: 4, 5b, 10, 13, 108, 112, 113, 115, and 117.
	Column D2—all, except: 14, 105, 112, 113, and 115.

(iii) The human health criteria shall be applied at the State-proposed 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c, in the criteria matrix in paragraph (b)(1) of this section.

(5) *District of Columbia, EPA Region 3.*

(i) All waters assigned to the following use classifications in chapter 11 Title 21 DCMR, Water Quality Standards of the District of Columbia are subject to the criteria in paragraph (d)(5)(ii) of this section, without exception:

1101.2 Class C waters

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classification identified in paragraph (d)(5)(i) of this section:

Use classification	Applicable criteria
Class C	This classification is assigned the additional criteria in: Column B2—#10, 118, 126. Column D1—#15, 16, 44, 67, 68, 79, 80, 81, 88, 114, 116, 118. Column D2—all.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(6) *Florida, EPA Region 4.*

(i) All waters assigned to the following use classifications in Chapter 17–301 of the Florida Administrative Code (i.e., identified in Section 17–302.600) are subject to the criteria in paragraph (d)(6)(ii) of this section, without exception:

Class I
Class II
Class III

(ii) The following criteria from the matrix paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(6)(i) of this section:

Use classification	Applicable criteria
Class I	This classification is assigned the criteria in: Column D1—#16
Class II Class III (marine)	This classification is assigned the criteria in:
Class III (freshwater)	This classification is assigned the criteria in: Column D2—#16

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(7) *Michigan, EPA Region 5.*

(i) All waters assigned to the following use classifications in the Michigan Department of Natural Resources Commission General Rules, R 323.1100 designated uses, as defined at R 323.1043. Definitions; A to N, (i.e., identified in Section (g) "Designated use") are subject to the criteria in paragraph (d)(7)(ii) of this section, without exception:

Agriculture
Navigation
Industrial Water Supply
Public Water Supply at the Point of Water Intake
Warmwater Fish
Other Indigenous Aquatic Life and Wildlife
Partial Body Contact Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(7)(i) of this section:

Use classification	Applicable criteria
Public Water supply	This classification is assigned the criteria in: Column B1—all, Column B2—all, Column D1—all.
All other designations	These classifications are assigned the criteria in: Column B1—all, Column B2—all, and Column D2—all.

(iii) The human health criteria shall be applied at the State-adopted 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(8) *Arkansas, EPA Region 6.*

(i) All waters assigned to the following use classification in section 4C (Waterbody uses) identified in Arkansas Department of Pollution Control and Ecology's Regulation No. 2 as amended and entitled, "Regulation Establishing Water Quality Standards for Surface Waters of the State of Arkansas" are subject to the criteria in paragraph (d)(8)(ii) of this section, without exception:

Extraordinary Resource Waters
Ecologically Sensitive Waterbody
Natural and Scenic Waterways
Fisheries:
(1) Trout
(2) Lakes and Reservoirs
(3) Streams
(a) Ozark Highlands Ecoregion
(b) Boston Mountains Ecoregion
(c) Arkansas River Valley Ecoregion
(d) Ouachita Mountains Ecoregion
(e) Typical Gulf Coastal Ecoregion
(f) Spring Water-influenced Gulf Coastal Ecoregion
(g) Least-altered Delta Ecoregion
(h) Channel-altered Delta Ecoregion
Domestic Water Supply

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classification identified in paragraph (d)(8)(i) of this section:

Use classification	Applicable criteria
Extraordinary Resource Waters Ecologically Sensitive Waterbody Natural and Scenic Waterways Fisheries: (1) Trout (2) Lakes and Reservoirs (3) Streams (a) Ozark Highlands Ecoregion (b) Boston Mountains Ecoregion (c) Arkansas River Valley Ecoregion (d) Ouachita Mountains Ecoregion (e) Typical Gulf Coastal Ecoregion (f) Spring Water-influenced Gulf Coastal Ecoregion (g) Least-altered Delta Ecoregion (h) Channel-altered Delta Ecoregion	These uses are each assigned the criteria in— Column B1—#4, 5a, 5b, 6, 7, 8, 9, 10, 11, 13, 14 Column B2—#4, 5a, 5b, 6 7, 8, 9, 10, 13, 14

(9) *Kansas, EPA Region 7.*

(i) All waters assigned to the following use classification in the Kansas Department of Health and Environment regulations, K.A.R. 28–16–28b through K.A.R. 28–16–28f, are subject to the criteria in paragraph (d)(9)(ii) of this section, without exception.

Section 28–16–28d
Section (2)(A)—Special Aquatic Life Use Waters
Section (2)(B)—Expected Aquatic Life Use Waters
Section (2)(C)—Restricted Aquatic Life Use Waters
Section (3)—Domestic Water Supply
Section (6)(c)—Consumptive Recreation Use.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(9)(i) of this section:

Use classification	Applicable criteria
Sections (2)(A), (2)(B), (2)(C), (6)(C)	These classifications are each assigned all criteria in:
	Column B1, all except #9, 11, 13, 102, 105, 107, 108, 111–113, 115, 117, and 126;
	Column B2, all except #9, 13, 105, 107, 108, 111–113, 115, 117, 119–125, and 126; and
	Column D2, all except #9, 112, 113, and 115.
Section (3)	This classification is assigned all criteria in:
	Column D1, all except #9, 12, 112, 113, and 115.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level.

(10) *California, EPA Region 9.*

(i) All waters assigned any aquatic life or human health use classifications in the Water Quality Control Plans for the various Basins of the State ("Basin Plans"), as amended, adopted by the California State Water Resources Control Board ("SWRCB"), except for ocean waters covered by the Water Quality Control Plan for Ocean Waters of California ("Ocean Plan") adopted by the SWRCB with resolution Number 90–27 on March 22, 1990, are subject to the criteria in paragraph (d)(10)(ii) of this section, without exception. These criteria amend the portions of the existing State standards contained in the Basin Plans. More particularly these criteria amend water quality criteria contained in the Basin Plan Chapters specifying water quality objectives (the State equivalent of federal water quality criteria) for the toxic pollutants identified in paragraph (d)(10)(ii) of this section. Although the State has adopted several use designations for each of these waters, for purposes of this action, the specific standards to be applied in paragraph (d)(10)(ii) of this section are based on the presence in all waters of some aquatic life designation and the presence or absence of the MUN use designation (Municipal and domestic supply). (See Basin Plans for more detailed use definitions.)

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the water and use classifications defined in paragraph (d)(10)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters of the State defined as bays or estuaries except the Sacramento-San Joaquin Delta and San Francisco Bay	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column C1—pollutant 14 Column C2—pollutant 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the Sacramento—San Joaquin Delta and waters of the State defined as inland (i.e., all surface waters of the State not bays or estuaries or ocean) that include a MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column D1—pollutants 1, 12, 15, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–48, 49, 52, 66, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the State defined as inland without an MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98 In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B2—pollutant 20
Waters of the San Joaquin River from the mouth of the Merced River to Vernalis	

Water and use classification	Applicable criteria
Waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River	In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B1—pollutant 10 Column B2—pollutant 10
Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta	These waters are assigned the criteria in: Column B1—pollutants 5a, 10* and 14 Column B2—pollutants 5a, 10* and 14 Column C1—pollutant 14 Column C2—pollutant 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D1—all pollutants except #2
All inland waters of the United States that do not include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or has deferred applicability of these tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D2—all pollutants except #2
All enclosed bays and estuaries that are waters of the United States and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column C1—all pollutants Column C2—all pollutants Column D2—all pollutants except #2

*The fresh water selenium criteria are included for the San Francisco Bay estuary because high levels of bioaccumulation of selenium in the estuary indicate that the salt water criteria are underprotective for San Francisco Bay.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(11) *Nevada, EPA Region 9.* (i) All waters assigned the use classifications in Chapter 445 of the Nevada Administrative Code (NAC), Nevada Water Pollution Control Regulations, which are referred to in paragraph (d)(11)(ii) of this section, are subject to the criteria in paragraph (d)(11)(ii) of this section, without exception. These criteria amend the existing State standards contained in the Nevada Water Pollution Control Regulations. More particularly, these criteria amend or supplement the table of numeric standards in NAC 445.1339 for the toxic pollutants identified in paragraph (d)(11)(ii) of this section.

(ii) The following criteria from matrix in paragraph (b)(1) of this section apply to the waters defined in paragraph (d)(11)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D1—pollutants #15, 16, 18, 19, 20, 21, 23, 26, 27, 29, 30, 34, 37, 38, 42, 43, 55, 58–62, 64, 66, 73, 74, 78, 82, 85, 87–89, 91, 92, 96, 98, 100, 103, 104, 105, 114, 116, 117, 118
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is not a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D2—all pollutants except #2.

(iii) The human health criteria shall be applied at the 10^{-6} risk level, consistent with State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(12) *Alaska, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Alaska Administrative Code (AAC), Chapter 18 (i.e., identified in 18 AAC 70.020) are subject to the criteria in paragraph (d)(12)(ii) of this section, without exception:

70.020.(1) (A) Fresh Water
70.020.(1) (A) Water Supply
(i) Drinking, culinary, and food processing,
(iii) Aquaculture;
70.020.(1) (B) Water Recreation
(i) Contact recreation,
(ii) Secondary recreation;
70.020.(1) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife
70.020.(2) (A) Marine Water
70.020.(2) (A) Water Supply
(i) Aquaculture,
70.020.(2) (B) Water Recreation
(i) contact recreation,
(ii) secondary recreation;
70.020.(2) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife;
70.020.(2) (D) Harvesting for consumption of raw mollusks or other raw aquatic life.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(12)(i) of this section:

Use classification	Applicable criteria
(1)(A) i	Column B1—all Column B2—#10 Column D1 #'s 2, 15, 16–21, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 53, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88, 89, 91–93, 96, 98, 102–105, 107–111, 117–126
(1)(A) iii	Column B1—all Column B2—#10 Column D1 #'s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126
(1)(B)i, (1)(B) ii, (1)(C)	Column B1—all Column B2—#10 Column D2 #'s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126
(2)(A) i, (2)(B)i, and (2)(B)ii, (2)(C), (2)(D)	Column C1—all Column C2—#10 Column D2 #s 2, 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126

(iii) The human health criteria shall be applied at the State-proposed risk level of 10^{-5}. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(13) *Idaho, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Idaho Administrative Procedures Act (IDAPA), Chapter 16 (i.e., identified in IDAPA 16.01.2100.02–16.01.2100.07) are subject to the criteria in paragraph (d)(13)(ii) of this section, without exception:

16.01.2100.01.b. Domestic Water Supplies
16.01.2100.02.a. Cold Water Biota
16.01.2100.02.b. Warm Water Biota
16.01.2100.02cc. Salmonid Spawning
16.01.2100.03.a. Primary Contact Recreation
16.01.2100.03.b Secondary Contact Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(13)(i) of this section:

Use classification	Applicable criteria
01.b	This classification is assigned the criteria in: Column D1—all *except* #14 and 115
02.a 02.b 02cc	These classifications are assigned the criteria in: Column B1—all Column B2—all Column D2—all
03.a	This classification is assigned the criteria in: Column D2—all
03.b	This classification is assigned the criteria in: Column D2—all

(iii) The human health criteria shall be applied at the 10^{-6} risk level, consistent with State policy.

(14) *Washington, EPA Region 10.*

(i) All waters assigned to the following use classifications in the Washington Administrative Code (WAC), Chapter 173–201 (i.e., identified in WAC 173–201–045) are subject to the criteria in paragraph (d)(14)(ii) of this section, without exception:

173–201–045
Fish and Shellfish
Fish
Water Supply (domestic)
Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(14)(i) of this section:

Use classification	Applicable criteria
Fish and Shellfish; Fish	These classifications are assigned the criteria in: Column B1 and B(2)—#2, 10 Column C1—#2, 10 Column C2—#2, 6, 10, 14 Column D2—all
Water Supply (domestic)	These classifications are assigned the criteria in: Column D1—all
Recreation	This classification is assigned the criteria in: Column D2—Marine waters and freshwaters not protected for domestic water supply

(iii) The human health criteria shall be applied at the State proposed risk level of 10^{-6}.

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North Star Creek	Class III
Okanogan River from Reservation north boundary to Columbia River.	Class II
Olds Creek	Class I
Omak Creek	Class II
Onion Creek	Class II
Parmenter Creek	Class III
Peel Creek	Class III
Peter Dan Creek	Class III
Rock Creek	Class I
San Poil River	Class I
Sanpoil, River West Fork	Class II
Seventeen Mile Creek	Class III
Silver Creek	Class III
Sitdown Creek	Class III
Six Mile Creek	Class III
South Nanamkin Creek	Class III
Spring Creek	Class III
Stapaloop Creek	Class III
Stepstone Creek	Class III
Stranger Creek	Class II
Strawberry Creek	Class III
Swimptkin Creek	Class III
Three Forks Creek	Class I
Three Mile Creek	Class III
Thirteen Mile Creek	Class II
Thirty Mile Creek	Class II
Trail Creek	Class III
Twentyfive Mile Creek	Class III
Twentyone Mile Creek	Class III
Twentythree Mile Creek	Class III
Wannacot Creek	Class III
Wells Creek	Class I
Whitelaw Creek	Class III
Wilmont Creek	Class II
(2) Lakes:	
Apex Lake	LC
Big Goose Lake	LC
Bourgeau Lake	LC
Buffalo Lake	LC
Cody Lake	LC
Crawfish Lakes	LC
Camille Lake	LC
Elbow Lake	LC
Fish Lake	LC
Gold Lake	LC
Great Western Lake	LC
Johnson Lake	LC
LaFleur Lake	LC
Little Goose Lake	LC
Little Owhi Lake	LC
McGinnis Lake	LC
Nicholas Lake	LC
Omak Lake	SRW
Owhi Lake	SRW
Penley Lake	SRW
Rebecca Lake	LC
Round Lake	LC
Simpson Lake	LC
Soap Lake	LC
Sugar Lake	LC
Summit Lake	LC
Twin Lakes	SRW

[54 FR 28625, July 6, 1989]

§ 131.36 Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B).

(a) *Scope.* This section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

(b)(1) EPA's Section 304(a) criteria for Priority Toxic Pollutants.

00848

	A		B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
	(#) Compound	CAS Number	Criterion Maximum Conc.[d] (µg/L) (B1)	Criterion Continuous Conc.[d] (µg/L) (B2)	Criterion Maximum Conc.[d] (µg/L) (C1)	Criterion Continuous Conc.[d] (µg/L) (C2)	Water & Organisms (µg/L) (D1)	Organisms Only (µg/L) (D2)
1	Antimony	7440360					14 a	4300 a
2	Arsenic	7440382	360 m	190 m	69 m	36 m	0.018 abc	0.14 abc
3	Beryllium	7440417					n	n
4	Cadmium	7440439	3.7 e	1.0 e	42 m	9.3 m	n	n
5a	Chromium (III)	16065831	550 e	180 e			n	n
b	Chromium (VI)	18540299	15 m	10 m	1100 m	50 m	n	n
6	Copper	7440508	17 e	11 e	2.4 m	2.4 m		
7	Lead	7439921	65 e	2.5 e	210 m	8.1 m	n	n
8	Mercury	7439976	2.1 m	0.012 ip	1.8 m	0.025 ip	0.14	0.15
9	Nickel	7440020	1400 e	160 e	74 m	8.2 m	610 a	4600 a
10	Selenium	7782492	20 p	5 p	290 m	71 m	n	n
11	Silver	7440224	3.4 e		1.9 m			
12	Thallium	7440280					1.7 a	6.3 a
13	Zinc	7440666	110 e	100 e	90 m	81 m		
14	Cyanide	57125	22	5.2	1	1	700 a	220000 aj
15	Asbestos	1332214					7,000,000 fibers/L k	
16	2,3,7,8-TCDD (Dioxin)	1746016					0.000000014 c	
17	Acrolein	107028					320	780
18	Acrylonitrile	107131					0.059 ac	0.66 ac
19	Benzene	71432					1.2 ac	71 ac
20	Bromoform	75252					4.3 ac	360 ac
21	Carbon Tetrachloride	56235					0.25 ac	4.4 ac
22	Chlorobenzene	108907					680 a	21000 aj
23	Chlorodibromomethane	124481					0.41 ac	34 ac
24	Chloroethane	75003						
25	2-Chloroethylvinyl Ether	110758						
26	Chloroform	67663					5.7 ac	470 ac
27	Dichlorobromomethane	75274					0.27 ac	22 ac
28	1,1-Dichloroethane	75343						
29	1,2-Dichloroethane	107062					0.38 ac	99 ac
30	1,1-Dichloroethylene	75354					0.057 ac	3.2 ac
31	1,2-Dichloropropane	78875						
32	1,3-Dichloropropylene	542756					10 a	1700 a
33	Ethylbenzene	100414					3100 a	29000 a
34	Methyl Bromide	74839					48 a	4000 a
35	Methyl Chloride	74873					n	n
36	Methylene Chloride	75092					4.7 ac	1600 ac
37	1,1,2,2-Tetrachloroethane	79345					0.17 ac	11 ac
38	Tetrachloroethylene	127184					0.8 c	8.85 c
39	Toluene	108883					6800 a	200000 a

00849

40	1,2-Trans-Dichloroethylene	156605					n	n
41	1,1,1-Trichloroethane	71556					0.60 ac	42 ac
42	1,1,2-Trichloroethane	79005					2.7 c	81 c
43	Trichloroethylene	79016					2 c	525 c
44	Vinyl Chloride	75014						
45	2-Chlorophenol	95578					93 a	790 aj
46	2,4-Dichlorophenol	120832						
47	2,4-Dimethylphenol	105679					13.4	765
48	2-Methyl-4,6-Dinitrophenol	534521					70 a	14000 a
49	2,4-Dinitrophenol	51285						
50	2-Nitrophenol	88755						
51	4-Nitrophenol	100027						
52	3-Methyl-4-Chlorophenol	59507				7.9	0.28 ac	8.2 acj
53	Pentachlorophenol	87865	20 f	13 f	13		21000 a	4600000 aj
54	Phenol	108952					2.1 ac	6.5 ac
55	2,4,6-Trichlorophenol	88062						
56	Acenaphthene	83329						
57	Acenaphthylene	208968						
58	Anthracene	120127					9600 a	110000 a
59	Benzidine	92875					0.00012 ac	0.00054 ac
60	Benzo(a)Anthracene	56553					0.0028 c	0.031 c
61	Benzo(a)Pyrene	50328					0.0028 c	0.031 c
62	Benzo(b)Fluoranthene	205992					0.0028 c	0.031 c
63	Benzo(ghi)Perylene	191242						
64	Benzo(k)Fluoranthene	207089					0.0028 c	0.031 c
65	Bis(2-Chloroethoxy)Methane	111911						
66	Bis(2-Chloroethyl)Ether	111444					0.031 ac	1.4 ac
67	Bis(2-Chloroisopropyl)Ether	108601					1400 a	170000 a
68	Bis(2-Ethylhexyl)Phthalate	117817					1.8 ac	5.9 ac
69	4-Bromophenyl Phenyl Ether	101553						
70	Butylbenzyl Phthalate	85687						
71	2-Chloronaphthalene	91587						
72	4-Chlorophenyl Phenyl Ether	7005723						
73	Chrysene	218019					0.0028 c	0.031 c
74	Dibenzo(ah)Anthracene	53703					0.0028 c	0.031 c
75	1,2-Dichlorobenzene	95501					2700 a	17000 a
76	1,3-Dichlorobenzene	541731					400	2600
77	1,4-Dichlorobenzene	106467					400	2600
78	3,3'-Dichlorobenzidine	91941					0.04 ac	0.077 ac
79	Diethyl Phthalate	84662					23000 a	120000 a
80	Dimethyl Phthalate	131113					313000	2900000
81	Di-n-Butyl Phthalate	84742					2700 a	12000 a
82	2,4-Dinitrotoluene	121142					0.11 c	9.1 c
83	2,6-Dinitrotoluene	606202						
84	Di-n-Octyl Phthalate	117840						
85	1,2-Diphenylhydrazine	122667					0.040 ac	0.54 ac
86	Fluoranthene	206440					300 a	370 a
87	Fluorene	86737					1300 a	14000 a
88	Hexachlorobenzene	118741					0.00075 ac	0.00077 ac
89	Hexachlorobutadiene	87683					0.44 ac	50 ac

A			B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
(#) Compound	CAS Number		Criterion Maximum Conc.[d] (µg/L) (B1)	Criterion Continuous Conc.[d] (µg/L) (B2)	Criterion Maximum Conc.[d] (µg/L) (C1)	Criterion Continuous Conc.[d] (µg/L) (C2)	Water & Organisms (µg/L) (D1)	Organisms Only (µg/L) (D2)
90	Hexachlorocyclopentadiene	77474					240 a	17000 aj
91	Hexachloroethane	67721					1.9 ac	8.9 ac
92	Indeno(1,2,3-cd)Pyrene	193395					0.0028 c	0.031 c
93	Isophorone	78591					8.4 ac	600 ac
94	Naphthalene	91203						
95	Nitrobenzene	98953					17 a	1900 aj
96	N-Nitrosodimethylamine	62759					0.00069 ac	8.1 ac
97	N-Nitrosodi-n-Propylamine	621647						
98	N-Nitrosodiphenylamine	86306					5.0 ac	16 ac
99	Phenanthrene	85018						
100	Pyrene	129000					960 a	11000 a
101	1,2,4-Trichlorobenzene	120821						
102	Aldrin	309002	3 g		1.3 g		0.00013 ac	0.00014 ac
103	alpha-BHC	319846					0.0039 ac	0.013 ac
104	beta-BHC	319857					0.014 ac	0.046 ac
105	gamma-BHC	58899	2 g	0.08 g	0.16 g		0.019 c	0.063 c
106	delta-BHC	319868						
107	Chlordane	57749	2.4 g	0.0043 g	0.09 g	0.004 g	0.00057 ac	0.00059 ac
108	4,4'-DDT	50293	1.1 g	0.001 g	0.13 g	0.001 g	0.00059 ac	0.00059 ac
109	4,4'-DDE	72559					0.00059 ac	0.00059 ac
110	4,4'-DDD	72548					0.00083 ac	0.00084 ac
111	Dieldrin	60571	2.5 g	0.0019 g	0.71 g	0.0019 g	0.00014 ac	0.00014 ac
112	alpha-Endosulfan	959988	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
113	beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	0.93 a	2.0 a
114	Endosulfan Sulfate	1031078					0.93 a	2.0 a
115	Endrin	72208	0.18 g	0.0023 g	0.037 g	0.0023 g	0.76 a	0.81 aj
116	Endrin Aldehyde	7421934					0.76 a	0.81 aj
117	Heptachlor	76448	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00021 ac	0.00021 ac
118	Heptachlor Epoxide	1024573	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00010 ac	0.00011 ac
119	PCB–1242	53469219		0.014 g		0.03 g		
120	PCB–1254	11097691		0.014 g		0.03 g		
121	PCB–1221	11104282		0.014 g		0.03 g		
122	PCB–1232	11141165		0.014 g		0.03 g		
123	PCB–1248	12672296		0.014 g		0.03 g		
124	PCB–1260	11096825		0.014 g		0.03 g		
125a	PCB–1016	12674112		0.014 g		0.03 g		
125b	Polychlorinated biphenyls (PCBs)						0.00017 q	0.00017 q
126	Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 ac	0.00075 ac
	Total Number of Criteria (h) =		24	29	23	27	85	84

00851

FOOTNOTES

a. Criteria revised to reflect current agency q_1* or RfD, as contained in the Integrated Risk Information System (IRIS). The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained in all cases.

b. The criteria refers to the inorganic form only.

c. Criteria in the matrix based on carcinogenicity (10^{-6} risk). For a risk level of 10^{-5}, move the decimal point in the matrix value one place to the right.

d. Criteria Maximum Concentration (CMC) = the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time (1-hour average) without deleterious effects. Criteria Continuous Concentration (CCC) = the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. µg/L = micrograms per liter.

e. Freshwater aquatic life criteria for these metals are expressed as a function of total hardness (mg/L as $CaCO_3$), the pollutant's water effect ratio (WER) as defined in §131.36(c) and multiplied by an appropriate dissolved conversion factor as defined in §131.36(b)(2). For comparative purposes, the values displayed in this matrix are shown as dissolved metal and correspond to a total hardness of 100 mg/L and a water effect ratio of 1.0.

f. Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows. Values displayed above in the matrix correspond to a pH of 7.8.

$$CMC = \exp(1.005(pH) - 4.830)$$
$$CCC = \exp(1.005(pH) - 5.290)$$

g. Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (FAV) which by the 1980 Guidelines are instantaneous values as contrasted with a CMC which is a one-hour average.

h. These totals simply sum the criteria in each column. For aquatic life, there are 31 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 85 priority toxic pollutants with either ''water + fish'' or ''fish only'' criteria. Note that these totals count chromium as one pollutant even though EPA has developed criteria based on two valence states. In the matrix, EPA has assigned numbers 5a and 5b to the criteria for chromium to reflect the fact that the list of 126 priority toxic pollutants includes only a single listing for chromium.

i. If the CCC for total mercury exceeds 0.012 µg/l more than once in a 3-year period in the ambient water, the edible portion of aquatic species of concern must be analyzed to determine whether the concentration of methyl mercury exceeds the FDA action level (1.0 mg/kg). If the FDA action level is exceeded, the State must notify the appropriate EPA Regional Administrator, initiate a revision of its mercury criterion in its water quality standards so as to protect designated uses, and take other appropriate action such as issuance of a fish consumption advisory for the affected area.

j. No criteria for protection of human health from consumption of aquatic organisms (excluding water) was presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.

k. The criterion for asbestos is the MCL (56 FR 3526, January 30, 1991).

l. [Reserved: This letter not used as a footnote.]

m. Criteria for these metals are expressed as a function of the water effect ratio, WER, as defined in 40 CFR 131.36(c).

CMC = column B1 or C1 value × WER
CCC = column B2 or C2 value × WER

n. EPA is not promulgating human health criteria for this contaminant. However, permit authorities should address this contaminant in NPDES permit actions using the State's existing narrative criteria for toxics.

o. [Reserved: This letter not used as a footnote.]

p. Criterion expressed as total recoverable.

q. This criterion applies to total PCBs (*e.g.*, the sum of all congener or isomer or homolog or Aroclor analyses).

GENERAL NOTES

1. This chart lists all of EPA's priority toxic pollutants whether or not criteria recommendations are available. Blank spaces indicate the absence of criteria recommendations. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A of 40 CFR Part 423. EPA has added the Chemical Abstracts Service (CAS) registry numbers, which provide a unique identification for each chemical.

2. The following chemicals have organoleptic based criteria recommendations that are not included on this chart (for reasons which are discussed in the preamble): copper, zinc, chlorobenzene, 2-chlorophenol, 2,4-dichlorophenol, acenaphthene, 2,4-dimethylphenol, 3-methyl-4-chlorophenol, hexachlorocyclopentadiene, pentachlorophenol, phenol.

3. For purposes of this rulemaking, freshwater criteria and saltwater criteria apply as specified in 40 CFR 131.36(c).

NOTE TO PARAGRAPH (b)(1): On April 14, 1995, the Environmental Protection Agency

issued a stay of certain criteria in paragraph (b)(1) of this section as follows: the criteria in columns B and C for arsenic, cadmium, chromium (VI), copper, lead, nickel, silver, and zinc; the criteria in B1 and C1 for mercury; the criteria in column B for chromium (III); and the criteria in column C for selenium. The stay remains in effect until further notice.

(2) Factors for Calculating Hardness-Dependent, Freshwater Metals Criteria

CMC=WER exp { m_A[ln(hardness)]+b_A} × Acute Conversion Factor

CCC=WER exp { m_C[ln(hardness)]+b_C} × Chronic Conversion Factor

Final CMC and CCC values should be rounded to two significant figures.

Metal	m_A	b_A	m_C	b_C	Freshwater conversion factors	
					Acute	Chronic
Cadmium	1.128	–3.828	0.7852	–3.490	[a] 0.944	[a] 0.909
Chromium (III)	0.8190	3.688	0.8190	1.561	0.316	0.860
Copper	0.9422	–1.464	0.8545	–1.465	0.960	0.960
Lead	1.273	-1.460	1.273	–4.705	[a] 0.791	[a] 0.791
Nickel	0.8460	3.3612	0.8460	1.1645	0.998	0.997
Silver	1.72	–6.52	[b] N/A	[b] N/A	0.85	[b] N/A
Zinc	0.8473	0.8604	0.8473	0.7614	0.978	0.986

Note to table: The term ''exp'' represents the base e exponential function.

Footnotes to table:

[a] The freshwater conversion factors (CF) for cadmium and lead are hardness-dependent and can be calculated for any hardness [see limitations in § 131.36(c)(4)] using the following equations:

Cadmium
Acute: CF=1.136672—[(ln hardness)(0.041838)]
Chronic: CF=1.101672—[(ln hardness)(0.041838)]
Lead (Acute and Chronic): CF = 1.46203—[(ln hardness)(0.145712)]

[b] No chronic criteria are available for silver.

(c) *Applicability*. (1) The criteria in paragraph (b) of this section apply to the States' designated uses cited in paragraph (d) of this section and supersede any criteria adopted by the State, except when State regulations contain criteria which are more stringent for a particular use in which case the State's criteria will continue to apply.

(2) The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are the other numeric toxics criteria when applied to the same use classifications including mixing zones, and low flow values below which numeric standards can be exceeded in flowing fresh waters.

(i) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones; otherwise the criteria apply throughout the waterbody including at the end of any discharge pipe, canal or other discharge point.

(ii) A State shall not use a low flow value below which numeric standards can be exceeded that is less stringent than the following for waters suitable for the establishment of low flow return frequencies (i.e., streams and rivers):

AQUATIC LIFE	
Acute criteria (CMC)	1 Q 10 or 1 B 3
Chronic criteria (CCC)	7 Q 10 or 4 B 3
HUMAN HEALTH	
Non-carcinogens	30 Q 5
Carcinogens	Harmonic mean flow

Where:

CMC—criteria maximum concentration—the water quality criteria to protect against acute effects in aquatic life and is the highest instream concentration of a priority toxic pollutant consisting of a one-hour average not to be exceeded more than once every three years on the average;

CCC—criteria continuous concentration—the water quality criteria to protect against chronic effects in aquatic life is the highest instream concentration of a priority toxic pollutant consisting of a 4-day average not to be exceeded more than once every three years on the average;

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and the harmonic mean

flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

(iii) If a State does not have such a low flow value for numeric standards compliance, then none shall apply and the criteria included in paragraph (d) of this section herein apply at all flows.

(3) The aquatic life criteria in the matrix in paragraph (b) of this section apply as follows:

(i) For waters in which the salinity is equal to or less than 1 part per thousand 95% or more of the time, the applicable criteria are the freshwater criteria in Column B;

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in Column C; and

(iii) For waters in which the salinity is between 1 and 10 parts per thousand as defined in paragraphs (c)(3) (i) and (ii) of this section, the applicable criteria are the more stringent of the freshwater or saltwater criteria. However, the Regional Administrator may approve the use of the alternative freshwater or saltwater criteria if scientifically defensible information and data demonstrate that on a site-specific basis the biology of the waterbody is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the waterbody is dominated by saltwater aquatic life and that saltwater criteria are more appropriate.

(4) *Application of metals criteria.* (i) For purposes of calculating freshwater aquatic life criteria for metals from the equations in paragraph (b)(2) of this section, the minimum hardness allowed for use in those equations shall not be less than 25 mg/l, as calcium carbonate, even if the actual ambient hardness is less than 25 mg/l as calcium carbonate. The maximum hardness value for use in those equations shall not exceed 400 mg/l as calcium carbonate, even if the actual ambient hardness is greater than 400 mg/l as calcium carbonate. The same provisions apply for calculating the metals criteria for the comparisons provided for in paragraph (c)(3)(iii) of this section.

(ii) The hardness values used shall be consistent with the design discharge conditions established in paragraph (c)(2) of this section for flows and mixing zones.

(iii) Except where otherwise noted, the criteria for metals (compounds #2, #4–# 11, and #13, in paragraph (b) of this section) are expressed as dissolved metal. For purposes of calculating aquatic life criteria for metals from the equations in footnote m. in the criteria matrix in paragraph (b)(1) of this section and the equations in paragraphs (b)(2) of this section, the water-effect ratio is computed as a specific pollutant's acute or chronic toxicity values measured in water from the site covered by the standard, divided by the respective acute or chronic toxicity value in laboratory dilution water.

(d) *Criteria for Specific Jurisdictions—*(1) *Rhode Island, EPA Region 1.* (i) All waters assigned to the following use classifications in the Water Quality Regulations for Water Pollution Control adopted under Chapters 46–12, 42–17.1, and 42–35 of the General Laws of Rhode Island are subject to the criteria in paragraph (d)(1)(ii) of this section, without exception:

6.21 Freshwater	6.22 Saltwater:
Class A	Class SA
Class B	Class SB
Class C	Class SC

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(1)(i) of this section:

Use classification	Applicable criteria
Class A Class B waters where water supply use is designated Class B waters where water supply use is not designated. Class C; Class SA; Class SB; Class SC	These classifications are assigned the criteria in Column D1—#2, 68 Each of these classifications is assigned the criteria in: Column D2—#2, 68

(iii) The human health criteria shall be applied at the 10^{-5} risk level, consistent with the State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(2) *Vermont, EPA Region 1.* (i) All waters assigned to the following use classifications in the Vermont Water Quality Standards adopted under the authority of the Vermont Water Pollution Control Act (10 V.S.A., Chapter 47) are subject to the criteria in paragraph (d)(2)(ii) of this section, without exception:

Class A
Class B
Class C

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(2)(i) of this section:

Use classification	Applicable criteria
1. Classes A1, A2, B1, B2, B3	These classification are assigned the criterion in: Column B2—#105.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level.

(3) *New Jersey, EPA Region 2.* (i) All waters assigned to the following use classifications in the New Jersey Administrative Code (N.J.A.C.) 7:9–4.1 et seq., Surface Water Quality Standards, are subject to the criteria in paragraph (d)(3)(ii) of this section, without exception.

N.J.A.C. 7:9–4.12(b): Class PL
N.J.A.C. 7:9–4.12(c): Class FW2
N.J.A.C. 7:9–4.12(d): Class SE1
N.J.A.C. 7:9–4.12(e): Class SE2
N.J.A.C. 7:9–4.12(f): Class SE3
N.J.A.C. 7:9–4.12(g): Class SC
N.J.A.C. 7:9–4.13(a): Delaware River Zones 1C, 1D, and 1E
N.J.A.C. 7:9–4.13(b): Delaware River Zone 2
N.J.A.C. 7:9–4.13(c): Delaware River Zone 3
N.J.A.C. 7:9–4.13(d): Delaware River Zone 4
N.J.A.C. 7:9–4.13(e): Delaware River Zone 5
N.J.A.C. 7:9–4.13(f): Delaware River Zone 6

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(3)(i) of this section:

Use classification	Applicable criteria
1. Freshwater Pinelands, FW2	These classifications are each assigned the criteria in: i. Column B1—#2, 4, 5a, 5b, 6–11, 13. ii. Column B2—#2, 4, 5a, 5b, 6–10, 13. iii. Column D1—#125b at a 10^{-6} risk level. iv. Column D2—#125b at a 10^{-6} risk level. v. Column D2—#23, 30, 37, 42, 87, 89, 93 and 105 at a 10^{-5} risk level.
2. PL (Saline Water Pinelands), SE1, SE2, SE3, SC, Delaware Bay Zone 6.	These classifications are each assigned the criteria in: i. Column C1—#2, 4, 5b, 6–11, 13. ii. Column C2—#2, 4, 5b, 6–10, 13. iii. Column D1—#125b at a 10^{-6} risk level. iv. Column D2—#125b at a 10^{-6} risk level. v. Column D2—#23, 30, 37, 42, 87, 89, 93 and 105 at a 10^{-5} risk level.
3. Delaware River Zones 1C, 1D, 1E, 2, 3, 4, and 5	i. Column B1—none. ii. Column B2—none. iii. Column D1—none. iv. Column D2—none.
4. Delaware River Zones 3, 4, and 5	These classifications are each assigned the criteria in: i. Column C1—none. ii. Column C2—none. iii. Column D2—none.

(iii) The human health criteria shall be applied at the State-proposed 10^{-6} risk level for EPA rated Class A, B_1, and B_2 carcinogens; EPA rated Class C carcinogens shall be applied at 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c. in the matrix in paragraph (b)(1) of this section.

(4) *Puerto Rico, EPA Region 2.* (i) All waters assigned to the following use classifications in the Puerto Rico

Water Quality Standards (promulgated by Resolution Number R–83–5–2) are subject to the criteria in paragraph (d)(4)(ii) of this section, without exception.

Article 2.2.2—Class SB
Article 2.2.3—Class SC
Article 2.2.4—Class SD

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(4)(i) of this section:

Use classification	Applicable criteria
Class SD	Column B1—# 118. Column B2—#s 8, 105, 115, 118, 119, 120, 121, 122, 123,124, 125a, 125b. Column D1—#s 12, 16, 27, 60, 61, 62, 64, 73, 74, 92, 93, 103, 104, 114, 116, 118, 119, 120, 121, 122, 123, 124, 125a, 125b.
Class SB, Class SC	Column C1—#s 5b, 112, 113, 118. Column C2—#s 5b, 8, 112, 113, 118, 119, 120, 121, 122, 123, 124, 125a, 125b. Column D2—#s 12, 16, 27, 60, 61, 62, 64, 73, 74, 87, 92, 93, 103, 104, 114, 116, 118, 119, 120, 121, 122, 123, 124, 125a, 125b.

(iii) The human health criteria shall be applied at the State-proposed 10^{-5} risk level. To determine appropriate value for carcinogens, see footnote c, in the criteria matrix in paragraph (b)(1) of this section.

(5) *District of Columbia, EPA Region 3.* (i) All waters assigned to the following use classifications in chapter 11 Title 21 DCMR, Water Quality Standards of the District of Columbia are subject to the criteria in paragraph (d)(5)(ii) of this section, without exception:

1101.2 Class C waters

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classification identified in paragraph (d)(5)(i) of this section:

Use classification	Applicable criteria
1. Class C	This classification is assigned the additional criteria in: Column B2; #10, 118, 126.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(6) *Florida, EPA Region 4.* (i) All waters assigned to the following use classifications in Chapter 17–301 of the Florida Administrative Code (i.e., identified in Section 17–302.600) are subject to the criteria in paragraph (d)(6)(ii) of this section, without exception:

Class I
Class II
Class III

(ii) The following criteria from the matrix paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(6)(i) of this section:

Use classification	Applicable criteria
Class I	This classification is assigned the criteria in: Column D1—#16
Class II	This classification is assigned the criteria in:
Class III (marine)	Column D2—#16
Class III (freshwater)	This classification is assigned the criteria in: Column D2—#16

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(7)–(8) [Reserved]

(9) *Kansas, EPA Region 7.* (i) All waters assigned to the following use classification in the Kansas Department of Health and Environment regulations, K.A.R. 28–16–28b through K.A.R. 28–16–28f, are subject to the criteria in paragraph (d)(9)(ii) of this section, without exception.

Section (2)(A)—Special Aquatic Life Use Waters
Section (2)(B)—Expected Aquatic Life Use Waters
Section (2)(C)—Restricted Aquatic Life Use Waters
Section (3)—Domestic Water Supply.
Section (4)—Food Procurement Use.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(9)(i) of this section:

Use classification	Applicable criteria
1. Sections (2)(A), (2)(B), (2)(C), (4)	These classifications are each assigned criteria as follows: i. Column B1, #2. ii. Column D2, #12, 21, 29, 39, 46, 68, 79, 81, 86, 93, 104, 114, 118.
2. Section (3)	This classification is assigned all criteria in: Column D1, all except #1, 9, 12, 14, 15, 17, 22, 33, 36, 39, 44, 75, 77, 79, 90, 112, 113, and 115.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(10) *California, EPA Region 9.* (i) All waters assigned any aquatic life or human health use classifications in the Water Quality Control Plans for the various Basins of the State (''Basin Plans''), as amended, adopted by the California State Water Resources Control Board (''SWRCB''), except for ocean waters covered by the Water Quality Control Plan for Ocean Waters of California (''Ocean Plan'') adopted by the SWRCB with resolution Number 90–27 on March 22, 1990, are subject to the criteria in paragraph (d)(10)(ii) of this section, without exception. These criteria amend the portions of the existing State standards contained in the Basin Plans. More particularly these criteria amend water quality criteria contained in the Basin Plan Chapters specifying water quality objectives (the State equivalent of federal water quality criteria) for the toxic pollutants identified in paragraph (d)(10)(ii) of this section. Although the State has adopted several use designations for each of these waters, for purposes of this action, the specific standards to be applied in paragraph (d)(10)(ii) of this section are based on the presence in all waters of some aquatic life designation and the presence or absence of the MUN use designation (Municipal and domestic supply). (See Basin Plans for more detailed use definitions.)

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the water and use classifications defined in paragraph (d)(10)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters of the State defined as bays or estuaries except the Sacramento-San Joaquin Delta and San Francisco Bay	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column C1—pollutant 14 Column C2—pollutant 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98

Water and use classification	Applicable criteria
Waters of the Sacramento—San Joaquin Delta and waters of the State defined as inland (i.e., all surface waters of the State not bays or estuaries or ocean) that include a MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column D1—pollutants 1, 12, 15, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–48, 49, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the State defined as inland without an MUN use designation	These waters are assigned the criteria in: Column B1—pollutants 5a and 14 Column B2—pollutants 5a and 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
Waters of the San Joaquin River from the mouth of the Merced River to Vernalis	In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B2—pollutant 10
Waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River	In addition to the criteria assigned to these waters elsewhere in this rule, these waters are assigned the criteria in: Column B1—pollutant 10 Column B2—pollutant 10
Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta	These waters are assigned the criteria in: Column B1—pollutants 5a, 10* and 14 Column B2—pollutants 5a, 10* and 14 Column C1—pollutant 14 Column C2—pollutant 14 Column D2—pollutants 1, 12, 17, 18, 21, 22, 29, 30, 32, 33, 37, 38, 42–44, 46, 48, 49, 54, 59, 66, 67, 68, 78–82, 85, 89, 90, 91, 93, 95, 96, 98
All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D1—all pollutants except #2

Water and use classification	Applicable criteria
All inland waters of the United States that do not include an MUN use designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or has deferred applicability of these tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column D2—all pollutants except #2
All enclosed bays and estuaries that are waters of the United States that do not include an MUN designation and that the State has either excluded or partially excluded from coverage under its Water Quality Control Plan for Inland Surface Waters of California, Tables 1 and 2, or its Water Quality Control Plan for Enclosed Bays and Estuaries of California, Tables 1 and 2, or has deferred applicability of those tables. (Category (a), (b), and (c) waters described on page 6 of Water Quality Control Plan for Inland Surface Waters of California or page 6 of its Water Quality Control Plan for Enclosed Bays and Estuaries of California.)	These waters are assigned the criteria for pollutants for which the State does not apply Table 1 or 2 standards. These criteria are: Column B1—all pollutants Column B2—all pollutants Column C1—all pollutants Column C2—all pollutants Column D2—all pollutants except #2

*The fresh water selenium criteria are included for the San Francisco Bay estuary because high levels of bioaccumulation of selenium in the estuary indicate that the salt water criteria are underprotective for San Francisco Bay.

(iii) The human health criteria shall be applied at the State-adopted 10^{-6} risk level.

(11) *Nevada, EPA Region 9.* (i) All waters assigned the use classifications in Chapter 445 of the Nevada Administrative Code (NAC), Nevada Water Pollution Control Regulations, which are referred to in paragraph (d)(11)(ii) of this section, are subject to the criteria in paragraph (d)(11)(ii) of this section, without exception. These criteria amend the existing State standards contained in the Nevada Water Pollution Control Regulations. More particularly, these criteria amend or supplement the table of numeric standards in NAC 445.1339 for the toxic pollutants identified in paragraph (d)(11)(ii) of this section.

(ii) The following criteria from matrix in paragraph (b)(1) of this section apply to the waters defined in paragraph (d)(11)(i) of this section and identified below:

Water and use classification	Applicable criteria
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D1—pollutants #15, 16, 18, 19, 20, 21, 23, 26, 27, 29, 30, 34, 37, 38, 42, 43, 55, 58–62, 64, 66, 73, 74, 78, 82, 85, 87–89, 91, 92, 96, 98, 100, 103, 104, 105, 114, 116, 117, 118
Waters that the State has included in NAC 445.1339 where Municipal or domestic supply is not a designated use	These waters are assigned the criteria in: Column B1—pollutant #118 Column B2—pollutant #118 Column D2—all pollutants except #2.

(iii) The human health criteria shall be applied at the 10^{-5} risk level, consistent with State policy. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(12) *Alaska, EPA Region 10.* (i) All waters assigned to the following use classifications in the Alaska Administrative Code (AAC), Chapter 18 (i.e., identified in 18 AAC 70.020) are subject to the criteria in paragraph (d)(12)(ii) of this section, without exception:

00859

70.020.(1) (A) Fresh Water
70.020.(1) (A) Water Supply
(i) Drinking, culinary, and food processing,
(iii) Aquaculture;
70.020.(1) (B) Water Recreation
(i) Contact recreation,
(ii) Secondary recreation;
70.020.(1) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife
70.020.(2) (A) Marine Water
70.020.(2) (A) Water Supply
(i) Aquaculture,
70.020.(2) (B) Water Recreation
(i) contact recreation,
(ii) secondary recreation;
70.020.(2) (C) Growth and propagation of fish, shellfish, other aquatic life, and wildlife;
70.020.(2) (D) Harvesting for consumption of raw mollusks or other raw aquatic life.

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(12)(i) of this section:

Use classification	Applicable criteria
(1)(A)(i)	Column D1—#s 16, 18–21, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 53, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88, 89, 91–93, 96, 98, 102–105, 107–111, 117–126.
(1)(A)(iii)	Column D2—#s 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126.
(1)(B)(i), (1)(B)(ii), (1)(C)	Column D2—#s 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126.
(2)(A)(i), (2)(B)(i), and (2)(B)ii, (2)(C), (2)(D)	Column D2—#s 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126.

(iii) The human health criteria shall be applied at the State-proposed risk level of 10^{-5}. To determine appropriate value for carcinogens, see footnote c in the criteria matrix in paragraph (b)(1) of this section.

(13) [Reserved]

(14) *Washington, EPA Region 10.* (i) All waters assigned to the following use classifications in the Washington Administrative Code (WAC), Chapter 173–201 (i.e., identified in WAC 173–201–045) are subject to the criteria in paragraph (d)(14)(ii) of this section, without exception:

173–201–045
Fish and Shellfish
Fish
Water Supply (domestic)
Recreation

(ii) The following criteria from the matrix in paragraph (b)(1) of this section apply to the use classifications identified in paragraph (d)(14)(i) of this section:

Use classification	Applicable criteria
Fish and Shellfish; Fish	These classifications are assigned the criteria in: Column D2—all.
Water Supply (domestic)	These classifications are assigned the criteria in: Column D1—all.
Recreation	This classification is assigned the criteria in: Column D2—Marine waters and freshwaters not protected for domestic water supply.

(iii) The human health criteria shall be applied at the State proposed risk level of 10^{-6}.

[57 FR 60910, Dec. 22, 1992]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §131.36, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§131.37 California.

(a) *Additional criteria.* The following criteria are applicable to waters specified in the Water Quality Control Plan for Salinity for the San Francisco Bay/Sacramento-San Joaquin Delta Estuary, adopted by the California State Water Resources Control Board in State Board Resolution No. 91–34 on May 1, 1991:

00860

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–6587–9]

RIN 2040–AC44

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This final rule promulgates: numeric aquatic life criteria for 23 priority toxic pollutants; numeric human health criteria for 57 priority toxic pollutants; and a compliance schedule provision which authorizes the State to issue schedules of compliance for new or revised National Pollutant Discharge Elimination System permit limits based on the federal criteria when certain conditions are met.

EPA is promulgating this rule based on the Administrator's determination that numeric criteria are necessary in the State of California to protect human health and the environment. The Clean Water Act requires States to adopt numeric water quality criteria for priority toxic pollutants for which EPA has issued criteria guidance, the presence or discharge of which could reasonably be expected to interfere with maintaining designated uses.

EPA is promulgating this rule to fill a gap in California water quality standards that was created in 1994 when a State court overturned the State's water quality control plans which contained water quality criteria for priority toxic pollutants. Thus, the State of California has been without numeric water quality criteria for many priority toxic pollutants as required by the Clean Water Act, necessitating this action by EPA. These Federal criteria are legally applicable in the State of California for inland surface waters, enclosed bays and estuaries for all purposes and programs under the Clean Water Act.

EFFECTIVE DATE: This rule shall be effective May 18, 2000.

ADDRESSES: The administrative record for today's final rule is available for public inspection at the U.S. Environmental Protection Agency, Region 9, Water Division, 75 Hawthorne Street, San Francisco, California 94105, between the hours of 8:00 a.m. and 4:30 p.m. For access to the administrative record, call Diane E. Fleck, P.E., Esq. at 415 744–1984 for an appointment. A reasonable fee will be charged for photocopies.

FOR FURTHER INFORMATION CONTACT: Diane E. Fleck, P.E., Esq. or Philip Woods, U.S. Environmental Protection Agency, Region 9, Water Division, 75 Hawthorne Street, San Francisco, California 94105, 415–744–1984 or 415–744–1997, respectively.

SUPPLEMENTARY INFORMATION: This preamble is organized according to the following outline:

A. Potentially Affected Entities

Citizens concerned with water quality in California may be interested in this rulemaking. Entities discharging pollutants to waters of the United States in California could be affected by this rulemaking since water quality criteria are used by the State in developing National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities that ultimately may be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to surface waters in California or to publicly-owned treatment works.
Municipalities	Publicly-owned treatment works discharging pollutants to surface waters in California

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility might be affected by this action, you should carefully examine the applicability criteria in § 131.38(c). If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Introduction and Overview

1. Introduction

This section introduces the topics which are addressed in the preamble and provides a brief overview of EPA's basis and rationale for promulgating Federal criteria for the State of California. Section C briefly describes the evolution of the efforts to control toxic pollutants; these efforts include the changes enacted in the 1987 CWA Amendments, which are the basis for this rule. Section D summarizes California's efforts since 1987 to implement the requirements of CWA section 303(c)(2)(B) and describes EPA's procedure and actions for determining whether California has fully implemented CWA section 303(c)(2)(B). Section E provides the rationale and approach for developing this final rule, including a discussion of EPA's legal basis for this final rule. Section F describes the development of the criteria included in this rule. Section G summarizes the provisions of the final rule and discusses implementation issues. Sections H, I, J, K , L, M, N, O, P, and Q briefly address the requirements of Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act, the Paperwork Reduction Act, the Endangered Species Act, the Congressional Review Act, Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, the National Technology Transfer and Advancement Act, and Executive Order 13132, Federalism, respectively.

The proposal for this rulemaking was published in the **Federal Register** on August 5, 1997. Changes from the proposal are generally addressed in the body of this preamble and specifically addressed in the response to comments document included in the administrative record for this rulemaking. EPA responded to all comments on the proposed rule, including comments received after the September 26, 1997, deadline. Although EPA is under no legal obligation to respond to late comments, EPA made a policy decision to respond to all comments.

Since detailed information concerning many of the topics in this preamble was published previously in the **Federal Register** in preambles for this and other rulemakings, references are frequently made to those preambles. Those rulemakings include: Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule, 62 FR 42159, August 5, 1997 (referred to as the ''proposed CTR''); Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants, 57 FR 60848, December 22, 1992 (referred to as the ''National Toxics Rule'' or ''NTR''); and the NTR as amended by Administrative Stay of Federal Water Quality Criteria for Metals and Interim Final Rule, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria, 60 FR 22228, May 4, 1995 (referred to as the ''National Toxics Rule [NTR], as amended''). The NTR, as amended, is codified at 40 CFR 131.36. A copy of the proposed CTR and its preamble, and the NTR, as amended, and its preambles are contained in the administrative record for this rulemaking.

EPA is making this final rule effective upon publication. Under the Administrative Procedure Act, 5 U.S.C. 553(d)(3), agencies must generally publish a rule no more than 30 days prior to the effective date of the rule except as otherwise provided for by the Agency for good cause. The purpose of the 30-day waiting period is to give affected parties a reasonable time to adjust their behavior before the final rule takes effect. See *Omnipoint Corp.* v. *F.C.C.,* 78 F.3d 620, 630–631 (D.C. Cir. 1996); *Riverbend Farms, Inc.* v. *Madigan*, 958 F.2d 1479, 1485 (9th Cir. 1992).

In this instance, EPA finds good cause to make the final rule effective upon publication. In order to find good cause, an Agency needs to find that the 30-day period would be: (1) Impracticable, (2) unnecessary, or (3) contrary to the public interest. Here EPA is relying on the second reason to support its finding of good cause. EPA also notes that the State has requested EPA to make the rule immediately effective.

EPA finds that in this instance, waiting 30 days to make the rule effective is unnecessary. As explained in further detail elsewhere in this preamble, this rule is not self implementing; rather it establishes ambient conditions that the State of California will implement in future permit proceedings. These permit proceedings will, by regulation, take longer than 30 days to complete. This means that although the rule is immediately effective, no discharger's conduct would be altered under the rule in less than 30 days, and therefore the 30-day period is unnecessary.

2. Overview

This final rule establishes ambient water quality criteria for priority toxic pollutants in the State of California. The criteria in this final rule will supplement the water quality criteria promulgated for California in the NTR, as amended. In 1991, EPA approved a number of water quality criteria (discussed in section D), for the State of California. Since EPA had approved these criteria, it was not necessary to include them in the 1992 NTR for these criteria. However, the EPA-approved criteria were subsequently invalidated in State litigation. Thus, this final rule contains criteria to fill the gap created by the State litigation.

This final rule does not change or supersede any criteria previously promulgated for the State of California in the NTR, as amended. Criteria which EPA promulgated for California in the NTR, as amended, are footnoted in the final table at 131.38(b)(1), so that readers may see the criteria promulgated in the NTR, as amended, for California and the criteria promulgated through this rulemaking for California in the same table. This final rule is not intended to apply to waters within Indian Country. EPA recognizes that there are possibly waters located wholly or partly in Indian Country that are included in the State's basin plans. EPA will work with the State and Tribes to identify any such waters and determine whether further action to protect water quality in Indian Country is necessary.

This rule is important for several environmental, programmatic and legal reasons. Control of toxic pollutants in surface waters is necessary to achieve the CWA's goals and objectives. Many of California's monitored river miles, lake acres, and estuarine waters have elevated levels of toxic pollutants. Recent studies on California water bodies indicate that elevated levels of toxic pollutants exist in fish tissue which result in fishing advisories or bans. These toxic pollutants can be attributed to, among other sources, industrial and municipal discharges.

Water quality standards for toxic pollutants are important to State and EPA efforts to address water quality problems. Clearly established water quality goals enhance the effectiveness of many of the State's and EPA's water programs including permitting, coastal water quality improvement, fish tissue quality protection, nonpoint source controls, drinking water quality protection, and ecological protection. Numeric criteria for toxic pollutants allow the State and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Numeric criteria also provide a more precise basis for deriving water quality-based effluent limitations (WQBELs) in

National Pollutant Discharge Elimination System (NPDES) permits and wasteload allocations for total maximum daily loads (TMDLs) to control toxic pollutant discharges. Congress recognized these issues when it enacted section 303(c)(2)(B) to the CWA.

While California recognizes the need for applicable water quality standards for toxic pollutants, its adoption efforts have been stymied by a variety of factors. The Administrator has decided to exercise her CWA authorities to move forward the toxic control program, consistent with the CWA and with the State of California's water quality standards program.

Today's action will also help restore equity among the States. The CWA is designed to ensure all waters are sufficiently clean to protect public health and/or the environment. The CWA allows some flexibility and differences among States in their adopted and approved water quality standards, but it should be implemented in a manner that ensures a level playing field among States. Although California has made important progress toward satisfying CWA requirements, it has not satisfied CWA section 303(c)(2)(B) by adopting numeric water quality criteria for toxic pollutants. This section was added to the CWA by Congress in 1987. Prior to today, the State of California had been the only State in the Nation for which CWA section 303(c)(2)(B) had remained substantially unimplemented after EPA's promulgation of the NTR in December of 1992. Section 303(c)(4) of the CWA authorizes the EPA Administrator to promulgate standards where necessary to meet the requirements of the Act. The Administrator determined that this rule was a necessary and important component for the implementation of CWA section 303(c)(2)(B) in California.

EPA acknowledges that the State of California is working to satisfy CWA section 303(c)(2)(B). When the State formally adopts, and EPA approves, criteria consistent with statutory requirements, as envisioned by Congress in the CWA, EPA intends to stay this rule. If within the applicable time frame for judicial review, the States' standards are challenged, EPA will withdraw this rule after such judicial review is complete and the State standards are sustained.

C. Statutory and Regulatory Background

The preamble to the August 5, 1997, proposed rule provided a general discussion of EPA's statutory and regulatory authority to promulgate water quality criteria for the State of California. See 62 FR 42160–42163. EPA is including that discussion in the record for the final rule. Commenters questioned EPA's authority to promulgate certain aspects of the proposal. EPA is responding to those comments in the appropriate sections of this preamble, and in the response to comments document included in the administrative record for this rulemaking. Where appropriate, EPA's responses expand upon the discussion of statutory and regulatory authority found in the proposal.

D. California Water Quality Standards Actions

1. California Regional Water Quality Control Board Basin Plans, and the Inland Surface Waters Plan (ISWP) and the Enclosed Bays and Estuaries Plan (EBEP) of April 1991

The State of California regulates water quality through its State Water Resources Control Board (SWRCB) and through nine Regional Water Quality Control Boards (RWQCBs). Each of the nine RWQCBs represents a different geographic area; area boundaries are generally along watershed boundaries. Each RWQCB maintains a Basin Plan which contains the designated uses of the water bodies within its respective geographic area within California. These designated uses (or ''beneficial uses'' under State law) together with legally-adopted criteria (or ''objectives'' under State law), comprise water quality standards for the water bodies within each of the Basin areas. Each of the nine RWQCBs undergoes a triennial basin planning review process, in compliance with CWA section 303. The SWRCB provides assistance to the RWQCBs.

Most of the Basin Plans contain conventional pollutant objectives such as dissolved oxygen. None of the Basin Plans contains a comprehensive list of priority toxic pollutant criteria to satisfy CWA section 303(c)(2)(B). The nine RWQCBs and the SWRCB had intended that the priority toxic pollutant criteria contained in the three SWRCB statewide plans, the Inland Surface Waters Plan (ISWP), the Enclosed Bays and Estuaries Plan (EBEP), and the Ocean Plan, apply to all basins and satisfy CWA section 303(c)(2)(B).

On April 11, 1991, the SWRCB adopted two statewide water quality control plans, the ISWP and the EBEP. These statewide plans contained narrative and numeric water quality criteria for toxic pollutants, in part to satisfy CWA section 303(c)(2)(B). The water quality criteria contained in the SWRCB statewide plans, together with the designated uses in each of the Basin Plans, created a set of water quality standards for waters within the State of California.

Specifically, the two plans established water quality criteria or objectives for all fresh waters, bays and estuaries in the State. The plans contained water quality criteria for some priority toxic pollutants, provisions relating to whole effluent toxicity, implementation procedures for point and nonpoint sources, and authorizing compliance schedule provisions. The plans also included special provisions affecting waters dominated by reclaimed water (labeled as Category (a) waters), and waters dominated by agricultural drainage and constructed agricultural drains (labeled as Category (b) and (c) waters, respectively).

2. EPA's Review of California Water Quality Standards for Priority Toxic Pollutants in the ISWP and EBEP, and the National Toxics Rule

The EPA Administrator has delegated the responsibility and authority for review and approval or disapproval of all new or revised State water quality standards to the EPA Regional Administrators (see 40 CFR 131.21). Thus, State actions under CWA section 303(c)(2)(B) are submitted to the appropriate EPA Regional Administrator for review and approval.

In mid-April 1991, the SWRCB submitted to EPA for review and approval the two statewide water quality control plans, the ISWP and the EBEP. On November 6, 1991, EPA Region 9 formally concluded its review of the SWRCB's plans. EPA approved the narrative water quality criterion and the toxicity criterion in each of the plans. EPA also approved the numeric water quality criteria contained in both plans, finding them to be consistent with the requirements of section 303(c)(2)(B) of the CWA and with EPA's national criteria guidance published pursuant to section 304(a) of the CWA.

EPA noted the lack of criteria for some pollutants, and found that, because of the omissions, the plans did not fully satisfy CWA section 303(c)(2)(B). The plans did not contain criteria for all listed pollutants for which EPA had published national criteria guidance. The ISWP contained human health criteria for only 65 pollutants, and the EBEP contained human health criteria for only 61 pollutants for which EPA had issued section 304(a) guidance criteria. Both the ISWP and EBEP contained aquatic life criteria for all pollutants except cyanide and chromium III (freshwater only) for which EPA has CWA section

304(a) criteria guidance. The SWRCB's administrative record stated that all priority pollutants with EPA criteria guidance were likely to be present in California waters. However, the SWRCB's record contained insufficient information to support a finding that the excluded pollutants were not reasonably expected to interfere with designated uses of the waters of the State.

Although EPA approved the statewide selenium objective in the ISWP and EBEP, EPA disapproved the objective for the San Francisco Bay and Delta, because there was clear evidence that the objective would not protect the designated fish and wildlife uses (the California Department of Health Services had issued waterfowl consumption advisories due to selenium concentrations, and scientific studies had documented selenium toxicity to fish and wildlife). EPA restated its commitment to object to National Pollutant Discharge Elimination System (NPDES) permits issued for San Francisco Bay that contained effluent limits based on an objective greater than 5 parts per billion (ppb) (four day average) and 20 ppb (1 hour average), the freshwater criteria. EPA reaffirmed its disapproval of Californias' site-specific selenium objective for portions of the San Joaquin River, Salt Slough, and Mud Slough. EPA also disapproved of the categorical deferrals and exemptions. These disapprovals included the disapproval of the State's deferral of water quality objectives to effluent dominated streams (Category a) and to streams dominated by agricultural drainage (Category b), and the disapproval of the exemption of water quality objectives to constructed agricultural drains (Category c). EPA found the definitions of the categories imprecise and overly broad which could have led to an incorrect interpretation.

Since EPA had disapproved portions of each of the California statewide plans which were necessary to satisfy CWA section 303(c)(2)(B), certain disapproved aspects of California's water quality standards were included in EPA's promulgation of the National Toxics Rule (NTR) (40 CFR 131.36, 57 FR 60848). EPA promulgated specific criteria for certain water bodies in California.

The NTR was amended, effective April 14, 1995, to stay certain metals criteria which had been promulgated as total recoverable. Effective April 15, 1995, EPA promulgated interim final metals criteria as dissolved concentrations for those metals which had been stayed (Administrative Stay of Federal Water Quality Criteria for Metals and Interim Final Rule, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance—Revision of Metals Criteria; 60 FR 22228, 22229, May 4, 1995 [the NTR, as amended]). The stay was in response to a lawsuit against EPA challenging, among other issues, metals criteria expressed as total recoverable concentrations. A partial Settlement Agreement required EPA to stay specific metals criteria in the NTR. EPA then promulgated certain metals criteria in the dissolved form through the use of conversion factors. These factors are listed in the NTR, as amended. A scientific discussion of these criteria is found in a subsequent section of this preamble.

Since certain criteria have already been promulgated for specific water bodies in the State of California in the NTR, as amended, they are not within the scope of today's final rule. However, for clarity in reading a comprehensive rule for the State of California, these criteria are incorporated into 40 CFR 131.38(d)(2). Footnotes to the Table in 40 CFR 131.38(b)(1) and 40 CFR 131.38(d)(3) clarify which criteria (and for which specific water bodies) were promulgated by the NTR, as amended, and are therefore excluded from this final rule. The appropriate (freshwater or saltwater) aquatic life criteria which were promulgated in the NTR, as amended, for all inland surface waters and enclosed bays and estuaries include: chromium III and cyanide. The appropriate (water and organism or organism only) human health criteria which were promulgated in the NTR, as amended, for all inland surface waters and enclosed bays and estuaries include:

antimony
thallium
asbestos
acrolein
acrylonitrile
carbon tetrachloride
chlorobenzene
1,2-dichloroethane
1,1-dichloroethylene
1,3-dichloropropylene
ethylbenzene
1,1,2,2-tetrachloroethane
tetrachloroethylene
1,1,2-trichloroethane
trichloroethylene
vinyl chloride
2,4-dichlorophenol
2-methyl-4,6-dinitrophenol
2,4-dinitrophenol
benzidine
bis(2-chloroethyl)ether
bis(2-ethylhexyl)phthalate
3,3-dichlorobenzidine
diethyl phthalate
dimethyl phthalate
di-n-butyl phthalate
2,4-dinitrotoluene
1,2-diphenylhydrazine
hexachlorobutadiene
hexachlorocyclopentadiene
hexachloroethane
isophorone
nitrobenzene
n-nitrosodimethylamine
n-nitrosodiphenylamine

Other pollutant criteria were promulgated in the NTR, as amended, for specific water bodies, but not all inland surface waters and enclosed bays and estuaries.

3. Status of Implementation of CWA Section 303(c)(2)(B)

Shortly after the SWRCB adopted the ISWP and EBEP, several dischargers filed suit against the State alleging that it had not adopted the two plans in compliance with State law. The plaintiffs in a consolidated case included: the County of Sacramento, Sacramento County Water Agency; Sacramento Regional County Sanitation District; the City of Sacramento; the City of Sunnyvale; the City of San Jose; the City of Stockton; and Simpson Paper Company.

The dischargers alleged that the State had not adopted the ISWP and EBEP in compliance with the California Administrative Procedures Act (Gov Code. Section 11340, *et seq.*), the California Environmental Quality Act (Pub. Re Code, Section 21000, *et seq.*), and the Porter-Cologne Act (Wat. Code, Section 13200, *et seq.*). The allegation that the State did not sufficiently consider economics when adopting water quality objectives, as allegedly required by Section 13241 of the Porter Cologne Act, was an important issue in the litigation.

In October of 1993, the Superior Court of California, County of Sacramento, issued a tentative decision in favor of the dischargers. In March of 1994, the Court issued a substantively similar final decision in favor of the dischargers. Final judgments from the Court in July of 1994 ordered the SWRCB to rescind the ISWP and EBEP. On September 22, 1994, the SWRCB formally rescinded the two statewide water quality control plans. The State is currently in the process of readopting water quality control plans for inland surface waters, enclosed bays and estuaries.

CWA section 303(c)(2)(B) was fully implemented in the State of California from December of 1992, when the NTR was promulgated, until September of 1994, when the SWRCB was required to rescind the ISWP and EBEP. The provisions for California in EPA's NTR together with the approved portions of

California's ISWP and EBEP implemented the requirements of CWA section 303(c)(2)(B). However, since September of 1994, when the SWRCB rescinded the ISWP and EBEP, the requirements of section 303(c)(2)(B) have not been fully implemented in California.

The scope of today's rule is to re-establish criteria for the remaining priority toxic pollutants to meet the requirements of section 303(c)(2)(B) of the CWA. Pursuant to section 303(c)(4), the Administrator has determined that it is necessary to include in today's action criteria for priority toxic pollutants, which are not covered by the NTR, as amended, or by the State through EPA-approved site-specific criteria, for waters of the United States in the State of California.

4. State-Adopted, Site-Specific Criteria for Priority Toxic Pollutants

The State has the discretion to develop site-specific criteria when appropriate e.g., when statewide criteria appear over-or under-protective of designated uses. Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete, the criteria become State law.

These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted under the State's process and has become State law.

a. State-Adopted Site-Specific Criteria Under EPA Review

The State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of the Basin Plans have completed the State review and adoption process and have been submitted to EPA for review and approval. Some of the Basin Plans contain site-specific criteria. In these cases, the State-adopted site-specific criteria are used for water quality programs.

EPA has not yet concluded consultation under the Endangered Species Act with the U.S. Department of Interior, Fish and Wildlife Service, and the U.S. Department of Commerce, National Marine Fisheries Service, on EPA's tentative approval/disapproval actions on the RWQCB Basin Plans. In this situation, the more stringent of the two criteria (the State-adopted site-specific criteria in the RWQCB Basin Plans, or the Federal criteria in this final rule), would be used for water quality programs including the calculation of water quality-based effluent criteria in National Pollutant Discharge Elimination System (NPDES) permits.

b. State-Adopted Site-Specific Criteria With EPA Approval

In several cases, the EPA Regional Administrator has already reviewed and approved State-adopted site-specific criteria within the State of California. Several of these cases are discussed in this section. All of the EPA approval letters referenced in today's preamble are contained in the administrative record for today's rule.

Sacramento River: EPA has approved site-specific acute criteria for copper, cadmium and zinc in the Sacramento River, upstream of Hamilton City, in the Central Valley Region (RWQCB for the Central Valley Region) of the State of California. EPA approved these site-specific criteria by letter dated August 7, 1985. Specifically, EPA approved for the Sacramento River (and tributaries) above Hamilton City, a copper criterion of 5.6 µg/l (maximum), a zinc criterion of 16 µg/l (maximum) and a cadmium criterion of 0.22 µg/l (maximum), all in the dissolved form using a hardness of 40 mg/l as CaCO3. (These criteria were actually adopted by the State and approved by EPA as equations which vary with hardness.) These ''maximum'' criteria correspond to acute criteria in today's final rule. Therefore, Federal acute criteria for copper, cadmium, and zinc for the Sacramento River (and tributaries) above Hamilton City are not necessary to protect the designated uses and are not included in the final rule. However, the EPA Administrator is making a finding that it is necessary to include chronic criteria for copper, cadmium and zinc for the Sacramento River (and tributaries) above Hamilton City, as part of the statewide criteria promulgated in today's final rule.

San Joaquin River: The selenium criteria in this rule are not applicable to portions of the San Joaquin River, in the Central Valley Region, because selenium criteria have been either previously approved by EPA or previously promulgated by EPA as part of the NTR. EPA approved and disapproved State-adopted site-specific selenium criteria in portions of the San Joaquin River, in the Central Valley Region of the State of California (RWQCB for the Central Valley Region). EPA's determination on these site-specific criteria is contained in a letter dated April 13, 1990.

Specifically, EPA approved for the San Joaquin River, mouth of Merced River to Vernalis, an aquatic life selenium criterion of 12 µg/l (maximum with the understanding that the instantaneous maximum concentration may not exceed the objective more than once every three years). Today's final rule does not affect this Federally-approved, State-adopted site-specific acute criterion, and it remains in effect for the San Joaquin River, mouth of Merced River to Vernalis. Therefore, an acute criterion for selenium in the San Joaquin River, mouth of Merced River to Vernalis is not necessary to protect the designated use and thus is not included in this final rule.

By letter dated April 13, 1990, EPA also approved for the San Joaquin River, mouth of Merced River to Vernalis, a State-adopted site-specific aquatic life selenium criterion of 5 µg/l (monthly mean); however, EPA disapproved a State-adopted site-specific selenium criterion of 8 µg/l (monthly mean—critical year only) for these waters. Subsequently, EPA promulgated a chronic selenium criterion of 5 µg/l (4 day average) for waters of the San Joaquin River from the mouth of the Merced River to Vernalis in the NTR. This chronic criterion applies to all water quality programs concerning the San Joaquin River, mouth of Merced River to Vernalis. Today's final rule does not affect the Federally-promulgated chronic selenium criterion of 5 µg/l (4 day average) set forth in the NTR. This previously Federally-promulgated criterion remains in effect for the San Joaquin River, mouth of Merced River to Vernalis.

Grassland Water District, San Luis National Wildlife Refuge, and Los Banos State Wildlife Refuge: EPA approved for the Grassland Water District, San Luis National Wildlife Refuge, and Los Banos State Wildlife Refuge, a State-adopted site-specific aquatic life selenium criterion of 2 µg/l (monthly mean) by letter dated April 13, 1990. This Federally-approved, State-adopted site-specific chronic criterion remains in effect for the Grassland Water District, San Luis National Wildlife Refuge and Los Banos State Wildlife Refuge. Therefore it is not necessary to include in today's final rule, a chronic criterion for selenium for the Grassland Water District, San Luis National Wildlife Refuge and Los Banos State Wildlife Refuge, and thus, it is not included in this final rule.

San Francisco Regional Board Basin Plan of 1986: EPA approved several priority toxic pollutant objectives (CWA criteria) that were contained in the1986 San Francisco Regional Board Basin Plan, as amended by SWRCB Resolution Numbers 87–49, 87–82 and 87–92, by letters dated September 2, 1987 and December 24, 1987. This Basin Plan, the SWRCB Resolutions, and the EPA approval letters are contained in the administrative record for this rulemaking. It is not necessary to include these criteria for priority toxic pollutants that are contained in the San Francisco Regional Board's 1986 Basin Plan as amended, and approved by EPA. Priority pollutants in this situation are footnoted in the matrix at 131.38(b)(1) with footnote ''b.'' Where gaps exist in the State adoption and EPA approval of priority toxic pollutant objectives, the criteria in today's rule apply.

EPA is assigning ''human health, water and organism consumption'' criteria to waters with the States' municipal or ''MUN'' beneficial use designation in the Basin Plan. Also, some pollutants regulated through the Basin Plan have different averaging periods, *e.g.,* one hour as compared with the rule's ''short-term.'' However, where classes of chemicals, such as polynuclear aromatic hydrocarbons, or PAHs, and phenols, are regulated through the Basin Plan, but not specific chemicals within the category, specific chemicals within the category are regulated by today's rule.

E. Rationale and Approach for Developing the Final Rule

This section explains EPA's legal basis for today's final rule, and discusses EPA's general approach for developing the specific requirements for the State of California.

1. Legal Basis

CWA section 303(c) specifies that adoption of water quality standards is primarily the responsibility of the States. However, CWA section 303(c) also describes a role for the Federal government to oversee State actions to ensure compliance with CWA requirements. If EPA's review of the States' standards finds flaws or omissions, then the CWA authorizes EPA to correct the deficiencies (see CWA section 303(c)(4)). This water quality standards promulgation authority has been used by EPA to issue final rules on several separate occasions, including the NTR, as amended, which promulgated criteria similar to those included here for a number of States. These actions have addressed both insufficiently protective State criteria and/or designated uses and failure to adopt needed criteria. Thus, today's action is not unique.

The CWA in section 303(c)(4) provides two bases for promulgation of Federal water quality standards. The first basis, in paragraph (A), applies when a State submits new or revised standards that EPA determines are not consistent with the applicable requirements of the CWA. If, after EPA's disapproval, the State does not amend its rules so as to be consistent with the CWA, EPA is to promptly propose appropriate Federal water quality standards for that State. The second basis for an EPA action is in paragraph (B), which provides that EPA shall promptly initiate promulgation ''* * * in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this Act.'' EPA is using section 303(c)(4)(B) as the legal basis for today's final rule.

As discussed in the preamble to the NTR, the Administrator's determination under CWA section 303(c)(4) that criteria are necessary to meet the requirements of the Act could be supported in several ways. Consistent with EPA's approach in the NTR, EPA interprets section 303(c)(2)(B) of the CWA to allow EPA to act where the State has not succeeded in establishing numeric water quality standards for toxic pollutants. This inaction can be the basis for the Administrator's determination under section 303(c)(4) that new or revised criteria are necessary to ensure designated uses are protected.

EPA does not believe that it is necessary to support the criteria in today's rule on a pollutant-specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA section 304(a) criteria guidance there is a ''discharge or presence'' of that pollutant which could reasonably ''be expected to interfere with'' the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) to the CWA. Moreover, because these criteria are ambient criteria that define attainment of the designated uses, their application to all water bodies will result in additional controls on dischargers only where necessary to protect the designated uses.

EPA's interpretation of section 303(c)(2)(B) is supported by the language of the provision, the statutory framework and purpose of section 303, and the legislative history. In adding section 303(c)(2)(B) to the CWA, Congress understood the existing requirements in section 303(c)(1) for States to conduct triennial reviews of their water quality standards and submit the results of those reviews to EPA and in section 303(c)(4)(B) for promulgation. CWA section 303(c) includes numerous deadlines and section 303(c)(4) directs the Administrator to act ''promptly'' where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. The legislative history of the provision demonstrates that chief Senate sponsors, including Senators Stafford, Chaffee and others wanted the provision to eliminate State and EPA delays and force quick action. Thus, to interpret CWA section 303(c)(2)(B) and (c)(4) to require such a cumbersome pollutant specific effort on each stream segment would essentially render section 303(c)(2)(B) meaningless. The provision and its legislative background indicate that the Administrator's determination to invoke section 303(c)(4)(B) authority can be met by the Administrator making a generic finding of inaction by the State without the need to develop pollutant specific data for individual stream segments. Finally, the reference in section 303(c)(2)(B) to section 304(a) criteria suggests that section 304(a) criteria serve as default criteria; that once EPA has issued them, States were to adopt numeric criteria for those pollutants based on the 304(a) criteria, unless they had other scientifically defensible criteria. EPA also notes that this rule follows the approach EPA took nationally in promulgating the NTR for States that failed to comply with CWA section 303(c)(2)(B). 57 FR 60848, December 22, 1992. EPA incorporates the discussion in the NTR preamble as part of this rulemaking record.

This determination is supported by information in the rulemaking record showing the discharge or presence of priority toxic pollutants throughout the State. While this data is not necessarily complete, it constitutes a strong record supporting the need for numeric criteria for priority toxic pollutants with section 304(a) criteria guidance where the State does not have numeric criteria.

Today's final rule would not impose any undue or inappropriate burden on the State of California or its dischargers. It merely puts in place numeric criteria

for toxic pollutants that are already used in other States in implementing CWA programs. Under this rulemaking, the State of California retains the ability to adopt alternative water quality criteria simply by completing its criteria adoption process. Upon EPA approval of those criteria, EPA will initiate action to stay the Federally-promulgated criteria and subsequently withdraw them.

2. Approach for Developing This Rule

In summary, EPA developed the criteria promulgated in today's final rule as follows. Where EPA promulgated criteria for California in the NTR, EPA has not acted to amend the criteria in the NTR. Where criteria for California were not included in the NTR, EPA used section 304(a) National criteria guidance documents as a starting point for the criteria promulgated in this rule. EPA then determined whether new information since the development of the national criteria guidance documents warranted any changes. New information came primarily from two sources. For human health criteria, new or revised risk reference doses and cancer potency factors on EPA's Integrated Risk Information System (IRIS) as of October 1996 form the basis for criteria values (see also 63 FR 68354). For aquatic life criteria, updated data sets resulting in revised criteria maximum concentrations (CMCs) and criteria continuous concentrations (CCCs) formed the basis for differences from the national criteria guidance documents. Both of these types of changes are discussed in more detail in the following sections. This revised information was used to develop the water quality criteria promulgated here for the State of California.

F. Derivation of Criteria

1. Section 304(a) Criteria Guidance Process

Under CWA section 304(a), EPA has developed methodologies and specific criteria guidance to protect aquatic life and human health. These methodologies are intended to provide protection for all surface waters on a national basis. The methodologies have been subject to public review, as have the individual criteria guidance documents. Additionally, the methodologies have been reviewed by EPA's Science Advisory Board (SAB) of external experts.

EPA has included in the record of this rule the aquatic life methodology as described in ''Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses'' to the ''Water Quality Criteria Documents; Availability'' (45 FR 79341, November 28, 1980) as amended by the ''Summary of Revisions to Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses'' (50 FR 30792, July 29, 1985). (**Note:** Throughout the remainder of this preamble, this reference is described as the 1985 Guidelines. Any page number references are to the actual guidance document, not the notice of availability in the **Federal Register**. A copy of the 1985 Guidelines is available through the National Technical Information Service (PB85–227049), is in the administrative record for this rule, and is abstracted in Appendix A of *Quality Criteria for Water,* 1986.) EPA has also included in the administrative record of this rule the human health methodology as described in ''Appendix C—Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents'' (45 FR 79347, November 28, 1980). (Note: Throughout the remainder of this preamble, this reference is described as the Human Health Guidelines or the 1980 Guidelines.) EPA also recommends that the following be reviewed: ''Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses,'' (45 FR 79357, November 28, 1980); ''Appendix E—Responses to Public Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria'' (45 FR 79368, November 28, 1980); and ''Appendix B—Response to Comments on Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses'' (50 FR 30793, July 29, 1985). EPA placed into the administrative record for this rulemaking the most current individual criteria guidance for the priority toxic pollutants included in today's rule. (**Note:** All references to appendices are to the associated **Federal Register** publication.)

EPA received many comments related to the issue of what criteria should apply in the CTR if the CWA section 304(a) criteria guidance is undergoing re-evaluation, or if new data are developed that may affect a recommended criterion. As science is always evolving, EPA is faced with the challenge of promulgating criteria that reflect the best science and sound science. EPA addressed this challenge in some detail in its **Federal Register** notice that contained the Agency's current section 304(a) criteria guidance (63 FR 68335, December 10, 1998). There, EPA articulated its policy, reiterated here, that the existing criteria guidance represent the Agency's best assessment until such time as EPA's re-evaluation of a criteria guidance value for a particular chemical is complete. The reason for this is that both EPA's human health criteria guidance and aquatic life criteria guidance are developed taking into account numerous variables. For example, for human health criteria guidance, EPA evaluates many diverse toxicity studies, whose results feed into a reference dose or cancer potency estimate that, along with a number of exposure factors and determination of risk level, results in a guidance criterion. For aquatic life, EPA evaluates many diverse aquatic toxicity studies to determine chronic and acute toxicity taking into account how other factors (such as pH, temperature or hardness) affect toxicity. EPA also, to the extent possible, addresses bioaccumulation or bioconcentration. EPA then uses this toxicity information along with exposure information to determine the guidance criterion. Importantly, EPA subjects such evaluation to peer review and/or public comment.

For these reasons, EPA generally does not make a change to the 304(a) criteria guidance based on a partial picture of the evolving science. This makes sense, because to address one piece of new data without looking at all relevant data is less efficient and results in regulatory impacts that may go back and forth, when in the end, the criteria guidance value does not change that much. Certain new changes, however, do warrant change in criteria guidance, such as a change in a value in EPA's Integrated Risk Information System (IRIS) because it represents the Agency consensus about human health impacts. These changes are sufficiently examined across the Agency such that EPA believes they can be incorporated into EPA's water quality criteria guidance. EPA has followed this approach in the CTR. Included in the administrative record for today's rule is a document entitled ''Status of Clean Water Act Section 304(a) Criteria'' which further explains EPA's policy on managing change to criteria guidance.

2. Aquatic Life Criteria

Aquatic life criteria may be expressed in numeric or narrative form. EPA's 1985 Guidelines describe an objective, internally consistent and appropriate way of deriving chemical-specific, numeric water quality criteria for the protection of the presence of, as well as

the uses of, both fresh and salt water aquatic organisms.

An aquatic life criterion derived using EPA's CWA section 304(a) method ''might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses.'' (45 FR 79341.) EPA's guidelines are designed to derive criteria that protect aquatic communities. EPA's 1985 Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of substantial overprotection or underprotection. As discussed in detail below, there are several individual factors which may make the criteria somewhat overprotective or underprotective. The approach EPA is using is believed to be as well balanced as possible, given the state of the science.

Numerical aquatic life criteria derived using EPA's 1985 Guidelines are expressed as short-term and long-term averages, rather than one number, in order that the criterion more accurately reflect toxicological and practical realities. The combination of a criterion maximum concentration (CMC), a short-term concentration limit, and a criterion continuous concentration (CCC), a four-day average concentration limit, are designed to provide protection of aquatic life and its uses from acute and chronic toxicity to animals and plants, without being as restrictive as a one-number criterion would have to be (1985 Guidelines, pages 4 & 5). The terms CMC and CCC are the formal names for the two (acute and chronic) values of a criterion for a pollutant; however, this document will also use the informal synonyms acute criterion and chronic criterion.

The two-number criteria are intended to identify average pollutant concentrations which will produce water quality generally suited to maintenance of aquatic life and designated uses while restricting the duration of excursions over the average so that total exposures will not cause unacceptable adverse effects. Merely specifying an average value over a time period may be insufficient unless the time period is short, because excursions higher than the average may kill or cause substantial damage in short periods.

A minimum data set of eight specified families is recommended for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. EPA's application of its guidelines to develop the criteria matrix in this rule is judged by the Agency to be appropriate for all waters of the United States (U.S.), and to all ecosystems (1985 Guidelines, page 4) including those waters of the U.S. and ecosystems in the State of California.

Fresh water and salt water (including both estuarine and marine waters) have different chemical compositions, and freshwater and saltwater species often do not inhabit the same water. To provide additional accuracy, criteria are developed for fresh water and for salt water.

For this rule, EPA updated freshwater aquatic life criteria contained in CWA section 304(a) criteria guidance first published in the early 1980's and later modified in the NTR, as amended, for the following ten pollutants: arsenic, cadmium, chromium (VI), copper, dieldrin, endrin, lindane (gamma BHC), nickel, pentachlorophenol, and zinc. The updates used as the basis for this rule are explained in a technical support document entitled, *1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water* (U.S. EPA–820–B–96–001, September 1996), available in the administrative record to this rulemaking; this document presents the derivation of each of the final CMCs and CCCs and the toxicity studies from which the updated freshwater criteria for the ten pollutants were derived.

The polychlorinated biphenyls (PCB) criteria in the criteria matrix for this rule differs from that in the NTR, as amended; for this rule, the criteria are expressed as the sum of seven aroclors, while for the NTR, as amended, the criteria are expressed for each of seven aroclors. The aquatic life criteria for PCBs in the CTR are based on the criteria contained in the 1980 criteria guidance document for PCBs which is included in the administrative record for this rule. This criteria document explains the derivation of aquatic life criteria based on total PCBs. For more information see the Response to Comments document for this rule. Today's chronic aquatic life criteria for PCBs are based on a final residue value (FRV). In EPA's guidelines for deriving aquatic life criteria, an FRV-based criterion is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting the wildlife that consume aquatic life.

The proposed CTR included an updated freshwater and saltwater aquatic life criteria for mercury. In today's final rule, EPA has reserved the mercury criteria for freshwater and saltwater aquatic life, but is promulgating human health criteria for mercury for all surface waters in California. In some instances, the human health mercury criteria included in today's final rule may not protect some aquatic species or threatened or endangered species. In such instances, more stringent mercury limits may be determined and implemented through use of the State's narrative criterion. The reasons for reserving the mercury aquatic life numbers are explained in further detail in Section L, Endangered Species Act.

a. Freshwater Acute Selenium Criterion

EPA proposed a different freshwater acute aquatic life criterion for selenium for this rule than was promulgated in the NTR, as amended. EPA's proposed action was consistent with EPA's proposed selenium criterion maximum concentration for the Water Quality Guidance for the Great Lakes System (61 FR 58444, November 14, 1996). This proposal took into account data showing that selenium's two most prevalent oxidation states, selenite and selenate, present differing potentials for aquatic toxicity, as well as new data which indicated that various forms of selenium are additive. Additivity increases the toxicity of mixtures of different forms of the pollutant. The proposed approach produces a different selenium acute criterion concentration, or CMC, depending upon the relative proportions of selenite, selenate, and other forms of selenium that are present.

The preamble to the August 5, 1997, proposed rule provided a lengthy discussion of this proposed criterion for the State of California. See 62 FR 42160–42208. EPA incorporates that discussion here as part of this rulemaking record. In 1996, a similar discussion was included in the proposed rule for the Great Lakes System. Commenters questioned several aspects of the Great Lakes proposal. EPA is continuing to respond to those comments, and to follow up with additional literature review and toxicity testing. In addition, the U.S. FWS and U.S. NMFS (collectively, the Services) are concerned that EPA's proposed criterion may not be sufficiently protective of certain threatened and endangered species in California. Because the Services believe there is a lack of data to show for certain that the proposed criterion would not affect threatened and endangered species, the Services prefer that EPA further investigate the protectiveness of the

criterion before finalizing the proposed criterion. Therefore, EPA is not promulgating a final acute freshwater selenium criterion at this time.

b. Dissolved Metals Criteria

In December of 1992, in the NTR, EPA promulgated water quality criteria for several States that had failed to meet the requirements of CWA section 303(c)(2)(B). Included among the water quality criteria promulgated were numeric criteria for the protection of aquatic life for 11 metals: arsenic, cadmium, chromium (III), chromium (VI), copper, lead, mercury, nickel, selenium, silver and zinc. Criteria for two metals applied to the State of California: chromium III and selenium.

The Agency received extensive public comment during the development of the NTR regarding the most appropriate approach for expressing the aquatic life metals criteria. The principal issue was the correlation between metals that are measured and metals that are bioavailable and toxic to aquatic life. It is now the Agency's policy that the use of dissolved metal to set and measure compliance with aquatic life water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of the metal in the water column than does total recoverable metal.

Since EPA's previous aquatic life criteria guidance had been expressed as total recoverable metal, to express the criteria as dissolved, conversion factors were developed to account for the possible presence of particulate metal in the laboratory toxicity tests used to develop the total recoverable criteria. EPA included a set of recommended freshwater conversion factors with its Metals Policy (see Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria, Martha G. Prothro, Acting Assistant Administrator for Water, October 1, 1993). Based on additional laboratory evaluations that simulated the original toxicity tests, EPA refined the procedures used to develop freshwater conversion factors for aquatic life criteria. These new conversion factors were made available for public review and comment in the amendments to the NTR on May 4, 1995, at 60 FR 22229. They are also contained in today's rule at 40 CFR 131.38(b)(2).

The preamble to the August 5, 1997, proposed rule provided a more detailed discussion of EPA's metals policy concerning the aquatic life water quality criteria for the State of California. See 62 FR 42160–42208. EPA incorporates that discussion here as part of this rulemaking record. Many commenters strongly supported the Agency's policy on dissolved metals aquatic life criteria. A few commenters expressed an opinion that the metals policy may not provide criteria that are adequately protective of aquatic or other species. Responses to those comments are contained in a memo to the CTR record entitled ''Discussion of the Use of Dissolved Metals in the CTR'' (February 1, 2000, Jeanette Wiltse) and EPA's response to comments document which are both contained in the administrative record for the final rule.

Calculation of Aquatic Life Dissolved Metals Criteria: Metals criteria values for aquatic life in today's rule in the matrix at 131.38(b)(1) are shown as dissolved metal. These criteria have been calculated in one of two ways. For freshwater metals criteria that are hardness-dependent, the metals criteria value is calculated separately for each hardness using the table at 40 CFR 131.38(b)(2). (The hardness-dependent freshwater values presented in the matrix at 40 CFR 131.38(b)(1) have been calculated using a hardness of 100 mg/l as CaCO3 for illustrative purposes only.) The hardness-dependent criteria are then multiplied by the appropriate conversion factors in the table at 40 CFR 131.38(b)(2). Saltwater and freshwater metals criteria that are not hardness-dependent are calculated by taking the total recoverable criteria values (from EPA's national section 304(a) criteria guidance, as updated and described in section F.2.a.) before rounding, and multiplying them by the appropriate conversion factors. The final dissolved metals criteria values, as they appear in the matrix at 40 CFR 131.38(b)(1), are rounded to two significant figures.

Translators for Dissolved to Total Recoverable Metals Limits: EPA's National Pollutant Discharge Elimination System (NPDES) regulations require that limits for metals in permits be stated as total recoverable in most cases (see 40 CFR 122.45(c)) except when an effluent guideline specifies the limitation in another form of the metal, the approved analytical methods measure only dissolved metal, or the permit writer expresses a metal's limit in another form (*e.g.,* dissolved, specific valence, or total) when required to carry out provisions of the CWA. This is because the chemical conditions in ambient waters frequently differ substantially from those in the effluent and these differences result in changes in the partitioning between dissolved and absorbed forms of the metal. This means that if effluent limits were expressed in the dissolved form, additional particulate metal could dissolve in the receiving water causing the criteria to be exceeded. Expressing criteria as dissolved metal requires translation between different metal forms in the calculation of the permit limit so that a total recoverable permit limit can be established that will achieve water quality standards. Thus, it is important that permitting authorities and other authorities have the ability to translate between dissolved metal in ambient waters and total recoverable metal in effluent.

EPA has completed guidance on the use of translators to convert from dissolved metals criteria to total recoverable permit limits. The document, *The Metals Translator: Guidance for Calculating a Total Recoverable Permit Limit From a Dissolved Criterion* (EPA 823–B–96–007, June 1996), is included in the administrative record for today's rule. This technical guidance examines how to develop a metals translator which is defined as the fraction of total recoverable metal in the downstream water that is dissolved, *i.e.,* the dissolved metal concentration divided by the total recoverable metal concentration. A translator may take one of three forms: (1) It may be assumed to be equivalent to the criteria guidance conversion factors; (2) it may be developed directly as the ratio of dissolved to total recoverable metal; and (3) it may be developed through the use of a partition coefficient that is functionally related to the number of metal binding sites on the adsorbent in the water column (*e.g.,* concentrations of total suspended solids or TSS). This guidance document discusses these three forms of translators, as well as field study designs, data generation and analysis, and site-specific study plans to generate site-specific translators.

California Regional Water Quality Control Boards may use any of these methods in developing water quality-based permit limits to meet water quality standards based on dissolved metals criteria. EPA encourages the State to adopt a statewide policy on the use of translators so that the most appropriate method or methods are used consistently within California.

c. Application of Metals Criteria

In selecting an approach for implementing the metals criteria, the principal issue is the correlation between metals that are measured and metals that are biologically available and toxic. In order to assure that the metals criteria are appropriate for the chemical conditions under which they are applied, EPA is providing for the

adjustment of the criteria through application of the ''water-effect ratio'' procedure. EPA notes that performing the testing to use a site-specific water-effect ratio is optional on the part of the State.

In the NTR, as amended, EPA identified the water-effect ratio (WER) procedure as a method for optional site-specific criteria development for certain metals. The WER approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory waters. A WER is an appropriate measure of the toxicity of a material obtained in a site water divided by the same measure of the toxicity of the same material obtained simultaneously in a laboratory dilution water.

On February 22, 1994, EPA issued *Interim Guidance on the Determination and Use of the Water-Effect Ratios for Metals* (EPA 823-B–94–001) now incorporated into the updated Second Edition of the Water Quality Standards Handbook, Appendix L. A copy of the Handbook is contained in the administrative record for today's rule. In accordance with the WER guidance and where application of the WER is deemed appropriate, EPA strongly encourages the application of the WER on a watershed or water body basis as part of a water quality criteria in California as opposed to the application on a discharger-by-discharger basis through individual NPDES permits. This approach is technically sound and an efficient use of resources. However, discharger specific WERs for individual NPDES permit limits are possible and potentially efficient where the NPDES discharger is the only point source discharger to a specific water body.

The rule requires a default WER value of 1.0 which will be assumed, if no site-specific WER is determined. To use a WER other than the default of 1.0, the rule requires that the WER must be determined as set forth in EPA's WER guidance or by another scientifically defensible method that has been adopted by the State as part of its water quality standards program and approved by EPA.

The WER is a more comprehensive mechanism for addressing bioavailability issues than simply expressing the criteria in terms of dissolved metal. Consequently, expressing the criteria in terms of dissolved metal, as done in today's rule for California, does not completely eliminate the utility of the WER. This is particularly true for copper, a metal that forms reduced-toxicity complexes with dissolved organic matter.

The *Interim Guidance on Determination and Use of Water-Effect Ratios for Metals* explains the relationship between WERs for dissolved criteria and WERs for total recoverable criteria. Dissolved measurements are to be used in the site-specific toxicity testing underlying the WERs for dissolved criteria. Because WERs for dissolved criteria generally are little affected by elevated particulate concentrations, EPA expects those WERs to be somewhat less than WERs for total recoverable criteria in such situations. Nevertheless, after the site-specific ratio of dissolved to total metal has been taken into account, EPA expects a permit limit derived using a WER for a dissolved criterion to be similar to the permit limit that would be derived from the WER for the corresponding total recoverable criterion.

d. Saltwater Copper Criteria

The saltwater copper criteria for aquatic life in today's rule are 4.8 µg/l (CMC) and 3.1 µg/l (CCC) in the dissolved form. These criteria reflect new data including data collected from studies for the New York/New Jersey Harbor and the San Francisco Bay indicating a need to revise the former copper 304(a) criteria guidance document to reflect a change in the saltwater CMC and CCC aquatic life values. These data also reflect a comprehensive literature search resulting in added toxicity test data for seven new species to the database for the saltwater copper criteria. EPA believes these new data have national implications and the national criteria guidance now contains a CMC of 4.8 µg/l dissolved and a CCC of 3.1 µg/l dissolved. In the amendments to the NTR, EPA noticed the availability of data to support these changes to the NTR, and solicited comments. The data can be found in the draft document entitled, *Ambient Water Quality Criteria—Copper, Addendum 1995.* This document is available from the Office of Water Resource Center and is available for review in the administrative record for today's rule.

e. Chronic Averaging Period

In establishing water quality criteria, EPA generally recommends an ''averaging period'' which reflects the duration of exposure required to elicit effects in individual organisms (TSD, Appendix D–2). The criteria continuous concentration, or CCC, is intended to be the highest concentration that could be maintained indefinitely in a water body without causing an unacceptable effect on the aquatic community or its uses (TSD, Appendix D–1). As aquatic organisms do not generally experience steady exposure, but rather fluctuating exposures to pollutants, and because aquatic organisms can generally tolerate higher concentrations of pollutants over a shorter periods of time, EPA expects that the concentration of a pollutant can exceed the CCC without causing an unacceptable effect if (a) the magnitude and duration of exceedences are appropriately limited and (b) there are compensating periods of time during which the concentration is below the CCC. This is done by specifying a duration of an ''averaging period'' over which the average concentration should not exceed the CCC more often than specified by the frequency (TSD, Appendix D–1).

EPA is promulgating a 4-day averaging period for chronic criteria, which means that measured or predicted ambient pollutant concentrations should be averaged over a 4-day period to determine attainment of chronic criteria. The State may apply to EPA for approval of an alternative averaging period. To do so, the State must submit to EPA the basis for such alternative averaging period.

The most important consideration for setting an appropriate averaging period is the length of time that sensitive organisms can tolerate exposure to a pollutant at levels exceeding a criterion without showing adverse effects on survival, growth, or reproduction. EPA believes that the chronic averaging period must be shorter than the duration of the chronic tests on which the CCC is based, since, in some cases, effects are elicited before exposure of the entire duration. Most of the toxicity tests used to establish the chronic criteria are conducted using steady exposure to toxicants for a least 28 days (TSD, page 35). Some chronic tests, however, are much shorter than this (TSD, Appendix D–2). EPA selected the 4-day averaging period based on the shortest duration in which chronic test effects are sometimes observed for certain species and toxicants. In addition, EPA believes that the results of some chronic tests are due to an acute effect on a sensitive life stage that occurs some time during the test, rather than being caused by long-term stress or long-term accumulation of the test material in the organisms.

Additional discussion of the rationale for the 4-day averaging period is contained in Appendix D of the TSD. Balancing all of the above factors and data, EPA believes that the 4-day averaging period falls within the scientifically reasonable range of values for choice of the averaging period, and is an appropriate length of time of

pollutant exposure to ensure protection of sensitive organisms.

EPA established a 4-day averaging period in the NTR. In settlement of litigation on the NTR, EPA stated that it was ''in the midst of conducting, sponsoring, or planning research related to the basis for and application of'' water quality criteria and mentioned the issue of averaging period. See Partial Settlement Agreement in *American Forest and Paper Ass'n, Inc. et al.* v. *U.S. EPA* (Consolidated Case No. 93–0694 (RMU), D.D.C.). EPA is re-evaluating issues raised about averaging periods and will, if appropriate, revise the 1985 Guidelines.

EPA received public comment relevant to the averaging period during the comment period for the 1995 Amendments to the NTR (60 FR 22228, May 4, 1995), although these public comments did not address the chronic averaging period separately from the allowable excursion frequency and the design flow. Comments recommended that EPA use the 30Q5 design flow for chronic criteria.

While EPA is undertaking analysis of the chronic design conditions as part of the revisions to the 1985 Guidelines, EPA has not yet completed this work. Until this work is complete, for the reasons set forth in the TSD, EPA continues to believe that the 4-day chronic averaging period represents a reasonable, defensible value for this parameter.

EPA added language to the final rule which will enable the State to adopt alternative averaging periods and frequencies and associated design flows where appropriate. The State may apply to EPA for approval of alternative averaging periods and frequencies and related design flows; the State must submit the bases for any changes. Before approving any change, EPA will publish for public comment, a notice proposing the changes.

f. Hardness

Freshwater aquatic life criteria for certain metals are expressed as a function of hardness because hardness and/or water quality characteristics that are usually correlated with hardness can reduce or increase the toxicities of some metals. Hardness is used as a surrogate for a number of water quality characteristics which affect the toxicity of metals in a variety of ways. Increasing hardness has the effect of decreasing the toxicity of metals. Water quality criteria to protect aquatic life may be calculated at different concentrations of hardnesses measured in milligrams per liter (mg/l) as calcium carbonate ($CaCO_3$).

Section 131.38(b)(2) of the final rule presents the hardness-dependent equations for freshwater metals criteria. For example, using the equation for zinc, the total recoverable CMCs at a hardness of 10, 50, 100 or 200 mg/l as $CaCO_3$ are 17, 67, 120 and 220 micrograms per liter (µg/l), respectively. Thus, the specific value in the table in the regulatory text is for illustrative purposes only. Most of the data used to develop these hardness equations for deriving aquatic life criteria for metals were in the range of 25 mg/l to 400 mg/l as $CaCO_3$, and the formulas are therefore most accurate in this range. The majority of surface waters nationwide and in California have a hardness of less than 400 mg/l as $CaCO_3$.

In the past, EPA generally recommended that 25 mg/l as $CaCO_3$ be used as a default hardness value in deriving freshwater aquatic life criteria for metals when the ambient (or actual) hardness value is below 25 mg/l as $CaCO_3$. However, use of the approach results in criteria that may not be fully protective. Therefore, for waters with a hardness of less than 25 mg/l as $CaCO_3$, criteria should be calculated using the actual ambient hardness of the surface water.

In the past, EPA generally recommended that if the hardness was over 400 mg/l, two options were available: (1) Calculate the criterion using a default WER of 1.0 and using a hardness of 400 mg/l in the hardness equation; or (2) calculate the criterion using a WER and the actual ambient hardness of the surface water in the equation. Use of the second option is expected to result in the level of protection intended in the 1985 Guidelines whereas use of the first option is thought to result in an even more protective aquatic life criterion. At high hardness there is an indication that hardness and related inorganic water quality characteristics do not have as much of an effect on toxicity of metals as they do at lower hardnesses. Related water quality characteristics do not correlate as well at higher hardnesses as they do at lower hardnesses. Therefore, if hardness is over 400 mg/l as $CaCO_3$, a hardness of 400 mg/l as $CaCO_3$ should be used with a default WER of 1.0; alternatively, the WER and actual hardness of the surface water may be used.

EPA requested comments in the NTR amendments on the use of actual ambient hardness for calculating criteria when the hardness is below 25 mg/l as $CaCO_3$, and when hardness is greater than 400 mg/l as $CaCO_3$. Most of the comments received were in favor of using the actual hardness with the use of the water-effect ratio (1.0 unless otherwise specified by the permitting authority) when the hardness is greater than 400 mg/l as $CaCO_3$. A few commenters did not want the water-effect ratio to be mandatory in calculating hardness, and other commenters had concerns about being responsible for deriving an appropriate water-effect ratio. Overall, the commenters were in favor of using the actual hardness when calculating hardness-dependent freshwater metals criteria for hardness between 0–400 mg/l as $CaCO_3$. EPA took those comments into account in promulgating today's rule.

A hardness equation is most accurate when the relationships between hardness and the other important inorganic constituents, notably alkalinity and pH, are nearly identical in all of the dilution waters used in the toxicity tests and in the surface waters to which the equation is to be applied. If an effluent raises hardness but not alkalinity and/or pH, using the hardness of the downstream water might provide a lower level of protection than intended by the 1985 guidelines. If it appears that an effluent causes hardness to be inconsistent with alkalinity and/or pH, the intended level of protection will usually be maintained or exceeded if either (1) data are available to demonstrate that alkalinity and/or pH do not affect the toxicity of the metal, or (2) the hardness used in the hardness equation is the hardness of upstream water that does not contain the effluent. The level of protection intended by the 1985 guidelines can also be provided by using the WER procedure.

In some cases, capping hardness at 400 mg/l might result in a level of protection that is higher than that intended by the 1985 guidelines, but any such increase in the level of protection can be overcome by use of the WER procedure. For metals whose criteria are expressed as hardness equations, use of the WER procedure will generally be intended to account for effects of such water quality characteristics as total organic carbon on the toxicities of metals. The WER procedure is equally useful for accounting for any deviation from a hardness equation in a site water.

3. Human Health Criteria

EPA's CWA section 304(a) human health criteria guidance provides criteria recommendations to minimize adverse human effects due to substances in ambient water. EPA's CWA section 304(a) criteria guidance for human health are based on two types of

toxicological endpoints: (1) carcinogenicity and (2) systemic toxicity (i.e., all other adverse effects other than cancer). Thus, there are two procedures for assessing these health effects: one for carcinogens and one for non-carcinogens.

If there are no data on how a chemical agent causes cancer, EPA's existing human health guidelines assume that carcinogenicity is a ''non-threshold phenomenon,'' that is, there are no ''safe'' or ''no-effect levels'' because even extremely small doses are assumed to cause a finite increase in the incidence of the effect (i.e., cancer). Therefore, EPA's water quality criteria guidance for carcinogens are presented as pollutant concentrations corresponding to increases in the risk of developing cancer. See Human Health Guidelines at 45 FR 79347.

With existing criteria, pollutants that do not manifest any apparent carcinogenic effect in animal studies (i.e., systemic toxicants), EPA assumes that the pollutant has a threshold below which no effect will be observed. This assumption is based on the premise that a physiological mechanism exists within living organisms to avoid or overcome the adverse effect of the pollutant below the threshold concentration.

Note: Recent changes in the Agency's cancer guidelines addressing these assumptions are described in the Draft Water Quality Criteria Methodology: Human Health, 63 FR 43756, August 14, 1998.

The human health risks of a substance cannot be determined with any degree of confidence unless dose-response relationships are quantified. Therefore, a dose-response assessment is required before a criterion can be calculated. The dose-response assessment determines the quantitative relationships between the amount of exposure to a substance and the onset of toxic injury or disease. Data for determining dose-response relationships are typically derived from animal studies, or less frequently, from epidemiological studies in exposed populations.

The dose-response information needed for carcinogens is an estimate of the carcinogenic potency of the compound. Carcinogenic potency is defined here as a general term for a chemical's human cancer-causing potential. This term is often used loosely to refer to the more specific carcinogenic or cancer slope factor which is defined as an estimate of carcinogenic potency derived from animal studies or epidemiological data of human exposure. It is based on extrapolation from test exposures of high doses over relatively short periods of time to more realistic low doses over a lifetime exposure period by use of linear extrapolation models. The cancer slope factor, q1*, is EPA's estimate of carcinogenic potency and is intended to be a conservative upper bound estimate (e.g. 95% upper bound confidence limit).

For non-carcinogens, EPA uses the reference dose (RfD) as the dose-response parameter in calculating the criteria. For non-carcinogens, oral RfD assessments (hereinafter simply ''RfDs'') are developed based on pollutant concentrations that cause threshold effects. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. See Human Health Guidelines. The RfD was formerly referred to as an ''Acceptable Daily Intake'' or ADI. The RfD is useful as a reference point for gauging the potential effect of other doses. Doses that are less than the RfD are not likely to be associated with any health risks, and are therefore less likely to be of regulatory concern. As the frequency of exposures exceeding the RfD increases and as the size of the excess increases, the probability increases that adverse effect may be observed in a human population. Nonetheless, a clear conclusion cannot be categorically drawn that all doses below the RfD are ''acceptable'' and that all doses in excess of the RfD are ''unacceptable.'' In extrapolating non-carcinogen animal test data to humans to derive an RfD, EPA divides either a No Observed-Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), or other benchmark dose observed in animal studies by an ''uncertainty factor'' which is based on professional judgment of toxicologists and typically ranges from 10 to 10,000.

For CWA section 304(a) human health criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. Thus, the criteria are based on an assessment of risks related to the surface water exposure route only where designated uses are drinking water and fish and shellfish consumption.

The assumed exposure pathways in calculating the criteria are the consumption of 2 liters per day of water at the criteria concentration and the consumption of 6.5 grams per day of fish and shellfish contaminated at a level equal to the criteria concentration but multiplied by a ''bioconcentration factor.'' The use of fish and shellfish consumption as an exposure factor requires the quantification of pollutant residues in the edible portions of the ingested species.

Bioconcentration factors (BCFs) are used to relate pollutant residues in aquatic organisms to the pollutant concentration in ambient waters. BCFs are quantified by various procedures depending on the lipid solubility of the pollutant. For lipid soluble pollutants, the average BCF is calculated from the weighted average percent lipids in the edible portions of fish and shellfish, which is about 3%; or it is calculated from theoretical considerations using the octanol/water partition coefficient. For non-lipid soluble compounds, the BCF is determined empirically. The assumed water consumption is taken from the National Academy of Sciences publication *Drinking Water and Health* (1977). (Referenced in the Human Health Guidelines.) This value is appropriate as it includes a margin of safety so that the general population is protected. See also EPA's discussion of the 2.0 liters/day assumption at 61 FR 65183 (Dec. 11, 1996). The 6.5 grams per day contaminated fish and shellfish consumption value was equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish and shellfish for the U.S. population. See Human Health Guidelines.

EPA assumes in calculating water quality criteria that the exposed individual is an average adult with body weight of 70 kilograms. EPA assumes 6.5 grams per day of contaminated fish and shellfish consumption and 2.0 liters per day of contaminated drinking water consumption for a 70 kilogram person in calculating the criteria. Regarding issues concerning criteria development and differences in dose per kilogram of body weight, RfDs are always derived based on the most sensitive health effect endpoint. Therefore, when that basis is due to a chronic or lifetime health effect, the exposure parameters assume the exposed individual to be the average adult, as indicated above.

In the absence of this final rule, there may be particular risks to children. EPA believes that children are protected by the human health criteria contained in this final rule. Children are protected against other less sensitive adverse health endpoints due to the conservative way that the RfDs are derived. An RfD is a public health protective endpoint. It is an amount of a chemical that can be consumed on a daily basis for a lifetime without expecting an adverse effect. RfDs are based on sensitive health endpoints and

are calculated to be protective for sensitive human sub-populations including children. If the basis of the RfD was due to an acute or shorter-term developmental effect, EPA uses exposure parameters other than those indicated above. Specifically, EPA uses parameters most representative of the population of concern (*e.g.,* the health criteria for nitrates based on infant exposure parameters). For carcinogens, the risk assessments are upper bound one in a million (10^{-6}) lifetime risk numbers. The risk to children is not likely to exceed these upper bounds estimates and may be zero at low doses. The exposure assumptions for drinking water and fish protect children because they are conservative for infants and children. EPA assumes 2 liters of untreated surface water and 6.5 grams of freshwater and estuarine fish are consumed each day. EPA believes the adult fish consumption assumption is conservative for children because children generally consume marine fish not freshwater and estuarine.

EPA has a process to develop a scientific consensus on oral reference dose assessments and carcinogenicity assessments (hereinafter simply cancer slope factors or slope factors or q1*s). Through this process, EPA develops a consensus of Agency opinion which is then used throughout EPA in risk management decision-making. EPA maintains an electronic data base which contains the official Agency consensus for oral RfD assessments and carcinogenicity assessments which is known as the Integrated Risk Information System (IRIS). It is available for use by the public on the National Institutes of Health's National Library of Medicine's TOXNET system, and through diskettes from the National Technical Information Service (NTIS). (NTIS access number is PB 90–591330.)

Section 304(a)(1) of the CWA requires EPA to periodically revise its criteria guidance to reflect the latest scientific knowledge: ''(A) On the kind and extent of all identifiable effects on health and welfare * * *; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on the biological community diversity, productivity, and stability, including information on the factors affecting eutrophication rates of organic and inorganic sedimentation for varying types of receiving waters.'' In developing up-to-date water quality criteria for the protection of human health, EPA uses the most recent IRIS values (RfDs and q1*s) as the toxicological basis in the criterion calculation. IRIS reflects EPA's most current consensus on the toxicological assessment for a chemical. In developing the criteria in today's rule, the IRIS values as of October 1996 were used together with currently accepted exposure parameters for bioconcentration, fish and shellfish and water consumption, and body weight. The IRIS cover sheet for each pollutant criteria included in today's rule is contained in the administrative record.

For the human health criteria included in today's rule, EPA used the Human Health Guidelines on which criteria recommendations from the appropriate CWA section 304(a) criteria guidance document were based. (These documents are also placed in the administrative record for today's rule.) Where EPA has changed any parameters in IRIS used in criteria derivation since issuance of the criteria guidance document, EPA recalculated the criteria recommendation with the latest IRIS information. Thus, there are differences between the original 1980 criteria guidance document recommendations, and those in this rule, but this rule presents EPA's most current CWA section 304(a) criteria recommendation. The basis (q1* or RfD) and BCF for each pollutant criterion in today's rule is contained in the rule's Administrative Record Matrix which is included in the administrative record for the rule. In addition, all recalculated human health numbers are denoted by an ''a'' in the criteria matrix in 40 CFR 131.38(b)(1) of the rule. The pollutants for which a revised human health criterion has been calculated since the December 1992 NTR include:

mercury
dichlorobromomethane
1,2-dichloropropane
1,2-trans-dichloroethylene
2,4-dimethylphenol
acenaphthene
benzo(a)anthracene
benzo(a)pyrene
benzo(b)flouranthene
benzo(k)flouranthene
2-chloronaphthalene
chrysene
dibenzo(a,h)anthracene
indeno(1,2,3-cd)pyrene
N-nitrosodi-n-propylamine
alpha-endosulfan
beta-endosulfan
endosulfan sulfate
2-chlorophenol
butylbenzyl phthalate
polychlorinated biphenyls.

In November of 1991, the proposed NTR presented criteria for several pollutants in parentheses. These were pollutants for which, in 1980, insufficient information existed to develop human health water quality criteria, but for which, in 1991, sufficient information existed. Since these criteria did not undergo the public review and comment in a manner similar to the other water quality criteria presented in the NTR (for which sufficient information was available in 1980 to develop a criterion, as presented in the 1980 criteria guidance documents), they were not proposed for adoption into the water quality criteria, but were presented to serve as notice for inclusion in future State triennial reviews. Today's rule promulgates criteria for these nine pollutants:

copper
1, 2-dichloropropane
1,2-trans-dichloroethylene
2,4-dimethylphenol
acenaphthene
2-chloronaphthalene
N-nitrosodi-n-propylamine
2-chlorophenol
butylbenzene phthalate

All the criteria are based on IRIS values—either an RfD or q1*—which were listed on IRIS as of November 1991, the date of the proposed NTR. These values have not changed since the final NTR was published in December of 1992. The rule's Administrative Record Matrix in the administrative record of today's rule contains the specific RfDs, q1*s, and BCFs used in calculating these criteria.

Proposed Changes to the Human Health Criteria Methodology: EPA recently proposed revisions to the 1980 ambient water quality criteria derivation guidelines (the Human Health Guidelines). See *Draft Water Quality Criteria Methodology: Human Health,* 63 FR 43756, August 14, 1998; see also *Draft Water Quality Criteria Methodology: Human Health,* U.S. EPA Office of Water, EPA 822–Z–98–001. The EPA revisions consist of five documents: *Draft Water Quality Criteria Methodology: Human Health,* EPA 822–Z–98–001; *Ambient Water Quality Criteria Derivation Methodology Human Health, Technical Support Document, Final Draft,* EPA–822–B–98–005; and three Ambient Water Quality Criteria for the Protection of Human Health, Drafts—one each for Acrylonitrile, 1,3-Dichloropropene (1,3-DCP), and Hexachlorobutadiene (HCBD), respectively, EPA–822–R–98–006, –005, and –004. All five documents are contained in the administrative record for today's rule.

The proposed methodology revisions reflect significant scientific advances that have occurred during the past nineteen years in such key areas as cancer and noncancer risk assessments, exposure assessments and bioaccumulation. For specific details on

these proposed changes and others, please refer to the **Federal Register** notice or the EPA document.

It should be noted that some of the proposed changes may result in significant numeric changes in the ambient water quality criteria. However, EPA will continue to rely on existing criteria as the basis for regulatory and non-regulatory decisions, until EPA revises and reissues a 304(a) criteria guidance using the revised final human health criteria methodology. The existing criteria are still viewed as scientifically acceptable by EPA. The intention of the proposed methodology revisions is to present the latest scientific advancements in the areas of risk and exposure assessment in order to incrementally improve the already sound toxicological and exposure bases for these criteria. As EPA's current human health criteria are the product of many years worth of development and peer review, it is reasonable to assume that revisiting all existing criteria, and incorporating peer review into such review, could require comparable amounts of time and resources. Given these circumstances, EPA proposed a process for revisiting these criteria as part of the overall revisions to the methodology for deriving human health criteria. This process is discussed in the Implementation Section of the Notice of *Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (see 63 FR 43771–43776, August 14, 1998).

The State of California in its Ocean Plan, adopted in 1990 and approved by EPA in 1991, established numeric water quality criteria using an average fish and shellfish consumption rate of 23 grams per day. This value is based on an earlier California Department of Health Services estimate. The State is currently in the process of readopting its water quality control plans for inland surface waters, enclosed bays, and estuaries. The State intends to consider information on fish and shellfish consumption rates evaluated and summarized in a report prepared by the State's Pesticide and Environmental Toxicology Section of the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency. The report, entitled, *Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States,* was published in final draft form in July of 1997, and released to the public on September 16, 1997. The report is currently undergoing final evaluation, and is expected to published in final form in the near future. This final draft report is contained in the administrative record for today's rule. Although EPA has not used this fish consumption value here because this information has not yet been finalized, the State may use any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans.

a. 2,3,7,8-TCDD (Dioxin) Criteria

In today's action, EPA is promulgating human health water quality criteria for 2,3,7,8-tetrachlorodibenzo-p-dioxin (''dioxin'') at the same levels as promulgated in the NTR, as amended. These criteria are derived from EPA's 1984 CWA section 304(a) criteria guidance document for dioxin.

For National Pollutant Discharge Elimination System (NPDES) purposes, EPA supports the regulation of other dioxin and dioxin-like compounds through the use of toxicity equivalencies or TEQs in NPDES permits (see discussion below). For California waters, if the discharge of dioxin or dioxin-like compounds has reasonable potential to cause or contribute to a violation of a narrative criterion, numeric water quality-based effluent limits for dioxin or dioxin-like compounds should be included in NPDES permits and should be expressed using a TEQ scheme.

EPA has been evaluating the health threat posed by dioxin nearly continuously for over two decades. Following issuance of the 1984 criteria guidance document, evaluating the health effects of dioxin and recommending human health criteria for dioxin, EPA prepared draft reassessments reviewing new scientific information relating to dioxin in 1985 and 1988. EPA's Science Advisory Board (SAB), reviewing the 1988 draft reassessment, concluded that while the risk assessment approach used in 1984 criteria guidance document had inadequacies, a better alternative was unavailable (see SAB's *Dioxin Panel Review of Documents from the Office or Research and Development relating to the Risk and Exposure Assessment of 2,3,7,8-TCDD* (EPA–SAB–EC–90–003, November 28, 1989) included in the administrative record for today's rule). Between 1988 and 1990, EPA issued numerous reports and guidances relating to the control of dioxin discharges from pulp and paper mills. See e.g., EPA Memorandum, ''Strategy for the Regulation of Discharges of PHDDs & PHDFs from Pulp and Paper Mills to the Waters of the United States,'' from Assistant Administrator for Water to Regional Water Management Division Directors and NPDES State Directors, dated May 21, 1990 (AR NL–16); EPA Memorandum, ''State Policies, Water Quality Standards, and Permit Limitations Related to 2,3,7,8-TCDD in Surface Water,'' from the Assistant Administrator for Water to Regional Water Management Division Directors, dated January 5, 1990 (AR VA–66). These documents are available in the administrative record for today's rule.

In 1991, EPA's Administrator announced another scientific reassessment of the risks of exposure to dioxin (see Memorandum from Administrator William K. Reilly to Erich W. Bretthauer, Assistant Administrator for Research and Development and E. Donald Elliott, General Counsel, entitled *Dioxin: Follow-Up to Briefing on Scientific Developments,* April 8, 1991, included in the administrative record for today's rule). At that time, the Administrator made clear that while the reassessment was underway, EPA would continue to regulate dioxin in accordance with existing Agency policy. Thereafter, the Agency proceeded to regulate dioxin in a number of environmental programs, including standards under the Safe Drinking Water Act and the CWA.

The Administrator's promulgation of the dioxin human health criteria in the 1992 NTR affirmed the Agency's decision that the ongoing reassessment should not defer or delay regulating this potent contaminant, and further, that the risk assessment in the 1984 criteria guidance document for dioxin continued to be scientifically defensible. Until the reassessment process was completed, the Agency could not ''say with any certainty what the degree or directions of any changes in the risk estimates might be'' (57 FR 60863–64).

The basis for the dioxin criteria as well as the decision to include the dioxin criteria in the 1992 NTR pending the results of the reassessment were challenged. See *American Forest and Paper Ass'n, Inc. et al.* v. *U.S. EPA* (Consolidated Case No. 93–0694 (RMU) D.D.C.). By order dated September 4, 1996, the Court upheld EPA's decision. EPA's brief and the Court's decision are included in the administrative record for today's rule.

EPA has undertaken significant effort toward completion of the dioxin reassessment. On September 13, 1994, EPA released for public review and comment a draft reassessment of toxicity and exposure to dioxin. See *Health Assessment Document for 2,3,7,8-Tetrachlorobenzo-p-Dioxin (TCDD) and Related Compounds,* U.S. EPA, 1994. EPA is currently addressing comments made by the public and the SAB and anticipates that the final

revised reassessment will go to the SAB in the near future. With today's rule, the Agency reaffirms that, notwithstanding the on-going risk reassessment, EPA intends to continue to regulate dioxin to avoid further harm to public health, and the basis for the dioxin criteria, both in terms of the cancer potency and the exposure estimates, remains scientifically defensible. The fact that EPA is reassessing the risk of dioxin, virtually a continuous process to evaluate new scientific information, does not mean that the current risk assessment is ''wrong''. It continues to be EPA's position that until the risk assessment for dioxin is revised, EPA supports and will continue to use the existing risk assessment for the regulation of dioxin in the environment. Accordingly, EPA today promulgates dioxin criteria based on the 1984 criteria guidance document for dioxin and promulgated in the NTR in 1992.

Toxicity Equivalency: The State of California, in its 1991 water quality control plans, adopted human health criteria for dioxin and dioxin-like compounds based on the concept of toxicity equivalency (TEQ) using toxicity equivalency factors (TEFs). EPA Region 9 reviewed and approved the State's use of the TEQ concept and TEFs in setting the State's human health water quality criteria for dioxin and dioxin-like compounds.

In 1987, EPA formally embraced the TEQ concept as an interim procedure to estimate the risks associated with exposures to 210 chlorinated dibenzo-p-dioxin and chlorinated dibenzofuran (CDD/CDF) congeners, including 2,3,7,8-TCDD. This procedure uses a set of derived TEFs to convert the concentration of any CDD/CDF congener into an equivalent concentration of 2,3,7,8-TCDD. In 1989, EPA updated its TEFs based on an examination of relevant scientific evidence and a recognition of the value of international consistency. This updated information can be found in EPA's 1989 *Update to the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and -dibenzofurans (CDDs and CDFs)* (EPA/625/3–89/016, March 1989). EPA had been active in an international effort aimed at adopting a common set of TEFs (International TEFs/89 or I–TEFs/89), to facilitate information exchange on environmental contamination of CDD/CDF. This document reflects EPA's support of an internationally consistent set of TEFs, the I–TEFs/89. EPA uses I–TEFs/89 in many of its regulatory programs.

In 1994, the World Health Organization (WHO) revised the TEF scheme for dioxins and furans to include toxicity from dioxin-like compounds (Ahlborg et al., 1994). However, no changes were made to the TEFs for dioxins and furans. In 1998, the WHO re-evaluated and revised the previously established TEFs for dioxins (Ds), furans (Fs) and dioxin-like compounds (Vanden Bers, 1998). The nomenclature for this TEF scheme is TEQDFP–WHO98, where TEQ represents the 2,3,7,8-TCDD Toxic Equivalence of the mixture, and the subscript DFP indicates that dioxins (Ds) furans (Fs) and dioxin-like compounds (P) are included in the TEF scheme. The subscript 98 following WHO displays the year changes were made to the TEF scheme.

EPA intends to use the 1998 WHO TEF scheme in the near future. At this point however, EPA will support the use of either the 1989 interim procedures or the 1998 WHO TEF scheme but encourages the use of the 1998 WHO TEF scheme in State programs. EPA expects California to use a TEF scheme in implementing the 2,3,7,8-TCDD water quality criteria contained in today's rule. The TEQ and TEF approach provide a methodology for setting NPDES water quality-based permit limits that are protective of human health for dioxin and dioxin-like compounds.

Several commenters requested EPA to promulgate criteria for other forms of dioxin, in addition to 2,3,7,8-TCDD. EPA's draft reassessment for dioxin examines toxicity based on the TEQ concept and I–TEFs/89. When EPA completes the dioxin reassessment, the Agency intends to adopt revised 304(a) water quality criteria guidance based on the reassessment for dioxin. If necessary, EPA will then act to amend the NTR and CTR to reflect the revised 304(a) water quality criteria guidance.

b. Arsenic Criteria

EPA is not promulgating human health criteria for arsenic in today's rule. EPA recognizes that it promulgated human health water quality criteria for arsenic for a number of States in 1992, in the NTR, based on EPA's 1980 section 304(a) criteria guidance for arsenic established, in part, from IRIS values current at that time. However, a number of issues and uncertainties existed at the time of the CTR proposal concerning the health effects of arsenic. These issues and uncertainties were summarized in ''Issues Related to Health Risk of Arsenic'' which is contained in the administrative record for today's rule. During the period of this rulemaking action, EPA commissioned a study of arsenic health effects by the National Research Council (NRC) arm of the National Academy of Sciences. EPA received the NRC report in March of 1999. EPA scientists reviewed the report, which recommended that EPA lower the Safe Drinking Water Act arsenic maximum contaminant level (MCL) as soon as possible (The arsenic MCL is currently 50 μg/l.) The bladder cancer analysis in the NRC report will provide part of the basis for the risk assessment of a proposed revised arsenic MCL in the near future. After promulgating a revised MCL for drinking water, the Agency plans to revise the CWA 304(a) human health criteria for arsenic in order to harmonize the two standards. Today's rule defers promulgating arsenic criteria based on the Agency's previous risk assessment of skin cancer. In the meantime, permitting authorities in California should rely on existing narrative water quality criteria to establish effluent limitations as necessary for arsenic. California has previously expressed its science and policy position by establishing a criterion level of 5 μg/l for arsenic. Permitting authorities may, among other considerations, consider that value when evaluating and interpreting narrative water quality criteria.

c. Mercury Criteria

The human health criteria promulgated here use the latest RfD in EPA's Integrated Risk Information System (IRIS) and the weighted average practical bioconcentration factor (PBCF) from the 1980 section 304(a) criteria guidance document for mercury. EPA considered the approach used in the Great Lakes Water Quality Guidance (''Guidance'') incorporating Bioaccumulation Factors (BAFs), but rejected this approach for reasons outlined below. The equation used here to derive an ambient water quality criterion for mercury from exposure to organisms and water is:

$$HHC = \frac{RfD \times BW}{WC + (FC \times PBCF)}$$

Where:

RfD = Reference Dose
BW = Body Weight
WC = Water Consumption
FC = Total Fish and Shellfish Consumption per Day
PBCF = Practical Bioconcentration Factor (weighted average)

For mercury, the most current RfD from IRIS is 1×10^{-4} mg/kg/day. The RfD used a benchmark dose as an estimate of a No Observed Adverse Effect Level (NOAEL). The benchmark dose was calculated by applying a Weibel model

for extra risk to all neurological effects observed in 81 Iraqi children exposed in utero as reported in Marsh, et. al. (1987). Maternal hair mercury was the measure of exposure. Extra risk refers to an adjustment for background incidence of a given health effect. Specifically, the extra risk is the added incidence of observing an effect above the background rate relative to the proportion of the population of interest that is not expected to exhibit such as effect. The resulting estimate was the lower 95% statistical bound on the 10% extra risk; this was 11 ppm mercury in maternal hair. This dose in hair was converted to an equivalent ingested amount by applying a model based on data from human studies; the resulting benchmark dose was 1×10^{-3} mg/kg body weight /day. The RfD was calculated by dividing the benchmark dose by a composite uncertainty factor of 10. The uncertainty factor was used to account for variability in the human population, in particular the wide variation in biological half-life of methylmercury and the variation that is observed in the ration of hair mercury to mercury in the blood. In addition the uncertainty factor accounts for lack of a two-generation reproductive study and the lack of data on long term effects of childhood mercury exposures. The RfD thus calculated is 1×10^{-4} mg/kg body weight/day or 0.1 μg/kg/day. The body weight used in the equation for the mercury criteria, as discussed in the Human Health Guidelines, is a mean adult human body weight of 70 kg. The drinking water consumption rate, as discussed in the Human Health Guidelines, is 2.0 liters per day.

The bioconcentration factor or BCF is defined as the ratio of chemical concentration in the organism to that in surrounding water. Bioconcentration occurs through uptake and retention of a substance from water only, through gill membranes or other external body surfaces. In the context of setting exposure criteria it is generally understood that the terms ''BCF'' and ''steady-state BCF'' are synonymous. A steady-state condition occurs when the organism is exposed for a sufficient length of time that the ratio does not change substantially.

The BCFs that were used herein are the ''Practical Bioconcentration Factors (PBCFs)'' that were derived in 1980: 5500 for fresh water, 3765 for estuarine coastal waters, and 9000 for open oceans. See pages C–100–1 of Ambient Water Quality Criteria for Mercury (EPA 440/5–80–058) for a complete discussion on the PBCF. Because of the way they were derived, these PBCFs take into account uptake from food as well as uptake from water. A weighted average PBCF was calculated to take into account the average consumption from the three waters using the following equation:

$$\text{Weighted Average Practical BCF} = \frac{\sum(\text{FC} \times \text{PBCF})}{\sum(\text{FC})} = \frac{(0.00172)(5500) + (0.00478)(3765) + (0.0122)(9000)}{0.00172 + 0.00478 + 0.0122} = \frac{137.3}{0.0187} = 7342.6$$

Given the large value for the weighted average PBCF, the contribution of drinking water to total daily intake is negligible so that assumptions concerning the chemical form of mercury in drinking water become less important. The human health mercury criteria promulgated for this rule are based on the latest RfD as listed in IRIS and a weighted PBCF from the 1980 § 304(a) criteria guidance document for mercury.

On March 23, 1995 (60 FR 15366), EPA promulgated the Great Lakes Water Quality Guidance (''Guidance''). The Guidance incorporated bioaccumulation factors (BAFs) in the derivation of criteria to protect human health because it is believed that BAFs are a better predictor than BCFs of the concentration of a chemical within fish tissue since BAFs include consideration of the uptake of contaminants from all routes of exposure. A bioaccumulation factor is defined as the ratio (in L/kg) of a substance's concentration in tissue to the concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time. The final Great Lakes Guidance establishes a hierarchy of four methods for deriving BAFs for non-polar organic chemicals: (1) Field-measured BAFs; (2) predicted BAFs derived using a field-measured biota-sediment accumulation factor; (3) predicted BAFs derived by multiplying a laboratory-measured BCF by a food chain multiplier; and (4) predicted BAFs derived by multiplying a BCF calculated from the log Kow by a food-chain multiplier. The final Great Lakes Guidance developed BAFs for trophic levels three and four fish of the Great Lakes Basin. Respectively, the BAFs for mercury for trophic level 3 and 4 fish were: 27,900 and 140,000.

The BAF promulgated in the GLI was developed specifically for the Great Lakes System. It is uncertain whether the BAFs of 27,900 and 140,000 are appropriate for use in California at this time; therefore, today's final rule does not use the GLI BAF in establishing human health criteria for mercury in California. The magnitude of the BAF for mercury in a given system depends on how much of the total mercury is present in the methylated form. Methylation rates vary widely from one water body to another for reasons that are not fully understood. Lacking the data, it is difficult to determine if the BAF used in the GLI represents the true potential for mercury to bioaccumulate in California surface waters. The true, average BAF for California could be higher or lower. For more information see EPA's Response to Comments document in the administrative record for this rule (specifically comments CTR–002–007(b) and CTR–016–007).

EPA is developing a national BAF for mercury as part of revisions to its 304(a) criteria for human health; however, the BAF methodology that will be used is currently under evaluation as part of EPA's revisions to its National Human Health Methodology (see section F.3 above). EPA applied a similar methodology in its Mercury Study Report to Congress (MSRC) to derive a BAF for methylmercury. The MSRC is available through NTIS (EPA–452/R–97–003). Although a BAF was derived in the MSRC, EPA does not intend to use this BAF for National application. EPA is engaged in a separate effort to incorporate additional mercury bioaccumulation data that was not considered in the MSRC, and to assess uncertainties with using a National BAF approach for mercury. Once the proposed revised human health methodology, including the BAF component, is finalized, EPA will revise its 304(a) criteria for mercury to reflect changes in the underlying methodology, recommendations contained in the MSRC, and recommendations in a National Academy of Science report on human health assessment of methylmercury. When EPA changes its 304(a) criteria recommendation for mercury, States and Tribes will be expected to review their water quality standards for mercury and make any revisions necessary to ensure their standards are scientifically defensible.

New information may become available regarding the bioaccumulation

of mercury in certain water bodies in California. EPA supports the use of this information to develop site-specific criteria for mercury. Further, if a California water body is impaired due to mercury fish tissue or sediment contamination, loadings of mercury could contribute to or exacerbate the impairment. Therefore, one option regulatory authorities should consider is to include water quality-based effluent limits (WQBELs) in permits based on mass for discharges to the impaired water body. Such WQBELs must be derived from and comply with applicable State water quality standards (including both numeric and narrative criteria) and assure that the discharge does not cause or contribute to a violation of water quality standards.

d. Polychlorinated Biphenyls (PCBs) Criteria

The NTR, as amended, calculated human health criteria for PCBs using a cancer potency factor of 7.7 per mg/kg-day from the Agency's IRIS. This cancer potency factor was derived from the Norback and Weltman (1985) study which looked at rats that were fed Aroclor 1260. The study used the linearized multistage model with a default cross-species scaling factor (body weight ratio to the ⅔ power). Although it is known that PCB mixtures vary greatly as to their potency in producing biological effects, for purposes of its carcinogenicity assessment, EPA considered Aroclor 1260 to be representative of all PCB mixtures. The Agency did not pool data from all available congener studies or generate a geometric mean from these studies, since the Norback and Weltman study was judged by EPA as acceptable, and not of marginal quality, in design or conduct as compared with other studies. Thereafter, the Institute for Evaluating Health Risks (IEHR, 1991) reviewed the pathological slides from the Norback and Weltman study, and concluded that some of the malignant liver tumors should have been interpreted as nonmalignant lesions, and that the cancer potency factor should be 5.1 per mg/kg-day as compared with EPA's 7.7 per mg/kg-day.

The Agency's peer-reviewed reassessment of the cancer potency of PCBs published in a final report, *PCBs: Cancer Dose-Response Assessment and Applications to Environmental Mixtures* (EPA/600/P–96/001F), adopts a different approach that distinguishes among PCB mixtures by using information on environmental processes. (The report is included in the administrative record of today's rule.) The report considers all cancer studies (which used commercial mixtures only) to develop a range of cancer potency factors, then uses information on environmental processes to provide guidance on choosing an appropriate potency factor for representative classes of environmental mixtures and different pathways. The reassessment provides that, depending on the specific application, either central estimates or upper bounds can be appropriate. Central estimates describe a typical individual's risk, while upper bounds provide assurance (*i.e.,* 95% confidence) that this risk is not likely to be underestimated if the underlying model is correct. Central estimates are used for comparing or ranking environmental hazards, while upper bounds provide information about the precision of the comparison or ranking. In the reassessment, the use of the upper bound values were found to increase cancer potency estimates by two or three-fold over those using central tendency. Upper bounds are useful for estimating risks or setting exposure-related standards to protect public health, and are used by EPA in quantitative cancer risk assessment. Thus, the cancer potency of PCB mixtures is determined using a tiered approach based on environmental exposure routes with upper-bound potency factors (using a body weight ratio to the ¾ power) ranging from 0.07 (lowest risk and persistence) to 2 (high risk and persistence) per mg/kg-day for average lifetime exposures to PCBs. It is noteworthy that bioaccumulated PCBs appear to be more toxic than commercial PCBs and appear to be more persistent in the body. For exposure through the food chain, risks can be higher than other exposures.

EPA issued the final reassessment report on September 27, 1996, and updated IRIS to include the reassessment on October 1, 1996. EPA updated the human health criteria for PCBs in the National Toxics Rule on September 27, 1999. For today's rule, EPA derived the human health criteria for PCBs using a cancer potency factor of 2 per mg/kg-day, an upper bound potency factor reflecting high risk and persistence. This decision is based on recent multimedia studies indicating that the major pathway of exposure to persistent toxic substances such as PCBs is via dietary exposure (*i.e.,* contaminated fish and shellfish consumption).

Following is the calculation of the human health criterion (HHC) for organism and water consumption:

$$HHC = \frac{RF \times BW \times (1{,}000\ \mu g/mg)}{q1^* \times [WC + (FC \times BCF)]}$$

Where:

RF = Risk Factor = 1 x 10^{-6}
BW = Body Weight = 70 kg
q1* = Cancer slope factor = 2 per mg/kg-day
WC = Water Consumption = 2 l/day
FC = Fish and Shellfish Consumption = 0.0065 kg/day
BCF = Bioconcentration Factor = 31,200

the HHC (μg/l) = 0.00017 μg/l (rounded to two significant digits).

Following is the calculation of the human health criterion for organism only consumption:

$$HHC = \frac{RF \times BW \times (1{,}000\ \mu g/mg)}{q1^* \times FC \times BCF}$$

Where:

RF = Risk Factor = 1 x 10^{-6}
BW = Body Weight = 70 kg
q1* = Cancer slope factor = 2 per mg/kg-day
FC = Total Fish and Shellfish Consumption per Day = 0.0065 kg/day
BCF = Bioconcentration Factor = 31,200

the HHC (μg/l) = 0.00017 μg/l (rounded to two significant digits).

The criteria are both equal to 0.00017 μg/l and apply to total PCBs. *See PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures* (EPA/600/9–96–001F). For a discussion of the body weight, water consumption, and fish and shellfish consumption factors, see the Human Health Guidelines. For a discussion of the BCF, see the 304(a) criteria guidance document for PCBs (included in the administrative record for today's rule).

e. Excluded Section 304(a) Human Health Criteria

As is the case in the NTR, as amended, today's rule does not promulgate criteria for certain priority pollutants for which CWA section 304(a) criteria guidance exists because those criteria were not based on toxicity to humans or aquatic organisms. The basis for those particular criteria is organoleptic effects (*e.g.,* taste and odor) which would make water and edible aquatic life unpalatable but not toxic. Because the basis for this rule is to protect the public health and aquatic life from toxicity consistent with the language and intent in CWA section 303(c)(2)(B), EPA is promulgating criteria only for those priority toxic pollutants whose criteria recommendations are based on toxicity. The CWA section 304(a) human health criteria based on organoleptic effects for zinc and 3-methyl-4-chlorophenol are excluded for this reason. See the 1992 NTR discussion at 57 FR 60864.

f. Cancer Risk Level

EPA's CWA section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer case per 100,000 people (10^{-5}), per 1,000,000 people (10^{-6}), and per 10,000,000 people (10^{-7}). However, the criteria documents do not recommend a particular risk level as EPA policy.

As part of the proposed rule, EPA requested and received comment on the adoption of a 10^{-5} risk level for carcinogenic pollutants. The effect of a 10^{-5} risk level would have been to increase (*i.e.,* make less stringent) carcinogenic pollutant criteria values (noted in the matrix by footnote c) that are not already promulgated in the NTR, by one order of magnitude. For example, the organism-only criterion for gamma BHC (pollutant number 105 in the matrix) is 0.013 µg/l; the criterion based on a 10^{-5} risk level would have been 0.13 µg/l. EPA received several comments that indicated a preference for a higher (10^{-4} and 10^{-5}) risk level for effluent dependent waters or other types of special circumstances.

In today's rule, EPA is promulgating criteria that protect the general population at an incremental cancer risk level of one in a million (10^{-6}) for all priority toxic pollutants regulated as carcinogens, consistent with the criteria promulgated in the NTR for the State of California. Standards adopted by the State contained in the Enclosed Bays and Estuaries Plan (EBEP), and the Inland Surface Waters Plan (ISWP), partially approved by EPA on November 6, 1991, and the Ocean Plan approved by EPA on June 28, 1990, contained a risk level of 10^{-6} for most carcinogens. The State has historically protected at a 10^{-6} risk level for carcinogenic pollutants.

EPA, in its recent human health methodology revisions, proposed acceptable lifetime cancer risk for the general population in the range of 10^{-5} to 10^{-6}. EPA also proposed that States and Tribes ensure the most highly exposed populations do not exceed a 10^{-4} risk level. However, EPA's draft methodology revisions also stated that it will derive 304(a) criteria at a 10^{-6} risk level, which the Agency believes reflects the appropriate risk for the general population and which applies a risk management policy which ensures protection for all exposed population groups. (Draft Water Quality Criteria Methodology: Human Health, EPA 822–Z–98–001, August 1998, Appendix II, page 72).

Subpopulations within a State may exist, such as recreational and subsistence anglers, who as a result of greater exposure to a contaminant are at greater risk than the standard 70 kilogram person eating 6.5 grams per day of fish and shellfish and drinking 2.0 liters per day of drinking water with pollutant levels meeting the water quality criteria. EPA acknowledges that at any given risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10^{-5} risk level. Similarly, individuals consuming 100 times the general population rate would be protected at a 10^{-4} risk level. EPA, therefore, believes that derivation of criteria at the 10^{-6} risk level is a reasonable risk management decision protective of designated uses under the CWA. While outside the scope of this rule, EPA notes that States and Tribes, however, have the discretion to adopt water quality criteria that result in a higher risk level (*e.g.,* 10^{-5}). EPA expects to approve such criteria if the State or Tribe has identified the most highly exposed subpopulation within the State or Tribe, demonstrates the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation.

This demonstration has not happened in California. Further, the information that is available on highly exposed subpopulations in California supports the need to protect the general population at the 10^{-6} level. California has cited the Santa Monica Bay Seafood Consumption Study as providing the best available data set for estimating consumption of sport fish and shellfish in California for both marine or freshwater sources (Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States, Final Draft Report, July 1997). Consumption rates of sport fish and shellfish of 21g/day, 50 g/day, 107 g/day, and 161 g/day for the median, mean, 90th, and 95th percentile rates, respectively, were determined from this study. Additional consumption of commercial species in the range of approximately 8 to 42 g/day would further increase these values. Clearly the consumption rates for the most highly exposed subpopulation within the State exceeds 10 times the 6.5 g/day rates used in the CTR. Therefore, use of a risk level of 10^{-5} for the general population would not be sufficient to protect the most highly exposed population in California at a 10^{-4} risk level. On the other hand, even the most highly exposed subpopulations cited in the California study do not have consumption rates approaching 100 times the 6.5 g/day rates used in the CTR. The use of the 10^{-6} risk level to protect average level consumers does not subject these subpopulations to risk levels as high as 10^{-4}.

EPA believes its decision to establish a 10^{-6} risk level for the CTR is also consistent with EPA's policy in the NTR to select the risk level that reflect the policies or preferences of CWA programs in the affected States. California adopted standards for priority toxic pollutants for its ocean waters in 1990 using a 10^{-6} risk level to protect human health (California Ocean Plan, 1990). In April 1991, and again in November 1992, California adopted standards for its inland surface waters and enclosed bays and estuaries in its Inland Surface Waters Plan (ISWP) and its Enclosed Bays and Estuaries Plan (EBEP) using a 10^{-6} risk level. To be consistent with the State's water quality standards, EPA used a 10^{-6} risk level for California in the NTR at 57 FR 60867. The State has continued using a 10^{-6} risk level to protect human health for its standards that were not withdrawn with the ISWP and EBEP. The most recent expression of risk level preference is contained in the Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan for Ocean Waters of California, October 1998, where the State recommended maintaining a consistent risk level of 10^{-6} for the human health standards that it was proposing to revise.

EPA received several comments requesting a 10^{-5} risk level based on the risk level chosen for the Great Lakes Water Quality Guidance (the Guidance). There are several differences between the guidelines for the derivation of human health criteria contained in the Guidance and the California Toxics Rule (CTR) that make a 10^{-5} risk factor appropriate for the Guidance, but not for the CTR. These differences result in criteria developed using the 10^{-5} risk factor in the Guidance being at least as stringent as criteria derived under the CTR using a 10^{-6} risk factor. The relevant aspects of the Guidance include:

- Use of fish consumption rates that are considerably higher than fish consumption rates for the CTR.
- Use of bioaccumulation factors rather than bioconcentration factors in

estimating exposure, considerably increasing the dose of carcinogens to sensitive subgroups.

• Consideration of additivity of effects of mixtures for both carcinogenic and noncarcinogenic pollutants.

This combination of factors increase the calculated carcinogenic risk substantially under the Guidance (the combination would generally be more than one order of magnitude), making a lower overall risk factor acceptable. The Guidance risk factor provides, in fact, criteria with at least the same level of protection against carcinogens as criteria derived with a higher risk factor using the CTR. A lower risk factor for the CTR would not be appropriate absent concomitant changes in the derivation procedures that provide equivalent risk protection.

G. Description of Final Rule

1. Scope

Paragraph (a) in 40 CFR 131.38, entitled ''Scope,'' states that this rule is a promulgation of criteria for priority toxic pollutants in the State of California for inland surface waters, enclosed bays, and estuaries. Paragraph (a) in 40 CFR 131.38 also states that this rule contains an authorizing compliance schedule provision.

2. EPA Criteria for Priority Toxic Pollutants

EPA's criteria for California are presented in tabular form at 40 CFR 131.38. For ease of presentation, the table that appears combines water quality criteria promulgated in the NTR, as amended, that are outside the scope of this rulemaking, with the criteria that are within the scope of today's rule. This is intended to help readers determine applicable water quality criteria for the State of California. The table contains footnotes for clarification.

Paragraph (b) in 40 CFR 131.38 presents a matrix of the applicable EPA aquatic life and/or human health criteria for priority toxic pollutants in California. Section 303(c)(2)(B) of the CWA addresses only pollutants listed as ''toxic'' pursuant to section 307(a) of the CWA for which EPA has developed section 304(a) criteria guidance. As discussed earlier in this preamble, the section 307(a) list of toxics contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. Of these, the Agency identified a list of 126 ''priority toxic pollutants'' to implement the CWA (see 40 CFR 131.36(b)). Reference in this rule to priority toxic pollutants, toxic pollutants, or toxics refers to the 126 priority toxic pollutants.

EPA has not developed both aquatic life and human health CWA section 304(a) criterion guidance for all of the priority toxic pollutants. The matrix in 40 CFR 131.38(b) contains human health criteria in Column D for 92 priority toxic pollutants which are divided into Column 1: criteria for water consumption (i.e., 2.0 liters per day) and aquatic organism consumption (i.e., 6.5 grams per day of aquatic organisms); and Column 2: criteria for aquatic organism consumption only. The term aquatic organism includes fish and shellfish such as shrimp, clams, oysters and mussels. One reason the total number of priority toxic pollutants with criteria today differs from the total number of priority toxic pollutants contained in earlier published CWA section 304(a) criteria guidance is because EPA has developed and is promulgating chromium criteria for two valence states with respect to aquatic life criteria. Thus, although chromium is a single priority toxic pollutant, there are two criteria for chromium for aquatic life protection. See pollutant 5 in today's rule at 40 CFR 131.38(b). Another reason is that EPA is promulgating human health criteria for nine priority pollutants for which health-based national criteria have been calculated based on information obtained from EPA's IRIS database (EPA provided notice of these nine criteria in the NTR for inclusion in future State triennial reviews. See 57 FR 60848, 60890).

The matrix contains aquatic life criteria for 23 priority pollutants. These are divided into freshwater criteria (Column B) and saltwater criteria (Column C). These columns are further divided into acute and chronic criteria. The aquatic life criteria are considered by EPA to be protective when applied under the conditions described in the section 304(a) criteria documents and in the TSD. For example, water body uses should be protected if the criteria are not exceeded, on average, once every three year period. It should be noted that the criteria maximum concentrations (the acute criteria) are short-term concentrations and that the criteria continuous concentrations (the chronic criteria) are four-day averages. It should also be noted that for certain metals, the actual criteria are equations which are included as footnotes to the matrix. The toxicity of these metals is water hardness dependent and may be adjusted. The values shown in the table are illustrative only, based on a hardness expressed as calcium carbonate of 100 mg/l. Finally, the criterion for pentachlorophenol is pH dependent. The equation is the actual criterion and is included as a footnote. The value shown in the matrix is for a pH of 7.8. Several of the freshwater aquatic life criteria are incorporated into the matrix in the format used in the 1980 criteria methodology which uses a final acute value instead of a continuous maximum concentration. This distinction is noted in footnote g of the table.

The final rule at 40 CFR 131.38(c) establishes the applicability of the criteria to the State of California. 40 CFR 131.38(d) is described later in Section F, of this preamble. EPA has included in this rule provisions necessary to implement numeric criteria in a way that maintains the level of protection intended. These provisions are included in 40 CFR 131.38(c) of today's rule. For example, in order to do steady state waste load allocation analyses, most States have low flow values for streams and rivers which establish flow rates for various purposes. These low flow values become design flows for sizing treatment plants and developing water quality-based effluent limits and/or TMDLs. Historically, these design flows were selected for the purposes of waste load allocation analyses which focused on instream dissolved oxygen concentrations and protection of aquatic life. With the publication of the 1985 TSD, EPA introduced hydrologically and biologically based analyses for the protection of aquatic life and human health. (These concepts have been expanded subsequently in EPA's *Technical Guidance Manual for Performing Wasteload Allocations, Book 6, Design Conditions,* U.S. EPA, 1986. These analyses are included in Appendix D of the revised TSD. The discussion here is greatly simplified and is provided to support EPA's decision to promulgate design flows for instream flows and thereby maintain the adequacy of the criteria for priority toxic pollutants.) EPA recommended either of two methods for calculating acceptable low flows, the traditional hydrologic method developed by the U.S. Geological Survey or a biological based method developed by EPA. Other methods for evaluating the instream flow record may be available; use of these methods may result in TMDLs and/or water quality-based effluent limitations which adequately protect human health and/or aquatic life. The results of either of these two methods, or an equally protective alternative method, may be used.

The State of California may adopt specific design flows for streams and rivers to protect designated uses against the effects of toxics. EPA believes it is

important to specify design flows in today's rule so that, in the absence of state design flows, the criteria promulgated today would be implemented appropriately. The TSD also recommends the use of three dynamic models to perform wasteload allocations. Dynamic wasteload models do not generally use specific steady state design flows but accomplish the same effect by factoring in the probability of occurrence of stream flows based on the historical flow record.

The low flows specified in the rule explicitly contain duration and frequency of occurrence which represent certain probabilities of occurrence. Likewise, the criteria for priority toxic pollutants are defined with duration and frequency components. Dynamic modeling techniques explicitly predict the effects of variability in receiving water, effluent flow, and pollution variation. Dynamic modeling techniques, as described in the TSD, allow for calculating wasteload allocations that meet the criteria for priority toxic pollutants without using a single, worst-case concentration based on a critical condition. Either dynamic modeling or steady state modeling can be used to implement the criteria promulgated today. For simplicity, only steady state conditions are discussed here. Clearly, if the criteria were implemented using design flows that are too high, the resulting toxic controls would not be adequate, because the resulting ambient concentrations would exceed EPA's criteria.

In the case of aquatic life, assuming exceedences occur more frequently than once in three years on the average, exceedences would result in diminished vitality of stream ecosystems characterized by the loss of desired species. Numeric water quality criteria should apply at all flows that are equal to or greater than flows specified below. The low flow values are:

Type of criteria	Design flow
Acute Aquatic Life (CMC).	1 Q 10 or 1 B 3
Chronic Aquatic Life (CCC).	7 Q 10 or 4 B 3
Human Health	harmonic mean flow

Where:

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedences for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

EPA is requiring that the harmonic mean flow be applied with human health criteria. The harmonic mean is a standard calculated statistical value. EPA's model for human health effects assumes that such effects occur because of a long-term exposure to low concentration of a toxic pollutant, for example, two liters of water per day for seventy years. To estimate the concentrations of the toxic pollutant in those two liters per day by withdrawal from streams with a high daily variation in flow, EPA believes the harmonic mean flow is the correct statistic to use in computing such design flows rather than other averaging techniques. (For a description of harmonic means see ''Design Stream Flows Based on Harmonic Means,'' Lewis A. Rossman, Jr. of Hydraulics Engineering, Vol. 116, No. 7, July, 1990.)

All waters (including lakes, estuaries, and marine waters), whether or not suitable for such hydrologic calculations, are subject to the criteria promulgated today. Such criteria will need to be attained at the end of the discharge pipe, unless the State authorizes a mixing zone. Where the State plans to authorize a mixing zone, the criteria would apply at the locations allowed by the mixing zone. For example, the chronic criteria (CCC) would apply at the defined boundary of the chronic mixing zone. Discussion of and guidance on these factors are included in the revised TSD in Chapter 4.

EPA is aware that the criteria promulgated today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting water quality criteria since they are not related to actual environmental impacts. The environmental impact of a pollutant is based on a scientific determination, not a measuring technique which is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. See 1985 Guidelines, page 21. As the methods improve, limits based on the actual criteria necessary to protect aquatic life and human health become measurable. The Agency does not believe it is appropriate to promulgate criteria that are not sufficiently protective. EPA discusses this issue further in its Response to Comment Document for today's final rule.

EPA does believe, however, that the use of analytical detection limits are appropriate for assessing *compliance* with National Pollutant Discharge Elimination System (NPDES) permit limits. This view of the role of detection limits was first articulated in guidance for translating dioxin criteria into NPDES permit limits. See ''Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the U.S.'' Memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors, May 21, 1990. This guidance presented a model for addressing toxic pollutants which have criteria less than current detection limits. EPA, in more recent guidance, recommends the use of the ''minimum level'' or ML for reporting sample results to assess compliance with WQBELs (TSD page 111). The ML, also called the ''quantification level,'' is the level at which the entire analytical system gives recognizable mass spectra and acceptable calibration points, i.e., the point at which the method can reliably quantify the amount of pollutant in the sample. States can use their own procedures to average and otherwise account for monitoring data, *e.g.,* quantifying results below the ML. These results can then be used to assess compliance with WQBELs. (See 40 CFR part 132, Appendix F, Procedure 8.B.) This approach is applicable to priority toxic pollutants with criteria less than current detection limits. EPA's guidance explains that standard analytical methods may be used for purposes of assessing compliance with permit limits, but not for purposes of establishing water quality criteria or permit limits. Under the CWA, analytical methods are appropriately used in connection with NPDES permit limit compliance assessments. Because of the function of water quality criteria, EPA has not considered the sensitivity of analytical methods in deriving the criteria promulgated today.

EPA has promulgated 40 CFR 131.38(c)(3) to determine when freshwater or saltwater aquatic life criteria apply. This provision incorporates a time parameter to better define the critical condition. The structure of the paragraph is to establish

applicable rules and to allow for site-specific exceptions where the rules are not consistent with actual field conditions. Because a distinct separation generally does not exist between freshwater and saltwater aquatic communities, EPA is establishing the following: (1) The freshwater criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) saltwater criteria apply at salinities of 10 parts per thousand and above at locations where this occurs 95% more of the time; and (3) at salinities between 1 and 10 parts per thousand the more stringent of the two apply unless EPA approves the application of the freshwater or saltwater criteria based on an appropriate biological assessment. The percentiles included here were selected to minimize the chance of overlap, that is, one site meeting both criteria. Determination of these percentiles can be done by any reasonable means such as interpolation between points with measured data or by the application of calibrated and verified mathematical models (or hydraulic models). It is not EPA's intent to require actual data collection at particular locations.

In the brackish water transition zones of estuaries with varying salinities, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply. In evaluating appropriate data supporting the alternative set of criteria, EPA will focus on the species composition as its preferred method. This assignment of criteria for fresh, brackish and salt waters was developed in consultation with EPA's research laboratories at Duluth, Minnesota and Narragansett, Rhode Island. The Agency believes such an approach is consistent with field experience.

Paragraph (d) in 40 CFR 131.38 lists the designated water and use classifications for which the criteria apply. The criteria are applied to the beneficial use designations adopted by the State of California; EPA has not promulgated any new use classifications in this rule.

Exceedences Frequency: In a water quality criterion for aquatic life, EPA recommends an allowable frequency for excursions of the criteria. See 1985 Guidelines, pages 11–13. This allowable frequency provides an appropriate period of time during which the aquatic community can recover from the effect of an excursion and then function normally for a period of time before the next excursion. An excursion is defined as an occurrence of when the average concentration over the duration of the averaging period is above the CCC or the CMC. As ecological communities are naturally subjected to a series of stresses, the allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stresses combined. See also TSD, Appendix D. In addition, providing an allowable frequency for exceeding the criterion recognizes that it is not generally possible to assure that criteria are never exceeded. (TSD, page 36.)

Based on the available data, today's rule requires that the acute criterion for a pollutant be exceeded no more than once in three years on the average. EPA is also requiring that the chronic criterion for a pollutant be exceeded no more than once in three years on the average. EPA acknowledges that States may develop allowable frequencies that differ from these allowable frequencies, so long as they are scientifically supportable, but believes that these allowable frequencies are protective of the designated uses where EPA is promulgating criteria.

The use of aquatic life criteria for developing water quality-based effluent limits in permits requires the permitting official to use an appropriate wasteload allocation model. (TSD, Appendix D–6.) As discussed above, there are generally two methods for determining design flows, the hydrologically-based method and the biologically-based method.

The biologically-based method directly uses the averaging periods and frequencies specified in the aquatic life criteria for determining design flows. (TSD, Appendix. D–8.) Because the biologically-based method calculates the design flow directly from the duration and allowable frequency, it most accurately provides the allowed number of excursions. The hydrologically based method applies the CMC at a design flow equal to or equivalent to the 1Q10 design flow (i.e., the lowest one-day flow with an average recurrence frequency of once in ten years), and applies the CCC at the 7Q10 design flow (i.e., the lowest average seven consecutive day flow with a recurrence frequency of once in ten years).

EPA established a three year allowable frequency in the NTR. In settlement of the litigation on the NTR, EPA stated that it was in the midst of conducting, sponsoring, or planning research aimed at addressing scientific issues related to the basis for and application of water quality criteria and mentioned the issue of allowable frequency. See Partial Settlement Agreement in *American Forest and Paper Ass'n, Inc. et al.* v. *U.S. EPA* (Consolidated Case No. 93–0694 (RMU) D.D.C. To that end, EPA is reevaluating issues raised about allowable frequency as part of its work in revising the 1985 Guidelines.

EPA recognizes that additional data concerning (a) the probable frequency of lethal events for an assemblage of taxa covering a range of sensitivities to pollutants, (b) the probable frequency of sublethal effects for such taxa, (c) the differing effects of lethal and sublethal events in reducing populations of such taxa, and (d) the time needed to replace organisms lost as a result of toxicity, may lead to further refinement of the allowable frequency value. EPA has not yet completed this work. Until this work is complete, EPA believes that where EPA promulgates criteria, the three year allowable frequency represents a value in the reasonable range for this parameter.

3. Implementation

Once the applicable designated uses and water quality criteria for a water body are determined, under the National Pollutant Discharge Elimination System (NPDES) program discharges to the water body must be characterized and the permitting authority must determine the need for permit limits. If a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric or narrative water quality criteria, the permitting authority must develop permit limits as necessary to meet water quality standards. These permit limits are water quality-based effluent limitations or WQBELs. The terms ''cause,'' ''reasonable potential to cause,'' and ''contribute to'' are the terms in the NPDES regulations for conditions under which water quality-based permit limits are required. See 40 CFR 122.44(d)(1).

Since the publication of the proposed CTR, the State of California adopted procedures which detail how water quality criteria will be implemented through NPDES permits, waste discharge requirements, and other regulatory approaches. These procedures entitled, *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California* were adopted on March 2, 2000. Once these procedures are submitted for review under CWA section 303(c), EPA will review them as they relate to water quality standards, and approve or disapprove them.

Several commenters understood the language in the preamble to the proposed rule regarding implementation

to mean that site-specific criteria, variances, and other actions would be prohibited or severely limited by the CTR. Site-specific criteria, variances and other actions modifying criteria are neither prohibited nor limited by the CTR. The State, if it so chooses, still can make these changes to its water quality standards, subject to EPA approval. However, with this Federal rule in effect, the State cannot implement any modifications that are less stringent than the CTR without an amendment to the CTR to reflect these modifications. EPA will make every effort to expeditiously accommodate Federal rulemaking of appropriate modifications to California's water quality standards. In the preamble to the proposed CTR, and here today, EPA is emphasizing that these efforts to amend the CTR on a case-by-case basis will generally increase the time before a modification can be implemented.

4. Wet Weather Flows

EPA has for a longtime maintained that CWA section 301(b)(1)(C) applies to NPDES permits for discharges from municipal separate storm sewer systems. Recently, the U.S. Court of Appeals for the Ninth Circuit upheld NPDES permits issued by EPA for five Arizona municipal separate storm sewer systems and addressed this issue specifically. *Defenders of Wildlife, et al.* v. *Browner,* No. 98–71080 (9th Cir., October 1999). The Court held that the CWA does not require ''strict compliance'' with State water quality standards for municipal storm sewer permits under section 301(b)(1)(C), but that at the same time, the CWA does give EPA discretion to incorporate appropriate water quality-based effluent limitations under another provision, CWA section 402(p)(3)(B)(iii).

The Court based its decision on the structure of section 402(p)(3), which contains distinct language for discharges of industrial storm water and municipal storm water. In section 402(p)(3)(A), Congress requires that ''dischargers associated with industrial activity shall meet all applicable provisions of [section 402] and section [301].'' 33 U.S.C. section 1342(p)(3)(A). The Court noted, therefore, that by incorporation, industrial storm water discharges need to achieve ''any more stringent limitation, including those necessary to meet water quality standards * * *'' The Court explained that industrial storm water discharges ''must comply strictly with State water quality standards'' but that Congress chose not to include a similar provision for municipal storm sewer discharges, including instead a requirement for controls to reduce pollutants to the maximum extent practicable or MEP standard in section 402(p)(3)(B). Reading the two related sections together, the Court concluded that section 402(p)(3)(B)(iii) does not require ''strict compliance'' by municipal storm sewer discharges according to section 301(b)(1)(C). At the same time, however, the Court found that the language in CWA section 402(p)(3)(B)(iii) which states that permits for discharges from municipal storm sewers shall require ''such other provisions as the Administrator of the state determines appropriate for the control of such pollutants'' provides EPA with discretion to incorporate provisions lending to ultimate compliance with water quality standards.

EPA believes that compliance with water quality standards through the use of Best Management Practices (BMPs) is appropriate. EPA articulated its position on the use of BMPs in storm water permits in the policy memorandum entitled, ''Interim Permitting Approach for Water Quality-Based Effluent Limitations In Storm Water Permits'' which was signed by the Assistant Administrator for Water, Robert Perciasepe on August 1, 1996 (61 FR 43761, August 9, 1996). A copy of this memorandum is contained in the administrative record for today's rule. The policy affirms the use of BMPs as a means to attain water quality standards in municipal storm water permits, and embraces BMPs as an interim permitting approach.

The interim permitting approach uses BMPs in first-round storm water permits, and expanded or better-tailored BMPs in subsequent permits, where necessary, to provide for the attainment of water quality standards. In cases where adequate information exists to develop more specific conditions or limitations to meet water quality standards, these conditions or limitations are to be incorporated into storm water permits, as necessary and appropriate.

This interim permitting approach, however, only applies to EPA. EPA encourages the State to adopt a similar policy for municipal storm water permits. This interim permitting approach provides time, where necessary, to more fully assess the range of issues and possible options for the control of storm water discharges for the protection of water quality. More information on this issue is included in the response to comment document in response to specific storm water issues raised by commenters.

5. Schedules of Compliance

A compliance schedule refers to an enforceable sequence of interim requirements in a permit leading to ultimate compliance with water quality-based effluent limitations or WQBELs in accordance with the CWA. The authorizing compliance schedule provision authorizes, but does not require, the permit issuing authority in the State of California to include such compliance schedules in permits under appropriate circumstances. The State of California is authorized to administer the National Pollutant Discharge Elimination System (NPDES) program and may exercise its discretion when deciding if a compliance schedule is justified because of the technical or financial (or other) infeasibility of immediate compliance. An authorizing compliance schedule provision is included in today's rule because of the potential for existing dischargers to have new or more stringent effluent limitations for which immediate compliance would not be possible or practicable.

New and Existing Dischargers: The provision allows compliance schedules only for an ''existing discharger'' which is defined as any discharger which is not a ''new California discharger.'' A ''new California discharger'' includes ''any building, structure, facility, or installation from which there is, or may be, a 'discharge of pollutants', the construction of which commences after the effective date of this regulation.'' These definitions are modeled after the existing 40 CFR 122.2 definitions for parallel terms, but with a cut-off date modified to reflect this rule. Only ''new California dischargers'' are required to comply immediately upon commencement of discharge with effluent limitations derived from the criteria in this rule. For ''existing dischargers'' whose permits are reissued or modified to contain new or more stringent limitations based upon certain water quality requirements, the permit could allow up to five years, or up to the length of a permit, to comply with such limitations. The provision applies to new or more stringent effluent limitations based on the criteria in this EPA rule.

EPA has included ''increasing dischargers'' within the category of ''existing dischargers'' since ''increasing dischargers'' are existing facilities with a change—an increase—in their discharge. Such facilities may include those with seasonal variations. ''Increasing dischargers'' will already have treatment systems in place for their current discharge, thus, they have less

opportunity than a new discharger does to design and build a new treatment system which will meet new water quality-based requirements for their changed discharge. Allowing existing facilities with an increasing discharge a compliance schedule will avoid placing the discharger at a competitive disadvantage vis-a-vis other existing dischargers who are eligible for compliance schedules.

Today's rule does not prohibit the use of a short-term ''shake down period'' for new California dischargers as is provided for new sources or new dischargers in 40 CFR 122.29(d)(4). These regulations require that the owner or operator of (1) a new source; (2) a new discharger (as defined in 40 CFR 122.2) which commenced discharge after August 13, 1979; or (3) a recommencing discharger shall install and implement all pollution control equipment to meet the conditions of the permit before discharging. The facility must also meet all permit conditions in the shortest feasible time (not to exceed 90 days). This shake-down period is not a compliance schedule. This approach may be used to address violations which may occur during a new facility's start-up, especially where permit limits are water quality-based and biological treatment is involved.

The burden of proof to show the necessity of a compliance schedule is on the discharger, and the discharger must request approval from the permit issuing authority for a schedule of compliance. The discharger should submit a description of the minimum required actions or evaluations that must be undertaken in order to comply with the new or more restrictive discharge limits. Dates of completion for the required actions or evaluations should be included, and the proposed schedule should reflect the shortest practicable time to complete all minimum required actions.

Duration of Compliance Schedules: Today's rule provides that compliance schedules may provide for up to five years to meet new or more stringent effluent limitations in those limited circumstances where the permittee can demonstrate to the permit authority that an extended schedule is warranted. EPA's regulations at 122.47 require compliance with standards as soon as possible. This means that permit authorities should not allow compliance schedules where the permittee fails to demonstrate their necessity. This provision should not be considered a default compliance schedule duration for existing facilities.

In instances where dischargers wish to conduct toxicological studies, analyze results, and adopt and implement new or revised water quality-based effluent limitations, EPA believes that five years is sufficient time within which to complete this process. See the preamble to the proposed rule.

Under this rule, where a schedule of compliance exceeds one year, interim requirements are to be specified and interim progress reports are to be submitted at least annually to the permit issuing authority, in at least one-year time intervals.

The rule allows all compliance schedules to extend up to a maximum duration of five years, which is the maximum term of any NPDES permit. See 40 CFR 122.46. The discharger's opportunity to obtain a compliance schedule occurs when the existing permit for that discharge is issued, reissued or modified to contain more stringent limits based on the water quality criteria in today's rule. Such compliance schedules, however, cannot be extended to any indefinite point of time in the future because the compliance schedule provision in this rule will sunset on May 18, 2005. The sunset applies to the authorizing provision in today's rule (40 CFR 131.38(e)), not to individual schedules of compliance included in specific NPDES permits. Delays in reissuing expired permits (including those which continue in effect under applicable NPDES regulations) cannot indefinitely extend the period of time during which a compliance schedule is in effect. This would occur where the permit authority includes the single maximum five-year compliance schedule in a permit that is reissued just before the compliance schedule provision sunsets (having been previously issued without WQBELS using the rule's criteria on the eve of the effective date of this rule). Instead, the effect of the sunset provision is to limit the longest time period for compliance to ten years after the effective date of this rule.

EPA recognizes that where a permit is modified during the permit term, and the permittee needs the full five years to comply, the five-year schedule may extend beyond the term of the modified permit. In such cases, the rule allows for the modified permit to contain a compliance schedule with an interim limit by the end of the permit term. When the permit is reissued, the permit authority may extend the compliance schedule in the next permit, provided that, taking into account the amount of time allowed under the previous permit, the entire compliance schedule contained in the permit shall not exceed five years. Final permit limits and compliance dates will be included in the record for the permit. Final compliance dates must occur within five years from the date of permit issuance, reissuance, or modification, unless additional or less time is provided for by law.

EPA would prefer that the State adopt an authorizing compliance schedule provision but recognizes that the State may not be able to complete this action for some time after promulgation of the CTR. Thus, EPA has chosen to promulgate the rule with a sunset provision which states that the authorizing compliance schedule provision will cease or sunset on May 18, 2005. However, if the State Board adopts, and EPA approves, a statewide authorizing compliance schedule provision significantly prior to May 18, 2005, EPA will act to stay the authorizing compliance schedule provision in today's rule. Additionally, if a Regional Board adopts, and the State Board adopts and EPA approves, a Regional Board authorizing compliance schedule provision, EPA will act to stay today's provision for the appropriate or corresponding geographic region in California. At that time, the State Board's or Regional Board's authorizing compliance schedule provision will govern the ability of the State regulatory entity to allow a discharger to include a compliance schedule in a discharger's NPDES permit.

Antibacksliding: EPA wishes to address the potential concern over antibacksliding where revised permit limits based on new information are the result of the completion of additional studies. The Agency's interpretation of the CWA is that the antibacksliding requirements of section 402(o) of the CWA do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations.

State Compliance Schedule Provisions: EPA supports the State in adopting a statewide provision independent of or as part of the effort to readopt statewide water quality control plans, or in adopting individual basin-wide compliance schedule provisions through its nine Regional Water Quality Control Boards (RWQCBs). The State and RWQCBs have broad discretion to adopt a provision, including discretion on reasonable lengths of time for final compliance with WQBELs. EPA recognizes that practical time frames within which to set interim goals may be necessary to achieve meaningful, long-term improvements in water quality in California.

At this time, two RWQCBs have adopted an authorizing compliance schedule provision as an amendment to

their respective Basin Plans during the Boards' last triennial review process. The Basin Plans have been adopted by the State and have come to EPA for approval. Thus, the Basin Plans' provisions are effective for the respective Basins. If and when EPA approves of either Regional Basin Plan, EPA will expeditiously act to amend the CTR, staying its compliance schedule provision, for the appropriate geographic region.

6. Changes From Proposed Rule

A few changes were made in the final rule from the proposal both as a result of the Agency's consideration of issues raised in public comments and Endangered Species Act consultation with the U.S. Fish and Wildlife Service (FWS) and U.S. National Marine Fisheries Service (NMFS). The important changes include: reserving the mercury aquatic life criteria; reserving the selenium freshwater acute aquatic life criterion; reserving the chloroform human health criteria; and adding a sunset provision to the authorizing compliance schedule provision. EPA also clarified that the CTR will not replace priority toxic pollutant criteria which were adopted by the San Francisco Regional Water Quality Control Board in its 1986 Basin Plan, adopted by the State Board, and approved by EPA; specifying the harmonic mean for human health criteria for non-carcinogens and adding a provision which explicitly allows the State to adopt and implement an alternative averaging period, frequency, and design flow for a criterion after opportunity for public comment.

The first two changes, the reservation of mercury criteria and selenium criterion, are discussed in more detail below in Section L., The Endangered Species Act (ESA). The selenium criterion is also discussed in more detail above in Section E., Derivation of Criteria, in subsection 2.b., Freshwater Acute Selenium Criterion. EPA has also decided to reserve a decision on numeric criteria for chloroform and therefore not promulgate chloroform criteria in the final rule. As part of a large-scale regulation promulgated in December l998 under the Safe Drinking Water Act, EPA published a health-based goal for chloroform (the maximum contaminant level goal or MCLG) of zero, see 63 FR 69390, Dec. 16, 1998. EPA provided new data and analyses concerning chloroform for public review and comment, including a different, mode of action approach for estimating the cancer risk, 63 FR 15674, March 31, 1998, but did not reach a conclusion on how to use that new information in establishing the final MCLG, pending further review by the Science Advisory Board. EPA has now concluded that any further actions on water quality criteria should take into account the new data and analysis as reviewed by the SAB. This decision is consistent with a recent federal court decision vacating the MCLG for chloroform (*Chlorine Chemistry Council* v. *EPA,* No. 98–1627 (DC Cir., Mar. 31,2000)). EPA intends to reassess the human health 304(a) criteria recommendation for chloroform. For these reasons, EPA has decided to reserve a decision on numeric criteria for chloroform in the CTR and not promulgate water quality criteria as proposed. Permitting authorities in California should continue to rely on existing narrative criteria to establish effluent limitations as necessary for chloroform.

The sunset provision for the authorizing compliance schedule provision has been added to ease the transition from a Federal provision to the State's provision that was adopted in March 2000 as part of its' new statewide implementation plan. The sunset provision is discussed in more detail in Section G.5 of today's preamble. The CTR matrix at 40 CFR 131.38(b)(1) makes it explicit that the rule does not supplant priority toxic pollutant criteria which were adopted by the San Francisco Regional Water Quality Control Board in its 1986 Basin Plan, adopted by the State Board, and approved by EPA. This change is discussed more fully in Section D.4. of today's preamble. EPA modified the design flow for implementing human health criteria for non-carcinogens from a 30Q5 to a harmonic mean. Human health criteria for non-carcinogens are based on an RfD, which is an acceptable daily exposure over a lifetime. EPA matched the criteria for protection over a human lifetime with the longest stream flow averaging period, i.e., the harmonic mean. Lastly, the CTR now contains language which is intended to make it easier for the State to adopt and implement an alternative averaging period, frequency and related design flow, for situations where the default parameters are inappropriate. This language is found at 40 CFR 131.38(c)(2)(iv).

H. Economic Analysis

This final rule establishes ambient water quality criteria which, by themselves, do not directly impose economic impacts (see section K). These criteria combined with the State-adopted designated uses for inland surface waters, enclosed bays and estuaries, and implementation policies, will establish water quality standards. Until the State implements these water quality standards, there will be no effect of this rule on any entity. The State will implement these criteria by ensuring that NPDES permits result in discharges that will meet these criteria. In so doing, the State will have considerable discretion.

EPA has analyzed the indirect potential costs and benefits of this rule. In order to estimate the indirect costs and benefits of the rule, an appropriate baseline must be established. The baseline is the starting point for measuring incremental costs and benefits of a regulation. The baseline is established by assessing what would occur in the absence of the regulation. At present, State Basin Plans contain a narrative water quality criterion stating that all waters shall be maintained free of toxic substances in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life. EPA's regulation at 40 CFR 122.44(d)(1)(vi) requires that where a discharge causes or has the reasonable potential to cause an excursion above a narrative criterion within a State water quality standard, the permitting authority must establish effluent limits but may determine limits using a number of options. These options include establishing ''effluent limits on a case-by-case basis, using EPA's water quality criteria published under section 304(a) of the CWA, supplemented where necessary by other relevant information'' (40 CFR 122.44(d)(1)(vi)(B)). Thus, to the extent that the State is implementing its narrative criteria by applying the CWA section 304(a) criteria, this rule does not impose any incremental costs because the criteria in this rule are identical to the CWA section 304(a) criteria. Alternatively, to the extent that the State is implementing its narrative criteria on a ''case-by-case basis'' using ''other relevant information'' in its permits this rule may impose incremental indirect costs because the criteria in these permits may not be based on CWA 304(a) criteria. Both of these approaches to establishing effluent limits are in full compliance with the CWA.

Because a specific basis for effluent limits in all existing permits in California is not known, it is not possible to determine a precise estimate of the indirect costs of this rule. The incremental costs of the rule may be as low as zero, or as high as $61 million. The high estimate of costs is based on the possibility that most of the effluent limits now in effect are not based on 304(a) criteria. EPA evaluated these

indirect costs using two different approaches. The first approach uses existing discharge data and makes assumptions about future State NPDES permit limits. Actual discharge levels are usually lower than the level set by current NPDES permit limits. This approach, representing the low-end scenario, also assumes that some of the discretionary mechanisms that would enhance flexibility (*e.g.,* site specific criteria, mixing zones) would be granted by the State. The second approach uses a sample of existing permit limits and assumes that dischargers are actually discharging at the levels contained in their permits and makes assumptions about limits statewide that would be required under the rule. This approach, representing the high-end scenario, also assumes that none of the discretionary mechanisms that would enhance flexibility (*e.g.,* site specific criteria, mixing zones) would be granted by the State. These two approaches recognize that the State has significant flexibility and discretion in how it chooses to implement standards within the NPDES permit program, the EA by necessity includes many assumptions about how the State will implement the water quality standards. These assumptions are based on a combination of EPA guidance and current permit conditions for the facilities examined in this analysis. To account for the uncertainty of EPA's implementation assumptions, this analysis estimates a wide range of costs and benefits. By completing the EA, EPA intends to inform the public about how entities might be potentially affected by State implementation of water quality standards in the NPDES permit program. The costs and benefits sections that follow summarize the methodology and results of the analysis.

1. Costs

EPA assessed the potential compliance costs that facilities may incur to meet permit limits based on the criteria in today's rule. The analysis focused on direct compliance costs such as capital costs and operation and maintenance costs (O&M) for end-of-pipe pollution control, indirect source controls, pollution prevention, monitoring, and costs of pursuing alternative methods of compliance.

The population of facilities with NPDES permits that discharge into California's enclosed bays, estuaries and inland surface waters includes 184 major dischargers and 1,057 minor dischargers. Of the 184 major facilities, 128 are publicly owned treatment works (POTWs) and 56 are industrial facilities. Approximately 2,144 indirect dischargers designated as significant industrial users discharge wastewater to those POTWs. In the EA for the proposed CTR, EPA used a three-phased process to select a sample of facilities to represent California dischargers potentially affected by the State's implementation of permit limits based on the criteria contained in this rule.

The first phase consisted of choosing three case study areas for which data was thought to exist. The three case studies with a total of 5 facilities included: the South San Francisco Bay (the San Jose/Santa Clara Water Pollution Control Plant and Sunnyvale Water Pollution Control Plant); the Sacramento River (the Sacramento Regional Wastewater Treatment Plant); and the Santa Ana River (the City of Riverside Water Quality Control Plant and the City of Colton Municipal Wastewater Treatment Facility). The second phase consisted of selecting five additional major industrial dischargers to complement the case-study POTWs.

The third phase involved selecting 10 additional facilities to improve the basis for extrapolating the costs of the selected sample facilities to the entire population of potentially affected dischargers. The additional 10 facilities were selected such that the group examined: (1) Was divided between major POTWs and major industrial discharger categories in proportion to the numbers of facilities in the State; (2) gave greater proportionate representation to major facilities than minor facilities based on a presumption that the majority of compliance costs would be incurred by major facilities; (3) gave a proportionate representation to each of four principal conventional treatment processes typically used by facilities in specified industries in California; and (4) was representative of the proportionate facilities located within the different California Regional Water Quality Control Boards. Within these constraints, facilities were selected at random to complete the sample.

In the EA for today's final rule, EPA primarily used the same sample as the EA for the proposed rule with some modifications. EPA increased the number of minor POTWs and minor industrial facilities in the sample. EPA randomly selected four new minor POTW facilities and five new minor industrial facilities to add to the sample. The number of sample facilities selected in each area under the jurisdiction of a Regional Water Quality Control Board was roughly proportional to the universe of facilities in each area.

For those facilities that were projected to exceed permit limits based on the criteria, EPA estimated the incremental costs of compliance. Using a decision matrix or flow chart, costs were developed for two different scenarios—a ''low-end'' cost scenario and a ''high-end'' cost scenario—to account for a range of regulatory flexibility available to the State when implementing permit limits based on the water quality criteria. The assumptions for baseline loadings also vary over the two scenarios. The low-end scenario generally assumed that facilities were discharging at the maximum effluent concentrations taken from actual monitoring data, while the high-end scenario generally assumed that facilities were discharging at their current effluent limits. The decision matrix specified assumptions used for selection of control options, such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and end-of-pipe treatment.

The annualized potential costs that direct and indirect dischargers may incur as a result of State implementation of permit limits based on water quality standards using today's criteria are estimated to be between $33.5 million and $61 million. EPA believes that the costs incurred as a result of State implementation of these permit limits will approach the low-end of the cost range. Costs are unlikely to reach the high-end of the range because State authorities are likely to choose implementation options that provide some degree of flexibility or relief to point source dischargers. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because the analysis tended to use conservative assumptions in calculating these permit limits and in establishing baseline loadings. The baseline loadings for the high-end were based on current effluent limits rather than actual pollutant discharge data. Most facilities discharge pollutants in concentrations well below current effluent limits. In addition, both the high-end and low-end cost estimates in the EA may be slightly overstated since potential costs incurred to reduce chloroform discharges were included in these estimates. EPA made a decision to reserve the chloroform human health criteria after the EA was completed.

Under the low-end cost scenario, major industrial facilities and POTWs would incur about 27 percent of the potential costs, indirect dischargers would incur about 70 percent of the potential costs, while minor dischargers would incur about 3 percent. Of the major direct dischargers, POTWs would incur the largest share of projected costs (87 percent). However, distributed

among 128 major POTWs in the State, the average cost per plant would be $61,000 per year. Chemical and petroleum industries would incur the highest cost of the industrial categories (5.6 percent of the annual costs, with an annual average of $25,200 per plant). About 57 percent of the low-end costs would be associated with pollution prevention activities, while nearly 38 percent would be associated with pursuing alternative methods of compliance under the regulations.

Under the high-end cost scenario, major industrial facilities and POTWs would incur about 94 percent of the potential costs, indirect dischargers would incur about 17 percent of the potential costs, while minor dischargers would incur about 5 percent. Among the major, direct dischargers, two categories would incur the majority of potential costs—major POTWs (82 percent), Chemical/Petroleum Products (9 percent). The average annual per plant cost for different industry categories would ranges from zero to $324,000. The two highest average cost categories would be major POTWs ($324,000 per year) and Chemical/Petroleum Products ($221,264 per year). The shift in proportion of potential costs between direct and indirect dischargers is due to the assumption that more direct dischargers would use end-of-pipe treatment under the high-end scenario. Thus, a smaller proportion of indirect dischargers would be impacted under the high-end scenario, since some municipalities are projected to add end-of-pipe treatment which would reduce the need for controls from indirect discharges. Over 91 percent of the annual costs are for waste minimization and treatment optimization costs. Waste minimization would represent nearly 84% of the total annual costs. Capital and operation and maintenance costs would make up less than 9 percent of annual costs.

Cost-Effectiveness: Cost-effectiveness is estimated in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness is derived by dividing the projected annual costs of implementing permit limits based on water quality standards using today's criteria by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

Based on this analysis, State implementation of permit limits based on today's criteria would be responsible for the reduction of about 1.1 million to 2.7 million toxic pound-equivalents per year, or 15 to 50 percent of the toxic-weighted baseline loadings for the high- and low-end scenarios, respectively. The cost-effectiveness of the scenarios would range from $22 (high-end scenario) to $31 (low-end scenario) per pound-equivalent.

2. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected as a result of implementation of water quality standards based on today's criteria. To the extent feasible, empirical estimates of the potential magnitude of the benefits were developed and then compared to the estimated costs of implementing water quality standards based on today's criteria.

To perform a benefits analysis, the types or categories of benefits that apply need to be defined. EPA relied on a set of benefits categories that typically apply to changes in the water resource environment. Benefits were categorized as either use benefits or passive (nonuse) benefits depending on whether or not they involve direct use of, or contact with, the resource. The most prominent use benefit categories are those related to recreational fishing, boating, and swimming. Another use benefit category of significance is human health risk reduction. Human health risk reductions can be realized through actions that reduce human exposure to contaminants such as exposure through the consumption of fish containing elevated levels of pollutants. Passive use benefits are those improvements in environmental quality that are valued by individuals apart from any use of the resource in question.

Benefits estimates were derived in this study using an approach in which benefits of discrete large-scale changes in water quality beyond present day conditions were estimated wherever feasible. A share of those benefits was then apportioned to implementation of water quality standards based on today's criteria. The apportionment estimate was based on a three-stage process:

First, EPA assessed current total loadings from all sources that are contributing to the toxics-related water quality problems observed in the State. This defines the overall magnitude of loadings. Second, the share of total loadings that are attributable to sources that would be controlled through implementation of water quality standards based on today's criteria was estimated. Since this analysis was designed to focus only on those controls imposed on point sources, this stage of the process entailed estimating the portion of total loadings originating from point sources. Third, the percentage reduction in loadings expected due to implementation of today's criteria was estimated and then multiplied by the share of point source loadings to calculate the portion of benefits that could be attributed to implementation of water quality standards based on today's criteria.

Total monetized annual benefits were estimated in the range of $6.9 to $74.7 million. By category, annual benefits would be $1.3 to $4.6 million for avoided cancer risk, $2.2 to $15.2 million for recreational angling, and $3.4 to $54.9 million for passive use benefits.

There are numerous categories of potential or likely benefits that have been omitted from the quantified and monetized benefit estimates. In terms of potential magnitudes of benefit, the following are likely to be significant contributors to the underestimation of the monetized values presented above:

- Improvements in water-related (in-stream and near stream) recreation apart from fishing. The omission of potential motorized and nonmotorized boating, swimming, picnicking, and related in-stream and stream-side recreational activities from the benefits estimates could contribute to an appreciable underestimation of total benefits. Such recreational activities have been shown in empirical research to be highly valued, and even modest changes in participation and or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (notably, swimming). Other recreational activities may be less directly related to the water quality improvements, but might nonetheless increase due to their association with fishing, swimming, or other activities in which the participants might engage.
- Improvements in consumptive and nonconsumptive land-based recreation, such as hunting and wildlife observation. Improvements in aquatic habitats may lead (via food chain and related ecologic benefit mechanisms) to healthier, larger, and more diverse populations of avian and terrestrial species, such as waterfowl, eagles, and otters. Improvements in the populations for these species could manifest as improved hunting and wildlife viewing opportunities, which might in turn increase participation and user day values for such activities. Although the scope of the benefits analysis has not allowed a quantitative assessment of these values at either pre- or post-rule

conditions, it is conceivable that these benefits could be appreciable.

• Improvements in human health resulting from reduction of non-cancer risk. EPA estimated that implementation of water quality standards based on the criteria would result in a reduction of mercury concentrations in fish tissue and, thus, a reduction in the hazard from consumption of mercury contaminated fish. However, EPA was unable to monetize benefits due to reduced non-cancer health effects.

• Human health benefits for saltwater anglers outside of San Francisco Bay were not estimated. The number of saltwater anglers outside of San Francisco Bay is estimated to be 673,000 (based on Huppert, 1989, and U.S. FWS, 1993). The omission of other saltwater anglers may cause human health benefits to be underestimated. In addition, benefit estimates in the EA may be slightly overstated since potential benefits from reductions in chloroform discharges were included in these estimates. EPA made a decision to reserve the chloroform human health criteria after the EA was completed.

EPA received a number of comments which requested the Agency use the cost-benefit analysis in the EA as a factor in setting water quality criteria. EPA does not use the EA as a basis in determining protective water quality criteria. EPA's current regulations at 40 CFR 131.11 state that the criteria must be based on sound scientific rationale and must protect the designated use. From the outset of the water quality standards program, EPA has explained that while economic factors may be considered in designating uses, they may not be used to justify criteria that are not protective of those uses. 44 FR 25223–226, April 30, 1979. See e.g. *Mississippi Commission on Natural Resources* v. *Costle,* 625 F. 2d 1269, 1277 (5th Cir. 1980). EPA reiterated this interpretation of the CWA and its implementing regulations in discussing section 304(a) recommended criteria guidance stating that ''they are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects and do not reflect consideration of economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water.'' 63 FR 36742 and 36762, July 7, 1998.

I. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

J. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating any regulation for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an Agency to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government Agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of the affected small governments to have meaningful and timely input in the development of regulatory proposals with significant Federal intergovernmental mandates, and EPA informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act (UMRA)) for State, local, or tribal governments or the private sector. Today's rule imposes no enforceable duty on any State, local or Tribal governments or the private sector; rather, the CTR promulgates ambient water quality criteria which, when combined with State-adopted uses, will create water quality standards for those water bodies with adopted uses. The State will then use these resulting water quality standards in implementing its existing water quality control programs. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This rule establishes ambient water quality criteria which, by themselves do not directly impact any entity. The State will implement these criteria by ensuring that NPDES permits result in discharges that will meet these criteria. In so doing, the State will have considerable discretion. Until the State implements these water quality standards, there will be no effect of this rule on any entity. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

K. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires Federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact of a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business according to RFA default definitions for small businesses (based on SBA size

standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities.

Under the CWA water quality standards program, States must adopt water quality standards for their waters that must be submitted to EPA for approval. If the Agency disapproves a State standard and the State does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA has authority to promulgate criteria or standards in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. These State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the National Pollutant Discharge Elimination System (NPDES) program that limits discharges to navigable waters except in compliance with an EPA permit or permit issued under an approved State NPDES program. The CWA requires that all NPDES permits must include any limits on discharges that are necessary to meet State water quality standards.

Thus, under the CWA, EPA's promulgation of water quality criteria or standards establishes standards that the State, in turn, implements through the NPDES permit process. The State has considerable discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet the standards. In circumstances where there is more than one discharger to a water body that is subject to water quality standards or criteria, a State also has discretion in deciding on the appropriate limits for the different dischargers. While the State's implementation of federally-promulgated water quality criteria or standards may result indirectly in new or revised discharge limits for small entities, the criteria or standards themselves do not apply to any discharger, including small entities.

Today's rule, as explained above, does not itself establish any requirements that are applicable to small entities. As a result of EPA's action here, the State of California will need to ensure that permits it issues include limits as necessary to meet the water quality standards established by the criteria in today's rule. In so doing, the State will have a number of discretionary choices associated with permit writing. While California's implementation of today's rule may ultimately result in some new or revised permit conditions for some dischargers, including small entities, EPA's action today does not impose any of these as yet unknown requirements on small entities.

The RFA requires analysis of the economic impact of a rule only on the small entities subject to the rule's requirements. Courts have consistently held that the RFA imposes no obligation on an Agency to prepare a small entity analysis of the effect of a rule on entities not regulated by the rule. *Motor & Equip. Mrfrs. Ass'n* v. *Nichols,* 142 F.3d 449, 467 & n.18 (D.C. Cir. 1998)(quoting *United States Distribution Companies* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996); see also *American Trucking Association, Inc.* v. *EPA,* 175 F.3d 1027 (D.C. Cir. 1999). This final rule will have a direct effect only on the State of California which is not a small entity under the RFA. Thus, individual dischargers, including small entities, are not directly subject to the requirements of the rule. Moreover, because of California's discretion in implementing these standards, EPA cannot assess the extent to which the promulgation of this rule may subsequently affect any dischargers, including small entities. Consequently, certification under section 605(b) is appropriate. *State of Michigan, et al.* v. *U.S. Environmental Protection Agency,* No. 98–1497 (D.C. Cir. Mar. 3, 2000), slip op. at 41–42.

L. Paperwork Reduction Act

This action requires no new or additional information collection, reporting, or record keeping subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

M. Endangered Species Act

Pursuant to section 7(a) of the Endangered Species Act (ESA), EPA has consulted with the U.S. Fish and Wildlife Service and the U.S. National Marine Fisheries Service (collectively, the Services) concerning EPA's rulemaking action for the State of California. EPA initiated informal consultation in early 1994, and completed formal consultation in April 2000. As a result of the consultation, EPA modified some of the provisions in the final rule.

As part of the consultation process, EPA submitted to the Services a Biological Evaluation for their review in October of 1997. This evaluation found that the proposed CTR was not likely to jeopardize the continued existence of any Federally listed species or result in the destruction or adverse modification of designated critical habitat. In April of 1998, the Services sent EPA a draft Biological Opinion which tentatively found that EPA's proposed rule would jeopardize the continued existence of several Federally listed species and result in the destruction or have adverse effect on designated critical habitat. After lengthy discussions with the Services, EPA agreed to several changes in the final rule and the Services in turn issued a final Biological Opinion finding that EPA's action would not likely jeopardize the continued existence of any Federally listed species or result in the destruction or adverse modification of designated critical habitat. EPA's Biological Evaluation and the Services' final Biological Opinion are contained in the administrative record for today's rule.

In order to ensure the continued protection of Federally listed threatened and endangered species and to protect their critical habitat, EPA agreed to reserve the aquatic life criteria for mercury and the acute freshwater aquatic life criterion for selenium. The Services believe that EPA's proposed criteria are not sufficiently protective of Federally listed species and should not be promulgated. EPA agreed that it would reevaluate these criteria in light of the Services concerns before promulgating them for the State of California. Other commitments made by EPA are described in a letter to the Services dated December 16, 1999; this letter is contained in the administrative record for today's rule.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a major rule as defined

by 5 U.S.C. 804(2). This rule will be effective May 18, 2000.

O. Executive Order 13084, Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments nor does it impose substantial direct compliance cots on them. Today's rule will only address priority toxic pollutant water quality criteria for the State of California and does not apply to waters in Indian country. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

P. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

Q. Executive Order 13132 on Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not affect the nature of the relationship between EPA and States generally, for the rule only applies to water bodies in California. Further, the rule will not substantially affect the relationship of EPA and the State of California, or the distribution of power or responsibilities between EPA and the State. The rule does not alter the State's authority to issue NPDES permits or the State's considerable discretion in implementing these criteria. The rule simply implements Clean Water Act section 303(c)(2)(B) requiring numeric ambient water quality criteria for which EPA has issued section 304(a) recommended criteria in a manner that is consistent with previous regulatory guidance that the Agency has issued to implement CWA section 303(c)(2)(B). Further, this rule does not preclude the State from adopting water quality standards that meet the requirements of the CWA. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with State and local government representatives in developing this rule. EPA and the State reached an agreement that to best utilize its respective resources, EPA would promulgate water quality criteria and the State would concurrently work on a plan to implement the criteria. Since the proposal of this rule, EPA has kept State officials fully informed of changes to the proposal. EPA has continued to invite comment from the State on these changes. EPA believes that the final CTR incorporates comments from State officials and staff.

R. Executive Order 13045 on Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we therefore have assessed the environmental health or safety effects of ambient water quality criteria on children. The results of this assessment are contained in section F.3., Human Health Criteria.

List of Subjects in 40 CFR Part 131

Environmental protection, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: April 27, 2000.

Carol Browner,

Administrator.

For the reasons set out in the preamble, part 131 of chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—[Amended]

2. Section 131.38 is added to subpart D to read as follows:

§ 131.38 Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California.

(a) *Scope.* This section promulgates criteria for priority toxic pollutants in the State of California for inland surface waters and enclosed bays and estuaries. This section also contains a compliance schedule provision.

(b)(1) Criteria for Priority Toxic Pollutants in the State of California as described in the following table:

BILLING CODE 6560–50–P

A		B Freshwater		C Saltwater		D Human Health (10^{-6} risk for carcinogens) For consumption of:	
# Compound	CAS Number	Criterion Maximum Conc. [d] B1	Criterion Continuous Conc. [d] B2	Criterion Maximum Conc. [d] C1	Criterion Continuous Conc. [d] C2	Water & Organisms (μg/L) D1	Organisms Only (μg/L) D2
1. Antimony	7440360					14 a,s	4300 a,t
2. Arsenic [b]	7440382	340 i,m,w	150 i,m,w	69 i,m	36 i,m		
3. Beryllium	7440417					n	n
4. Cadmium [b]	7440439	4.3 e,i,m,w,x	2.2 e,i,m,w	42 i,m	9.3 i,m	n	n
5a. Chromium (III)	16065831	550 e,i,m,o	180 e,i,m,o			n	n
5b. Chromium (VI) [b]	18540299	16 i,m,w	11 i,m,w	1100 i,m	50 i,m	n	n
6. Copper [b]	7440508	13 e,i,m,w,x	9.0 e,i,m,w	4.8 i,m	3.1 i,m	1300	
7. Lead [b]	7439921	65 e,i,m	2.5 e,i,m	210 i,m	8.1 i,m	n	n
8. Mercury [b]	7439976	[Reserved]	[Reserved]	[Reserved]	[Reserved]	0.050 a	0.051 a
9. Nickel [b]	7440020	470 e,i,m,w	52 e,i,m,w	74 i,m	8.2 i,m	610 a	4600 a
10. Selenium [b]	7782492	[Reserved] p	5.0 q	290 i,m	71 i,m	n	n
11. Silver [b]	7440224	3.4 e,i,m		1.9 i,m			
12. Thallium	7440280					1.7 a,s	6.3 a,t
13. Zinc [b]	7440666	120 e,i,m,w,x	120 e,i,m,w	90 i,m	81 i,m		
14. Cyanide [b]	57125	22 o	5.2 o	1 r	1 r	700 a	220,000 a,j
15. Asbestos	1332214					7,000,000 fibers/L k,s	
16. 2,3,7,8-TCDD (Dioxin)	1746016					0.000000013 c	0.000000014 c
17. Acrolein	107028					320 s	780 t
18. Acrylonitrile	107131					0.059 a,c,s	0.66 a,c,t
19. Benzene	71432					1.2 a,c	71 a,c
20. Bromoform	75252					4.3 a,c	360 a,c
21. Carbon Tetrachloride	56235					0.25 a,c,s	4.4 a,c,t
22. Chlorobenzene	108907					680 a,s	21,000 a,j,t
23. Chlorodibromomethane	124481					0.401 a,c	34 a,c
24. Chloroethane	75003						
25. 2-Chloroethylvinyl Ether	110758						

26. Chloroform	67663					[Reserved]	[Reserved]
27. Dichlorobromomethane	75274					0.56 a,c	46 a,c
28. 1,1-Dichloroethane	75343						
29. 1,2-Dichloroethane	107062					0.38 a,c,s	99 a,c,t
30. 1,1-Dichloroethylene	75354					0.057 a,c,s	3.2 a,c,t
31. 1,2-Dichloropropane	78875					0.52 a	39 a
32. 1,3-Dichloropropylene	542756					10 a,s	1,700 a,t
33. Ethylbenzene	100414					3,100 a,s	29,000 a,t
34. Methyl Bromide	74839					48 a	4,000 a
35. Methyl Chloride	74873					n	n
36. Methylene Chloride	75092					4.7 a,c	1,600 a,c
37. 1,1,2,2-Tetrachloroethane	79345					0.17 a,c,s	11 a,c,t
38. Tetrachloroethylene	127184					0.8 c,s	8.85 c,t
39. Toluene	108883					6,800 a	200,000 a
40. 1,2-Trans-Dichloroethylene	156605					700 a	140,000 a
41. 1,1,1-Trichloroethane	71556					n	n
42. 1,1,2-Trichloroethane	79005					0.60 a,c,s	42 a,c,t
43. Trichloroethylene	79016					2.7 c,s	81 c,t
44. Vinyl Chloride	75014					2 c,s	525 c,t
45. 2-Chlorophenol	95578					120 a	400 a
46. 2,4-Dichlorophenol	120832					93 a,s	790 a,t
47. 2,4-Dimethylphenol	105679					540 a	2,300 a
48. 2-Methyl-4,6-Dinitrophenol	534521					13.4 s	765 t
49. 2,4-Dinitrophenol	51285					70 a,s	14,000 a,t
50. 2-Nitrophenol	88755						
51. 4-Nitrophenol	100027						
52. 3-Methyl-4-Chlorophenol	59507						
53. Pentachlorophenol	87865	19 f,w	15 f,w	13	7.9	0.28 a,c	8.2 a,c,j
54. Phenol	108952					21,000 a	4,600,000 a,j,t
55. 2,4,6-Trichlorophenol	88062					2.1 a,c	6.5 a,c
56. Acenaphthene	83329					1,200 a	2,700 a
57. Acenaphthylene	208968						
58. Anthracene	120127					9,600 a	110,000 a

59. Benzidine	92875					0.00012 a,c,s	0.00054 a,c,t
60. Benzo(a)Anthracene	56553					0.0044 a,c	0.049 a,c
61. Benzo(a)Pyrene	50328					0.0044 a,c	0.049 a,c
62. Benzo(b)Fluoranthene	205992					0.0044 a,c	0.049 a,c
63. Benzo(ghi)Perylene	191242						
64. Benzo(k)Fluoranthene	207089					0.0044 a,c	0.049 a,c
65. Bis(2-Chloroethoxy)Methane	111911						
66. Bis(2-Chloroethyl)Ether	111444					0.031 a,c,s	1.4 a,c,t
67. Bis(2-Chloroisopropyl)Ether	39638329					1,400 a	170,000 a,t
68. Bis(2-Ethylhexyl)Phthalate	117817					1.8 a,c,s	5.9 a,c,t
69. 4-Bromophenyl Phenyl Ether	101553						
70. Butylbenzyl Phthalate	85687					3,000 a	5,200 a
71. 2-Chloronaphthalene	91587					1,700 a	4,300 a
72. 4-Chlorophenyl Phenyl Ether	7005723						
73. Chrysene	218019					0.0044 a,c	0.049 a,c
74. Dibenzo(a,h)Anthracene	53703					0.0044 a,c	0.049 a,c
75. 1,2 Dichlorobenzene	95501					2,700 a	17,000 a
76. 1,3 Dichlorobenzene	541731					400	2,600
77. 1,4 Dichlorobenzene	106467					400	2,600
78. 3,3'-Dichlorobenzidine	91941					0.04 a,c,s	0.077 a,c,t
79. Diethyl Phthalate	84662					23,000 a,s	120,000 a,t
80. Dimethyl Phthalate	131113					313,000 s	2,900,000 t
81. Di-n-Butyl Phthalate	84742					2,700 a,s	12,000 a,t
82. 2,4-Dinitrotoluene	121142					0.11 c,s	9.1 c,t
83. 2,6-Dinitrotoluene	606202						
84 Di-n-Octyl Phthalate	117840						
85. 1,2-Diphenylhydrazine	122667					0.040 a,c,s	0.54 a,c,t
86. Fluoranthene	206440					300 a	370 a
87. Fluorene	86737					1,300 a	14,000 a
88. Hexachlorobenzene	118741					0.00075 a,c	0.00077 a,c
89. Hexachlorobutadiene	87683					0.44 a,c,s	50 a,c,t
90. Hexachlorocyclopentadiene	77474					240 a,s	17,000 a,j,t
91. Hexachloroethane	67721					1.9 a,c,s	8.9 a,c,t

92. Indeno(1,2,3-cd) Pyrene	193395					0.0044 a,c	0.049 a,c
93. Isophorone	78591					8.4 c,s	600 c,t
94. Naphthalene	91203						
95. Nitrobenzene	98953					17 a,s	1,900 a,j,t
96. N-Nitrosodimethylamine	62759					0.00069 a,c,s	8.1 a,c,t
97. N-Nitrosodi-n-Propylamine	621647					0.005 a	1.4 a
98. N-Nitrosodiphenylamine	86306					5.0 a,c,s	16 a,c,t
99. Phenanthrene	85018						
100. Pyrene	129000					960 a	11,000 a
101. 1,2,4-Trichlorobenzene	120821						
102. Aldrin	309002	3 g		1.3 g		0.00013 a,c	0.00014 a,c
103. alpha-BHC	319846					0.0039 a,c	0.013 a,c
104. beta-BHC	319857					0.014 a,c	0.046 a,c
105. gamma-BHC	58899	0.95 w		0.16 g		0.019 c	0.063 c
106. delta-BHC	319868						
107. Chlordane	57749	2.4 g	0.0043 g	0.09 g	0.004 g	0.00057 a,c	0.00059 a,c
108. 4,4'-DDT	50293	1.1 g	0.001 g	0.13 g	0.001 g	0.00059 a,c	0.00059 a,c
109. 4,4'-DDE	72559					0.00059 a,c	0.00059 a,c
110. 4,4'-DDD	72548					0.00083 a,c	0.00084 a,c
111. Dieldrin	60571	0.24 w	0.056 w	0.71 g	0.0019 g	0.00014 a,c	0.00014 a,c
112. alpha-Endosulfan	959988	0.22 g	0.056 g	0.034 g	0.0087 g	110 a	240 a
113. beta-Endosulfan	33213659	0.22 g	0.056 g	0.034 g	0.0087 g	110 a	240 a
114. Endosulfan Sulfate	1031078					110 a	240 a
115. Endrin	72208	0.086 w	0.036 w	0.037 g	0.0023 g	0.76 a	0.81 a,j
116. Endrin Aldehyde	7421934					0.76 a	0.81 a,j
117. Heptachlor	76448	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00021 a,c	0.00021 a,c
118. Heptachlor Epoxide	1024573	0.52 g	0.0038 g	0.053 g	0.0036 g	0.00010 a,c	0.00011 a,c
119-125. Polychlorinated biphenyls (PCBs)			0.014 u		0.03 u	0.00017 c,v	0.00017 c,v
126. Toxaphene	8001352	0.73	0.0002	0.21	0.0002	0.00073 a,c	0.00075 a,c
Total Number of Criteria [h]		22	21	22	20	92	90

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Footnotes to Table in Parargraph (b)(1):

a. Criteria revised to reflect the Agency q1* or RfD, as contained in the Integrated Risk Information System (IRIS) as of October 1, 1996. The fish tissue bioconcentration factor (BCF) from the 1980 documents was retained in each case.

b. Criteria apply to California waters except for those waters subject to objectives in Tables III–2A and III–2B of the San Francisco Regional Water Quality Control Board's (SFRWQCB) 1986 Basin Plan, that were adopted by the SFRWQCB and the State Water Resources Control Board, approved by EPA, and which continue to apply.

c. Criteria are based on carcinogenicity of 10 (-6) risk.

d. Criteria Maximum Concentration (CMC) equals the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time without deleterious effects. Criteria Continuous Concentration (CCC) equals the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. ug/L equals micrograms per liter.

e. Freshwater aquatic life criteria for metals are expressed as a function of total hardness (mg/L) in the water body. The equations are provided in matrix at paragraph (b)(2) of this section. Values displayed above in the matrix correspond to a total hardness of 100 mg/l.

f. Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows: Values displayed above in the matrix correspond to a pH of 7.8. CMC = exp(1.005(pH) − 4.869). CCC = exp(1.005(pH) − 5.134).

g. This criterion is based on 304(a) aquatic life criterion issued in 1980, and was issued in one of the following documents: Aldrin/Dieldrin (EPA 440/5–80–019), Chlordane (EPA 440/5–80–027), DDT (EPA 440/5–80–038), Endosulfan (EPA 440/5–80–046), Endrin (EPA 440/5–80–047), Heptachlor (440/5–80–052), Hexachlorocyclohexane (EPA 440/5–80–054), Silver (EPA 440/5–80–071). The Minimum Data Requirements and derivation procedures were different in the 1980 Guidelines than in the 1985 Guidelines. For example, a ''CMC'' derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

h. These totals simply sum the criteria in each column. For aquatic life, there are 23 priority toxic pollutants with some type of freshwater or saltwater, acute or chronic criteria. For human health, there are 92 priority toxic pollutants with either ''water + organism'' or ''organism only'' criteria. Note that these totals count chromium as one pollutant even though EPA has developed criteria based on two valence states. In the matrix, EPA has assigned numbers 5a and 5b to the criteria for chromium to reflect the fact that the list of 126 priority pollutants includes only a single listing for chromium.

i. Criteria for these metals are expressed as a function of the water-effect ratio, WER, as defined in paragraph (c) of this section. CMC = column B1 or C1 value x WER; CCC = column B2 or C2 value x WER.

j. No criterion for protection of human health from consumption of aquatic organisms (excluding water) was presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.

k. The CWA 304(a) criterion for asbestos is the MCL.

l. [Reserved]

m. These freshwater and saltwater criteria for metals are expressed in terms of the dissolved fraction of the metal in the water column. Criterion values were calculated by using EPA's Clean Water Act 304(a) guidance values (described in the total recoverable fraction) and then applying the conversion factors in § 131.36(b)(1) and (2).

n. EPA is not promulgating human health criteria for these contaminants. However, permit authorities should address these contaminants in NPDES permit actions using the State's existing narrative criteria for toxics.

o. These criteria were promulgated for specific waters in California in the National Toxics Rule (''NTR''), at § 131.36. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays or estuaries and waters of the State defined as inland, i.e., all surface waters of the State not ocean waters. These waters specifically include the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta. This section does not apply instead of the NTR for this criterion.

p. A criterion of 20 ug/l was promulgated for specific waters in California in the NTR and was promulgated in the total recoverable form. The specific waters to which the NTR criterion applies include: Waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River. This section does not apply instead of the NTR for this criterion. The State of California adopted and EPA approved a site specific criterion for the San Joaquin River, mouth of Merced to Vernalis; therefore, this section does not apply to these waters.

q. This criterion is expressed in the total recoverable form. This criterion was promulgated for specific waters in California in the NTR and was promulgated in the total recoverable form. The specific waters to which the NTR criterion applies include: Waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to Vernalis. This criterion does not apply instead of the NTR for these waters. This criterion applies to additional waters of the United States in the State of California pursuant to 40 CFR 131.38(c). The State of California adopted and EPA approved a site-specific criterion for the Grassland Water District, San Luis National Wildlife Refuge, and the Los Banos State Wildlife Refuge; therefore, this criterion does not apply to these waters.

r. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays or estuaries including the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta. This section does not apply instead of the NTR for these criteria.

s. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: Waters of the Sacramento-San Joaquin Delta and waters of the State defined as inland (*i.e.,* all surface waters of the State not bays or estuaries or ocean) that include a MUN use designation. This section does not apply instead of the NTR for these criteria.

t. These criteria were promulgated for specific waters in California in the NTR. The specific waters to which the NTR criteria apply include: Waters of the State defined as bays and estuaries including San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta; and waters of the State defined as inland (i.e., all surface waters of the State not bays or estuaries or ocean) without a MUN use designation. This section does not apply instead of the NTR for these criteria.

u. PCBs are a class of chemicals which include aroclors 1242, 1254, 1221, 1232, 1248, 1260, and 1016, CAS numbers 53469219, 11097691, 11104282, 11141165, 12672296, 11096825, and 12674112, respectively. The aquatic life criteria apply to the sum of this set of seven aroclors.

v. This criterion applies to total PCBs, e.g., the sum of all congener or isomer or homolog or aroclor analyses.

w. This criterion has been recalculated pursuant to the 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water, Office of Water, EPA–820-B–96–001, September 1996. See also Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water, Office of Water, EPA–80–B–95–004, March 1995.

x. The State of California has adopted and EPA has approved site specific criteria for the Sacramento River (and tributaries) above Hamilton City; therefore, these criteria do not apply to these waters.

General Notes to Table in Paragraph (b)(1)

1. The table in this paragraph (b)(1) lists all of EPA's priority toxic pollutants whether or not criteria guidance are available. Blank spaces indicate the absence of national section 304(a) criteria guidance. Because of variations in chemical nomenclature systems, this listing of toxic pollutants does not duplicate the listing in Appendix A to 40 CFR Part 423–126 Priority Pollutants. EPA has added the Chemical Abstracts Service (CAS) registry numbers, which provide a unique identification for each chemical.

2. The following chemicals have organoleptic-based criteria recommendations that are not included on this chart: zinc, 3-methyl-4-chlorophenol.

3. Freshwater and saltwater aquatic life criteria apply as specified in paragraph (c)(3) of this section.

(2) Factors for Calculating Metals Criteria. Final CMC and CCC values should be rounded to two significant figures.

(i) $CMC = WER \times (Acute\ Conversion\ Factor) \times (\exp\{m_A[\ln(hardness)]+b_A\})$

(ii) $CCC = WER \times (Acute\ Conversion\ Factor) \times (\exp\{m_C[\ln(hardness)]+b_C\})$

(iii) Table 1 to paragraph (b)(2) of this section:

Metal	m_A	b_A	m_C	b_C
Cadmium	1.128	−3.6867	0.7852	−2.715
Copper	0.9422	−1.700	0.8545	−1.702
Chromium (III)	0.8190	3.688	0.8190	1.561
Lead	1.273	−1.460	1.273	−4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	−6.52		
Zinc	0.8473	0.884	0.8473	0.884

Note to Table 1: The term ''exp'' represents the base e exponential function.

(iv) Table 2 to paragraph (b)(2) of this section:

Metal	Conversion factor (CF) for freshwater acute criteria	CF for freshwater chronic criteria	CF for saltwater acute criteria	CF [a] for saltwater chronic criteria
Antimony	[d]	[d]	[d]	[d]
Arsenic	1.000	1.000	1.000	1.000
Beryllium	[d]	[d]	[d]	[d]
Cadmium	[b] 0.944	[b] 0.909	0.994	0.994
Chromium (III)	0.316	0.860	[d]	[d]
Chromium (VI)	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	[b] 0.791	[b] 0.791	0.951	0.951
Mercury	.....	.....	.....	.....
Nickel	0.998	0.997	0.990	0.990
Selenium	.....	[c]	0.998	0.998
Silver	0.85	[d]	0.85	[d]
Thallium	[d]	[d]	[d]	[d]
Zinc	0.978	0.986	0.946	0.946

Footnotes to Table 2 of Paragraph (b)(2):

[a] Conversion Factors for chronic marine criteria are not currently available. Conversion Factors for acute marine criteria have been used for both acute and chronic marine criteria.

[b] Conversion Factors for these pollutants in freshwater are hardness dependent. CFs are based on a hardness of 100 mg/l as calcium carbonate ($CaCO_3$). Other hardness can be used; CFs should be recalculated using the equations in table 3 to paragraph (b)(2) of this section.

[c] Bioaccumulative compound and inappropriate to adjust to percent dissolved.

[d] EPA has not published an aquatic life criterion value.

Note to Table 2 of Paragraph (b)(2): The term ''Conversion Factor'' represents the recommended conversion factor for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column. See ''Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria'', October 1, 1993, by Martha G. Prothro, Acting Assistant Administrator for Water available from Water Resource Center, USEPA, Mailcode RC4100, M Street SW, Washington, DC, 20460 and the note to § 131.36(b)(1).

(v) Table 3 to paragraph (b)(2) of this section:

	Acute	Chronic
Cadmium	CF=1.136672—[(ln {hardness}) (0.041838)]	CF = 1.101672—[(ln {hardness})(0.041838)]
Lead	CF=1.46203—[(ln {hardness})(0.145712)]	CF = 1.46203—[(ln {hardness})(0.145712)]

(c) *Applicability.* (1) The criteria in paragraph (b) of this section apply to the State's designated uses cited in paragraph (d) of this section and apply concurrently with any criteria adopted by the State, except when State regulations contain criteria which are more stringent for a particular parameter and use, or except as provided in footnotes p, q, and x to the table in paragraph (b)(1) of this section.

(2) The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are other Federally-adopted and State-adopted numeric toxics criteria when applied to the same use classifications including mixing zones, and low flow values below which numeric standards can be exceeded in flowing fresh waters.

(i) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones; otherwise the criteria apply throughout the water body including at the point of discharge into the water body.

(ii) The State shall not use a low flow value below which numeric standards can be exceeded that is less stringent than the flows in Table 4 to paragraph (c)(2) of this section for streams and rivers.

(iii) Table 4 to paragraph (c)(2) of this section:

Criteria	Design flow
Aquatic Life Acute Criteria (CMC).	1 Q 10 or 1 B 3
Aquatic Life Chronic Criteria (CCC).	7 Q 10 or 4 B 3
Human Health Criteria.	Harmonic Mean Flow

Note to Table 4 of Paragraph (c)(2): 1. CMC (Criteria Maximum Concentration) is the water quality criteria to protect against acute effects in aquatic life and is the highest instream concentration of a priority toxic pollutant consisting of a short-term average not to be exceeded more than once every three years on the average.

2. CCC (Continuous Criteria Concentration) is the water quality criteria to protect against chronic effects in aquatic life and is the highest in stream concentration of a priority toxic pollutant consisting of a 4-day average not to be exceeded more than once every three years on the average.

3. 1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically.

4. 1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model).

5. 7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically.

6. 4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model).

(iv) If the State does not have such a low flow value below which numeric standards do not apply, then the criteria included in paragraph (d) of this section apply at all flows.

(v) If the CMC short-term averaging period, the CCC four-day averaging period, or once in three-year frequency is inappropriate for a criterion or the site to which a criterion applies, the State may apply to EPA for approval of an alternative averaging period, frequency, and related design flow. The State must submit to EPA the bases for any alternative averaging period, frequency, and related design flow. Before approving any change, EPA will publish for public comment, a document proposing the change.

(3) The freshwater and saltwater aquatic life criteria in the matrix in paragraph (b)(1) of this section apply as follows:

(i) For waters in which the salinity is equal to or less than 1 part per thousand 95% or more of the time, the applicable criteria are the freshwater criteria in Column B;

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in Column C except for selenium in the San Francisco Bay estuary where the applicable criteria are the freshwater criteria in Column B (refer to footnotes p and q to the table in paragraph (b)(1) of this section); and

(iii) For waters in which the salinity is between 1 and 10 parts per thousand as defined in paragraphs (c)(3)(i) and (ii) of this section, the applicable criteria are the more stringent of the freshwater or saltwater criteria. However, the Regional Administrator may approve the use of the alternative freshwater or saltwater criteria if scientifically defensible information and data demonstrate that on a site-specific basis the biology of the water body is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the water body is dominated by saltwater aquatic life and that saltwater criteria are more appropriate. Before approving any change, EPA will publish for public comment a document proposing the change.

(4) *Application of metals criteria.* (i) For purposes of calculating freshwater aquatic life criteria for metals from the equations in paragraph (b)(2) of this section, for waters with a hardness of 400 mg/l or less as calcium carbonate, the actual ambient hardness of the surface water shall be used in those equations. For waters with a hardness of over 400 mg/l as calcium carbonate, a hardness of 400 mg/l as calcium carbonate shall be used with a default Water-Effect Ratio (WER) of 1, or the actual hardness of the ambient surface water shall be used with a WER. The same provisions apply for calculating the metals criteria for the comparisons provided for in paragraph (c)(3)(iii) of this section.

(ii) The hardness values used shall be consistent with the design discharge conditions established in paragraph (c)(2) of this section for design flows and mixing zones.

(iii) The criteria for metals (compounds #1—#13 in the table in paragraph (b)(1) of this section) are expressed as dissolved except where otherwise noted. For purposes of calculating aquatic life criteria for metals from the equations in footnote i to the table in paragraph (b)(1) of this section and the equations in paragraph (b)(2) of this section, the water effect ratio is generally computed as a specific pollutant's acute or chronic toxicity value measured in water from the site covered by the standard, divided by the respective acute or chronic toxicity value in laboratory dilution water. To use a water effect ratio other than the default of 1, the WER must be determined as set forth in Interim Guidance on Determination and Use of Water Effect Ratios, U.S. EPA Office of Water, EPA–823–B–94–001, February 1994, or alternatively, other scientifically defensible methods adopted by the State as part of its water quality standards program and approved by EPA. For calculation of criteria using site-specific values for both the hardness and the water effect ratio, the hardness used in the equations in paragraph (b)(2) of this section must be determined as required in paragraph (c)(4)(ii) of this section. Water hardness must be calculated from the measured calcium and magnesium ions present, and the ratio of calcium to magnesium should be approximately the same in standard laboratory toxicity testing water as in the site water.

(d)(1) Except as specified in paragraph (d)(3) of this section, all waters assigned any aquatic life or human health use classifications in the Water Quality Control Plans for the various Basins of the State (''Basin Plans'') adopted by the California State Water Resources Control Board (''SWRCB''), except for ocean waters covered by the Water Quality Control Plan for Ocean Waters of California (''Ocean Plan'') adopted by the SWRCB with resolution Number 90–27 on March 22, 1990, are subject to the criteria in paragraph (d)(2) of this section, without exception. These criteria apply to waters identified in the Basin Plans. More particularly, these criteria apply to waters identified in the Basin Plan chapters designating beneficial uses for waters within the region. Although the State has adopted several use designations for each of these waters, for purposes of this action, the specific standards to be applied in paragraph (d)(2) of this section are based on the presence in all waters of some aquatic life designation and the presence or absence of the MUN use designation (municipal and domestic supply). (See Basin Plans for more detailed use definitions.)

(2) The criteria from the table in paragraph (b)(1) of this section apply to the water and use classifications defined in paragraph (d)(1) of this section as follows:

Water and use classification	Applicable criteria
(i) All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that include a MUN use designation.	(A) Columns B1 and B2—all pollutants (B) Columns C1 and C2—all pollutants (C) Column D1—all pollutants
(ii) All inland waters of the United States or enclosed bays and estuaries that are waters of the United States that do not include a MUN use designation.	(A) Columns B1 and B2—all pollutants (B) Columns C1 and C2—all pollutants (C) Column D2—all pollutants

(3) Nothing in this section is intended to apply instead of specific criteria, including specific criteria for the San Francisco Bay estuary, promulgated for California in the National Toxics Rule at § 131.36.

(4) The human health criteria shall be applied at the State-adopted 10 (−6) risk level.

(5) Nothing in this section applies to waters located in Indian Country.

(e)*Schedules of compliance.* (1) It is presumed that new and existing point source dischargers will promptly comply with any new or more restrictive water quality-based effluent limitations (''WQBELs'') based on the water quality criteria set forth in this section.

(2) When a permit issued on or after May 18, 2000 to a new discharger contains a WQBEL based on water quality criteria set forth in paragraph (b) of this section, the permittee shall comply with such WQBEL upon the commencement of the discharge. A new discharger is defined as any building, structure, facility, or installation from which there is or may be a ''discharge of pollutants'' (as defined in 40 CFR 122.2) to the State of California's inland surface waters or enclosed bays and estuaries, the construction of which commences after May 18, 2000.

(3) Where an existing discharger reasonably believes that it will be infeasible to promptly comply with a new or more restrictive WQBEL based on the water quality criteria set forth in this section, the discharger may request approval from the permit issuing authority for a schedule of compliance.

(4) A compliance schedule shall require compliance with WQBELs based on water quality criteria set forth in paragraph (b) of this section as soon as possible, taking into account the dischargers' technical ability to achieve compliance with such WQBEL.

(5) If the schedule of compliance exceeds one year from the date of permit issuance, reissuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The dates of completion between each requirement may not exceed one year. If the time necessary for completion of any requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of interim requirements.

(6) In no event shall the permit issuing authority approve a schedule of compliance for a point source discharge which exceeds five years from the date of permit issuance, reissuance, or modification, whichever is sooner. Where shorter schedules of compliance are prescribed or schedules of compliance are prohibited by law, those provisions shall govern.

(7) If a schedule of compliance exceeds the term of a permit, interim permit limits effective during the permit shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect final permit limits and final compliance dates. Final compliance dates for final permit limits, which do not occur during the term of the permit, must occur within five years from the date of issuance, reissuance or modification of the permit which initiates the compliance schedule. Where shorter schedules of compliance are prescribed or schedules of compliance are prohibited by law, those provisions shall govern.

(8) The provisions in this paragraph (e), Schedules of compliance, shall expire on May 18, 2005.

[FR Doc. 00–11106 Filed 5–17–00; 8:45 am]

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IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Nos. 93-35973 & 93-36000

DIOXIN/ORGANOCHLORINE CENTER, et al.,

Plaintiffs-Appellants, and

LONGVIEW FIBRE CO., et al.,

Plaintiffs-Intervenors and Cross-Appellants,

v.

CHUCK CLARKE, Regional Administrator, and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

BRIEF FOR THE DEFENDANTS-APPELLEES

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May 31, 1994

TABLE OF CONTENTS

TABLE OF AUTHORITIES

GLOSSARY

As used in this brief, the following abbreviations and short forms have the meanings indicated below:

APA	Administrative Procedure Act, 5 U.S.C. §§ 701-06
AR No.	Administrative Record item number as listed in EPA's Certified Index to the Administrative Record
BAT	best available technology economically achievable
BCF	bioconcentration factor
BEF	bioaccumulation equivalency factor
BCT	best conventional pollution control technology
BMPs	best management practices
BPJ	best professional judgment
BPT	best practicable control technology currently available
CDDs	chlorinated dibenzo-p-dioxins
CDFs	chlorinated dibenzo-furans
CR No.	Clerk's Record Number. Refers to the item number on the District Court Clerk's official docket sheet.
CRITFC	Columbia River Intertribal Fish Commission
CWA or the Act	Clean Water Act, 33 U.S.C. §§ 1251-1387
dioxin	2,3,7,8-tetrachlorodibenzo-p-dioxin
DOC	Plaintiffs-Appellants Dioxin/Organochlorine Center, et al.
DOC Br.	Opening Brief of Plaintiffs-Appellants Dioxin/Organochlorine Center, et al.
DOC ER	Excerpts of Record of Plaintiffs-Appellants Dioxin/Organochlorine Center, et al.
EPA or the Agency	U.S. Environmental Protection Agency

ESA	Endangered Species Act
ICS	individual control strategy
LA	load allocation
Mills or Pulp Mills	Plaintiffs-Intervenors and Cross-Appellants Longview Fibre Co., et al.
Mills Br.	Opening Brief of Plaintiffs-Intervenors and Cross-Appellants Longview Fibre Co., et al.
Mills ER	Excerpts of Record of Appellants Longview Fibre Co., et al.
NPDES	National Pollutant Discharge Elimination System
NPS	nonpoint source
NYDEC	New York Department of Environmental Conservation
PCBs	polychlorinated biphenyls
ppq	parts per quadrillion
ppt	parts per trillion
SER	Defendant-Appellee EPA's Supplemental Excerpts of Record
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TCDF	2,3,7,8 tetrachlorodibenzofuran
TEF	toxic equivalency factor
TMDL	Total Maximum Daily Load
USFWS	United States Fish & Wildlife Service
WLA	wasteload allocation
WQL	water quality limited
WQS	water quality standard

ISSUES PRESENTED

1. Whether the Environmental Protection Agency ("EPA") reasonably interpreted the Clean Water Act as authorizing it to calculate a Total Maximum Daily Load ("TMDL") necessary to achieve water quality standards for a highly toxic pollutant, in the absence of national, technology-based effluent limitations for pulp mill discharges of that pollutant.

2. Whether there is sufficient support in the administrative record for EPA's conclusion that the Columbia River TMDL is set at a level that will implement applicable water quality standards with a margin of safety.

STATEMENT OF JURISDICTION

Pursuant to Circuit Rule 28-2.2, appellees provide the following statement regarding jurisdiction:

(a) EPA had jurisdiction under 33 U.S.C. § 1313(d)(2) to issue the TMDL. The district court had jurisdiction under 28 U.S.C. § 1331 and the Administrative Procedure Act, 5 U.S.C. §§ 701 et seq., to review the TMDL.1/

(b) The district court granted EPA's motion for summary judgment on August 10, 1993, and subsequently entered final

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1/ The basis on which the district court exercised jurisdiction may have relevance to plaintiffs' claim for attorneys' fees in the event they prevail on appeal. Contrary to the jurisdictional statement of Dioxin/Organochlorine Center and Columbia River United (collectively, "DOC"), DOC Br. at 1, the court did not possess jurisdiction under the citizen suit provision of the Clean Water Act, 33 U.S.C. § 1365(a), which authorizes suits against EPA's Administrator to compel the Agency to perform an act or duty which is not discretionary. Rather, jurisdiction was present only to review the discretionary content of final agency action, pursuant to the standards of the Administrative Procedure Act.

judgment in favor of EPA pursuant to that order. This Court has jurisdiction to review that judgment under 28 U.S.C. § 1291.

(c) The district court's judgment was entered on August 17, 1993. DOC and Plaintiffs-Intervenors Longview Fibre Co., et al. (the "Pulp Mills"), filed notices of appeal on October 8, 1993, and October 20, 1993, respectively. The notices were timely under Fed. R. App. P. 4(a)(1) & (3).

STATEMENT OF THE CASE

A. Nature of the Case and Disposition Below

This case arises on complaints for judicial review of a final EPA action to establish a Total Maximum Daily Load ("TMDL"), under the Clean Water Act, 33 U.S.C. § 1313(d), for discharges of dioxin to the Columbia River basin in Oregon, Washington and Idaho.[2/] DOC and the Pulp Mills[3/] moved for summary judgment, and Defendants Environmental Protection Agency and Chuck Clarke, Regional Administrator[4/] (collectively "EPA"), filed a cross-

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2/ EPA's decision establishing the TMDL is embodied in a Decision Document appearing in the Pulp Mills' Excerpts of Record ("Mills ER") at 87-127, and in DOC's Excerpts of Record ("DOC ER") at tab ER 47/AR 19(2). That decision is also supported by a Response to Comment Document, Mills ER at 128-59; DOC ER tab ER 47/AR 19(3). "AR" refers to documents as numbered in EPA's Administrative Record, which was filed with the district court as an exhibit, Clerk's Record ("CR") No. 47. For convenience, we provide parallel citations to the Mills ER or EPA's Supplemental Excerpts of Record ("SER"), where included therein.

3/ Although nominally a plaintiff, Intervenor Pope & Talbot, Inc. did not join in the other pulp mills' motion for summary judgment. See CR No. 18. Rather, Pope & Talbot's participation in the district court proceedings was limited to opposing DOC's attempt to invalidate the TMDL. See CR No. 59.

4/ By Order entered March 1, 1994, the Court substituted Gerald Emison, Acting Regional Administrator, for his predecessor in office, Dana A. Rasmussen. Subsequently, on March 7, 1994, Chuck Clarke became Regional Administrator, and he should now be substituted for Mr. Emison pursuant to Fed. R. App. P. 43(c)(1).

motion for summary judgment. The district court denied plaintiffs' motions for summary judgment, and granted summary judgment in favor of EPA in an unreported opinion. CR No. 88, Mills ER 232-49. These consolidated appeals followed.[5/]

B. Statutory and Regulatory Background

1. The NPDES Permit System

The Clean Water Act, 33 U.S.C. §§ 1251-1387 ("CWA" or the "Act"), was adopted "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). See Rybachek v. EPA, 904 F.2d 1276, 1282 (9th Cir. 1990). As the cornerstone of the CWA scheme for the control of point source pollution, the Act prohibits the "discharge of any pollutant" except as authorized by a National Pollutant Discharge Elimination System ("NPDES") permit. 33 U.S.C. § 1311(a). The CWA authorizes EPA, or a state approved by EPA to administer its NPDES permit program, to "issue a permit for the discharge of any pollutant," provided that the permit contains conditions that implement various requirements of the Act. 33 U.S.C. § 1342(a)(1).[6/] In authorized states, NPDES permits are issued by the appropriate state agency, but are subject to EPA objection. 33 U.S.C. § 1342(d), 40 C.F.R. § 123.44 (1992).

[5/] Plaintiff-Intervenors Pope & Talbot and Potlatch Corp. did not join in the notice of cross-appeal filed by the other Pulp Mills. CR No. 113, Mills ER 253-54.

[6/] EPA may authorize a state meeting certain requirements to issue NPDES permits. 33 U.S.C. § 1342(b). Oregon and Washington are authorized to administer their own NPDES permit programs; EPA is responsible for issuing permits for point sources in Idaho.

NPDES permits commonly contain numerical limits on the amounts of specified pollutants that may be discharged. See Rybachek, 904 F.2d at 1283. These "effluent limitations" implement both technology-based and water quality-based requirements of the Act. See 33 U.S.C. § 1362(11). Technology-based effluent limitation guidelines are developed by EPA for classes or categories of point sources. 33 U.S.C. § 1314(b). These guidelines represent the degree of control that can be achieved by point sources using various levels of pollution control technology, and are used in establishing enforceable technology-based effluent limitations in NPDES permits. See 33 U.S.C. §§ 1311, 1314; E.I. Du Pont de Nemours & Co. v. Train, 430 U.S. 112, 126-36 (1977). Development and revision of such guidelines is a continuing process. See 33 U.S.C. § 1314(m) (requiring EPA to prepare effluent guideline development plans annually).7/ When EPA has not yet issued national effluent limitation guidelines for a category of point sources, the Agency is authorized under 33 U.S.C. § 1342(a)(1) to develop such limitations for NPDES permits on a case-by-case basis. Natural Resources Defense Council v. Costle, 568 F.2d 1369, 1378 (D.C. Cir. 1977). EPA refers to such permit limits as "Best Professional Judgment" ("BPJ") limits. See Natural Resources Defense Council v. EPA, 863 F.2d 1420, 1424 (9th Cir. 1988).

7/ As of September, 1992, EPA was in the process of developing new or revised effluent guidelines for nine industrial categories (including the pulp and paperboard category), and announced plans to develop an additional 12 effluent guidelines over an 11 year period. 57 Fed. Reg. 41,000 (Sept. 8, 1992).

Congress required NPDES permits to include limitations for conventional pollutants[8/] based upon "best practicable control technology currently available" ("BPT") by July 1, 1977, and upon "best conventional pollution control technology" ("BCT") by March 31, 1989. 33 U.S.C. §§ 1311(b)(1)(A) & (2)(E), 1314(b)(1) & (4). For toxic pollutants such as dioxin[9/] and for non-conventional pollutants,[10/] NPDES permits were to include limitations based upon BPT by July 1, 1977, and limitations based upon "best available technology economically achievable" ("BAT") by March 31, 1989. 33 U.S.C. §§ 1311(b)(1)(A) & (2)(A), 1314(b)(1)-(2), 1342(a). See Rybachek, 904 F.2d at 1283. NPDES permits also must contain limitations more stringent than the technology-based standards if necessary to implement any applicable water quality standard. 33 U.S.C. § 1311(b)(1)(C).

2. Water Quality Standards and TMDLs

Section 303 of the Act, 33 U.S.C. § 1313, requires each state to adopt water quality standards applicable to its intrastate and interstate waters. See 33 U.S.C. § 1313(a)-(c). Water quality standards consist of two principal elements: (1) designated "uses" of the water, such as for public water supply, recreation, or propagation of fish, consistent with the Act's goals as set forth

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8/ "Conventional" pollutants include suspended solids, fecal coliform, biochemical oxygen demand, and pH. See 33 U.S.C. § 1314(a)(4); 40 C.F.R. § 401.16. Unless otherwise noted, all citations to the Code of Federal Regulations refer to the 1992 edition.

9/ Toxic pollutants are identified pursuant to 33 U.S.C. § 1317(a). See 40 C.F.R. § 401.15.

10/ Non-conventional pollutants are all pollutants not classified as either conventional or toxic.

in 33 U.S.C. § 1251(a)(2), see 40 C.F.R. § 130.3, and (2) "criteria" specifying the amounts of various pollutants which may be present in those waters without impairing the designated uses, expressed as numerical concentration limits or in narrative form. 33 U.S.C. § 1313(c)(2)(A). EPA reviews standards adopted by the states to ensure their consistency with the Act's requirements. 33 U.S.C. § 1313(c)(3)-(4).

The Act required EPA and the states to impose, by 1977, effluent limitations necessary to meet water quality standards. 33 U.S.C. § 1311(b)(1)(C). To facilitate imposition of water quality-based effluent limitations where the technology-based effluent limitations required by 1977 were not sufficient, standing alone, to bring polluted waterbodies into attainment with the water quality standards, Congress also established a mechanism for determination of Total Maximum Daily Loads, or "TMDLs." Section 1313(d) creates a systematic means for states to identify and prioritize waters within their boundaries for which the BPT-based effluent limitations required by section 1311(b)(1)(A)-(B) are not stringent enough to implement the applicable water quality standards.11/ States are required to develop TMDLs on a priority basis for each identified waterbody and for each relevant pollu-

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11/ Waters so identified are referred to as "water quality limited segments." 40 C.F.R. § 130.2(j). EPA regulations require establishment of TMDLs where all existing pollution control requirements (including BAT-based limitations, enforceable controls on nonpoint sources, etc.) are inadequate to lead to attainment of standards, 40 C.F.R. § 130.7, thereby ensuring that limited state and federal resources for TMDL development will be addressed to curing water quality impairments.

tant at a level necessary to implement the water quality standards with a margin of safety. 33 U.S.C. § 1313(d)(1)(A), (C).12/

States must submit lists of water quality limited segments to EPA for review every two years, 40 C.F.R. § 130.7(d), and must submit TMDLs developed on a priority basis to EPA from time to time. 33 U.S.C. § 1313(d)(2). If EPA disapproves the list and/or load, it must itself identify water quality limited segments and establish TMDLs as necessary to implement the applicable water quality standards. 33 U.S.C. § 1313(d)(2).

For waterbodies with multiple sources of a particular pollutant, a TMDL provides a mechanism for determining the permissible "loading" from each source necessary for the overall water to meet water quality standards. A TMDL represents the maximum amount of pollutant loadings which can be introduced into a receiving water without violating the standards, taking into account seasonal variations and a margin of safety. 33 U.S.C. § 1313(d)(1)(C). It is the sum of the "load allocations," which are best estimates of the loading attributed to nonpoint sources of pollution or natural background sources, 40 C.F.R. § 130.2(g), and individual wasteload allocations ("WLAs"), which are the portions of a receiving water's loading capacity allocated to specific point sources. 40 C.F.R. § 130.2(h)-(i). Where a TMDL and WLAs have been estab-

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12/ Pursuant to 33 U.S.C. § 1314(a)(2)(D), EPA has identified all pollutants as generally suitable for TMDL development. See 43 Fed. Reg. 60,662 (Dec. 28, 1978).

lished, permits for point sources must be consistent with their requirements. 40 C.F.R. § 122.44(d)(1)(vii)(B).[13/]

3. Additional Controls for Toxic Pollutants

In amending the Clean Water Act in 1987, Congress emphasized attainment of state water quality standards for toxic pollutants. One important component of this emphasis was the establishment of the toxics control program under 33 U.S.C. § 1314(l), in order to identify and control "toxic hotspots." 133 Cong. Rec. 1287 (1987) (statement of Sen. Moynihan); Westvaco Corp. v. EPA, 899 F.2d 1383, 1385 (4th Cir. 1990). To accomplish this purpose, section 1314(l)(1) required each state, by February 1989, to submit three lists of waters to EPA. The only one of the three relevant here is the "B list," listing those waters that the state "does not expect" to achieve applicable water quality standards, after application of technology-based controls, due to discharges of toxic pollutants from point sources. 33 U.S.C. § 1314(l)(1)(B). For each water segment on any of the three lists, the state was required by the same date to submit a "C list" of point sources discharging toxic pollutants "believed to be preventing or impairing . . . water quality." 33 U.S.C. § 1314(l)(1)(C); Natural Resources Defense Council v. EPA, 915 F.2d 1314 (9th Cir. 1990).

Section 1314(l) also required the states to evaluate the dischargers on the C list and submit to EPA, for each such discharger, an individual control strategy ("ICS") which the state had determined would serve to reduce point source discharges of

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13/ Even if a TMDL has not been completed, 33 U.S.C. § 1311(b)(1)(C) requires permits to include limits necessary to implement applicable water quality standards.

toxic pollutants to a degree sufficient to attain water quality standards within three years after the date of the establishment of the ICS. 33 U.S.C. § 1314(l)(1)(D); Westvaco, 899 F.2d at 1385; Natural Resources Defense Council, 915 F.2d at 1323-24. EPA has defined an ICS to be a final or draft NPDES permit, with supporting documentation showing that effluent limits are "consistent with an approved wasteload allocation [under section 1313(d)], or other documentation which shows that applicable water quality standards will be met not later than three years after the individual control strategy is established." 40 C.F.R. § 123.46(c); see also 54 Fed. Reg. 246-58 (Jan. 4, 1989), and 54 Fed. Reg. 23,868, 23,888 (June 2, 1989).

C. The Columbia River TMDL

1. Identification of the Columbia River as Water Quality Limited for Dioxin

2,3,7,8-tetrachlorodibenzo-p-dioxin -- which we will refer to by the shorthand "dioxin" or the acronym "TCDD" -- is "an unusually toxic compound with demonstrated acute, subacute and chronic effects in animals and man." AR No. 107, at C-178, SER 40; CR No. 88 at 2, Mills ER 233. Indeed, it has been identified as "one of the most toxic substances known." AR No. 107, at A-8, SER 19. Exposure can adversely affect the skin, liver, nervous system and immune system. Id. at C-178, SER 40. Dioxin also "displays an unusually high degree of reproductive toxicity." Id. It has been shown to be mutagenic and carcinogenic. Id. at A-8, SER 19; CR No. 88 at 2, Mills ER 233. These findings have led EPA to conclude that dioxin represents a potential hazard to both

aquatic and terrestrial life, and that it is "one of the major concerns for public health." AR No. 107, at A-8, SER 19.

The fact that dioxin can be toxic in minute quantities causes great practical difficulties in detecting and controlling sources of dioxin contamination. It is now known that dioxin is a by-product of, among other things, the bleaching of wood pulp with chlorine or chlorine derivatives. See AR No. 19(1), Mills ER at 83; 58 Fed. Reg. 66,078, 66,092 (Dec. 17, 1993). In the mid-to-late 1980's, EPA undertook an ambitious series of studies in an effort to quantify the extent of dioxin in our nation's waters, particularly as a result of pulp and paper mill production. It was not until 1987 that the first major study, the "Five Mill Study," confirmed that chlorine-bleaching pulp and paper mills were potential sources of dioxin contamination. See CR No. 88 at 6-7, Mills ER 237-38. These findings led EPA to conduct two additional national studies. First, the National Bioaccumulation Study indicated that TCDD was bioaccumulating in (i.e., building up in the tissues of) fish collected downstream from a number of pulp and paper mills. AR No. 105, SER 17; AR No. 19(2) at 2-2, Mills ER 92. The second study, the "104 Mill Study," was conducted jointly with an industry group, and was a greatly expanded survey of dioxin in the wastewater, treatment plant sludge, and pulp of every chlorine-bleaching mill in the country. Completed in 1989, it confirmed that bleached kraft pulp and paper mills are a significant source of TCDD contamination in the Columbia River system. AR No. 19(2) at 2-2, Mills ER 92; AR No. 114, SER 51-54. See also AR Nos. 124, 128.

The plaintiff Pulp Mills own and operate bleached kraft pulp and paper mills which discharge effluent into the Columbia River or its tributaries in Idaho, Oregon and Washington. See AR No. 19(2) at 3-3, Mills ER 96. EPA and the relevant states addressed concerns over the discharge of dioxin from these mills through two complementary programs: the section 1314(l) toxics control program and the section 1313(d) TMDL program. Under the section 1314(l) program for controlling "toxic hot spots," both Oregon and Washington submitted lists identifying the plaintiffs' mills as point sources of dioxin believed to be impairing the water quality of the Columbia River. See 33 U.S.C. § 1314(l)(1)(C); AR No. 19(2) at 3-7, Mills ER 100; AR Nos. 148-49. Thus, under section 1314(l)(1)(D), these states were required to issue ICSs, in the form of NPDES permits, which would reduce these point source discharges of dioxin to a degree sufficient to attain water quality standards. 40 C.F.R. § 123.46(a).

Concurrent with the actions under section 1314(l), the states of Oregon, Washington, and Idaho identified the Columbia River as requiring a TMDL for dioxin under section 1313(d)(1). AR Nos. 32-34, 41, SER 6-9; see also AR Nos. 123, 130. This designation meant that existing effluent limitations and other controls were not stringent enough to achieve the water quality criteria for dioxin. 40 C.F.R. § 130.7(b). After consultation with EPA, the states concluded that EPA should establish the TMDL to assure equitable distribution of the loading capacity of the river among the multiple sources in this interstate basin. In their letters formally identifying the Columbia River as impaired due to dioxin,

the states declined to establish a TMDL and requested that EPA do so. AR Nos. 32-34, SER 6-8. EPA responded by approving the listing of the Columbia River as impaired due to dioxin, disapproving the states' decision not to establish a TMDL, and proceeding to develop the TMDL itself. AR No. 10, SER 1.

2. The Proposed TMDL

On June 14, 1990, EPA published public notice of the proposed TMDL, and invited public comments. AR No. 10(1), 10(2), Mills ER at 1-31. As EPA noted, the focus on toxic pollutants mandated by the 1987 amendment to section 1314(l) supported establishment of the TMDL on an urgent basis. AR No. 10(2) at 4, Mills ER at 8.[14/]

The proposal discussed the steps in the TMDL-setting process and EPA's proposed resolution of various issues. First, EPA determined that applicable water quality criteria for the protection of human health required that long-term dioxin concentration in the river be no greater than 0.013 parts per quadrillion ("ppq"). AR No. 10(2) at 7, Mills ER at 11.[15/] The Agency also concluded that an ambient concentration of 0.013 ppq would protect aquatic life and wildlife, and would therefore implement state narrative water quality standards for aquatic life

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14/ The TMDL would provide a yardstick for evaluating the adequacy of the pulp mill ICSs being developed at the same time by the relevant states. Id. ("Limits included in ICSs, developed under § [1314(l)], must be consistent with waste load allocations (WLAs) where a TMDL has been established.").

15/ At the time, EPA based this determination on Oregon's applicable numeric water quality criterion for dioxin of 0.013 ppq, and Idaho's and Washington's narrative dioxin standards. EPA has since adopted a numeric water quality criterion of 0.013 ppq for Washington and Idaho. See 57 Fed. Reg. 60,848, 60,911, 60,922-23 (Dec. 22, 1992).

and wildlife protection. Declaration of Richard Albright ¶ 6, CR No. 47 Exh. C, SER 65-66.16/

Next, EPA analyzed flow volumes at various points in the river to ascertain its loading capacity, i.e., the greatest amount of dioxin loading that the river could receive without violating the water quality criteria. AR No. 10(2) at 8, Mills ER 12. EPA acknowledged evidence that some dioxin may adhere to particulate matter and settle to the bottom of some rivers, but proposed to make the conservative assumption that no net attenuation occurs, in light of the fact that sedimentation may be offset by a re-suspension of existing sediments. AR No. 10(2) at 12-13, Mills ER 16-17. EPA calculated that the loading capacity of the entire Columbia River was 5.97 milligrams per day. AR No. 10(2) at 8, Mills ER 12.

Second, EPA proposed an allocation of the loading capacity to the various sources of dioxin in the watershed. This involved evaluating the existing loading from all dioxin sources. AR No. 10(2) at 10-12, Mills ER at 14-16. Because chlorine bleaching pulp mills constituted the only source type for which EPA had site specific quantitative information on effluent quality sufficient to establish wasteloads, and were also the source category that EPA believed to be the largest contributor of dioxin to the river, EPA proposed to establish WLAs only for the pulp mills at this

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16/ The district court allowed EPA to supplement the administrative record with Mr. Albright's declaration, finding it admissible as additional information from the agency explaining the basis of its decision. Order entered June 21, 1993, CR No. 80. DOC consented to the admission of this declaration, CR No. 72 at 3, and does not contest its admissibility on appeal.

time, leaving a portion of the loading capacity unallocated to account for other sources, future growth, and a margin of safety. AR No. 10(2) at 18, Mills ER at 22.

EPA's calculation of specific WLAs for the individual mills was influenced by the analytical detection limit for dioxin -- i.e., the smallest concentration of dioxin that can be reliably detected by available methods. AR No. 10(2) at 19, Mills ER at 23. If EPA applied the current general method detection limit of 10 ppq[17/] as a long term average effluent limit at the point of discharge, the cumulative load from pulp mills alone would be more than twice the Columbia River's daily loading capacity. AR No. 10(2) at 19, Mills ER at 23. Because a permit condition set at a level below the general analytical detection limit would make it difficult or impossible to determine compliance, AR No. 10(2) at 20, Mills ER at 24, EPA considered alternative methods for reducing loading from pulp mills without presuming an ability to detect concentrations lower than 10 ppq. One such method was to move the compliance monitoring point upstream in the mills' production processes, to the bleaching plant where dioxin is generated. By limiting average concentrations in the combined bleach plant waste stream to 10 ppq, before dilution later in the pulp mills' production processes, EPA could reduce pulp mill discharges of dioxin to 67 percent of the Columbia River's loading capacity. Id. Finally, EPA determined that by limiting effluent

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17/ The detection limit varies to some extent above and below the 10 ppq value depending on interferences present in the sample and the equipment available to the analytical laboratory performing the analyses. AR No. 19(3) at 2, Mills ER at 129.

concentrations at the pulp mills' bleaching plants to a maximum concentration of 10 ppq rather than a long-term average of 10 ppq, and adjusting for production levels, it could effectively lower cumulative dioxin loading from pulp mills to about 34 percent of the river's capacity. AR No. 10(2) at 21-22, Mills ER at 25-26.

In order to allow a sufficient share of the loading capacity for other types of dischargers and a margin of safety, EPA proposed to adopt the latter method for calculating WLAs for the individual pulp mills. AR No. 10(2) at 24, Mills ER at 28. EPA's public notice of the proposed TMDL specifically requested comment on a number of technical issues, including the adequacy of the margin of safety to be held in reserve for other, unquantified sources. AR No. 10(1) at 4, Mills ER at 4.[18/]

During the development of the TMDL, EPA entered into informal consultation with the U.S. Fish and Wildlife Service ("USFWS") concerning the effects of dioxin on bald eagles. EPA wrote to the USFWS requesting informal consultation on October 17, 1990. AR No. 15, SER 2. The USFWS responded to EPA's consultation request

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18/ EPA received dozens of written comments on the proposed TMDL from the Pulp Mills and other state, industry, tribal, private and environmental interests. AR Nos. 56-59, 61-67, 69-101. The Pulp Mills filed voluminous comments criticizing various aspects of the proposal. AR Nos. 88-91. In particular, the Mills suggested that EPA should have allocated nearly 100 percent of the river's loading capacity to pulp mills. See AR No. 89 at 18-19, Mills ER at 65-66; compare AR No. 88(1) at 19 (advocating that dioxin loading from pulp mills in the Columbia River basin be allocated a cumulative loading of 5.96 mg/day), with AR No. 10(2) at 16, Mills ER at 20 (total loading capacity of Columbia River estimated at 5.97 mg/day). Environmental groups, on the other hand, filed comments alleging that the proposed TMDL would allow too much dioxin loading to the river to protect human health and the environment. They also asked that the TMDL be broadened in scope to address other pollutants that they believed operated with dioxin to create "toxic stress" in the river.

on November 21, 1990, AR No. 103, SER 14-16, and commended EPA's actions in developing a TMDL that would reduce pulp mill discharges of dioxin to the Columbia River by 95 percent. The USFWS also acknowledged that much was unknown about the effect that past discharges of dioxin had had on bald eagles residing in the Columbia River basin. Id.; AR No. 22, SER 4.

3. The Final TMDL

On February 25, 1991, EPA established the final TMDL for discharges of dioxin to the Columbia River. AR No. 19(2), Mills ER 87-127. EPA responded to the major comments received both in the Decision Document and in a supplemental Response to Comments document. AR No. 19(3), Mills ER 128-59. EPA discussed its response to the comments in detail, and explained its chosen course at length.

Although several adjustments were made in response to additional information received, EPA adopted final wasteload allocations generally equivalent to the preferred option in the proposed TMDL, see AR No. 19(2) at 3-8 to 3-9, Mills ER at 101-02, assigning approximately 35 percent of the river's loading capacity to United States pulp mills in the basin. EPA concluded that the Pulp Mills' proposal to allocate 100 percent of the loading capacity to chlorine bleaching pulp mills was inappropriate because it did not account for dioxin loadings from other sources on the river, and would not include a margin of safety to account for uncertainties. AR No. 19(2) at 3-9 to 3-10, Mills ER 102-03.

In developing the final TMDL, EPA concluded that the reduction of the existing dioxin discharges to the Columbia River

basin would not adversely affect any threatened or endangered species. AR Nos. 15, 22, SER 2, 4. The USFWS agreed with this conclusion. AR Nos. 22, 103, SER 4, 14. The USFWS indicated that it did not expect EPA to engage in any further consultation unless additional information became available indicating a potential for dioxin discharges to adversely affect threatened or endangered species. Id.

As required by section 1314(l), the states of Oregon and Washington have since issued NPDES permits consistent with the TMDL to these pulp and paper mills, and EPA has issued such a permit to Potlatch. The permits issued in all three states are undergoing review either at the administrative level or in state court, although the permits issued to the Oregon mills are in effect in the interim.

D. Court Challenges to the TMDL

The Pulp Mills and DOC have launched several diametric attacks on the TMDL. In Longview Fibre Co. v. Rasmussen, 980 F.2d 1307 (9th Cir. 1992), this Court dismissed the Pulp Mills' and DOC's petitions for review of the TMDL for lack of original jurisdiction. Thereafter, DOC filed suit challenging the TMDL in district court, and the Pulp Mills intervened as plaintiffs, raising numerous challenges distinct from those pressed by DOC.[19/] The parties filed cross-motions for summary judgment, and on August 10, 1993, Judge Carolyn Dimmick granted EPA's motion for

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19/ Plaintiff-Intervenor Pope & Talbot, Inc., although nominally joining in the Pulp Mills' complaint in intervention, in fact filed a brief supporting the TMDL and opposing DOC's motion for summary judgment. CR No. 59.

summary judgment, and denied the motions of DOC and the Pulp Mills. CR No. 88, Mills ER 232.

The district court first considered and rejected the Pulp Mills' argument that EPA lacked the statutory authority to establish the TMDL in the absence of technology-based effluent limitations specifically addressing pulp mill discharges of dioxin. CR No. 88 at 4-10, Mills ER 235-41. Recognizing that pulp mill discharges of dioxin were not identified as posing a significant pollution problem until long after technology-based effluent limitations were to have been implemented under the statutory timetable, the court found nothing in the Clean Water Act that mandated delaying water quality-based controls, such as a TMDL, until after establishment and evaluation of technology-based restrictions. CR No. 88 at 7, Mills ER at 238. Instead, the court found that the Act vests EPA with broad authority to accomplish one of the Act's central objectives, the achievement of water quality standards. CR No. 88 at 9, Mills ER 240. The court then rejected several additional arguments which the Pulp Mills do not raise on appeal. CR No. 88 at 10-13, Mills ER 241-44.

DOC claimed, as it does here, that the TMDL fails to provide adequate protection for wildlife and for human populations who consume larger than average amounts of fish from the Columbia River. Turning to those claims, the court found that the administrative record supported EPA's determination that applicable narrative water quality standards were equally stringent to Oregon's numeric criterion of 0.013 ppq. CR No. 88 at 14-15, Mills ER 245-46. The court then reviewed the evidence in the

record and held that EPA's conclusion that a TMDL designed to achieve a 0.013 ppq standard would provide adequate protection for fish and wildlife was not arbitrary or capricious. CR No. 88 at 15-16, Mills ER at 246-47. The court also found adequate support for EPA's judgment that the 0.013 water quality standard provides sufficient protection for certain human populations in the region, such as Native Americans and subsistence fishermen, that eat higher than average amounts of fish. CR No. 88 at 16-17, Mills ER 247-48. Finally, the district court rejected DOC's claim that EPA acted arbitrarily by failing to consider synergistic and additive effects of other pollutants besides dioxin. The court ruled that the Clean Water Act and EPA's implementing regulations authorize the Agency to calculate separate TMDLs for different pollutants, and to prioritize TMDL development to address the worst pollution problems first. CR No. 88 at 17-18, Mills ER 248-49.

Summarizing, the district court concluded that "EPA performed scientifically valid analysis to arrive at the proper total maximum daily load for the River," and that the "considerable number of conservative assumptions incorporated into EPA calculations . . . ensures the margin of safety required by the Clean Water Act." CR No. 88 at 18, Mills ER 249. Following formal entry of the court's judgment for EPA, both DOC and the Pulp Mills filed their notices of appeal.

STANDARD OF REVIEW

This Court reviews a grant of summary judgment de novo to determine whether there are any genuine issues of material fact. Nevada Land Action Ass'n v. United States Forest Service, 8 F.3d

713, 716 (9th Cir. 1993); Norfolk Energy, Inc. v. Hodel, 898 F.2d 1435, 1439 (9th Cir. 1990). In the context of reviewing a decision by an administrative agency, de novo review means that this Court views the case from the same position as the district court. Nevada Land, 8 F.3d at 716; Daly-Murphy v. Winston, 837 F.2d 348, 351 (9th Cir. 1987).

A grant of summary judgment is appropriate if it appears that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 630-31 (9th Cir. 1987); Lew v. Kona Hospital, 754 F.2d 1420, 1423 (9th Cir. 1985). In reviewing agency action under the Administrative Procedure Act, the Court sits not to determine facts de novo, but reviews an agency's action for error on the basis of the administrative record presented by the agency. The decision of an administrative agency "should not be reversed unless it is arbitrary, capricious, an abuse of discretion, or contrary to law." Norfolk Energy, 898 F.2d at 1439 (citing 5 U.S.C. § 706(2)(A)); Marathon Oil Co. v. United States, 807 F.2d 759, 765 (9th Cir. 1986), cert. denied, 480 U.S. 940 (1987); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 413-14 (1971). This is a deferential standard that presumes the validity of agency actions and upholds them if they satisfy minimum standards of rationality. Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976).

When a question of statutory construction is raised, federal courts must show "great deference to the interpretation given the

statute by the officers or agency charged with its administration." EPA v. National Crushed Stone Ass'n, 449 U.S. 64, 83 (1980). See Rybachek, 904 F.2d at 1284; Norfolk Energy, 898 F.2d at 1439. Even if the statute is susceptible to more than one interpretation, a court must accept the interpretation chosen by the agency if it is "reasonable." Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 844 (1984); Central Montana Elec. Power Coop. v. Administrator, Bonneville Power Admin., 840 F.2d 1472, 1476-77 (9th Cir. 1988). As explained in Chevron, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." 467 U.S. at 843. See Wyckoff Co. v. EPA, 796 F.2d 1197, 1200 (9th Cir. 1986).

EPA's statutory interpretation is entitled to special deference where, as here, "the regulatory scheme is technical and complex," and EPA "considered the matter in a detailed and reasoned fashion." Chevron, 467 U.S. at 865. The court "'must look at the [agency's] decision not as the chemist, biologist or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising . . . certain minimal standards of rationality.'" American Paper Inst. v. EPA, 660 F.2d 954, 963 (4th Cir. 1981) (quoting Ethyl Corp., 541 F.2d at 36).20/

20/ Courts are also particularly deferential "where the Agency's decision on the meaning or reach of the Clean Water Act involves reconciling conflicting policies committed to the Agency's care and expertise under the Act." Rybachek, 904 F.2d at 1284. See Chevron, 467 U.S. at 844.

ARGUMENT

I. TECHNOLOGY-BASED EFFLUENT LIMITATIONS WERE NOT A PREREQUISITE TO ESTABLISHMENT OF THIS TMDL.

EPA properly decided, based on the states' designation of the Columbia River as impaired due to dioxin, to establish a TMDL at this time. On appeal the Pulp Mills' sole attack on the TMDL is their argument that control measures aimed at achieving state water quality standards for dioxin in the Columbia River must be delayed until after the future development and implementation of national, technology-based effluent limitation guidelines for dioxin discharges from the pulp and paper industry. EPA interprets section 1313(d) as requiring TMDLs where existing pollution controls will not lead to attainment of water quality standards. AR No. 19(3), at 5-6, Mills ER at 132-33; 40 C.F.R. § 130.7(b). As we show below, this interpretation of the statutory scheme is reasonable whether or not existing technology-based effluent limitation guidelines specifically address dioxin. Because EPA's interpretation of its substantial statutory authority is reasonable, the Court must defer to that interpretation. Arkansas v. Oklahoma, 112 S. Ct. 1046, 1057, 1060 (1992); Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-45 (1984).

A. The Clean Water Act Authorizes Numerous Mechanisms to Achieve State Water Quality Standards.

In adopting the Clean Water Act, Congress set a "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985," and established a national policy that the discharge of toxic pollutants in toxic amounts be prohibited. 33

U.S.C. § 1251(a)(1), (3). The authority provided by specific statutory provisions must be interpreted in light of the overall goals expressed in the statute.

To achieve the Act's ambitious goals, Congress intended that both "BPT" limitations and any more stringent limitations necessary to meet water quality standards be implemented by 1977. 33 U.S.C. § 1311(b)(1). Congress also expected states to begin developing TMDLs by April, 1974.21/ On top of these requirements, Congress also directed that "BAT" limitations be achieved by 1989, and, by the same year, required states to develop ICSs for specific point sources discharging toxic pollutants to waters with impaired water quality for those pollutants. 33 U.S.C. §§ 1311(b)(2), 1314(l)(1). Congress did not specifically address how EPA should coordinate these statutory requirements to address severe pollution problems first identified long after the deadlines for the initial control actions had passed. EPA, however, has promulgated regulations that provide unequivocally that permits must contain whatever limitations are necessary to meet water quality standards, regardless of the status of development of technology-based guidelines. 40 C.F.R. § 122.44(d)(1).

As we described above, it was not until 1987 that the "Five Mill Study" confirmed that chlorine-bleaching pulp and paper mills were potential sources of dioxin contamination, and not until 1989

21/ The Act originally directed EPA to identify the pollutants suitable for daily load measurement by October, 1973, 33 U.S.C. § 1314(a)(2) (1976), and states to establish their first TMDLs within 180 days thereafter, 33 U.S.C. § 1313(d)(2) (1976). In fact, EPA published the required identification in late 1978, meaning that states' first TMDLs were due in June, 1979.

that the "104 Mill Study" confirmed that bleached kraft pulp and paper mills are a significant source of TCDD contamination in the Columbia River and its tributaries. AR No. 19(2) at 2-2, Mills ER 92; AR No. 114, SER 51-54. See also AR Nos. 124, 128. The question here is this: When new information reveals a need to control discharges of a highly toxic chemical such as dioxin, does EPA have authority to require attainment of water quality standards for that toxin without awaiting the time-consuming process of establishing, implementing, and evaluating the effectiveness of national, technology-based effluent limitation guidelines?

The Act plainly gives EPA such authority. The achievement of state water quality standards is "one of the Act's central objectives." Arkansas v. Oklahoma, 112 S. Ct. at 1056. That Congress intended water quality standards to be attained without regard to technology-based controls is evident from the structure of the Act. "Congress had a deep respect for the sanctity of water quality standards and a firm conviction of need for technology-forcing measures." Natural Resources Defense Council v. EPA, 859 F.2d 156, 208-09 (D.C. Cir. 1988). Congress granted states the authority to set their own water quality standards, and to impose stricter requirements than the nationwide minima required by the Act. 33 U.S.C. §§ 1313(c), 1370; Roosevelt Campobello Int'l Park Comm'n v. EPA, 684 F.2d 1041, 1056 (1st Cir. 1982).

> It is clear from §§ [1311] and [1370] of the Act, and the legislative history, that the states are free to force technology. . . . Only the federal effluent limitations must be technology-based, and they represent

> the minimum level of pollution reduction required by the Act. [Citation omitted.] If the states wish to achieve better water quality, they may, even at the cost of economic and social dislocations . . . .

United States Steel Corp. v. Train, 556 F.2d 822, 838 (7th Cir. 1977).

Under section 1311(b)(1)(C), EPA must include in NPDES permits whatever effluent limitations it determines are necessary to achieve state water quality standards. Trustees for Alaska v. EPA, 749 F.2d 549, 556-57 (9th Cir. 1984).[22/] On a waterway such as the Columbia which violates water quality standards because of discharges of dioxin from numerous sources, a TMDL provides a rational mechanism for deciding how much those discharges must be reduced from each source in order to achieve the applicable standards. The TMDL thus serves as a planning mechanism, which is then implemented through NPDES permit limitations, to achieve the water quality standards set by the relevant states, as required by section 1311(b)(1)(C). Those standards must be attained, even if it requires control measures more stringent than whatever technology-based standards may exist.

Moreover, Congress clearly intended TMDLs to be established on an expeditious schedule. E.g., 33 U.S.C. § 1313(d)(2) (states

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22/ See also In re City of Jacksonville, District II Wastewater Treatment Plant, NPDES Appeal No. 91-19, 1992 NPDES LEXIS 8 (EPA Envt'l Appeals Board, Aug. 4, 1992) (EPA has independent duty under section 1311(b)(1)(C) to include more stringent permit limitation when such limitation is required to meet state water quality standards); In re Star-Kist Caribe, Inc., NPDES Appeal No. 88-5, 1990 NPDES LEXIS 4 (EPA Admin'r, Apr. 16, 1990) (same). States issuing NPDES permits under section 1342(b) stand in the shoes of EPA, so that the same substantive requirements apply. Natural Resources Defense Council v. EPA, 859 F.2d 156, 183 (D.C. Cir. 1988).

to make first TMDL submission within 180 days of EPA's identification of pollutants suitable for TMDL calculation); see Scott v. City of Hammond, 741 F.2d 992, 998 (7th Cir. 1984); Environmental Defense Fund v. Costle, 657 F.2d 275, 295 (D.C. Cir. 1981).[23] If EPA and the states were required to wait until every discharger to an impaired water was covered by national technology-based standards applicable to every pollutant, see Pulp Mill Br. at 13, no TMDLs would be established for a very long time.[24] Congress plainly did not intend such delay. Section 1313(d) and EPA's implementing regulations require states to establish TMDLs when certain technology-based effluent limitations and other control measures have failed to attain water quality standards, but they neither prohibit use of TMDLs earlier nor establish TMDLs as a "last resort" to be postponed as long as possible. See 33 U.S.C. § 1313(d); 40 C.F.R. § 130.7.

Even if section 1311(b)(1)(C) and 1313(d) did not require EPA to establish the TMDL, the Act clearly authorizes it. Section 1342(a)(1) expressly authorizes EPA to require "such [permit] conditions as [EPA] determines are necessary to carry out the

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[23] As we have shown, this TMDL was promulgated in conjunction with the establishment of ICSs for the Pulp Mills pursuant to the requirements of section 1314(l). The similarly short deadlines in that section clearly do not contemplate a delay in applying limitations in order to await development of technology-based standards.

[24] See 58 Fed. Reg. 66,078 (Dec. 17, 1993) (nationwide effluent guidelines for BAT relating to dioxin discharges from pulp mills proposed in late 1993). See Natural Resources Defense Council v. Reilly, 32 Env't Rep. Cas. (BNA) 1969, 1973 (D.D.C. 1991) (referring to the "ponderousness and enormity of the agency's task" in establishing effluent limitations guidelines); Chemical Mfrs. Ass'n v. Natural Resources Defense Council, 470 U.S. 116, 132 & n.24 (1985).

provisions of [the Act]," prior to taking actions necessary to implement the requirements of 33 U.S.C. §§ 1311, 1312, 1316, 1317, 1318, and 1343. Here, EPA has determined that the WLAs established by the TMDL are necessary to carry out the provisions of the Act -- specifically sections 1251(a)(3), 1311(b)(1)(C), 1313(c), 1313(d) and 1314(l) -- prior to taking the regulatory actions necessary to establish nationwide technology-based effluent limitations for dioxin. See Trustees for Alaska, 749 F.2d at 558. Thus, the TMDL is authorized by EPA's broad discretion under section 1342(a)(1) without regard to whether technology-based limitations for dioxin have been established or would lead to future attainment of water quality standards.25/

In light of this broad statutory authority to achieve water quality standards, EPA interpreted section 1313(d) as authorizing the Columbia River TMDL where the applicable standards for dioxin had not been achieved by the existing effluent limitations in the Pulp Mills' NPDES permits, even though the existing permits did not contain a specific technology-based, numeric limitation on dioxin discharges. AR No. 19(3), at 5-6, Mills ER at 132-33. EPA reasoned that if technology-based limits developed in the future, based either on national effluent limitation guidelines or on a BPJ basis, are more stringent than the wasteload allocations established as part of the TMDL, those stricter limits will have to be complied with, and the WLAs will have no practical effect.

25/ Cf. Arkansas v. Oklahoma, 112 S. Ct. at 1056 (Congress has vested in EPA "broad discretion" to establish conditions for NPDES permits, and to oversee state permit programs); id. at 1058 (the Act grants EPA and the states "broad authority" to develop area-wide programs to alleviate and eliminate existing pollution).

AR No. 19(3) at 5, Mills ER at 132. But if future technology-based limits are less stringent, then the water quality-based allocations in the TMDL will continue to be necessary to satisfy the requirements of the Act, and there is no valid reason to allow continued violation of the water quality standards in the interim. See id. This interpretation of the statutory scheme is reasonable, and must therefore be upheld.

Finally, the Pulp Mills' argument that the TMDL disadvantages the pulp and paper mills of the Pacific Northwest as against their rivals in other regions, Pulp Mill Br. at 12, is a red herring. The Act gives states primary authority to establish water quality standards, and those standards may vary across the country, because states may set more stringent water quality standards than the minimum protections required by the Act.[26/] If the Pulp Mills have a complaint about the applicable water quality standards in Washington, Oregon and Idaho, they should petition the states for a modification of those standards.

B. Even If Technology-Based Controls Were Required Before Establishment of TMDLs, That Language Refers to BPT Controls, Not BAT Controls.

Even if the Pulp Mills were correct that a TMDL may be established only after pollutant-specific, national technology-based effluent limitations have been incorporated in their permits and have failed to achieve water quality standards, their suggestion that BAT limits must first be applied, see Pulp Mill

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26/ States may establish their own water quality standards provided that EPA approves them as scientifically defensible and generally consistent with the requirements of the Act. 40 C.F.R. Part 131.

Br. at 15, 17-18, is plainly erroneous.[27] Sections 1313(d)(1)(A) & (C) direct states to establish TMDLs where effluent limitations required by sections 1311(b)(1)(A) and (B) are not adequate to implement water quality standards. In turn, those sections require effluent limitations consistent with application of "best practicable control technology currently available" ("BPT" limitations) for industrial point sources, and "secondary treatment" for publicly owned treatment works.[28] Section 1313(d) does not mention BAT limitations.

The Pulp Mills would supplement the plain language of section 1313(d) by requiring EPA to consider whether future application of nationwide BAT limitations for toxic pollutants might also lead to attainment of water quality standards. Pulp Mill Br. at 13-18.[29] BAT, or "best available technology economically achievable" limitations, are developed under sections 1311(b)(2)(A) and

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[27] In comments submitted to the Agency, the Pulp Mills argued that BAT limitations must be applied before a TMDL can be established. See AR No. 49, at 2 (Preliminary Comments of Weyerhaeuser); AR No. 90, at 13, 18 (Comments of Longview Fibre); AR No. 19(3) at 5, Mills ER at 132. In their brief here, the Mills attempt to blur the distinction between BPT and BAT limitations, but it is apparent that their goal is to delay implementation of a TMDL until after BAT limits are established. See Pulp Mill Br. at 17-18. Moreover, the Pulp Mills are limited here to arguments they presented to the Agency in a meaningful way in the first instance. See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, 435 U.S. 519, 553-54 (1978). Thus, we do not understand the Mills to be suggesting here that EPA should establish BPT limits for dioxin discharges from pulp mills, rather than the more stringent BAT limits required by 33 U.S.C. § 1311(b)(2).

[28] See Homestake Mining Co. v. EPA, 595 F.2d 421, 427 (8th Cir. 1979).

[29] The Pulp Mills refer to EPA's schedule for developing BAT effluent limitations guidelines, which contemplates establishment of such guidelines for pulp mill discharges of dioxin in 1995. Id. at 17 & n.13.

1314(b)(2)(A), and are not mentioned in section 1313(d). There is no basis in the statutory language for the Mills' proposed additional constraint on EPA's TMDL authority.30/ Moreover, when Congress adopted the TMDL provisions in 1972, it expected states to establish TMDLs long before BAT limitations were in place. Congress initially intended that BAT effluent limitations be attained by July, 1983. 33 U.S.C. § 1311(b)(2)(A) (1976). In contrast, Congress expected states to begin developing TMDLs by April, 1974, well before Congress expected BAT effluent limitation guidelines to be in place. See supra at 23.

C. The Pulp Mills Are Already Subject to Technology-Based Limitations.

The Pulp Mills' challenge to EPA's TMDL authority must also fail because the Mills are already subject to technology-based effluent limitations in their permits, and those limitations have not been adequate to attain all applicable water quality standards. EPA has promulgated nationally-applicable BPT and BAT limitations for discharges of a number of pollutants by members of the pulp and paper industry. 40 C.F.R. Part 430. These guidelines, implemented through NPDES permits, have been inadequate to provide for attainment of the water quality standards for dioxin

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30/ EPA regulations provide that TMDLs are not required under section 1313(d)(1) where various pollution control measures other than BPT and secondary treatment limitations are in place and are sufficient to implement water quality standards. See 40 C.F.R. § 130.7(b). That regulation does not require EPA or the states to adopt such other controls before exercising TMDL authority. In construing administrative regulations, courts must give "controlling weight" to the agency's interpretation, "unless it is plainly erroneous or inconsistent with the regulation." United States v. Larionoff, 431 U.S. 864, 872 (1977); Nevada Land, 8 F.3d at 717; Norfolk Energy, 898 F.2d at 1439.

in the Columbia River. Since these guidelines do not specifically address dioxin, it is clear that BPT and BAT limitations based on the national guidelines are inadequate to remedy waters impaired due to dioxin discharges. Thus, even if establishment of national BPT and BAT limitation guidelines were a prerequisite to TMDL development, that prerequisite has been established here.

In addition, every discharger is already covered by technology-based limits determined by the best professional judgment ("BPJ") of permit writers. Natural Resources Defense Council v. EPA, 859 F.2d 156, 183, 185 (D.C. Cir. 1988) (citing section 1342(a)(1)); Natural Resources Defense Council v. Reilly, 32 Env't Rep. Cas. (BNA) 1969, 1975 (D.D.C. 1991); see AR No. 19(3) at 4, Mills ER at 131. These existing BPJ limitations (which do not specifically address dioxin) have also been inadequate to ensure that the Pulp Mills' discharges comply with the water quality standards for dioxin. See AR No. 19(3) at 5, Mills ER at 132.

As EPA noted in establishing the TMDL, it is not reasonable to assume that future BAT limitations based on any revised national guidelines will result in attainment of water quality standards for dioxin in the Columbia River. AR No. 19(3) at 5, Mills ER at 132. Indulging in such an assumption could lead to the water quality standards being violated for another five years, plus further delays while additional controls are implemented. Id. EPA believed that such delay in imposing effective controls on such a highly toxic pollutant would be "contrary to the very essence" of section 1313(d). Id. Thus, EPA reasonably determined that establishment of the TMDL need not be delayed until after the

implementation of BAT limitations on discharges of dioxin, and the district court properly entered summary judgment in favor of EPA on the Pulp Mills' complaint.

II. EPA'S DECISION TO BASE THE TMDL ON TCDD ALONE WAS NOT ARBITRARY OR CAPRICIOUS.

EPA established its TMDL for 2,3,7,8-TCDD -- the toxic pollutant identified by the states under section 1313(d)(1)(A) as impairing the water quality of the Columbia River, and for which ICSs under section 1314(l) were required on an expeditious time schedule. DOC challenges EPA's decision to address only TCDD in this TMDL, DOC Br. at 11-14, 32-33, but fails to provide a single citation to any provision of the Clean Water Act in support of its position that a TMDL must address all pollutants in a single analysis. DOC completely ignores the rationale provided by the Agency for focussing on TCDD alone, and instead asks this Court to override EPA's reasoned determination on the proper scope of its TMDL.

A. The Clean Water Act Does Not Preclude EPA from Establishing Pollutant-Specific TMDLs.

DOC claims that EPA's TMDL is arbitrary and capricious because it establishes TCDD loadings without accounting for the presence in the Columbia River of a number of pollutants other than TCDD that may also be impairing water quality. DOC claims EPA was also required to consider the presence of an unidentified number of PCBs, PCCs, naphthalenes, and other related chemicals when determining loading limits for TCDD. DOC Br. at 11-12.

Essentially DOC argues that all water quality impairments must be addressed in a single TMDL. These arguments have no merit.31/

Nothing in the Clean Water Act or EPA regulations suggests that a single TMDL must address all pollution problems in a waterbody. Indeed, in the preamble to its regulations implementing section 1313(d), EPA explained that:

> [A] single TMDL covers only one specific pollutant or one property of pollution, for example acidity, biochemical oxygen demand, radioactivity or toxicity. Thus, more than one TMDL may be required for a segment where there may be violations of more than one criterion in the applicable [water quality standard].

50 Fed. Reg. 1,774, 1,776 (Jan. 11, 1985). Thus, EPA interprets the Act as allowing multiple TMDLs where there are multiple pollutants or pollutant properties causing impairments in a given waterbody.

EPA's interpretation of the proper scope of a TMDL is consistent with the Act's mandate that TMDLs be developed on a priority basis. Section 1313(d)(1)(C) requires that TMDLs be developed in accordance with a priority ranking of impaired waters established by the states pursuant to section 1313(d)(1)(A). As the district court found, the Act's prioritized approach to the worst pollution problems would be hampered if all impairments in a waterbody were required to be addressed in a single TMDL. CR No.

31/ DOC's arguments also ignore the fact that limitations required to meet water quality standards must be included in NPDES permits issued under section 1342 of the Act, whether or not TMDLs have been established. 33 U.S.C. §§ 1311(b)(1)(A) & (C), 1342(a)(1); 40 C.F.R. §§ 122.44(b)(1), 122.44(d)(1). Trustees for Alaska, 749 F.2d at 556-57. Thus, there is no valid reason based on environmental or human health concerns to require that EPA's TMDL address all of the possible water quality problems in the Columbia River.

88 at 17, Mills ER 248. Rather, the states and EPA must be allowed to address the worst problems in various waters first, retaining the ability to perform additional TMDLs for these waters and for other pollutants at a later date.

Thus, the Act does not require that EPA's TMDL for TCDD also cover the host of chemicals which DOC now alleges to be of concern in the Columbia River. Separate TMDLs can be prepared for these various chemicals if and when it is determined that they are causing an impairment in the Columbia River, either singly or as a group. Accordingly, if DOC believes that a toxic mixture of chemicals is present in the Columbia River notwithstanding implementation of the TMDL for TCDD, it should present its evidence to the states of Oregon, Washington and Idaho and request that they list the Columbia River under section 1313(d)(1)(A) as impaired due to the presence of these mixtures and identify development of a TMDL for them as a high priority.[32/] DOC should not be allowed to circumvent this statutorily-prescribed listing and prioritization process through an end-run against EPA's TMDL for dioxin.[33/]

32/ The States are required to update and revise their section 1313(d) lists of impaired waters and their priority ranking of waters for TMDL development every two years. 40 C.F.R. § 130.7(d)(1).

33/ Cf. Hazardous Waste Treatment Council v. EPA, 861 F.2d 277, 287 (D.C. Cir. 1988), cert. denied, 490 U.S. 1106 (1989) ("[A]n agency's failure to regulate more comprehensively is not ordinarily a basis for concluding that the regulations already promulgated are invalid.").

B. EPA Had Good Reasons to Limit the Scope of its TMDL to TCDD.

EPA considered establishing the TMDL to account for the presence of all chlorinated dibenzo-p-dioxins ("CDDs") and chlorinated dibenzo-furans ("CDFs") in the river, and explained a number of reasons why it did not do so. AR No. 19(3) at 25-26, Mills ER 152-53. For example, EPA explained that since TCDD is the most toxic of these compounds, its control would greatly reduce the risk posed by dioxins and furans in general.34/ EPA also explained that there was as yet inadequate information available to determine the degree to which CDDs and CDFs other than TCDD can be expected to persist in the environment and bioconcentrate in fish. Such considerations are of critical importance in establishing numeric interpretations of narrative criteria.

Since establishing the TMDL for TCDD, EPA has conducted research on the environmental fate of CDDs and CDFs, and has solicited comment on a protocol for equating their relative properties in this regard to the properties of TCDD.35/ EPA's

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34/ As one of the 65 toxic pollutants identified for heightened attention under section 1317(a) of the Act, TCDD is the only CDD or CDF for which Congress mandated that individual control strategies be developed. 33 U.S.C. § 1314(l)(1)(D); 40 C.F.R. § 401.15; see Natural Resources Defense Council v. EPA, 915 F.2d at 1316 n.1. EPA noted in its TMDL Decision Document that the TMDL would be used by the states in developing these ICSs. AR No. 19(2) at 2-1, Mills ER 91. Thus, the state and EPA prioritization of TCDD for TMDL development reflects a priority for action established directly by Congress.

35/ EPA derived "bioaccumulation equivalency factors" ("BEFs") for CDDs and CDFs as part of its proposed water quality standards guidance for the Great Lakes developed pursuant to 33 U.S.C. § 1268(c)(2). 58 Fed. Reg. 20,802, 20,943 (April 16, 1993). The (continued...)

TMDL decision allowed it to move forward with controls on TCDD while developing the technical capacity for doing more, if needed. The alternative, apparently preferred by DOC, would have involved lengthy delay in regulating TCDD while EPA developed a protocol for evaluating the environmental fate of other CDDs and CDFs.

EPA also explained that with respect to protection of human health from carcinogenic effects, the states bordering the Columbia River regulated pollutants on a chemical-by-chemical basis such that no one chemical would cause more than one additional cancer per one million people exposed. AR No. 19(3) at 26, Mills ER 153. EPA views decisions regarding tolerable cancer risk of pollutants in surface waters to be primarily a risk management decision of the states. 57 Fed. Reg. 60,864. The states' chemical-by-chemical approach to regulating carcinogens supported EPA's single-pollutant approach to establishing the TMDL.

As the district court held, EPA rationally chose to pursue regulation of dioxin as the most toxic of those chemicals threatening the Columbia River. CR No. 88 at 18, Mills ER 249. The Agency's judgment was based on complex scientific determinations and technical expertise, and is entitled to deference. See Hercules, Inc. v. EPA, 598 F.2d 91, 106 (D.C. Cir. 1978).

III. EPA REASONABLY SELECTED 0.013 PPQ AS AN AMBIENT TCDD CONCENTRATION PROTECTIVE OF HUMAN HEALTH.

By imposing dioxin allocations set at the very limit of detection capabilities, EPA's TMDL will reduce pulp mill

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35/ (...continued)
proposed BEFs vary between 0.003 and 1.8, indicating that the bioaccumulation potential of the various CDDs and CDFs studied ranges from three one-thousandths to roughly twice that of TCDD.

discharges of dioxin by approximately 95 percent. See AR Nos. 19(1), 19(2) at 3-9 and C-2 to -3, Mills ER 84, 102, 124-25. Nonetheless, DOC argues that these control measures -- the most stringent in the nation -- should be overturned as inadequate to protect the health of Native Americans and other populations that consume more fish than is found in an average diet. While EPA is committed to gathering and evaluating additional data on consumption of Columbia River fish, the record before the Agency at the time it acted establishes that the TMDL is sufficiently stringent to protect the health of all persons living in the Columbia River basin, including those with diets high in fish.

A. EPA Is Continuing to Collect and Analyze Data on Fish Consumption Patterns.

At the time EPA established the TMDL in 1991, it had before it a draft report by two EPA scientists discussing the possible risk to human populations in the Columbia River basin from consumption of fish caught near pulp mills, on which DOC relies here, AR No. 121, and a study commissioned by the Pulp Mills showing much lower estimates of fish consumption rates by Native Americans and other exposed populations, see AR No. 116. While EPA acted reasonably in establishing the TMDL based on the record before it, the Agency noted that "follow-up work is in progress." AR No. 19(3) at 10, Mills ER 137. Since that time, EPA has commissioned a more detailed study by the Columbia River Intertribal Fish Commission ("CRITFC") of fish consumption patterns among Native Americans in the Columbia River basin. The first phase of that study, nearly completed, has collected data on the amount of fish from the Columbia River consumed by Native Americans in the area.

On February 11, 1994, President Clinton signed Executive Order 12898, regarding federal actions to address environmental justice concerns in minority and low income populations. 59 Fed. Reg. 7,629 (Feb. 16, 1994). Among other things, that order directs federal agencies to collect and analyze information on consumption patterns of populations who principally rely on fish and/or wildlife for subsistence, and to develop guidance for the evaluation of human health risks associated with the consumption of pollutant-bearing fish or wildlife. Id. § 4-4.[36/] Consistent with the Executive Order, EPA has recently decided to move forward with a second phase of the CRITFC study, to assess the concentrations of dioxin found in the specific types of fish that make up the diet of Native Americans in the Columbia River basin. If the new studies suggest that the current state water quality standards for the Columbia River are not sufficiently protective of the health of Native Americans, one appropriate avenue for seeking revisions is through the states' triennial review of their water quality standards. See 33 U.S.C. § 1313(c)(1); AR No. 19(3) at 10, Mills ER 137. Of course, any change in the applicable numeric water quality standards would warrant consideration of whether a new TMDL is necessary to implement the revised standards.

B. On the Basis of the Administrative Record Before It, EPA Acted Reasonably in Establishing the TMDL to Achieve Existing State Water Quality Standards.

As we have shown, EPA's calculation of wasteload allocations for the Pulp Mills was influenced by the analytical detection

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[36/] The order does not create any judicially-enforceable rights, id. § 6-609, and cannot in any event affect the legal validity of agency action taken three years earlier.

limit for dioxin. AR No. 10(2) at 19, Mills ER 23; see supra at 14. As EPA explained, a permit condition set at a level below the general analytical detection limit would make it difficult or impossible to measure compliance. AR No. 10(2) at 20, Mills ER 24. See also AR No. 19(2) at 3-9, Mills ER 102.

EPA searched for creative approaches to reduce the dioxin loading from pulp mills even further than could be achieved by monitoring concentrations in total plant effluent. Because dioxin concentrations are higher in bleach plant flow than in total plant effluent, EPA determined that wasteload allocations which result in total plant effluent concentration limits even below the analytical detection limit could be monitored for compliance if monitoring were moved upstream in the mill to the bleach plant. AR No. 19(2) at C-2, Mills ER 124. In addition, EPA determined statistically that it could reduce total dioxin loading to the river still further by setting a maximum concentration at the 10 ppq detection limit, rather than using a long term average of 10 ppq. AR No. 19(2) at C-2 to C-3, Mills ER 124-25. Thus, EPA established the most stringent wasteload allocations for the Pulp Mills that it could monitor using existing analytical detection capabilities.

1. EPA Interpreted the States' Narrative Criteria Consistent With EPA's Technical Dioxin Guidance.

Although EPA is continuing to gather fish consumption data in the Columbia River basin, the administrative record demonstrates that EPA's interpretation of the state narrative dioxin criteria was sensible and protective based on the information available to the Agency at the time it acted. Fish consumption estimates are

just one factor in an equation used to estimate health risk, and EPA made generally conservative (i.e., protective) assumptions with respect to the other factors. Even assuming the higher fish consumption levels cited by DOC, the TMDL provides protection for Native Americans and other populations that is well within the cancer risk range that EPA has found to be adequately protective.

At the time the Columbia River TMDL was established, only Oregon had a numeric water quality criterion for dioxin, and it addressed human health concerns only. Accordingly, EPA interpreted the narrative criteria in Washington and Idaho to derive an ambient TCDD concentration protective of human health for Columbia River waters within those states.[37/] For reasons articulated in EPA's TMDL Decision Document, EPA interpreted the narrative water quality criteria in Washington and Idaho to be consistent with Oregon's numeric standard.[38/] EPA explained that the 0.013 ppq value it selected to implement narrative criteria in Washington and Idaho was based on the assumptions and analyses in EPA's Dioxin Criteria Document, AR No. 107. See AR No. 19(2) at 2-2, Mills ER 92. This 300-page analysis provides a comprehensive summary of information relevant to deriving a human health criterion, and suggests various criterion values -- including the 0.013 ppq value used as a basis for the Columbia River TMDL --

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37/ The narrative criteria provide generally that toxic substances may not be introduced in concentrations that may adversely affect public health or designated uses of the waters. See AR No. 10(2) at 7, Mills ER 11.

38/ EPA also interpreted the state narrative criteria as necessary to protect aquatic life and wildlife. See Part IV, infra.

that would protect human health with varying degrees of risk. AR No. 107 at C-181, SER 43.

DOC claims that the TMDL should have been based on attaining a lower ambient level of dioxin than 0.013 ppq. Specifically, it argues that the 0.013 ppq value was derived by assuming a fish consumption rate of 6.5 grams per day, and that the criterion will not protect those residents of the Columbia River Basin who eat 150 grams per day of fish. DOC Br. at 10, 29-31. Contrary to DOC's assertions, EPA's interpretation of the states' narrative criteria was reasonable, and is entitled to deference.[39/]

2. Scientific Background for Derivation of a Dioxin Water Quality Criterion

A numeric water quality criterion to protect human health from the presence of a chemical such as dioxin in surface waters is based on three fundamental considerations: (1) an assessment of the degree or probability of harm associated with varying doses of the chemical, (2) an estimate of the dose to humans that is likely to result from varying concentrations of the chemical in surface waters, and (3) a decision regarding the degree of risk to human health that is tolerable. See AR No. 107.

To determine the probability of adverse human health effects as a result of exposure to varying doses of dioxin, EPA calculated a "potency factor" for dioxin that is the most stringent of any

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39/ Since establishment of the TMDL, EPA has promulgated numeric human health dioxin criteria of 0.013 ppq for Idaho and Washington. 57 Fed. Reg. 60,922-23. Thus, all states in the Columbia River basin have now incorporated a numeric 0.013 ppq TCDD criterion into their water quality standards.

used by any regulatory agency in the world.[40/] AR No. 116 at 19a, SER 56. All else being equal, use of the potency factors or "safe" dioxin levels calculated by other federal agencies or foreign governments would result in a criterion from five to sixteen hundred times less stringent than EPA's 0.013 ppq value. Id.

The second step in calculating a numeric dioxin water quality criterion involves estimating the dose of dioxin to humans that is likely to result from its presence in surface waters. There are two primary human routes of exposure: drinking the water, and eating fish and shellfish. Because of the tendency of dioxin to concentrate in fish tissues at levels thousands of times greater than in the ambient water, the fish consumption exposure route is by far the most significant. AR No. 107 at C-181, SER 43.

EPA has calculated a "bioconcentration factor" ("BCF") of 5,000 that can be used to estimate dioxin concentration in fish as a multiple of the chemical's concentration in surface water. AR No. 107 at B-3 to B-10, C-179, SER 22-29, 41. With this tool for estimating fish tissue residues, the next step in estimating the potential dose to humans as a result of the presence of dioxin in surface water is to derive an estimate of the amount of pollutant-bearing fish likely to be consumed. As described in more detail

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40/ The EPA potency factor is expressed mathematically as 1.56×10^{-4} for every picogram (one trillionth of a gram) per kilogram per day of dioxin exposure. AR No. 107 at C-243, SER 49. In other words, the EPA potency factor estimates that an upper bound of 1.56 out of every 10,000 people who are exposed to a dose of one picogram per kilogram per day will develop cancer over a lifetime of exposure.

below, EPA used a value of 6.5 grams per day for this purpose.[41] AR No. 107 at C-181, C-183, SER 43, 45.

The last major consideration in deriving a criterion is an assessment of the degree of risk that should be deemed tolerable. EPA's 0.013 ppq dioxin criterion is based on a plausible upper bound one-in-one-million risk of developing cancer over a lifetime of exposure. AR No. 107 at C-181, SER 43. This risk level is in the more protective range of risk levels that EPA has used or approved in state and federal regulatory actions. See, e.g., 57 Fed. Reg. 60,848, 60,864 (EPA promulgation of water quality criteria for states using either a one-in-one million or a one-in-one-hundred-thousand risk level, depending on state policies.) All else being equal, use of the one-in-a-million target risk level yields criteria ten times more stringent than those criteria that are based on a risk level of one-in-one-hundred-thousand. Id.[42]

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[41] Assuming that a waterbody has ambient dioxin concentrations of 0.013 ppq (0.013 picograms per liter), the dioxin expected in fish flesh would be equal to that ambient concentration times the BCF of 5,000, or 65 picograms of dioxin per kilogram of fish. Assuming consumption of 6.5 grams (0.0065 kilograms) per day of such fish, the total dioxin ingested per day as a result of fish consumption would be 0.4225 picograms of dioxin.

[42] EPA combines the various risk assessment factors described above in the following formula to derive a numeric dioxin water quality criterion for protection of human health:

$$\text{CRITERION} = \frac{\text{RISK LEVEL X BODY WEIGHT}}{\text{POTENCY X ((WATER INTAKE) + (FISH CONSUMPTION X BCF))}}$$

Derivation of this formula is discussed generally at 45 Fed. Reg. 79,353, col. 1 (Nov. 28, 1980).

3. The 6.5 Gram Per Day Value Is Intended to Represent Only a Subset of Total Fish Consumption.

As described above, pollutant-bearing fish consumption rates are considered in setting water quality criteria because consumption of pollutant-bearing fish is a major pathway for human exposure to pollutants present in surface waters. Of course, fish consumption is only a concern to the extent that fish contain pollutant residues. The fish consumption rate is used in the criteria derivation formula to account for consumption of pollutant-bearing fish. Thus, all of the fish in the estimate are assumed to include a level of dioxin determined by the maximum level in ambient water (0.013 ppq here) and the dioxin bioconcentration factor (5,000), or 0.065 parts per trillion.[43/] In other words, all of the fish covered by the fish consumption rate are assumed to have the maximum residues of dioxin permitted by the water quality criterion. See 57 Fed. Reg. 60,848, 60,863, col. 1.

Actual consumption rates of such maximum residue fish are likely to vary from one waterbody to another, depending on such factors as the presence of anadromous fish (i.e., fish that live their adult lives in the ocean and only enter rivers in order to spawn). For purposes of deriving numeric water quality criteria, EPA made a reasonable assumption that the consumption rates of such maximum residue fish would be equal to the national average total consumption rate for all (pollutant-bearing and non pollutant-bearing) freshwater and estuarine fish, or 6.5 grams per day. 45 Fed. Reg. 79,348, col. 3 (Nov. 28, 1980).

43/ EPA rounded this value up to 0.07 parts per trillion in describing its final TMDL. AR No. 19(2) at 2-2, Mills ER 92.

DOC notes that some individuals in the Columbia River area consume 150 grams per day of fish. However, nothing in the administrative record suggests that those individuals will, after implementation of the TMDL, ingest more dioxin than they would by consuming 6.5 grams per day of maximum residue fish. Indeed, due to the large runs of anadromous fish on the Columbia River, see AR No. 116 at 30-31, SER 57-58, there is likely to be a significant difference between the total fish consumption rate and the rate of consumption of pollutant-bearing fish only. Anadromous fish such as salmon that frequent the Columbia River spend their adult lives in the oceans far from sources of dioxin discharge and would not be expected to bioconcentrate dioxin to any considerable degree during their brief stay in the Columbia River to spawn. AR No. 51(4) at 2, SER 11.

Thus, the total fish consumption rate of various individuals is not determinative; the central question is whether the actual rate of ingestion of dioxin is greater than that assumed by EPA. In Natural Resources Defense Council v. EPA, 16 F.3d 1395, 37 Env't Rep. Cas. (BNA) 1953 (4th Cir. 1993), use of a 6.5 gram per day fish consumption rate was challenged in the context of EPA approval of dioxin criteria adopted by the states of Maryland and Virginia. There, too, plaintiffs alleged that certain individuals consumed more than a total of 6.5 grams per day of fish. 37 Env't Rep. Cas. at 1958. The court, however, recognized that the 6.5 gram per day value is premised upon the subset of fish that contain the maximum residues of dioxin permissible under state law, id. at 1959, and held that EPA had relied on a scientifically

defensible means to reach reasoned judgments concerning fish consumption levels. Id. Accordingly, the court upheld EPA's approval of the criteria. Id. at 1963.44/ Similarly here, DOC has failed to overcome the presumption of validity accorded to EPA's TMDL. See Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 419 (1971); Ethyl Corp v. EPA, 541 F.2d at 34; Mt. Airy Ref. Co. v. Schlesinger, 481 F. Supp. 257, 264 (D.D.C. 1979).

As shown above, the 0.013 ppq value is designed to provide protection to the one-in-a-million risk level assuming consumption of maximum residue fish at the rate of 6.5 grams per day. Even assuming arguendo that the individuals DOC has described who eat 150 grams per day of fish are eating exclusively maximum residue fish, 23 times the value assumed by EPA, those individuals would bear a dioxin risk of 23 in a million. EPA has historically set health-based standards at risk levels between one-in-a-million (10^{-6}) and one-hundred-in-a-million (10^{-4}), and courts have upheld such levels as adequately protective of human health. See Ohio v. EPA, 997 F.2d 1520, 1533 (D.C. Cir. 1993); CR No. 88 at 16-17 n.5, Mills ER 247-48 n.5. See also, 56 Fed. Reg. 33,050, 33,081 (July 18, 1991); 57 Fed. Reg. 60,848, 60,864 (Dec. 22, 1992). Moreover, if individuals in the Columbia River basin are exposed to an increased cancer risk of 23 in a million, they would still be

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44/ It is noteworthy that the state numeric criteria at issue in NRDC were established at 1.2 ppq, see id. at 1958 -- approximately one hundred times less stringent than the 0.013 ppq standard that the Columbia River TMDL is designed to achieve. Notwithstanding an attack on virtually every component of the risk assessment used by the states to derive these criteria, the court upheld EPA's approval of the criteria as protective of human health. Id. at 1963.

subject to four times less risk than an average resident of Virginia or Maryland, where the Fourth Circuit has upheld EPA's approval of water quality standards for dioxin that are approximately 100 times less stringent.

C. DOC's Attacks on the TMDL Are Based on Misleading and Erroneous Characterizations of the Record and the Applicable State Water Quality Standards.

DOC's contention that the TMDL subjects certain populations to risk levels of 8,600 in a million, DOC Br. at 10-11, 30-31, is based on a simple misunderstanding or mischaracterization of the record. The hypothetical discussion of possible risk on which DOC relies, AR No. 121, was prepared before the TMDL was established, and it analyzed the risk to Native Americans, Asians and subsistence fishermen living in the Columbia River basin in the absence of the TMDL. It thus supported the need to address dioxin contamination in the Columbia River and the establishment of a TMDL. That draft analysis assumed a maximum dioxin concentration of 24 picograms per gram -- or 24,000 picograms per kilogram -- in the tissues of fish consumed. DOC ER Tab 47, AR No. 121, at 3. As we explained above, supra at 43 n.41, implementation of the TMDL is expected to result in maximum dioxin concentrations in fish tissue of only 65 picograms per kilogram, resulting in risk figures approximately three orders of magnitude smaller than those claimed by DOC. Thus, DOC is simply in error in claiming that EPA calculated post-TMDL risk levels in excess of those relied upon by the district court. See DOC Br. at 31; Mills ER 247-48 & n.5.

DOC's argument is also misleading in suggesting that the states of Washington, Oregon and Idaho have selected a one per

million risk level as the applicable water quality standard to be achieved by the TMDL. DOC Br. at 31. As shown above, supra at 41-43 & n.42, the designated risk level is merely one factor included in the equation for calculating a numeric water quality standard. The risk level is applied together with certain reasonable assumptions, such as fish and water consumption rates, bioconcentration factor, and so on, in order to arrive at a numeric criterion.45/ The risk level chosen by a state is not part of the state's narrative criteria, nor is it a freestanding "standard" to be applied to the particularized exposure levels of specific individuals or sub-populations. Rather, states' choice of a highly protective risk level already reflects consideration of the fact that some people invariably have higher exposure to certain risks than others. In other words, states may choose to provide a high level of protection for the average population in order to provide what they deem adequate protection for more sensitive populations.46/ There is no basis for DOC's suggestion that the use by Washington, Oregon and Idaho of a one per million risk level as one of several factors used to establish numerical

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45/ See, e.g., 57 Fed. Reg. at 60,863 (detailing assumptions used in deriving criteria, and indicating that "individuals that ingest ten times more of a pollutant than is assumed in derivation of the criteria at a 10^{-6} risk level will be protected to a 10^{-5} level, which EPA has historically considered to be adequately protective.").

46/ See, id. (referring to EPA's "focus on promulgation of appropriate State-wide criteria that will reduce risks to all exposed individuals, including highly exposed subpopulations.").

criteria requires that every individual be protected to at least a one per million risk level.47/

In sum, EPA's TMDL provides adequate protection for all residents of the Columbia River basin, and EPA will continue to gather additional data on fish consumption patterns. Based on the administrative record compiled by EPA in devising the TMDL, the TMDL is protective of human health, and implements all state numeric and narrative water quality standards. Therefore, the district court properly granted EPA's motion for summary judgment.

IV. THE TMDL WILL IMPLEMENT STATE WATER QUALITY STANDARDS FOR THE PROTECTION OF AQUATIC LIFE AND WILDLIFE.

DOC's final claim is based on the contention that EPA failed to consider the possible effects of dioxin on aquatic life and wildlife, and therefore failed to implement all applicable water quality standards for dioxin as required under section 1313(d). DOC Br. at 6, 18-20. This is simply wrong. Although the Columbia River was identified as being water quality impaired as a result of exceeding the 0.013 ppq human health criterion, AR No. 19(2) at 2-2 to 2-3, Mills ER 92-93, EPA was mindful of the toxic effects of dioxin on aquatic life and wildlife as well, see AR No. 107, and took them into account in deriving the TMDL.

Richard Albright, the Chief of the Water Quality Section in EPA's Regional Office in Seattle, and one of three EPA officials primarily responsible for development of the Columbia River TMDL, explained in a declaration accepted by the district court, CR No.

47/ DOC's strained argument would also establish as state water quality "standards" other factors in the criterion derivation formula, such as the consumption of 6.5 grams per day of fish, or a human life span of 70 years.

47 Exh. C, SER 64, that EPA did not limit its consideration to human health effects. On the contrary, "the TMDL was intended and designed to provide protection to humans, aquatic life, and wildlife." Id. at 3, SER 66. Mr. Albright determined, based on a review of record materials, that the 0.013 ppq human health criterion would also be broadly protective of aquatic life and wildlife. Id. at 2-3, SER 65-66.

The record supports this conclusion. First, a 1986 Biological Report issued by the USFWS (the "USFWS Dioxin Hazard Document") provides that "2,3,7,8-TCDD concentrations in water should not exceed 0.01 ppt [part per trillion] to protect aquatic life, or 10 to 12 ppt in food items of birds and other wildlife." AR No. 142, at iii, SER 60. The 0.013 ppq ambient concentration set by the TMDL is one one-thousandth of the 0.01 ppt ambient value that the USFWS Dioxin Hazard Document indicates is protective of aquatic life.48/ The TMDL is designed to yield maximum fish tissue residues of 0.07 ppt in fish. AR No. 19(2) at 2-2, Mills ER 92. This is roughly one hundred fortieth to one

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48/ The effects of dioxin on aquatic life are also discussed in EPA's dioxin criteria guidance document. AR No. 107, at B-1 through B-18, SER 20-37. The document reports that the lowest dioxin concentration at which adverse effects to aquatic animal life were observed was 0.0001 micrograms per liter (100 ppq). See AR No. 107 at B-7, SER 26. The 0.013 ppq goal of the TMDL is approximately one ten-thousandth of this value. Also, dioxin was not found to cause adverse effects to aquatic plants exposed to dioxin at concentrations up to 1.3 micrograms per liter. Id. at B-3, SER 22. The TMDL will attain an ambient dioxin concentration that is one hundred million times less than this value. Thus, contrary to DOC's assertions, DOC Br. at 21, this document certainly supports EPA's finding that the TMDL will protect aquatic life.

hundred seventieth of the USFWS' recommended value for the protection of birds and other wildlife.

Second, EPA's Background Document to the Integrated Risk Assessment for Dioxins and Furans from Chlorine Bleaching in Pulp and Paper Mills provides further confirmation that the TMDL will protect wildlife. Using a somewhat more conservative analysis than the USFWS Dioxin Hazard Document, it indicates that adverse effects to wildlife could potentially occur if there were greater than 3 ppt dioxin in their diet. DOC ER 47, AR No. 144, at 13-33. The concentration of dioxin in fish expected to occur through implementation of the TMDL is one forty-third of this value.[49/]

DOC expresses particular concern about possible impacts on bald eagles, DOC Br. at 8-9, 23-24, and alleges that "EPA never addressed any of these concerns," id. at 9, except by "abdicating" its responsibilities in favor of the USFWS. Id. at 24-25. By seeking the benefit of USFWS' expertise on wildlife issues, EPA

49/ The district court referred to this record document as support for EPA's finding that the TMDL would protect wildlife. CR 88 at 15, Mills ER 246. DOC strains to find error in the district court's reasoning by an irrelevant quotation from the document to the effect that insufficient data exist to derive a national aquatic life criterion for dioxin. DOC Br. at 22. DOC also distorts the facts by alleging that the 3 ppt fish residue value referenced in the Background Document was based on data showing that 3 ppt represented the "lowest observed adverse effects level," rather than a level at which no adverse effects are expected. DOC Br. at 22. To the contrary, that value was derived based on a dietary intake level in Rhesus monkeys found to have no adverse effect. See New York Department of Environmental Conservation ("NYDEC"), Niagara River Biota Contamination Project: Fish Flesh Criteria for Piscivorous Wildlife, at 71-72 (1987) (Appendix A hereto), cited in AR No. 144, at 13-33. Although not itself part of the administrative record, the NYDEC document may properly be considered for the limited purpose of explaining the meaning of the Background Document, which is in the record and which relied upon the NYDEC document.

was not "abdicating" its own responsibilities, but was instead seeking input from a sister agency with expertise in protection of endangered species.[50] EPA engaged in informal consultation with the USFWS before finalizing the TMDL to ensure that there would be no jeopardy to bald eagles as a result of implementation of the TMDL. AR No. 15, SER 2.[51] USFWS "commend[ed] the EPA in its actions to develop a total maximum daily load for dioxins in the Columbia River." AR No. 103 at 2, SER 15. Also, USFWS "agree[d] ... that the proposed reduction in dioxin discharges would not adversely affect any threatened or endangered species." AR No. 22, SER 4.[52] Thus, as the district court properly found, the administrative record provides sufficient evidence to support

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[50] EPA had also received public comments suggesting that consultation with USFWS was appropriate. AR No. 19(3) at 7-8, Mills ER 134-35; DOC ER Tab 47, AR No. 94.

[51] Whether EPA fully satisfied its obligations under the Endangered Species Act ("ESA") by engaging in informal consultation is not before this Court. As DOC notes, DOC Br. at 24 n.23, DOC settled its ESA claims against EPA in separate litigation. Thus, notwithstanding intimations in DOC's argument, e.g. DOC Br. at 23, no ESA issues are present in this case.

[52] DOC cites a formal biological opinion issued by USFWS in January 1994 for the proposition that the TMDL will not provide adequate protection for bald eagles. DOC Br. at 24 n.23. On March 1, 1994, the Court granted EPA's motion to strike that document from the record. That ruling was proper because the USFWS opinion was not part of the administrative record, and is based heavily on recent studies and data that were not available when EPA established the TMDL in early 1991. However, the Court allowed DOC's extra-record exhibit to remain "lodged" for such consideration as the merits panel deems necessary. While EPA does not believe that such post-decisional material may be properly considered for any purpose, we note that DOC has grossly mischaracterized USFWS' conclusions in that document. In fact, USFWS concluded that the establishment of the TMDL will not jeopardize the continued existence of the bald eagle, and recommended that EPA continue to implement the TMDL during the next five years while it gathers further data. DOC Appendix F at 2-3, 22.

EPA's conclusion that the TMDL will protect aquatic biota and wildlife. CR No. 88 at 15-16 & n.4, Mills ER 246-47 & n.4.

DOC claims that EPA never addressed USFWS' recommendation that EPA "strive toward . . . zero discharge." DOC Br. at 9, 23, 25. In fact, EPA did "strive" towards zero discharge by imposing a TMDL based on the limits of detection capability, and which requires a 95 percent reduction in pulp mill discharges of dioxin. EPA then explained why it rejected a zero discharge option: "All available information has been carefully considered. Based on that information the 'zero discharge' option is not necessary to achieve water quality standards . . . ." AR No. 19(2) at 3-9, Mills ER 102. DOC does not contest EPA's technical conclusion that it could not measure compliance with stricter wasteload allocations using currently available technology. Thus, EPA addressed the zero discharge option and provided adequate explanation of the basis for the choices it made.[53/]

V. EVEN IF THE COURT AGREES WITH DOC'S ARGUMENTS, THE TMDL SHOULD BE LEFT IN PLACE PENDING FURTHER AGENCY ACTION.

Even if the Court agrees with one or more of DOC's arguments and remands the TMDL to EPA to consider whether the TMDL should be redesigned to implement a more stringent water quality standard, the existing TMDL should be left in place pending revision. Vacatur of the TMDL would be counterproductive, because the TMDL provides substantially more protection to all users of the

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53/ Courts must uphold a decision even if it is of less than ideal clarity if the agency's path may reasonably be discerned. Northern Plains Resource Council v. EPA, 645 F.2d 1349, 1358 (9th Cir. 1981).

Columbia River, including the wildlife and human populations of concern to DOC, than the pre-TMDL regulatory regime.

As the D.C. Circuit recently recognized in the context of a notice and comment challenge, "when equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy." Fertilizer Inst. v. EPA, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (court allowed certain exemptions provided by EPA to remain in place pending full opportunity for notice and comment because vacating rules on remand may affect EPA's ability to respond adequately to serious safety hazards). As this Court has stated, judicial "intervention into the process of environmental regulation, a process of great complexity, should be accomplished with as little intrusiveness as feasible." Western Oil & Gas Ass'n v. EPA, 633 F.2d 803, 813 (9th Cir. 1980).54/ Similarly, in Chemical Mfrs. Ass'n v. EPA, 870 F.2d 177 (5th Cir. 1989), cert. denied, 495 U.S. 910 (1990), the Fifth Circuit left certain Clean Water Act effluent limitations in place pending full notice and comment, for three reasons equally applicable here:

54/ In Western Oil & Gas, the Court held that a reviewing court has discretion to shape an equitable remedy when reviewing agency regulations. There, the Court declined to invalidate certain Clean Air Act designations pending a fuller opportunity for notice and comment, based on the Court's "desire to avoid thwarting in an unnecessary way the operation of the Clean Air Act . . . during the time that the deliberative process is reenacted," and the "possibility of undesirable consequences which we cannot now predict that might result from invalidation of the designations." Id. at 813. See also Forelaws on Board v. Johnson, 743 F.2d 677, 685-86 (9th Cir. 1984) (refusing to enjoin ongoing agency contracts despite violation of National Environmental Policy Act), cert. denied, 478 U.S. 1004 (1986).

> First, we recognize Congress' concern for limiting the discharge of toxic pollutants within the statutory deadline. Second, the notice-and-comment proceedings may disclose that the . . . parameter urged by [petitioner environmental group] is neither necessary nor feasible. Finally, the industrial petitioners are not prejudiced by being subjected to . . . limitations which, if anything, may be too lenient.

Id. at 236. For the same reasons, the Court should leave the TMDL in effect on remand, even if it is persuaded by DOC's arguments that further consideration is appropriate.

CONCLUSION

The district court properly found that establishment of the Columbia River TMDL was not arbitrary or capricious, an abuse of discretion, or contrary to law. CR No. 88 at 18, Mills ER 249. For the foregoing reasons, that judgment should be affirmed.

Respectfully submitted,

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Dated: May 31, 1994

STATEMENT OF RELATED CASES

The only related case known to Defendant-Appellee is identified in the Brief of Appellants Longview Fibre Co., et al. at 4 and 21, and in the Brief of Appellants Dioxin/Organochlorine Center, et al., at 4 n.7.

CERTIFICATE OF SERVICE

I, Christopher S. Vaden, hereby certify that on May 31, 1994, I caused two true and correct copies of the foregoing Brief for the Defendants-Appellees to be served by Federal Express, overnight delivery, to:

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WASHINGTON STATE DEPARTMENT OF ECOLOGY

CR-102 Cover Sheet

Rule Citation(s) and Title(s):

Repealing Chapter 173-201WAC and replacing it with Chapter 173-201A WAC, Water Quality Standards for Surface Waters of the state of Washington.

Proposed Adoption Date:

October 7, 1992

Executive Summary (*attach separate sheet if necessary*):

Proposing revisions to the State's surface water quality standards regulation, Chapter 173-201 WAC.

Key elements of this revision include:

- Correction of typographic errors, restructuring of subsections, and minor language clarifications.
- Repealing and replacing the existing rule citation (173-201) as Chapter 173-201A WAC.
- Updating the State's antidegradation policy.
- Adopting aquatic life toxic criteria for four substances.
- Revised language clarifying the applicability of the standards to nonpoint sources and stormwater.
- Establishing criteria on allowing mixing zones for waste discharges.
- Upgrading Totten Inlet and Little Skookum Inlet and the Lower Cedar River to Class AA.
- Clarifying the intent to use toxicity testing and biological assessments to ensure aquatic life protection.
- Adding special temperature condition to the Skagit River George bypass.

Date signature required:

May 19, 1992

This filing package contains:

- ■ CR-102 Cover Sheet
- ■ Completed CR-102 Form
- ■ Small Business Economic Impact Statement
- ■ Proposed rules presented in OTS computer printout in WAC order

Reviewed by Rules Coordinator on:

(j) Short explanation of rule, its purpose, and anticipated effects:

The Department of Ecology is proposing revisions to the State's surface water quality standards regulation, Chapter 173-201 WAC. These revisions are designed to provide improved protection for water quality, in accordance with the purpose and authority established by Chapter 90.48 RCW, Water Pollution Control Act.

Does proposal change existing rules? ☒ YES ☐ NO If yes, describe changes:

Key elements of this revision include:
- Correction of typographic errors, restructuring of subsections, and minor language clarifications.
- Repealing and replacing the existing rule citation (173-201) as Chapter 173-201A WAC.
- Updating the State's antidegradation policy.
- Adopting aquatic life toxic Criteria for four substances.
- Revised language clarifying the applicability of the standards to nonpoint sources and stormwater.
- Establishing criteria on allowing mixing zones for waste discharges.
- ** See bottom of page for the rest.

(k) Is small business economic impact statement required by chapter 19.85 RCW? ☒ YES ☐ NO
(Use this space, if possible. Attach extra sheets if necessary.)

See attached SBEIS summaries.

- Upgrading Totten Inlet and Little Skookum Inlet and the Lower Cedar River to Class AA.
- Clarifying the intent to use toxicity testing and biological assessments to ensure aquatic life protection.
- Adding special temperature condition to the Skagit River Gorge Bypass.

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED
MAY 19 1995
TIME
BY

SMALL BUSINESS ECONOMIC IMPACT STATEMENT

for

WATER QUALITY STANDARDS FOR SURFACE WATERS
OF THE STATE OF WASHINGTON
CHAPTER 173-201A WAC

SUMMARY

INTRODUCTION

This document summarizes the Small Business Economic Impact Statement (SBEIS) written for the amendments to the state surface water quality standards. The full SBEIS may be obtained from Ecology's Water Quality Program.

The state Regulatory Fairness Act requires that a SBEIS be written for rules which have an economic impact on more than twenty percent of all industries or more than ten percent of any one industry. The SBEIS must describe the costs of complying with the rule. It must compare the compliance costs of small and large businesses to determine whether the rule disproportionately impacts small business.

A small business is defined as a profit-seeking enterprise, which is independently owned and operated from all other businesses, and which has fifty or fewer employees.

AMENDMENTS TO THE SURFACE WATER QUALITY STANDARDS

The Clean Water Act requires that states review their surface water quality standards at least once every three years. As a result of this review, many amendments have been made to the standards. There are seven primary amendments to the standards that cause economic impacts:

1. Subsections 040(2): Whole Effluent Toxicity Testing and Bioassessments for Aquatic Life Protection.
2. Subsections 040(3): Additional Aquatic Life Criteria.
3. Subsection 040(6). Human Health Risk Level for Establishing Criteria for Carcinogens.
4. Section 100: Mixing Zones.
5. Subsection 130(6): Reclassification of Lower Cedar River.
6. Subsection 130(93): Special Condition for Skagit River.
7. Subsection 140(25): Reclassification of Totten Inlet.

AO# 92-29

PROPOSED RULE MAKING
(RCW 34.05.320)

CR-102 (7/1/89)

- [X] Original Notice
- [ ] Supplemental Notice to WSR _____
- [ ] Continuance of WSR _____

Agency: Department of Ecology

(a) Title of rule: (Describe Subject)

Repealing Chapter 173-201 WAC and replacing it with Chapter 173-201A WAC, Water Quality Standards for Surface Waters of the state of Washington.

Purpose:

To establish water quality standards for surface waters of the State consistent with public health and public enjoyment thereof, and the propogation and protection of fish, shellfish and wildlife, pursuant to the provisions of Chapter 90.48 RCW and the policies established thereof.

Other identifying information:

To improve the regulation's structural efficiency, it is necessary to change the title to new Chapter 173-201A.

(b) Statutory authority for adoption:	Statute being implemented:
Chapter 90.48 RCW	Chapter 90.48 RCW

(c) Summary: The Department of Ecology is proposing revisions to the State's surface water quality standards which will improve their effectiveness in protecting water quality in accordance with the purpose and authority established by Chapter 90.48 RCW, Water Pollution Control Act.

Reasons supporting proposal:

- Authority and mandate to protect Water Quality as established by Chapter 90.48 RCW.
- State Committments to the USEPA to carry out provisions of the Clean Water Act.
- Revisions consistent with existing state standards for the protection of Surface Water.

(d) Name of Agency Personnel Responsible For:

		Office Location	Telephone
1. Drafting	Mark Hicks	Prudential Building	438-7087
2. Implementation	Michael T. Llewelyn	Prudential Building	438-7090
3. Enforcement	Michael T. Llewelyn	Prudential Building	438-7090

(e) Name of proponent (person or organization)

Department of Ecology

- [ ] Private
- [ ] Public
- [X] Governmental

(f) Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

This rule has complied with the requirements of RCW 90.70.080.

(g) Is rule necessary because of:

Federal Law?	[X] Yes [ ] No	If yes, *ATTACH COPY OF TEXT*	Federal Water Pollution Control Act, as amedned by the Clean Water Act of 1977. (See attached reproduction of the relevant Section 303(c).)
Federal Court Decision?	[ ] Yes [ ] No	Citation:	
State Court Decision?	[ ] Yes [ ] No		

(h) HEARING LOCATION:

July 21: Moses Lake, Washington, PUD Auditorium, 312 W 3rd, 7:00 pm

July 22: Bellevue, Washington, Ecology NWRO, 3190 160th Ave SE, 7:00 pm

Date: July 21 & 22, 1992 Time: 7:00 pm

Submit written comments to:

Mark Hicks
Water Quality Program
Dept. of Ecology PO Box 47600 By (date): 7/30/92

DATE OF INTENDED ADOPTION:

October 7, 1992

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

MAY 19 1992

TIME 9:03 AM

WSR 92-11-041

00971

1E (TYPE OR PRINT)

Fred Olson

SIGNATURE

Fred Ols

TITLE

Deputy Director

DATE

5/18/92

(COMPLETE REVERSE SIDE)

WSR 97-23-064

PERMANENT RULES

DEPARTMENT OF ECOLOGY

[Order 94-19--Filed November 18, 1997, 4:04 p.m.]

Date of Adoption: November 18, 1997.

Purpose: To amend chapter 173-201A WAC to update the standards, streamline language, add new language to improve and solve water quality problems, and to clarify rule language changes.

Citation of Existing Rules Affected by this Order: Amending chapter 173-201A WAC, the surface water quality standards.

Statutory Authority for Adoption: Chapter 90.48 RCW.

Other Authority: 40 CFR 131.

Adopted under notice filed as WSR 97-12-034 on May 30, 1997.

Changes Other than Editing from Proposed to Adopted Version: Additional language has been added to the definitions for "action value," "lake specific-study," and "trophic state." Some language was amended and changed in WAC 173-201A-030(6) for lake nutrient criteria guidance. WAC 173-201A-040 for toxic substances had some minor numeric changes and changes to footnotes affecting where the criteria applied. There was a minor language change to WAC 173-201A-060 (2) and (4)(c) and language added to WAC 173-201A-110 (1)(c).

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, amended 0, repealed 0; Federal Rules or Standards: New 0, amended 8, repealed 0; or Recently Enacted State Statutes: New 0, amended 0, repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, amended 2, repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, amended 8, repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, amended 8, repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, amended 0, repealed 0; Pilot Rule Making: New 0, amended 0, repealed 0; or Other Alternative Rule Making: New 0, amended 0, repealed 0.

Effective Date of Rule: Thirty-one days after filing.

November 18, 1997

Tom Fitzsimmons

Director

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-020 Definitions. The following definitions are intended to facilitate the use of chapter 173-201A WAC:

"Action value" means a total phosphorus (TP) value established at the upper limit of the trophic states in each ecoregion. Exceedance of an action value indicates that a problem is suspected. A lake-specific study may be needed to confirm if a nutrient problem exits.

"Acute conditions" are changes in the physical, chemical, or biologic environment which are expected or demonstrated to result in injury or death to an organism as a result of short-term exposure to the substance or detrimental environmental condition.

"AKART" is an acronym for "all known, available, and reasonable methods of prevention, control, and treatment." AKART shall represent the most current methodology that can be reasonably required for preventing, controlling, or abating the pollutants associated with a discharge. The concept of AKART applies to both point and nonpoint sources of pollution. The term "best management practices," typically applied to nonpoint source pollution controls is considered a subset of the AKART requirement. "The Stormwater Management Manual for the Puget Sound Basin" (1992), may be used as a guideline, to the extent appropriate, for developing best management practices to apply AKART for storm water discharges.

"Background conditions" means the biological, chemical, and physical conditions of a water body, outside the area of influence of the discharge under consideration. Background sampling locations in an enforcement action would be up-gradient or outside the area of influence of the discharge. If several discharges to any water body exist, and enforcement action is being taken for possible violations to the standards, background sampling would be undertaken immediately up-gradient from each discharge. When assessing background conditions in the headwaters of a disturbed watershed it may be necessary to use the background conditions of a neighboring or similar watershed as the reference conditions.

"Best management practices (BMP)" means physical, structural, and/or managerial practices approved by the department that, when used singularly or in combination, prevent or reduce pollutant discharges.

"Biological assessment" is an evaluation of the biological condition of a water body using surveys of aquatic community structure and function and other direct measurements of resident biota in surface waters.

"Bog" means those wetlands that are acidic, peat forming, and whose primary water source is precipitation, with little, if any, outflow.

"Carcinogen" means any substance or agent that produces or tends to produce cancer in humans. For implementation of this chapter, the term carcinogen will apply to substances on the United States Environmental Protection Agency lists of A (known human) and B (probable human) carcinogens, and any substance which causes a significant increased incidence of benign or malignant tumors in a single, well conducted animal bioassay, consistent with the weight of evidence approach specified in the United States Environmental Protection Agency's Guidelines for Carcinogenic Risk Assessment as set forth in 51 FR 33992 et seq. as presently published or as subsequently amended or republished.

"Chronic conditions" are changes in the physical, chemical, or biologic environment which are expected or demonstrated to result in injury or death to an organism as a result of repeated or constant exposure over an extended period of time to a substance or detrimental environmental condition.

"Created wetlands" means those wetlands intentionally created from nonwetland sites to produce or replace natural wetland habitat.

"Critical condition" is when the physical, chemical, and biological characteristics of the receiving water environment interact with the effluent to produce the greatest

potential adverse impact on aquatic biota and existing or characteristic water uses. For steady-state discharges to riverine systems the critical condition may be assumed to be equal to the ((~~7010~~)) 7Q10 flow event unless determined otherwise by the department.

"Damage to the ecosystem" means any demonstrated or predicted stress to aquatic or terrestrial organisms or communities of organisms which the department reasonably concludes may interfere in the health or survival success or natural structure of such populations. This stress may be due to, but is not limited to, alteration in habitat or changes in water temperature, chemistry, or turbidity, and shall consider the potential build up of discharge constituents or temporal increases in habitat alteration which may create such stress in the long term.

"Department" means the state of Washington department of ecology.

"Director" means the director of the state of Washington department of ecology.

"Drainage ditch" means that portion of a designed and constructed conveyance system that serves the purpose of transporting surplus water; this may include natural water courses or channels incorporated in the system design, but does not include the area adjacent to the water course or channel.

"Ecoregions" are defined using EPAs *Ecoregions of the Pacific Northwest* Document No. 600/3-86/033 July 1986 by Omernik and Gallant.

"Fecal coliform" means that portion of the coliform group which is present in the intestinal tracts and feces of warm-blooded animals as detected by the product of acid or gas from lactose in a suitable culture medium within twenty-four hours at 44.5 plus or minus 0.2 degrees Celsius.

"Geometric mean" means either the nth root of a product of n factors, or the antilogarithm of the arithmetic mean of the logarithms of the individual sample values.

"Ground water exchange" means the discharge and recharge of ground water to a surface water. Discharge is inflow from an aquifer, seeps or springs that increases the available supply of surface water. Recharge is outflow downgradient to an aquifer or downstream to surface water for base flow maintenance. Exchange may include ground water discharge in one season followed by recharge later in the year.

"Hardness" means a measure of the calcium and magnesium salts present in water. For purposes of this chapter, hardness is measured in milligrams per liter and expressed as calcium carbonate ($CaCO_3$).

"Irrigation ditch" means that portion of a designed and constructed conveyance system that serves the purpose of transporting irrigation water from its supply source to its place of use; this may include natural water courses or channels incorporated in the system design, but does not include the area adjacent to the water course or channel.

"Lakes" shall be distinguished from riverine systems as being water bodies, including reservoirs, with a mean detention time of greater than fifteen days.

"Lake-specific study" means a study intended to quantify existing nutrient concentrations, determine existing characteristic uses for lake class waters, and potential lake uses. The study determines how to protect these uses and if any uses are lost or impaired because of nutrients, algae, or aquatic plants. An appropriate study must recommend a criterion for total phosphorus (TP), total nitrogen (TN) in g/l, or other nutrient that impairs characteristic uses by causing excessive algae blooms or aquatic plant growth.

"Mean detention time" means the time obtained by dividing a reservoir's mean annual minimum total storage by the thirty-day ten-year low-flow from the reservoir.

"Migration or translocation" means any natural movement of an organism or community of organisms from one locality to another locality.

"Mixing zone" means that portion of a water body adjacent to an effluent outfall where mixing results in the dilution of the effluent with the receiving water. Water quality criteria may be exceeded in a mixing zone as conditioned and provided for in WAC 173-201A-100.

"Natural conditions" or "natural background levels" means surface water quality that was present before any human-caused pollution. When estimating natural conditions in the headwaters of a disturbed watershed it may be necessary to use the less disturbed conditions of a neighboring or similar watershed as a reference condition.

"Nonpoint source" means pollution that enters any waters of the state from any dispersed land-based or water-based activities, including but not limited to atmospheric deposition, surface water runoff from agricultural lands, urban areas,

or forest lands, subsurface or underground sources, or discharges from boats or marine vessels not otherwise regulated under the National Pollutant Discharge Elimination System program.

"Permit" means a document issued pursuant to RCW 90.48.160 et seq. or RCW 90.48.260 or both, specifying the waste treatment and control requirements and waste discharge conditions.

"pH" means the negative logarithm of the hydrogen ion concentration.

"Pollution" means such contamination, or other alteration of the physical, chemical, or biological properties, of any waters of the state, including change in temperature, taste, color, turbidity, or odor of the waters, or such discharge of any liquid, gaseous, solid, radioactive, or other substance into any waters of the state as will or is likely to create a nuisance or render such waters harmful, detrimental, or injurious to the public health, safety, or welfare, or to domestic, commercial, industrial, agricultural, recreational, or other legitimate beneficial uses, or to livestock, wild animals, birds, fish, or other aquatic life.

"Primary contact recreation" means activities where a person would have direct contact with water to the point of complete submergence including, but not limited to, skin diving, swimming, and water skiing.

"Secondary contact recreation" means activities where a person's water contact would be limited (wading or fishing) to the extent that bacterial infections of eyes, ears, respiratory or digestive systems, or urogenital areas would normally be avoided.

"Shoreline stabilization" means the anchoring of soil at the water's edge, or in shallow water, by fibrous plant root complexes; this may include long-term accretion of sediment or peat, along with shoreline progradation in such areas.

"Storm water" means that portion of precipitation that does not naturally percolate into the ground or evaporate, but flows via overland flow, interflow, pipes, and other features of a storm water drainage system into a defined surface water body, or a constructed infiltration facility.

"Storm water attenuation" means the process by which peak flows from precipitation are reduced and runoff velocities are slowed as a result of passing through a surface waterbody.

"Surface waters of the state" includes lakes, rivers, ponds, streams, inland waters,

saltwaters, wetlands and all other surface waters and water courses within the jurisdiction of the state of Washington.

"Temperature" means water temperature expressed in degrees Celsius (C).

"Treatment wetlands" means those wetlands intentionally constructed on nonwetland sites and managed for the primary purpose of wastewater or storm water treatment. Treatment wetlands are considered part of a collection and treatment system, and generally are not subject to the criteria of this chapter.

"Trophic state" means a classification of the productivity of a lake ecosystem. Lake productivity depends on the amount of biologically available nutrients in water and sediments and may be based on total phosphorus (TP). Secchi depth and chlorophyll-a measurements may be used to improve the trophic state classification of a lake. Trophic states used in this rule include, from least to most nutrient rich, ultra-oligotrophic, oligotrophic, lower mesotrophic, upper mesotrophic, and eutrophic.

"Turbidity" means the clarity of water expressed as nephelometric turbidity units (NTU) and measured with a calibrated turbidimeter.

"Upwelling" means the natural process along Washington's Pacific Coast where the summer prevailing northerly winds produce a seaward transport of surface water. Cold, deeper more saline waters rich in nutrients and low in dissolved oxygen, rise to replace the surface water. The cold oxygen deficient water enters Puget Sound and other coastal ((~~estauries~~)) estuaries at depth where it displaces the existing deep water and eventually rises to replace the surface water. Such surface water replacement results in an overall increase in salinity and nutrients accompanied by a depression in dissolved oxygen. Localized upwelling of the deeper water of Puget Sound can occur year-round under influence of tidal currents, winds, and geomorphic features.

"USEPA" means the United States Environmental Protection Agency.

"Wetlands" means areas that are inundated or saturated by surface water or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas. Wetlands do not include those artificial wetlands intentionally created from nonwetland sites, including, but not limited to, irrigation and drainage ditches, grass-lined swales, canals, detention facilities, wastewater treatment facilities, farm ponds, and landscape amenities, or those wetlands

created after July 1, 1990, that were unintentionally created as a result of the construction of a road, street, or highway. Wetlands may include those artificial wetlands intentionally created from nonwetland areas to mitigate the conversion of wetlands. (Waterbodies not included in the definition of wetlands as well as those mentioned in the definition are still waters of the state.)

"Wildlife habitat" means waters of the state used by, or that directly or indirectly provide food support to, fish, other aquatic life, and wildlife for any life history stage or activity.

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-020, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-030 General water use and criteria classes. The following criteria shall apply to the various classes of surface waters in the state of Washington:

(1) **Class AA (extraordinary).**

(a) General characteristic. Water quality of this class shall markedly and uniformly exceed the requirements for all or substantially all uses.

(b) Characteristic uses. Characteristic uses shall include, but not be limited to, the following:

(i) Water supply (domestic, industrial, agricultural).

(ii) Stock watering.

(iii) Fish and shellfish:

Salmonid migration, rearing, spawning, and harvesting.

Other fish migration, rearing, spawning, and harvesting.

Clam, oyster, and mussel rearing, spawning, and harvesting.

Crustaceans and other shellfish (crabs, shrimp, crayfish, scallops, etc.) rearing,

spawning, and harvesting.

(iv) Wildlife habitat.

(v) Recreation (primary contact recreation, sport fishing, boating, and aesthetic enjoyment).

(vi) Commerce and navigation.

(c) Water quality criteria:

(i) Fecal coliform organisms:

(A) Freshwater - fecal coliform organism levels shall both not exceed a geometric mean value of 50 colonies/100 mL and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 100 colonies/100 mL.

(B) Marine water - fecal coliform organism levels shall both not exceed a geometric mean value of 14 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 43 colonies/100 mL.

(ii) Dissolved oxygen:

(A) Freshwater - dissolved oxygen shall exceed 9.5 mg/L.

(B) Marine water - dissolved oxygen shall exceed 7.0 mg/L. When natural conditions, such as upwelling, occur, causing the dissolved oxygen to be depressed near or below 7.0 mg/L, natural dissolved oxygen levels may be degraded by up to 0.2 mg/L by human-caused activities.

(iii) Total dissolved gas shall not exceed 110 percent of saturation at any point of sample collection.

(iv) Temperature shall not exceed 16.0C (freshwater) or 13.0C (marine water) due to human activities. When natural conditions exceed 16.0C (freshwater) and 13.0C (marine water), no temperature increases will be allowed which will raise the receiving water temperature by greater than 0.3C.

Incremental temperature increases resulting from point source activities shall not,

at any time, exceed t=23/(T+5) (freshwater) or t=8/(T-4) (marine water). Incremental temperature increases resulting from nonpoint source activities shall not exceed 2.8C.

For purposes hereof, "t" represents the maximum permissible temperature increase measured at a mixing zone boundary; and "T" represents the background temperature as measured at a point or points unaffected by the discharge and representative of the highest ambient water temperature in the vicinity of the discharge.

(v) pH shall be within the range of 6.5 to 8.5 (freshwater) or 7.0 to 8.5 (marine water) with a human-caused variation within ((~~a~~)) the above range of less than 0.2 units.

(vi) Turbidity shall not exceed 5 NTU over background turbidity when the background turbidity is 50 NTU or less, or have more than a 10 percent increase in turbidity when the background turbidity is more than 50 NTU.

(vii) Toxic, radioactive, or deleterious material concentrations shall be below those which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department (see WAC 173-201A-040 and 173-201A-050).

(viii) Aesthetic values shall not be impaired by the presence of materials or their effects, excluding those of natural origin, which offend the senses of sight, smell, touch, or taste.

(2) **Class A (excellent).**

(a) General characteristic. Water quality of this class shall meet or exceed the requirements for all or substantially all uses.

(b) Characteristic uses. Characteristic uses shall include, but not be limited to, the following:

(i) Water supply (domestic, industrial, agricultural).

(ii) Stock watering.

(iii) Fish and shellfish:

Salmonid migration, rearing, spawning, and harvesting.

Other fish migration, rearing, spawning, and harvesting.

Clam, oyster, and mussel rearing, spawning, and harvesting.

Crustaceans and other shellfish (crabs, shrimp, crayfish, scallops, etc.) rearing, spawning, and harvesting.

(iv) Wildlife habitat.

(v) Recreation (primary contact recreation, sport fishing, boating, and aesthetic enjoyment).

(vi) Commerce and navigation.

(c) Water quality criteria:

(i) Fecal coliform organisms:

(A) Freshwater - fecal coliform organism levels shall both not exceed a geometric mean value of 100 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 200 colonies/100 mL.

(B) Marine water - fecal coliform organism levels shall both not exceed a geometric mean value of 14 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 43 colonies/100 mL.

(ii) Dissolved oxygen:

(A) Freshwater - dissolved oxygen shall exceed 8.0 mg/L.

(B) Marine water - dissolved oxygen shall exceed 6.0 mg/L. When natural conditions, such as upwelling, occur, causing the dissolved oxygen to be depressed near or below 6.0 mg/L, natural dissolved oxygen levels may be degraded by up to 0.2 mg/L by human-caused activities.

(iii) Total dissolved gas shall not exceed 110 percent of saturation at any point of sample collection.

(iv) Temperature shall not exceed 18.0C (freshwater) or 16.0C (marine water) due to human activities. When natural conditions exceed 18.0C (freshwater) and 16.0C (marine water), no temperature increases will be allowed which will raise the receiving water temperature by greater than 0.3C.

Incremental temperature increases resulting from point source activities shall not, at any time, exceed t=28/(T+7) (freshwater) or t=12/(T-2) (marine water). Incremental temperature increases resulting from nonpoint source activities shall not exceed 2.8C.

For purposes hereof, "t" represents the maximum permissible temperature increase measured at a mixing zone boundary; and "T" represents the background temperature as measured at a point or points unaffected by the discharge and representative of the highest ambient water temperature in the vicinity of the discharge.

(v) pH shall be within the range of 6.5 to 8.5 (freshwater) or 7.0 to 8.5 (marine water) with a human-caused variation within ((~~a~~)) the above range of less than 0.5 units.

(vi) Turbidity shall not exceed 5 NTU over background turbidity when the background turbidity is 50 NTU or less, or have more than a 10 percent increase in turbidity when the background turbidity is more than 50 NTU.

(vii) Toxic, radioactive, or deleterious material concentrations shall be below those which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department (see WAC 173-201A-040 and 173-201A-050).

(viii) Aesthetic values shall not be impaired by the presence of materials or their effects, excluding those of natural origin, which offend the senses of sight, smell, touch, or taste.

(3) **Class B (good).**

(a) General characteristic. Water quality of this class shall meet or exceed the requirements for most uses.

(b) Characteristic uses. Characteristic uses shall include, but not be limited to, the following:

(i) Water supply (industrial and agricultural).

(ii) Stock watering.

(iii) Fish and shellfish:

Salmonid migration, rearing, and harvesting.

Other fish migration, rearing, spawning, and harvesting.

Clam, oyster, and mussel rearing and spawning.

Crustaceans and other shellfish (crabs, shrimp, crayfish, scallops, etc.) rearing, spawning, and harvesting.

(iv) Wildlife habitat.

(v) Recreation (secondary contact recreation, sport fishing, boating, and aesthetic enjoyment).

(vi) Commerce and navigation.

(c) Water quality criteria:

(i) Fecal coliform organisms:

(A) Freshwater - fecal coliform organism levels shall both not exceed a geometric mean value of 200 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 400 colonies/100 mL.

(B) Marine water - fecal coliform organism levels shall both not exceed a geometric mean value of 100 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 200 colonies/100 Ml.

(ii) Dissolved oxygen:

(A) Freshwater - dissolved oxygen shall exceed 6.5 mg/L.

(B) Marine water - dissolved oxygen shall exceed 5.0 mg/L. When natural

conditions, such as upwelling, occur, causing the dissolved oxygen to be depressed near or below 5.0 mg/L, natural dissolved oxygen levels may be degraded by up to 0.2 mg/L by human-caused activities.

(iii) Total dissolved gas shall not exceed 110 percent of saturation at any point of sample collection.

(iv) Temperature shall not exceed 21.0C (freshwater) or 19.0C (marine water) due to human activities. When natural conditions exceed 21.0C (freshwater) and 19.0C (marine water), no temperature increases will be allowed which will raise the receiving water temperature by greater than 0.3C.

Incremental temperature increases resulting from point source activities shall not, at any time, exceed t=34/(T+9) (freshwater) or t=16/(T) (marine water). Incremental temperature increases resulting from nonpoint source activities shall not exceed 2.8C.

For purposes hereof, "t" represents the maximum permissible temperature increase measured at a mixing zone boundary; and "T" represents the background temperature as measured at a point or points unaffected by the discharge and representative of the highest ambient water temperature in the vicinity of the discharge.

(v) pH shall be within the range of 6.5 to 8.5 (freshwater) and 7.0 to 8.5 (marine water) with a human-caused variation within ((~~a~~)) the above range of less than 0.5 units.

(vi) Turbidity shall not exceed 10 NTU over background turbidity when the background turbidity is 50 NTU or less, or have more than a 20 percent increase in turbidity when the background turbidity is more than 50 NTU.

(vii) Toxic, radioactive, or deleterious material concentrations shall be below those which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department (see WAC 173-201A-040 and 173-201A-050).

(viii) Aesthetic values shall not be reduced by dissolved, suspended, floating, or submerged matter not attributed to natural causes, so as to affect water use or taint the flesh of edible species.

(4) **Class C (fair).**

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(a) General characteristic. Water quality of this class shall meet or exceed the requirements of selected and essential uses.

(b) Characteristic uses. Characteristic uses shall include, but not be limited to, the following:

(i) Water supply (industrial).

(ii) Fish (salmonid and other fish migration).

(iii) Recreation (secondary contact recreation, sport fishing, boating, and aesthetic enjoyment).

(iv) Commerce and navigation.

(c) Water quality criteria - marine water:

(i) Fecal coliform organism levels shall both not exceed a geometric mean value of 200 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 400 colonies/100 mL.

(ii) Dissolved oxygen shall exceed 4.0 mg/L. When natural conditions, such as upwelling, occur, causing the dissolved oxygen to be depressed near or below 4.0 mg/L, natural dissolved oxygen levels may be degraded by up to 0.2 mg/L by human-caused activities.

(iii) Temperature shall not exceed 22.0C due to human activities. When natural conditions exceed 22.0C, no temperature increases will be allowed which will raise the receiving water temperature by greater than 0.3C.

Incremental temperature increases shall not, at any time, exceed $t=20/(T+2)$.

For purposes hereof, "t" represents the maximum permissible temperature increase measured at a mixing zone boundary; and "T" represents the background temperature as measured at a point or points unaffected by the discharge and representative of the highest ambient water temperature in the vicinity of the discharge.

(iv) pH shall be within the range of 6.5 to 9.0 with a human-caused variation within a range of less than 0.5 units.

(v) Turbidity shall not exceed 10 NTU over background turbidity when the background turbidity is 50 NTU or less, or have more than a 20 percent increase in turbidity when the background turbidity is more than 50 NTU.

(vi) Toxic, radioactive, or deleterious material concentrations shall be below those which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department (see WAC 173-201A-040 and 173-201A-050).

(vii) Aesthetic values shall not be interfered with by the presence of obnoxious wastes, slimes, aquatic growths, or materials which will taint the flesh of edible species.

(5) **Lake class.**

(a) General characteristic. Water quality of this class shall meet or exceed the requirements for all or substantially all uses.

(b) Characteristic uses. Characteristic uses shall include, but not be limited to, the following:

(i) Water supply (domestic, industrial, agricultural).

(ii) Stock watering.

(iii) Fish and shellfish:

Salmonid migration, rearing, spawning, and harvesting.

Other fish migration, rearing, spawning, and harvesting.

Clam and mussel rearing, spawning, and harvesting.

Crayfish rearing, spawning, and harvesting.

(iv) Wildlife habitat.

(v) Recreation (primary contact recreation, sport fishing, boating, and aesthetic enjoyment).

(vi) Commerce and navigation.

(c) Water quality criteria:

(i) Fecal coliform organism levels shall both not exceed a geometric mean value of 50 colonies/100 mL, and not have more than 10 percent of all samples obtained for calculating the geometric mean value exceeding 100 colonies/100 mL.

(ii) Dissolved oxygen - no measurable decrease from natural conditions.

(iii) Total dissolved gas shall not exceed 110 percent of saturation at any point of sample collection.

(iv) Temperature - no measurable change from natural conditions.

(v) pH - no measurable change from natural conditions.

(vi) Turbidity shall not exceed 5 NTU over background conditions.

(vii) Toxic, radioactive, or deleterious material concentrations shall be below those which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department (see WAC 173-201A-040 and 173-201A-050).

(viii) Aesthetic values shall not be impaired by the presence of materials or their effects, excluding those of natural origin, which offend the senses of sight, smell, touch, or taste.

(6) **Establishing lake nutrient criteria.**

(a) The following table shall be used to aid in establishing nutrient criteria:

[Open Style:Columns Off]

(WAC 173-201A-030, Table 1)

[Open Style:Columns On]

Lakes in the Willamette, East Cascade Foothills, or Blue Mountain ecoregions do not have recommended values and need to have lake-specific studies in order to receive criteria as described in (c)(i) of this subsection.

(b) The following actions are recommended if ambient monitoring of a lake shows the epilimnetic total phosphorus concentration, as shown in Table 1 of this section, is below the action value for an ecoregion:

(i) Determine trophic status from existing or newly gathered data. The recommended minimum sampling to determine trophic status is calculated as the mean of four or more samples collected from the epilimnion between June through September in one or more consecutive years. Sampling must be spread throughout the season.

(ii) Propose criteria at or below the upper limit of the trophic state; or

(iii) Conduct lake-specific study to determine and propose to adopt appropriate criteria as described in (c) of this subsection.

(c) The following actions are recommended if ambient monitoring of a lake shows total phosphorus to exceed the action value for an ecoregion shown in Table 1 of this section or where recommended ecoregional action values do not exist:

(i) Conduct a lake-specific study to evaluate the characteristic uses of the lake. A lake-specific study may vary depending on the source or threat of impairment. Phytoplankton blooms, toxic phytoplankton, or excessive aquatic plants, are examples of various sources of impairment. The following are examples of quantitative measures that a study may describe: Total phosphorus, total nitrogen, chlorophyll-a, dissolved oxygen in the hypolimnion if thermally stratified, pH, hardness, or other measures of existing conditions and potential changes in any one of these parameters.

(ii) Determine appropriate total phosphorus concentrations or other nutrient criteria to protect characteristic lake uses. If the existing total phosphorus concentration is protective of characteristic lake uses, then set criteria at existing total phosphorus concentration. If the existing total phosphorus concentration is not protective of the existing characteristic lake uses, then set criteria at a protective concentration. Proposals to adopt appropriate total phosphorus criteria to protect characteristic uses must be developed by considering technical information and stakeholder input as part of a public involvement process equivalent to the Administrative Procedure Act (chapter 34.05 RCW).

(iii) Determine if the proposed total phosphorus criteria necessary to protect characteristic uses is achievable. If the recommended criterion is not achievable and if the characteristic use the criterion is intended to protect is not an existing use, then a higher criterion may be proposed in conformance with 40 CFR part 131.10.

(d) The department will consider proposed lake-specific nutrient criteria during any water quality standards rule making that follows development of a proposal. Adoption by rule formally establishes the criteria for that lake.

(e) Prioritization and investigation of lakes by the department will be initiated by listing problem lakes in a watershed needs assessment, and scheduled as part of the water quality program's watershed approach to pollution control. This prioritization will apply to lakes identified as warranting a criteria based on the results of a lake-specific study, to lakes warranting a lake-specific study for establishing criteria, and to lakes requiring restoration and pollution control measures due to exceedance of an established criterion. The adoption of nutrient criteria are generally not intended to apply to lakes or ponds with a surface area smaller than five acres; or to ponds wholly contained on private property owned and surrounded by a single landowner; and nutrients do not drain or leach from these lakes or private ponds to the detriment of other property owners or other water bodies; and do not impact designated uses in the lake. However, if the landowner proposes criteria the department may consider adoption.

(f) The department may not need to set a lake-specific criteria or further investigate a lake if existing water quality conditions are naturally poorer (higher TP) than the action value and uses have not been lost or degraded, per WAC 173-201A-070(2).

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-030, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-040 Toxic substances. (1) Toxic substances shall not be introduced above natural background levels in waters of the state which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic toxicity to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the department.

(2) The department shall employ or require chemical testing, acute and chronic

toxicity testing, and biological assessments, as appropriate, to evaluate compliance with subsection (1) of this section and to ensure that aquatic communities and the existing and characteristic beneficial uses of waters are being fully protected.

(3) The following criteria shall be applied to all surface waters of the state of Washington for the protection of aquatic life. The department may revise the following criteria on a state-wide or waterbody-specific basis as needed to protect aquatic life occurring in waters of the state and to increase the technical accuracy of the criteria being applied. The department shall formally adopt any appropriate revised criteria as part of this chapter in accordance with the provisions established in chapter 34.05 RCW, the Administrative Procedure Act. The department shall ensure there are early opportunities for public review and comment on proposals to develop revised criteria. Values are g/L for all substances except Ammonia and Chloride which are mg/L:

Freshwater Marine Water

Substance Acute Chronic Acute Chronic

Aldrin/Dieldrin 2.5a 0.0019b 0.71a 0.0019b

Ammonia f,c g,d 0.233h,c 0.035h,d

(un-ionized NH3) hh

Arsenic ((~~ff~~)) dd 360.0c 190.0d ((~~69.0c 36.0d,cc~~))

69.0c,ll 36.0d,cc,ll

Cadmium dd i,c j,d ((~~37.2c 8.0d~~))

42.0c 9.3d

Chlordane 2.4a 0.0043b 0.09a 0.004b

Chloride (Dissolved) k 860.0h,c 230.0h,d - -

Chlorine (Total Residual) 19.0c 11.0d 13.0c 7.5d

((~~Chloropyrifos~~)) 0.083c 0.041d 0.011c 0.0056d

Chlorpyrifos

Chromium (Hex) dd ((~~16.0c1 11.0d 1,100.0c,1 50.0d~~))

15.0c,l,ii 10.0d,jj 1,100.0c,l,ll 50.0d,ll

Chromium (Tri) gg m,c n,d - -

Copper dd o,c p,d ((~~2.5c -~~))

4.8c,ll 3.1d,ll

Cyanide ee 22.0c 5.2d ((~~1.0c -~~))

1.0c,mm -

DDT (and metabolites) 1.1a 0.001b 0.13a 0.001b

Dieldrin/Aldrin e 2.5a 0.0019b 0.71a 0.0019b

Endosulfan 0.22a 0.056b 0.034a 0.0087b

Endrin 0.18a 0.0023b 0.037a 0.0023b

Heptachlor 0.52a 0.0038b 0.053a 0.0036b

Hexachlorocyclohexane

(Lindane) 2.0a 0.08b 0.16a -

Lead dd q,c r,d ((~~151.1c 5.8d~~))

210.0c,ll 8.1d,ll

Mercury s((~~, ff 2.4c 0.012d 2.1c 0.025d~~))

2.1c,kk,dd 0.012d,ff 1.8c,ll,dd 0.025d,ff

Nickel dd t,c u,d ((~~71.3c 7.9d~~))

74.0c,ll 8.2d,ll

Parathion 0.065c 0.013d - -

Pentachlorophenol (PCP) w,c v,d 13.0c 7.9d

Polychlorinated

Biphenyls (PCBs) 2.0b 0.014b 10.0b 0.030b

Selenium ((ff)) 20.0c,ff 5.0d,ff ((~~300.0c 71.0d,x~~))

290c,ll,dd 71.0d,x,ll,dd

Silver dd y,a - ((~~1.2a~~)) -

1.9a,ll

Toxaphene 0.73c,z 0.0002d 0.21c,z 0.0002d

Zinc dd aa,c bb,d ((~~84.6c 76.6d~~))

90.0c,ll 81.0d,ll

Notes to Table:

a. An instantaneous concentration not to be exceeded at any time.

b. A 24-hour average not to be exceeded.

c. A 1-hour average concentration not to be exceeded more than once every three years on the average.

d. A 4-day average concentration not to be exceeded more than once every three years on the average.

e. Aldrin is metabolically converted to Dieldrin. Therefore, the sum of the Aldrin and Dieldrin concentrations are compared with the Dieldrin criteria.

f. Shall not exceed the numerical value given by:

((~~0.52~~

~~----------~~

~~(FT)(FPH)(2)~~))

0.52 (FT)(FPH)(2)

where: FT = $10^{[0.03(20-TCAP)]}$; TCAP T 30

FT = $10^{[0.03(20-T)]}$; 0 T TCAP

FPH = 1 ; 8 pH 9

FPH = ((~~1+10$^{(7.4-pH)}$~~)) (1 + 10$^{(7.4-pH)}$) 1.25 ; 6.5 pH 8.0

((~~----------~~

~~1.25~~))

TCAP = 20C; Salmonids present.

TCAP = 25C; Salmonids absent.

g. Shall not exceed the numerical value

given by: ((~~0.80~~

~~----------~~

~~(FT)(FPH)(RATIO)~~))

0.80 (FT)(FPH)(RATIO)

where: RATIO = ((~~16~~)) 13.5 ; 7.7 pH 9

RATIO = ((~~24 x 10$^{(7.7-pH)}$~~))

(20.25 x 10$^{(7.7-pH)}$) (1 + 10$^{(7.4-pH)}$) ; 6.5 pH 7.7

((~~----------~~

~~$1+10^{(7.4-pH)}$~~))

where: FT and FPH are as shown in (f) above except:

TCAP = 15C; Salmonids present.

TCAP = 20C; Salmonids absent.

h. Measured in milligrams per liter rather than micrograms per liter.

i. ((~~$(0.865)(e^{(1.128[ln(hardness)]-3.828)})$~~))

$(0.944)(e^{(1.128[In(hardness)]-3.828)})$ at hardness = 100. Conversion factor (CF) of 0.944 is hardness dependent. CF is calculated for other hardnesses as follows: CF = 1.136672 - [(In hardness)(0.041838)].

j. ((~~$(0.865)(e^{(0.7852[ln(hardness)]-3.490)})$~~)) $(0.909)(e^{(0.7852[In(hardness)]-3.490)})$ at hardness = 100. Conversions factor (CF) of 0.909 is hardness dependent. CF is calculated for other hardnesses as follows: CF = 1.101672 - [(In hardness)(0.041838)].

k. Criterion based on dissolved chloride in association with sodium. This criterion probably will not be adequately protective when the chloride is associated with potassium, calcium, or magnesium, rather than sodium.

l. Salinity dependent effects. At low salinity the 1-hour average may not be sufficiently protective.

m. $(0.316)e^{(0.8190[ln(hardness)] +3.688)}$

n. $(0.860)e^{(0.8190[ln(hardness)] +1.561)}$

o. ((~~(0.862)~~)) $(0.960)(e^{(0.9422[ln(hardness)] -1.464)})$

p. ((~~(0.862)~~)) $(0.960)(e^{(0.8545[ln(hardness)] -1.465)})$

q. ((~~$(0.687)(e^{(1.273[ln(hardness)] -1.460)})$~~)) $(0.791)(e^{(1.273[In(hardness)] -1.460)})$ at hardness = 100. Conversion factor (CF) of 0.791 is hardness dependent. CF is calculated for other hardnesses as follows: CF = 1.46203 - [(In hardness)(0.145712)].

r. ((~~$(0.687)(e^{(1.273[ln(hardness)] -4.705)})$~~)) $(0.791)(e^{(1.273[In(hardness)] -4.705)})$ at hardness = 100. Conversion factor (CF) of 0.791 is hardness dependent. CF is calculated for other hardnesses as follows: CF = 1.46203 - [(In hardness)(0.145712)].

00995

s. If the four-day average chronic concentration is exceeded more than once in a three-year period, the edible portion of the consumed species should be analyzed. Said edible tissue concentrations shall not be allowed to exceed 1.0 mg/kg of methylmercury.

t. ((~~(0.95)~~)) (0.998)($e^{(0.8460[\ln(\text{hardness})] + 3.3612)}$)

u. ((~~(0.95)~~)) (0.997)($e^{(0.8460[\ln(\text{hardness})] + 1.1645)}$)

v. $e^{[1.005(\text{pH}) - 5.290]}$

w. $e^{[1.005(\text{pH}) - 4.830]}$

x. The status of the fish community should be monitored whenever the concentration of selenium exceeds 5.0 ug/1 in salt water.

y. ((~~(0.531)~~)) (0.85)($e^{(1.72[\ln(\text{hardness})] - 6.52)}$)

z. Channel Catfish may be more acutely sensitive.

aa. ((~~(0.891)~~)) (0.978)($e^{(0.8473[\ln(\text{hardness})] + 0.8604)}$)

bb. ((~~(0.891)~~)) (0.986)($e^{(0.8473[\ln(\text{hardness})] + 0.7614)}$)

cc. Nonlethal effects (growth, C-14 uptake, and chlorophyll production) to diatoms *(Thalassiosira aestivalis* and *Skeletonema costatum)* which are common to Washington's waters have been noted at levels below the established criteria. The importance of these effects to the diatom populations and the aquatic system is sufficiently in question to persuade the state to adopt the USEPA National Criteria value (36 g/L) as the state threshold criteria, however, wherever practical the ambient concentrations should not be allowed to exceed a chronic marine concentration of 21 g/L.

dd. These ambient criteria in the table are ((~~based on~~)) for the dissolved fraction ((~~(for cyanide criteria using the weak and dissociable method) of the metal. The department shall apply the criteria as total recoverable values to calculate effluent limits unless data is made available to the department clearly demonstrating the seasonal partitioning of the dissolved metal in the ambient water in relation to an effluent discharge~~)). The cyanide criteria are based on the weak acid dissociable method. The metals criteria may not be used to calculate total recoverable effluent limits unless the seasonal partitioning of the dissolved to total metals in the ambient water are known. When this information is absent, these metals criteria shall be applied as total recoverable values, determined by back-calculation, using the conversion factors incorporated in the criterion equations. Metals criteria may be adjusted on a site-specific basis when data ((~~is~~)) are made

available to the department clearly demonstrating the effective use of the water effects ratio approach established by USEPA, as generally guided by the procedures in USEPA *Water Quality Standards Handbook,* December 1983, as supplemented or replaced. Information which is used to develop effluent limits based on applying metals partitioning studies or the water effects ratio approach shall be identified in the permit fact sheet developed pursuant to WAC 173-220-060 or 173-226-110, as appropriate, and shall be made available for the public comment period required pursuant to WAC 173-220-050 or 173-226-130(3), as appropriate.

ee. The criteria for cyanide is based on the weak and dissociable method in the 17th Ed. *Standard Methods for the Examination of Water and Wastewater*, 4500-CN I, and as revised (see footnote dd, above).

ff. These criteria are based on the total-recoverable fraction of the metal.

gg. Where methods to measure trivalent chromium are unavailable, these criteria are to be represented by total-recoverable chromium.

hh. Tables for the conversion of total ammonia to un-ionized ammonia for freshwater can be found in the USEPA's *Quality Criteria for Water*, 1986. Criteria concentrations based on total ammonia for marine water can be found in USEPA *Ambient Water Quality Criteria for Ammonia (Saltwater)-1989*, EPA440/5-88-004, April 1989.

ii. Conversion factor to calculate dissolved metal concentration is 0.982.

jj. Conversion factor to calculate dissolved metal concentration is 0.962.

kk. Conversion factor to calculate dissolved metal concentration is 0.85.

ll. Marine conversion factors (CF) used for calculating dissolved metals concentrations. Conversion factors are applicable to both acute and chronic criteria for all metals except mercury. CF for mercury is applicable to the acute criterion only. Conversion factors are already incorporated into the criteria in the table. Dissolved criterion = criterion x CF

Metal CF

Arsenic 1.000

Cadmium 0.994

Chromium (VI) 0.993

Copper 0.83

Lead 0.951

Mercury 0.85

Nickel 0.990

Selenium 0.998

Silver 0.85

Zinc 0.946

mm. The cyanide criteria are: 9.1g/l chronic and 2.8g/l acute and are applicable only to waters which are east of a line from Point Roberts to Lawrence Point, to Green Point to Deception Pass; and south from Deception Pass and of a line from Partridge Point to Point Wilson.

(4) *USEPA Quality Criteria for Water, 1986* shall be used in the use and interpretation of the values listed in subsection ((~~(1)~~)) (3) of this section.

(5) Concentrations of toxic, and other substances with toxic propensities not listed in subsection ((~~(1)~~)) (3) of this section shall be determined in consideration of *USEPA Quality Criteria for Water, 1986,* and as revised, and other relevant information as appropriate. Human health-based water quality criteria used by the state are contained in 40 CFR 131.36 (known as the National Toxics Rule).

(6) Risk-based criteria for carcinogenic substances shall be selected such that the upper-bound excess cancer risk is less than or equal to one in one million.

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-040, filed 11/25/92, effective 12/26/92.]

NOTES:

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear in the Register pursuant to the requirements of RCW 34.08.040.

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-050 Radioactive substances. (1) Deleterious concentrations of radioactive materials for all classes shall be as determined by the lowest practicable concentration attainable and in no case shall exceed:

(a) ((~~1/100~~)) 1/12.5 of the values listed in WAC 246-221-290 (Column 2, Table II, ((~~Appendix A~~)) effluent concentrations, rules and regulations for radiation protection); or

(b) USEPA Drinking Water Regulations for radionuclides, as published in the Federal Register of July 9, 1976, or subsequent revisions thereto.

(2) Nothing in this chapter shall be interpreted to be applicable to those aspects of governmental regulation of radioactive waters which have been preempted from state regulation by the Atomic Energy Act of 1954, as amended, as interpreted by the United States Supreme Court in the cases of *Northern States Power Co. v. Minnesota 405 U.S. 1035 (1972) and Train v. Colorado Public Interest Research Group, 426 U.S. 1 (1976).*

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-050, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-060 General considerations. The following general guidelines shall apply to the water quality criteria and classifications set forth in WAC 173-201A-030 through 173-201A-140 hereof:

(1) At the boundary between waters of different classifications, the water quality criteria for the higher classification shall prevail.

(2) In brackish waters of estuaries, where the fresh and marine water quality criteria differ within the same classification, the criteria shall be ((~~interpolated on the basis of salinity; except that the marine water quality criteria shall apply for dissolved oxygen when the salinity is one part per thousand or greater and for fecal coliform organisms when the salinity is ten parts per thousand or greater~~)) applied on the basis of vertically averaged salinity. The freshwater criteria shall be applied at any point where ninety-five percent of the vertically averaged daily maximum salinity values are less than or equal to one part per thousand. Marine

criteria shall apply at all other locations; except that the marine water quality criteria shall apply for dissolved oxygen when the salinity is one part per thousand or greater and for fecal coliform organisms when the salinity is ten parts per thousand or greater.

(3) In determining compliance with the fecal coliform criteria in WAC 173-201A-030, averaging of data collected beyond a thirty-day period, or beyond a specific discharge event under investigation, shall not be permitted when such averaging would skew the data set so as to mask noncompliance periods.

(4)(a) The water quality criteria herein established for total dissolved gas shall not apply when the stream flow exceeds the seven-day, ten-year frequency flood.

(b) The total dissolved gas criteria may be adjusted to aid fish passage over hydroelectric dams when consistent with a department approved gas abatement plan. This gas abatement plan must be accompanied by fisheries management and physical and biological monitoring plans. The elevated total dissolved gas levels are intended to allow increased fish passage without causing more harm to fish populations than caused by turbine fish passage. The specific allowances for total dissolved gas exceedances are listed as special conditions for sections of the Snake and Columbia rivers in WAC 173-201A-130 and as shown in the following exemption:

Special fish passage exemption for sections of the Snake and Columbia rivers: When spilling water at dams is necessary to aid fish passage, total dissolved gas must not exceed an average of one hundred fifteen percent as measured at Camas/Washougal below Bonneville dam or as measured in the forebays of the next downstream dams. Total dissolved gas must also not exceed an average of one hundred twenty percent as measured in the tailraces of each dam. These averages are based on the twelve highest hourly readings in any one day of total dissolved gas. In addition, there is a maximum total dissolved gas one hour average of one hundred twenty-five percent, relative to atmospheric pressure, during spillage for fish passage. These special conditions for total dissolved gas in the Snake and Columbia rivers are viewed as temporary and are to be reviewed by the year 2003.

(c) Nothing in these special conditions allows an impact to existing and characteristic uses.

(5) Waste discharge permits, whether issued pursuant to the National Pollutant Discharge Elimination System or otherwise, shall be conditioned so the discharges authorized will meet the water quality standards.

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(a) However, persons discharging wastes in compliance with the terms and conditions of permits shall not be subject to civil and criminal penalties on the basis that the discharge violates water quality standards.

(b) Permits shall be subject to modification by the department whenever it appears to the department the discharge violates water quality standards. Modification of permits, as provided herein, shall be subject to review in the same manner as originally issued permits.

(6) No waste discharge permit shall be issued which results in a violation of established water quality criteria, except as provided for under WAC 173-201A-100 or 173-201A-110.

(7) Due consideration will be given to the precision and accuracy of the sampling and analytical methods used as well as existing conditions at the time, in the application of the criteria.

(8) The analytical testing methods for these criteria shall be in accordance with the *"Guidelines Establishing Test Procedures for the Analysis of Pollutants" (40 C.F. R. Part 136)* and other or superseding methods published and/or approved by the department following consultation with adjacent states and concurrence of the USEPA.

(9) Nothing in this chapter shall be interpreted to prohibit the establishment of effluent limitations for the control of the thermal component of any discharge in accordance with Section 316 of the federal Clean Water Act (33 U.S.C. 1251 et seq.).

(10) The primary means for protecting water quality in wetlands is through implementing the antidegradation procedures section (WAC 173-201A-070).

(a) In addition to designated uses, wetlands may have existing beneficial uses that are to be protected that include ground water exchange, shoreline stabilization, and storm water attenuation.

(b) Water quality in wetlands is maintained and protected by maintaining the hydrologic conditions, hydrophytic vegetation, and substrate characteristics necessary to support existing and designated uses.

(c) Wetlands shall be delineated using the Washington State Wetlands Identification and Delineation Manual, in accordance with WAC 173-22-035.

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-060, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-110 Short-term modifications. ((~~(1)~~)) The criteria and special conditions established in WAC 173-201A-030 through 173-201A-140 may be modified for a specific water body on a short- basis when necessary to accommodate essential activities, respond to emergencies, or to otherwise protect the public interest, even though such activities may result in a temporary reduction of water quality conditions below those criteria and classifications established by this regulation. ((~~Such modification shall be issued in writing by the director or his/her designee subject to such terms and conditions as he/she may prescribe, and such modification shall not exceed a twelve-month period.~~

~~(2)~~)) Such activities must be conditioned, timed, and restricted (i.e., hours or days rather than weeks or months) in a manner that will minimize water quality degradation to existing and characteristic uses. In no case will any degradation of water quality be allowed if this degradation significantly interferes with or becomes injurious to ((~~existing~~)) characteristic water uses or causes long-term harm to the environment.

((~~(3) Notwithstanding the above, the aquatic application of herbicides which result in water use restrictions shall be considered an activity for which a short-term modification generally may be issued subject to the following conditions:~~

~~(a)~~)) (1) A short-term modification may be issued in writing by the director or his/her designee to an individual or entity proposing the aquatic application of pesticides, including but not limited to those used for control of federally or state listed noxious and invasive species, and excess populations of native aquatic plants, mosquitoes, burrowing shrimp, and fish, subject to the following terms and conditions:

(a) A short-term modification will in no way lessen or remove the project proponent's obligations and liabilities under other federal, state and local rules and regulations.

(b) A request for a short-term modification shall be made to the department on forms supplied by the department. Such request ((~~generally~~)) shall be made at least thirty days prior to ((~~herbicide application;~~

~~(b) Such herbicide application shall be in accordance with state of Washington department of agriculture regulations;~~

~~(c) Such herbicide application shall be in accordance with label provisions promulgated by USEPA under the federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136, et seq.);~~

~~(d) Notice, including identification of the herbicide, applicator, location where the herbicide will be applied, proposed timing and method of application, and water use restrictions shall be given according to the following requirements:~~

~~(i) Appropriate public notice as determined and prescribed by the director or his/her designee shall be given of any water use restrictions specified in USEPA label provisions;~~

~~(ii) The appropriate regional offices of the departments of fisheries and wildlife shall be notified twenty-four hours prior to herbicide application; and~~

~~(iii) In the event of any fish kills, the departments of ecology, fisheries, and wildlife shall be notified immediately~~)) initiation of the proposed activity, and after the project proponent has complied with the requirements of the State Environmental Policy Act (SEPA);

(c) A short-term modification shall be valid for the duration of the activity requiring modification of the criteria and special conditions in WAC 173-201A-030 through 173-201A-140, or for one year, whichever is less. Ecology may authorize a longer duration where the activity is part of an ongoing or long-term operation and maintenance plan, integrated pest or noxious weed management plan, waterbody or watershed management plan, or restoration plan. Such a plan must be developed through a public involvement process consistent with the Administrative Procedure Act (chapter 34.05 RCW) and be in compliance with SEPA, chapter 43.21C RCW, in which case the standards may be modified for the duration of the plan, or for five years, whichever is less;

(d) Appropriate public notice as determined and prescribed by the director or his/her designee shall be given, identifying the pesticide, applicator, location where the pesticide will be applied, proposed timing and method of application, and any water use restrictions specified in USEPA label provisions;

(e) The ((~~herbicide~~)) pesticide application shall be made at times so as to:

(i) Minimize public water use restrictions during weekends; and

(ii) ((~~Completely~~)) Avoid public water use restrictions during the opening week of fishing season, Memorial Day weekend, Independence Day weekend, and Labor Day weekend;

(f) Any additional conditions as may be prescribed by the director or his/her designee.

(2) A short-term modification may be issued for the control or eradication of noxious weeds identified as such in accordance with the state noxious weed control law, chapter 17.10 RCW, and Control of spartina and purple loosestrife, chapter 17.26 RCW. Short-term modifications for noxious weed control shall be included in a water quality permit issued in accordance with RCW 90.48.445, and the following requirements:

(a) Water quality permits for noxious weed control may be issued to the Washington state department of agriculture (WSDA) for the purposes of coordinating and conducting noxious weed control activities consistent with their responsibilities under chapter 17.10 and 17.26 RCW. Coordination may include noxious weed control activities identified in a WSDA integrated noxious weed management plan and conducted by individual landowners or land managers.

(b) Water quality permits may also be issued to individual landowners or land managers for noxious weed control activities where such activities are not covered by a WSDA integrated noxious weed management plan.

(3) The turbidity criteria established under WAC 173-201A-030 shall be modified to allow a temporary mixing zone during and immediately after necessary in-water or shoreline construction activities that result in the disturbance of in-place sediments. A temporary turbidity mixing zone is subject to the constraints of WAC 173-201A-100 (4) and (6) and is authorized only after the activity has received all other necessary local and state permits and approvals, and after the implementation of appropriate best management practices to avoid or minimize disturbance of in-place sediments and exceedances of the turbidity criteria. A temporary turbidity mixing zone shall be as follows:

(a) For waters up to 10 cfs flow at the time of construction, the point of compliance shall be one hundred feet downstream from activity causing the turbidity exceedance.

(b) For waters above 10 cfs up to 100 cfs flow at the time of construction, the

point of compliance shall be two hundred feet downstream of activity causing the turbidity exceedance.

(c) For waters above 100 cfs flow at the time of construction, the point of compliance shall be three hundred feet downstream of activity causing the turbidity exceedance.

(d) For projects working within or along lakes, ponds, wetlands, estuaries, marine waters or other nonflowing waters, the point of compliance shall be at a radius of one hundred fifty feet from activity causing the turbidity exceedance.

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-110, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-130 Specific classifications--Freshwater. Specific fresh surface waters of the state of Washington are classified as follows:

(1) American River. Class AA

(2) Big Quilcene River and tributaries. Class AA

(3) Bumping River. Class AA

(4) Burnt Bridge Creek. Class A

(5) Cedar River from Lake Washington to the Maplewood Bridge (river mile 4.1). Class A

(6) Cedar River and tributaries from the Maplewood Bridge (river mile 4.1) to Landsburg Dam (river mile 21.6). Class AA

(7) Cedar River and tributaries from Landsburg Dam (river mile 21.6) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(8) Chehalis River from upper boundary of Grays Harbor at Cosmopolis (river mile 3.1, longitude 12345'45" W) to Scammon Creek (river mile 65.8). Class A

(9) Chehalis River from Scammon Creek (river mile 65.8) to Newaukum River (river mile 75.2). Special condition - dissolved oxygen shall exceed 5.0 mg/L from June 1 to September 15. For the remainder of the year, the dissolved oxygen shall meet Class A

criteria. Class A

(10) Chehalis River from Newaukum River (river mile 75.2) to Rock Creek (river mile 106.7). Class A

(11) Chehalis River, from Rock Creek (river mile 106.7) to headwaters. Class AA

(12) Chehalis River, south fork. Class A

(13) Chewuch River. Class AA

(14) Chiwawa River. Class AA

(15) Cispus River. Class AA

(16) Clearwater River. Class A

(17) Cle Elum River. Class AA

(18) Cloquallum Creek. Class A

(19) Clover Creek from outlet of Lake Spanaway to inlet of Lake Steilacoom. Class A

(20) Columbia River from mouth to the Washington-Oregon border (river mile 309.3). Special conditions - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed 0.3C due to any single source or 1.1C due to all such activities combined. Dissolved oxygen shall exceed 90 percent of saturation. Special condition - special fish passage exemption as described in WAC 173-201A-060 (4)(b). Class A

(21) Columbia River from Washington-Oregon border (river mile 309.3) to Grand Coulee Dam (river mile 596.6). Special condition from Washington-Oregon border (river mile 309.3) to Priest Rapids Dam (river mile 397.1). Temperaturell not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Special condition - special fish passage exemption as described in WAC 173-201A-060 (4)(b). Class A

(22) Columbia River from Grand Coulee Dam (river mile 596.6) to Canadian border (river mile 745.0). Class AA

(23) Colville River. Class A

(24) Coweeman River from mouth to Mulholland Creek (river mile 18.4). Class A

(25) Coweeman River from Mulholland Creek (river mile 18.4) to headwaters. Class AA

(26) Cowlitz River from mouth to base of Riffe Lake Dam (river mile 52.0). Class A

(27) Cowlitz River from base of Riffe Lake Dam (river mile 52.0) to headwaters. Class AA

(28) Crab Creek and tributaries. Class B

(29) Decker Creek. Class AA

(30) Deschutes River from mouth to boundary of Snoqualmie National Forest (river mile 48.2). Class A

(31) Deschutes River from boundary of Snoqualmie National Forest (river mile 48.2) to headwaters. Class AA

(32) Dickey River. Class A

(33) Dosewallips River and tributaries. Class AA

(34) Duckabush River and tributaries. Class AA

(35) Dungeness River from mouth to Canyon Creek (river mile 10.8). Class A

(36) Dungeness River and tributaries from Canyon Creek (river mile 10.8) to headwaters. Class AA

(37) Duwamish River from mouth south of a line bearing 254 true from the NW corner of berth 3, terminal No. 37 to the Black River (river mile 11.0) (Duwamish River continues as the Green River above the Black River). Class B

(38) Elochoman River. Class A

(39) Elwha River and tributaries. Class AA

(40) Entiat River from Wenatchee National Forest boundary (river mile 20.5) to headwaters. Class AA

(41) Grande Ronde River from mouth to Oregon border (river mile 37). Special condition - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Class A

(42) Grays River from Grays River Falls (river mile 15.8) to headwaters. Class AA

(43) Green River (Cowlitz County). Class AA

(44) Green River (King County) from Black River (river mile 11.0 and point where Duwamish River continues as the Green River) to west boundary of Sec. 27-T21N-R6E (west boundary of Flaming Geyser State Park at river mile 42.3). Class A

(45) Green River (King County) from west boundary of Sec. 27-T21N-R6E (west boundary of Flaming Geyser State Park, river mile 42.3) to west boundary of Sec. 13-T21N-R7E (river mile 59.1). Class AA

(46) Green River and tributaries (King County) from west boundary of Sec. 13-T21N-R7E (river mile 59.1) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(47) Hamma Hamma River and tributaries. Class AA

(48) Hanaford Creek from mouth to east boundary of Sec. 25-T15N-R2W (river mile 4.1). Special condition - dissolved oxygen shall exceed 6.5 mg/L. Class A

(49) Hanaford Creek from east boundary of Sec. 25-T15N-R2W (river mile 4.1) to headwaters. Class A

(50) Hoh River and tributaries. Class AA

(51) Hoquiam River (continues as west fork above east fork) from mouth to river mile 9.3 (Dekay Road Bridge) (upper limit of tidal influence). Class B

(52) Humptulips River and tributaries from mouth to Olympic National Forest boundary on east fork (river mile 12.8) and west fork (river mile 40.4) (main stem continues as west fork). Class A

(53) Humptulips River, east fork from Olympic National Forest boundary (river mile 12.8) to headwaters. Class AA

(54) Humptulips River, west fork from Olympic National Forest boundary (river mile 40.4)

to headwaters. Class AA

(55) Issaquah Creek. Class A

(56) Kalama River from lower Kalama River Falls (river mile 10.4) to headwaters. Class AA

(57) Klickitat River from Little Klickitat River (river mile 19.8) to boundary of Yakima Indian Reservation. Class AA

(58) Lake Washington Ship Canal from Government Locks (river mile 1.0) to Lake Washington (river mile 8.6). Special condition - salinity shall not exceed one part per thousand (1.0 ppt) at any point or depth along a line that transects the ship canal at the University Bridge (river mile 6.1). Lake Class

(59) Lewis River, east fork, from Multon Falls (river mile 24.6) to headwaters. Class AA

(60) Little Wenatchee River. Class AA

(61) Methow River from mouth to Chewuch River (river mile 50.1). Class A

(62) Methow River from Chewuch River (river mile 50.1) to headwaters. Class AA

(63) Mill Creek from mouth to 13th Street Bridge in Walla Walla (river mile 6.4). Special condition - dissolved oxygen concentration shall exceed 5.0 mg/L. Class B

(64) Mill Creek from 13th Street Bridge in Walla Walla (river mile 6.4) to Walla Walla Waterworks Dam ((~~(river mile 25.2)~~)) (river mile 11.5). Class A

(65) Mill Creek and tributaries from city of Walla Walla Waterworks Dam ((~~(river mile 25.2)~~)) (river mile 21.6) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(66) Naches River from Snoqualmie National Forest boundary (river mile 35.7) to headwaters. Class AA

(67) Naselle River from Naselle "Falls" (cascade at river mile 18.6) to headwaters. Class AA

(68) Newaukum River. Class A

(69) Nisqually River from mouth to Alder Dam (river mile 44.2). Class A

(70) Nisqually River from Alder Dam (river mile 44.2) to headwaters. Class AA

(71) Nooksack River from mouth to Maple Creek (river mile 49.7). Class A

(72) Nooksack River from Maple Creek (river mile 49.7) to headwaters. Class AA

(73) Nooksack River, south fork, from mouth to Skookum Creek (river mile 14.3). Class A

(74) Nooksack River, south fork, from Skookum Creek (river mile 14.3) to headwaters. Class AA

(75) Nooksack River, middle fork. Class AA

(76) Okanogan River. Class A

(77) Palouse River from mouth to south fork (Colfax, river mile 89.6). Class B

(78) Palouse River from south fork (Colfax, river mile 89.6) to Idaho border (river mile 123.4). Special condition - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Class A

(79) Pend Oreille River from Canadian border (river mile 16.0) to Idaho border (river mile 87.7). Special condition - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Class A

(80) Pilchuck River from city of Snohomish Waterworks Dam (river mile 26.8) to headwaters. Class AA

(81) Puyallup River from mouth to river mile 1.0. Class B

(82) Puyallup River from river mile 1.0 to Kings Creek (river mile 31.6). Class A

(83) Puyallup River from Kings Creek (river mile 31.6) to headwaters. Class AA

(84) Queets River and tributaries. Class AA

(85) Quillayute River. Class AA

(86) Quinault River and tributaries. Class AA

(87) Salmon Creek (Clark County). Class A

(88) Satsop River from mouth to west fork (river mile 6.4). Class A

(89) Satsop River, east fork. Class AA

(90) Satsop River, middle fork. Class AA

(91) Satsop River, west fork. Class AA

(92) Skagit River from mouth to Skiyou Slough-lower end (river mile 25.6). Class A

(93) Skagit River and tributaries (includes Baker, Suak, Suiattle, and Cascade rivers) from Skiyou Slough-lower end, (river mile 25.6) to Canadian border (river mile 127.0). Special condition - Skagit River (Gorge by-pass reach) from Gorge Dam (river mile 96.6) to Gorge Powerhouse (river mile 94.2). Temperature shall not exceed 21C due to human activities. When natural conditions exceed 21C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C, nor shall such temperature increases, at any time, exceed t=34/(T+9). Class AA

(94) Skokomish River and tributaries. Class AA

(95) Skookumchuck River from Bloody Run Creek (river mile 21.4) to headwaters. Class AA

(96) Skykomish River from mouth to May Creek (above Gold Bar at river mile 41.2). Class A

(97) Skykomish River from May Creek (above Gold Bar at river mile 41.2) to headwaters. Class AA

(98) Snake River from mouth to Washington-Idaho-Oregon border (river mile 176.1). Special condition:

(a) Below Clearwater River (river mile 139.3). Temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Special condition - special fish passage exemption as described in WAC 173-201A-060 (4)(b).

(b) Above Clearwater River (river mile 139.3). Temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increases will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed 0.3C due to any single source or 1.1C due to all such activities combined. Class A

(99) Snohomish River from mouth and east of longitude 12213'40"W upstream to latitude 4756'30"N (southern tip of Ebey Island at river mile 8.1). Special condition - fecal coliform organism levels shall both not exceed a geometric mean value of 200 colonies/100 mL and not have more than 10 percent of the samples obtained for calculating the mean value exceeding 400 colonies/100 mL. Class A

(100) Snohomish River upstream from latitude 4756'30"N (southern tip of Ebey Island river mile 8.1) to confluence with Skykomish and Snoqualmie River (river mile 20.5). Class A

(101) Snoqualmie River and tributaries from mouth to west boundary of Twin Falls State Park on south fork (river mile 9.1). Class A

(102) Snoqualmie River, middle fork. Class AA

(103) Snoqualmie River, north fork. Class AA

(104) Snoqualmie River, south fork, from west boundary of Twin Falls State Park (river mile 9.1) to headwaters. Class AA

(105) Soleduck River and tributaries. Class AA

(106) Spokane River from mouth to Long Lake Dam (river mile 33.9). Special condition - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed $t=34/(T+9)$. Class A

(107) Spokane River from Long Lake Dam (river mile 33.9) to Nine Mile Bridge (river mile 58.0). Special conditions:

(a) The average euphotic zone concentration of total phosphorus (as P) shall not exceed 25g/L during the period of June 1 to October 31.

(b) Temperature shall not exceed 20.0C, due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases,

at any time exceed t=34/(T+9). Lake Class

(108) Spokane River from Nine Mile Bridge (river mile 58.0) to the Idaho border (river mile 96.5). Temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time exceed t=34/(T+9). Class A

(109) Stehekin River. Class AA

(110) Stillaguamish River from mouth to north and south forks (river mile 17.8). Class A

(111) Stillaguamish River, north fork, from mouth to Squire Creek (river mile 31.2). Class A

(112) Stillaguamish River, north fork, from Squire Creek (river mile 31.2) to headwaters. Class AA

(113) Stillaguamish River, south fork, from mouth to Canyon Creek (river mile 33.7). Class A

(114) Stillaguamish River, south fork, from Canyon Creek (river mile 33.7) to headwaters. Class AA

(115) Sulphur Creek. Class B

(116) Sultan River from mouth to Chaplain Creek (river mile 5.9). Class A

(117) Sultan River and tributaries from Chaplain Creek (river mile 5.9) to headwaters. Special condition - no waste discharge will be permitted above city of Everett Diversion Dam (river mile 9.4). Class AA

(118) Sumas River from Canadian border (river mile 12) to headwaters (river mile 23). Class A

(119) Tieton River. Class AA

(120) Tolt River, south fork and tributaries from mouth to west boundary of Sec. 31-T26N-R9E (river mile 6.9). Class AA

(121) Tolt River, south fork from west boundary of Sec. 31-T26N-R9E (river mile 6.9) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(122) Touchet River, north fork from Dayton water intake structure (river mile 3.0) to headwaters. Class AA

(123) Toutle River, north fork, from Green River to headwaters. Class AA

(124) Toutle River, south fork. Class AA

(125) Tucannon River from Umatilla National Forest boundary (river mile 38.1) to headwaters. Class AA

(126) Twisp River. Class AA

(127) Union River and tributaries from Bremerton Waterworks Dam (river mile 6.9) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(128) Walla Walla River from mouth to Lowden (Dry Creek at river mile 27.2). Class B

(129) Walla Walla River from Lowden (Dry Creek at river mile 27.2) to Oregon border (river mile 40). Special condition - temperature shall not exceed 20.0C due to human activities. When natural conditions exceed 20.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Class A

(130) Wenatchee River from Wenatchee National Forest boundary (river mile 27.1) to headwaters. Class AA

(131) White River (Pierce-King counties) from Mud Mountain Dam (river mile 27.1) to headwaters. Class AA

(132) White River (Chelan County). Class AA

(133) Wildcat Creek. Class A

(134) Willapa River upstream of a line bearing 70 true through Mailboat Slough light (river mile 1.8). Class A

(135) Wishkah River from mouth to river mile 6 (SW 1/4 SW 1/4 NE 1/4 Sec. 21-T18N-R9W). Class B

(136) Wishkah River from river mile 6 (SW 1/4 SW 1/4 NE 1/4 Sec. 21-T18N-R9W) to west fork (river mile 17.7). Class A

(137) Wishkah River from west fork of Wishkah River (river mile 17.7) to south boundary of Sec. 33-T21N-R8W (river mile 32.0). Class AA

(138) Wishkah River and tributaries from south boundary of Sec. 33-T21N-R8W (river mile 32.0) to headwaters. Special condition - no waste discharge will be permitted. Class AA

(139) Wynoochee River from mouth to Olympic National Forest boundary (river mile 45.9). Class A

(140) Wynoochee River from Olympic National Forest boundary (river mile 45.9) to headwaters. Class AA

(141) Yakima River from mouth to Cle Elum River (river mile 185.6). Special condition - temperature shall not exceed 21.0C due to human activities. When natural conditions exceed 21.0C, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3C; nor shall such temperature increases, at any time, exceed t=34/(T+9). Class A

(142) Yakima River from Cle Elum River (river mile 185.6) to headwaters. Class AA

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-130, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-140 Specific classifications--Marine water. Specific marine surface waters of the state of Washington are classified as follows:

(1) Budd Inlet south of latitude 4704'N (south of Priest Point Park). Class B

(2) Coastal waters: Pacific Ocean from Ilwaco to Cape Flattery. Class AA

(3) Commencement Bay south and east of a line bearing 258 true from "Brown's Point" and north and west of line bearing 225 true through the Hylebos waterway light. Class A

(4) Commencement Bay, inner, south and east of a line bearing 225 true through Hylebos waterway light except the city waterway south and east of south 11th Street. Class B

(5) Commencement Bay, city waterway south and east of south 11th Street. Class C

(6) Drayton Harbor, south of entrance. Class A

(7) Dyes and Sinclair Inlets west of longitude 12237'W. Class A

(8) Elliott Bay east of a line between Pier 91 and Duwamish head. Class A

(9) Everett Harbor, inner, northeast of a line bearing 121 true from approximately 4759'5"N and 12213'44"W (southwest corner of the pier). Class B

(10) Grays Harbor west of longitude 12359'W. Class A

(11) Grays Harbor east of longitude 12359'W to longitude 12345'45"W (Cosmopolis Chehalis River, river mile 3.1). Special condition - dissolved oxygen shall exceed 5.0 mg/L. Class B

(12) Guemes Channel, Padilla, Samish and Bellingham Bays east of longitude 12239'W and north of latitude 4827'20"N. Class A

(13) Hood Canal. Class AA

(14) Mukilteo and all North Puget Sound west of longitude 12239' W (Whidbey, Fidalgo, Guemes and Lummi islands and State Highway 20 Bridge at Deception Pass), except as otherwise noted. Class AA

(15) Oakland Bay west of longitude 12305'W (inner Shelton harbor). Class B

(16) Port Angeles south and west of a line bearing 152 true from buoy "2" at the tip of Ediz Hook. Class A

(17) Port Gamble south of latitude ((~~4715'20"N~~)) 4751'20"N. Class A

(18) Port Townsend west of a line between Point Hudson and Kala Point. Class A

(19) Possession Sound, south of latitude 4757'N. Class AA

(20) Possession Sound, Port Susan, Saratoga Passage, and Skagit Bay east of Whidbey Island and State Highway 20 Bridge at Deception Pass between latitude 4757'N (Mukilteo) and latitude 4827'20"N (Similk Bay), except as otherwise noted. Class A

(21) Puget Sound through Admiralty Inlet and South Puget Sound, south and west to longitude 12252'30"W (Brisco Point) and longitude 12251'W (northern tip of Hartstene Island). Class AA

(22) Sequim Bay southward of entrance. Class AA

(23) South Puget Sound west of longitude 12252'30"W (Brisco Point) and longitude 12251'W (northern tip of Hartstene Island, except as otherwise noted). Class A

(24) Strait of Juan de Fuca. Class AA

(25) Totten Inlet and Little Skookum Inlet, west of longitude ((~~1225'32"~~)) 12256'32" (west side of Steamboat Island). Class AA

(26) Willapa Bay seaward of a line bearing 70 true through Mailboat Slough light (Willapa River, river mile 1.8). Class A

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-140, filed 11/25/92, effective 12/26/92.]

AMENDATORY SECTION (Amending Order 92-29, filed 11/25/92, effective 12/26/92)

WAC 173-201A-160 Implementation. (1) **Discharges from municipal, commercial, and industrial operations.** The primary means to be used for controlling municipal, commercial, and industrial waste discharges shall be through the issuance of waste disposal permits, as provided for in RCW 90.48.160, 90.48.162, and 90.48.260.

(2) **Miscellaneous waste discharge or water quality effect sources.** The director shall, through the issuance of regulatory permits, directives, and orders, as are appropriate, control miscellaneous waste discharges and water quality effect sources not covered by subsection (1) of this section.

(3) **Nonpoint source and storm water pollution.**

(a) Activities which generate nonpoint source pollution shall be conducted so as to comply with the water quality standards. The primary means to be used for requiring compliance with the standards shall be through best management practices required in waste discharge permits, rules, orders, and directives issued by the department for activities which generate nonpoint source pollution.

(b) Best management practices shall be applied so that when all appropriate combinations of individual best management practices are utilized, violation of water quality criteria shall be prevented. If a discharger is applying all best

management practices appropriate or required by the department and a violation of water quality criteria occurs, the discharger shall modify existing practices or apply further water pollution control measures, selected or approved by the department, to achieve compliance with water quality criteria. Best management practices established in permits, orders, rules, or directives of the department shall be reviewed and modified, as appropriate, so as to achieve compliance with water quality criteria.

(c) Activities which contribute to nonpoint source pollution shall be conducted utilizing best management practices to prevent violation of water quality criteria. When applicable best management practices are not being implemented, the department may conclude individual activities are causing pollution in violation of RCW 90.48.080. In these situations, the department may pursue orders, directives, permits, or civil or criminal sanctions to gain compliance with the standards.

(d) Activities which cause pollution of storm water shall be conducted so as to comply with the water quality standards. The primary means to be used for requiring compliance with the standards shall be through best management practices required in waste discharge permits, rules, orders, and directives issued by the department for activities which generate storm water pollution. The consideration and control procedures in (b) and (c) of this subsection apply to the control of pollutants in storm water.

(4) **Allowance for compliance schedules.**

(a) Permits, orders, and directives of the department for existing discharges may include a schedule for achieving compliance with water quality criteria contained in this chapter. Such schedules of compliance shall be developed to ensure final compliance with all water quality-based effluent limits in the shortest practicable time. Decisions regarding whether to issue schedules of compliance will be made on a case-by-case basis by the department. Schedules of compliance may not be issued for new discharges. Schedules of compliance may be issued to allow for: (i) construction of necessary treatment capability; (ii) implementation of necessary best management practices; (iii) implementation of additional storm water best management practices for discharges determined not to meet water quality criteria following implementation of an initial set of best management practices; (iv) completion of necessary water quality studies; or (v) resolution of a pending water quality standards' issue through rule-making action.

(b) For the period of time during which compliance with water quality criteria is deferred, interim effluent limitations shall be formally established, based on the

best professional judgment of the department. Interim effluent limitations may be numeric or nonnumeric (e.g., construction of necessary facilities by a specified date as contained in an ecology order or permit).

(c) Prior to establishing a schedule of compliance, the department shall require the discharger to evaluate the possibility of achieving water quality criteria via noncontruction changes (e.g., facility operation, pollution prevention). Schedules of compliance may in no case exceed ten years, and shall generally not exceed the term of any permit.

[Statutory Authority: Chapter 90.48 RCW. 92-24-037 (Order 92-29), 173-201A-160, filed 11/25/92, effective 12/26/92.]

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OFFICE OF
WATER AND
WATERSHEDS

DEC 19 2013

The Honorable Rudy Peone
Chairman
Spokane Tribe of Indians
P.O. Box 100
Wellpinit, Washington 99040

Re: EPA's Action on the Spokane Tribe of Indians 2010 Revision to Their Surface Water Quality Standards

Dear Chairman Peone:

The U.S. Environmental Protection Agency (EPA) has completed its Clean Water Act (CWA) review of the new and revised water quality standards that the Spokane Tribe submitted to the EPA on April 7, 2010. Under CWA Section 303, 33 U.S.C § 1313, tribes that are authorized for treatment in a manner similar to a state for the purpose of administering a water quality standards program must establish water quality standards and submit them to the EPA for approval or disapproval. Likewise, revisions to a tribe's water quality standard must also be submitted to the EPA for approval or disapproval. A summary of the EPA's actions is provided below and further described in the enclosed *Technical Support Document for Action on the Revised Surface Water Quality Standards of the Spokane Tribe of Indians Submitted April 2010* (hereafter referred to as the TSD).

Summary of the EPA's Action

I. Pursuant to the EPA's authority under CWA Section 303(c) and implementing regulations found at 40 CFR Part 131, the EPA is approving the following provisions:

- Section 2, Definitions
  - 7-day average of the daily maximum
  - Federal clean up law
  - Mixing zone
  - Nonpoint source
  - Trophic state
- Section 6, Narrative Provisions
  - Provision 5 – application of non-carcinogenic material
  - Minor editorial changes
- Section 6, Human Health Criteria (µg/L) in Table 1
  - 160 of 210 new or revised criteria are being approved (see Section V.D.1, page 23 for a list of criteria that are approved).
- Section 9, Temperature Criteria for Class AA waters

  This provision is being approved in part and disapproved in part. The EPA is approving the part that states: "Temperatures from June 1 to September 1 may be allowed to reach a

7-day average of the daily maximum (7-DADM) temperatures of 16.5 C.....The 7-DADM temperature shall not exceed 11°C between October 1st and March 31st."

- Section 11, Surface Water Classification
  - Specific classification of Ente' Creek as Class AA, and correction of spelling of Chamokane (Tshimikain) Creek.
- Section 13, Mixing Zone Provision
  - The EPA is approving this provision but notes that there is a typographical error in provision (2)(c). This provision should reference subsection (e) rather than subsection (f). This should be corrected when the Tribe does its next water quality standards revision (i.e., provision (2)(c) should state "overlapping mixing zones shall only be allowed if, in combination, the requirements of subsection (e) are satisfied; and").

II. Pursuant to the EPA's authority under CWA Section 303(c) and implementing regulations found at 40 CFR Part 131, the EPA is disapproving the following provisions:

- Section 6, Narrative Provisions
  - Provision 9, which states "Site-specific numerical criteria as described in the Tribal Cleanup Law must be developed in the event these assumptions are incorrect. If natural background conditions exceed the risk criteria defined in this section, then the natural background conditions are the numerical standard."
- Section 6, Human Health Criteria (µg/L) in Table 1
  - Removal of Asbestos criterion from Table 1 (see Section V.D.2 of TSD, page 25).
  - Criteria for Dichlorodiflouromethane (Section V.D.3 of TSD, page 26), Mercury (Section V.D.4 of TSD, page 28), and 45 other criteria (Section V.D.5. Table 4 in the TSD for a list of the pollutants, page 29).
- Section 6, Aquatic Life Criteria in Table 1
  - Revisions to acute and chronic aquatic life ammonia criteria.
  - Revisions to acute and chronic aquatic life pentachlorophenol criteria.
    - Removal of chronic aquatic life criterion for iron.
- Section 9, Temperature Provisions for Class AA and Class A waters
  - Provision (1)(c)(4) for Class AA waters. This provision is being approved in part and disapproved in part. The EPA is disapproving the part that states: "Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st." The EPA is also disapproving the associated temperature criteria for Class AA waters contained in Table 5.
  - Provision (2)(c)(iv), temperature revisions for Class A waters. The EPA is disapproving the entire provision, which states: "temperatures (sic) from June 1 to August 31 may be allowed to reach a 7-day average (7-DADM) of the daily maximum temperature of 18.5° C. Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st. The 7-DADM temperature shall not exceed 11°C between October 1st and March 31st." The EPA is also disapproving the associated temperature criteria for Class A waters contained in Table 5.

III. The EPA is not taking action on the following provisions because they are not considered water quality standards under Section 303(c) of the CWA:

- Section 1, Introduction
  - New language in provision 4 and 6.
- Section 2, Definitions
  - 1-day maximum temperature
  - Background
  - Cumulative Risk
- Section 6, Narrative Provisions
  - Provisions 6 and 7 fish consumption rate and drinking water intake rate. The language in provision 6 and 7 provide two of the input values used by the Tribe to develop the human health criteria. The EPA incorporated this information into its analysis of the individual human health criteria. Because these two provisions do not operate as independent water quality standards, in isolation from the human health criteria, the EPA is taking no action to approve or disapprove them.
  - The EPA did not act on the following language in provision 9:
    "Table 1 is developed using the following assumptions:
    a. the receptor (e.g. human) receives a dose from a single contamination (e.g. cadmium) from a single medium (e.g. surface water) via direct ingestion of water or fish and waters; and
    b. the dose from natural background condition is negligible."

Additional information and a detailed discussion of the rationale supporting all of the EPA's actions is included in the enclosed TSD.

Background on the EPA's Evaluation of the Revised Human Health Criteria
The most significant change made in the Spokane Tribe's 2010 Water Quality Standards submittal was the Tribe's revisions to their human health toxics criteria, including the use of a new fish consumption rate of 865 grams per day and drinking water intake rate of 4 liters per day. As a result of these revisions, the Spokane Tribe's human health toxics criteria are generally more stringent than the default values recommended by the EPA in national guidance, which are provided to assist states and tribes who may not have the data or resources to develop their own criteria values. Due to the current public attention and interest in human health water quality criteria and how they are derived, a brief summary of the EPA's decision rationale for the human health criteria revisions is provided below. As previously noted, a more detailed discussion is provided in the enclosed TSD.

The EPA's regulations at 40 CFR § 131.11(a) provide that new or revised criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect designated uses." If these requirements are met, states and tribes are able to develop criteria that may be more (or less) stringent than those recommended by the EPA. The EPA evaluated the Spokane Tribe's revised human health criteria as follows:

- First, the EPA acknowledged the Tribe's decision to ensure water quality sufficient to support traditional subsistence practices, which is fundamentally a question of tribal policy and within

their authority under the CWA. The CWA does not require that decision to be justified by reference to the number of persons who currently rely on tribal waters for such purposes.

- Second, the EPA evaluated the scientific defensibility of the assumptions and methodology the Tribe used in deriving criteria to protect its water quality goals, including the derivation of fish consumption and drinking water rates characteristic of the Spokane Tribe's subsistence traditions.
- Third, the EPA evaluated whether the Tribe's criteria are sufficient to protect not only 304(a) fishable/swimmable goals but also the goal of protecting fish consumption and drinking water rates characteristic of the traditional Spokane subsistence lifestyle.

The EPA is approving the majority of the Tribe's revised human health criteria because the methodology used by the Tribe to develop the fish consumption rate, and other variables used in developing the criteria, are scientifically sound and sufficient to protect the designated uses, which are designed to protect fish consumption and drinking water rates characteristic of the traditional Spokane subsistence lifestyle. The EPA is disapproving some of the revised human health criteria because they were not scientifically defensible and were not protective of the Tribe's designated uses.

Remedy to Address the EPA's Disapproval Actions

Under CWA Section 303(c)(3) and the EPA's regulations at 40 CFR Sections 131.21 and 131.22, if the EPA disapproves a state or tribe's new or revised water quality standards, it must "specify the changes" necessary to meet the applicable requirements of the CWA and the EPA's regulations. As previously noted, a comprehensive summary of the EPA's actions and the specific changes necessary for each disapproval are included in the TSD.

The EPA has appreciated our work together throughout this process and we remain committed to providing assistance to the Tribe in its development of WQS that meet the requirements of the CWA and its implementing regulations. We also look forward to engaging with you and others in the Spokane River Basin to ensure thoughtful consideration of your WQS in water quality protection and improvement efforts. If you have any questions concerning this letter, please contact me at (206) 553-1855 or you may contact Angela Chung, Water Quality Standards Unit Manager, at (206) 553-6511.

Sincerely,

Daniel D. Opalski, Director
Office of Water and Watersheds

Enclosures

cc: Brian Crossley, Spokane Tribe of Indians
BJ Keiffer, Spokane Tribe of Indians

U.S. ENVIRONMENTAL PROTECTION AGENCY – REGION 10

Technical Support Document

for Action on the Revised Surface Water Quality Standards of the Spokane Tribe of Indians Submitted April 2010

December 11, 2013

TABLE OF CONTENTS

Contents

I. INTRODUCTION

This document provides the basis for EPA's decisions under the federal water quality standards regulations at 40 CFR § 131.11 and § 303(c) of the Clean Water Act (CWA) to approve or disapprove the new or revised water quality standards that the Spokane Tribe of Indians ("Tribe") submitted to EPA on April 7, 2010.

A. Background

In 2006, the Tribe began the process of revising the *Spokane Tribe of Indians Surface Water Quality Standards* (WQS). The Spokane Tribal Business Council (TBC), the governing body of the Tribe, adopted the draft revised WQS on July 29, 2008.

The Tribe provided a 45-day formal public comment period on the draft revisions, and held a public hearing on October 1, 2008. Additionally, an e-mail was sent to local governments and Spokane River stakeholders notifying interested parties of proposed changes, and notification was placed on the Washington Department of Ecology listserve.

Final revisions to the WQS were adopted by the TBC on February 25, 2010, by Resolution 2010-173. The Tribe's submittal included a letter dated March 15, 2010, from Ted C. Knight, Attorney-at-Law, certifying that the revisions were adopted in accordance with all applicable laws. In accordance with § 303(c) of the CWA, the Tribe submitted these revisions to EPA for review and action in a letter dated April 7, 2010.

The revisions addressed in today's decision can be divided into the general categories described below.

- Revisions to the Introductory language to the water quality standards
- New definitions
- Revised human health criteria based on consuming 865 g of fish per day and 4 liters of water per day
- Revised aquatic life criteria
- Revised temperature criteria for waters designated as Class AA and Class A
- New mixing zone provisions
- Minor editorial and formatting changes

B. Clean Water Act Requirements for Water Quality Standards

Under § 303(c) of the CWA and federal implementing regulations at 40 CFR § 131.4, states and authorized tribes[1] have the primary responsibility for reviewing, establishing, and revising WQS, which consist of the designated uses of a waterbody or waterbody segment, the water quality criteria necessary to protect those designated uses, and an antidegradation policy. This statutory framework allows states to work with local communities to adopt appropriate designated uses (as required in 40 CFR § 13l.10 (a)) and to adopt criteria to protect those designated uses (as required in 40 CFR § 131.11 (a)).

[1] The term "authorized tribe" means a tribe eligible under CWA § 518(e) and 40 CFR § 131.8 for treatment in a manner similar to a state for the purpose of administering a water quality standards program.

States are required to review applicable WQS, and as appropriate, modify and adopt these standards (40 CFR § 131.20). Each state must follow its own legal procedures for adopting such standards (40 CFR § 131.5) and submit certification by the state's attorney general or other appropriate legal authority within the state that the WQS were duly adopted pursuant to state law (40 CFR § 131.6(e)).

Section 303(c)(2)(B) of the CWA requires states to adopt water quality criteria for toxic pollutants listed pursuant to § 307(a)(1) for which EPA has published criteria under § 304(a) where the discharge or presence of these toxics could reasonably be expected to interfere with the designated uses adopted by the state. In adopting such criteria, states must establish numeric values based on one of the following:

(1) 304(a) guidance;
(2) 304(a) guidance modified to reflect site-specific conditions; or,
(3) Other scientifically defensible methods (40 CFR § 131.11 (b)(1)).

In addition, states can establish narrative criteria where numeric criteria cannot be determined or to supplement numeric criteria (see 40 CFR § 131.11(b)(2)).

Section 303(c) of the CWA also requires states to submit new or revised WQS to EPA for review. EPA is required to review these changes to ensure revisions to water quality standards are consistent with the CWA. EPA determines whether a provision is a new or revised WQS after considering the following four questions:[2]

(1) Is it a legally binding provision adopted or established pursuant to state or tribal law?
(2) Does the provision address designated uses, water quality criteria (narrative or numeric) to protect designated uses, and/or antidegradation requirements for waters of the United States?
(3) Does the provision express or establish the desired condition (e.g. uses, criteria) or instream level of protection (e.g. antidegradation requirements) for waters of the United States immediately or mandate how it will be expressed or established for such waters in the future?
(4) Does the provision establish a new WQS or revise an existing WQS?

Furthermore, the federal water quality standards regulations at 40 CFR § 131.21 state, in part, that when EPA disapproves a state's water quality standards, EPA shall specify the changes that are needed to ensure compliance with the requirements of § 303(c) of the CWA and federal water quality standards regulations.

II. INTRODUCTORY LANGUAGE (Section 1, Provisions 4 and 6)

A. Provisions that EPA Is Not Taking An Action On

The following presents the new and revised introductory language to the WQS contained in Section 1, provisions 4 and 6. All underlined text indicates language that is new and strikeout text indicates the language that was removed by the 2010 water quality standards adoption.

[2] See EPA's *What Is A New or Revised Water Quality Standard Under CWA 303(c)(3)? Frequently Asked Questions*, October 2012 at http://water.epa.gov/scitech/swguidance/standards/cwa303faq.cfm

…(4) These standards are designed to establish the uses for which the surface waters of the Spokane Tribe shall be protected, to prescribe narrative and numeric water quality criterion to sustain the designated uses, to protect existing water quality, and to prevent water quality degradation.

As part of this chapter:

(a) All surface waters are protected by narrative criteria, designates uses, and an antidegradation policy.

(b)Based on the use designations, numeric and narrative criteria are assigned to a water body to protect the existing and designated uses.

(c) Where multiple criteria for the same water quality parameter are assigned to a water body to protect different uses, the most stringent criteria for each parameter is to be applied.

(d) Where multiple contaminants of concern have been identified or where multiple media has been contaminated, or where more than one exposure pathway has been identified, water quality standards shall be determined using the cumulative risk assessment approach and definitions described in the Tribal Cleanup Law.

(5) The Water use and quality criteria set forth herein are established in general conformance with water uses of the surface waters of the Spokane Indian Reservation and in consideration of the natural water quality potential and limitations of the same.

(6) The Surface Water Quality Standards were first adopted by the Spokane Business Council on December 17, 1999 by Resolution 2000-105. As a result of public comments received after hearings were held on February 10, 2000, the standards were revised on June 19, 2000, by Resolution 2000-105. To address further comments these standards were again revised on February 13, 2001, by Resolution 2001-144. Finally, the standards were revised on March 7, 2003, by Resolution 2003-244 to address a technical correction identified by staff. These revised standards supersede and replace all previous standards. These revised standards supersede and replace the ~~June 19, 2000~~ all previous standards. These standards shall become effective on the date of adoption, and shall be applicable and in force, to the full extent of the law, until repealed or replaced by the Spokane Business Council.

EPA Action

Section I of the Tribe's water quality standards provides an introduction to the water quality standards language[3]. The introduction discusses the Executive Order confirming that the Spokane Reservation is reserved for the Spokane Tribe of Indians, describes the Tribe's authority to adopt standards, and sets forth the purposes of the standards. EPA acknowledges the new and revised language contained in provisions 4 and 6 of the introductory language. However, water quality standards are provisions of Tribal or Federal law that consist of designated uses for waters of the United States, water quality criteria necessary to protect those designated uses, and an antidegradation policy (40 CFR § 131.3(i)). Provision 4 is a general statement describing what the water quality standards are intended to achieve. The new language added to provision 4 is simply outlining what is contained in Sections 2 through 14 of the water quality standards (e.g., the water

[3] On April 22, 2003 EPA approved the Tribe's Original water quality standards. In that decision EPA did not act on any of the provisions contained in Section I because they were not considered water quality standards they are simply introducing concepts that are in the body of the water quality standards.

quality standards provisions outline in 4(c) and (d) are contained in Section 6, provision 9). Provision 6 merely discusses the history of various rulemakings. The provisions do not establish designated uses or criteria to protect the uses and as such are not a water quality standard under § 303(c) of the CWA. Therefore, EPA is not required to take an action on these provisions under the CWA.

III. DEFINITIONS (SECTION 2)

A. Definitions that EPA Is Not Taking An Action On

All new text is underlined and indicates the language that was added in the 2010 water quality standards adoption. EPA is not taking an action on the following definitions because they are not water quality standards:

1. ***"1-day maximum temperature" or "1-dm"****is the highest water temperature reached on any given day. This measure can be obtained using calibrated maximum/minimum thermometers or continuous monitoring probe having sampling intervals of thirty minutes or less.*

2. *"**Background**" means the natural three dimensional distribution of physico-chemical conditions associated with the volume of media in which the release occurred, prior to the release. In many instances, location immediately outside of the nature and extent of contamination can be used by the Department to determine background. In instances in which no such locations are available, the Department shall identify an "appropriate reference site or region."*

3. *"**Cumulative Risk**" means risk caused from post release doses from multiple pathways, multiple media (primary and secondary sources), and/or multiple hazardous substances. This definition is consistent with Tribal cleanup law.*

These three terms are not referenced in any provision within the Tribe's water quality standards. For example, the 1-day maximum temperature (1-dm) is a metric for temperature, however, the temperature criteria in the Tribe's water quality standards are expressed as a 7-day average of the daily maximum temperatures not a 1-day maximum. Because these terms are not used in any water quality criteria or provision, they do not establish a legally binding requirement under tribal law nor do they describe a desired ambient condition of a water body to support a particular designated use. Therefore, the terms and the associated definitions are not water quality standards subject to EPA review and approval under 303(c) of the CWA and EPA is taking no action to approve or disapprove these new terms and definitions.

EPA recommends the Tribe delete the terms and definitions from their water quality standards since they are not relevant.

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B. Definitions that EPA is Taking Action On

The following presents the new definitions contained in Section 2 of the WQS. All new text is underlined and indicates the language that was added in the 2010 water quality standards adoption.

1. ***"7-day average of the daily maximum temperatures or 7-DADM"*** *is the arithmetic average of seven consecutive measures of daily maximum temperatures. The 7-DADM for any individual day is calculated by averaging that day's daily maximum temperature with the daily maximum temperatures of the three days prior and the three days after that date.*

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "7-day average of the daily maximum temperatures or 7-DADM" because it is scientifically defensible, protective of the use, and consistent with § 303(c) of the CWA and its implementing regulations.

The 7-DADM metric is the metric used for temperature criteria in the Tribe's water quality standards. The 7-DADM metric is recommended for temperature standards by the USEPA *Region 10 Guidance for Pacific Northwest State and Tribal Temperature Water Quality Standards* (EPA910-B-03-002, April 2003, hereafter referred to as the Temperature Guidance). The Temperature Guidance and the six Technical Issue Papers that serve as the scientific basis for the recommendations in this document may be found at: www.epa.gov/r10earth/temperature.htm.

The 7-DADM metric adequately protects aquatic life against acute[4] effects because it incorporates daily maximum temperatures. This metric can also be protective of chronic[5] effects to aquatic life because it describes the thermal exposure over 7 days. The Temperature Guidance considered both acute and chronic effects to fish when developing its recommended temperature criteria.

2. *"Federal clean up law" means the Comprehensive Environmental Response, Compensation and Liability Act, 42, U.S. Sec.9601, et seq."*

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "Federal clean up law" because it is needed for the proper implementation of the Tribe's mixing zone policy, which defines the limited circumstances under which a mixing zone may be allowed.

3. *"Mixing zone" means that portion of a water body affected by the discharge of effluents in accordance with Section 13(2) of this chapter where mixing results in the dilution of the effluent with the receiving water.*

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "mixing zone" because it provides information needed for the application and implementation of WQS. In addition, it is consistent with the definition incorporated into EPA guidance (Technical Support Document for Water Quality-based Toxics Control (EPA, March 1991)).

[4] Acute – a stimulus severe enough to rapidly induce an effect such as lethality.
[5] Chronic - a stimulus that lingers over a relatively long period of time. It is measured as reduced growth, reduced reproduction, lethality, etc.

4. *"Nonpoint source" means pollution that enters any waters of the reservation from any dispersed land based or water-based activities, including but not limited to atmospheric deposition, surface water runoff from agricultural lands, urban area, or forest lands, subsurface or underground sources, or discharges from boats or marine vessels not otherwise regulated under the National Pollutant Discharge Elimination System.*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "nonpoint source" because it is generally consistent with the EPA guidance (*NPDES Permit Writer's Manual*, EPA-833-K-10-001, September 2010).

5. *"Tribal clean up law" means the Hazardous Substances Control Act, Chapter 34, Law and Order Code of the Spokane Tribe of Indians.*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "Tribal clean up law" because the term is needed for the implementation of the Tribe's mixing zone policy, which defines the limited circumstances under which a mixing zone may be allowed.

6. *"Trophic state" means a classification of the productivity of a lake ecosystem. Lake productivity depends on the amount of biologically available nutrients in water and sediment and may be based on total phosphorus (TP). Secchi depth and chlorophyll-a measurements may be used to improve the trophic state classification of a lake. Trophic states used in this rule include oligotrophic, lower mesotrophic, upper mesotrophic, and eutrophic.*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the definition for "trophic state" because it explains the term as it is used in the water quality standards.

IV. NARRATIVE PROVISIONS (SECTION 6, Provisions 5 through 9)

A. EPA Action on Narrative Provisions

The following presents the new and revised language to the WQS contained in Section 6, provisions 5 through 9. All underlined text indicates language that is new and strikeout text indicates the language that was removed by the 2010 water quality standards adoption.

~~*(5) The aquatic organism consumption rate utilized in determining the human health criteria shall be 86.3 g/day. This figures does not reflect the actual consumption rate typical of the Spokane Tribe of Indians, but has been used for the limited purpose of establishing these Surface*~~

~~*Water Quality Standards based on current EPA guidance (63 F.R. 43756). This rate may be modified to reflect consumption rate analysis specific to the Spokane Tribe.*~~

(5) Human-health risk-based criteria for non-carcinogenic material shall be applied such that the hazard index, as defined in the Tribal Cleanup Law for a given mixture, does not exceed 1.0.

~~*(6) The guidelines set forth in 40 CFR Part 136 shall be used as guidance for analytical methodologies.*~~

(6) The aquatic organism consumption rate utilized in determining the human health criteria shall be 865 g/day.

~~*(7) The criteria in Table 1 shall be applied to all surface waters of the tribe for the protection of aquatic life and human health. The concentration for each compound listed in Table 1 is a criterion for aquatic life or human health protection. Selecting values for regulatory purposes will depend on the most sensitive beneficial use to be protected and the level of protection necessary for aquatic life and human health as specified within Table 1. Application for a reduction in the list of compounds or elements must be based on proof that one or more of the proposed compounds are not of concern. Authorization of such a reduction is at the discretion of the Department. All concentrations, except asbestos, are micrograms per liter (µg/L).*~~

(7) The surface water consumption rate utilized in determining the human health criteria shall be 4 L/day.

(8) The guidelines set forth in 40 CFR Part 136 shall be used as guidance for analytical methodologies.

(9) The criteria in Table 1 shall be applied to all surface waters of the tribe for the protection of aquatic life and human health. The concentration for each compound listed in Table 1 is a criterion for aquatic life or human health protection. Table 1 is developed using the following assumptions:

a. the receptor (e.g. human) receives a dose from a single contaminant (e.g. cadmium) from a single medium (e.g. surface water) via direct ingestion of water or fish and water; and

b. the dose from natural background conditions is negligible,

Site-specific numerical criteria as described in the Tribal Cleanup Law must be developed in the event these assumptions are incorrect. If natural background conditions exceed the risk criteria defined in this section, then the natural background conditions are the numerical standard.

Selecting values for regulatory purposes will depend on the most sensitive beneficial use to be protected and the level of protection necessary for aquatic life and human health as specified within Table 1. Application for a reduction in the list of compounds or elements must be based on proof that one or more of the proposed compounds are not of concern. Authorization of such a reduction is at the discretion of the Department. All concentrations, except asbestos, are micrograms per liter (µg/L).

EPA Action

Section 6, Provision (5)

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the new Provision (5), which states: *(5) Human–health risk-based criteria for non-carcinogenic material shall be applied such that the hazard index, as defined in the Tribal Cleanup Law for a given mixture, does not exceed 1.0.*

The hazard index (HI) is the sum of hazard quotients (HQs) for substances that affect the same target organ or organ system. Because different pollutants can cause similar adverse health effects, it may be appropriate to combine HQs associated with different substances. A HQ is the ratio of potential exposure to the substance and the level at which no adverse effects are expected. If the HQ is calculated to be less than 1 then no adverse effects are expected as a result of exposure. Similarly, aggregate exposures below a HI of 1.0 would likely not result in adverse non-cancer health effects.

EPA is approving this provision because it is a reasonable methodology to ensure that mixtures of chemicals do not adversely affect the human health uses adopted by the Tribe.

Section 6, Provisions (6) and (7)

Provision (6) provides the fish consumption rate used to develop the human health criteria and provision (7) provides the surface water consumption rate used to develop the human health criteria. EPA is not taking action on provisions (6) and (7) because the language does not establish a legally binding requirement under tribal law and it does not describe a desired ambient condition of a waterbody to support a particular designated use. Therefore it is not considered a WQS subject to EPA review and approval under 303(c) of the CWA.

EPA has addressed the new and revised human health criteria in Section 6, Table 1 of the tribal water quality standards in this technical support document. The language in provisions (6) and (7) explains two of the inputs used when the Tribe derived their human health criteria values (see Section 6, in Table 1 of the water quality standards for the human health criteria). EPA incorporated the explanatory information provided in these two provisions into its analysis of the individual human health criteria values in Section 6, Table 1. However, because these two provisions do not operate as independent water quality standards in isolation from the human health criteria values contained in Table 1, EPA is taking no action to approve or disapprove provisions (6) and (7).

It should be noted that the Tribe's 2003 water quality standards contained a provision which stated that the fish consumption rate of 86.3 g/d (in the 2003 WQS the fish consumption rate was in Section 6, provision 5, when the Tribe revised its water quality standards in 2010 some provisions were re-numbered, in the 2010 water quality standards the fish consumption rate is contained in provision 6) and in April 2003 EPA approved that provision. EPA hereby rescinds its 2003 approval of the fish consumption rate based on the above analysis.

Provision 9

EPA is not taking on action on part of Provision 9, and is disapproving part of Provision 9.

- EPA not taking action on the following new language added to provision 9 because it is not a water quality standard:

  Table 1 is developed using the following assumptions:

  a. the receptor (e.g. human)receives a dose from a single contamination (e.g. cadmium) from a single medium (e.g. surface water) via direct ingestion of water or fish and water; and

  b. the dose from natural background conditions is negligible.

EPA is not taking action on the above language because it does not establish a legally binding requirement under tribal law and it does not describe a desired ambient condition of a waterbody to support a particular designated use, therefore, it is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. This language simply explains two of the assumptions used in developing criteria. EPA considered these assumptions in its analysis of the individual criteria values in Section 6, Table 1. But because these two assumptions do not operate as independent water quality standards, in isolation from the criteria values in Section 6, Table 1 of the tribal water quality standards (which EPA acted on individually), EPA is taking no action to approve or disapprove this new language in provision 9.

- In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the following new language in Provision (9):

  Site-specific numerical criteria as described in the Tribal Cleanup Law must be developed in the event these assumptions are incorrect. If natural background conditions exceed the risk criteria defined in this section, then the natural background conditions are the numerical standard.

EPA is disapproving this language because it requires that the criteria be revised should the assumptions in Provision 9.a and 9.b be incorrect. While it may be appropriate to develop site-specific criteria, this provision does not require that the revised criteria be subject to a public involvement process, be adopted into the Spokane Tribal water quality standards, or be submitted to EPA for review and approval as required in 40 CFR Part 131.

EPA's water quality standards regulations do not provide specific requirements for establishing criteria based on natural background conditions. However, any water quality criteria adopted by states or tribes must be established based on a sound scientific rationale and assure protection of designated uses (see 40 CFR § 131.11(a)(1)). This would include establishing criteria based on natural background conditions.

EPA's November 1997 policy titled *Establishing Site Specific Aquatic Life Criteria Equal to Natural Background* recognized that there may be naturally occurring concentrations of pollutants which may exceed the national criteria published under § 304(a) of the CWA. This policy articulates that States and Tribes may establish site specific numeric aquatic life water quality criteria by setting the criteria value equal to the natural background of a waterbody.

Natural background is defined as the background water quality concentration due only to non-anthropogenic sources. The policy explains that "For aquatic life uses, where the natural background concentration for a specific parameter is documented, by definition that concentration is sufficient to support the level of aquatic life expected to occur naturally at the site absent any interference by humans."

In setting criteria equal to natural background, the policy recommends that "…the State or Tribe should, at a minimum, include in their water quality standards:

> (1) a definition of natural background consistent with the above;
> (2) a provision that site specific criteria may be set equal to natural background;
> (3) a procedure for determining natural background, or alternatively, a reference in their water quality standards to another document describing the binding procedure that will be used."

Furthermore, it explains that where the natural background concentration exceeds the state adopted human health criterion, at a minimum, the State or Tribe should re-evaluate the human health use designation. The policy states that "it does not apply to human health uses."

The Tribe has not developed guidance describing the binding procedure that would be used to determine the natural background. Additionally, the regulatory language in provision (9) allows the "natural background condition" to become the criterion for human health criteria as well as aquatic life uses.

Impacts to humans due to exposure to waterborne toxicants occur through three primary routes: contact recreation; drinking water; and ingestion of contaminated fish and shellfish tissues. The human health protection criteria are based on data regarding human absorption, distribution, metabolism, and excretion of toxic pollutants. Human health effects from toxicants are divided into categories based on the human biological endpoints observed as well as data on human acute, sub-acute, and chronic toxicity, synergistic and antagonistic effects, and specific information on human mutagenicity, teratogenicity, and carcinogenicity. In addition, the human health methodology used to develop human health criteria includes the contribution of other sources, such as dietary intake other than fish and air inhalation, in the assessment of total exposure to a pollutant.

The level of a naturally occurring pollutant does not necessarily protect human health or designated uses which may include people drinking directly from streams, and/or eating fish and shellfish. In cases where the natural condition exceeds the numeric criteria, an evaluation of whether the natural level would protect human health uses is needed. An evaluation of whether the human health uses are supported by the natural condition criterion would include an assessment of potential and known human exposure pathways and any risks to adverse human health effects of the pollutant at the natural condition concentrations. Because human exposure and health effects assessments are not part of this provision and no guidance for implementing its "natural background condition" provision has been developed, there is no evaluation as to whether or not the naturally occurring level protects human health uses. Consistent with the CWA and the federal regulations, the Tribe must assure that the water quality criteria provide protection to the designated uses.

EPA has determined that the new language in provision 9 (i.e., *Site-specific numerical criteria as described in the Tribal Cleanup Law must be developed in the event these assumptions are incorrect. If natural background conditions exceed the risk criteria defined in this section, then the natural background conditions are the numerical standard.)* is inconsistent with the CWA and the federal water quality standards regulations at 40 CFR § 131.l1(a), because this provision allows the Tribe to establish criteria based on natural conditions that do not assure protection of the designated human health uses in tribal waters. The level of a naturally occurring pollutant does not necessarily protect designated human health uses. Natural levels of a pollutant are assumed to protect aquatic life species which naturally occur in these waters. However, waterbodies are not the natural habitat for humans and therefore, the same assumptions of protectiveness cannot be made with regard to human health uses (e.g., people drinking directly from streams, eating fish or shellfish from tribal waters, and recreating in tribal waters). Therefore, the tribe has not demonstrated how its approach would protect designated human health uses. Additionally, as mentioned previously, the Tribe has not provided EPA with a binding procedure for determining natural background conditions as envisioned by EPA's November 1997 policy.

Remedy to Address EPA's Disapproval

To address this disapproval, the Tribe could delete the provision as the Tribe's approved numeric criteria are protective of designated uses. Additionally, the Tribe may use the natural condition provision in Section 3, Provision 2 of its water quality standards which states that the "…the Department may determine that the natural conditions shall constitute the water quality criteria." In a December 26, 2000 letter from Rudy Peone it was clarified that any natural condition criterion will be developed as a site specific criterion that would be submitted to EPA for review and approval.

Alternatively, the Tribe could revise the water quality standard to clarify that it applies only to aquatic life criteria and adopt into its WQS (directly or by reference) a binding methodology[6] that provides a transparent, predictable, repeatable, and scientifically defensible procedure for the protection of designated aquatic life uses. This approach, known as a "performance-based" approach, relies on the adoption of a systematic process (i.e., a criterion derivation methodology) rather than a specific outcome (i.e., concentration limit for a pollutant) consistent with 40 CFR § 131.11 and 131.13. EPA would need to review any such binding methodology that the Tribe develops as part of a performance-based approach. The performance-based approach could be used to derive site-specific adjustments to numeric criteria or to translate a narrative criterion into quantifiable measures. When such a performance-based approach is sufficiently detailed and has suitable safeguards to ensure predictable, repeatable outcomes, the EPA approval of such an approach also serves as approval of the outcomes as well. Note, however, that one approach is likely not suited to derive all pollutant targets and metrics given the breadth of pollutants over which the natural condition criterion applies. Individual methodologies for each pollutant or subsets of pollutants with similar sources and cycling would likely be necessary in order to ascertain the scientific defensibility of the methodology and the level of protection afforded to designated uses as a result of using the methodology.

[6] EPA 2000. *EPA Review and Approval of State and Tribal Water Quality Standards.* Federal Register: April 27, 2000 (Volume 65, Number 82); Rules and Regulations; Page 24641-24653. Procedures to identify opportunities by which their adoption of criteria, as well as EPA's approval, can be streamlined.

B. EPA Action On Editorial Changes Section 6, Provisions 5 through 9

Minor Editorial Changes made to Provisions 5 through 9

In addition to the new language added in Provisions (5) through (9) the provisions were re-numbered. EPA acknowledges the re-numbering of provisions (5) through (9) as minor editorial changes and approves them as non-substantive changes.

V. Human Health Criteria in Section 6, Table 1

Table 1, below, presents the new and revised human health criteria for "water and organisms" and for "organisms only" as well as the revised aquatic life criteria. All new or revised criteria included in the 2010 water quality standards adoption are underlined and are expressed as *µg/L*.

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Acenaphthene	*n*			*1.97E+01*	*2.01E+01*
Acrolein	*n*			*5.75E+00*	*5.87E+00*
Acrylonitrile	*y*			*4.33E-03*	*5.00E-03*
Aldrin (e)	*y*	*3.0E+00*	*1.9E-03*	*1.02E-06*	*1.02E-06*
Aluminum (pH 6.5 - 9.0)	*n*	*7.5E+02*	*8.7E+01*	-----	-----
Ammonia, un-ionized (f, g)	*n*	*2.4E+04*	*5.9E+03*	-----	-----
Anthracene	*n*			*7.01E+02*	*8.09E+02*
Antimony	*n*			*5.76E+00*	*3.24E+01*
Arsenic (h)	*y*	*3.4E+02*	*1.5E+02*	*9.51E-04*	*1.05E-03*
Asbestos	*y*			*see footnote 1*	-----
Barium	*n*			*1.00E+03*	-----
Benz(a)anthracene	*y*			*3.2E-04*	*3.7E-04*
Benzene	*y*			*2.84E-01*	*5.37E-01*
Benzidine	*y*			*3.82E-06*	*4.02E-06*
Benzo(a)pyrene	*y*			*3.2E-04*	*3.7E-04*
3,4-Benzo(b)fluoranthene	*y*			*3.2E-04*	*3.7E-04*
Benzo(k)fluoranthene	*y*			*3.2E-04*	*3.7E-04*
alpha BHC	*y*			*9.54E-05*	*9.88E-05*
beta BHC	*y*			*3.34E-04*	*3.46E-04*
gamma BHC (e)	*y*	*9.5E-01*	*8.E-02*	*4.53E-04*	*4.69E-04*
Bis(2-chloroethyl) Ether	*y*			*6.38E-03*	*1.07E-02*
Bis(2-chloroisopropyl) Ether	*n*			*4.56E+02*	*1.31E+03*
Bis(2-chloromethyl)ether	*y*			*7.00E-05*	*5.84E-04*
Bis(2-ethylhexyl)phthalate	*y*			*4.29E-02*	*4.45E-02*
Bromoform	*y*			*1.22E+00*	*2.73E+00*
Butylbenzyl phthalate	*n*			*3.87E+01*	*3.91E+01*
Cadmium (j)	*n*	*3.7E+00*	*1.0E+00*	*8.75E+00*	-----
Carbon tetrachloride	*y*			*2.66E-02*	*3.32E-02*
Chlordane (e)	*y*	*2.4E+00*	*4.3E-03*	*4.41E-06*	*4.41E-06*

Compound	Carcinogen?	Acute (a) Criteria	Chronic (b) Criteria	Water & Organisms	Organisms Only
Chloride		8.6E+05	2.3E+05	-----	-----
Chlorine	n	1.9E+01	1.1E+01	1.75E+03	-----
Chlorobenzene	n			1.08E+02	1.57E+02
Chlorodibromomethane	y			1.15E-01	2.57E-01
Chloroform	y			1.58E+00	3.54E+00
2-Chloronaphthalene	n			3.13E+01	3.20E+01
2-Chlorophenol	n			2.92E+00	3.02E+00
Chlorpyrifos	n	8.3E-02	4.1E-02	5.25E+01	-----
Chromium (Hex)	n	1.5E+01	1.0E+01	5.25E+01	-----
Chromium (Tri)	n	5.5E+02	7.4E+01	2.63E+04	-----
Chrysene	y			3.20E-04	3.70E-04
Copper	n	1.3E+01	9.0E+00	1.21E+01	1.21E+01
Cyanide	n	2.2E+01	5.2E+00	2.88E+02	1.62E+03
4,4'-DDD	y			6.29E-06	6.29E-06
4,4'-DDE	y			4.44E-06	4.44E-06
4,4'-DDT	y	1.1E+00	1.E-03	4.44E-06	4.44E-06
Demeton	n		1.E-01	-----	-----
Dibenz(a,h)anthracene	y			3.20E-04	3.70E-04
Dibutyl phthalate	n			8.64E+01	9.09E+01
1,2-(o)Dichlorobenzene	n			1.21E+02	1.31E+02
1,3-(m)Dichlorobenzene	n			1.80E+01	1.95E+01
1,4-(p)Dichlorobenzene	n			1.80E+01	1.95E+01
3,3-Dichlorobenzidine	y			5.68E-04	5.76E-04
Dichlorobromomethane	y			1.56E-01	3.48E-01
Dichlorodifluoromethane	n			1.93E+03	4.32E+03
1,2-Dichloroethane	y			1.53E-01	7.41E-01
1,2-trans-Dichloroethylene	n			2.61E+02	1.02E+03
1,1-Dichloroethylene	y			1.32E-02	2.41E-02
2,4-Dichlorophenol	n			5.36E+00	5.96E+00
1,2-Dichloropropane	n			1.40E-01	2.97E-01
1,3-Dichloropropylene	n			3.72E+00	1.27E+01
Dieldrin	y	2.4E-01	1.9E-03	1.08E-06	1.08E-06
Diethyl phthalate	n			8.34E+02	8.87E+02
2,4-Dimethylphenol	n			1.64E+01	1.73E+01
Dimethyl phthalate	n			1.99E+04	2.25E+04
2,4-Dinitrophenol	n			2.64E+01	1.08E+02
2,4-Dinitotoluene	y			3.06E-02	6.78E-02
2,3,7,8-TCDD (Dioxin)	y			1.04E-10	1.04E-10
1,2-Diphenylhydrazine	y			3.43E-03	4.06E-03
alpha Endosulfan	n	2.2E-01	5.6E-02	1.77E+00	1.80E+00
beta Endosulfan	n	2.2E-01	5.6E-02	1.77E+00	1.80E+00
Endosulfan sulfate	n			1.77E+00	1.80E+00
Endrin	n	8.6E-02	2.3E-03	6.11E-03	6.12E-03
Endrin aldehyde	n			6.11E-03	6.12E-03
Ethylbenzene	n			1.92E+02	2.16E+02
Fluoranthene	n			2.80E+00	2.81E+00

Compound	Carcinogen?	Acute (a) Criteria	Chronic (b) Criteria	Water & Organisms	Organisms Only
Fluorene	n			9.35E+01	1.08E+02
Guthion	n		1.0E-02	-----	-----
Heptachlor	y	0.52e	3.8E-03	1.60E-06	1.61E-06
Heptachlor epoxide	y	0.52e	3.8E-03	7.94E-07	7.94E-07
Hexachlorobenzene	y			5.82E-06	5.82E-06
Hexachlorobutadiene	y			1.40E-01	3.73E-01
Hexachlorocyclopentadiene	n			6.32E+01	1.31E+02
Hexachloroethane	y			6.32E-02	6.65E-02
Indeno(1,2,3-cd)pyrene	y			3.20E-04	3.70E-04
Iron (1)	n			3.00E+02	
Isophorone	y			9.46E+00	1.94E+01
Lead (j)	n	6.5E+01	2.5E+00	-----	-----
Malathion	n		1.E-01	-----	-----
Manganese	n			-----	-----
Mercury (m)	n	1.4E+00	1.2E-02	1.1E-03	1.1E-03
Methoxychlor	n		3.E-02	1.65E+00	1.69E+00
Methyl bromide	n			1.35E+01	3.02E+01
2-Methyl-4,6-Dinitrophenol	n			3.12E+00	5.74E+00
Methylene chloride	y			1.95E+00	1.20E+01
Mirex	n		1.E-03	-----	-----
Nickel (j)	n	4.7E+02	5.2E+01	3.14E+01	3.44E+01
Nitrobenzene	n			5.38E+00	1.40E+01
N-Nitrosodimethylamine	y			3.41E-04	6.10E-02
N-Nitrosodi-n-propylamine	y			2.01E-03	1.02E-02
N-Nitrosodiphenylamine	y			1.17E-01	1.21E-01
N-Nitrosopyrrolidine	y			8.24E-03	7.01E-01
Parathion	n	6.5E-02	1.3E-02	----	----
PCB Total	y	2.0E+00	1.4E-02	1.30E-06	1.30E-06
Pentachlorobenzene	n			3.04E-02	3.05E-02
Pentachlorophenol (n)	y	9.1E+00	5.7E+00	4.32E-02	6.13E-02
Phenol	n			8.06E+03	3.47E+04
Pyrene	n			7.01E+01	8.09E+01
Selenium (NTSWQS)	n	2.0E+01	5.E+00	4.29E+01	8.43E+01
Silver (j)	n	3.4E+00		-----	-----
Sulfide - Hydrogen Sulfide	n		2.0E+00	-----	-----
1,1,2,2-Tetrachloroethane	y			4.20E-02	8.09E-02
Tetrachloroethylene	y			5.78E-02	6.65E-02
Thallium	n			4.45E-02	4.62E-02
Toluene	n			1.06E+03	1.51E+03
Toxaphene	y	7.3E-01	2.E-04	5.61E-06	5.62E-06
Tributyltin	n	4.6E-01	6.3E-01	1.73E-03	1.73E-03
1,2,4-Trichlorobenzene	n			6.82E+00	7.10E+00
1,1,2-Trichloroethane	y			1.56E-01	3.15E-01
Trichloroethylene	y			4.22E-01	6.06E-01
2,4,6-Trichlorophenol	y			4.76E-02	4.90E-02
Vinyl chloride	y			8.03E-01	3.98E+00

01039

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Zinc (j)	*n*	*1.1E+02*	*1.0E+02*	*4.70E+02*	*5.17E+02*

Footnote 1: The previously approved criterion was removed from Table 1in the 2010 water quality standards revision.

A. Human Health Criteria and Application to Spokane Tribe's Designated Uses

In the Tribe's WQS, each water body is assigned to a particular "Class." Fresh waters are designated as Class AA, Class A, or Lake Class waters. Each "Class" contains a suite of designated uses. A designated use of Class AA protects waters for:

- Primary contact ceremonial and spiritual
- Cultural
- Water supply (domestic, industrial, agricultural)
- Stock watering
- Fish and shellfish, including:
    - Salmonid migration, rearing, spawning, and harvesting.
    - Other fish migration rearing, spawning, and harvesting.
    - Clam, and mussel rearing, spawning, and harvesting.
    - Mollusks, crustaceans and other shellfish rearing, spawning, and harvesting
- Primary contact recreation
- Commerce and navigation

Class A and Lake Class waters are assigned the same designated uses as Class AA, except for the "Clam, mussel rearing, spawning and harvesting" sub-category which is listed under the Fish and shellfish designated use.

Additionally, the tribal standards (Section 10) state that waters not specifically identified as Class AA, A or Lake Class, shall be designated as Class A. Therefore, all tribal waters are protected for fish and shellfish, including harvesting, domestic water supply and recreation.

Furthermore, Section 6 (Toxic Pollutants), provision 9 of the Tribe's WQS states:

> (*9) The criteria in Table 1 shall be applied to all surface waters of the tribe for the protection of aquatic life and human health. The concentration for each compound listed in Table 1 is a criterion for aquatic life or human health protection….*

Table 1 of Section 6 (Toxic Pollutants) in the Tribes WQS provides the human health and aquatic life water quality criteria for toxic pollutants. The Tribe's "water + organism" criteria in Table 1 were established to limit the pollutant to levels that provide for the safe consumption of drinking water and fish. The "organism only" criteria in Table 1 were established to limit the pollutant to levels that provide for the safe consumption of fish and shellfish only; this does not include the consumption of water. The human health and aquatic life criteria apply to all surface waters on the reservation.
For human health protection, EPA recommends that states and tribes apply human health criteria for toxics to all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route), recreation, and/or aquatic life protection (and therefore a

potential fish consumption route).[7] The Tribe's approach is consistent with EPA's recommended approach.

The Tribe's 2010 revised human health criteria for toxic pollutants are developed, for the most part, pursuant to methods presented in EPA's 2000 Human Health Methodology.[8] This methodology protects human health from long-term exposure to toxic pollutants in drinking water and through eating fish containing these pollutants. These criteria take into consideration the cancer potency or systemic toxicity of a pollutant, the exposure related to surface water exposure and a risk characterization. The criteria calculations for non-carcinogens and carcinogens differ depending upon the exposure scenario for which the criteria are derived and are further described below.

EPA reviewed the Tribe's 2010 revised human health criteria for toxic pollutants to assess whether they were consistent with the CWA and its implementing regulations. EPA's evaluation focused on whether the criteria were consistent with 40 CFR § 131.11(a), which states that criteria must be based on sound scientific rationale and contain sufficient parameters or constituents to protect designated uses.

B. Criteria Methodology and Input Variables Used by the Tribe

Pursuant to CWA § 304(a), EPA has published recommended criteria for use by states and tribes in adopting and revising criteria.[9] For human health criteria, the values reflect the "national default" values for the risk assessment parameters provided in the 2000 Human Health Methodology, the reference dose values (RfD) contained in EPA's Integrated Risk Information System[10] (IRIS) at the time of publication, and the use of bioconcentration factors (BCFs) as opposed to site-specific bioaccumulations factors (BAFs).[11] While the 2000 Human Health Methodology provides national default values, it also provides necessary guidance to adjust criteria to reflect local conditions and encourages states and tribes to use the guidance to appropriately reflect local conditions and/or protect identifiable subpopulations.[12] The Tribe revised and adopted human health criteria that were derived, for the most part, using EPA's 2000 Human Health Methodology as well as local fish consumption and drinking water intake rates.

The risk assessment-based procedures EPA puts forth in the 2000 Human Health Methodology are

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[7] EPA 1994. *Water Quality Standards Handbook*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C., EPA-823-B-94-005a. August 1994.

[8] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004

[9] EPA National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health. Published pursuant to section 304(a) of the CWA. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html.

[10] IRIS is a human health assessment program that evaluates information on health effects that may result from exposure to environmental contaminants. Through the IRIS program EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities.

[11] The 2000 Human Health Methodology recommends the use of national BAFs in the calculation of ambient water quality criteria. However, EPA has only provided guidance on the calculation of national BAFs; BAFs have not been calculated for individual pollutants. EPA uses BCFs in their nationally recommended criteria. States and Tribes have the option to use these BCFs or to calculate BAFs using EPA guidance documents. Development of BAFs is time and resource intensive and BAFs can vary from site to site. Thus it is difficult to develop BAFs on a national or statewide scale. Therefore, until BAFs are developed, EPA's national 304(a) human health recommendations continue to be based on the use of BCFs which reflect the uptake and retention of a pollutant by an aquatic organism from water alone (as opposed to a BAF which reflects the uptake of a pollutant from all sources [e.g., ingestion, sediment]).

[12] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. Pages iii, 1-11.

specific to whether the endpoint is cancer or non-cancer. When using cancer as the critical risk assessment endpoint, the criteria are presented as a range of concentrations associated with specified incremental lifetime risk levels.[13] The following briefly provides the key features of each procedure. A simplified version of this equation is provided in Figure 1 below.

Figure 1. Simplified version of the equation used by the Tribe in deriving the human health criteria for carcinogens.

$$AWQC = \frac{(Risk\ Level \bullet BW)}{[CSF \bullet (DI + (FCR \bullet BAF))]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
Risk Level	=	Risk level (unitless)
CSF	=	Cancer slope factor (milligrams per kilogram per day)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCR	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

*Note that criteria calculations for organism only criteria are not shown and can be derived by removing the drinking water intake (DI) term.

When using noncancer effects as the critical endpoint, the criteria reflect an assessment of a "no-effect" level. Criteria for non-carcinogenic pollutants are calculated through an equation that relies on pollutant-specific and general risk-assessment values for each parameter. A simplified version of this equation is provided in Figure 2 below.

[13] EPA's methodology recognizes that states and tribes have the flexibility to adopt human health criteria within a risk level range of 1 X 10^{-6} to 1 X 10^{-5} as long as highly exposed populations would be protected at a minimum of 1X 10^{-4} risk level (i.e., there is a 1:10,000 risk of getting cancer).

Figure 2. Simplified version of the equation used by the Tribe in deriving the human health criteria for non-carcinogens.

$$AWQC = RfD \bullet RSC \bullet \frac{(BW)}{[DI + (FCR \bullet BAF)]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
RfD	=	Reference dose for noncancer effects (milligrams per kilogram per day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure (unit less)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCR	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

*Note that criteria calculations for organism only criteria are not shown and can be derived by removing the drinking water intake (DI) term.

The Tribe's new and revised criteria were derived using the following input variables:

RfD: Most of values the Tribe used were values recommended by EPA in the 2002 and 2003 CWA § 304(a) criteria recommendations.[14, 15] Alternative values used by the Tribe will be discussed in more detail when EPA reviews specific human health criteria.

RSC: Most of the values the Tribe used were values recommended by EPA in the 2002 and 2003 CWA § 304(a) criteria recommendations.[16, 17] Alternative values used by the Tribe will be discussed in more detail when EPA reviews specific human health criteria.

BW: 70 kilograms[18] (value recommended by EPA).

DI: 4 liters per day (value reflects a subsistence lifestyle; EPA's review of the tribal value is presented below in section C).

[14] See: EPA. 2002. *National Recommended Water Quality Criteria 2002 – Human Health Criteria Calculation Matrix*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-R-02-012. Available at: http://www.epa.gov/waterscience/criteria/wqctable/hh_calc_matrix.pdf.

[15] See: EPA. 2003. *National Recommended Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 68, Issue: 250, Page: 75507 (68 FR 75507), December 31, 2003. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2003/December/Day-31/w32211.htm.

[16] See: EPA. 2002. *National Recommended Water Quality Criteria 2002 – Human Health Criteria Calculation Matrix*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-R-02-012. Available at: http://www.epa.gov/waterscience/criteria/wqctable/hh_calc_matrix.pdf.

[17] See: EPA. 2003. *National Recommended Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 68, Issue: 250, Page: 75507 (68 FR 75507), December 31, 2003. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2003/December/Day-31/w32211.htm.

[18] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. Pages 4-18 to 4-19.

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FCR: 865 grams per day (value reflects a subsistence lifestyle; EPA's review of the tribal value is presented below in section C).

BAF: Most of the values the Tribe used were values recommended by EPA in the 2002 and 2003 CWA § 304(a) criteria recommendations. Alternative values used by the Tribe will be discussed in more detail when EPA reviews specific human health criteria.

Cancer risk level: 1×10^{-6} (value recommended by EPA)

CSF: values provide in EPA's Integrated Risk Information System (IRIS).

Further information regarding each of these variables is available in EPA's 2000 Human Health Methodology.

C. EPA's Review of Fish Consumption Rate and Drinking Water Intake

As described above, the Tribe calculated its human health criteria using several exposure and risk variables, and determined a risk level it deemed acceptable while still protecting the use – in this case, the level of protection provided to consumers of organisms and water taken from the tribal waters to which the criteria apply.

The regulations at 40 CFR § 131.11(a) provide that new or revised criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect designated uses." However, at the same time, EPA may not disapprove water quality criteria that are more stringent than EPA's CWA section 304(a) criteria solely on the grounds that the proposed criteria are too stringent.[19] While all criteria must be "developed based on scientifically defensible methods," a state or tribe need not justify its policy decision to develop criteria based on stated goals that differ from those underlying EPA's 304(a) recommendations and that, therefore, result in the calculation of more stringent criteria values.[20]

Thus, for the Tribe's criteria that are more stringent than the 304(a) recommendations, EPA evaluated the criteria under the CWA as follows:

- First, EPA acknowledged the Tribe's decision to ensure that its water quality is sufficient to support traditional subsistence practices. Specifically, EPA acknowledged that the selection of the objective to be protected by the criterion is a question of Spokane tribal policy. More generally, EPA noted that the CWA does not require a state or tribe to justify its decision to protect a particular use by establishing that a sufficient number of persons will participate in that use. Neither did the Tribe purport to justify its policy objectives by reference to the number of persons who currently rely on tribal waters for subsistence purposes.
- Second, EPA evaluated the scientific defensibility of the assumptions and methodology the Tribe used in deriving criteria to protect its water quality goals, including the derivation of fish

[19] EPA's established interpretation of its regulations reflects that they must be understood consistent with the statutory limits on EPA's review authority under the CWA. See 56 FR 64885-6 (1991) (recognizing, in light of CWA § 510, that EPA "may not disapprove either Tribal or State standards solely on the grounds that the standard is too stringent").
[20] Id.

consumption and drinking water rates characteristic of the Spokane Tribe's subsistence traditions.

- Third, EPA evaluated whether the Tribe's criteria are sufficient to protect not only 304(a) fishable/swimmable goals, but also the Tribe's goal that tribal water quality be sufficient to support the traditional subsistence lifestyle.

As stated above, the Tribe generally relied on EPA's 2000 Human Health Methodology to derive human health criteria. The Tribe applied that methodology using EPA recommended default values, except for the specific variables for the specific pollutants discussed in Section V.D.3, 4 and 5 (below).

The 2000 Human Health Methodology allows states and tribes flexibility by providing scientifically valid options for developing criteria based on local or regional fish consumption rates. The 2000 Human Health Methodology suggests the following preference hierarchy for the data to be used in determining fish consumption rates: (1) local data, (2) data reflecting similar geography/population groups, (3) data from national surveys, and (4) EPA's default intake rates.

Traditional Lifestyle Studies

To implement its policy choice to develop water quality standards that protect traditional subsistence practices, the Tribe determined fish and drinking water consumption rates corresponding to traditional diet and cultural practices specific to the Spokane Reservation, using sources that were summarized as part of an exposure assessment,[21] as confirmed by traditional knowledge obtained from tribal members.

According to those sources, the Reservation is located at the confluence of the Spokane and Columbia Rivers. It is an arid region that is fairly pristine and undeveloped. It currently provides enough resources for some members to continue a traditional subsistence dietary lifestyle, and for all members to obtain traditional foods. The traditional lifestyle is governed by the seasons. Hunting, fishing, and gathering support nutritional, cultural, spiritual, and medicinal needs of the tribal members. Among families engaged in a subsistence lifestyle, the family members work in the field on a regular basis to keep the extended family unit stocked with a wide variety of plants and wildlife. While in the field, a subsistence consumer lives off the land by consuming surface and spring water, fish, wild plants and wildlife. In addition to time spent in hunting, fishing, or gathering, time is spent cleaning, processing, and preserving hides, drying vegetal food or medicines, and making a wide variety of items. A subsistence lifestyle (except for infants) involves participating in daily sweat lodge throughout the year. Based on these activities, the caloric needs of a tribal member range from 2,000 to 4,000 kilocalories (kcal) per day for adult males, depending on the level of activity, with 2,500 to 3,000 kcal representing a moderately active traditional outdoor lifestyle for tribal members.

Tribal Fish Consumption Rate

The Tribe uses a fish consumption rate of 865 g/d. The article by Harper et al. reviewed studies of the mid-Columbia River Indians and found that the original Spokane diet was based on salmon and included large and small game, roots, berries, and other plants. One study indicated that traditionally, 45% of the native Columbia Plateau dietary calories came from fish and game, with higher estimates for upriver tribes such as the Spokane Tribe.[22] Another study found that the most robust estimate of the salmon

[21] Harper, B.L., Flett B., Harris S., Abeyta C., Kirschner F. 2002. *TheSpokane Tribe's Multipathway Subsistence Exposure Scenario and Screening Level RME.* Society for Risk analysis, Risk Analysis Vol. 22. No. 3.

[22] Hunne, E.S. 1990. *Nch'i-Wana, The Big River: Mid-Columbia Indians and Their Land.* Seattle, WA: University of Washington Press.

intake by the Spokane Tribe was the "Walker estimate" of approximately 1,200 pounds per year,[23] which translates to approximately 1,492 g/d.[24] The Harper article concluded that this consumption rate would translate to 2,566 kcal/day from consumption of fish in estuaries (prior to migration).[25] The Harper article stated that the caloric content of salmon was reduced by about 1/3 after migrating to the Spokane area, resulting in approximately 1,600 kcal/day from fish (2,566 X 0.64).

The Harper article next sought to estimate an appropriate high fish diet for a tribal member practicing a traditional lifestyle today, as opposed to the estimate of historical consumption discussed above. The authors assumed that approximately 80 percent of a traditional diet today would be similar to a historical native diet. Based on this assumption caloric intake from fish would be approximately 1,300 kcal/d (0.8 × 1,600 kcal/day).[26] Furthermore, due to the construction of the Grand Coulee Dam, the anadromous fish runs have been destroyed, so there has been a shift in diet to Kokanee (land-locked sockeye salmon), Dolly varden, rainbow trout, whitefish, mussels, crayfish, and other species. The authors assumed a caloric content for sockeye salmon of 400 kcal/275 g. This would translate into a fish consumption rate of approximately 890 g/d, in order to maintain the caloric intake characteristic of a traditional subsistence lifestyle, given the fish currently available (1,300 kcal/d × 275g/400kcal).

Based on all of the above factors, as well as interviews with tribal members, Harper et al. estimated that a fish consumption rate of 885 g/d would be the realistic high fish consumption rate for the Spokane Tribe. The Tribe's proposed criteria are based on a fish consumption rate of 865 g/d, which is slightly lower than this estimated "high" rate, and well within the accuracy of the estimation methodology.

Tribal Drinking Water

The Tribe's criteria are also based on a drinking water intake rate of 4 L/d. The drinking water intake rate (DI) for the Confederated Tribes of the Umatilla Indian Reservation (CTUIR), 3 L/d for adults, was used as a starting point to determine the drinking water intake rate for the Spokane Tribe since the CTUIR reservation is also located in an arid region, and the DI was based on the water intake needs of a person engaged in the traditional lifestyle.[27] The CTUIR rate estimates an average intake rate based on interviews with CTUIR tribal members. The CTUIR intake rate is based on using 1L of water consumed at the home, 1L of water consumed from home to worksite, and 1L of water consumed at the worksite (i.e., field where tribal member live off the land and consume surface and spring water). In addition to the above activities, the traditional lifestyle for a Spokane Tribal member includes daily use of a sweat lodge for several hours. The Harper article estimated that an additional 1 L of water is needed to re-hydrate after using the sweat lodge, resulting in the assumed intake rate of 4 L/day.

SUMMARY

As discussed above, the Tribe's estimates of the fish consumption and water intake rates for a traditional subsistence lifestyle were based on (1) open peer-reviewed literature, (2) ethnographic documents and reports concerning traditional lifestyles and practices, and (3) confirmatory statements from tribally

[23] Scholz, A, O'Laughlin, K., Geist, D., Peone, D., Uehara, J., Fileds, L., Kleist, T., Zozaya, I., Peone, T., and Teesatuskie, K., 1985. *Compilation of Information on Sal mon and Steelhead Total Run Size, Catch, and Hydropower Related Losses in the Upper Columbia River Basin, Above Grand Coulee Dam. Fisheries Technical Report No. 2., Upper Columbian United Tribes Fisheries Center.* Cheney, WA:Eastern Washington University Department of Biology.

[24] 1,200 lb/yr X 454 g/lb ÷ 365.24 days/yr.

[25] Harper et al., p 518.

[26] The authors also tried to approximate the historic dietary balance which found that approximately 45% of caloric intake was from fish, and concluded that, based on a calorie intake of 2,500 to 3,000 kcal/day, this provided further support for a fish consumption intake rate of approximately 1,300 kcal/d.

[27] Harris, S.G. and Harper, B.L. 1997. A native American Exposure Scenario. *Risk Analysis,* 17: 789 – 785.

recognized cultural experts whose expertise derives from their traditional environmental knowledge. EPA concludes the FCR used by the tribe corresponds to obtaining approximately 2,000 to 4,000 kcal/day under subsistence conditions, around tribal lands. EPA also concludes that this estimate of caloric input could correspond to physiological needs while undertaking the subsistence lifestyle described. Finally, historical and ethnographic reports corroborate that the subsistence lifestyle described accurately corresponds to the traditional practices of the Spokane Tribe. EPA also believes a drinking water intake of 4L/d could be representative of the subsistence lifestyle in an arid environment with daily sweat lodge use.

D. EPA Action on New and Revised Human Health Criteria

1. EPA Approval Action on 160 Revised Human Health Criteria

The Tribe has developed and adopted 160 human health criteria using EPA's 2000 Human Health methodology, a fish consumption rate of 865 g/d, a drinking water intake of 4 L/d, and values for RfD, RSC, BW, BAF, CSF and risk level that are consistent with the default values that EPA utilized in deriving its national CWA § 304(a) human health criteria guidance values. The following table contains the 160 human health criteria:

Table 1: Human Health Criteria for Toxics (µg/L)

Compound	*Carcinogen?*	*Water & Organisms*	*Organisms Only*
Acenaphthene	*n*	*1.97E+01*	*2.01E+01*
Acrolein	*n*	*5.75E+00*	*5.87E+00*
Acrylonitrile	*n*	*4.33E-03*	*5.00E-03*
Aldrin (e)	*y*	*1.02E-06*	*1.02E-06*
Anthracene	*n*	*7.01E+02*	*8.09E+02*
Arsenic (h)	*n*	*9.51E-04*	*1.05E-03*
Benz(a)anthracene	*y*	*3.2E-04*	*3.7E-04*
Benzene	*y*	*2.84E-01*	*5.37E-01*
Benzidine	*y*	*3.82E-06*	*4.02E-06*
Benzo(a)pyrene	*y*	*3.2E-04*	*3.7E-04*
3,4-Benzo(b)fluoranthene	*y*	*3.2E-04*	*3.7E-04*
Benzo(k)fluoranthene	*y*	*3.2E-04*	*3.7E-04*
alpha BHC	*y*	*9.54E-05*	*9.88E-05*
beta BHC	*y*	*3.34E-04*	*3.46E-04*
Bis(2-chloroethyl) Ether	*y*	*6.38E-03*	*1.07E-02*
Bis(2-chloroisopropyl) Ether	*n*	*4.56E+02*	*1.31E+03*
Bis(2-chloromethyl)ether	*y*	*7.00E-05*	*5.84E-04*
Bis(2-ethylhexyl)phthalate	*y*	*4.29E-02*	*4.45E-02*
Bromoform	*y*	*1.22E+00*	*2.73E+00*
Butylbenzyl phthalate	*n*	*3.87E+01*	*3.91E+01*
Carbon tetrachloride	*y*	*2.66E-02*	*3.32E-02*
Chlorodibromomethane	*y*	*1.15E-01*	*2.57E-01*
Chloroform	*y*	*1.58E+00*	*3.54E+00*
2-Chloronaphthalene	*n*	*3.13E+01*	*3.20E+01*
2-Chlorophenol	*n*	*2.92E+00*	*3.02E+00*

Compound	Carcinogen?	Water & Organisms	Organisms Only
Chrysene	y	3.20E-04	3.70E-04
4,4'-DDD	y	6.29E-06	6.29E-06
4,4'-DDE	y	4.44E-06	4.44E-06
4,4'-DDT	y	4.44E-06	4.44E-06
Dibenz(a,h)anthracene	y	3.20E-04	3.70E-04
Dibutyl phthalate	n	8.64E+01	9.09E+01
1,3-(m)Dichlorobenzene	n	1.80E+01	1.95E+01
3,3-Dichlorobenzidine	y	5.68E-04	5.76E-04
Dichlorobromomethane	y	1.56E-01	3.48E-01
1,2-Dichloroethane	y	1.53E-01	7.41E-01
2,4-Dichlorophenol	n	5.36E+00	5.96E+00
1,2-Dichloropropane	n	1.40E-01	2.97E-01
Dieldrin (e)	y	1.08E-06	1.08E-06
Diethyl phthalate	n	8.34E+02	8.87E+02
2,4-Dimethylphenol	n	1.64E+01	1.73E+01
Dimethyl phthalate	n	1.99E+04	2.25E+04
2,4-Dinitrophenol	n	2.64E+01	1.08E+02
2,4-Dinitotoluene	y	3.06E-02	6.78E-02
2,3,7,8-TCDD (Dioxin)	y	1.04E-10	1.04E-10
1,2-Diphenylhydrazine	y	3.43E-03	4.06E-03
alpha Endosulfan	n	1.77E+00	1.80E+00
beta Endosulfan	n	1.77E+00	1.80E+00
Endosulfan sulfate	n	1.77E+00	1.80E+00
Endrin aldehyde	n	6.11E-03	6.12E-03
Fluoranthene	n	2.80E+00	2.81E+00
Fluorene	n	9.35E+01	1.08E+02
Heptachlor	y	1.60E-06	1.61E-06
Heptachlor epoxide	y	7.94E-07	7.94E-07
Hexachlorobenzene	y	5.82E-06	5.82E-06
Hexachlorobutadiene	y	1.40E-01	3.73E-01
Hexachloroethane	y	6.32E-02	6.65E-02
Indeno(1,2,3-cd)pyrene	y	3.20E-04	3.70E-04
Isophorone	y	9.46E+00	1.94E+01
Methyl bromide	n	1.35E+01	3.02E+01
2-Methyl-4,6-Dinitrophenol	n	3.12E+00	5.74E+00
Methylene chloride	y	1.95E+00	1.20E+01
Nickel	n	3.14E+01	3.44E+01
Nitrobenzene	n	5.38E+00	1.40E+01
N-Nitrosodimethylamine	y	3.41E-04	6.10E-02
N-Nitrosodi-n-propylamine	y	2.01E-03	1.02E-02
N-Nitrosodiphenylamine	y	1.17E-01	1.21E-01
N-Nitrosopyrrolidine	y	8.24E-03	7.01E-01
PCB Total	y	1.30E-06	1.30E-06
Pentachlorobenzene	n	3.04E-02	3.05E-02
Pentachlorophenol	y	4.32E-02	6.13E-02
Phenol	n	8.06E+03	3.47E+04
Pyrene	n	7.01E+01	8.09E+01

Compound	*Carcinogen?*	*Water & Organisms*	*Organisms Only*
Selenium (NTSWQS)	*n*	*4.29E+01*	*8.43E+01*
1,1,2,2-Tetrachloroethane	*y*	*4.20E-02*	*8.09E-02*
Tetrachloroethylene	*y*	*5.78E-02*	*6.65E-02*
Toxaphene	*y*	*5.61E-06*	*5.62E-06*
1,1,2-Trichloroethane	*y*	*1.56E-01*	*3.15E-01*
Trichloroethylene	*y*	*4.22E-01*	*6.06E-01*
2,4,6-Trichlorophenol	*y*	*4.76E-02*	*4.90E-02*
Zinc	*n*	*4.70E+02*	*5.17E+02*

EPA Action
In accordance with its CWA, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the Tribe's revised human health toxic criteria for the 160 human health criteria listed in Table 1 above.

EPA Rationale
EPA's WQS regulations at 40 CFR Part 131 require that criteria protect the designated uses. As noted previously, the Tribe's human health criteria apply to all waters on the reservation, including those protected for fishing, water supply, and recreation uses and, thus, must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect the Tribe's human health uses.

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether the Tribe's criteria protect the designated uses, EPA looked at the input values used by the Tribe and whether there was Tribal-specific information relative to each value that should be considered in the review. When calculating the criteria in Table 1, the Tribe used EPA's national default values for all inputs except the FCR and DI. As discussed above, EPA has found that the Tribe has appropriately considered local and regional data, (relevant to an objective that was within the Tribe's policy discretion to protect) when selecting input variables for the FCR and DI.

The 2000 Methodology document provides an extensive technical basis and justification as to how EPA's recommended human health criteria and methodology adequately protect human health uses. The Tribe's human health criteria identified in Table 1 were developed consistent with these recommendations, therefore, EPA has determined that these criteria protect human health uses in accordance with 40 CFR § 131.11(a)(1).

In any future updates the Tribe makes to its human health criteria, EPA recommends the Tribe consider using an RSC value of 0.2, or an appropriate alternative up to 0.8, rather than 1 when calculating non-carcinogen criteria.

2. EPA Disapproval of the Deletion of Asbestos Human Health Criterion

In 2003, the Tribe adopted an asbestos criterion (7 MFL) for the protection of human health into Table 1 of their water quality standards. The water quality standards specifically state that the criteria in Table 1 are for the protection of human health. Additionally, the Tribe adopted the same asbestos criterion (7 MF/L) into Table 2 of their water quality standards for the protection of primary contact ceremonial

uses. Many of the criteria in Table 2 are higher than the concentrations necessary to protect human health so it is not clear that the criteria in Table 2 were established to protect human health. In the 2010 water quality standards revision, the Tribe removed the water and organisms human health criterion for asbestos (7 MF/L) from Section 6, Table 1 of their water quality standards. However, the asbestos criterion in Table 2 was retained.

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's removal of the water and organisms human health toxic criteria for asbestos from Table 1 of the Tribe's water quality standards.

EPA Rationale
As discussed previously, for human health protection, EPA recommends that states and tribes apply human health criteria for toxics to all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route), recreation, and/or aquatic life protection (and therefore a potential fish consumption route). Asbestos is a priority pollutant and EPA's 304(a) recommendation for the protection of human health (water and organisms) is 7 MF/L.
While the Tribe has retained an asbestos criterion in Table 2, it is not clear that Table 2 criteria are intended to protect human health or aquatic life. Given the lack of clarity of the intended level of protection in Table 2, EPA does not view this Table as providing the same level of protection for human health as Table 1.

The Tribe has not provided any rationale to show that removing the asbestos criterion from Table 1will still result in the protection of human health; therefore, EPA is disapproving the removal of the human health (water and organism) asbestos criterion from Table 1.

Remedy to Address EPA Disapproval
To address this disapproval, the Tribe must adopt human health criteria that are based on a sound scientific rationale and protect human health uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Adopt EPA's 304(a) recommendation for human health (water and organisms) of 7 MF/L into Table 1.
- Provide a sound scientific rationale to establish that an asbestos criterion is not necessary for the protection of human health uses.
- Develop an alternative human health criterion for the consumption of water and organisms and provide a sound scientific justification to establish that it is protective of human health uses.

3. EPA Disapproval Action for Dichlorodiflouromethane Human Health Criteria

The Tribe revised their human health criteria for dichlorodifluoromethane to the following:

Table 2. Human Health for Toxic Pollutants (µg/L)

Compound	*Carcinogen?*	*Water & Organisms*	*Organisms Only*
Dichlorodiflouromethane	*n*	*1.93E+03*	*4.32E+03*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revised human health toxic criteria for the dichlorodifluoromethane human health criteria listed in Table 2 above.

EPA Rationale
EPA's WQS regulations at 40 CFR Part 131 require that criteria protect the designated uses. As noted previously, the Tribe's human health criteria apply to all waters on the reservation, including those protected for fishing, water supply and recreational uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect the Tribe's human health uses.

The Tribe used EPA's 2000 Human Health Methodology to develop the human health criteria for dichlorodifluoromethane. As part of evaluating whether the Tribe's criteria protect the designated uses, EPA looked at the input values used by the Tribe and whether there was adequate scientific information to support the use of each value.

For dichlorodifluoromethane the Tribe used the equations for non-carcinogens to develop the human health criteria. The following variables were used:

RfD = 0.2 mg/kg/d	RSC = 1	BW = 70 kg
DI = 4 L/d	FCR = 865 g/d	BAF = 3.75 L/kg

The values the Tribe used for RfD, BW, DI, FCR are consistent with EPA recommendations. The Tribe has not provided any scientific information to support the use of the non-carcinogen equations, or for the values used for the BAF or RSC. Additionally, in EPA's *Ambient Water Quality for Halomethanes* (EPA 440/5-80-051, October 1980) dichlorodifluoromethane was treated as a carcinogen.

Criteria must be based on sound scientific rationale and contain sufficient parameters or constituents to protect designated uses. The Tribe has not provided supporting documentation to show that the values used for the RSC and BAF are based on sound science and will be protective of human health or if using the non-carcinogen equation is appropriate. Therefore, EPA is disapproving the human health criteria for dichlorodifluoromethane.

Remedies to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt human health criteria that are based on a sound scientific rationale and protect human health uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- EPA has not developed human health criteria for dichlorodifluoromethane using the 2000 Human Health Methodology. For a pollutant for which EPA has published a recommended Section 304(a) water quality criterion based on the 1980 Methodology and for which EPA has not promulgated a Maximum Contaminant Level Goal[28] (MCLG), EPA recognizes the current Section 304(a) water

[28] The MCLG is the level of a contaminant in drinking water below which there is no known or expected risk to health. EPA does not recommend using MCLs which are set as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration.

quality criterion (see 65 FR 66450). Therefore, the Tribe may use EPA's 1980 human health criteria developed in October 1980 (*Ambient Water Quality Criteria for Halomethanes*, EPA 440/5-80-051).

- Resubmit the previously adopted human health criteria with a sound scientific rationale to establish that the use of the non carcinogen equation and the application of the input values are protective of human health uses.

4. EPA Disapproval Action for Mercury Human Health Criteria

The Tribe revised their human health criteria for mercury to the following:

Table 3. Human Health for Toxic Pollutants (µg/L)

Compound	*Carcinogen?*	*Water & Organisms*	*Organisms Only*
Mercury	*n*	*1.1E-03*	*1.1E-03*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revised human health toxic criteria for mercury listed in Table 3 above.

EPA Rationale
EPA's WQS regulations at 40 CFR Part 131 require that criteria protect the designated uses. As noted previously, the Tribe's human health criteria apply to all waters on the reservation, including those protected for fishing, water supply and recreational uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect the Tribe's human health uses.

The Tribe used EPA's 2000 Human Health Methodology to develop the human health criteria for mercury. As part of evaluating whether the Tribe's criteria protect the designated uses, EPA looked at the input values used by the Tribe and whether there was adequate scientific information to support the use of each value.

For mercury, the Tribe used the equations for non-carcinogens to develop the human health criteria. The following variables were used:

RfD = 0.0001 mg/kg/d	RSC = 1	BW = 70 kg
DI = 4 L/d	FCR = 865 g/d	BAF = 7343 L/kg

The values the Tribe used for RfD, BW, DI, FCR are consistent with EPA recommendations.

The BAF value is the Practical Bioconcentration Factor (PBCF, weighted average) used to develop human health criteria for mercury in California waters (see 62 FR 42179).[29] The value used is based on a weighted average of the amount of fish eaten from fresh waters, estuarine-coastal waters, and open oceans.

[29] The PCBFs were derived in 1980 and are: 5500 for fresh water, 3765 for estuarine-coastal waters, and 9000 for open oceans (see pages C-100-1 of *Ambient Water Quality Criteria for Mercury* (EPA 440/5-80-058)). A weighted average is calculated to take into account the average consumption from the three waters.

EPA's current 304(a) guidance recommends methylmercury be expressed as a fish tissue concentration. It was calculated using the criterion equation in the 2000 Human Health Methodology. The equation was rearranged to result in a protective concentration in fish tissue rather than water (see *Water Quality Criterion for the Protection of Human Health: Methylmercury*, EPA-823-R-01-001, January 2001).

The Tribe may adopt a water column number for mercury, however, the criteria must be based on sound scientific rationale and contain sufficient parameters or constituents to protect designated uses. The Tribe's submission lacked supporting documentation to show that the values used for the RSC and BCF are based on sound science and will be protective of human health. For example, the Tribe has not provided information to show that the PBCF on tribal land is similar to that of California. Therefore, EPA is disapproving the human health criteria for mercury.

Remedies to Address EPA's Disapproval

To address this disapproval, the Tribe must adopt human health criteria that are based on a sound scientific rationale and protect human health uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- EPA used the 2000 Human Health Methodology to develop a 304(a) criterion for methylmercury and expressed the criterion as a fish tissue value (mg/kg). The Tribe may adopt EPA's current 304(a) recommendation for methylmercury fish tissue (as modified by the Tribal fish consumption rate), and implement it without water column translation; or adopt a water column concentration, using the translation methodologies outlined in section 3.1.3.1 of EPA's *Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion* (EPA 823-R-10-001, April 2010); or use a combination of the above two approaches. For example, the Tribe could adopt a fish tissue criterion and implement it without water column translation in some waters and with water column translation in other waters.

  Site specific data for translating the fish tissue criterion to water column concentration, where needed, will take time to collect. Therefore, the Tribe should consider retaining their existing water column criteria (or adopting an updated water column criterion which reflects their new fish consumption rate), on a temporary basis, particularly for waters where there is a relatively high direct water input of mercury. In such a case where the tribe has retained the existing water column criteria, permits include both a limit based on the numeric water column criterion and other requirements based on the fish tissue criterion (see Chapter 7 of EPA's *Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion*).

- Resubmit the previously adopted human health criteria with a sound scientific rationale to establish that the application of input values is protective of human health uses.

5. EPA Disapproval Action of 45 New and Revised Human Health Criteria

The Tribe has developed and adopted 45 human health criteria using EPA's 2000 Human Health methodology, a fish consumption rate of 865 g/d, a drinking water intake of 4 L/d, and values for BW, CSF, and risk level that are consistent with the default values that EPA used in deriving its national CWA § 304(a) human health criteria guidance values. However, the Tribe used values for the RfD,

RSC, and/or BAF(BCF) that were not consistent with the default values that EPA used in deriving its national CWA § 304(a) human health criteria guidance values, and the Tribe did not explain how these values were derived. The following table contains these 45 human health criteria:

Table 4. Human Health for Toxic Pollutants(µg/L)

Compound	*Carcinogen?*	*Water & Organisms*	*Organisms Only*
Antimony	*n*	*5.76E+00*	*3.24E+01*
gamma BHC	*y*	*4.53E-04*	*4.69E-04*
Chlordane	*y*	*4.41E-06*	*4.41E-06*
Chlorobenzene	*n*	*1.08E+02*	*1.57E+02*
Cyanide	*n*	*2.88E+02*	*1.62E+03*
1,2-(o)Dichlorobenzene	*n*	*1.21E+02*	*1.31E+02*
1,4-(p)Dichlorobenzene	*n*	*1.80E+01*	*1.95E+01*
1,2-trans-Dichloroethylene	*n*	*2.61E+02*	*1.02E+03*
1,1-Dichloroethylene	*y*	*1.32E-02*	*2.41E-02*
1,3-Dichloropropylene	*n*	*3.72E+00*	*1.27E+01*
Endrin	*n*	*6.11E-03*	*6.12E-03*
Ethylbenzene	*n*	*1.92E+02*	*2.16E+02*
Hexachlorocyclopentadiene	*n*	*6.32E+01*	*1.31E+02*
Thallium	*n*	*4.45E-02*	*4.62E-02*
Toluene	*n*	*1.06E+03*	*1.51E+03*
1,2,4-Trichlorobenzene	*n*	*6.82E+00*	*7.10E+00*
Vinyl chloride	*y*	*8.03E-01*	*3.98E+00*
Cadmium	*n*	*8.75E+00*	---
Chlorine	*n*	*1.75E+03*	---
Chlorpyrifos	*n*	*5.25E+01*	---
Chromium III	*n*	*2.63E+04*	---
Chromium VI	*n*	*5.25E+01*	---
Copper	*n*	*1.21E+01*	*1.21E+01*
Methoxychlor	*n*	*1.65E+00*	*1.69E+00*
Tributyltin	*n*	*1.73E-03*	*1.73E-03*

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revised human health toxic criteria for the 45 human health criteria listed in Table 4 above.

EPA Rationale

EPA's WQS regulations at 40 CFR Part 131 require that criteria protect the designated uses. As noted previously, the Tribe's human health criteria apply to all waters on the reservation, including those protected for fishing, water supply, and recreational uses and, thus, must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect the Tribe's human health uses.

As part of evaluating whether the Tribe's criteria protect the designated uses, EPA looked at the input values used by the Tribe and whether there was Tribal-specific information relative to each value that should be considered in the review. The Tribe used some of the EPA's "national default values" but EPA found that the Tribe did not appropriately consider data in selecting some input variables for use in

deriving the criteria identified in Table 4 above. Specifically, the Tribe used input variables for the RfD, RSC, CSF and BAF without providing sufficient scientific support for the values used.
The following tables show the input values that the Tribe used and the values that EPA recommends.

Table 5: CSF Value Used in Developing Human Health Criteria

Compound	*CSF*	
	EPA recommended value	*Value Used by Tribe*
Chlordane	0.35	1.3
gamma BHC (Lindane)	See Footnote 1	1.3
1,1-Dichloroethylene	See Footnote 1	0.6
1,3-Dichloropropylene	0.1	Not used, see footnote 2
Vinyl chloride	1.4	0.0174
1. The Tribe calculated gamma BHC and 1,1 dichlorethylene using the carcinogen equations, however these parameters are non-carcinogens, therefore a CSF value is not used when developing the criteria. 2. The Tribe calculated 1,3-Dichloroprpylene using the non-carcinogen equations. The parameter is a carcinogen and the equations for carcinogens should have been used to calculate the criteria.		

Table 6: RfD Value Used in Developing Human Health Criteria

Compound	*RfD*	
	EPA recommended value	*Value Used by Tribe*
gamma BHC (Lindane)	0.0047	No value used
1,1-Dichloroethylene	0.05	No value used
1,3-Dichloropropylene	See Footnote 1	0.0003
Hexachlorocyclopentadiene	0.006	0.007
Chlorpyrifos	See Footnote 2	0.003
Copper	See Footnote 2	0.15
Cyanide	0.0006	0.02
Toluene	0.08	0.2
1. 1,3 dichloropropylene is a carcinogen therefore an RfD is not used when calculating the criterion. 2. Data is not available to calculate an RfD.		

01055

Table 7: RSC value Used in Developing Human Health Criteria

Compound	*RSC*	
	EPA recommended value	*Value Used by Tribe*
Antimony	0.4	1
gamma BHC (Lindane)	0.2 – 0.8	1
Chlorobenzene	0.2	1
Cyanide	0.2	1
1,2-(o)Dichlorobenzene	0.2	1
1,4-(p)Dichlorobenzene	0.2	1
1,2-trans-Dichloroethylene	0.2	1
1,1-dichloroethylene	0.2	1
Endrin (e)	0.2	1
Ethylbenzene	0.2	1
Hexachlorocyclopentadiene	0.2	1
Thallium	0.2	1
Toluene	0.2	1
1,2,4-Trichlorobenzene	0.2	1
Cadmium	0.25[1]	1
Chlorine	0.2	1
Chlorpyrifos	0.2	1
Chromium III	0.2	1
Chromium VI	0.2	1
Copper	0.2	1
Methoxychlor	0.2	1
Tributyltin	0.2	1
1. RSC is based on the RSC used to develop the cadmium drinking water MCLG.		

Table 8: BAF Used in Developing Human Health Criteria

Compound	*BAF*	
	EPA recommended value	*Value Used by Tribe*
Cadmium	See Footnote 1	0
Chlorine	See Footnote 1	0
Chlorpyrifos	See Footnote 1	0
Chromium III	See Footnote 1	0
Chromium VI	See Footnote 1	0
Copper	See Footnote 1	0
Methoxychlor	See Footnote 2	240
Tributyltin	See Footnote 1	14000
1. EPA does not have data to form a basis for a recommendation and the tribe has not provided any information to support the values used. 2. 8,963 L/kg for tropic level 2, 8860 L/kg for trophic level 3, and 9,001 L/kg for trophic level 4.		

01056

The water quality standards regulations at 40 CFR § 131.11(a) state that new or revised criteria must be based on a sound scientific rationale and contain sufficient parameters or constituents to protect designated uses. To ensure the Tribe's criteria are consistent with this requirement, EPA evaluated the appropriateness of the variables used by the Tribe in deriving its criteria: specifically, whether the variables were based on sound science and led to criteria that would protect human health endpoints consistent with the designated uses of tribal waters. The 2000 Human Health Methodology provides an extensive technical basis and justification as to how EPA's recommendations adequately protect human health. Each of the criteria identified in Table 4 of the Tribe's submission lacked the supporting documentation to show that one or more of the variables (identified in Tables 5 through 8) used to develop the criteria are based on sound science and lead to criteria that are protective of human health uses. Therefore, EPA is disapproving each of the human health criteria contained in Table 4.

Remedies to Address EPA's Disapproval

To address this disapproval, the Tribe must adopt human health criteria that are based on a sound scientific rationale and protect human health uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- For the following parameters, the Tribe may revise the water and organisms and the organisms only human health criteria by incorporating the input values recommended in EPA's 304(a) guidance, as shown below.

Antimony:	RSC = 0.4
Gamma BHC (Lindane):	RfD = 0.0047, use non-carcinogen equations, RSC = 0.2, or an appropriate alternative up to 0.8
Chlordane:	CSF = 0.35
Chlorobenzene:	RSC = 0.2
Cyanide:	RfD = 0.0006, RSC = 0.2
1,2-(o)Dichlorobenzene:	RSC = 0.2
1,4-(p)Dichlorobenzene:	RSC = 0.2
1,2-trans-Dichloroethylene:	RSC = 0.2
1,1-Dichloroethylene:	RfD = 0.05, RSC = 0.2, use non-carcinogen equations
1,3-Dichlorpropylene	CSF = 0.1, risk level = 1×10^{-6}, use carcinogen equations
Endrin:	RSC = 0.2
Ethylbenzene:	RSC = 0.2
Hexachlorocyclopentadiene:	RfD = 0.006, RSC = 0.2
Thallium:	RSC = 0.2
Toluene:	RfD = 0.08, RSC = 0.2
1,2,4 Trichlorobenzene:	RSC = 0.2
Vinyl chloride:	CSF = 1.4

- For the human health criteria associated with **cadmium, copper, chromium III, and chromium VI**: EPA is in the process of developing draft BAFs values for these parameters and expects to have these drafts values available by the beginning of 2014. When these draft values are available, the Tribe may use this information to update their HH criteria for these parameters.

- For the human health criteria associated with **methoxychlor**, the following BAFs may be used when developing the human health criteria: 8,963 L/kg for trophic level 2, 8860 L/kg for trophic level 3, and 9,001 L/kg for trophic level 4.

01057

- The Tribe may resubmit the previously adopted human health criteria for any of the 45 pollutants listed in Table 4 with a sound scientific rationale to establish that the application of each input value is protective of human health uses. Alternatively, the Tribe may re-evaluate any of the criteria to determine if the criterion is necessary for the protection of human health uses on the reservation.

VI. AQUATIC LIFE CRITERIA

A. EPA Action on Freshwater Acute and Chronic Aquatic Life Criteria for Ammonia

In the 2010 water quality standards adoption, the Tribe sought to correct mistakes for its aquatic life ammonia criteria. The ammonia criteria were initially adopted into Table 1 of the Tribe's water quality standards in 2003. The ammonia values adopted in 2003 were expressed in µg/L (rather than mg/L) and two footnotes were referenced (f and g) which provide the equations used to develop the values in the table below. The 2003 values were:

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Ammonia (f, g)	*n*	*24.1*	*4.15*	-----	-----

In the 2010 adoption the ammonia values are still expressed in µg/L but the following changes were made (new language is underlined):

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Ammonia, <u>unionized</u> (f, g)	*n*	*<u>2.4E+04</u>*	*<u>5.9E+03</u>*	-----	-----

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revisions to the freshwater acute and chronic aquatic life ammonia criteria.

EPA Rationale
In 2003, the Tribe adopted the EPA's 1999 304(a) recommendations for freshwater acute and chronic aquatic life criteria for ammonia. The 1999 recommendations were the most recent 304(a) recommendation when the Tribe adopted their water quality criteria. In 2003, the Tribe adopted the correct equations into footnotes f and g, however, they incorrectly identified the metric associated with the criteria as µg/L rather than mg/L.

The Tribe sought to correct this error in their 2010 water quality standards adoption. However, in trying to correct the error several other errors were made, including the following:

(1) The form of ammonia was changed from total ammonia to un-ionized ammonia. This change effectively increased the allowable amount of un-ionized ammonia (the more toxic form of

ammonia) than was recommended by EPA's 1999 304(a) recommendation. The Tribe did not provide any scientific rationale to show that using the equations as un-ionized ammonia is protective of aquatic life uses.

(2) The ammonia value in the table was changed to µg/L, however, using the equations in footnotes f and g will provide a result mg/L. However, this is not stated anywhere in either footnote f or g, so there is no indication that the result of the equations in f and g must be multiplied by 1,000 in order to get a final result in µg/L. Therefore, simply changing the value in Table 1 did not address the error the Tribe was trying to correct.

The equation for the chronic criterion in µg/L would be:

$$\left(\left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right)X\left(\text{MIN }(2.85, 1.45 \text{ X } 10^{0.026 \text{ X } (250-T)})\right)\right) \text{ X } 1000$$

The equation for the acute criterion in µg/L would be:

$$\left(\frac{0.275}{1+10^{7.204-pH}}+\frac{39}{1+10^{pH-7.204}}\right) \text{ X } 1000$$

(3) The chronic ammonia value in Table 1 is in error and the chronic criterion should be 4.15 mg/L (or 4150 µg/L). The Tribe used the incorrect equation when trying to develop the criterion value.

Furthermore on August 22, 2013 EPA published its revised recommended water quality criteria for ammonia. The acute and chronic criteria are more stringent than the 1999 304(a) recommended criteria due to the new toxicity data for freshwater molluscs that are very sensitive to ammonia.

In developing recommendations under § 304(a) of the CWA, EPA bases its criteria on approximately the 5th percentile genera for a given pollutant, which is often the four or five most sensitive genera.[30] Based on the toxicity data, the most sensitive genera used to develop the new acute criterion recommendation are freshwater molluscs. This stands in contrast to the 1999 304(a) recommendation where, in the absence of the more recent mollusc data, the most sensitive genera used to develop the acute criterion were fish, which now appear to be less sensitive to ammonia than freshwater molluscs.

Similarly, based on the available acquired chronic toxicity data, three of the four most sensitive genera used to develop the 2013 recommended chronic criterion were freshwater molluscs. This stands in contrast to the 1999 304(a) recommendation, where only one of the four most sensitive genera used to develop the chronic criterion was a mollusc. The most important difference between the calculation of the 2013 recommendations for chronic criteria and the 1999 304(a) recommendation is the more recent

[30] As per EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection Of Aquatic Organisms and Their Uses* (PB85-227049, 1985), whenever there are 59 or greater GMAVs in the acute criteria dataset, the FAV is calculated using the four GMAVs which have cumulative probabilities closest to 0.05. In the draft 2009 update of the acute water quality criteria for ammonia, the four GMAVs with cumulative probabilities closest to 0.05 are sensitivity rank 2-5. If there are fewer than 59 GMAVs, the four lowest GMAVs are used to calculate the FAV regardless of cumulative probabilities.

data for molluscs, particularly freshwater mussels which appear to be more sensitive to ammonia than fish (*Draft 2009 Update Aquatic Life Ambient Water Quality Criteria for Ammonia – Freshwater,* December 2009).

Freshwater mussels are widely distributed throughout Washington State (*Freshwater Mussels of the Pacific Northwest*, Ethan Nedeau, Allan K. Smith, Jen Stone, U.S. Fish and Wildlife Service), and each of the Tribe's Class Uses (i.e., Class AA, Class A, and Lake Class) specifically protect molluscs and Class AA waters also protect mussels. Given the wide distribution of freshwater mussels in Washington State, the Tribe's protection of molluscs (and mussels), and toxicity data showing that freshwater mulloscs are particularly sensitive to ammonia, there is not a sound scientific rationale demonstrating that the Tribe's submitted ammonia criteria protect the designated aquatic life uses. Therefore the criteria are inconsistent with CWA § 303(c) and 40 CFR § 131.11.

Remedies to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt ammonia criteria that are based on a sound scientific rationale and protect the Tribe's designated aquatic life uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Revise the ammonia criteria to be consistent with EPA's *Aquatic Life Ambient Water Quality Criteria for Ammonia – Freshwater, 2013* (EPA 822-R-13-001).

- Revise the ammonia criteria to ensure protection of the Tribe's designated aquatic life uses. Also supply a sound scientific rationale to explain why the alternative ammonia criteria are protective of the Tribe's designated aquatic life uses, taking into account any data on freshwater molluscs.

Freshwater Acute and Chronic Ammonia Aquatic Life Criteria Currently in Effect
Until EPA approves or promulgates numeric acute and chronic aquatic life criteria for ammonia, the previously approved acute and chronic aquatic life criteria are in effect for CWA purposes. The criteria are expressed as total ammonia (as mg N/L):

$$\text{CMC (mg/L)} = \left(\frac{0.275}{1+10^{7.204-pH}} + \frac{39}{1+10^{pH-7.204}}\right)$$

$$\text{CCC (mg/L)} = \left(\frac{0.0577}{1+10^{7.688-pH}} + \frac{2.487}{1+10^{pH-7.688}}\right) \text{X MIN } (2.85, 1.45\ 10^{0.026\ \text{X}\ [25\ -\ T]})$$

B. EPA Action on Freshwater Chronic Aquatic Life Criteria for Iron

In their 2010 water quality standards adoption, the Tribe removed the chronic aquatic life criterion for iron of 1.00 E+03 µg/L, which was originally adopted in its 2003 water quality standards.

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's removal of the freshwater chronic aquatic life criterion for iron.

EPA Rationale
The chronic aquatic life criterion of 1.00E+03 µg/L is the most recent 304(a) recommendation. The Tribe has not provided a scientific justification to show that the aquatic life uses on the Reservation will

be protected in the absence of an iron criterion. EPA has determined that the removal of the chronic aquatic life criterion for iron is inconsistent with CWA § 303(c) and 40 CFR § 131.11.

Remedies to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt a freshwater chronic aquatic life iron criterion that is based on a sound scientific rationale and protects the Tribe's designated aquatic life uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Adopt iron criterion to be consistent with EPA's 304(a) criterion (i.e., 1000 µg/L).

- Provide a sound scientific rationale to explain why removing the chronic criterion for iron is protective of the Tribe's designated aquatic life uses.

Freshwater Chronic Aquatic Life Iron Criterion Currently In Effect
Until EPA approves or promulgates a numeric chronic aquatic life criterion for iron, the previously approved aquatic life chronic criterion for iron is in effect for CWA purposes. The chronic criterion is 1.00E+03 µg/L.

C. EPA Action on Freshwater Acute and Chronic Aquatic Life Criteria for Pentachlorophenol

In the 2010 water quality standards adoption, the Tribe changed the values for pentachlorophenol in Section 6, Table 1 but retained the same equations in footnote n. Specifically, the following changes were made (new language is underlined):

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Pentachlorophenol (n)	*y*	*9.1E+00*	*5.7E+00*	-----	-----

The 2003 water quality standards contained the following values for pentachlorophenol in Section 6, Table 1:

Compound	*Carcinogen?*	*Acute (a) Criteria*	*Chronic (b) Criteria*	*Water & Organisms*	*Organisms Only*
Pentachlorophenol (n)	*y*	*2.03E+01*	*1.28E+01*	-----	-----

Footnote n was referenced and it provides the equations used to develop the pentachlorophenol values indicated in the table above (footnote n also states that the values were derived using a pH value of 7.8).

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revisions to the freshwater acute and chronic aquatic life values for pentachlorophenol contained in Section 6, Table 1.

EPA Rationale
EPA is disapproving the values adopted in Section 6, Table 1 because they do not provide the correct value in accordance with the associated equations found in footnote n, and it is not clear which criteria are the correct, applicable values (i.e., the values in Table 1 or the values resulting from the equations in footnote n).

Remedy to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt the appropriate values into Section 6, Table 1 based on the equations found in footnote n (i.e., acute criterion is 2.03E+01 and the chronic criterion is 12.8E+01).

D. EPA Action on Freshwater Chronic Aquatic Life Criteria for Tributyltin

In the 2010 water quality standards adoption, the Tribe changed the chronic aquatic life criteria for tributyltin from 0.063 µg/L to 0.63 µg/L (6.3E-01) in Section 6, Table 1.

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revisions to the freshwater chronic aquatic life values for tributyltin contained in Section 6, Table 1.

EPA Rationale
The chronic aquatic life criterion of 0.072 µg/L is the most recent 304(a) recommendation. The Tribe has not provided a scientific justification to show that the aquatic life uses on the Reservation will be protected with the revised tributyltin criterion. EPA has determined that the revised chronic aquatic life criterion for tributyltin is inconsistent with CWA § 303(c) and 40 CFR § 131.11.

Remedies to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt a chronic tributyltin criterion that is based on a sound scientific rationale and protects the Tribe's designated aquatic life uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Adopt a chronic criterion to be consistent with EPA's 304(a) criterion (i.e., 0.072 µg/L).

- Provide a sound scientific rationale to explain why the chronic criterion for tributyltin is protective of the Tribe's designated aquatic life uses.

Freshwater Chronic Aquatic Life Tributyltin Criterion Currently In Effect
Until EPA approves or promulgates a numeric chronic aquatic life criterion for tributyltin the previously approved aquatic life chronic criterion is in effect for CWA purposes. The chronic criterion is 0.063 µg/L.

E. EPA Action on Minor Revisions to Aquatic Life Criteria

In the 2010 water quality standards adoption, the Tribe rounded the following aquatic life criteria to two significant figures:
Lead (acute and chronic)
Nickel (acute)
Silver (acute)
Zinc (acute and chronic)

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the Tribe's revisions to the freshwater aquatic life criteria contained in Section 6, Table 1 and as listed above.

EPA Rationale
The Tribes changes are consistent with EPA recommendation to round criteria to two significant figures (86 FR 22236).

VII. TEMPERATURE CRITERIA IN SECTION 9

A. EPA's Action On Revised Temperature Criteria for Class AA Waters

The following presents the new language contained in Section 9 Paragraph 1(c)(iv), of the WQS. Deleted text indicates text that was removed and new text is underlined and indicates the language that was added by the 2010 water quality standards adoption.

> *(iv) ~~Water used for spawning or rearing by naturalized populations of indigenous salmon or trout. Not to exceed a 7-day average of the daily maximum temperature values greater than 16.5 C from June 1 to September 1. Not to exceed a 7-day average of the daily maximum temperature values greater than 13.5 C between September 1 and October 1 and between April 1 and June 1, and not to exceed 11 C from October 1 to April 1; with no single daily maximum temperature exceeding 18.5 C. Exception for Non-Anadromous Rainbow and Redband Trout. In waters where the only salmonid present is non-anadromous form of naturalized rainbow or redband trout. Temperatures from June 1 to September 1 may be allowed to reach a 7-day average of the daily maximum temperatures of 18.5 C.~~ Temperatures from June 1 to September 1 may be allowed to reach a 7-day average of the daily maximum (7-DADM) temperatures of 16.5 C. Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st. The 7-DADM temperature shall not exceed 11°C between October 1st and March 31st.*

Table 5, which is referenced in the above provision is found in Section 9 and is provided below:

Table 5. Temperature Standards (degree C).

Date	Class AA 16.5 Standard	Class A 18.5 Standard
01-Apr	11.09	11.12
02-Apr	11.18	11.25
03-Apr	11.27	11.37
04-Apr	11.36	11.49
05-Apr	11.45	11.61
06-Apr	11.54	11.74
07-Apr	11.63	11.86
08-Apr	11.72	11.98
09-Apr	11.81	12.11
10-Apr	11.90	12.23
11-Apr	11.99	12.35
12-Apr	12.08	12.47
13-Apr	12.17	12.60
14-Apr	12.26	12.72
15-Apr	12.35	12.84
16-Apr	12.44	12.97
17-Apr	12.53	13.09
18-Apr	12.62	13.21
19-Apr	12.71	13.34
20-Apr	12.80	13.46
21-Apr	12.89	13.58
22-Apr	12.98	13.70
23-Apr	13.07	13.83
24-Apr	13.16	13.95
25-Apr	13.25	14.07
26-Apr	13.34	14.20
27-Apr	13.43	14.32
28-Apr	13.52	14.44
29-Apr	13.61	14.56
30-Apr	13.70	14.69
01-May	13.80	14.81
02-May	13.89	14.93
03-May	13.98	15.06
04-May	14.07	15.18
05-May	14.16	15.30
06-May	14.25	15.43
07-May	14.34	15.55
08-May	14.43	15.67
09-May	14.52	15.80
10-May	14.61	15.92
11-May	14.70	16.04
12-May	14.79	16.16
13-May	14.88	16.29
14-May	14.97	16.41
15-May	15.06	16.53
16-May	15.15	16.66
17-May	15.24	16.78
18-May	15.33	16.90

Date	Class AA 16.5 Standard	Class A 18.5 Standard
01-Sep	16.32	18.25
02-Sep	16.13	18.00
03-Sep	15.95	17.75
04-Sep	15.77	17.50
05-Sep	15.58	17.25
06-Sep	15.40	17.00
07-Sep	15.22	16.75
08-Sep	15.03	16.50
09-Sep	14.85	16.25
10-Sep	14.67	16.00
11-Sep	14.48	15.75
12-Sep	14.30	15.50
13-Sep	14.12	15.25
14-Sep	13.93	15.00
15-Sep	13.75	14.75
16-Sep	13.57	14.50
17-Sep	13.38	14.25
18-Sep	13.20	14.00
19-Sep	13.02	13.75
20-Sep	12.83	13.50
21-Sep	12.65	13.25
22-Sep	12.47	13.00
23-Sep	12.28	12.75
24-Sep	12.10	12.50
25-Sep	11.92	12.25
26-Sep	11.73	12.00
27-Sep	11.55	11.75
28-Sep	11.37	11.50
29-Sep	11.18	11.25
30-Sep	11.00	11.00

19-May	15.42	17.02
20-May	15.51	17.15
21-May	15.60	17.27
22-May	15.69	17.39
23-May	15.78	17.52
24-May	15.87	17.64
25-May	15.96	17.76
26-May	16.05	17.89
27-May	16.14	18.01
28-May	16.23	18.13
29-May	16.32	18.25
30-May	16.41	18.38
31-May	16.50	18.50

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA is approving part of the revised language and disapproving part of the revised language. Specifically EPA approves the revised language in the first and last sentence in Paragraph 1(c)(iv) as a non-substantive change. This language is as follows:

> *Temperatures from June 1 to September 1 may be allowed to reach a 7-day average of the daily maximum (7-DADM) temperatures of 16.5 C…… The 7-DADM temperature shall not exceed 11°C between October 1st and March 31st.*

The language above is an editorial change that does not change the temperature criteria in effect between June 1 to September 1, and October 1 to March 31 that EPA previously approved in 2003.

EPA disapproves the revisions to the temperature criteria from September 1st to September 30th and from April 1st to May 31st. Specifically, EPA disapproves the revised language in the second sentence in Paragraph 1(c)(iv), which states:

> *…Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st…*

EPA is also disapproving the Class AA temperature criteria in Table 5.

EPA Rationale

The Tribal water quality standards include the following aquatic life uses in their Class AA waters:

Fish and Shellfish, including:
- Salmonid migration, rearing, spawning, and harvesting.
- Other fish migration rearing, spawning, and harvesting.
- Clam and mussel rearing and, spawning, and harvesting.
- Mollusks, crustaceans and other shellfish rearing, spawning and harvesting.
- The table below summarizes the revisions made to the 2003 WQS:

The table below summarizes the revisions made to the 2003 WQS:

2003 Water Quality Standards		2010 Water Quality Standards	
Time Period	***Criteria***	***Time Period***	***Criteria***
September 1 – October 1	13.5 °C	**September 1 – September 30[1]**	16.32 °C – 11 °C
October 1 – April 1	11.0 °C	**October 1 – March 31**	11.0 °C
April 1 – June 1	13.5 °C	**April 1 – May 31[2]**	11.09 °C – 16.5 °C
June 1 – September 1 **June 1- September 1** (when only non-anadromous form of naturalized rainbow or redband trout are present)	16.5 °C 18.5 °C	**June 1 – August 31** **N/A**	16.5 °C **N/A**
No single daily maximum temperature may exceed	18.5 °C	**No single daily maximum temperature may exceed**	N/A
Footnotes: 1. Temperature criterion decreases incrementally each day (i.e., Sept 1 is 16.32, Sept 2 is 16.13, etc). 2. Temperature criterion increases incrementally each day (April 1 is 11.09°C, April 2 is 11.18 °C, April 3 is 11.27°C, etc).			

EPA relied on the temperature guidance document titled *EPA Region 10 Guidance for Pacific Northwest State and Tribal Temperature Water Quality Standards* (April 2003, hereafter referred to as the Temperature Guidance) to review the Tribe's revisions to its temperature criteria. The Temperature Guidance contains recommended temperature criteria for different salmonid uses (these uses and associated criteria are summarized in the table below), and it also contains a recommended approach for applying the different salmonid uses based on actual fish use information in streams. The scientific rationale and basis for EPA's recommended criteria is described in the Temperature Guidance and the supporting Technical Issue Papers. For more detail on the derivation of the numbers in the tables, see the Temperature Guidance and the Technical Issue Papers. The Temperature Guidance recommends the following temperatures for protecting specific salmonid uses:

SALMONID USES AND CRITERIA	
Salmonid Uses During the Summer Maximum Conditions	Criteria
Salmon/Trout "Core" Juvenile Rearing (Salmon adult holding prior to spawning, and adult and subadult bull trout foraging and migration may also be included in this use category)	16 °C
Salmon/Trout Migration plus "Non-core" Juvenile Rearing	18 °C
Salmon/Trout Migration	20 °C
Salmonid Uses Where/When Occur	
Salmon/Trout Spawning, Egg Incubation, and Fry Emergence	13 °C
NOTES: 1. The temperature metric for each criterion is the 7-DADM. 2. "Salmon" refers to Chinook, Coho, Sockeye, Pink, and Chum salmon. 3. "Trout" refers to Steelhead and coastal cutthroat trout. 4. Bull trout is also known as Char.	

The Tribe has provided no fish information documenting that Class AA waters on the Reservation lack salmon/trout, egg incubation, and fry emergence from September 1 through September 20th (i.e., the time period when the temperature exceeds the 13 °C which is the recommended temperature for spawning, egg incubation and fry emergence); or from April 23 through May 31 (time period when the temperature is greater than the recommended 13 °C). Absent this information there is no way to determine if the revised criteria are protective of the Tribe's designated uses (which include salmonid spawning and rearing) during these time periods. Therefore, EPA is disapproving the revised language

(i.e., *Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st*), and the associated temperature criteria in Table 5 because it allows the temperature criterion to exceed 13°C during possible spawning, egg incubation, and fry emergence periods

Remedy to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt temperature criteria that are based on a sound scientific rationale and protect designated uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Revise the temperature criteria consistent with EPA Region 10's Temperature Guidance.

- Resubmit the temperature criteria with a sound scientific rationale to establish that the application of the temperature values is protective of designated uses.

Temperature Criteria Currently in Effect
Until EPA approves or promulgates revised temperature criteria for aquatic life for the time periods September 1 – October 1and April 1- June 1, the previously approved aquatic life temperature criteria are in effect for CWA purposes. The criteria are:

September 1 – October 1:	13.5 °C (7DADM)
April 1- June 1:	13.5 °C (7DADM)

B. EPA Action On Revised Temperature Criteria for Class A Waters

The following presents the new language contained in Section 9 Provision 2(c)(iv) of the WQS. Deleted text indicates text that was removed and new text is underlined and indicates the language that was added in the 2010 water quality standards adoption.

> (iv) ~~*Water used for spawning or rearing by naturalized populations of indigenous salmon or trout. Not to exceed a 7-day average of the daily maximum temperature values greater than 16.5 C from June 1 to September 1. Not to exceed a 7-day average of the daily maximum temperature values greater than 13.5 C between September 1 and October 1 and between April 1 and June 1, and not to exceed 11 C from October 1 to April 1; with no single daily maximum temperature exceeding 18.5 C. Exception for Non-Anadromous Rainbow and Redband Trout. In waters where the only salmonid present is non-anadromous form of naturalized rainbow or redband trout. Temperatures from June 1 to September 1 may be allowed to reach a 7-day average of the daily maximum temperatures of 18.5 C.*~~ *temperatures (sic) from June 1 to August 31 may be allowed to reach a 7-day average (7-DADM) of the daily maximum temperature of 18.5 C. Temperature shall not exceed the 7-DADM Table 5 value from September 1st through September 30th as well as from April 1st through May 31st. The 7-DADM temperature shall not exceed 11°C between October 1st and March 31st.*

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA disapproves the Tribe's revisions to the temperature criteria for Class A waters, and the associated temperature criteria for Class A waters contained in Table 5.

EPA Rationale
The Tribal water quality standards include the following aquatic life uses in their Class A waters:

Fish and Shellfish, including:
- Salmonid migration, rearing, spawning, and harvesting.
- Other fish migration rearing, spawning, and harvesting.
- Mollusks, crustaceans and other shellfish rearing, spawning and harvesting.

The table below summarizes the revisions made to the 2003 WQS:

2003 Water Quality Standards		**2010 Water Quality Standards**	
Time Period	***Criteria***	***Time Period***	***Criteria***
June 1 – September 1	16.5 °C	**June 1 – August 31**	18.5 °C
June 1- September 1 (when only non anadromous form of naturalized rainbow or redband trout are present)	18.5 °C	**N/A**	**N/A**
September 1 – October 1	13.5 °C	**September 1 – September 30**[1]	18.25 °C – 11 °C
April 1 – June 1	13.5 °C	**April 1 – May 31**[2]	11.12 °C – 18.5 °C
October 1 – April 1	11.0 °C	**October 1 – March 31**	11.0 °C
No single daily maximum temperature may exceed	18.5 °C	**No single daily maximum temperature may exceed**	**N/A**
Footnotes: 1. Temperature criterion decrease by 0.25 °C each day (i.e., Sept 1 is 18.25, Sept 2 is 17.75, etc). 2. Temperature criterion increases by approximately 0.12 °C each day (April 1 is 11.12°C, April 2 is 11.25 °C, April 3 is 11.37°C, etc).			

As stated previously, the Temperature Guidance contains recommended temperature criteria for different salmonid uses (these uses and associated criteria are summarized in the "Salmon Uses and Criteria" table above in Section VII.A) and it also contains a recommended approach for applying the different salmonid uses based on actual fish use information in streams.

The Temperature Guidance recommends applying a 16° C temperature criterion for streams that currently have one or more of the following 5 factors:

1. moderate-to-high density summer juvenile salmon rearing
2. summer salmon/steelhead spawning or incubation
3. summer adult/sub-adult bull trout foraging and migration
4. summer juvenile rearing with current streams temperature at or below 16°C
5. the potential to support moderate-to-high density summer juvenile rearing that is important for the recovery of salmonids

The Tribe provided no fish information documenting that Class A waters on the Reservation lack the above referenced factors, or that higher temperatures between April 17th and May 31st, and between September 1st and September 21st, will be protective of the Tribes designated aquatic life uses (which include salmonid spawning and rearing). This temperature revision appears to protect only rainbow and redband trout and does not necessarily provide adequate spring and summer temperatures needed to protect other types of salmonids. Without specific information documenting which types of salmonids reside in Class A waters, it is not possible to determine if the Tribe's designated uses are being protected. Therefore, EPA is disapproving the revisions to Section 9, Paragraph (2)(c)(iv).

Remedy to Address EPA's Disapproval
To address this disapproval, the Tribe must adopt temperature criteria that are based on a sound scientific rationale and protect designated uses. There are several means by which the Tribe may potentially accomplish this objective. They include:

- Revise the temperature criteria consistent with EPA Region 10's Temperature Guidance.

- Resubmit the temperature criteria with a sound scientific rationale to establish that the applications of temperature values are protective of designated uses.

Temperature Criteria Currently in Effect
Until EPA approves or promulgates revised temperature criteria for aquatic life, the previously approved aquatic life temperature criteria are in effect for CWA purposes.

VIII. Surface Waters Classifications

In Section 11 of the Tribe's water quality standards, specific surface waters on the Spokane Reservation are classified. In the 2010 water quality standards adoption, the Tribe included Ente' Creek as a Class A water. Additionally, the Tribe corrected a spelling error. The Tribe corrected the following (new letters that were added in the 2010 WQS adoption are underlined):

Chamokane (Tsh<u>i</u>m<u>i</u>k<u>ai</u>n) Creek.

EPA Action
In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the Tribe's addition of Ente' Creek as a Class A water in Section 11 of the water quality standards. In the 2003 water quality standards, all unclassified streams that were not tributaries to Class AA streams were designated as Class A waters (Section 10); therefore, Ente' Creek was previously classified as a Class A water by default. Ente' Creek is now specifically designated as Class A in Section 11.

Additionally, EPA acknowledges the editorial change to the spelling of *Tshimikain* and approves it as a non-substantive editorial change.

IX. Mixing Zone Provisions

The following presents the new language contained in Section 13 of the WQS. Deleted text indicates text that was removed and new text is underlined and indicates the language that was added in the 2010 water quality standards adoption.

13. IMPLEMENTATION

(1) All discharges from point sources and all activities which generate nonpoint source pollution shall be conducted so as to comply with this chapter.

~~*(2) Activities which cause pollution of storm water shall be conducted so as to comply with these water quality standards.*~~

(2) The standards required in this chapter may not be met by using a mixing zone, except where:

(a) the allowable size, location and duration of the mixing zone and associated effluent limits are established by the Department as part of a cleanup performed under the Federal or Tribal cleanup laws, and as established, the mixing zone will be at least as protective of human health and the environment as a mixing zone established under the laws of the State of Washington; and

(b) the size of the mixing zone and the concentrations of pollutants present shall be minimized; and

(c) overlapping mixing zones shall only be allowed if, in combination, the requirements of subsection (f)(sic) are satisfied; and

(d) water quality criteria shall not be violated outside of the boundary of a mixing zone as a result of the discharge for which the mixing zone was authorized; and

(e) the discharge is either:

(i) at a sufficient depth below the surface of the receiving water body that the criteria applicable to the constituent of concern being addressed by using the mixing zone is met at the water body's surface; or

(ii) located at a distance from the shore that ensures sensitive human and wildlife receptors are not likely exposed at the water body's surface for extended periods.(3) Activities which cause pollution of stormwater shall be conducted so as to comply with these water quality standards.(sic)

EPA Action

In accordance with its CWA authority, 33 U.S.C. § 1313(c)(3) and 40 CFR Part 131, EPA approves the Tribe's mixing zone policy.

EPA Rationale

Mixing zones are areas where instantaneous or rapid and complete mixing of discharges with receiving waters does not occur, and pollutant concentrations are allowed to exceed otherwise applicable water quality criteria. The federal water quality standards regulation at 40 CFR § 131.13 provides that states and tribes have the discretionary authority to include regulatory mixing zone policies in their water quality standards. When mixing zone policies are included, they are subject to EPA review and approval or disapproval pursuant to § 303(c) of the CWA. As explained in EPA's Advanced Notice of Proposed Rule Making, 63 FR 36787, July 7, 1998, EPA interprets the CWA as allowing the use of mixing zones as long as the provisions addressing toxicity at CWA § 101(a)(3) are met and the designated uses of the waterbody as a whole are protected. EPA's allowance of mixing zones is based on a premise that surface water quality criteria can be exceeded under limited circumstances without causing unacceptable toxicity and impairment of a water's uses.

In general, the Spokane Tribe's mixing zone policy does not allow the use of mixing zones with an exception made for effluent limitations that are established as part of a cleanup performed under Federal or Tribal Clean up Laws.[31] The purpose of the Tribal clean up law is to provide remedial law for the cleanup of hazardous substances sites, and to prevent the creation of future hazards due to improper use or disposal of hazardous substances on or into the Reservation Environment. The chapter is consistent with CERCLA.

Since the mixing zone policy is so limited in what it pertains to, is associated with CERCLA clean up sites, and limits the sizing of the mixing zone to be consistent with the State of Washington's requirements, this policy is consistent with the requirements of CWA 40 CFR Part 131.

[31] The WQS define Federal clean up law as the Comprehensive Environmental, Response, Compensation and Liability Act, 42 U.S Sec 9601, *it seq* (more commonly known as Superfund); and it defines "Tribal clean up law as the Hazardous Substances Control Act, Chapter 34, Law and Order Code of the Spokane Tribe of Indians. Tribal clean up laws are consistent with CERCLA.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA-HQ-OW-2012-0095; FRL-]

RIN 2040-AF33

Response-to-Comments for Water Quality Standards; Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

SUMMARY: On April 5, 2012 the Environmental Protection Agency (EPA) issued a Notice of Proposed Rulemaking to amend the federal regulations to withdraw certain human health and aquatic life water quality criteria applicable to waters of New Jersey, Puerto Rico, and California's San Francisco Bay.

In 1992, EPA promulgated the "National Toxics Rule" ("NTR") to establish numeric water quality criteria for 12 states and two Territories, including New Jersey, Puerto Rico and parts of California. On May 18, 2000, EPA then promulgated a final rule known as the ''California Toxics Rule'' (''CTR'') in order to establish numeric water quality criteria for priority toxic pollutants for the State of California that were not previously in the NTR. These two states and one territory have now adopted, and EPA has approved, water quality criteria for certain pollutants included in the NTR. Since California, New Jersey, and Puerto Rico now have criteria effective under the Clean Water Act, for the same priority toxic pollutants in the NTR, EPA has determined that the federally promulgated criteria are no longer needed for these pollutants. The comments received and the EPA's Response to those comments is listed below.

PUBLIC SUBMISSION

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Submission Type: Web

Docket: EPA-HQ-OW-2012-0095
Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Comment On: EPA-HQ-OW-2012-0095-0001
Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Document: EPA-HQ-OW-2012-0095-0002
Anonymous public comment

The EPA should not withdraw the federally promulgated water quality criteria for the state of New Jersey because establishing less stringent standards for the listed pollutants is contrary to the purpose and goals of both the CWA and the National Toxics Rule, particularly with regard to protecting human health.

As laid out in 40 CFR 131.2, the National Toxics Rule (codified in 40 CFR 131.36) was promulgated under §303(c)(2)(B) of the CWA for "the dual purposes of establishing the water quality goals for a specific water body and serve as the regulatory basis for the establishment of water-quality-based treatment controls and strategies *beyond the technology-based levels of treatment required* by sections 301(b) and 306 of the Act." (emphasis added).

The phrase "beyond the technology-based levels of treatment" indicates that water quality standards for bodies of water were enacted to improve water quality *in addition to* the effluent limitations of the CWA, so that both strategies could work in tandem. Water quality criteria were not produced to replace effluent limitations, but rather, were necessary to reach the

goals of the CWA which could not be attained simply through effluent limitations due to the difficulty in regulating point sources.

All but one of the pollutants to which New Jersey seeks to apply laxer standards are toxic pollutants, as listed under 40 CFR 401.15. These pollutants are numbered on the list: 22. Copper, 27. Ichloroethylene, 43. Isophrone, 44. Lead, 45. Mercury, 47. Nickel, 59. Tetrachloroethane, and 63. Trichloroethane. The one pollutant not on the toxic list, gamma-BHC (also called Lindane) is still of serious concern as it was dubbed "moderately toxic" by the World Health Organization in 2005.

Looking only at the effluent standards for toxic pollutants clearly shows the will of our Legislature to treat all toxic pollutants with more rigorous standards to carry out the purpose of the CWA: "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." Toxic pollutants are subject to the most rigorous technology treatment standard for existing sources under the CWA, the "best available technology economically achievable... which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants..." §301(b)(2)(A). Since the EPA only is required to *consider* costs in determining the BAT and does not have to carry out a cost-benefit analysis, weighing costs against the benefits of effluent reduction as it does with the BPT and BCT standards, the choice to apply BAT to toxic pollutants confirms Congress's intent to regard them with heightened caution.

Since the CWA unambiguously established its goal of treating toxic pollutants more rigorously than conventional pollutants, any regulation promulgated to explicitly further this interest should be read to require states to impose standards at least as stringent as federal standards. Giving states power to regulate their water bodies is a reasonable goal as far as it

recognizes the familiarity state agencies have with their geographic area and how that can make them more effective in responding to the specific water quality challenges than the EPA. This concept, however, should not translate into an allowance for states to pick and choose which federal regulations they wish to implement, particularly in states like NJ that have a troubled history of compliance.

Given the current problems in NJ's ability to meet water quality criteria for aquatic life, and the fact that NJ exceeds federal phosphorus standards, it is inappropriate to consider lower standards of any kind on water quality. According to the 2010 Integrated Water Quality Report published by the NJDEP, the number of limited use and impaired waterways in the state grew by 9.8% in the past two years. The report also stated that the three largest sources of pollution are non-point, stormwater discharges, and combined sewer overflow. Since all three of these are difficult or impossible to regulate through effluent limitations, it is necessary to maintain stringent quality standards for the surface waters to meet the overall goal of improving water quality nationwide.

Additionally, as the 2010 report suggests, NJ should not be taken off of NTR because it has been sanctioned in the past for not expanding their water quality monitoring network, indicating that the state is not yet ready to take on the full responsibility of regulating its waters.

Furthermore, NJ's proposed changes could lead to harmful conditions in the Delaware and Chesapeake bay as water body specific criteria ignores that water moves between water bodies and ultimately ends up in bays that provide water to other states. In this sense, allowing NJ an exemption to the strict federal standards would be inequitable as it could negatively impact other states that are held to higher standards.

> "The [NJDEP's] goal is for all waters to fully support <u>all</u> uses, except for fish consumption. Non-support of the fish consumption use is caused by unsafe

> levels of toxic contaminants in fish tissues, which is generally due to legacy pollutants (like PCBs) or air deposition (like mercury), rather than active point source discharges. These types of pollutants generally require national or regional approaches to restore water quality. In New Jersey, non-support of the fish consumption use is addressed through public health advisories rather than pollution control measures." (http://www.state.nj.us/dep/wms/bwqsa/generalinfo.htm)

It is imperative that the standards for the toxic pollutants listed by the NJDEP remain subject to the more protective federal standards. Consideration of just two of the pollutants, lead and copper, illustrates this point:

Lead is "a highly toxic metal the agency considers a major public health threat.", according to the EPA. The national Centers for Disease Control considers lead to be the country's number one preventable pediatric health problem. More than 30 Million Americans are drinking water with lead levels in excess of the Maximum Contaminant Level set by the EPA. (http://www.pure-earth.com/lead.html)

The "Action Level" (concentration which, if exceeded, triggers treatment) for copper has also been set at 1.3 ppm because EPA believes, given present technology and resources, this is the lowest level to which water systems can reasonably be required to control this contaminant should it occur in drinking water at their customers home taps. EPA has found copper to potentially cause the following health effects when people are exposed to it at levels above the Action Level. (http://www.freedrinkingwater.com/water-contamination/copper-contaminants-removal-water.htm)

In order to further the goals of both the CWA and the NJDEP, NJ should remain subject to the NTR, and be required to adopt standards at least as stringent as the federal ones.

EPA Response:

EPA appreciates the comments and to the extent a response is necessary, within the scope of this final rule, are addressed below.

The Clean Water Act tasks the States, Territories and authorized Tribes with adopting designated uses for their surface waters, and in adopting criteria to protect those uses. Federal criteria are being withdrawn for New Jersey where the state has adopted, and EPA has approved criteria that, while not as stringent as the promulgated criteria, are scientifically defensible, protective of the designated uses and consistent with the Clean Water Act and EPA's implementing regulations at 40 CFR 131.11.

The following is the list of pollutants (12 criteria) for which New Jersey adopted criteria, and which EPA approved, that are less stringent than the promulgated federal criteria, but that nonetheless meet the requirements of the CWA and EPA's implementing regulations at 40 CFR 131.11 covered in this proposal:

• Copper (aquatic life—marine (acute and chronic)).
• Lead (aquatic life—freshwater (chronic) and marine water (chronic)).
• Mercury (aquatic life—freshwater (chronic) and marine water (chronic)).
• Nickel (aquatic life—marine water (chronic)).
• 1,1–Dichloroethylene (human health—organisms only).
• 1,1,2,2–Tetrachloroethane (human health—organisms only).
• 1,1,2–Trichloroethane (human health—organisms only).
• Isophrone (human health— organisms only).
• gamma-BHC (human health—organisms only).

The following six New Jersey criteria are less stringent than the NTR because they are equal to EPA's most recent 304(a) criteria recommendations:

- Copper (aquatic life – marine (acute and chronic))
- Mercury (aquatic life – freshwater (chronic) and marine water (chronic))
- Isophrone (human health – organisms only)
- gamma-BHC (human health – organisms only)

The following three New Jersey criteria are less stringent than the NTR because New Jersey developed applicable criteria as outlined below:

- Lead (aquatic life – freshwater (chronic) and marine water (chronic)): New Jersey updated its aquatic freshwater criteria for lead as nonhardness-dependent criteria. In addition, the State used conversion factors recalculated by the Delaware River Basin Commission for both fresh and marine criteria, which are more stringent than the nationally recommended conversion factors, as well as the national species list and updated toxicity data reviewed and accepted by EPA (Great Lakes Water Quality Initiative, 1991).

- Nickel (aquatic life – marine water (chronic)): New Jersey adopted saltwater criteria for nickel which were recalculated based upon the most recent peer reviewed saltwater toxicity data available.

The following three New Jersey criteria are less stringent than the NTR because New Jersey developed applicable criteria following the scientific methodology recommended by EPA, but used toxicity factors recommended by the New Jersey Drinking Water Quality Institute (NJDWQI) rather than the toxicity factors available in IRIS to ensure consistency with the State's Safe Drinking Water Program

- 1,1-Dichloroethylene (human health – organisms only)
- 1,1,2,2-Tetrachloroethane (human health – organisms only)
- 1,1,2-Trichloroethane (human health – organisms only)

In summary the above-referenced criteria have all been found to be scientifically defensible, protective of the designated uses, and consistent with the Clean Water Act and EPA's implementing regulations at 40 CFR 131.11.

In terms of the specific concerns raised by the commenter, EPA offers the following:

- In terms of the development of water quality based effluent limitations (WQBELs) for point source discharges, where such limits are found to be required the resultant criteria are used by States to derive these WQBELs in order to protect designated uses.

- The withdrawal of the federal criteria is not intended to impact the scope of the State's water quality monitoring network.

- With regard to the protection of Delaware and Chesapeake Bay, New Jersey remains obligated to comply with the requirements of 40 CFR 131.10(b) which states that, "in designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."

- Finally, with regard to the protection of drinking water, States adopt different sets of water quality criteria for the protection of aquatic life or human health. One of the purposes of this rule is to withdraw the federal aquatic life criteria, not human health criteria, for chronic and acute copper and lead, for fresh and marine waters designated for aquatic life use. The removal of the federal aquatic life criteria will allow New Jersey to implement its adopted and EPA-approved aquatic life criteria for copper and lead, and will not impact any drinking water-based criteria that are already adopted by the State. Therefore, the level of protection currently provided by the State for drinking water will not change with this rulemaking.

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Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Comment On: EPA-HQ-OW-2012-0095-0001
Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Document: EPA-HQ-OW-2012-0095-0027
Anonymous public comment

Submitter Information

Government Agency Type: Federal

General Comment

HELP ! Our water which falls from the sky onto our neighborhoods, fields and mountains, runs down our gutters and creeks, swells our rivers and cleans and maintains the Sacramento Delta is being 'sold' by folks I don't remember electing ! I know those folks and corporations in southern California need some of our water but they are killing the Delta, an area that supports vast amounts of 'Aquatic nurseries'. If this was happening in Brazil, ecologist from Davis to 'Frisco would be screaming and signing petitions about how 'We Must Save....', But..because its in our back yard, We say / do nothing.
As a remedy I suggest we triple the price of our water being shipped via the massive salmon killing pumps. When water is expensive to the mega corporations they will find a more sustainable means to farm the desert! I personally am willing to pay 25 cents more per melon for wanting my grand kids see a delta I saw when I was young.

EPA Response:

EPA thanks you for your interest in water issues concerning the San Francisco Delta. Your comment concerns water quantity (water flow) issues in the Delta, while our proposed rule concerns water quality in the Bay, specifically, the aquatic life saltwater cyanide criteria in San Francisco Bay. EPA is only taking comment on the water quality criteria for cyanide in San

Francisco Bay at this time. However, we appreciate your interest in the Delta, and hope you continue to express your thoughts and concerns on these important matters.

PUBLIC SUBMISSION

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Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Comment On: EPA-HQ-OW-2012-0095-0001
Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Document: EPA-HQ-OW-2012-0095-0028
Comment submitted by Naomi Feger, Division Chief, San Francisco Bay Regional Water Quality Control Board

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Submitter Information

Submitter's Representative: Barbara Baginska
Organization: San Francisco Bay Water Board
Government Agency Type: State

General Comment

See attached file(s)

Attachments

Cover Letter

Comment

May 17, 2012
CWIQs Place no. 718825
U.S. Environmental Protection Agency, Region 9
75 Hawthorne Street, WTR-3
San Francisco, California 94105
Sent via email to ow-docket@epa.gov
Sent via email to Diane Fleck: fleck.diane@epa.gov
Subject: PROPOSED WITHDRAWAL OF CERTAIN FEDERAL WATER QUALITY CRITERIA APPLICABLE TO CALIFORNIA, NEW JERSEY AND PUERTO RICO
Docket No. EPA-HQ-OW-2012-0095
Dear Ms. Fleck:

Please accept these comments into the docket for the withdrawal of the federally promulgated saltwater aquatic life cyanide criteria for San Francisco Bay, as referenced above.

The San Francisco Bay Regional Water Quality Control Board (Water Board) is the State of California's regional office with responsibility for enhancing and maintaining the water quality of the San Francisco Estuary. The San Francisco Bay Water Quality Control Plan establishes applicable water quality standards, including beneficial uses and water quality objectives, to protect water quality in the Estuary. The Water Board strives to implement water quality standards that are most relevant and protective of beneficial uses in the Bay.
We fully support the EPA action to amend the federal regulations to withdraw promulgated federal water quality criteria for cyanide applicable to San Francisco Bay and the EPA's approval of the site-specific aquatic life objectives put forward by the Water Board.

In December 2006, the Water Board adopted Resolution (R2-2006-0086) to establish site-specific marine cyanide objectives (acute 9.4 μg/L and chronic 2.9 μg/L) for all segments of San Francisco Bay to replace the existing National Toxics Rule (NTR) acute and chronic objectives of 1 μg/L. The adopted site-specific objectives reflect the relevant aquatic organisms present in the Bay and follow both state and federal guidance and policy guiding development of site-specific objectives. The state Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California allows for consideration of site-specific objectives when permit limits based on existing water quality objectives may not be attainable, the current objectives are not appropriate for the water body, and there is no evidence of adverse water quality impacts. All these conditions are met for cyanide in San Francisco Bay. In particular, the NTR water quality criteria are heavily influenced by toxicological data for one species that is not present in San Francisco Bay, and are therefore not fully applicable. Despite the fact that the site-specific objectives are less stringent than the NTR criteria, cyanide data collected in the Bay consistently show concentrations that are well below the NTR objective. Furthermore, cyanide does not persist in natural waters and does not bioaccumulate in biota. We appreciate the opportunity to support the EPA action to update the NTR criteria for cyanide in San Francisco Bay.

If you have any further questions, please contact Barbara Baginska at 510 622-2474, or via e-mail at bbaginska@waterboards.ca.gov.

Sincerely,
Naomi Feger
Division Chief

EPA Response:

EPA appreciates this letter of support from the State of California's San Francisco Bay Regional Water Quality Control Board. We look forward to continuing to work with the Board on water quality issues.

PUBLIC SUBMISSION

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Submission Type: Web

Docket: EPA-HQ-OW-2012-0095
Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Comment On: EPA-HQ-OW-2012-0095-0001
Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

Document: EPA-HQ-OW-2012-0095-0029
Comment submitted by Jill Lipoti, Director, Water Monitoring and Standards, New Jersey Department of Environmental Protection (NJDEP)

Submitter Information

Submitter's Representative: Jill Lipoti, Director of Water Monitoring and Standards
Organization: Water Monitoring and Standards, New Jersey Department of Environmental Protection (NJDEP)
Government Agency Type: State
Government Agency: Water Monitoring and Standards, New Jersey Department of Environmental Protection (NJDEP)

General Comment

See attached file(s)

Attachments

Comment

June 4, 2012
U.S. Environmental Protection Agency
Mail Code: 28221 T
Water Docket
1200 Pennsylvania Ave., NW
Washington, DC 20460
PO Box 420 (Mail Code 401-041)
401 East State Street
Trenton, New Jersey 08625-0420
Telephone: 609-292-1623
Fax: 609-633-1276
http://www.nj.gov/dep/wms/
Attn: Docket ID No. EPA- HQ-OW-2012-0095
Via email to: OW-Docket@epa.gov
Re: Docket ID No. EPA-HQ-OW-2012-0095
Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico

The New Jersey Department of Environmental Protection (NJDEP) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (USEPA), Proposed Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico (Proposed Withdrawal) (66 FR 20585, April 5, 2012). NJDEP is pleased with USEPA's action to withdraw National Toxics Rule (NTR) aquatic life and human health water quality criteria applicable to New Jersey. NJDEP adopted criteria for those pollutants under the NTR through several revisions to the New Jersey Surface Water Quality Standards (N.J.A.C. 7:9B) since 1992. These criteria were approved by the USEP A subsequent to each revision.

USEPA has identified nine pollutants (12 criteria), which New Jersey adopted and USEPA approved, that are less stringent than the Federal promulgated NTR criteria. USEPA has compared NJDEP's current surface water quality criteria with the 1992 NTR criteria to arrive at the conclusion that these criteria are less stringent. However, USEPA has updated several of their criteria since 1992. When compared with the current USEPA National Recommended Water Quality Criteria http://water.epa.gov/scitech/swguidance/standards/current/index.cfm), only six criteria are less stringent than USEPA's current recommended criteria. The following are comments on the criteria that are less stringent than current USEP A current recommendations.

Lead:
NJDEP has updated aquatic freshwater criteria for Lead in 2002 (34 N.J.R. 537(a); January 22, 2002), as a non-hardness-dependent criteria. In addition, NJDEP used conversion factors recalculated by the Delaware River Basin Commission (DRBC) for both fresh and marine criteria. USEPA approved these criteria on August 16, 2002 and indicated that they are in the

process of updating criteria for lead. NJDEP may review its aquatic criteria for lead when USEPA updates its recommendations to determine if NJDEP criteria are still protective using the most recent scientific data.

Nickel:
NJDEP has updated aquatic marine criteria for update in 2006 (38 N.J.R. 4449(a); October 16, 2006) based on newer scientific information because USEPA failed to include its criteria recommendations based on new information. Marine criteria were recalculated using Technical Information Related to Developing a Saltwater Nickel Addendum to the Ambient Water Quality Criteria Document, 2003 (http://www.state.nj .us/dep/wms/bwqsa/support_ docs.htm).
USEPA approved these criteria on December 20, 2006. On April 6, 2010, USEPA, through a letter to Ronald Popowski, USFWS, indicated these criteria are more scientifically-sound and are not likely to adversely affect any applicable federally-listed aquatic or aquatic-dependent species under USFWS jurisdiction.

1,1,2,2-Tetrachloroethane, 1,1,2-Trichloroethane, and 1,1-Dichloroethylene:
NJDEP has updated human health criteria for saline water based upon fish only exposure for 1,1 ,2,2-Tetrachloroethane, 1,1,2- Trichloroethane, and 1,1 - Dichloroethylene in 2006 (38 N.J.R. 4449(a); October 16, 2006).
NJDEP developed these criteria following the scientific methodology recommended by USEPA. However, the NJDEP used toxicity factors recommended by the New Jersey Drinking Water Quality Institute (NJDWQI) rather than the toxicity factors available in IRIS to ensure consistency with our Safe Drinking Water Program. USEPA approved these criteria on December 20, 2006.

As part of the 2009 NJDWQI review, 1,1 ,2,2-Tetrachloroethane, 1,1 ,2-Trichloroethane, and 1, 1-Dichloroethylene, were classified as Suggestive Carcinogens (Possible Human Carcinogens). NJDWQI has reviewed the health effects information and has recommended revisions to these health based criteria. NJDWQI recommendations are: the human health criteria in saline waters for 1,1 ,2,2-Tetrachloroethane should be 14)µg/L which is equal to the current USEPA recommendation; the human health marine criteria for 1,1,2- Trichloroethane should be 14)µg/L which will be more stringent than the current US EPA recommendation of 16 µg/L; and the human health marine criteria for 1,1 -Dichloroethylene should be 1,286 µg/L which will be more stringent than the current US EPA recommendation of 1700 µg/L. In accordance with N.J.A.C. 7:9B-1.5(c) 6, once the Maximum Contaminant Levels (MCL)'s for these criteria are revised in the Safe Drinking Water Act Rules, the Department will publish a notice of administrative change in the New Jersey Register to update these criteria in the Surface Water Quality Standards.

I hope that the above comments on the Proposed Withdrawal will assist you in finalizing the document. Feel free to contact Debra Hammond by email at Debra.hammond@dep.state.nj .us or by phone at 609-777-1753 if you have any questions.

Sincerely
Jill Lipoti, Director, Water Monitoring and Standards
NJ Department of Environmental Protection

P.O. Box 420 (Mail Code 401-041)
401 East State Street
Trenton, NJ 08625-0420

EPA Response:

EPA appreciates this letter of support from the State of New Jersey's Department of Environmental Protection (NJDEP). We look forward to continuing to work with the NJDEP on water quality issues.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
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Seattle, WA 98101-3140

OFFICE OF
WATER AND WATERSHEDS

January 20, 2015

Don Essig
Idaho Department of Environmental Quality
1410 N. Hilton
Boise, Idaho 83706

RE: EPA comments on Idaho's Discussion Paper #7 Risk Management and Protection of Human Health

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We look forward to continued work with DEQ on this effort and are available if you would like to discuss our comments further. Please contact Lon Kissinger (206-553-2115) or myself (206-553-1834) if you have any questions.

Sincerely,

Lisa Macchio
Water Quality Standards Coordinator

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Subject: FW: EPA Comments on Idaho's Discussion Paper #7 Risk Management
Attachments: EPA Comments to Discussion Paper #7 Risk Management.pdf

From: "Macchio, Lisa" <Macchio.Lisa@epa.gov>
Date: Wednesday, January 21, 2015 2:29 PM
To: Kris Holm <krisholm@comcast.net>
Cc: "Fleisig, Erica" <Fleisig.Erica@epa.gov>, "Chung, Angela" <Chung.Angela@epa.gov>
Subject: FW: EPA Comments on Idaho's Discussion Paper #7 Risk Management

From: Macchio, Lisa
To: Don Essig; Jeffrey.Fromm@deq.idaho.gov
Subject: EPA Comments on Idaho's Discussion Paper #7 Risk Management

Don and Jeff – Please find attached EPA's comments on your most recent discussion paper. Thank you for the opportunity to comment. If you have any questions please feel free to contact Lon or myself.

Lisa Macchio
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January 20, 2015

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6. The Idaho paper discusses the origins of use of one in a million risk (pg. 3). However, the origin of the use of one in a million risk is really not relevant if an analysis of the factors involved in developing risk based standards lead to use of this risk level (e.g. What is the appropriate risk level associated with criteria regulating involuntary exposure of all U.S. citizens to chemicals in the Nation's waters?). The focus should be on evaluation and discussion of the issues covered in the Idaho paper as limited by the enabling statute, the Clean Water Act, not the historical origin of one in a million risk.

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01092

Subject: FW: EPA Comments on Idaho's Discussion Paper #7 Risk Management REALLY THIS IS THE FINAL VERSION

Attachments: EPA Comments on Discussion Paper #7 Risk Management FINAL.pdf

From: "Macchio, Lisa" <Macchio.Lisa@epa.gov>
Date: Wednesday, January 21, 2015 3:06 PM
To: "Don.Essig@deq.idaho.gov" <Don.Essig@deq.idaho.gov>, "jeffrey.fromm@deq.idaho.gov" <jeffrey.fromm@deq.idaho.gov>
Cc: "Kissinger, Lon" <Kissinger.Lon@epa.gov>, "Soscia, Marylou" <Soscia.Marylou@epa.gov>, "Chung, Angela" <Chung.Angela@epa.gov>, "Fleisig, Erica" <Fleisig.Erica@epa.gov>
Subject: RE: EPA Comments on Idaho's Discussion Paper #7 Risk Management REALLY THIS IS THE FINAL VERSION

I have to apologize for sending the incorrect version to you. Here is the FINAL version of our comments.

Lisa Macchio
U.S. EPA, Region 10 (OWW-131)
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OFFICE OF
WATER AND WATERSHEDS

January 20, 2015

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01096

Arch Toxicol
DOI 10.1007/s00204-013-1104-7

REVIEW ARTICLE

Origin of the linearity no threshold (LNT) dose–response concept

Edward J. Calabrese

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© Springer-Verlag Berlin Heidelberg 2013

Abstract This paper identifies the origin of the linearity at low-dose concept [i.e., linear no threshold (LNT)] for ionizing radiation-induced mutation. After the discovery of X-ray-induced mutations, Olson and Lewis (Nature 121(3052):673–674, 1928) proposed that cosmic/terrestrial radiation-induced mutations provide the principal mechanism for the induction of heritable traits, providing the driving force for evolution. For this concept to be general, a LNT dose relationship was assumed, with genetic damage proportional to the energy absorbed. Subsequent studies suggested a linear dose response for ionizing radiation-induced mutations (Hanson and Heys in Am Nat 63(686):201–213, 1929; Oliver in Science 71:44–46, 1930), supporting the evolutionary hypothesis. Based on an evaluation of spontaneous and ionizing radiation-induced mutation with *Drosophila*, Muller argued that background radiation had a negligible impact on spontaneous mutation, discrediting the ionizing radiation-based evolutionary hypothesis. Nonetheless, an expanded set of mutation dose–response observations provided a basis for collaboration between theoretical physicists (Max Delbruck and Gunter Zimmer) and the radiation geneticist Nicolai Timoféeff-Ressovsky. They developed interrelated physical science-based genetics perspectives including a biophysical model of the gene, a radiation-induced gene mutation target theory and the single-hit hypothesis of radiation-induced mutation, which, when integrated, provided the theoretical mechanism and mathematical basis for the LNT model. The LNT concept became accepted by radiation geneticists and recommended by national/international advisory committees for risk assessment of ionizing radiation-induced mutational damage/cancer from the mid-1950s to the present. The LNT concept was later generalized to chemical carcinogen risk assessment and used by public health and regulatory agencies worldwide.

Keywords Ionizing radiation · Linearity · Dose response · Risk assessment · Threshold dose response · Target theory · Eugenics · LNT

Introduction

In 1956, the US National Academy of Sciences (NAS) Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel issued the most far reaching recommendation in the history of risk assessment that genomic risks associated with exposure to ionizing radiation should be evaluated with a linear dose–response model, no longer via the threshold dose–response model that had long been the "gold" standard for medicine and physiology (Calabrese 2005, 2009a, 2011). The Genetics Panel members believed that there was no safe exposure to ionizing radiation for reproductive cells with the mutation risk being increased even with a single ionization (Hamblin 2007). The LNT concept was generalized in 1958 to somatic cells and cancer risk assessment by the National Committee for Radiation Protection and Measurement (NCRPM) (Whittemore 1986). Quickly thereafter, other national and international advisory committees and organizations adopted such judgments for ionizing radiation (Calabrese 2009b). In 1977, the Safe Drinking Water Committee (SDWC) of the US NAS extended the linear dose–response risk assessment model of the BEAR/

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Biological Effects of Ionizing Radiation (BEIR) committees to chemical carcinogens, a recommendation that was soon adopted and implemented by the Environmental Protection Agency (EPA). On a parallel track, similar LNT risk assessment procedures were adopted by the Food and Drug Administration (FDA) in 1977 concerning animal carcinogen drug residues.

Despite the fact that the LNT model has been of central importance in chemical and ionizing radiation regulatory risk assessment, its origin is not within the environmental/occupational risk assessment domain. The current paper provides a novel historical assessment of the scientific origin of the LNT. It will show that the LNT was first applied to the field of biology in 1928 to explain the occurrence of genetic variation that would serve as the "biological engine" for evolution. The paper will also demonstrate how the linear dose–response model as proposed by Olson and Lewis (1928), which soon afterward became transformed into a "Proportionality Rule" by Muller (1930), became mechanistically framed within the context of a single-"hit" hypothesis based on the target theory by Timoféeff-Ressovsky et al. (1935) in a unique collaborative effort between leading theoretical physicists and radiation genetics. This paper extends two earlier publications within Archives of Toxicology concerning historical foundations of the LNT concept (Calabrese, 2009b) and threshold/hormetic (Calabrese 2009a) models.

Evolution and LNT

Since the publication of the Origin of Species in 1859 by Darwin and the rediscovery of the works of Mendel on gene inheritance, there was intense interest in the biological community to determine the cause of genetic change or novelty that would be subject to natural selection, thereby providing an important mechanism of evolution. As noted by Patterson (1933), a well-known colleague of Hermann J. Muller at the University of Texas/Austin, "the important question in biology is the problem of evolution" referring to the need to understand the mechanism of evolution at the gene level. Despite the fact that the gene was more of a concept than a physical entity during the early decades of the twentieth century, it was widely believed that the gene was the basic unit of heredity and that the driving force for evolutionary change must be via the induction of heritable genetic changes or mutations at the gene level (Muller 1922). This perspective provided the basis for intense interest by numerous genetics researchers in the second and third decades of the twentieth century to induce alterations in heritable traits by environmental (e.g., temperature) alterations, physiological stressors (e.g., starvation), as well as toxic chemicals and ionizing and non-ionizing radiation.

Given the central importance of evolution in biology and underscoring the intensity of the competition to be the first to demonstrate inducible heritable changes, Muller (1927) provided only an initial "discussion" of his mutagenicity findings with no data in his now famous *Science* paper that led to his Nobel Prize in 1946. This was done in order to secure recognition of being the first to report induction of heritable mutations by an environmental agent (i.e., X-rays). The supporting data were published the next year in a conference proceeding of very limited distribution based on the World Cat database (Muller 1928a) and also within the *Proceedings of the National Academy of Sciences* (PNAS) (Muller 1928b). Not only were the findings of mutation significant so too was the fact that the mutation rate was increased by about 150-fold at the highest dose tested.

Muller speculated that naturally occurring ionizing radiation might be a significant explanatory factor for genetic variation and may drive the evolution process. However, Muller was cautious in making the mutation–evolution link as the doses he had used to induce mutation were extremely high, exceeding background by about 200,000-fold, causing sterility or mortality in a substantial proportion of the fruit flies tested. In addition, the dose response was not linear but closer to a square root function due to a modest decline from linearity at the highest dose (Muller 1927, 1928a). If the true dose response for ionizing radiation-induced gene mutation was linear at low dose, as a general condition, then it may have explanatory implications for an evolution mechanism. Consequently, he soon directed several members in his laboratory to assess the topic of dose response more fully than he did in his groundbreaking mutation discovery. While the follow-up research by Muller's group was being undertaken, Axel R. Olson and the prestigious physical chemist Gilbert N. Lewis (1928) of the University of California/Berkeley published a proposal on April 28, 1928, in *Nature* that natural radioactivity was likely a significant cause of mutation that could generate variability from the parent generation and affect the process of evolution. These authors based this supposition on a report of January 1, 1928, in *PNAS* by Goodspeed and Olson on X-ray-induced heritable changes in tobacco. These authors claimed that the tobacco plant studies were specially planned to facilitate a direct comparison of mutation rates between the artificial X-rays and "naturally occurring radiations." Olson and Lewis (1928) also stated that "since the rays can only be effective when they are absorbed, and this produces ionizations, it seems safe to assume that the various rays will produce biological effects *in proportion to the ionization which they cause*" (emphasis added), a perspective based on the emerging target theory for radiation-induced biological effects proposed by leaders in the physics community (Glocker 1927; Crowther 1924).

Olson and Lewis (1928) then utilized a simple linear mathematical model to derive a mutation estimate at a selected natural background radiation dose. With this method, they estimated the number of variants (mutants) induced per year by natural radiation. These authors concluded that "it seems, therefore not altogether extravagant to assume that such variations as actually occur in nature are due largely to the radioactivity of the environment." The involvement of Gilbert Lewis in this activity, while unexpected, was derived from his research in the 1920s in the area of radiation physics (Coffey 2008). Furthermore, his eclectic research activities had also drawn him toward evolutionary theory, the subject of his major presentation (i.e., Silliman Lecture) at Yale, just preceding the development of the LNT paper in *Nature* (Lewis 1926). This lecture followed that of Thomas Hunt Morgan of Columbia University in 1925, Muller's Ph. D. advisor and 1936 Nobel Prize recipient. The perspective of Olson and Lewis (1928) was also independently advanced by Muller in a paper read before the National Academy of Sciences on April 24, 1928, and published on September 14, 1928. The statement of Muller (1928b) was principally conceptual, lacking the detailed formulation of Olson and Lewis (1928).

The following year, Babcock and Collins (1929a, b) tested the hypothesis of Olson and Lewis (1928). They found a location in which the natural radiation was twice that found in their University of California/Berkeley laboratory. Using the ClB strain sex-linked recessive *Drosophila* assay, they reported an increase in mutation that corresponded in the same proportion as the difference in background radiation, supporting the proportionality hypothesis. Detailed experimental methods including the actual radioactivity levels were never published, although such data were promised to be provided in a subsequent paper. In 1930, Hanson and Heys provided further support for the hypothesis that "natural radiation may be responsible for the mutations that are the grist of the natural selection mill with the resulting evolution of new forms." Their findings were based on a study of fruit fly mutations in an abandoned carnotite (i.e., uranium) mine. Such interpretations were initially supported by commentaries by various authors (Lind 1929; Dixon 1929, 1930).

In 1930 Muller and Rice University physicist, Mott-Smith, challenged this LNT evolution perspective by reporting that natural radiation, which was of such a low-dose rate, could only account for about 1/1,300 of the gene mutations that occurred spontaneously in *Drosophila melanogaster*, assuming a linear dose response. The authors concluded that other causes must explain the origin of most mutations that spontaneously occur. Nonetheless, in his dissertation, under the direction of Muller, Oliver (1931) stated that cosmic and terrestrial radiations must account for some proportion of the spontaneous mutations (see Muller 1930). This conclusion was justified on the belief that the response is linear at low dose, with there being no threshold for a mutation response. This relationship was stated as holding true for all types of high-energy radiation (e.g., gamma, beta, X-rays and probably ultra-violet rays). Thus, Oliver (1931) concluded that "by inference it can be added that the cosmic and the terrestrial radiations also are capable of producing mutations in proportion to their power of ionization." Oliver (1931) also extended the concept of proportionality to chromosomal inversions and translocations further arguing for the support of a background radiation influence. For example, Muller and Altenburg (1930) noted that translocations are induced at a similar frequency as gene mutations. Given these circumstances, Oliver (1931) noted that "one would expect each of the classes of changes considered to occur with the same frequency when the individuals are subjected only to the natural conditions, if natural radiation can account for all mutations…" Despite this interpretation of environmental radiation-induced genetic changes, Oliver (1931) concluded that "some other condition must, therefore, enter in order to explain the difference in non-radiated material, between the frequency of gene mutation and that of the other type of genetic changes." (p. 34)

Even though Muller dismissed natural radiation as providing a quantifiably significant mutational influence to derive genetic novelty for evolutionary change, he still retained his belief in the linear dose–response relationship (p. 238) (Muller 1930) based on the findings of Hanson and Heys (1929, 1930) and Oliver (1930). Even though the hypothesis of Olson and Lewis (1928) did not maintain significant support for long within the scientific community, Muller and other leaders of the radiation genetics community became strong advocates of the LNT model to account for genomic mutations and the occurrence of cancer.

It may seem difficult to understand in retrospect why prominent scientific leaders such as Gilbert N. Lewis, Hermann J. Muller and others so quickly adopted a belief in linearity at low dose. In the case of Muller, he was fully committed to this view after the publication of only three studies (Hanson and Heys 1929, 1930; Oliver 1930) in which the lowest cumulative dose was roughly 285 r, administered in an acute manner, the rough approximation of 1,000 modern chest X-rays in 3.5 min or 5 chest X-rays/s.

In his rather copious publications during this period of "belief"/concept formulation, Muller never addressed contemporary publications that did not support a linear interpretation (Patterson 1928; Weinstein 1928; Stadler 1930, 1931). Yet, he was well aware that the lowest doses in the Hanson and Heys (1929, 1930) and Oliver (1930) papers were acute studies that grossly exceeded background radiation exposure. To think within a linear dose–response term

framework ran counter to pharmacological and chemical toxicological experience at that time. As Zimmer (1966) reflectively wrote, toxic chemicals in the early decades of the twentieth century demonstrated "no effect up to a threshold dose and then climbed steeply up to 100 %." Muller and others argued that the genetic response to ionizing radiation demanded a different evaluative framework.

Target theory and LNT

A likely explanation for Muller's (and possibly Gilbert N. Lewis's) acceptance of the LNT in the absence of convincing dose–response data may be found within the scientific culture at the time. X-ray-induced mutational effects were placed within the context of what was called the radiation target theory. This theory was quantitative and dosimetric, with mathematical calculations related to quantum mechanics, reflecting the leadership of prestigious theoretical physicists (von Schwerin 2010). The formation of a physics-based target theory was established prior to the discovery of inducible mutations by Muller (1927) by medical physicists such as Dessauer (1922), Glocker (1927) and Crowther (1924, 1926, 1927), setting the stage for a novel scientific framing of the mutational data in the 1930s. The mutation findings of Muller (1927) were a major scientific advance that easily fit into the target theory concept while also markedly advancing the scientific standing of target theory itself.

The radiation target theory as applied to mutations was formulated by the detailed interactions and collaborations of leading radiation geneticists and theoretical physicists during the mid-1930s. During this time, radiation geneticists, lead by Nicolai Timoféeff-Ressovsky, and physicists, including Niels Bohr, with a profound interest in the interface of physics and biology, would meet each year, typically in Copenhagen and Belgium for extensive discussions. From these exchanges developed the seminal conceptual paper by Timoféeff-Ressovsky and the physicists Max Delbruck and Kevin Gunter Zimmer (Timoféeff-Ressovsky et al. 1935) that would establish a conceptual framework for gene structure, target theory for the induction of mutations via ionizing radiation, the single-hit mechanism hypothesis to account for the shape of the LNT dose response and the application of this dose–response model for what was to become modern cancer risk assessment. The genetic target theory saw mutation as a purely physical action following an all or none law in which a single ionization or energy absorption produces the mutational effect independent of all other ionizations and energy absorptions.

This linearity feature stands in contrast to normal physiology that invariably deals with large numbers of molecules of each kind, and where the elimination of a single molecule would not result in observable effects (Delbruck 1940). The energy of ionizing radiation was assumed to be essentially transformed into a genetic effect. According to the physicist turned biologist Max Delbruck (1969 Nobel Prize recipient in Biology and Medicine), the proportionality rule that was proposed earlier by Muller, based on the research of Hansen and Heys (1929) and Oliver (1930, 1931) and supported in experimental research by Timoféeff-Ressovsky et al. (1935), provided the basis of the single-hit mechanism interpretation and the calculation of the size of the gene (Delbruck 1940). Table 1 provides a listing of quotes in which the early conceptual framing of the dose–response proportionality concept occurred. The transforming of a dose–response hypothesis based on a very limited amount of data into a biological "Rule" by Muller was done without significant discussion of the concept, its possible mechanisms as well as the recognition of data that may contradict this "Rule."

Although Muller was a geneticist, he was drawn quickly toward the physics-mutation interface, accepting significant elements of target theory for radiation-induced mutational effects, including the important assumptions that damage was proportional to the energy absorbed, linear dose–response modeling and that effects were cumulative and deleterious (Muller et al. 1936). Muller knew Timoféeff-Ressovsky, having met him in the Soviet Union in 1922, encouraging him and his colleagues to transform his laboratory to one of the *Drosophila* genetics. Muller renewed contact with Timoféeff-Ressovsky during the 5th International Congress on Genetics in 1927. From November 1932 to September 1933, Muller researched in Berlin with Timoféeff-Ressovsky. He also participated in the physics-biology/mutation discussions in Copenhagen in 1936, engaging Niels Bohr and other leading physicists. Experiments of radiation geneticists during this period were often designed within the context of this target theory framework. This was also the case for critical studies performed a decade later under the aegis of the Manhattan Project at the University of Rochester under the direction of Curt Stern (with Muller serving as a consultant) (Spencer and Stern 1948; Caspari and Stern 1948).

The hit hypothesis

As noted above, in his Nobel Prize research, Muller reported that the induction of mutations was not directly proportional to the X-ray dose, but rather to the square root of the dose (Muller 1927). Based on discussion with the physicist and future Nobel Prize winner Irving Langmuir (1932 Nobel Prize in Chemistry), Muller (1927) stated that this observation suggested that the induction of mutation was not caused directly by a single quantum of energy.

Table 1 Documentation of the introduction of the proportionality rule concept into the mutation literature, 1929–1960

References	Quote
Hanson and Heys (1929)	"It is only to be expected that the number of mutations be directly *proportional* to the number of rays to which the organisms are exposed." Page 207
Muller (1930)	"Since then Hanson, using radium, and Oliver in our laboratories using X-rays, have both found that the frequency of mutations produced is exactly *proportional* to the energy of the dosage absorbed… There is, then, no trace of a critical or threshold dosage beneath which the treatment is too dilute to work." Page 236
Oliver (1930)	"That is there is a direct *proportionality* between the percent of lethals and the length of time of treatment may be seen more readily by a comparison of the t_1 values calculated from the results for each of the given doses." Page 45
Stadler (1930)	"Mutation frequency increased approximately in direct *proportion* to dosage." Page 13
Hanson et al. (1931)	"Taking the amount of ionization in air as a measure, the mutation rate seems to vary approximately in direct *proportion* to the intensity." Page 142
Oliver (1931)	"By inference it can be added that the cosmic and the terrestrial radiations of higher energy content also are capable of producing mutations in *proportion* to their power of ionization." Page 480
Oliver (1931)	"The relation of *proportionality* to the dosage applies not merely to the lethals in general, but, more specifically, to the lethal gene mutations." Page 485
Oliver (1931)	"…[gene mutations and gene rearrangements] all probably occur in direct *proportion* to the dosage, no matter how small a dose is used." Page 486
Patterson (1931)	"In general their results [i.e., Hanson and Heys 1928 and Oliver 1930] justify the conclusion that the rate is directly *proportional* to the dosage employed." Page 133
Hanson and Heys (1932)	"Further evidence of the *proportionality rule* from a study of the effects of equivalent doses differently applied." Page 335
Hanson and Heys (1932)	"Experiments planned with a view to determining within what limits the *proportionality rule* holds show again a strict correspondence existing between the amount of radium administered and the consequent biological effect, the induced mutation frequency obtained varying directly with the dosage." Page 343
Hanson (1933)	"The rate seems to be directly *proportional* to the dosage. Muller has named this the '*proportionality rule.*' For example, when all other factors are kept constant, doubling the time of exposure also doubles the number of lethal mutations." Page 486
Oliver (1934)	"The frequency of induced mutations is directly *proportional* to the intensity of the treatment." Page 391
Delbruck (1940)	"The *proportionality rule* gave the basis for the single-hit interpretation…" Page 359
Stern (1950)	"The *proportionality rule* has been proven to hold over a wide range. Figure 155 shows that, for Drosophila, the relation is essentially linear over the range from 25 r to several thousand r. It has further been shown that the frequency of induced mutations is independent of the time over which the radiation is applied." Page 433
Stern (1960)	"It has been established for a variety of experimental organisms that the number of mutations induced by radiation is proportional to the dose. This *proportionality* has been proven to hold over a wide range of dosages." Page 491

However, subsequent exposure experiments by Hanson and Heys (1929), Oliver (1930, 1931) and later by Timoféeff-Ressovsky et al. (1935), even though all experiments were at very high dose, supported a proportionality relationship, which was consistent with the "hit" theory of mutation in which the X-ray treatment excites an electron in the target gene. This excitation was proposed to affect a permanent change or mutation to a different molecular structure. Ionizing irradiation was the only effective way to induce mutations; it showed no threshold, suggesting that the absorption of radiation is a quantized and additive process (von Schwerin 2010). A "quantum-jump" was considered to be the physical process caused by a hit on a target, resulting in mutation. Treatment effects induced by a physical agent like ionizing radiation were believed to be caused by one or several discrete biophysical events, that is, hits on a target. Based on hypotheses about what constituted a hit, statistical models were used to construct dose–response relationships. If there was only a single hit on a single target, the dose response was linear. As the number of assumed hits increased, a more threshold like the dose response would appear. In a practical sense, the mathematical model-derived dose response based on an assumed number of hits could be visually matched against the laboratory-obtained dose–response curve. Using this direct and simplified approach, researchers like Muller, Timoféeff-Ressovsky and participating physicists decided the theoretical number of hits. This type of target theory was especially strong in Germany, with support from leaders such as Boris Rajewsky (Director of the KWI for biophysics, 1936), Timoféeff-Ressovsky and others (von Schwerin 2010). This conceptual framework led to the conclusion that mutation was a

single-hit process, proceeding from a single ionization, from a quantum of ionizing radiation in a specific sensitive zone of the gene.

This theoretically based perspective became not only a workable model but a firm belief within the radiation genetics community even though there was no knowledge of the physical nature of the gene. As coauthor of the Timoféeff-Ressovsky et al. (1935) paper, Delbruck subsequently noted in his Nobel Prize lecture that it was thought that genes were very stable and, therefore, showed characteristics of molecules. However, the gene concept at that time was simply that of Mendelian algebraic rates, lacking structural chemistry insight. There was much speculation of gene structure including that of submicroscopic steady-state systems or even an entity not readily analyzable in chemistry as proposed by Bohr (1933).

The paper of Timoféeff-Ressovsky et al. (1935), as noted above, was striking in its collaboration between physics and genetics, its proposed chemical nature of the gene, size of the gene and in the proposal of a "hit" hypothesis as the foundation of the linear dose response for ionizing radiation-induced mutation. While the gene structure and size framework would be bypassed and replaced by the DNA structure of Watson and Crick (1953), the hit theory component of Timoféeff-Ressovsky et al. (1935) was accepted and implemented by the radiation genetics community. The term "hit hypothesis" became commonly used in the lexicon of radiation genetics, including those comprising the BEAR I Committee/Genetics Panel that recommended changing to a linear model from a threshold model for assessing mutation risks from ionizing radiation (Calabrese 2013).

The impact of this 1935 article was facilitated by the actions of Timoféeff-Ressovsky who sent reprints to key researchers. However, the overall immediate impact of the paper was very limited as it was published in an obscure Gottingen journal that was not cited in any leading index with only four issues being printed before ceasing publication. This paper, which provides the origin of the single-hit hypothesis to support a linear dose–response model, was not even cited in the BEAR I report that implemented the concept. Yet, the term "hit" hypothesis and target theory became commonly used, even if credit was not often given to the original paper (Timoféeff-Ressovsky et al. 1935). Nonetheless, this paper did receive a major endorsement in the 1944 book *"What is Life"* by Erwin Schrodinger, a Nobel Prize physicist (1933), raising its visibility in the physics community.

The concept of the gene and its striking stability suggested it must have a unique atomic composition. Delbruck (1970) believed that such stability might be due to each atom of a gene being fixed in its mean position and electron-stable, sunk in an energy well, now seen having stability due to the function of the hydrogen bond. Mutations of such genes could only occur following the absorption of high energies as from ionizing radiation, not from heat under physiological conditions. In fact, a modest increase in vibrational energy was estimated to increase the atomic stability, decreasing mutational risk. Since a transaction in an atom can be affected by a single digit eV and that the initial impact of an X-ray can be several fold greater, it was believed that any gene would be at risk for mutation from radiation. Since the initial energy of impact exceeds a threshold energy of activation, ionizing-radiation should affect not only the induction of a localized mutation but also that of a broad range of gene targets.

The mutation hit theory was challenged by Caspari and Stern (1948) in a chronic, very low-dose rate study, leading to the hypothesis that either a threshold exists or multiple independent primary actions are required for a mutation to occur, or that a recovery or repair effect/process occurred at a very low-dose rate (Howarth et al. 1950; Key 1951). Over the next several decades, the dominance of the physics-based target theory would yield to improved chemical/biological/physiological understandings of the mutation process, including such modified target theory effects of ionizing radiation as DNA repair (in reproductive and somatic cells), adaptive response, the bystander effect as well as the recognition that the biological effects of ionizing radiation are principally due to the generation of hydroxyl radicals/hydrated electrons from cellular water and their migration to cellular targets (Collinson et al. 1962; Czapski and Schwartz 1962; Weiss 1944). In fact, even as the target theory was being applied to mutation by Timoféeff-Ressovsky et al. (1935), the recognition of repair processes, including DNA repair, were emerging (Hanawalt 1994). Such challenges to the hit theory would eventually be brought to the BEAR Committee by Russell (1956, 1963) from Oak Ridge, but only after the BEAR 1 Committee made its linearity recommendation.

Edward Lewis (1957a), another radiation geneticist Nobel Prize (1995) recipient, published a very influential *Science* article in 1957, strongly supporting a linear relationship for cancer, relying on linearity data in the Uphoff and Stern (1949) paper. In subsequent Congressional Testimony, Lewis (1957b) would argue that the dose response was linear, regardless of the mechanism, and should be accepted as such whether or not a mechanism could even be discerned. These comments of Lewis suggested that he recognized the growing mechanistic challenge to the single-hit theory as well as new conceptual problems (e.g., multiple biological processes could yield a linear relationship that did not require a single-hit process) emerging from the physics and genetics communities, including Zimmer (1941), a coauthor of the Timoféeff-Ressovsky et al. (1935) paper and radiation biologists/geneticists (Haas et al. 1950;

Kimball 1952). However, the time period within which Muller's mutation findings were produced was one of the cultural scientific dominance of physics. Association with the leadership of the physics community served to enhance the significance of the mutational findings and its assumed linearity at low dose, as well as providing Muller with an expanded scientific and cultural context that recognized his achievements and enhanced his scientific reputation.

The influence of the hit concept of Timoféeff-Ressovsky et al. (1935) was facilitated via subsequent publications of Lea (1940, 1946), which offered further justification for the target theory-based LNT-single-hit hypothesis for mutation. The publications of Lea were not only authoritative extensions of Timoféeff-Ressovsky et al. (1935) but more readily available than the Timoféef-Ressovsky et al. (1935) paper with its publication in a defunct journal.

Regulatory agency actions

Ionizing radiation

In the radiation risk assessment area, two endpoints were adopted to which linearity was applied: germ cell mutations and cancer. In the case of germ cell mutations, based on several publications in the early 1950s by Muller (1951, 1954), the BEAR I Genetics Panel (1956) proposed to limit exposure to ionizing radiation such that exposure would not exceed doubling of background mutations from conception through the first 30 years of life. The panel assumed that exposure to ionizing radiation could cause mutations to germ cells in a linear manner and had the potential to cause adverse genetic effects in individuals and future generations. The panel derived a risk assessment methodology for application to both first-generation offspring and total genetic risk, including future generations. The panel derived a doubling dose method (i.e., the dose of ionizing radiation, assuming linearity at low dose, that would equal the number of mutations resulting from background exposure), to estimate population-based risks. This doubling dose methodology would predict the number of genetic diseases based on three parameters: the assumed doubling dose, the proposed exposure limit and the background incidence of genetic disease. Based on this risk assessment framework, the panel recommended a "uniform national standard" such that the members of the general population would not receive more than a cumulative dose of 10R from conception through 30 years. This basic method of the BEAR I Committee, using the doubling dose/linear framework, has been refined with recent advances allowing one to integrate between rates of radiation-induced mutation based on mouse studies and the risk of inducible genetic disease in people [Sankaranarayanan and Chakraborty 2000a, b; Sankaranarayanan and Wassom 2008 (see Lyon 2003 for an alternative view)].

In the case of somatic effects, cancer risks were estimated via the use of a linear dose–response model. Assuming linearity to zero, it was estimated that exposure of one rem to one million people each year would cause one to two new cases of leukemia on an annual basis for first decade of life (ICRP 1962; Sowby 1965; UNSCEAR 1962, 1964). As with chemical carcinogenesis risk assessment, therefore, the foundations of the LNT modeling for ionizing radiation-increased cancer risks are directly traced back to Lea, Timoféeff-Ressovsky et al. and ultimately to Muller's proportionality rule.

Chemical carcinogens

Five years after the publication of the BEAR 1 report, Mantel and Bryan (1961) published their influential paper entitled "Safety' Testing of Carcinogenic Agents" based on the probit dose–response model in order to estimate tumor incidence for carcinogens. Biostatistical estimates of cancer risks were first provided by Bryan and Shimkin (1943) when they applied the probit model to estimate the cancer risk of three carcinogenic hydrocarbons (i.e., 20-methylcholanthrene; 1,2,5,6-dibenzanthracene; 3,4-benzpyrene) in strain C_3H male mice.

The motivation for Mantel and Bryan to develop the biostatistical model for predicting carcinogen risk was due to the fact that Mantel, a biostatistician at the US National Cancer Institute (NCI), was asked by the Director of the NCI to develop guidelines for the number of laboratory animals that would be needed to establish the safety of a test agent within the context of a hazard assessment. This response followed a request, after the Thanksgiving cranberry scare of 1959, by the Secretary of the Department of Health, Education and Welfare (HEW) to the NCI. The cranberry scare was a public relations nightmare in which trace residues of a cancer-causing herbicide [i.e., amitrole (3-amino-1,2,4-triazole)] were detected in some sources of cranberries just before the holiday. The secretary of HEW recommended against buying cranberries that year, leading to a consumer panic that threatened the industry. In order to avoid such situations in the future, the secretary of HEW requested the NCI to provide guidance on which cancer-causing substances were "safe" and at what dosage levels.

Mantel and Bryan (1961) noted the generality of their modeling approach and proposed the concept of a virtually safe dose with an estimated risk of 1/100 million. Some 12 years later, the FDA would propose the use of the Mantel-Bryan (1961) model and recommend the 1/100 million safety guide in their July 19, 1973 risk assessment proposal in the Federal Register. When the rule was finalized in

1977, the Mantel-Bryan probit model was retained but with several modifications and with the acceptable (de minimus) risk being reduced to 1/million. This value was considered as the level below which no additional regulatory action would be taken within the context of the safety of animal carcinogen residues. The finalized Mantel-Bryan model of the FDA was the first quantitative risk assessment model approved by a regulatory agency. Two years later, the FDA (1979) significantly revised the cancer risk assessment policy, replacing the modified Mantel-Bryan model with a linear dose–response model based on multiple factors, including its more conservative risk estimation and ease of calculations (Anonymous, 1979). In the low-dose zone, the one-hit model discussed above is closely approximated by a simple linear model.

The US EPA strategy for assessment and regulation of carcinogens displayed a profound evolution during the 1970s. Based on expert testimony during pesticide hearings, EPA attorneys developed a legal brief that embodied "cancer principles" (NAS 1983). These "principles" suggested that carcinogen exposures should be prevented. As the concept of "banning" carcinogenic agents was soon seen as unrealistic, EPA quickly adopted non-regulatory guidelines for a general risk assessment process (EPA 1976). This process advocated the use of quantitative risk assessment as a means to differentiate risks among chemicals and engineering processes. The guidance was very general, being limited to less than a page within the Federal Register. These guidelines were followed by a paper from the EPA Carcinogen Assessment Group (CAG) (Albert et al. 1977), which provided a strong endorsement of the LNT concept, arguing that linearity was supported by human epidemiological studies (e.g., ionizing radiation and cigarette smoking related lung cancer) and mutagenicity studies that were also claimed to follow a linear dose response and believed to be the underlying mechanisms of carcinogenesis. In a March 15, 1979, Federal Register, the EPA Administrator Douglas Castle stated that "Risk assessment from animal data is performed using the 'one-hit' model" based on the 1976 Interim Guidelines (EPA 1976). He went on to state that "the one-hit model was endorsed by the four agencies in the Interagency Regulatory Liaison Group" based on its highly conservative nature and the uncertainties in extrapolating from animal data to human responses and the possibility that humans may be more susceptible than the animal model, because of broad human interindividual variability in exposures and "other unknown factors". The strongly clarifying and underlying statement of the administrator was due in part to the fact that EPA had used other cancer risk assessment models under other regulatory acts and by other US federal agencies.

According to Albert (1994), Chair of the EPA Cancer Assessment Group (CAG) during the 1970s, the EPA adopted the linear no threshold model (LNT) of the Atomic Energy Commission (AEC) that had been applied to estimating risks from fallout from atomic weapon tests. The LNT model was attractive to EPA since it was very simple to apply; all that was needed in a toxicological sense was to identify the lowest dose of agent that induced a statistically significant response and draw a straight line to the origin of the graph for the dose versus cancer incidence. Its biological plausibility was based on the linearity of mutation dose response within the framework of target theory. He noted that "any difference between chemical carcinogens and ionizing radiation could be waived aside as they both cause genetic damage…"

Statisticians would argue that the straight line extrapolation to zero from the lowest statistically significant response ignored data at the high doses. Thus, during a meeting of leading statisticians called by the CAG, a decision was made to change from the single-hit model to the multi-stage model since it used all the data, while retaining linearity at low dose and being compatible with the concept of cancer being a multi-stage process. Consistent with this assessment, the NAS Safe Drinking Water Committee (1977) recommended the adoption of LNT modeling for risk assessment using a multi-stage model. However, in 1982, the Safe Drinking Water Committee (SDWC) was skeptical about LNT modeling for chemicals and rescinded its endorsement of the LNT model noting "…more confidence could be placed in mathematical models for extrapolation if they incorporated biological characteristics of the animal studies… since the users of this volume will be likely to favor different varieties of the conventional extrapolation models or will have access to some of the newer developmental methodologies, it is premature at this stage to recommend any single approach by selecting it for calculations…" (p 8). However, since LNT modeling was already in use by EPA, in 1983, the SDWC again endorsed the LNT model and its subsequent use became the default methodology for chemical cancer risk assessment. According to Albert (1994), none of the possible models (single hit, multi-hit, logit, probit, multi-stage, others) were biologically credible. The agency simply needed one that would be acceptable. The agency applied LNT risk assessment methods using the multi-stage model for the regulation of trihalomethanes in drinking water in a November 29, 1979, notice in the Federal Register (EPA Environmental Protection Agency (US EPA) 1979a, b), a process that would be followed in subsequent EPA cancer risk assessments.

The parallel, yet converging linear dose–response strategies of the EPA and FDA represent the regulatory origin of current cancer risk assessment practices throughout the world. They are directly traced back to the efforts of Lea (1946) and Timoféeff-Ressovsky et al. (1935), all of which stemmed from the "Proportionality Rule" of Muller (1930).

Eugenics

While the LNT concept for mutation was born within the intellectual and scientific framework of the physics-based radiation target theory, its applications also found supportive resonance within the philosophical, ideological and political frameworks of eugenics. German eugenicists expressed considerable concern that ionizing radiation may hurt the German germ plasm (Proctor 1999; Martius 1931). Educational programs based on these concerns cautioned against exposures to ionizing radiation that might adversely affect future generations of Germans. Recommendations as early as 1927 by the Bavarian Society for Pediatrics and Gynecology stated that women receiving excess X-rays during pregnancy should abort their fetuses. Pushing this concept even further, in 1930, Eugene Fisher, director of the Kaiser Wilhelm Institute for Anthropology, argued that women exposed to X-rays should be permanently prevented from having children (Proctor 1999). Muller's own history is replete with his highly visible association with national and international activities advancing eugenics philosophy and agenda. Even as late as 1955, Muller gave a strong eugenics advocacy presentation in Germany, testing such ideas with a large audience of Nobel Prize winners (The Lindau Mediatheque 1955).

The biophysical concept of the gene had important eugenics implications. Since mutations could be induced by ionizing radiation in a linear at low-dose manner, this concept provided the principal foundation that all ionizing radiation—whether via medical diagnosis/treatment or industrially—was a concern for "genetic health". The genetic toxicology studies of Timoféeff-Ressovsky et al. (1935) transformed these above-cited radiation health concerns, providing biophysical models and the LNT-single-hit model risk assessment paradigm. Such actions provided a key vehicle by which eugenics would focus on radiation protection for preventing the occurrence of genetic defects. In fact, the development and activities of the genetics department of the Kaiser Willheim Institute under the direction of Timoféeff-Ressovsky was affected by such perspectives (Gausemeier 2010).

The concept of LNT for ionizing radiation-induced mutation was, therefore, built upon a scientific/cultural framework and applied to a range of health-related policies, especially those of eugenics during the early decades after the discovery of X-ray-induced mutations. In fact, the eugenics area would serve as an intellectual training ground for how ideas such as LNT could be "softened", humanized and successfully integrated within a post-World War II society. Some aspects of eugenics advocacy and the LNT concept would morph into modern regulatory policy for carcinogen regulation, evolving from that of preserving the gene pool of certain racial subgroups or other targeted populations to a humanistic framework that would reduce mutational risks to entire populations.

Evolution and endogenous mutations

The LNT had its start in an attempt to explain evolution, finding other outlets in the world of eugenics and later public health regulatory policies. While Muller was a leader in these activities, he did not abandon his quest to determine those underlying factors that served to provide the novel mutations for natural selection. In fact, prior to his discovery of X-ray-induced mutations in 1927, Muller reported that temperature increases enhanced the mutation rate by about two-fold (Muller 1928c). However, the temperature hypothesis was placed on the research back burner when high doses of X-rays were found to markedly enhance mutation frequency. Muller would return to the temperature–evolution hypothesis some three decades later, completing an intellectual and professional circle, reflected in the comments of Plough and Ives (1934), his former colleagues at Amherst College (1940–1945) who noted that "since Muller and Mott-Smith conclude that natural radiation is inadequate to account for mutations in nature, it seems possible to suggest that ubiquitous temperature variations may play that role". If Muller had lived into the decades of the 1980s (he died in the 1967), he would have begun to appreciate the so-called other conditions suggested by Oliver (1931) as the cause of the overwhelming proportion of spontaneously occurring mutations is now believed to be derived from endogenous metabolism, for which complex and integrative DNA repair processes have been selected for via natural selection (De Bont and van Larebeke 2004; Lindahl 1996).

Summary

The LNT concept was initially proposed to account for evolutionary change and then later applied for the assessment of risks for some genetic diseases and cancer incidence (Table 2). The initial data upon which the LNT concept was based were limited to a few studies of an acute nature and at very high doses. Within a decade, the LNT dose–response model was provided with a mechanistic foundation via the integration of the single-hit concept within target theory. The LNT-single-hit model was then used by radiation geneticists to frame the intellectual debate on low-dose ionizing radiation risk to the human genome. It provided the basis for the recommendations of the US NAS BEAR I Committee in 1956 for

Table 2 LNT history: the temporal sequence leading to the LNT dose–response model for cancer risk assessment

References	Specific temporal events
Muller (1927)	Mutation findings—X-rays induce mutations in fruit flies ⇓
Olson and Lewis (1928)	LNT model proposed to account for evolutionary changes following Muller's discovery that X-rays can induce mutations in fruit fly germ cells ⇓
Muller (1930)	Develops proportionality rule (i.e., linear dose response) for ionizing radiation-induced mutagenicity ⇓
Timoféeff-Ressovsky et al. (1935)	Application of radiation target theory for mutagens. Used target theory to propose a hit theory for ionizing radiation-induced mutation. The hit mechanism was used to explain the LNT dose response ⇓
BEAR I 1956 (Biological Effects of Atomic Radiation Committee, Genetics Panel)	Proposes the use of the linear dose–response model for germ cell mutation, using the "doubling rule" ⇓
Mantel and Bryan (1961)	Develops carcinogen risk assessment model based on the probit model. This activity was undertaken to advise US governmental agencies on chemical risk assessment ⇓
FDA (1973)	Proposes a probit-based quantitative risk assessment method for cancer risk based on the Mantel and Bryan 1961 paper. The proposal stated that an acceptable risk was 1/100 million ⇓
EPA (1976) (see Albert et al. (1977), Anonymous (1979)	Proposed guidelines for carcinogen risk assessment based on quantitative risk assessment. Recommended a linear dose–response model ⇓
FDA (1977)	FDA rule finalized, retaining the Mantel-Bryan model with some modifications. The acceptable risk value was changed to 1/1 million (10^{-6}) ⇓
U.S. NAS Safe Drinking Water Committee (1977)	Recommended that EPA adopt LNT for carcinogen risk assessment. This recommendation was profoundly significant given the widespread multimedia regulatory functions of EPA. Within 2 years of the recommendation, EPA applied the LNT to the regulations of trihalomethanes (e.g., chloroform) in drinking water ⇓
FDA (1979)	Replaced the modified Mantel-Bryan model with the LNT model for carcinogen risk assessment, based on the following reasons: 1. Linear procedure is least likely to underestimate risk. 2. Linear extrapolation does not require complicated mathematical procedures. 3. No arbitrary slope is needed to carry out linear extrapolation. 4. Several significant limitations were found with the application of the Mantel-Bryan model (Anonymous 1979) ⇓
EPA (1979a, b)	EPA established a national drinking water standard for trihalomethanes (including chloroform) based on an LNT methodology as recommended by the US NAS Safe Drinking Water Committee (1977)

the switch from a threshold to a linear dose–response model for estimating ionizing radiation-induced germ cell mutation using the doubling dose concept. The LNT-single-hit model was soon generalized to the process of cancer risk assessment and adopted by national and international committees concerned with ionizing radiation by the late 1950s and early 1960s. Five years later, Mantel and Bryan (1961), researchers at the US National Cancer Institute, proposed a probit model-based cancer risk assessment method. It was the Mantel and Bryan (1961) model that was proposed by the FDA in 1973 for cancer risk assessment procedures, being replaced with a LNT model by the FDA in 1979, the same year that EPA applied the LNT for the regulation of carcinogens (i.e., trihalomethanes) in drinking water. The LNT model and its single-hit explanation/mechanism theory, therefore, can be traced back to the concept of radiation-induced mutation target theory as proposed by Timoféeff-Ressovsky et al. (1935), which was founded on the proportionality rule of Muller (1930) which itself had its origins in the 1928 paper of Olson and Gilbert that created the LNT concept following the seminal findings of Muller (1927) that ionizing radiation could induce mutation in the germ cells of fruit flies.

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Public officials shoulder the responsibility of determining which involuntary threats to human health are unacceptable and which are acceptable. For example, how much exposure to a cancer-causing chemical, if any, should be regarded as acceptable for regulatory purposes? In this issue of RISK IN PERSPECTIVE, we offer a historical perspective on this question as well as some principles that should govern future decisions.

The Demise of the "Safe" Dose

Early thinking about acceptable risk was contributed by regulatory toxicologists, who suggested that "safe" levels of human exposure to chemicals could be defined. While virtually all chemicals are toxic at sufficiently high doses, many toxicologists believe in the concept of a "threshold" dose below which no one will be harmed. Laboratory experiments are undertaken to determine the highest level of exposure to a chemical that does not have an adverse effect on test animals. This no-observed-adverse-effect-level (NOAEL) is then divided by a safety factor of 100 or 1,000 to determine the "safe" human dose.

While the concept of a "safe" dose continues to have substantial support today, many scientists believe the concept is not applicable to cancer-causing chemicals. On the basis of radiation biology and epidemiology, it has been hypothesized that any exposure to a cancer-causing chemical is associated with some increase in the probability of tumor formation. If chemicals cause tumors through direct interaction with DNA (so-called "genotoxic carcinogens"), the relationship between dose and response may have no threshold. Although cells can repair damage to DNA, these mechanisms may not always be 100 per cent effective.

Even if carcinogens exhibit threshold doses, the levels may be too small to be helpful to regulators. People are exposed to numerous chemicals from natural and man-made sources, and this background exposure may exceed whatever threshold exists for a particular cancer-causing mechanism. Moreover, some people may be more susceptible to cancer than others, which means that background levels of exposure may already exceed thresholds for those individuals in the population who are particularly susceptible to cancer. On the basis of these arguments, some scientists emphasize that background levels of exposure to cancer-causing agents are already initiating the carcinogenic process.

De minimis Risk at FDA

The emerging notion of "non-threshold" chemicals challenged regulators at the Food and Drug Administration, who are responsible for guaranteeing the safety of the nation's food supply. How much of a carcinogenic food additive, if any, should be permitted in meat?

During the 1970's, the FDA recognized that some procedure would be necessary to quantify low-dose cancer risks from meat additives and to determine a degree of risk that could be regarded as "essentially zero." FDA rejected detectability as a standard for safety because serious health risks might exist below chemical detection limits and detection technologies were improving rapidly.

FDA's earliest proposal was to use animal data and a probit model to define a "virtually safe dose" that was associated with an incremental lifetime cancer risk of 1 in 100,000,000. Later, FDA replaced the probit model with a linear dose-response model, which was considered more protective than the probit model. When switching to the more protective dose-response model, FDA determined that a risk level of 1 in 1,000,000 would be adequate to protect public health. FDA considered but rejected 1 in 10,000 as an "essentially zero" level of excess cancer risk. Note that if 200 million Americans were each exposed to a meat additive that posed an 1-in-10,000 lifetime risk, 20,000 excess cases of cancer would be predicted over a lifetime. This

01110

example illustrates that the size of the exposed population, as well as the level of individual risk, need to be considered by public officials.

The federal courts have upheld the authority of regulatory agencies to define *de minimis* levels of risk from exposure to toxic chemicals unless the statute in question compels zero risk. The Delaney Clause, for example, effectively compels the federal government to set zero tolerance levels for any cancer-causing additive that concentrates in food. Agency efforts to permit risks as large as 1-in-1,000,000 from color additives and selected food additives have been overturned by federal courts. Given the impracticality of the zero-risk standard, Congress is now considering legislation to modernize the Delaney Clause.

Significant Risk at OSHA

In the late 1970's the Occupational Safety and Health Administration proposed a generic standard for identifying and regulating chemical carcinogens in the workplace. The proposal called for reduction of all carcinogenic exposures to the lowest levels that are technologically and economically feasible, regardless of the number of workers exposed or the size of the risks to workers. A "carcinogen" was defined as any chemical that has been shown to cause cancer in one sound study of animals or people. Industry petitioners challenged OSHA's emerging policy and argued for both quantitative risk assessment and benefit-cost analysis.

In the 1980 benzene case the Supreme Court held that OSHA must determine that a cancer risk is "significant" before taking steps to reduce or eliminate the risk. Justice John Paul Stevens commented favorably on the developing discipline of quantitative risk assessment. Stevens also opined that a reasonable person might regard a lifetime risk of 1 in 1,000 as significant yet regard a risk of 1 in 1,000,000,000 as trivial. In 1981, Justice William Brennan wrote for a majority of the Court (including Stevens) rejecting the legitimacy of benefit-cost analysis under the Occupational Safety and Health Act. Since these two rulings, OSHA has embraced quantitative risk assessment and used 1 in 1,000 as a threshold of significant risk.

EPA's Range of Acceptable Risks

The creation of the Superfund program in 1980 spawned an explosion of risk assessments at abandoned waste sites across the country. In the Superfund program, excess cancer risk is estimated based on exposure to a hypothetical highly exposed individual living near a hazardous waste site. In the early years of the program, a range of acceptable risk from 1 in 10,000 to 1 in 10,000,000 was used informally by some Superfund managers. In the 1980's the 1 in 1,000,000 standard became more frequently used as a justification for no-action decisions and, in some circumstances, as a cleanup goal. This number was apparently borrowed from FDA, even though the size of the exposed populations are not comparable and the costs of compliance in the two cases are not comparable. More recently, the Superfund program has defined acceptable excess cancer risk as a range from 1 in 10,000 to 1 in 1,000,000, which provides managers flexibility to consider site-specific factors such as population density, feasibility, and cost-effectiveness.

The range-of-risk approach has also been adopted by other program offices within EPA. In setting guidance for state water quality standards, EPA recommends a range of acceptable risk from 1 in 100,000 to 1 in 10,000,000, although in recent years the agency has approved state plans with an implicit risk level as large as 1 in 10,000. Meanwhile, EPA's air office seeks to reduce risk to as many people as possible to 1 in 1,000,000 while assuring that the maximally exposed individual is protected against risks greater than 1 in 10,000. During deliberations over the 1990 Amendments to the Clean Air Act, Congress rejected a prominent proposal to shut down any industrial facility that could not comply with a cancer risk level of 1 in 10,000 and ultimately 1 in 1,000,000 for the maximally exposed individual. While Congress retained the 1-in-1,000,000 benchmark as a screening tool to guide EPA priorities in setting residual emission standards, Congress expressed a healthy skepticism about the scientific basis of current risk assessment practices. Congress called for a National Academy of Sciences study of EPA's risk assessment methods and a Commission on Risk Assessment and Management to recommend a new legislative framework.

Beyond Magical Risk Levels

Although some observers see value in "bright-line" levels of acceptable risk, history suggests that acceptable risk will ultimately be defined on a case-by-case basis. Key decision factors such as the size of the exposed population, the resource costs of meeting risk targets, and the scientific quality of risk assessments vary enormously from one decision context to another. Administrative discretion is necessary to weigh these factors on a case-by-case basis. No magic risk number can substitute for informed and thoughtful consideration by accountable officials who work with the public to make balanced decisions.

Further Reading
Alon Rosenthal, George M. Gray, and John D. Graham, "Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals," *Ecology Law Quarterly*, vol. 19, pp. 269–362, 1992.

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History

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U.S. Food and Drug Administration

Title:	**A Brief History of Risk Assessment**
Lecturer:	**Peter Barton Hutt, Esq.**
Date:	**November 1, 2000**

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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INDEX

A Brief History of Risk Assessment

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TAPE 1, SIDE A

Good morning, everyone. I very much wish that I could be with us at the seminar this morning, but, unfortunately, I have a prior commitment on the West Coast, and thus this videotape appearance will have to substitute. But I am pleased that I can at least fill you in on some of the development of quantitative risk assessment over the past 30 years at the Food and Drug Administration.

But first you must understand that no regulatory policy simply springs full-blown from the head of a regulatory agency without prior history and prior development. And quantitative risk assessment is indeed one of the oldest concepts in human history.

If you go back in history, you find that for centuries, literally from the beginning of recorded history, every recorded civilization has regulated food and drugs one way or another, through laws, regulations, tradition, from biblical times, indeed from the clay tablets of ancient Sumaria to the present. And when you

try to regulate, one of the issues is, how do you define safety.

Let me give you, for example, one of my favorite statutes enacted by Parliament in 1266. The statute prohibited the addition of any substance to the then-staple food supply if that substance was -- and I give you a direct quote -- “not wholesome for man’s body.” Now, that is no different than our current definition of safety, but it provides no operational content. And thus from the beginning of time to today, the whole search in regulatory law is to provide good science that will in fact incorporate an operational definition of safety.

In those days, of course, in 1266 and, indeed, going back to early recorded history, how did we find what was safe? By having either wild animals or domesticated animals or even humans eat the substance. And if you think that’s far-fetched, and if you think that’s ancient history, let me give you just something that happened a hundred years ago.

In 1902 to 1904, the famous FDA Commissioner, Dr. Harvey W. Wiley, wanted to publicize the issue of food safety, and he chose a way to do that that I’m sure you are all going to be somewhat amused by. What he did was find the 10 youngest members of the then Center -- it really

wasn’t a Center, it was a Division of Chemistry in the United States Department of Agriculture, and he took the five leading food preservatives of that time and fed them to those people for two years, a human feeding experiment. There was no concept of animal testing in those days. And to further illustrate just how remarkable this was, one of those preservatives was formaldehyde. So we have, just a hundred years ago, a human feeding study in formaldehyde. That was the way because there was no operational definition of safety that things were determined either to be harmful or to be safe in those days, not that long ago.

Now, things began to change very rapidly. For reasons that are lost in history, suddenly scientists, academic scientists, throughout the country began to develop inbred colonies of test animals. By 1920, animal testing had suddenly come into vogue, and it was, some people hypothesize, largely a rediscovery of Mendel’s laws of heredity that resulted in this scientific progress. But we begin to see in 1920, and going on up through the decades, increased reliance in our country and throughout the world on use of animal testing experiments to determine safety. But the issue remained, what was the definition, the operational definition, of safety that came out of those experiments?

In the 1930s, people began to think about an operational definition, and indeed, there's a wonderful paper in 1935 by Dr. Berenblum in which he began to focus on the issue of chemical potency. And, of course, everyone knew at that time, that has often been said, that dose makes the poison, but no one knew where to draw the line between a poison and a safe dose. Berenblum was the first person in the area of carcinogenicity that I have been able to find who attacked that on a mathematical basis and tried to resolve it.

But then came along, as it often does in history, a remarkable event no one could have predicted that suddenly began to focus people on the real issue of operational definitions of safety.

In the fall of 1937, a well-known pharmaceutical company of that era, still with us today, Massengill, brought out what today we would call a breakthrough drug, elixir sulfanilamide. The scientific progress that this represented was that sulfa had never before been put into solution, and Massengill solved that problem. They did some chemical testing, no animal testing, rushed this product out into the market, and managed to kill 120 people in two days, because the solvent they used was diethylene glycol. Now, of course, this led to not only a nationwide

recall, but it also led to the enactment of our current Federal Food, Drug and Cosmetic Act of 1938.he was involved in.

But there were two brilliant and really thoughtful FDA scientists who said, “Let’s learn from this. How often do you have this kind of a tragedy that you can turn into a real benefit to public health?” And so Dr. H.O. Calvary and Dr. Hogarth Fitzhugh, FDA toxicologists, both went out and did a remarkable set of experiments. The first thing they did was they collected all the information on the people who had taken elixir sulfanilamide, the dose they had taken, the amount of time they had taken it, and their body weight, and then they figured out who lived and who died.

Following that -- and you can imagine, that’s obtaining an LD50, a human LD50 for elixir sulfanilamide.

Then what they did was go back and do the animal experiments that Massengill should have done. They did them in a wide variety of species: rats and mice and hamsters and dogs, and everything else. And what they discovered was that there was roughly a tenfold variation among humans and roughly a tenfold variation among the animals. They multiplied 10 times 10, arrived at 100, of

course, and therein lies the history of the famous FDA 100-to-1 safety factor.

You will be interested to know that I have never seen this written up. Someday I am going to write up this story.

I interviewed Hogarth Fitzhugh before he died, as well as all the other then-living FDA toxicologists of that era, and discovered that this was one of the great unknown heroic stories of the Food and Drug Administration of that era.

Well, you might say, okay, we have a 100-to-1 safety factor for acute toxicity. What about chronic toxicity? And, more important, what about carcinogenicity?

Fitzhugh told me that all of the folklore I had learned, that the 100-to-1 safety factor had initially been applied to carcinogens, then they had increased it to 2,000-to-1, and then 5,000-to-1, was all nonsense. It was untrue. FDA never once applied a safety factor to a carcinogen. And, in fact, I went back and discovered, as early as 1945, FDA banned its first carcinogen, a substance called butter yellow. In 1950, FDA banned two non-nutritive sweeteners. You probably have never heard of them before: dulcin and P4000. And, thus, long before Mr. Delaney invented his famous Delaney Anti-Cancer Clause and

put it in the Federal Food, Drug and Cosmetic Act of 1958, FDA had adopted a policy of zero tolerance, no permitted amount of carcinogen in any food in the United States could be had.

Now, this was, of course, incorporated into the law. But the Delaney Clause, I have always thought, was misunderstood. The Delaney Clause does not say that Congress knew that one molecule of any carcinogen would cause human cancer. What the Delaney Clause said was basically the same thing that Fitzhugh and Calvary and the others were saying much earlier, 15 years earlier, and that is, we don't know how much of a substance is needed. We don't know how potency plays in the area of carcinogenicity. And, therefore, we will, until we learn more, adopt a policy. We won't add carcinogens to the food supply. It was a principle of conservatism. It was not based on scientific knowledge; it was based on the lack of scientific knowledge.

Now, only four years after the Delaney Clause was enacted as part of the Food Additives Amendment of 1958, Congress was presented, surprisingly, with quite a different issue, and one that, for our purposes this morning, is very important. Congress had to face this. Part of the food-additives definition excludes from the

definition of food additive any substance that had been approved by FDA or USDA prior to 1958. Included in those substances was a well-known chemical, you all know it very well, diethylstilbestrol, or DES. And what happened was that the largest manufacturer of DES in the country had a prior sanction for that substance. His plant burned down. He built another plant across the street to make the same substance, and FDA took the position that he couldn't make it because the prior sanction only applied to the first plant and did not apply to the second plant. So, surprisingly, Congress enacted a law as an exception to the Delaney Clause, saying that FDA could approve a carcinogenic animal drug if in fact the residues of that animal drug were not found in the food produced by the animal using methods of analysis approved by the Food and Drug Administration. That basically is what that amendment stated. And, as we will see in one moment, it was that amendment that led to the development of quantitative risk assessment as a regulatory tool in this country.

Now, FDA, faced in 1962 with this amendment, had to come up with a definition of what method of analysis is approved, and what they did was they came up with a mouse uterine acid sensitive to two parts per billion. So from 1962 to 1972, FDA allowed DES to be used, to be made and to

be used in food-producing animals, both in the feed and in implants, based on the mouse uterine acid.

Well, in 1971, unfortunately, just at the time that I arrived at FDA as Chief Counsel, things began to change, and ominous clouds gathered over this entire enterprise. There were three congressional hearings in 1971 questioning FDA's policy on DES. And USDA decided they would definitively resolve this matter. They later, I might add, regretted that decision very much.

So in early 1972, USDA undertook a study in which they tagged, did radioactive tagging of DES to find out exactly what happened to it in the food, in the cattle that it was used in. And, not surprising -- I'll never forget it -- July 28th, 1972, I got a telephone call that in effect said, "Not only have we found it, we found it everywhere. We know exactly where the DES is going. It doesn't get out of the animal. It's still there, at very low levels, but it's there." I spent the next three days writing a *Federal Register* notice that banned DES from animal feed, and a year later, of course, we did the same thing with implants.

Now, it was one thing to lose DES. The Secretary of Agriculture informed me I had just raised the price of beef seven cents. I must admit, that did not concern me. What did concern me was, we had been approving carcinogenic

animal drugs for 10 years based on this concept of what I came to call, to the consternation of scientists throughout the country, hide-and-go-seek toxicology, i.e., if you can't find it, it isn't there. We all know that's not true. If you can't find it, it's because you don't have good enough analytical methods to find it. That is true.

So I said to the Center for Veterinary Medicine, I sent them a memorandum shortly after the DES controversy abated, and I said, "I will approve no more animal drugs that are carcinogenic based on the old policy. We must come up with a new policy that is both legally and scientifically sound."

Now, you might say, "Well, who cares what the General Counsel says about animal drugs?" The answer was, since they all, all the approvals had to be published in the *Federal Register*, they could only get there if I approved them. And since I declined to approve them, there was a growing stack on the right-hand side of my desk of *Federal Register* notices that, as far as I was concerned, would never see the light of day unless and until we came up with a new method of approaching this. So there was, in a sense, a mounting crisis both in the Bureau of Veterinary Medicine as well as in my own mind.

During this entire time, during this saga of DES, things were going on that, frankly, I had no knowledge about, both in the Center of Veterinary Medicine as well as in academia. People had been trying to confront, on a purely academic level, this issue that Berenblum had started with in 1935. And this culminated in the National Institutes of Health (NIH) in two well-known and well-respected scientists, Mantel and Bryan, coming up in 1961 with a concept that not only quantified carcinogenic risk, but purported to determine what was, in their terms, a virtually safe dose. And they did it by a mathematical model, but they chose as the virtually safe dose a, if you will, safety factor of no greater than 1-in-10-billion risk, 10^{-8}. That was in the scientific literature for 10 years. And, of course, because it was an academic issue, no one in FDA paid any attention to it at all, except for one person, Adrian Gross, an FDA toxicologist.

Now, Adrian Gross at that time was at FDA. Later -- in fact, he was in the Bureau of Veterinary Medicine. Later, he went to the Environmental Protection Agency (EPA). EPA. He was a difficult person. He was personally not the easiest individual in the world to get along with. He was highly persistent, he was a very, very strong consumer advocate, but he was also a very intelligent and

thoughtful person. And as early as 1970, Adrian had published an article applying the Mantel-Bryan, not to a carcinogen, to a chemical that he thought, erroneously as it turned out, was a reproductive toxicant, the flavoring substance methyl salicylate.

Well, Adrian, in 1971, internally in the Center, or then, as it was, Bureau of Veterinary Medicine, began to write memoranda that I discovered literally 10 years later by reading congressional hearings, stating that Mantel-Bryan ought to be used on substances like DES. Those internal memoranda never got out of the Bureau, never got to me, never got to the Commissioner's office, and, thus, we were unaware of it.

But when those applications began to pile up on my desk, one afternoon a very, very fine, bright, extraordinary scientist from the Bureau of Veterinary Medicine walked into my office, his name Dick Layman [sp.] -- he's retired from FDA now -- and he sat down and said, "Peter, I've got to talk to you. Here is a possible way to solve this problem." In less than a half hour, Dick laid out to me the concept of Mantel-Bryan, the concept of a quantified risk, and the solution to the problem. It took me probably five minutes to realize this was in fact the solution, not a perfect solution, but this was the only way

to go, to quantify risk and then determine what level of risk is acceptable to our society.

That night I called Charlie Edwards, the Commissioner of FDA, and said, “Charlie, this is the way to go.”

And Charlie, being the person he was, said, “We go with it.” That decision was made in a matter of minutes.

Nonetheless, it took more than a year to draft this up for purposes of the *Federal Register*.

You’ll be amused to know that almost everybody in FDA found objections to it. Now, why was that? Well, the Bureau of Foods opposed it because Leo Friedman, the great toxicologist that he was, and Al Copey [sp.] both said, “We want to rely on scientific judgment. We don’t want to be hemmed in by rules and mathematical formula and specific levels of acceptable risk. Charlie and I simply said, “You can’t go that way.”

Then the Bureau of Veterinary Medicine weighed in, Dr. Van Houweling and others there, who said, “We can’t meet this standard of 10^{-8}. That would mean that almost all of these carcinogenic animal drugs would not survive.”

Now, let me explain exactly why they were concerned. The way that Mantel-Bryan was proposed to be used was as follows: What you did was calculate the amount of residue in the food that would be permitted in order to assure only

a 10^{-8} risk, and then you require the applicant to come up with a method of analysis sensitive to that level that represented 10^{-8}. Once you did that, and then you showed no residue at that level, it was approvable.

Now, Van Houweling kept saying to me -- and we came to call this the Sensitivity of the Method proposal -- that the SOM proposal was unworkable. Simply, it was a lovely academic idea, but, in fact, what it would do is ban everything. Well, we now know that it hasn't banned everything. It is still the policy that is pursued by FDA today in approving carcinogenic animal drugs.

Now, events that we could not have foreseen way back in 1972, when I was dealing with this, have now made this policy, the concept of using quantitative risk assessment, far more effaceable an any of us ever could have imagined.

As you know, and as we all know now, almost 30 years later, many, many more chemicals have been tested and, for example, in the National Toxicology program (NTP) NTP program, 50 percent of the tested chemicals have turned out to be carcinogenic. The improvements in analytical methodology means that we can find these substances everywhere, absolutely everywhere. As early as 1979, FDA actually published a statement in the *Federal Register* saying that, in fact, every bit of food in the country

contains some carcinogen of one form or another. We could not live without eating substances that have been tested and found to be carcinogenic in test animals. And thus, the old policy that Olgarth Fitzhugh followed in 1945 and thereabouts of banning every carcinogen, we can't do, and we haven't been able to do it for 30 years.

Thus, as it turns out -- and none of us, I can tell you, certainly not me, and I drafted much of it, none of us at the time anticipated it would become as pervasive in the entire government and as important to FDA as it, in fact, has become.

There are a couple of other principles we developed at the same time. One of them is that we realized that not everything that came up carcinogenic in a test animals was in fact appropriately designated a carcinogen. And we began to take into account whether in fact the animal was a good model for the human. And these are well-known examples. The most amusing to me is, if you feed calcium to bulls, they get cancer. That has never driven FDA to ban or restrict calcium in our diet. As you well know, BHA and BHT are suspect carcinogens, but FDA has done nothing because they have concluded that the animal model is not a useful model for the human.

A second area where FDA has taken action is to recognize that some carcinogens act through a secondary rather than a primary method. And, in fact, I wrote the regulations back in the 1970s that said that FDA would not ban alcoholic beverages -- that was an easy one; I had little doubt about that one -- or selenium because they were carcinogens, indeed, human carcinogens, but they acted through a secondary mechanism of action and thus were not under the Delaney Clause.

And, finally, we realized, though, that those ways of getting substances out from under Delaney were [unclear]. The basic mechanism, the basic policy that we had to rely on, had to do with quantitative risk assessment.

What we then saw was the proliferation of quantitative risk assessment throughout the entire food and drug area. For example, the hair dyes 4-MMPD and lead acetate were approved by FDA based on quantitative risk assessment. Food contaminants like aflatoxin and dioxin were approved, or not approved but at least permitted based on quantitative risk assessment. Acrylonitrile and vinyl chloride was recognized to be permitted in food packaging based on these principles, and, of course, other food constituents.

FDA had to go in through this piecemeal, finally came to a food-constituents policy, which states that if there is a constituent in food that is carcinogenic -- and there are hundreds of them -- they are not required to be banned as long as they do not present a significant carcinogenic risk.

The final part of this is, what is an acceptable level of safety? Now, Mantel and Bryan started at 10^{-8}, 1 in 10 million, and -- I'm sorry, 1 in 100 million. And after considering that and listening to both the industry and to the scientists in FDA, the final regulation on sensitivity of the method and the level chosen by FDA ever since there was reduced to 1 in a million, so that this is a much more realistic risk.

Now, FDA has not only reduced it to 1 in a million, but FDA has flatly said, in probably 50 different *Federal Register* notices, that the 1-in-a-million risk, 10^{-6}, means no carcinogenic risk at all, that while that is a mathematical possibility, it is not a real risk in the actual practical world. Moreover, my feeling is that, in the future, there are possibilities for reducing that. Under Proposition 65, for example, California has gone to 1 in 100,000.

Now, where can we reduce that? We can reduce that with better science. If we can understand better the pathways, the mechanism of action of some of these carcinogens, we can understand how animal and humans are either the same or different in particular chemicals or for classes of chemicals. We will be able to have greater confidence in extrapolation from high dose to low dose, and therefore will be able to reduce the 1 in a million not only down to 1 in 100,000, but in some chemicals, much lower than that. I don't know if we'll ever get to the same level that we started with Calvary and Fitzhugh of 100 to 1 for acute risk, but certainly we will get below 1 in a million.

What we need most of all in this area is public education. The public doesn't understand this at all. They hear the word cancer or carcinogen and they freak out. I don't blame them. It's a frightening thought. We need to educate people about risk assessment. We need to educate them about the enormous amount of conservatism built into our present system.

There are still consumer activists out there who want to ban every single carcinogen that exists. Fortunately, FDA has never felt that way, they know it's not possible, and they are willing to rely on good science.

Well, I simply want to close by saying it’s been a pleasure this morning to be able to be with you, even if by videotape. I hope this bit of history is of interest to you and that it will, in a sense, pave the way for the real experts, the scientists, my good friends from Environ, who are going to go into the details of quantitative risk assessment in just a few minutes.

Thank you very much for being with me and for allowing me to be with you.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 27]

QUALITY STANDARD FOR CANNED CHERRIES

Proposed Revision of Blemish Limitation

Notice is given that a petition has been filed by the National Canners Association, 1133 20th St., NW., Washington, DC 20036, proposing that the standard of quality for canned cherries (21 CFR 27.31) be amended by:

(1) Changing the definition of a blemished cherry; and

(2) Increasing the aggregate area of the blemish from $\frac{1}{16}$ inch to $\frac{9}{32}$ inch in diameter.

Grounds set forth in the petition in support of the proposal are that: (1) The proposed change in the definition of a blemished unit would be consistent with objections received to an order, published in the FEDERAL REGISTER on February 23, 1971 (36 FR 3364) ruling on a proposed cherry pie standard of quality (21 CFR 28.2). These objections requested that the $\frac{1}{16}$ inch diameter limit for blemished units be changed to a $\frac{9}{32}$ inch diameter limit. The Commissioner of Food and Drugs granted this request in the FEDERAL REGISTER of June 13, 1973 (38 FR 15503).

(2) Mechanical harvesting and bulk handling in tanks of water have replaced the traditional hand picking and handling. As a result there has been a greatly increased problem with a mild form of discoloration known as "tank or water scald" which results in minor color variation but does not affect the tissues or eating quality or the cherries.

(3) Since the present standard was established 32 years ago, changes in cultural practices have resulted in the production of larger and softer cherries. Presently, there are as few as 100 to 110 cherries per pound as compared to 140 to 150 per pound when the standard was adopted. The larger, softer cherries have aggravated the blemish problem because they are more susceptible to blemishes and contain a greater surface area compared to the permitted area of skin discoloration.

(4) Increasing the area of the blemish to 9/32 inch would bring the quality standard for canned cherries (21 CFR 27.31) into agreement with the present voluntary U.S. Department of Agriculture standard for grades of frozen cherries.

(5) The proposed change will insure consumers a continued supply of canned cherries without significantly affecting the quality.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 27 be amended in § 27.31 by revising paragraph (a)(5) to read as follows:

§ 27.31 Canned cherries; quality; label statement of substandard quality.

(a) * * *

(5) Not more than 15 percent by count of the cherries in the container are blemished with scab, hail injury, discoloration, scar tissue or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle 9/32 inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into the fruit tissue is also considered to be blemished.

* * * * *

Interested persons may, on or before September 17, 1973 file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 20, 1973.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.73-14749 Filed 7-18-73;8:45 am]

[21 CFR Part 135]

COMPOUNDS USED IN FOOD-PRODUCING ANIMALS

Procedures for Determining Acceptability of Assay Methods Used for Assuring the Absence of Residues in Edible Products of Such Animals

The Federal Food, Drug, and Cosmetic Act requires that compounds administered to animals as food additives, color additives, or animal drugs be shown to be safe for use. The term "safe" refers to the health of man or animal under section 201(u) of the act. In evaluating the safety of such compounds used in food-producing animals, consideration must be given to the safety of possible residues in the products of those animals which are a source of food for man. When there is insufficient evidence to establish that a finite or negligible residue of the compound is safe in human food, or when the anticancer clauses contained in sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) of the act are applicable, a zero tolerance (no residue) must be required. (Under the provisions of the anticancer clauses no compound may be administered to animals which are raised for food production if such compound has been shown to induce cancer when ingested by man or animal, unless such compound will not adversely affect the animal and no residues, as determined by methods of analysis prescribed or approved by the Secretary, are found in the edible products of such animals under conditions of use specified in labeling and reasonably certain to be followed in practice. A decision is then required as to whether a practicable method exists to determine the absence of such residues in food, under sections 409(b)(2)(D), 512(b)(7), and 706(b)(5)(A)(iv) of the act.

The Commissioner of Food and Drugs has determined that it would be in the public interest to set forth the principles involved in application of these safety provisions of the law with respect to the adequacy of the sensitivity of the required regulatory assay method for monitoring compounds which may be administered to food-producing animals, but for which no residue is permitted in human food. Therefore, a new regulation is proposed to establish the minimum standards for determining the acceptability of assay methods used to assure the absence of residues in edible products of such animals. These proposed regulations do not apply to drugs for which a finite or negligible residue is established as safe for human food.

The proposed new regulation will apply to two classes of compounds administered to food-producing animals: (1) Exogenous compounds, defined as those compounds which are not produced by the normal animal and are not required for normal animal body function (e.g., diethylstilbestrol), and (2) Endogenous compounds, defined as those compounds which are present in and produced by the normal animal and are not required from an exogenous source (e.g., estradiol).

In evaluation of the safety of compounds of both classes the initial testing must involve detailed metabolism studies in the target species. Radiotracer studies are usually the method of choice. The purpose of these studies will be to identify the metabolites of the compound, both qualitatively and quantitatively, and the concentrations of the compound and its metabolites in specific tissues ("tissues" include milk and eggs, if applicable). Another aspect of these studies will be the determination of the effect of the administration of the compound on tissue levels of related endogenous compounds.

For acceptable studies, it is necessary to follow the degradation of the compound and/or its metabolites after slaughter and during the period that the edible tissue would normally be held under storage conditions as well as to determine the impact of cooking at appropriate temperatures on the compounds in question.

EXOGENOUS COMPOUNDS

Determination as to whether an exogenous compound and/or its metabolites will require carcinogenicity testing will be based on the results of the metabolism studies, standard toxicity testing, structural relationships of the compound and or its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended use pattern of the compound. Tests for carcinogenicity will be routinely required for any new compound for which a priori knowledge is incomplete and which is intended to be used for disease prophylaxis and, or production purposes (e.g., increased rate of weight gain, estrus synchronization, etc.).

01133

If it is determined that tests for carcinogenicity are not required, or if the results of such tests are negative, consideration leading to approval will be based on standard toxicological procedures. These procedures will include, in addition to subacute studies in a minimum of two species, such studies as multi-generation reproduction studies, teratological and any other special studies which may be indicated from the nature of the biological action of the compound, including life-time studies. These studies will involve collecting data from appropriately designed dose-response experiments that demonstrate a maximum "no harmful effect level" as well as a minimum "harmful effect level" in appropriate animal species.

Where a residue is permitted as safe in human food (either as a finite tolerance level or as a negligible residue of less than a specified level), the sensitivity of the assay method will be required to meet the specified level, and the other provisions of this proposed new regulation relating to the required sensitivity of the method will be inapplicable. Where no residue (zero tolerance) is permitted, the provisions of this proposed new regulation are fully applicable.

Under the proposed new regulation the dose-response slope estimated from the toxicological experiments will be used to extrapolate to the required level of sensitivity of the method using appropriate confidence interval techniques in accordance with the concepts underlying the Mantel-Bryan procedure discussed below. Where such extrapolation is not scientifically appropriate, e.g., if no dose-response slope can be estimated from the data, other conservative methods will be invoked to determine an appropriate safety margin based on a thorough evaluation of the quality of the experiments, their rigor as predictive tests and the nature and significance of the observed biological effects.

Where tests for carcinogenicity are required for a compound there are two basic objectives of the tests. The first is to determine whether or not the compound and/or its metabolites is a carcinogen. The second is to determine the relative potency of the compound and/or its metabolites with respect to both its carcinogenic and its noncarcinogenic but toxic effects, through appropriate oral dose-response experiments. Test systems will be selected which maximize sensitivity to detect a minimal dose which induces a carcinogenic effect. These systems will include a sufficiently stable control population to avoid false-positive indications of carcinogenesis.

There is a general lack of agreement within the scientific community regarding appropriate protocols for determining the dose-response relationship of carcinogenic compounds. Until they are revised, the guidelines for protocols set out by the Food and Drug Administration Advisory Committee on Protocols for Safety Evaluation: Panel on Carcinogenesis Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides (Toxicology and Applied Pharmacology Vol. 20, pp 419–438, 1971) will be followed by the Food and Drug Administration.

If the results of the test for carcinogenicity establish that the compound or its metabolites will induce cancer in test animals, the required sensitivity of the regulatory assay method will be determined based on the Mantel-Bryan procedure described in the article entitled "Safety" Testing of Carcinogenic Agents (Journal of the National Cancer Institute, Vol. 27, pp 455–470, 1961). However, rather than assuming a dose-response relationship with a slope of one, as suggested in the reference, experimental data obtained from the carcinogenicity studies will be used to obtain a statistical estimate of the slope of the dose-response relationship. The lower 90 percent confidence limit of the estimated slope will be used for extrapolation to the required level of sensitivity of the regulatory assay method. If the data indicate that some linearizing transformation other than the probit-log transformation used in the modified Mantel-Bryan procedure better describes the observed response and has a biological rationale, then this other linearizing transformation may be used for such extrapolation. Examples of the application of this technique are given in the above reference.

Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g., 1/100,000,000), under those exposure conditions of the basic animal studies. Such test conditions generally involve continuous daily lifetime exposure to the compound in question. In contrast, many types of foods are consumed only intermittently, e.g., turkey or broiler kidneys, and therefore any drug residues contained in such foods will be consumed only intermittently. If the same procedure was used to determine the level of exposure for turkey kidneys as was used to determine the level of exposure for foods consumed more frequently, such as beef muscle, the population would not be equally protected in both situations. Consequently, it will be necessary to adjust the procedure for establishing the exposure level to account for usual as well as specific human consumption patterns. Any such adjustments initially will be made on a conservative basis. These adjustments will take into consideration the consumption expected by those who consume the greatest amounts of food, not the average consumption of the food. More definitive information is being complied on food consumption patterns by the Food and Drug Administration, and this information will be used to arrive at more refined adjustments as it becomes available.

It will also be necessary to modify the procedure for establishing the exposure level to account for drug usage, patterns, e.g., the administration of a drug in the treatment of diseased animals. As with consumption patterns, justified modifications will be made on a conservative basis. If a disease has a maximum incidence of 10 percent, then no more than 10 percent of the marketed animals would have been treated with the drug. Under these conditions, the probability of continuous daily exposure for an individual consumer could be very conservatively estimated as 0.10. In this situation, the true probability of risk for the individual consumer would then equal the probability of individual risk under conditions of continuous daily exposure to the drug multiplied by the probability of an individual actually experiencing continuous daily exposure to the drug. If a true exposure of 1/100,000,000 were deemed acceptable for an individual on the basis of risk-benefit considerations, this value could be held constant by assuming a continuous exposure risk of 1/10,000,000 (1/100,000,000=1/10,000,000 X 0.10) in the estimate of the Mantel-Bryan level. The true individual consumer risk would remain at 1/100,000,000 since the consumer is only intermittently exposed to residues of the compound in food.

The maximum level of exposure as estimated above, after standard adjustment for the differences between daily food intake per unit of body weight of the laboratory animal as compared with man, will be the required sensitivity of the assay method for a compound. In the event that both non-carcinogenic harmful effects and carcinogenic effects are observed during testing, the lowest level for the regulatory assay sensitivity as determined for the different effects will be adopted.

Withdrawal or post-medication periods for exogenous compounds shall be based on data obtained from tissue depletion studies. The compound must be administered to test animals for a sufficient time for concentration equilibrium to be achieved. On the basis of the developed assay and/or other suitable methods, a determination must be made as to the time when tissue levels of the parent compound and/or its metabolites and/or any affected endogenous compounds are below the required level of sensitivity for the regulatory assay method.

The withdrawal period shall be the longer of: (1) The number of days for tissue levels to be depleted to less than the maximum level of exposure extrapolated by the modified Mantel-Bryan procedure plus a safety factor to account for animal to animal variation (as determined by appropriate confidence interval techniques) or (2) the number of days for any affected endogenous compound to return to normal levels plus a safety factor to account for animal to animal variation. (The normal level of the affected endogenous compound will be established as described below for endogenous compounds.) For example, if excretion data indicate that the average depletion time for an exogenous compound is 72 hours with a safety factor of 27 hours, the withdrawal period becomes (72 hours+27 hours) = 24 hours or, after

01134

rounding upward, 5 days. Current livestock management techniques must be considered in establishing the withdrawal period and may necessitate the lengthening of this period.

The provisions of the proposed new regulation govern the required level of sensitivity of the regulatory assay method for those compounds for which a zero tolerance (no residue) is established. If a regulatory assay method of lower sensitivity is later developed and validated, however, the Commissioner will adopt that more sensitive method and publish it in the FEDERAL REGISTER, even though its development was not required under the law.

ENDOGENOUS COMPOUNDS

It is proposed that animals shown to contain tissue levels of endogenous compounds above the normal due to the administration of such compounds will not be permitted to be marketed for human consumption. Thus, neither tests for carcinogenicity nor standard toxicity testing will be required for endogenous compounds.

Naturally occurring (background) tissue levels of endogenous compounds and/or their metabolites and/or other related endogenous compounds in the target species must be determined in studies designed to show the effect of geographical location, stage of estrus, age, etc., on normal animals receiving no external source of the endogenous compound. The tissue distribution of the levels of the compound and/or its metabolites and/or other related endogenous compounds will be estimated from these studies. This distribution will be used to establish the required sensitivity of the regulatory assay method. The required sensitivity will be that level of the tissue distribution which is exceeded by only one percent of the normal animals. Tissue samples from animals at slaughter will be considered suspect if a level is found above normal background. For example, if 99.0 percent of background tissue levels for a parent endogenous compound and/or its metabolites and/or other related endogenous compounds are below 16 ppt., then a tissue level greater than 16 ppt shall be considered suspect. The final determination with respect to regulatory action will be based on a field investigation to determine if the observed value was due to a misuse of the compound or if it was due to normal biological variability.

Withdrawal periods following the last dosage for endogenous compounds shall be established based on the time required for the level of the parent compound and/or its metabolites and/or other related endogenous compounds in the tissue to return to the median background level of contemporary controls. The maximum approvable level of the compound shall be administered to target animals for a period of time sufficient to establish equilibrium in tissues. The number of days required for tissue levels of any affected endogenous compounds to return to the median background level plus a safety factor to account for animal to animal variation (as determined by appropriate confidence interval techniques) shall be used to establish the required withdrawal period. Current livestock management techniques must be considered in establishing the withdrawal period and may necessitate the lengthening of this period.

ASSAY EVALUATION CRITERIA

Prior to approval, the accuracy and reliability of the regulatory assay must be determined by validation of the method in appropriate Food and Drug Administration laboratories and other laboratories. The objectives of the validation will be to determine the feasibility, specificity, accuracy, and precision of the method (including a determination of the amounts recovered as well as an estimation of the variation associated with the recovered amounts).

Prior to submission of a method for evaluation and subsequent validation, it is recommended that the method be reviewed and tested, both qualitatively and quantitatively, by independent laboratories. This evaluation should fulfill the objectives of the validation as listed above.

The required sensitivity of the regulatory assay method as previously defined will be the regulatory action level and will be published in the FEDERAL REGISTER. Since any "positive" finding reported at a level lower than the published level of sensitivity may actually be a false positive, regulatory action will be taken only at or above the published level. This is necessary in order to assure that a residue is in fact a true positive. In the past the lack of such a procedure has led to finding violative samples in one laboratory which could not be confirmed in a second laboratory.

The assay method will be published or referenced in the FEDERAL REGISTER and will include a definition of the response criteria unique for each method which represents a reliable positive finding based on the validation studies. The criteria will take into account adjustments based on the accuracy and precision of the method. If the method is not specific for the identification of the compound or there are reasons to suspect the occurrence of false positives due to interference, a practical confirmatory test must be provided which will identify the residue at the level of sensitivity required.

In summary, the development and validation of a regulatory assay method for monitoring purposes must consider the following criteria:

1. The method must be capable of reproducibly extracting, at the required level of sensitivity, the significant compounds from target tissues obtained from treated animals as well as from tissues containing known added amounts of the compounds.

2. The method must be capable of measuring residues with a sufficient degree of specificity, precision, and accuracy to preclude the occurrence of false negatives or false positives.

3. The equipment, reagents and compounds used in the assay must be commercially available. Any required specialization in terms of equipment or personnel must be consistent with that normally available in a modern well-equipped analytical control laboratory.

4. The time required for completion of the assay must not be so excessive as to delay regulatory action, when necessary.

5. The assay must offer minimal hazard in the laboratory.

It is proposed that the requirements contained in this regulation will be applicable to all NADA's and supplemental NADA's approved by the Food and Drug Administration after the effective date of the new regulation. In determining the applicability of the provisions of the regulation to already-existing new animal drug approvals, the Commissioner will first determine those drugs for which a zero residue requirement now exists but for which a finite or negligible residue should instead be permitted. The Commissioner recognizes that many of these zero tolerances were established several years ago, at a time when detection methodology was substantially less sensitive and the available toxicology information was not as extensive. For some of these zero tolerances, it may now be possible and consistent with protection of the public health, to establish a finite or negligible residue. Where a finite or negligible residue is established on the basis of adequate safety data, the provisions of the new regulation will not be applicable.

Where a zero tolerance is deemed necessary, either because of a determination of carcinogenicity or because the compound is a suspect carcinogen or is otherwise sufficiently toxic that a determination of a safe level of residue in human food cannot be made at this time, the provisions of the new regulation will be applicable. The Commissioner recognizes that these new requirements cannot be imposed immediately. Accordingly, a determination will be made with respect to each drug as to a reasonable amount of time within which compliance will be permitted. In those instances in which the Commissioner concludes that a health hazard may exist, or where there is a failure to undertake the requisitie studies, the Commissioner will proceed immediately to withdraw approval of the drug. Hence, the above approach will permit a reasonable transition to the new requirements without compromising the public health or disrupting the use of drugs for which there is no known health hazard.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046–1048, 1055, 72 Stat. 1785–1788 as amended, 74 Stat. 399–404, 82 Stat. 343–351; U.S.C. 342, 343, 348, 706, 360b, 371(a), 376), and under authority delegated to the Commissioner (21 CFR

01135

2.120), it is proposed that Part 135 be amended by adding the following new section:

§ 135.38 Compounds used in food-producing animals; procedures for determining the acceptability of assay methods used for assuring the absence of residues in edible products of such animals.

(a) The act provides that feed and drugs intended for animals shall be safe, that food produced from animals shall be safe, and that any compound administered to a food-producing animal which is found to induce cancer when ingested by man or animal is prohibited from the food supply, unless it can be determined by methods of examination prescribed or approved by the Secretary by regulation, that no residues of any such compound are found in the food produced from such animals under conditions of use reasonably certain to be followed in practice. Petitions for use of a compound in food-producing animals shall include data for determining the absence of residues of any unsafe compounds in the food produced from such animals. The provisions of this section shall determine the required level of sensitivity of the regulatory assay method for any compound for which the Commissioner of Food and Drugs has established a zero tolerance (no residue) in food.

(b) Exogenous compounds, defined as those compounds which are not produced by the normal animal and are not required for normal animal body function, are subject to the following requirements:

(1) Metabolism studies shall be conducted in the target species to identify and quantify metabolites of the parent compound and the concentrations of the compound and its metabolites in specific tissues ("tissues" to include milk and eggs, if applicable). The effect of the exogenous compound on tissue levels of related endogenous compounds also shall be determined.

(2) Degradation of the compound and/or its metabolites during the period of time after slaughter that edible tissue would normally be held under storage conditions and the impact of cooking on the compound and/or its metabolites in question shall be determined.

(3) Determination of whether an exogenous compound and/or its metabolites shall be subjected to appropriate testing for carcinogenicity will be based on the results of the metabolism studies, standard toxicity testing, structural relationships of the compound and/or its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended use patterns of the compounds.

(4) If it is determined that carcinogenicity tests are not required or if the results of carcinogenic testing are negative, consideration for approval shall be based on standard toxicological procedures. These procedures shall include in addition to subacute studies in a minimum of two species, such studies as a multi-generation reproduction studies, teratology and any other special studies which may be indicated from the nature of the biological action of the compound, including lifetime studies. These studies shall involve collection of data from appropriately designed dose-response experiments that demonstrate a "maximum no harmful effect level" as well as a "minimum harmful effect level" in appropriate animal species.

(i) Where a finite or negligible residue of the parent compound and/or its metabolites is determined to be safe in food, the required level of sensitivity of the regulatory assay method will be the level of the tolerance published in the FEDERAL REGISTER and the remaining provisions of this paragraph shall be inapplicable.

(ii) Where no residue of the compound and/or its metabolites is determined to be safe in food, the dose-response slope estimated from the toxicological experiments will be used to extrapolate to the required level of sensitivity of the method using appropriate confidence interval techniques in accordance with the concepts underlying the Mantel-Bryan procedure described in paragraph (b) (6) of this section. Where such extrapolation is not scientifically appropriate, e.g., if no dose-response slope can be estimated from the data, other conservative methods shall be invoked to determine an appropriate safety margin based on a thorough evaluation of the quality of the experiments, their rigor as predictive tests and the nature and significance of the observed biological effects.

(5) If it is determined that testing for carcinogenicity is required, test procedures shall be used which maximize sensitivity to detect a minimal dose which induces a carcinogenic effect and with a sufficiently stable control population to avoid false positive indications of carcinogenesis. Appropriate dose-response experiments shall be conducted to (i) clearly establish whether or not the compound and/or its metabolites are carcinogens, and (ii) determine the relative potency of the compound and/or its metabolites with respect to both its carcinogenic and its other toxic effects.

(6) If it is determined that the compound is carcinogenic, the required sensitivity of the regulatory assay method shall be established according to a modification of the Mantel-Bryan procedure. (Mantel, N. and W. R. Bryan, "Safety" Testing of Carcinogenic Agents, Journal of the National Cancer Institute, Vol. 27, pp. 455–470, 1961).[1] This modification shall consist of using the lower 90 percent confidence limit of the experimentally determined dose-response slope from the carcinogenicity studies for extrapolation to a maximum exposure level with appropriate adjustments to account for drug usage and human consumption patterns and for the differences between daily food intake per unit of body weight of the laboratory animal and of man. (i) If the data indicate that some linearizing transformation other than the probit-log transformation used in the modified Mantel-Bryan procedure better describes the observed response and has a biological rationale, then this other linearizing transformation will be used for the extrapolation. (ii) In the event that both significant noncarcinogenic harmful effects and carcinogenic effects are observed during testing, the lowest level for the regulatory assay sensitivity as determined for the different effects shall be adopted.

(7) The sensitivity of the regulatory assay method as defined above, the method, and a definition of the criteria used to establish a reliable positive finding shall be published in the FEDERAL REGISTER.

(8) The withdrawal period for the compound shall be based, using the regulatory assay method and/or other suitable methods, on the time required after the last dosage for tissue levels of the parent compound and/or its metabolites and/or any affected endogenous compounds to fall below the required regulatory assay sensitivity.

(9) The withdrawal period shall be the longer of either (i) the number of days required for tissue levels to be depleted to less than the maximum exposure level plus a safety factor to account for animal to animal variation as determined by appropriate confidence interval techniques or (ii) the number of days required for any affected endogenous compound to return to a normal level plus a safety factor to account for animal to animal variation. Current livestock management techniques may justify a longer withdrawal period. The normal level of any affected endogenous compound shall be established as described in paragraph (c) of this section.

(10) Based on tissue depletion studies and animal management practices, conditions of use that are reasonably certain to be followed in practice shall be specified for the compounds so that, if followed, they assure that no residue shall occur in food produced from treated animals.

(11) Notwithstanding a determination pursuant to this paragraph of the required level of sensitivity of the regulatory assay method, if a regulatory assay method of lower sensitivity is later developed and validated the Commissioner will adopt that more sensitive method and publish it in the FEDERAL REGISTER even though its development was not required.

(c) Endogenous compounds, defined as those compounds which are present in and are produced by the normal animal and are not required from an external source, are subject to the following requirements:

[1] Copies may be obtained from: Director, Division of Nutritional Sciences (VM–100), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

(1) Metabolism studies shall be conducted in the target species to identify and quantify the metabolites of the parent compound and the concentrations of the compound and its metabolites in specific tissues ("tissues" include milk and eggs, if applicable). The effect of the endogenous compound on tissue levels of related endogenous compounds also shall be determined.

(2) Degradation of the compound and/or its metabolites during the period of time after slaughter that the edible tissue would normally be held under storage conditions and the impact of cooking on the compounds and/or its metabolites in question shall be determined.

(3) Animals containing tissue levels of endogenous compounds above the normal due to the administration of endogenous compounds may not be marketed for human consumption. Thus, neither tests for carcinogenicity nor standard toxicity testing shall be required for endogenous compounds.

(4) The naturally occurring or background tissue levels of endogenous compounds and/or their metabolites and/or other related endogenous compounds in the target species shall be determined in studies designed to show the effect of geographical location, stage of estrus, age, etc., on normal animals receiving no external source of the endogenous compound. The tissue distribution will be used to establish the required sensitivity of the regulatory assay method. The required sensitivity of the regulatory assay method will be that value of the distribution which is exceeded by only one percent of the normal animals.

(5) The sensitivity of the regulatory assay method as defined above, the method, and a definition of the criteria used to establish a reliable positive finding shall be published in the FEDERAL REGISTER.

(6) The withdrawal period for the compound shall be based using the regulatory assay method and/or other suitable methods, on the time required after the last dosage for the tissue levels of the parent compound and/or its metabolites and or any affected other related endogenous compounds to return to the median background level of contemporary controls. The withdrawal period shall be the number of days required for tissue levels of any affected endogenous compounds to return to the median background level plus a safety factor to account for animal to animal variation as determined by appropriate confidence interval techniques. Current livestock management techniques may justify a longer withdrawal period.

(7) The characteristics of the distribution of tissue levels of the compound normally found in animals not exposed to external sources of the compound and the specified conditions of use shall be published in the FEDERAL REGISTER as part of the approval of any endogenous drug compound.

(8) Based on tissue depletion studies and animal management practices, a withdrawal period and conditions of use that are reasonably certain to be followed in practice shall be specified for the compound so that, if followed, they assure that no residue shall occur in excess of the established normal level in food from untreated animals.

(d) Prior to approval, the adequacy of the regulatory assay method shall be determined by validation of the method in appropriate Food and Drug Administration laboratories and other laboratories. The validation shall determine the feasibility, specificity, accuracy, and precision of the method. This validation of an assay method used for regulatory purposes shall be based on the following criteria:

(1) The method shall be capable of reproducibly extracting, at the required level of sensitivity, the significant compounds from target tissues obtained from treated animals, as well as from tissues containing known added amounts of the compounds.

(2) The method shall be capable of measuring residues with a sufficient degree of specificity, precision, and accuracy to preclude the occurrence of false negatives or false positives.

(3) The equipment, reagents and compounds used in the assay shall be commercially available. Any required specialization in terms of equipment or personnel shall be consistent with that normally available in a modern well-equipped analytical control laboratory.

(4) The time required for completion of the assay shall not be so excessive as to delay regulatory action.

(5) The assay shall offer minimal hazard in the laboratory.

(e) After publication in the FEDERAL REGISTER of an assay method in accordance with paragraphs (b) through (d) of this section, compliance shall be determined as follows:

(1) Samples of the food produced from appropriate animals will be routinely collected and evaluated using the regulatory assay method(s).

(2) Any sample subject to paragraph (b) of this section yielding a residue of the compound at or above the published level of sensitivity of the method will be liable to regulatory action.

(3) Any sample subject to paragraph (c) of this section yielding a residue of the compound at or above the published level of sensitivity of the method will be subject to investigation. Any such residue which is determined to be the result of improper use of the compound will be liable to regulatory action.

(4) No regulatory action may be based on the measurement of a value which is below the established level of sensitivity of the approved regulatory assay method(s) as published in the FEDERAL REGISTER.

(f) The provisions of this section shall be applicable to all new animal drug applications, including supplements, approved by the Food and Drug Administration subsequent to the effective date of the final regulation, except that supplemental applications meeting the requirements of § 135.13a(d) or that in the opinion of the Commissioner otherwise protect the public health will be permitted to be put into effect in accordance with § 135.13a(e) through (k).

(g) The provisions of this section shall be applicable to existing approvals of new animal drugs in accordance with the following priorities:

(1) The Commissioner will review existing zero tolerances (no residues) to determine whether the drugs involved should be the subject of finite or negligible residues. Those drugs for which finite or negligible residues are established are not subject to the provisions of paragraphs (b) or (c) of this section.

(2) Those drugs for which the Commissioner has determined the appropriateness of a zero tolerance (no residue) will be the subject of a notice published in the FEDERAL REGISTER or a letter to every holder of a new animal drug application establishing a time within which the provisions of this section shall be satisfied. Notices already published in the FEDERAL REGISTER and letters already sent by the Food and Drug Administration requiring additional studies and/or a more sensitive regulatory assay method for a drug subject to a zero tolerance shall remain in effect, and the provisions of this section shall be used in determining compliance with the requirements of the act pursuant to those notices and letters. The Commissioner will immediately proceed to withdraw approval of any drug on the basis of data or information indicating a health hazard or a failure to undertake studies necessary to comply with the provisions of this section.

Interested persons may, on or before September 17, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be viewed in the above office during working hours, Monday through Friday.

Dated: July 13, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.73-14746 Filed 7-18-73;8:45 am]

Social Security Administration

[20 CFR Part 405]

[Reg. No. 5]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Payment for Services of Physicians in Teaching Hospitals, for Physician Costs to Hospitals and Medical Schools, and for Volunteer Services

Notice is hereby given, pursuant to the Administrative Procedure Act (5 U.S.C. 552 et seq.) that the amended regulations set forth in tentative form below are proposed by the Acting Commissioner of Social Security, with the approval of

01137

Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 F.R. 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 72-00287-98-29800. Applicant: University of Hawaii, High Energy Physics Group, 2565 The Mall, Physical Science Building, Honolulu, Hawaii 96822. Article: Automatic Film Measuring Device. Manufacturer: Laser-Scan, Ltd., United Kingdom. Intended use of article: The article is intended to be used in bubble-chamber research in studies of three dimensional events as recorded on film occurring in high energy physics.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article is specially designed to examine photographic records of events occurring in a bubble chamber. We are advised by the National Bureau of Standards (NBS) in its memorandum dated June 7, 1972, that the general specifications of the article are pertinent to the purposes for which the article is intended to be used. NBS also advises that it knows of no domestically manufactured instrument which is scientifically equivalent to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.72-12187 Filed 8-3-72;8:49 am]

UNIVERSITY OF WASHINGTON

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 F.R. 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 72-00090-55-17500. Applicant: University of Washington, Department of Oceanology, Seattle, Wash. 98195. Article: Recording current meter, Model 4. Manufacturer: Ivar Aanderaa, Norway. Intended use of article: The article is intended to be used to monitor current speed and direction, and water temperature during deployment of the current meter in the 2,600-meter-deep Greenland-Spitsbergen passage. Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides self-contained operation and recording for a duration of 1 year. The most closely comparable domestic instrument, the Model 502, manufactured by Hydro Products, San Diego, Calif., provides the capabilities described above for 30 days. We are advised by the National Bureau of Standards (NBS) in its memorandum dated June 23, 1972, that the longer duration of self-contained operation of the foreign article is pertinent to the purposes for which the article is intended to be used. For this reason we find that the Model 502 is not of equivalent scientific value to the foreign article for such purposes as the article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.72-12188 Filed 8-3-72;8:49 am]

YALE UNIVERSITY

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 F.R. 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 72-00382-33-43400. Applicant: Yale University, Purchasing Department, 260 Whitney Avenue, New Haven, CT 06520. Article: Micromanipulator. Manufacturer: A.B. Transvertex, Sweden. Intended use of article: The article will be used in research to obtain intracellular recordings from mitral cells and other cells in the olfactory bulb. Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides precise penetration of cell membranes through electrode advance in a stepping manner. We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated July 7, 1972, that the capability described above is pertinent to the purposes for which the article is intended to be used. HEW also advises that it knows of no comparable domestic apparatus which is scientifically equivalent to the foreign article for such purposes as the article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc.72-12189 Filed 8-3-72;8:49 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Dockets Nos. FDC-D-452, 494; NADA's Nos. 11-295V, 9525, etc.]

DIETHYLSTILBESTROL

Order Denying Hearing and Withdrawing Approval of New Animal Drug Applications for Liquid and Dry Premixes, and Deferring Ruling on Implants

In the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5264), a notice of opportunity for a hearing was published announcing that the Commissioner of Food and Drugs proposed to issue an order under section 512(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of new animal drug applications for diethylstilbestrol (DES) liquid premixes for use in the manufacture of feeds for cattle and sheep.

In the FEDERAL REGISTER of June 21, 1972 (37 F.R. 12251), a notice of opportunity for a hearing was published announcing that the Commissioner proposed to issue an order under section 512(e) of the act withdrawing approval of new animal drug applications for DES liquid and dry premixes for use in the manufacture of feeds for cattle and sheep and for DES implants for cattle and sheep. This notice stated that the earlier notice of opportunity for a hearing with respect to DES liquid premixes would be acted upon at the same time.

Objections and requests for a public hearing were received from 15 of the 25 holders of the new animal drug applications for DES liquid and dry premixes for use in the manufacture of animal feed for cattle and sheep. For the reasons stated below, a hearing is denied with respect to these new animal drug applications. The new animal drug applications for such products are hereby withdrawn, effective immediately.

This matter is a regulatory, not a public health, problem. The animal feeding industry, the pharmaceutical industry, and the U.S. Department of Agriculture have been unable to come forward with restrictions and controls on the use of DES in animal feed that are reasonably certain to be followed in practice and that will result in the absence of detectable residues in the edible portions of the animals. Accordingly, the law requires that use of the drug must be discontinued.

Because there is no evidence of a public health hazard, however, there is no justification for an abrupt disruption of the production of the Nation's meat supply. An immediate ban on use of DES in feed could result in an unwarranted public concern and an unjustified increase in meat prices. It is estimated that there is about a 4-months supply of DES liquid and dry premixes already manufactured and at various stages in the chain of distribution. Accordingly, the Commissioner has determined that the manufacture of liquid and dry premixes will be discontinued effective immediately. Feeding of DES will be discontinued as soon as existing supplies are used up, but no later than January 1, 1973. This will permit both an orderly phaseout of the use of the drug in animal feed and an opportunity for the animal feeding industry to switch to DES implants, to other implants, or to other methods of meat production. DES implants and other implants have been shown to be approximately as effective for growth promotant purposes as DES in feed.

Objections and requests for a public hearing were also received with respect to all new animal drug applications for DES implants. For the reasons stated below, the Commissioner has concluded that the further testing now underway and scheduled to be completed within several weeks should be concluded before a ruling is made on these objections and requests for a hearing. Accordingly, such a ruling is deferred pending completion of those tests, at which time it will promptly be made and published in the FEDERAL REGISTER.

DES LIQUID AND DRY FEED PREMIXES

The following new animal drug applications for liquid and dry feed premixes for cattle and sheep were covered by the March 11 and June 21 notices of opportunity for a hearing:

Elanco Products Co., Post Office Box 750, Indianapolis, Ind. 46206. NADA's Nos. 9525, 11090, and 42162.

Pfizer, Inc., New York, N.Y. 10017. NADA's Nos. 9767 and 9770.

Walnut Grove Products, Division of W. R. Grace Co., Atlantic, Iowa 50022. NADA No. 10132.

Dawes Laboratories, Chicago, Ill. 60632. NADA's Nos. 10421, 11485, and 34916.

Simonsen Manufacturing Co., Quimby, Iowa 51049. NADA No. 10566.

Hess and Clark, Division of Rhodia, Inc., Ashland, Ohio 44805. NADA's Nos. 11205, 44344, 45982, and 45981.

Peter Hand Foundation, Inc., Waukegan, Ill. 60085. NADA No. 14773.

Thompson-Hayward Chemical Co., Kansas City, Kans. 66106. NADA's Nos. 35019 and 35017.

Feed Additives, Inc., Fremont, Nebr. 68025. NADA's Nos. 36313 and 37869.

Dale Alley Co., Post Office Box 444, St. Joseph, Mo. 64501. NADA's Nos. 36671 and 36554.

Standard Chemical Manufacturing Co., Omaha, Nebr. 68103. NADA's Nos. 36976 and 34735.

National Oats Co., East St. Louis, Ill. 62205. NADA's Nos. 37148 and 37541.

Texas Nutrition & Service Co., Fort Worth, Tex. 76106. NADA's Nos. 38507, 38510, and 39509.

Bresley-Koelling, Inc., Ord, Nebr. 68862. NADA No. 39491.

Feed Products, Inc., Denver, Colo. 80211. NADA's Nos. 39716, 39718, 39717, and 39715.

Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, N.J. 07065. NADA's Nos. 39772, 42840, and 10261.

Chemetron Corp., Chicago, Ill. 60611. NADA No. 42355.

Farmland Industries, Kansas City, Mo. 64116. NADA No. 42702.

Western Farmers Association, Seattle, Wash. 98111. NADA No. 44526.

Western Feed Supplements, Ellensburg, Wash. 98926. NADA No. 40014.

Ultra Life Laboratories, Inc., East St. Louis, Ill. 62201. NADA No. 38682.

Square Deal Fortification Co., Kouts, Ind. 46347. NADA No. 39161.

Falstaff Brewing Corp., St. Louis, Mo. 63166. NADA No. 44795.

American Cyanamid Co., Princeton, N.J. 08540. NADA No. 10258.

S. B. Penick Co., New York, N.Y. 10008. NADA No. 36479.

Of these all but the following firms submitted objections and requests for a hearing:

Peter Hand Foundation, Inc., Waukegan, Ill. 60085.

Feed Additives, Inc., Fremont, Nebr. 68025.

Dale Alley Co., St. Joseph, Mo. 64501.

National Oats Co., East St. Louis, Ill. 62205.

Texas Nutrition & Service Co., Fort Worth, Tex. 76108.

Feed Products, Inc., Denver, Colo. 80211.

Ultra Life Laboratories, Inc., East St. Louis, Ill. 62201.

Square Deal Fortification Co., Kouts, Ind. 46347.

Falstaff Brewing Corp., St. Louis, Mo. 63166.

American Cyanamid Co., Princeton, N.J. 08540.

The Commissioner has concluded that these objections, in the light of new evidence from radioactive tracer studies on animals withdrawn from DES feed for 7 days, fail to show reasonable grounds for a hearing on a basis of evidence.

Virtually all of the objections and requests for a hearing fail to comply with 21 CFR 135.15(b), which requires that the objector file a full factual analysis of the data upon which it relies. In this case, the objections received generally rest upon mere allegations or denials and fail to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing.

The objections contend that there are genuine and substantial issues of fact requiring a hearing as follows:

1. The number of violative residues may not actually have increased and, in fact, may have decreased.

2. New and more sophisticated laboratory methodology may be detecting residues at a level that previously was not detected.

3. The validity of the new methodology for detection has not adequately been established at the lower levels.

4. Some of the positives reported may be false positives rather than DES residues.

5. The compound found in animal livers is the monoglucuronide ester, not DES, and this ester has not been tested for carcinogenicity.

6. The level of compliance necessary to satisfy the statutory standard of "reasonably certain to be followed in practice" is unclear and, in any event, a degree of violation was contemplated by Congress.

7. The directions for use of DES may presently be inadequate and may be capable of improvement to assure the safe use of DES.

8. Present manufacturing controls may be inadequate to prevent cross-contamination of withdrawal feeds, and may be capable of improvement to preclude such cross-contamination.

9. A substantial portion of the current violative residues may be the result of cross-contamination of withdrawal feeds rather than of misuse of the drug.

10. Some violative residues may be the result of other sources of DES contamination, rather than misuse of the drug, and more restrictive controls over DES and of animals on withdrawal feed may reduce or eliminate such violative residues.

11. There may be alternative restrictive conditions under which DES may safely be used, such as disposal of animal livers, restrictions on the size or capability of feed lots authorized to use the drug, or other means of testing cattle for DES withdrawal prior to slaughter.

12. Withdrawal of approval of DES may have adverse effects on the environment as a result of increased manure production per day and increased number of days required for feeding to a specific weight.

These objections were stated largely as questions, without a presentation or analysis of the data necessary to support hypotheses advanced and without specific data from tests designed to answer the questions or to support specific proposals or recommendations sufficient to correct the problems demonstrated. Changes in labeling and new restrictions to reduce or eliminate cross-contamination, misuse of the drug, or other sources of violative residues are properly requested through supplemental new animal drug applications rather than through a hearing.

The effectiveness of DES as a growth promotant has not been and is not questioned. Until Friday, July 28, 1972, the Commissioner was unaware of the existence of any data indicating that use under the conditions contained in the approved label would result in detectable residues of DES in the edible portion of animals. Prior studies, using the most sensitive research tools available, showed no detectable residues in the animal liver after 48 hours and even in inedible waste after 132 hours. On December 8, 1971 (36 F.R. 23292), the withdrawal period

01139

was extended from 48 hours to 7 days as a prudent precautionary measure to provide an extra margin of safety.

On Friday, July 28, 1972, the Commissioner was informed of the results of a research study undertaken by the U.S. Department of Agriculture in which it was found, using radioactive-tagged DES in six steers, that detectable residues occurred in the liver from a single 10 mg. oral dose of DES after withdrawal for 3, 5, and even 7 days. Two steers each were slaughtered at 72, 120, and 168 hours after being fed the radioactive-tagged DES. The results of that study are as follows:

Hours after withdrawal	Parts per billion	Residue in animal liver
72	1.06	0.41
120	.65	.15
168	.21	.52

These cattle were fed 10 mg. DES twice daily for a sufficient time period to establish the usual feeding pattern and were then fed a single radioactive-tagged 10 mg. dose of DES. Because only this split dose was tagged, FDA and USDA scientists project from these data that, even after withdrawal for 7 days, some cattle fed the approved level of 10 mg. DES twice daily in liquid or dry feed could be expected to have up to 1 p.p.b. DES in the liver.

From earlier data, it was thought that the half-life of DES in the animal was 12 hours. The new data show that, after 3 days, the elimination rate appears to decrease substantially. Because the experiment has not been carried out for longer than 7 days, it is impossible at this time to determine the rate of residue elimination beyond this period. It is hypothesized that, after 30 days withdrawal, the residue would be reduced to the practical equivalent of zero. There are, however, no data available to substantiate this hypothesis. The law requires that the holder of a new animal drug application submit all data necessary to show that it is possible to use the drug without any residue remaining in the edible portions of the animal. In the absence of such data, the new animal drug application must be withdrawn.

Even if data were available to demonstrate a suitable withdrawal period, it is now questionable whether a sufficiently precise regulatory surveillance method is available to permit continued approval of the drug in animal feed. In view of the new USDA study, it now appears that the test results thought possibly to be false positives may indeed have been true positives. The Commissioner is unaware of any data which could reasonably be interpreted to show that a 30-day feed withdrawal period, which in any event can only be hypothesized as a suitable withdrawal period, would be reasonably certain to be followed in practice. Even if a 30-day withdrawal period were ordered, no regulatory surveillance method now available would be sufficiently sensitive to detect violations of this requirement. The imposition of new and more stringent restrictions on the use of DES in feed, such as an increased withdrawal period, measures to avoid cross-contamination, and similar requirements, is therefore no longer a controlling factor in view of the new USDA study showing that even proper use of the drug under existing restrictions may result in violative residues.

Neither the new USDA study no other information available to the Commissioner demonstrates that there are residues of DES in muscle tissue, which represents the major source of meat for the country. This raises the possibility of permitting continued use of DES in animal feed but of destroying beef livers and kidneys from any animal so fed. The Commissioner has concluded, however, that there are insufficient scientific data on which to base a clear decision when DES residues will not be found in muscle tissue. In addition, no evidence has been submitted with the objections or is otherwise known to the Commissioner that would permit a conclusion that a requirement that the liver and kidneys of cattle fed DES must be destroyed would be reasonably certain to be followed in practice. The maintaining of identification and records to differentiate between animals fed DES and animals not fed DES would be extremely difficult. Such a control system would require a significant change in the method of handling cattle in this country, the complexity of which does not permit such institution hurriedly or on the basis of conjecture. If any such system is to be developed, it must be the subject of pilot programs conducted through investigational new animal drug plans that will demonstrate its feasibility and after further radioactive tracer studies which show the exact time when residues in muscle tissue are eliminated.

The new USDA study involved only cattle, and not sheep. The information available to the Commissioner, however, shows that the problem of DES residues is approximately the same in both animals. Previous data establish roughly the same level of residue under the same conditions of DES use in feed. Violative residues have been found in sheep at roughly the same rate as in cattle. The two animals are biologically quite similar. Accordingly, the Commissioner concludes that there is no basis for distinguishing between them with respect to approval of DES for use in feed.

Finally, the Commissioner has reviewed the potential environmental impact of this action. It has been estimated that there would be a substantial increase in animal waste and in available nitrogen if DES were to be withdrawn from use as an animal growth promotant. In view of the fact that this action permits the continued use of DES implants pending the results of a study now in progress, as described below, and in view of the availability of at least one alternative implant drug, the Commissioner is unable to conclude that the environmental aspects of this problem outweigh the clear requirements of the law. Pursuant to proposed § 6.3(c) of the proposed regulations governing environmental impact considerations published in the FEDERAL REGISTER of July 12, 1972 (37 F.R. 13636), the Commissioner has concluded that the Federal Food, Drug, and Cosmetic Act requires immediate action on this matter without preparation and filing of a draft or final environmental impact statement. By publication of this order, the Council on Environmental Quality and the public are so informed.

For the foregoing reasons, therefore, the Commissioner concludes that the objections fail to demonstrate the existence of a genuine and substantial issue of fact and, accordingly, a hearing is denied with respect to the use of DES in liquid and dry premixes for feed for cattle and sheep.

This action is required under the strict terms of sections 512(d)(1)(H) and 512(e)(1)(B) of the act. These provisions, which contain the so-called Delaney Clause, require that there be no detectable residue. The new USDA study clearly shows residues at levels that are in the range of current detection methodology; new detection methodology is being developed that would be significantly more sensitive. Thus, under the law there is no alternative but to withdraw approval of the drug, even though there is no known public health hazard resulting from its use.

It should be emphasized that the Commissioner has no reason to believe that use of DES in animal feed represents a public health hazard. No human harm has been demonstrated in over 17 years of use. Under the law, however, this continued use of the drug may no longer be permitted.

The Commissioner has concluded that withdrawal of approval of the new animal drug applications for the DES liquid and dry premixes should be effective immediately. This means that these premixes may not be manufactured effective as of the date of publication of this order in the FEDERAL REGISTER.

In the Commissioner's judgment, although withdrawal of approval is warranted by the facts, the continued use of meat from animals fed DES, of feed already containing DES, and of premixes already manufactured does not present a health hazard. Approval is being withdrawn not because there is a proof of danger from DES, but because at this time the new USDA study shows a lack of clear and convincing proof that the requirements of the law are fully satisfied. Accordingly, no recall or cessation of shipment or use of existing stocks is warranted. As long as there is no further manufacturing of these premixes, existing supplies of feed and premixes may be used in an orderly phaseout of the drug. In order to place an end point on this phase out, the Commissioner has determined that all feeding of DES shall be discontinued by January 1, 1973.

01140

DES IMPLANTS

The following new animal drug applications for DES implants for cattle and sheep were covered by the June 21 notice of opportunity for a hearing:

Pfizer, Inc., New York, N.Y. 10017. NADA's Nos. 9783 and 11356.
Vineland Laboratories, Inc., Subsidiary of Damon, Vineland, N.J. 08360. NADA No. 10964.
Hess & Clark, Division of Rhodia, Inc., Ashland, Ohio 44805. NADA No. 12553.
O. M. Franklin Serum Co., Denver, Colo. 80216. NADA No. 15274.
Fort Dodge Laboratories, Fort Dodge, Iowa. 50501. NADA No. 31446.
E. R. Squibb & Sons, New Brunswick, N.J. 08902. NADA No. 11365.

The new USDA study did not include implants. Earlier testing has shown that implants result in no detectable residues, and that there is at least a 10-fold, and probably a 30-fold or greater, difference in the potential for such residues. Thus far, the USDA in its sampling program has not found a single residue resulting from implants alone, but the significance of that fact is uncertain because there is no information on the amount of cattle administered DES solely by implant and the USDA sampling has uncovered instances in which a residue was found in animals fed DES and implanted at the same time.

Use of implants represents a substantially reduced total dose of DES as compared with use of medicated feed. The 20 mg. per day normal dose of DES in feed represents 3,000 mg. per head over the customary 150 days of feeding. During the same period, the maximum dose of DES that would be expected from the use of implants would be approximately 100 mg. per head, based upon the approved use of three 12 mg. implants for a 60-day period, and this dose would ordinarily be less because a smaller implant is customarily used when the animal is younger. This difference represents at least a 30-fold dosage factor, with respect to both the possibility of residues and any potential environmental implant.

USDA has previously begun preparations for a radioactive tracer study using implants. The test using these radioactive-tagged implants has just begun, and the results will be available within several weeks.

The Commissioner has therefore concluded that it is premature to rule at this time on the objections and requests for a hearing with respect to DES implants. A ruling on this matter will await the results of the USDA implant study now underway.

At the present time, the Commissioner has no reason to believe that DES implants raise a public health hazard. Thus, while it is prudent to pursue and to resolve existing scientific questions about DES implants, it is unnecessary to remove existing implants or to be concerned about the safety of meat from animals implanted with DES.

CONCLUSION

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (Sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), the requests for evidentiary hearings with respect to the above-listed new animal drug applications for DES liquid and dry premixes for cattle and sheep are denied and approval of the applications, including all amendments and supplements thereto, is hereby withdrawn. Manufacturing of such premixes shall stop immediately, and feeding of existing supplies of such premixes shall stop as soon as existing supplies are exhausted but in any event no later than January 1, 1973. The Commissioner defers a ruling on withdrawal of the above listed new animal drug applications for DES implants for cattle and sheep. This order shall be effective on its date of publication in the FEDERAL REGISTER (8-4-72).

Dated: July 31, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-12286 Filed 8-3-72;8:55 am]

ATOMIC ENERGY COMMISSION

[Dockets Nos. 50-369, 50-370]

DUKE POWER CO.

Notice Rescheduling Hearing

In the matter of Duke Power Co. (William B. McGuire Nuclear Station, Units 1 and 2), Dockets Nos. 50-369 and 50-370.

Notice is hereby given that the hearing in the captioned proceeding previously set to reconvene on August 8, 1972, has been rescheduled to 10 a.m. on Wednesday, September 6, 1972, at the:

Mecklenberg County Administration Building, Commissioner's Meeting Room, Fourth Floor, 720 East Fourth Street, Charlotte, NC 28202.

Issued: July 31, 1972, Washington, D.C.

ATOMIC SAFETY AND LICENSING BOARD,

ROBERT M. LAZO,
Chairman.

[FR Doc.72-12212 Filed 8-3-72;8:50 am]

[Docket No. 50-410]

NIAGARA MOHAWK POWER CORP.

Notice of Receipt of Application for Construction Permit and Facility License and Applicant's Environmental Report; Time for Submission of Views on Antitrust Matter

Niagara Mohawk Power Corp., 300 Erie Boulevard West, Syracuse, NY 13202, pursuant to section 103 of the Atomic Energy Act of 1954, as amended, has filed an application dated June 7, 1972, for authorization to construct and operate a single cycle, forced circulation, boiling water nuclear reactor at its site, located in the town of Scriba, Oswego County, N.Y. The site consists of 900 acres and is located 300 feet due west of Nine Mile Point Unit 1 (Docket No. 50-220) on the southeast shore of Lake Ontario, approximately 7 miles northeast of the city of Oswego.

The proposed nuclear facility, designated by the applicant as Nine Mile Point Unit 2, is designed for initial operation at approximately 3,300 megawatts (thermal) with a net electrical output of approximately 1,100 megawatts.

Any person who wishes to have his views on the antitrust aspects of the application presented to the Attorney General for consideration shall submit such views to the Commission within sixty (60) days after July 14, 1972.

A copy of the application is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20545, and at the Oswego City Library, 120 East Second Street, Oswego, NY 13126.

Niagara Mohawk Power Corp. has also filed, pursuant to the National Environmental Act of 1969 and the regulations of the Commission in Appendix D to 10 CFR Part 50, a report entitled "Applicant's Environmental Report—Construction Permit Stage," dated June 1972. The report has been made available for public inspection at the aforementioned locations. The report, which discusses environmental considerations related to the proposed construction of Nine Mile Point Unit 2, is also being made available at the New York State Office of Planning Services, 488 Broadway, Albany, NY 12207, and at the Central New York Regional Planning and Development Board, 321 East Water Street, Syracuse, NY 13202.

After the report has been analyzed by the Commission's Director of Regulation or his designee, a draft environmental statement related to the proposed action will be prepared by the Commission. Upon preparation of the draft environmental statement, the Commission will, among other things, cause to be published in the FEDERAL REGISTER a summary notice of availability of the draft statement. The summary notice will request comments from Federal agencies, State and local officials, and interested persons on the proposed action and on the draft statement. The summary notice will also contain a statement to the effect that comments will be made available when received.

Dated at Bethesda, Md., this 6th day of July 1972.

For the Atomic Energy Commission.

ROGER S. BOYD,
Assistant Director for Boiling Water Reactors, Directorate of Licensing.

[FR Doc.72-10706 Filed 7-13-72;8:45 am]

[Docket No. 50-135]

WALTER REED ARMY MEDICAL CENTER

License Termination Order

The Atomic Energy Commission (the Commission) has found that the Walter

01141

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 27]

QUALITY STANDARD FOR CANNED CHERRIES

Proposed Revision of Blemish Limitation

Notice is given that a petition has been filed by the National Canners Association, 1133 20th St., NW., Washington, DC 20036, proposing that the standard of quality for canned cherries (21 CFR 27.31) be amended by:

(1) Changing the definition of a blemished cherry; and

(2) Increasing the aggregate area of the blemish from $\frac{3}{16}$ inch to $\frac{9}{32}$ inch in diameter.

Grounds set forth in the petition in support of the proposal are that: (1) The proposed change in the definition of a blemished unit would be consistent with objections received to an order, published in the FEDERAL REGISTER on February 23, 1971 (36 FR 3364) ruling on a proposed cherry pie standard of quality (21 CFR 28.2). These objections requested that the $\frac{3}{16}$ inch diameter limit for blemished units be changed to a $\frac{9}{32}$ inch diameter limit. The Commissioner of Food and Drugs granted this request in the FEDERAL REGISTER of June 13, 1973 (38 FR 15503).

(2) Mechanical harvesting and bulk handling in tanks of water have replaced the traditional hand picking and handling. As a result there has been a greatly increased problem with a mild form of discoloration known as "tank or water scald" which results in minor color variation but does not affect the tissues or eating quality or the cherries.

(3) Since the present standard was established 32 years ago, changes in cultural practices have resulted in the production of larger and softer cherries. Presently, there are as few as 100 to 110 cherries per pound as compared to 140 to 150 per pound when the standard was adopted. The larger, softer cherries have aggravated the blemish problem because they are more susceptible to blemishes and contain a greater surface area compared to the permitted area of skin discoloration.

(4) Increasing the area of the blemish to 9/32 inch would bring the quality standard for canned cherries (21 CFR 27.31) into agreement with the present voluntary U.S. Department of Agriculture standard for grades of frozen cherries.

(5) The proposed change will insure consumers a continued supply of canned cherries without significantly affecting the quality.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 27 be amended in § 27.31 by revising paragraph (a)(5) to read as follows:

§ 27.31 Canned cherries; quality; label statement of substandard quality.

(a) * * *

(5) Not more than 15 percent by count of the cherries in the container are blemished with scab, hail injury, discoloration, scar tissue or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle 9/32 inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into the fruit tissue is also considered to be blemished.

* * * * *

Interested persons may, on or before September 17, 1973 file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: June 20, 1973.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.73-14749 Filed 7-18-73;8:45 am]

[21 CFR Part 135]

COMPOUNDS USED IN FOOD-PRODUCING ANIMALS

Procedures for Determining Acceptability of Assay Methods Used for Assuring the Absence of Residues in Edible Products of Such Animals

The Federal Food, Drug, and Cosmetic Act requires that compounds administered to animals as food additives, color additives, or animal drugs be shown to be safe for use. The term "safe" refers to the health of man or animal under section 201(u) of the act. In evaluating the safety of such compounds used in food-producing animals, consideration must be given to the safety of possible residues in the products of those animals which are a source of food for man. When there is insufficient evidence to establish that a finite or negligible residue of the compound is safe in human food, or when the anticancer clauses contained in sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) of the act are applicable, a zero tolerance (no residue) must be required. (Under the provisions of the anticancer clauses no compound may be administered to animals which are raised for food production if such compound has been shown to induce cancer when ingested by man or animal, unless such compound will not adversely affect the animal and no residues, as determined by methods of analysis prescribed or approved by the Secretary, are found in the edible products of such animals under conditions of use specified in labeling and reasonably certain to be followed in practice. A decision is then required as to whether a practicable method exists to determine the absence of such residues in food, under sections 409(b)(2)(D), 512(b)(7), and 706(b)(5)(A)(iv) of the act.

The Commissioner of Food and Drugs has determined that it would be in the public interest to set forth the principles involved in application of these safety provisions of the law with respect to the adequacy of the sensitivity of the required regulatory assay method for monitoring compounds which may be administered to food-producing animals, but for which no residue is permitted in human food. Therefore, a new regulation is proposed to establish the minimum standards for determining the acceptability of assay methods used to assure the absence of residues in edible products of such animals. These proposed regulations do not apply to drugs for which a finite or negligible residue is established as safe for human food.

The proposed new regulation will apply to two classes of compounds administered to food-producing animals: (1) Exogenous compounds, defined as those compounds which are not produced by the normal animal and are not required for normal animal body function (e.g., diethylstilbestrol), and (2) Endogenous compounds, defined as those compounds which are present in and produced by the normal animal and are not required from an exogenous source (e.g., estradiol).

In evaluation of the safety of compounds of both classes the initial testing must involve detailed metabolism studies in the target species. Radiotracer studies are usually the method of choice. The purpose of these studies will be to identify the metabolites of the compound, both qualitatively and quantitatively, and the concentrations of the compound and its metabolites in specific tissues ("tissues" include milk and eggs, if applicable). Another aspect of these studies will be the determination of the effect of the administration of the compound on tissue levels of related endogenous compounds.

For acceptable studies, it is necessary to follow the degradation of the compound and/or its metabolites after slaughter and during the period that the edible tissue would normally be held under storage conditions as well as to determine the impact of cooking at appropriate temperatures on the compounds in question.

EXOGENOUS COMPOUNDS

Determination as to whether an exogenous compound and/or its metabolites will require carcinogenicity testing will be based on the results of the metabolism studies, standard toxicity testing, structural relationships of the compound and or its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended use pattern of the compound. Tests for carcinogenicity will be routinely required for any new compound for which a priori knowledge is incomplete and which is intended to be used for disease prophylaxis and, or production purposes (e.g., increased rate of weight gain, estrus synchronization, etc.).

01142

If it is determined that tests for carcinogenicity are not required, or if the results of such tests are negative, consideration leading to approval will be based on standard toxicological procedures. These procedures will include, in addition to subacute studies in a minimum of two species, such studies as multi-generation reproduction studies, teratological and any other special studies which may be indicated from the nature of the biological action of the compound, including life-time studies. These studies will involve collecting data from appropriately designed dose-response experiments that demonstrate a maximum "no harmful effect level" as well as a minimum "harmful effect level" in appropriate animal species.

Where a residue is permitted as safe in human food (either as a finite tolerance level or as a negligible residue of less than a specified level), the sensitivity of the assay method will be required to meet the specified level, and the other provisions of this proposed new regulation relating to the required sensitivity of the method will be inapplicable. Where no residue (zero tolerance) is permitted, the provisions of this proposed new regulation are fully applicable.

Under the proposed new regulation the dose-response slope estimated from the toxicological experiments will be used to extrapolate to the required level of sensitivity of the method using appropriate confidence interval techniques in accordance with the concepts underlying the Mantel-Bryan procedure discussed below. Where such extrapolation is not scientifically appropriate, e.g., if no dose-response slope can be estimated from the data, other conservative methods will be invoked to determine an appropriate safety margin based on a thorough evaluation of the quality of the experiments, their rigor as predictive tests and the nature and significance of the observed biological effects.

Where tests for carcinogenicity are required for a compound there are two basic objectives of the tests. The first is to determine whether or not the compound and/or its metabolites is a carcinogen. The second is to determine the relative potency of the compound and/or its metabolites with respect to both its carcinogenic and its noncarcinogenic but toxic effects, through appropriate oral dose-response experiments. Test systems will be selected which maximize sensitivity to detect a minimal dose which induces a carcinogenic effect. These systems will include a sufficiently stable control population to avoid false-positive indications of carcinogenesis.

There is a general lack of agreement within the scientific community regarding appropriate protocols for determining the dose-response relationship of carcinogenic compounds. Until they are revised, the guidelines for protocols set out by the Food and Drug Administration Advisory Committee on Protocols for Safety Evaluation: Panel on Carcinogenesis Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides (Toxicology and Applied Pharmacology Vol. 20, pp 419–438, 1971) will be followed by the Food and Drug Administration.

If the results of the test for carcinogenicity establish that the compound or its metabolites will induce cancer in test animals, the required sensitivity of the regulatory assay method will be determined based on the Mantel-Bryan procedure described in the article entitled "Safety" Testing of Carcinogenic Agents (Journal of the National Cancer Institute, Vol. 27, pp 455–470, 1961). However, rather than assuming a dose-response relationship with a slope of one, as suggested in the reference, experimental data obtained from the carcinogenicity studies will be used to obtain a statistical estimate of the slope of the dose-response relationship. The lower 90 percent confidence limit of the estimated slope will be used for extrapolation to the required level of sensitivity of the regulatory assay method. If the data indicate that some linearizing transformation other than the probit-log transformation used in the modified Mantel-Bryan procedure better describes the observed response and has a biological rationale, then this other linearizing transformation may be used for such extrapolation. Examples of the application of this technique are given in the above reference.

Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g., 1/100,000,000), under those exposure conditions of the basic animal studies. Such test conditions generally involve continuous daily lifetime exposure to the compound in question. In contrast, many types of foods are consumed only intermittently, e.g., turkey or broiler kidneys, and therefore any drug residues contained in such foods will be consumed only intermittently. If the same procedure was used to determine the level of exposure for turkey kidneys as was used to determine the level of exposure for foods consumed more frequently, such as beef muscle, the population would not be equally protected in both situations. Consequently, it will be necessary to adjust the procedure for establishing the exposure level to account for usual as well as specific human consumption patterns. Any such adjustments initially will be made on a conservative basis. These adjustments will take into consideration the consumption expected by those who consume the greatest amounts of food, not the average consumption of the food. More definitive information is being complied on food consumption patterns by the Food and Drug Administration, and this information will be used to arrive at more refined adjustments as it becomes available.

It will also be necessary to modify the procedure for establishing the exposure level to account for drug usage, patterns, e.g., the administration of a drug in the treatment of diseased animals. As with consumption patterns, justified modifications will be made on a conservative basis. If a disease has a maximum incidence of 10 percent, then no more than 10 percent of the marketed animals would have been treated with the drug. Under these conditions, the probability of continuous daily exposure for an individual consumer could be very conservatively estimated as 0.10. In this situation, the true probability of risk for the individual consumer would then equal the probability of individual risk under conditions of continuous daily exposure to the drug multiplied by the probability of an individual actually experiencing continuous daily exposure to the drug. If a true exposure of 1/100,000,000 were deemed acceptable for an individual on the basis of risk-benefit considerations, this value could be held constant by assuming a continuous exposure risk of 1/10,000,000 (1/100,000,000=1/10,000,000 X 0.10) in the estimate of the Mantel-Bryan level. The true individual consumer risk would remain at 1/100,000,000 since the consumer is only intermittently exposed to residues of the compound in food.

The maximum level of exposure as estimated above, after standard adjustment for the differences between daily food intake per unit of body weight of the laboratory animal as compared with man, will be the required sensitivity of the assay method for a compound. In the event that both non-carcinogenic harmful effects and carcinogenic effects are observed during testing, the lowest level for the regulatory assay sensitivity as determined for the different effects will be adopted.

Withdrawal or post-medication periods for exogenous compounds shall be based on data obtained from tissue depletion studies. The compound must be administered to test animals for a sufficient time for concentration equilibrium to be achieved. On the basis of the developed assay and/or other suitable methods, a determination must be made as to the time when tissue levels of the parent compound and/or its metabolites and/or any affected endogenous compounds are below the required level of sensitivity for the regulatory assay method.

The withdrawal period shall be the longer of: (1) The number of days for tissue levels to be depleted to less than the maximum level of exposure extrapolated by the modified Mantel-Bryan procedure plus a safety factor to account for animal to animal variation (as determined by appropriate confidence interval techniques) or (2) the number of days for any affected endogenous compound to return to normal levels plus a safety factor to account for animal to animal variation. (The normal level of the affected endogenous compound will be established as described below for endogenous compounds.) For example, if excretion data indicate that the average depletion time for an exogenous compound is 72 hours with a safety factor of 27 hours, the withdrawal period becomes (72 hours+27 hours) = 24 hours or, after

01143

rounding upward, 5 days. Current livestock management techniques must be considered in establishing the withdrawal period and may necessitate the lengthening of this period.

The provisions of the proposed new regulation govern the required level of sensitivity of the regulatory assay method for those compounds for which a zero tolerance (no residue) is established. If a regulatory assay method of lower sensitivity is later developed and validated, however, the Commissioner will adopt that more sensitive method and publish it in the FEDERAL REGISTER, even though its development was not required under the law.

ENDOGENOUS COMPOUNDS

It is proposed that animals shown to contain tissue levels of endogenous compounds above the normal due to the administration of such compounds will not be permitted to be marketed for human consumption. Thus, neither tests for carcinogenicity nor standard toxicity testing will be required for endogenous compounds.

Naturally occurring (background) tissue levels of endogenous compounds and/or their metabolites and/or other related endogenous compounds in the target species must be determined in studies designed to show the effect of geographical location, stage of estrus, age, etc., on normal animals receiving no external source of the endogenous compound. The tissue distribution of the levels of the compound and/or its metabolites and/or other related endogenous compounds will be estimated from these studies. This distribution will be used to establish the required sensitivity of the regulatory assay method. The required sensitivity will be that level of the tissue distribution which is exceeded by only one percent of the normal animals. Tissue samples from animals at slaughter will be considered suspect if a level is found above normal background. For example, if 99.0 percent of background tissue levels for a parent endogenous compound and/or its metabolites and/or other related endogenous compounds are below 16 ppt., then a tissue level greater than 16 ppt shall be considered suspect. The final determination with respect to regulatory action will be based on a field investigation to determine if the observed value was due to a misuse of the compound or if it was due to normal biological variability.

Withdrawal periods following the last dosage for endogenous compounds shall be established based on the time required for the level of the parent compound and/or its metabolites and/or other related endogenous compounds in the tissue to return to the median background level of contemporary controls. The maximum approvable level of the compound shall be administered to target animals for a period of time sufficient to establish equilibrium in tissues. The number of days required for tissue levels of any affected endogenous compounds to return to the median background level plus a safety factor to account for animal to animal variation (as determined by appropriate confidence interval techniques) shall be used to establish the required withdrawal period. Current livestock management techniques must be considered in establishing the withdrawal period and may necessitate the lengthening of this period.

ASSAY EVALUATION CRITERIA

Prior to approval, the accuracy and reliability of the regulatory assay must be determined by validation of the method in appropriate Food and Drug Administration laboratories and other laboratories. The objectives of the validation will be to determine the feasibility, specificity, accuracy, and precision of the method (including a determination of the amounts recovered as well as an estimation of the variation associated with the recovered amounts).

Prior to submission of a method for evaluation and subsequent validation, it is recommended that the method be reviewed and tested, both qualitatively and quantitatively, by independent laboratories. This evaluation should fulfill the objectives of the validation as listed above.

The required sensitivity of the regulatory assay method as previously defined will be the regulatory action level and will be published in the FEDERAL REGISTER. Since any "positive" finding reported at a level lower than the published level of sensitivity may actually be a false positive, regulatory action will be taken only at or above the published level. This is necessary in order to assure that a residue is in fact a true positive. In the past the lack of such a procedure has led to finding violative samples in one laboratory which could not be confirmed in a second laboratory.

The assay method will be published or referenced in the FEDERAL REGISTER and will include a definition of the response criteria unique for each method which represents a reliable positive finding based on the validation studies. The criteria will take into account adjustments based on the accuracy and precision of the method. If the method is not specific for the identification of the compound or there are reasons to suspect the occurrence of false positives due to interference, a practical confirmatory test must be provided which will identify the residue at the level of sensitivity required.

In summary, the development and validation of a regulatory assay method for monitoring purposes must consider the following criteria:

1. The method must be capable of reproducibly extracting, at the required level of sensitivity, the significant compounds from target tissues obtained from treated animals as well as from tissues containing known added amounts of the compounds.

2. The method must be capable of measuring residues with a sufficient degree of specificity, precision, and accuracy to preclude the occurrence of false negatives or false positives.

3. The equipment, reagents and compounds used in the assay must be commercially available. Any required specialization in terms of equipment or personnel must be consistent with that normally available in a modern well-equipped analytical control laboratory.

4. The time required for completion of the assay must not be so excessive as to delay regulatory action, when necessary.

5. The assay must offer minimal hazard in the laboratory.

It is proposed that the requirements contained in this regulation will be applicable to all NADA's and supplemental NADA's approved by the Food and Drug Administration after the effective date of the new regulation. In determining the applicability of the provisions of the regulation to already-existing new animal drug approvals, the Commissioner will first determine those drugs for which a zero residue requirement now exists but for which a finite or negligible residue should instead be permitted. The Commissioner recognizes that many of these zero tolerances were established several years ago, at a time when detection methodology was substantially less sensitive and the available toxicology information was not as extensive. For some of these zero tolerances, it may now be possible and consistent with protection of the public health, to establish a finite or negligible residue. Where a finite or negligible residue is established on the basis of adequate safety data, the provisions of the new regulation will not be applicable.

Where a zero tolerance is deemed necessary, either because of a determination of carcinogenicity or because the compound is a suspect carcinogen or is otherwise sufficiently toxic that a determination of a safe level of residue in human food cannot be made at this time, the provisions of the new regulation will be applicable. The Commissioner recognizes that these new requirements cannot be imposed immediately. Accordingly, a determination will be made with respect to each drug as to a reasonable amount of time within which compliance will be permitted. In those instances in which the Commissioner concludes that a health hazard may exist, or where there is a failure to undertake the requisitie studies, the Commissioner will proceed immediately to withdraw approval of the drug. Hence, the above approach will permit a reasonable transition to the new requirements without compromising the public health or disrupting the use of drugs for which there is no known health hazard.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046–1048, 1055, 72 Stat. 1785–1788 as amended, 74 Stat. 399–404, 82 Stat. 343–351; U.S.C. 342, 343, 348, 706, 360b, 371(a), 376), and under authority delegated to the Commissioner (21 CFR

01144

2.120), it is proposed that Part 135 be amended by adding the following new section:

§ 135.38 Compounds used in food-producing animals; procedures for determining the acceptability of assay methods used for assuring the absence of residues in edible products of such animals.

(a) The act provides that feed and drugs intended for animals shall be safe, that food produced from animals shall be safe, and that any compound administered to a food-producing animal which is found to induce cancer when ingested by man or animal is prohibited from the food supply, unless it can be determined by methods of examination prescribed or approved by the Secretary by regulation, that no residues of any such compound are found in the food produced from such animals under conditions of use reasonably certain to be followed in practice. Petitions for use of a compound in food-producing animals shall include data for determining the absence of residues of any unsafe compounds in the food produced from such animals. The provisions of this section shall determine the required level of sensitivity of the regulatory assay method for any compound for which the Commissioner of Food and Drugs has established a zero tolerance (no residue) in food.

(b) Exogenous compounds, defined as those compounds which are not produced by the normal animal and are not required for normal animal body function, are subject to the following requirements:

(1) Metabolism studies shall be conducted in the target species to identify and quantify metabolites of the parent compound and the concentrations of the compound and its metabolites in specific tissues ("tissues" to include milk and eggs, if applicable). The effect of the exogenous compound on tissue levels of related endogenous compounds also shall be determined.

(2) Degradation of the compound and/or its metabolites during the period of time after slaughter that edible tissue would normally be held under storage conditions and the impact of cooking on the compound and/or its metabolites in question shall be determined.

(3) Determination of whether an exogenous compound and/or its metabolites shall be subjected to appropriate testing for carcinogenicity will be based on the results of the metabolism studies, standard toxicity testing, structural relationships of the compound and/or its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended use patterns of the compounds.

(4) If it is determined that carcinogenicity tests are not required or if the results of carcinogenic testing are negative, consideration for approval shall be based on standard toxicological procedures. These procedures shall include in addition to subacute studies in a minimum of two species, such studies as a multi-generation reproduction studies, teratology and any other special studies which may be indicated from the nature of the biological action of the compound, including lifetime studies. These studies shall involve collection of data from appropriately designed dose-response experiments that demonstrate a "maximum no harmful effect level" as well as a "minimum harmful effect level" in appropriate animal species.

(i) Where a finite or negligible residue of the parent compound and/or its metabolites is determined to be safe in food, the required level of sensitivity of the regulatory assay method will be the level of the tolerance published in the FEDERAL REGISTER and the remaining provisions of this paragraph shall be inapplicable.

(ii) Where no residue of the compound and/or its metabolites is determined to be safe in food, the dose-response slope estimated from the toxicological experiments will be used to extrapolate to the required level of sensitivity of the method using appropriate confidence interval techniques in accordance with the concepts underlying the Mantel-Bryan procedure described in paragraph (b)(6) of this section. Where such extrapolation is not scientifically appropriate, e.g., if no dose-response slope can be estimated from the data, other conservative methods shall be invoked to determine an appropriate safety margin based on a thorough evaluation of the quality of the experiments, their rigor as predictive tests and the nature and significance of the observed biological effects.

(5) If it is determined that testing for carcinogenicity is required, test procedures shall be used which maximize sensitivity to detect a minimal dose which induces a carcinogenic effect and with a sufficiently stable control population to avoid false positive indications of carcinogenesis. Appropriate dose-response experiments shall be conducted to (i) clearly establish whether or not the compound and/or its metabolites are carcinogens, and (ii) determine the relative potency of the compound and/or its metabolites with respect to both its carcinogenic and its other toxic effects.

(6) If it is determined that the compound is carcinogenic, the required sensitivity of the regulatory assay method shall be established according to a modification of the Mantel-Bryan procedure. (Mantel, N. and W. R. Bryan, "Safety" Testing of Carcinogenic Agents, Journal of the National Cancer Institute, Vol. 27, pp. 455–470, 1961).[1] This modification shall consist of using the lower 90 percent confidence limit of the experimentally determined dose-response slope from the carcinogenicity studies for extrapolation to a maximum exposure level with appropriate adjustments to account for drug usage and human consumption patterns and for the differences between daily food intake per unit of body weight of the laboratory animal and of man. (i) If the data indicate that some linearizing transformation other than the probit-log transformation used in the modified Mantel-Bryan procedure better describes the observed response and has a biological rationale, then this other linearizing transformation will be used for the extrapolation. (ii) In the event that both significant noncarcinogenic harmful effects and carcinogenic effects are observed during testing, the lowest level for the regulatory assay sensitivity as determined for the different effects shall be adopted.

(7) The sensitivity of the regulatory assay method as defined above, the method, and a definition of the criteria used to establish a reliable positive finding shall be published in the FEDERAL REGISTER.

(8) The withdrawal period for the compound shall be based, using the regulatory assay method and/or other suitable methods, on the time required after the last dosage for tissue levels of the parent compound and/or its metabolites and/or any affected endogenous compounds to fall below the required regulatory assay sensitivity.

(9) The withdrawal period shall be the longer of either (i) the number of days required for tissue levels to be depleted to less than the maximum exposure level plus a safety factor to account for animal to animal variation as determined by appropriate confidence interval techniques or (ii) the number of days required for any affected endogenous compound to return to a normal level plus a safety factor to account for animal to animal variation. Current livestock management techniques may justify a longer withdrawal period. The normal level of any affected endogenous compound shall be established as described in paragraph (c) of this section.

(10) Based on tissue depletion studies and animal management practices, conditions of use that are reasonably certain to be followed in practice shall be specified for the compounds so that, if followed, they assure that no residue shall occur in food produced from treated animals.

(11) Notwithstanding a determination pursuant to this paragraph of the required level of sensitivity of the regulatory assay method, if a regulatory assay method of lower sensitivity is later developed and validated the Commissioner will adopt that more sensitive method and publish it in the FEDERAL REGISTER even though its development was not required.

(c) Endogenous compounds, defined as those compounds which are present in and are produced by the normal animal and are not required from an external source, are subject to the following requirements:

[1] Copies may be obtained from: Director, Division of Nutritional Sciences (VM–100), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

(1) Metabolism studies shall be conducted in the target species to identify and quantify the metabolites of the parent compound and the concentrations of the compound and its metabolites in specific tissues ("tissues" include milk and eggs, if applicable). The effect of the endogenous compound on tissue levels of related endogenous compounds also shall be determined.

(2) Degradation of the compound and/or its metabolites during the period of time after slaughter that the edible tissue would normally be held under storage conditions and the impact of cooking on the compounds and/or its metabolites in question shall be determined.

(3) Animals containing tissue levels of endogenous compounds above the normal due to the administration of endogenous compounds may not be marketed for human consumption. Thus, neither tests for carcinogenicity nor standard toxicity testing shall be required for endogenous compounds.

(4) The naturally occurring or background tissue levels of endogenous compounds and/or their metabolites and/or other related endogenous compounds in the target species shall be determined in studies designed to show the effect of geographical location, stage of estrus, age, etc., on normal animals receiving no external source of the endogenous compound. The tissue distribution will be used to establish the required sensitivity of the regulatory assay method. The required sensitivity of the regulatory assay method will be that value of the distribution which is exceeded by only one percent of the normal animals.

(5) The sensitivity of the regulatory assay method as defined above, the method, and a definition of the criteria used to establish a reliable positive finding shall be published in the FEDERAL REGISTER.

(6) The withdrawal period for the compound shall be based using the regulatory assay method and/or other suitable methods, on the time required after the last dosage for the tissue levels of the parent compound and/or its metabolites and or any affected other related endogenous compounds to return to the median background level of contemporary controls. The withdrawal period shall be the number of days required for tissue levels of any affected endogenous compounds to return to the median background level plus a safety factor to account for animal to animal variation as determined by appropriate confiidence interval techniques. Current livestock management techniques may justify a longer withdrawal period.

(7) The characteristics of the distribution of tissue levels of the compound normally found in animals not exposed to external sources of the compound and the specified conditions of use shall be published in the FEDERAL REGISTER as part of the approval of any endogenous drug compound.

(8) Based on tissue depletion studies and animal management practices, a withdrawal period and conditions of use that are reasonably certain to be followed in practice shall be specified for the compound so that, if followed, they assure that no residue shall occur in excess of the established normal level in food from untreated animals.

(d) Prior to approval, the adequacy of the regulatory assay method shall be determined by validation of the method in appropriate Food and Drug Administration laboratories and other laboratories. The validation shall determine the feasibility, specificity, accuracy, and precision of the method. This validation of an assay method used for regulatory purposes shall be based on the following criteria:

(1) The method shall be capable of reproducibly extracting, at the required level of sensitivity, the significant compounds from target tissues obtained from treated animals, as well as from tissues containing known added amounts of the compounds.

(2) The method shall be capable of measuring residues with a sufficient degree of specificity, precision, and accuracy to preclude the occurrence of false negatives or false positives.

(3) The equipment, reagents and compounds used in the assay shall be commercially available. Any required specialization in terms of equipment or personnel shall be consistent with that normally available in a modern well-equipped analytical control laboratory.

(4) The time required for completion of the assay shall not be so excessive as to delay regulatory action.

(5) The assay shall offer minimal hazard in the laboratory.

(e) After publication in the FEDERAL REGISTER of an assay method in accordance with paragraphs (b) through (d) of this section, compliance shall be determined as follows:

(1) Samples of the food produced from appropriate animals will be routinely collected and evaluated using the regulatory assay method(s).

(2) Any sample subject to paragraph (b) of this section yielding a residue of the compound at or above the published level of sensitivity of the method will be liable to regulatory action.

(3) Any sample subject to paragraph (c) of this section yielding a residue of the compound at or above the published level of sensitivity of the method will be subject to investigation. Any such residue which is determined to be the result of improper use of the compound will be liable to regulatory action.

(4) No regulatory action may be based on the measurement of a value which is below the established level of sensitivity of the approved regulatory assay method(s) as published in the FEDERAL REGISTER.

(f) The provisions of this section shall be applicable to all new animal drug applications, including supplements, approved by the Food and Drug Administration subsequent to the effective date of the final regulation, except that supplemental applications meeting the requirements of § 135.13a(d) or that in the opinion of the Commissioner otherwise protect the public health will be permitted to be put into effect in accordance with § 135.13a(e) through (k).

(g) The provisions of this section shall be applicable to existing approvals of new animal drugs in accordance with the following priorities:

(1) The Commissioner will review existing zero tolerances (no residues) to determine whether the drugs involved should be the subject of finite or negligible residues. Those drugs for which finite or negligible residues are established are not subject to the provisions of paragraphs (b) or (c) of this section.

(2) Those drugs for which the Commissioner has determined the appropriateness of a zero tolerance (no residue) will be the subject of a notice published in the FEDERAL REGISTER or a letter to every holder of a new animal drug application establishing a time within which the provisions of this section shall be satisfied. Notices already published in the FEDERAL REGISTER and letters already sent by the Food and Drug Administration requiring additional studies and/or a more sensitive regulatory assay method for a drug subject to a zero tolerance shall remain in effect, and the provisions of this section shall be used in determining compliance with the requirements of the act pursuant to those notices and letters. The Commissioner will immediately proceed to withdraw approval of any drug on the basis of data or information indicating a health hazard or a failure to undertake studies necessary to comply with the provisions of this section.

Interested persons may, on or before September 17, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be viewed in the above office during working hours, Monday through Friday.

Dated: July 13, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.73-14746 Filed 7-18-73;8:45 am]

Social Security Administration

[20 CFR Part 405]

[Reg. No. 5]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Payment for Services of Physicians in Teaching Hospitals, for Physician Costs to Hospitals and Medical Schools, and for Volunteer Services

Notice is hereby given, pursuant to the Administrative Procedure Act (5 U.S.C. 552 et seq.) that the amended regulations set forth in tentative form below are proposed by the Acting Commissioner of Social Security, with the approval of

01146

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 77N-0026]

CHEMICAL COMPOUNDS IN FOOD-PRODUCING ANIMALS

Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

The Food and Drug Administration (FDA) is establishing procedures and minimum criteria to ensure the absence of carcinogenic residues in edible products derived from food-producing animals that are administered drugs, food additives, or color additives. These regulations set forth below provide an operational definition of the no-residue requirement of the so-called "DES proviso" to the anticancer clauses, sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A), 360b(d)(1)(H), and 376(b)(5)(B)). The regulations also establish criteria for acceptance of assay methods and procedures for establishing suitable post-administration withdrawal periods to prevent the occurrence of carcinogenic residues in edible products. The regulations shall become effective on March 21, 1977.

Prior to July 19, 1973, FDA had applied the proviso to the anticancer clauses of the act on a case-by-case basis, without published criteria. The Commissioner of Food and Drugs concluded that it was appropriate and necessary to establish such criteria and procedures for their application through rule making in order to permit public discussion of the scientific, legal, and policy issues involved. Accordingly, the Commissioner issued these regulations as a proposal, published in the FEDERAL REGISTER of July 19, 1973 (38 FR 19226), and afforded 60 days for public comment.

Forty-six comments on the proposal were received. These were submitted by scientists affiliated with consumer groups, universities, scientific societies, State and Federal agencies, trade associations, and affected manufacturers, and some from nonaffiliated individuals. Many comments revealed sharp divergence of opinion concerning FDA's interpretation of the proviso to the anticancer clauses of the act. For this reason, the Commissioner has set forth, initially, the legal and scientific rationale for these final regulations. Specific comments are described and discussed later in the preamble in connection with the provisions of the regulations to which they relate.

I. INTRODUCTION

A. STATUTORY BACKGROUND

Section 409 of the Federal Food, Drug, and Cosmetic Act establishes criteria and prescribes procedures for the approval of food additives that have been shown to be safe. As enacted in 1958, the anticancer (or so-called Delaney) clause of section 409 flatly proscribed the approval of any additive that "is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." As applied to additives added directly to human food, this language has remained unchanged. Accordingly, as a legal matter, section 409 precludes a finding by FDA that a direct food additive that has been shown to cause cancer in laboratory animals (or, of course, in man) can be safely added to food, in any amount, for any purpose. Section 706 of the act similarly prohibits the approval of any carcinogenic color additive.

The use of chemical compounds as additives to the feed of animals or as animal drugs has posed more complex problems. The act requires that compounds administered to animals as food additives, color additives, or animal drugs be shown to be safe for use. Under section 201(u) of the act (21 U.S.C. 321(u)), the term "safe" clearly embraces the health of man, as well as the health of the animals to which such compounds are given. Thus, in evaluating the safety compounds to be administered to animals raised or maintained for production of food for man, such as cattle, swine, and poultry, Congress has from the beginning recognized that consideration had to be given to the safety of possible residues of the compounds in the products of animals that become sources of food for man, i.e., meat, milk, and eggs.

Prior to 1962, the anticancer clauses in section 409 and section 706 did not distinguish between compounds added directly to human food and compounds that might indirectly enter human food through administration, as feed additives or drugs, to food-producing animals. The act was interpreted as forbidding FDA to approve the use of a carcinogenic animal drug whether or not the compounds might leave any residues in the edible tissues of the animal. However, Congress modified this flat prohibition in 1962 as part of the Drug Amendments of 1962, to focus on the likelihood that a compound would produce detectable residues. Section 409(c)(3)(A) now reads:

> * * * [N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (1) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal * * *

Modification of the effect of the anticancer clause of section 409 was first suggested during congressional consideration of the Color Additive Amendments of 1960. In May 1960, the then-Secretary of Health, Education, and Welfare urged Congress to modify the act, explaining:

> There is * * * one respect to which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food * * *.
>
> We therefore have included in the enclosed draft bill an amendment to permit use of an additive in animal feed under the above-mentioned conditions.
>
> * * * * *
>
> [U]nder the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive. H.R. Rep. No. 2664, 86th Cong., 2d Sess. (1960).

The amendments proposed by the Department were not included in the color additive legislation. During the following 2 years, however, concern continued to be expressed about application of the anticancer clause in section 409. As a result, legislation similar to that earlier recommended by the Department of Health, Education, and Welfare was introduced in 1962. The House Committee on Interstate and Foreign Commerce ultimately included modifications of the anticancer clause in its report on the Drug Amendments of 1962, with the following explanation:

> The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal

01147

after slaughter or in any food such as milk or eggs yielded by or derived from the living animal. H.R. Rep. No. 2464, 87th Cong., 2d Sess. (1962).

Although controversial, these amendments were agreed to by the full House of Representatives. The Senate accepted the House-passed modifications of the anticancer clauses in conference (H.R. Rep. No. 2526, 87th Cong., 2d Sess. (1962)).

Beginning in 1962, efforts were also made in Congress to consolidate the various provisions of the law applicable to animal drugs under the new drug, food additive, and antibiotic sections of the statute, with the objectives of clarifying the applicable requirements and expediting approvals of new animal drugs. No attempt was made to reopen the issue of the anticancer clause, however, and neither the committee reports nor the floor debates in the resulting legislation mentioned the anticancer clause which precluded approval of a new animal drug if:

* * * such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals * * *. (21 U.S.C. 360b(d)(1)(H).)

The legislation was enacted without controversy as the Animal Drug Amendments of 1968, and without evident congressional desire to alter the anticancer clauses, as modified in 1962 for animal drugs.

B. STATUTORY INTERPRETATION

The enactment in 1962 of the so-called DES proviso to the Delaney anticancer clause has been a source of continuing controversy. There has not been unanimity on the proper interpretation of Congress' action, and the legislative history of the proviso, summarized above, does not lay to rest all doubts.

Two interpretations of the proviso are, in theory, possible. The first interpretation, which in the Commissioner's judgment is the less probable, is that Congress intended to allow FDA to approve the use of a carcinogenic compound in food-producing animals only if it could be absolutely positive that no traces whatever—no matter how small—would remain in edible tissues.

This interpretation presents several difficulties, all stemming from the fact that any introduction of a compound (whether or not carcinogenic) is likely to leave minute residues in edible tissues that are below the level of detection of any known or likely to be developed method of analysis (assay). It is a fundamental fact of analytical science that for every assay developed to measure the concentration of a chemical compound in a medium (in this case, a residue in an edible tissue, there is some lowest concentration or level of such compound below which the assay will not yield an interpretable result. If, for example, an assay measures a particular compound in muscle tissue (an edible tissue), and the assay has been shown to have a lowest limit of measurement of one part per billion (1 ppb—one part compound in one billion parts tissue on a weight basis, such as 1 nanogram of compound per 1 gram of tissue), examination of muscle tissue using this assay will reveal that the compound is present only if its concentration in muscle tissue is 1 ppb or higher. If the compound is present in the tissue at levels below 1 ppb, use of the assay will yield no interpretable result. Thus, the assay cannot distinguish between muscle tissues containing the compound at levels below 1 ppb and muscle tissues from which the compound is absent in the absolute sense of the term.

Although different assays may have different lowest limits of measurement, all assays are subject to the same limitation. Thus, when a tissue is examined with an assay having a lowest limit of measurement of 1 ppb and no interpretable response is observed, the analyst can only conclude that the compound under analysis is not present at levels of 1 ppb and above. It can never be concluded that the compound is "not present" in the absolute sense. It is thus impossible to determine the conditions under which edible tissues derived from food-producing animals that have received a carcinogen will contain no residue if the phrase "no residue" is to be interpreted literally. Accordingly, this first possible interpretation of the DES proviso would not permit the approval of any animal drug known to be carcinogenic because the Commissioner could never find that no trace whatever would remain in the edible tissues of the animals to which the compound was administered.

This interpretation would thus render the DES proviso a "Catch-22." The proviso would permit the approval of carcinogenic drugs for animals if the Commissioner could be certain that no residues whatever would remain, but since he would only conclude that some trace might well remain, no such drug could ever be approved. This seems, at the very least, an improbable interpretation of an amendment Congress enacted precisely because it wanted to relieve animal drugs from the rigid strictures of the anticancer clauses.

Furthermore, this interpretation is difficult to reconcile with the language of the DES exception, which specifies that "no residue" may be "found (by methods of examination prescribed or approved by the Secretary * * *) in any edible portion of such animals * * *." This language conspicuously avoids such words as "occur" or "remain," and instead emphasizes detectability. Moreover, the same proviso refers to "conditions of use * * * reasonably certain to be followed in practice," suggesting a congressional recognition that the occurrence of some residues, i.e., residues resulting from unforeseeable misuse, might not require disapproval of a compound even if they were detected.

A second, and in the Commissioner's view more plausible, interpretation of the DES proviso accepts the words of the amendment and focuses on the language previously quoted: "no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations * * *." Under this interpretation, an animal drug that is carcinogenic may be approved for use in animals if examination of edible tissues by an assay approved by FDA reveals no residues.

This in essence is the interpretation that FDA has followed since the passage of the DES proviso: The agency has approved carcinogenic compounds for use in animal feed or as animal drugs on the basis of assays capable of measuring prescribed levels of residues. However, the agency has not previously attempted to define and explain the criteria it employs in evaluating assays submitted in support of approval of animal drugs, feed additives, and color additives. That is the purpose of this document.

The Commissioner believes that the criteria to be applied in evaluating assays for residues of carcinogenic compounds in the edible tissue of food animals must further the congressional objective of minimizing public exposure to carcinogenic compounds, without nullifying the decision reflected in the DES proviso, which the first interpretation of the proviso would do. As explained more fully below, the criteria set forth in these regulations for the evaluation of assays for carcinogenic residues are minimum requirements. They are designed to identify assays that are (1) reliable and practical for use by a regulatory agency and (2) capable of measuring residues at levels that have been determined, on the basis of animal toxicity tests, to present no significant increase in human risk of cancer. An assay that does not meet both criteria cannot be approved. The Commissioner recognizes that for some compounds currently in use no reliable and practical assay capable of sufficiently low limits of measurement now exists, and that approval of their continued use must be reexamined.

The Commissioner further believes that the policy embodied in the anticancer clauses requires application of a third criterion to the evaluation of assays: The agency therefore will insist that of the available assays, the one approved for controlling carcinogenic residues must be the one having the lowest limit of reliable measurement and capable of satisfying the other two criteria. This means that, as new practical assays capable of reliably measuring lower levels of residues become available, approved compounds will be controlled with such assays and petitioners will be required to make any modifications in the conditions of use of a compound necessary to prevent residues from occurring.

01148

The Commissioner recognizes that this third criterion may lead to the withdrawal of approval of some compounds because they cannot be used without detection by newer assays. (This prospect is in part theoretical, however, because the other minimum criteria defined in this regulation demand a low limit of measurement for assays that for many compounds is at or below the lower limits of present technology.) Any other posture, however, would place FDA in the position of approving the use of carcinogenic compounds that could be measured by new, practical assays capable of reliably measuring lower levels of residues.

It is, of course, also true that the criteria outlined in these regulations will sometimes permit the approval, for use in animal feed or as animal drugs, of carcinogenic compounds that are likely to leave miniscule residues below the lowest level of reliable measurement of any assay that meets the other criteria herein set forth. This, however, is the result of congressional enactment of the DES proviso. Moreover, this result makes sense in practical terms, for a regulatory agency cannot effectively control residues—of any compound—that are so small that they escape measurement by every current assay, simply on the assumption that such residues must be occurring.

In sum, the interpretation adopted in these regulations is reconcilable with both the purpose and language of the DES proviso, and will further the congressional objective of minimizing public exposure to residues of carcinogenic compounds.

C. OVERVIEW OF THE REGULATION

The proviso to the anticancer clauses allows the approval of the use of carcinogens in food-producing animals if, under conditions of use "reasonably certain to be followed in practice," no residue is found by an (assay) prescribed or approved by the Secretary. To assure protection of the public in a manner consistent with the anticancer provisions of the act, the Commissioner must establish criteria for approval of assays to include, among other things, a required lowest limit of measurement.

Accordingly, these regulations establish criteria for accepting assays used to measure carcinogenic residues in edible tissues of food-producing animals which have been administered carcinogens. Such criteria cover assay attributes such as dependability, practicability, specificity, accuracy, and precision. Additionally, the regulations establish a specific criterion for the lowest limit of reliable measurement which an assay must meet, as a minimum, before it can be approved by the agency for the control of carcinogenic residues. This criterion for the required lowest limit of measurement of an assay derives from toxicological data obtained for carcinogenic residues and from an operational definition of the no-residue objective standard of the act. Only if an assay meeting the above criteria is available does the Commissioner have a mechanism to discriminate between tissues containing a residue and tissues containing no residue. Without such a monitoring mechanism, the commissioner has no way to determine if a carcinogenic drug or additive administered to a food-producing animal is or even can be used in compliance with the act.

In these regulations the Commissioner has established a rigorous premarket testing process for sponsored compounds intended for use in food-producing animals. The process treats all compounds initially as potential carcinogens and embodies conservative assumptions at each stage of the inquiry to determine the minimally acceptable lowest limit of reliable measurement for a regulatory assay. Because this minimally acceptable limit is determined by toxicity data, the Commissioner may conclude that an assay satisfying the requirements of the regulations is capable of demonstrating the absence of carcinogenic residues in food. By thus particularizing the statutory requirements, the Commissioner has established the basis for rejecting sponsored compounds which are claimed to satisfy the no-residue standard by other mechanisms.

1. *Fundamental questions.* For every drug or additive proposed for use in food-producing animals (hereinafter the sponsored compound), the Commissioner is required by the act to determine whether such sponsored compound can be used in ways which are safe for the animals to which the compound will be administered (target animals) and whether food (meat, milk, and eggs) derived from such animals (hereinafter edible tissues) will be safe for human consumption. The sponsor of such compound (hereinafter the petitioner) is therefore required to furnish the Commissioner the scientific and technological information necessary for such a determination; the Commissioner in turn is required by the act to determine on the basis of all available data whether, in actual practice, the sponsored compound can be used in compliance with the law.

Although a major obligation of a petitioner proposing the use in food-producing animals of a compound that is a carcinogen is the development of a practical and reliable assay capable of discriminating tissues containing residues from tissues free of such residues, as defined operationally, such as an assay cannot be developed in the absence of certain scientific and technological information whose nature is not strictly analytic.

Specifically, for every sponsored compound, several questions must be answered before assay development can be undertaken or compound approval considered:

(a) What is the chemical nature of the sponsored compound and how is it to be used?

(b) On the basis of preliminary toxicological and biochemical information, can it be concluded that the compound has the potential to contaminate human food (edible tissues) with residues of carcinogenic concern?

(c) If so, what is the chemical nature of the residues of the compound, in what tissues are they found, at what levels, and for what length of time?

(d) Is the sponsored compound or any of the residues it produces in edible tissue carcinogenic in experimental animals?

(e) If so, what level of residues can be operationally defined as satisfying the no residue requirement of the act?

(f) Can a reliable and practical assay be developed to measure the edible tissue residues at a level at least as low as that which operationally satisfies the no-residue requirement of the act?

(g) At what time after cessation of compound exposure do the edible tissues of exposed food-producing animals satisfy the no-residue requirement of the act, i.e., what is the necessary withdrawal time?

2. *Data collection process.* To provide answers to the preceding questions, a petitioner must gather pertinent scientific information, the nature of which is particularized below. These regulations establish the procedure for gathering and evaluating the requisite scientific information. The process is stepwise and evolutionary because the need, as well as ability, to proceed to the next step of data collection depends upon the results obtained at each preceding step. If the evaluation of the data collected at each step indicates that questions regarding residues of carcinogenic concern remain, the process of data collection must continue. If at some point in the process of data collection it can be decided that the sponsored compound presents no human risk of carcinogenesis, the sponsored compound shall be evaluated under the general food safety provisions of the act. In such a case, the compound may be assigned a safe tolerance level in human food if the petitioner provides the data necessary to establish that the compound can be used safely.

These regulations deal with carcinogenesis, which is a dominant concern in appraising the safety of any sponsored compound intended for use in food-producing animals. Nevertheless, each compound must also be evaluated for other potential adverse effects. Thus, for example, if the available information raises issues concerning the health of progeny, multigeneration studies of the sponsored compound and/or its residues shall be codesigned and conducted as a part of the process of data collection and evaluation.

If the Commissioner makes a threshold determination, based on (1) preliminary biochemical, chemical, toxicological and physiological data, and (2) proposed patterns of use, that a sponsored compound has the potential to contaminate food from food-producing animals with residues whose consumption would pose a human risk of carcinogenesis, the petitioner will be required to undertake the following six-step procedure for data collection and evaluation.

(a) A metabolic study in the target animals designed to identify edible tissue residues of carcinogenic concern.

01149

(b) A metabolic study of the sponsored compound in experimental animals designed to aid in assessing the carcinogenicity of residues that can not practicably be tested individually (so-called "intractable residue").

(c) Chronic toxicity testing to assess the carcinogenic potential of residues of the sponsored compound and to furnish data suitable for statistical treatment to permit the no-residue requirement of the act to be defined and implemented.

(d) A detailed metabolic study of the sponsored compound in target animals designed to identify a residue and tissue that can serve as indicators ("marker residue" and "target tissue") to determine whether the no-residue requirement of the act is satisfied.

(e) Development of a regulatory assay to measure the marker residue in the target tissue at and above the level established in step (d).

(f) Establishment of the premarketing withdrawal period required for the safe use of the sponsored compound.

Because the partial provisos to the anticancer clauses of the act, sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B), although varying slightly in their language, have a similar intent, the Commissioner has concluded that the criteria for their implementation should also be identical. To avoid needless repetition, however, where appropriate the Commissioner has used the language of section 512 of the act in discussing specific generic issues because the primary impact of these regulations will be on new animal drugs regulated under that section. The criteria set forth in these regulations shall, however, apply to all chemicals intended for use in food-producing animals, and the appropriate regulations will be amended to adopt these criteria by reference.

Since issuing the proposal under § 135.-38 (21 CFR 135.38), FDA has recodified all regulations applicable to animal products in Subchapter E of Title 21 of the Code of Federal Regulations to provide space for the orderly development of future regulations and to provide the public and other affected parties with regulations that are easy to find, read, and understand. For these reasons, the final order has subdivided the proposal into 10 individual regulations and established a new subpart in Part 500, Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals.

II. Threshold Assessment

In the 1973 notice of proposed rulemaking, the Commissioner proposed that carcinogenicity testing not be required for every sponsored compound. Rather, he concluded that the necessity for such testing will be dictated by an evaluation of the existing evidence from metabolic studies, standard toxicity testing, structural relationships of the sponsored compound and/or its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended method of use of the sponsored compound.

Comments of two types were received on this feature of the proposal. The first suggested that extensive studies should be conducted for every sponsored compound to determine whether it is a carcinogen. One comment insisted that extensive carcinogenesis testing for every sponsored compound is the only accurate indicator of carcinogenic potential. Several contended that the criteria proposed for use in the threshold determination were too vague, and objected to the lack of explanation of how such criteria could be applied in practice.

Many other comments agreed with the Commissioner's proposal that extensive carcinogenicity testing should not be required for every sponsored compound. These comments recommended that the Commissioner review all available data pertaining to a sponsored compound before he concludes that the stepwise testing procedure set forth in the proposal and adopted in this regulation should be invoked.

When a petitioner initiates the process of gaining approval for use of a compound, information is provided to the agency on matters such as compound efficacy and its proposed patterns of use. Often a petitioner will also provide preliminary physiological, metabolic, or toxicological data derived from its own studies or from the scientific literature. At this juncture, the Commissioner believes it necessary that a threshold assessment be made, based on the available data, on the need to proceed to the first of the six steps of data collection required by these regulations. Because entry into the six steps of data collection requires that a petitioner undertake a series of very complex and costly experimental studies, imposing demands on the limited national resources available for determining the safety of chemicals entering the environment, the Commissioner concludes that it is not reasonable to demand such studies on a sponsored compound if the preliminary data available justified the judgment that public health can be protected without so proceeding.

Criteria for this threshold assessment cannot be elaborated in detail. The Commissioner must examine the available preliminary data, which may vary considerably in quality and content from one compound to the next, on a case-by-case basis and determine whether a sponsored compound has the potential to contaminate edible tissues with residues of carcinogenic concern. However, certain general characteristics of the compound shall always be considered in making the threshold assessment:

(1) Is the compound a known carcinogen or is it related, in a chemical or biological sense, to other known carcinogens?

(2) Is there an indication in preliminary toxicity studies that the sponsored compound may be carcinogenic?

(3) Does preliminary information on the fate of the compound in target animals indicate that, in combination with information on the proposed pattern of use, there is a high or low probability that residues can occur in edible tissues when such tissues become available as food?

In making a threshold assessment, the Commissioner may or may not have answers to these questions and, in some instances, may not need answers to all of them to make a decision. It will sometimes be obvious that the first step of the six-step process will have to be undertaken. In other cases, it will be equally clear that no such inquiry need be begun, and the compound can be evaluated under the general food safety provisions of the act. Finally, in some cases, available information will be so incomplete or ambiguous that a decision will be made to move to the first step to assure protection of public health. As will be shown later, it is possible that information developed in later steps may support or require revision of the threshold assessment that a compound had the potential to contaminate tissues with residues of carcinogenic concern, in which case the remaining steps of these regulations will not be required and evaluation will proceed under the general food safety sections of the act.

The following examples illustrate how a threshold assessment can be made:

Case I.—A drug is proposed for use in day-old chickens. Preliminary information indicates that:

(a) Neither chemical structure nor preliminary (short-term) toxicity testing raise a suspicion that the drug is a carcinogen.

(b) The drug is proposed for therapeutic use only in a single administration to day-old birds.

(c) The disease to be treated occurs infrequently.

(d) Preliminary metabolic data indicate accumulation of residues in kidney and no detectable residues in muscle.

(e) Residues deplete rapidly and none are detected many weeks before the chickens reach marketing weight.

If presented with the foregoing information, the Commissioner would see no justification for demanding that the petitioner proceed to the first step of these regulations which governs compounds having the potential to contaminate edible tissues with residues of carcinogenic concern. However, if the preliminary metabolic study in the example had been conducted with an assay having a lowest limit of reliable measurement of residues substantially higher than current technology can attain, the Commissioner would conclude that the available data were insufficient to justify a favorable threshold assessment about the sponsored compound, and the petitioner would be required to proceed to the first step of these regulations. It is precisely because of such contingencies that the Commissioner concludes that no more specific criteria for threshold assessment should be established by regulation.

Case II.—A drug having growth promoting properties is proposed for use in cattle. The preliminary information indicates that:

(a) The observed physiological activity of the drug in cattle indicates that it is

01150

in a class of other known carcinogens whose carcinogenic properties appear to be related to this particular physiological activity (i.e., the drug is a suspect carcinogen).

(b) The drug is used during a large fraction of the lifetime of the animal.

(c) The drug is likely to be widely used in animal husbandry.

(d) Preliminary metabolic data show that residues of the drug accumulate in muscle tissue (meat) and deplete very slowly. On the basis of such information, it is obvious that the Commissioner would have to require the petitioner to proceed to the first step of the required six-step process.

III. Metabolic Study in Target Animals To Identify Residues of Concern

A. Need to Identify Residues in Edible Tissue

Before any decision can be made concerning conditions of safe use of a sponsored compound, it is necessary to obtain information on the residues that occur in edible tissues when the compound is administered to the animals for which it is intended (target animals). Without such information, rational decisions about the human safety of edible tissues derived from treated animals are not possible.

A compound administered to an animal can be acted upon by the enzymatic systems or physiological fluids of the animal and new compounds (metabolites and degradation products of the sponsored compound) are produced in the process. Therefore, the sponsored compound is not the only tissue residue of concern. And sections 512(b)(7) and 512(d)(2) of the act explicitly require the Commissioner to consider the safety of any substance formed in or on food by a sponsored compound before approving its use.

Numerous comments were received on the proposal's requirement for metabolic studies. Several comments stated that there should be no attention paid to metabolites. Others contended that metabolism studies should not be routinely required, on the ground that the pathway of excretion is of no toxicological importance if all of the administered compound has been eliminated from the tissues of the target animal. Most comments recommended that a metabolism study should only be required to determine the major metabolites in the edible tissue of target animals, suggesting that the public health would not be served if petitioners are required to pursue endless structural elucidations and quantitations of all metabolites even though some of them might constitute minor fractions of the residue of the sponsored compound. Comments also contended that it may not be experimentally possible to administer to animals sufficient quantities of a compound to obtain amounts of residues sufficient for structural identification. Several comments asserted the studies should be limited to identification of residues in the edible tissues of target animals and that generally it would be unnecessary to have such information on metabolites in inedible tissues. Further, some comments stated that radiotracer studies can be employed to determine the time by which the sponsored compound and its metabolic products are eliminated ("out time"). However, other comments suggested that all metabolites should be identified and tested for toxicity.

The Commissioner reiterates that the objective of requiring metabolic studies is to assure collection of sufficient scientific information on residues to permit a food safety evaluation which in turn can be used to establish parameters for regulatory assays. Therefore, he has concluded that the following metabolic studies are necessary to permit a determination of whether the proposed use of a sponsored compound is safe.

B. Conduct of Metabolic Study

1. *Test animals.* The metabolic fate of an administered compound in an animal may be unique for each livestock production class. Therefore, the Commissioner concludes that a metabolic study in the animals for which a sponsored compound is intended (target animals) is necessary. If the petitioner can demonstrate that the data from the metabolic study obtained for one production class are applicable to a second, the Commissioner may modify the extent of investigation required for the latter.

2. *Required technology.* Because the metabolic fate of a compound administered to food-producing animals plays a pivotal role in decisions regarding the need for an extent of carcinogenesis testing required to assure public health and safety, it is mandatory that such fate be adequately determined, i.e., it must be demonstrated that residues of potential carcinogenic significance have been detected at levels obtainable by the best analytical technology available. Therefore, the Commissioner concludes that the required metabolic studies shall be conducted with the best analytical methods technology can provide.

As will be seen in part VI of this preamble, it is necessary to select one residue that can serve as a practical indicator to assure that the no-residue requirement of the act is met. Such a residue can only be selected by reference to a metabolic study in which residues are detected and measured at levels dictated by the outcome of actual carcinogenicity testing. Because these levels cannot be known at the outset of this phase of the metabolic study in target animals and because the "best available technology" may not be adequate to measure the levels dictated by the outcome of carcinogenicity testing, it may be necessary to develop improved technology and to repeat the metabolic study in target animals, after carcinogenicity testing has been completed. Another requirement of the second metabolic study will be the development of enough data to construct tissue concentration-time profiles for some residues.

3. *Analytical techniques.* For the foreseeable future, the general technique of choice for metabolic studies will be the use of radiotracers. The regulations, therefore, recommend that the required metabolic studies be conducted with radiolabeled compounds of the highest specific activity that is available and is consistent with principles that assure scientific quality. These principles concern the types, the chemical nature, the chemical and metabolic stability, and the suitability of radiolabels for metabolic studies having specific objectives. They have been developed from past metabolic studies with radiotracers and should be followed to assure the scientific quality of the required metabolic studies.

The task of experimental residue detection can often be made easier by available information on the metabolism of related compounds. It is recommended that metabolically feasible pathways applicable to the sponsored compound be proposed based on relevant literature references about compounds of similar structure. This information can usually simplify the choice of radiolabel positions which will assure that all residues containing structural moieties of potential toxicological concern can be detected. However, such projections of likely metabolism can never be a substitute for experimental observation of the metabolic fate of the sponsored compound.

Although the use of radiotracers is the preferred experimental procedure, some compounds possess inherent physicochemical characteristics (e.g., strong fluorescence associated with the structural moiety of potential toxicological significance) that will allow the necessary detection of residues. In such cases, the use of radiolabels may not be required.

4. *Dose regimen.* The dosing regimen for the metabolic study in the target animals shall be consistent with the maximum proposed use level and duration of exposure to the sponsored compound. For compounds administered continuously over long periods of time, administration for the metabolic study need continue only until equilibration or saturation of edible tissues has been demonstrated.

The metabolic fate of a compound administered to target animals is likely to depend on the conditions (level, method, and duration) of use. Because the purpose of the required metabolic studies is to characterize and quantitate residues under conditions of proposed use, these conditions shall be followed in the metabolic studies. However, it is possible that under such conditions certain residues are produced in amounts that do not allow extensive chemical characterization. If the structure of any such residues must be determined, and residues can be produced in sufficient amounts by administering to target animals larger doses of the sponsored compound, the petitioner will be allowed to follow this procedure. In some instances, chemical synthesis of residues may be more feasible, especially if they are needed for chronic toxicity testing.

5. *Required data.* Since the relative persistence of residues in edible tissues is

01151

one consideration in selecting specific residues for toxicity testing, the regulations require that the total number and the relative quantities of residues shall be determined immediately following cessation of treatment, as well as some later time. The Commissioner has concluded that the identification process shall ordinarily continue until the total residue burden in the edible tissues of the target animals has depleted through at least three half-lives. After such time, it is unlikely that new residues previously undetected will appear to alter the residue picture.

The need for and extent of chemical characterization of residues depend on a number of factors. Ordinarily, compounds that constitute a significant fraction of the total residue require sufficient physical and chemical characterization to ascertain whether or not a structural change has taken place which could increase the carcinogenic potency of the residue over that expected of the sponsored compound. In some instances, it may be impossible to judge whether the residue has carcinogenic potential, but significant structural alteration alone may be enough to signal the need for further characterization. Since such structural changes are not uncommon during metabolism and since it is the tissue residues to which human beings will be potentially exposed, such characterization will normally be required. When the agency determines a component of the residue requires chronic toxicity testing (because of tissue concentration and persistence and/or exportation of increased carcinogenic potential), chemical characterization will ordinarily have to be complete and an effort to obtain sufficient quantities of the residue(s) for toxicity testing will be necessary. (See, however, paragraph III.C., below in this preamble.)

In some instances, a petitioner may be required to pursue the complete characterization of certain relatively minor metabolites if partial physiochemical characterization indicates that a structural change during metabolism in the target animal has introduced molecular moieties of carcinogenic potential greater than that expected of the sponsored compound, e.g., nitrosation of an amine of unknown carcinogenic potential to product nitrosamines of known carcinogenic potential.

Because uncharacterized tissue residues pose a risk to public health, the regulation requires that the procedures for separation, purification, and characterization be consistent with the best available scientific and technological capabilities. Ordinarily, the agency will require attempts at characterization to include use of a variety of procedures based on the various forms of chromatography, spectroscopy, and spectrometry.

6. *Format for data submission.* The Commissioner has concluded that the format for presenting results of metabolic studies should be standardized to minimize possibility for misinterpretation of data. Because these studies will provide the basis for major public health decisions, the Commissioner considers it essential that they be carried out and reported in a manner consistent with the best available criteria. The two professional societies listed in the regulations (American Chemical Society and American Society of Biological Chemists) follow policies for acceptance of manuscripts that embody the best available criteria for collecting, interpreting, and reporting scientific data of the type required by this regulation.

C. COMPARATIVE METABOLISM STUDY TO AID IN ASSESSING CARCINOGENICITY OF INTRACTABLE RESIDUES

1. *Sponsored compound always tested: Rationale and procedure.* When it is determined that a sponsored compound has the potential to contaminate edible tissues with residues whose consumption may pose a human risk of carcinogenesis, the sponsored compound itself shall always be tested for carcinogenesis. Residues are selected for testing according to those criteria already discussed in paragraph III.B., but there are overriding reasons for testing the sponsored compound, even if it is not detected as a residue. Metabolic transformation or nonenzymatic degradation of a sponsored compound can lead to a number of tissue residues which cannot be obtained (either by isolation or synthesis) in sufficient amounts for carcinogenicity testing (such residues are herein and in the regulation referred to as "intractable residues"). Testing the sponsored compound itself therefore provides one experimental means for acquiring data on the carcinogenic potential of such residues.

Although the dominant criterion for selecting test animal species or strains for chronic toxicity testing will be the degree to which a species or strain models man, the application of a secondary criterion for selection can provide a means for addressing the problem of intractable residues. Specifically, selection of test animals can also be based on comparative metabolism data (target animal and test animal) which can be used to determine the extent to which particular species or strains, by virtue of the way they metabolically convert the sponsored compound, will be exposed during testing to the same complement of residues expected in tissues derived from target animals.

For example, if a metabolite detected as a residue in edible tissues of the target animal is determined to be toxicologically important, the petitioner will be asked to pursue isolation or synthesis of the compound for toxicity testing purposes. If all attempts at this fail, then the comparative metabolism approach is available if a potential test animal species is shown to produce the same metabolite when it is administered the sponsored compound. In this way, there is some degree of assurance that the toxicity test of the sponsored compound also provides some estimate of the toxicity of the intractable metabolite. Because human food could be contaminated with the intractable metabolite, such a test provides a practical approach to a complex and important issue.

This construct has been included in the final regulations in response to comments that either suggested that all metabolites ought to be ignored (which the Commissioner concludes is neither legally nor scientifically acceptable) or that all metabolites must be isolated and independently tested (which is not technologically possible).

2. *Selection of residues for chronic toxicity testing.* On the basis of all of the studies described above, the Commissioner will select those residues, in addition to the sponsored compound, that require chronic toxicity testing.

IV. CHRONIC TOXICITY TESTING

The sponsored compound and any residues selected for testing shall be subjected to oral, lifetime, dose-response studies in two of the test animal species/strains selected in accordance with the criteria described in the foregoing paragraphs. The purpose of these studies is to determine if the compounds under test are carcinogenic and, if so, to establish the lowest limit of reliable measurement that must be achieved by any regulatory assay for monitoring residues resulting from use of the sponsored compound.

Several comments on this feature of the proposal dealt with the testing of chemical compounds for carcinogenic potential, and addressed two major issues: (i) The design of chronic studies, and (ii) the relevance of animal testing in evaluating human safety.

The Commissioner appreciates the inherent complexity of these issues. He further recognizes that they are common to many areas of food safety, as well as environmental safety, and must be dealt with in an integrated manner in forthcoming regulations on general food safety. However, he believes some discussion of these issues must be included in this preamble as they relate to the context of this regulation.

A. DESIGN OF CARCINOGENICITY STUDIES

Comments on the proposal expressed a variety of contrasting opinions regarding the design features of carcinogenicity studies with experimental animals. The comments specifically addressed: (i) selection of appropriate test animals; (ii) conditions, levels, and duration of exposure; and (iii) statistical design as it relates to number of animals in bioassay, distribution of animals to the various levels of exposure, and adequacy of controls.

The Commissioner recognizes that the impact of these design features on the meaning of animal carcinogenesis data is an important and controversial matter that is currently the subject of intense scientific investigation. The major effort at FDA's National Center for Toxicological Research is specifically directed towards development of relevant protocols and experimental designs for carcinogenicity testing. Until these efforts are concluded and the results incorporated into regulations, the Commissioner recommends that guidance be found in the

01152

report of the Food and Drug Advisory Committee on Protocols for Safety Evaluation: Panel on Carcinogenesis, Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides ("Toxicology and Applied Pharmacology," 20:419–438, 1971). This report reviews and analyzes all facets of experimental design that have been developed and scrutinized by competent scientists prior to 1971. To facilitate incorporation of later developments in testing standards as they have and will evolve, the regulations suggest that petitioners submit developed protocols to the Commissioner for review and updating prior to initiating studies.

B. RELEVANCE OF ANIMAL TESTING IN EVALUATING POTENTIAL FOR HUMAN CARCINOGENESIS

Several comments on this aspect of the proposed regulation dealt with the merits of animal testing as an experimental tool. Some comments pointed out that even animal testing done under the best experimental protocols can never prove conclusively that a compound is not carcinogenic, and that under such circumstances, some weak carcinogens are likely to escape identification. Other comments expressed the contrasting view that adequate protocols can be devised. Still others questioned the propriety of drawing conclusions about human carcinogenesis from data collected with experimental animals.

The act requires that in assessing the safety of animal drugs, the carcinogenic potential of residues shall be evaluated. Ordinarily, such evaluation must be based on appropriate testing. Given the gravity of the decisions that depend on the results of such evaluations, the best relevant scientific information must be developed and assembled. As a source of information, direct carcinogenesis testing of chemical compounds in man is and must remain beyond the ethical bounds placed by society on human experimentation. In the absence of this source of information, which incidentally would be most relevant, alternate sources are human epidemiology studies and animal experimentation. Human epidemiology may provide post facto information about the carcinogenic effects of chemical compounds on man. However, while potentially useful in assessing the significance of new exposures or the risk posed by related compounds, such experience cannot be a central basis for food safety evaluations for several reasons, including the same ethical objections that make direct experimentation in man unacceptable.

The Commissioner therefore concludes that the agency must continue to rely on animal testing for the evaluation of the safety for humans of chemical compounds proposed for use in food-producing animals. Moreover, the act does not distinguish between compounds demonstrated to be carcinogenic in test animals and human carcinogens. Instead, it assumes without proof that an animal carcinogen may be carcinogenic in human beings. In this context, the issue of relevance to man of data from tests in animals must be refocused. The regulatory objective must be to avoid falsely negative determinations of the carcinogenic potential of compounds under test in experimental animals that are appropriate models for man. In this setting, the only tenable regulatory posture for the agency is to select bioassay protocols which utilize test-animal species/strains that have the greatest possible susceptibility to the test compound and are also appropriate models for man. Available toxicologic and metabolic information shall provide a basis for such selection.

C. INTERPRETATION OF TEST DATA—IS THE COMPOUND A CARCINOGEN?

The objective of collecting and interpreting test data is to decide whether or not the compound under test (the sponsored compound and any selected metabolites) is a carcinogen. Within certain limits of confidence, statistical treatment of chemical carcinogenesis data can provide objective criteria for such determinations. To the question "Is the tested compound a test-animal carcinogen?" statistics can provide one of two types of answers:

(i) With "x" percent confidence (i.e., in "x" cases out of 100), "y" dose of the test compound will increase the carcinogenesis risk of test-animals over controls by no more than "s" and no less than "t"; or

(ii) With "x" percent confidence, "y" dose of the test compound will increase carcinogenesis risk of test animals over controls by no more than "s."

Answers of the first type are possible only when the observed incidence of carcinogenesis in the test animals is significantly greater than that in the controls. When the observed incidence is the same for test and control animals, only answers of the second type are possible.

A statistically significant increase in the incidence of carcinogenesis in test animals (i.e., an answer of the first type) is sufficient evidence to classify the test compound as a test-animal carcinogen. Because the act does not distinguish between human and animal carcinogens, for the purpose of these regulations, classification of a test compound as a test-animal carcinogen brings into play the requirements of the anticancer clauses. Revisions of such classification on the basis of phyllogenetic considerations can have no bearing on the applicable legal requirements.

If the animal test data will permit only answers of the second type, the decision whether to classify the test compound as a test-animal carcinogen is more difficult. A negative test finding, as pointed out in some comments, can mean either that the test compound is not a test-animal carcinogen at the tested dose, or that the bioassay protocol lacks a sufficient number of animals, or animal susceptibility, or both, to discern an increase in the risk of carcinogenesis in the test animals. In such cases, a decision must be made whether to classify a tested compound as a noncarcinogen or to require further experimentation appropriate for resolving questions of safety.

V. OPERATIONAL DEFINITION OF THE NO-RESIDUE REQUIREMENT

A. ALTERNATE OPERATIONAL DEFINITIONS

If its has been determined that a sponsored compound, when administered to food-producing animals, has the potential to contaminate edible tissue with residues whose consumption may pose a risk of human carcinogenesis, the agency cannot approve the sponsored compound unless it can be demonstrated that conditions of use can be established that ensure the no-residue requirement of the act can be met. To establish such conditions of use and to provide a means for ascertaining whether these conditions are met in actual practice, some operational definition of the term, "no residue," is necessary. Indeed, the act contemplates that the Commissioner will provide such an operational definition, for he must have some criteria for prescribing or approving methods of examination for measuring residues.

The Commissioner has considered three alternate approaches to an operational definition of the phrase. Under one approach the term, "no residue," might be operationally defined as satisfied when the levels of residues fall below those that can be measured by available analytical methodology (alternative 1). A second approach would be to establish some low finite level (e.g., one part per billion) as a "practical zero" and to require assays that can reliably measure this "zero," insisting on the development of new assays if available assays were not adequate (alternative 2). Finally, "no residue" might be operationally defined on the basis of quantitative carcinogenicity testing of residues and the extrapolation of test data using one of a number of available procedures to arrive at levels that are safe in the total diet of test animals and that would, if they occurred, be considered safe in the total diet of man. Under this approach, the Commissioner would require assays that can reliably measure that safe level in edible tissues (alternative 3). For the reasons discussed in section V.B. of this preamble, the Commissioner has concluded that alternative 3 should be adopted. The results of the carcinogenicity testing of the sponsored compound and any selected residues shall be treated by the statistical procedures described in this part V and prescribed in § 500.87 (21 CFR 500.87).

B. CHOICE OF AN OPERATIONAL DEFINITION

1. *Alternative one.* A number of assays might be developed to measure the concentration of a chemical compound (i.e., residue) in an edible tissue, but for each there would be some level below which the compound under analysis could not be measured. (See section I.B. of this preamble). Generally, different assays for the same chemical compound will have different, and sometimes vastly difficult, lowest limits of measurement. The "no residue" requirement of the act could be translated into an operational definition that is based solely on available analytical methodology and specifically on the lowest limit of measurement of an avail-

01153

able assay. Thus, the degree of public risk associated with the use of a sponsored compound would become a function solely of the capability of available analytical technology.

The Commissioner concludes that this approach is unsound because it ignores all quantitative aspects of carcinogenicity testing. The carcinogenic potency of different chemicals varies widely; failure to consider this fact in developing criteria for the evaluation of sponsored compounds would be scientifically unsound. It could produce situations in which residues of extremely potent carcinogens were not measured in edible tissues at levels as low as the measurable levels of residues of relatively weak carcinogens, if the assay available to measure the former happened to have a lowest limit of measurement that was higher than that of the assay available to measure the latter. Accordingly, failure to consider quantitative carcinogenicity data in establishing the criterion of lowest limit of measurement that an assay must meet would be tantamount to ignoring public health protection in evaluating the use of sponsored compounds.

2. *Alternative two.* A second approach the Commissioner has considered would be to establish "practical zero" for the residues of all carcinogens. This approach would have one advantage over alternative one; it would provide a well-defined criterion for the lowest limit of measurement that any petitioner's assay would have to satisfy. This approach would not, however, take into account differences in carcinogenic potency among various carcinogens and is therefore unacceptable for the same reason as alternative one.

Under alternative two the criterion for lowest limit of measurement would reflect consideration of what lowest level of measurement is "practical," given the state of the art of analytical chemistry or biochemistry. In addition to failing to link the no-residue standard to any consideration of carcinogenic potency, this approach fails on the ground of practicality. The science and technology of analytical chemistry and biochemistry are continuously changing, and a lowest limit of measurement which might be considered reasonable at one time would have to be discarded as unreasonable at some later time. Whenever a new and lower criterion for the limit of measurement were established, it would be incumbent upon the Commissioner to then require that use of all compounds approved under the prior criterion be suspended until methods were developed to measure the residues at this lower level. Such a situation, in the Commissioner's judgment, would be both unreasonable and unmanageable.

3. *Alternative three.* A third approach to defining operationally the no-residue requirement is to establish a required lowest limit of measurement for each sponsored compound on the basis of data derived from carcinogenicity testing of the compound and selected metabolites. Under this approach carcinogenic potency is given specific consideration because actual chronic toxicity test data are used to determine the level of residues in edible tissue that an assay must be capable of reliably measuring. Thus, it permits a rational, uniform procedure for establishing the required lowest limit of measurement for assays and avoids the major deficiencies inherent in alternatives one and two.

Should new information relating to the carcinogenic potency of residues of a sponsored compound later appear, this approach provides a practical basis for determining whether a new assay is required to establish compliance with the no-residue requirement. But only under such circumstances will it be necessary for the Commissioner to insist that the petitioner develop a new assay; thus, this approach contributes to regulatory stability and predictability. If an assay becomes available with a lowest limit of measurement that is lower than the level required by the analysis of quantitative carcinogenicity data, the Commissioner will adopt that method if it also meets the other rigorous criteria described in part VIII of this preamble and § 500.90 (21 CFR 500.90). However, for compounds that have been approved for use on the basis of an assay that satisfies the requirements of the regulation, the development of such a method will not be required. Thus, following this approach, the Commissioner can provide the maximum public-health protection based on both quantitative carcinogenesis data and improved analytical technology. For these reasons, the Commissioner concludes that alternative three is the most rational approach to developing an operational definition of "no residue."

By adopting this approach to implementing the "no residue" standard, the Commissioner has assumed that: (i) The carcinogenic potency of chemical compounds can be quantified, and (ii) a dietary level of a carcinogen can be identified at which no significant human risk of carcinogenesis would derive from consumption of food containing residues below this level.

The carcinogenic potency of compounds can be determined by testing in experimental animals, although such determinations are subject to known limitations inherent in every measuring device or system. The second assumption, that potential residue levels representing no significant human risk of carcinogenesis can be assigned, is controversial, but it must be fully confronted and resolved if the public is to be protected from the potential and real dangers that inhere in the interpretations of the no-residue standard of the act outlined as alternatives one and two.

C. ANALYSIS OF ANIMAL CARCINOGENESIS DATA TO DEFINE OPERATIONALLY THE NO-RESIDUE STANDARD OF THE ACT

1. *Introduction.* The modified extrapolation procedure of Mantel and Bryan proposed for use in defining the no-residue standard for a sponsored compound is a statistical technique that allows estimation of the level, or dose, or a carcinogen that would lead to cancer incidence rates in test animals well below those rates that can be detected in practical experimentation. In normal experiments in which test animals are administered various levels (doses) of a suspected carcinogen, the observed responses (i.e., the percent of test animals developing cancer if the compound is carcinogenic) are usually in the range of about 5 percent to 95 percent. To observe responses at incidence rates less than about five percent requires large numbers of test animals. As will be seen, experiments designed to observe responses in the range of interest in establishing the no-residue standard, would require very large and often impractical populations of test animals. Therefore, the procedure of Mantel and Bryan,[1] and Mantel et al.,[2] as modified, is used to treat statistically the dose-response data from actual experimentation and to estimate the dose or level of the compound under test that would result in lifetime test-animal cancer rates no higher than a certain preselected rate.

Before discussing the many comments received on this feature of the proposal, the Commissioner reemphasizes that some operational zero must be defined if the no-residue requirement of the act is to be implemented. Regardless of the arguments for or against the Mantel-Bryan procedure, the Commissioner maintains that a procedure that takes into account the carcinogenic potency in test animals of residues (which the Mantel-Bryan procedures does) is far superior to any approach that fails to do so.

The modified Mantel-Bryan procedure described in the proposal was labeled excessively conservative by some comments and recklessly liberal by others. Those who considered the procedure too conservative objected to the proposed use of a series of conservative assumptions (shallow-slope, dose-response relations, low acceptable level of risk) and contended that any one of these assumptions alone could provide adequate protection to the public. Further, these comments argued that the practical application of the procedure has not been demonstrated, and suggested that it would prohibit the use of many valuable compounds. Persons who considered the proposed procedure too liberal objected to the proposed use of a lower confidence limit on the observed slope of the dose-response curve. Their objection is that the proposed statistical technique for extrapolating dose-response data obtained from animal tests seriously underestimates public risk. The technique provides a basis for establishing a dose level where there would be no significant human risk of cancer, thereby establishing a criterion for a residue detection method. Specifically, the comments contended that if the true statistics of the dose-response relation are logistic or linear, ex-

[1] Mantel, N. and W. R. Bryan, "'Safety' Testing of Carcinogenic Agents," "Journal of the National Cancer Institute," 27(2):455-470 (1961).

[2] Mantel, N., et al., "Improved Mantel-Bryan Procedure for 'Safety' Testing of Carcinogens," "Cancer Research," 35:865-872 (1975).

trapolation with the slope of a probit transformation would seriously underestimate public risk. Further, these comments argued that the probit transformation leads to a paradox, in that strong carcinogens are treated less conservatively than weak ones. Regardless of their point of view, however, most of the comments supported the Commissioner's effort to elicit public discussion of the implementation of the anticancer provisions of the act.

2. *Choice of the Mantel-Bryan procedure*—(a) *Alternative statistical models.* Most of the comments favored the proposed adoption of the Mantel-Bryan procedure but without the modifications suggested in the proposal. A smaller number of comments recommended that a linear extrapolation would be a better alternative to the Mantel-Bryan procedure, and even fewer suggested the logistic or the angle distributions. Still other comments suggested that a comparative analysis of animal carcinogenesis data be required employing all alternative distributions and the smallest estimate of the "safe" level be used to define the no-residue standard for a compound. Finally, some comments indicated that, although the logistic and angle distributions have been used in biological sciences, there is no indication that either one provides advantages over the probit (Mantel-Bryan) or the linear distribution, and that, therefore, neither was appropriate for regulatory purposes.

Some comments favoring the Mantel-Bryan procedure argued that it has a theoretical rationale which is probably relevant to the carcinogenic action of chemical agents. A similar argument was made by some of the comments favoring the linear extrapolation. These comments also contended that the linear extrapolation has the public health advantage of being the most conservative of all procedures.

(b) *Limitations in available procedures and choice of procedure.* The Commissioner has extensively reviewed the known procedures that may be used to derive an operational definition of the no-residue standard of the act from animal carcinogenesis data. This review has persuaded him the same scientific and technological limitations are common to all. Specifically, because the mechanism of chemical carcinogenesis is not understood, none of these procedures has a fully adequate biological rationale. All require extrapolation of risk-level relations from responses in the observable range to that area of the dose-response curve where the responses are not observable. Matters are further complicated by the fact that the risk-level relations adopted by the various procedures are practically indistinguishable in the observable range of risk (5 percent to 95 percent incidence) but diverge substantially in their projections of risks in the unobservable range. Finally, the Commissioner concludes, no procedure is intrinsically more conservative than any other; the conservatism of any procedure depends entirely upon the restrictions and modifications imposed.

The comments failed to demonstrate that another procedure is superior to that of Mantel and Bryan [1] and Mantel et al.,[2] (Mantel-Bryan) and therefore the Commissioner has adopted it with some modifications. Moreover, the Commissioner concludes that some aspects of the Mantel-Bryan procedure offer distinct advantages over the other statistical procedures. It provides a clearly defined means for pooling data from multiple experiments and from multiple dose levels within a single experiment, thus permitting decisions based on the fullest use of available data. Further, the Mantel-Bryan procedure has a clearly defined mechanism for handling the spontaneous tumor rate. (See paragraph V.C.4.(d) of this preamble, below.) To overcome certain limitations of the Mantel-Bryan procedure, the Commissioner has adopted a number of modifications, which are described in § 500.87 and discussed in paragraph V.C.4 below in the preamble.

The Commissioner recognizes the significance of the decision to adopt the modified Mantel-Bryan procedure to implement the no-residue requirement at a time when that procedure, and similar procedures, as well as the relationship between test-animal experience and human risk, are under active and intense scientific study. He therefore has concluded that a review of this decision shall be undertaken in 2 years, and any appropriate modifications in the regulation will then be initiated.

3. *Time-to-tumor and other considerations.* Several comments contended that the proposal was deficient because it did not address the time-to-tumor aspects of chemical carcinogenesis. Some comments pointed out that Albert and Altshuler have developed preliminary statistical relationships between low levels of carcinogen exposure and time of tumor manifestation. It is the view of these authors that characterization of carcinogenic potential on the basis of incidence alone is not appropriate, because it ignores the life-shortening aspects of carcinogenesis.

The Commissioner generally agrees with these comments. He is faced, however, with a dilemma similar to that presented by the choice of statistical distributions. While statistical analyses based on incidence have been subjected to the scrutiny of use, the time-to-tumor relations developed by Albert and Altshuler have not. For this reason, the Commissioner concludes that the basis for extrapolation prescribed in the regulation shall be only incidence statistics, but the agency will initiate a review of the matter of time-to-tumor statistics in 2 years and consider the desirability and practicability of providing for their consideration.

One comment stated that "effects produced at higher dose levels * * * are useful for delineating the mechanism of action, but for any material and adverse effect, some dose level exists for man or animal below which adverse effects will not appear." The comment analyzed in detail the deficiencies of all statistical extrapolations and stated that approaches are available to define a true carcinogenic "no-effect" level. It contended that it is more appropriate to determine a biologically insignificant level using a safety factor based on competent scientific judgment.

The Commissioner disagrees with the contention that the classical toxicology concepts of "thresholds" and "biologically insignificant levels" are generally applicable to carcinogenesis. There is substantial scientific controversy over whether such concepts apply to irreversible processes, such as the chemical induction of malignant neoplasia. "Threshold" and "biologically significant level" concepts derive from short-term toxicity experiments which have no established meaning in biological processes that require long latent periods (up to 20 or 30 years) before lesion manifestation.

Several comments opposing the proposal suggested that the agency should maintain flexibility and evaluate the approvability of sponsored compounds based on assessments of benefit and risk, in effect offering another approach to establishing the operational zero for carcinogenic residues. The Commissioner concludes, however, that an approach that contemplates consideration of the benefits of use of a sponsored compound in defining the no-residue standard is incompatible with the anticancer provisions of the act.

4. *Modifications and restrictions on the Mantel-Bryan procedure*—(a) *Expression of dose level.* Several comments addressed the adjustments the Commissioner proposed to make in the "safe" level of Mantel and Bryan derived from the experimental animal data in order to establish an appropriate value for man. Some comments stated that adjustments for differences in food intake between experimental animals and man inappropriate when dealing with carcinogens. The comments stated that such adjustments would assume erroneously that all toxic materials have the same mode of action on a body weight basis. They further suggested that the relationship should be expressed in terms of concentration in the feed of the test animals and in the food of man when the diet in both cases is consumed ad libitum, other than on an amount-per-body-weight basis. Other comments argued that the conversion of animal data to man should be based on surface areas.

The final regulations specify that carcinogenicity tests shall be conducted with the test compound's concentration in the diet of the experimental animals held constant throughout the study. And the "safe" level derived from the modified Mantel-Bryan extrapolation of test-animal data shall be expressed as a concentration in the total diet (weight of compound/weight of total diet) of the animals and shall be directly applied at the "safe" level for the total diet of man. The Commissioner concludes that the arguments for conversion based on surface areas or on intake per unit of body weight have little basis. The comments

01155

provided no evidence that these concepts are applicable to low-dose chronic exposures. The surface area concept is based on experience with short-term, high-dose studies. Furthermore, measurements of surface area are crude. Finally, surface area and body weight will vary, as will food intake per day, throughout the chronic study, thus requiring constant adjustments of dose.

Until evidence is compiled demonstrating that there is a more appropriate means of conversion from experimental animal to man with respect to chronic exposure and carcinogenic manifestation, the Commissioner will assume that the animal is the integrator throughout its lifetime of any observed response to a fixed concentration in the diet. The Commissioner has thus adopted the direct conversion approach (the "safe" level in parts per million, parts per billion, etc., of the diet of the experimental animals directly applied to the diet of man), which is the most conservative, as well as most practical, of the approaches considered.

(b) *Degree of data confidence.* The Commissioner disagrees with comments that characterized the proposal's requirement for 99 percent confidence intervals as another in a series of unnecessarily conservative assumptions. Confidence intervals characterize the quality of experimental measurement. The Commissioner concludes that a high degree of confidence should be demanded for decisions respecting carcinogens. He therefore has adopted the 99 percent level of confidence, and the final regulations require that all calculations based on experimental observations shall be made from or with the 99 percent confidence limits.

(c) *Slope used for extrapolation.* The proposal would have required that extrapolation be made with the lower 90th percentile of the observed dose-response curves. Numerous comments stated that the extrapolation should be performed with a slope of one, as proposed by Mantel and Bryan.

The Commissioner agrees with comments that suggested that use for extrapolation of the observed slope of the experimental dose-response curve could underestimate public risk, and has modified the regulation to call for a maximum slope of one. This requirement affords a high degree of confidence that, regardless of the actual configuration of the dose-response curve in the unobservable region, the maximum projected risk will be higher than the actual risk.

If the experimental dose-response curve exhibits a slope that is less than one, it is possible that this slope characteristic may also prevail in the unobservable region. To maintain the conservatism of the procedure, in such situations, the regulations require that the extrapolation be performed with the shallower slope. The Commissioner recognizes that there may be weak carcinogens whose actual dose-response curve slope may be relatively steep at the lower levels of response, with a plateauing (i.e., very shallow slope) in the experimentally observed region. In such a case, the procedure adopted would be ultraconservative. However, it is not possible to know the nature of the true slope in the unobservable region, and the agency must have a high degree of confidence that the maximum projected risk is above the actual risk.

(d) *Spontaneous tumor rates and data combination.* In the proposal the Commissioner recognized certain limiting features that are common to all extrapolation procedures, including that of Mantel and Bryan. These limitations concern the rate of tumor incidence in the control groups of animal bioassays and the selection or combination of data from different experiments. Since publication of the proposal, Mantel and coworkers[2] have developed procedures to deal with these issues. The Commissioner sees merit in these improvements and has adopted them in the final regulations.

In the original procedure published by Mantel and Bryan, the tumor incidence attributable to a given level of a chemical carcinogen was measured as the difference between the upper 99 percent confidence limit of the observed response of test animals and the lower 99 percent confidence limit of the observed response of control animals. The effect of this procedure on the derived "safe" level is minor when the tumor rate in control animals is low; however, when the control animals exhibit a high rate of spontaneous tumors, the effect of the procedure is far more pronounced. The improved procedure published by Mantel et al.[2] treats the rate of spontaneous tumors as an additional statistical parameter, which it is, and thus resolves this problem.

In many instances, the male and female animals of the same strain may exhibit significantly different responses to a compound. It is also apparent that the responses of different strains and species may be similar. It is always desirable to make maximum use of available information by appropriate combination of different data sets however, but prudence must govern the process of selecting and combining data. Combining different data sets increases the number of animals used in the analysis and therefore increases the confidence in the results. Yet, in many instances, different data sets contain different types of information. Mantel et al.[2] discuss the informational aspects of data combination with respect to pooling data from different experiments and from different doses. The Commissioner agrees in principle with most of their conclusions; nevertheless, he anticipates that situations will arise where the evidence in support of combining or not combining data will be equivocal. Therefore, he concludes that the statistical and biological evaluation of data will determine which data sets, if any, will be appropriate for pooling. Where there are significant statistical and/or biological differences in the observed responses, only subsets of data representing statistically and biologically compatible bioassays will be used for analysis.

(e) *Level of risk.* The proposal suggested that an accepted level of risk for test animals, and thus for man, could be 1 in 100 million. Many comments argued that this level of risk was unnecessarily conservative in light of the many other cumulative, conservative restrictions already imposed by the regulations. For the reasons set forth below, the Commissioner has concluded that this level of risk is unduly limiting without substantial compensation in terms of public health.

As the level of risk is decreased, the number of animals that are required in each test to bring the lowest limit of the assay's measurement derived from a no-carcinogenic-response test into the range of current analytical technology vastly increases. Thus, the time and resources that are necessary to plan, perform, and evaluate the test before submission to the agency in proper form increase enormously. This in turn increases the potential for interference from irrelevant variables or intervening forces. Then the amount of agency resources that must be committed to evaluate the data also increases almost geometrically. Finally, all these additional factors provide only a minor incremental increase in the degree of confidence in any decision that must be made on the results of these chronic toxicity tests. Consequently, the final regulations establish the maximum risk to be used in the Mantel-Bryan calculation as 1 in 1 million. The following clarifications of the meaning of the 1 in 1 million risk level demonstrate why the Commissioner believes that such a risk level can properly be considered of insignificant public health concern.

(i) The risk level of 1 in 1 million is a risk level for the entire lifetime of an individual.

(ii) This lifetime risk is the maximum, and therefore unlikely, human risk level. Because of the series of conservative assumptions built into the modified Mantel-Bryan procedure and into the derivation of the final "safe" level (see paragraph V.D., below in this preamble), the most likely human risk level will be several orders of magnitude less than this maximum.

(iii) The 1 in 1 million lifetime risk level assumes that an individual will consume maximum residue levels every day over a lifetime.

(iv) The use of this procedure for estimating acceptable level is based on the assumption that the only risk to the human population is that from residues of the sponsored compound, not from such intervening causes as disease or accidents (e.g., the average risk of fatality by motor vehicle accident per year is approximately 1 in 4,000). Because the population is constantly at risk from a wide range of factors, however, any increment of increased risk associated with exposure to residues of multiple compounds is at most in the vanishingly small range.

01156

D. DERIVATION OF THE LEVEL OF TOTAL RESIDUES OF CARCINOGENIC CONCERN WHICH CAN BE TAKEN AS SATISFYING THE NO-RESIDUE REQUIREMENT OF THE ACT

As explained in the previous section, a potential residue level corresponding to a risk of 1 in 1 million in test animals (i.e., the "safe" level derived from the modified Mantel-Bryan procedure) can be considered the level that represents no significant carcinogenic burden in the total diet of man. This level is assigned in the final regulations the symbol S_0, and, expressed as a fraction in the total diet (i.e., parts per billion, parts per trillion) of the test animals, shall be directly taken as the potential undetected residue level that is safe in the total diet of man.

In some cases, residues in addition to the sponsored compound itself will have been selected for carcinogenicity testing. In these instances, "safe" levels will be derived for each of the compounds that have undergone testing. The compound exhibiting the lowest value for the "safe" level is the most potent carcinogen of those tested and constitutes the greatest potential carcinogenic threat among the residues. The Commissioner will, accordingly, choose the smallest value of the various "safe" levels, assign to it the symbol S_0, and assume that it represents the potential carcinogenic burden that may result from the administration of a sponsored compound to food-producing animals. Additionally, because other tested residues may have exhibited carcinogenic properties (albeit less potent) and still other, untested residues may represent carcinogenic risks, the S_0 will be taken as the sum of the levels of all of the residues. Potential residues in the total human diet cannot exceed S_0 if that diet is to bear no significant carcinogenic risk to man. The only residues that can be excluded from the sum of residue levels are those that have been unambiguously shown to be noncarcinogenic.

Although it will already be apparent to the attentive reader and to the trained scientist, it bears reiteration at this point that S_0 (or any figure derived on the basis of adjustments described below) does not represent a level of residues "approved" for introduction into the human diet. The purpose of these regulations is to establish criteria for the evaluation of assays for the measurement of carcinogenic animal drugs. These criteria must include some lowest level of reliable measurement that an assay is required to meet. In defining a level of potential residues that can be considered "safe," therefore, the Commissioner is establishing a criterion of assay measurement that, if it can be met for a compound, will assure that any undetected residues resulting from the compound's use will not increase the risk of human cancer.

E. CORRECTIONS FOR FOOD INTAKE

Several comments argued for and others opposed further adjustments based on patterns of food consumption. Some comments contended that the "safe" level of Mantel and Bryan in the animal diet should be directly applied as the upper allowable limit in man's diet and in any component food in the human diet. These comments argued that this limit should not be raised by consideration of intermittency of consumption of particular foods or of the proportion of the total diet represented by an individual food. They suggested that individuals who consume above average amounts of food would be exposed to above average, and thus possibly harmful, levels of residues. Further, these comments contended that the act does not provide a distinction between people who consume average diets and people who consume above-average quantities of exotic foods; both groups are entitled to equal protection. They argued that adjustments for exposure frequency based on food consumption patterns assume that continuous long-term exposure to a carcinogen precedes the development of cancer.

Many other comments urged that adjustments should be made based on the proportion of the specific food in the total diet and the frequency of exposure. These comments generally favored the use of food consumption data, so that the degree of conservatism was more uniformly applied taking into account the relationship of the particular food to the total diet.

The Commissioner disagrees with the contention that no adjustments should be made for factors of exposure. Section 512(d)(2)(A) of the act requires the Commissioner to consider the probable consumption of a drug and of any substance formed in or on food because of its use. Analysis of carcinogenesis data provides S_0. The no-residue standards of the act has been defined as satisfied when the sum of the levels of all potential undetected residues of the sponsored compound (excluding only those that have been found to be noncarcinogenic) would not exceed S_0 in the total diet of man. Because products derived from food-producing animals do not constitute the total human diet, it is therefore appropriate that S_0 be corrected for probable human consumption of specific tisues. The Commissioner agrees, however, that any adjustments must be conservative to assure that all segments of the population are protected.

The Commissioner has consulted available data on food consumption patterns in the United States, and concludes that muscle tissue and eggs can be considered, conservatively, to each constitute one-third of the total daily human diet. Since milk can constitute the total daily diet of any individuals (e.g., infants), no adjustment will be made for this commodity. Adjustments for frequency of exposure for tissues other than muscle, milk, or eggs (i.e., kidney, liver, etc.) will be considered only if the proportionate levels of potential undetected residues in such other tissues, compared to muscle, are such that intake of muscle tissue on days when other tissues are not being consumed provides an insignificant contribution to the total exposure to residues (i.e., S_0 is never exceeded in the total diet of human beings).

The final regulations use the symbol S_m to represent the level of total residues of carcinogenic concern that can be operationally defined as satisfying the no-residue requirement of the act for specific tissues. If, for example, a particular animal drug used in cattle were found to have an S_0 of 10 parts per trillion, the assay required for approval of the drug would have to be capable of reliably measuring residues of 30 parts per trillion and above in muscle tissue.

F. OTHER POSSIBLE ADJUSTMENTS

Several comments urged that the regulation should not provide for adjustments for the degradation of residues in food under normal conditions of storage and cooking. Others suggested that such data should not be required but should be taken into account when available. Still other comments expressed the fear that such data would be used to dilute the conservative intent of the regulation; they argued that the term "normal condition of storage and cooking" would be difficult to define, and it might reduce protection in situations where actual storage and food preparation practices did not approximate experimental conditions. Finally, some comments suggested, generally, that such studies should be required only when there is reason to believe that such information would assist in protecting public health.

The Commissioner agrees that the parameters appropriate to such studies have not been defined, and he has deleted from the final regulations references to postslaughter residue degradation studies. When there is reason to believe that storage conditions or food preparation methods might lead to the formation of potentially toxic residue products, however, the Commissioner will require appropriate special investigations. Petitioners are encouraged to explore the postslaughter stability of residues. Experience has shown that residue stability can be a complicating factor in studies for the validation of assays for dosed tissues. The Commissioner encourages research in this area but until appropriate information can be reliably incorporated in the food safety decisions, such data will not be used to liberalize the requirements of the regulations.

G. CONSIDERATION OF OTHER RELEVANT SAFETY FACTORS

Originally, the Commissioner proposed that the Mantel-Bryan calculation be modified to account conservatively for drug use patterns, e.g., the administration of a drug in the treatment of diseased animals. Comments demonstrated that disease incidence does not occur randomly within a geographic area or within specific animal groups. Although a disease may have an overall incidence of only 10 percent, the affected group may be located in a single area. Therefore, the Commissioner is unable to conclude that evidence exists, or other safety factors are available, to permit him to calculate the effect of such drug usage, and he has deleted this provision from the regulation.

01157

VI. Metabolic Study to Select Marker Residue and Target Tissue

A. The Concept

Before he can approve the use of a sponsored compound, the Commissioner must assure that a practical and reliable assay is available that can measure carcinogenic residues at the level which discriminates safe from unsafe food, i.e., the assay must be capable of determining when S_m is exceeded in each edice tissue. One approach to this problem would be to require assays that can be used to measure every residue in each of the various edible tissues. Because the number of residues in edible tissues and the number of tissues can sometimes be large, it is unlikely that such an approach could be put to practical use. The Commissioner has determined that another approach is possible that is far more practicable and sacrifices no principle of safety. This alternative approach centers on the concepts of a marker residue and a target tissue.

A marker residue is a residue whose level in a particular tissue is in a known relationship to the level of the total residue of carcinogenic concern in all edible tissues and which, therefore, can be taken as measure of the total residue of interest in the target animal. Once a marker residue is selected and its quantitative relationship to the total residue is determined, it is possible to calculate a level, for purposes of these regulations, R_m, which is that level of the marker residue that must not be exceeded in a selected tissue (the target tissue) if the total residue of carcinogenic concern in the edible tissues of the target animal is not to exceed S_m. The marker residue can be the sponsored compound or any of its metabolites, or a combination of residues for which a common assay can be developed.

The target tissue is that tissue in which the absence of the marker residue at R_m or above can be taken as confirmation that the safe residue level, S_m, is not exceeded in any of the edible tissues. When a marker residue and a target tissue are selected, a practicable assay must be developed that can reliably measure the marker residue in the target tissue at levels at least as low as R_m, and conditions of use of the sponsored compound must be established that assure that, in practice, the potential marker residue level in the target tissue does not exceed R_m.

When it is determined, using as assay demonstrated to be capable of reliably measuring the marker residue in the target tissue at levels at least as low as R_m, that there is no such residue at levels at or above R_m, it can be concluded that the no-residue standard of the act has been satisfied for all edible tissues in the animal under examination. Conversely, if the market residue is found in target tissue at levels equal to or greater than R_m, all edible tissues must be considered unsafe for human consumption.

B. Application: Data Development and Calculation of R_m

1. *Marker residue.* Application of the concepts of marker residue and target residue requires an experimental determination of the quantitative relationships of residues that might serve as markers (including any which have definitely been shown to be noncarcinogenic, since theoretically one of these might be selected as marker residue) to the total residue in each of the various edible tissues which might serve as target tissues. Further, because these relationships change with time, the levels of potential marker residues in the potential target tissues must be measured over time, and tissue concentration-time profiles must be constructed. These depletion profiles will be derived from measurements made in target animal tissues after cessation of exposure to the sponsored compound. Finally, because the results of carcinogenicity testing have been used to set limits for total potential undetected residues in each of the individual edible tissues, the depletion profiles must include measurements of the total residue in each potential target tissue to levels at least as low as the S_m appropriate to the tissue. Additionally, depletion profiles for one or more potential marker residues must be constructed and include measurements of levels of residues corresponding to the times when the total residue has reached S_m (Plates I and II set forth in § 500.89 (31 CFR 500.89).)

Part III of this preamble describes the requirements for the study of the metabolic fate of a sponsored compound in target animals. Although the purpose of this earlier metabolic study is to provide information for selecting residues for carcinogenicity testing, the same principles and requirements are applicable here and must be followed in acquiring the information necessary to construct depletion profiles. However, to meet the depletion profile requirements prescribed by the regulations, a second metabolic study of the sponsored compound in the target animals may be necessary. This second and possibly more refined study may require the use of a larger number of animals, for it will be necessary to determine the total number and the quantities of residues, not only at two points in time, but at several appropriately spaced time intervals starting immediately after cessation of exposure and continuing until the residues in each of the potential target tissues has reached a level corresponding to a total residue level of the appropriate S_m (e.g., for meat, milk, or eggs). If the initial metabolic study were done with the degree of precision required to select a marker residue and a target tissue, of course, it need not be repeated.

Selection of a marker residue will be based on examination of depletion profiles. Generally, there will be some time at which the sum of the levels of the individual residues of carcinogenic concern will fall below the S_m appropriate to the tissue under examination. Residues that are potential markers will be present at a known concentration (R_m) at this same time (T_L of Plate I), and in a definite (although perhaps rapidly changing) quantitative relationship to the total residue (Plate II).

With the quantitative relationships established, it will be possible to select one of the residues as a marker. Ordinarily, the residue selected will have the following characteristics: (i) It will represent at least 10 percent, and usually a great deal more, of the total residue burden at the time when the total residue was depleted to S_m; (ii) it will be stable, easily isolated and characterized, and susceptible to manipulation for assay development and implementation; (iii) it will be undergoing relatively rapid change in concentration at the time the total residue burden is at or near S_m (i.e., a change in its concentration will be a sensitive indicator of the time when the total residue burden has depleted below S_m. While other considerations may enter into the selection of a marker residue, these three will ordinarily be most important.

There may be instances in which no single residue can adequately fulfill the requirements which a marker residue must meet. In such instances, it may be necessary to select some combination of residues which, taken together, can represent the total residue burden. It should be noted that a marker residue can be a compound which is not a carcinogen, but is an unambiguous indicator, in the manner already described, of the presence or absence of carcinogenic residues.

2. *Target tissue.* Selection of a target tissue requires a comparison of the depletion profiles for each of the edible tissues (Plate I set forth in § 500.89). A target tissue will be selected based on assurance that the absence of the marker residue at or above R_m assures that carcinogenic residues are absent from the slowest depleting tissue, and thus that the entire animal is free of carcinogenic residues:

When a compound is to be used in milk- and egg-producing animals, milk and eggs will be target tissues in addition to one tissue selected as the target tissue to represent the depletion of residues in all of the edible carcass. In such cases, it may be necessary to select a marker residue for milk or eggs that is different from the marker residue selected for the target tissue representing the edible carcass.

3. *Calculation of R_m.* The level of the marker residue which is present in the target tissue at the time (T_L) when the sum of the levels of the residues in the slowest depleting tissue (excluding any residues that have definitely been shown to be noncarcinogenic) is equal to S_m for that tissue, is the R_m for that marker residue. The depletion profiles will be used to select R_m (Plate II set forth in § 500.89).

For example, assume (i) that liver is the target tissue of animal drug, P, intended for use in cattle; (ii) that the

01158

only residues of P are the parent compound, P, and a metabolite P_1; (iii) that T_L is 3; (iv) that S_m for the sponsored compound is 29 parts per trillion; and (v) that the following is a chart of the depletion profile of the drug.

[In parts per trillion]

Time	Total residue burden	P	P_1
0	100.0	75.0	25.0
1	65.4	44.6	21.8
2	42.0	25.3	17.3
3	29.0	15.0	14.0
4	21.0	9.0	12.0
5	15.0	5.0	10.0

In this case, before the drug can be approved for use, the petitioner must develop an assay that will satisfy the evaluation criteria in liver for either P at least as low as 15 parts per trillion or P_1 at least as low as 14 parts per trillion. Because P is depleting faster than P_1, when the total residue burden is 29 parts per trillion, P may be the preferred compound to select as the marker residue since it does provide a more accurate assessment of when the total residue burden reaches 29 parts per trillion (S_m). Another example is provided in Plate II in § 500.89.

VIII. Sponsored Compounds Affecting Pools of Carcinogenic or Potentially Carcinogenic Substances Endogenous to Target Animals

A. Applicability of No-Residue Requirement

The act requires that in making food safety decisions, the Commissioner take into account all substances formed in or on food by the administration of sponsored compounds to food-producing animals. It is well recognized that: (i) Several substances endogenous to food-producing animals are suspect or proven carcinogens; (ii) in any given animal species or breed, the size of pools of such endogenous substances vary widely with such attributes as sex, age, lactation, state of estrus, pregnancy, geographic location, and animal husbandry practices; and (iii) man has had sustained exposure to such endogenous substances for centuries. Whether normal levels of human exposure to these substances are responsible for human carcinogenesis is unknown, but the Commissioner maintains that the use of drugs that can cause an increase in human exposure to such compounds has the potential of increasing the risk of human carcinogenesis. The use of such drugs must therefore be controlled.

In dealing with potentially carcinogenic endogenous compounds, the proposal declared that the intent of the no-residue requirement of the act is the maintenance of the normal human dietary content. Thus, the regulations require the determination of the effects of sponsored compounds on the normal background levels of potentially carcinogenic endogenous compounds. If a compound is found to increase such levels, conditions of use must be established so that normal background levels are not exceeded in the animal when the animal is slaughtered. The regulations also require the development of practical assays for measuring endogenous compound levels.

Several comments on this segment of the proposal expressed concern over the meaning of the term "endogenous compounds" and questioned how such compounds are to be distinguished from "exogenous compounds." Others questioned whether the former term includes chemical derivatives (estradiol benzoate) of bona fide endogenous compounds (estradiol) or essential nutrients (some amino acids, minerals, vitamins). Comments also expressed doubt about the distinction between endogenous and exogenous compounds in cases where the administered compound can be metabolized to residues of both classes. Some comments also argued that all externally administered compounds should be considered exogenous, as the true meaning of the term implies.

Other comments suggested that endogenous substances of interest be subjected to toxicological testing and tolerances be set if such substances are found to be not carcinogenic. Some expressed doubt that available technology could meet the requirements of the proposed regulation. They contended that the terms "normal conditions of use" and "normal background levels of endogenous compounds" would be either extremely difficult or impossible to define. The Commissioner recognizes the difficulty of the task, but concludes that administered compounds that increase the naturally occurring level of potentially carcinogenic endogenous compounds present special problems of control which the regulation must address and resolve.

B. Definitions

An endogenous compound is any compound that is metabolically produced by and is present in untreated target animals. Any sponsored compound that is found to increase the normal background levels of a potentially carcinogenic endogenous compound shall be subject to these regulations regardless of how the increase is brought about.

For instance, estradiol benzoate, which is by the above definition clearly not an endogenous compound, is metabolically converted to the endogenous compound, estradiol, and may thus cause an increase in normal background levels of that substance. Estradiol may itself be administered, possibly again causing target animal pools of estradiol to increase above background. Finally, a sponsored compound may indirectly cause an increase in tissue levels of estradiol by affecting any number of hormonal regulatory systems in the target animals. While in each of the above cases the cause of the increases in normal background levels of estradiol was different, the result was the same. And it is the result that must be monitored and controlled. It is thus of little use to distinguish between "endogenous" and "exogenous" sponsored compounds. Rather, it is useful only to distinguish between administered compounds that can cause changes in normal background levels of potentially carcinogenic endogenous compounds, which can unambiguously be defined, and those administered compounds that do not affect such levels.

Essential nutrients are not included in the definition of the classes of compounds that will be regulated by these regulations. In a strict sense, essential nutrients are not endogenous. Although present in the tissues of animals and required for growth and health, they are not produced by the animals and must be supplied from external sources. These features place essential nutrients in a distinct class of "required exogenous compounds," which must continue to be regulated in a unique manner. Determination of the allowable use of essential nutrients must reflect the nutritional requirements of the target animals. When used according to label directions, essential nutrient supplements should restore but must not exceed the essential nutrient levels found in natural foods adequately sustaining normal growth of healthy animals. Furthermore, the levels of animal essential nutrients found in human food derived from supplemented animals must not exceed the levels in food derived from normal healthy animals fed a nutritionally adequate natural diet.

C. General Procedures

If available information shows a sponsored compound might affect pools of potentially carcinogenic endogenous substances in target animals, and cause an increase in the level of such substances above the level considered to be safe by the criteria of these regulations, the petitioner shall be required to demonstrate whether or not these suspicions are true. The need for, and the depth and breadth of, studies required to demonstrate this effect must be specified on a case-by-case basis.

The procedure required is fourfold: (i) Establishment of normal background levels (or "norm") of the endogenous compound of carcinogenic concern in the target animals; (ii) determination of the effects of the sponsored compound on the norm; (iii) establishment of safe conditions of use of the sponsored compound by demonstrating how the compound can be used in a way that assures that the norm is restored in the target animals before slaughter; and (iv) development and validation of a practical assay to measure the endogenous compound at levels determined to be normal. The regulations specify how each of these steps is to be accomplished.

D. Specific Steps Required

The petitioner shall first be required to determine experimentally the normal background levels, or norms of the potentially carcinogenic endogenous compounds of concern in untreated target animals. A norm must be specific for the target animals and for the intended conditions of animal husbandry, and must include the effects of age, sex, breed, and geographic location. The sponsor shall

01159

provide the norm in the form of a curve of cumulative frequency distribution of untreated target animals over the observed levels of the endogenous compound. The curve shall also include 99 percent confidence bounds (Plate III appearing in § 500.89).

The median and shape of the frequency distribution must be known so that shifts in the norm can be measured. For this reason, the assay used to determine a norm must yield values for the endogenous compound different from zero for at least two-thirds of the untreated target animals. This latter requirement will permit calculation of the median and frequency distribution with a high degree of reliability, while recognizing the practical limits of technology. Morever, because the area of interest is that around the median, the requirement does not compel the petitioner to gather unnecessary data since the values at the lower end of the distribution are irrelevant.

The sponsor shall then determine the effects of the sponsored compound on the norm, and shall provide data on the postexposure decay of any observed increases in the norm. The norm shall be considered restored when the distribution of values for the endogenous substance of concern observed in a group of treated animals is with 99 percent confidence the same as the norm.

The norm, as defined, takes into account those variables that affect background levels. The final regulations thus attempt to respond to those comments suggesting that "normal background levels" would be difficult to define.

E. ENDOGENOUS MARKER RESIDUE; CALCULATION OF R_m

If the norm of an endogenous substance of carcinogenic concern can be increased by the administration of a sponsored compound, the endogenous substance can become an endogenous marker residue, i.e., its presence above certain levels can be considered an indicator of potentially carcinogenic residues in food. Approval of the use of such a sponsored compound shall be contingent upon the petitioner's furnishing data demonstrating that the norms are restored in the target animals before slaughter, and upon the availability of a practical assay that can reliably measure the endogenous marker residue in target animals. Such a regulatory assay must be capable of measuring the marker residue at the level, R_m, corresponding to the 33d percentile of the norm (Plate III set forth in § 500.89).

The R_m for an endogenous marker residue derives from an entirely different conceptual approach to safety than that used for the derivation of an R_m for an exogenous marker residue. To monitor shifts in the norm, the Commissioner must be able to measure the median and to determine the shape of the distribution. An assay capable of measuring the 33d percentile of the norm, and levels above this, provides the required analytical capability. The same assay evaluation criteria apply to endogenous compounds as to other compounds covered by these regulations.

Accordingly, the Commissioner has revised the regulations, which as proposed, would have established the lowest limit of reliable measurement at the 99th percentile of the norm. As the comments noted, an assay that can measure only the upper 99th percentile would not be able to detect many shifts in the norm, which is its primary function. The final regulations require an assay capable of a lowest limit of reliable measurement of the 33d percentile of the norm, which will readily detect any shifts in the median or mean of the norm. Actual monitoring, which is performed by the Animal Plant and Health Inspection Service of the United States Department of Agriculture, may occur at or above the 50th percentile of the norm but such monitoring will detect violative residues and detect significant shifts in the norm.

F. ALTERNATIVE PROCEDURE

Comments contended that an alternative to the foregoing procedure should be available for regulating endogenous substances. It was suggested that a tolerance for an endogenous compound can be established, even at levels above the norm, provided appropriate toxicity testing on the compound is carried out and a safe level can be established in accordance with parts IV through VII of the preamble and §§ 500.84 through 500.90 (21 CFR 500.84 through 500.90). Separate mechanisms with distinctly different rationales have been developed to measure compliance with the no-residue standard of the act for endogenous and exogenous compounds.

As noted earlier, for exogenous compounds the regulations require development of an assay with a minimally acceptable lowest limit of reliable measurement at or below the level needed to assure that any undetected residues pose essentially no increased risk of cancer in the population. Moreover, should a new assay with a lower limit of reliable measurement be developed at a later time that will satisfy the essay evaluation criteria, that assay will be adopted by the Commissioner. On the other hand, the method for measuring compliance with the no-residue standard for an endogenous substance is based on calculation of the norm, a calculation that is independent of and probably unrelated to the lowest limit of an appropriate assay's reliable measurement. The Commissioner concludes that monitoring of changes in the norm is the best available method for regulating the use of compounds that may increase pools of potentially carcinogenic endogenous substances, and rejects the suggestion that a tolerance for such compounds be established. The Commissioner would be receptive to suggestions for alternative mechanisms of control, but until an acceptable alternative is identified, all such compounds will be required to comply with the requirements imposed by §§ 500.89 (c) through (e) and 500.90.

VIII. REGULATORY ASSAY: EVALUATION CRITERIA AND APPROVAL PROCESS

A. INTRODUCTION

The Commissioner can approve a sponsored compound for use in food-producing animals only if the intended use of the compound does not result in the accumulation of potentially carcinogenic residues in edible tissues and if an assay is available that can reliably measure such residues at and above the R_m. The assay must also be suitable for monitoring food from animals administered the compound to prevent food from reaching the marketplace if it is adulterated with potentially carcinogenic residues resulting from misuse of the compound.

Several comments argued that the proposal would discourage the search for better assays, and that this was not in keeping with the intent of the cancer provisions of the act. Further, some comments contended that FDA should only be concerned with the approval of assays that avoid false negative results and that any detected residue should be investigated to determine its identity. Other comments proposed that when more "sensitive" assay methods (i.e., assays with still lower limits of reliable measurement) are developed, the assays should only be used as screening tests and that the required "sensitivity" (or safe level) derived from the statistical analysis of animal carcinogenesis data should be retained for regulatory action. These comments argued that unless new biological information warrants a change in assay "sensitivity," new regulatory assays should not be adopted. Comments stated that the efforts to increase "sensitivity" had to be balanced by the need to assure the practicability of an assay for regulatory use, the desirability of avoiding false negatives, and the importance of reproducibility of results. These comments implied that, given these countervailing concerns, more "sensitive" assay methods should not be adopted because the proposed statistical treatment of carcinogenesis data is sufficiently conservative to protect the public health.

Still other comments suggested that more practical methods should be approved for purposes of screening which would accept a low level of false positives with a high degree of assurance that false negatives would not occur. Confirmatory methods, which would undoubtedly require more time for cleanup of samples and greater instrument specialization, should then be used to provide evidence that can withstand legal scrutiny. Some comments stated that certain reagents and instruments required for an assay may not be readily available because of their unique applicability. They suggested that the regulation be changed to allow sponsors to supply such items when necessary. One comment pointed out that the word "control" in the phrase "well-equipped analytical control laboratory" connotes a highly specialized laboratory which is unlikely to have the necessary instrumentation for residue analysis, and hence urged that it be deleted.

01160

Because the assays required by these regulations are to be used for regulatory monitoring of residues of potential carcinogenic concern in human food, the Commissioner concludes that rigorous criteria must be established for approval of these assays. Furthermore, a proposed assay must be subjected to an objective evaluation to determine if it meets the criteria. Only then can the Commissioner assure that an assay will provide a reliable and practical monitoring device to prevent violative residues in food. Many comments in essence contended that more explicit criteria and evaluation procedures should be specified, and the Commissioner concurs with these comments.

Any assay is characterized by a set of attributes which determine its quality: dependability, practicability, specificity, accuracy, and precision. These regulations specify objective criteria for these attributes. A proposed assay must be shown to meet these criteria during study in a single laboratory and also in interlaboratory study in government regulatory laboratories. The latter requirement is essential, because the assays are to be used in several regulatory laboratories (FDA, USDA, and State laboratories), and the Commissioner must determine in advance that an assay will perform in more than one such laboratory. The regulations specify that the interlaboratory validation study shall be carried out in those laboratories (USDA and FDA) that will be using the method in surveillance and enforcement programs.

The steps in obtaining approval of an asay are: (i) Assay development and study by the petitioner to determine if the assay satisfies the acceptability criteria; (ii) FDA review of the petitioner's study to determine suitability of the assay for evaluation in interlaboratory study; and (iii) interlaboratory validation study, again approval contingent upon satisfaction of acceptability criteria.

B. SOURCES OF DATA TO SUPPORT THE ASSAY

Data from studies of an assay using three types of samples are necessary to support approval. The petitioner must prepare samples of target tissue to which known amounts of marker residue are added ("spiked" tissues), and compare responses obtained from assays using these tissues with responses obtained from assays of target tissues known to be free of marker residues (control tissues). In constructing an analytical curve from these data and determining its 99 percent confidence limits (plot of observed response versus concentration of marker residue), as many samples as possible should be run, preferably by different analysts, for interlaboratory validation of the assay will eventually be required. The variability among different analysts can be determined at the developmental stage and adjustments made before the assay is submitted for FDA review.

A petitioner should also be satisfied that the assay meets all of the evaluation criteria and also that it is consistent with general principles of good analytical practice before submittal for FDA review. Past experience shows that a petitioner's failure to follow good analytical practices during initial assay studies often results in interlaboratory failure even though the initial results may appear satisfactory during a paper review of the assay by FDA. A petitioner should assure that no results enter the construction of an analytical curve when it is known that the results were obtained using other than acceptable principles of analytical practice.

In addition to the spiked tissue tests, a petitioner must also submit data showing the applicability of the proposed assay to target tissues taken from target animals treated with the sponsored compound ("dosed" tissues). To validate the assay, dosed tissue samples are required that contain the marker residue at a level approximating R_m. A standard curve must also be submitted, constructed by taking the marker residue of known purity at different concentrations, determining the response, and plotting the relationship.

C. SUBMISSION OF DATA

Agency resources for reviewing and validating assays are limited. The Commissioner therefore has established a precise format for submitting the data to support acceptance of an assay. It is a well-recognized principle, applied both by the courts and administrative agencies, that a standard format can be required for pleadings, requests for licenses, and other applications. This format may also designate special types of information that must be contained in the submission. Therefore, the agency will refuse to accept a petition or review an assay when the request for approval fails to conform to the format outlined below.

1. *Assay description and petitioner's evaluation.* The petitioner must provide a complete description of the assay to allow FDA to determine whether it is potentially acceptable. Because this threshold determination of acceptability will trigger an extensive interlaboratory validation procedure, the Commissioner concludes that the discussion must be sufficiently rigorous to minimize waste of agency resources. Therefore, the submission must discuss in detail:

(a) What equipment and reagents are necessary;

(b) How the assay is performed; and

(c) How the assay complies with the dependability, practicability, specificity, accuracy, and lowest limit of reliable measurement criteria prescribed in § 500.90(d) (21 CFR 500.90(d)) and discussed under paragraph VIII. E. below in this preamble.

2. *Data.* The data and worksheets, including spectrograms, chromatograms, etc., from the spiked tissue, dosed tissue, and control tissue analyses are also necessary for the preliminary review of the assay to determine whether it actually complies with the evaluation criteria.

D. FDA REVIEW

The Commissioner will conduct a paper review of a petitioner's submission to determine whether an assay complies with the acceptability criteria. These regulations generally alert potential petitioners to the applicable statutory standards and criteria, which should permit a petitioner to assess preliminarily the acceptability of an assay before filing a petition, and thereby reduce the agency's workload.

If on preliminary review an assay appears to comply with the evaluation criteria, it will then be subjected to the interlaboratory assay validation study to determine whether it is indeed a practicable and reliable regulatory tool. Should the initial review establish that the assay fails to meet these criteria, the petition will be denied. A conclusion that an interlaboratory assay validation study should be initiated, however, in no way guarantees that a proposed assay will be eventually approved.

E. ASSAY ATTRIBUTES AND ACCEPTABILITY CRITERIA

An assay must meet the following attributes and criteria:

1. *Dependability.* Dependability is the attribute denoting the likelihood that the proposed assay will yield no result because of uncontrollable features inherent in its design. Almost all assays will, on occasion, fail to yield any result. Often this occurs because of mishandling by the analyst, but sometimes failure may be the result of some aspect of the assay itself that may have been inadequately studied and defined or that cannot be controlled. For example, assays depend upon the availability of a standard against which measurements are compared. If the integrity of the standard depends on certain environmental factors (e.g., purity of the solvent in which it is maintained, temperature, light intensity, etc.) and these factors are understood, it may be possible to prevent assay failure. If this dependence is not known, however, the assay may fail and, depending on the sensitivity of standard integrity to the environmental factor of importance, may fail often. In this example, failure can mean a highly inaccurate result, assuming some fraction of the standard's integrity is retained, or it can mean no result at all, assuming complete loss of integrity.

The Commissioner concludes that assays used to monitor carcinogenic residues in food must be free of such uncontrollable features, and failure of a proposed assay to yield results during the petitioner's assay development studies or interlaboratory validation study can be a cause for refusing to accept the assay and for denying the underlying petition. Accordingly, the regulations require a petitioner to record and furnish all the information on, and provide an explanation of, runs of the developed assay that are begun, but never finished.

2. *Practicability.* The regulation under § 500.90(d)(2) defines the practicability attribute as follows:

01161

The assay shall be considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay must be consistent with regulatory objectives (monitoring, compliance, etc.). All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay must be commercially available except that reference standards may be supplied by the petitioner if they are not commercially available. The Commissioner will withdraw approval of any assay method and initiate regulatory action against the sponsored compound, if the petitioner breaches such a condition of the compound's approval.

An assay must possess no characteristics that may counteract the purpose for which it is developed. Accordingly, the Commissioner has established criteria for practicability in terms that relate specifically to the nature of the laboratories in which the assay will be used (i.e., regulatory laboratories where time and availability of equipment and reagents are critical factors in their ability to perform satisfactorily the mandated functions).

The inability to use an assay at a regulatory laboratory because a needed reagent is not readily available or because excessive time is required to complete the assay presents potential risks to public health and cannot be sanctioned. Obviously, some assays will require some unique items, particularly reference standards. The Commissioner agrees with comments suggesting that as long as a sponsor makes reference standards available to all persons having an interest, the requirements of the regulation will be met. A commitment to supply reference standards when they are not commercially available may be made a condition of the sponsored compound's approval, and failure to supply the government or other laboratories as required is a basis for withdrawing a compound's approval. The Commissioner concludes that an assay is not practical if it is dependent on the use of any other unique equipment or materials that are not commercially available.

3. *Specificity.* The regulations specify that for an assay to be accepted, an observed response must without question be due to the compound being measured and that compound only. It is a fundamental part of the development of an assay to determine whether or not it possesses this important attribute. Among analytical chemists and biochemists, an "assay" that does not demonstrate this attribute is of little value, and indeed, in a regulatory setting, such an assay could be dangerously misleading. For this reason, the Commissioner has established rigorous specifications for this attribute.

In general terms, specificity describes the uniqueness of the relationship between the observed effect (or response) and the applied stimulus (in this case the chemical under analysis). In analytical chemistry and biochemistry, the term specificity is commonly used in reference to the uniqueness of a response resulting from the application of a stimulus having specific characteristics; that is, the term has a qualitative dimension only in that it does not relate to either the quantity of response or stimulus or to the nature of the relationship between response and stimulus. Both of the latter criteria, which might also be considered aspects of specificity, are central to good analytical practice. The regulations consider both the qualitative and quantitative aspects and groups them together under the general attribute of specificity. The Commissioner's objective is to assure that, whatever the observed response, it is uniquely related to the marker residue both qualitatively and quantitatively. The establishment of an analytical curve (not simply a standard curve, but one derived from actual measurements obtained on tissue samples containing known amounts of marker residue at different levels and from control samples) provides the means to determine whether the responses produced by an assay are single-valued, as they must be if an assay is to be considered fully specific. Only assays that yield continuously increasing or decreasing analytical curves will satisfy the criterion of single-valuedness.

Finally, the regulations require that the assay contain a sufficient number of independent measurements utilizing independent physicochemical principles to assure specificity (i.e., the identity of the marker residue must be confirmed). There may be many ways in which specificity can be demonstrated experimentally. A petitioner may use highly sophisticated research tools to demonstrate that a proposed assay is specific in the senses discussed above. However, a regulatory analyst, using an approved assay, must have at his disposal some technique (again capable of meeting other criteria) which can provide assurance that an observed response is due to the marker residue. At present, mass spectroscopy is probably an ideal choice for acquiring the requisite specificity, although there are other possibilities. Some determinations (e.g., those requiring enzymes) may have an inherent high specificity, but others have low specificity (e.g., gas, thin-layer, and liquid chromatography) and require other, independent, types of measurements to achieve the requisite confirmation of identity. By adopting this definition of specificity, the Commissioner concludes that all concerns expressed in the comments over "false positives" or "false negatives" are moot.

4. *Accuracy.* Assays yield measurements of concentration that are in some proportion to the true concentration of the compound being measured. The accuracy of an assay is expressed as a percent of the compound's true concentration. The regulations prescribe a specific accuracy criterion: The averages of the observed responses must fall within 60 to 110 percent of the true value. The criterion is consonant with current, good analytical practice and is based on agency experience with methods that are routinely used for trace analysis.

5. *Lowest limit of reliable measurement* (L_m). To be accepted for regulatory purposes, an assay must be able to distinguish, with a very high degree of certainty, target tissues that contain levels of the marker residue at or above R_m from target tissues that do not. This distinction must be reproducible and capable of supporting legal action when violative residues of the sponsored compound occur.

To provide the necessary degree of discrimination, the regulations require that the assay be capable of producing a response when the marker residue is present in target tissue at or above R_m that is, with 99 percent confidence, different from the response in nontreated (control) target tissue (i.e., the difference between the responses of control target tissue and target tissue containing the marker residue in target tissues at or above R_m is, with 99 percent confidence, greater than zero). The actual lowest limit of reliable measurement, L_m, will be determined by reference to the analytical curve of the proposed assay. If the determined lowest limit of reliable measurement, L_m, of the proposed assay is at or below the R_m as determined in accordance with paragraph VI.B.3. or paragraph VII.E. of this preamble, this criterion shall be considered satisfied. This procedure tests the critical factor of assay precision. Thus, an assay that satisfies this criterion will provide a reliable regulatory tool to enable the Commissioner to discriminate safe from unsafe food.

An assay that satisfies this criterion will often have a high signal-noise ratio, although this ratio may be a function of the fluctuations in the equipment used to conduct the assay. The mechanism established by the regulations is geared to the assay's variability; if the assay yields readily reproducible results, the importance of determining the signal-noise ratio is diminished. Every regulation has a zone of ambiguity, however, and the Commissioner believes that it is not now appropriate to define more precisely this requirement for an assay's approvability. In such instances, the professional judgment of the reviewing scientist will come in to play within prescribed limits. Sophisticated methods of statistically analyzing the results of assays offer the promise of more refined standards for this criterion that will take into account assay variation and yet yield the high degree of confidence in assay results, e.g., regression analysis of the spiked tissue, dosed tissue, and tissue blank results. The agency, in conjunction with the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (APHIS), will be developing in guidelines for further refining this criterion and may subsequently propose amendment of the regulations to prescribe precise standards for evaluating assay accuracy.

The Commissioner recognizes that the term "method sensitivity" is widely used to describe the lowest level of a compound under analysis which can be detected as measured with an analytical assay. Indeed, the original proposal used this term to describe what in the final order has been termed "the lowest limit of reliable measurement." However, there is some confusion surrounding the term "sensitivity," which derives in part from the fact that the term has been

01162

used in two senses: (1) As the lowest level of a compound which can be detected by an assay; and (2) as the lowest level of a compound which can be measured reliably by an assay. In fact, the correct meaning of the term "method sensitivity" is unrelated to a particular level of compound concentration, but rather relates to the ratio of change in instrument response to the change in compound concentration. The term "sensitivity" has therefore been dropped from the final regulations. The Commissioner has adopted the term "lowest level of reliable measurement" because that term more precisely describes the attribute.

In response to comments urging that any "detected residue" should be subject to regulatory control, the Commissioner points out that it is an inherent characteristic of almost all analytical methods that compounds can sometimes be detected at levels below the levels at which they can be reliably measured. More precisely, detection of a compound simply means that there is some instrument response above background levels which could be the compound of interest, but this response cannot be considered as a reliable measurement of the compound. Since protection of public health is the issue, the Commissioner must be in a position to document conclusions based on analytical data, often in a court of law. A major aim of these regulations is to assure that assays used to obtain such data can reliably measure residues. Hence, the Commissioner concludes that the discriminant for samples containing potentially violative exogenous marker residues shall be the lowest limit of reliable measurement, L_m, of the approved assay. Moreover, by imposing these criteria at the preapproval stage, the Commissioner will provide an added measure of public health protection by barring potentially unsafe compounds from the market place.

F. INTERLABORATORY VALIDATION OF ASSAY.

Although FDA will review the assays for each sponsored compound, the actual regulatory field screening of foods of animal origin will be primarily performed by APHIS, pursuant to the Meat and Poultry Products Inspection Acts, and by the States pursuant to the Public Health Service Act. The Food and Drug Administration performs a complementary regualtory function: followup analytical and field investigations of violative residues to assemble evidence for use in regulatory actions.

The initial paper review by FDA of material in a petition permits the agency to make a threshold determination of the acceptability of an assay. Adequate protection of the public health, however, requires assurance that these assays will function in the Government's regulatory laboratories. Therefore, these regulations also prescribe the procedure that will be used to assure that an assay is appropriate for use as a regulatory tool by Government laboratories.

The Commissioner will require that three Government laboratories (two FDA facilities and one USDA facility) independently validate an assay before he can determine that use of a sponsored compound can be approved. The delicate nature of the assays, their importance in assuring that no residues of carcinogenic concern will occur in food of animal origin, and the practical limitations on the Government's capacity to monitor food production and distribution make this requirement mandatory. These three laboratories must study an assay sufficiently to assure that the conclusions about its acceptability drawn by the petitioner in his submission are correct and that all criteria are met.

G. CONCLUSION

If an assay complies with the criteria described above and prescribed by the final regulations, and compliance can be verified under actual conditions of regulatory use, the Commissioner will approve the assay. A full description of the approved assay will be published in the FEDERAL REGISTER upon approval of the petition, in accordance with the provisos to the anticancer clauses and section 512(i) of the act.

IX. WITHDRAWAL PERIODS

A. INTRODUCTION

The regulations define the withdrawal period for a sponsored compound as the time required, after cessation of target animal exposure to the sponsored compound, for the marker residue to deplete to L_m in the target tissue. The withdrawal period must also be compatible with actual conditions of livestock management and reasonably certain to be followed in practice. Because of the way in which the regulations define marker residue, target tissue, and L_m, the use of a sponsored compound in accordance with the prescribed withdrawal period will assure that no carcinogenic residues of such compound will be present in human food derived from treated animals. At any point after cessation of exposure but prior to the determined withdrawal period, treated animal tissues must be considered as containing residues of carcinogenic concern. Thus, the withdrawal period specifies the length of time after the last treatment with a sponsored compound in which animals shall not be slaughtered for food and during which milk shall be discarded.

Several comments addressed the procedures for establishing posttreatment withdrawal periods. Some contended that the requirement for tissue equilibration with residues in the experimental procedure for establishing withdrawal times was inappropriate for therapeutic drugs. Other comments suggested that the withdrawal periods be established to assure the absence of residues from edible tissues only, since they are the ones destined for human consumption. Finally, some comments expressed concern about the practicality of applying confidence-interval techniques to establishing withdrawal periods, especially when dealing with large animals.

B. DATA TO SUPPORT WITHDRAWAL PERIODS

The depletion studies required by the regulations to establish withdrawal periods must take into account the biological variability among animals and other variables that may influence depletion times.

Residue depletion studies must be conducted under conditions of the sponsored compound's maximum proposed use. If a petitioner can demonstrate target tissue equilibration with the marker residue, however, a shorter period of administration of the maximum dose can be permitted. The conditions of the study must also simulate actual use practice. That a compound is intended for a therapeutic use is irrelevant, because the function of this study is to determine the safe withdrawal period, regardless of the compound's intended mode of use. The proposed regulatory assay must be used to measure the marker residue in the target tissue, including milk and eggs where appropriate, because it is this assay that will be used for regulatory monitoring.

All raw data and evaluations must be submitted with the petition along with a graphical presentation of the tissue depletion curve (concentration of marker residue in target tissue versus time).

The analysis of the data must include the estimated depletion curve, which in most instances can be adequately approximated by a first order decay process. The upper 99 percent confidence bound will be determined for the samples from individual target animals and the time of intersection of this upper 99 percent confidence bound with the L_m value will be determined. The withdrawal period is the interval of time between the last administration of the compound and the time of intersection of the upper 99 percent confidence bound on the observations and the L_m of the approved regulatory assay, plus an additional interval determined by rounding out this time interval to provide a practical withdrawal period compatible with animal management practices.

For example, if the time of intersection of the upper 99 percent confidence bound on the individual tissue determinations and the L_m for the marker residue is 39 hours, the withdrawal period (preslaughter interval) would be established as 2 days. In the case of milk samples, if the time of intersection were 63 hours, a withdrawal time of 72 hours (discard of 6 milkings) would be established.

The use of a compound could not be approved if the necessary withdrawal period exceeds a period that is compatible with animal management practices. For example, the use of a compound in lactating animals will not be approved if the required withdrawal time for milk exceeds 96 hours (4 days) because the economics of milk production make observance of such discard times unlikely, or at least not reasonably certain, to be followed in practice.

When the marker residue is an endogenous compound, the withdrawal period is the time after cessation of ad-

01163

ministration of the sponsored compound required for the norm to be restored, with 99 percent assurance, extended if necessary to be compatible with conditions of livestock management. The validated regulatory assay must be used to collect this information.

C. RATIONALE FOR USING THE CONFIDENCE BOUND APPROACH

To establish that carcinogenic residues are absent from edible tissues of food-producing animals treated with the sponsored compound, the Commissioner must have information about the rate of residue depletion and the inherent metabolic variabilities among individual target animals, Confidence bounds on experimental data are the only means to allow prediction, with a given degree of confidence, of what will occur in the total target animal population. The Commissioner has prescribed 99 percent confidence bounds throughout these regulations as the degree of confidence necessary to assure protection of public health.

X. WAIVER OF REQUIREMENTS

The regulations permit the Commissioner, in response to a petitioner's request or on his own initiative, to waive, in whole or in part, any of the foregoing requirements for the scientific evaluation of sponsored compounds that have the potential to contaminate human food with residues whose consumption could engender a human risk of carcinogenesis. When an agency particularizes a statutory standard of conduct by regulation, due process requires that it permit affected parties to demonstrate how their alternative mechanism satisfies the statutory standard, and why the regulation should then be waived in the public interest. "Weinberger v. Hynson, Westcott, and Dunning, Inc.," 412 U.S. 609, 620 (1973). Moreover, it has been long settled that an agency may adopt a rule shown to be appropriate for the generality of instances and leave the correction of injustices to applications by those concerned. "National Nutritional Foods Ass'n v. Food and Drug Administration," 504 F.2d 761, 784 (2d Cir. 1974). For these reasons, the Commissioner has expressly included the waiver provision. The Commissioner advises, however, that a waiver will be granted only in exceptional circumstances, and, as the regulation provides, the basis for any waiver must be extensively documented.

XI. IMPLEMENTATION

The proposal would have applied the requirements of the regulations to all new approvals (basic or supplemental) filed or approved after the effective date of the regulations. Prior approvals were to be dealt with on a class-by-class basis, beginning with known carcinogens, suspect carcinogens, and continuing through all compounds previously approved on the basis of zero tolerance. These were to be reviewed as part of the agency's general safety review for previously approved new animal drugs.

The final regulations apply to all new animal drug applications, feed additive petitions, and appropriate color additive petitions, including appropriate supplemental applications, submitted subsequent to the effective date of the regulations. In addition, the requirements of the regulations shall apply to all pending petitions and applications unless the Commissioner determines that compliance with the anticancer provisions of the act can be adequately assured by requiring completion of one or more of the required studies subsequent to approval. The criteria set forth in the regulations are based on generally recognized scientific principles for testing and evaluating chemical compounds for potential carcinogenesis requirements that Congress contemplated FDA would adhere to when it enacted the Food Additives Amendment of 1958 and the Animal Drug Amendments of 1968 (21 U.S.C. 348 (b) and (c) and 360b (b) and (d)).

The Food and Drug Administration has already applied these standards to compounds currently being evaluated for approval or subject to proposals to withdraw approval (e.g. diethylstilbestrol published in the FEDERAL REGISTER of November 2, 1976 (41 FR 52105) and the nitrofurans published in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906) and August 17, 1976 (41 FR 34884)). Accordingly, all previously approved applications for compounds subject to the anticancer clauses will be reviewed as part of the general review of the safety of marketed animal drugs. When the agency finds deficiencies in the data supporting a prior approval, it will issue either a FEDERAL REGISTER notice or a letter pursuant to section 512(l)(1) of the act establishing the time within which the provisions of these regulations must be satisfied. For notices previously published or letters previously issued, the criteria of these regulations will be used to determine whether the data supporting applications are acceptable. The Commissioner will, however, immediately proceed to withdraw approval of applications on the basis of information indicating that a health hazard exists or that no studies necessary to bring a sponsored compound into compliance with the regulation have been conducted.

ADDITIONAL TIME FOR COMMENT

These final regulations largely reflect not only the proposal published in July 1973, but the current FDA practice in reviewing sponsored compounds. Comments on the proposal and petitions filed during the intervening 3 years have raised most of the issues discussed in this preamble and resolved in the final regulations. In the main, therefore, the regulations embody no new decisions. The DES proviso to the anticancer clauses is self-executing, and FDA has therefore been obligated to deal with the issues posed by carcinogenic compounds proposed for use in food-producing animals in the absense of regulations. Accordingly, the Commissioner concludes that these regulations shall become effective March 23, 1977.

Nevertheless, the Commissioner recognizes that it has been over 3 years since these regulations were proposed and that the final regulations resolve some issues not specifically dealt with in the proposal but raised by the comments. For these reasons, the Commissioner is providing an additional 60 days for any interested person to submit further comments on these specific issues. The Commissioner will evaluate any additional comments and will later publish any revisions to the final regulations, if appropriate.

The Commissioner urges that any comments submitted within this additional period address only new issues, and not reopen matters raised by the initial proposal and discussed in this preamble. The Commissioner is particularly interested in receiving comments on four specific areas of the regulations. First, he invites further discussion of the acceptable level of risk for use in the modified Mantel-Bryan calculation. At the present time, FDA is involved in administrative adjudications concerning potentially carcinogenic animal drugs. These proceedings may assemble additional evidence on the acceptable level of risk. Because this issue is important to application of the regulations, the Commissioner believes additional comment will contribute to public understanding. This action will in no way jeopardize the public health, for the administrative record adequately supports the current level of risk; the Commissioner is interested in comments on whether the level of risk should be further reduced.

Second, the Commissioner will entertain comments on the concept of comparative metabolism. This unique approach was developed in response to the diverse comments on the issue of which metabolites of a sponsored compound, if any, should be tested. An analogous procedure of the Environmental Protection Agency has received judicial approval. "Environmental Defense Fund, Inc., et al., v. Environmental Protection Agency," No. 75-2259, (D.C. Cir., November 10, 1976), slip op. at 14. The Commissioner welcomes suggestions for alternatives to this approach.

Third, as previously noted, the Commissioner invited suggestions for alternative mechanisms for dealing with endogenous compounds. Several comments on the proposal urged that an alternative procedure for evaluation of such compounds should be available, but failed to suggest any feasible approaches.

Finally, the Commissioner welcomes suggestions of refined mechanisms for statistically differentiating target tissue containing the market residue from blank target tissue.

The Commissioner concludes that all of the provisions of the final regulations should be implemented pending reconsideration of any specific provisions based upon additional comments. This will work no hardship since all provisions of the regulations are supported by the record, and, except for the level of risk, the only changes the Commissioner contemplates concern alternative methods of satisfying the statutory requirements.

The Commissioner has carefully considered the environmental effects of the regulations and, because this action will not significantly affect the quality of the

01164

human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

This final order was proposed prior to Executive Order 11821, requiring agencies in the executive branch to review regulatory and legislative proposals they initiate for inflation impact, and so does not require inflation impact review.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sections 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046–1048 as amended, 1055, 72 Stat. 1785–1788 as amended, 74 Stat. 399–403, 82 Stat. 343–351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 8—COLOR ADDITIVES

1. In Part 8, by amending § 8.36 by adding new paragraph (c) to read as follows:

§ 8.36 Application of the cancer clause of section 706 of the act.

* * * * *

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals that are raised for food production must satisfy the requirements imposed by subpart E of Part 500 of this chapter.

PART 500—GENERAL

2. In Part 500, by adding a new Subpart E, consisting of §§ 500.80 through 500.98, to read as follows:

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

Secs.

AUTHORITY: Secs. 402, 408, 409, 512, 701(a), 706, 52 Stat. 1046–1048 as amended, 1055, 72 Stat. 1785–1788 as amended, 74 Stat. 399–403, 82 Stat. 343–351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

§ 500.80 Chemical compounds used in food-producing animals; procedures and criteria for determining the acceptability of assay methods for carcinogenic residues in edible products of such animals.

(a) *Purpose and applicability of this subpart.* (1) The act requires that compounds intended for use in food-producing animals shall be safe and that food produced from animals exposed to such compounds be safe for human consumption, and prohibits the use of any compound found to induce cancer when ingested by man or animal in food-producing animals unless it can be determined by methods of examination prescribed or approved by the Commissioner that no residue of such compound will be found in the food produced from such animals under conditions of use reasonably certain to be followed in practice. Petitions for the approval of the use of a compound in food-producing animals shall include adequate data for establishing the absence of residues of carcinogenic compounds in the food produced from such animals.

(2) The provisions of this subpart establish the following: (i) The lowest limit of reliable measurement for the regulatory assay required for carcinogenic residues by sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) and sections 409(b)(2)(D), 512(b)(7) and 706(b)(5)(A)(iv) of the act;

(ii) The procedures and criteria for evaluation and approving such assays; and

(iii) The procedures and criteria for establishing the premarketing withdrawal period for use of compounds likely to produce such residues.

(3) This subpart shall apply specifically to compounds intended for use in food-producing animals and their feed that have the potential to contaminate human food with residues whose consumption could engender a human risk of carcinogenesis. The determination of this potential shall be based on considerations of chemical, biochemical, physiological, and toxicological data derived from the scientific literature and from other sources available to the sponsor or to the Commissioner and on the proposed patterns of compound use. The subpart establishes a sequential process for the collection of other chemical, biochemical, physiological, and toxicological data pertinent to the safety of the proposed use of the sponsored compound. This subpart shall not apply to essential nutrients.

(b) *General approach.* (1) When the Commissioner determine that a sponsored compound has the potential to contaminate food from food-producing animals with residues (the sponsored compound, metabolites, conversion products, or any other substances formed in or on food because of the compound's use) whose consumption may engender a human risk of carcinogenesis, the following procedure for data collection and evaluation shall become applicable:

(i) A metabolic study in the animals in which the sponsored compound is intended for use (target animals) designed to identify metabolites of concern;

(ii) A metabolic study of the sponsored compound in experimental animals designed to aid in assessing the carcinogenicity of residues that cannot practicably be tested individually (intractable residues);

(iii) Chronic testing in test animals to assess the carcinogenic potential of residues of the sponsored compound and to furnish data suitable for statistical treatment by the procedure of Mantel and Bryan, (Mantel, N., and W. R. Bryan, "'Safety' Testing of Carcinogenic Agents," "Journal of the National Cancer Institute," 27(2):455–470 (1971)) as modified by Mantel et al. (Mantel, N., et al., "Improved Mantel-Bryan Procedure for 'Safety' Testing of Carcinogens," "Cancer Research," 35:865–872 (1975)) [1] and by this subpart, to permit the no-residue requirement of the act to be operationally defined for purposes of establishing a lowest limit of reliable measurement for an assay to measure residues of the sponsored compound;

(iv) A detailed metabolic study of the sponsored compound in target animals designed to identify a specific residue and tissue to serve as indicators (marker residue and target tissue) to determine whether the no-residue requirement of the act is satisfied;

(v) Development of a regulatory assay to measure the marker residue in the target tissue at and above the level operationally defined as satisfying the no-residue requirement of the act; and

(vi) Establishment of the premarketing withdrawal period required for the safe use of the sponsored compound.

(2) If, at any point in the sequential process of data collection set forth in paragraph (b)(1) of this section, the evaluation of the data satisfies the Commissioner that no human risk of carcinogenesis attaches to the proposed use of the sponsored compound, the compound shall be considered for approval under the general safety provisions of the act.

§ 500.84 Metabolic study in target animals to identify residues for chronic testing.

(a) A metabolic study, described in paragraph (b) of this section, shall be conducted in target animals to provide data on the physicochemical characteristics of residues, their relative proportions, their distribution among the various edible tissues (which include milk or eggs when applicable), and their retention and depletion by the animals.

(b) The target animal metabolic study shall satisfy the following minimum requirements:

(1) The metabolic study shall be conducted in target animals with the spon-

[1] Copies may be obtained from: Associate Director for Scientific Evaluation (HFV-100), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

01165

sored compound bearing appropriate radiolabels, unless other expermental methods permit equivalent measurement of residues. Such labels must assure that residues containing structural moieties of potential carcinogenic concern can be detected and measured in edible tissues at levels as low as the best available technology will permit. Hypotheses about the sponsored compound's projected metabolic pathways may be used as a guide to experimentation, but shall not be a substitute for actual experimentation.

(2) The dosing regimen shall be consistent with the maximum proposed use level and proposed duration of exposure to the sponsored compound. For a compound that is proposed for continuous or repeated use in target animals, administration for the metabolic study need continue only until residue equilibration or tissue saturation has been demonstrated.

(3) The metabolic study shall be designed to yield the following information:

(i) The concentrations and total number of residues detected in edible tissues of target animals immediately following cessation of exposure;

(ii) Except when the Commissioner specifies otherwise, the concentrations and total number of residues detected in edible tissues of target animals when the total residue burden has depleted for at least three half-lives; and

(iii) The physicochemical properties of the detected residues to identify compounds of potential carcinogenic concern.

(4) The results of the metabolic study shall be submitted in the form of a detailed report conforming to the standards required of scientific manuscripts submitted for publication in the journals of professional scientific societies such as the American Chemical Society and the American Society of Biological Chemists. In addition, all raw data shall accompany and be referenced in the report.

(c) If the Commissioner determines that a sponsored compound has potential to contaminate food with residues whose consumption engenders human risk of carcinogenesis, the petitioner shall be required to determine the carcinogenic potency of the sponsored compound and any of its residues that might be of public health concern because of chemical structure or persistence and concentration in edible tissues. Ordinarily, chronic testing of the sponsored compound and selected residues in experimental animals shall be the preferred means of assessing carcinogenic potency. (Section 500.85 describes an alternative means of assessing the carcinogenic potency of residues whose isolation or synthesis in sufficient quantities for chronic testing proves to be beyond the practical limits of current chemical technology (intractable residues) by establishing additional criteria for selecting test animal species/strains used to conduct chronic toxicity testing of the sponsored compound.)

§ 500.85 Criteria for test animal selection; comparative metabolic studies to aid in assessing the carcinogenicity of residues that cannot practicably be tested individually (intractable residues).

(a) The primary criterion for the selection of species or strains of test animals for chronic testing of the sponsored compound and any metabolites selected in accordance with § 500.84 shall be the suitability of the species or strain as a model for man.

(b) If one or more intractable residues are also selected for chronic testing based upon the metabolic study in the target animal, a secondary criterion for the selection of species or strains of animals for the testing of the sponsored compound shall be employed. Metabolic studies of the sponsored compound in the test animal species or strains deemed suitable for chronic testing by the primary criterion shall be conducted to determine if the intractable residues present in the tissues of target animals are also produced in the test animals. Chronic testing of the sponsored compound in a species or strain of test animals in which the residues produced are similar to the complement of residues in the tissues of the target animals shall be considered an appropriate method of assessing the carcinogenic potency of the intractable residues.

§ 500.87 Chronic testing.

(a) Chronic toxicity tests shall be conducted to assess the carcinogenic potential of the residues of the sponsored compound.

(1) The sponsored compound and any residues selected for chronic toxicity testing shall be subjected to oral, lifetime, dose-response studies in the test animal species or strains selected in accordance with § 500.85. Each of these studies must be designed to determine whether the test compound is carcinogenic. Protocols for these studies should be submitted to the Commissioner for review prior to commencing testing.

(2) The Commissioner will determine whether any of the compounds tested is carcinogenic on the basis of the results of these chronic toxicity studies and other available information. If this evidence is equivocal, the compound shall be classed as a carcinogen until further testing resolves any remaining questions regarding carcinogenicity.

(b) When the Commissioner determines that a sponsored compound has the potential to increase the normal levels (pools) of carcinogenic and potentially carcinogenic substances endogenous to the target animals, the petitioner shall meet the requirements of § 500.89 (c), (d) and (e).

(c) For each tested compound classed as a carcinogen, the appropriate data from the chronic dose-response studies shall be analyzed according to procedures described by Mantel and Bryan (Mantel, N., and W. R. Bryan, " 'Safety' Testing of Carcinogenic Agents," "Journal of the National Cancer Institute," 27(2):455–470 (1961)) and Mantel et al. (Mantel, N., et al., "Improved Mantel-Bryan Procedure for 'Safety' Testing of Carcinogens," "Cancer Research," 35:865–872 (1975)) [2]; subject to the modifications and restrictions set forth in paragraph (c)(1) through (9) of this section. The purpose of this analysis shall be to define the no-residue requirement of the act as it applies to the total residue of carcinogenic concern of the sponsored compound and thereby to determine the lowest level of reliable measurement that shall be required for a regulatory assay to be approved for the measurement of such residues.

(1) The administered dose of each test compound shall be expressed as a fraction of the total diet fed the test animal species/strains, e.g., parts per million, parts per billion, etc.

(2) The "safe" level of Mantel and Bryan, calculated for each test compound in accordance with this section, shall be expressed as a fraction of the total diet fed the test animal species/strains. It shall be calculated with 99 percent confidence for a maximum lifetime risk that is essentially zero but never expected to exceed 1 in 1 million.

(3) A slope of one probit per unit log dose shall be used for extrapolation to the "safe" level unless the experimental data indicate that a shallower slope is required to maintain the conservatism of the procedure.

(4) Data obtained from more than one dose level fed to groups of experimental animals of the same strain shall be combined as described by Mantel et al. (Mantel, N., et al., "Improved Mantel-Bryan Procedure for 'Safety' Testing of Carcinogen," "Cancer Research", 35:865–872 (1975)),[2] and subject to the restrictions specified by these authors.

(5) Pooling data from various chronic tests using different animal sexes, species, or strains shall be permitted if it can be demonstrated that the protocols are of compatible design. If statistically significant biological differences in tumorigenic responses are observed between sexes or among species or strains of experimental animals, only subsets of data representing statistically and biologically compatible bioassays may be combined for analysis.

(6) All tumors (benign and/or malignant) shall be considered in the analysis.

(7) The number of animals at risk may be adjusted for competing risks unrelated to the compound-induced carcinogenesis only when the data clearly support such an adjustment.

(8) When only the sponsored compound is subjected to chronic testing, the calculated "safe" level shall be designated at S_a. When more than one compound is subjected to chronic testing, the

01166

lowest of all calculated "safe" levels shall be designated S_s. S_s shall be expressed as the fraction of the diet fed the test animals (e.g., parts per million, parts per billion, etc.).

(9) The no-residue requirement of the the act shall be considered satisfied when conditions and use of the compound, including any required withdrawal period, can be prescribed to assure that the sum of the levels of all potential residues of carcinogenic concern will not exceed S_s in the total diet of man and a regulatory assay is available that is capable of reliably measuring such residues at and above that level. All residues of the sponsored compound shall be classed as carcinogenic except those that have been unequivocally shown to be noncarcinogenic.

(d) The S_s value represents the sum of all residues of carcinogenic concern that must not be exceeded in the total diet of man. For individual edible tissues, the value that must not be exceeded shall be designated S_m and calculated according to the following formula:

$$S_m = \frac{S_s}{T}$$

NOTE.—T is the fraction of the total daily diet of man represented by an individual edible tissue.

(1) The principal S_m calculations are as follows:

Edible tissue	T	S_m
Muscle	1/3	$3S_s$
Milk	1	S_s
Eggs	1/3	$3S_s$

(2) Calculation of S_m for tissues consumed less frequently than muscle may take into consideration the frequency of consumption of such tissues if it can be clearly shown that S_s will not be exceeded in the total human diet.

§ 500.89 Metabolic study to identify the marker residue and target tissue.

(a) The petitioner shall conduct a study of the metabolic fate of the sponsored compound in target animals adequate to provide the data necessary for the selection of a marker residue in target tissue.

(1) The target tissue is that tissue in which measurement of the total residue burden of carcinogenic concern is a reliable measure of the total residue burden of carcinogenic concern in all edible tissues.

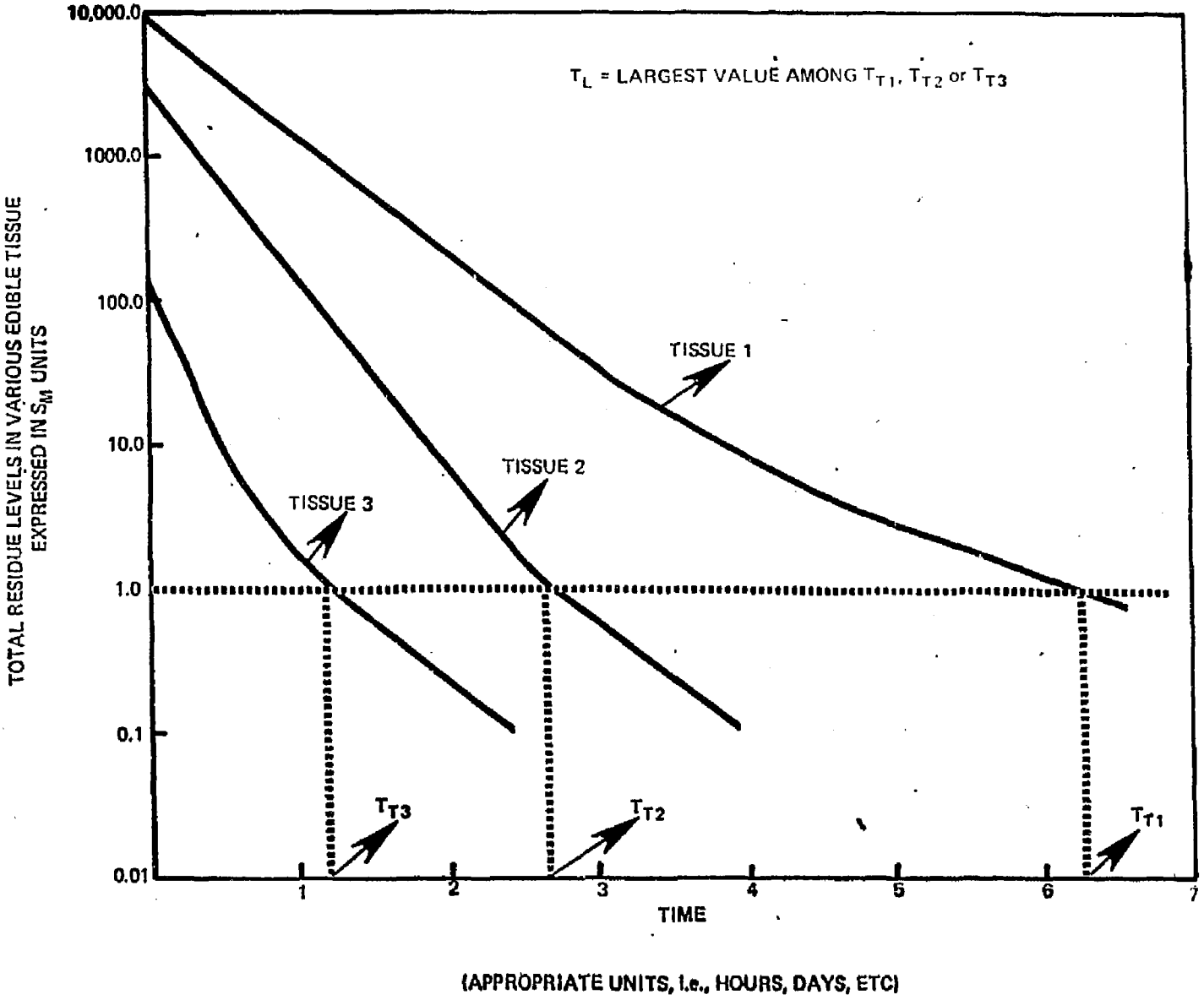
(2) The marker residue for the sponsored compound shall be that residue (the sponsored compound, any metabolite, or more than one of these) whose level in the target tissue is a reliable measure of the total burden of all residues of carcinogenic concern in all edible tissues.

(b) The metabolic study to establish the marker residue and target tissue shall comply with the requirements set forth in § 500.84(b) (2) and (4), with the following additional specifications:

(1) For each edible tissue, the depletion profile of the total residue of carcinogenic concern shall be constructed and shall include measurements of levels at least as low as the S_m appropriate to the tissue under study, set forth in Plate I as follows:

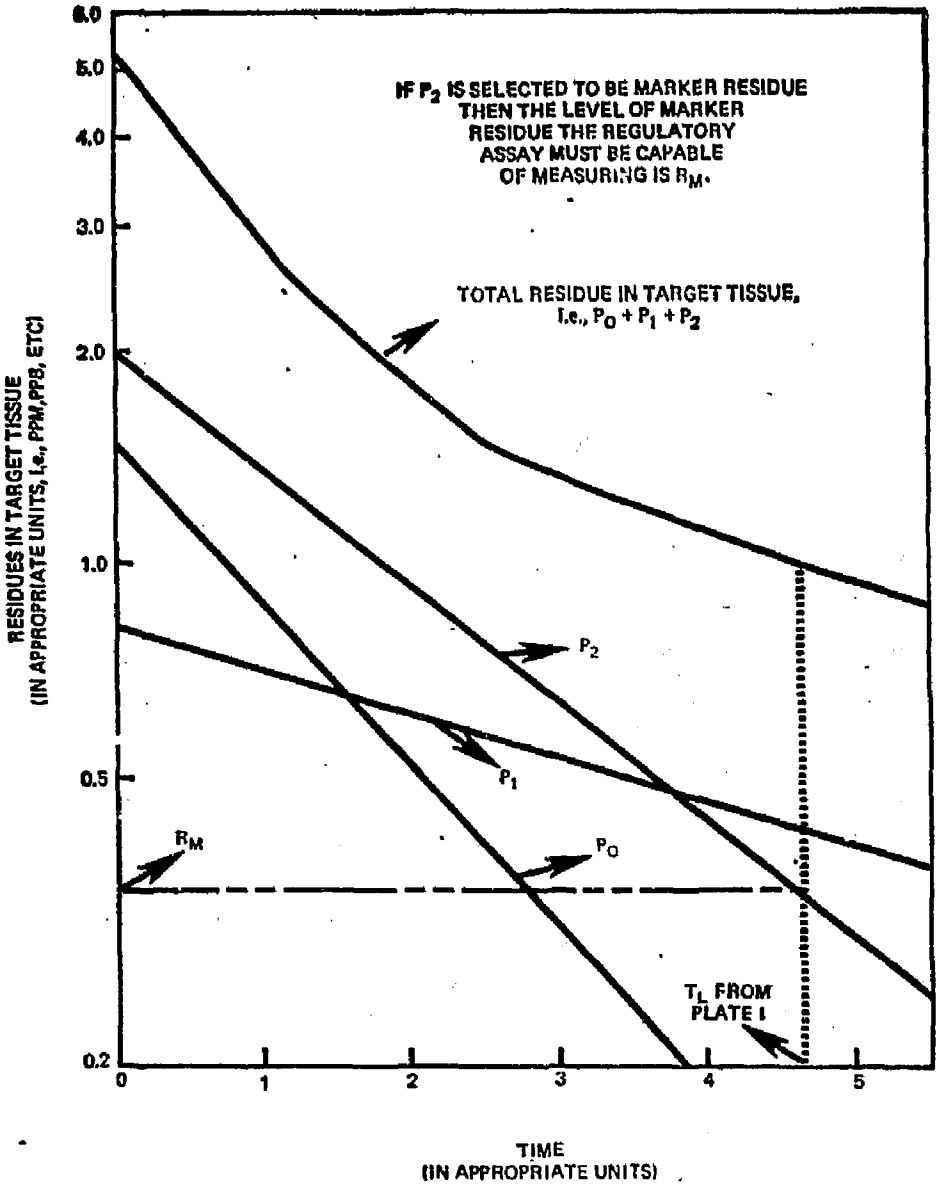
01167

PLATE I. RESIDUE DEPLETION CURVES TO BE USED IN THE DETERMINATION OF MARKER RESIDUE AND TARGET TISSUE.



(2) Depletion profiles for one or more potential marker residues shall be constructed as set forth in Plate II in this paragraph, and shall include measurements of levels corresponding to the time when the total residue level has reached S_m in the edible tissue requiring the longest time to deplete to S_m (T_L of Plate I in paragraph (b) (1) of this section).

PLATE II. SELECTION OF MARKER RESIDUE AND ITS LEVEL R_M THAT MUST BE MEASURED BY THE REGULATORY ASSAY.



(3) If these specifications have been met by the metabolic study required by § 500.84(b), a second metabolic study need not be performed to satisfy this section.

(4) From these data, the Commissioner will select a marker residue and target tissue, and he will also designate the required level of marker residue, R_m (set forth in Plate II in paragraph (b)(2) of this section), that regulatory assays must be capable of measuring in the target tissue. The selection of R_m shall be such that the absence of the marker residue in target tissue above R_m can be taken as confirmation that the total residue burden of carcinogenic concern does not exceed S_m in each of the various edible tissues and therefore that the total burden of carcinogenic concern in the human diet does not exceed S_0.

(c) When the Commissioner determines on the basis of available scientific information that a sponsored compound has the potential to increase the normal levels (pools) of potentially carcinogenic substances endogenous to target animals, the petitioner shall provide the following additional data:

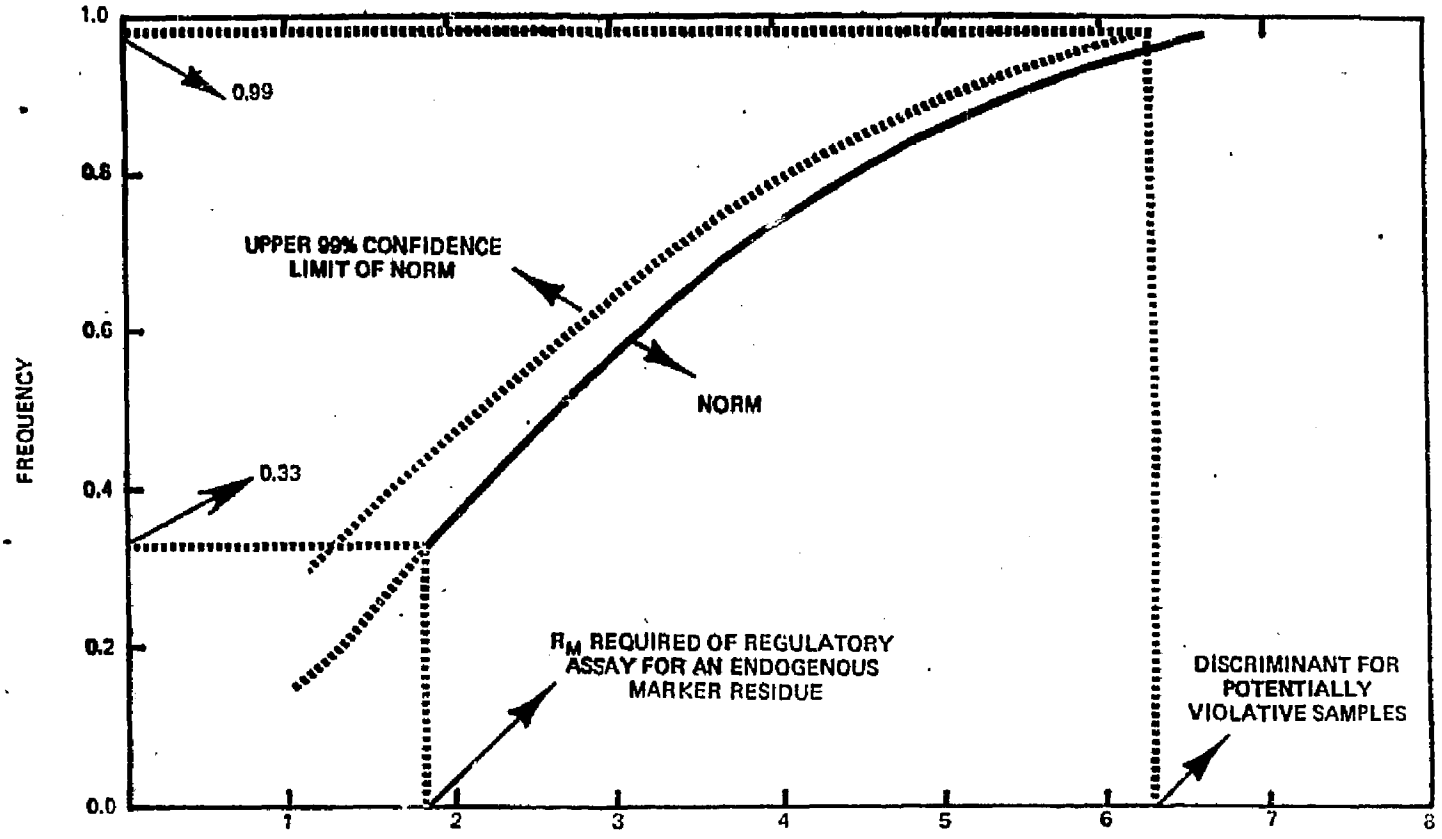
(1) An experimental determination of the background levels (norm) of each of the potentially carcinogenic endogenous substances of concern in untreated target animals.

(i) The norm shall be specific for the target animals and the intended conditions of animal husbandry, and shall be determined from studies designed to take into account differences due to factors such as breed, age, sex, state of estrus, and geographic location.

(ii) Each norm shall be submitted in the form of a graph of the cumulative frequency distribution versus the observed naturally occurring levels, including the 99 percent confidence bounds, set forth in Plate III as follows:

01169

PLATE III. SAMPLE OF A NORM



(iii) An assay shall be acceptable for the determination of a norm only if it yields values for the endogenous compound of interest greater than zero in at least two-thirds of the untreated target animals.

(2) Studies to measure the effect of the sponsored compound on the norm and the postexposure decay of any increase in the norm caused by administration of the sponsored compound.

(3) All data from these studies submitted in accordance with the requirements established in paragraph § 500.84(b)(4).

(d) For a potentially carcinogenic endogenous compound whose norm is increased by the administration of a sponsored compound, the no-residue requirement of the act shall be considered satisfied when the norm is restored.

(1) The norm shall be considered restored when the distribution of values for the endogenous substance of concern observed in a group of treated animals is with 99 percent confidence the same as the norm.

(2) The marker residue for a sponsored compound that affects a potentially carcinogenic endogenous substance shall be the affected endogenous substance.

(3) When the norm of more than one potentially carcinogenic endogenous compound is increased by administration of the sponsored compound, the marker residue for all endogenous compounds of concern shall be that endogenous compound whose norm requires the longest time for restoration.

(e) For an endogenous compound selected to be a marker residue, the required level of measurement, R_m, for the regulatory assay shall be the level of that endogenous compound corresponding to the 33d percentile of the norm, set forth in Plate III in paragraph (c)(1)(ii) of this section.

§ 500.90 Evaluation and approval of a regulatory assay.

(a) Before a petition can be considered for approval, the petitioner shall submit for evaluation and validation a regulatory assay developed to monitor compliance with no-residue requirement of the act. The regulatory assay shall reliably measure the marker residue in the target tissue at levels at least equal to and above R_m, as defined in § 500.89 (b) and (e). The criteria and procedures in paragraphs (b) through (g) of this section shall apply to the evaluation and approval of assays.

(b) The regulatory assay shall be evaluated and validated using data collected from three types of samples:

(1) Samples containing various known concentrations of marker residue added to the target tissue, i.e., "spiked" tissue samples.

(2) Samples containing various levels of the marker residue obtained from target tissue at appropriate time intervals after the sponsored compound is administered in accordance with the proposed labeling, i.e., "dosed" tissue samples.

(3) Samples obtained from untreated target animals, i.e., "control" tissue samples.

(c) The petition for approval of the proposed regulatory assay shall contain the following:

(1) A complete description of the assay.

(2) A list of all necessary equipment and reagents.

(3) A standard curve prepared from samples of the marker residue of known purity.

(4) An analytical curve of the observed assay response versus the tissue concentrations of the marker residue in spiked target tissue. The curve shall include the 99 percent confidence bounds of a single assay response.

(5) All raw data and worksheets from the analyses of spiked, dosed, and control tissue samples, and from the analysis used in preparing the standard curve, including spectrograms, chromatograms, etc.

(6) A discussion of the data generated in the assay development process pertinent to the evaluation criteria set forth in paragraph (d) of this section explain-

01170

ing how the data show that the proposed assay conforms to those criteria.

(d) A regulatory assay must satisfy the following criteria:

(1) *Dependability.* The assay shall be considered dependable if it does not result in an unreasonable number of failures due to unknown, uncontrollable, or random factors. Evaluation of the data to support the dependability criterion will be based on the total number of assay runs that are started to provide data points for the analytical curve of paragraph (c) (4) of this section. An explanation shall be required for any assay run started that yields no final determination.

(2) *Practicability.* The assay shall be considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay must be consistent with regulatory objectives (monitoring, compliance, etc.). All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay must be commercially available except that reference standards may be supplied by the petitioner if they are not commercially available. The Commissioner will withdraw approval of any assay method and initiate regulatory action against the sponsored compound, if the petitioner breaches such a condition of the compound's approval.

(3) *Specificity.* The assay shall be considered specific if the observed response is a smooth and continuously decreasing or increasing function of the concentration of the marker residue and that compound only. The regulatory assay must be comprised of a sufficient number of independent measurements based on a different biological, biochemical, or physiochemical principles to assure that the identity of the marker residue is confirmed.

(4) *Accuracy.* The assay shall be considered accurate if the measurements it yields are normally no less than 60 percent nor greater than 110 percent of the marker residue's true concentration in the spiked target tissues.

(5) *Lowest limit of reliable measurement.* The regulatory assay shall be considered approvable if it can reliably discriminate with 99 percent confidence the marker residue response from the target tissue background response at or below the required lowest limit of reliable measurement, the R_m of § 500.89 (b) or (e). If the regulatory assay for an exogenous compound can reliably discriminate the marker residue response from the target tissue background response at a level below the required lowest limit of reliable measurement determined in accordance with § 500.89(b), the Commissioner shall approve the compound for use only under conditions that will not result in residues above that level.

(e) The Commissioner will review and evaluate the data submitted in accordance with paragraphs (a), (b), and (c) of this section. If the Commissioner concludes that the assay satisfies the evaluation criteria of paragraph (d) of this section, it will then be subjected to the interlaboratory validation study described in paragraph (f) of this section.

(f) Two Food and Drug Administration laboratories and one U.S. Department of Agriculture laboratory will independently run a number of assays to ascertain whether the regulatory assay method conforms to the criteria set forth in paragraph (d) of this section.

(1) The petitioner shall supply the validating laboratories with the number and amount of dosed and control tissue samples requested by the Commissioner.

(2) The petitioner shall supply reagents, standards, supplies, and equipment not readily available to the validating laboratories, as requested by the Commissioner.

(g) The Commissioner will evaluate the data gathered from the study described in paragraph (f) of this section. The assay shall be approved if it meets the criteria set forth in paragraph (d) of this section in each of the three validating laboratories.

§ 500.92 Withdrawal periods.

(a) The withdrawal period shall be the time after cessation of administration of the sponsored compound necessary for the marker residue to deplete, with 99 percent assurance, to L_m in the target tissue. The time will be extended if necessary to be consistent with conditions of livestock management reasonably certain to be followed in practice. The petitioner shall submit studies of the marker residue's depletion from the target tissue of animals dosed according to the maximum level of use proposed in the petition. The validated regulatory assay must be used to collect these data.

(1) The petitioner shall submit a plot of the concentration of marker residues in target tissue as a function of time (depletion curve) including the 99 percent confidence limits on the observed values.

(2) All raw data and statistical analyses shall be submitted along with a referenced discussion of the results.

(3) Use of the sponsored compound shall be approved only if the available evidence demonstrates that the proposed conditions of use, including any withdrawal period, are reasonably certain to be followed in practice.

(b) When the marker residue is an endogenous compound, the withdrawal period shall be the time required after cessation of administration of the sponsored compound for the norm to be restored, with 99 percent assurance. The time will be extended if necessary, but not reduced, to be compatible with conditions of livestock management reasonably certain to be followed in practice. The validated regulatory assay must be used to collect data on the rate of restoration of the norm.

(1) The petitioner shall submit a series of curves that demonstrate the time required for restoration of the norm.

(2) All raw data and statistical analysis shall be submitted along with a referenced discussion of the results.

(3) Approval of the petition for the sponsored compound shall be granted only if the available evidence demonstrates that the proposed labeling is reasonably certain to be followed in practice.

§ 500.94 Publication of the approved regulatory assay.

The lowest level of reliable measurement (L_m), the complete regulatory assay for measuring the marker residue in the target tissue, and the analytical curve shall be published in the FEDERAL REGISTER, in accordance with the provisions of sections 409(c)(3)(A), 512 (d)(1)(H) and (i), and 706(b)(5)(B) of the act. For an endogenous marker residue, the norm shall also be published.

§ 500.96 Waiver of requirements.

The Commissioner, in response to a petitioner or on his own initiative, may waive, in whole or in part, any of the foregoing requirements for the scientific evaluation of sponsored compounds that have the potential to contaminate human food with residues whose consumption could engender a human risk of carcinogenesis. A petition for such waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why some or all of the requirements are not reasonably applicable to the compound, and describe the alternative procedures that have been, or could be, followed to assure that use of the compound will not contaminate human food with residues whose consumption could engender a human risk of carcinogenesis and that an assay method exists that satisfies the requirements of § 500.90(d) (1) through (4) and that is capable of measuring any such residues that might occur when the compound was improperly used. The petition shall set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines on his own initiative that waiver of any of the foregoing requirements is appropriate, he shall so state and set forth the basis for that determination in the regulation approving marketing of the sponsored compound.

§ 500.98 Implementation.

(a) The requirements of this subpart shall apply to all new animal drug applications, feed additive petitions, and appropriate color additive petitions (i.e., all compounds intended for use in food-producing animals) submitted to the Food and Drug Administration subsequent to the effective date of the subpart, including appropriate supplemental applications, and to all such applications or petitions on file with the agency on the effective date of the subpart except to the extent that the Commissioner determines that consumer protection can be adequately assured by imposing such requirements in accordance with the provisions of paragraph (b) of this section.

(b) The provisions of this subpart shall also apply to the following compounds already approved:

01171

(1) Those compounds that the Commissioner determines, on the basis of available, reliable information, have been shown to induce cancer when ingested by man or animals.

(2) Those compounds that the Commissioner determines may induce cancer when ingested by man or animals, i.e., suspect carcinogens.

(3) Any compound for which the Commissioner concludes sufficient information has not been provided to determine whether that compound is appropriately regulated under the general food safety provisions of the act or under the anticancer provisions of the act.

(c) Any compound already approved to which the Commissioner determines the anticancer provisions of the act are applicable, or for which additional data are required for such a determination, will be the subject of a notice published in the FEDERAL REGISTER or a letter issued pursuant to section 512(1) of the Act establishing the time within which the requirements of this subpart must be satisfied.

(1) Notices already published in the FEDERAL REGISTER and letters already sent by the Food and Drug Administration requiring additional studies or submission of an improved regulatory assay shall remain in effect, and the provisions of this subpart shall be used in determining compliance with the requirements of the act identified in those notices and letters.

(2) The Commissioner will proceed to withdraw approval of any compound on the basis of data or information indicating a health hazard or in response to any failure to undertake studies necessary to comply with the provisions of this subpart.

PART 514—NEW ANIMAL DRUG APPLICATIONS

3. In Part 514, by amending § 514.111, by adding a new paragraph (a)(10) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(10) Such drug fails to satisfy the requirements imposed by Subpart E of Part 500 of this chapter.

* * * * *

PART 571—FOOD ADDITIVE PETITIONS

4. In Part 571, by adding a new § 571.115, to read as follows:

§ 571.115 Application of the anticancer cause of section 409].

Food additives intended for use as an ingredient in food for animals that are raised for food production must satisfy the requirements imposed by Subpart E of Part 500 of this chapter.

Effective date. These regulations shall be effective March 23, 1977. Interested persons may, on or before April 25, 1977 submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments, in quadruplicate and identified with the Hearing Clerk docket number found in brackets on the heading of this document, regarding these regulations. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this order justified by such comments will be the subject of a further order amending the specific regulations involved.

(Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).)

NOTE.—Incorporation by reference provisions approved by the Director of the Office of the Federal Register on July 11, 1973, and February 15, 1977, and on file in the library of that office.

Dated: February 14, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-5266 Filed 2-16-77;8:45 am]

01172

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 70, 500, 514, 571]

[Docket No. 77N-0026]

CHEMICAL COMPOUNDS IN FOOD-PRODUCING ANIMALS

Criteria and Procedures for Evaluating Assays for Carcinogenic Residues

AGENCY: Food and Drug Administration.

ACTION: Proposal.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish procedures and minimum criteria to ensure the absence of cancer-causing residues in edible products of food-producing animals to which drugs, food additives, or color additives have been administered. This is a reproposal of regulations revoked in accordance with a court order.

DATES: Comments by July 18, 1979: Notices of participation for the public hearing by May 4, 1979. Public hearing before the Commissioner June 4, 1979.

ADDRESSES: Comments and notices of participation are to be submitted to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR INFORMATION ON THIS PROPOSAL, CONTACT:

Robert J. Condon, Bureau of Veterinary Medicine (HFV-105), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1580.

FOR FURTHER INFORMATION ON THE HEARING BEFORE THE COMMISSIONER CONTACT:

Constantine Zervos, Director, Scientific Liaison and Intelligence Staff (HFY-31), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4490.

SUPPLEMENTARY INFORMATION: These proposed regulations would provide an operational definition of the no-residue requirement of the so-called "DES proviso" to the anticancer clauses, sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A), 360(d)(1)(H), and 376(b)(5)(B)). The regulations also propose to establish criteria for accepting assays and procedures for establishing suitable postadministration withdrawal periods to prevent the occurrence of carcinogenic residues in edible animal products.

Prior to July 19, 1973, FDA had applied the DES proviso on a case-by-case basis, without published criteria. However, the Commissioner of Food and Drugs concluded that it was appropriate to establish criteria and procedures for their application through rulemaking to permit public discussion of the scientific, legal, and policy issues involved. Accordingly, the Commissioner proposed a set of regulations, in the FEDERAL REGISTER of July 19, 1973 (38 FR 19226), and afforded 60 days for public comment.

The numerous comments received were submitted by scientists affiliated with consumer groups, universities, scientific societies, State and Federal agencies, trade associations, and affected manufacturers; some were from nonaffiliated individuals. Many comments revealed a sharp divergence of opinion concerning FDA's interpretation of the proviso to the anticancer clauses of the act.

The Commissioner promulgated the final regulations in the FEDERAL REGISTER of February 22, 1977 (42 FR 10412), but solicited comments on four specific issues: (1) The acceptable level of risk, (2) comparative metabolism, (3) regulation of endogenous compounds, and (4) methods of determining an assay's lowest limit of reliable measureent. On March 23 and 24, 1977, the Animal Health Institute (AHI) and three other groups petitioned the Commissioner to stay the effective date of the regulations and to then revoke them. The Commissioner denied these petitions on April 27. In response to a separate request by AHI, however, the Commissioner extended the comment period to July 25, 1977 (42 FR 24254).

On May 12, AHI filed a complaint in the United States District Court for the District of Columbia alleging that the regulations were unlawful: (1) because they broadened the scope of the Delaney, i.e., anticancer, clause of the act to include substance that have not been determined to be carcinogenic, and (2) because they foreclosed marketing of a compound unless there exists an assay of sufficient "sensetivity" to detect residues of the compound at "theoretically" safe levels determined by the regulations. Also, AHI alleged that the regulations were impractical and embodied novel on highly suspect technical principles that would impose enormous financial and environmental costs on the animal health industry. Finally, it alleged that the final regulations violated the Administrative Procedure Act (5 U.S.C. 551 note) because they departed from and radically changed the proposed regulations and were not republished for comment.

Based on AHI's affidavits contending that the statistical procedure for extrapolation of animal data adopted in the final order was significantly different from and more complex than that proposed, and perhaps improperly interpreted, the court remanded the case to the agency for further consideration. The court also required the agency to assess the question raised by AHI about the technical feasibility of the regulations, and it suggesed that the Commissioner repropose the regulations (*Animal Health Institute* v. *Food and Drug Administration*, Civil No. 77—806 (D.D.C. Feb. 8, 1978)). In accordance with the court's order, the Commissioner revoked the regulations on May 26, 1978 (43 FR 22675) and is now reproposing all the regulations for public comment. In this proposal, the Commissioner has evaluated and responded to AHI's allegations, the court's questions, the citizen petitions to revoke the regulations, and all comments filed on the final order. (For the sake of clarity, the final order is hereafter designated the "February notice" or the "1977 notice".)

Since the July 1973 proposal, the Commissioner has used the risk assessment element of the regulations as the prototype for segments of the agency's anticancer policy. Before attempting to build a uniform procedure for regulating all chemicals in the food supply, the Commissioner has adopted where appropriate, the best elements of the emerging scientific and regulatory procedures of risk assessment, metabolism studies, in vitro mutagenesis tests, etc., for regulating residues in food derived from food-producing animals.

The Commissioner selected this class of compounds as the test model because FDA has premarket approval authority over the chemicals intentionally used in these animals, and the DES proviso to the Delaney clause has made regulation of these compounds one of the agency's most difficult tasks.

Based on experience with the principles outlined in the proposal, gained through several years of regulating these chemicals on a case-by-case basis, the Commissioner believes that they have potential applicability for regulating all compounds covered by the act. Moreover, due to the extensive interest in the issues, the Commissioner now believes that the time is ripe for formulating a comprehensive approach for regulating all chemical carcinogens. Expanding the use of the principles set out in these regulations into other areas regulated by the agency seems desirable from the perspectives of science and public health protection, but the results of their ex-

01173

panded use, e.g., cost, cannot now be calculated.

Because an error in selecting the basic principles could lead to a future tragedy, the principles adopted at this time must be reasonable and must not underestimate the potential risks associated with the use of chemicals. Accordingly, the Commissioner is proposing to adopt principles that some may consider too "conservative." The term "conservative," however, is relative. Further, although the principles form an integrated scheme of regulation, individual segments can be severed and replaced.

For all the foregoing reasons, the Commissioner has determined that, in addition to the 120-day comment period for filing written comments, an informal public hearing should be held in accordance with Part 15 (21 CFR Part 15). The informal public hearing will provide an open forum for the presentation of information, views, and discussions on all aspects of the proposal. Because the general principles articulated in the regulations have widespread potential use, the Commissioner asks that the witnesses focus on the principles that form the basis of the regulations, in addition to the issue of the technical feasibility of the required analytical technology. In particular, the Commissioner requests discussion of the following:

1. Threshold assessment procedures.
2. Criteria for selecting residues for chronic toxicity testing.
3. The types of investigations necessary to study how chemicals are metabolized, and the role of these studies in assessing the parent compound's safety.
4. The use of comparative metabolism studies for selecting the laboratory animal species to be used as surrogates for man in chronic toxicity testing.
5. The utility of short-term in vitro mutagenesis tests in assessing the safety of a compound.
6. Mathematical risk estimation procedures, including (a) methods of assessing risks within a species and (b) methods of cross-species extrapolation.
7. Procedures for combining data from the same or different carcinogenesis bioassays.
8. The regulation of endogenous substances.
9. The acceptable level of risk.

In preparing final regulations, the Commissioner will consider the administrative record of this hearing along with all other written comments received during the comment period specified in this proposal and on the transcript of the Part 15 hearing.

The hearing will be held on June 4, 1979, starting at 9 a.m. in the Washington, DC area at a place to be announced later.

A written notice of participation must be filed in accordance with § 12.45 (21 CFR 12.45) with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, not later than May 4, 1979. The envelope containing the notice of participation, and the notice of participation itself, should be prominently marked "SOM Hearing." The notice of participation must also contain Hearing Clerk Docket No. 77N-0026, the name, address, and telephone number of the person desiring to make a statement, along with any business affiliation, the text of the presentation, and the approximate length of time requested for the presentation. The Commissioner is requiring submission of the text of all presentations before the hearing to promote a comprehensive discussion of the issues, but the Commissioner recognizes that some revisions in the text before the hearing may be necessary. A schedule for the hearing will be mailed to each person who files a notice of participation; the schedule will also be available from the FDA Hearing Clerk. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations.

If the responses to this notice of hearing are so numerous that insufficient time is available to accommodate the full amount of time requested in the notices of participation received, the Commissioner will allocate the available time among the persons making the oral presentation to be used as they wish. Final versions of written statements (preferably four copies) should be presented to the presiding officer on the day of the hearing or submitted to the Hearing Clerk by June 19, 1979 for inclusion in the administrative record.

The plenary hearing will be open to the public, and any interested person who has filed a written notice of participation may be heard concerning matters raised in the written statement which are relevant to the issues under consideration.

Additional comments from interested persons may be submitted during the period following the hearing until the end of the comment period.

I. Introduction

A. Statutory Background

1. Food Additives Amendment of 1958

Section 409 of the Federal Food, Drug, and Cosmetic Act (Food Additives Amendment of 1958, Pub. L. 85-929) establishes criteria and prescribes procedures for FDA's premarket review and approval of food additives that have been shown to be safe. Section 409 was enacted to protect consumers by requiring substances that are intentionally added to food, or may reasonably be expected to become components or otherwise affect the characteristics of food, to be shown to be safe through rigorous scientific testing procedures. As the legislative history of the amendment demonstrates, one primary function was to protect the health of consumers by requiring manufacturers of food additives and food processors to test any potentially unsafe substances that are added to food in accordance with principles deemed appropriate by qualified scientists (Ref. 1).

Before the amendment, FDA's authority for ensuring the safety of food additives was limited to sections 402(a)(1) and 402(a)(2)(A) as enacted in 1938. Under these sections the agency must show that an intentionally added food substance may be injurious to health. Thus, the agency has to test the poisonous or deleterious substance before taking action. Therefore, the amendment shifted the burden of both testing and proving safety to the proponent of the additive.

When the Committee on Interstate and Foreign Commerce reported the bill to the full House of Representatives, the bill did not contain an anticancer clause, but it did contain a section requiring the premarketing testing of food additives to demonstrate safety. That section is now known as the general safety provision (section 409(c)(3)(A)). After the bill was reported out, Congressman Delaney suggested the addition of the anticancer proviso to the bill, and the following proviso was added to the bill as a Committee amendment on August 13, 1958:

> * * * *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *.

Reportedly to assure enactment of the legislation, the Committee and the Department of Health, Education, and Welfare (HEW) agreed to the amendment, but in a letter to the Chairman of the Committee, then Assistant Secretary Elliot L. Richardson noted that the amendment did not change the meaning of the bill. Moreover, the letter also illustrates the interaction between the general safety and anticancer provisions of the bill and the broad scope that the Delaney anticancer clause is to be given. It makes clear that the anticancer clause is a corollary of the general safety clause; and that compounds, even when subject to the anticancer clause, are also subject to the general safety clause:

> This Department is in complete accord with the intent of these suggestions—that

no substance should be sanctioned for use in food that might produce cancer in man. H.R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting the use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions of use. This would afford good, strong public health protection (Ref. 2).

As enacted in 1958, the anticancer (or so-called Delaney) clause of section 409 flatly proscribed the approval of any additive if after "a fair evaluation of the data before the Secretary" the additive "is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." As applied to additives added directly to human food, this language has remained unchanged, although hotly debated. Accordingly, as a legal matter, section 409 precludes a finding by FDA that a direct food additive that has been shown, by ingestion or other appropriate studies, to cause cancer in laboratory animals (or, of course, in man) can be safely added to food, in any amount, for any purpose.

2. Color Additive Amendments of 1960

The Color Additive Amendments of 1960 (Pub. L. 86-618) added a provision to the basic act for colors that is directly analogous to the food additives provision. Petitioners for color additive regulations must demonstrate by rigorous testing the safety of these additives before they can be approved by FDA for addition to food, drugs, or cosmetics. In addition, the amendments added another anticancer clause to the act.

The legislative history of the Color Additive Amendments of 1960 describes the congressional and executive (HEW) concern about the potential carcinogenicity of these color additives; nevertheless, the Secretary of HEW again explained that an express anticancer clause was unnecessary to prevent approval of carcinogenic or potentially carcinogenic color additives because it did not provide any public protection that is not already provided by the general safety clause (Ref. 3).

3. Drug Amendments of 1962

In 1962, Congress culminated several years of hearings on the drug industry by enacting the Drug Amendments of 1962 (Pub. L. 87-781); the infamous thalidomide incident provided the impetus for the bill's passage. The drug amendments brought about a comprehensive revision in the regulation of new drugs, which at the time included both human and animal drugs. The drug legislation also amended the anticancer clauses to rectify what Congress perceived as the inequity associated with the prior sanctioned use of diethylstilbestrol (DES) in animal feed. Under the Food Additives Amendment of 1958, certain DES uses in animals were prior sanctioned because they were covered by an effective New Drug Application (NDA). Thus, continued use in accordance with the prior sanction was appropriate until that use was cancelled (the NDA revoked), but no new uses in food or food-producing animals were approvable due to the Delaney clause (Refs. 4 and 5).

The act requires that compounds administered to animals as food additives, color additives, or animal drugs be shown to be safe for use. As defined in section 201(u) of the act (21 U.S.C. 321(u)), the term "safe" clearly embraces the health of man, as well as the health of the animals to which the compounds are given. Thus, in evaluating the safety of compounds to be administered to animals raised or maintained for production of food for man, such as cattle, swine, and poultry, Congress has from the beginning recognized that consideration must be given to the safety of possible residues of the compounds in the products of animals that become food for man, i.e., meat, milk, and eggs.

Before 1962, the anticancer clauses in sections 409 and 706 did not distinguish between compounds added directly to human food and compounds that might indirectly enter human food through administration, as feed additives or drugs, to food-producing animals. The act was interpreted as forbidding FDA to approve the use of a carcinogenic animal drug whether or not the compounds might leave any residues in the edible tissues of the animal.

Modification of the effect of the anticancer clause of section 409 had first been suggested during congressional consideration of the Color Addition Amendments of 1960. In May 1960, the then Secretary of Health, Education, and Welfare had urged Congress to modify the act, explaining:

> There is * * * one respect to which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food. * * *
>
> We therefore have included in the enclosed draft bill an amendment to permit use of an additive in animal feed under the above-mentioned conditions.
>
> * * * * *
>
> Under the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive (Ref. 3).

The amendments proposed by the Department had not been included in the color additive legislation. During the following 2 years, however, concern had been continuing about application of the anticancer clause in section 409. As a result, legislation similar to that earlier recommended by HEW was introduced in 1962. The House Committee on Interstate and Foreign Commerce ultimately included modifications of the anticancer clause in its report on the Drug Amendments of 1962, with the following explanation:

> The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal (Ref. 4).

Representative Leonor K. Sullivan objected to the proviso in the floor debate on the amendments and proposed a separate amendment to delete the proviso from the bill because "they (the provisos to the Delaney clauses) weaken instead of strengthen consumer protection." She reminded the House that DES had been regarded as safe for use in poultry at one

01175

time because no residue was found in the meat; later, that use had to be terminated when DES residues were found as a result of improved testing methods. But her amendment was defeated principally on the argument that, if DES were available for manufacture by those who obtained approvals before 1958, i.e., the prior-sanctioned uses, it should be made available for manufacture by everyone (Ref. 6).

The Senate accepted the modifications of the anticancer clauses in conference while preserving, as Senator Hubert Humphrey noted, the full vigor of consumer protection afforded by Delaney clause (Ref. 7). These modifications have come to be known as "the DES proviso."

4. Animal Drug Amendments of 1968

The animal feed industry experienced an era of unprecedented growth and innovation beginning in the 1950's. That industry and the animal drug industry began an effort in the mid-1960's to consolidate the various provisions of the Federal Food, Drug, and Cosmetic Act governing the premarketing approval of drugs intended for use in animals, i.e., sections 409, 505, 507 (21 U.S.C. 348, 355, and 357) which culminated in the enactment of the Animal Drug Amendments of 1968 (Pub. L. 90-399). Neither the committee reports on the bill nor the floor debates raised the issue of the Delaney clause. Consequently, the Animal Drug Amendments of 1968 passed without controversy and added, under section 512(d)(i)(H) of the act, the following anticancer clause and proviso:

(H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals, * * *.

Again, the legislative history indicates that the legislation in no way weakens FDA's authority to regulate new animal drugs (Ref. 8).

B. STATUTORY INTERPRETATION

The enactment in 1962 of the so-called DES proviso to the Delaney clause has been a source of continuing controversy. There is no unanimity on the proper interpretation of the proviso; and the legislative history of the proviso, summarized above, does not lay to rest all doubts.

Two interpretations of the proviso are, in theory, possible. The first interpretation, which in the Commissioner's judgment is the less probable, is that Congress intended to allow FDA to approve the use of a carcinogenic compound in food-producing animals only if the agency could be absolutely positive that no traces whatever—no matter how small—would remain in edible tissues.

This interpretation presents several difficulties, all stemming from the fact that any introduction of a compound, whether or not carcinogenic, is likely to leave in edible tissues minute residues, which are below the level of detection of any known or likely to be developed method of analysis, i.e., assay. It is a fundamental fact of analytical science that for every assay developed to measure the concentration of a chemical compound in a medium (in this case, a residue in an edible tissue), there is some lowest concentration or level of the compound below which the assay will not yield an interpretable result (Ref. 9). If, for example, an assay measures a particular compound in muscle tissue, i.e., an edible tissue, and the assay has been shown to have a lowest limit of measurement of 1 part per billion (1 ppb—1 part compound in 1 billion parts tissue on a weight basis, such as 1 nanogram of compound per 1 gram of tissue), examination of muscle tissue using this assay will reveal that the compound is present only if its concentration in muscle tissue is 1 ppb or higher. If the compound is present in the tissue at a level below 1 ppb, use of the assay will yield no interpretable result. Thus, the assay connot distinguish between muscle tissues containing the compound at levels below 1 ppb and muscle tissues from which the compound is absent in the absolute sense of the term.

Although different assays may have different lowest limits of measurement, all assays are subject to the same type of limitation. Thus, when a tissue is examined with an assay having a lowest limit of measurement of 1 ppb and no interpretable response is observed, the analyst can conclude only that the compound under analysis is not present at a level of 1 ppb or above. It can never be concluded that the compound is "not present" in the absolute sense. It is thus impossible to determine the conditions under which edible tissues derived from food-producing animals that have received a carcinogen will contain no residue if the phrase "no residue" is to be interpreted literally. Accordingly, this first possible interpretation of the DES proviso would not permit approving any known carcinogenic animal drug because the Commissioner could never find that no trace whatever would remain in the edible tissues of the animals to which the compound was administered.

This interpretation would thus render the DES proviso a "Catch-22." The proviso would permit the Commissioner to approve carcinogenic drugs for animals only when certain that no residues whatever would remain, but since the Commissioner could conclude only that some trace might well remain, no such drug could ever be approved.

Nevertheless, one comment on the February notice contended that Congress did indeed intend that the no-residue provision be a flat prohibition on any molecules of a carcinogen in food. The comment further argued that Congress did not understand fully the scientific ramifications of its action when it amended the pristine Delaney clause.

As the Commissioner noted in the February notice, the "absolutely no molecules" interpretation seems, at the very least, an improbable interpretation of an amendment enacted by Congress precisely because it wanted to relieve animal drugs from the rigid strictures of the anticancer clauses. Moreover, any interpretation of a statutory provision that would render it totally inoperative should be rejected unless considerations of overwhelming persuasiveness require that interpretation. No such considerations have been advanced in support of the "absolutely no molecules" interpretation of the DES proviso.

Furthermore, this interpretation is difficult to reconcile with the language of the DES proviso itself. It specifies that "no residue" may be "found * * * by methods of examination prescribed or approved by the Secretary * * * in any edible portion of such animals * * *." This language conspicuously avoids such words as "occur" or "remain," and instead, by use of the word "found" emphasizes detectability. Moreover, the same proviso refers to "conditions of use * * * reasonably certain to be followed in practice", suggesting a congressional recognition that some occurrences of these residues (i.e., resulting from unforeseeable misuse) might not require withdrawal of approval of a compound even if they were detected.

A second, and in the Commissioner's view more plausible, interpretation of the DES proviso accepts the words of the amendment and focuses on the previously quoted language, "no residue of such drug will be found * * * by methods of examination prescribed or approved by the Secretary by regulations * * *." Under this interpretation, a sponsored compound that is carcinogenic may be approved for use in ani-

01176

mals if examination of edible tissues by an assay approved by FDA reveals no residues. This interpretation also appears implicit in the limited case law addressing the issue (*Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, 495 F.2d 975 (D.C. Cir. 1974), *Chemetron Corp.* v. *United States DHEW*, 495 F.2d 995 (D.C. Cir. 1974), and *AHI* v. *FDA*, *supra*).

This second interpretation is in essence the one that FDA has followed since the passage of the DES proviso. The agency has approved carcinogenic compounds for use in animal feed or as animal drugs on the basis of assays capable of measuring prescribed levels of residues.

The court in *AHI* v. *FDA* found lacking the agency's previous attempt to define and explain, as a binding rule, the criteria and procedures for evaluating assays for carcinogenic residues in edible products of animals. The court held that FDA had failed to provide adequate public notice. One purpose of this document is to correct that defect.

The Commissioner believes that the criteria to be applied in evaluating assays for carcinogenic residues in the edible tissue of food-producing animals must further the congressional intent to minimize public exposure to carcinogens, without nullifying the decision reflected in the DES proviso, as the first interpretation of the proviso would do. As explained more fully below, the criteria set forth in these regulations for evaluating assays for carcinogenic residues are minimum requirements. They are designed to identify assays that are (1) reliable and practical for use by a regulatory agency and (2) capable of measuring residues at levels that have been determined, on the basis of animal toxicity tests, to present no significant increase in human risk of cancer. An assay that does not meet both criteria cannot be approved. The Commissioner recognizes that, for some compounds currently in use, no reliable and practical assay capable of sufficiently low limits of measurement now exists and that approval of their continued use must therefore be reexamined.

Arguing that the Commissioner has incorrectly interpreted the Delaney clause, AHI contends that it is a precise statutory provision that must be construed very narrowly. Therefore, AHI charges that the Commissioner's interpretation has unduly, and illegally, broadened the scope of the anticancer clause. AHI contends that FDA must prove that a compound is a carcinogen before the petitioner for the compound's use is required to comply with any provision of the proposed regulations. Ostensibly, AHI argues that FDA must prove that the sponsored compound is a carcinogen before a petitioner is required to submit either comprehensive data from long-term animal studies (the fundamental information for assessing a compound's carcinogenicity), or certain data regarding the residues in food to which man will be exposed if the compound is approved. Also, AHI argues that FDA cannot prevent a sponsor from marketing a compound when any assay for a carcinogen is available, even if the assay fails to exhibit a lowest limit of reliable measurement required by the data and extrapolation procedure proposed in the regulations. Citing *Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, AHI further contends that the Delaney clause imposes upon FDA a standard corresponding to the level of technology at the time the application for the compound (new animal drug application (NADA) or food additive petition) is approved. Moreover, AHI argues that the modified Mantel-Bryan procedure for statistically assessing the risk of chemical carcinogenesis, which was included in the February notice, is a theoretical procedure that would require petitioners to develop assays capable of measuring residues of compounds at levels that are far too conservative and that are technically and economically infeasible. The court in *AHI* v. *FDA* requested FDA to consider AHI's arguments on technical and economic feasibility.

AHI's argument concerning the burden of proof on the issue of carcinogenicity might have merit if the Delaney clauses stood alone and were applied in isolation from the other provisions of the FFDC Act. However, ever since their enactment, the anticancer clauses have been regarded as a particularization of the general safety sections of the act, to which they attach as provisos; and they have been applied in conjunction with the general safety provisions. They do not expand the scope of these sections. Under these general safety provisions, a compound cannot be approved unless it is shown to be safe and in every case the petitioner has the burden of showing safety. Section 409(c)(3)(A) prohibits approval of a food additive if "the data before the Secretary * * * fails to establish that the proposed use of the food additive * * * will be safe * * *." Section 706(b)(4) prohibits the Secretary from approving a color additive "unless the data before him establish that such use * * * will be safe * * *." Section 512(d)(1)B) requires the Secretary to deny approval of a new animal drug if "the results [of tests submitted to the Secretary] show that such drug is unsafe for use under [the conditions prescribed, recommended, or suggested in the proposal labeling thereof] * * * or do not show that such drug is safe * * *." These sections of the act do not impose on FDA any burden to prove that a substance is unsafe. Rather, they impose on the petitioner for approval the burden of showing that, under the proposed conditions of use, the compound is safe.

"Safe" means safe in all respects—including safe from carcinogenicity. Thus, AHI's argument that the burden is on FDA to show carcinogenicity rather than on the sponsor to show noncarcinogenicity is contrary to the clear language of the act. It would impose on FDA two burdens that Congress manifestly intended to impose on petitioners for approval of substances under the act—the burden of testing for safety and the burden of proof on the issue of safety. The Delaney clauses clarify and emphasize the congressional intent to protect the public from carcinogenic risks; AHI would transform them into clauses that reduce the protection from carcinogenic risks already provided by the general safety provisions.

The general safety provisions of the act provide the context for the Delaney clauses. Under them the sponsor of a compound must submit adequate tests by all reasonably applicable methods to show that the sponsored compound will be safe when used. This showing, of course, requires not only toxicity testing but also an assay suitable for measuring the compound and substances formed in or on food as a result of its use. Only after the sponsor of a compound has conducted all the required tests and submitted the resulting data is FDA required to make any showing that the Delaney clause or the DES proviso is applicable or that the compound has not otherwise been shown to be safe.

Adoption of AHI's interpretation that FDA must prove that a compound is a carcinogen before the necessary data are submitted requires an illogical reading of the statute in light of its overall purpose and the legislative mandate surrounding it. Therefore, the Commissioner rejects AHI's scheme of regulating chemical carcinogens and potential carcinogens.

Scrutiny of the *Hess & Clark* decision shows that the court did not even consider the procedure that FDA used to designate requiremens for an assay under the DES proviso to the Delaney clause; rather, the court accepted as valid the agency's designation of an assay. To the extent that the procedures and criteria set forth in this notice for assessing assays differ from those used in evaluating the assay involved in *Hess & Clark*, they are being adopted by rulemaking in an area in which the agency has considerable expertise and discretion because the area involves protecting the public against cancer.

AHI's allegations that the regulations are technically and economically infeasible is an attempt to characterize the agency's actions as arbitrary and capricious. Several environmental statutes (e.g., Clean Air Act, Federal Water Pollution Control Act, Federal

01177

Insecticide, Fungicide, and Rodenticide Act) contain specific provisions requiring the Environmental Protection Agency (EPA) in certain instances to make elaborate cost/benefit calculations in setting safe levels of human exposure to chemicals in the environment. Also, these statutes provide that EPA protect the environment from contaminants by setting standards for the discharges permitted. EPA is authorized to establish two types of standards—health-based standards and technology-based standards. For certain health-based standards the Supreme Court has authorized that agency to require pollution reduction by methods that are neither economically nor technically feasible when the agency is not explicitly required to consider cost (*Union Electric Company v. EPA*, 427 U.S. 241 (1976)). The United States Court of Appeals for the District of Columbia Circuit has subsequently reached similar conclusions when interpreting analogous provisions of the Federal Water Pollution Control Act, concerning regulation of the discharge of toxaphene endrin, and polychlorinated biphenyls (PCB's) (see *Hercules, Inc., et al v. Environmental Protection Agency, No. 77-1248, (D.C. Cir. Nov. 3, 1978); Environmental Defense Fund, et al. v. Environmental Protection Agency*, No. 77-1091 (D.C. Cir. Nov. 3, 1978)).

The two possible exceptions not applicable here (establishment of tolerances for unavoidable contaminants under section 406 and for pesticides under section 408(h)), the Federal Food, Drug, and Cosmetic Act contains no provisions requiring the Commissioner to consider costs or technical feasibility in making any safety decision, including any decision involving cancer-causing chemicals. The distinction between the statutory provisions applicable to food additives, color additives, and animal drugs and those applicable to pesticides and unavoidable contaminant tolerances demonstrates Congress' decision to make costs and technical feasibility relevant to some public health matters but not to others. Nevertheless, in light of the court's remand order, the Commissioner recognized the agency's obligations to review this element of the proposal. Based on the act's legislative history, the case law, and the agency's public protection function, the Commissioner concludes that the procedures used to designate requirements for assays can be technology-forcing if necessary.

The Commissioner's interpretation recognizes the tension between the need to provide health protection and the costs of that protection, and it attempts to spur the private sector into technological change only when such change is necessary for protection of the public health. To do otherwise might force the public to accept an increased disease burden that it would unknowingly have to bear. The agency recognizes that the public health is not advanced by imposing requirements for what is neither economically nor technically possible. It also recognizes that public health regulation requires common sense, a sense of proportion, and awareness of economic and technical factors. In particular, the agency should not impose economic costs that are not justified by some reduction of risks to the public health. Nevertheless, the agency can properly require improvements in or developments beyond currently available technology when there is sufficient reason to believe that those improvements or developments are feasible and are needed to protect the public health. In enacting public health legislation, Congress intends that administrative agencies carry out their assigned missions with intelligence, good sense, and an awareness of the context and consequences of their actions; but unless it has expressly said so, there is no reason to think that it intended them to be in thrall to the technological or economic status quo.

In the immediate context, the statutory structure and language provide considerable guidance with respect to the issue of feasibility and costs. The language permitting the use of carcinogenic substances under certain circumstances is a proviso to a clause prohibiting the use of carcinogens, and that clause itself is a particularization of a provision requiring safety generally. It is clear that in enacting the DES proviso Congress intended to create no additional risk of human cancer beyond what would have existed in the absence of the DEX proviso. That is why Congress used the language "no residue * * * will be found." By enacting and twice re-enacting the Delaney clause, Congress made clear its willingness to ban entirely from the human food supply food additives, color additives, and animal drugs that present a carcinogenic risk to man. It enacted the DES proviso with the intent and expectation that the provision that "no residue * * * will be found" would sufficiently protect the human food supply from any significant cancer risk from food additives, color additives, and animal drugs. Thus, in enacting the DES proviso, Congress did not change in any way the policy of the Delaney clause to protect the human food supply from carcinogenic additives and animal drugs; it merely eliminated an application of the clause that it considered unnecessary to the complete achievement of that policy.

From this statutory structure and language, it is evident that any consideration of feasibility and costs is subsidiary to the overriding congressional purpose to permit no additional human cancer risk from food additives, color additives, or animal drugs. The Commissioner's discretion to establish "methods of examination" for detecting residues is to be exercised so as to carry out that congressional purpose. the factor that determines the acceptable level of measurment of an assay method is protection of the human food supply from carcinogenic risks. If, on the basis of toxicological considerations, the Commissioner determines that a certain level of assay measurement is necessary to prevent a significant human cancer risk from use of a carcinogenic substance in food animals, then a method having that level of measurement is necessary to carry out the congressional purpose. If no such method is feasible, or if it is too costly to develop or apply one, then the choice is between refusing to permit the use of the substance altogether and permitting its use despite the fact there is no method of examination that can prevent the use of the substance from presenting a significant human cancer risk. Under the general safety clause and the Delaney clause, that choice can be resolved in only one way: by refusing to permit the use of the substance.

During the last decade, FDA has been monitoring significant trends in the development of chemical, physical, and biochemical methods of analysis of trace toxicants in biological matrices, i.e., tissues, biological fluids, etc. In some cases the agency has examined the available methods, and the trends, of analysis of specific toxicants of public health concern (Ref. 10). In other cases the agency has prepared and submitted to Congress reports on the advancing frontiers of the analytical sciences (Refs. 11 and 12). One of the central findings of this continuing activity is the observation of what can properly be regarded as spectacular scientific progress in achieving ever-decreasing lowest limits of measurement. There is no reason to believe that this progress in analytical chemistry will stop or slacken in the foreseeable future.

Table I shows the trend of the increasing capacity of analytical chemistry to detect the measure the presence of chemicals. Depending on the substance or class of substances, this decrease in the lowest limits of measurement during the last 20 years ranges between two and five orders of magnitude. Table I also suggests that recognition of a public health problem associated with a toxicant accelerates the improvement of analytical methods needed to detect and measure it. In this connection it should be noted that accelerated rates of improvement in analytical methods have generally been the result of public health concerns diffused among the members of the scientific community at large. They have not usually been the result of the concerted effort of a sponsor or industry to gain approval for use of a substance of commercial value.

TABLE I.—*Trends in Analytical Chemistry Detection Techniques*

Compound and date	Detection technique	Limit of measurement	Relative specificity
DDT:			
1940's, 1950's	Colorimetric	10 ppm	Low.
1950's, 1960's	Paper chromatography	1 ppm	Moderate.
1970's	Gas chromatography	Few ppb	Do.
	Gas chromatography/mass spec	Few ppb	High.
Dioxins:			
1940's			
1950's, 1960's	Thin layer chromatography	Nots quant	Moderate.
1970's	Gas chromatography/mass spec	Less than .1 ppb	High.
Nitrosamines:			
1940's			
1950's, 1960's	Thin layer chromatography	10-20 ppb	Moderate.
1970's	Gas chromatography/mass spec	2 ppb	High.
Cortisone:			
1940's			
1950's, 1960's	Colorimetric	4 mg/ml	Low.
1970's	High press liquid chromatography	About 5 ng	Moderate.
Chlorpromazine:			
1940's, 1950's	Titrimetric	50-100 mcg	Low.
1960's, 1970's	chromatography	A few mcg	Low.
Hallucinogens (LSD, mescaline):			
1940's			
1950's			
1960's	Colorimetry	mcg/ml	Low.
	Gas chromatography, fluorescence	25 ng	Moderate.
1970's	NMR	Sub ng	High.
Reserpine:			
1940's			
1950's, 1960's	Colorimetry	Greater than 10 ppm	Low.
1970's	Fluorescence	About 5 mcg/ml	High.
Lead:			
1940's	Colorimetry	About 10 ppm	Low.
	Polarography	About 0.1 ppm	High.
1950's	do	do	Do.
1960's	Atomic absorption	About 1 ppm	Do.
1970's	do	do	Do.
Cadmium:			
1940's			
1950's, 1960's	Colorimetry	About 50 ppb	Medium.
1960's, 1970's	Atomic absorption	About 0.5 ppb	High.
Digitalis drug:			
1940's	Bioassay	LD_{50} 80 mg/kg	Low.
1950's	do	do	Do.
1960's	do	do	Do.
1970's	Radioimmunoassay	About 0.5 ppb	High.
Carbamates:			
1940's			
1950's, 1960's	Thin layer chromatography, gas chromatography.	50-100 ng	Moderate.
1970's	Gas chromatography	About 1 ng	High.
Organophosphates:			
1940's			
1950's			
1960's	Gas chromatography	About 40 pg	Moderate.
1970's	do	do	High.

Next, Table II shows the capability of some assays that are currently being used to measure trace contaminants in food. Although the assays have not been evaluated by all the specific criteria proposed by the regulation, they are useful regulatory tools; and the lowest limits of reliable measurement for these assays (which were principally developed by the government for monitoring purposes) illustrate the forefront of current analytical chemistry.

TABLE II.—*Some Assays for Trace Contaminants in Food That Reflect Current Analytical Capabilities*

Substance under assay	Food	Limit of measurement [1]	Detection and confirmatory techniques	Reference [2]
Cadmium, copper, and lead	Several types	5	Anodic stripping voltammetry [3].	Jones, et al. (1977).
N-Nitrosamines	Several types including meat.	10	Gas-liquid chromatography (GLC); mass spectrometry (MS).	Fazio, et al. (1971); Fine, et al. (1975).
Aflatoxins, B1, B2, G1, G12	Peanut butter	5.0 [4]	High pressure liquid chromatography; fluorescence detector.	Pansalkate and Scott (1977).
Benzo(a)pyrene	Smoked foods	3	Thin layer chromatography [5] (TLC) ultraviolet and fluorescence detection.	Howard, et al. (1966).
Aflatoxin M1	Milk	0.1	TLC-fluorescence detection [6] chemical derivation.	Official Methods of Analysis of the AOAC.
Aflatoxin B1, B2, G1, G2	Peanut butter	5.0	TLC-fluorescence detection [6].	Official Methods of Analysis of the AOAC.
	Corn		TLC chemical derivation	Official Methods of Analysis of the AOAC.
Aflatoxin B1	Eggs	0.1	TLC-flourescence detection; chemical derivation.	Neaheim, et al. (1978).
Arsenic, selenium, antimony, and tellurium.	Several foods	10 to 30	Atomic absorption; spectrometry; chemical derivation.	Florino, et al. (1976).

TABLE II.—*Some Assays for Trace Contaminants in Food That Reflect Current Analytical Capabilities*—Continued

Substance under assay	Food	Limit of measurement [1]	Detection and confirmatory techniques	Reference [2]
Several chlorinated pesticides	Several foods	30 to 50	GLC-2 different	Official Methods of Analysis of the AOAC.
Tetrachlorodibenzodioxin	Fat, milk, others.	.0001 to .010.	Chromatography resolution MS probe).	high (direct O'Keefe, et al. (1975); Hummell, P. A. (1977).

[1] Parts per billion.
[2] References available from: John Arnold, Industry Information (HFV-228), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.
[3] Found reliable in interlaboratory validation study.
[4] Sum of all four compounds.

In view of these trends, the Commissioner has examined the general analytical requirements that these regulations will place on animal drug sponsors. Table III below shows the acceptable total level of residues in the diet for representative compounds believed to be carcinogens. These estimated acceptable total dietary levels are derived from bioassay data on the parent compounds alone. The lowest limits of reliable measurement for these compounds that would be required if the compounds were subject to the proposed regulation cannot be calculated in the absence of metabolism data in animals in which a sponsored compound is proposed or intended for use (target aminals). Nevertheless, the values do approximate the limits of measurement that would be required by the regulations and are therefore suitable for comparison with the current analytical capabilities that are shown in Tables I and II. It should be noted that for some compounds the lowest limit of reliable measurement derived from toxicity data may go beyond current analytical capabilities; that it may, however, reflects the technology-forcing aspects of the proposed regulation.

TABLE III.—*Estimated Acceptable Total Dietary Levels of Several Known or Suspected Carcinogens for a Lifetime Risk Level of 1 in 1 Million*

Compound	Reference [1]	Dose [2]
DDT	Tomatis, et al. (1972)	.4
Dimethylnitrosamine	Terracini, et al. (1967)	.06
Ethylene Thiourea	Graham, et al.	2.0
NTA	National Cancer Institute Clearinghouse on Carcinogenesis.	360.0
Vinyl chloride	Maltoni (1975)	6.7

[1] Available from John Arnold, Industry Information (HFV-226), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.
[2] Calculated according to Hoel, et al. (1975) (Ref. 65). (In parts per billion.)

The Commissioner concludes that given the known trends in the development of improved analytical methodology the imposed requirements are attainable at the expense of reasonable effort.

The goal of regulating compounds that are to be used in food-producing animals is to ensure that none is permitted to yield residues in edible tissues at concentrations presenting a risk of carcinogenesis above an acceptable level. This acceptable level of maximum allowable risk (see section V. C. 8 in this preamble) is applied to all carcinogens; thus, equitable treatment of all such substances is afforded by these regulatory requirements. Different carcinogens will require different assay capabilities because of differences in carcinogenic potency. The regulations are designed to require that the lowest limit of measurement of an assay be commensurate with a compound's carcinogenic potency. Because it is not possible to specify the required limits of measurement for carcinogens in the absence of animal bioassay data, it is not possible to ensure in advance that all compounds for which approval is sought in the future will be able to be used in ways that satisfy the requirements of the regulations. It may be that some substances present health risks so great that there is no current technology available that can permit their safe use. In these instances the Delaney clause (including the proviso) requires that the Commissioner not relax health standards in order to approve such substances.

From the information described above, the Commissioner believes that analytical science can meet these regulatory requirements. The Commissioner is not aware of any data to the contrary. Based on this review, the Commissioner has concluded that compliance with the proposed regulations is feasible, although some technological innovation may be necessary.

Questions have arisen about the practicality, efficiency, and overall public protection afforded by automatically adopting new assays that reliably measure lower levels of residues is such assays becomes available after a sponsored compound has been approved for use. In the February notice the Commissioner suggested that this problem is largely theoretical once an assay meeting the minimum criteria is approved. The decision to approve an assay for a sponsored compound under these principles represents the agency's conclusion that the compound has been shown to meet all the statutory requirements of safety. Accordingly, once assay methods have been approved, new methods will not be required wthout new toxicological data showing that the lowest limit of reliable measurement of residues under these regulations is inappropriate.

It is true that these proposed regulations will permit the approval, for use in animals feed or for use as animal drugs, of carcinogenic compounds that are likely to leave residues below the lowest level of reliable measuremnt of any assay meeting all the criteria of the regulation. Indeed, as a result of Congress' enacting the DES proviso, the agency will not have any certainty that these residues, in amounts below the level of detectability, are not always present. This result makes sense in practical terms, however, for a regulatory agency cannot effectively control residues—of any compound—that are so small that they escape measurement by every available assay. In sum, the interpretation adopted in these proposed regulations is reconcilable with both the purpose and language of the DES proviso. This interpretation will further the congressional objective of minimizing public exposure to residues of carcinogenic compounds. It does not force technology beyond the point that needs to be reached to carry out the purpose of the Delaney clause and the general safety provisions. It does not impose infeasible requirements or costs except to the extent that they are necessary to carry out that purpose.

C. OVERVIEW OF THE REGULATIONS

The proviso to the anticancer clauses allows the approval of the use of carcinogens in food-producing animals if, under conditions of use "reasonably certain to be followed in practice," no residue is found by an assay prescribed or approved by the Secretary. To ensure public protection consistent with the anticancer and the general safety provisions of the act, the Commissioner must establish criteria for approving assays to include, among other things, an adequate lowest limit of measurement.

Accordingly, these proposed regulations would establish criteria for accepting assays used to measure residues of carcinogens in edible tissues of food-producing animals to which carcinogens have been administered. Such criteria cover assay attributes such as dependability, practicability, specificity, accuracy, and precision. Also, the regulations would establish a specific criterion for the lowest limit of reliable measurement that an assay must meet, as a minimum, before it can be approved by the agency for control of carcinogenic residues. This criterion for the required lowest limit of measurement of an assay derives from toxicological data obtained from carcinogenicity studies and from an operational definition of the no-residue standard of the act. Only if an assay meeting the above criteria is available would the Commissioner have a mechanism to discriminate be-

01180

tween tissue containing a residue and tissue containing no residue. Without such a monitoring mechanism, the Commissioner would have no way to detemine whether a carcinogenic drug or additive administered to a food-producing animal is being or even can be used in compliance with the act.

In these regulations the Commissioner proposes to establish a rigorous premarket testing process for sponsored compounds intended for use in food-producing animals. As proposed, all sponsored compounds must initially undergo a threshold assessment for carcinogenic potential. For those sponsored compounds having a carcinogenic potential, a procedure is prescribed to determine the minimally acceptable lowest limit of reliable measurement for a regulatory assay. Because this limit is determined on the basis of toxicity data, the Commissioner may conclude that an assay satisfying the requirements of the regulations is capable of demonstrating the absence in food of residues that present a risk of cancer to man. By thus particularizing the statutory requirements, the Commissioner proposes to establish the basis for accepting or rejecting compounds which the sponsor claims satisfy the no-residue standards.

1. *Fundamental questions.* For every drug of additive proposed for use in food-producing animals (the sponsored compound), the Commissioner is required by the act to determine whether that sponsored compound can be used in ways that are safe for the animals to which the compound will be administered (target animals) and whether food (meat, milk, and eggs) derived from such animals (edible tissues) will be safe for human consumption. The sponsor of the compound is therefore required to furnish the Commissioner the scientific and technical information necessary for that determination; the Commissioner in turn is required by the act to determine on the basis of all available data whether, in actual practice, the sponsored compound can be used in compliance with the law.

Although a petitioner proposing to use a carcinogenic compound in food-producing animals has a major obligation to develop a practical and reliable assay capable of discriminating tissues that contain residues from tissues free of such residues, as defined operationally, such an assay cannot be developed without certain scientific and technical information.

Specifically, for every sponsored compound, several questions must be answered before an assay can be developed or approval of the compound considered:

a. What is the chemical nature of the sponsored compound and how is it to be used?

b. Based on preliminary toxicological and biochemical information, does the compound have the potential to contaminate human food (edible tissues) with residues of carcinogenic concern?

c. If so, what is the chemical nature of the residues of the compound? In what tissues are they found? at what levels? and for what length of time?

d. Is the sponsored compound or any of the residues it produces in edible tissue carcinogenic in experimental animals or man?

e. If so, what level of residues can be operationally defined as satisfying the no-residue requirement of the act?

f. Can a reliable and practical assay be developed to measure the edible tissue residues at levels equal to or greater than those which operationally satisfy the no-residue requirement of the act?

g. At what time after exposure to the compound ceases do the edible tissues of exposed food-producing animals satisfy the no-residue requirement of the act, i.e., what is the necessary withdrawal time?

2. *Date collection process.* To answer the preceding questions, a petitioner must gather pertinent scientific information, the nature of which is particularized in this document. These proposed regulations would establish the procedure for gathering and evaluating the requisite scientific information. The process is stepwise and evolutionary because the need, as well as ability, to proceed to the next step of data collection depends upon the results obtained at each preceding step. If the evaluation of the data collected at each step indicates that questions on residues of carcinogenic concern remain, data collection must continue. If at some point in the data collection process it can be decided that the sponsored compound presents no human risk of carcinogenesis, the sponsored compound must be evaluated for any other health concerns under the general safety provisions of the act. In this case, the compound may be assigned a safe tolerance level in human food if the petitioner provides the data necessary to establish that the compound can be used safely.

These proposed regulations deal with carcinogenesis, which is a dominant concern in appraising the safety of any sponsored compound intended for use in food-producing animals. Nevertheless, each compound must also be evaluated for other potential adverse effects. Thus, for example, if the available information raises an issue as to the health of progeny, multigeneration studies of the sponsored compound and/or its residues must be codesigned and conducted as part of the process of collection and evaluation of data.

Under this proposal, if the Commissioner makes a threshold determination that a sponsored compound has the potential to contaminate food from food-producing animals with residues whose consumption would pose a human risk of carcinogenesis, the petitioner will be required to undertake the following six-step procedure for data collection and evaluation.

a. A metabolic study in the target animals designed to identify edible tissue residues of carcinogenic concern.

b. Metabolic studies of the sponsored compound in different species/strains of experimental animals designed to aid in selecting the test animal species to be used in chronic toxicity bioassays and in assessing the carcinogenicity of residues that cannot practicably be tested individually ("intractable residues").

c. Chronic toxicity testing to assess the carcinogenic potential of residues of the sponsored compound and to furnish data suitable for statistical treatment so that the no-residue requirement of the act can be applied and implemented.

d. A detailed metabolic study of the sponsored compound in target animals designed to identify both a residue and tissue that can serve as indicators ("marker residue" and "target tissue") to determine whether the no-residue requirement of the act is satisfied.

e. Development of a regulatory assay to measure the marker residue in the target tissue at and above the level established in step d.

f. Establishment of the premarketing withdrawal period required for the safe use of the sponsored compound.

Although the particular provisos to the anticancer clauses of the act, sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B), vary slightly in their language, they have a common purpose. Therefore, the Commissioner believes that the criteria for their implementation should be identical. To avoid needless repetition, the Commissioner has used the language of section 512 of the act in discussing specific generic issues because the primary impact of these proposed regulations would be on new animal drugs regulated under that statute. The criteria set forth in this proposal would, however, apply to all chemicals intended for use in food-producing animals, and the appropriate regulations would be amended to adopt these criteria by reference.

II. Threshold Assessment

In the 1973 notice of proposed rulemaking, the Commissioner proposed that carcinogenicity testing not be required for every sponsored compound. Rather, the Commissioner concluded that the necessity for such testing will be dictated by an evaluation of the ex-

01181

isting evidence from metabolic studies, toxicity testing, structural relationships of the sponsored compound and its metabolites to known carcinogens, modes of physiological actions and interactions, and the intended method of use of the sponsored compound.

Comments of two types were received on this feature of the proposal. The first suggested that extensive studies should be conducted from every sponsored compound to determine whether it is a carcinogen. One comment insisted that extensive carcinogenesis testing for every sponsored compound is the only accurate indicator of carcinogenic potential. Several contended that the criteria proposed for use in the threshold assessment were too vague, and objected to the failure to explain how such criteria could be applied in practice. Many other comments agreed with the Commissioner's proposal that extensive carcinogencity testing should not be required for every sponsored compound. These comments recommended that the Commissioner review all available data on a sponsored compound before concluding that the stepwise testing procedure set forth in the proposals should be invoked. Comments of a similar nature were received on the 1977 notice. Furthermore, several comments asserted that the guidelines for the threshold assessment were not specific enough.

The Commissioner agrees that the guidelines for the threshold assessment were insufficiently specific, and the following discussion elaborates the agency's guidelines for conducting threshold assessments.

For every compound intended for use in food-producing animals, the fundamental question to be answered is: "What is the potential that the proposed use of the sponsored compound will contaminate the edible tissue of target animals with residues that engender a risk of cancer to humans?"

When a sponsor starts the process of obtaining approval for use of a compound, it provides to the agency information on matters such as the compound effectiveness and its proposed patterns of use. Often a sponsor will also provide preliminary physiological, metabolic, or toxicological data derived from its own studies or from the scientific literature. At this juncture, the Commissioner believes it necessary that a threshold assessment be made, based on the available data, on the need to proceed to the first of the six steps of data collection required by these proposed regulations. Because entry into the six steps of data collection requires that a petitioner undertake a series of complex and costly experimental studies, the Commissioner concludes that it is not reasonable to demand such studies on a sponsored compound if the preliminary data available justify the determination that public health can be protected without so proceeding.

For the sake of clarity, "the total residue of the sponsored compound" and "residue of toxicological concern" are defined in proposed § 500.83 as follows:

> "The total residue of a sponsored compound" means all compounds present in edible tissues of target animals that result from the use of the sponsored compound, including the sponsored compound, its metabolites, conversion products, and any other substances formed in or on food because of the sponsored compound's use. (The term "residue" means any single compound present among the total residue.)
>
> "Residue of toxicological concern" means the total residue minus any constituent residue shown to be safe.

A. GENERAL PRINCIPLES

The threshold assessment is based on the principle that the probability that the use of a sponsored compound will yield edible food animal tissue presenting a risk of human carcinogenesis from residue is the product of the following three factors:

(1) The probability of human exposure to residues that may cause cancer, given the proposed pattern of the sponsored compound's use (Factor 1—Use);

(2) The expected average level or concentration of residues of toxicological concern in the edible tissue of treated target animals under the proposed conditions of use, i.e., when the animals have the potential for marketing as food (Factor 2—Residues of toxicological concern); and

(3) The probable toxicological significance of the residues, based on an assessment of the chemical structure of the sponsored compound, its likely metabolites, and other information suitable for predicting toxicity (Factor 3—Potential toxicological significance).

The threshold assessment functions on the premise that all three of these factors must be considered to answer the fundamental safety question posed above. Under the agency's threshold assessment approach, numerical scores are assigned to the sponsored compound, and each of the three scoring factors contributes to the total score. The following paragraphs describe the scoring system and procedures that can be used to collect data that may lead to information yielding the most reliable scores. By consulting this guideline, sponsors of compounds can assess the status of the sponsored compounds for which they seek approval and may therefore provide relevant and useful preliminary data.

The scoring system uses a value of 1,000 to discriminate between those compounds that will be regulated solely according to the general food safety requirements of the act and those compounds that will, in addition, be subject to this proposed regulation. This system will provide uniformity to the threshold assessment of the risk to the public health from a sponsored compound's residues.

When the only preliminary information available is the proposed pattern of use (factor 1 above), the sponsored compounds will be subject to step 1 of the proposed regulations (§ 500.80(b)(1)(i)). Since without the necessary information FDA must make assumptions that require entry into step 1, petitioners have an incentive to gather pertinent information before approaching FDA.

This decision may be altered or confirmed by subsequent collection of data under these proposed regulations or under the other aspects of the general safety provisions of the act. For example, data collected to satisfy other concerns also covered in the general safety provisions may show that the compound is a potential carcinogen. In that case the compound will be evaluated under these proposed regulations. The obverse is also true.

B. THE SCORING SYSTEM

The total threshold assessment score for a sponsored compound is the product of the values for the three assessment factors.

1. *Factor 1—Use.* The use classification of sponsored compounds is divided into three categories, based on the frequency and extent of the target animal's treatment with the sponsored compound. The use factor is the probability that potentially consumable target animals will be treated with the sponsored compound. (See Table IV.) The values in Table IV represent ratios that approximate the likelihood of human exposure from the proposed use patterns in animals.

TABLE IV.—USE FACTOR ASSESSMENT

Frequency and scope of target animal treatment	Score
Administration to individual animals to prevent or treat disease	1
Administration on a herd-wide or flock basis for disease treatment or specific disease prevention (for problem herds or when outbreak of disease has occurred)	10
Administration on a herd-wide or flock basis for production improvement or general disease prevention (e.g., coccidiosis)	100

2. *Factor 2—Residues of toxicological concern.* For this scoring factor, the agency assigns the number equal to the concentration in parts per billion of the total residue of toxicological concern occurring in the edible tissue that is the most efficient accumulator of residues in the target animals at the earliest time the animals

01182

are expected to be marketable as food. Without total residue data, the sponsored compound will automatically be required to proceed to step 1 in proposed § 500.80(b)(1)(i).

Lacking information on the composition of the total residue in the edible tissues, the agency must assume that the total residue is of toxicological concern. The score value may be lowered if the sponsor gathers information on the composition of the total residue. For example, a sponsor may demonstrate that a portion of the total residue is a compound for which adequate studies have already been conducted to show that its presence as a residue is not of human health concern.

3. *Factor 3—Potential toxicological significance.* The values for scoring factor 3 reflect the agency's concern that the residues resulting from use of the sponsored compound are likely to cause cancer. The value will be obtained by taking into account available information concerning the potential toxicological activity of the residues themselves or of structurally related compounds, and compounds related by common physiological activity. The Commissioner recognizes that structure/activity relationships and the short-term biological tests discussed later have not been sufficiently developed to permit definitive predictions of carcinogenic activity (Refs. 13, 14, and 15). Nevertheless, the Commissioner believes that they can make a contribution to the threshold assessment.

In the following paragraphs, three sources of information on the basis of which the third factor is scored are discussed: (a) Structure/activity relations; (b) short-term screening tests for carcinogenic potential; and (c) other biological, physiological, and pharmacological data.

The possible values for scoring factor 3 are 1, 10, and 100. A score of 100 is assigned if there is evidence from any of the three sources of information that raises a suspicion that the residue is carcinogenic. A score of 10 is assigned if short-term screening tests for carcinogenic potential have not been conducted and there is no basis for suspecting carcinogenic activity based on the other sources of data.

A score of 1 is assigned when a battery of short-term screening tests for carcinogenic potential has been conducted, when the results show no reason to suspect carcinogenesis, and when there is no suspicion of a carcinogenic potential raised by the other information sources.

(a) Structure/activity assessment: FDA maintains a list of structural characteristics that can be used as a guide in initially determining when, based on structure alone, there may be concern about carcinogenic potential. The list includes all structural types for which one or more compounds have been shown to produce cancer in animals or man. Specific functional groups, e.g., aromatic nuclei, are included where there is evidence that these groups are the dominant influence in carcinogenic potential (Ref. 16).

Because new information is rapidly gathering in this area, the Commissioner expects the FDA list to be updated frequently and recognizes that this list is not exhaustive. An FDA committee on structure/activity relationships will provide an in-depth evaluation of substances with structural features found on the list before a final score is assigned.

(b) Screening tests for carcinogens: Evidence about the validity and utility of short-term in vitro tests as tools for regulating chemicals is growing rapidly. The Commissioner has concluded, however, that they cannot be used as the principal tool in assessing the safety of a compound. An appropriate battery of such tests can provide useful but not conclusive information about the safety of chemicals quickly, and at a reasonable cost. For these reasons, the Commissioner has included this section in the preamble as a guide to using these tests.

Currently, an appropriate battery of short-term tests includes both mammalian and nonmammalian test systems. The battery should test the ability of a sponsored compound to induce point mutations in two test systems that have been demonstrated to have a high correlation between detected mutagens and positive results in in vivo carcinogenesis bioassays. Systems that have shown this correlation include (1) point mutations in bacteria, (2) point mutations in the X-linked recessive lethal test in Drosophila, and (3) point mutations in mammalian cells in culture. Unscheduled DNA repair synthesis in mammalian cells in culture should also be included in the battery.

There is extensive literature correlating results in bacterial mutagenicity tests and carcinogenicity as determined by chronic toxicity studies (Refs. 17 through 20). This correlation is not perfect, and certain classes of carcinogens cannot be detected in mutagenicity assays.

The published data on mutations and DNA repair in eukaryotic cells are not as extensive as data concerning the Ames bacterial mutagenesis tests. The tests in mammalian cells appear to complement those in bacterial cells for the correlation of mutagenicity and carcinogenicity (Ref. 21). Testing in other systems is particularly important when the chemical is toxic to bacteria, as are many animal drugs, especially antibiotics. This toxicity will often make it impossible to test the chemical at a sufficiently high dose for negative results in bacterial tests to be meaningful.

All short-term tests for carcinogenicity should be performed separately in the presence, and in the absence, of a metabolic activation system, generally derived from rodent liver or the liver, or other relevant tissue, of the target animal. When appropriate, metabolites should be treated with glucuronidase and aryl sulfatase before testing.

Due to the rapid advances being made in the field (Refs. 22 through 34), it would be inappropriate for this proposal to prescribe or recommend detailed protocols for each general type of test. At the present time the most reliable, perhaps the best, results are obtained with the plate incorporation assay described by Ames (Ref. 22).

Application of the screening tests for scoring factor 3 requires some knowledge about the composition of the total residue to determine which residues should be subjected to the complete battery of tests. Although the sponsored compound should always be subjected to the complete battery of tests, for some or all metabolites it may sometimes suffice to perform less extensive testing, e.g., bacterial testing only. The sponsor should explain the reasons for selecting certain metabolites for testing and the reasons for not testing others. Similarly, use of an incomplete battery of tests should be explained. Factors such as structure and residue concentration in tissue should be addressed. In addition, a reduction in testing for any major metabolites should be justified based on factors such as the structural relationship to more exensively tested compounds.

Because of evidence that some structural classes of carcinogens may not yield a positive response in the short-term tests, there will be cases when results from such tests cannot be accepted.

(c) Other biological and pharmacological data: The sponsor should provide the results of a literature search on the sponsored compound and postulated metabolites. This search should also include relevant information on biological activity of structurally related compounds, particularly when very little information is available on the sponsored compound. The sponsor should also include and discuss any relevant information on the pharmacologic and physiologic activity, such as studies that may provide clues regarding the mode of action and expected toxicity. Frequently, in support of the investigational use for the chemical, the sponsor will have gathered some information on pharmacolo-

01183

gic and physiologic activity and will also have developed subchronic test data in experimental animals, e.g., 90-day rodent and nonrodent studies. The data must be submitted for incorporation in the threshold assessment.

The foregoing types of information will be analyzed in the threshold assessment to identify any evidence suggesting that the sponsored compound or its expected metabolites is carcinogenic. This evidence will include findings of hyperplasia or of an abnormal proliferation of any type of cells. These findings lead to a suspicion of carcinogenic potential because such changes have frequently been shown to progress to cancer in studies of longer duration. Also, suspicion is raised by evidence of liver or kidney necrosis and evidence of the formation of regenerative nodules. Certain endometrial changes may also be indicative of possible preneoplastic effects (Ref. 35).

Other examples of biological information raising a suspicion of carcinogenic potential of a compound or its metabolites are binding to cellular nucleophiles, or an indication of the alteration of nucleic acid. Estrogenic compounds will be considered to be suspect carcinogens. Any compound that has the ability to disturb normal hormonal balance, a fact that may be known from pharmacologic studies, or that may be suspected from the organ effects observed in short-term toxicity studies, will be of carcinogenic concern.

4. *Scoring system and the threshold decision.* After the threshold assessment has been completed, each compound is assigned a scoring number that is determined by multiplying score factor 1 (use) times score factor 2 (amount of the residue) times score factor 3 (structure/biological activity). A compound with a score number above 1,000 raises enough concern about the potential contamination of food with carcinogenic residues that is must at least enter the first step of data collection specified by the regulations. The data collection process for a sponsored compound receiving a score equal to or less than 1,000 begins in accordance with the requirements (for risks other than cancer of the general safety provisions of the act. If, at any time after this data collection process begins, the data show that the risk of cancer is greater than that indicated by the threshold assessment score, the sponsored compound will become subject to these regulations.

Table V below shows the maximum concentrations of total residues of toxicological concern that could be found in the most efficient accumulator among the edible tissues and the corresponding scores of factors 1 and 3 that together would permit a sponsored compound to be exempt from the requirements of the regulation.

TABLE V—THRESHOLD ASSESSMENT*

Use (factor 1)	Residue maximum (factor 2) parts per billion	Structure/ biological activity (factor 3)
1	1,000	1
1	100	10
1	10	100
10	100	1
10	10	10
10	1	100
100	10	1
100	1	10
100	0.1	100

*Maximum concentration of total residue of toxicological concern that could be found in the most efficient accumulator among the edible tissues and the corresponding score of factors 1 and 3 that would permit sponsored compounds to be exempted from the regulations.

III. METABOLIC STUDY IN TARGET ANIMALS TO IDENTIFY RESIDUES OF CONCERN

A. NEED TO IDENTIFY RESIDUES IN EDIBLE TISSUES

Before any decision can be made concerning conditions of safe use of a sponsored compound, it is necessary to obtain information on the residues that occur in edible tissues when the compound is administered to the animals for which it is intended (target animals). Without such information, informed decisions about human safety regarding edible tissues derived form treated animals are not possible.

A substance administered to target animals is not necessarily the substance consumed by persons who eat the edible products of target animals. The enzymatic system or physiological fluids of an animal can act upon a compound administered to the animal and produce new compounds in the process (metabolites and degradation products of the sponsored compound). Therefore, the sponsored compound is not the only tissue residue of concern. Sections 512(b)(7) and 512(d)(2) of the act explicitly provide that, before approving its use, the Commissioner must consider the safety of any substance formed in or on food by a sponsored compound. The toxicity of substances derived from a sponsored compound (metabolites and degradation products) is not necessarily of the same magnitude and type as the toxicity of the parent compound, i.e., some metabolites may be considerable more toxic and some considerably less toxic (Refs. 36, 37, 38). Moreover, metabolites of the sponsored compound that were at one time considered "detoxification" products of the target animals (e.g., glutathione conjugates, mercapturic acid conjugates, and sulfates) actually may represent a hazard when consumed by humans (Ref. 38).

Numerous comments were received on the requirements of the 1973 and 1977 notices for metabolic studies. Several comments stated that no attention should be paid to metabolites. Other contended that metabolism studies should not be routinely required, on the ground that the pathway of excretion is of no toxicological importance if all the administered compound has been eliminated from the tissues of the target animal. Most comments recommended that a metabolism study be required only to determine the major metabolites in the edible tissue of target animals; they suggested that the public health would not be served if sponsors were required to pursue endless structural elucidations and quantitations of all metabolites even though some of them might constitute minor fractions of the total residue of the sponsored compound. Comments also contended that it may not be experimentally possible to administer to animals sufficient quantities of a compound to obtain adequate amounts of residues for structural identification. Several comments asserted that studies should be limited to identification of residues in the edible tissues of target animals and that generally it would be unnecessary to have this information on metabolites in inedible tissues. Further, some comments stated that radiotracer studies can be employed to determine the time by which the sponsored compound and its metabolic products are eliminated ("out time"). However, many other comments suggested that all metabolites be identified and tested for toxicity.

The Commission reiterates that metabolic studies are necessary to assure that sufficient information on residues is collected to permit a food safety evaluation, which in turn can be used to establish criteria for regulatory assays. Therefore, the Commissioner has concluded that the metabolic studies discussed below in this preamble are necessary to determine whether the proposed use of a sponsored compound is safe. Also rejected are the arguments that the agency can consider, under the Delaney clause, only the carcinogenic potential of the sponsored (parent) compound. The Commissioner concludes that industry argument that metabolites of the sponsored compound are excluded from regulation under the Delaney clause and covered only by the general safety provisions of the act rests on a strained reading of the act, which ignores the language and purpose of the Delaney clause. A substance may properly be said to induce cancer when it or any substance which it may become through metabolism induces cancer. Consequently, in determining whether a substance induces cancer, it is appro-

01184

priate—and in accordance with the congressional purpose of protecting the human food supply from added carcinogens—to examine metabolites as well as parent compounds.

Further, even if the Delaney clause were inapplicable to metabolites, the general safety standard would still apply, i.e., it imposes the same requirements that the Delaney clause imposes. So even if the industry argument were correct, it would not change the regulatory outcome. Nevertheless, the industry argument also illustrates that the general safety provisions encompass the anticancer clauses of the act. Assessment of a compound's safety requires a comprehensive examination of the sponsored compound and all of its metabolites and breakdown products. To the extent that the language in § 514.1 (21 CFR 514.1) implies a different view, the Commissioner is proposing to reword that regulation to correct any possible misunderstanding.

B. CONDUCT OF METABOLIC STUDY

1. *Test animals.* The metabolic fate of an administered compound in an animal may be unique for each livestock production class. Therefore, the Commissioner concludes that a metabolic study in the animals for which a sponsored compound is intended (target animals) is necessary. If the petitioner can demonstrate that the data from the metabolic study obtained for one production class are applicable to a second, the Commissioner may modify the extent of the investigation required for the latter.

2. *Required technology.* The metabolic fate of a compound administered to food-producing animals is pivotal in determining the need for and extent of carcinogenesis testing. It is mandatory that the metabolic fate be adequately determined. It is necessary that residues of potential carcinogenic significance have been detected at levels obtainable by the best analytical technology available. Therefore, the Commissioner concludes that the required metabolic studies must be conducted with the best analytical methods that technology provides.

As set forth in part VI of this preamble, one residue must be selected to serve as a practical indicator to assure that the "no-residue" standard of the act is met. This residue can be selected only by reference to a metabolic study in which residues are detected and measured at levels dictated by the outcome of actual carcinogenicity testing. Because these levels cannot be known at the outset of this phase of the metabolic study in target animals and because the "best available technology" may not be adequate to measure the levels dictated by the outcome of carcinogenicity testing, it may be necessary to develop improved technology and to repeat the metabolic study in target animals after carcinogenicity testing has been completed. Another requirement of the second metabolic study will be the collection of enough data to construct tissue concentration-time profiles for some residues.

3. *Analytical techniques.* For the foreseeable future, the general technique of choice for metabolic studies will be the use of radiotracers. The proposed regulations, therefore, consistent with principles that assure scientific quality, recommend that the required metabolic studies be conducted with radiolabeled compounds of the highest specific activity available. These principles concern the types, the chemical nature, the chemical and metabolic stability, and the suitability of radiolabels for metabolic studies having specific objectives. The principles have been developed from past metabolic studies with radiotracers, and adherence to them ensures the scientific quality of the required metabolic studies (Refs. 39 and 40).

The task of residue detection can often be made easier by available information on the metabolism of related compounds. It is recommended that proposed metabolic pathways which appear applicable to the sponsored compound be based on relevant literature references about compounds of similar structure. This information can usually simplify the choice of radiolabel positions, which will ensure that all residues containing structural moieties of potential toxicological concern can be detected. However, these projections of likely metabolism can never be a substitute for experimental observation of the metabolic fate of the sponsored compound.

Although use of radiotracers is the preferred experimental procedure, some compounds possess inherent physicochemical characteristics (e.g., strong fluorescence associated with the structural moiety of potential toxicological significance) that will allow the necessary detection of residues. In such cases, the use of radiolabels may not be required.

4. *Dose regimen.* The dosing regimen for the metabolic study in the target animals must be consistent with the maximum proposed use level and duration of exposure to the sponsored compound. For compounds administered continuously over long periods of time, administration for the metabolic study need continue only until equilibration or saturation of edible tissues has been demonstrated. If tissue equilibration cannot be shown, the sponsor must show that the pattern of residues has stabilized.

The metabolic fate of a compound administered to target animals is likely to depend on the conditions (level, method, and duration) of use (Refs. 41 and 42). Because the purpose of the required metabolic studies is to characterize and quantitate residues under conditions of proposed use, these conditions must be followed in the metabolic studies. However, it is possible that under these conditions certain residues are produced in amounts that do not allow extensive chemical characterization. If the structure of any such residues must be determined, and if sufficient amounts of residues can be produced by administering larger doses of the sponsored compound to target animals, the petitioner would be allowed to follow this procedure. In some instances, chemical synthesis of residues may be easier.

5. *Required data.* Because the relative persistence of residues in edible tissues (i.e., the likelihood that residues will be found in edible tissue) is one consideration in selecting specific residues for toxicity testing, the proposed regulations require that the total number and the relative quantities of residues be determined immediately following cessation of treatment, as well as at a sufficient number of intervals after the initial measurement to determine the depletion trend of individual residues. The number of these measurements needed to identify depletion trends depends upon the kinetics of depletion of the sponsored compound, and for this reason the complete extent of data collection cannot be specified in advance.

The need for, and extent of, chemical characterization of residues depends on a number of factors. Ordinarily, compounds constituting a significant fraction of the total residue require sufficient physical and chemical characterization to permit a determination of whether or not a structural change has taken place that could increase the carcinogenic potency of the residue over that expected of the sponsored compound, e.g., formation of epoxides from olefins, N-hydroxylation of aromatic amines, cyclization of hydroxyacids to suspect lactones (Refs. 14 and 15). In some instances, it may be impossible to judge whether the residue has carcinogenic potential, but sufficient structural alteration alone may be enough to establish the need for further characterization. Because these structural changes are common during metabolism and because it is the tissue residues to which human beings potentially will be exposed, this characterization will normally be required. When the agency determines that a component of the residue requires chronic toxicity testing (because of tissue concentration and persistence and/or expectation of increased carcinogenic potential), chemical characterization and an effort to obtain sufficient quantities of

01185

the residue(s) for toxicity testing will be necessary. (See, however, section III.C., below.)

Residues that appear to become "bound" to tissue components (i.e., those whose rate of depletion appears to be no greater than the turnover rates of tissue components) cannot be automatically exempted from the requirements of the regulation. These residues may be hazardous to humans ingesting edible tissues. The residues can be identified by a variety of standard techniques (Refs. 44, 45, and 46). Of course, any such residue will be exempt from the regulation's requirements if it can be shown that it is a normal tissue constituent deriving from a metabolite of the sponsored compound that has entered normal pathways of intermediary metabolism of target animals (Ref. 43).

In some instances, a sponsor may be required to pursue the complete characterization of certain relatively minor metabolites if partial physiochemical characterization indicates that a structural change during metabolism in the target animal has introduced molecular moieties of carcinogenic potential greater than that expected of the sponsored compound, e.g., nitrosation of an amine of unknown carcinogenic potential to produce nitrosamines of known carcingenic potential (Refs. 14 and 47).

Because uncharacterized tissue residues may pose a risk to public health, the proposed regulation would require that the procedures for separation, purification, characterization, and identification be consistent with the best available scientific and technological capabilities. Ordinarily, the agency will require attempts at characterization to include use of a variety of procedures based on the various forms of chromatography, spectroscopy, and spectrometry.

Allegations have been made that the regulations impose unreasonable requirements (i.e., that the regulations require inordinately complex, and therefore costly, experimental procedures) and that the information to be gained from these tests is not worth the costs of gathering it. Both allegations either ignore the current state of these sciences or misunderstand the requirements of the proposed regulations. All the procedures described in the proposal are standard techniques that are widely used in basic biochemistry and pharmacology investigations. A few comments showed confusion about the requirements associated with the metabolite identification study. To correct any potential misunderstanding, the Commissioner has eliminated the earlier requirement that all residues of the sponsored compound be identified until the sponsored compound has been depleted for three half-lives in the target animals. A safety assessment requires information on the trends of residue depletion in the target animal's tissues. Therefore, the Commissioner proposes to substitute the requirement that residues be identified at sufficient intervals to permit determination of the trends of depletion of individual tissue residues.

6. *Format for data submission.* The Commissioner has concluded that the format for presenting results of metabolic studies should be standardized to minimize the possibility of misinterpreting the data. Because these studies will be the basis for major public health decisions, the Commissioner considers it essential that they be carried out and reported in keeping with the best available criteria. The two professional societies listed in the proposed regulations (American Chemical Society and American Society of Biological Chemists) follow policies for accepting manuscripts that embody the best available criteria for collecting, interpreting, and reporting scientific data of the type required by this regulation.

C. COMPARATIVE METABOLISM STUDY TO AID IN ASSESSING CARCINOGENICITY OF INTRACTABLE RESIDUES

1. *Sponsored compound always tested: rationale and procedure.* The sponsored compound itself must always be tested for carcinogenesis when it is determined on the basis of the threshold assessment and the initial metabolism study required by the regulation that a sponsored compound has the potential to contaminate edible tissues with residues whose consumption may pose a human risk of carcinogenesis. Even if the sponsored compound is not detected among the residues, there are compelling reasons for testing the sponsored compound in addition to testing any residues identified according to the criteria already discussed in section III.B above. Metabolic transformation or nonenzymatic degradation of a sponsored compound can lead to a number of tissue residues that cannot be obtained (either by isolation or synthesis) in sufficient amounts for carcinogenicity testing. (These residues are referred to in this document as "intractable residues".) Testing the sponsored compound itself, therefore, provides an experimental means for acquiring data bearing on the carcinogenic potential of such residues.

Although the dominant criterion for selecting test animal species or strains for chronic toxicity testing will be the degree to which a species or strain models man, applying a secondary criterion for selection can help to address the problem of intractable residues. Specifically selection of test animals can also be based on comparative metabolism data (target animal versus test animal). These data can be used to determine the extent to which particular species or strains, due to the way they metabolically convert the sponsored compound, will be exposed during testing to the same complement of residues to which man may be exposed in tissues derived from target animals.

For example, if a metabolite detected as a residue in edible tissues of the target animal is determined to be toxicologically important, the sponsor will be asked to isolate or synthesize the compound for purposes of toxicity testing. If all such attempts fail, then the comparative metabolism approach is available if a potential test animal species, when adminstered the sponsored compound, is shown to produce the same metabolite. There is thus some assurance that the toxicity test of the sponsored compound also provides an estimate of the toxicity of the intractable metabolite. Because human food could be contaminated with the intractable metabolite, this test is a practical approach to a complex and important issue.

This construct was included in the February 1977 notice in response to comments that either suggested that all metabolites ought to be ignored (which the Commissioner concludes is neither legally nor scientifically acceptable) or that all metabolites must be isolated and independently tested (which is not always possible, for technical reasons). Further, the Commissioner invited additional comment on this construct.

Comments on the use of comparative metabolism to deal with intractable residues addressed several points: the definition of "intractable residues," the criteria for determining whether a test species will produce the same complement of intractable residues as the target animals, the basis for treating tractable and intractable residues differently for chronic testing, and the potential use of "relay" toxicity testing.

One comment misinterpreted the definition of "intractable residues." It suggested that they are substances about which nothing is known. The regulation, however, proposes to define the term "intractable residues" as those that either cannot be isolated from biological material or cannot be synthesized for purposes of further testing. The experiments that will already have been conducted for determining the presence of intractable residues (e.g., chromatographic and spectroscopic experiments) will furnish considerable information about the physical and chemical characteristics of the residues. Accordingly, basic techniques of biochemistry and phar-

01186

macology can determine whether the test animal species will be exposed to the same complement of residues that appear in the target animals' tissues. These techniques will ordinarily supply enough information to make such an evaluation. Therefore, the Commissioner concludes that the comparative metabolism studies have merit for the purpose of dealing with intractable residues.

The Commissioner established a series of requirements that can be satisfied by different experimental techniques having varying degrees of rigor. To avoid multiple interpretations of the same set of experimental observations, the Commissioner concluded that there must be established an additional general requirement that the experimental technique with the greatest degree of rigor be the one used for metabolic studies, and the agency adopted the term "best available technology" to describe this requirement. Thus, if the nature of residues can be determined by ultraviolet spectroscopy (a method of very low specificity) or by mass spectrometry (a method of high specificity) the Commissioner will require the use of the mass spectrometric method.

The Commissioner rejects the suggestion that all compounds be treated as the intractable residues are. Animal bioassay of specific metabolites is the best method of determining potential for chronic toxicity, and the Commissioner would prefer to have all metabolites chronically tested. However, recognizing the limitations of organic synthesis, separation sciences, and facilities available to conduct long-term bioassays in animals, the Commissioner has settled for using comparative metabolism for safety assessment of those residues requiring the application of techniques beyond the bounds of the best available technology. Nevertheless, sponsors will be held to the task of conducting the best type of toxicity study for selected residues that are susceptible to identification and isolation, or synthesis, by the best available technology. Although deeming it essential that sponsors pursue those goals with the best science and technology available, the Commissioner recognizes that the somewhat less than ideal toxicity assessment rendered by the comparative metabolism approach is useful for intractable residues. This position is a reasonable balance between completely ignoring all intractable residues and requiring their pursuit in the absence of the necessary technology.

One comment suggested feeding to test animals the contaminated tissues from treated target animals to assess the safety of residues to which humans will be exposed ("relay" toxicity testing). The Commissioner rejects using relay testing because it has two important limitations. Practical animal testing is limited to a relatively small number of animals as surrogates for the entire human population, and the only way to overcome the known limitations of such bioassays is to feed the small number of animals levels of the test compounds that are far in excess of the levels of animal drug residues to which humans are expected to be exposed. Because tissues of animals do not contain residue levels sufficiently high to compensate for the known limitations of standard bioassays and because they therefore are not a suitable basis for evaluating the residue's carcinogenic potency, as that term is used in this notice, the Commissioner must reject the use of relay toxicity testing. Further, the direct use of tissues from treated animals as test material does not permit determining which, if any, specific residues are responsible for the observed effects and the contribution of the residues to the effects.

Data collected according to the procedures and criteria above will: (i) Establish the number of metabolities in target animals and in a number of species/strains of test animals; (ii) provide information about the chemical structure of these metabolities (the structure of some metabolities will be known completely although for others only partial information will be available); (iii) provide information about the persistence of these metabolities in tissues; and (iv) provide information about their mutagenic, cell transformation, or their DNA damage potentialities. This information will permit FDA to classify the residues into the tractable and intractable categories, to select from the category of tractable residues those that must be subjected to chronic toxicity testing, and to document this selction. Criteria for classifying residues into the tractable and intractable categories were discussed earlier. Criteria for selceting tractable residues for chronic toxicity testing will be discussed in turn below.

First, it is unnecessary to require that all tractable residues be subjected to chonic toxicity testing. Most often, judicious use of well-established biochemical knowledge will eliminate the need for such extensive testing. A good estimate of the carcinogenic potential of the sponsored compound and its metabolities can be obtained without testing each of the tractable metabolities.

Ordinarily, xenobiotics are metabolicly transformed by target animals, test animals, and man in sequences of enzyme-catalyzed reactions, with considerable interspecies similarities (Ref. 48). The described metabolic studies, especially the studies in comparative metabolism, will provide significant information about these reaction sequences and there interspecies similarities.

It is obviously unnecessary to subject to independent chronic toxicity testing intermediates in sequences that are reasonable expected to be similar in man and the selected species of test animals, and which also are residues in target animal tissues. Testing the leading substrate of each sequence will be sufficient. Tractable residues in target animals that are not produced by the selected test animal species must be tested independently in the absence of information that they are not carcinogenic.

Finally, to estimate reasonably the carcinogenic poetential of the sponsored compound and its metabolites in target animal tissues, one must eliminate the confounding effects of metabolites or sequences of biotransformation reactions unique to the chosen test animal species. These metabolities, if present, could be subjected to short-term tests (mutagenicity, cell transformation, or DNA repair) to assess their inherent potential to produce irreversible effects when in intimate contact with tissues and tissue components. Negative findings would eliminate these residues from further consideration as factors likely to confound the results of bioassays. Further, if these residues are known or expected to be common to the chosen test animals and man, negative findings would eliminate them from the residues of toxicological (in this instance carcinogenic) concern. On the other hand, a positive finding would be a clear indication that they are prime candidates as the causative agents of adverse findings in test animals.

2. *Selection of residues for chronic toxicity testing.* Based on all the studies described above, the Commissioner will select those residues, in addition to the sponsored compound, that require chronic toxicity testing.

IV. Chronic Toxicity Testing

The sponsored compound and any residues selected for testing must be subjected to oral, lifetime, dose-response studies in two of the test animal species strains selected under the criteria described in the foregoing paragraphs. The purpose of these studies is to determine whether the compounds under test are carcinogenic and, if so, to establish the lowest limit of reliable measurement that must be achieved by any regulatory assay for monitoring residues resulting from use of the sponsored compound.

Several comments on this feature dealt with testing chemical compounds for carcinogenic potential, and addressed two major issues: (i) The design of chronic studies, and (ii) the

01187

relevance of animal testing in evaluating human safety.

A. DESIGN OF CARCINOGENICITY STUDIES

Comments on the proposal and the notice expressed contrasting opinions on the design features of carcinogenicity studies with experimental animals. The comments specifically addressed: (i) Selection of appropriate test animals; (ii) conditions, levels, and duration of exposure; (iii) statistical design as it relates to number of animals assigned to the various levels of exposure; and (iv) the adequacy of controls.

The impact of these design features on interpreting animal carcinogenesis data is an important and controversial matter currently under intense scientific investigation. The major effort at FDA's National Center for Toxicological Research (NCTR) is specifically aimed at developing relevant protocols and experimental designs for carcinogenicity testing. The agency has also begun to work on supplementing the NCTR effort within the Interagency Regulatory Liaison Group (IRLG). Until these efforts are concluded and the results incorporated into regulations or into official publications, the Commissioner recommends as guidance the report of the Food and Drug Advisory Committee on Protocols for Safety Evaluation: Panel on Carcinogenesis, Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides ("Toxicology and Applied Pharmacology," 20:419-438, 1971). This report reviews and analyzes all facets of experimental design that have been developed and scrutinized by competent scientists before 1971. To facilitate incorporating later developments in testing standards as they evolve, the proposed regulations suggest that petitioners submit developed protocols to the Commissioner for review and updating before initiating studies.

B. RELEVANCE OF ANIMAL TESTING IN EVALUATING POTENTIAL FOR HUMAN CARCINOGENESIS

Several comments on this aspect of the regulation dealt with the merits and shortcomings of animal testing as an experimental tool. Some comments pointed out that even animal testing using the best experimental protocols can never prove conclusively that a compound is not carcinogenic, and that under these circumstances some weak carcinogens may escape identification. Other comments expressed the contrasting view that adequate protocols can be devised. Still others questioned the propriety of drawing conclusions about human carcinogenesis from data collected with experimental animals. Additional comments of the same type were received on these issues after the February 1977 notice. None of these comments provided any evidence or argument that persuades the Commissioner to revise any provision of this part of the regulations. Several comments sugested using short-term in vitro tests, singly or as part of a tiered testing system, as a substitute for long-term toxicity testing. One comment stated that the regulation should apply only to directly acting carcinogens and that indirectly acting carcinogens should be treated differently.

The act requires that in assessing the safety of animal drugs the carcinogenic potential of residues be evaluated. Ordinarily, the evaluation must be based on appropriate testing. Given the gravity of the decisions that depend on the results of these evaluations, the most relevant scientific information must be collected. As a source of information, direct carcinogenesis testing of chemical compounds in man is and must remain beyond the ethical bounds placed by society on human experimentation. Without this information source, which would be the most relevant, alternative sources are human epidemiology studies and animal experimentation. Human epidemiology may provide post facto information about the carcinogenic effects of chemical compounds on man. However, this experience cannot be the central basis for food safety valuations for several reasons, including the inherent imprecision of human epidemiology and the same ethical objections that make direct experimentation in man unacceptable.

There may be a high degree of confidence that a compound found to be a carcinogen in an epidemiology study is a human carcinogen because no interspecies extrapolation is required. However, so-called "negative" epidemiology data (data not showing carcinogenesis associated with a substance) are generally inadequate to overcome positive evidence of carcinogenesis from an animal study. Sources of data are often inadequate for identifying a specific exposed human population. Human beings are exposed to multiple potential carcinogens, and it is difficult or impossible to distinguish their several effects. Moreover, the precise amount of human exposure to particular substances is rarely known. Thus, limitations on the use of epidemiology data include (1) the degree to which the study population can be defined in terms of potential exposure, number exposed to the suspected risk, and the length of the observation intervals, (2) the degree to which the "standard" population used as the control is comparable to the study population, and (3) the role of other factors that might be related to different carcinogenic responses. Further, seldom are there sufficient numbers of subjects available to permit broad-scale conclusions.

The degree to which study populations can be characterized by the level of exposure to specific carcinogens will ordinarily vary considerably because of the lack of measurement in the early years of exposure. Comparison of exposed populations requires contrasting morbidity and mortality statistics of a target population with those of a "standard" population. However, the validity of any conclusion reached from these comparisons depends upon the extent to which other variables related to cancer incidence can be matched, adjusted, or accounted for in the analysis. These controls on data are costly, time consuming, and fraught with imprecision. Finally, detailed human pathology, which is important in demonstrating the role of specific carcinogens in the induction of rare tumors, is seldom available.

The Commissioner therefore concludes that the agency must continue to rely on animal testing for evaluating the safety for humans of chemical compounds proposed for use in food-producing animals. Extensive evidence substantiates this view (Refs. 13, 49, and 50). Consequently, the use of animal tests is generally recognized and accepted by regulatory agencies as the principal basis for assessing potential risks from exposure to chemicals (Refs. 51, 52, and 53). This basis has been universally recognized and accepted by the courts (see e.g. *EDF* v. *EPA*, 510 F. 2d 1292 (D.C. Cir. 1975)). Moreover, the act does not distinguish beteen human carcinogens and compounds demonstrated to be carcinogenic in test animals. Instead, it assumes that an animal carcinogen presents an unacceptable risk of cancer in human beings. In this context, the issue of relevance to man of data from tests in animals must be refocused. In view of the strong policy in the general safety provisions of the act, which includes the Delaney clause, the primary regulatory objective must be to avoid falsely negative determinations of the carcinogenic potential of compounds under test in experimental animals. In this setting, the agency's only tenable regulatory posture is to select bioassay protocols that utilize test animal species/strains that are considered the best surrogates for man. The selection is based on available toxicologic and metabolic information.

Numerous terms are used to describe various proposed mechanisms of induction of chemical carcinogenesis, e.g., direct carcinogens, indirect carcinogens, promoter, initiators, cocarcinogens. The current knowledge of the mechanism of chemical induction of cance is generally not adequate to

01188

permit these subtle distinctions. Further, the types of scientific studies necessary to identify precise modes of action for specific carcinogens are not yet refined to the point that they can be commonly applied (Ref. 54).

Moreover, the act does not distinguish between so-called "direct" and "indirect" carcinogens, and all types (assuming they are experimentally distinguishable) pose the same kinds of health risk to the public—namely, the risk of human cancer—that the act seeks to prevent. Therefore, the Commissioner concludes that there is generally no scientific basis for making regulatory distinctions among carcinogens.

The Commissioner agrees that short-term in vitro tests have a place in assessing the carcinogenicity of chemicals, as described in the preceding sections of this preamble, when they are intelligently applied and interpreted. However, the Commissioner does not agree that these tests can now substitute for long—term bioassays. The reasons for this conclusion were articulated by the expert committee on the National Cancer Institute on the use of these tests (Ref. 13).

At present, none of the short-term tests can be used to establish whether a compound will or will not be carcinogenic in humans or experimental animals. Positive results obtained in these systems suggest extensive testing of the agent in long-term animal bioassays, particularly if there are other reasons for testing. Negative results in a short-term test, however, do not establish the safety of the agent.

C. INTERPRETATION OF TEST DATA—IS THE COMPOUND A CARCINOGEN?

The majority of comments on the February 1977 notice requested greater specificity concerning classification of sponsored compounds as carcinogens, potential or suspect carcinogens, and noncarcinogens.

The objective of collecting and interpreting test data is to decide whether or not the compounds under test (the sponsored compound and any selected metabolites) are carcinogens. Within certain limits of confidence, statistical treatment of chemical carcinogenesis data can provide objective criteria for such determinations. To the question "Is the tested compound a test-animal carcinogen?" statistics can supply one of two types of answer:

(i) With "x" percent confidence (i.e., in "x" cases out of 100), "y" dose of the test compound will increase the carcinogenesis risk of test-animals over controls by no more than "s" and no less that "t"; or

(ii) With "x" percent confidence, "y" dose of the test compound will increase the carcinogenesis risk of test animals over controls by not more than "s."

An answer of the first type is possible only when the observed incidence of carcinogenesis in the test animals is significantly greater than that in the controls. When the observed incidence is the same for test and control animals, only an answer of the second type is possible.

A statistically significant increase in the incidence of carcinogenesis in one species or strain of test animals (i.e., an answer of the first type) is sufficient evidence to classify the test compound as a test-animal carcinogen. Because, for the purpose of these regulations, the act does not distinguish between human and animal carcinogens, a test compound as a test-animal carcinogen brings into play the requirements of the anticancer clause.

If the animal test data will permit only an answer of the type, the decision whether to classify the test compound as a test-animal carcinogen is more difficult. A negative test finding, as pointed out in some comments, can mean either that the test compound is not a test-animal carcinogen of that the bioassay protocol lacks a sufficient number of animals to discern an increase in the risk of carcinogenesis in the test animals. In those cases, a decision must be made whether to classify a tested compound as a noncarcinogen or to require further experimentation appropriate for resolving questions of safety. The Commissioner will conclude that a sponsored compound is not a carcinogen if the sponsored compound and each of the tested metabolites yields negative results. For purposes of these regulations, the Commissioner is proposing that the absence of a significant increase in tumor incidence in each of two different animal bioassays, conducted in accordance with good laboratory practices and designed according to principles referenced above, is (in the absence of other, positive data) sufficient evidence of noncarcinogenicity.

V. OPERATIONAL DEFINITION OF THE NO-RESIDUE REQUIREMENT

A. ALTERNATE OPERATIONAL DEFINITIONS

If it has been determined that a sponsored compound when admnistered to food-producing animals has the potential to contaminate edible tissue with residues whose consumption may pose a risk to human carcinogenesis, the agency cannot approve the sponsored compound unless it can be demonstrated that conditions of use can be established that ensure that the no-residue requirement of the act will be met. To establish those conditions of use and to provide a means for ascertaining whether these conditions are met in actual practice, some operational definition of "no residue" is necessary. Indeed, the act contemplates that the Commissioner will provide such operational definition, for there must be some criteria for prescribing or approving methods of examination for measuring residues.

The Commissioner has considered three basic alternative approaches to an operational definition of the phrase. Under one approach, the term "no residue" might be operationally defined as satisfied when the levels of residues fall below those that can be measured by available analytical methodology (alternative 1). A second approach would be to establish some low finite level (e.g., 1 part per billion) as a "practical zero" and to require assays that can reliably measure this zero, and to insist on the development of new assays if available assays are not adequate (alternative 2). Finally, "no residue" might be operationally defined on the basis of quantitative carcinogenicity testing of residues and the extrapolation of test data using one of a number of available procedures to arrive at levels that are safe in the total diet of test animals and that would, if they occurred, be considered safe in the total of man. Under this approach, the Commissioner would require assays that can reliably measure that safe level in edible tissues (alternative 3). For the reasons discussed in section V.B. below in this preamble, the Commissioner has concluded that alternative 3 should be adopted. The results of the carcinogenicity testing of the sponsord compound and any selected residues will be treated by the statistical procedures described in section V.

B. CHOICE OF AN OPERATIONAL DEFINITION

1. *Alternative one.* A number of assays might be development to measure the concentration of a chemical compound (i.e., residue) in an edible tissue, but for each there would be some level below which the compound under analysis could not be measured. (See section I.B. of this preamble.) Generally, different assays for the same chemical compound will have different, and sometimes vastly different, lowest limits of measurement. The no-residue requirement of the act could be translated an operational definition that is based solely on available analytical methodology and specifically on the lowest limit of measurement of an available assay. Thus, the degree of public risk associated with the use of a sponsored compound would become a function solely of the capability of available analytical technology.

The Commissioner concludes that this approach is unsound because it ignores all quantitative aspects of carcinogenicity testing. The carcinogenic potency of different chemicals varies widely. As used in this document, the

01189

term "potency" refers to the dose required to produce a given rate of cancer. Disregard of "potency" in developing criteria for evaluating spnsored compounds would scientifically unsound, and would make no sense from the perspective of public health protection in accordance with the Delaney clause and the general safety provisions. Such disregard would produce situations in which residues of different compounds could present widely varying risks. The regulatory assays selected that way would not represent a consistent policy of protecting the human food supply from cancer risks. Indeed, the pattern of protection from one compound to another would be haphazard.

2. *Alternative two.* A second approach that the Commissioner considered was to establish a "practical zero" for the residues of all carcinogens. This approach would have one advantage over alternative one: it would provide a well-defined criterion for the lowest limit of measurement that any sponsor's assay would have to satisfy. This approach also would not, however, take into account differences in carcinogenic "potency" among various carcinogens. (See Table III.) Therefore, it is unacceptable for the same as alternative one. Unless the "practical zero" were set at the level appropriate for the most "potent" carcinogen, it would provide insufficient protection; but if it were set at that level, it might be unnecessarily stringent for carcinogens that produce a response that is of a lower magnitude. In sum, no one "practical zero" is appropriate for all carcinogens.

Moreover, under alternative two, the criterion for lowest limit of measurement probably would reflect consideration of what lowest level of measurement is "practical," given the state of the art analytical chemistry or biochemistry. In addition to failing to link the no-residue standard to any consideration of carcinogenic potency, this approach fails on the ground of practicality. The science and technology of analytical chemistry and biochemistry are continuously changing, and a lowest limit of measurement considered reasonable at one time would have to be discarded as unreasonable at a later time. Whenever a new and lower criterion for the limit of measurement would be established, the Commissioner would then presumably require that use of all compounds approved under the prior criterion be suspended until methods were developed to measure the residues at this lower level. Such a situation, in the Commissioner's judgment, would be both unreasonable and unmanageable.

On the other hand, to disregard advances in analytical chemistry and adhere to a previously established practical lowest level of reliable measurement with no public health rationale for doing so would be contrary to the statutory purpose and, ultimately, arbitrary and capricious.

A modification of the basic "practical zero" also has been suggested, i.e., that Congress intended FDA to adopt a practical zero set at the level of analytical technology at the time the various Delaney clauses were adopted. Under this theory for food additives, the practical zero would be set at the level of technology in 1958; the DES proviso would be governed by the level of technology in 1962; and new animal drugs, by the level in 1968. This uneven floor of technology is inappropriate not only for the reasons that make any "practical zero" level inappropriate, but also because it would be impossible for the agency to administer and has no basis in the policy or legislative history of the various amendments to the act.

3. *Alternative three.* A third approach to defining operationally the no-residue requirement is to establish a required lowest limit of measurement for each sponsored compound on the basis of data derived from measurements of the carcinogenic response resulting from various amounts of the compound itself or selected metabolites (Dose-response studies). A result of the increasing understanding of chemical carcinogenesis is that the question asked is no longer merely whether a substance is a carcinogen, but what is the amount required to produce a given incidence of cancer (Ref. 55). This concept of a dose-response relationship has long been used in medicine to determine safe and effective does of therapeutic agents. It is customarily used to describe the commonplace observation that in the majority of cases, different quantities of two different pharmacological agents are needed to elicit the same pharmacological effect (relative potency) (Ref. 56).

Both pharmacological effects and carcinogenic effects are biological effects, and there is no a priori reasons why the concept of relative potency should apply to the former but not to the latter. Carcinogenesis bioassays of increasing refinement conducted over the last 20 or so years have borne out this notion of relative potency for carcinogens. Thus, scientists ever more frequently speak of weak and strong carcinogens. In doing so, they express what is implied by the observation, for example, that dietary exposure to comparatively small amounts of 2-acetylamino fluorine causes bladder cancer in rodents at the same rate as does exposure to comparatively large dietary amounts of saccharin. Under this approach, relative carcinogenic potency is given specific consideration because actual chronic toxicity test data are used to determine the level of residues in edible tissue that an assay must be capable of measuring reliably. Thus, it permits a rational, uniform procedure for establishing the required lowest limit of measurement for assays and avoids the major deficiencies inherent in alternatives one and two. This approach directly carries out the statutory purpose of protecting the human food supply from residues that pose a carcinogenic risk to man.

Should new information develop on the dose-response relationship between the level of residues of a sponsored compound and the incidence of cancer, this approach would provide a practical basis for determining whether a new assay is required to establish compliance with the no-residue standard. Thus, this approach contributes to regulatory stability and predictability. Likewise, the Commissioner can provide the maximum public-health protection based on quantitative carcinogenesis data. For these reasons, the Commissioner concludes that alternative three is the most appropriate means for implementing the statute and the most rational approach to developing an operational definition of "no residue."

By adopting this approach to implementing the no-residue standard, the Commissioner has assumed that: (i) The dose-response relationship between chemical compounds and carcinogenesis can be quantified, and (ii) a dietary level of a carcinogen can be identified at which no significant human risk of carcinogenesis would derive from consuming food containing residues below this level.

The dose-response relationships between compounds and carcinogenesis can be determined by testing in experimental animals, although the determinations are subject to known limitations inherent in every measuring device or system (Ref. 11). The second assumption, that residue levels representing no significant human risk of carcinogenesis can be assigned, protects the public from the potential and real dangers inherent in the interpretations of the "no-residue" standard of the act discussed as alternatives one and two. This second assumption and related issues are fully discussed in the next section of this preamble.

C. ANALYSIS OF ANIMAL CARCINOGENESIS DATA TO DEFINE OPERATIONALLY THE "NO RESIDUE" STANDARD OF THE ACT.

1. *Introduction.* The 1973 proposal included a modified version of the extrapolation procedure of Mantel and Bryan 1961 for use in defining the "no residue" standard for a sponsored compound (Refs. 57 and 58). The 1977 notice adopted a modified version of

01190

the Mantel et al. 1975 procedure, which updated the 1961 procedure. The basic Mantel-Bryan procedure is one of several statistical techniques that allow estimation of the level, or dose, of a carcinogen that would lead to cancer rates in test animals well below detectable rates in practical experimentation. In normal experiments in which test animals are administered various levels (doses) of a suspected carcinogen, the observed responses (i.e., the percentage of test animals developing cancer if the compound is a carcinogen) usually range from about 5 percent to 95 percent. To observe responses at rates less than about 5 percent would require many test animals. Experiments designed to observe responses in the range of interest in establishing the "no residue" standard would require impossibly large populations of test animals. Therefore, the procedures of Mantel and Bryan and Mantel et al., as modified, were proposed respectively to be used in the statistical treatment of the dose-response data from actual experimentation to estimate the dose of the compound under test that would result in lifetime test-animal cancer rates no higher than a preselected rate.

Some operational zero must be defined in order for the "no residue" requirement of the act to be implemented. Regardless of the arguments for or against any particular procedure, the Commissioner maintains that the use of some procedure that quantitatively takes into account the carcinogenic potency of substances in test animals is far superior to any approach that fails to take that fact into account.

The modified Mantel-Bryan procedure described in the 1973 proposal was labeled excessively conservative (i.e., too protective of the public health) by some comments and recklessly liberal (i.e., insufficiently protective of the public health) by others. Those who considered the procedure too conservative objected to the proposed use of a series of conservative assumptions (shallow-slope dose-response relations, low acceptable level of risk, use of upper 99 percent confidence limits, etc.) and contended that any one of these assumptions alone could provide adequate public health protection. Further, these comments argued that the practical application of the procedyre had not been demonstrated, and suggested that it would prohibit the use of many valuable compounds.

Persons who considered the procedure too liberal objected to the proposed use of a lower confidence limit on the observed slope of the dose-response curve. They protested that the proposed statistical technique for extrapolating dose-response data obtained from animal tests seriously underestimated public risk. The technique provides a basis for establishing a dose level where there is no significant human risk of cancer, thereby establishing a criterion for a residue detection method. Specifically, the comments contended that if the true dose-response follows a logistic or linear distribution, extrapolation with the slope from a probit transformation would seriously underestimate public risk. Further, these comments argued that the probit transformation leads to a paradox because strong carcinogens are treated less conservatively than weak ones.

2. *Choice of the statistical procedure.* Most of the comments concerning the statistical procedure proposed in 1973 favored adoption of the Mantel-Bryan procedure without the modifications suggested in the proposal. A smaller number of comments contended that a linear extrapolation would be better than the Mantel-Bryan procedure and even fewer suggested the logistic or the angle distributions. Still other comments suggested that FDA require a comparative analysis of animal carcinogenesis data employing all alternative distributions, and that the smallest estimate of the "safe" level be used to define the "no-residue" standard for a compound. Finally, some comments stated that, although the logistic and angle distributions have been used in biological sciences, there is no indication that either one provides advantages over the probit (Mantel-Bryan) or the linear distribution, and that, therefore, neither is appropriate for regulatory purposes.

Some comments favoring the Mantel-Bryan procedure argued that it has a theoretical rationale that probably is relevant to the carcinogenic action of chemical agents. A similar argument was made by some of the comments favoring linear extrapolation. These comments also contended that linear extrapolation has the public health advantage of being the most conservative of all procedures.

In the period 1973 through 1977, the Commissioner extensively reviewed the known procedures that may be used to derive an operational definition of the no-residue standards of the act from animal carcinogenesis data. This review persuaded the Commissioner that the same scientific and technical limitations are common to all. Specifically, because the mechanism of chemical carcinogenesis is not sufficiently understood, none of the procedures has a fully adequate biological rationale. All require extrapolation of risk-dose relations from responses in the observable range to that segment of the dose-response curve where the responses are not observable. Matters are further complicated by the fact that the risk-dose relations assumed by the various procedures are practically indistinguishable in the observable range of risk (5 percent to 95 percent incidence) but diverge substantially in their projections of risks in the unobservable range.

In the 1977 notice, the Commissioner concluded that the comments failed to demonstrate that another procedure was superior to that of Mantel and Bryan and Mantel et al., and the Commissioner therefore adopted it with some modifications. Moreover, the Commissioner concluded that some aspects of the Mantel-Bryan procedure offered advantages over the other statistical procedures. It provided a means for pooling data from multiple experiments and from multiple dose levels within a single experiment, and thus permitted decisions based on the fullest use of available data. Further, the Mantel-Bryan procedure had a defined mechanism for handling the spontaneous tumor rate. To overcome certain limitations of the Mantel-Bryan procedure, the Commissioner adopted a number of modifications, which were discribed and discussed in the 1977 notice. The Commissioner also concluded that a review of the decision should be undertaken in 2 years and any appropriate modifications in the regulation initiated.

Since publication of the February 1977 notice, the Commissioner has received many additional comments on the statistical procedure chosen. Several suggested that the adopted Mantel-Bryan procedure is very complicated and requires a sophisticated computer program for handling and analyzing data and that such programs are not widely available. Also, a comment stated that the procedure uses a relatively untried mathematical theorem and applies it in a fashion for which it was never intended. Another comment contended that the Mantel-Bryan procedure is "disturbing" in that, for certain sets of data, it is possible that different answers will be produced by different starting points in the computer interation, i.e., there may be an infinite number of possible answers. A comment stated that neither Mantel paper was published in a recognized statistical journal, and, therefore, that the papers have not been subjected to proper peer review. Another comment argued that the procedure is based on unwarranted assumptions. Other comments suggested that the procedure is too lenient, and several suggested use of the linear procedure for extrapolation. Finally, another comment recommended the use of the Hartley-Sielken procedure (Ref. 59) and contended that this procedure "has never been challenged."

In light of these comments, the Commissioner reexamined alternative statistical procedures for estimating

01191

test animal exposure levels that correspond to specified levels of risk. None of the procedures suggested in the comments is known to be entirely compatible with current knowledge about chemical carcinogenesis. The procedure chosen must be that best supported by current science and also most protective of the public health. Of the three general procedures recommended by the comments or available in the literature (the curvilinear models, linear extrapolation and the Mantel and Bryan procedure (Refs. 57 through 63)), the Commissioner has now decided that for purposes of this regulation, linear extrapolation best meets the above criteria:

(1) Of the available procedures, the linear procedure is least likely to underestimate risk. That is, at the level of acceptable risk (1 in 1 million over a lifetime), the maximum permissible dose of residues calculated by use of the linear extrapolation is usually lower than that obtained by the use of the other procedures.

(2) Linear extrapolation does not require the use of complicated mathematical procedures and can be carried out without the aid of complex computer programs. The Commissioner now agrees with those comments suggesting that the Mantel-Bryan procedure is, for such reasons, unsatisfactory. The curvilinear model of Hartley and Sielken (1977) and Crump et al. (1977), like the Mantel-Bryan procedure, have many computational difficulties and require data from several dose levels.

(3) No arbitrary selection of slope is required to carry out linear extrapolation. For this reason, the Commissioner believes that it possesses an operational advantage over the Mantel-Bryan procedure; again, the Commissioner agrees with those comments that pointed out this difficulty in the previously proposed procedure.

(4) an approach to risk estimation recently proposed by Cornfield (Ref. 64) has been suggested to the Commissioner. Although Cornfield's approach may have merit, its assumptions and concepts have not yet been sufficiently scrutinized, evaluated, and accepted for the agency to adopt it at this time, as illustrated by the recent dicussion in *Science* (Ref. 64).

(5) Finally, the Commissioner has accepted the recommendations contained in a report issued by an expert scientific committee of the Department of Health, Education, and Welfare (Ref. 63) Linear extrapolation was proposed as the procedure of choice by the members of this committee.

For the above reasons the Commissioner now proposes to adopt linear extrapolation for regulating compounds subject to these regulations. The Commissioner recognizes that alternative procedures may have merit. Accordingly, comments are solicited on the property of those alternative procedures and what is believed to be their advantages over the proposed linear procedure. Of particular interest is the applicability of the curvilinear procedures to an interpretation of data on time-to-tumor observations.

3. *Time-to-tumor and other considerations.* Serveral comments contended that the 1973 proposal was deficient because it did not address the time-to-tumor aspects of chemical carcinogenesis. Some comments pointed out that Albert and Altshuler have developed preliminary statistical relationships between low levels of carcinogen exposure and time of tumor manifestation (Ref. 65). These authors maintain that characterization of carcinogenic potential and potency on the basis of incidence alone is not appropriate because it ignores the life-shortening aspects of carcinogenesis. A comment of the same type was received in 1977.

The Commissioner generally agrees with these comments. He recognizes that he must consider all manifestations of chemically induced carcinogenesis, including decreases in latency times (life-shortening effects). Accordingly, the Commissioner has reviewed recent scientific publications that attempt to address comprehensively all manifestations of chemical carcinogenesis (Refs. 54, 59, and 65). These publications offer generalized statistical techniques purportedly suitable for estimating all types of risks from experimental animal data. As expected, they are complex in concept and demanding in skills required for use. Without prejudice toward the technical and scientific merits of these generalized techniques, the Commissioner proposes that the linear technique be adopted in these regulations. In the Commissioner's view, this simple-to-use technique can be adopted to deal with all manifestations of chemical carcinogenesis even though it was not originally elaborated with life-shortening effects in mind.

Simplicity of use, however, is only one aspect of the procedure that must be considered. Other important aspects are technical and scientific merits or deficiencies. Therefore, the Commissioner invites those interested and knowledgeable in statistical techniques for risk estimation to consider and comment on the scientific and technical merits or deficiencies not only of the procedure proposed but those of the curvilinear procedures as well. The Commissioner will review comments on the time-to-tumor issue and will make any appropriate modifications in the procedure finally adopted.

One comment in 1973 stated that "effects produced at higher dose levels * * * are useful for delineating the mechanism of action, but for any material and adverse effect, some dose level exists for man or animal below which adverse effects will not appear." The comment analyzed in detail the deficiencies of all statistical extrapolations and stated that approaches are available to define a true carcinogenic no-effect level. It contended that it is more appropriate to determine a biologically insignificant level using a safety factor based on competent scientific judgment. In 1977, several comments reiterated the threshold issue but provided no supporting information or justification. Further, one comment has claimed that threshold levels have been established for 23 chemical carcinogens, although it provided no data or information to support this assertion.

The Commissioner disagrees with the contention that the classical toxicology concepts of the terms "thresholds" and "biologically insignificant levels" are generally applicable to carcinogenesis. There is substantial scientific controversy over whether these concepts apply to irreversible processes, such as the chemical induction of malignant neoplasia. The concepts of "threshold" and "biologically insignificant level" derive from short-term toxicity experiments. They have no established meaning with respect to biological processes that require long latent periods (up to 20 or 30 years) before the manifestation of lesions.

If it could be shown that there exists a threshold level for carcinogenic effects below which no member of the exposed human population would be at risk of developing cancer, and if a method were available to establish such a level for specific carcinogens, the Commissioner would seriously consider adopting such a level as the no-residue standard for this regulation. There is reason to believe, however, that the classic toxicological concepts of "thresholds" and "biologically insignificant levels" may not apply to carcinogenesis, and, further, that even if they do apply, there is no known method for establishing them in a manner that will provide the public health protection necessary.

It is true that "no effect" levels have been observed for some carcinogens in bioassays conducted in experimental animals. Such observed "no effect" levels should not, however, be mistaken for "thresholds" or for "biologically insignificant levels." There are several reasons for this conclusion.

In the first place, animal experiments are limited in their power to detect carcinogenic effects. Most such bioassays test approximately only 100 animals at each dose level. If no response is observed in 100 test animals, the upper 99 percent confidence limit

01192

of the response is approximately 5 percent. Thus there is a probability that a dose level producing "no observed effect" in this type of bioassay actually produces a response up to 5 percent; such a response (cancer incidence) can by no means be considered insignificant, even for the small test animal population, let alone for the entire human population of the United States. Of course, an observed "no effect" level in a carcinogenesis bioassay may indeed represent a "true no effect" level for the test animal population; there is, however, no way to ascertain which of these two possible interpretations of observed "no effect" levels is correct.

Even if it were assumed that a "no observed effect" level derived from a carcinogenesis bioassay represented a "biologically insignificant" level for the test animal population, it is unclear how knowledge of such a level would permit establishment of a threshold level for an exposed human population. Animal studies are performed under carefully controlled conditions that allow as little variation as possible in the environments of treated and control groups. The test animals have a uniform diet, are generally of the same age and state of health, and are otherwise living under uniform conditions. Further, the animals usually used in experimentation are genetically homogeneous.

By contrast, the human population exhibits a broad range of dietary habits, health status, age, occupational environment and genetic background; such factors are known to influence responses to toxic substances. For this reason, the human population is expected to exhibit a far broader range of susceptibilities to carcinogens than does the small and relatively homogenous test animal population for which "no effect" data may be available. Some segments of the human population may be less susceptible to the effects of a carcinogen, and some more susceptible, than the test animal group (Ref. 74). There is no information available that permits a quantitative determination of the relative susceptibilities of test animal and human populations. Therefore, it is not possible to devise a "safety factor" that can be applied to the animal "no effect" level (even assuming such a level were biologically insignificant for the test animal) to arrive at a level that can be considered safe for the entire human population. Moreover, if the animal "no effect" level is biologically significant for the test animal population (and, as has been shown this is not likely), the use of such a level to assign a safe level of human exposure, even after application of their safety factor, could lead to dangerously high levels of risk for humans.

Although the available information regarding the relative susceptibilities of test animal and human populations does not permit a quantitative determination of relative susceptibility, there are comparisons of a limited number of carcinogens (Refs. 66, 67, and 75). These comparisons only indicate that the lifetime cancer incidence induced by exposures in man can be approximated by the lifetime incidence induced by similar exposures in laboratory animals and that man may be no more susceptible than the most sensitive test animals species for which test data are available.

In addition to the variety of difficulties associated with methods for assigning threshold levels, there is considerable uncertainty whether such thresholds actually exist. There is, for example, evidence that cancer can arise from a single transformed cell and that this transformation results from a single exposure and can occur long after the causative agent has been removed (Ref. 68).

The question of whether population thresholds exist for carcinogens is open for comment, and the Commissioner is willing to accept and take into consideration evidence that may develop on this issue. For the present, however, the Commissioner takes the position that there is no known method for establishing thresholds.

The Commissioner's view on this issue accords with that of an expert Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens contained in their Report to the Surgeon General, United States Public Health Service, April 22, 1970. The Report, which was published in full in "Chemicals and the Future of Man," Hearings before the Subcommittee on Executive Reorganization and Government Research of the Committee on Government Operations, United States Senate, April 6 and 7, 1971, contains the following conclusion:

> It is impossible to establish any absolutely safe level of exposure to a carcinogen for man. The concept of "toxicologically insignificant" levels (as advanced by the Food Protection Committee of the NAS/NRC in 1969), of dubious merit in any life science, has absolutely no validity in the field of carcinogenesis. Society must be willing to accept some finite risk as the price of using any carcinogenic material in whatever quantity. The best that science can do is to estimate the upper probable limit of that risk. For this reason, the concept of safe level for man, as applied to carcinogenic agents, should be replaced by that of a socially acceptable level of risk.

No information developed in the past 7 to 8 years warrants modification of this view.

Several comments opposing the proposal suggested that the agency should maintain flexibility and evaluate the approvability of sponsored compounds based on assessments of benfit and risk—in effect offering another approach to establishing the operational zero for carcinogenic residues. The Commissioner concludes, however, that an approach that contemplates considering the benefits of use of a sponsored compouund in defining the no-residue standard is incompatible with the anticancer provisions of the act.

It is the Commissioner's opinion, at least for new animal drugs, food additives, and color additives in animal feed, that it is improper to use risk/benefit considerations in making decisions about their safe use. The legislative history of the Food Additives Amendment of 1958 shows that the benefits of food additives are not to be considered in assessing whether they can be safely used. This position was strongly supported by the food industry. The industry feared that FDA would refuse to approve new, safe additives that provided only marginal benefits to the consumers or marginal improvements over additives already on the market (Ref. 69). Further, in that amendment Congress also added the flat proscription on the addition of animal carcinogens to the food supply. That action provides additional support for the position that (except for the very limited role assigned to the determination of functionality) risk is the only appropriate consideration in assessing safety under the food additive provisions of the act, which in large part governed the use of new animal drugs intended for use in food-producing animals from 1958 until the enactment of the Animal Drug Amendments in 1968.

As explained in Part I of this preamble, the legislative history of the Drug Amendments of 1962 shows that the DES proviso to the Delaney clause was added only to correct what Congress perceived to be an inequity in the regulatory system caused by FDA's application of the food additive provisions to the existing use of DES in cattle. But there is no basis for concluding that Congress by that action intended that an express risk/benefit consideration be added to the procedure for assessing the safety of substances intended for use in food-producing animals. Rather, Congress noted that the protection afforded the public would remain unchanged despite enactment of the proviso (see Part I.A.3 of this preamble).

The Animal Drug Amendments were enacted in 1968 to consolidate the various provisions of the act that were being used to regulate new animal drugs. The legislative history of that statute also contains no directive to FDA that the agency consider benefits in assessing the safety and approvabil-

01193

ity of a new animal drug. In the absence of explicit Congressional direction on this point, FDA historically has considered it inappropriate to balance the risk of cancer that may be associated with the use of a sponsored compound (and assumed by one societal group) against the benefits that may be derived from the compound's use (and accruing to a different societal group). Recent case law in United States Courts of Appeals for the 5th and the District of Columbia Circuit has addressed different situations (see *American Petroleum Institute* v. *OSHA*, 581 F.2d 493 (5th Cir. 1978); Petition for cert. pending No. 1036 (U.S. 1979); *Agna Slide 'N' Dive Corp.* v. *CPSC*, 569 F. 2d 831 (5th Cir. 1978); *Environmental Defense Fund et al.* v. *Environmental Protection Agency*, No. 77-1091 (D.C. Cir. Nov. 3, 1978); and *Hercules Inc., et al.* v. *Environmental Protection Agency*, No. 77-1248 (D.C. Cir. Nov. 3, 1978).

4. *Expression of dose level.* Several comments received before the February notice addressed the adjustments the Commissioner had proposed to make in the "safe" level derived from the experimental animal data in order to establish an appropriate value for man. Some comments stated that adjustments for differences in food intake between experimental animals and man were inappropriate when dealing with carcinogens. The comments stated that such adjustments would assume erroneously that all toxic materials have the some mode of action on a body weight basis. They further suggested expressing the relationship in terms of concentration in the feed of the test animals and in the food of man when the diet in both cases in consumed adlibitum, not on an amount-per-body-weight basis. Other comments argued that the extrapolation of animal data to man should be based on body-surface-area ratios.

The notice specified that carcinogenicity tests must be conducted with the test compound's concentration in the diet of the experimental animals held constant throughout the study. The safe or "acceptable" level derived from extrapolation of test animal data would be expressed as a concentration in the total diet (weight of compound/weight of total diet) of the animals and would be directly used as the acceptable level for the total diet of man. The Commissioner concluded that the arguments for conversion based on surface area ratios or on intake per unit of body weight have little basis. The comments provided no evidence that those concepts are applicable to low-dose chronic exposures. The concept of surface-area ratios is based on experience with short-term high-dose studies. Furthermore, measurements of surface area are crude. Finally, surface area and body weight will vary, as will food intake per day, throughout the chronic study, thus requiring constant adjustments of dose.

Until evidence is compiled demonstrating that there is a more appropriate means to extrapolate from experimental animal to man for chronic exposure and carcinogenic manifestation, the Commissioner will assume that the animal is the integrator throughout its lifetime of any observed response to a fixed concentration in the diet. The Commissioner has thus adopted the direct extrapolation approach (the safe level in parts per million, parts per billion, etc., of the diet of the experimental animals directly applied to the diet of man), which is appropriately conservative as well as the most practical of the approaches considered.

5. *Degree of data confidence.* The Commissioner disagrees with comments that characterized the proposal's requirement for 99 percent confidence intervals as another in a series of unnecessarily conservative assumptions. Confidence intervals characterize the quality of experimental measurement. The Commissioner maintains that a high degree of confidence should be demanded for decisions respecting carcinogens. The Commissioner therefore has adopted the 99 percent level of confidence, and the final regulations, reproposed herein, require that all calculations based on experimental observations be made from or with the 99 percent confidence limits.

6. *Slope used for extrapolation.* Because the Commissioner is proposing to adopt the linear model for risk estimation, comments on the slope used for the extrapolation are now irrelevant.

7. *Spontaneous tumor rates and data combination.* In the 1973 proposal the Commissioner recognized certain limiting features common to all extrapolation procedures, including that of Mantel and Bryan. These limitations concern the tumor incidence rate in the control groups of animal bioassays and the selection or combination of data from different experiments.

In response to comments, the Commissioner adopted in the February 1977 notice the procedure developed and utilized by Mantel et al. (1975) for handling spontaneous tumors. This procedure is an extension of the principles first articulated in the appendix to the 1961 Mantel paper and treats the rate of spontaneous tumors as an additional statistical parameter to be estimated from the data. The linear procedure in this proposal also treats spontaneous tumors in control animals as an additional statistical parameter to be estimated when two or more non-zero dose devels are utilized. When only one non-zero dose level is used for the linear extrapolation, an upper confidence limit on the increase in response of the dosed animals over the control animals is used. These methods of handling the data resolve some of the problems that arise when attempting to deal with spontaneous tumor rates.

Two comments in 1977 cautioned against the requirement for using the most "sensitive" test animals (i.e., the strain with the greatest tendency to develop tumors) as well as the "conservative" Mantel-Bryan procedure. They contended that these two requirements are incompatible because the high spontaneous tumor rate in the control animals reduces the number of animals that can manifest the effects of the chemical being tested.

The issue of sensitivity or susceptibility of the test animal species is relevant regardless of the statistical model selected for conducting the extrapolation. The commissioner does not intend to apply the term "sensitivity" or "susceptibility" in a way that is detrimental to the ability of the bioassay to detect carcinogenic potential, which has to be the overriding concern in selecting the test animal species.

In many instances, the male and female animals of the same strain may exhibit significantly different responses to a compound. Also, the responses of different strains and species may differ significantly. It is always desirable to make maximum use of available information by appropriately combining different data sets, but prudence must govern the process of selecting and combining data. Combining different data sets from the same or different experiments increases the number of animals used in the analysis and therefore increases the confidence in the results. Yet, in many instances, different data sets contain different types of information. Mantel et al. discuss the informational aspects of data combination for pooling data from different experiments and from different data sets in the same experiment. Although the Commissioner agreed in principle with most of their conclusions, it was nevertheless anticipated that situations would arise where the evidence in support of combining or not combining data would be equivocal. Therefore, the Commissioner concluded that the statistical and biological evaluation of data will determine which data sets, if any, will be appropriate for pooling. Where there are significant statistical and/or biological differences in the observed responses, only subsets of data representing statistically and biologically compatible bioassays will be combined for analysis.

01194

Further comments on this segment of the February notice alleged that the agency's criteria for combining data are vague, arbitrary, and always unnecessarily conservative. A comment stated that FDA always combines the data to produce the highest risk regardless of the rationale for that combination. Other comments contended that cancer is a disease of old age. For this reason, it was argued, animal tests should be conducted in a way that reduces interference in the relevant observations caused by the high spontaneous tumor rates expected in animals of advanced age. It was also argued that, for the purpose of selecting data for a risk analysis, the agency should disregard all benign tumors occurring late in the test animals' lives.

There are many examples in which carcinogenic response to a chemical insult is limited to a segment of exposed human or animal populations, e.g., a single sex. It is only reasonable, therefore, that bioassay data be evaluated for the presence of such specific responses, and that the results of these analyses determine the ultimate manner of pooling data. These ultimate analyses are neither artibrary nor vague and are based on well-established scientific principles. Further, they do not always lead to the "most conservative" interpretation of the data; these analyses attempt to identify the data base that will result in the closest approximation of the true risk. In the Commissioner's opinion, this process is not regulatory "overkill" by any means; rather, an examination of the process shows that each decision in the process is independent and must be made on the merits of the data available. The proposed methods for combining data are, in each case, reasonable and well accepted, and the end result of the process is also reasonable because of the independent nature of the individual steps. For example, the regulation stipulates that the appearance of either benign or malignant tumors or both is evidence of carcinogenicity. As numerous experts have noted, both types of tumors will ordinarily be taken into account for the purpose of estimating risk as long as they are dose-related. Both types of tumors represent a carcinogenic threat, and neither can properly be ignored (Ref. 12).

The occurrence of tumors late in the life of test animals is also evidence of carcinogenicity as long as tumors are dose-related and occur at a greater rate in the treated than in the control animals. The Commissioner has no basis to ignore, as one 1977 comment suggested, the occurrence of benign tumors that occur late in life.

The Commissioner believes that the correlation between the type and rate of occurrence of tumors in the test animals and in man is poorly known and that to ignore benign tumors merely because they occur late in the lives of test animals would be imprudent.

8. *Level of risk.* The 1973 proposal suggested that an acceptable level of risk for test animals, and thus for man, could be 1 in 100 million over a lifetime. Many comments argued that this level of risk was unnecessarily conservative in light of the many other cumulative, conservative restrictions already in the proposed regulations. In the February notice the Commissioner concluded that the 1 in 100 million level of risk was unduly limiting without substantial compensation in terms of public health. Consequently, the notice established the maximum risk to be used in the Mantel-Bryan calculation as 1 in 1 million. The Commissioner explained the basis for selecting that level. Although additional comments on the level of risks were expressly requested, the Commissioner received only two comments on this issue. They contended that the level of risk selected was inconsistent with the congressional intent in enacting the proviso to the Delaney clause and was insufficiently protective of the public health.

Because Congress specified that the use of carcinogenic animal drugs and feed additives should leave "no residue" to be found (by methods prescribed by the Secretary) in edible tissue, it appears that Congress intended that the use of such animal drugs and feed additives not significantly increase the human risk of cancer from that use. It is also evident, however, that Congress intended to permit the use of carcinogenic animal drugs and feed additives if there would be no significant increase in the human risk of cancer from that use. Historically, safety decisions involving the use of chemicals have been made with the aid of numerical safety factors that do not consider the actual level of risk to the public. Observed no-effect levels from animal data are divided by an absolute safety factor to give a "safe" level for humans. For carcinogens, the Commissioner has concluded that it is necessary for the agency squarely to face the level of risk associated with a chemical compound's use before the agency will permit the use, and it is for that reason the Commissioner is proposing the statistical procedure for assessing risks prescribed in this document.

In the Commissioner's opinion, the acceptable risk level should (1) not significantly increase the human cancer risk and (2), subject to that constaint, be as high as possible in order to permit the use of carcinogenic animal drugs and food additives as decreed by Congress. For the following reasons the Commissioner believes that a risk level of 1 in 1 million over a lifetime meets these criteria better than does any other that would differ significantly from it:

(a) The risk level of 1 in 1 million is an increased risk over the entire lifetime of a human being.

(b) The upper 99-percent limit on the response data is used throughout the procedure, and the extrapolation procedure is conservative by nature. For these reasons, the maximum concentration of residues of carcinogenic concern that will go undetected in edible tissues is expected to increase the lifetime risk of excess cancer in humans by less than 1 in 1 million.

(c) This 1 in 1 million *lifetime* risk is expected only if the maximum concentration of residues potentially undetected in edible tissues is consumed every day over a lifetime. Because there is little likelihood that these residues will be so consumed by humans, the actual risk is likely to be lower than 1 in 1 million.

(d) The use of the procedures explained in the proposed regulations for deriving a concentration of residues that may go undetected in edible tissues rests on the assumption that the only risk to the exposed human population is that from residues of the sponsored compound. Other causes of disease or death are not considered. Because the population is constantly at risk from a wide range of factors, any increment of risk associated with residues subject to this proposed regulation is in comparison with other risks, likely to be vanishingly small.

(e) Several other prudent procedures apply to the derivation of the concentration of residues that will be permitted to go undetected (see section V.D. of this preamble below). For these and the above reasons the most likely human risk is expected to be less than 1 in 1 million.

(f) Once the level of risk is as low as 1 in 1 million, any further reduction in the level would not significantly increase human protection from cancer.

(g) An increase in the level of risk to 1 in 10,000 might significantly increase human risk. It is difficult to choose between 1 in 1 million and 1 in 10,000 but the agency chose the more conservative number in the general interest of protecting human health.

Furthermore, considerable discussion of the issue of acceptable level of risk has taken place recently (Refs. 55, 70, 71, 72, and 73), suggestions for the acceptable level of risk range from 1 in 20,000 per lifetime to 1 in 100 million. In addition to protecting the public health and satisfying the congressional directive, the Commissioner believes the selected level of risk should be consistent with acceptable levels of

01195

risk for other materials that are considered safe, and should prevent any false sense of security in the calculations. After reviewing data on acceptable levels of risk and knowing the limitations on the procedures, the Commissioner has concluded that a level of risk of 1 in 1 million over a lifetime satisifies all of these criteria.

The Commissioner notes that for a few carcinogens, some limited comparisons have been made between risks estimated from animal experiments and those caluclated from human epidemiology studies (Ref. 66, 67, and 75). The tentative conclusion from these comparisons is that the lifetime cancer incidence induced by chronic exposures in man can be approximated by the lifetime incidence induced by similar exposures in laboratory animals. For this reason, the various conservative procedures and assumptions attached to the establishment of the permissible concentrations of potentially undetected carcinogenic residues should compensate for the possibility that for some carcinogens humans in general or some numerically significant groups of humans are more sensitive than test animals. Likewise, compensation must be made for the possibility of additive and multiplicative effects among the many carcinogens to which people are exposed daily. It is impossible to supply a quantitative estimate of the degree of compensation that results from the application of the various prudent procedures and assumptions. For these reasons the Commissioner has exercised caution by proposing an acceptable level of risk as low as 1 in 1 million.

In summary, the Commissioner has concluded that a risk level of 1 in 1 million over a lifetime imposes no additional risk of cancer to the public. A lower risk would not significantly increase the public health protection, but would probably proscribe the use of most animal drugs or feed additives. A risk level significantly higher than 1 in 1 million, for example 1 in 10,000, might present a significant additional risk of cancer to the public.

D. DERIVATION OF THE LEVEL OF TOTAL RESIDUES OF CARCINOGENIC CONCERN THAT CAN BE TAKEN AS SATISFYING THE NO-RESIDUE REQUIREMENT OF THE ACT.

As explained previously, a potential residue level corresponding to a lifetime risk of 1 in 1 million in test animals (i.e., the safe level derived from a statistical extrapolation procedure) can be considered the level that represents no significant carcinogenic burden in the total diet of man. This level was assigned the symbol "S_0" in the February 1977 notice, and expressed as a fraction in the total diet of the test animals, i.e., parts per billion, parts per trillion. The Commissioner concluded that it is the potential undetected residue level that is safe in the total diet of man.

In some cases, residues in addition to the sponsored compound itself will have been selected for carcinogenicity testing. In these instances, safe or acceptable levels will be derived for each of the compounds that has undergone testing. The compound exhibiting the lowest value for the safe level is the most potent carcinogen of those tested and poses the greatest potential carcinogenic threat among the residues. The Commissioner assumes that the smallest value of the safe levels of all the carcinogenic compounds tested represents the acceptable, total potential carcinogenic burden to man that may result from the administration of a sponsored compound to food-producing animals. This smallest value is assigned the symbol S_0. Because tested residues other than the one selected for S_0 may have exhibited carcinogenic properties (although less potent) and still other, untested residues may represent carcinogenic risks, the sum of the levels of all of the residues must be less than S_0 to ensure that any undetected residues do not present a significant risk of cancer to humans. Potential residues in the total human diet cannot exceed S_0 if that diet is to bear no significant carcinogenic risk to man as a result of the residues. The only residues that can be excluded from the sum or residue levels are those that have been unambiguously shown to be noncarcinogenic in accordance with the principles described earlier.

One comment stated that the Commissioner failed to provide a mechanism to ensure that the total residue (S_0) will be accurately measured in edible tissues.

The comment has misunderstood the construct of the regulations. The S_0 value is a projected acceptable total level of residue that is determined by calculations using bioassay (toxicology) data; it is not determined by totally individual analytical measurements. Therefore, the appropriate tasks with regard to safety are (1) determining the time when the total residues in edible tissue of target animals have depleted to S_0 and below, and (2) selecting a suitable marker compound to monitor total residues. The determination of the expected time of the depletion of the total residues to S_0 will be made in the second metabolism study, which is described in section VI below in this preamble. The second metabolism study will normally be conducted with radiotracer techniques that permit identification of a marker residue and target tissue. The regulatory assay will be used to monitor whether the total residue has depleted to S_0. The accuracy and precision of these techniques is well recognized and accepted.

E. CORRECTIONS FOR FOOD INTAKE

Several comments on the original proposal argued for, and others opposed, further adjustments based on patterns of food consumption. Some comments contended that the "safe" level of Mantel and Bryan in the animal diet should be directly applied as the upper allowable limit in man's diet and in any component food in the human diet. These comments argued that this limit should not be raised by considering the intermittency of consumption of particular foods or the proportion of the total diet represented by an individual food. They suggested that individuals who consume above average amounts of food would be exposed to above average, and thus possible harmful, levels of residues. Further, these comments contended that the act does not distinguish between the people who consume average diets and people who consume above average quantities of certain foods; the two groups are entitled to equal protection. They argued that adjustments for exposure frequency based on food consumption patterns assume that continuous long-term exposure to a carcinogen precedes the development of cancer.

Many other comments urged that adjustments be made based on the proportion of the specific food in the total diet and the frequency of exposure. These comments generally favored the use of food consumption data, so that the degree of conservatism would be more uniformly applied and would take into account the relationship of the particular food to the total diet.

The Commissioner disagreed with the contention that no adjustments should be made for factors of exposure. Section 512(d)(2)(A) of the act requires the Commissioner to consider the probable consumption of a drug and of any substance formed in or on food because of its use. All drugs, including carcinogens, are subject to the general safety provisions of the act. Consideration of the formation of chemical residues on food is necessary whether the drug is a carcinogen or a chemical toxicant of another type. There is no legal, scientific, or policy basis for concluding otherwise. The no-residue standard of the act has been defined as satisfied when the sum of the levels of all potential undetected residues of the sponsored compond (excluding only those that have been found to be noncarcinogenic) would not exceed S_0 in the total diet of man. Because products derived from food-producing animals do not constitute the total human diet, it is appro-

01196

priate that S_0 be corrected for probable human consumption of specific tissues. The Commissioner agreed, however, that any adjustments must be conservative to assure that all segments of the population are protected.

Muscle tissue and eggs can be considered, conservatively, to each constitute one-third of the total daily human diet. Because milk can constitute the total daily diet of some individuals (e.g., infants), the Commissioner concluded that no adjustment for this commodity is appropriate. Adjustments for frequency of exposure for tissues other than muscle, milk, or eggs, (i.e., kidney, liver, etc.) will be considered when data are available that permit the Commissioner to conclude that the average daily intake of residues will not exceed S_0.

The February 1977 notice used the symbol "S_m" to represent the level of total residues of carcinogenic concern that can be operationally defined as satisfying the no-residue requirement of the act for specific tissues. The S_m value represents the level of residues that is acceptable for specific classes of edible products that constitute finite percentages of the total diet. Because milk may constitute the entire diet of an infant, the S_m value is its S_0 value. But because muscle tissue constitutes one-third of the diet, the S_m value is 3 times the S_0 value of the compound.

One comment on this section of the regulations said that the Commissioner was opening an avenue to permit as much as 20 times the S_0 value in muscle tissue. This is emphatically not the case. The comment failed to recognize that the regulation establishes specific dietary conversion factors for muscle tissue, eggs, and milk (⅓, ⅓, 1, respectively), and conversions will be permitted for other tissues only when there are data to ensure that the S_0 will not be exceeded in the total diet.

One comment raised a question about the quality of data used to establish the dietary factors for the major tissues, but the Commissioner concludes that the factors are correct. Although there are indications that the American diet has changed considerably in some areas in the past few years (e.g., the consumption of fabricated foods), there is no evidence that the consumption of muscle tissue, milk, and eggs, which serve as the basis for the basic dietary factors, has changed.

F. OTHER POSSIBLE ADJUSTMENTS

Several 1973 comments urged that the regulation not provide for adjustments for the degradation of residues in food under normal conditions of storage and cooking. Other suggested that this data should not be required, but should be taken into account when available. Still other comments expressed the fear that this data would be used to dilute the conservative intent of the regulation; they argued that the term "normal condition of storage and cooking" would be difficult to define, and it might reduce protection in situations where actual storage and food preparation practices did not approximate experimental conditions. Finally, some comments suggested that these studies be required only when there is reason to believe that the information would assist in protecting public health.

One comment on the February 1977 notice averred that the agency proposed to permit food with illegal residues to be marketed on the theory that violative levels of residues would "dissolve" before the food could be consumed.

The Commissioner agreed that the criteria appropriate to these studies were not defined, and he deleted the references to postslaughter residue degradation studies from the February 1977 notice. When there is reason to believe that storage conditions or food preparation methods might lead to the formation of potentially toxic residue products, however, the Commissioner will require appropriate special investigations. Petitioners are encouraged to explore the postslaughter stability of residues. Experience has shown that residue stability can be a complicating factor in studies for validating assays for dosed tissues. The Commissioner encourages research in this area; but until appropriate information can be reliably incorporated into food safety decisions, these data will not be used to liberalize the regulatory requirements.

G. OTHER POSSIBLE SAFETY FACTORS

Originally, the Commissioner proposed that the calculated does be modified to account conservatively for drug use patterns, e.g., the administration of the drug in the treatment of diseased animals. Comments stated that disease incidence does not occur randomly within a geographic area or within specific animal groups. Although a disease may have an overall incidence of only 10 percent, the affected group may be located in a single area. Therefore, the Commissioner was unable to conclude that evidence exists, or other safety factors are available, to permit the agency to calculate the effect of such drug usage, and this provision was deleted. No later comments have been received on this point.

VI. METABOLIC STUDY TO SELECT MARKER RESIDUE AND TARGET TISSUE

A. THE CONCEPT

Before the use of a sponsored compound can be approved, the Commissioner must determine that a practical and reliable assay is available to measure carcinogenic residues at the level which discriminates safe from unsafe food, i.e., the assay must be capable of determining when S_m is exceeded in each edible tissue. One approach to this problem would be to require assays that can be used to measure every residue in each of the various edible tissues. Because the number of residues in edible tissues and the number of tissues can sometimes be large, it is unlikely that such an approach would be practical. There is another far more practicable approach, which sacrifices no principle of safety. This alternative approach centers on the concepts of a marker residue and a target tissue.

A market residue is a residue whose level in a particular tissue is in a known relationship to the level of the total residue of carcinogenic concern in all edible tissues and which, therefore, can be taken as a measure of the total residue of interest in he target animal. Once a marker residue is selected and its quantitative relationship to the total residue is determined, it is possible to calculate a level, for purposes of these regulations, R_m, which is that level of the marker residue that must not be exceeded in a selected tissue (the target tissue) if the total residue of carcinogenic concern in the edible tissues of the target animal is not to exceed S_m. The marker residue can be the sponsored compound or any of its metabolites, or a combination of residues for which a common assay can be developed.

The target tissue is that tissue in which the absence of the marker residue at R_m or above can be taken as confirmation that the safe residue level, S_m, is not exceeded in any of the edible tissues. When a marker residue and a target tissue are selected, a practicable assay must be developed that can reliably measure the marker residue in the target tissue at levels at least as low as R_m, and conditions of use of the sponsored compound must be established that assure that, in practice, the potential marker residue level in the target tissue does not exceed R_m.

When it is determined, using an assay demonstrated to be capable of reliably measuring the marker residue in the target tissue at levels at least as low as R_m, that there is no such residue at levels at or above R_m, it can be concluded that the no-residue standard of the act has been satisfied for all edible tissues in the animal under ex-

01197

amination. Conversely, if the marker residue is found in target tissue at levels equal to or greater than R_m, all edible tissues must be considered unsafe for human consumption.

B. APPLICATION: DATA COLLECTION AND CALCULATION OF R_m

1. *Marker residue.* Application of the concepts of marker residue and target tissue requires an experimental determination of the quantitative relationships of residues that might serve as marker residues (including any that have definitely been shown to be noncarcinogenic, because theoretically one of these might be selected as marker residue) to the total residue in each of the various edible tissues that might serve as target tissues. Further, because these relationships change with time, the levels of potential marker residues in the potential target tissues must be measured over time, and tissue concentration-time profiles must be constructed. These depletion profiles will be derived from measurements made in target animal tissues after cessation of exposure to the sponsored compound. Finally, because the results of carcinogenicity testing have been used to set limits for total potential undetected residues in each of the individual edible tissues, the depletion profiles must include measurements of the total residue in each potential target tissue to levels at least as low as the S_m appropriate to the tissue. Also, depletion profiles for one or more potential marker residues must be constructed and include measurements of levels of residues corresponding to the times when the total residue has reached S_m (Plates I and II set forth in proposed § 500.89).

Part III of this preamble describes the requirements for the study of the metabolic fate of a sponsored compound in target animals. Although the purpose of this earlier metabolic study is to provide information for selecting residues for carcinogenicity testing, the same principles and requirements are applicable here and must be followed in acquiring the information necessary to construct depletion profiles. However, to meet the depletion profile requirements prescribed by the regulations, a second metabolic study of the sponsored compound in the target animals may be necessary. This second and possibly more refined study may require using a larger number of animals. It will be necessary to determine the total number and the quantities of residues at several appropriate times, starting immediately after cessation of exposure and continuing until the residues in each of the potential target tissues have reached a level corresponding to a total residue level of the appropriate S_m for that tissue. If the initial metabolic study is done in a manner adequate to select a marker residue and a target tissue, of course, it need not be repeated.

Selection of a marker residue will be based on examination of depletion profiles. Generally, there will be a time at which the sum of the levels of the individual residues of carcinogenic concern will fall below the S_m appropriate to the tissue under examination. Residues that are potential markers will be present at a known concentration (R_m) at this same time (Plate I), and in a definite (although perhaps rapidly changing) quantitative relationship to the total residue (Plate II).

With the quantitative relationships established, it will be possible to select one of the residues as a marker. Ordinarily, the residue selected will have the following characteristics: (i) It will represent at least 10 percent, and usually more, of the total residue burden at the time the total residue was depleted to S_m; (ii) it will be stable, easily isolated and characterized, and susceptible to manipulation for assay development and implementation; and (iii) it will be undergoing relatively rapid change in concentration at the time the total residue burden is at or near S_m (i.e., a change in its concentration will be a sensitive indicator of the time when the total residue burden has depleted below S_m). Although other considerations may enter into the selection of a marker residue, these three will ordinarily be most important.

There may be instances in which no single residue can adequately fulfill the requirements a marker residue must meet. In such instances, it may be necessary to select some combination of residues which, taken together, can represent the total residue burden. It should be noted that a marker residue can be a compound which is not a carcinogen, but is an unambiguous indicator, in the manner already described, of the presence or absence of carcinogenic residues.

2. *Target tissue.* Selecting a target tissue requires a comparison of the depletion profiles for each of the edible tissues (Plate I set forth in proposed § 500.89). A target tissue will be selected on the basis of assurance that the absence of the market residue at or above R_m means that carcinogenic residues are absent from the tissue that requires the longest time to achieve its S_m, and thus that the entire animal is free of carcinogenic residues.

When a compound is to be used in milk- or egg-producing animals, milk and eggs will be target tissues in addition to one tissue selected as the target tissue to represent the depletion of residues in all of the edible carcass. In these cases, it may be necessary to select a marker residue for milk or eggs that is different from the marker residue selected for the target tissue representing the edible carcass.

3. *Calculation of R_m.* The R_m for a marker residue is the level of that marker residue which is present in the target tissue at the time, T_L, when the sum of the levels of the residues in the tissue that requires the longest time to achieve its S_m (excluding any residues that have definitely been shown to be noncarcinogenic) is equal to S_m for that tissue. The depletion profiles will be used to select R_m (Plate II set forth in proposed § 500.89).

For example, assume (i) that liver is the target tissue of animal drug, P, intended for use in cattle; (ii) that the only residues of P are the parent compound, P, and a metabolite, P_{101}; (iii) that T_L is 3; (iv) that S_m for the sponsored compound is 29 parts per billion; and (v) that the following is a chart of the depletion profile of the drug.

Time	Total residue burden	P	P_1
0	100.00	75.0	25.0
1	65.4	41.6	21.8
2	42.0	25.3	17.3
3	29.0	15.0	14.0
4	21.0	9.0	12.0
5	15.0	5.0	10.0

In this case, before the drug can be approved for use, the petitioner must develop an assay that will satisfy the evaluation criteria in liver for either P at least as low as 15 parts per billion or P_1 at least as low as 14 parts per billion. Because P is depleting faster than P_1, when the total residue burden is 29 parts per billion, P may be the preferred compound to select as the market residue because it provides a more sensitive assessment of when the total residue burden reaches 29 parts per billion (S_m). Another example is provided in Plate II in proposed § 500.89.

Comments on the marker residue-target tissue segment of the regulations posed questions about the definition of terms and the implementation of procedures. One comment requested that the Commissioner add a table of definitions for the entire subpart, and it suggested that the agency coin a new term for the "marker residues." Another comment questioned whether the studies required to identify the marker residue and target tissue are truly "metabolism" studies. The February 1977 notice stated that the Commissioner would select the target tissue and marker residue, and one comment suggested that they be selected by the petitioner, who has a better knowledge of both the sponsored compound and of the availability of technology to develop assays for metabolities. Another comment questioned whether the agency is requesting sufficient information on edible

01198

tissues to permit a determination of a marker residue or target tissue. It also questioned why the most slowly depleting tissue is not always the target tissue. It further requested that the target tissue concept be clarified when a target animal is used for milk or egg production.

The terms "marker residue" and "target tissue" are defined in proposed § 500.83, and their meanings will be codified by the final regulations. For clarity, a new section is added to define all new terms for the subpart. The term "metabolic study" has been used by FDA to describe the types of studies called for by the regulations for many years. The Commissioner disagrees that the term is inappropriate.

The Commissioner agrees that the petitioner for a sponsored compound has a role in selecting the marker residue and target tissue. Under current agency procedures, the selections are made with the opportunity for participation by the petitioner, and thus the petitioner's knowledge and proponent status are recognized. Because the agency must make the decision on whether the sponsored compound can be safely used, however, it must remain the ultimate decisionmaker.

The regulations require petitioners to determine the tissue depletion profiles for residues, and for a sponsored compound a considerable part of this information will already have been gathered by the initial metabolism study. (See section III of the preamble.) The Commissioner concludes that it is appropriate to select the target tissue from among tissues likely to become storage depots or to be involved in metabolism and excretion of the sponsored compound. Routinely examining other more specialized tissues in great detail will yield little additional useful information. Material balance calculations will be used as necessary to determine whether other tissues are potential storage depots and therefore may be target tissues.

The criteria for selecting the marker residue and target tissue are such that, when the marker residue concentration passes through its R_m in the target tissue, all other residues in the tissues, including the most slowly depleting tissues, will have passed through their R_m. Therefore, the most slowly depleting tissue need not be the target tissue.

Finally, the Commissioner explained in the February notice that for milk- and egg-producing animals, it is necessary to have a target tissue in addition to the milk or eggs. To clarify this matter, the Commissioner added this requirement to the regulations.

VII. Sponsored Compounds Affecting Pools of Carcinogenic or Potentially Carcinogenic Substances Endogenous To Target Animals

A. Applicability of No-Residue Requirement

The act requires that in making food safety decisions, the Commissioner take into account all substances formed in or on food by the administration of sponsored compounds to food-producing animals. It is well recognized that: (i) Several substances endogenous to food-producing animals are suspect or proven carcinogens (Ref. 64); (ii) in any given animal species or breed, the size of pools of such endogenous substances may vary widely and are affected by such factors as sex, age, lactation, state of estrus, pregnancy, and geographic location; and (iii) humans have had sustained exposure to such endogenous substances for centuries. Whether normal levels of human exposure to these substances are responsible for human carcinogenesis is unknown, but using drugs that can cause an increase in human exposure to these compounds has the potential of increasing the risk of human carcinogenesis. Under the act, therefore, the use of such drugs must be controlled.

In dealing with potentially carcinogenic endogenous compounds, the 1973 proposal declared that the intent of the no-residue requirement of the act is the maintenance of the normal human dietary content. Thus, the February 1977 notice required the determination of the effects of sponsored compounds on the normal background levels of potentially carcinogenic endogenous compounds. If a compound is found to increase these levels, conditions of use are to be established so that normal background levels are not exceeded in the animal when the animal is slaughtered. The notice also required development of practical assays for measuring levels of endogenous compounds.

Several comments on this segment of the 1973 proposal expressed concern over the meaning of the term "endogenous compounds" and questioned how these compounds are to be distinguished from "exogenous compounds." Others questioned whether the former term includes chemical derivatives (estradiol benzoate) of bona fide endogenous compounds (estradiol) or essential nutrients (some amino acids, minerals, vitamins). Comments also expressed doubt about the distinction between endogenous and exogenous compounds when the administered compound can be metabolized to residues of both classes. Some comments also argued that all externally administered compounds should be considered exogenous, as the true meaning of the term implies.

Other comments suggested that endogenous substances of interest be subjected to toxicological testing and tolerances be set if such substances are found to be not carcinogenic. Some doubted that available technology could meet the proposed requirements. They contended that the terms "normal conditions of use" and "normal background levels of endogenous compounds" would be either extremely difficult or impossible to define. While recognizing the difficulty of the task, the Commissioner concluded that administered compounds that increase the naturally occurring level of potentially carcinogenic endogenous compounds present special problems of control, which the proposed regulations had to address and resolve.

As the Commissioner explained in the February 1977 notice, an endogenous compound is any compound that is metabolically produced by and is present in untreated target animals. Any sponsored compound which, when administered to a target animal, is found to increase the normal background levels of a potentially carcinogenic endogenous compound is subject to these proposed regulations, regardless of how the increase is brought about. For instance, estradiol benzoate, which by the above definition clearly is not an endogenous compound, is metabolically converted to the endogenous compound estradiol and may thus cause an increase in normal background levels of that substance. Estradiol may itself be administered and possibly cause target animal pools of estradiol to increase above background. Finally, a sponsored compound may indirectly cause an increase in tissue levels of estradiol by affecting any number of hormonal regulatory systems in the target animals.

Although in each of the above-cited cases the cause of the increases in normal background levels of estradiol is different, the result is the same. And it is the result that must be monitored and controlled. It is thus of little use to distinguish between "endogenous" and "exogenous" administered compounds. Rather, it is useful only to distinguish between administered compounds that can cause changes in normal background levels of potentially carcinogenic endogenous compounds and those administered compounds that do not affect such levels.

Essential nutrients are not included in the definition of the classes of compounds that will be regulated by these proposed regulations. In a strict sense, essential nutrients are not endogenous. Although present in the tissues of animals and required for growth

01199

and health, they are not produced by the animals and must be supplied from external sources. These features place essential nutrients in a distinct class of "required exogenous compounds," which must continue to be regulated in a unique manner. Determination of the allowable use of essential nutrients must reflect the target animals' nutritional requirements. When used according to label directions, supplements of essential nutrients that present carcinogenic risks should restore, but must not exceed, the essential nutrient levels found in natural foods adequately sustaining normal growth of healthy animals. Furthermore, the levels of such essential animal nutrients found in human food derived from animals with diets supplemented with essential nutrients must not exceed the levels in food derived from normal healthy animals fed a nutritionally adequate natural diet.

B. GENERAL PROCEDURES

If available information shows that a sponsored compound might affect pools of potentially carcinogenic endogenous substances above the level considered to be safe under the criteria of these proposed regulations, the petitioner would be required to investigate whether such effects occur under the conditions of the compound's proposed use.

The Commissioner proposes the following requirements: (i) Establishment of normal background levels (or "norm") of the endogenous compound of carcinogenic concern in the target animals; (ii) determination of the effects of the sponsored compound on the norm; (iii) establishment of safe conditions of use of the sponsored compound by demonstrating how the compound can be used in a way that ensures that the norm is restored in the target animals before slaughter; and (iv) development and validation of a practical assay to measure the endogenous compound at levels specified by the norm. The proposed regulations specify how each of these steps is to be accomplished.

C. SPECIFIC STEPS REQUIRED

The petitioner would first be required to determine experimentally the normal background levels, or norms, of the potentially carcinogenic endogenous compounds of concern in untreated target animals. A norm must be specific for the untreated target animals. The petitioner would provide the norm in the form of a cumulative frequency distribution of the observed levels of the endogenous compound. This curve must also include 99 percent confidence limits (Plate III appearing in proposed § 500.89).

The median and shape of the frequency distribution must be known so that shifts in the norm can be measured. For this reason, the assay used to determine a norm must yield values for the endogenous compound different from zero for at least two-thirds of the untreated target animals. This latter requirement is a compromise between the need to determine the frequency distribution with a high degree of reliability and at the same time to recognize the difficulties thay may be encountered in measuring levels at the lower end of the norm.

The petitioner would then determine the effects of the sponsored compound on the norm and provide data on the postexposure decay of any observed increases in the norm. The norm is considered restored when the distribution of values for the endogenous substance of concern observed in a group of treated animals is, with 99 percent confidence, the same as the norm.

The norm, as defined, takes into account those variables that affect background levels. The proposed regulations thus resolve the difficulties raised by 1973 comments suggesting that "normal background levels" would be difficult to define.

D. ENDOGENOUS MARKER RESIDUE: CALCULATION OF R_m

If the norm of an endogenous substance of carcinogenic concern can be increased by the administration of a sponsored compound, the endogenous substance can become an endogenous marker residue, i.e., its presence above certain levels can be considered an indicator of potentially carcinogenic residues in food. Approval of the use of such a sponsored compound is contingent upon the petitioner's furnishing of data demonstrating that the norms are restored in the target animals before slaughter, and upon the availability of a practical assay that can reliably measure the endogenous marker residue in target animals. This regulatory assay must be capable of measuring the marker residue at the level, R_m, corresponding to the 33d percentile of the norm (Plate III set forth in proposed § 500.89).

The R_m for an endogenous marker residue derives from a conceptual approach entirely different from that used for the derivation of an R_m for an exogenous marker residue. To monitor shifts in the norm, the Commissioner must be able to measure the median and to determine the shape of the distribution. An assay capable of measuring the 33d percentile of the norm provides the analytical capability necessary to determine whether the norm has been shifted by administering the sponsored compound to the target animals because it permits measuring two-thirds of the points on the distribution curve. The same assay evaluation criteria apply to endogenous compounds as to other compounds covered by these proposed regulations.

Accordingly, the commissioner in the February 1977 notice revised the provisions which, as proposed, would have originally established the lowest limit of reliable measurement at the 99th percentile of the norm. As the comments noted, as assay that can measure only the upper 99th percentile would not be able to detect any shifts in the norm, which is its primary function. The proposed regulations require an assay capable of a lowest limit of reliable measurement of the 33d percentile of the norm, which will readily detect any shifts in the median or mean of the norm. Determination of compliance depends on a regulatory system that monitors shifts in the norms and not levels of endogenous substances in individual animals.

E. ALTERNATIVE PROCEDURE

Earlier comments contended that an alternative to the foregoing procedure should be available for regulating endogenous substances. It was suggested that a tolerance for an endogenous compound can be established at levels above the norm, provided that appropriate toxicity testing on the compound is carried out and a safe level can be established in accordance with sections IV through VI of this preamble and proposed §§ 500.84 through 50090.

Separate mechanisms with distinctly different rationales have been developed to measure compliance with the no-residue standard of the act for endogenous and exogenous compounds. As noted earlier, for exogenous compounds, the regulations would require development of an assay with a lowest limit of reliable measurement at or below the level needed to ensure that any undetected residues pose essentially no increased risk of cancer in the population. On the other hand, the method for measuring compliance with the no-residue standard for an endogenous substance is based on the norm.

In the absence of toxicology data of the type needed to determine a safe level for exogenous compounds, described in section V of this preamble, the Commissioner maintains that restoring the norm is the only way to ensure the absence of unaccepatble risks resulting from the use of compounds that may increase pools of potentially carcinogenic endogenous substances. If the toxicology data are available, however, and are suitable for extrapolation by the procedures described in section V of this preamble, the Commissioner will permit a shift in the norm equal to the incre-

01200

ment shown to produce a lifetime cancer risk no greater than 1 in 1 million.

The 1977 notice announced that the Commissioner was receptive to suggestions for other alternative mechanisms of control. Two comments argued that the Commissioner has no authority to regulate increases in potentially carcinogenic endogenous substances that occur "indirectly" from the administration of the sponsored compound. They contended that the Commissioner can only regulate substances that derive directly from the sponsored compound, not from its use. The Commissioner rejects these comments, which are analogous to the earlier comments that the agency can regulate only a parent compound, not metabolites, under the Delaney clause. As explained in the February 1977 notice, the Commissioner is concerned about the use of compounds that may increase the pools of potentially dangerous endogenous substances that may be formed in or on food because of a sponsored compound's use. The general safety provisons of the act clearly cover all substances formed in or on food due to the use of a sponsored compound, and it is proper to consider excess levels of endogenous compounds of carcinogenic concern as such substances.

A comment requested that the Commissioner specify which potentially carcinogenic endogenous compounds are within the purview of this section. The Commissioner concludes that the proposed regulation covers all endogenous compounds that animal or human data show may present a carcinogenic risk.

Concerning the comment that all endogenous substances should be proscribed from use in animals, the Commissioner advises that there is no legal basis for their outright prohibition. Furthermore, the regulations prescribe procedures for use of these substances that ensure the same degree of safety as that required for the use of exogenous compounds.

Finally, a comment stated that the studies described in the February 1977 notice are costly, and it contended that, unless the data collected are considered proprietary, the requirement puts pioneers in the field at a disadvantage. The comment also requested that the Commissioner specify the studies required to define the norm and measure its restoration.

Under the current law, the Commissioner concludes that data on the norm are safety data required for every application and are proprietary data for new animal drugs. However, to reduce unnecessary testing, expenses to the regulated industry, and costs to the government, it is the agency's policy to encourage joint funding of tests.

The Commissioner believes it inappropriate to establish, as part of the regulations, detailed protocols for studies required to establish norms. However, the following example is offered as a guideline. To determine, with a high degree of confidence (99 percent), the characteristics of the distribution of the individual values that constitute the norm, the petitioner will ordinarily be required to examine a reasonable number of animals in each production class of target animals in which the sponsored compound is proposed for use, both treated and untreated. In each group, 450 to 500 animals will be sufficient to determine with 99 percent confidence:

(1) That the 99th percentile of the norm is less than the largest observed value; and

(2) That the cumulative frequency distributions of the observed levels of the endogenous compound in untreated target animals and in the treated target animals do not differ by more than .10 at any specific point.

To test whether the norm for the sample of untreated animals and the values for the sample of treated animals came from the same population, i.e., there was no effect due to treatment with the drug, the petitioner may use the Kolmogorov-Smirnov two-sample test. This test is concerned with the agreement between two cumulative frequency distributions. This test is sensitive to any type of difference in the distributions from which the two samples (treated and untreated) were taken, e.g., differences in location (mean, median, etc.), differences in variation, differences in skewness, etc.

The only assumptions required for this test are—

(1) That the samples are random samples;

(2) That the two samples are mutually independent; and

(3) That the samples are from a continuous population.

Specifically, the Kolmogorov-Smirnov test evaluates the probability of the maximum absolute difference that would occur between two cumulative distributions if they were obtained from the same population. For the details of conducting the test see Refs. 77 and 78. It must also be remembered that the above-described study may be conducted in lieu of chronic toxicity tests, and it can be conducted during the effectiveness studies. Thus the costs of developing and marketing an endogenous compound will be comparable to the corresponding costs for an exogenous compound.

VIII. Regulatory Assay: Evaluation Criteria and Approval Process

A. Introduction

The Commissioner can approve a sponsored compound for use in food-producing animals only if the intended use of the compound does not result in the accumulation of potentially carcinogenic residues in edible tissues and if an assay is available that can reliably measure such residues at and above the R_m. The assay must also be suitable for monitoring food from animals administered the compound to prevent food from reaching the marketplace if it is adulterated with potentially carcinogenic residues resulting from misuse of the compound.

Many comments in response to the 1973 notice contended that more explicit criteria and evaluation procedures should be specified.

The Commissioner agrees with these comments. Because the assays required by these proposed regulations are to be used for regulatory monitoring of residues of potential carcinogenic concern in food, rigorous criteria must be established for approval of these assays. Furthermore, the proposed assay must be subjected to an objective evaluation to determine whether it meets the criteria. Only then can there be assurance that an assay will provide a reliable and practical monitoring device to prevent violated residues in food. Most of the questions raised in the comments arose because the 1973 notice contained only a brief description of the assay evaluation criteria and procedures. Accordingly, the following discussion sets forth, as in the 1977 notice, the evaluation criteria and their bases.

Any assay used for regulatory purposes is characterized by a set of attributes that determine its quality: dependability, practicability, specificity, accuracy, and precision. These regulations specify objective criteria for these attributes. A proposed assay must be shown to meet these criteria during studies in a single laboratory and also in interlaboratory studies in government regulatory laboratories. The latter requirement is essential because the assays are to be used in Federal regulatory laboratories (FDA, USDA) and State laboratories, and the Commissioner must determine in advance that an assay will perform satisfactorily in more than one such laboratory. The proposed regulations specify that the interlaboratory validation study must be carried out in those laboratories (USDA and FDA) that will be using the method in surveillance and enforcement programs.

The steps in obtaining approval of an assay are—(1) assay development and study by the petitioner to deter-

01201

mine whether the assay satisfies the acceptability criteria; (ii) FDA review of the petitioner's study to determine suitability of the assay for evaluation in interlaboratory study; and (iii) interlaboratory validation study, again with approval contingent upon satisfaction of acceptability criteria.

B. SOURCES OF DATA TO SUPPORT THE ASSAY

Data from studies of an assay using three types of samples are necessary to support approval. The petitioner must prepare and analyze samples of target tissue to which known and varying concentrations of marker residue, including R_m and concentrations above and below R_m, are added ("spiked" tissues). The petitioner must also compare responses obtained from assays using these tissues with responses obtained from assays of target tissues known to be free of marker residues (control tissues). In plotting observed instrumental response versus concentration of marker residue, i.e., in constructing the analytical curve from these data, as many samples as possible should be run, preferably by different analysts, because interlaboratory validation of the assay will eventually be required. The variability among different analysts can be determined at the developmental stage and adjustments made before the assay is submitted for FDA review.

Before submitting an assay to FDA for review, a sponsor should be satisfied that it meets all of the evaluation criteria and also that it is consistent with general principles of good analytical practice. Past experience shows that a petitioner's failure to follow good analytical practices during initial assay studies often results in interlaboratory failure even though the initial results may appear satisfactory during a paper review of the assay by FDA. A petitioner should assure that no results enter the construction of an analytical curve when it is known that the results were obtained using other than acceptable principles of analytical practice.

In addition to the spiked tissue tests, a petitioner must also submit data showing the applicability of the proposed assay to target tissues taken from target animals treated with the sponsored compound ("dosed" tissues). Validation of the assay requires dosed tissue samples that contain the marker residue at a level approximating R_m. The petitioner is required also to submit a standard analytical curve constructed by taking the marker residue of known purity at different concentrations, determining the response, and plotting the relationship.

C. SUBMISSION OF DATA

Agency resources for reviewing and validating assays are limited. The Commissioner therefore would establish in this proposal a precise format for submitting the data to support acceptance of an assay. It is a well-recognized principle, applied both by the courts and administrative agencies, that a standard format can be required for pleadings, requests for licenses, and other applications. This format may also designate special types of information that must be contained in the submission. Therefore, the agency would refuse to accept a petition or review an assay when the request for approval fails to conform to the format outlined below.

1. *Assay description and petitioner's evaluation.* The petitioner must provide a complete description of the assay to allow FDA to determine whether it is potentially acceptable. Because this threshold determination of acceptability will trigger an extensive interlaboratory validation procedure, the discussion must be sufficiently rigorous to minimize waste of agency resources. Therefore, the submission must discuss in detail—

(a) What equipment and reagents are necessary;

(b) How the assay is performed; and

(c) How the assay complies with the criteria of dependability, practicability, specificity, accuracy, and lowest limit of reliable measurement prescribed in proposed § 500.90(d) and discussed under section VIII. E. below in this preamble.

2. *Data.* The data and worksheets, including spectrograms, chromatograms, etc., from the spiked tissue, dosed tissue, and control tissue analyses and the external standard and quality control data are also necessary for the preliminary review of the assay to determine whether it actually complies with the evaluation criteria.

D. FDA REVIEW

The agency will conduct a paper review of a petitioner's submission to determine whether an assay complies with the acceptability criteria. These regulations generally alert potential petitioners to the applicable statutory standards and criteria, which should permit a petitioner to assess preliminarily the acceptability of an assay before filing a petition, and thereby reduce the agency's workload.

If on preliminary review an assay appears to comply with the evaluation criteria, it will then be subjected to the interlaboratory assay validation study to determine whether it is indeed a practicable and reliable regulatory tool. Should the initial review establish the assay fails to meet these criteria, the petition will be denied. A conclusion that an interlaboratory assay validation study should be initiated, however, in no way guarantees that a proposed assay will eventually be approved.

The assay criteria and attributes set out in the proposed regulations represent and amalgamation of statutory and scientific standards. Because a variety of terms are in use, the Commissioner is proposing to adopt and define the basic terms in the regulations in simple language for the sake of clarity. Accordingly, an assay must meet the following attributes and criteria for approval:

1. *Dependability.* Dependability is the likelihood that the proposed assay will not fail to yield a result because of uncontrollable features inherent in its design. Almost all assays will, on occasion, fail to yield any result. Often this failure occurs due to mishandling by the analyst, but sometimes failure may be the result of some aspect of the assay itself that may have been inadequately studied and defined or that cannot be controlled. For example, assays depends upon the availability of a standard against which measurements are compared. If the integrity of the standard depends on certian environmental factors (e.g., purity of the solvent in which it is maintained, temperature, light intensity, etc.) and these factors are understood, it may be possible to prevent assay failure. If this dependence is not know, however, the assay may fail and may fail often depending on the effect of the environmental factor of importance on stability of the standard. In this example, failure can mean a highly inaccurate result, assuming some fraction of the standard's intergrity is retained, or it can mean no result at all, assuming complete loss of integrity.

Assays used to monitor carcinogenic residues in food must be free of such uncontrollable features. Failure of a proposed assay to yield results during the petitioner's assay development studies or interlaboratory validation study can be a ground for refusing to accept the assay and for denying the underlying petition. Accordingly, the regulations require a petitioner to furnish information on, and provide an explanation of, runs of the assay that are begun, but never finished, during the analyses of samples used to construct the submitted analytical curve.

2. *Practicability.* Proposed § 500.90(d)(2) defines the practicability attribute as follows:

The assay is considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay must be consistent with regulatory objectives, monitoring, compliance, etc. All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay must be either commercially available, or readily available from the petitioner, on request. The Commission-

01202

er will withdraw approval of any assay and initiate regulatory action against the sponsored compound if such a condition of the compound's approval is no longer satisfied.

The Commissioner has established criteria for practicability in terms that relate specifically to the nature of the laboratories in which the assay will be used, i.e., regulatory laboratories where the time and availability of equipment and reagents are critical factors in their ability to perform satisfactorily the mandate functions.

The inability to use an assay at a regulatory laboratory because a needed reagent is not readily available or because excessive time is requred to complete the assay presents potential risks to publish health and, therefore, precludes approval of the assay. Obviously, some assays will require some unique items, particularly reference standards. The Commissoner agrees with comments suggesting that, as long as a sponsor makes reference standards available to all persons having an interest, this requirement of the regulation will be met. A commitment to supply reference standards when they are not commercially available may be made a condition of the sponsored compound's approval, and failure to supply the governmental or other laboratories as required is a basis for withdrawing a compound's approval. The Commissioner concludes that an assay is not practical if it is dependent on the use of any other unique equipment or materials that are not commercially available.

3. *Specifity.* The regulations provide that, for an assay to be accepted, and observed response must be due to the compound that is being measured, and to that compound only. It is a fundamental part of the development of an assay to determine whether or not it possesses this important attribute. Among analytical chemists and biochemists, an "assay" that does not demonstrate this attribute is of little value; and indeed, in a regulatory setting, such an assay could be dangerously misleading. For this reason, the Commissioner has established rigorous specifications for this attribute.

In general terms, "specificity" refers to the uniqueness of the relationship between the observed effect (or response) and the applied stimulus (in this case the chemical under analysis). In analytical chemistry and biochemistry, the term "specificity" is commonly used to refer to the uniqueness of a response resulting from the application of a stimulus having specific characteristics; that is, the term has a qualitative dimension only in that it does not relate to either the quality of response or stimulus or to the nature of the relationship between response and stimulus. Both of the latter criteria, which might also be considered aspects of specificity, are central to good analytical practices. The regulations consider both the qualitative and quantitative aspects and groups them together under the general attribute of "specificity." The Commissioner's objective is to assure that, whatever the observed response, it is uniquely related to the marker residue both qualitatively and quantitatively.

The establishment of an analytical curve (not simple a standard curve, but one derived from actual measurements obtained on tissue samples containing known amounts of marker residue at different levels and from control samples) provides the means to detemine whether the responses produced by an assay are single-valued, as they must be if an assay is to be considered fully specific. Only assays that yield continuously increasing or decreasing analytical curves will satisfy the criterion of single-valuedness. The criterion of single-valuedness, or montonicity, must be established for the full range of possible contamination of residues, i.e., from zero residue levels up to levels of residues that will be present if no withdrawal period is observed.

The regulations require that the assay contain a sufficient number of independent measurements utilizing independent physicochemical principles to assure specificity (i.e., the identity of the marker residue must be confirmed). There are many ways in which specificity can be demonstrated experimentally. A petitioner may use highly sophisticated research tools to demonstrate that a proposed assay is specific in the ways discussed above. However, a regulatory analyst, using an approved assay, must have available some technique that can provide assurance that an observed response is due to the market residue. At present, although there are other possibilities, mass spectrometry is probably an ideal choice for acquiring the requisite specificity. Some determinations (e.g., those requiring enzymes) may have an inherent high specificity, but others have low specificity (e.g., gas, thin-layer, and liquid chromatography) and require other independent types of measurements to achive the requiste confirmation of identity. The requirement in the regulations that an assay contain a sufficient number of independent measurements negates the effect of a false positive measurement.

4. *Accuracy.* Assays yield measurements of concentration that are in some proportion to the true concentration of the compound being measured. The ratio of the measured to the true concentration of the compound, expressed as a percentage, is a measure of the assay's accuracy. The accuracy of an assay is determined from data collected from two types of studies.

One type of study must yield graphs of the observed concentrations of the marker residues, as determined by analysis, plotted against the corresponding levels of marker residue added to the analyzed target tissue. The plot is to be used to ascertain whether the assay meets the above-specified criteria.

The other type of study must measure the assay's recovery of marker residue from target tissue of target animals exposed to the sponsored compound. If target animals exposed to a radiolabeled sponored compound produce radiolabeled marker residue, it will always be possible to measure the proposed assay's recovery by directly comparing measurements obtained from the proposed assay and appropriate measurements of radioactivity. If it is not possible to have radiolabeled marker residue, the true concentration of marker residue in target tissue from exposed animals must be determined by exhaustive extraction of such tissues after appropriate standard treatments which hydrolytic enzymes.

The regulations prescribe specific accuracy criteria The average of observed responses must be between 60 and 110 percent of the true level of the marker residue when the lowest limit of reliable measurement, L_m, which is described in the next paragraph, is less than 100 parts per billion and between 80 and 100 percent of the true value if L_m is equal to or greater than 100 parts per billion. These criteria need not be satified throughout the full range of the analytical curve, but they must be satified in the range from L_m to three times L_m. These criteria are consonant with current good analytical practice.

5. *Lowest limit of reliable measurement (L_m).* To be accepted for regulatory purposes, an assay must be able to distinguish, with a high degree of confidence, target tissues that contain levels of the marker residue at or above R_m from target tissues that do not. This distinction must be reproducible and capable of supporting legal action when violative residues of the sponsored compound occur.

To provide the necessary degree of discrimination, the regulations require that the assay be capable of producing when the marker residue is present in target tissue at or above R_m a response that is, with 99 percent confidence, different from the response in nontreated (control) target tissue, i.e., the difference between the responses of control target tissue and target tissue containing the marker residue at or above R_m is, with 99 percent confidence, greater than zero.

The actual lowest limit of reliable measurement for the proposed assay is termed the "L_m", and it will be determined by reference to the analytical

01203

curve of the proposed assay. The L_m will be the level of marker residue that gives a response above the expected blank value that is greater than, or equal to, 0.75 times the spread of the 99 percent confidence limits of a single assay response measured parallel to the observed assay response axis (see Plate IV in proposed § 500.90(d)(5)).

If the determined lowest limit of reliable measurement, L_m, of the proposed assay is equal to or less than the R_m, this criterion will be considered satisfied. This procedure takes into account the attribute of precision. Thus, an assay that satisfies this criterion will provide a reliable regulatory tool to enable the Commissioner to discriminate safe from unsafe food.

The Commissioner recognizes that the term "method sensitivity" is widely used to describe the lowest level of a compound under analysis that can be detected and measured with an analytical assay. Indeed, the original proposal used this term to describe what is now termed "the lowest limit of reliable measurement." However, there is some confusion surrounding the term "sensitivity." It derives in part from the fact that the term has been used in two senses: (1) As the lowest level of a compound that can be detected by an assay; and (2) as the lowest level of a compound that can be measured reliably by an assay. In fact, the correct meaning of the term "method sensitivity" is unrelated to a particular level of compound concentration, but rather relates to the ratio of change in instrument response to the change in compound concentration. The term "sensitivity" has therefore been dropped from this proposal. The Commissioner has adopted the term "lowest level of reliable measurement" because that term more accurately describes the attribute.

In response to comments urging that any "detected residue" should be subject to regulatory control, the Commissioner points out that it is an inherent characteristic of almost all analytical methods that componds can sometimes be detected at levels below the levels at which they can be reliably measured. More precisely, detection of a compound simply means that there is some instrument response above background levels that could be the compound of interest, but this response cannot be considered a reliable measurement or identification of the compound (Ref. 9). Since public protection is the goal, the Commissioner must be in a position to document conclusions based on analytical data, often in a court of law. A major aim of these proposed regulations is to assure that assays used to obtain such data can reliably measure residues. Hence, the Commissioner concludes that the discriminant for samples containing potentially violative exogenous marker residues must be the lowest limit of reliable measurement, L_m, of the approved assay.

Several comments on the 1977 notice stated that the definition of L_m and the procedures for determining L_m were incompletely specified. Most comments applauded the Commissioner's attempts to specify analytical attributes and agreed that the criteria were in accord with current good analytical practice. Several comments suggested that further specification of the interagency validation procedure might be desirable, and thus offered assistance if detailed guidelines were to be drafted in the future.

The Commissioner agrees with these comments and is proposing to define L_m in detail in the regulation as described above.

There was some confusion regarding the definition of "accuracy," and one comment stated that the regulations confused the terms "accuracy" and "recovery." The Commissioner agrees that in the February notice the term "accuracy" is used in a manner equivalent to what is normally termed "recovery." The term "accuracy," however, is more in line with analytical chemistry terminology, and the differences between accuracy and recovery occur only when dealing with absolute analytical methods, which will not be of concern here. For these reasons the Commissioner is proposing to retain the term "accuracy."

E. INTERLABORATORY VALIDATIONS OF ASSAY

Although FDA will review the assays for each sponsored compound, the actual regulatory field examination of foods of animal origin will be primarily performed by USDA under the Meat and Poultry Products Inspection Acts, and by the States under the Public Health Service Act. The Food and Drug Aministration performs a complementary regulatory function: Followup analytical and field investigations of violative residues to assemble evidence for use in regulatory actions.

The initial paper review by FDA of material in a petition permits the agency to make initial determination of the acceptability of an assay. Adequate protection of the public health, however, requires assurance that these assays will function in the government's regulatory laboratories. Therefore, these regulations also prescribe the procedure that will be used to assure that an assay is appropriate for use as as regulatory tool by government laboratories.

The Commissioner is proposing to require that three government laboratories (two FDA facilities and one USDA facility) independently validate an assay before it can be determined that use of a sponsored compound can be approved. This requirement is necessary because of the delicate nature of the assays, their importance in assuring that no residues of carcinogenic concern will occur in food of animal origin, and the practical limitations on the government's capacity to monitor food production and distribution. These three laboratories must study an assay sufficiently to assure that all criteria are met and that the petitioner has drawn correct conclusions in the submission about the assay's acceptability.

A comment on the 1977 notice suggested that FDA adopt the Association of Analytical Chemists' procedure for validating the assays. At this time, the Commissioner believes the AOAC process is inappropriate. It is very time consuming and permits testing in laboratories other those of FDA or USDA, where the assay will be used as a regulatory tool. Because of the delicate nature of the assays covered by these regulations and the time periods imposed for evaluating applications, the Commissioner declines to adopt the AOAC procedure. When the agency gains experience with the assays, however, the Commissioner will reconsider adopting in the regulations the AOAC assay validation process.

F. CONCLUSION

If an assay complies with the criteria described above and prescribed by the proposed regulations, and compliance can be verified under actual conditions of regulatory use (see section IX of this preamble), the Commissioner will approve the assay. A full description of the approved assay will be published in the FEDERAL REGISTER upon approval of the petition, in accordance with the provisos to the anticancer clauses and section 512(i) of the act.

IX. WITHDRAWAL PERIODS

A. INTRODUCTION

The regulations propose to define the withdrawal period for a sponsored compound as the time required, after cessation of target animal exposure to the sponsored compound, for the marker residue to deplete to L_m in the target tissue. The withdrawal period must also be compatible with actual conditions of livestock management and reasonably certain to be followed in practice. Because of the way in which the regulations define "marker residue," "target tissue," and "L_m," the use of a sponsored compound in accordance with the prescribed withdrawal period will assure that no carcinogenic residues of the compound will be present in human food derived from treated animals. At any point after cessation of exposure but before

01204

the determined withdrawal period, treated animal tissues must be considered as containing residues of carcinogenic concern. Thus, the withdrawal period specifies the length of time after the last treatment with a sponsored compound in which animals must not be slaughtered for food and during which milk or eggs must be discarded.

Several comments on the 1973 proposal addressed the procedures for establishing post treatment withdrawal periods. Some contended that the requirement for tissue equilibration (no change in concentration of residues in the tissue with change in time) with residues in the experimental procedure for establishing withdrawal times was inappropriate for therapeutic drugs. Other comments suggested that the withdrawal periods be established to assure the absence of residues from edible tissues only, because they are the ones destined for human consumption. Some of these comments expressed concern about the practicality of applying confidence-interval techniques to establishing withdrawal periods, especially when dealing with large animals. Finally, one comment requested clarification on whether confidence limits or tolerance limits were to be used in setting withdrawal periods. The following paragraphs contain the Commissioner's response.

B. DATA TO SUPPORT WITHDRAWAL PERIODS

The depletion studies required by the proposed regulations to establish withdrawal periods must take into account the biological variability among animals and other vairables, e.g., assay variability, that may influence depletion times.

Residue depletion studies must be conducted under conditions of the sponsored compound's maximum proposed use. If a sponsor can demonstrate target tissue equilibration with the marker residue, however, a shorter period of administration than the maximum dose for the longest proposed conditions of use will be permitted. The conditions of the study must also simulate actual use conditions. The commissioner agrees that a compound intended for therapeutic use need only be administered according to the compound's maximum conditions of proposed use. The proposed regulatory assay must be used to measure the marker residue in the target tissue, including milk and eggs where appropriate, because it is this assay that will be used for regulatory monitoring.

All relevant data and evaluations must be submitted with the petition, along with a graphical presentation of the tissue depletion curve (concentration of marker residue in target tissue versus time).

The analysis of the data must include the estimated depletion curve, which in most instances may be adequately approximated by a first-order decay process. The statistical tolerance limit for the 99th percentile will be determined for the samples from individual target animals, and the time of intersection of this limit with the L_m value will be determined. The withdrawal period is the interval of time between the last administration of the compound and the time of intersection of this statistical tolerance limit on the observations and the L_m of the approved regulatory assay, plus an additional interval determined by rounding out this time interval to provide a practical withdrawal period compatible with animal management practices (Ref. 79).

For example, if the time of intersection of the statistical tolerance limit for the 99th percentile on the individual tissue determinations and the L_m for the marker residue is 39 hours, the withdrawal period (preslaughter interval) would be established as 2 days. In the case of milk samples, if the time of intersection were 63 hours, a withdrawal time of 72 hours (discard of six milkings) would be established.

The use of a compound will not be approved if the necessary withdrawal period is incompatible with animal management practices. For example, the use of a compound in lactating animals will not be approved if the required withdrawal time for milk exceeds 96 hours (4 days) because the management practices of milk production make observance of such discard times unlikely, or at least not reasonably certain, to be followed in practice.

When the marker residue is an endogenous compound, the withdrawal period is the time after cessation of administration of the sponsored compound required for the norm to be restored (see sections VII., C, D, and E above) and extended if necessary to be compatible with conditions of livestock management. The validated regulatory assay must be used to collect this information.

C. RATIONALE FOR USING THE STATISTICAL TOLERANCE LIMITS APPROACH

To establish that carcinogenic residues are absent from edible tissues of food-producing animals treated with the sponsored compound, the Commissioner must have information about the rate of residue depletion and the inherent metabolic variabilities among individual target animals.

The Commissioner is proposing to use statistical tolerance limits for this section to provide the degree of confidence (99 percent) necessary to ensure protection of the public health. Confidence limits, as used elsewhere in this regulation, estimate population parameters (e.g., 99 percent confidence limits will result in an interval that contains the true response rate 99 times out of 100). Statistical tolerance limits, however, are used to provide a specified degree of confidence that a specified portion of a population is below a given value (e.g., 99 percent confidence that, if the withdrawal period is followed, 99 percent of the target tissues will contain residue levels below L_m).

One comment on the February notice argued that withdrawal periods are unenforceable and contrary to the normal practices of the meat industry.

Section 512(d)(2)(D) of the act (21 U.S.C. 360b(d)(2)(D)) provides expressly that, in determining whether a compound is approvable, the Commissioner is to consider whether the conditions of use of a sponsored compound are reasonably certain to be followed in practice. Historically, safe conditions of use have included a preslaughter withdrawal period for many compounds intended for food-producing animals, and the compound's labeling requires that this period be discussed. In the Commissioner's opinion, withdrawal periods are being followed for most compounds, although some violation will always occur. However, one of the primary functions of this regulation is to improve the procedure for setting withdrawal periods and thereby provide FDA with stronger tools for enforcing compliance with withdrawal periods and for taking regulatory action if violative residues are detected.

Three comments raised questions about the use of the term "99 percent confidence interval." Another comment suggested that using the 99 percent confidence limits on the data in calculating the withdrawal period is too conservative and will result in unduly long withdrawal periods.

To clarify, the Commissioner has defined the term "99 percent confidence interval" in the proposed definition section. The Commissioner does not agree that the proposed approach is "too conservative." By using the statistical tolerance limit on the data, the Commissioner ensures with 99 percent confidence that in 100 sampled tissues there is no more than one violative residue when the labeled withdrawal period is followed. Minimizing the likelihood that a violative residue will occur is an important public health objective, and the Commissioner maintains that the procedures provided in these regulations (the use of a validated assay to collect residue data under proposed conditions of use; the use of statistical tolerance limits to establish withdrawal periods; and the use of good animal husbandry practice to aid

01205

in determining whether withdrawal periods will actually be followed) provide the proper balance in setting a withdrawal period that ensures that (1) the food consumed, if the withdrawal period is followed, will be safe, (2) the withdrawal period is in accord with good animal husbandry practice and will be followed, and (3) violations can and will be detected.

Two comments raised questions about collecting data with the validated assay in the tissue depletion studies to determine the withdrawal period. Because assays are not validated until the final stages of a petition's review, the comments stated that it is impossible to collect data to establish a withdrawal period with the validated assay.

The Commissioner disagrees. For reasons already stated, the withdrawal period must be established with the assay for which approval is sought. Further, collecting the data by any method not proposed for validation imposes a repetitive administrative burden on the agency that is costly and unwarranted. When the data are collected with a different assay, the agency must first assess the quality of the data-collection assay and the appropriateness of the data submitted. Then it must attempt to compare the data-collection assay with the one proposed for validation. In the Commissioner's opinion this simply is an unacceptable waste of limited government resources; therefore, the Commissioner rejects any suggestion that the withdrawal period be established using an assay that is not submitted for validation.

A comment on withdrawal periods for endogenous substances contended that it is unnecessary to show when the norm is restored. The comment argued that merely showing that the norm is restored is adequate, regardless of when the restoration takes place. The Commissioner disagrees because the rate of the norm's restoration is an important consideration in setting the withdrawal period. It determines when food derived from treated target animals will be safe for human consumption. Only with such information can the necessary withdrawal periods be established.

Finally, two comments found unclear the statement that sponsors shall submit all raw data collected in determining withdrawal periods. They suggested that the regulation be reworded to require submission of all appropriate supporting data. The Commissioner agrees and intends to require submission only of all data that are relevant to determining withdrawal periods. Relevant data include, for example, descriptions of all assays on specific tissues, worksheets, and calculations, as well as daily calibration data (i.e., standard curves, spiked tissue, and background values).

X. Compliance

When a target tissue is examined with the approved assay and is found to contain the marker residue at or above its L_m, the Commissioner will conclude that the carcass from which the target tissue was taken contains carcinogenic residues and, therefore, that the sponsored compound has been used in violation of the act.

When target animals are found to contain an endogenous marker residue at or above the 99th percentile of the norm (Plate III in proposed § 500.89(c)(1)(ii)), they will be designated as potentially violative. Because there is at least a 1-percent probability that untreated target animals will contain endogenous marker residue above the 99th percentile of the norm, further investigation will be necessary to determine whether the sponsored compound has been used in violation of the act. The function of this investigation will be to determine whether the potentially violative sample originated from target animals whose median level of the endogenous marker residue is greater than the median of the norm (and hence, the need for a regulatory assay having an L_m at the 33d percentile of the norm). The proposed regulation also requires that, before regulatory action is begun, it must be determined whether or not the approved compound was used to treat the target animals under investigation.

Guarding against any shifts in the norms should allay all fears expressed in comments that monitoring only at the 99th percentile, as proposed, would not permit detection of any general increase in human exposure to potentially carcinogenic endogenous substances.

Food containing residues of any approved sponsored compound that has been used in accordance with the conditions of the compound's approval is specifically excluded from the adulteration provisions of section 402(a)1) of the act by sections 409(a), 512(k), and 706(a). Thus, administration of the sponsored compound according to the approved labeling is a defense to any criminal action that might arise for a violation of section 402(a)(1) of the act. However, within the meaning of section 402(a)(2) of the act, such food is adulterated if it contains a residue of the approved sponsored compound which is unsafe within the meaning of sections 409, 512, and 706. A residue is unsafe under those sections when it occurs in food at levels above those approved for use, and any residue found at levels equal to or above the L_m is unapproved and therefore illegal. To establish that the residue is unsafe (an adulterant) within the meaning of sections 409 and 512 of the act, the agency must establish that the detected residue actually is a residue of the sponsored compound; and when the agency can prove this point, it has proved that the food is adulterated as a matter of law.

The proposed regulation requires each assay to meet specific criteria before the Commissioner will approve the sponsored compound or use, and an assay satisfying these criteria will permit the agency to discriminate between target tissue background responses and responses due to the marker residue. Levels of residues that are below the L_m value cannot be distinguished from background with confidence, and the results of these findings are inadequate to support a regulatory action. On the other hand, when marker residues are detected and measured at or above L_m with the approved regulatory assay, this finding will unquestionably support regulatory action since it constitutes evidence that the food is adulterated within the meaning of section 402(a)(2) of the act. (See *United States v. Ewing Bros. Co., Inc.*, 502 F.2d 715, 725-726 (7th Cir. 1974), cert. denied 420 U.S. 945 (1975).) Moreover, a finding of a violative residue will warrant further administrative action because it will constitute a prima facie case that the compound has not been used in accordance with its conditions of approval, and the agency will conduct a further investigation to determine what additional regulatory action, if any, is appropriate.

XI. Waiver of Requirements

The proposal would permit the Commissioner, in response to a petitioner's request or on the Commissioner's own initiative, to waive, in whole or in part, any of the foregoing requirements for the scientific evaluation of sponsored compounds that have the potential to contaminate human food with residues whose consumption could engender a human risk of carcinogenesis. It has long been settled that an agency may adopt a rule shown to be appropriate for the generality of instances and leave the correction of injustices to applications by those concerned (e.g., *National Nutritional Foods Ass'n v. Food and Drug Administration*, 504 F.2d 761, 784 (2d Cir. 1974) cert. denied 420 U.S. 946 (1975)). For these reasons, the Commissioner has expressly included the waiver provision. The Commissioner advises, however, that a waiver will be granted only in exceptional circumstances, and, as the regulation provides, the basis for any waiver must be documented.

01206

XII. IMPLEMENTATIONS

The criteria set forth in the regulations are based on generally recognized scientific principles for testing and evaluating chemical compounds for potential carcinogenesis. Congress comtemplated that FDA would adhere to these principles when it enacted the Food Additives Amendment of 1958 and the Animal Drug Amendments of 1968 (21 U.S.C. 348 (b) and (c) and 360b (b) and (d)).

The 1973 proposal would have applied the regulatory requirements to all new applications (basic or supplemental) filed or approved after the effective date of the regulations. Prior approvals were to be dealt with on a class-by-class basis, and the classes, in order of decreasing priority, were known carcinogens, suspected carcinogens, and continuing through all compounds previously approved on the basis of zero tolerance. These were to be reviewed as part of the agency's general safety review for previously approved new animal drugs.

The February 1977 notice announced that the regulations would apply to all new animal drug applications, feed additive petitions, and appropriate color additive petitions, including appropriate supplemental applications, submitted after the effective date of the regulations. In addition, the regulations would apply to all pending petitions and applications unless the Commissioner determined that compliance with the act could be adequately assured by requiring completion of one or more of the required studies subsequent to approval.

Because some standards are needed for the day to day evaluation of petitions under sections 409 and 512, FDA has applied all the basic aspects of these proposed standards on a case-by-case basis for several years (e.g., diethylstilbestrol published in the FEDERAL REGISTER of November 26, 1976 (41 FR 52105) and the nitrofurans published in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906) and August 17, 1976 (41 FR 34883)). It continues to apply them to compounds currently being evaluated for approval or subject to proposals to withdraw approval.

All previously approved applications for compounds will be reviewed as part of the cyclic review of the safety of marketed animal drugs, which will be described in detail in a separate forthcoming notice in the FEDERAL REGISTER. When the agency finds deficiencies in the data supporting a prior approval, it will issue either a FEDERAL REGISTER notice or a letter in accordance with section 512(e) of the act. The criteria of these regulations will be used to determine whether the data supporting applications are acceptable and adequate.

One comment argued that the final regulations, when promulgated, should apply only to all applications pending approval at that time. For previously approved compounds, the comment stated that the holders of the approvals should be required to submit data for at least a threshold assessment. For any compound found to require submission of additional data as set forth in the proposed regulations, the comment argued that the petitions for those compounds should immediately be suspended. Another comment, however, argued that the Commissioner lacks authority to apply the regulations to any previously approved compound without new evidence.

The Commissioner disagrees with both comments. The act expressly deals with these situations. It defines the new evidence that the Commissioner can consider in determining whether a previously approved compound is safe to include: "Tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available * * * when the application was approved" (section 512(e)(1)(B)). The tests proposed in these regulations are necessary to show that a sponsored compound is safe under the act. For that reason, the absence of data satisfying the above criteria, in conjunction with the evidence already available about a compound, clearly can support the withdrawal of approval of an application. A reasonable implementation program is, of course, necessary to avoid chaos in the marketplace, permit an efficient application of the criteria, and provide the maximum public health protection. Proposed § 500.98 provides for such a plan.

XIII. CONCLUSION

The proposed regulations are designed to provide a comprehensive, systematic data collection procedure for evaluating the carcinogenic potential of chemical compounds intended for use in food-producing animals and to ensure that edible tissues derived from such animals are safe. The system is constructed with severable portions that can be modified or replaced as the capacity of science to resolve, or the need for resolving, the issues improves.

This regulation establishes a multistep procedure for evaluating the carcinogenic risk presented by a sponsored compound and criteria for the conduct of each step. In developing the steps and criteria, FDA applied high standards of scientific acceptability and public health protection. In the agency's view, each decision, reflected in the regulations can be defended on that ground. The agency recognizes, however, that the totality of these decisions may impose a set of requirements that cannot feasibly be met by sponsors of compounds—for economic, technical, or other reasons. The agency, therefore, invites comments on whether the regulation imposes requirements that, as a totality, are unreasonable; and, if so, comments are invited on what specific provisions should be modified so that the requirements imposed by the modified regulation would be reasonable. Proposed modifications should be analyzed with respect to their impact on protection of the public health. No modification or set of modifications would be acceptable if its effect would be that the regulation would fail to provide satisfactory assurance that compounds approved for use pursuant to the regulation will not subject humans to any significant increase in carcinogenic risk.

The Commissioner has carefully considered the environmental effects of the regulations and, because this action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk. (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

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01207

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01208

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Therefore, under the Federal Food, Drug, and Cosmetic Act (sections 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 70—COLOR ADDITIVES

1. In Part 70, by amending § 70.50 by adding new paragraph (c), to read as follows:

§ 70.50 Application of the cancer clause of section 706 of the act.

* * * * *

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals raised for food production must satisfy the requirments of subpart E of Part 500 of this chapter.

PART 500—GENERAL

2. In Part 500, by adding a new Subpart E, consisting of §§ 500.80 through 500.98, to read as follows:

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

Sec.

AUTHORITY: Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

§ 500.80 Chemical compounds used in food-producing animals: Procedures and criteria for determining acceptability of assays for carcinogenic residues in edible products.

(a) *Scope of this subpart.* (1) The Food, Drug, and Cosmetic Act requires that compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for human consumption. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by human or animal unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs under § 5.1 of this chapter) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice.

(2) Petitions for the approval of the use of a compound in food-producing animals must include adequate data for establishing the absence of residues of carcinogenic concern in the food produced from those animals.

(3) This subpart establishes the following: (i) The lowest limit of reliable measurement for the regulatory assay required for carcinogenic residues by sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) and sections 409(b)(2)(D), 512(b)(7) and 706(b)(5)(A)(iv) of the act.

(ii) The procedures and criteria for evaluation and approval of such assays.

(iii) The procedures and criteria for establishing the premarketing withdrawal period for use of compounds likely to produce such residues.

(4) This subpart applies specifically to the use in food-producing animals and in their feed of compounds that have the potential to contaminate human food with residues whose consumption could present a human risk of cancer. The determination of this potential will be based on considerations of chemical, biochemical, physiological, and toxicological data derived from the scientific literature and from other sources available to the petitioner or to the Commissioner and on the proposed patterns of compound use. This subpart establishes a sequential process for the collection of other chemical, biochemical, physiological, and toxicological data pertinent to the

01209

safety of the proposed use of the sponsored compound.

(5) This subpart does not apply to essential nutrients.

(b) *General approach.* (1) When the Commissioner determines that a sponsored compound has the potential to contaminate food from food-producing animals with residues (the sponsored compound, metabolites, or any other substances formed in or on food (e.g., endogenous substances) because of the compound's use) whose consumption could present a human risk of cancer, the following procedure for data collection and evaluation will apply:

(i) A metabolic study in the animals in which the sponsored compound is intended for use (target animals) designed to identify metabolites of concern and, when appropriate, to determine if normal levels of carcinogenic or potentially carcinogenic endogenous substances are affected.

(ii) Metabolic studies of the sponsored compound in different species of experimental animals designed to aid in selecting the appropriate species for chronic toxicity testing and in assessing the carcinogenicity of residues that cannot practicably be tested individually (intractable residues).

(iii) Chronic testing in test animal to assess the carcinogenic potential of residues of the sponsored compound, to furnish data suitable for statistical treament by the linear extrapolation procedure of Gross, M. A., O. G. Fitzhugh, and N. Mantel, "Evaluation of Safety of Food Additives," *Biometrics*, 26 (2): 181-194 (1970) and Hoel, D. G., et al., "Estimation of Risks of Irreversible, Delayed Toxicity," *Journal of Toxicology and Environmental Health*, 1:133-151 (1975)[1] (which are incorporated by reference), and to permit the no-residue requirement of the act to be operationally defined for purposes of establishing a lowest limit of reliable measurement for an assay to measure residues of the sponsored compound.

(iv) A detailed metabolic study of the sponsored compound in target animals designed to identify a specific residue and tissue to serve as indicators (marker residue and target tissue) to determine whether the no-residue requirement of act is satisfied.

(v) Development of a regulatory assay to measure the marker residue in the target tissue at and above the level operationally defined as satisfying the no-residue requirement of the act.

(vi) Establishment of the premarketing withdrawal period required for the safe use of the sponsored compound.

(2) If, at any point in the sequential process of data collection set forth in paragraph (b)(1) of this section, the evaluation of the data satisfies the Commissioner that no human risk of carcinogenesis arises from the proposed use of the sponsored compound, the compound will be considered for approval under the general safety provisions of the act for risks other than cancer.

§ 500.83 Definitions.

The following definitions apply to this subpart:

(a) "Sponsored compound" means any drug or additive proposed for use, or used in, food-producing animals.

(b) "Target animals" means the production class of animals in which a sponsored compound is proposed or intended for use.

(c) "Sponsor" means the person proposing or holding an approval by the Food and Drug Administration for the use of a sponsored compound.

(d) "Threshold assessment" means the Food and Drug Administration's review of data and information available about a sponsored compound to determine whether the compound should be subject to regulation under this subpart as well as under the other general safety provisions of the Federal Food, Drug, and Cosmetic Act for risks other than cancer.

(e) "Total residue of the sponsored compound" means all compounds present in edible tissues of the target animal that result from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

(f) "Residue" means any single compound present among the total residue.

(g) "Residue of toxicological concern" means all compounds in the total residue minus any compounds shown to be safe.

(h) "Metabolic studies" means studies designed to identify the residues that occur in edible tissues when the sponsored compound is administered to target animals and to determine the depletion characteristics of the residues.

(i) "Intracable residues" means residues of the sponsored compond that, using the best available technology, cannot be obtained, by isolation, synthesis, etc., in sufficient amounts for carcinogenicity testing.

(j) "Comparative metabolism" means the study of the metabolism of a sponsored compound in different species/strains of test animals that are potential surrogates for man in chronic toxicity testing. Comparative metabolism studies will assist in assessing the toxicity testing. Comparative metabolism studies will assist in assessing the toxicity of intrectable residues and in selecting species/strains of test animals for bioassays of selected tractable residues.

(k) "S_o" means the residue level of a sponsored compound in a total test diet of animals that corresponds to a lifetime risk of cancer of 1 in 1 million in the test animals. For the purpose of this subpart, this S_o level in the test animal corresponds to a level in the total human diet that is assumed to represent a level of risk to humans of no more than 1 in 1 million over a lifetime.

(l) "S_m" means the level of total residues of carcinogenic concern for a specific edible tissue as determined by the formula in § 500.87(d).

(m) "Marker residue" means the selected residue whose level in a particular tissue is in a known relationship to the level of the total residue of carcinogenic concern in all edible tissues and that can be taken as a measure of the total residue of concern in the target animal.

(n) "Target tissue" means the tissue selected to monitor for residues in the target animal. The target tissue is selected so that the absence of marker residue at or above the required level of measurement (R_m) can be taken as confirmation that the safe, or acceptable, residue level (S_m) is not exceeded in any of the edible tissues of the target animal.

(o) "R_m" means the level of the marker residue(s) in the target tissue when the sum of the levels of the residues of toxicological concern is equal to S_m for the edible tissue requiring the longest time to deplete to its S_m.

(p) "Endogenous compound" means any compound that its metabolically produced by and is present in untreated target animals.

(q) "Essential nutrients" means compounds that are found in the tissues of untreated target animals and required for the animals' growth, and that must be supplied from external sources, e.g., essential amino acids.

(r) "Norm" means the normal background levels of an endogenous substance in untreated target animals, plotted as a cumulative frequency distribution of levels.

(s) "R_m for an endogenous marker residue" means the level of the endogenous marker residue that corresponds to the 33d percentile of the norm.

(t) "Spiked tissue samples" means samples of target tissue to which known amounts of marker residue have been added.

(u) "Control tissue samples" means samples of target tissue from untreated target animals.

(v) "Dosed tissue samples" means samples of target tissues from target

[1] Copies may be obtained from: Industry Information (HFV-226), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

01210

animals administered the sponsored compound.

(w) "L_m" means the level of marker residue in target tissue that gives a response greater than, or equal to, 0.75 times the spread of the 99 percent confidence bounds of a single assay response measured parallel to the observed assay response axis based on the analytical curve of the assay. (See Plate IV in § 500.90(d)(5).)

(x) "Assay" means the aggregate of all experimental procedures for measuring the presence of the marker residue of the sponsored compound in the target tissue of the target animals at or above the L_m. It includes the procedures for sample of instrument preparation. The assay must satisfy criteria set forth in § 500.90, and it will usually consist of multiple measurement procedures that utilize different physiocochemial principles, e.g., gas chromatography-mass spectrometry, to assure compliance with the regulatory requirements.

(y) "Withdrawal period" means the time required, after cessation of target animal exposure to the sponsored compound, for the marker residue to deplete to L_m in the target tissue.

(z) "Analytical curve" means the plot of the observed responses of the regulatory assay when analyzing "spiked" tissues compared to the amount of marker residue added to the "spiked" tissues.

(aa) "Ninety nine percent confidence interval" means an interval, determined by confidence limits, that is expected to contain the population parameter being estimated 99 times out of 100 times.

(bb) "Upper ninety nine percent confidence limit" means a value that is expected to be equal to or larger than the population parameter being estimated 99 times out of 100 times.

(cc) "Statistical tolerance limits" means upper and lower values between which it can be stated with a given level of confidence that a specified portion of the population will be included.

§ 500.84 Metabolic study in target animals to identify residues for chronic testing.

(a) A metabolic study, described in paragraph (b) of this section, shall be conducted in target animals to provide data on the physicochemical characteristics of residues, their relative proportions, their distribution among the various edible tissues (which include milk or eggs when applicable), and their retention and depletion in animal tissues.

(b) The metabolic target animal study shall satisfy the following minimum requirements:

(1) The metabolic study shall be conducted in target animals with the sponsored compound bearing appropriate radiolabels, unless other experimental methods permit measurement of total residues with accuracy and precision equivalent to radiolabel methods. Such labels shall assure that residues containing structural moieties of potenetial carcinogenic concern are detected and measured in edible tissues at levels as low as the best available technology will permit. Hypotheses about the sponsored compound's projected metabolic pathways may be used as a guide to experimentation, but they are not a substitute for actual experimentation.

(2) The dosing regimen shall be the maximum proposed use level and proposed duration of exposure to the sponsored compound. For a compound that is proposed for continuous or repeated use in target animals, administration for the metabolic study need continue only until tissue saturation has been demonstrated. If tissue saturation cannot be attained, residue equilibration or showing a stable metabolite profile will be adequate.

(3) The metabolic study shall be designed to yield the following information:

(i) The concentrations and total number of residues detacted in edible tissues of target animals immediately following cessation of exposure.

(ii) The concentrations and total number of residues detacted in edible tissues of target animals at a sufficient number of different time intervals, following the initial measurement, to determine the depletion trend of individual residues.

(iii) The physicochemical properties of the detected residues to identify compounds of potential carcinogenic concern.

(4) The results of the metabolic study shall be submitted in the form of a detailed report conforming to the standards required of scientific manuscripts submitted for publication in the journals of professional scientific societies, such as the American Chemical Society and the American Society of Biological Chemists. In addition, all raw data shall accompany and be referenced in the report.

(c) If the Commissioner determines that a sponsored compound has potential to contaminate food with residues whose consumption presents a human risk of cancer, the petitioner shall determine the carcinogenic potency of the sponsored compound and those residues that may be of public health concern due to chemical structure or persistence and concentration in edible tissues.

(d) Ordinarily, chronic testing of the sponsored compound and selected residues in experimental animals will be the preferred means of assessing carcinogenic potency.

(e) Reisidues in edible tissues of target animals that are intermediate metabolites in metabolic pathways that are reasonably expected to be similar in humans and the selected test animal species/strain need not be subjected to independent chronic toxicity testing. Testing the leading substrate in each metabolic pathway is sufficient. In the absence of information that the leading substrate is noncarcinogenic, tractable residues that are produced in the target animals but that are not produced in the test animal species/strain shall be subjected to independent chronic toxicity testing.

(f) Section 500.85 describes an alternative means of assessing the carcinogenic potency of residues whose isolation or synthesis in sufficient quantities for chronic testing proves to be beyond the practical limits of current chemical technology (intractable residues) by establishing additional criteria for selecting test animal species/strains used to conduct chronic toxicity testing of the sponsored compound.

§ 500.85 Criteria for test animal selection: Comparative metabolic studies to aid in assessing the carcinogenicity

(a) The primary criterion for selecting species or strains of test animals for chronic testing of both the sponsored compound and any metabolities selected in accordance with § 500.84 shall be the suitability of the species or strain as a model for man.

(b) If one or more intratable residues are also selected for chronic testing based upon the matabolic study in target animals, a secondary criterion shall be employed for selecting species or strains of animals for testing the sponsored compound. Metabolic studies of the sponsored compound in test animal species or strains determined to be suitable for chronic testing by the primary criterion shall be conducted to determine whether the intractabel residues present in the tissues of target animals are also produced in the test animals. Chronic testing of the sponsored compound in a species or strain of test animals in which the complement of residues produced is similar to the complement of residues produced in the tissues of the target animals is considered an appropriate method of assessing the carcinogenic potency of the intractable residues.

§ 500.87 Chronic testing.

(a) Chronic toxicity tests shall be conducted to assess the carcinogenic potential of the residues of the sponsored compound.

(1) The sponsored compound and any residues selected for chronic toxicity testing shall be subjected to oral, lifetime, dose-response studies in the test animal species or strains selected

01211

in accordance with § 500.85. Each of these studies shall be designed to determine whether the test compound is carcinogenic. Protocols for these studies should be submitted to the Food and Drug Administration for review before commencing testing.

(2) On the basis of the results of these chronic toxicity studies and other available information, the Commissioner will determine whether any of the compounds tested is carcinogenic. If this evidence is equivocal, the compound will be regulated as a carcinogen until further testing resolves the remaining questions regarding carcinogenicity.

(b) When the Commissioner determines that a sponsored compound has the potential to increase the normal levels (pools) of carcinogenic and potentially carcinogenic substances endogenous to the target animals, the petitioner shall meet the requirements of § 500.89(c), (d), and (e) or (f).

(c) For each tested compound regulated as a carcinogen, the appropriate data from the chronic dose-response studies shall be analyzed according to procedures described by Gross, et al. and Hoel, et al. subject to the modifications and restrictions set forth in paragraph (c)(1) through (8) of this section. The purpose of this analysis is to interpret the "no residue" requirement of the act as it applies to the total residue of carcinogenic concern of the sponsored compound and thereby to determine the lowest level of reliable measurement required for a regulatory assay to be approved for the monitoring of the total residue.

(1) The administered dose of each test compound shall be expressed as a fraction of the total diet fed the test animal species/strains, e.g., parts per million, parts per billion.

(2) The permissible level, determined by the linear extrapolation model for each test compound in accordance with this section, shall be expressed as a fraction of the total diet fed the test animal species/strains. It shall be calculated using the 99 percent confidence limit of the observations for a maximum lifetime risk that is essentially zero but never expected to exceed 1 in 1 million.

(3) Data obtained from more than one dose level fed to groups of experimental animals of the same strain shall be combined as described by Gross, et al. and Hoel, et al. and are subject to the restrictions specified by these authors.

(4) Pooling data from various chronic tests using different animal sexes, species, or strains is permitted if it can be demonstrated that the protocols are of compatible design. If statistically significant biological differences in tumorigenic responses are observed between sexes or among species or strains of experiental animals, only subsets of data representing statistically and biologically compatible bioassays may be combined for analysis.

(5) All tumors, benign and/or malignant, shall be considered in the analysis.

(6) The number of animals at risk may be adjusted for competing risks unrelated to compound-induced carcinogenesis only when the data clearly support such an adjustment.

(7) When only the sponsored compound is subjected to chronic testing, the calculated "acceptable" level is to be designated as S_o. When more than one compound is subjected to chronic testing, the lowest of all calculated acceptable levels is to be designated S_o. S_o shall be expressed as the fraction of the diet fed the test animals, e.g., parts per million, parts per billion.

(8) The no-residue requirement of the act is considered satisfied when conditions and use of the compound, including any required withdrawal period, can be prescribed to assure that the sum of the levels of all potential residues of carcinogenic concern will not exceed S_o in the total diet of man, and a regulatory assay is available that is capable of reliably measuring such residues at and above that level. All residues of the sponsored compound are regulated as carcinogenic except those that have been shown to be noncarcinogenic.

(d) The S_o value represents the sum of all residues of carcinogenic concern that shall not be exceeded in the total diet of man. For individual edible tissues, the value that shall not be exceeded is to be designated S_m and calculated according to the following formula:

$$S_m = S_o/T$$

NOTE.—T is the fraction of the total daily diet of man represented by an individual edible tissue.

(1) The principal S_m calculations (defining T as noted in the formula above in paragraph (c) of this section) are as follows:

Edible tissue	T	S_m
Muscle	⅛	$3S_o$
Milk	1	S_o
Eggs	⅛	$3S_o$

(2) Calculation of S_m for tissues consumed less frequently than muscle may take into consideration the frequency of consumption of those tissues if it can be clearly shown that S_o will not be exceeded in the total human diet.

§ 500.89 Metabolic study to identify the marker residue and target tissue.

(a) The petitioner shall conduct a study of the metabolic fate of the sponsored compound in target animals adequate to provide the data necessary for selecting a marker residue in target tissue.

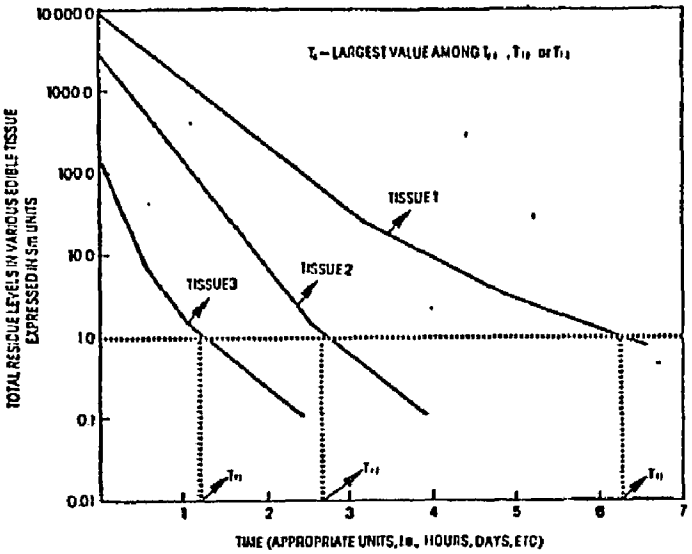
(1) The target tissue is that tissue in which measurement of the total residue burden of carcinogenic concern is a reliable measure of the total residue burden of carcinogenic concern in all edible tissues.

(2) The marker residue for the sponsored compound is that residue (the sponsored compound, any metabolite, or more than one of these) whose level in the target tissue is a reliable measure of the total burden of all residues of carcinogenic concern in all edible tissues.

(b) The metabolic study to establish the marker residue and target tissue shall comply with the requirements set forth in § 500.84(b) (2) and (4), with the following additional specifications:

(1) For each edible tissue, the depletion profile of the total residue of carcinogenic concern shall be constructed and shall include measurements of levels at least as low as the S_m appropriate to the tissue under study, as set forth in Plate I as follows:

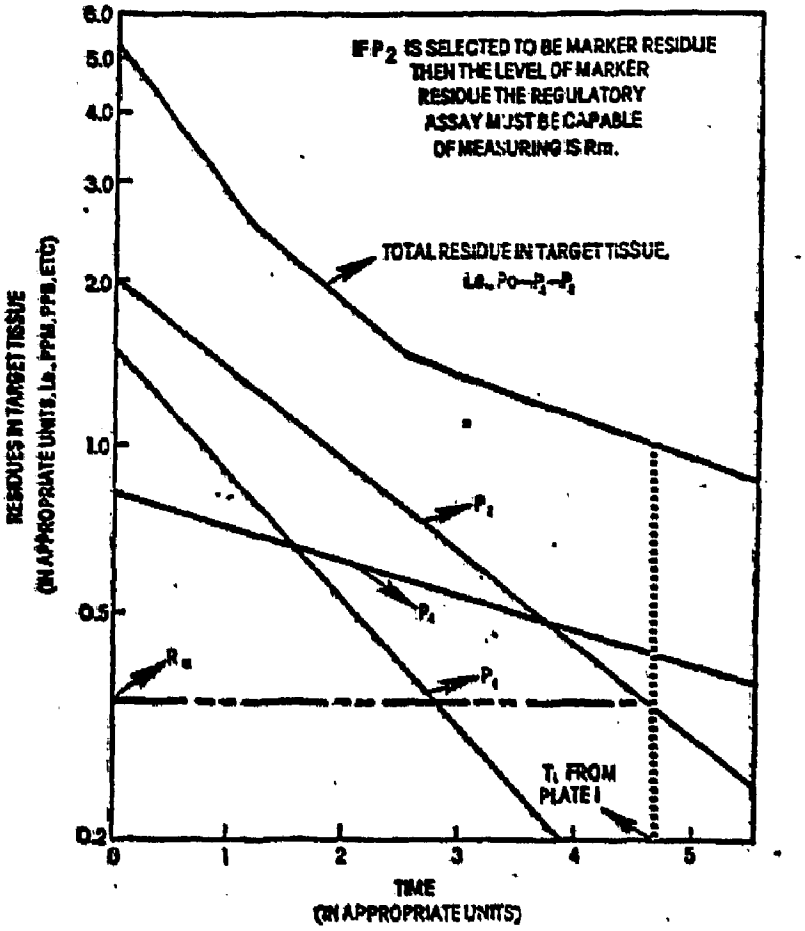
PLATE I. RESIDUE DEPLETION CURVES TO BE USED IN THE DETERMINATION OF MARKER RESIDUE AND TARGET TISSUE.



01212

(2) Depletion profiles for one or more potential marker residues shall be constructed as set forth in Plate II as follows, and shall include measurements of levels corresponding to the time when the total residue level has reached S_m in the edible tissue requiring the longest time to deplete to S_m (T_L of Plate I in paragraph (b)(1) of this section).

PLATE II. SELECTION OF MARKER RESIDUE AND ITS LEVEL Rm THAT MUST BE MEASURED BY THE REGULATORY ASSAY.



(3) If these specifications have been met by the metabolic study required by § 500.84(b), a second metabolic study need not be performed to satisfy the section.

(4) From these data, the Commissioner will select a marker residue and target tissue and will also designate the required level of marker residue, R_m (set forth in Plate II in paragraph (b)(2) of this section), that regulatory assays shall be capable of measuring in the target tissue. The selection of R_m will be such that the absence of the marker residue in the target tissue above R_m can be taken as confirmation that the total residue burden of carcinogenic concern does not exceed S_m in each of the various edible tissues and therefore that the total burden of carcinogenic concern in the human diet does not exceed S_m. When a compound is to be used in milk- or egg-producing animals, milk or eggs will be the target tissue in addition to one tissue selected to represent the depletion of residues in the edible carcass.

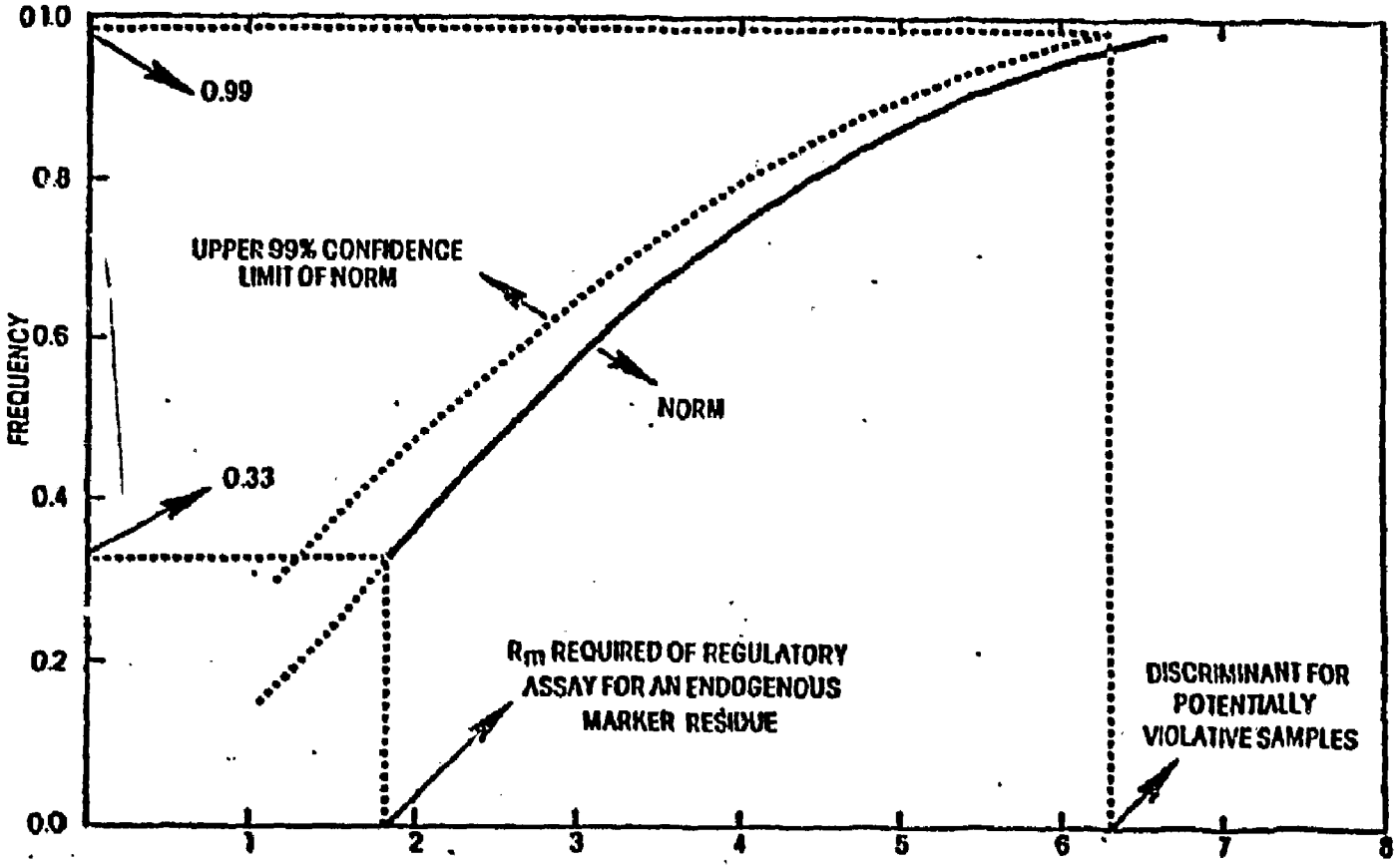
(c) When the Commissioner determines on the basis of available scientific information that a sponsored compound has the potential to increase the normal levels (pools) of potentially carcinogenic substances edogenous to target animals, the petitioner shall provide the following additional data:

(1) An experimental determination of the background levels (norm) of each of the potentially carcinogenic endogenous substances of concern in untreated target animals that are increased by administration of the sponsored compound.

(i) The norm shall be specific for the untreated target animals.

(ii) Each norm shall be submitted in the form of a graph of the cumulative frequency distribution versus the observed naturally occurring levels, including the upper 99 percent confidence limit set forth in Plate III as follows:

PLATE III. SAMPLE OF A NORM



(iii) An assay will be acceptable for the determination of a norm only if it yields values for the endogenous compound of interest greater than zero in at least two-thirds of the untreated target animals.

(2) Studies to measure the effect of the sponsored compound on the norm and the postexposure decay of any increase in the norm caused by administration of the sponsored compound. All data from these studies submitted in accordance with the requirements of § 500.84(b)(4).

(d) For a potentially carcinogenic endogenous compound whose norm is increased by the administration of a sponsored compound, the no-residue requirement of the act is considered satisified when the norm is restored.

(1) The norm is considered restored when, with 99 percent confidence, the cumulative frequency distributions of the observed levels of the endogenous compound in the untreated target animals and in the treated target animals do not differ by more than 0.1 at any specific point.

(2) The market residue is the affected endogenous substance.

(3) When the norm of more than one potentially carcinogenic endogenous compound is increased by administration of the sponsored compound, the market residue for all endogenous compounds of concern is that endogenous compound whose norm requires the longest time for restoration.

(e) For an endogenous compound selected to be a marker residue, the required level of measurement, R_m, for the regulatory assay is the level of that endogenous compound corresponding to the 33d percentile of the norm, set forth in Plate III in paragraph (c)(1)(ii) of this section.

(f) The Commissioner will permit a shift in the norm of a potentially carcinogenic endogenous compound if there are available toxicology data of the type specified by §§ 500.84, 500.85, 500.87, and 500.89 that permit estimation of a permissible level corresponding to a lifetime cancer risk increment no greater than 1 in 1 million. If the endogenous compound is also selected to be the marker residue, the required level of measurement, R_m, for the regulatory assay is the level of that endogenous compound corresponding to the 33d percentile of the norm set forth in Plate III in paragraph (c)(1)(ii) of this section.

§ 500.90 Evaluation and approval of a regulatory assay.

(a) Before an application is considered for approval, the petitioner shall submit for evaluation and validation a regulatory assay developed to monitor compliance with the no-residue requirement of the act. The regulatory assay shall reliably measure the marker residue in the target tissue at levels at least equal to and above R_m, as defined in § 500.89(b), (e), and (f). The criteria and procedures in paragraphs (b) through (g) of this section apply to the evaluation and approval of assays.

(b) The regulatory assay will be evaluated and validated using data collected from three types of samples:

(1) Samples containing various known concentrations of marker residue added to the target tissue, i.e., "spiked" tissue samples.

(2) Samples containing various levels of the marker residue obtained from target tissue at appropriate time intervals after the sponsored compound is administered in accordance with the proposed labeling, i.e., "dosed" tissue samples.

(3) Samples obtained from untreated target animals, i.e., "control" tissue samples.

01214

(c) The petition for approval of the proposed regulatory assay shall contain the following:

(1) A complete description of the assay.

(2) A list of all necessary equipment and reagents.

(3) A standard curve prepared from samples of the marker residue of known purity.

(4) An analytical curve of the observed assay response compared to the tissue concentrations of the marker residue in spiked target tissue. The curve shall include the 99 percent confidence limits for individual predicted assay responses.

(5) All relevant data, including worksheets, calculations, any statistical analyses, spectrograms, chromatograms, etc., from the analyses of spiked, dosed, and control tissue samples, and from the analysis used in preparing the standard curve including data on runs started but not completed.

(6) A discussion of the data collected in the assay development process pertinent to the evaluation criteria set forth in paragraph (d) of this section explaining how the data show that the proposed assay conforms to those criteria.

(d) A regulatory assay shall satisfy the following criteria:

(1) *Dependability.* The assay is considered dependable if it does not result in an unreasonable number of failures due to unknown, uncontrollable, or random factors. Evaluation of the data to determine dependability will be based on the total number of assay runs that are started to provide data points for the analytical curve required by paragraph (c)(4) of this section. An explanation will be required for any assay run started that yields no final determination.

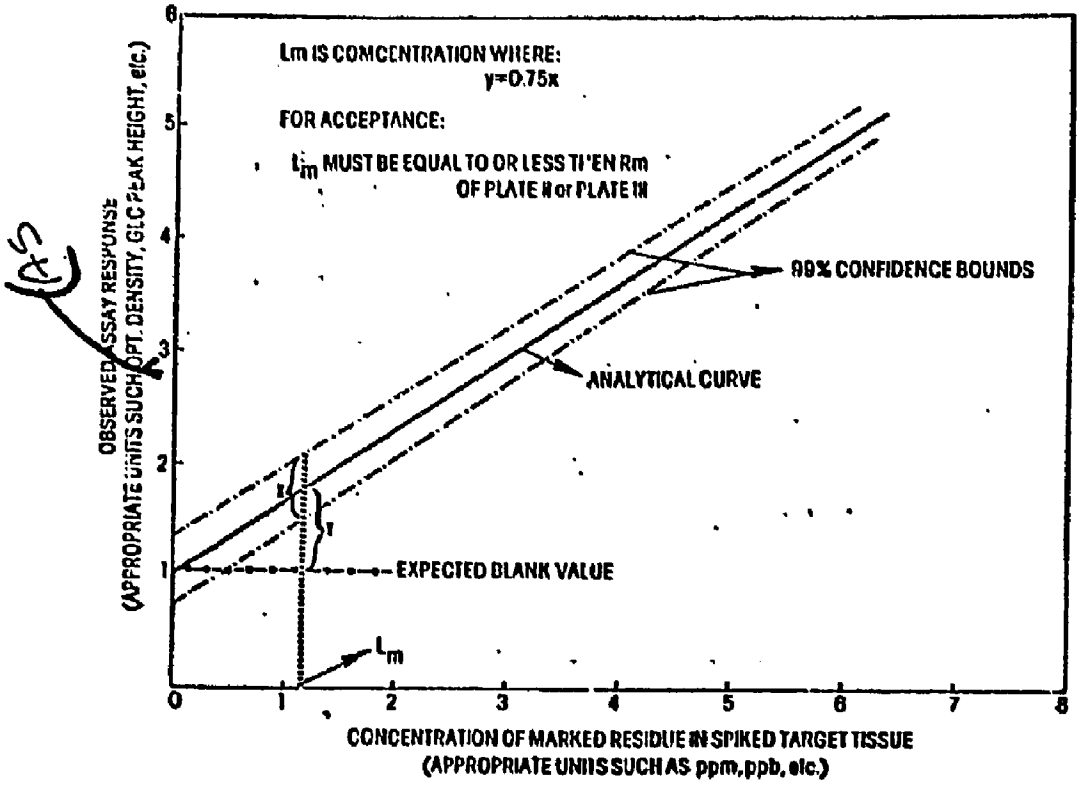
(2) *Practicability.* The assay is considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay shall be consistent with regulatory objectives, e.g., monitoring, compliance, etc. All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay shall either be commercially available or readily available from the petitioner upon request. The Commissioner will withdraw approval of any assay and initiate regulatory action against the sponsored compound if such a condition of the compound's approval is no longer satisfied.

(3) *Specificity.* The assay is considered specific if the observed response is a smooth and continuously decreasing or increasing function of the concentration of the marker residue and of that compound only. The regulatory assay shall be composed of a sufficient number of independent measurements based on different biological, biochemical, or physicochemical principles to ensure that the identity of the marker residue is confirmed.

(4) *Accuracy.* The assay is considered accurate if the averages of the observed responses fall within 80 to 110 percent of the true value when the lowest level of reliable measurement (L_m) is equal to or greater than 100 parts per billion and within 60 to 110 percent of the true value when L_m is below 100 parts per billion. This requirement need not be met throughout the full range of the analytical curve; it shall be met in the range between L_m and $3L_m$.

(5) *Lowest limit of reliable measurement.* The regulatory assay is considered approvable if it can reliably discriminate with 99 percent confidence the marker residue response from the target tissue background response at or below the required lowest limit of reliable measurement, the R_m, defined in § 500.89(b), (e), or (f). The lowest limit of reliable measurement of the proposed assay is that level, L_m, which gives a response above the expected blank value that is greater than or equal to 0.75 times the spread of the 99 percent confidence limits on a single assay response measured paralle to the observed assay response axis (Plate IV below in this paragraph). If the L_m for the assay is at or below the applicable R_m of § 500.89(b), (e), or (f), the Commissioner will approve the compound for use only under conditions that will not result in residues above that level.

PLATE IV. ANALYTICAL CURVE OF A REGULATORY ASSAY



01215

(e) The Commissioner will review and evaluate the data submitted in accordance with paragraphs (a), (b), and (c) of this section. If the assay satisfies the evaluation criteria of paragraph (d) of this section, it will then be subjected to the interlaboratory validation study described in paragraph (f) of this section.

(f) Two Food and Drug Administration laboratories and one U.S. Department of Agriculture laboratory will independently run a number of assays to ascertain whether the regulatory assay conforms to the criteria set forth in paragraph (d) of this section.

(1) The petitioner shall supply the validating laboratories with the number and amount of dosed and control tissue samples, requested by the Commissioner.

(2) The petitioner shall supply reagents, standards, supplies, and equipment to the validating laboratories, as requested by the Commissioner.

(g) The Commissioner will evaluate the data gathered from the study run by the three validating laboratories described in paragraph (f) of this section. The assay will be approved if it meets the criteria set forth in paragraph (d) of this section in each laboratory.

§ 500.92 Withdrawal periods.

(a) The withdrawal period is the time after cessation of administration of the sponsored compound necessary for the marker residue to deplete to the lowest level of reliable measurement (L_m) in the target tissue. This time is the interval required for the statistical tolerance limit for the 99th percentile of the marker residue concentration for individual animals to deplete to L_m. The time will be extended if necessary to be consistent with conditions of livestock management so that directions for use of the compound with respect to the withdrawal period will be reasonably certain to be followed in practice.

(b) The sponsor shall submit studies of the marker residue's depletion from the target tissue of animals dosed according to the maximum level of use proposed in the petition and maintained under field conditions. The validated regulatory assay shall be used to collect these data.

(1) The petitioner shall submit a plot of the concentration of marker residues in target tissue as a function of time (depletion curve) including the statistical tolerance limits for the 99th percentile of the expected marker residue concentrations for individual animals.

(2) All relevant data, including worksheets, calculations, and statistical analyses, shall be submitted along with a referenced discussion of the results.

(3) Use of the sponsored compound will be approved only if the available evidence demonstrates that the proposed conditions of use, including any withdrawal period, are reasonably certain to be followed in practice.

(c) When the marker residue is an endogenous compound, the withdrawal period will be the time required after cessation of administration of the sponsored compound for the norm to be restored, as described in § 500.89(d)(1). The time will be extended if necessary, but not reduced, to be compatible with conditions of livestock management so that the directions for use of the compound with respect to the withdrawal period will be reasonably certain to be followed in practice. The validated regulatory assay shall be used to collect data on the rate of restoration of the norm.

(1) The petitioner shall submit a series of curves that demonstrate the time required for restoration of the norm.

(2) All relevant data including worksheets, calculations, and statistical analyses shall be submitted along with a referenced discussion of the results.

(3) Approval of the petition for the sponsored compound will be granted only if the available evidence demonstrates that the proposed labeling is reasonably certain to be followed in practice.

§ 500.94 Publication of the approved regulatory assay.

The lowest level of reliable measurement (L_m), the complete regulatory assay for measuring the marker residue in the target tissue, and the analytical curve will be published in the FEDERAL REGISTER, in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(H) and (i), and 706(b)(5)(B) of the act. For an endogenous marker residue, the norm will also be published.

§ 500.95 Compliance.

Compliance with the act will be determined as follows:

(a) When a target tissue is found to contain the marker residue at or above the lowest level of reliable measurement (L_m), the Commissioner will conclude (1) that the carcass from which the target tissue was taken is unsafe for human consumption; and (2) that the sponsored compound may have been used in violation of the act.

(b) When animals are found to contain an endogenous marker residue at or above the 99th percentile of the norm (Plate III under § 500.89(c)(1)(ii)), they will be designated as potentially violative. Before regulatory action will be initiated, and investigation will be undertaken. This investigation is to determine whether the potentially violative sample came from target animals adminstered the sponsored compound whose median level of the endogenous marker residue is greater than the median of the norm.

§ 500.96 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, any of the requirements of this subpart for the scientific evaluation of sponsored compounds that have the potential to contaminate food with residues which, when consumed, could engender a human risk of cancer. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why some or all of the requirements are not reasonably applicable to the compound, and describe the alternative procedures that have been, or could be, followed to assure that use of the compound will not contaminate human food with residues whose consumption could engender a human risk of cancer and that an assay exists that satisfies the requirements of § 500.90(d)(1) through (5) and that is capable of measuring any residues that might occur when the compound was improperly used. Interagency validation of the assay will always be required. The petition shall set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the

01216

basis for the determination in the regulation approving marketing of the sponsored compound.

§ 500.98 Implementation.

(a) This subpart applies to all new animal drug applications, feed additive petitions, and relevant color additive petitions (i.e., applications and petitions concerning any compound intended for use in food-producing animals) submitted to the Food and Drug Administration, including relevant supplemental applications and amendments to petitions, and to all these applications or petitions on file with the agency. If the Commissioner determines that consumer protection can be adequately ensured by imposing the requirements under paragraph (b) of this section, the Commissioner will do so.

(b) This subpart also applies to the following compounds already approved:

(1) Those compounds that the Commissoner determines, on the basis of available information, have been shown to induce cancer when ingested by man or animals.

(2) Those compounds that the Commissioner determines may induce cancer when ingested by man or animals, i.e., suspect carcinogens.

(3) Any compound for which the Commissioner concludes sufficient information has not been provided to determine whether residues of the sponsored compound present a risk of cancer to man.

(c) Any compound already approved, to which the Commissioner determines the anticancer provisions of the act apply, or for which additional data are required for such a determination, will be the subject of a notice published in the FEDERAL REGISTER or a letter issued under section 512(e) of the act establishing the time within which the requirements of this subpart shall be satisfied.

(1) Notices already published in the FEDERAL REGISTER and letters already sent by the Food and Drug Administration requiring additional studies or submission of an improved regulatory assay will remain in effect, and this subpart will be used in determining compliance with the requirements of the act identified in those notices and letters.

(2) The Commissioner will proceed to withdraw approval of any compound on the basis of data or information indicating a health hazard or in response to any failure to undertake studies necessary to comply with this subpart.

PART 514—NEW ANIMAL DRUG APPLICATIONS

3. In Part 514:

a. By amending § 514.1, by revising paragraph (b)(7) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(7) *Assays for residues.* A description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions for this drug if any tolerance or withdrawal period or other use restrictions are required to ensure that the proposed use of this drug will be safe.

(i) The required information may include: Complete experimental protocols for determining drug residue levels in the edible products, and the time required for residues to be eliminated from the edible products following the drug's use; residue studies conducted under appropriate (i. e., consistent with the proposed usage) conditions of dosage, time, and route of administration to show levels, if any, of the drug and/or its metabolites in test animals during and upon ceasing treatment and at intervals thereafter to establish a depletion curve; if the drug is to be used in combination with other drugs, possible effects of interaction demonstrated by the appropriate disappearance curve or depletion patterns after drug withdrawal under appropriate (i. e., consistent with the proposed usage) conditions of dosage, time, and route of administration; if the drug is given in the feed or water, appropriate consumption records of the medicated feed or water and appropriate performance data in the treated animal; if the drug is to be used in more than one species, drug residue studies or appropriate metabolic studies conducted for each food-producing species. Appropriate use of labeled compounds (e.g., radioactive tracers) may be used to establish metabolism and depletion curves. Drug residue levels ordinarily should be determined in muscle, liver, kidney, fat, and where applicable, in skin, milk, and eggs (yolk and white). As a part of the metabolic studies, levels of the drug or metabolite should be determined in blood when feasible. Samples may be combined if necessary. When residues are suspected or known to be present in litter from treated animals, it may be necessary to include data on those residues' becoming components of other agricultural commodities because of the use of litter from treated animals.

(ii) If the new animal drug has the potential to contaminate human food with residues (parent compound, metabolites, conversion products, or other substances found in or on food because of the drug's use) whose consumption could engender a human risk of carcinogenicity, the applicant and the new animal drug are subject to the requirements of Subpart E of Part 500 of this chapter.

* * * * *

b. By amending § 514.111, by adding a new paragraph (a)(10) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(10) The drug fails to satisfy the requirements of Subpart E of Part 500 of this chapter.

* * * * *

PART 571—FOOD ADDITIVE PETITIONS

4. In Part 571, by adding new § 571.115, to read as follows:

§ 571.115 Application of the anticancer clause of section 409.

Food additives intended for use as an ingredient in food for animals that are raised for food production must satisfy the requirements of Subpart E of Part 500 of this chapter.

Interested persons may, on or before May 21, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: February 26, 1979.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

NOTE—Incorporations by reference provisions approved by the Director of the Office of the Federal Register on December 21, 1978 and on file in the library of that office.

[FR Doc. 79-8215 Filed 3-19-79; 8:45 am]

01217

47 FR 24278-01

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 74, 81, and 82

[Docket No. 81N-0301]

D&C Green No. 6; Listing as a Color Additive in Externally Applied Drugs and Cosmetics; Confirmation of Effective Date

Friday, June 4, 1982

***24278** AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of May 4, 1982, for a final rule that amended the color additive regulations by "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That document also provided for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive.

DATE: Effective date confirmed: May 4, 1982.

FOR FURTHER INFORMATION CONTACT:

Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: FDA published a final rule in the Federal Register of April 2, 1982 (47 FR 14138) that amended the color additive regulations by "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That document also provided for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive.

Interested persons were given until May 3, 1982, to file objections. FDA received no objections on the final rule. Therefore, the agency concludes that the final rule published on April 2, 1982, for D&C Green No. 6 should be confirmed.

List of Subjects in 21 CFR Parts 74, 81, 82

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), notice is given that no objections or requests for a hearing were filed in response to the final rule of April 2, 1982. Accordingly, the amendments promulgated thereby became effective on May 4, 1982.

Dated: May 27, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-14964 Filed 5-28-82; 11:30 am]

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50 FR 45530-01
PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 70, 500, 514, and 571
[Docket No. 77N-0026]

Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues

Thursday, October 31, 1985

***45530** AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish procedures and minimum criteria to ensure the absence of significant concentrations of cancer-causing residues in edible products of food-producing animals to which drugs, food additives, or color additives have been administered. The procedures and criteria implement the DES Proviso, an exception to the Delaney anticancer clause, which permits approval of the use of carcinogenic compounds in food-producing animals, provided that the level of any residue remaining in edible tissues is so minimal that it would not present any significant risk of cancer for human consumption.

DATE: Written comments on or before February 28, 1986.

ADDRESS: Written comments are to be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert Benson, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

SUPPLEMENTARY INFORMATION: The Food Additives Amendment of 1958 (Pub. L. 85-929) added the “Delaney Clause” to the Federal Food, Drug, and Cosmetic Act (the act). The clause proscribes the approval of any food additive found to induce cancer in man or in laboratory animals. FDA interpreted the clause as applying to compounds for use in food-producing animals. This interpretation barred the approval of carcinogenic compounds that were potentially useful in raising food-producing animals. Accordingly, the Drug Amendments of 1962 (Pub. L. 87-781) included an additional provision to the Delaney Clause that permitted the approval of the use of a carcinogenic compound in food-producing animals if “no residue” of the compound would be found in the edible tissues of treated animals by an FDA-approved analytical method capable of verifying the absence of residues. This provision is referred to as the DES Proviso. The DES Proviso also proved to be unworkable because the development of more sensitive analytical methods for detecting residues of a compound resulted in the identification of residues in tissue at concentrations much lower than expected when the DES Proviso was enacted. In fact, beginning in the early 1970's, progress in analytical chemistry was so rapid that even approved methods of analysis soon became dated or obsolete. FDA could never conclude that no trace of a carcinogenic compound or residue would remain in the edible tissues of animals to which the compound had been administered.

As a result FDA attempted to reconcile the purpose and language of the DES Proviso with the basic statutory objective of minimizing public exposure to carcinogenic compounds. FDA attempted to establish procedures and criteria for approving methods for identifying unacceptable concentrations of residues in edible products of food-producing animals to which drugs, food additives, or color additives had been administered. The procedures and criteria were proposed as regulations comprising what are commonly referred to as the “sensitivity of the method” or “SOM” procedures. As discussed in further detail

below, the procedures were proposed in 1973, finalized in 1977, withdrawn in 1978, and reproposed in 1979. FDA is now proposing the procedures again. The procedures are designed to permit the identification of that concentration of residue of a carcinogenic compound that presents an insignificant risk of cancer to the consuming public. Accordingly, the procedures call for a quantitative estimation of the risk of cancer presented by the residues of any carcinogenic compound proposed for use in food-producing animals. The procedures provide that, before a carcinogenic compound can be approved for use in food-producing animals, an analytical method must be available that can accurately and dependably measure the carcinogenic residues of the compound at concentrations greater than that estimated to be insignificant. That concentration is defined under the procedures as “no residue.” The definition renders the DES Proviso operable.

I. Introduction

A. Satutory Background

The act contains three Delaney, or anticancer, clauses: sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) (21 U.S.C. 348(c)(3)(A), 360b(d)(1)(H), and 376 (b)(5)(B)). Each clause contains an exception applicable to compounds administered to food-producing animals. The exception, the DES Proviso, hinges on the finding of “no residue” of carcinogenic concern. The DES Proviso is the statutory basis for these proposed regulations. A discussion of the history, interpretation, and application of the DES Proviso follows.

1. Food Additives Amendment of 1958. Section 409 of the act, the Food Additives Amendment of 1958, establishes a licensing procedure for food additives, substances that are likely to become components of food. Section 409 of the act provides that a food additive must be shown to be safe through adequate scientific testing procedures. A primary function of the amendments was to require that manufacturers of food additives test substances that are added to food even if the substances are only potentially unsafe.

Before the amendment, FDA's authority for ensuring the safety of substances added to food was limited to section 402 (a)(1) and (2)(A) of the act (21 U.S.C. 342 (a)(1) and (2)(A)). The section applies to intentionally added food substances that may be injurious to health. The section places a burden upon the agency to show that an added substance may be injurious. The Food Additives Amendment of 1958 shifted this burden by requiring a sponsor or proponent of a food additive to prove that the additive could be safely used.

When first introduced in Congress, the Food Additives Amendment of 1958 did not contain a specific anticancer clause. The amendment contained a section requiring that food additives be demonstrated by premarketing testing to be safe. That section was enacted and is known as the General Food Safety Clause (section 409(c)(3)(A) of the act). Elliott L. Richardson, then Assistant Secretary of the Department of Health, Education, and Welfare (HEW), noted in commenting on the amendment that the General Food Safety Clause provided adequate grounds to protect the public from cancer-causing agents as well as from other toxins. (Ref. 1):

The scientific tests [required by the General Food Safety Clause] that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary [of HEW] from approving the ***45531** proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and, thus, would be safe under the proposed conditions of use.

After the amendment was reported out of committee, Congressman Delaney from New York suggested the addition of an express anticancer clause. As a result, the following provision was added to the bill on August 13, 1958:

[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal or if it is found after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *.

The House Committee on Interstate and Foreign Commerce and HEW agreed to the amendment. HEW, however, continued to maintain that the amendment did not change the meaning of the bill and that the power to regulate carcinogenic substances, as Assistant Secretary Richardson explained, was already contained in the General Food Safety Clause.

2. Color Additive Amendments of 1960. Section 706 of the act, the Color Additive Amendments of 1960, applies to all substances used to impart color to food and requires that before a color additive may be marketed it must be demonstrated to be safe by scientific testing. Section 706 of the act also has an anticancer clause for color additives in food. The clause is nearly identical to that promulgated in the Food Additives Amendment of 1958. Before the amendments became law, HEW commented again that an express anticancer clause was unnecessary to prevent approval of carcinogenic or potentially carcinogenic color additives because the clause did not offer any public protection that was not already provided by the general requirement to perform premarketing safety tests (Ref. 2).

3. Drug Amendments of 1962 and Animal Drug Amendments of 1968. Until 1962, the anticancer clauses in sections 409 and 706 did not distinguish between compounds added directly to human food and compounds that might indirectly enter human food by virtue of having been administered to food-producing animals. FDA interpreted the act as prohibiting the approval of a carcinogenic substance for use in animals. Accordingly, FDA did not consider whether a carcinogenic compound administered to animals left any residues in the edible tissue of the animal. A modification of section 706, however, was suggested by the Secretary of HEW during congressional consideration of the Color Additive Amendments of 1960. The Secretary explained (Ref. 2):

There is * * * one respect to which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food * * *.

We therefore have included in the enclosed draft bill an amendment to permit use of an additive in animal feed under the above-mentioned conditions.* * *

Under the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive.

The amendments proposed by the Secretary were not included in the color additive legislation.
In 1962 Congress extensively amended the new drug provisions of the act. At the time “new drugs” included animal drugs as well as human drugs. The amendments were designed, among other things, to rectify the problems identified by the Secretary in 1960 regarding the application of the anticancer clause in section 409 of the act to substances used in food-producing animals. Under section 409 of the act, the drug diethylstilbestrol (DES) could legally be administered to animals for certain longstanding uses. However, no “new” uses of the drug in food-producing animals were permissible under section 409 of the act by operation of the Delaney Clause. Citing this situation, the House Committee on Interstate and Foreign Commerce modified the anticancer clause by adding the DES Proviso. The committee explained the modification as follows (Ref. 3):

The committee amended the anticancer clause of the Food Additives Amendment and the Color Additive Amendments of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds: (1) That under the conditions of use and feeding specified in the

proposed labeling and reasonably certain to be followed in practice such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animals.

The Senate accepted the addition of the DES Proviso and modified the anticancer clauses. In 1968, Congress consolidated the various provisions of the act that govern the premarketing approval of drugs used in animals into section 512 of the act. The DES Proviso in section 512(d)(1)(H) of the act provides that the Secretary shall deny an application for approval of a new animal drug if he finds that the "drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals.* * *" (emphasis added). (A nearly identical proviso exists for food additives (section 409(c)(3)(A) of the act) and for color additives (section 706(b)(5)(B) of the act). To avoid repetition, the language quoted above from section 512(d)(1)(H) of the act will be used or referred to throughout this document.)

B. Interpretation of the DES Proviso

Most compounds used in food-producing animals require premarketing approval under the act. Accordingly, the Delaney Clause as modified by the DES Proviso is potentially applicable to many compounds. Because the DES Proviso is an exception to the application of the Delaney Clause, arriving at an appropriate interpretation of the proviso has been controversial. Several interpretations are possible. FDA believes that there are three plausible interpretations.

***45532** Under one interpretation, the term "no residue" in the DES Proviso could be considered satisfied when no residue can be found at the lowest limit of measurement of the available analytical methodology. Under this interpretation, the application of the DES Proviso would be geared to advancements in techniques of measurement. The resulting degree of public health protection would be a function solely of the capability of available technology.

A second interpretation is to construe "no residue" as calling for the definition of some low finite concentration of residues (such as 1 part per billion) as "no residue" for any compound. Under this interpretation, a sponsor of a product would merely have to develop an analytical method that could reliably measure residues of a sponsored compound at the benchmark concentration. This interpretation would not take into account the potency of different carcinogenic residues.

A third interpretation is that which the agency has adopted in these proposed regulations. Under this interpretation, the term "no residue" is defined on the basis of quantitative carcinogenicity testing of residues and the extrapolation of the test data to that estimated concentration of residues that may be considered safe in the total diet of people. Under this approach, the estimated concentration of residues that will be considered safe will vary from compound to compound depending on the carcinogenic potency of the residues. Also, under this approach any future development of a regulatory assay with the capability of measuring even lower concentrations of residues would not result, as under the first interpretation, in precluding the application of the DES Proviso in a given case.

C. History of the SOM Procedures

In addition to the General Food Safety Clause for food additives (section 409(c)(3)(A) of the act), there are virtually identical clauses for new animal drugs (section 512(d)(1)(B) of the act) and color additives (section 706(b)(4) of the act). The essence of these clauses is that a food additive, new animal drug, or color additive for use in food-producing animals cannot be approved for use until it is shown to be safe. "Safe" means a reasonable certainty of no harm from any toxicity, including carcinogenicity. In the case of a drug or food or color additive proposed for use in food-producing animals, FDA must determine not only

whether the sponsored compound has been shown to be safe for the animals to which it will be administered, but also whether food derived from the animals will be safe for consumption by people. The sponsor of a compound is required to furnish to FDA the scientific and technical information necessary to make a determination as to safety. Prior to 1973, FDA did not have a consistently applied system for showing the safety of carcinogenic compounds proposed for use in food-producing animals or for invoking the DES Proviso to the Delaney Clause.

In the Federal Register of July 19, 1973 (38 FR 19226), FDA published a proposal to establish "the minimum standards for determining the acceptability of assay methods used to assure the absence of residues [of carcinogenic concern] in edible products of food-producing animals." The proposal was the agency's first attempt to provide a consistent and predictable approach: (1) To approve methods of measurement that would trigger the application of the DES Proviso and, therefore, (2) to demonstrate the safety of carcinogenic compounds for use in food-producing animals.

In the Federal Register of February 22, 1977 (42 FR 10412), the Commissioner of Food and Drugs promulgated final regulations based on the 1973 proposal. The Commissioner also solicited comments on four specific issues: (1) Acceptable level of risk, (2) comparative metabolism, (3) regulation of endogenous compounds, and (4) methods of determining an assay's lowest limit of reliable measurement.

On May 12, 1977, the Animal Health Institute (AHI) filed a complaint in the United States District Court for the District of Columbia alleging that the regulations were unlawful because they broadened the scope of the Delaney Clause to include substances not determined to be carcinogenic and because they foreclosed the marketing of a compound unless there exits an assay of sufficient sensitivity to detect residues of the compound at "theoretically" safe concentration. Also, AHI alleged that the regulations were impractical and embodied novel and highly suspect technical principles that would impose an environmental burden on the public and enormous financial costs on the animal health industry. AHI also alleged that the regulations violated the Administrative Procedure Act (5 U.S.C. 551 et seq.) because the regulations were not republished for comment.

The court agreed with AHI's letter contention because it found that the final order was significantly different from that proposed. The court remanded the case to FDA for further consideration. The court did not suggest that the agency's basic approach was suspect. The court, however, requested FDA specifically to consider AHI's question regarding the technical feasibility of the regulations. The court recommended that FDA repropose the regulations.

FDA revoked the regulations on May 26, 1978 (43 FR 22675), and on March 20, 1979 (44 FR 17070), reproposed them for public comment. The 1979 proposal contained an evaluation of the response to AHI's criticisms, the court's questions, and the substantative comments filed on the final rule. The reproposal was also supported by a lengthy and detailed administrative record. Furthermore, in an effort to promote the submission of well-directed comments, FDA held a public hearing on the proposal on June 21-22, 1979 (44 FR 23538, April 29, 1979; 44 FR 26899, May 8, 1979). A transcript of the hearing has been made a part of the administrative record of this proceeding.

II. The New Proposal

In reviewing the comments and in listening to participants at the June 1979 public hearing, FDA has concluded that there was a misunderstanding regarding the scope and purpose of the regulations proposed in 1979. In the interest of: (1) Increasing understanding about the SOM procedures and criteria; (2) continuing to draw upon valuable public comment; (3) being open to developments in science, and, most importantly; (4) developing a workable system for ensuring the safety of edible products of food-producing animals, FDA has decided to repropose less detailed regulations and to make available specific guidelines for implementing the regulations. (A notice of availability of the guidelines is published elsewhere in this issue of the Federal Register.)

A. Overview of the Proposed Procedures

The proposed regulations and guidelines identify the procedures and the criteria that if followed will permit the approval of carcinogenic compounds intended for use in food-producing animals, provided that the level of any residue remaining in edible tissues is so minimal that it would not present any significant risk of cancer. FDA emphasizes that the proposed regulations pertain to only one potential adverse effect: carcinogenicity. Every sponsored compound must also be evaluated for other potential adverse effects, which are not the subject of the proposed regulations, but which are included in the guidelines made available with this proposed rule.

***45533** The first step in the evaluation of any compound proposed for use in animals is the "threshold assessment," the agency's pivotal determination whether carcinogenicity testing is necessary for a sponsored compound. The elements FDA considers in making the threshold assessment are contained in a guideline. The elements include the relationship of the chemical structure of the sponsored compound to that of known carcinogens, the biological activity of the sponsored compound, the possible mutagenic activity of the compound, and the potential exposure of people to residues of the compound. See section III below.

If, after conducting the threshold assessment, FDA determines, under the General Food Safety Clause, that carcinogenicity testing (lifetime feeding studies) of the compound in laboratory animals is necessary, FDA will request the sponsor to test the parent compound and the metabolites identified by FDA to be of carcinogenic concern. (A compound that is administered to a food-producing animal can result in residues in the edible products of the animal that differ in structure from the compound. The enzymatic systems and physiological fluids of the animal often act upon a compound administered to the animal and produce these new substances, commonly known as metabolites or degradation products. Thus, the toxic response in animals could result from the administered parent compound or from the metabolites that the test animals produce by their own metabolism. The latter phenomenon is known as autoexposure.) As an alternative to separate toxicological testing of each metabolite, the guideline provides that FDA will compare metabolite profiles from tissues of target and test animals and will determine whether the bioassay has adequately tested the metabolites by autoexposure. FDA may require separate studies on a metabolite if it appears that a metabolite has not been adequately tested and is likely to have carcinogenic potency greater than the parent compound. If the data from the chronic tests do not demonstrate carcinogenicity, the sponsored compound is not subject to the proposed regulations.

If the data collected demonstrate carcinogenicity, the proposed regulations provide that FDA will evaluate the data on the quantitative aspects of the carcinogenicity of the compound and its metabolites and determine the concentration of the residues of carcinogenic concern that may be considered safe in the total diet of people. That concentration, for purposes of approval, will be defined as "no residue" and will be the permitted concentration of residue in edible tissues of treated animals.

The proposed regulations then provide that the sponsor of the compound must develop a reliable and practical regulatory assay to monitor the permitted concentration of residues in the edible tissues of treated animals.

The final step in the procedure is the determination of when the concentration of residues of carcinogenic concern in the edible tissues of the treated animals reaches the permitted concentration. This information allows for the determination of the last time before marketing an animal may be administered the sponsored compound.

B. Summary of Significant Changes in the Proposed Procedures

The proposed procedures differ significantly in several respects from the 1979 proposal. First, the regulations have been extensively revised to emphasize general principles. Much of the detail in the 1977 and 1979 regulations is now contained in guidelines. The guidelines describe an appropriate way of conducting scientific tests and provide FDA's criteria for evaluating data collected from the tests. If a sponsor follows the procedure prescribed in the regulations and guidelines, the sponsor is assured that the data collected will be sufficient to support an approval of the sponsored carcinogenic compound, assuming that the data that are collected are adequate to demonstrate the safety of the compound. The existence of guidelines does not preclude a sponsor from meeting the statutory and regulatory requirements by collecting data of information in a manner different from that described in the guidelines. Alternative means of showing that a given statutory standard is met may exist.

The proposed regulations and implementing guidelines represent FDA's perception of one acceptable way to show that a carcinogenic compound may be safely used in food.

Second, the guidelines explain how to conduct studies to identify residues for chronic testing. SOM procedures proposed in the past, without offering guidance, called for rigorous metabolic studies to identify and then test metabolites of carcinogenic concern in edible tissue. The guidelines now provide that usually only major metabolites will need to be identified. The guidelines define a major metabolite as one that, upon administration to an animal, is either present in an amount greater than 10 percent of the total residue in an edible tissue or has a concentration that exceeds 0.1 part per million in tissue.

Third, the proposed procedures rely upon the linear interpolation model for determining from the results of chronic tests in animals the amount of residue of a sponsored compound permitted in the diet of people. The new model takes into account all the dose response data collected from the chronic tests.

Fourth, the proposed procedures do not focus on what constitutes the lowest limit of reliable measurement of a regulatory assay, but rather on whether the assay reliably identifies the concentration defined as “no residue.” Under the proposed regulations, if a regulatory assay identifies any residue below that defined as “no residue,” FDA will consider the edible tissues containing the detected residue to be safe. FDA will consider actionable only the finding of a concentration of residues above that concentration defined as “no residue.”

III. Threshold Assessment

A. Background

When considering whether a sponsored compound for use in food-producing animals is safe within the meaning of the General Food Safety Clause, the agency determines whether the compound has the potential to contaminate the edible tissues of food-producing animals with residues that, if consumed, would present a risk of cancer to people. As each Federal Register notice concerning these procedures and criteria, has recognized, FDA will not require carcinogenicity testing for every sponsored compound. The mechanism by which FDA makes the determination that carcinogenicity testing is necessary is explained in the threshold assessment guideline.

Since the 1973 proposal, the elements of the threshold assessment have been refined. In the Federal Register of February 2, 1982 (47 FR 4972), FDA made available a threshold assessment guideline that superseded the approach recommended in the 1979 proposal. FDA received many favorable and well-focused comments on the revised guideline. In response to comments, FDA has further modified the 1982 guideline. Elsewhere in this issue of the Federal Register, FDA announces the availability of the new threshold assessment guideline.

B. Overview of the Threshold Assessment

The threshold assessment guidelines offers a decision-tree approach for deciding whether the sponsored ***45534** compound should be tested for carcinogenicity. The guideline is based on the assumption that the potential of a sponsored compound to present the risk of cancer to people includes two primary elements: (1) The potential carcinogenicity of the compound and (2) the exposure of people to residues of the compound. A brief discussion of how FDA applies the threshold assessment guideline follows.

When considering the potential carcinogenicity of the sponsored compound, FDA will evaluate the structure of the parent compound as well as data from short-term genetic toxicity tests and from subchronic toxicity tests performed on the compound. FDA will also evaluate any other available relevant information concerning the potential carcinogenicity of the compound. As a measure of that potential, FDA will assign a “toxicity factor” to the sponsored compound. FDA will assign an “A” toxicity factor to compounds for which the available information reveals there is a low potential for carcinogenicity. FDA will assign a

"B," "C," or "D" toxicity factor to compounds with higher potentials for carcinogenicity, with D representing the compounds with the highest potential to be carcinogenic.

When considering the potential exposure of people to residues of the compound, FDA will evaluate both the frequency of exposure to residues and the amount of residue ingested during a single exposure. As a measure of the frequency of exposure of people to the compound in food from food-producing animals, FDA will assign to the compound either a "high" or "low" use factor. For example, if most of the animals in a given herd or flock would normally be treated with the sponsored compound, then people would frequently ingest residues of the compound. Under these circumstances, FDA will assign that compound to the "high" use factor. If only a few animals would normally be treated with the compound, then people would ingest residues of the compound only intermittently. Under these circumstances, FDA will assign the sponsored compound to the "low" use factor.

As a measure of the amount of residue of a compound ingested by a person during a single exposure, FDA will use the results of a residue depletion study on the compound, which takes into account the duration of treatment, the dose administered, the time of treatment in relation to slaughter, and the contribution of various edible tissues to the total diet of people.

After all available information is evaluated and the toxicity, use, and residue factors have been assigned, FDA will follow the decision elements of the threshold assessment guideline to determine whether it will request carcinogenicity testing. For example, FDA will not request carcinogenicity testing for any compound assigned an A toxicity factor. FDA will request testing for a compound assigned a B toxicity factor only if the compound is assigned the high use factor and a total residue factor that exceeds 0.25 microgram per kilogram body weight per day or if the compound is assigned the low use factor and a total residue factor that exceeds 6.25 micrograms per kilogram body weight per day. FDA will request testing for any compound assigned a C or D toxicity factor. However, in the case of a compound that has a short half-life in edible tissue and is administered a long time before slaughter of the animal, FDA may conclude that any potential risk to people will be too low to justify requesting carcinogenicity testing regardless of its assigned toxicity factor.

If FDA does not request testing for carcinogenicity, the proposed regulations do not apply to the compound. Although not likely, it is possible that subsequent testing performed under the general food safety requirements of the act and necessary for approval of the product may indicate that the compound possesses the potential to be carcinogenic. Under these circumstances, the compound may be reassigned to a toxicity category that may result in a request for carcinogenicity testing.

C. Comments on the 1982 Guideline

As discussed above, many comments were received on the 1982 guideline. As a result of the comments, FDA has revised the guideline. In the following discussion, FDA responds to the substantive comments received.

1. A comment stated that FDA in the threshold assessment should not automatically request carcinogenicity testing even when adverse data are obtained. The comment suggested that FDA should also consider use patterns, pharmacokinetic data, and residue concentration.

FDA agrees with the comment and has modified the threshold assessment accordingly. The guideline now provides that: "After all available information is evaluated, FDA will request carcinogenicity testing for a compound assigned a C or D toxicity factor. If, however, a specific compound imparts residues that have a short half-life in edible tissue and the compound is administered a long time before slaughter (for example, several months), then FDA may not require carcinogenicity testing. Under these circumstances FDA can conclude that any potential risk to people will be too low to justify chronic testing."

2. Another comment interpreted the threshold assessment as classifying a compound as a carcinogen if the short-term tests of the compound yield positive results. The comment stated that positive results in short-term tests do not provide sufficient evidence to classify a compound as a carcinogen.

FDA agrees with the comment's position regarding the limitations of short-term testing. When positive data are obtained from a battery of short-term tests, FDA does not classify the sponsored compound as a carcinogen. Rather, FDA requests the sponsor of the compound to conduct adequate carcinogenicity testing to provide definitive data to determine whether the compound is a carcinogen.

3. Many comments stated that the threshold assessment placed too much weight on structure-activity relationships and insufficient weight on the results of biological testing. The comments contended that under the threshold assessment FDA should assign all compounds an A toxicity factor when no adverse biological data are submitted by the sponsor.

FDA believes that none of the types of information relied upon in the threshold assessment to assign compounds a toxicity factor (that is, structure, results from short-term genetic toxicity tests, and results from subchronic feeding studies) is sufficient to determine whether a compound is carcinogenic. Information from each category may raise or lower concern that a given sponsored compound is carcinogenic. Even negative results from genetic toxicity tests and subchronic feeding studies cannot completely eliminate concern that arises from a compound that possesses a structural relationship with known carcinogens because genetic toxicity tests and subchronic feeding studies may not be sufficiently sensitive and may give false-negative or false-positive results. The comments correctly argued, however, that FDA has in past threshold assessment guidelines placed undue weight on structure-activity relationships. Accordingly, FDA has revised that aspect of the guideline that applies to a compound that gives no adverse data from genetic toxicity and subchronic feeding tests but possesses a structural relationship to a known carcinogen. The compound will be assigned a B toxicity factor but in determining whether carcinogenicity ***45535** testing will be requested the agency will take into account not only the proposed use of the compound but also its residue concentration. The guideline now provides that:

“FDA will request a sponsor to conduct chronic bioassays for carcinogenicity for a compound assigned a B toxicity factor if it is assigned a high-use factor and a total residue factor exceeds 0.25 microgram/kilogram body weight/day (equivalent to a concentration of 10 parts per billion in the total diet of people, assuming a 60-kilogram body weight and a total solid diet of 1,500 grams).

“FDA will request a sponsor to conduct chronic bioassays for carcinogenicity for a compound assigned to a B toxicity factor if it is assigned to a low-use factor and a total residue factor that exceeds 6.25 micrograms/kilogram body weight/day (equivalent to a concentration of 250 parts per billion in the total diet of people).”

FDA suggests the 0.25 microgram/kilogram body weight/day value for a high use compound assigned a B toxicity factor because demonstrated carcinogens recently reviewed by FDA have been determined to present an insignificant risk of cancer using criteria similar to these proposed in these regulations. As FDA gains more experience using the criteria in these proposed regulations, FDA may change this value. FDA suggests the 6.25 micrograms/kilogram body weight/day value for a low use compound assigned a B toxicity factor because FDA uses this value in deciding whether carcinogenicity testing is necessary for direct human food additives.

4. Several comments stated that the structure list, although improved, remained too broad and inclusive.

In response to a similar comment, FDA stated in the 1982 notice (47 FR 4975) that: “The list of structures was intentionally general to ensure that compounds with some carcinogenic potential would not be missed. Because of the uncertainties in selecting potential carcinogens on the basis of molecular structure, the guide will be used as a screening tool by an internal committee of agency scientists.” FDA continues to believe in the propriety of an inclusive structure list. Any relevant information on the potential carcinogenicity of a compound should be considered during the threshold assessment. As noted above, however, FDA has modified the threshold assessment so as not to place undue emphasis on the significance of structure-activity relationships in the absence of other relevant evidence bearing on the question of the carcinogenicity of a sponsored compound.

5. One comment requested that FDA explain how it will interpret equivocal results from a battery of genetic toxicity tests.

Because the burden of demonstrating the safety of a compound is on the sponsor, FDA under the threshold assessment will not assign a compound to a more favorable toxicity factor on the basis of equivocal results from the battery of genetic toxicity tests. Under these circumstances, a sponsor has the option of submitting additional genetic toxicity data or of conducting chronic bioassays to resolve questions concerning the carcinogenicity of the compound.

6. Some comments also argued that the threshold assessment should take into account in the use factor the difference between drugs given to a herd or flock early in an animal's life as opposed to those administered to a herd or flock throughout an animal's life.

The threshold assessment guideline does take these distinctions into account. An anthelmintic and a growth promotant, for example, could be assigned to the same use category if they would both be given to approximately the same number of animals, an entire herd or flock, on a routine basis. However, the respective total residue factors assigned to each use would differ, for that factor accounts for the amount of residue present at the time of slaughter.

7. One comment contended that for compounds available only through a veterinarian by prescription the threshold assessment should provide for the assignment of a compound to the low use factor.

A product available through prescription is usually administered after signs of disease are present and after a diagnosis has been made. Thus, FDA will usually assign a prescription product a low use factor.

8. One comment asked how approved compounds would be classified if the criteria in the threshold assessment were applied to them.

FDA does not have the results of genetic toxicity testing and total residue data on all approved compounds. However, approximately one-third of the approved products would be classified as “suspect structure, high use.”

9. Several comments requested that FDA revise the correction factors to reflect more closely the actual consumption by people of organ tissue.

FDA has obtained new data on the consumption of organ tissues and is presently evaluating this information to ascertain if a revision of the current guideline is warranted. Pending such a change, FDA will continue to use the “Guideline for Establishing a Tolerance” made available for comment elsewhere in this issue of the Federal Register.

IV. Studies to Identify Residues of Toxicological Concern

A. The Need To Identify Residues in Edible Tissues

In determining whether a sponsored compound proposed for use in food-producing animals is safe, section 512(d)(2)(A) of the act provides that FDA should consider the safety of any substance formed in or on food by the sponsored compound. A similar requirement is found in section 512(b)(7) of the act. The compound administered to food-producing animals is not necessarily the substance or substances that will be present in the edible products of the treated animals. The enzymatic systems and physiological fluids of an animal can act upon a compound administered to the animal and produce new substances, which are commonly referred to as metabolites or degradation products. The amount of these substances in edible animal products will be a complex function of the rate and extent of absorption of the parent compound, the rate and extent of the metabolism of the absorbed parent compound, and the rate of excretion of the parent compound and metabolites (Refs. 4 through 7).

Because the structure of metabolites can vary greatly from that of the parent compound, the toxicological properties of these metabolites may also vary. In many instances, a metabolite may be less toxic than the parent compound. However, in other instances, a metabolite may be more toxic than the parent compound (Refs. 8, 9, and 10).

The total residue of the sponsored compound in edible animal products will consist of the parent compound, free metabolites, and metabolites that are covalently bound to endogenous molecules. The relative and absolute amounts of each residue will vary among the tissues according to the time following the last administration of the sponsored compound to the animal. Because different components of the total residue may possess dissimilar toxicological potential, a compound cannot be shown to be safe until the sponsor has collected information on the amount, persistence, and chemical nature of the total residue in the edible products of the treated animals.

Comments on past notices concerning the SOM procedures and criteria have ***45536** complained that FDA has not provided adequate guidance on how to design and conduct appropriate studies for identifying residues of toxicological concern. In the absence of this guidance, comments have mistakenly believed that FDA required that every metabolite be identified and tested for carcinogenicity in separate chronic bioassays. In an effort to provide guidance and clarification in this area, FDA has prepared a detailed " Guideline for Metabolism Studies and for Identification of Residues for Toxicological Testing." The guideline is made available for comment elsewhere in this issue of the Federal Register. The guideline identifies the extent of metabolite identification and testing FDA believes is necessary. For example, the guideline permits reliance upon autoexposure testing to the extent scientifically appropriate in an effort to avoid the need to conduct separate testing on individual metabolites. The autoexposure approach assumes that the toxic response in the treated animals results from the administered parent compound or the substances that test animals produce from the administered compound by their own metabolism.

If FDA requires that a sponsored compound be subjected to carcinogenicity testing, a sponsor will always be required to test the parent compound in chronic bioassays. FDA uses the information on the amount, persistence, and chemical nature of the metabolites in target animals to select those metabolites of the parent compound that should also be subjected to carcinogenicity testing. FDA will compare data submitted by the sponsor on the metabolites of the compound in target and test animals and will use scientific judgment in determining the adequacy of autoexposure to test metabolites of the sponsored compound. FDA may still require separate toxicity studies if a metabolite is not adequately tested through autoexposure and is likely to have carcinogenic potency significantly greater than the parent compound.

B. Comments on the 1979 Proposal

Many comments were received concerning how to perform studies of the metabolism of a sponsored compound in target and test animals. The comments identified many issues that the proposed regulations did not describe in sufficient detail. The guideline and the responses to the comments, below, provide needed clarification in this area.

Metabolite Identification

10. Comments stated that FDA should clearly distinguish a study that provides a qualitative profile of metabolites for comparative purposes from a study that involves exhaustive identification of all drug-related residues. The comments stated that the first type of study is feasible and scientifically supportable. The comments argued, however, that the second type of study is technically infeasible and not very relevant to an assessment of the carcinogenicity of a residue. One of the comments recommended that FDA require the study in the target animal to provide information on excretion rates, total residue depletion rates in tissue, and a qualitative chromatographic pattern of residues in the tissue.

Comments also noted that there are no standardized procedures for the identification of an unknown metabolite in tissue at the parts per billion level and that standard techniques used in the identification of metabolites in excreta are generally not useful in the identification of metabolites in tissues. Additional comments stated that the identification of metabolites should be limited to state-of-the-art procedures, and that sponsors should be required to identify major metabolites but only to estimate the number and properties of minor metabolites. Another comment suggested that complete structural identification of minor metabolites

should not be required because the fact that the metabolite is present in small amounts is sufficient information to conclude that the metabolite is of insignificant carcinogenic risk to people. Another comment expressed the view that references cited in the 1979 proposal are not germane to the proposed rule because they deal with classic drug metabolism and not with drug-related metabolites in tissue.

The comments demonstrate that FDA did not clearly explain its position on the need for identification of metabolites in edible animal tissue. FDA intended to say that techniques used in the identification of metabolites (e.g., ultraviolet-visible spectroscopy, infrared spectroscopy, nuclear magnetic resonance spectrometry, and mass spectrometry) are routine state-of-the-art techniques employed in basic biochemical and pharmacological investigations. FDA recognizes that procedures for the isolation of metabolites from edible tissues may be quite different from procedures used to isolate metabolites from urine and that there are practical limitations on the isolation of metabolites from tissues. The sponsor may isolate metabolites from excreta or from overdosed animals for purposes of chemical characterization and structural identification and should provide information to ensure that metabolites identified in excreta are the metabolites present in tissue.

FDA acknowledges the difficulties in the isolation, purification, and structural characterization of metabolites in tissue and recognizes that complete structural elucidation of minor metabolites is not possible. As discussed in the guideline, FDA will usually require structural identification of major metabolites, but will normally not require structural identification or chemical characterization of minor metabolites. FDA will consider a metabolite to be a major metabolite if either: (1) It is present in an amount greater than 10 percent of the total residue in an edible tissue at zero withdrawal, or (2) its concentration exceeds 0.1 part per million at zero withdrawal. In some cases, chemical characterization rather than unequivocal structural identification will be sufficient for major metabolites.

FDA disagrees with the assertion that the presence of only small amounts of a metabolite in tissue is sufficient information upon which to conclude that the metabolite presents an insignificant risk of cancer to people. The comment ignores the fact that the potency of chemical carcinogens varies over orders of magnitude (Ref. 11).

Radiolabeling

11. Several comments noted that the radiopurity of the parent compound used in the studies is critical because contaminants can greatly affect the interpretation of results. Comments also suggested that obtaining adequate radiopurity would be particularly difficult for high specific activity preparations because a certain degree of radiodecomposition of the parent compound is anticipated.

Many comments stated that the use of compounds with the highest specific activity available would be enormously costly, would be dangerous to personnel, and would create a waste disposal problem. Another comment stated that the investigator conducts these studies to address different questions and should be allowed to choose the specific activity for each study. Another comment stated that the use of compounds with such high specific activity is often unwarranted because individual metabolites in the tissue cannot feasibly be identified when they occur at very low concentrations.

***45537** FDA agrees that radiolabeled contaminants in a preparation of the parent compound can render the interpretation of metabolism studies difficult or impossible. In FDA's experience, radiochemical purity of 98 percent will usually give satisfactory results, but lower percentages may suffice. If the sponsor believes that a residue is present in tissue solely as a result of a contaminant in the radiolabeled preparation of the parent compound, FDA will consider submitted data pertinent to this issue when deciding if that residue is of concern.

All phases of the studies need not be conducted with radiolabeled compounds of the highest specific activity available. The sponsor may choose a specific activity that will be compatible with the objective of the experiment, thus reducing costs. FDA believes that any hazard incurred by personnel in the handling and disposal of radioactive substances may be minimized by usual laboratory safety procedures associated with the use of radioisotopes.

FDA disagrees with the comment's assertion that merely because detected residues may not be identified, the use of a high specific activity radiolabel is unnecessary. Even in the absence of structural identification of individual residues, a sensitive measure of the total residue in edible animal tissue is an essential aspect in a safety evaluation. For a compound that is to be regulated as a carcinogen, FDA will require that the specific activity of the compound be high enough to measure the metabolites at the concentration that will satisfy the operational definition of no residue.

Maximum Proposed Dosage

12. One comment stated that it is not possible to know the maximum proposed dosage of a drug because field trials for efficacy will often still be in progress, and the maximum proposed dosage may change after evaluation of these results.

The sponsor may choose to await completion of field trials before beginning metabolism studies. Alternatively, the sponsor may choose the likely maximum dosage and proceed with the studies. If the maximum proposed dosage changes, FDA will determine if any additional information is necessary.

Reporting Format

13. Some comments stated that the American Chemical Society and American Society of Biological Chemists publication formats were too restrictive in terms of data presentation for FDA to evaluate the information properly.

FDA's purpose in requiring that results of these studies be presented in a format similar to publications of professional societies is to ensure that data are submitted in a clear, concise manner. This will facilitate FDA review. FDA will not require rigid adherence to any specific format. The sponsor should include in the report a statement of the purpose for conducting the experiment, a description of the methods used, and a discussion of the results obtained.

Selecting Metabolites For Chronic Bioassay

14. Several comments dealt with FDA's proposal to use structure-activity relationships to select metabolites for separate chronic bioassays. The consensus of these comments was that structural identification of residues and physicochemical data are of little value in predicting the carcinogenic potential of metabolites. Other comments recommended that FDA use data obtained from genetic toxicity tests, instead of structure-activity relationships, to select metabolites for separate chronic bioassays. One comment stated that, because short-term genetic toxicity tests are of proven accuracy and prediction of carcinogenicity based on structure is not, a compound yielding negative results in genetic toxicity tests (provided that known carcinogens of the same chemical class have been shown to be positive in these tests) should not be of carcinogenic concern even if it possesses a structural moiety of carcinogenic concern. Another comment alleged that FDA's proposal may require separate chronic bioassays for many metabolites, that this testing will not yield meaningful data, and that research and development of drugs and feed additives will be deterred.

Structural information is of value in predicting the pharmacological and toxicological (including carcinogenic) properties of a compound (Ref. 12). FDA also recognizes the merit of using data obtained from genetic toxicity tests in selecting metabolites for separate chronic bioassays. However, FDA believes that there are limitations in the use of these data. For example, certain classes of compounds are carcinogenic, but are not well detected in some genetic toxicity tests. (See appendix 2 of the “Guideline for Threshold Assessment.”) Because of these limitations, the results from genetic toxicity tests cannot always be used to reduce the concern for potential carcinogenicity arising from structure-activity relationships.

FDA may require separate toxicological studies on a metabolite if it is not adequately tested through autoexposure and is likely to have toxicological potency significantly greater than the parent compound. FDA will normally conclude that autoexposure provides an adequate test of the toxicity of the sponsored compound if at least one species of laboratory animal produces the metabolites that collectively comprise over 90 percent of the amount of residue that people will consume from tissues of treated

target animals. Failing that, FDA will use the information obtained from target animals on the concentration, persistence, and chemical structure or characterization of that metabolite to determine whether separate toxicological testing is required.

Relay Toxicity

15. Many comments recommended that results of relay toxicity tests should be used in evaluating the safety of a sponsored compound. Another comment recommended that relay toxicity testing completely replace chronic testing of the parent and any or all metabolites.

FDA disagrees with the proposal that relay toxicity testing of metabolites replace testing of the parent compound or any of its metabolites. Methods for relay toxicity testing provide an excellent means of equating test animal and human exposure. However, no appropriate means of exaggerating this exposure are available. The exaggeration of dose is an essential part of any toxicity test. Should future developments in relay toxicity testing successfully overcome this deficiency, then FDA will reconsider its position on the ability of this type of study to address the lack of carcinogenic potential of metabolites in edible animal tissue. However, a positive response in a relay toxicity test indicates a serious toxicological hazard and cannot be ignored.

Bound Metabolites and Bioavailability

16. Many comments urged FDA to consider that bound metabolites are probably of little or no carcinogenic concern because: (1) The bound metabolites are unlikely to be bioavailable; (2) if they are bioavailable, then they will be rapidly cleared from the body by excretory processes; (3) the reactive portion of a bound metabolite is already involved in a covalent linkage, and it is unlikely that further metabolic activation to a toxic metabolite will occur due to thermodynamic considerations; and (4) FDA's contention that bound metabolites may be of carcinogenic concern is undocumented.

***45538** One comment recommended that separate chronic bioassays should be necessary for bound metabolites only when: (1) The bound metabolite is bioavailable, (2) the bound metabolite gives a positive response in in vitro mutagenicity tests, and (3) the bound metabolite is of greater potency than the parent compound in a mutagenicity test. Another comment contended that because bound metabolites cannot be synthesized for toxicity testing, they should not be considered to be residues.

Under the act, FDA must consider the safety of any substance formed in or on food as the result of use of the sponsored compound, including bound metabolites. Information on the toxicity of covalently bound metabolites is quite sparse because of difficulties in the isolation, identification, and synthesis of these residues for toxicity testing. Some information is available indicating that a covalently bound metabolite of aflatoxin-B1 isolated from rats fed radiolabeled aflatoxin is not reincorporated in liver DNA when the covalently metabolite is fed to a second set of rats (Ref. 23). FDA is unaware of any chronic feeding studies designed to test the carcinogenic potential of bound metabolites, and has no basis for concluding that bound metabolites cannot be carcinogenic.

FDA does not believe that results obtained from bioavailability studies alone can be used in a routine fashion to evaluate the safety of a compound. It would not be scientifically defensible for FDA to conclude that a metabolite is not of carcinogenic concern because only a small portion of that metabolite is absorbed. Additional information, such as the results of genetic toxicity tests, may be required to evaluate properly the potential carcinogenic risk from exposure to these metabolites. Although FDA agrees that genetic toxicity testing and other data may be useful on a case-by-case basis to reduce the concern that a covalently bound metabolite may be carcinogenic, there are not sufficient scientific data to conclude that potency in a genetic toxicity test correlates well with carcinogenci potency.

In situations where the concentration of total residue (free plus covalently bound) is below the concentration of residue that will satisfy FDA's operational definition of no residue, the sponsored compound is shown to be safe. Therefore, further study of the covalently bound residue is unnecessary. In situations where the concentration of covalently bound residue exceeds the concentration of residue that will satisfy FDA's operational definition of no residue, the sponsor may propose a series of studies

to remove the concern for the covalently bound residue. FDA will determine on a case-by-case basis the adequacy of the studies to address the issue.

Alternative Data Collection Schemes

17. Several comments stated that the data collection steps of the 1979 proposal do not follow a logical sequence.

The sponsor of a product may choose to collect the required information in any sequence. For example, a sponsor may believe that it is to its advantage to choose a marker substance and to develop an analytical method early in the data collection process. FDA, however, will not be able to determine whether the choice of marker is appropriate or if the limit of measurement is sufficiently low until results of chronic bioassays and metabolism and total residue studies in target animals have been evaluated and an So is determined.

18. FDA received many comments that recommended alternative data collection schemes for showing the safety of a sponsored compound that may be carcinogenic.

As stated in the proposal, FDA will accept data collected under alternative procedures provided that the data permit an adequate evaluation of the carcinogenic potential of residues. Below are several data collection schemes presented in comments.

Scheme A. 1. Lifetime chronic studies should be performed on those compounds that exceed an accepted threshold score based on the use of the compound, the concentration of metabolites, and the potential hazard of these residues to the consumer. After the lifetime studies have been completed, a second threshold assessment should be conducted. Compounds receiving overall scores below the accepted threshold value should be released from the proposed requirements and be judged by conventional toxicological criteria.

2. Studies of the metabolism of the compound should be conducted in the target animal and in one of the two species employed in the chronic study. The specific radioactivity of the radiotracer should be chosen to provide a measurable response at a concentration at which characterization of the radiocative residue is reasonable, recommended in the comment to be about 10 parts per billion. Positive results in the lifetime study with the sponsored compound would be reason for more rigorous approaches if the sponsor elected to continue with development of the compound.

3. Metabolites comprising 50 parts per billion or more should be identified to the extent possible. All metabolites that have been identified and synthesized should be subjected to the mutagenicity tests in bacteria and/or other short-term mutagenicity tests deemed appropriate by toxicologists. A positive response in these tests should be considered reason for further study.

4. The lifetime bioassay of the sponsored compound should be considered an acceptable evaluation of those metabolites present in both test and target species and all metabolites present at levels below 50 parts per billion, or comprising less than 10 percent of the total residue in the edible tissue.

5. Relay-toxicity and bioavailability testing should be recommended in those cases where the metabolic patterns of commonly used test animals are not similar to the metabolic patterns of the target species.

FDA agrees with many aspects of this alternative data collection process. FDA will require lifetime studies on those products that the threshold assessment indicates require further evaluation to resolve issues of carcinogenicity. When the issue of carcinogenicity is satisfactorily addressed with no finding of carcinogenicity, FDA may regulate the sponsored compound under its general food safety requirements for risks other than cancer. A second threshold assessment is, therefore, unnecessary.

FDA will generally require studies on the metabolism of the compound in target and in laboratory animals (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). A limit of detection in the 10 parts per billion range will generally be

sufficient for an initial residue depletion study. However, if the product is a carcinogen, FDA will require that the residue of carcinogenic concern be measurable at the concentration that will satisfy FDA's operational definition of no residue.

The sponsor should identify metabolites that are major metabolites as defined in section IV.B. “Metabolite Identification,” above, if they represent an amount greater than 10 percent of the total residue at zero withdrawal regardless of the possibility that the concentration may be below 0.1 part per million. FDA will generally rely on autoexposure testing of the metabolites (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). If a metabolite is not adequately tested by autoexposure, then genetic toxicity testing may be useful in deciding whether chronic bioassays are ***45539** necessary (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). FDA's position on relay toxicity testing and bioavailability studies are discussed in sections IV.B. “Relay Toxicity” and “ Bound Metabolites and Bioavailability,” above.

Scheme B. Information on the absorption, distribution, and excretion of a single dose of radiolabeled drug in target and test animals would first be collected. Emphasis would be placed on the isolation and identification of major metabolites, with an estimation of the number and properties of minor metabolites. From this study, an estimate of the required specific activity of radiolabeled drug would be made. Following multiple dosing with labeled material, excreted metabolites would be examined in target and test animals. Urinary metabolites that constitute less than 2 percent of the dose would likely be artifacts. Metabolites extractable from target tissues of the target species would be examined at steady state and at one and two half-lives of depletion. The extent of covalent binding would also be determined at these times. Metabolites in target tissues that constitute 20 percent or less of extractable material would likely be artifacts and would be considered for chronic bioassays only if they are also excreted in large amounts. From these studies, metabolic pathways would be established, metabolites would be selected for in vitro testing, and a marker substance would be selected.

FDA also agrees with aspects of this alternative. Single dose studies with a radiolabeled compound are useful to the sponsor. These studies are useful for delineating basic metabolic pathways for the product, for determining the required specific activity for future studies, for providing information on likely major and minor metabolites, and for providing information on a likely marker substance. However, single dose studies are not sufficient for the safety evaluation of a product given continuously or in repeated doses. FDA discusses appropriate metabolism studies for compounds given continuously in the “Guideline for Metabolism Studies and for Identification of Residues for Toxicological Testing.” FDA agrees that the sponsor first collect information on the major metabolites and obtain an estimate of the number and properties of minor metabolites. If necessary for its evaluation of the compound, FDA will request additional information on the minor metabolites. FDA specifically rejects the proposal to examine metabolites at one and two half-lives because the residues may require more than two half-lives to deplete to the concentration that will satisfy the operational definition of no residue. FDA cannot accept without experimental verification the assertion that metabolites that comprise less than 2 percent of the radioactivity in urine or less than 20 percent of radioactivity in tissue are artifacts. FDA's experience is that actual metabolites of sponsored compounds are frequently less than 20 percent of the total residue in tissue.

Scheme C. 1. The parent compound is administered to the food-producing animal and tissues are analyzed for parent compound and metabolites.

2. The metabolism of the parent compound is investigated in vitro using a series of tissues from potential test species/strains and human autopsy material. Using this information, test animals are selected that have a metabolite profile closest to people.

3. The metabolites are synthesized and chronic bioassays are conducted with the mixture of metabolites at the maximum tolerated dose.

4. Individual metabolites are evaluated in genetic toxicity tests using human autopsy tissue for metabolic activation. If any matabolite shows a potential for genetic toxicity, then a separate chronic bioassay on this metabolite is necessary.

FDA believes agrees that this approach, too, may have merit in evaluating the carcinogenic potential of residues. Sponsors proposing in vitro studies on the metabolism of the compound should also present information demonstrating that the tissue preparations used are representative of in vivo metabolism for the species. Sponsors should also be aware that suitable human autopsy material may not be available.

V. Cronic Toxicity Testing

A. Introduction

The sponsored compound and any metabolites selected for separate carcinogenicity testing must be subjected to oral, lifetime, dose-response studies in two test animal species. The purpose of these studies is to determine whether the compounds under test are carcinogenic and, if so, to establish the concentration that will satisfy FDA's operational definition of no residue.

B. Comments on the 1979 Proposal

The two major issues raised by comments on this feature of the 1979 proposal were: (1) The design of chronic studies and (2) the interpretation of the test data to determine whether the compound is a carcinogen.

Design of Carcinogenicity Studies

19. Comments stated that FDA did not give the criteria or any other guidance for designing carcinogenicity studies.

The purpose of the proposal was to detail the type of information required to evaluate the possible carcinogenicity of the sponsored compounds, not to provide protocols for conducting studies. For guidance in developing an acceptable protocol, FDA recommends the report of the Food and Drug Advisory Committee on Protocols for Safety Evaluation of Food Additives and Pesticides (Toxicology and Applied Pharmacology, 20:419-438, 1971) as well as “Guidelines for Carcinogen Bioassays in Small Rodents” (National Cancer Institute, Carcinogenesis Technical Report Series No. 1. HEW Publication No. (NIH) 76-8601, 1976). FDA has also adopted minimum protocols and required quality standards for chronic bioassays (Ref. 13). FDA recommends that the sponsor submit protocols for review before starting the projects.

20. One comment argued that a time limit must be included for FDA comment on submitted protocols. The comment suggested that FDA should be deemed to have approved the protocol in the absence of a timely response.

FDA does not agree that the use of time limits is desirable or feasible. The availability of detailed protocols (Ref. 13) acceptable to FDA should reduce the need for extensive FDA comment on protocols.

21. Comments suggested that when extrapolating tumor data from animals to people it is not appropriate to use the dietary concentration of the test substance because young animals consume more food than adults in proportion to their body weight and thus receive a higher dose. The comments further suggested that the increased consumption of food by young animals under test might lead to metabolic overload. Accordingly, comments suggested that dose be expressed as miligrams per kilogram body weight and be held constant by varying the dietary concentration to match the food consumption and growth of the animals.

The two common ways of dosing animals on bioassay are: (1) To administer the test ***45540** substance as a constant fraction of the daily diet (parts per million) or (2) to administer the test substance as a constant fraction of the body weight (milligrams per kilogram). Each approach has advantages and disadvantages. FDA previously required that the sponsor administer the test substance as a constant fraction of the daily diet to minimize the potential for dosing errors. FDA is aware of the principal disadvantage of this approach; that is, the change in the relative dose with the change in the body weight of the test animals.

FDA is eliminating the requirement that the test substance be administered as a constant fraction of the daily diet. Also, FDA will accept bioassays in which the test substance has been administered as a constant fraction of the test animal's body weight.

However, a sponsor who chooses this procedure must maintain and submit with the report detailed records of individual animal weights and food consumption and the concentration of the test substance in the diet. Further, the sponsor's choice for dosing the animals will commit the sponsor to accept risk estimates from the bioassay data calculated on the same basis. For example, if the study were conducted with the dose administered as a constant fraction of the test animal's daily diet, then the extrapolated safe dose in parts per million will be used to determine directly the permitted dose in the total diet of people. If the study were conducted with the dose administered as a constant fraction of the test animal's body weight, then the extrapolated safe dose in milligrams per kilogram would be multiplied by the weight in kilograms of the average adult (approximately 60 kilograms) to determine the permitted dose in milligrams in the total diet of people.

The change introduced as a result of this comment was brought about by advances in good laboratory practices, not by the argument based on metabolic overload. It is possible, of course, to overload the metabolic machinery of test animals. However, FDA will not use the potential for metabolic overload to modify its interpretation of data unless the sponsor provides convincing experimental data justifying such a modification.

22. Some comments suggested that the sharply increasing incidence of naturally occurring tumors with age could confuse the determination of the true carcinogenicity of a compound. The comments hypothesized that some compounds, although not carcinogenic themselves, can change the pattern of these naturally occurring tumors, increasing some types while decreasing others. These comments also stated that all potent carcinogens induce tumors in rodents within 1 year and suggest that the bioassays could be terminated at 1 year.

FDA does not agree that the bioassays should be terminated after 1 year. FDA is interested in detecting carcinogens with long time-to-tumor periods, as well as potent carcinogens with short time-to-tumor periods. Therefore, these proposed regulations continue to require lifetime bioassays.

FDA does not agree that naturally occurring late tumors can necessarily obscure carcinogen-induced tumors. Proper consideration of experimental design should assure that a carcinogenic effect of a given magnitude over the control animal tumor background can be determined to a given degree of statistical significance. In some cases, FDA may use a time-to-tumor analysis to evaluate the incidence of early appearing tumors in treated groups versus late appearing tumors in the control group.

It is true, as the comments state, that certain bioassay results show not only a statistically significant increase in a particular tumor type (which may result in a finding that the test substance is a carcinogen), but also on occasion a statistically significant decrease in another tumor type. When FDA evaluates the results, it will emphasize the increase in frequency of a given tumor.

Interpretation of Test Data

23. The 1979 proposal (44 FR 17086) stated that "* * * the absence of a significant increase in tumor incidence in each of two different animal bioassays, conducted in accordance with good laboratory practices and designed according to principles referenced above, is * * * sufficient evidence of noncarcinogenicity." During the public hearing and in written comments, FDA was asked to define the term carcinogen and to specify the criteria FDA would use to decide if there is no significant increase in tumor incidence.

In determining whether a tested substance is a carcinogen, FDA will rely upon the criteria given by the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board (Ref. 14):

The carcinogenicity of a substance is established when the administration to groups of animals in adequately designed and conducted experiments results in increases in the incidence of one or more types of maligant neoplasms (or a combination of benign and malignant neoplasms) in the treated groups as compared to control groups maintained under identical conditions but not given the test compound.* * *"

In general, FDA evaluates the results of chronic bioassays by the guidelines contained in the "General Criteria for Assessing the Evidence for Carcinogenicity of chemical Substances," National Cancer Advisory Board, 1976, and the "Guidelines for Carcinogen Bioassay in Small Rodents," National Cancer Institute, 1976. FDA considers both the statistical and biological significance of the data as part of the review.

24. Comments stated that an evaluation procedure is deficient unless it screens out results from inappropriate routes of exposure, results from exposure to above tolerable doses, results affected by the genetic proclivity of the strains, and results from a single species that produces a unique metabolite.

FDA will not disregard positive results (excess tumors) from experiments that use a nonoral route of exposure, excessive doses, or unique test animals because, at the very least, these results raise questions concerning the safety of the compound that must be resolved by more definitive testing. However, because people will ingest residues of compounds that are the subject of these regulations, the regulations specify that the bioassays must be conducted using the oral route of exposure. FDA expects that the sponsor will use commonly available rodent species for this testing.

FDA will consider a positive result (excess tumors) from a study conducted at a dose above the maximum tolerated dose as providing evidence of carcinogenicity unless there is convincing evidence to the contrary. FDA will not, however, always be able to consider a negative result (no excess tumors) from a study conducted at a dose above the maximum tolerated dose as providing convincing evidence of safety because the study may not have placed a sufficient number of animals at risk for a sufficiently long period of time. Accordingly, in some cases, the sponsor will have to provide additional evidence and a persuasive scientific rationale to support the conclusion that a negative study demonstrates the safety of the sponsored compound.

25. Many comments suggested that because benign tumors are not life threatening and do not affect animal mortality, FDA, when evaluating the residues of chronic bioassays, should discount the effects of benign tumors. One comment stated that the majority of benign tumores do not turn malignant and FDA should ignore them.

FDA will continue to consider both benign and malignant tumor incidences when evaluating the results of chronic bioassays. In reaching this conclusion, FDA will rely upon the criteria of the Subcommittee on Environmental Carcinogenesis, National Cancer ***45541** Advisory Board, which has stated (Ref. 14):

The occurrence of benign neoplasms raises the strong possibility that the agent in question is also carcinogenic since compounds that induce benign neoplasms frequently induce malignant neoplasms. In addition, benign neoplasms may be an early stage in a multi-step carcinogenic process and they may progress to malignant neoplasms; also, benign neoplasms may themselves jeopardize the health and life of the host. For these reasons, if a substance is found to induce benign neoplasms in experimental animals, it should be considered a pontential human health hazard which requires further evaluation. In experiments where the increased incidence of malignant neoplasms in the treated group is of questionable significance, a parallel increase in incidence of benign tumors in the same tissue adds weight to the evidence for carcinogenicity of the test substance.

VI. Operational Definition of No Residue

A. The Level of Risk

If FDA has concluded that a sponsored compound is carcinogenic, FDA cannot approve the use of that sponsored compound unless the sponsor can demonstrate with an acceptable regulatory method that no residue of the sponsored compound remains in the edible products of treated animals. As discussed in the 1979 proposal (47 FR 17073), FDA has concluded that Congress did not intend a literal interpretation of the term no residue. Because there will always be some residue, albeit below the limit of measurement of the analytical method, such an interpretation would preclude approval of any carcinogen. Instead, FDA has concluded that Congress intended that any remaining residues should present an insignificant risk of cancer to people. As discussed earlier in this document, FDA has chosen to define operationally "no residue" on the basis of quantitative carcinogenicity testing of residues and the extrapolation of test data to arrive at a concentration of residue that presents an

insignificant risk to test animals and, by extrapolation of the animal bioassay data to people, would also present an insignificant risk to people.

FDA cannot avoid the fact that the actual risk to people presented by carcinogenic compounds in meat, milk, and eggs is not known and cannot be precisely quantified. The 1973 proposal suggested that the insignificant level of risk could be 1 in 100 million over a lifetime using a “liberal” extrapolation procedure (Mantel-Bryan). The 1977 final regulations raised that level to 1 in 1 million over a lifetime using a slightly modified Mantel-Bryan extrapolation procedure. The 1979 reproposal retained the 1 in 1 million level of risk but used a more “conservative” extrapolation procedure (linear). Industry panelists at the June 21-22, 1979, public hearing observed that selecting a level of risk is a “no-man's land.” Others testified that they had no way of knowing whether 1 in 1 million is “right or wrong.” The reasons and factors offered by FDA in the 1979 proposal do not definitively resolve this issue. The selection of an insignificant level of risk is a choice which, although susceptible to being posed as a question of fact, cannot be answered solely by science or currently available information (Ref. 15). It is, instead, a policy question that must be answered by weighing a number of subjective considerations.

No comments on the 1979 proposal were received that disagreed with FDA's decision that the 1 in 1 million level presents an insignificant risk to the public. No comments at all, however, were received from the general public. All comments were from regulated industry. These comments contended that, the 1 in 1 million level represented an insignificant risk but that higher levels might also represent insignificant risks. The comments, however, as discussed below, failed to demonstrate that any higher level satisfied FDA's responsibility under the statute to protect the public health. FDA has carefully studied the submitted comments, the suggested alternatives, and other available information on risk assessment and has concluded that the 1 in 1 million level represents an insignificant level of risks.

FDA emphasize that the 1 in 1 million level of risk adopted for these regulations does not mean that 1 in every 1 million people will contact cancer as a result of this regulation. Rather, as far as can be determined, in all probability no one will contact cancer as a result of this regulation. The 1 in 1 million level represents a (1) 1 in 1 million increase in risk over the normal risk of cancer and (2) a lifetime—not annual—risk. Furthermore, because of a number of assumptions used in the risk assessment procedure (see Section VI.B., below) and the extrapolation model used (See Section VI.C., below), FDA expects that the actual risk to an individual will be between 1 in 1 million and some much lower, but indeterminable, level.

No Specific Level of Risk

26. Some comments on the 1979 proposal suggested, without support, that no specific level of risk should be adopted for general use, but that a level of risk should be chosen for each compound on an individual basis.

FDA disagrees. Under the suggested procedure sponsors would receive no guidance about the likelihood of approval of a compound during the expensive stage of drug development or about the factors consider in determining whether the compound should be approved. This unstructured ad hoc approach would be contrary to the interests of the public health and would result in inequitable treatment of sponsors.

The Use of Public Preference in Selecting a Level of Risk

27. Comments argued that FDA could determine a level of insignificant risk by comparing risk presented from carcinogens in food with risks individuals voluntarily assume from using their occupation, from common forms of transportation, from leisure activities, and the like. Comments also contended that FDA could similarly use involuntary risks. Accordingly, comments argued that because risks of a magnitude of 1 in 15,000 over a lifetime (1 in 1 million yearly) do not concern (that is, are “accepted by”) most people, FDA should adopt that level of risk for these regulations. Other comments used similar reasoning to support a 1 in 100,000 risk level.

The comments overlook the fact that when FDA approves the use of a carcinogenic compound, FDA affirmatively allows a risk to be imposed on the public. The public is not “accepting” that risk because (1) The public has no information on the risk

presented by carcinogenic compounds in its food, and (2) the public has no way of avoiding that risk assuming it wishes to continue to eat meat, milk, or eggs. Furthermore, these comments do not address the growing evidence that group attitudes and group choices do not follow the same patterns as individual choices (Ref. 16). Reliance on group preference, therefore, might cause the imposition of a risk that is unacceptable to many individuals.

In the final analysis, the comments and information regarding public perception of risk at best allow FDA to infer the increment of risk of cancer that certain members of society would consider unavoidable, tolerable, or unnoticeable. Although FDA has considered the comments and information provided, FDA concludes that the sole use of social preferences and the magnitude of involuntary risks to select an insignificant level of risk provides an incomplete basis for determining the level of risk to which the public should be exposed by substances permitted in the food supply. ***45542** FDA also concludes that an increase in the level of risk to 1 in 15,000 might significantly increase the risk of cancer to people, and, until better information is provided, such a level must be viewed as unacceptable in light of current knowledge and legal standards.

The 1 in 100,000 Level of Risk

Adoption of the 1 in 15,000 level in FDA's view might significantly increase the risk of cancer. FDA and those who commented on the point agree that the 1 in 1 million risk level will not significantly increase the risk of cancer. The question that logically follows is whether a level of 1 in 100,000 presents a significant risk to people. If FDA were to propose 1 in 100,000 as the insignificant level of risk, the permitted concentration of residue would increase by a factor of 10. Table III in the 1979 proposal (44 FR 17077) indicated dietary concentrations for carcinogens corresponding to lifetime risk of 1 in 1 million. The concentrations varied from 0.05 to 260 parts per billion. The range with a 1 in 100,000 level of risk would be from 0.5 part per billion to 2.6 parts per million. (FDA was criticized in some comments for not including animal health products in the table. There is no scientific reason to believe that the carcinogenic potency of animal health products will differ greatly from other chemicals.) Whether the 1 in 100,000 level would pose a significant increase in the risk of cancer to people is, however, the critical question. It is not a question which can be unequivocally answered, and it calls for a difficult decision by FDA: for no matter what arguments are made and no matter what numbers are used, the actual risk of cancer to people remains unquantifiable.

The 1 in 100,000 level does not carry with it the degree of concern presented by the 1 in 15,000 level. Similarly, it is not as insignificant as the 1 in 1 million level. The approval of a carcinogenic sponsored compound, at any level of risk, does not include consideration of the potential interaction or synergy between an approved compound and any other substance or substances to which people are exposed. Certainly, the more approved carcinogenic compounds that are marketed the greater is the likelihood of cancer induction in people.

In the presence of these uncertainties, FDA cannot, with assurance, state that the 1 in 100,000 level would pose an insignificant level of risk of cancer to people. FDA can state, and comments agree, that the 1 in 1 million level presents an insignificant level of risk of cancer to people. Furthermore, FDA has developed confidence in the merit of the 1 in 1 million level because in recent years the agency has considered that level as its benchmark in evaluating the safety of carcinogenic compounds administered to food-producing animals. Under these circumstances, the agency believes that the most reasonable level of risk to apply in these regulations is the 1 in 1 million level. In making this decision, FDA recognizes that there may be a higher level of risk that is more appropriate but, that in light of the current uncertainties that accompany making a decision as to the most appropriate level of risk, the agency believes that choosing to rely on the 1 in 1 million level is reasonable and defensible.

B. Uncertainties in Quantitative Risk Assessment

28. Several comments requested that FDA identify the conservative assumptions used in the risk assessment procedures proposed for these regulations, identify the sources of uncertainty in those risk assessment procedures, and determine the actual or most likely estimate of risk rather than the upper bound on the risk.

FDA agrees that a discussion of the uncertainties, assumptions, and conservatisms in the risk assessment procedures is warranted. Pervasive uncertainty is the primary analytical difficulty in making a risk assessment that involves trying to define the

human health effects of exposure to harmful residues. Although the risk assessment procedures proposed for these regulations draw extensively on science, which has developed a basis for linking exposure to residues to potential chronic health effects, there is uncertainty in types, probability, and magnitude of the health effects that will be associated with a given compound and its residues. These problems have no immediate solutions because of the many gaps in FDA's understanding of the causal mechanisms of carcinogenesis and in FDA's ability to ascertain the nature or extent of the effects associated with specific exposures. Where science fails to provide solutions, FDA applies conservative assumptions to ensure that its decisions will not adversely affect the public health.

For example, FDA relies upon the results of animal bioassays on a given substance to make a regulatory decision. FDA recognizes the inherent limitations and uncertainties in such bioassays, but relies on their results because there is scientific consensus that the bioassay is the best way currently available of determining the carcinogenicity of a compound. However, if one were to conduct a superb bioassay in which 1,000 animals were placed at risk and no tumors were detected, one could not conclude that the compound was not a carcinogen, but only that at the 99 percent confidence level the lifetime risk of cancer to the test animal was less than approximately 1 in 200. In such circumstances, FDA would regulate the compound under the general food safety requirements of the act for risks other than cancer and would apply a safety factor of 100 to the dose giving no observed effect in the bioassay. Thus, assuming a superb bioassay and assuming that the highest dose used in the bioassay is also the dose that gives no observed toxicological effect, FDA may be imposing a maximum lifetime risk of cancer of 1 in 20,000 on the public. FDA allows marketing of the compound because there is a scientific consensus that the results of such an assay are sufficient to create a rebuttable presumption that the compound is not carcinogenic.

On the other hand, if FDA concludes that the bioassay shows that the sponsored compound or its residues are carcinogenic, there are uncertainties in the estimate of risk to people from the compound's residues in edible products of target animals. These uncertainties exist because people are exposed to much lower residue levels than are experimental animals and because it has not been determined whether the potency of a carcinogen is proportionately the same at that lower level. The scientific community has not reached a consensus on the procedure for making this extrapolation of risk.

The risk assessment procedure used by FDA requires that the upper 95 percent confidence limit on the tumor incidence data be used to estimate the carcinogenic potency of a substance. Assuming a typical bioassay conducted on a sponsored compound (e.g., 50 animals per sex per dose) and a 20 percent incidence of tumors, this requirement causes an overestimate of the most probable potency by a factor of two. In addition, data from the most sensitive species and the most sensitive sex are used, resulting in an overestimate of the most probable potency by a factor of one to four.

The risk assessment procedure used by FDA assumes that each residue is as potent as the most potent compound detected in the bioassay. This is unlikely to be true, but in the absence of a bioassay on each residue and of knowlege of the quantity of each residue in the tissue, the effect on risk to the consuming public cannot be quantified.

The risk assessment procedure used by FDA assumes that a lower frequency of dosing has no effect on carcinogenic ***45543** potency. This is unlikely to be true. Because the animals used in the bioassay receive a constant and daily dose, but people will most likely be exposed to sporadic doses, the carcinogenic potency to people is most likely overestimated. However, FDA has no data that will allow a reliable prediction of the magnitude of this overestimate.

The risk assessment procedure used by FDA includes a calculation of the upper limit of carcinogenic potency at low dose, a dose representative of what people are exposed to. The statistical procedure used in this calculation is discussed in section VI.C., below.

The risk assessment procedure used by FDA assumes a one to one correspondence between the carcinogenic potency of the compound in the test animals and in people. The available, but extremely limited, data submitted in a comment suggest that carcinogenic potency of a specific chemical in rodents and people may vary by an order of magnitude, but is as likely to be high as low.

The risk assessment procedure used by FDA assumes that the concentration of residue in the edible product is at the permitted concentration, that consumption of that edible product by all people is equal to the consumption by the 90th percentile eater, and that all marketed animals are treated with the carcinogen (market penetration of 100 percent). These assumptions may overestimate risk. The extent of the overestimation cannot be quantified.

For the comments, the assumptions and requirements discussed above are multiple conservatisms; for FDA, each of these assumptions and requirements is a matter of prudence dictated by the lack of scientific consensus and FDA's responsibility under the statute to ensure to a reasonable certainty that the public will not be harmed.

C. Analysis of Animal Carcinogenesis Data Introduction

FDA's interpretation of the DES Proviso where “no residue” is construed to mean “no significant risk” requires an assessment of the risk anticipated from a known carcinogen as a function of the dose. Experiments designed to observe responses in the range of interest (that is, 1 in 1 million) would require impossibly large populations of test animals. Therefore, some method is required to extrapolate data from the standard bioassays, which use much smaller and more manageable numbers of animals, to the range of interest. Because the mechanism of chemical carcinogenesis is not sufficiently understood, none of the available statistical extrapolation procedures has a fully adequate biological rationale. Matters are further complicated by the fact that the dose-response relations assumed by the various procedures diverge substantially in the projections of risks presented in the range below the lowest dose tested.

FDA's objective has been to select an extrapolation procedure that is reasonably well supported by current science and a level of risk that is protective of the public health. FDA still believes that its objectives are best met by a nonthreshold, linear-at-low-dose extrapolation procedure that determines the upper limit of the risk. After considering the comments on the 1979 proposal and other available information on extrapolation procedures, FDA has concluded that the linear interpolation procedure of Gaylor and Kodell should be adopted for these proposed regulations. (Gaylor, D. W. and R. L. Kodell, “Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,” Journal of Environmental Pathology and Toxicology, 4:305-312, 1980.) As discussed in this paper, the linear interpolation procedure consists of the following steps:

1. Use any appropriate mathematical model which adequately fits the data to approximate the dose response relationship in the experimental data range.

2. Obtain the upper confidence limits on the excess tumor rate above the spontaneous background rate in the experimental dosage range.

3. Connect a straight line from the origin to the point on the upper confidence limit at the lowest experimental dosage.

4. Obtain upper limits of risk for low dosages or, conversely, dosages corresponding to low upper limits of risk from the interpolation line obtained in Step 3.

FDA will require the use of the upper 95 percent confidence limit and the upper limit of lifetime risk of 1 in 1 million. The principal advantage of the linear interpolation procedure over the extrapolation procedure adopted in the 1979 proposal is that it uses all of the data in the experimental dosage range.

FDA recognizes that alternative procedures may have merit. Accordingly, FDA solicits comments on the propriety of those alternative procedures and what is believed to be their advantages over the proposed linear interpolation procedure. Of particular interest are the Crump modified multi-stage model (Ref. 17) and the one-hit model (Ref. 18).

Comments on the 1979 Proposal

29. The most frequent comment on the 1979 proposal stated or requested that other extrapolation models be used or that a class of acceptable extrapolation models be established and that the best model be selected on a case-by-case basis. The comments stated that an extrapolation model should be based on its scientific merit, how well it agrees with the observed data, and its consistency with other information available about the carcinogen. Many additional comments stated that the linear model was not a valid model for representation of the mechanism of action of a carcinogen. The arguments presented were based on: (1) The lack of close agreement between observed responses and a straight line fit of these observed responses, (2) the concept that most physical and biological systems follow exponential relationships, (3) the existence of biological thresholds, and (4) the knowledge about DNA repair mechanisms.

Neither the linear extrapolation procedure adopted in the 1979 proposal nor the linear interpolation procedure adopted in this reproposal should be construed as a mechanistic model of carcinogenicity. FDA selected the linear interpolation procedure primarily because of the procedures that do not disregard data from a chronic bioassay; the linear interpolation procedure is the least likely to underestimate risk.

The futility of attempting to select an extrapolation procedure based on how closely the procedure can describe the observed data and then predict risk at a low dose was illustrated in one of the comments. Six different models, each with a different biological rationale, were compared. The models were the one-hit, Weibull, logistic, log-probit, multi-hit, and multi-stage. The data used were derived from the ED01 study conducted at FDA's National Center for Toxicological Research. Because this study was specifically designed to investigate the carcinogenic response in the low dose region, many of the deficiencies found in studies designed to give only qualitative answers about carcinogenicity were not present. For liver neoplasms, the Weibull, logistic, and log-probit models could equally describe responses in the observed regions, but the predicted responses at a dose of 10 parts per billion varied by a factor of 1012 . For bladder hyperplasia, none of the models even came close to describing the observed responses.

30. Several comments stated that use of the linear extrapolation procedure would result in stagnating the ***45544** development of new products and better methods of extrapolation. These comments and several additional comments stated that the linear extrapolation procedure was too conservative, needlessly inflexible, restrictive, arbitrary, and unnecessarily rigid.

FDA does not believe that adopting a specific extrapolation procedure will stagnate development of new products or new methods of extrapolation. FDA is always open to new concepts and procedures when they are supported by sound data or cogent scientific rationale and when they provide the required degree of protection to the public health. The waiver provisions of the regulations were included for this reason.

31. Several comments stated that simplicity of use and ease of calculation should not be part of the consideration in selecting an extrapolation procedure.

FDA agrees that simplicity and ease of calculation should not be a major consideration in the selection of an extrapolation procedure. However, the availability, complexity, reliability, and reproducibility of the Mantel et al. extrapolation procedure (Ref. 19) and the associated computer programs were issues raised by AHI in its suit against the 1977 regulations. Therefore, these aspects were discussed in the 1979 proposal and were considered by FDA in the selection of the linear extrapolation procedure.

32. Several comments stated that the proposed regulations did not have clearly defined provisions for combining data from different dose levels, different sexes, different experiments, and different species. These comments concluded that as a result of this deficiency, additional unnecessary conservatism is introduced because the extrapolation is not based on all of the available data. Several comments advocated using the Mantel et al. procedure (Ref. 19) because it has specific methods for pooling data.

As noted previously, the linear interpolation procedure uses data from all the dose levels of the experiment to determine the upper confidence limit and to estimate the risk. In some instances, combining data from different experiments could reduce the

upper confidence limit; however, in other instances data from different experiments may contain different types of information and should not be pooled. The sponsor must provide the scientific rationale that will justify combining data. FDA will use its statistical and biological evaluation of the data to determine which data, if any, will be appropriate for pooling. Where there are significant statistical or biological differences in the observed responses, FDA will not combine the data for analysis.

FDA, as stated in the 1979 proposal, does not believe that the Mantel et al. procedure is appropriate for these regulations because it may underestimate the risk at low doses. This deficiency is not outweighed by the procedure's specific methods for pooling data.

33. Several comments stated that the actual risk, or at least a realistic projection of the potential hazard, should be used for extrapolation rather than the upper bound on the risk.

As a policy matter, FDA has decided to continue to base the extrapolation on the upper confidence limit of the responses from the animal bioassay. This approach provides added assurance that the risk will not be underestimated. However, FDA will now use the upper 95 percent confidence limit, rather than the upper 99 percent confidence limit.

34. Several comments stressed that extrapolation was only one part of the risk estimation procedure and undue emphasis should not be placed on the use of mathematical procedures. These comments suggested that several extrapolation models be used to bracket the acceptable dose and then judgment be used in selecting the final acceptable dose.

FDA does not believe that this approach would be helpful. If the suggested procedure were adopted, FDA would have a set of residue concentrations that would vary by orders of magnitude, but no way of choosing among them. FDA has already used its judgment to select the extrapolation procedure that best meets the objectives of the regulations.

35. One comment posed the question of which lesions should be counted when attempting low dose extrapolations.

When chronic bioassays are conducted in such a way that dependable data are available for determining dose-response curves for various lesions at various ages of test animals, then FDA believes that the appropriate dose-response curve to use is the one that yields the lowest dose at the level of insignificant risk. However, the opportunity to select among various age-dependent dose-response curves will usually not occur with the chronic bioassays recommended under these proposed regulations. FDA does not require that sponsors use the number of animals or the number of doses necessary to yield well-defined dose-response curves from serial sacrifices. Of course, sponsors are free on their own initiative to test a larger number of animals and a larger number of doses than FDA requests.

36. Two comments stated that no extrapolation procedure should be used because the animal bioassays were, at best, qualitative and not quantitative. One of these comments went on to state that carcinogens should be classified as either weak, moderate, or strong. Strong carcinogens would not be approved for use. Weak and moderate carcinogens would be assigned a preselected safe concentration of residue that would satisfy the operational definition of no residue.

FDA disagrees. Accepting this comment would be the equivalent of adopting an alternative interpretation of the DES Proviso that was rejected by FDA because a single permitted concentration of residue is not suitable for weak and moderate carcinogens that have large differences in measured carcinogenic potencies (Ref. 11). (See also Section I.B., “Interpretation of the DES Proviso.”)

37. Several comments urged that FDA use any available epidemiological data to establish an upper limit on the risk.

FDA agrees and will accept risk estimates based on appropriate epidemiological data when the data are relevant to decisions on the approval of sponsored compounds for use in food-producing animals.

38. One comment stated that FDA should establish general standards for an acceptable extrapolation and allow the sponsors to demonstrate that these standards have been satisfied by the specific procedure selated by the sponsor.

In these regulations, FDA has established acceptable procedures for extrapolating data from animal bioassays. In acting upon submitted applications, FDA will consider alternate procedures that provide the equivalent degree of assurance that the sponsored compound can be used in animals without posing an unacceptable risk of cancer to people. For example, if a sponsor has information establishing the mechanism of carcinogenicity for a specific compound, then the sponsor may use that information to develop a more suitable extrapolation procedure. The waiver provisions were included for this purpose.

D. Derivation of the Concentration of the Residue of Carcinogenic Concern That Will Be Defined as No Residue

As used in these regulations, S_0 means the concentration of the test compound in the total diet of test animals that corresponds to a maximum lifetime risk ***45545** of cancer in the test animals of 1 in 1 million. For these regulations, FDA will also assume that if the S_0 concentration of residue were to occur in the total human diet, no significant increase in the risk of cancer to people would result. In some cases a sponsor will have tested for carcinogenicity metabolites in addition to the sponsored compound. In these instances, FDA will assume that the most potent carcinogen of those tested poses the greatest potential carcinogenic threat among the residues. FDA will use that carcinogen to calculate S_0.

Because the total human diet is not derived from food-producing animals, FDA will make corrections for food intake in determining the permitted concentration of residue of carcinogenic concern (see “Guideline for Establishing A Tolerance”). The S_m value represents the concentration of total residue of carcinogenic concern that FDA will permit for specific classes of edible products that constitute finite percentages of the total human diet.

VII. Studies To Select Marker Residue and Target Tissue

A. Introduction

Before the use of a carcinogenic compound can be approved, FDA must determine that a practical and reliable assay is available to measure the residue of carcinogenic concern at the concentration that will satisfy FDA's operational defintion of no residue. One approach to this problem would be to require assays that can be used to measure every residue in each of the various edible tissues. Because the number of residues in edible tissues is likely to be large, such an approach would be impractical. There is another, far more more practical approach which sacrifices no principle of safety. This alternative approach centers on the concept of a marker residue and a target tissue.

A marker residue is a residue whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to achieve its permitted concentration. The marker residue can be the sponsored compound, any of its metabolites, or a combination of residues for which a common assay can be developed. The marker residue can be a carcinogenic or a noncarcinogenic residue.

The target tissue is the edible tissue selected to monitor for residues in the target animal. The target tissue and marker residue are selected so that the absence of marker residue above the permitted concentration will confirm that each edible tissue has a concentration of residue of carcinogenic concern below its S_m, and, therefore, FDA's operational defintion of no residue has been satisfied for all edible tissues of the animal.

When a compound is to be used in milk- or egg-producing animals, milk or eggs will be a target tissue in addition to one tissue selected for the edible carcass. If a compound is used in both milk- and egg-producing animals, milk and eggs each must be a target tissue in addition to the one selected for the edible carcass. This is necessary because milk or eggs enter the food supply independently. In these cases, it may be necessary to select a marker residue for milk or eggs that is different from the marker residue selected for the target tissue representing the edible carcass.

Application of the concepts of marker residue and target tissue requires an experimental determination of the quantitative relationships among the residues that might serve as marker residues in each of the various edible tissues that might serve as target tissues. Because these relationships change with time, the sponsor must measure the depletion of the potential marker residues in the potential target tissues starting after the last treatment with the compound and continuing until the total residue of carcinogenic concern has reached Sm for that tissue. FDA will use the residue depletion profiles and the regulatory method to determine the Rm for the marker residue. The Rm is the concentration of the marker in the target tissue when the concentration of the total residue of carcinogenic concern is equal to Sm in the last tissue to achieve this value.

B. Comments on the 1979 Proposal

39. One comment argued that it was wrong to require that milk or eggs also be the target tissue when a sponsored compound is to be used in milk- or egg-producing animals.

FDA disagrees and will retain the requirement. As discussed above, milk or eggs and the edible portions of the carcass enter the food supply independently. Therefore, a regulatory method must be available to measure the residue of carcinogenic concern in eggs or milk as well as the edible portion of the carcass.

40. One comment contended that because FDA will select the target tissue, the marker residue, and the Rm, it will be many months before the sponsor can begin developing the regulatory method for the marker residue. The comment requested that once sponsors have submitted adequate data, they should be free to make these selections and begin the necessary testing rather than again having to wait for FDA review and approval.

FDA expects that sponsors will select the target tissue and the marker residue, and designate Rm. Upon submission of these data, FDA will review the information to ensure that the sponsor has reached a valid conclusion. Sponsors generally make excellent choices in selecting a marker residue and target tissue, FDA, therefore, does not believe its particular role in validating the selections is likely to result in delays in data development.

VIII. Sponsored Compounds Affecting Pools of Carcinogenic or Potentially Carcinogenic Substances Endogenous to Target Animals

FDA is withdrawing those sections of the 1979 proposal that were concerned with endogenous substances. The criteria and procedues FDA will employ in evaluating the safety of endogenous substances will be discussed in the “Guideline for Toxicological Testing.”

IX. Regulatory Method

A. Introduction

Under the proposed regulations, FDA will approve a carcinogenic compound for use in food-producing animals if the concentration of residue of carcinogenic concern satisfies the operational definition of no residue, and if a method is available that can reliably measure that concentration of residues in edible animal products. The criteria for determining whether a method is acceptable are described in the “Guideline for Approval of Methods of Analysis for Residues.”

B. Comments on the 1979 Proposal

41. FDA received many comments on the criteria for evaluating regulatory methods. Generally, the comments criticized FDA for referring to the nonstandard analytical attributes dependability and practicability.

FDA believes that in large part the criticisms made in the comments are well taken. FDA's new guideline for analytical methods refers only to standard attributes of an analytical method. In approving a regulatory method, however, FDA believes that it is

important to consider some of the aspects of practicability, a nonstandard attribute. Therefore, FDA will continue to consider the following items, in addition to the standard attributes of analytical methodology, when evaluating a regulatory assay: The commercial availability of equipment and supplies; the degree of training required to complete the assay ***45546** successfully; the length of time required to complete the procedure; and the costs associated with developing and running the assay.

42. Comments stated that it would be hard to envision a method satisfying the proposed regulations that would not involve the modification of existing instrumentation of the use of sophisticated techniques. Comments also stated that the proposed regulations are unreasonable because they either demand that the equipment and materials employed be commercially available or else force the sponsor to advance and market the analytical instrumentation. Furthermore, the comments argued that one of the biggest obstacles to gaining new animal drug application (NADA) approval has been that government regulatory laboratories do not have the equipment or expertise to implement the proposed procedures, a problem that will increase in severity with the greater demands put on analytical capability by these procedures. Another comment noted that some methods are now available for detecting animal drugs in tissue in the 5 to 100 parts per trillion range, but that these methods require the participation of highly skilled and careful scientists. The comment further complained that even these methods do not allow the determination of residues in tissue for a large number of samples in one day's time. The comment concluded that procedures that require new technology and that involve detection limits at ultra low levels will, for the foreseeable future, require great skill and a significant amount of time to carry out sample analysis.

FDA is aware of the problems in developing a method for detecting a carcinogenic compound in edible tissue. When a sponsor develops a method based on new technology and the method passes FDA's desk review, then FDA will gain the expertise needed to perform the method. FDA agrees that one must not label all new and ultrasensitive methodologies impracticable.

43. One comment found the phrases “suitable for routine use in a government regulatory laboratory” and “consistent with regulatory objectives” meaningless as goals for the developmental analytical chemist. The comment asserted that FDA should accept a method on its merits, not on the length of time required to conduct the procedure.

The phrases in question pertain mostly to the time requried to complete the procedure in a government laboratory. For research purposes, the time required to complete the procedure may be of a secondary consideration; for the regulatory purposes of compliance and surveillance, the time required to complete the procedure is of great importance. The U.S. Department of Agriculture (USDA) and FDA would be unable to fulfill their regulatory responsibilities with a method yielding, for example, one analytical result per day. Although FDA agrees that practicability may not be a scientific attribute of a method, FDA must consider collateral factors when evaluating the proposed regulatory method. FDA discusses these factors in the “Guideline for Approval of Methods of Analysis for Residues.”

44. One comment suggested redefining practicability such that a method is practicable if four out of five laboratories can successfully repeat it.

Practicability has been defined mainly in terms of timeliness, though other factors such as safety of reagents and procedures will be assessed. The comment refers to attributes of the method that are considered under the requirements for reproducibility.

45. One comment emphasized that no method can claim to provide a response that is due to “that compound only” and, accordingly, recommended that “should” replace “must” in the first sentence of the definition of specificity which appeared in the preamble to the 1979 proposal. The same comment stated that the preamble implied that mass spectrometry is the only acceptable confirmatory technique, a proposition that would be unreasonable and technology limiting. The comment added that FDA should clarify the distinction between a method for screening of samples and a method for confirming positive results found by the screening method.

FDA agrees that no method can guarantee that an analytical response is unique to that compound. The regulatory method must be able to quantify the marker residue (sometimes referred to as the determinative aspect of the method) and to verify the

identity of the marker residue (confirmatory procedure). FDA did not and does not mean to limit sponsors to the use of mass spectrometry for confirming the identity of the marker residue. In fact, FDA proposed only the regulatory method be composed of a sufficient number of independent measurements to ensure that the identity of the marker residue is confirmed.

46. Another comment declared as meaningless FDA's statement that “the method is considered specific if the observed response is a smooth and continuously decreasing or increasing function of the concentration of the marker residue and of that compound only.” The comment also stated that the regulations should address what other residues must be tested to characterize the method.

The quoted statement was intended simply to remind sponsors of a criterion central to good analytical practice, single-valuedness. FDA agrees that it should give guidance to sponsors about possible interfering substances that could affect the analysis.

47. One comment proposed that a confirmatory procedure be made available only for a method that tends to generate an unusual number of false-positives. A related comment argued that confirmation of marker residue is necessary while developing the method but not during routine operation of the method.

FDA disagrees that a regulatory method should be capable of confirming the marker residue only when special conditions exist. Because compounds regulated for animal use may yield violative residues in edible tissues, FDA must be able to ensure that the compound responsible for a violation can be measured and identified. In a surveillance situation, if initial measurements demonstrate that tissues are nonviolative with respect to a particular drug, further inquiry is not necessary. However, confirmatory procedures must always be available for those instances in which violations occur.

48. Comments argued that a method which produced average recoveries somewhat below the 60 to 110 percent or 80 to 110 percent ranges, but which had high precision, would be disapproved under the proposed regulations even though current technology might consider the method good. Several comments also pointed to the use of internal standards containing stable isotopes. The comments argued that the use of these internal standards provides accurate analyses even with extremely low recoveries.

The average recovery for an acceptable assay will ordinarily be within the stated ranges. However, FDA may consider a different range if a method provides high precision with lower recoveries.

49. One comment noted that the 60 to 110 percent and 80 to 110 percent limits are unrealistic for measurement at or near the detection limit of an analytical method and proposed a limit for the average recoveries of 25 to 175 percent. Another comment proposed that 80 to 110 percent should always be the limits; however, should FDA accept methodolgy with average recoveries ***45547** between 60 to 80 percent, it should require that a correction factor be applied to the analytical result. One comment asked that FDA specify maximum and minimum acceptable values for individual recoveries.

Because it relies substantially on analytical chemistry to carry out its regulatory responsibility to ensure public protection, FDA must establish reasonable and defensible criteria for evaluating a method proposed to monitor edible tissue. It has been FDA's experience that average recoveries of 80 to 110 percent for 100 parts per billion and above are attainable. Although average recoveries of compounds below 100 parts per billion are more variable, FDA's regulatory objective to monitor effectively for carcinogenic residues would be compromised if recoveries of 25 to 175 percent, as suggested, were accepted. In choosing 60 to 110 percent as an acceptable limit for recoveries, FDA sought both to make allowances for the increased variability that could be expected to occur below a concentration of 100 parts per billion and to establish a standard that would not render the method unreliable. Rather than becoming entangled in justifying how to determine and use a correction factor to adjust an observed analytical result, FDA, having rigorously evaluated and validated the method, prefers to rely upon the analytical result itself.

With regard to maximum and minimum acceptable values for individual recoveries, FDA expects that for average recoveries to fall within the designated 60 to 110 percent and 80 to 110 percent limits, the individual recoveries will ordinarily fall near those

same ranges. Average recoveries of 60 to 110 percent or 80 to 110 percent can be obtained by averaging very high and very low values; however, in such cases, the precision will be adversely affected. When a set of data contains a result that appears to deviate excessively from the average or median, FDA will base the decision to retain or disregard that result upon usual statistical considerations such as those recommended by the Association of Official Analytical Chemists (AOAC) in “Statistical Techniques for Collaborative Tests” (Ref. 20).

50. One comment stated that the proposed regulations failed to specify what type of hydrolytic enzymes should be used if exhausitve extraction is used to ascertain accuracy.

FDA is deleting the requirement for treatment of target tissue from dosed animals with hydrolytic enzymes to free bound or conjugated marker residue (unless, of course, it is part of the proposed method) because the method need not measure all the potential marker residue present in tissue. The method must, however, consistently remove an amount of marker residue that has been demonstrated to be in some known relation to the total residue.

51. One comment noted that the proposed regulations would require that a series of spiked samples be run to obtain a response curve each time a set of unknown samples is assayed. The comment noted that this procedure will reduce the number of samples that can be run in a given period of time.

FDA will develop an analytical curve from spiked tissue during the method trial. In actual surveillance situations, an analyst will conduct several trials to determine that the method works in his or her hands, and, assured of that, he or she will then conduct the analyses of the unknown samples and analyze a series of spiked samples if such a procedure is an integral part of the regulatory method.

52. Many comments expressed disagreement with the proposed validation procedure. The comments stated that the use of only three laboratories is not statistically sound; accordingly, the comments suggested that additional laboratories, including commercial and State laboratories, be required to participate in the validation. In addressing the appropriateness of AOAC involvement in method validation, the comments indicated that AOAC applies requirements similar to those listed under section VIII. of the 1979 proposal. In response to FDA's statement that the AOAC process was time-consuming, one comment suggested that the collaborative study be conducted simultaneously with the development of other data, rather than after the NADA was submitted.

FDA agrees that a method trial involving more than three laboratories would improve the characterization of the method. However, FDA believes the sampling procedure to be followed by the three laboratories will provide sufficient data to judge the adequacy of a proposed regulatory method for surveillance purposes.

FDA's decision in the 1979 proposal to decline to accept the AOAC procedure was based on considerations of time and practical implementation. Up until then it had been the experience of FDA analysts and laboratory managers that the mechanics of coordinating a collaborative study, such as that developed by AOAC, required more time than is needed to initiate and complete a three-government laboratory study. However, because the purpose of method trials is to ascertain whether the regulatory method conforms to the criteria for acceptance, FDA would not object to a sponsor's trying its proposed regulatory method in an expanded study in laboratories in addition to the three government laboratories. Sponsors should be aware that such a procedure might increase the time required for completion of the method trial and would require the sponsors to furnish an increased number of samples and other materials that are not available commercially. In any event, however, the three government laboratories participating in the method trial must be able to perform the method satisfactorily because they have the responsibility for surveillance and enforcement.

The suggestion that FDA validate a method while other data are being collected is not an acceptable time-saving idea. Under this scheme, a method trial could begin before collection of the toxicity and metabolism data necessary for establishing the target tissue, marker residue, So, and Rm. Without such information, FDA cannot initiate a method trial.

53. Other comments contended that the requirements on method evaluation were unclear and that FDA should clarify at what stage in the review process validation will occur. The comment also requested that appropriate time for preparation of samples by the applicant be allowed.

The criteria and procedures for evaluating the proposed regulatory method are discussed in FDA's guideline. Provided a desk review of the data submitted in support of the methodology satisfies the criteria in the guideline, FDA will recommend that the method undergo an interlaboratory validation trial. In notifying the sponsor of the acceptance of its method for a validation trial, FDA will outline the number and type of tissue samples to be forwarded to each participating laboratory. FDA will work closely with sponsors in setting up the method trial and will allow ample time for preparation of the samples.

54. In connection with the validation process, one comment suggested that the interlaboratory study should include and provide for a prevalidation desk review and evaluation of the regulatory method by each laboratory that is to participate in the validation study.

FDA agrees with this comment. If FDA finds a proposed regulatory method acceptable for a validation trial, each participating laboratory reviews the method prior to initiation of the trial. ***45548** FDA forwards comments made by each laboratory to the sponsor.

55. Another comment suggested that if one of the three government laboratories failed to validate the method, a fourth laboratory should be asked to repeat the method. At the same time, the laboratory in which the method failed should provide all raw data to the sponsor so that the sponsor can comment knowledgeably on the inability to validate.

As indicated previously, FDA requires that the proposed method be validated in three participating government laboratories. In the course of method validation, should problems arise, FDA will investigate the reason. FDA will discuss with the sponsor problems encountered with the method and, if warranted, repeat the trial.

56. A related comment raised concern that the requirement that the sponsor provide supplies to the laboratories involved in the method trial could represent an open-ended potential for requiring industry to supply the government laboratories with equipment and supplies, and therefore suggested that the phrase “if they are not commercially available” be appended to the regulation. The comment added that the sponsor should be allowed to supply training to the government personnel involved in the validation if FDA considers training necessary.

FDA agrees that the sponsor will have to supply the government laboratories with equipment and supplies that are not commercially available. FDA already allows a sponsor to demonstrate its proposed regulatory method. Demonstrations help government scientists to become acquainted with proposed methods and to identify defects prior to initiating a validation trial.

X. Withdrawal Periods

A. Introduction

The regulations propose to define the preslaughter withdrawal period or the milk discard time for a sponsored compound as the period of time required, after the last administration of the sponsored compound, for the concentration of the marker residue to deplete to Rm in the target tissue. The preslaughter withdrawal period or milk discard time must also be compatible with actual conditions of livestock management and be reasonably certain to be followed in practice. Because of the way in which the regulations define marker residue, target tissue, and Rm, the use of the sponsored compound in accordance with the prescribed preslaughter withdrawal period or milk discard time will assure that unacceptable levels of a carcinogenic residue will not be present in human food derived from treated animals. The data required and the procedure for determining the preslaughter withdrawal period or the milk discard time are described in the “Guideline for Establishing Withdrawal Periods.”

B. Comments on the 1979 Proposal

57. A comment contended that in choosing the Rm as the concentration to which the residues must deplete, FDA is inconsistent with its interpretation of no residue. The comment contended that this procedure is the same as alternative two—rejected by FDA—found on page 17086 of the 1979 proposal.

FDA has revised this aspect of the proposed regulations. FDA now proposes that when the residues have depleted to or below Rm, then FDA's operational definition of no residue has been satisfied. If the residues do not deplete to or below Rm, then FDA cannot approve the use of the sponsored compound.

58. Comments contended that the statement “validated regulatory method” is improperly used, because methods are not validated until the final stages of a petition's review, and the sponsor cannot wait for this method validation before initiating residue depletion studies to establish a withdrawal period.

FDA does not agree with the suggestion that the withdrawal period be established using a method that is not the one submitted for validation. Because different methods may have a different specificity, precision, or systematic error, the data collected with different methods could establish different withdrawal periods. However, the sponsor does not need to wait until after official FDA validation to collect the required data for establishing the withdrawal period. The key requirement is that the method submitted for validation also be the one used to collect the data for establishing the withdrawal period.

59. One comment questioned the use of withdrawal periods based on individual animals because the risk to people is related to the average residue concentration at a given withdrawal period and the fact that compounds may be given to production units containing more than one animal, e.g., flocks, herds, pens, etc. The comment suggested that the variability of these units be used in the calculations of the required withdrawal periods.

FDA agrees that if the mean of the herd or flock is at or below Rm, then the herd or flock is in compliance with FDA's operational definition of no residue. However, because the withdrawal period is established from only a limited number of animals that are maintained under typical field conditions, FDA will use a tolerance limit on these observations to establish the withdrawal period. A tolerance limit provides an internal within which a given percentile of the population lies, with a given confidence that the interval does contain that percentile of the population. When calculating a tolerance limit, FDA will use the 99th percentile of the population and the 95 percent confidence level. This procedure will ensure with a high degree of confidence that the mean residue concentration of any future herd or flock presented for slaughter will be in compliance.

FDA believes that the tolerance limit approach is necessary because a number of variables associated with normal husbandry practices may alter the extent to which residues accumulate or the rate with which residues deplete. Relevant variables may include breed, diet, state of confinement, geographical location, age of animals, state of health, and other herd-to-herd variables.

60. One comment stated that the 1979 proposal indicates that extended withdrawal periods will not be approved for drug products if the withdrawal period is longer than that commonly accepted in livestock management practices. The comment continued that these “commonly accepted livestock management practices” have not been determined empirically by livestock producers and are often a result of producers following the withdrawal periods set by FDA. The comment concluded that it was incongruous for FDA to say that it will not approve any withdrawal periods longer than those it has previously established.

FDA does not agree with this comment. As stated in the 1979 proposal, section 512(d)(2)(D) of the act provides expressly that, in determining whether a compound is approvable, FDA must consider whether the conditions of use of a sponsored compound are reasonably certain to be followed in practice. The withdrawal period is one of the conditions of use. In determining a withdrawal period, FDA does not base its decision on previously established withdrawal periods, but rather on available data and the proposed conditions of use for the sponsored compound.

***45549 XI. Compliance**

The approved regulatory method will be used to monitor the concentration of the marker residue in the target tissue of slaughtered animals. Information and data from monitoring will be used by FDA in conjunction with USDA in a comprehensive effort to assure the safety of food from food-producing animals. If the concentration of the marker residue is found above the Rm in target issue, the remainder of the carcass may contain violative residues and the carcass may be seized under 21 U.S.C. 334 as adulterated under 21 U.S.C. 342(a). If the circumstances are appropriate, the articles may also be detained under the Poultry Producers or Meat Inspection Acts (see 21 U.S.C. 451 et seq. and 601 et seq.).

61. A comment on the 1979 proposal questioned whether an entire animal carcass is required to be condemned under the regulations when it is found that the concentrations of the marker residue in target tissue exceeds Rm.

Based on data submitted to FDA, the agency may be able to make reliable and accurate predictions of the concentration of residue in other tissues when the concentration of residue in target tissue is above Rm. If FDA can determine from these data that muscle does not contian residues of carcinogenic concern in excess of its Sm, then the muscle is nonviolative and will not be subject to regulatory action. Whether regulatory action will be taken in any particular case will depend not only upon the degree of confidence FDA has in extrapolating results from one tissue to another but also upon the applicable legal standard; for example, whether the government has to show that the carcass is unfit for food or merely that it bears or contains unapproved concentrations of an animal drug. FDA will work closely with USDA in providing the necessary evaluations for determining whether regulatory action is advisable.

Regardless of whether a seizure occurs, information gathered from monitoring may assist both FDA and USDA in identifying producers who customarily submit for slaughter animals adulterated within the meaning of the act. This information may be helpful in detaining for prophylactice investigation herds, flocks, etc., from such producers. Lastly, and perhaps most importantly, information regarding the rate and extent of residues above safe concentrations in edible tissue may result in formal FDA action under section 512(e) of the act to withdraw the approval of the sponsored compound.

XII. Waiver of Requirements

In response to a petition or on his own initiative, the Commissioner may waive, in whole or in part, the requirements of the proposed regulations, except the requirement under proposed 21 CFR 500.88 for a regulatory method. (The possibility always exists that the agency may be precluded from enforcing a statutory requirement. In the special circumstances attending estradiol-containing products in cattle, for example, FDA has decided that imposing the requirement for a regulatory method for estradiol would be legally inappropriate because doing so would yield a result so unreasonable that it "could not be thoroughly attributed to Congressional design." United States v. Rutherford, 442 U.S. 544, 545 (1979). This exception is very narrow and rarely capable of being met.)

A petition for a waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition should explain and document why some or all of the requirements are not reasonably applicable to the compound, and describe the alternative procedures that have been, or coud be, followed to assure that use of the compound will not contaminate human food with residues whose consumption could present a risk of cancer to people. The petition shall clearly set forth the reasons and supporting information that demonstrate why the alternative procedures will provide an adequate basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of proposed Subpart E of 21 CFR Part 500 is appropriate, the Commissioner will state the basis for the determination in the regulation approving marketing of the sponsored compound.

XIII. Implementation

The proposed regulations are based on recognized scientific principles for testing and evaluating compounds for potential carcinogenicity. Until a final rule is published, FDA will use these proposed regulations as a guideline for determining whether a sponsored compound is shown to be safe. FDA will apply the proposed regulations and guidelines to compounds being evaluated for approval or subject to proposals to withdraw approval.

Accordingly, FDA will apply the threshold assessment to all sponsored compounds currently in any stage of review and for all future applications, except when each of the following conditions is satisfied:

1. Substantial and acceptable work on the human food safety data requirements for an application was begun before March 20, 1979.

2. The administrative file reveals an FDA commitment to the sponsor before March 20, 1979, concerning the human food safety data required for approval.

3. The sponsor has continued its efforts to obtain a new animal drug application or a food or color additive petition approval after receiving FDA's commitment.

4. The compound is shown to be safe under standards being applied shortly before March 20, 1979, and no apparent safety concerns exist regarding the product under the conditions prescribed, recommended, or suggested in the proposed labeling as required under section 512(d)(2) of the act.

Recently, FDA published a notice in the Federal Register in which the agency discussed this implementation plan in greater detail (see 48 FR 6361; February 11, 1983). FDA continues to solicit comments on the plan.

XIV. General Comments on the 1979 Proposal

A. Statutory Construction

62. Several comments argued that, because the Delaney Clause applies only to substances found to induce cancer when ingested by man or animals, the clause cannot be applied to compounds for which carcinogenicity is merely suspected.

FDA agrees. The comments went on to reason that FDA could not require chronic testing of compounds that are merely potential carcinogens. In making this analysis, the comments overlooked the fact that the General Food Safety Clause requires that an additive or new animal drug be shown to be safe. If there is good reason to suspect that a compound is a carcinogen, the compound cannot be shown to be safe until evidence is available that adequately answers the questions concerning carcingenicity. In evaluating for approval any additive or new animal drug, FDA applies the threshold assessment criteria to determine whether there is a reasonable basis to suspect the carcinogenicity of a compound. If there is, FDA requires that chronic tests be conducted on the compound and where applicable, on its metabolites of carcinogenic concern. If the tests demonstrate that the compound or its metabolites are carcinogenic, then the compound comes under the ***45550** proscription of the Delaney Clause, in which case these proposed regulations provide a mechanism for implementing the DES Proviso and approving the use of the compound.

63. Several comments contended that the proposed regulations exceeded FDA's statutory authority because the agency stated that it would apply the operational definition, standards, and criteria put forth in the 1979 proposal to withdrawal actions against approved compounds. Comments contended that the agency may not evaluate an approved compound under the SOM procedures and consider the evaluation new evidence under section 512(e)(1) of the act supporting withdrawal of an approved NADA.

FDA agrees that new evidence is necessary before bringing action under section 512(e)(1) of the act. In specific situations the application of these proposed regulations and guidelines to the reevaluation of approved products may constitute new evidence

sufficient to demonstrate that the approved products no longer are shown to be safe. Section 512(e)(1)(B) of the act provides as follows:

(e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds—
* * * * *
(B) that new evidence not contained in such application or not available * * * until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved * * *. [Emphasis added.]

Thus, if new evidence evaluated together with previously existing evidence shows that the drug is no longer shown to be safe, the burden of proof under this provision is met by the agency, and unless the product can be shown to be safe by the manufacturing party, the approval of the product must be withdrawn. Congress was careful to make clear that new evidence includes any evidence not available at the time the application was approved. New evidence includes tests by new methods, tests by methods not originally considered applicable, and new interpretations of previously collected data and information. In withdrawing the approval of a new animal drug, it is not the agency's burden to show that the use of the drug is unsafe. Instead, FDA must provide a reasonable basis for concluding that there are important questions about the safety of the compound and the residues that may result from its use. FDA may appropriately reach this conclusion and satisfy its burden under the new evidence clause of section 512(e)(1)(B) of the act by relying on the standards and criteria provided in the regulations and the guidelines. In fact, this interpretation was followed by the Commissioner in his withdrawal of the NADA's for DES and was upheld by the reviewing court in Rhone Poulenc, Inc. v. FDA, 626 F.2d 750 (D.C. Cir. 1980).
64. A related comment argued that any attempt to withdraw the approval of a compound like DES “where no residues have been detected using approved test methods is inconsistent with the law both as it appears on the face of the statute, and as the statute has been judicially construed.”

The sponsor of an NADA for a carcinogenic drug must submit as part of that NADA an acceptable method of analysis to detect residues of the drug in edible products of the treated animal. The statute requires the submission of “a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; * * *” (see section 512(b)(7) of the act, see also section 512(d)(1)(H) of the act). In addition, the legislative history of the DES Proviso shows that that provision contemplates that the sponsor will have the responsibility for developing an analytical method for a carcinogenic drug (Ref. 21). When the sponsor of an NADA for a carcinogen fails to submit an adequate analytical method to detect residues, FDA cannot approve the NADA. In the case of an approved NADA for a carcinogenic compound, if FDA determines based on new information that the approved analytical method for detecting residues is inadequate, FDA has two grounds upon which it may withdraw the approval. First, FDA may withdraw the approval because the compound is no longer shown to be safe (see section 512(e)(1)(B) of the act). This ground was relied upon by the Commissioner in his decision to withdraw the approved NADA's for the use of DES (see 44 FR 54859; September 21, 1979). Second, FDA could withdraw the approval on the basis of the Delaney Clause. Faced with evidence that an approved method was inadequate, FDA could not make a finding that “no residue” of the sponsored compound would be found in the edible products of treated animals. The DES Proviso cannot begin to operate without that finding, and, accordingly, the Delaney Clause would preclude continued approval. A more lengthy discussion of this position may be found in the Commissioner's order withdrawing the approved NADA's for DES (44 FR 54858-54860).

65. Several comments contended that the proposed regulations were arbitrary, capricious, and vague and therefore violated the Administrative Procedure Act. The primary grounds for the contention were: FDA's failure in the proposal to define carcinogen and FDA's failure in general to follow statutory time limits for action upon an application for approval.

As discussed above, when determining whether a tested substance is a carcinogen, FDA will rely upon the criteria given by the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board (Ref. 14).

In response to the comments on statutory time limits, FDA would like to clarify that, once an application is complete and accepted for filing, or once an application is filed over protest, the statutory time limits provided in the respective sections of the act begin to run. Much of the delay in the approval process of a sponsored compound is attributable to the time needed to collect the data necessary to complete an application, not to FDA's review of the data.

66. One comment argued that the comment period for the proposed regulations should be extended until FDA has established criteria for evaluating chronic tests for carcinogenicity, until FDA has prepared and published guidelines on critical parts of the proposed regulation, and until criteria for considering exceptions to the proposed criteria are prepared.

Instead of extending the comment period and promulgating a final rule, FDA has decided to repropose the regulations and make available the implementing guidelines.

67. One comment suggested that FDA should consider allowing the conditional marketing of compounds prior to approval and prior to the completion of the data collection process provided in the regulations. The comment contended that the periods required for the review of data were excessively long. Another comment suggested that unapproved compounds should be subjected to veterinary prescription provisions and be marketed under the supervision of a veterinarian on a limited basis once short-term tests had been performed.

FDA recognizes that the data collection process may be time consuming. Nevertheless, the statute requires that the sponsor demonstrate ***45551** safety by adequate tests by all methods reasonably applicable before any compound can be approved. Unit that statutory standard is met, FDA cannot, either conditionally or otherwise, legally approve a sponsored compound. FDA will make every effort to expedite not only its review of collected data but also the review of protocols for desired testing.

68. One comment recommended the creation of an “evaluation and classification panel” to be composed of government and nongovernment experts to identify, classify, and categorize carcinogens. The panel's cancer determinations would be binding upon the various regulatory agencies, including FDA. The determinations would be limited to scientific issues and, according to the comment, would not intrude upon the regulatory responsibilities of the agencies involved. The comment suggested that the panel would make scientific judgments as opposed to regulatory judgments.

FDA recognizes the benefit of consulting qualified experts for opinions concerning difficult scientific questions. Accordingly, FDA often seeks outside advice and, to the extent possible under the act (see 21 U.S.C. 331(j)) and FDA's regulations (see 21 CFR 514.11), FDA will continue to do so. However, FDA does not agree that the creation of an outside panel that would make decisions binding on FDA is either necessary or desirable.

B. Economic Issues

69. Several comments contended that in making a decision as to the safety of the sponsored compound FDA should consider whether the societal and economic benefits which a sponsored compound might produce outweigh the costs of restricting its use. A comment contended that the decision in American Petroleum Institute v. Occupational Safety and Health Administration (OSHA), 581 F.2d 493 (5th Cir. 1978), aff'd on other grounds sub. nom., Industrial Union Department v. American Petroleum Institute, 488 U.S. 607 (1980), supports such a consideration by the agency.

FDA is required to make an assessment of the costs and benefits of every rule it issues and to prepare a regulatory impact analysis and/or regulatory flexibility analysis if the rule meets the criteria of Executive Order 12291 or the Regulatory Flexibility Act. This assessment is intended to assist in making regulatory decisions and/or to inform the public of the consequences of those decisions. In preparing an assessment, FDA considers whether alternative acceptable methods of accomplishing the desired end, in this case the showing of safety, exist. FDA recognizes the obligation to select the alternative that involves the least cost to society. However, FDA is not allowed to factor into the determination of the safety of the compound the costs or benefits to society of that compound (see 44 FR 54881-54883).

The decision in American Petroleum Institute (API) provides little support for the comments' contentions. And, a related, more recent case, American Textile Manufacturers Institute, Inc. v. Donovan, 617 F.2d 636 (D.C. Cir. 1979), aff'd 452 U.S. 490 (1981), is contrary to the comment's position. In API the Supreme Court found that the Occupational Safety and Health Administration (OSHA), prior to setting an exposure limit on the airborne concentration of a toxic substance in the work place, had to make a finding that the toxic substance in question posed a significant health risk and that the proposed standard was necessary and appropriate. The Court declined to decide whether the Occupational Safety and Health Act (OSH Act) required that in making such a decision OSHA had to determine whether the benefits expected from the new standard bore a reasonable relationship to the costs that it imposed. However, in American Textile the Court held that risk benefit balancing under the OSH Act would be inconsistent with the congressional design and that no cost-benefit analysis requirement on the issuance of the standard existed under this act. The statutory language in the General Food Safety Clause is less equivocal concerning cost than the provisions of the OSH Act that were the subject of the Court's attention.

70. Comments contended that the 1979 proposed regulations would be overly burdensome because nearly every compound currently regulated or to be regulated would be included under the regulations.

The comment assumes that every compound for which an approval is sought is carcinogenic. In fact, only a minority of sponsored compounds, probably 20 percent or less, have or will be determined to be carcinogenic in laboratory animals (Ref. 22). Only carcinogenic compounds will be regulated under these proposed regulations.

71. A comment contended that the regulations resulted in an unfair restriction of trade because small companies producing limited numbers of drug products are not financially able to compete with larger, better financed companies, and because the proposed regulation would be effective only in the United States.

The act makes no distinction between large, well-financed manufacturers of sponsored compounds and smaller, less well-financed manufacturers. The legal requirements remain: The sponsored product must be demonstrated to be safe by adequate tests by all methods reasonably applicable. However, FDA recognizes the necessity for being especially attentive to the needs of small business to the extent that its obligation to protect the public health allows. FDA specifically solicits focused comment and alternatives as to how FDA may, within the requirements of the act, minimize the economic impact of the proposed regulations on small—as well as big—business. To date no small firm has sponsored a compound that would be subject to this proposed rule.

The comment is correct that the regulations are only effective for the approval of compounds for use in this country. Compounds administered in foreign countries to animals that may be imported into this country will not be approved under these proposed regulations because FDA has no control over the compounds that are given or administered to food-producing animals in other countries. To the extent that FDA is aware of an adulterated or misbranded product being offered for importation into this country, FDA will take action to preclude that importation under section 801 of the act (21 U.S.C. 381).

C. Technology Forcing Issues

72. Comments argued that the development of a practical and reliable assay to measure residues in animal tissues in the low parts per billion or high parts per trillion will not always be possible with current technology. Although the comments agreed in general that analytical chemistry has shown great progress in recent years, the comments argued with what they perceived to be FDA's position that continued progress will allow the development of the methodologies called for under the SOM procedures and criteria. In support of these arguments, the comments stated that Tables I and II contained in the preamble to the 1979 proposal (44 FR 17076) do not accurately reflect the state of the art in analytical chemistry for two reasons: (1) The compounds cited as examples either possess intense fluorescence or are substituted with halogen atoms permitting easy detection; and (2) the development of acceptable regulatory methods for detecting residues in the edible products ***45552** of food-producing animals is simple not supported by trends in specific methodology in areas of technology.

FDA agrees that for some sponsored compounds the development of an adequate regulatory method may be beyond the capacity of current technology. FDA never intended to give a contrary impression, for it is indisputable that some compounds will be so potent that a sponsor will be unable to develop a regulatory method with a sufficiently low limit of measurement. Other compounds may leave residues too difficult to characterize and identify sufficiently. Not all sponsored compounds, however, will create similar problems. FDA recognizes that the development of an analytical method for monitoring residues is not an easy task. FDA does not minimize the problems that can be associated with extracting and measuring residues contained in animal tissues. Nevertheless, as Tables I and II in the 1979 proposal showed, methodology for trace analysis has been characterized by marked and continuous improvements over the past three decades. Developments and improvements in available technology are the result of efforts by industry and the government to resolve public health protection problems like those presented by carcinogenic residues in edible tissue.

D. Additional Comments

Several comments provided, in addition to narrative comments on the proposal, specific comments on proposed sections of the regulations. Many of these comments duplicated comments received on the 1979 proposal.

21 CFR 500.80

73. One comment contended that the term “sponsored compound” should not be used in the regulations but rather the terms “drug” and “food additive” should be used because, according to the comment, those terms are more generally acceptable.

The term “sponsored compound” means any drug or additive proposed for use or used in food-producing animals. Thus, by definition it includes not only new animal drugs and food additives, but also color additives. For purposes of clarity and convenience, the term “sponsored compound,” FDA believes, is more acceptable than the comment's proposal.

74. One comment questioned why the term “residues of carcinogenic concern” was not defined and also queried whether the term was synonymous with “residues of toxicological concern.”

FDA meant the two terms to be synonymous. To avoid confusion, this reproposal will use the term “residues of carcinogenic concern.”

75. A comment contended that § 500.80 should contain a statement to the effect that the regulations do not apply to new animal drugs or food additives intended solely for investigational use.

These regulations are not meant to supersede the provisions of 21 CFR Part 511. The regulations in no manner hinder or affect the securing under 21 CFR 511.1 of an exemption to ship or deliver an investigational drug. The regulations and guidelines, however, will provide models for data collection under an investigational new animal drug application. These standards may also be used to determine whether an authorization for use of edible products of animals receiving the investigational drug is warranted (see CFR 511.1(b)(5)).

76. A comment requested that for purposes of clarity § 500.80 should be revised to read as follows: “If at any point in the process of data collection set forth in paragraph (b)(1) of this section, the evaluation of the data shows that the compound should not be regulated under these regulations, the sponsored compound will continue to be considered for approval under the general safety provisions of the act for risks other than cancer.”

FDA has amended § 500.80(c) to reflect the substance of this comment.

Definitions

77. One comment suggested that “target tissue” be defined as the edible tissue selected to monitor for residues.

FDA agrees with this comment.

78. Another comment requested that the definition of essential nutrients be expanded to read “is required for the animal's growth, development, function, and reproduction and that must be supplied from external sources, e.g., minerals, trace minerals, essential amino acids, and essential fatty acids.”

FDA has amended the regulations to reflect the substance of this comment.

21 CFR 514.1

79. One comment noted that the proposed revision to § 514.1(b)(7) omitted the last sentence of the introductory paragraph. The sentence provided that “when data or other adequate information establish that it is not reasonable to expect a new animal drug to become a component of food, assay methodology is not required.” The comment contended that the sentence is important and should be reinstated, arguing that certain drugs used in food-producing animals are so poorly absorbed or so rapidly deplete from the tissues that they shoud not be considered as components of food. The comment also contended that it may be impractical to develop a regulatory method with sufficient sensitivity to detect traces of residues that are not unsafe.

FDA agrees that the sentence referred to should be retained, with some modification in § 514.1(b)(7). The following sentence has been added. “When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required.”

XV. Conclusion

The proposed regulations and the implementing guidelines are designed to ensure that edible tissues derived from animals treated with sponsored compounds are safe. In developing these regulations and guidelines, FDA followed well-recognized scientific procedures and applied high standards of public health protection. All sponsored compounds will be evaluated under the general safety provisions of the act. Sponsored compounds shown by adequate testing to be carcinogens will be regulated under proposed Subpart E of 21 CFR Part 500.

Executive Order 12291 and the Regulatory Flexibility Act require economic impact analyses of proposed regulations that are likely to have significant consequences on the overall regulated industry or on particular sections of it. In the economic impact analysis prepared for the 1979 proposal, FDA concluded that the expenses of conducting the biological studies and developing the regulatory method of analysis would be several million dollars for each carcinogenic compound. Without this testing, however, the carcinogenic compound could not be approved. In the economic analysis prepared for this proposal, FDA makes similar conclusions. However, because FDA is unlikely to receive requests to approve a large number of carcinogenic compounds, this regulation will not impose an annual effect on the economy of $100 million or more, the threshold value established by Executive Order 12291. In accordance with the Regulatory Flexibility Act, FDA has considered the effect that this proposal would have on small entities including small businesses and has determined that to date no small firm has sponsored a compound that would be subject to this proposed rule. Therefore, FDA certifies in accordance with section ***45553** 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action. The economic and regulatory flexibility analyses are on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Sections 500.86, 500.88, 500.90, and 514.1(b)(7) of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the

Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim.

The following information has been placed on display in the Dockets Management Branch (address above), and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday.

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12. "Carcinogen Structure Guide," Prepared by the Bureau of Foods, Food and Drug Administration.

13. "Toxicological Principles for the Safety Assessment of Direct Food Additives," Food and Drug Administration, 47 FR 46141, October 15, 1982.

14. "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances: Report of the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board," Journal of the National Cancer Institute, 58:461-465, 1977.

15. Rodgers, W. H., Jr., "Benefits, Costs, and Risks: Oversight of Health and Environmental Decision Making," Harvard Environmental Law Review, 4:191-226, 1980.

16. Symposium on Risk/Benefit Decisions and the Public Health, Proceedings of the Third FDA Science Symposium, held at Colorado Springs, CO, February 15-17, 1978.

17. Crump, K. S., "Statistical Aspects of Linear Extrapolation," Health Risk Analysis, edited by C. Richmond, P. Walsh, and E. Copenhaven, Franklin Institute Press, pp. 381-390, 1981.

18. Gaylor, D. W. and R. E. Shapiro, "Extrapolation and Risk Estimation for Carcinogenesis," Advance in Modern Toxicology, Volume I part 2, edited by M. A. Mehlman, et al., John Wiley and Sons, pp. 65-87, 1979.

19. Mantel, N., N. R. Bohidar, C. C. Brown, J. L. Ciminera, and J. W. Tukey, "An Improved Mantel-Bryan Procedure for 'Safety' Testing of Carcinogens," Cancer Research, 35:865-872, 1975.

20. Youden, W. J., "Statistical Techniques for Collaborative Tests," The Association of Official Analytical Chemists, Washington, DC, 1967.

21. Hearings on FDA "Study of the Delaney Clause and Other Anticancer Clauses" Before a Subcommittee on Appropriations, 93d Cong., 2d Sess. 203-204, 1974.

22. "Risk Assessment in The Federal Government: Managing the Process," National Research Council, National Academy Press, Washington, DC, p. 11, 1983.

23. Jaggi, W., W. K. Lutz, J. Lu#4thy, U. Zneifel, and Ch. Schlatter, "In Vivo Covalent Binding of Aflatoxin Metabolites Isolated from Animal Tissue to Rat-Liver DNA, Food and Cosmetic Toxicology, 18:257-260, 1980.

List of Subjects

21 CFR Part 70
Color additives, Cosmetics, Definitions, Drugs, Labeling, Packaging and containers.

21 CFR Part 500
Animal drugs, Animal feeds, Labeling.

21 CFR Part 514
Administrative practice and procedure, Animal drugs.

21 CFR Part 571
Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Parts 70, 500, 514, and 571 be amended as follows:

PART 70—COLOR ADDITIVES
21 CFR § 70.50

1. The authority citation for 21 CFR Part 70 is revised as set forth below, and the authority citation under 21 CFR 70.50 is removed.

Authority: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10, 5.11.

21 CFR § 70.50

2. Part 70 is amended in § 70.50 by adding new paragraph (c) to read as follows:

21 CFR § 70.50

§ 70.50 Application of the cancer clause of section 706 of the act.

* * * * *

(c) Color additives for use as an ingredient of feed for animals that are raised for food production. Color additives that are an ingredient of the feed for animals raised for food production that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

PART 500—GENERAL

2. Part 500 is amended by adding a new Subpart E to read as follows:

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

Sec.500.80 Scope of this subpart.500.82 Definitions.500.84 Operational definition of no residue.500.86 Marker residue and target tissue.500.88 Regulatory method.500.90 Waiver of requirements.

Authority: Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 ***45554** Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

21 CFR § 500.80

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs under § 5.10 of this chapter) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice. This subpart provides an operational definition of no residue and identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidelines contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidelines are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests for these guidelines should be identified with Docket No. 83D-0288.

(b) If FDA concludes on the basis of the threshold assessment that a sponsor shall conduct carcinogenicity testing on the sponsored compound, FDA will also determine whether and to what extent the sponsor shall conduct carcinogenicity testing on metabolites of the sponsored compound. The bioassays that sponsor conducts must be oral, lifetime, dose-response studies and must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.

(c) If FDA concludes on the basis of the threshold assessment or at a later time during the approval process that the data show that the sponsored compound and its metabolites should not be subject to these regulations, FDA will continue to consider the compound for approval under the general safety provisions of the act for risks other than cancer.

(d) This subpart does not apply to essential nutrients.
21 CFR § 500.82

§ 500.82 Definitions.
(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this subpart.

(b) The following definitions apply to this subpart:

“Act” means the Federal Food, Drug, and Cosmetic Act (sections 201-901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301-392)).

“Essential nutrients” means compounds that are found in the tissues of untreated, healthy target animals and not produced in sufficient quantity to support the animal's growth, development, function, or reproduction, e.g., vitamins, essential minerals, essential amino acids, and essential fatty acids. These compounds must be supplied from external sources.

“FDA” means the Food and Drug Administration.

“Marker residue” means the residue selected for assay whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its permitted concentration.

“Preslaughter withdrawal period” or “milk discard time” means the time after cessation of administration of the sponsored compound for the residue of carcinogenic concern in the edible product to deplete to the concentration that will satisfy the operational definition of no residue.

“Regulatory method” means the aggregate of all experimental procedures for measuring and confirming the presence of the marker residue of the sponsored compound in the target tissue of the target animal.

“Rm” means the concentration of the marker residue in the target tissue when the residue of carcinogenic concern is equal to Sm in the last tissue to deplete to its permitted concentration.

‘'Residue” means any compound present in edible tissues of the target animal that results from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

“Residue of carcinogenic concern” means all compounds in the total residue of a demonstrated carcinogen excluding any compounds judged by FDA not to present a carcinogenic risk.

“Sm” means the permitted concentration of residue of carcinogenic concern for a specific edible tissue.

“So” means the concentration of the test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million. For the purpose of this subpart, FDA will also assume that this So will correspond to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people.

“Sponsor” means the person or organization proposing or holding an approval by FDA for the use of a sponsored compound.

“Sponsored compound” means any drug or food additive or color additive proposed for use, or used, in food-producing animals or in their feed.

“Target animals” means the production class of animals in which a sponsored compound is proposed or intended for use.

“Target tissue” means the edible tissue selected to monitor for residues in the target animals.

“Test animals” means the species selected for use in the toxicity tests.

“Threshold assessment” means FDA's review of data and information available about a sponsored compound to determine whether chronic bioassays in test animals are necessary to resolve questions concerning the carcinogenicity of the compound.
21 CFR § 500.84

§ 500.84 Operational definition of no residue.
(a) On the basis of the results of the chronic bioassays and other available information, FDA will determine whether any of the substances tested are carcinogenic. If the results of the chronic bioassays are equivocal, FDA will regulate the sponsored compound as a carcinogen until further testing resolves the remaining questions regarding carcinogenicity.

(b) If FDA concludes that the results of the bioassays do not establish carcinogenicity, then FDA will not subject the sponsored compound to the remainder of the requirements of this subpart.

(c) For each sponsored compound that FDA decides should be regulated as a carcinogen, FDA will analyze the data from the bioassays according to the linear interpolation procedure described by Gaylor, D.W. and R.L. Kodell, “Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,” Journal of Environmental Pathology and Toxicology, 4:305-312, 1980.

(1) For each substance tested in a separate bioassay, FDA will calculate, using the upper 95 percent confidence limit on the observations, the concentration of the residue of carcinogenic concern that corresponds to a maximum lifetime risk to the test animal of 1 in 1 million. FDA will ***45555** designate the lowest value obtained as So.

(2) FDA will consider that “no residue” of the compound remains in the edible tissue when conditions of use of the sponsored compound, including any required preslaughter withdrawal period or milk discard time, assure that the concentration of the residue of carcinogenic concern in the total diet of people will not exceed So. Because the total diet is not derived from food-producing animals, FDA will make corrections for food intake. FDA will designate as Sm the concentration of residue of carcinogenic concern that is permitted in a specific edible product.
21 CFR § 500.86

§ 500.86 Marker residue and target tissue.
(a) For each edible tissue, the sponsor shall measure the depletion of the residue of carcinogenic concern until its concentration is at or below Sm.

(b) For each edible tissue, the sponsor shall also measure the depletion of one or more potential marker residues until the concentration of the residues of carcinogenic concern is at or below Sm.

(c) From these data, FDA will select a target tissue and a marker residue and designate the concentration of marker residue (Rm) that the regulatory method must be capable of measuring in the target tissue. FDA will select Rm such that the absence of the marker residue in the target tissue above Rm can be taken as confirmation that the residue of carcinogenic concern does not exceed Sm in each of the edible tissues and, therefore, that the residue of carcinogenic concern in the diet of people does not exceed So.

(d) When a compound is to be used in milk- or egg-producing animals, milk or eggs must be the target tissue in addition to the tissue selected to monitor for residues in the edible carcass.
21 CFR § 500.88

§ 500.88 Regulatory method.

(a) The sponsor shall submit for evaluation and validation a regulatory method developed to monitor compliance with FDA's operational definition of no residue.

(b) The regulatory method must reliably measure and confirm the identity of the marker residue in the target tissue at concentrations equal to and above Rm.

(c) FDA will publish in the Federal Register the complete regulatory method for measuring the marker residue in the target tissue in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(H) and (i), and 706(b)(5)(B) of the act.

21 CFR § 500.90

§ 500.90 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, the requirements of this subpart except those provided under § 500.88. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why some or all of the requirements are not reasonably applicable to the compound, and set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the basis for that determination in the regulation approving marketing of the sponsored compound.

PART 514—NEW ANIMAL DRUG APPLICATIONS

21 CFR § 514.1

4. The authority citation for 21 CFR Part 514 is revised to read as set forth below, and the authority citations under 21 CFR 514.1, 514.8, 514.11, 514.15, 514.50, 514.51, 514.55, 514.60, 514.110, 514.111, 514.115, 514.150, 514.155, 514.160, and 514.200 are removed.

Authority: Secs. 512 (i) and (n), 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b(i) and (n), 371(a)); 21 CFR 5.10, 5.11; §§ 514.50, 514.55, 514.60, 514.150, 514.155, 514.160 are issued only under secs. 507 and 512(n), 59 Stat. 463 as amended, 82 Stat. 350-351 (21 U.S.C. 357, 360b(n)); 21 CFR 5.10, 5.11.

21 CFR § 514.1

5. Part 514 is amended in § 514.1 by revising the introductory text of paragraph (b)(7) and by revising paragraph (b)(7)(ii), to read as follows.

21 CFR § 514.1

§ 514.1 Applications.

* * * * *

(b) * * *

(7) Analytical methods for residues. Applications shall include a description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions to ensure that the proposed use of this drug will be safe. When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required.

* * * * *

(ii) A new animal drug that has the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

* * * * *21 CFR § 514.111

6. In § 514.111 by adding new paragraph (a)(10) to read as follows:
21 CFR § 514.111

§ 514.111 Refusal to approve an application.
(a) * * *

(10) The drug fails to satisfy the requirements of Subpart E of Part 500 of this chapter.
* * * * *

PART 571—FOOD ADDITIVE PETITIONS
21 CFR § 571.1
7. The authority citation for 21 CFR Part 571 is revised to read as set forth below and the authority citations under 21 CFR 571.1 and 571.6 are removed.

Authority: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371); 21 CFR 5.10 5.11.
21 CFR § 571.115
8. Part 571 is amended by adding new § 571.115 to read as follows:
21 CFR § 571.115

§ 571.115 Application of the anticancer clause of section 409 of the act.
Food additives intended for use as an ingredient in food for animals that are raised for food production that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

Interested persons may, on or before, February 28, 1986, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-25808 Filed 10-30-85; 8:45 am]

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50 FR 51551-03
PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 700
[Docket No. 85N-0536]

Cosmetics; Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products

Wednesday, December 18, 1985

***51551** AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to ban the use of methylene chloride as an ingredient of cosmetic products. The agency is proposing this action because recent scientific studies have revealed that inhalation of methylene chlolride causes cancer in laboratory animals. These studies have shown that the continued use of methylene chloride in cosmetic products may pose a significant risk to the public health, especially to specific segments of the population that are continually exposed to cosmetics containing methylene chloride. FDA is not proposing to lower the maximum permitted residue level of methylene chloride in decaffeinated coffee because that level is considered to be safe.

DATES: Comments by February 18, 1986. The agency proposes that any final rule based on this proposal become effective 60 days after its date of publication for products initially introduced and initially delivered for introduction into interstate commerce.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:John M. Taylor, Center for Food Safety and Applied Nutrition (HFF-300), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0160.

SUPPLEMENTARY INFORMATION:

I. Introduction

Methylene chloride (CAS Reg. No. 75-09-2, dichloromethane) is a colorless, volatile liquid that is used in a variety of consumer and industrial products as a solvent and flame suppressant. The cosmetic use of methylene chloride is primarily in hair sprays. In these products, it is used as a solvent and flame suppressant, and because of its volatility, it serves to cause quick drying and setting of the applied resin.

Methylene chloride is also used in foods as an extraction solvent in the processing of coffee beans, spices, and hops. When used to decaffeinate coffee, methylene chloride is a food additive within the meaning of section 201(s) of the Federal Food, and Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)).

II. Carcinogenicity of Methylene Chloride

Several recent chronic studies of methylene chloride have raised questions about the safety of this chemical. The National Toxicology Program (NTP) sponsored inhalation studies in rats and mice; the National Coffee Association (NCA) sponsored drinking water studies in rats and mice; and the Dow Chemical Co. performed three inhalation studies, two in rats and one in hamsters. In addition to these seven studies, NTP sponsored gavage studies in rats and mice. These gavage studies may have no

value for carcinogenicity assessment because of serious problems with the manner in which the studies were conducted. NTP did not draw any conclusions from the gavage studies, and, therefore, FDA is not employing them in this proposal.

In one NTP-sponsored 2-year inhalation study, test groups of B6C3F1 mice were exposed to air containing 0 ppm, 2,000 ppm, and 4,000 ppm of methylene chloride for 6 hours per day, 5 days per week (Ref. 1). Increases in the incidence of mice with benign and malignant neoplasms derived from hepatocytes (liver cells), as well as benign and malignant neoplasms of the lung, were observed in the treatment groups of both sexes. The increases in these neoplasms were distinctly dose related. The agency concludes that methylene chloride is carcinogenic to the liver and lung of male and female mice. This study also demonstrates that methylene chloride induces cancer at a site (the liver) remote from the tissues directly exposed by the inhalation treatment (Ref. 2).

In the other NTP-sponsored 2-year inhalation study, test groups of Fischer 344 rats were exposed to air containing 0 ppm, 1,000 ppm, 2,000 ppm, and 4,000 ppm of methylene chloride for 6 hours per day, 5 days a week (Ref. 1). In the female rat groups, the incidence of animals with benign fibroadenomas of the mammary glands was increased by treatment and provided some evidence of a dose-response effect. The agency considers these results to be suggestive of a tumorigenic effect of methylene chloride on the mammary glands of female rats (Ref. 2).

***51552** The NTP studies were reviewed and validated by NTP's Board of Scientific Counselors, which concluded that methylene chloride is a carcinogen in mice, but that the evidence is equivocal in rats (Ref. 3).

Dow performed a pair of 2-year inhalation studies in Sprague-Dawley rats: a high-dose study and a low-dose study in which groups of animals were exposed to vaporized methylene chloride at 0 ppm, 500 ppm, 1,500 ppm, and 3,500 ppm; and 0 ppm, 50 ppm, 200 ppm, and 500 ppm, respectively, for 6 hours per day, 5 days per week (Refs. 4 and 5). Compound-related neoplastic effects were not observed in the low-dose study. In the high-dose inhalation study, an increase in the incidence of male rats with sarcomas in the region of the salivary gland was reported at the 1,500 ppm and 3,500 ppm exposure levels. The study investigators believed that this effect was associated with a viral infection of the salivary gland. However, similar tumorigenic effects from viral infections of the salivary gland were not observed among the female or male animals in the other test groups in this study.

Moreover, two unusual sarcomas of the salivary gland/integument were observed in treatment groups in the NTP-sponsored inhalation study on Fischer 344 rats. FDA and NTP pathologists found these two sarcomas to be very similar to those observed in the Dow high-dose study. The agency believes that these observations provide suggestive evidence that methylene chloride induces sarcomas of the salivary gland/integument in rats upon inhalation (Ref. 2).

Dow also performed a 2-year inhalation bioassay in Syrian Golden hamsters in which test groups were exposed to vaporized methylene chloride at 0 ppm, 500 ppm, 1,500 ppm, and 3,500 ppm for 6 hours per day, 5 days per week (Ref. 4). There were no treatment-related toxic effects observed in this study.

NCA sponsored 2-year multidose drinking water studies in Fischer 344 rats and B6C3F1 mice. In the rat study, the concentration of methylene chloride in the drinking water provided intakes for test groups ranging from 5 milligrams per kilogram of body weight per day (mg/kg/day) to 250 mg/kg/day (Ref. 6). In the mouse study, the methylene chloride intakes for the test groups ranged from 60 mg/kg/day to 250 mg/kg/day (Ref. 7). In these drinking water studies, there were no significant increases in the incidences of rats or mice with neoplasms at any site examined. However, higher treatment levels could have enhanced the sensitivity of this study. Because the treatment levels were relatively low, the animals that received methylene chloride via drinking water may not have received as much as those receiving methylene chloride by inhalation (Ref. 2).

Two epidemiology studies have been conducted on workers exposed to methylene chloride in manufacturing plants (Refs. 8 and 9). Neither study reported an increase in cancer attributable to methylene chloride. Design limitations such as small numbers

of workers and insufficient duration of exposure make it impossible for FDA to draw any definitive conclusions from these studies about the potential for methylene chloride to cause cancer in humans.

A variety of genotoxicity studies have been performed on methylene chloride. Methylene chloride gave positive results for mutagenicity in bacteria (Salmonella typhimurium strains TA-98, TA-100, and TA-1535) (Refs. 10 through 17) and in yeast (Saccharomyces cerevisiae) (Ref. 18) without metabolic activation.

A more complete assessment of the specific types of tumors found in testing of methylene chloride and of the significance of these findings is presented in the report of the Cancer Assessment Committee of FDA's Center for Food Safety and Applied Nutrition (Ref. 2).

Based on these adverse findings, the agency concludes that methylene chloride is an animal carcinogen by inhalation and may be carcinogenic to humans. It has been the agency's policy that substances that cause cancer in laboratory animals should be considered potential human carcinogens unless there is clear epidemiological evidence to the contrary or unless there is other evidence that the effects observed in animals are not relevant to humans. In the case of methylene chloride, FDA has found that although the epidemiological studies that have been conducted have not reported any increase in cancer attributable to methylene chloride, these results must be considered inconclusive due to design limitations such as small numbers of workers and insufficient duration of exposure. The Environmental Protection Agency reached a similar conclusion about these studies in its Federal Register notice of October 17, 1985 (50 FR 42037). In addition, the agency is unaware of any basis on which to find that the animal studies discussed above are not relevant to humans. Although there is some evidence indicating that at high doses the metabolic pathways of methylene chloride may become saturated, FDA agrees with EPA that currently available data are insufficient to assess the effect of saturation on the carcinogenic potential of methylene chloride (50 FR 42038-42039). FDA will evaluate any additional data from ongoing studies on this point when they become available.

III. Risk Estimate—Cosmetic Uses

The agency has examined the potential level of exposure from the use of methylene chloride as an ingredient of aerosol cosmetic products and has made preliminary estimates of the carcinogenic risks to users of these products.

In calculating the risk from exposure to methylene chloride, the agency considered two population groups. One group, hair care specialists, represents the group with the highest exposure level expected from aerosol hair sprays. The other group is the segment of the population that routinely uses aerosol hair sprays as part of their grooming practices.

The exposure estimates used in the agency's risk assessment are based on data obtained from studies published in 1976 that measures methylene chloride concentration in the breathing zone after use (Refs. 19 and 20). The agency needed to make various assumptions in order to calculate exposure levels for consumers. For example, FDA's exposure estimates assumes that a consumer will use the hair spray once a day, that the spray period is 5 seconds, that the consumer will remain in the spraying zone for 5 to 10 minutes, and that the average concentrations of methylene chloride in the breathing zone is 50 ppm. The agency believes that these assumptions reasonably reflect the actual consumer use conditions and are not drawn to represent worst-case conditions (Ref. 21).

To make comparisons between mice exposed to 2,000 ppm methylene chloride by inhalation in the NTP study and potential human exposure at different exposure levels and for different time intervals, the agency has chosen to use a time-weighted average. The time-weighted average air concentration represents the concentration of methylene chloride to which individuals are exposed on a continuous daily basis, calculated by averaging over time the intermittent air concentrations for fractions of the day or fractions of the week. Use of this averaging concept permits a direct comparison between average human exposure and test animal exposure.

Accordingly, a consumer exposed to 50 ppm methlyene chloride in air for 5 ***51553** minutes per day, 7 days a week, would have a time-weighted average exposure of 0.174 ppm

(50 ppm x 5 min x 1 hr x 7 days =0.174 ppm),
--------- -------- ---------
60 min 24 hr 7days

and a mouse exposed to 2,000 ppm for 6 hours per day, 5 days a week, would have a time-weighted average exposure of 357 ppm
(2,000 ppm x 6 hr x 5 days =357)ppm.
-------- ---------
24 hr 7 days

time-weighted average human exposure to methlyene chloride from consumer use of hair spray is thus 0.174 ppm of air inhaled. Assuming that all of the inhaled methylene chloride is absorbed from the lungs into the blood stream, the time-weighted average human exposure is 0.15 milligrams per kilogram of body weight per day.
FDA's time-weighted exposure estimates for hair care specialists are about one order of magnitude higher (1.74 ppm or 1.5 milligrams per kilogram of body weight per day).

Extrapolating, using a linear model, from the incidence of benign and malignant neoplasms in female mice exposed to 2,000 ppm (357 ppm time-weighted exposure) in the NTP study to average human exposure from use of aerosol cosmetics containing methylene chloride, the upper bound estimated lifetime cancer risk for consumers is in the range of 1x10-3 (1 in 1,000) to 1x10-4 (1 in 10,000), depending on whether the animal-to-human dose comparison is based on the concentration in air or on milligrams per kilogram of body weight per day. For hair care specialist, the upper bound of lifetime risk is in the range of 1x10-2 (1 in 100) to 1x10-3 (1 in 1,000). These risks are relatively high primarily because the anticipated exposures from aerosol uses are high. Methylene chloride is not a particularly potent carcinogen. Additional discussion of how FDA has calculated the potency of methylene chloride is provided in the discussion of its use in decaffeinated coffee.

The agency assumed a linear dose-response model from zero dose to the experimental level of 2,000 ppm. Extrapolation models incorporating low dose linearity have been recommended by the Office of Science and Technology Policy when uncertainty exists regarding the mechanism of carcinogenicity, as is the case with methlyene chloride (50 FR 10371-10442; March 14, 1985).

Full details of the specific assumptions and methods used to project these upper bound risk assessments are described in Ref. 21.

IV. Risk Estimate—Food Additive Use for Decaffeination

Methylene chloride has been listed in FDA's food and color additive regulations for more than 20 years. It is currently listed in the following regulations: § 73.1 Diluents in color additive mixtures for food use exempt from certification (21 CFR 73.1), § 172.560 Modified hop extract (21 CFR 172.560), § 173.255 Methylene chloride (21 CFR 173.255), § 175.105 Adhesives (21 CFR 175.105), and § 177.1580 Polycarbonate resins (21 CFR 177.1580).

The agency has sufficient information to determine that the existing methylene chloride residue level for decaffeinated coffee is safe. Because the U.S. population consumes a large volume of decaffeinated coffee, the majority of which is manufactured using methylene chloride in the extraction procedure, it is important to make an assessment of safety. FDA is deferring consideration of the other uses of methylene chloride in food (as well as its presence as an impurity in food additives) because the agency is not aware of any information indicating that the other uses of methylene chloride present a public health hazard.

Methylene chloride is regulated as a food additive in § 173.255. Paragraph (c) of that section authorizes the use of this additive to extract caffeine from green coffee beans and limits residual methylene chloride to a level not to exceed 10 parts per million (ppm) in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee).

FDA issued § 173.255(c) in the Federal Register of August 31, 1967 (32 FR 12605), in response to a food additive petition (FAP 7A2061). The petitioner submitted data showing that use of both decaffeinated roasted coffee and decaffeinated instant coffee

containing 10 ppm methylene chloride would result in approximately 0.1 ppm methylene chloride in a 5 ounce (148 gram) cup of coffee. The petitioner also showed that the average level of methylene chloride in dried decaffeinated instant coffee was approximately 2 ppm, based on an analysis of 33 batches.

As discussed in section II above, methylene chloride has been shown to be carcinogenic to both sexes of B6C3F1 mice upon inhalation. The NTP inhalation mouse bioassay demonstrates that methylene chloride can induce cancer at sites remote from the site of administration. The evidence is also suggestive that methylene chloride may induce tumors in two strains of rats upon inhalation. Based on this evidence, the agency concludes that methylene chloride is an animal carcinogen, and that the NTP inhalation study provides a suitable basis for evaluating the safety of its food additive uses because methylene chloride displayed the greatest potency in this study.

General Foods Corp., the manufacturer that produces the largest amount of decaffeinated coffee, has surveyed its decaffeinated coffee products from 10 nationwide grocery locations (Ref. 22). For 69 samples of decaffeinated roasted and ground coffee products that it has analyzed since 1982, General Foods found methylene chloride levels of 0.01 ppm or less in 82.6 percent of the samples, 0.05 ppm or less in 91.3 percent of the samples, and 0.10 ppm or less in 100 percent of the samples. For 54 samples of decaffeinated instant coffee products that it has analyzed over the same period, General Foods found methylene chloride levels of 0.01 ppm or less in 96.3 percent of the samples, 0.05 ppm or less in 98.2 percent of the samples, and 0.10 ppm or less in 100 percent of the samples.

The agency is aware of four other manufacturers of decaffeinated coffee (Ref. 23). Although FDA does not know whether any methylene chloride residues in the products of these manufacturers are as low as those in the products of General Foods, the agency is aware that these products comply with the current regulation.

Quantitative risk assessment of methylene chloride consists of two parts: (1) Assessment of probable exposure to methylene chloride from its use to decaffeinate coffee under a specific residue limitation, and (2) extrapolation of the risk from methylene chloride observed in the NTP bioassay to the conditions of probable exposure to humans.

1. Exposure to methylene chloride. The exposure to methylene chloride from its use in decaffeinating coffee is a product of three factors: (a) The methylene chloride concentration in ***51554** coffee products, (b) the amount of coffee product used to make the coffee beverage, and (c) the amount of beverage consumed.

(a) Methylene chloride concentration in coffee products. FDA decided to assess the risk from the existing limitation on the concentration of methylene chloride of 10 ppm. The agency recognizes that the average level of methylene chloride likely to be present in decaffeinated coffee would be much lower than that limitation. The available data, however, did not allow the agency to estimate what the average residue level would be under the 10 ppm limitation. Therefore, in conducting the risk assessment, FDA assumed that all products would contain methylene chloride at a concentration equal to the limitation of 10 ppm.

(b) Amount of coffee product used to make the coffee beverage. The General Foods' submission of August 7, 1985, reported that 1 pound of roasted and ground coffee makes 70 to 90 cups of coffee (each cup containing 5 fluid ounces or 148 grams) based on current brewing practices (Ref. 22). Therefore, approximately 5.7 grams of roasted and ground product is used for each cup. General Foods also reported that instant coffee drinkers use about 2.2 grams soluble solids per cup. The agency used these numbers as elements of its exposure estimate (Ref. 23).

In estimating methylene chloride exposure, the agency also assumed that all of the methylene chloride in the roasted and ground product is extracted during brewing and becomes a part of the coffee beverage. Although this assumption may result in an overestimate of exposure, the agency does not now have sufficient reliable data to refine this estimate (Ref. 24).

(c) Beverage consumption. The agency considered three surveys in estimating decaffeinated coffee beverage consumption. Based on 1977-1978 surveys, the Market Research Corp. of America (MRCA) estimated a 90th percentile consumption of

decaffeinated coffee (among persons who consumed decaffeinated coffee) of 389 grams per day for roasted and ground coffee and 435 grams per day for instant coffee. MRCA estimated average consumption for decaffeinated coffee drinkers of 136 grams per day for roasted and ground coffee and 192 grams per day for instant coffee. MRCA's survey involved a 14-day menu census of 10,819 individuals in the 2 years and older age group. The values for decaffeinated coffee are based on 458 “eaters” of brewed decaffeinated coffee and 1,362 “eaters” of instant decaffeinated coffee (Ref. 25).

The International Coffee Organizataion (ICO) performs a survey each winter. Its winter 1985 coffee drinking survey indicates that 17.3 percent of the U.S. population was drinking decaffeinated coffee at the time of the survey. Decaffeinated coffee drinkers consume the beverage at a rate of 2.42 cups per day (358 grams per day). The ICO data are bsed on wintertime telephone inverviews of 7,500 individuals who were questioned about their coffee consumption on the previous day (Ref. 26).

In 1977-1978, the U.S. Department of Agriculture (USDA) also performed a food consumption survey. This survey included 37,874 individuals of whom 7.3 percent consumed decaffeinated coffee at least once in 3 days. For those individuals consuming decaffeinated coffee at least once in 3 days, USDA computed average consumption and 90th percentile consumption of 347 grams per day and 720 grams per day, respectively (Ref. 27).

Based on these surveys, the agency believes that the estimated consumption of 740 grams per day (five cups) is adequate to represent consumers of large amounts of decaffeinated coffee for a time span of several years (Ref. 28). It is unlikely, however, that individuals will average this consumption rate over a lifetime because decaffeinated coffee drinking varies from essentially no consumption by children to the highest consumption among the oldest age group. In the ICO survey, for example, the percentages of the individuals who drank decaffeinated coffee were 1.7 percent for the 10 to 19 year old age group, 7.3 percent for the 20 to 29 year old age group, 21.0 percent for the 30 to 59 year old age group, and age group, 21.0 percent for the 30 to 59 year old age group, and 33.8 percent for the 60 year old and older age group (Ref. 26). Because of this variation in consumption across age groups, the agency believes that individuals are unlikely to average more than 370 grams per day consumption of decaffeinated coffee over their lifetime (which is equivalent to one-half a lifetime at 740 grams per day) (Ref. 28). The agency used this 370 gram consumption level in computing its exposure estimate.

Dietary exposure can be calculated by multiplying together the three factors (10 ppm methylene chloride in the product, 5.7 grams roasted and ground or 2.2 grams instant product per 148 gram cup, and 370 grams per person per day consumption). By this approach the agency estimated that the lifetime-averaged exposure to methylene chloride under a 10 ppm regulatory limitation would not be likely to exceed 140 micrograms per day for consumers of brewed (roasted and ground) decaffeinated coffee and 55 micrograms per day for consumers of instant decaffeinated coffee (Ref. 28).

2. Risk extrapolation. The second part of the evaluation of risk presented by the dietary exposure to methylene chloride is an extrapolation from the actual compound-related incidence of animals with tumors (risk) found in animal bioassays under conditions of exaggerated exposure to the conditions of probable exposure for humans. Among the available studies, the agency considers the NTP inhalation study in mice and the NCA drinking water study in mice to be suitable studies for risk assessment. The NTP study is used because methylene chloride displayed the greatest potency in it.

The agency recognizes, however, that there are problems with using an inhalation study for assessing the risk from ingestion of methylene chloride. The problems stem from a lack of knowledge about the differences in the pharmacokinetics of the absorptioh, distribution, metabolism, and excretion of methylene chloride (and the ultimate carcinogenic entity, which also is not known) when it is inhaled as opposed to when it is ingested.

The NCA drinking water study in mice provides a way of confirming that using the inhalation study for upper bound risk estimation is not likely to underestimate any potential risk. Although the NCA study, which was performed in the same strain of mice as the NTP study, negative, it is useful for determining a maximum possible potency for methylene chloride by ingestion.

In the NTP inhalation study in mice, methylene chloride induced liver cell neoplasms and lung neoplasms. The agency used the female mice data for risk assessment because the female mice give a somewhat stronger response than the male mice. To estimate the risk, the agency considered the lung and liver neoplasia to be independent and added them together. The agency then computed the carcinogenic potency based on the incidence of animals with tumors at the low dose (2,000 ppm).

The computed carcinogenic potency is the risk (the probability that an animal will develop a tumor) divided by the dose that produced that risk. An inhalation exposure of 2,000 ppm for mice is equivalent to an exposure of 2,250 mg/kg/day if it is assumed that all the inhaled methylene chloride vapor is absorbed systemically. Thus, for methylene chloride, the calculated ***51555** carcinogenic potency is 4.x10-4 per kilogram of body weight per day (Refes. 21 and 28).

The NCA drinking water study in mice did not demonstrate any distinct neoplastic effects to liver or lung. However, the dosage levels were considerably lower than those in the inhalation study. Making the assumption that methylene chloride would induce neoplasia at a dose just above the highest level tested in the drinking water study, a maximum potency can be estimated. This estimate is approximately the same as the potency estimated from the inhalation study and provides more confidence that the inhalation study is not likely to underestimate the potency of methylene chloride by ingestion (Ref. 28).

The agency therefore finds that the available bioassays are consistent with a methylene chloride carcinogenic potency of no greater than 4.4X10-4 per milligram per kilogram of body weight per day when ingested. For a 60 kilogram human, this corresponds to a potency of 7.3X10-6 per milligram per day.

The potency for methylene chloride derived by the Environmental Protection Agency (EPA) is about 26 times higher than FDA's value. Most of the difference (a factor of 13) between the two estimates is attributable to the fact that EPA uses body surface area for interspecies comparison of exposure, whereas FDA uses body weight for such comparison. An additional factor of two is attributable to a combination of other small differences in risk assessment procedures employed by the two agencies.

FDA has traditionally used body weight scaling to compare doses among laboratory test species and for estimating comparable levels of exposure in humans. Under contract with FDA, the Life Sciences Research Office of the Federation of American Societies for Experimental Biology in initiating a study to examine the biological basis extrapolating doese among laboratory test species and humans (50 FR 45669; November 1, 1985). In the meantime, FDA will continue to use body weight scaling for interspecies comparison of doses.

In FDA's view, the overall risk assessment procedures used by both FDA and EPA are conservative. Neither FDA's nor EPA's procedures are likely to underestimate the actual risk from very low doses. In fact, both are likely to exaggerate the risk because the overall procedures of both agencies are designed to estimate an upper bound risk consistent with the data.

FDA has estimated the upper bound risk from exposure to methylene chloride from consumption of decaffeinated coffee produced in compliance with the 10 ppm limitation. Using 7.3X10-6 per milligram per day as the potency for methylene chloride when ingested at very low levels and the estimated lifetime-averaged methylene chloride exposure of 140 micrograms per day for consumers of large amounts of decaffeinated brewed coffee and 55 micrograms per day for consumers of large amounts of decaffeinated instant coffee, the agency estimates upper bound of lifetime risks to be 1X10-6 (i.e., 1 in million) and 4X10-7 (i.e., 1 in 2.5 million), respectively (Ref. 28).

It should be emphasized that the actual levels of residual methylene chloride in the decaffeinated coffee produced by the major manufacturer are much less than 10 ppm and, therefore, pose an even smaller risk. Most decaffeinated coffee contains mehtylene chloride residue of less than 0.1 ppm. The risks posed by this level of residue are two orders of magnitude lower than the already small risk posed by the 10 ppm level, i.e., 1X-8 (1 in 100 million) and 4X-9 (1 in 250 million), respectively.

V. Determination That Existing Limit for Decaffeination is Consistent with Safe Use of Methylene chloride

Because decaffeinated coffee that meets a 10 ppm regulatory limitation presents such extremely low levels of risk, FDA is not proposing to amend § 173.255(c).

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, FDA cannot approve a food additive for a particular use unless the data presented to FDA establish that the food additive is safe for that use. The concept of safety embodied in this requirement was explained in the House Report on the Food Additives Amendment of 1958:

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not —and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

H. Rept. 2284, 85th Cong., 2d Sess. 1, 4-5 (1958).
This determination of safety has been incorporated into FDA's food additive regulations in 21 CFR 170.3(i).

The Delaney anticancer clause of the Food Additives Amendment of 1958 (section 409(c)(3)(A) of the act) provides further:

That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * * .

Because methylene chloride has been shown at a statistically significant level to be a carcinogen by inhalation in the NTP mouse bioassay, if the Delaney anticancer clause (21 U.S.C. 348(c)(3)(A)) is to be interpreted as applying even it a de minimis risk is involved, FDA could not find that use of methylene chloride for decaffeinating coffee is safe. Yet, if the associated risk is essentially negligible, there is no gain to the public, and the statutory purpose is not implemented, if the words of the statute are interpreted not to leave the agency any discretion to apply it reasonably. The calculated risk for this use of methylene chloride is extremely low. The risk (no greater than 1 in 1 million and probably closer to 1 in 100 million) is so low as to be essentially nonexistent. Given such a low level of risk, FDA has concluded that there would be no safety gain to the public if it interpreted the Delaney Clause to require a ban on this use of methylene chloride. Therefore, FDA, exercising its inherent authority under the de minimis doctrine, concludes that the Delaney Clause does not require a ban in this situation. Because there are no other known safety problems with this use of methylene chloride, FDA finds that the use of methylene chloride to decaffeinate coffee is safe.

A. The de Minimis Doctrine

The de minimis doctrine holds that the law does not concern itself with trifling matters, and that courts consequently should be reluctant to apply the literal terms of a statute to mandate pointless results. Alabama Power Co. v. Costle, 636 F.2d 323, 360 (D.C. Cir. 1979). In District of Columbia v. Orleans, 406 F.2d 957, 959 (D.C. Cir. 1968), the United States Court of Appeals for the District of Columbia Circuit stated that this doctrine was properly applied to the administration by the government of its regulatory programs. Thus, an administrative agancy has the inherent power under most statutory schemes to overlook circumstances that are contrary to the literal terms of a statute when those ***51556** circumstances can fairly be considered de minimis. As the court in Alabama Power Co. v. Costle, supra, explained:

Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value.

636 F.2d at 360-361. Accord, Environmental Defense Fund, Inc. v. Environmental Protection Agency, 636 F.2d 1267, 1284 n. 46 (D.C. Cir. 1980).

B. The de Minimis Doctrine and the Federal Food, Drug, and Cosmetic Act

Section 201(s) of the act states that a "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *." Yet, in Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), the court held that not all chemicals that become components of food need be considered food additives. The court stated that FDA has the authority to ignore a chemical that migrates from plastic packaging material into beverages if the amount of the chemical that migrates is de minimis.

The Monsanto decision is important to the agency's present action even though that case involved the definition of "food additive" and not the application of the Delaney Clause, and even though the carcinogenicity of the chemical at issue in that case, acrylonitrile monomer, had not been established at the time of the decision. The court held that the de minimis concept is appropriately used to allow marketing of a product that would otherwise be banned by a Delaney Clause. In that case, the agency had interpreted the statute as defining a carcinogenic substance that migrated into food in low amounts as technically a "food additive" whose approval is banned by the food additive provision's Delaney Clause, see 21 U.S.C. 321(s), 331(a), 342(a)(2)(C), 348 (a) and (c)(3)(A). Although the reviewing court accepted that interpretation, it nevertheless held that the "de minimis" concept, applied to the threshold "food additive" definition, could be utilized to allow such a substance into the market when it presents no real public health risk, see 613 F.2d at 955-956. Thus, the court's decision in Monsanto has the practical effect of shielding substances that present effectively no carcinogenic risk from the Delaney Clause. Although the court did not explicitly interpret the Delaney Clause as inapplicable to such substances, the court presumably knew that if a carcinogenic chemical was disregarded as de minimis in relation to the food additive definition, the chemical would not be subject to the Delaney Clause, which applies only when that definition is met. Necessarily, therefore, the court regarded this consequence as legally warranted.[FN1]

Moreover, in Scott v. FDA, 728 F.2d 322, 325 (6th Cir. 1984), the Sixth Circuit upheld the so-called constituents policy, whereby FDA may approve known carcinogens present in color additives as intermediaries or impurities present at levels too low to cause a response using conventional tests. Noting that FDA had determined the public health risk presented by D and C Green 5 was negligible, the Court reasoned:

. . . We find this determination by the Monsanto court persuasive and relevant to the particular facts of the instant case. We agree with the FDA's conclusion that since it 'has discretion to find that low level migration into food of substances in indirect additives is so insignificant as to present no public health or safety concern . . . . it can make a similar finding regarding a carcinogenic constituent or impurity that is present in a color additive' 47 FR 24280 (1982).

C. Application of the de Minimis Doctrine

Two conditions must apply to justify an agency's exercise of its authority to interpret a legal requirement as not requiring action in de minimis situations. First, it must be consistent with the legislative design for the agency to find that a situation is trivial and, therefore, one that need not be regulated. Alabama Power Co. v. Costle, supra, 636 F.2d at 630. Second, it must be clear that the situation is in fact trivial, and that no real benefit will flow from regulating the particular situation. Environmental Defense Fund v. Environmental Protection Agency, 636 F.2d 1267, 1283-1284 (D.C. Cir. 1980). Both conditions apply here.

1. The establishment of a de minimis exception to the Delaney Clause is consistent with the legislative design.

In Alabama Power Co. v. Costle, supra, the court stated that the implication of de minimis authority is consistent with most statutes. The court stated that unless Congress has been extraordinarily rigid, there is likely a basis for an implication of such authority. Id. at 360-361. That Congress was not so rigid as to preclude the implication of de minimis authority under the Delaney Clause is evidenced both by the stated congressional intent in enacting the Clause and by the stated purpose of this provision.

Although the Delaney Clause in section 409(c)(3)(A) of the act was passed as part of the Food Additives Amendment of 1958, the clearest statement of the congressional intent for that provision is in the legislative history of the Color Additive Amendments of 1960. The Color Additive Amendments contain a provision that is very similar to section 409(c)(3)(A) of the act. See section 706(b)(5)(B) of the act (21 U.S.C. 376(b)(5)(B)).

The Senate considered that the calculation of risk would permit interpretation of the Delaney Clause to allow approval of color additives producing a negligible risk. This is clear from a colloquy on the Senate floor initiated by Senator Jacob Javits in debate on his motion to reconsider the vote to approve the Color Additive Amendments. Senator Javits, focusing on the Delaney Clause, made the record clear in discussion with Republican leader Senator Dirksen and committee chairman Senator Hill that the Senate had agreed to pass the Color Additive Amendments with the Delaney Clause based upon its understanding that the authority conferred by that clause "should be used and applied within the 'rule of reason.' " 106 Congressional Record 15381 (July 1, 1960).[FN2] Both Senator Dirksen and Senator Hill agreed that the "rule of reason" was to be applied in interpreting the Delaney Clause. Id. On that basis, Senator Javits did not pursue his motion to reconsider.

The term "rule of reason" was taken from a report to the President from the President's Science Advisory Committee and from the Departments of Agriculture and of Health, Education, and Welfare (the predecessor to the Department of Health and Human Services) that analyzed the effect of the Delaney Clause that is applicable to food additives. That report defines the "rule of reason" as meaning that: "Every ***51557** statute must be interpreted in the light of reason and common understanding to reach the results intended by the legislature." 106 Congressional Record 15380. The report stated its conclusion that "an area of administrative discretion based on the rule of reason is unavoidable if the clause is to be workable." 106 Congressional Record 15381.

This report on implementation of the food additive provision, relied upon by the Senators as illustrating their understanding of the types of circumstances in which the "rule of reason" would appropriately be applied, in fact accurately predicted the advent of the science of risk assessment, the science that the agency is now applying in making its determination about the use of methylene chloride in decaffeinating coffee. The report stated that: "From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available." 106 Congressional Record 15380-15381.

Thus, the Senate agreed to adopt the color additive Delaney Clause only with the understanding that the clause would, like the food additive Delaney Clause, be administered with a "rule of reason," premised on the expectation that scientists would be able to determine the "probability of cancer induction." Thus, far from having been "extraordinarily rigid," Congress clearly contemplated that those administering the Delaney Clause would have discretion to implement that provision in a reasonable way.

The purpose of the Delaney Clause in section 409 of the act is, after all, to protect the public from the possibility of increasing cancer risks through the use of food additives. It does not advance this purpose to prohibit uses that present a risk that is, for all practical purposes, zero. Congress recognized this fact in warning FDA not to "go overboard" in applying the Delaney Clause. 106 Congressional Record 15381. Thus, it is not inconsistent with the Delaney Clause to permit some uses of a carcinogenic food additive when those uses are shown to present a potential carcinogenic risk that is so trivial, based on conservative statistical analyses, as to be the functional equivalent of no risk at all.

2. FDA finds that the risk from the use of methylene chloride in decaffeinating coffee (no greater than 1 in 1 million) is so small as to be effectively no risk. The agency makes this finding for the following reasons:

a. This computed level of risk is an upper bound level. It is not an actuarial risk. An actuarial risk is the risk determined by the actual incidence of an event. In contrast, the computed risk is a projection based on certain assumptions that enable the

agency to estimate a risk that is too small to actually be measured. The agency uses conservative assumptions to ensure that the computation does not understate the risk. Among the assumptions that the agency relied upon in this computation are that:

(i) FDA assumes that methylene chloride is as effective in inducing cancer on a proportional basis at extremely low doses as it is at the exaggerated doses used in the animal studies.

(ii) FDA assumes that methylene chloride is present in all decaffeinated coffee at the highest level permitted by the regulation.

(iii) FDA assumes that lifetime-average consumption for the high consumer is used, rather than the average consumer.

Based on its computations, the agency is confident that the risk from the use of methylene chloride to decaffeinate coffee will not exceed 1 in 1 million and is likely to be somewhere between that level and zero. FDA emphasizes that the 1 in 1 million level of risk does not mean that 1 in every 1 million people will contract cancer as a result. Rather, in all likelihood, no one will contract cancer as a result of this exposure. The 1 in 1 million level represents a 1 in 1 million increase in risk over the normal risk of cancer in a lifetime—not annual—risk.

Because of the conservative assumptions in the foregoing risk assessement computation, it is probable that the incidence of tumors that would result the use of methylene chloride is likely to be even lower. In fact, the level of risk from most decaffeinated coffee is an incidence of less than one tumor after a lifetime of consumption in the entire population of coffee drinkers. As previously noted, it is likely that in fact there will be no increase incidence.

b. FDA has previously considered the risk level of 1 in 1 million in serveral contexts. In the ongoing rulemaking proceeding to establish procedures and standards for applying the so-called DES-proviso to the Delaney Clause for carcinogenic drug and food additive residues in edible animal tissues (21 U.S.C. 360b(d)(1)(H)), FDA has proposed than an assay method sufficient to detect a residue posing a calculated upper bound risk of 1 in 1 million be required posing a calculated upper bound risk of 1 in 1 million be required becasue “a risk level of 1 in 1 million over a lifetime imposes no additional risk of cancer to the public” (44 FR 17070, 17093; March 20, 1979). The agency noted that by using that level of risk, “as far as can be determined, in all probability no one will contract cancer” (50 FR 45530, 45541; October 31, 1985).

In several proceedings involving the agency's policy for carcinogenic impurities in food and color additives, FDA has used the risk of 1 in 1 million as a standard for determining whether the calculated upper bound risk of cancer posed by an impurity is low enough to be considered “safe” within the meaning of the general safety clause. See, e.g., the administrative record compiled in the rulemaking on D&C Green No. 6, 47 FR 14138; April 2, 1985.

FDA believes that these uses of the 1 in 1 million risk level are indistinguishable from the use 1 in 1 million as a de minimis level of risk with respect to the Delaney Clause. A finding that a substance with a 1 in 1 million risk is “safe,” or that it “imposes no additional risk of cancer to the public,” is the same as a finding that the risk is of no public health consequence or that it is insignificant. It is in just those circrumstances, where there is no meaningful increase in public health protection from applying the strict terms of a legal standard, that the courts have found the de minimis doctrine to be applicable. For example, the court in Monsanto equated “de minimis” with a finding that migration of an indirect food additive is “insignificant” (613 F.2d at 947) in a context where the court clearly recognized that the real question was the toxicity of a particular level of migration.

For these reasons, FDA concludes that a risk level on the order of 1 in 1 million for cancer constitutes a de minimis level of risk, and that its use of that level of risk in other regulatory contexts is consistent with that conclusion, although the agency until now has not had occasion to consider what levels of risk might be considered de minimis under the Delaney Clause with respect to be considered de minimis under the Delaney Clause with respect to a food or color additive.

Based on the foregoing, FDA concludes that the risk of cancer from the use of methylene chloride to decaffeinate coffee is so low as to be effectively no risk, and that there would be no benefit to the public from prohibiting its use in this case. Further,

consistent with section 409 of the act, FDA concludes, for the same reasons ***51558** and because there are no other safety problems with this use of methylene chloride, that methylene chloride is safe for use to decaffeinate coffee. Therefore, FDA will permit the continued use of methylene chloride to decaffeinate coffee so long as the residue levels are kept within the limits established in § 173.25.

VI. Regulatory Action

Under section 601(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 361(a)), a cosmetic is deemed to be adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling therof, or, under such conditions of use as use are customary or usual * * *." FDA believes that the evidence discussed above establishes that methylene chloride is a poisonous or deleterious substance, and that its use in cosmetic products may render those products injurious to users. Therefore, FDA has tentatively concluded that cosmetics that contain methylene chloride are adulterated under section 601(a) of the act, and the agency is consequently proposing to prohibit the use of methylene chloride in all cosmetic products.

FDA has been informed by several cosmetic manufacturers that they have either ceased using methylene chloride in their hair spray products or are in the process or will soon be in the process to so reformulate. The agency acknowledges these substantial voluntary efforts and the availability of safe substitutes. Consequently, given the severity of the public health risk presented, a regulation is necessary to ensure that all hair spray manufacturers cease using methylene chloride and that no new hair spray manufacturers being using it.

FDA, however, is not taking any action with regard to the use of methylene chloride is decaffeinated coffee.

VII. Economic Impact

FDA, in accordance with the Reguatory Flexibilitiy Act, has considered the effect that this proposed rule would have on small entities including small businesses. The agency has determined that the economic impact arising from this proposed rule will result from one-time reformulation and relabeling costs for those cosmetic products currently containing methylene chloride. Information available to the agency has indicated that the only products potentially affected by this proposal are aerosol hair spray products, and that the use of methylene chloride in these products has declined sharply in recent years. The agency estimates the aggregate costs of this proposed rule to be approximately $1 million. Therefore, FDA certifies, in accordance with section 605(b) of the Regulatory Flexibiltiy Act, that no significant ecomonic impact on a substantial number of small entities will derive from this action.

Further, in accordance with Executive Order 12291, FDA has analyzed the economic effects of this proposal and has determined that it is not major rule as defined by that Order. A copy of the threshold assessment is on file the Dockets Managment Branch.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that findings, contained in an environmental assessment, may be seen in the Dockets Managment Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the Federal Register of April 26, 1985 (50 FR 16636, effective July 25, 1985).

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. “Technical Report on the Toxicology and Carcinogenesis Studies of Dichloromethane (Methylene Chloride) in F344/N Rats and B6C3F1 Mice,” NTP Draft Report, NTP-TR-306, National Institutes of Health Publication No. 85-2562, 1985.

2. Cancer Assessment Committee, Memorandum of Conferences, “Methylene Chloride,” January 20, 1983, August 8, 1984, and June 13, 1985.

3. Summary Minutes for Peer Review of Draft Technical Reports of Long-Term Toxicological Studies by the Technical Review Subcommittee of the Board of Scientific Counselors and Panel of Experts, March 29, 1985.

4. Burek, J.E., et al., “Methylene Chloride: A Two-Year Inhalation Toxicity and Oncogenicity Study in Rats and Hamsters,” Toxicological Research Laboratories, Dow Chemical U.S.A., December 31, 1980.

5. Nitschke, K.D., “Methylene Chloride: A Two-Year Inhalation Toxicity and Oncogenicity Study,” Toxicological Research Laboratories, Dow Chemical U.S.A., October 1982.

6. National Coffee Association, “24-Month Chronic Toxicity and Oncogenicity Study of Methylene Chloride in Rats—Final Report,” August 11, 1982, and “Addition to Final Report,” November 5, 1982, Hazelton Laboratories America, Inc. Vienna, VA.

7. National Coffee Association, “24-Month Oncogenicity Study of Methylene Chloride in Mice—Final Report,” Hazelton Laboratories America, Inc., Vienna, VA, November 30, 1983.

8. Friedlander, B. R., et al., “Epidemiologic Investigation of Employees Chronically Exposed to Methylene Chloride: Mortality Analysis,” Journal of Occupational Medicine, 20:675-666, 1978.

9. Ott, M.G., et al., “Health Evaluation of Employees Occupationally Exposed to Methylene Chloride,” Scandinavian Journal of Work, Environment & Health, 9:Suppl 1:1-38, 1983.

10. Jongen, W.M.F., et al., “Mutagenic Effect of Dichloromethane on Salmonella typhimurium,” Mutation Research, 56:245-248, 1978.

11. Kanada, T., and M. Uyeta, “Mutagenicity Screening of Organic Solvents in Microbial Systems,” Mutation Research, 54:215, 1978.

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13. Snow, L., et al., “Mutagenesis Testing of Methylene Chloride and 1,1,1-Trichloroethane in Salmonella Strains TA100 and TA98,” Northrop Services, Inc., Research Triangle Park, NC, September 19, 1979.

14. Brusick, D.J., “Mutagenicity Evaluation of Methylene Chloride—Final Report,” Litton Bionetics, Kensington, MD, July 30, 1976.

15. Green, T., “The Metabolic Activation of Dichloromethane and Chlorofluoromethane in a Bacterial Mutation Assay Using S. typhimurium,” Mutation Research, 118:277-288, 1983.

16. Simmon, V.F., et al., “Mutagenic Activity of Chemicals Identified in Drinking Water,” in “Progress in Genetic Toxicology,” Scott, I.D., et al., editors, Elsevier, Amsterdam, pp. 249-258, 1977.

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18. Callen, D.F., et al., "Cytochrome P-450 Medicated Genetic Activity and Cytotoxicity of Seven Halogenated Aliphatic Hydrocarbons in Saccharomyces cerevisiae," Mutation Research, 77:55-63, 1980.

19. Sayad, R.S., et al., "Methylene Chloride in Hair Sprays," Soap/Cosmetic/Chemical Specialties, March 1976.

20. Skory, L.K., T. Anthony, and M.P. Stevenson, "Carboxyhemoglobin Studies Show Methylene Chloride Safe in Aerosol Use," Aerosol Age, 20(5), May 1975.

21. Quantitative Risk Assessment Committee, Memorandum, "Preliminary Assessment of Upper-Bound Cancer Risk from Exposure to Methylene Chloride Used in Cosmetic Aerosol Sprays," April 23, 1985.

***51559** 22. Letter dated August 7, 1985, J. Kirschman, General Foods Corp., to R. Scheuplein, FDA, with attachment.

23. Memorandum dated November 12, 1985, G. Cramer, Food Additive Chemistry Evaluation Branch, FDA.

24. Memorandum dated November 14, 1985, G. Cramer, Food Additive Chemistry Evaluation Branch, FDA.

25. Letter dated November 18, 1985, I. Abrams, MRCA Information Service, to A. Beloian, FDA.

26. International Coffee Organization, "United States of America Coffee Drinking Study, Winter 1985," London, England.

27. Pao, E., et al., "Foods Commonly Eaten by Individuals: Amounts Per Day and Per Eating Occasion," U.S. Department of Agriculture, Home Economics Research Report No. 44, pp. 24-25, 1982.

28. Quantitative Risk Assessment Committee, Memorandum, "Upper Bound Estimate of Cancer Risk from Methylene Chloride (MC) in MC-based Decaffeinated Coffee Products," November 15, 1985.

X. Comments

Interested persons may, on or before February 18, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 700

Cosmetics, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 700 be amended as follows:

PART 700—GENERAL

1. The authority citation for 21 CFR Part 700 is revised to read as follows:

Authority: Secs. 601, 602, 701(a), 704, 52 Stat. 1054 as amended, 1055, 67 Stat. 477 as amended (21 U.S.C. 361, 362, 371(a), 374); 21 CFR 5.10 and 5.11.

21 CFR § 700.19

2. By adding new § 700.19, to read as follows:

21 CFR § 700.19

§ 700.19 Use of methylene chloride as an ingredient of cosmetic products.

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

Dated: December 12, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-29851 Filed 12-17-85; 8:45 am]

BILLING CODE 4160-01-M

Footnotes

1 FDA has not always been clear about its position on the Monsanto decision. For example, in questioning by Senator Orrin G. Hatch that took place in 1983 during hearings on food safety by the Senate Committee on Labor and Human Resources, then-Commissioner Arthur Hull Hayes, Jr. expressed some uncertainty about whether the Monsanto decision should be interpreted beyond its specific factual context (S. Hearing 98-309, 98th Cong., 1st Sess. 248 (1983)). FDA has concluded that the Monsanto decision is correctly interpreted as extending to the Delaney Clause.

2 Senator Javits, now retired, recently reviewed this discussion. On July 10, 1985, he sent Margaret Heckler, Secretary of the Department of Health and Human Services, a letter stating that his views had not changed since 1960. He stated that it was his continuing understanding that the rule of reason “would dictate that where the danger to the public is negligible in using products with such color additives, then use should not be prohibited.” A copy of Senator Javits' letter to Secretary Heckler is included in the record of this rulemaking.

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(9:00 a.m. to 5:00 p.m.) and June 16, 1976 (9:00 a.m. to 12 Noon) at the Consumer Product Safety Commission, 1750 K Street, N.W., 6th Floor Conference Room.

The purpose of the Technical Advisory Committee is to provide advice and recommendations on the types and kinds of packaging that will protect children from injury or illness resulting from handling or ingestion of household substances.

The agenda for the June 15 meeting will include a discussion of outstanding petitions and the regulations covering ammonia. The afternoon session of the meeting will be devoted to further discussion of adult protocol.

On Wednesday, June 16, there will be a discussion of consumer oriented programs of the Consumer Product Safety Commission and presentation of certificates to the outgoing members of the Committee.

Persons wishing to make oral or written presentations to the Committee should notify the Secretary of the Consumer Product Safety Commission at least five days in advance of the meeting. The meeting is open to the public, however, space is limited. Further information concerning this meeting may be obtained from the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, phone (202) 634-7700.

Dated: May 19, 1976.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc.76-15168 Filed 5-24-76;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 547-7; OPP-42011A]

COMMONWEALTH OF PENNSYLVANIA

Approval of State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136), and the implementing regulations of 40 CFR Part 171 require each State desiring to certify applicators to submit a plan for its certification programs. Any State certification program under this section shall be maintained in accordance with the State Plan approved under this section.

On March 4, 1976, notice was published in the FEDERAL REGISTER (41 FR 9418) of the intent of the Regional Administrator, EPA Region III, to approve, on a contingency basis, the Commonwealth of Pennsylvania State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides (Pennsylvania State Plan). Contingency approval was requested by the Commonwealth of Pennsylvania pending promulgation of regulations pursuant to the "Pennsylvania Pesticide Control Act of 1973". Complete copies of the Pennsylvania State Plan were made available for public inspection at the Agency's Region III office in Philadelphia, Pennsylvania, at the Bureau of Plant Industry, Pennsylvania Department of Agriculture, Harrisburg, Pennsylvania, and at the Agency's Technical Services Division, Federal Register Section, Office of Pesticide Programs, EPA Headquarters, Washington, D.C.

There were no comments received concerning the State Plan during the 30 day comment period.

The Pennsylvania State Plan will remain available for public inspection at Room 102, Agriculture Office Building, 2301 N. Cameron Street, Harrisburg, Pennsylvania.

It has been determined that the Pennsylvania State Plan will satisfy the requirements of Section 4(a)(2) of the amended FIFRA and of 40 CFR Part 171 if proposed regulations implementing the Pennsylvania Pesticide Control Act of 1973 are promulgated by the Pennsylvania Department of Agriculture. Accordingly, the Pennsylvania State Plan is approved contingent upon promulgation of implementing regulations in accordance with and as prescribed in the Pennsylvania State Plan.

This contingency approval shall expire one (1) year from its effective date, if these terms and conditions are not satisfied by that time. On or before the expiration of the period of contingency approval, a notice shall be published in the FEDERAL REGISTER concerning the extent to which these terms and conditions have been satisfied, and the approval status of the Pennsylvania State Plan as a result thereof.

Effective date: Pursuant to Section 4(d) of the Administrative Procedures Act, 5 U.S.C. 553(d), the Agency finds that there is good cause for providing that the one year contingency approval granted herein to the Pennsylvania State Plan shall be effective immediately. Neither the Pennsylvania State Plan itself nor this Agency's contingency approval of the Plan create any direct or immediate obligations on pesticide applicators or other persons in the Commonwealth of Pennsylvania. Delays in starting the work necessary to implement the Plan, such as may be occasioned by providing some later effective date for this contingency approval, are inconsistent with the public interest. Accordingly, this contingent approval shall become effective immediately.

Dated: April 15, 1976.

A. R. MORRIS,
Acting Regional Administrator.

[FR Doc.76-15138 Filed 5-24-76;8:45 am]

[FRL 548-2]

HEALTH RISK AND ECONOMIC IMPACT ASSESSMENTS OF SUSPECTED CARCINOGENS

Interim Procedures & Guidelines

In issuing the Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens, I think it appropriate to state once again EPA's approach to regulatory action for suspect carcinogens.

Cancer is the second ranking cause of death in this country; it has a particularly severe impact on the affected individuals and their families in terms of physical and mental suffering and economic costs. There is evidence that a substantial amount of human cancer is caused by chemical and physical agents in the environment. Bioassay programs, currently testing hundreds of substances, are beginning to show that some important industrial and agricultural chemicals are carcinogenic for animals and are, therefore, candidates for regulatory action.

The EPA, by law, has responsibility to regulate many agents which may either cause or promote the development of cancer. At present, EPA is charged with the responsibility to prohibit or restrict the use of carcinogenic pesticides. EPA also has authority to regulate those carcinogens which are emitted directly to the outside air by stationary sources (such as factories) and motor vehicles, or discharged into water from point sources, or found in drinking water. Other agencies such as the Occupational Safety and Health Administration and the Food and Drug Administration also have responsibilities to regulate carcinogens. It is important to emphasize that there are serious regulatory gaps which permit understandable exposure of the public to carcinogens. I have strongly advocated the passage of a toxic substances bill to help close those gaps.

Regulatory action against chemical carcinogens is relatively new. Until the late 1950's, no agents, either chemical or physical, had been regulated in this country on the basis of their carcinogenic action with the sole exception of ionizing radiation, which had been known to cause cancer since the turn of the century. Standards of permissible exposure to ionizing radiation were set by the arbitrary use of safety factors applied to exposure levels that were known to have produced damaging health effects. It was not assumed that these permissible exposure standards were safe but rather that they represented upper limits of exposure with the understanding that actual exposures were to be kept as low as possible. In the debate over the health effects of radioactive fallout from atomic weapons in the 1950's, the evidence for a no-threshold concept for cancer induction emerged, which supported the idea that there is no such thing as a completely safe dose; in other words any exposure, however small, will confer some risk of cancer on the exposed population.

Evidence has accumulated that indicates that the no-threshold concept can also be applicable to chemical carcinogens. On the basis of this concept, the first significant regulatory legislation relating to chemical carcinogens, the Delaney Clause of the Pure Food and Drug Act, imposed a complete ban on any food additive that showed evidence of tumorigenic activity for humans or animals. This statutory requirement represents the approach of eliminating all risk. However, it has become increasingly clear that in many areas risks cannot

01281

be eliminated completely without unacceptable social and economic consequences.

Consonant with this view, the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), which is the enabling legislation for the control of health hazards for pesticides, requires a balancing of risks and benefits as the basis for final regulatory action. We, thus, have a comparable conceptual basis for the regulation of chemicals as for ionizing radiation where the philosophy has been to eliminate or reduce exposure to the greatest extent possible consistent with the acceptability of the costs involved.

I believe that it is important to emphasize the two-step nature of the decision-making process with regard to the regulation of a potential carcinogen. Although different EPA statutory authorities have different requirements, in general two decisions must be made with regard to each potential carcinogen. The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk.

With respect to the first decision—whether a particular substance constitutes a cancer risk—in very few cases is it possible to "prove" that a substance will cause cancer in man, because in most instances the evidence is limited to animal studies. In this regard, a substance will be considered a presumptive cancer risk when it causes a statistically significant excess incidence of benign or malignant tumors in humans or animals. However, the decision that a cancer risk may exist does not mean that the EPA will automatically take regulatory action. In the case of pesticides, the decision that a presumptive cancer risk exists will trigger the detailed and independent risk and economic assessments that form the basis for the second decision, namely, what, if any, regulatory action to take to eliminate or restrict the use of the pesticide. In other regulatory areas, for example those under the Clean Air Act, the Federal Water Pollution Control Act, or the Safe Drinking Water Act where a large number of suspect carcinogens may exist in the atmosphere or public water supplies, the detailed risk benefit assessment will, because of limited Agency resources, necessarily have to be carried out on a priority basis in terms of which agents appear to be the most important.

Once the detailed risk and benefit analyses are available, I must consider the extent of the risk, the benefits conferred by the substance, the availability of substitutes and the costs of control of the substance. On the basis of careful review, I may determine that the risks are so small or the benefits so great that no action or only limited action is warranted. Conversely, I may decide that the risks of some or all uses exceed the benefits and that stronger action is essential.

In considering the risks, it will be necessary to view the evidence for carcinogenicity in terms of a warning signal, the strength of which is a function of many factors including those relating to the quality and scope of the data, the character of the toxicological response, and the possible impact on public health. It is understood that qualifications relating to the strength of the evidence for carcinogenicity may be relevant to this consideration because of the uncertainties in our knowledge of the qualitative and quantitative similarities of human and animal responses. In all events, it is essential in making decisions about suspect carcinogens that all relevant information be taken into consideration.

In my opinion, the current guidelines represent a significant improvement in the Agency's approach to the processes of decision-making for carcinogens by providing improved procedures for making risks and benefit assessments while providing the maximum opportunity for public review of the Agency's deliberations. However, while these guidelines should improve Agency procedures, I do not view them as representing a change in the Agency's cancer policy. Earlier regulatory decisions involving various pesticides were also based in each case on a comprehensive evaluation of the scientific evidence and a careful weighing of risks and benefits. These decisions in every instance resulted in selective control measures rather than a complete prohibition of use.

I want to emphasize that I will not permit these new procedural guidelines to unduly delay regulatory decision-making. I will be closely reviewing them to assure that they do not do so. If they do cause undue delay, they will be revised. I would like to point out that these guidelines provide a means of organizing available information rather than requirements for the acquisition of new information.

I believe that the approach presented here is a significant step toward the objective of achieving real benefits in improved public health while avoiding the burden of undesirable regulatory action. I recognize that the aspect of cancer research dealing specifically with the issues involved in decision-making is relatively undeveloped, but hopefully the commitment of this Agency and other Federal agencies to the development of new knowledge in this area will improve the scientific basis for regulatory decisions and that the Interim Procedures and Guidelines will thereby benefit from periodic revision.

I consider it extremely important that the leading government agencies work closely with each other and with experts outside the government in the field of carcinogenicity in the development of government procedures and policies concerning cancer. I am publishing these interim procedures and the guidelines in the FEDERAL REGISTER not only to provide public notice of the approach which EPA will be following in our current activities but also to stimulate commentary from all sources upon that approach. I am also furnishing copies of these Interim Procedures and Guidelines to and requesting the views of the Secretaries of Health, Education, and Welfare, Interior, Labor, Commerce and Agriculture and also the Council on Environmental Quality, the National Academy of Sciences, the National Science Foundation, EPA's Pesticide Policy Advisory Committee and EPA's Science Advisory Board, among others. I also plan to meet personally with leading authorities in this area as part of a continuing process to discuss these cancer policies and exchange information and views.

RUSSELL TRAIN,
Administrator.

MAY 19, 1976.

INTERIM ADMINISTRATIVE PROCEDURES FOR REGULATORY DECISIONS INVOLVING SUSPECTED CARCINOGENS

Procedures described in this paper provide a more uniform Agency approach to regulatory decisions involving cancer risk. Procedure A applies to pesticide decisions involving the cancellation, suspension and registration of potentially carcinogenic pesticides. Procedure B applies to other selected Agency decisions where the pivot factor in the decision is cancer risk.

The purpose of these procedures is to assure that appropriate analyses of the risks and benefits of suspected carcinogenic chemicals are performed as part of the regulatory process. Appendices I and II establish guidelines for risk assessment and economic impact analyses. These guidelines are procedural guidelines and are not intended to affect the substantive regulatory standards of any statute. Therefore, the assessment of the risk posed by potentially carcinogenic substances will be made pursuant to the individual standards of the applicable statute and regulations. Furthermore, these analyses will be carried out within the constraints of Agency resources and will not delay actions by the Agency to address urgent environmental problems.

The Cancer Assessment Group (CAG) is an advisory body comprised of senior scientists from within the Agency with a liaison member from the Department of Health, Education and Welfare. It will also utilize, as appropriate, expert consultants and advisors from various Federal Agencies and the private sector. The CAG will conduct analyses of data related to risk and make recommendations to the lead program office and the appropriate Working Group concerning the risk associated with each suspect carcinogen. These analyses will be directed towards risk assessment and will be conducted independently of economic impact analyses. The CAG will also review the final risk assessment portion of the regulatory package.

APPLICABILITY

For all decisions involving the cancellation, suspension, reregistration and registration of potentially carcinogenic pesticides, Procedure A will be followed inclusive of the preparation of (1) a risk assessment pursuant to the interim guidelines contained in Appendix I and (2) an economic impact analysis pursuant to the interim guideline contained in Appendix II.

For the following rulemaking, where the pivotal factor in the decision is cancer risk, the procedures outlined in EPA Order 1000.6 will be followed, and in addition, a risk assessment pursuant to Appendix I will be prepared and will be reviewed in accordance with Procedure B:

1. Proposed regulations to augment the current list of toxic substances published

01282

pursuant to Section 307(a) of the FWPCA and any standard proposed under this augmented list.

2. Primary drinking water regulations or revisions thereof under Section 1412 of SDWA.

3. Additions to or revisions of the water quality criteria (pursuant to Section 304(a) of FWPCA) currently pending publication, except that detailed exposure patterns and estimates of cancer risk need not be prepared.

4. Proposed technology-based regulations or revisions pursuant to Sections 301, 304, 306, 307(b) and 307(c) of the FWPCA (proposed after April 1, 1977), and Section 111 of the CAA, except that detailed exposure patterns and estimates of cancer risk need not be prepared.

For all other rulemaking under existing legislation which involves the regulation of a potential carcinogen(s), and which is not currently under development, the determination of whether and to what extent to use Appendix I and Procedure B will be made at the time the Administrator approves the plan for such rulemaking.

Where the development of a surrogate parameter is being proposed to regulate one or more potential carcinogens and perhaps other pollutants (e.g., a total organic carbon standard for drinking water), the risk assessment, as required above, will address at least one of the potential carcinogens and should address, to the extent feasible, as many of the others as possible.

All risk assessments need only be based on currently available information. These procedures do not require the undertaking of research or monitoring to expand the available data base.

A. Procedure for pesticide decisions involving potential carcinogens. This procedure is similar to the current procedure for informal rulemaking set forth by EPA Order 1000.6.

1. Formation of the working group. The Deputy Assistant Administrator for Pesticides, in cooperation with the Office of Planning and Management, establishes a working group.

2. OPP/working group responsibility. The Office of Pesticide Programs (OPP), in consultation with the Working Group, is responsible for developing a Data Summary Report, a Position Document (including health risk assessment and the economic impact analysis) and a proposed FEDERAL REGISTER notice at the appropriate points in the regulatory process. Guidelines for health risk assessment and economic analysis are included as Appendices I and II.

3. Review of a suspect chemical prior to reregistration or the issuance of a rebuttable presumption against registration (RPAR).

a. Data relevant to the carcinogenicity of a pesticide is submitted to the CAG for review and comment. Following review by the CAG, a Data Summary Report is prepared by OPP and the Working Group. This report includes a summary of all available data relevant to carcinogenicity.

b. A draft Position Document including the Data Summary Report, a summary of the issues surrounding potential regulatory actions, and a proposed FEDERAL REGISTER notice are presented to the Pesticide Chemical Review Committee (PCRC) which includes a representative from the CAG.

c. On the basis of PCRC comments, the OPP and the Working Group revise the draft Position Document and the FEDERAL REGISTER notice. The PCRC reviews the revised package.

d. The package recommending a reregistration or the issuance of a RPAR goes to the Deputy Assistant Administrator for Pesticide Programs for a final decision.

4. Post-RPAR: Issuance of a notice of intent to cancel, suspend or reregister.

a. After a RPAR is issued, and rebuttal information if any is submitted, the OPP and the Working Group develop a final Position Document. This document includes a summary of all information available in rebuttal of the RPAR, a recommended finding on whether or not the presumption against registration has been rebutted (including the risk assessment), economic impact analysis as necessary, a summary of the issues surrounding potential regulatory actions, and a draft FEDERAL REGISTER notice.

b. The final Position Document is reviewed by PCRC and the risk assessment is reviewed by CAG.

c. If the decision is to reregister the product, a notice to this effect is published in the FEDERAL REGISTER.

d. If the decision is to cancel or suspend the product, the proposed notice of intent to cancel or suspend is forwarded to USDA and the Scientific Advisory Panel for comment, pursuant to the 1975 amendments to Section 6(b) of FIFRA. However, if it is determined that suspension of the pesticide is necessary to prevent an imminent hazard to humans, the 1975 amendments provide for waiver of the requirement for consultation with USDA and the Scientific Advisory Panel.

The notice of intent to register, cancel or suspend, including the risk assessment and economic impact analyses, is circulated for General Counsel and Assistant Administrator concurrence and forwarded to the Administrator for a final decision.

B. Other rulemaking to regulate carcinogens. All other Agency decisions involving carcinogenesis as the pivotal factor will follow EPA Order 1000.6 with the following additions:

1. The CAG will review the relevant data during the development of the rulemaking and make recommendations to the lead office and the working group regarding the interpretation of the data and provide other advice, as appropriate, concerning the risk assessment.

2. The CAG will review that portion of the rulemaking package containing the risk assessment. CAG comments will be presented to the Steering Committee.

C. External scientific review. In addition to the external reviews required by statute and the 1000.6 process, other external scientific review will be obtained in appropriate cases as determined by the lead program office. This review may take place at any time in the development of the regulatory package.

While risk and economic impact analyses may be reviewed externally, regulatory recommendations will not normally be submitted for external review. Reviewers for risk analyses may be from the Science Advisory Board, National Cancer Institute, or other appropriate Institutions.

APPENDIX I

INTERIM GUIDELINE FOR CARCINOGEN RISK ASSESSMENT

1.0 Introduction. This preliminary guideline describes the general framework to be followed in developing an analysis of carcinogen risks and some salient principles to be used in evaluating the quality of data and formulating judgments concerning the nature and magnitude of the cancer hazard from suspect carcinogens.

This guideline is to be used within the policy framework already provided by applicable statutes and does not alter such policies. The guideline provides a general format for analyzing and organizing available data. It does not imply that one kind of data or another is prerequisite for regulatory action to control, prohibit, or allow the use of a carcinogen. Also, the guideline does not change any statutory-prescribed standards as to which party has the responsibility of remonstrating the safety, or alternatively the risk, of an agent.

The analysis of health risks will be carried out independently from considerations of the socio-economic consequences of regulatory action.

The risk assessment document will contain or identify by reference the background material essential to substantiate the evaluations contained therein.

2.0 General Principles Concerning the Assessment of Carcinogenesis Data. The central purpose of the health risk assessment[1] is to provide a judgment concerning the weight of evidence that an agent is a potential human carcinogen and, if so, how great an impact it is likely to have on public health.

Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds of responses induced by the suspect carcinogen. The best evidence that an agent is a human carcinogen comes from epidemiological studies in conjunction with confirmatory animal tests. Substantial evidence is provided by animal tests that demonstrate the induction of malignant tumors in one or more species including benign tumors that are generally recognized as early stages of malignancies. Suggestive evidence includes the induction of only those nonlife shortening benign tumors which are generally accepted as not progressing to malignancy, and indirect tests of tumorigenic activity, such as mutagenicity, in-vitro cell transformation, and initiation-promotion skin tests in mice. Ancillary reasons that bear on judgments about carcinogenic potential, e.g., evidence from systematic studies that relate chemical structure to carcinogenicity should be included in the assessment.

When an agent is judged to be a potential human carcinogen, estimates should be made of its possible impact on public health at current and anticipated levels of exposure. The available techniques for assessing the magnitude of cancer risk to human populations on the basis of animal data only are very crude due to uncertainties in the extrapolation of dose-response data to very low dose levels and also because of differences in levels of susceptibility of animals and humans. Hence, the risk estimates should be regarded only as rough indications of effect. Where appropriate, a range of estimates should be given on the basis of several modes of extrapolation.

Expert scientific judgments in the areas of toxicology, pathology, biometry, and epidemiology are required to resolve uncertainties about the quality, adequacy, and interpretation of experimental and epidemiology data to be used for the risk assessment.

3.0 Format of the Risk Analysis.

3.1 Exposure Patterns. This section should summarize the known and possible modes of exposure attendant to the various uses of the

[1] This health risk assessment is part of the risk-benefit analyses. In actions taken to regulate pesticides, this assessment is made after a determination that a health risk exists

01283

agent. It should include or identify by reference available data on factors relevant to effective dosage, physical and chemical parameters, e.g., solubility, particle size for aerosols, skin penetration, absorption rates, etc. Interaction of agents which may produce a synergistic or antagonistic effect should also be indicated, if available.

3.2 Metabolic Characteristics. This section should summarize known metabolic characteristics including transport, fate and excretion, and biochemical similarities to other known classes of carcinogens at high and low dose levels and should provide comparisons between relevant species as well as variations in different strains of certain species.

3.3 Experimental Carcinogenesis Studies. Available experimental reports should be summarized. If some experiments are to be rejected for the risk assessment, give reasons for doing so. Reprints of key papers and reports should be included as appendices to the analysis.

Judgements should be provided on the quality of the experimental data and their interpretations for each study on the basis of (a) experimental protocols, (b) survival rates in controls particularly in relation to acceptance of negative results, (c) incidence of spontaneous tumors in the control compared to general laboratory experience for the same species or strain, (d) diagnostic criteria and nomenclature used for tumor characterization (additional evaluation of histological material should be obtained when appropriate), and (e) observed results of positive controls (i.e., a test group given a standardized exposure to a known carcinogen) in light of expected results.

3.4 Epidemiological Studies. Summarize epidemiological studies, together with critiques of the work with respect to its limitations and significance. Summarize other published critiques whether supportive or at variance with the judgement made here.

3.5 Cancer Risk Estimates.

3.5.1 Exposure Patterns. Describe likely exposure levels with respect to long-term temporal trends, short-term temporal patterns, and weighted averages for both the total exposed populations and for subgroups whose exposure patterns may be distinctly different from the average. Characterize, to the extent possible, the size of the exposed population for each of the above categories with an indication of whether the exposures are likely to involve children and pregnant women. Discuss the adequacy of the methods used to estimate exposures and indicate the range of uncertainty in the estimates.

3.5.2 Dose-Response Relationships. Both human and animal data should be used as available. Include available human data, even if inadequate for a characterization of the actual magnitude of risk, where such data could be helpful in interpreting animal responses in relation to human sensitivity.

3.5.3 Estimates of Cancer Risk. The procedure will involve a variety of risk extrapolation models, e.g., the linear non-threshold model and the log-probit model. Analyses will be done separately for all suitable experimental data and human epidemiological data. The results should be presented in terms of excess lifetime incidence, or average excess cancer rates; life-shortening estimates should also be made when the data permit. The uncertainty in the data and extrapolation techniques should be clearly indicated. The results predicted for humans should be presented in relationship to the current cancer experience in the assumed target organ(s).

Some judgements should be included regarding the relevance of the mode of exposure used in animal studies to that associated with human exposure.

4.0 Summary. The summary section of the risk assessment should provide a statement which encompasses answers to the following questions: (1) How likely is the agent to be a human carcinogen? (2) If the agent is a human carcinogen, what is the estimated impact on human health?

Appendix II

Interim Guideline for Economic Impact Analysis of Proposed Regulatory Actions to Control Carcinogenic Pesticides

The purpose of this guideline is to define the factors to be considered and the procedures to be utilized in assessing the economic impact resulting from future regulatory actions, (as described below) affecting carcinogenic pesticides. Economic impact assessment for other regulatory actions to control environmental carcinogens will follow established agency procedures.

The principal concern in the economic analysis will be the assessment of economic impacts on pesticides users and on the consumers of the products of the users. The impacts on pesticide manufacturers are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefit of those uses.

As used in this guideline the economic impact of the regulation is equated to the anticipated loss in benefit from use of the pesticide. For agricultural pesticides the analysis will focus on the impacts on farmers, farm productivity, and consumer costs associated with farm productivity. Similarly, analyses of other pesticides will focus on the impacts on other user groups and related effects on the economy.

Regulatory procedures. The purpose of this section of the guidelines is to define how the economic impact analysis fits into the regulatory framework for pesticide-related actions.

If a pesticide meets or exceeds criteria defined in 40 CFR 162.11, a Rebuttable Presumption Against Registration (RPAR) will be issued. The Agency will analyze any rebuttal information that is submitted; it may also take into account other available information to determine whether the RPAR has been rebutted. At the conclusion of this risk assessment, the Administrator will be presented with sufficient evidence to determine if the use of a pesticide poses the risk of a significant adverse effect. If such is the case, then the Administrator must determine what type of regulatory response is warranted.

In making that decision, 40 CFR 162.11 provides that the Administrator will be provided with a preliminary assessment of the benefits of the use of the pesticide. Furthermore, § 162.11 essentially provides: (1) That if the risks appear to outweigh the benefits, the Administrator will issue a notice of intent to cancel, which may lead to a full adjudicatory hearing on the question of whether the pesticide causes or will cause unreasonable adverse effects on the environment, or (2) if the benefits appear to outweigh the risks, the Administrator will either issue a notice of intent to hold a hearing (adjudicatory or non-adjudicatory) or a notice of intent to register. Such notice of intent to register provides an opportunity for a hearing upon request (accompanied by submission of a statement of factual reasons) of an interested party that a hearing is warranted. The decision to cancel reached at this time will not result in the removal of a product from the market if the decision is contested. Instead, any such regulatory action will be preceded by a hearing to weigh fully the risks and benefits of the uses of a product.

The benefit evidence provided to the Administrator at this stage is by definition a preliminary staff analysis. A specific effort will be made by the Agency to contact parties that have an interest in the use of the pesticide and to attempt to solicit their comments on the benefits of the pesticide under review. In particular, EPA intends that the U.S. Department of Agriculture will be heavily relied upon from the earliest stages of review to provide its special expertise and data resources on uses.

Because of the many variables surrounding the multiple uses of different pesticides, the benefit or economic impact analysis must of necessity be done on a case-by-case basis. All relevant economic considerations raised in criticisms of the preliminary benefit analysis will be addressed prior to final action.

Content of the economic impact analyses

Based upon all the available information, a preliminary analysis will be developed. Such analysis will be organized in the following manner:

1. Identification of the major uses of the pesticide, including estimated quantities used by crop or other application.
2. Preliminary identification of the minor uses of the pesticide, including estimated quantities used by category such as lawn and garden uses and household uses.
3. Identification of registered alternative products for the uses set forth in (1) and (2) above, including an estimate of their availability.
4. Determination of the change in costs to the use of providing equivalent pesticide treatment with any available substitute products.
5. Assessment of regulation impact upon user productivity (e.g., yield per acre and/or total output) from using available substitute pesticides or from using no other pesticide.
6. If the impacts upon either user costs or productivity are significant, a qualitative assessment of the regulation's impact on production of major agricultural commodities and retail food prices of such commodities.

[FR Doc.76-15254 Filed 5-24-76;8:45 am]

[FRL 547-8; PP4G1495/T59]

RENEWAL OF A TEMPORARY TOLERANCE

2-Ethoxy-2,3-Dihydro-3,3-Dimethyl-5-Benzofuranyl Methanesulfonate

On March 11, 1976, the Environmental Protection Agency (EPA) announced (41 FR 10476) that in response to a request from the Fisons Corp., Agricultural Chemicals Div., Two Preston Court, Bedford MA 01730, the temporary tolerances which were established in response to pesticide petition (PP 4G1495) (40 FR 6389) for combined residues of the herbicide 2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and its metabolites 2 - hydroxy-2,3-dihydro-3,3-dimethyl - 5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo - 5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities sugarbeet tops at 1 part per million (ppm), sugarbeet roots at 0.1 ppm, and in the meat, fat, and meat byproducts cattle, goats, hogs, horses, and sheep at 0.03 ppm, were extended until April 4, 1976.

01284

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1623-3]

Water Quality Criteria Documents; Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of Water Quality Criteria Documents.

SUMMARY: EPA announces the availability and provides summaries of water quality criteria documents for 64 toxic pollutants or pollutant categories. These criteria are published pursuant to section 304(a)(1) of the Clean Water Act.

AVAILABILITY OF DOCUMENTS: Summaries of both aquatic-based and health-based criteria from the documents are published below. Copies of the complete documents for individual pollutants may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650). A list of the NTIS publication order numbers for all 64 criteria documents is published below. These documents are also available for public inspection and copying during normal business hours at: Public Information Reference Unit, U.S. Environmental Protection Agency, Room 2404 (rear), 401 M St., S.W., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services. Copies of these documents are also available for review in the EPA Regional Office libraries.

Copies of the documents are not available from the EPA office listed below. Requests sent to that office will be forwarded to NTIS or returned to the sender.

1. Acenaphthene, PB81-117269.
2. Acrolein, PB81-117277.
3. Acrylonitrile, PB81-117285.
4. Aldrin/Dieldrin, PB81-117301.
5. Antimony, PB81-117319.
6. Arsenic, PB81-117327.
7. Asbestos, PB81-117335.
8. Benzene, PB81-117293.
9. Benzidine, PB81-117343.
10. Beryllium, PB81-117350.
11. Cadmium, PB81-117368.
12. Carbon Tetrachloride, PB81-117376.
13. Chlordane, PB81-117384.
14. Chlorinated benzenes, PB81-117392.
15. Chlorinated ethanes, PB81-117400.
16. Chloroalkyl ethers, PB81-117418.
17. Chlorinated naphthalene, PB81-117426.
18. Chlorinated phenols, PB81-117434.
19. Chloroform, PB81-117442.
20. 2-chlorophenol, PB81-117459.
21. Chromium, PB81-117467.
22. Copper, PB81-117475.
23. Cyanides, PB81-117483.
24. DDT, PB81-117491.
25. Dichlorobenzenes, PB81-117509.
26. Dichlorobenzidine, PB81-117517.
27. Dichloroethylenes, PB81-117525.
28. 2,4-dichlorophenol, PB81-117533.
29. Dichloropropanes/propenes, PB81-117541.
30. 2,4-dimethylphenol, PB81-117558.
31. Dinitrotoluene, PB81-117566.
32. Diphenylhydrazine, PB81-117731.
33. Endosulfan, PB81-117574.
34. Endrin, PB81-117582.
35. Ethylbenzene, PB81-117590.
36. Fluoranthene, PB81-117608.
37. Haloethers, PB81-117616.
38. Halomethanes, PB81-117624.
39. Heptachlor, PB81-117632.
40. Hexachlorobutadiene, PB81-117640.
41. Hexachlorocyclohexane, PB81-117657.
42. Hexachlorocyclopentadiene, PB81-117665.
43. Isophorone, PB81-117673.
44. Lead, PB81-117681.
45. Mercury, PB81-117699.
46. Naphthalene, PB81-117707.
47. Nickel, PB81-117715.
48. Nitrobenzene, PB81-117723.
49. Nitrophenols, PB81-117749.
50. Nitrosamines, PB81-117756.
51. Pentachlorophenol, PB81-117764.
52. Phenol, PB81-117772.
53. Phthalate esters, PB81-117780.
54. Polychlorinated biphenyls (PCBs), PB81-117798.
55. Polynuclear aromatic hydrocarbons, PB81-117806.
56. Selenium, PB81-117814.
57. Silver, PB81-117822.
58. Tetrachloroethylene, PB81-117830.
59. Thallium, PB81-117848.
60. Toluene, PB81-117855.
61. Toxaphene, PB81-117863.
62. Trichloroethylene, PB81-117871.
63. Vinyl chloride, PB81-117889.
64. Zinc, PB81-117897.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Gostomski, Criteria and Standards Division (WH-585), United States Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 245-3042.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 304(a)(1) of the Clean Water Act, 33 U.S.C. 1314(a)(1), EPA is required to periodically review and publish criteria for water quality accurately reflecting the latest scientific knowledge:

(A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including groundwater, (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

EPA is today announcing the availability of criteria documents for 64 of the 65 pollutants designated as toxic under section 307(a)(1) of the Act. The document on TCDD (Dioxin) will be published within the next month after review of recent studies. Criteria for the section 307(a)(1) toxic pollutants being published today will replace the criteria for those same pollutants found in the EPA publication, *Quality Criteria for Water*, (the "Red Book.") Criteria for all other pollutants and water constituents found in the "Red Book" remain valid. The criteria published today have been derived using revised methodologies for determining pollutant concentrations that will, when not exceeded, reasonably protect human health and aquatic life. Draft criteria documents were made available for public comment (44 FR 15926, March 15, 1979, 44 FR 43660, July 25, 1979, 44 FR 56628, October 1, 1979). These final criteria have been derived after consideration of all comments received.

These criteria documents are also issued in satisfaction of the Settlement Agreement in *Natural Resources Defense Council, et al.* v. *Train*, 8 E.R.C. 2120 (1976), modified, 12 E.R.C. 1833 (D.D.C. 1979). Pursuant to paragraph 11 of that agreement, EPA is required to publish criteria documents for the 65 pollutants which Congress, in the 1977 amendments to the Act, designated as toxic under section 307(a)(1). These documents contain recommended maximum permissible pollutant concentrations consistent with the protection of aquatic organisms, human health, and some recreational activities. Although paragraph 11 imposes certain obligations on the Agency, it does not create additional authority.

The Development of Water Quality Criteria

Section 304(a)(1) criteria contain two essential types of information: (1) discussions of available scientific data on the effects of pollutants on public health and welfare, aquatic life and recreation, and (2) quantitative concentrations or qualitative assessments of the pollutants in water which will generally ensure water

quality adequate to support a specified water use. Under section 304(a)(1), these criteria are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Criteria values do not reflect considerations of economic or technological feasibility.

Publication of water quality criteria of this type has been an ongoing process which EPA, and its predecessor Agency, the Federal Water Pollution Control Administration, have been engaged in since 1968. At that time the first Federal compilation of water quality criteria, the so-called "Green Book" *(Water Quality Criteria)*, was published. As now, these criteria contained both narrative discussions of the environmental effects of pollutants on a range of possible uses and concentrations of pollutants necessary to support these uses. Since that time, water quality criteria have been revised and expanded with publication of the "Blue Book" *(Water Quality Criteria 1972)* in 1973 and the "Red Book" *(Quality Criteria for Water)* in 1976.

Since publication of the Red Book there have been substantial changes in EPA's approach to assessing scientific data and deriving section 304(a)(1) criteria. Previous criteria were derived from a limited data base. For many pollutants, an aquatic life criterion was derived by multiplying the lowest concentration known to have acute lethal effect on half of a test group of an aquatic species (the LC50 value) by an application factor in order to protect against chronic effects. If data showed a substance to be bioaccumulative or to have other significant long-term effects, a factor was used to reduce the indicated concentrations to a level presumed to be protective. Criteria for the protection of human health were similarly derived by considering the pollutants' acute, chronic, and bioaccumulative effects on non-human mammals and humans.

Although a continuation of the process of criteria development, the criteria published today were derived using revised methodologies (Guidelines) for calculating the impact of pollutants on human health and aquatic organisms. These Guidelines consist of systematic methods for assessing valid and appropriate data concerning acute and chronic adverse effects of pollutants on aquatic organisms, non-human mammals, and humans. By use of these data in prescribed ways, criteria are formulated to protect aquatic life and human health from exposure to the pollutants. For some pollutants, bioconcentration properties are used to formulate criteria protective of aquatic life uses. For almost all of the pollutants, bioconcentration properties are used to assess the relative extent of human exposure to the pollutant either directly through ingestion of water or indirectly through consumption of aquatic organisms. Human health criteria for carcinogens are presented as incremental risks to man associated with specific concentrations of the pollutant in ambient water. The Guidelines used to derive criteria protective of aquatic life and human health are fully described in appendices B and C, respectively, of this Notice.

The Agency believes that these Guidelines provide criteria which more accurately reflect the effects of these pollutants on human health and on aquatic organisms and their uses. They are based on a more rational and consistent approach for using scientific data. These Guidelines were developed by EPA scientists in consultation with scientists from outside the Agency and they have been subjected to intensive public comment.

Neither the Guidelines nor the criteria are considered inflexible doctrine. Even at this time, EPA is taking action to employ the resources of peer review groups, including the Science Advisory Board, to evaluate recently published data, and EPA is conducting its own evaluation of new data to determine whether revisions to the criteria documents would be warranted.

The criteria published today are based solely on the effect of a single pollutant. However, pollutants in combination may have different effects because of synergistic, additive, or antagonistic properties. It is impossible in these documents to quantify the combined effects of these pollutants, and persons using criteria should be aware that site-specific analysis of actual combinations of pollutants may be necessary to give more precise indications of the actual environmental impacts of a discharge.

Relationship of the Section 304(a)(1) Criteria to Regulatory Programs

Section 304(a)(1) criteria are not rules and they have no regulatory inpact. Rather, these criteria present scientific data and guidance on the enviromental effect of pollutants which can be useful to derive regulatory requirements based on considerations of water quality impacts. Under the Clean Water Act, these regulatory requirements may include the promulgation of water quality-based effluent limitations under section 302, water quality standards under section 303, or toxic pollutant effluent standards under section 307. States are encouraged to begin to modify or, if necessary, develop new programs necessary to support the implementation of regulatory controls for toxic pollutants. As appropriate, States may incorporate criteria for toxic pollutants, based on this guidance, into their water quality standards.

Section 304(a)(1) criteria have been most closely associated with the development of State water quality standards, and the "Red Book" values have, in the past, been the basis for EPA's assessments of the adequacy of State requirements. However, EPA is now completing a major review of its water quality standards policies and regulations. After consideration of comments received on an Advance Notice of Proposed Rulemaking (43 FR 29588, July 10, 1978) and the draft criteria documents, the Agency intends to propose, by the end of this year, a revised water quality standards regulation which will clarify the Agency's position on a number of significant standards issues.

With the publication of these criteria, however, it is appropriate to discuss EPA's current thinking on standards issues relating to their use. This discussion does not establish new regulatory requirements and is intended as guidance on the possible uses of these criteria and an indication of future rulemaking the Agency may undertake. No substantive requirements will be established without further opportunity for public comment.

Water Quality Standards

Section 303 of the Clean Water Act provides that water quality standards be developed for all surface waters. A water quality standard consists basically of two parts: (1) A "designated use" for which the water body is to be protected (such as "agricultural," "recreation" or "fish and wildlife"), and (2) "criteria" which are numerical pollutant concentration limits or narrative statements necessary to preserve or achieve the designated use. A water quality standard is developed through State or Federal rulemaking proceedings and must be translated into enforceable effluent limitations in a point source (NPDES) permit or may form the basis of best management practices applicable to nonpoint sources under section 208 of the Act.

Relationship of Section 304(a)(1) Criteria to the Criteria Component of State Water Quality Standards:

In the ANPRM, EPA announced a policy of "presumptive applicability" for

section 304(a)(1) criteria codified in the "Red Book." Presumptive applicability meant that a State had to adopt a criterion for a particular water quality parameter at least as stringent as the recommendation in the Red Book unless the State was able to justify a less stringent criterion based on: natural background conditions, more recent scientific evidence, or local, site-specific information. EPA is rescinding the policy of presumptive applicability because it has proven to be too inflexible in actual practice.

Although the section 304(a)(1) criteria represent a reasonable estimate of pollutant concentrations consistent with the maintenance of designated water uses, States may appropriately modify these values to reflect local conditions. In certain circumstances, the criteria may not accurately reflect the toxicity of a pollutant because of the effect of local water quality characteristics or varying sensitivities of local populations. For example, in some cases, ecosystem adaptation may enable a viable, balanced aquatic population to exist in waters with high natural background levels of certain pollutants. Similarly, certain compounds may be more or less toxic in some waters because of differences in alkalinity, temperature, hardness, and other factors.

Methods for adjusting the section 304(a)(1) criteria to reflect these local differences are discussed below.

Relationship of Section 304(a)(1) Criteria to Designated Water Uses:

The criteria published today can be used to support the designated uses which are generally found in State standards. The following section discusses the relationship between the criteria and individual use classifications. Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use should be applied.

1. *Recreation:* Recreational uses of water include such activities as swimming, wading, boating and fishing. Although insufficient data exist on the effects of toxic pollutants resulting from exposure through such primary contact as swimming, section 304(a)(1) criteria based on human health effects may be used to support this designated use where fishing is included in the State definition of "recreation." In this situation only the portion of the criterion based on fish consumption should be used.

2. *Protection and Propagation of Fish and Other Aquatic Life:* The section 304(a)(1) criteria based on toxicity to aquatic life may be used directly to support this designated use.

3. *Agricultural and Industrial Uses:* The section 304(a)(1) criteria were not specifically developed to reflect the impact of pollutants on agricultural and industrial uses. However, the criteria developed for human health and aquatic life are sufficiently stringent to protect these other uses. States may establish criteria specifically designed to protect these uses.

4. *Public Water Supply:* The drinking water exposure component of the human health effects criteria can apply directly to this use classification or may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control, and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of toxic pollutants in finished ("end-of-tap") drinking water. A brief description of relevant sections of this Act is necessary to explain how the SDWA will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water.

Pursuant to section 1412 of the SDWA, EPA has promulgated "National Interim Primary Drinking Water Standards" for certain organic and inorganic substances. These standards establish "maximum contaminant levels" ("MCLs") which specify the maximum permissible level of a contaminant in water which may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also technological and economic feasibility of the contaminants' removal from the supply. EPA is required to establish revised primary drinking water regulations based on the effects of a contaminant on human health, and include treatment capability, monitoring availability, and costs. Under Section 1401(1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water which may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "end of tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria may be analogous to the recommended maximum contaminant levels (RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allows an adequate margin of safety". RMCLs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the RMCLs. Specific mandates of the SDWA such as the consideration of multi-media exposure, as well as different methods for setting maximum contaminant levels under the two Acts, may result in differences between the two numbers.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment and the fact that only a relatively small number of MCLs have been developed, ambient water criteria may be used by the States as a supplement to SDWA regulations. States will have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria or controls more stringent than these three to protect against the effects of toxic pollutants by ingestion from drinking water.

For untreated drinking water supplies, States may control toxics in the ambient water through either use of MCLs (if they exist for the pollutants of concern), section 304(a)(1) human health effects criteria, or a more strigent contaminant level than the former two options.

For treated drinking water supplies serving less than 25 people, States may choose toxics control through application of MCLs (if they exist for the pollutants of concern and are attainable by the type of treatment) in the finished drinking water. States also have the options to control toxics in the ambient water by choosing section 304(a)(1,) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment procedure reduces the level of pollutants, or a more stringent contaminant level than the former three options.

For treated drinking water supplies serving 25 people or greater, States *must* control toxics down to levels at least as stringent as MCLs (where they exist for

the pollutants of concern) in the finished drinking water. However, States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment process reduces the level of pollutants, or a more stringent contaminant level than the former three options.

Inclusion of Specific Pollutants in State Standards:

To date, EPA has not required that a State address any specific pollutant in its standards. Although all States have established standards for most conventional pollutants, the treatment of toxic pollutants has been much less extensive. In the ANPRM, EPA suggested a policy under which States would be required to address a set of pollutants and incorporate specific toxic pollutant criteria into water quality standards. If the State failed to incorporate these criteria, EPA would promulgate the standards based upon these criteria pursuant to section 303(c)(4)(B).

In the forthcoming proposed revision to the water quality standard regulations, a significant change in policy will be proposed relating to the incorporation of certain pollutants in State water quality standards. This proposal will differ from the proposal made in the ANPRM. The ANPRM proposed an EPA-published list of pollutants for which States would have had to develop water quality standards. This list might have contained some (or all) of the 65 toxic pollutants. However, the revised water quality standards regulation will propose a process by which EPA will assist States in identifying specific toxic pollutants required for assessment for possible inclusion in State water quality standards. For these pollutants, States will have the option of adopting the published criteria or of adjusting those criteria based on site-specific analysis.

These pollutants would generally represent the greatest threat to sustaining a healthy, balanced ecosystem in water bodies or to human health due to exposure directly or indirectly from water. EPA is currently developing a process to determine which pollutants a State must assess for possible inclusion in its water quality standards. Relevant factors might include the toxicity of the pollutant, the frequency and concentration of its discharge, its geographical distribution, the breadth of data underlying the scientific assessment of its aquatic life and human health effects, and the technological and economic capacity to control the discharge of the pollutant. For some of the pollutants, all States may be required to assess them for possible inclusion in their standards. For others, assessment would be restricted to States or limited to specific water bodies where the pollutants pose a particular site-specific problem.

Criteria Modification Process

Flexibility is available in the application of these and any other valid water quality criteria to regulatory programs. Although in some cases they may be used by the States as developed, the criteria may be modified to refect local environmental conditions and human exposure patterns before incorporation into programs such as water quality standards. If significant impacts of site-specific water quality conditions in the toxicities of pollutants can be demonstrated or significantly different exposure patterns of these pollutants to humans can be shown, section 304(a)(1) criteria may be modified to reflect these local conditions. The term "local" may refer to any appropriate geographic area where common aquatic environmental conditions or exposure patterns exist. Thus, "local" may signify a Statewide, regional, river reach, or entire river basin area. On the other hand, the criteria of some pollutants might be applicable nationwide without the need for adaptation to reflect local conditions. The degree of toxicity toward aquatic organisms and humans characteristic of these pollutants would not change significantly due to local water quality conditions.

EPA is examining a series of environmental factors or water quality parameters which might realistically be expected to affect the laboratory-derived water quality criterion recommendation for a specific pollutant. Factors such as hardness, pH, suspended solids, types of aquatic organisms present, etc. could impact on the chemical's effect in the aquatic environment. Therefore, local information can be assembled and analyzed to adjust the criterion recommendation if necessary.

The Guidelines for deriving criteria for the protection of aquatic life suggest several approaches for modifying the criteria. First, toxicity data, both acute and chronic, for local species could be substituted for some or all of the species used in deriving criteria for the water quality standard. The minimum data requirements should still be fulfilled in calculating a revised criterion. Second, criteria may be specifically tailored to a local water body by use of data from toxicity tests performed with that ambient water. A procedure such as this would account for local environmental conditions in formulating a criterion relevant to the local water body. Third, site-specific water quality characteristics resulting in either enhancement or mitigation of aquatic life toxicity for the pollutant could be factored into final formulation of the criterion. Finally, the criteria may be made more stringent to ensure protection of an individual species not otherwise adequately protected by any of the three modification procedures previously mentioned.

EPA does not intend to have States assess every local stream segment and lake in the country on an individual basis before determining if an adjustment is necessary. Rather, it is envisioned that water bodies having similar hydrological, chemical, physical, and biological properties will be grouped for the purpose of criteria adjustment. The purpose of this effort is to assist States in adapting the section 304(a) criteria to local conditions where needed, thereby precluding the setting of arbitrary and perhaps unnecessarily stringent or underprotective criteria in a water body. In all cases, EPA will still be required, pursuant to section 303(c), to determine whether the State water quality standards are consistent with the goals of the Act, including a determination of whether State-established criteria are adequate to support a designated use.

Criteria for the Protection of Aquatic Life

Interpretation of the Criteria

The aquatic life criteria issued today are summarized in Appendix A of this Federal Register notice. Criteria have been formulated by applying a set of Guidelines to a data base for each pollutant. The criteria for the protection of aquatic life specify pollutant concentrations which, if not exceeded, should protect most, but not necessarily all, aquatic life and its uses. The Guidelines specify that criteria should be based on an array of data from organisms, both plant and animal, occupying various trophic levels. Based on these data, criteria can be derived which should be adequate to protect the types of organisms necessary to support an aquatic community.

The Guidelines are not designed to derive criteria which will protect all life stages of all species under all conditions. Generally some life stage of one or more tested species, and

probably some untested species, will have sensitivities below the maximum value or the 24-hour average under some conditions and would be adversely affected if the highest allowable pollutant concentrations and the worst conditions existed for a long time. In actual practice, such a situation is not likely to occur and thus the aquatic community as a whole will normally be protected if the criteria are not exceeded. In any aquatic community there is a wide range of individual species sensitivities to the effects of toxic pollutants. A criterion adequate to protect the most susceptible life stage of the most sensitive species would in many cases be more stringent than necessary to protect the overall aquatic community.

The aquatic life criteria specify both maximum and 24-hour average values. The combination of the two values is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity and bioconcentration without being as restrictive as a one-number criterion would have to be to provide the same amount of protection. A time period of 24 hours was chosen in order to ensure that concentrations not reach harmful levels for unacceptably long periods. Averaging for longer periods, such as a week or a month for example, could permit high concentrations to persist long enough to produce significant adverse effects. A 24-hour period was chosen instead of a slightly longer or shorter period in recognition of daily fluctuations in waste discharges and of the influence of daily cycles of sunlight and darkness and temperature on both pollutants and aquatic organisms.

The maximum value, which is derived from acute toxicity data, prevents significant risk of adverse impact to organisms exposed to concentrations above the 24-hour average. Merely specifying the average value over a specified time period is insufficient because concentrations of chemicals higher than the average value can kill or cause irreparable damage in short periods. Furthermore, for some chemicals the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed. The two-number criterion is intended to describe the highest average ambient water concentration which will produce a water quality generally suited to the maintenance of aquatic life while restricting the extent and duration of the excursions over that average to levels which will not cause harm. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

Since some substances may be more toxic in freshwater than in saltwater, or vice versa, provision is made for deriving separate water quality criteria for freshwater and for saltwater for each substance. However, for some substances sufficient data may not be available to derive one or both of these criteria using the Guidelines.

Specific aquatic life criteria have not been developed for all of the 65 toxic pollutants. In those cases where there were insufficient data to allow the derivation of a criterion, narrative descriptions of apparent threshold levels for acute and/or chronic effects based on the available data are presented. These descriptions are intended to convey a sense of the degree of toxicity of the pollutant in the absence of a criterion recommendation.

Summary of the Aquatic Life Guidelines

The Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and its Uses were developed to describe an objective, internally consistent, and appropriate way of ensuring that water quality criteria for aquatic life would provide, on the average, a reasonable amount of protection without an unreasonable amount of overprotection or underprotection. The resulting criteria are not intended to provide 100 percent protection of all species and all uses of aquatic life all of the time, but they are intended to protect most species in a balanced, healthy aquatic community. The Guidelines are published as Appendix B of this Notice. Responses to public comments on these Guidelines are attached as Appendix D.

Minimum data requirements are identified in four areas: acute toxicity to animals (eight data points), chronic toxicity to animals (three data points), toxicity to plants, and residues. Guidance is also given for discarding poor quality data.

Data on acute toxicity are needed for a variety of fish and invertebrate species and are used to derive a Final Acute Value. By taking into account the number and relative sensitivities of the tested species, the Final Acute Value is designed to protect most, but not necessarily all, of the tested and untested species.

Data on chronic toxicity to animals can be used to derive a Final Chronic Value by two different means. If chronic values are available for a specified number and array of species, a final chronic value can be calculated directly. If not, an acute-chronic ratio is derived and then used with the Final Acute Value to obtain the Final Chronic Value.

The Final Plant Value is obtained by selecting the lowest plant toxicity value based on measured concentrations.

The Final Residue Value is intended to protect wildlife which consume aquatic organisms and the marketability of aquatic organisms. Protection of the marketability of aquatic organisms is, in actuality, protection of a use of that water body ("commercial fishery"). Two kinds of data are necessary to calculate the Final Residue Value: a bioconcentration factor (BCF) and a maximum permissible tissue concentration, which can be an FDA action level or can be the result of a chronic wildlife feeding study. For lipid soluble pollutants, the BCF is normalized for percent lipids and then the Final Residue Value is calculated by dividing the maximum permissible tissue concentration by the normalized BCF and by an appropriate percent lipid value. BCFs are normalized for percent lipids since the BCF measured for any individual aquatic species is generally proportional to the percent lipids in that species.

If sufficient data are available to demonstrate that one or more of the final values should be related to a water quality characteristic, such as salinity, hardness, or suspended solids, the final value(s) are expressed as a function of that characteristic.

After the four final values (Final Acute Value, Final Chronic Value, Final Plant Value, and Final Residue Value) have been obtained, the criterion is established with the Final Acute Value becoming the maximum value and the lowest of the other three values becoming the 24-hour average value. All of the data used to calculate the four final values and any additional pertinent information are then reviewed to determine if the criterion is reasonable. If sound scientific evidence indicates that the criterion should be raised or lowered, appropriate changes are made as necessary.

The present Guidelines have been revised from the earlier published versions (43 FR 21506, May 18, 1978; 43 FR 29028, July 5, 1978; 44 FR 15926, March 15, 1979). Details have been added in many places and the concept of a minimum data base has been incorporated. In addition, three adjustment factors and the species sensitivity factor have been deleted. These modifications were the result of the Agency's analysis of public comments and comments received from the Science Advisory Board on earlier

versions of the Guidelines. These comments and the Resultant modifications are addressed fully in Appendix D to this notice.

Criteria for the Protection of Human Health

Interpretation of the Human Health Criteria

The human health criteria issued today are summarized in Appendix A of this Federal Register notice. Criteria for the protection of human health are presented for 62 of the 65 pollutants based on their carcinogenic, toxic, or organoleptic (taste and odor) properties. The meanings and practical uses of the criteria values are distinctly different depending on the properties on which they are based.

The objective of the health assessment portions of the criteria documents is to estimate ambient water concentrations which, in the case of non-carcinogens, prevent adverse health effects in humans, and in the case of suspect or proven carcinogens, represent various levels of incremental cancer risk.

Health assessments typically contain discussions of four elements: Exposure, pharmacokinetics, toxic effects, and criterion formulation.

The exposure section summarizes information on exposure routes: ingestion directly from water, indirectly from consumption of aquatic organisms found in ambient water, other dietary sources, inhalation, and dermal contact. Exposure assumptions are used to derive human health criteria. Most criteria are based solely on exposure from consumption of water containing a specified concentration of a toxic pollutant and through consumption of aquatic organisms which are assumed to have bioconcentrated pollutants from the water in which they live. Other multimedia routes of exposure such as air, non-aquatic diet, or dermal are not factored into the criterion formulation for the vast majority of pollutants due to lack of data. The criteria are calculated using the combined aquatic exposure pathway and also using the aquatic organism ingestion exposure route alone. In criteria reflecting both the water consumption and aquatic organism ingestion routes of exposure, the relative exposure contribution varies with the propensity of a pollutant to bioconcentrate, with the consumption of aquatic organisms becoming more important as the bioconcentration factor (BCF) increases. As additional information on total exposure is assembled for pollutants for which criteria reflect only the two specified aquatic exposure routes, adjustments in water concentration values may be made. The Agency intends to publish guidance which will permit the States to identify significantly different exposure patterns for their populations. If warranted by the demonstration of significantly different exposure patterns, this will become an element of a process to adapt/modify human health-based criteria to local conditions, somewhat analogous to the aquatic life criteria modification process discussed previously. It is anticipated that States at their discretion will be able to set appropriate human health criteria based on this process.

The pharmacokinetics section reviews data on absorption, distribution, metabolism, and excretion to assess the biochemical fate of the compounds in the human and animal system. The toxic effects section reviews data on acute, subacute, and chronic toxicity, synergistic and antagonistic effects, and specific information on mutagenicity, teratogenicity, and carcinogenicity. From this review, the toxic effect to be protected against is identified taking into account the quality, quantity, and weight of evidence characteristic of the data. The criterion formulation section reviews the highlights of the text and specifies a rationale for criterion development and the mathematical derivation of the criterion number.

Within the limitations of time and resources, current published information of significance was incorporated into the human health assessments. Review articles and reports were used for data evaluation and synthesis. Scientific judgment was exercised in reviewing and evaluating the data in each criteria document and in identifying the adverse effects for which protective criteria were published.

Specific health-based criteria are developed only if a weight of evidence supports the occurrence of the toxic effect and if dose/response data exist from which criteria can be estimated.

Criteria for suspect or proven carcinogens are presented as concentrations in water associated with a range of incremental cancer risks to man. Criteria for non-carcinogens represent levels at which exposure to a single chemical is not anticipated to produce adverse effects in man. In a few cases, organoleptic (taste and odor) data form the basis for the criterion. While this type of criterion does not represent a value which directly affects human health, it is presented as an estimate of the level of a pollutant that will not produce unpleasant taste or odor either directly from water consumption or indirectly by consumption of aquatic organisms found in ambient waters. A criterion developed in this manner is judged to be as useful as other types of criteria in protecting designated water uses. In addition, where data are available, toxicity-based criteria are also presented for pollutants with derived organoleptic criteria. The choice of criteria used in water quality standards for these pollutants will depend upon the designated use to be protected. In the case of a multiple use water body, the criterion protecting the most sensitive use will be applied. Finally, for several pollutants no criteria are recommended due to a lack of information sufficient for quantitative criterion formulation.

Risk Extrapolation

Because methods do not now exist to establish the presence of a threshold for carcinogenic effects, EPA's policy is that there is no scientific basis for estimating "safe" levels for carcinogens. The criteria for carcinogens, therefore, state that the recommended concentration for maximum protection of human health is zero. In addition, the Agency has presented a range of concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5} (one additional case of cancer in populations ranging from ten million to 100,000, respectively). Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Summary of the Human Health Guidelines

The health assessments and corresponding criteria published today were derived based on *Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents* (the Guidelines) developed by EPA's Office of Reserch and Development. The estimation of health risks associated with human exposure to environmental pollutants requires predicting the effect of low doses for up to a lifetime in duration. A combination of epidemiological and animal dose/response data is considered the preferred basis for quantitative criterion derivation. The complete Guidelines are presented as Appendix C. Major issues associated with these Guidelines and responses to public comments are presented as Appendix E.

No-effect (non-carcinogen) or specified risk (carcinogen) concentrations were estimated by extrapolation from animal toxicity or

human epidemiology studies using the following basic exposure assumptions: a 70-kilogram male person (*Report of the Task Group on Reference Man*, International Commission for Radiation Protection, November 23, 1957) as the exposed individual; the average daily consumption of freshwater and estuarine fish and shellfish products equal to 6.5 grams/day; and the average ingestion of two liters/day of water (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977). Criteria based on these assumptions are estimated to be protective of an adult male who experiences average exposure conditions.

Two basic methods were used to formulate health criteria, depending on whether the prominent adverse effect was cancer or other toxic manifestations. The following sections detail these methods.

Carcinogens

Extrapolation of cancer responses from high to low doses and subsequent risk estimation from animal data is performed using a linearized multi-stage model. This procedure is flexible enough to fit all monotonically-increasing dose response data, since it incorporates several adjustable parameters. The multi-stage model is a linear non-threshold model as was the "one-hit" model originally used in the proposed criteria documents. The linearized multi-stage model and its characteristics are described fully in Appendix C. The linear non-threshold concept has been endorsed by the four agencies in the Interagency Regulatory Liaison Group and is less likely to underestimate risk at the low doses typical of environmental exposure than other models that could be used. Because of the uncertainties associated with dose response, animal-to-human extrapolation and other unknown factors, because of the use of average exposure assumptions, and because of the serious public health consequences that could result if risk were underestimated, EPA believes that it is prudent to use conservative methods to estimate risk in the water quality criteria program. The linearized multistage model is more systematic and invokes fewer arbitrary assumptions than the "one-hit" procedure previously used.

It should be noted that extrapolation models provide estimates of risk since a varitey of assumptions are built into any model. Models using widely different assumptions may produce estimates ranging over several orders of magnitude. Since there is at present no way to demonstrate the scientific validity of any model, the use of risk extrapolation models is a subject of debate in the scientific community. However, risk extrapolation is generally recognized as the only tool available at this time for estimating the magnitude of health hazards associated with non-threshold toxicants and has been endorsed by numerous Federal agencies and scientific organizations, including EPA's Carcinogen Assessment Group, the National Academy of Sciences, and the Interagency Regulatory Liaison Group as a useful means of assessing the risks of exposure to various carcinogenic pollutants.

Non-Carcinogens

Health criteria based on toxic effects of pollutants other than carcinogenicity are estimates of concentrations which are not expected to produce adverse effects in humans. They are based upon Acceptable Daily Intake (ADI) levels and are generally derived using no-observed-adverse-effect-level (NOAEL) data from animal studies although human data are used wherever available. The ADI is calculated using safety factors to account for uncertainties inherent in extrapolation from animal to man. In accordance with the National Research Council recommendations (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977), safety factors of 10, 100, or 1,000 are used depending on the quality and quantity of data. In some instances extrapolations are made from inhalation studies or limits to approximate a human response from ingestion using the Stokinger-Woodward model (Journal of American Water Works Association, 1958). Calculations of criteria from ADIs are made using the standard exposure assumptions (2 liters of water, 6.5 grams of edible aquatic products, and an average body weight of 70 kg).

Dated: October 24, 1980.

Douglas M. Costle,

Administrator.

Appendix A—Summary of Water Quality Criteria

Acenaphthene

Freshwater Aquatic Life

The available data for acenaphthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,700 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acenaphthene to sensitive freshwater aquatic animals but toxicity to freshwater algae occur at concentrations as low as 520 μg/l.

Saltwater Aquatic Life

The available data for acenaphthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 970 and 710 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 500 μg/l.

Human Health

Sufficient data is not available for acenaphthene to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Acrolein

Freshwater Aquatic Life

The available data for acrolein indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 68 and 21 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for acrolein indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 55 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acrolein to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of acrolein ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 320 μg/l.

For the protection of human health from the toxic properties of acrolein ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 780 μg/l.

Acrylonitrile

Freshwater Aquatic Life

The available data for acrylonitrile indicate that acute toxicity to freshwater aquatic life occurs at concentrations as

low as 7,550 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of acrylonitrile to sensitive freshwater aquatic life but mortality occurs at concentrations as low as 2,600 μg/l with a fish species exposed for 30 days.

Saltwater Aquatic Life

Only one saltwater species has been tested with acrylonitrile and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of acrylonitrile through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .58 μg/l, .058 μg/l and .006 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 6.5 μg/l, .65 μg/l, and .065 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Aldrin-Dieldrin

Dieldrin

Freshwater Aquatic Life

For dieldrin the criterion to protect fresh water aquatic life as derived using the Guidelines is 0.0019 μg/l as a 24-hour average and the concentration should not exceed 2.5 μg/l at any time.

Saltwater Aquatic Life

For dieldrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0019 μg/l as a 24-hour average and the concentration should not exceed 0.71 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dieldrin through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .71 ng/l, .071 ng/l, and .0071 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .76 ng/l, .076 ng/l, and .0076 ng/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Aldrin

Freshwater Aquatic Life

For freshwater aquatic life the concentration of aldrin should not exceed 3.0 μg/l at any time. No data are available concerning the chronic toxicity of aldrin to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of aldrin should not exceed 1.3 μg/l at any time. No data are available concerning the chronic toxicity of aldrin to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of aldrin through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .74 ng/1, .074 ng/1, and .0074 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .79 ng/1, .079 ng/1, and .0079 ng/1, respectively. Other concentrations respresenting different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Antimony

Freshwater Aquatic Life

The available data for antimony indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 9,000 and 1,600 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 610 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been adequately tested with antimony, and no statement can be made concerning acute or chronic toxicity.

Human Health

For the protection of human health from the toxic properties of antimony ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 146 μg/l.

For the protection of human health from the toxic properties of antimony ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 45,000 μg/l.

Arsenic

Freshwater Aquatic Life

For freshwater aquatic life the concentration of total recoverable trivalent inorganic arsenic should not exceed 440 μg/l at any time. Short-term effects on embryos and larvae of aquatic vertebrate species have been shown to occur at concentrations as low as 40 μg/l.

Saltwater Aquatic Life

The available data for total recoverable trivalent inorganic arsenic indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 508 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trivalent inorganic arsenic to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of arsenic through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are

estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 22 ng/l, 2.2 ng/l, and .22 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 175 ng/l, 17.5 ng/l, and 1.75 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Asbestos

Freshwater Aquatic Life

No freshwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of asbestos through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 300,000 fibers/1,30,000 fibers/1, and 3,000 fibers/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzene

Freshwater Aquatic Life

The available data for benzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,300 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for benzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of benzene to sensitive saltwater aquatic life, but adverse effects occur at concentrations as low as 700 μg/l with a fish species exposed for 168 days.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.6 μg/l, .66 μg/l, and .066 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 400 μg/l, 40.0 μg/l, and 4.0 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzidine

Freshwater Aquatic Life

The available data for benzidine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzidine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with benzidine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.2 ng/1, .12 ng/1, and .01 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.3 ng/1, .53 ng/1, and .05 ng/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Beryllium

Freshwater Aquatic Life

The available data for beryllium indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 130 and 5.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Hardness has a substantial effect on acute toxicity.

Salt water Aquatic Life

The limited saltwater data base available for beryllium does not permit any statement concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beryllium through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 37 ng/l, 3.7 ng/l, and .37 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 641 ng/l, 64.1 ng/l, and 6.41 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Cadmium

Freshwater Aquatic Life

For total recoverable cadmium the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given

by $e^{(1.05\ [\ln(\text{hardness})]-8.63)}$ as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by $e^{(1.05\ [\ln(\text{hardness})]-3.73)}$ at any time. For example, a hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.012, 0.025, and 0.051 μg/l, respectively, and the concentration of total recoverable cadmium should not exceed 1.5, 3.0 and 6.3 μg/l, respectively, at any time.

Saltwater Aquatic Life

For total recoverable cadmium the criterion to protect saltwater aquatic life as derived using the Guidelines is 4.5 μg/l as a 24-hour average and the concentration should not exceed 59 μg/l at any time.

Human Health

The ambient water quality criterion for cadmium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Carbon Tetrachloride

Freshwater Aquatic Life

The available date for carbon tetrachloride indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 35,200 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of carbon tetrachloride to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for carbon tetrachloride indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 50,000 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No data are available concerning the chronic toxicity of carbon tetrachloride to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of carbon tetrachloride through ingestion of contaminated water and contaminated aquatic organisms the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.0μg/l, .40 μg/l, and .04 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 69.4 μg/l, 6.94 μg/l, and .69 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Chlordane

Freshwater Aquatic Life

For chlordane the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0043 μg/l as a 24-hour average and the concentration should not exceed 2.4 μg/l at any time.

Saltwater Aquatic Life

For chlordane the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0040 μg/l as a 24-hour average and the concentration should not exceed 0.09 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chlordane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.6 ng/l, .46 ng/l, and .046 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 4.8 ng/l, .48 ng/l, and .048 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Chlorinated Benzenes

Freshwater Aquatic Life

The available data for chlorinated benzenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 250 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of the more toxic of the chlorinated benzenes to sensitive freshwater aquatic life but toxicity occurs at concentrations as low as 50 μg/l for a fish species exposed for 7.5 days.

Saltwater Aquatic Life

The available data for chlorinated benzenes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 160 and 129 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachlorobenzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding recommended criteria are 7.2 ng/l, .72 ng/l, and .072 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 7.4 ng/l, .74 ng/l, and .074 ng/l, respectively.

For the protection of human health from the toxic properties of 1,2,4,5-tetrachlorobenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 38 μg/l.

For the protection of human health from the toxic properties of 1,2,4,5-tetrachlorobenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

For the protection of human health from the toxic properties of pentachlorobenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of pentachlorobenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 85 μg/l.

Using the present guidelines, a satisfactory criterion cannot be derived

at this time due to the insufficiency in the available data for trichlorobenzene.

For comparison purposes, two approaches were used to derive criterion levels for monochlorobenzene. Based on available toxicity data, for the protection of public health, the derived level is 488 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Chlorinated Ethanes

Freshwater Aquatic Life

The available freshwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination, and that acute toxicity occurs at concentrations as low as 118,000 μg/l for 1,2-dichloroethane, 18,000 μg/l for two trichloroethanes, 9,320 μg/l for two tetrachloroethanes, 7,240 μg/l for pentachloroethane, and 980 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 20,000 μg/l for 1,2-dichloroethane, 9,400 μg/l for 1,1,2-trichloroethane, 2,400 μg/l for 1,1,2,2,-tetrachloroethane, 1,100 μg/l for pentachloroethane, and 540 μg/l for hexachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination and that acute toxicity to fish and invertebrate species occurs at concentrations as low as 113,000 μg/l for 1,2-dichloroethane, 31,200 μg/l for 1,1,1-trichloroethane, 9,020 μg/l for 1,1,2,2-tetrachloroethane, 390 μg/l for pentachloroethane, and 940 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 281 μg/l for pentachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-dichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 9.4 μg/l, .94 μg/l, and .094 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2,430 μg/l, 243 μg/l, and 24.3 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of 1,1,1-trichloroethane ingested through water and contaminated aquatic organism, the ambient water criterion is determined to be 18.4 mg/l.

For the protection of human health from the toxic properties of 1,1,1,-trichloroethane ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.03 g/l.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2-trichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.0 μg/l, .6 μg/l, and .06 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 418 μg/l, 41.8 μg/l, and 4.18 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2,2-tetrachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.7 μg/l, .17 μg/l, and .017 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 107 μg/l, 10.7 μg/l, and 1.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 19 μg/l, 1.9 μg/l, and .19 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 87.4 μg/l, 8.74 μg/l, and .87 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for monochloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,-dichloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,1,2-tetrachloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for pentachloroethane.

Chlorinated Naphthalenes

Freshwater Aquatic Life

The available data for chlorinated naphthalenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,600 μg/l and would occur at lower concentrations among species that are

more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated naphthalenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for chlorinated napthalenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.5 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated naphthalenes to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for chlorinated napthalenes.

Chlorinated Phenols

Freshwater Aquatic Life

The available freshwater data for chlorinated phenols indicate that toxicity generally increases with increasing chlorination, and that acute toxicity occurs at concentrations as low as 30 μg/l for 4-chloro-3-methylphenol to greater than 500,000 μg/l for other compounds. Chronic toxicity occurs at concentrations as low as 970 μg/l for 2,4,6-trichlorophenol. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated phenols indicate that toxicity generally increases with increasing chlorination and that acute toxicity occurs at concentrations as low as 440 μg/l for 2,3,5,6-tetrachlorophenol and 29,700 μg/l for 4-chlorophenol. Acute toxicity would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated phenols to sensitive saltwater aquatic life.

Human Health

Sufficient data is not available for 3-monoclilorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 4-monochlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,3-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .04 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,5-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .5 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,6-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .2 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3,4-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .3 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,3,4,6-tetrachlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

For comparison purposes, two approaches were used to derive criterion levels for 2,4,5-trichlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 2.6 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 2,4,6-trichlorophenol through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 12 μg/l, 1.2 μg/l, and .12 μg/l respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 36 μg/l, 3.6 μg/l, and .36 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 2 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2-methyl-4-chlorophenol to derive a level which would protect against any potential toxicity of this compound. Using available organoleptic data for controlling undesirable taste and odor quality of ambient water, the estimated level is 1800 μg/l. It should be

recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-4-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 3000 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-6-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Chloroalkyl Ethers

Freshwater Aquatic Life

The available data for chloroalkyl ethers indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 238,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of chloroalkyl ethers to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with any chloroalkyl ether and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis-(chloromethyl)-ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .038 ng/l, .0038 ng/l, and .00038 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.4 ng/l, 1.84 ng/l, and .184 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis (2-chloroethyl) ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .3 μg/l, .03 μg/l, and .003 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 13.6 μg/l, 1.36 μg/l, and .136 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34.7 μg/l.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 4.36 mg/l.

Chloroform

Freshwater Aquatic Life

The available data for choloroform indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 28,900 μg/l, and would occur at lower concentrations among species that are more sensitive than the three tested species. Twenty-seven-day LC50 values indicate that chronic toxicity occurs at concentrations as low as 1,240 μg/l, and could occur at lower concentrations among species or other life stages that are more sensitive than the earliest life cycle stage of the rainbow trout.

Saltwater Aquatic Life

The data base for saltwater species is limited to one test and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloroform through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.90 μg/l, .19 μg/l, and .019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

2-Chlorophenol

Freshwater Aquatic Life

The availabe data for 2-chlorophenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 4,380 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No definitive data are available concerning the chronic toxicity of 2-chlorophenol to sensitive freshwater aquatic life but flavor impairment occurs in one species of fish at concentrations as low as 2,000 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2-chlorophenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data is not available for 2-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no

demonstrated relationship to potential adverse human health effects.

Chromium

Freshwater Aquatic Life

For total recoverable hexavalent chromium the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.29 μg/l as a 24-hour average and the concentration should not exceed 21 μg/l at any time.

For freshwater aquatic life the concentration (in μg/l) of total recoverable trivalent chromium should not exceed the numerical value given by "e{1.08[ln(hardness)]+3.48)" at any time. For example, at hardnesses of 50, 100 and 200 mg/l as $CaCO_3$ the concentration of total recoverable trivalent chromium should not exceed 2,200, 4,700, and 9,900 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life occurs at concentrations as low a 44 μg/l and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

For total recoverable hexavalent chromium the criterion to protect saltwater aquatic life as derived using the Guidelines is 18 μg/l as a 24-hour average and the concentration should not exceed 1,260 μg/l at any time.

For total recoverable trivalent chromium, the availabe data indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 10,300 μg/l, and would occur at lower concentrations amoung species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trivalent chromium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of Chromium III ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 170 mg/l.

For the protection of human health from the toxic properties of Chromium III ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3433 mg/l.

The ambient water quality criterion for total Chromium VI is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Copper

Freshwater Aquatic Life

For total recoverable copper the criterion to protect freshwater aquatic life as derived using the Guidelines is 5.6 μg/l as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e{0.94[ln(hardness)]-1.23} at any time. For example, at hardnesses of 50, 100, and 200 mg/l $CaCO_3$ the concentration of total recoverable copper should not exceed 12, 22, and 43 μg/l at any time.

Saltwater Aquatic Life

For total recoverable copper the criterion to protect saltwater aquatic life as derived using the Guidelines is 4.0 μg/l as a 24-hour average and the concentration should not exceed 23 μg/l at any time.

Human Health

Sufficient data is not available for copper to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Cyanide

Freshwater Aquatic Life

For free cyanide (sum of cyanide present as HCN and CN^-, expressed as CN) the criterion to protect freshwater aquatic life as derived using the Guidelines is 3.5 μg/l as a 24-hour average and the concentration should not exceed 52 μg/l at any time.

Saltwater Aquatic Life

The available data for free cyanide (sum of cyanide present as HCN and CN^-, expressed as CN) indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 30 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. If the acute-chronic ratio for saltwater organisms is similar to that for freshwater organisms, chronic toxicity would occur at concentrations as low as 2.0 μg/l for the tested species and at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for cyanide is recommended to be identical to the existing drinking water standard which is 200 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

DDT and Metabolites

Freshwater Aquatic Life

DDT

For DDT and its metabolites the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0010 μg/l as a 24-hour average and the concentration should not exceed 1.1 μg/l at any time.

TDE

The available data for TDE indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 0.6 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of TDE to sensitive freshwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,050 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive freshwater aquatic life.

Saltwater Aquatic Life

DDT

For DDT and its metabolites the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0010 μg/l as a 24-hour average and the concentration should not exceed 0.13 μg/l at any time.

TDE

The available data for TDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 3.6 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the

chronic toxicity of TDE to sensitive saltwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 14 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of DDT through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment of an "acceptable" risk level.

Dichlorobenzenes

Freshwater Aquatic Life

The available data for dichlorobenzenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 1,120 and 763 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichlorobenzenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 1,970 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichlorobenzenes to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 400 μg/l.

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.6 mg/l.

Dichlorobenzidines

Freshwater Aquatic Life

The data base available for dichlorobenzidines and freshwater organisms is limited to one test on bioconcentration of 3,3'-dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dichlorobenzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero base on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .103 μg/l, .0103 μg/l, and .00103 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .204 μg/l, .0204 μg/l, and .00204 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Dichloroethylenes

Freshwater Aquatic Life

The available data for dichloroethylenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,600 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of dichlorethylenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for dichlorethylenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 224,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity dichloroethylenes to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1-dichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .33 μg/l, .033 μg/l, and .0033 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.5 μg/l, 1.85 μg/l, and .185 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficency in the available data for 1,2-dichloroethylene.

2,4-Dichlorophenol

Freshwater Aquatic Life

The available data for 2,4-dichlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 2,020 and 365 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive that those tested. Mortality to early life stages of one species of fish occurs at concentrations as low as 70 μg/l.

Saltwater Aquatic Life

Only one test has been conducted with saltwater organisms on 2,4-dichlorophenol and no statement can be made concerning acute or chronic toxicity.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for 2,4-dichlorophenol.

Based on available toxicity data, for the protection of public health, the derived level is 3.09 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.3 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Dichloropropanes/Dichloropropenes

Freshwater Aquatic Life

The available data for dichloropropanes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 23,000 and 5,700 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

The available data for dichloropropenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 6,060 and 244 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichloropropanes indicate that acute and chronic toxicity to saltwater aquatic life occurs at concentrations as low as 10,300 and 3,040 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

The available data for dichloropropenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low a as 790 μg/l, and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichloropropenes to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for dichloropropanes.

For the protection of human health from the toxic properties of dichloropropenes ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 87 μg/l.

For the protection of human health from the toxic properties of dichloropropenes ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 14.1 mg/l.

2,4-Dimethylphenol

Freshwater Aquatic Life

The available data for 2,4-dimethylphenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,120 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dimethylphenol to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2,4-dimethylphenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data are not available for 2,4-dimethylphenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undersirable taste and odor quality of ambient water, the estimated level is 400 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

2,4-Dinitrotoluene

Freshwater Aquatic Life

The available data for 2,4-dinitrotoluene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 330 and 230 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for 2,4-diritrotoluenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 590 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of 2,4-dinitrotoluenes to sensitive saltwater aquatic life but a decrease in algal cell numbers occurs at concentrations as low as 370 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 2,4-dinitrotoluene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.1 μg/l, 0.11 μg/l, and 0.011 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 91 μg/l, 9.1 μg/l, and 0.91 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

1,2-Diphenylhydrazine

Freshwater Aquatic Life

The available data for 1,2-diphenylhydrazine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 270 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of 1,2-diphenylhydrazine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with 1,2-diphenylhydrazine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-diphenylhydrazine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 422 ng/l, 42 ng/l, and 4 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.6 μg/l, 0.56 μg/l, and 0.056 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not

represent an Agency judgment on an "acceptable" risk level.

Endosulfan

Freshwater Aquatic Life

For endosulfan the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.056 μg/l as a 24-hour average and the concentration should not exceed 0.22 μg/l at any time.

Saltwater Aquatic Life

For endosulfan the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0087 μg/l as a 24-hour average and the concentration should not exceed 0.034 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of endosulfan ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of endosulfan ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 159 μg/l.

Endrin

Freshwater Aquatic Life

For endrin the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.18 μg/l at any time.

Saltwater Aquatic Life

For endrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.037 μg/l at any time.

Human Health

The ambient water quality criterion for endrin is recommended to be identical to the existing drinking water standard which is 1 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Ethylbenzene

Freshwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 32,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of ethylbenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 430 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of ethylbenzene to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of ethylbenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 1.4 mg/l.

For the protection of human health from the toxic properties of ethylbenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3.28 mg/l.

Fluoranthene

Freshwater Aquatic Life

The available data for fluoranthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 3980 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of fluoranthene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for fluoranthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 40 and 16 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of fluoranthene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 42 μg/l.

For the protection of human health from the toxic properties of fluoranthene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 54 μg/l.

Haloethers

Freshwater Aquatic Life

The available data for haloethers indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 360 and 122 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

No saltwater organisms have been tested with any haloether and no statement can be made concerning acute or chronic toxicity.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for haloethers.

Halomethanes

Freshwater Aquatic Life

The available data for halomethanes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of halomethanes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for halomethanes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 12,000 and 6,400 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. A decrease in algal cell numbers occurs at concentrations as low as 11,500 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloromethane, bromomethane, dichloromethane, bromodichloromethane, tribromomethane, dichlorodifluoromethane, trichlorofluoromethane, or combinations of these chemicals through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are

1.9 μg/l, 0.19 μg/l, and 0.019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Heptachlor

Freshwater Aquatic Life

For heptachlor the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0038 μg/l as a 24-hour average and the concentration should not exceed 0.52 μg/l at any time.

Saltwater Aquatic Life

For heptachlor the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0036 μg/l as a 24-hour average and the concentration should not exceed 0.053 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of heptachlor through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 2.78 ng/l, .28 ng/l, and .028 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2.85 ng/l, .29 ng/l, and .029 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Hexachlorobutadiene

Freshwater Aquatic Life

The available data for hexachlorobutadiene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 90 and 9.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for hexachlorobutadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 32 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No data are available concerning the chronic toxicity of hexachlorobutadiene to sensitive saltwater aquatic life

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachlorobutadiene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.47 μg/l, 0.45 μg/l, and 0.045 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 500 μg/l, 50 μg/l, and 5 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Hexachlorocyclohexane

Lindane

Freshwater Aquatic Life

For Lindane the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.080 μg/l as a 24-hour average and the concentration should not exceed 2.0 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of lindane should not exceed 0.16 μg/l at any time. No data are available concerning the chronic toxicity of lindane to sensitive saltwater aquatic life.

BHC

Freshwater Aquatic Life

The available date for a mixture of isomers of BHC indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of a mixture of isomers of BHC to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available date for a mixture of isomers of BHC indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 0.34 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of a mixture of isomers of BHC to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of alpha-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 92 ng/l, 9.2 ng/l, and .92 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 310 ng/l, 31.0 ng/l, and 3.1 ng/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beta-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 163 ng/l, 16.3 ng/l, and 1.63 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 547 ng/l, 54.7 ng/l, and 5.47 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not

represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tech-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 123 ng/l, 12.3 ng/l, and 1.23 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 414 ng/l, 41.4 ng/l, and 4.14 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of gamma-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentrations should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 186 ng/l, 18.6 ng/l, and 1.86 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 625 ng/l, 62.5 ng/l, 6.25 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for delta-HCH.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for epsilon-HCH.

Hexachlorocyclopentadiene

Freshwater Aquatic Life

The available data for hexachlorocyclopentadiene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 7.0 and 5.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data to hexachlorocyclopentadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.0 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of hexachlorocyclopentadiene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for hexachlorocyclopentadiene. Based on available toxicity data, for the protection of public health, the derived level is 206 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Isophorone

Freshwater Aquatic Life

The available data for isophorone indicate that acute toxicity to freshwater aquatic life ocurs at concentrations as low as 117,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for isophorone indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 12,900 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of isophorone ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 5.2 mg/l.

For the protection of human health from the toxic properties of isophorone ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 520 mg/l.

Lead

Freshwater Aquatic Life

For total recoverable lead the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(2.35[ln(hardness)]-9.48) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(1.22[ln(hardness)]-0.47) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.75, 3.8, and 20 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 74, 170, and 400 μg/l, respectively, at any time.

Saltwater Aquatic Life

The available data for total recoverable lead indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 668 and 25 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for lead is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective to human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Mercury

Freshwater Aquatic Life

For total recoverable mercury the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.00057 μg/l as a 24-hour average and the concentration should not exceed 0.0017 μg/l at any time.

Saltwater Aquatic Life

For total recoverable mercury the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.025 μg/l as a 24-hour average and the concentration should not exceed 3.7 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of mercury

ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 144 ng/l.

For the protection of human health from the toxic properties of mercury ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 146 ng/l.

Note.—These values include the consumption of freshwater, estuarine, and marine species.

Naphthalene

Freshwater Aquatic Life

The available data to naphthalene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 2,300 and 620 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for naphthalene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,350 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of naphthalene to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for naphthalene.

Nickel

Freshwater Aquatic Life

For total recoverable nickel the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(0.76 [ln (hardness)] + 1.06) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(0.76[ln (hardness)] + 4.02) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 56, 96, and 160 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 1,100, 1,800, and 3,100 μg/l, respectively, at any time.

Saltwater Aquatic Life

For total recoverable nickel the criterion to protect saltwater aquatic life as derived using the Guidelines is 7.1 μg/l as a 24-hour average and the concentration should not exceed 140 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of nickel ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13.4 μg/l.

For the protection of human health from the toxic properties of nickel ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 100 μg/l.

Nitrobenzene

Freshwater Aquatic Life

The available data for nitrobenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 27,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of nitrobenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for nitrobenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 6,680 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrobenzene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for nitrobenzene. Based on available toxicity data, for the protection of public health, the derived level is 19.8 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Nitrophenols

Freshwater Aquatic Life

The available data for nitrophenols indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 230 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrophenols to sensitive freshwater aquatic life but toxicity to one species of algae occurs at concentrations as low as 150 μg/l.

Saltwater Aquatic Life

The available data for nitrophenols indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 4,850 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrophenols to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of 2,4-dinitro-o-cresol ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13.4 μg/l.

For the protection of human health from the toxic properties of 2,4-dinitro-o-cresol ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 765 μg/l.

For the protection of human health from the toxic properties of dinitrophenol ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 70 μg/l.

For the protection of human health from the toxic properties of dinitrophenol ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 14.3 mg/l.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for mononitrophenol.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for tri-nitrophenol.

Nitrosamines

Freshwater Aquatic Life

The available data for nitrosamines indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,850 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrosamines to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for nitrosamines indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 3,300,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrosamines to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodimethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 14 ng/l, 1.4 ng/l, and .14 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 160,000 ng/l, 16,000 ng/l, and 1,600 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodiethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 ng/l, 0.8 ng/l, and 0.08 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 12,400 ng/l, 1,240 ng/l, and 124 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodi-n-butylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 64 ng/l 6.4 ng/l and .064 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,868 ng/l, 587 ng/l, and 58.7 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodiphenylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 49,000 ng/l 4,900 ng/l and 490 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 161,000 ng/l, 16,100 ng/l, and 1,610 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosopyrrolidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 160 ng/l 16.0 ng/l and 1.60 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 919,000 ng/l, 91,900 ng/l, and 9,190 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Pentachlorophenol

Freshwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 55 and 3.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 53 and 34 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for pentachlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 1.01 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phenol

Freshwater Aquatic Life

The available data for phenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 10,200 and 2,560 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phenol indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,800 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phenol to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for phenol. Based on available toxicity data, for the protection of public health, the derived level is 3.5 mg/l. Using available organoleptic data, for controlling

undesirable taste and odor quality of ambient water, the estimated level is 0.3 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phthalate Esters

Freshwater Aquatic Life

The available data for phthalate esters indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 940 and 3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phthalate esters indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2944 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phthalate esters to sensitive saltwater aquatic life but toxicity to one species of algae occurs at concentrations as low as 3.4 μg/l.

Human Health

For the protection of human health from the toxic properties of dimethyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 313 mg/l.

For the protection of human health from the toxic properties of dimethyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.9 g/l.

For the protection of human health from the toxic properties of diethyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 350 mg/l.

For the protection of human health from the toxic properties of diethyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.8 g/l.

For the protection of human health from the toxic properties of dibutyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34 mg/l.

For the protection of human health from the toxic properties of dibutyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 154 mg/l.

For the protection of human health from the toxic properties of di-2-ethylhexyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 15 mg/l.

For the protection of human health from the toxic properties of di-2-ethylhexyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 50 mg/l.

Polychlorinated Biphenyls

Freshwater Aquatic Life

For polychlorinated biphenyls the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.014 μg/l as a 24-hour average. The available data indicate that acute toxicity to freshwater aquatic life probably will only occur at concentrations above 2.0 μg/l and that the 24-hour average should provide adequate protection against acute toxicity.

Saltwater Aquatic Live

For polychlorinated biphenyls the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.030 μg/l as a 24-hour average. The available data indicate that acute toxicity to saltwater aquatic life probably will only occur at concentrations above 10 μg/l and that the 24-hour average should provide adequate protection against acute toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of PCBs through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .79 ng/l, 0.79 ng/l, and .0079 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .79 ng/l, .079 ng/l, and .0079 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Polynuclear Aromatic Hydrocarbons (PAHs)

Freshwater Aquatic Life

The limited freshwater data base available for polynuclear aromatic hydrocarbons, mostly from short-term bioconcentration studies with two compounds, does not permit a statement concerning acute or chronic toxicity.

Saltwater Aquatic Life

The available data for polynuclear aromatic hydrocarbons indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 300 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of polynuclear aromatic hydrocarbons to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of PAHs through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 28 ng/l, 2.8 ng/l, and .28 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 311 ng/l, 31.1 ng/l, and 3.11 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Selenium

Freshwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect freshwater aquatic life as derived using the Guidelines is 35 μg/l as a 24-hour average and the concentration should not exceed 260 μg/l at any time.

The available data for inorganic selenate indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 760 μg/l and would occur at lower concentrations among species that are more sensitive

than those tested. No data are available concerning the chronic toxicity of inorganic selenate to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect saltwater aquatic life as derived using the Guidelines is 54 μg/l as a 24-hour average and the concentration should not exceed 410 μg/l at any time.

No data are available concerning the toxicity of inorganic selenate to saltwater aquatic life.

Human Health

The ambient water quality criterion for selenium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Silver

Freshwater Aquatic Life

For freshwater aquatic life the concentration (in μg/l) of total recoverable silver should not exceed the numerical value given by "e[1.72(ln (hardness)-6.52)]" at any time. For example, at hardnesses of 50, 100, 200 mg/l as $CaCO_3$ the concentration of total recoverable silver should not exceed 1.2, 4.1, and 13 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life may occur at concentrations as low as 0.12 μg/l.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of total recoverable silver should not exceed 2.3 μg/l at any time. No data are available concerning the chronic toxicity of silver to sensitive saltwater aquatic life.

Human Health

The ambient water quality criterion for silver is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Tetrachloroethylene

Freshwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 5,280 and 840 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations low as 10,200 and 450 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tetrachloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 μg/l, .8 μg/l, and .08 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 88.5 μg/l, 8.85 μg/l, and .88 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Thallium

Freshwater Aquatic Life

The available data for thallium indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 1,400 and 40 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to one species of fish occurs at concentrations as low as 20 μg/l after 2,600 hours of exposure.

Saltwater Aquatic Life

The available data for thallium indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,130 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of thallium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of thallium ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13 μg/l.

For the protection of human health from the toxic properties of thallium ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

Toluene

Freshwater Aquatic Life

The available data for toluene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 17,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of toluene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for toluene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 6,300 and 5,000 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of toluene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 14.3 mg/l.

For the protection of human health from the toxic properties of toluene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 424 mg/l.

Toxaphene

Freshwater Aquatic Life

For toxaphene the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.013 μg/l as a 24-hour average and the concentration should not exceed 1.6 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of toxaphene should not exceed 0.070 μg/l at any time. No data

are available concerning the chronic toxicity of toxaphene to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of toxaphene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 7.1 ng/l, .71 ng/l, and .07 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 7.3 ng/l, .73 ng/l, and .07 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Trichloroethylene

Freshwater Aquatic Life

The available data for trichloroethylene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 45,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trichloroethylene to sensitive freshwater aquatic life but adverse behavioral effects occurs to one species at concentrations as low as 21,900 μg/l.

Saltwater Aquatic Life

The available data for trichloroethylene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trichloroethylene to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of trichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 27 μg/l, 2.7 μg/l, and .27 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 807 μg/l, 80.7 μg/l, and 8.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Vinyl Chloride

Freshwater Aquatic Life

No freshwater organisms have been tested with vinyl chloride and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with vinyl chloride and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of vinyl chloride through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 20 μg/l, 2.0 μg/l, and .2 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,246 μg/l, 525 μg/l, and 52.5 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Zinc

Freshwater Aquatic Life

For total recoverable zinc the criterion to protect freshwater aquatic life as derived using the Guidelines is 47 μg/l as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by $e^{(0.83[\ln(\text{hardness})]+1.95)}$ at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the concentration of total recoverable zinc should not exceed 180, 320, and 570 μg/l at any time.

Saltwater Aquatic Life

For total recoverable zinc the criterion to protect saltwater aquatic life as derived using the Guidelines is 58 μg/l as a 24-hour average and the concentration should not exceed 170 μg/l at any time.

Human Health

Sufficient data is not available for zinc to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 5 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have not demonstrated relationship to potential adverse human health effects.

Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses

Introduction

This version of the Guidelines provides clarifications, additional details, and technical and editorial changes in the last version published in the **Federal Register** [44 FR 15970 (March 15, 1979)]. This version incorporates changes resulting from comments on previous versions and from experience gained during U.S. EPA's use of the previous versions. Future versions of the Guidelines will incorporate new ideas and data as their usefulness is demonstrated.

Criteria may be expressed in several forms. The numerical form is commonly used, but descriptive and procedural forms can be used if numerical criteria are not possible or desirable. The purpose of these Guidelines is to describe an objective, internally consistent and appropriate way of deriving numerical water quality criteria for the protection of the uses of, as well as the presence of, aquatic organisms.

A numerical criterion might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses. Thus the Guidelines are intended to derive criteria which will protect aquatic communities by protecting most of the species and their uses most of the time, but not

necessarily all of the species all of the time. Aquatic communities can tolerate some stress and occasional adverse effects on a few species, and so total protection of all of the species all of the time is not necessary. Rather, the Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of considerable overprotection or underprotection. Within these constraints, it seems appropriate to err on the side of overprotection.

The numerical aquatic life criteria derived using the Guidelines are expressed as two numbers, rather than the traditional one number, so that the criteria can more accurately reflect toxicological and practical realities. The combination of both a maximum value and a 24-hour average value is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity to animals, toxicity to plants and bioconcentration by aquatic organisms without being as restrictive as a one-number criterion would have to be to provide the same amout of protection. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

The two-number criterion is intended to identify an average pollutant concentration which will produce a water qualtiy generally suited to the maintenance of aquatic life and its uses while restricting the extent and duration of excursions over the average so that the total exposure will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient, unless the period of time is rather short, because of concentration higher than the average value can kill or cause substantial damage in short periods. Furthermore, for some substances the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed, especially when the maximum value is not much higher than the average value. For some substances the maximum may be so much higher than the 24-hour average that in any real-world situation the maximum will never be reached if the 24-hour average is achieved. In such cases the 24-hour average will be limiting and the maximum will have no practical significance, except to indicate that elevated concentrations are acceptable as long as the 24-hour average is achieved.

These Guidelines have been developed on the assumption that the results of laboratory tests are generally useful for predicting what will happen in field situations. The resulting criteria are meant to apply to most bodies of water in the United States, except for the Great Salt Lake. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available, with at least one specific exception. This exception is the accumulation of residues of organic compounds in the siscowet subspecies of lake trout which occurs in Lake Superior and contains up to 67% fat in the fillets (Thurston, C.E., 1962, Physical Characteristics and Chemical Composition of Two Subspecies of Lake Trout, J. Fish. Res. Bd. Canada 19:39–44). Neither siscowet nor organisms in the Great Salt Lake are intentionally protected by these Guidelines because both may be too atypical.

With appropriate modifications these Guidelines can be used to derive criteria for any specified geographical area, body of water (such as the Great Salt Lake), or group of similar bodies of water. Thus with appropriate modifications the Guidelines can be used to derive national, state, or local criteria if adequate information is available concerning the effects of the substance of concern on appropriate species and their uses. However, the basic concepts described in the Guidelines should be modified only when sound scientific evidence indicates that a criterion produced using the Guidelines would probably significantly overprotect or underprotect the presence or uses of aquatic life.

Criteria produced by these Guidelines are not enforceable numbers. They may be used in developing enforceable numbers, such as water quality standards and effluent standards. However, the development of standards may take into account additional factors such as social, legal, economic, and hydrological considerations, the environmental and analytical chemistry of the substance, the extrapolation from laboratory data to field situations, and the relationship between the species for which data are available and the species which are to be protected.

Because fresh water and salt water (including both estuarine and marine waters) have basically different chemical compositions and because freshwater and saltwater species rarely inhabit the same water simultaneously, separate criteria should be derived for these two kinds of waters. However, for some substances sufficient data may not be available to allow derivation of one or both of these criteria using the Guidelines.

These Guidelines are meant to be used after a decision is made that a criterion is needed for a substance. The Guidelines do not address the rationale for making that decision. If the potential for adverse effects on aquatic life and its uses are part of the basis for deciding whether or not a criterion is needed for a substance, these Guidelines may be helpful in the collection and interpretation of relevant data.

I. Define the Substance for Which the Criterion Is To Be Derived

A. Each separate chemical which would not ionize significantly in most natural bodies of water should usually be considered a separate substance, except possibly for structurally similar organic compounds that only differ in the number and location of atoms of a specific halogen, and only exist in large quantities as commercial mixtures of the various compounds, and apparently have similar chemical, biological, and toxicological properties.

B. For chemicals, which would ionize significantly in most natural bodies of water, such as inorganic salts, organic acids and phenols, all forms that would be in chemical equilibrium should usually be considered one substance. For metals, each different valence and each different covalently bonded organometallic compound should usually be considered a separate substance.

C. The definition of the substance may also need to take into account the analytical chemistry and fate of the substance.

II. Collect and Review Available Data

A. Collect all available data on the substance concerning (1) toxicity to, and bioaccumulation by, aquatic animals and plants, (2) FDA action levels, and (3) chronic feeding studies with wildlife.

B. Discard all data that are not available in hard copy (publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. Do not assume that all published data are acceptable.

C. Discard questionable data. For example, discard data from tests for which no control treatment existed, in which too many organisms in the control treatment died or showed signs of stress or disease, or in which distilled or deionized water was used as the dilution water for aquatic organisms. Discard data on formulated mixtures and emulsifiable concentrates of the

substance of concern, but not necessarily data on technical grade material.

D. Do not use data obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations resident in—but not necessarily native to—North America. Resident North American species of fishes are defined as those listed in "A List of Common and Scientific Names of Fishes from the United States and Canada", 3rd ed., Special Publication No. 6, American Fisheries Society, Washington, D.C., 1970. Data obtained with non-resident species can be used to indicate relationships and possible problem areas, but cannot be used in the derivation of criteria.

3. Organisms that were previously exposed to significant concentrations of the test material or other pollutants.

III. Minimum Data Base

A. A minimum amount of data should be available to help ensure that each of the four major kinds of possible adverse effects receives some consideration. Results of acute and chronic toxicity tests with a reasonable number and variety of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of the numerous untested species. The requirements concerning toxicity to aquatic plants are less stringent because procedures for conducting tests with plants are not as well developed and the interpretation of the results is more questionable. Data concerning bioconcentration by aquatic organisms can only be used if other relevant data are available.

B. To derive a criterion for freshwater aquatic life, the following should be available:

1. Acute tests (see Section IV) with freshwater animals in at least eight different families provided that of the eight species:
—at least one is a salmonid fish
—at least one is a non-salmonid fish
—at least one is a planktonic crustacean
—at least one is a benthic crustacean
—at least one is a benthic insect
—at least one of the benthic species is a detritivore

2. Acute-chronic ratios (see Section VI) for at least three species of aquatic animals provided that of the three species:
—at least one is a fish
—at least one is an invertebrate
—at least one is a freshwater species (the other two may be saltwater species)

3. At least one test with a freshwater alga or a chronic test with a freshwater vascular plant (see Section VIII). If plants are among the aquatic organisms that are most sensitive to the substance, tests with more than one species should be available.

4. At least one acceptable bioconcentration factor determined with an aquatic animal species, if a maximum permissible tissue concentration is available (see Section IX).

C. To derive a criterion for saltwater aquatic life, the following should be available:

1. Acute tests (see Section IV) with saltwater animals in at least eight different families provided that of the eight species:
—at least two different fish families are included
—at least five different invertebrate families are included
—either the Mysidae or Penaeidae family or both are included
—at least one of the invertebrate families is in a phylum other than Arthropoda

2. Acute-chronic ratios (see Section VI) for at least three species of aquatic animals provided that of the three species:
—at least one is a fish
—at least one is an invertebrate
—at least one is a saltwater species (the other two may be freshwater species)

3. At least one test with a saltwater alga or a chronic test with a saltwater vascular plant (see Section VIII). If plants are among the aquatic organisms most sensitive to the substance, tests with more than one species should be available.

4. At least one acceptable bioconcentration factor determined with an aquatic animal species, if a maximum permissible tissue concentration is available (see Section IX).

D. If all the requirements of the minimum data base are met, a criterion can usually be derived, except in special cases. For example, a criterion might not be possible if the acute-chronic ratios vary greatly with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic, (see Sections V and VII), more data will be necessary.

Similarly, if the minimum data requirements are not satisfied, generally a criterion should not be derived, except in special cases. One such special case would be when less than the minimum amount of acute and chronic data are available, but the available data clearly indicate that the Final Residue Value would be substantially lower then either the Final Chronic Value or the Final Plant Value.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the substance to various species of aquatic animals are used to calculate the Final Acute Value. If acute values are available for fewer than twenty species, the Final Acute Value probably should be lower than the lowest value. On the other hand, if acute values are available for more than twenty species, the Final Acute Value probably should be higher than the lowest value, unless the most sensitive species is an important one. Although the procedure used to calculate the Final Acute Value has some limitations, it apparently is the best of the procedures currently available.

B. Acute toxicity tests should be conducted using procedures such as those described in:

ASTM Standard E 729–80, Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

ASTM Standard E 724–80, Practice for Conducting Static Acute Toxicity Tests with Larvae of Four Species of Bivalve Molluscs. American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

C. Results of acute tests in which food was added to the test solutions should not be used, because this may unnecessarily affect the results of the test.

D. Results of acute tests conducted with embryos should not be used (but see Section IV.E.2), because this is often an insensitive life stage.

E. Acute values should be based on endpoints and lengths of exposure appropriate to the life stage of the species tested. Therefore, only the following kinds of data on acute toxicity to aquatic animals should be used:

1. 48-hr EC50 values based on immobilization and 48-hr LC50 values for first-instar (less than 24 hours old) daphnids and other cladocerans, and second- or third-instar midge larvae.

2. 48- to 96-hr EC50 values based on incomplete shell development and 48- to 96-hr LC50 values for embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters, and scallops), sea urchins, lobsters, crabs, shrimps, and abalones.

3. 96-hr EC50 values based on decreased shell deposition for oysters.

4. 96-hr EC50 values on immobilization or loss of equilibrium or both and 96-hr LC50 values for aquatic animals, except for cladocerans, midges, and animals whose behavior or physiology allows them to avoid

exposure to toxicant or for whom the acute adverse effect of the exposure cannot be adequately measured. Such freshwater and saltwater animals include air-breathing molluscs, unionid clams, operculate snails, and bivalve molluscs, except for some species that cannot "close up" and thus prevent exposure to toxicant, such as the bay scallop (*Argopecten irradians*).

F. For the use of LC50 or EC50 values for durations shorter and longer than those listed above, see Section X.

G. If the acute toxicity of the substance to aquatic animals has been shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Acute Equation should be derived based on that water quality characteristic. Go to Section V.

H. If the acute toxicity of the substance has not been adequately shown to be related to a water quality characteristic, for each species for which at least one acute value is available, calculate the geometric mean of the results of all flow-through tests in which the toxicant concentrations were measured. For a species for which no such result is available, calculate the geometric mean of all available acute values, i.e., results of flow-through tests in which the toxicant concentrations were not measured and results of static and renewal tests based on initial total toxicant concentrations.

Note.—The geometric mean of N numbers is obtained by taking the N^{th} root of the product of N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers can also be calculated as the square root of the product of the two numbers. The geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithm used.

I. Count the number=N of species for which a species mean acute value is available.

J. Order the species mean acute values from low to high. Take the common logarithms of the N values (log mean values).

K. The intervals (cell widths) for the lower cumulative proportion calculations are 0.11 common log units apart, starting from the lowest log value. The value of 0.11 is an estimate of average precision and was calculated from replicate species acute values.

L. Starting with the lowest log mean value, separate the N values into intervals (or cells) calculated in Step IV. K.

M. Calculate cumulative proportions for each non-empty interval by summing the number of values in the present and all lower intervals and dividing by N. These calculations only need to be done for the first three non-empty intervals (or cells).

N. Calculate the arithmetic mean of the log mean values for each of the three intervals.

O. Using the two interval mean acute values and cumulative proportions closest to 0.05, linearly extrapolate or interpolate to the 0.05 log concentration. The Final Acute Value is the antilog of the 0.05 concentration.

In other words, where

Prop(1) and conc(1) are the cumulative proportion and mean log value for the lowest non-empty interval.

Prop(2) and conc(2) are the cumulative proportion and mean log value for the second lowest non-empty interval.

A=Slope of the cumulative proportions

B=The 0.05 log value

Then:

$A=[0.05-Prop(1)]/[Prop(2)-Prop(1)]$

$B=conc(1)+A\,[conc(2)-conc(1)]$

Final Acute Value=10^B

P. If for an important species, such as a recreationally or commercially important species, the geometric mean of the acute values from flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Value, then that geometric mean should be used as the Final Acute Value.

Q. Go to Section VI.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly affected by a water quality characteristic, this effect can be taken into account as described below. Pooled regression analysis should produce similar results, although data available for individual species would be weighted differently.

B. For each species for which comparable acute toxicity values are available at two or more different values of a water quality characteristic which apparently affects toxicity, perform a least squares regression of the natural logarithms of the acute toxicity values on the natural logarithms of the values of the water quality characteristic. [Natural logarithms [logarithms to the base e, denoted as ln] are used herein merely because they are easier to use on some hand calculators and computers than common logarithms [logarithms to the base 10]. Consistent use of either will produce the same result.] No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section.

C. Determine whether or not each acute slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If meaningful slopes are not available for at least two species or if the available slopes are not similar, return to Section IV. H., using the results of tests conducted under conditions and in water similar to those commonly used for toxicity tests with the species.

D. Calculate the mean acute slope (V) as the arithmetic average of all the meaningful acute slopes for individual species.

E. For each species calculate the geometric mean (W) of the acute toxicity values and the geometric mean (X) of the related values of the water quality characteristic.

F. For each species calculate the logarithmic intercept (Y) using the equation: $Y=\ln W-V(\ln X)$.

G. For each species calculate the species mean acute intercept as the antilog of Y.

H. Obtain the Final Acute Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

I. If for an important species, such as a recreationally or commercially important species, the intercept calculated only from results of flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Intercept, then that intercept should be used as the Final Acute Intercept.

J. The Final Acute Equation is written as $e^{(V[\ln(\text{water quality characteristic})]+\ln Z)}$, where V=mean acute slope and Z=Final Acute Intercept.

VI. Final Chronic Value

A. The Final Chronic Value can be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio, depending on the data available. In some cases it will not be possible to calculate a Final Chronic Value.

B. Use only the results of flow-through (except renewal is acceptable for

daphnids) chronic tests in which the concentrations of toxicant in the test solutions were measured.

C. Do not use the results of any chronic test in which survival, growth, or reproduction among the controls was unacceptably low.

D. Chronic values should be based on endpoints and lengths of exposure appropriate to the species. Therefore, only the results of the following kinds of chronic toxicity tests should be used:

1. Life-cycle toxicity tests consisting of exposures of each of several groups of individuals of a species to a different concentration of the toxicant throughout a life cycle. To ensure that all life stages and life processes are exposed, the test should begin with embryos or newly hatched young less than 48 hours old (less than 24 hours old for daphnids), continue through maturation and reproduction, and with fish should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, embryos spawned per female, embryo viability (salmonids only) and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female.

2. Partial life-cycle toxicity tests consisting of exposures of each of several groups of individuals of a species of fish to a different concentration of the toxicant through most portions of a life cycle. Partial life-cycle tests are conducted with fish species that require more than a year to reach sexual maturity, so that the test can be completed in less than 15 months, but still expose all major life stages to the toxicant. Exposure to the toxicant begins with immature juveniles at least 2 months prior to active gonad development, continues through maturation and reproduction, and ends not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, embryos spawned per female, embryo viability (salmonids only) and hatchability.

3. Early-life-stage toxicity tests consisting of 28- to 32-days (60 days post-hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

E. Do not use the results of an early-life-stage test if results of a life-cycle or partial life-cycle test with the same species are available.

F. A chronic value is obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test. A lower chronic limit is the highest tested concentration (1) in an acceptable chronic test, (2) which did not cause the occurrence (which was statistically significantly different from the control at $p=0.05$) of a specified adverse effect, and (3) below which no tested concentration caused such an occurrence. An upper chronic limit is the lowest tested concentration (1) in an acceptable chronic test, (2) which did cause the occurrence (which was statistically significantly different from the control at $p=0.05$) of a specified adverse effect and (3) above which all tested concentrations caused such an occurrence.

Note.—Various authors have used a variety of terms and definitions to interpret the results of chronic tests, so reported results should be reviewed carefully.

G. If the chronic toxicity of the substance to aquatic animals has been adequately shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Chronic Equation should be derived based on that water quality characteristic. Go to Section VII.

H. If chronic values are available for eight species as described in Section III. B.1 or III. C.1, a species mean chronic value should be calculated for each species for which at least one chronic value is available by calculating the geometric mean of all the chronic values for the species. The Final Chronic Value should then be obtained using the procedures described in Section IV. I–O. Then go to Section VI. M.

I. For each chronic value for which at least one appropriate acute value is available, calculate an acute-chronic ratio, using for the numerator the arithmetic average of the results of all standard flow-through acute tests in which the concentrations were measured and which are from the same study as the chronic test. If such an acute test is not available, use for the numerator the results of a standard acute test performed at the same laboratory with the same species, toxicant and dilution water. If no such acute test is available, use the species mean acute value for the numerator.

Note.—If the acute toxicity or chronic toxicity or both of the substance have been adequately shown to be related to a water quality characteristic, the numerator and the denominator must be based on tests performed in the same water.

J. For each species, calcuate the species mean acute-chronic ratio as the geometric mean of all the acute-chronic ratios available for that species.

K. For some substances the species mean acute-chronic ratio seems to be the same for all species, but for other substances the ratio seems to increase as the species mean acute value increases. Thus the Final Acute-Chronic Ratio can be obtained in two ways, depending on the data available.

1. If no major trend is apparent and the acute-chronic ratios for a number of species are within a factor of ten, the final Acute-Chronic Ratio should be calculated as the geometric mean of all the species mean acute-chronic ratios available for both freshwater and saltwater species.

2. If the species mean acute-chronic ratio seems to increase as the species mean acute value increases, the value of the acute-chronic ratio for species whose acute values are close to the Final Acute Value should be chosen as the Final Acute-Chronic Ratio.

L. Calculate the Final Chronic Value by dividing the Final Acute Value by the Final Acute-Chronic Ratio.

M. If the species mean chronic value of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Value, then that species mean chronic value should be used as the Final Chronic Value.

N. Go to Section VIII.

VII. Final Chronic Equation

A. For each species for which comparable chronic toxicity values are available at two or more different values of a water quality characteristic which apparently affects chronic toxicity, perform a least squares regression of the natural logarithms of the chronic toxicity values on the natural logarithms of the water quality characteristic values. No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in Section V.

B. Determine whether or not each chronic slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If a

meaningful chronic slope is not available for at least one species, return to Section VI. H.

C. Calculate the mean chronic slope (L) as the arithmetic average of all the meaningful chronic slopes for individual species.

D. For each species calculate the geometric mean (M) of the toxicity values and the geometric mean (P) of the related values of the water quality characteristic.

E. For each species calculate the logarithmic intercept (Q) using the equation: $Q = \ln M - L(\ln P)$.

F. For each species calculate a species mean chronic intercept as the antilog of Q.

G. Obtain the Final Chronic Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

H. If the species mean chronic intercept of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Intercept, then that species mean chronic intercept should be used as the Final Chronic Intercept.

I. The Final Chronic Equation is written as $e^{(L[\ln(\text{Water quality characteristic})]+\ln R)}$, where L = mean chronic slope and R = Final Chronic Intercept.

VIII. Final Plant Value

A. Appropriate measures of the toxicity of the substance to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals.

B. A value is a concentration which decreased growth (as measured by dry weight, chlorophyll, etc.) in a 96-hr or longer test with an alga or in a chronic test with an aquatic vascular plant.

C. Obtain the Final Plant Value by selecting the lowest plant value from a test in which the toxicant concentrations were measured.

IX. Final Residue Value

A. The Final Residue Value is derived in order to (1) prevent commercially or recreationally important aquatic organisms from exceeding relevant FDA action levels and (2) protect wildlife, including fishes and birds, that eat aquatic organisms from demonstrated adverse effects. A residue value is calculated by dividing a maximum permissible tissue concentration by an appropriate bioconcentration factor (BCF), where the BCF is the quotient of the concentration of a substance in all or part of an aquatic organism divided by the concentration in water to which the organism has been exposed. A maximum permissible tissue concentration is either (1) an action level from the FDA Administrative Guidelines Manual for fish oil or for the edible portion of fish or shellfish, or (2) a maximum acceptable dietary intake based on observations on survival, growth or reproduction in a chronic wildlife feeding study. If no maximum permissible tissue concentration is available, go to Section X because no Final Residue Value can be derived.

B. 1. A BCF determined in a laboratory test should be used only if it was calculated based on measured concentrations of the substance in the test solution and was based on an exposure that continued until either steady-state or 28-days was reached. Steady-state is reached when the BCF does not change significantly over a period of time, such as two days or 16 percent of the length of the exposure, whichever is longer. If a steady-state BCF is not available for a species, the available BCF for the longest exposure over 28 days should be used for that species.

2. A BCF from a field exposure should be used only when it is known that the concentration of the substance was reasonably constant for a long enough period of time over the range of territory inhabited by the organisms.

3. If BCF values from field exposures are consistently lower or higher than those from laboratory exposures, then only those values from field exposures should be used if possible.

4. A BCF should be calculated based on the concentration of the substance and its metabolites, which are structurally similar and are not much more soluble in water than the parent compound, in appropriate tissue and should be corrected for the concentration in the organisms at the beginning of the test.

5. A BCF value obtained from a laboratory or field exposure that caused an observable adverse effect on the test organism may be used only if it is similar to that obtained with unaffected organisms at lower concentrations in the same test.

6. Whenever a BCF is determined for a lipid-soluble substance, the percent lipids should also be determined in the tissue for which the BCF was calculated.

C. A BCF calculated using dry tissue weights must be converted to a wet tissue weight basis by multiplying the dry weight BCF value by 0.1 for plankton and by 0.2 for individual species of fishes and invertebrates.

Note.—The values of 0.2 and 0.1 were derived from data published in:

McDiffett, W. F., 1970. Ecology 51:975–988.
Brocksen, R. W., et al. 1968. J. Wildlife Management 32:52–75.
Cummins, K. W., et al. 1973. Ecology 54: 336–345.
Pesticide Analytical Manual, Volume I. Food and Drug Administration, 1969.
Love, R. M., 1957. In The Physiology of Fishes, Vol. I, M. E. Brown, ed. Academic Press, New York. p. 411.
Ruttner, F., 1963. Fundamentals of Limnology. 3rd ed. Trans. by D. G. Frey and F. E. J. Fry. Univ. of Toronto Press, Toronto.

Some additional values can be found in:

Sculthorpe, C. D., 1967. The Biology of Aquatic Vascular Plants. Arnold Publishing Ltd., London.

D. If enough pertinent data exist, several residue values can be calculated by dividing maximum permissible tissue concentrations by appropriate BCF values.

1. For each available maximum acceptable dietary intake derived from a chronic feeding study with wildlife, including birds and aquatic organisms, the appropriate BCF is based on the whole body of aquatic species which constitute or represent a major portion of the diet of the tested wildlife species.

2. For an FDA action level, the appropriate BCF is the highest geometric mean species BCF for the edible portion (muscle for decapods, muscle with or without skin for fishes, adductor muscle for scallops and total living tissue for other bivalve molluscs) of a consumed species. The highest species BCF is used because FDA action levels are applied on a species-by-species basis.

E. For lipid-soluble substances, it may be possible to calculate additional residue values. Because steady-state BCF values for a lipid-soluble chemical seem to be proportional to percent lipids from one tissue to another and from one species to another, extrapolations can be made from tested tissues or species to untested tissues or species on the basis of percent lipids.

1. For each BCF for which the percent lipids is known for the same tissue for which the BCF was measured, the BCF should be normalized to a one percent lipid basis by dividing the BCF by the percent lipids. This adjustment to a one percent lipid basis makes all the measured BCF values comparable regardless of the species or tissue for which the BCF was measured.

2. Calculate the geometric mean normalized BCF. Data for both saltwater and freshwater species can be used to determine the mean normalized BCF, because the normalized BCF seems to be about the same for both kinds of organisms.

3. Residue values can then be calculated by dividing the maximum permissible tissue concentrations by the mean normalized BCF and by a percent lipids value appropriate to the maximum permissible tissue concentration, *i.e.*,

$$\text{Residue Value} = \frac{\text{(maximum permissible tissue concentration)}}{\text{(mean normalized BCF)(appropriate percent lipids)}}$$

a. For an FDA action level for fish oil, the appropriate percent lipids value is 100.

b. For an FDA action level for fish, the appropriate percent lipids value is 15 for freshwater criteria and 16 for saltwater criteria because FDA action levels are applied on a species-by-species basis to commonly consumed species. The edible portion of the freshwater lake trout averages about 15 percent lipids, and the edible portion of the saltwater Atlantic herring averages about 16 percent lipids (Sidwell, V. D., et al. 1974 Composition of the Edible Portion of Raw (Fresh or Frozen) Crustaceans, Finfish, and Mollusks. I. Protein, Fat, Moisture, Ash, Carbohydrate, Energy Value, and Cholesterol. Marine Fisheries Review 36:21–35).

c. For a maximum acceptable dietary intake derived from a chronic feeding study with wildlife, the appropriate percent lipids is the percent lipids of an aquatic species or group of aquatic species which constitute a major portion of the diet of the wildlife species.

F. The Final Residue Value is obtained by selecting the lowest of the available residue values. It should be noted that in many cases the Final Residue Value will not be low enough. For example, a residue value calculated from an FDA action level would result in an average concentration in the edible portion of a fatty species that is at the action level. On the average half of the individuals of the species would have concentrations above the FDA action level. Also, the results of many chronic feeding studies are concentrations that cause adverse effects.

X. Other Data

Pertinent information that could not be used in earlier sections may be available concerning adverse effects on aquatic organisms and their uses. The most important of these are data on flavor impairment, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically significant. Especially important are data for species for which no other data are available. Data from behavioral, micorcosm, field, and physiological studies may also be available.

XI. Criterion

A. The criterion consists of two concentrations, one that should not be exceeded on the average in a 24-hour period and one that should not be exceeded at any time during the 24-hour period. This two-number criterion is intended to identify water quality conditions that should protect aquatic life and its uses from acute and chronic adverse effects of both cumulative and noncumulative substances without being as restrictive as a one-number criterion would have to be to provide the same degree of protection.

B. The maximum concentration is the Final Acute Value or is obtained from the Final Acute Equation.

C. The 24-hour average concentration is obtained from the Final Chronic Value, the Final Plant Value, and the Final Residue Value by selecting the lowest available value, unless other data (see Section X) from tests in which the toxicant concentrations were measured show that a lower value should be used. If toxicity is related to a water quality characteristic, the 24-hour average concentration is obtained from the Final Chronic Equation, the Final Plant Value, and the Final Residue Value by selecting the one that results in the lowest concentrations in the normal range of the water quality characteristic, unless other data (see Section X) from tests in which the toxicant concentrations were measured show that a lower value should be used.

D. The criterion is (the 24-hour average concentration) as a 24-hour average and the concentration should not exceed (the maximum concentration) at any time.

XII. Review

A. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of the Guidelines.

These Guidelines were written by Charles E. Stephan, Donald I. Mount, David J. Hansen, John H. Gentile, Gary A. Chapman and William A. Brungs of the U.S.E.P.A. Environmental Research Laboratories in Corvallis, Oregon, Duluth, Minnesota, Gulf Breeze, Florida, and Narragansett, Rhode Island. Numerous other people, many of whom do not work for U.S.E.P.A., provided assistance and suggestions.

Appendix C–Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents

I. Objective

The objective of the health effect assessment chapters of the ambient water criteria documents is to estimate ambient water concentrations which do not represent a significant risk to the public. These assessments should constitute a review of all relevant information on individual chemicals or chemical classes in order to derive criteria that represent, in the case of suspect or proven carcinogens, various levels of incremental cancer risk, or, in the case of other pollutants, estimates of no-effect levels.

Ideally, ambient water quality criteria should represent levels for compounds in ambient water that do not pose a hazard to the human population. However, in any realistic assessment of human health hazard, a fundamental distinction must be made between absolute safety and the recognition of some risk. Criteria for absolute safety would have to be based on detailed knowledge of dose-response relationships in humans, including all sources of chemical exposure, the types of toxic effects elicited, the existence of thresholds for the toxic effects, the significance of toxicant interactions, and the variances of sensitivities and exposure levels within the human population. In practice, such absolute criteria cannot be established because of deficiencies in both the available data and the means of interpreting this information. Consequently, the individual human health effects chapters propose criteria which minimize or specify the potential risk of adverse human effects due to substances in ambient water. Potential social or economic costs and benefits are not considered in the formulation of the criteria.

II. Types of Criteria

Ambient water quality criteria are based on three types of biological endpoints: carcinogenicity, toxicity (i.e., all adverse effects other than cancer), and organoleptic effects.

For the purpose of deriving ambient water quality criteria, carcinogenicity is regarded as a non-threshold phenomenon. Using this assumption, "safe" or "no effect" levels for carcinogens cannot be established because even extremely small doses must be assumed to elicit a finite increase in the incidence of the response. Consequently, water quality

criteria for carcinogens are presented as a range of pollutant concentrations associated with corresponding incremental risks.

For compounds which do not manifest any apparent carcinogenic effect, the threshold assumption is used in deriving a criterion. This assumption is based on the premise that a physiological reserve capacity exists within the organism which is thought to be depleted before clinical disease ensues. Alternatively, it may be assumed that the rate of damage will be insignificant over the life span of the organism. Thus, ambient water quality criteria are derived for non-carcinogenic chemicals, and presumably result in no observable-adverse-effect levels (NOAELs) in the exposed human population.

In some instances, criteria are based on organoleptic characteristics, i.e., thresholds for taste or odor. Such criteria are established when insufficient information is available on toxicologic effects or when the estimate of the level of the pollutant in ambient water based on organoleptic effects is lower than the level calculated from toxicologic data. It should be recognized that criteria based solely on organoleptic effects do not necessarily represent approximations of acceptable risk levels for human health.

Several ambient water quality criteria documents deal with classes of compounds which include chemicals exhibiting varying degrees of structural similarity. Because prediction of biological effects based solely on structural parameters is difficult, the derivation of compound-specific criteria is preferable to a class criterion. A compound-specific criterion is defined as a level derived from data on each individual subject compound that does not represent a significant risk to the public. For some chemical classes, however, a compound-specific criterion cannot be derived for each member of a class. In such instances, it is sometimes justifiable to derive a class criterion in which available data on one member of a class may be used to estimate criteria for other chemicals of the class because a sufficient data base is not available for those compounds.

For some chemicals and chemical classes, the data base was judged to be insufficient for the derivation of a criterion. In those cases, deficiencies in the available information are detailed.

III. Approach

The human health effects chapters attempt to summarize all information on the individual chemicals or classes of chemicals which might be useful in the risk assessment process to develop water quality criteria. Although primary emphasis is placed on identifying epidemiologic and toxicologic data, these assessments typically contain discussions on four topics: existing levels of human exposure, pharmacokinetics, toxic effects, and criterion formulation.

For all documents, an attempt is made to include the known relevant information. Review articles and reports are often used in the process of data evaluation and synthesis. Scientific judgment is exercised in the review and evaluation of the data in each document and in the identification of the adverse effects against which protective criteria are sought. In addition, each of these documents is reviewed by a peer committee of scientists familiar with the specific compound(s). These work groups evaluate the quality of the available data, the completeness of the data summary, and the validity of the derived criterion.

In the analysis and organization of the data, an attempt is made to be consistent with respect to the format and the application of acceptable scientific principles. Evaluation procedures used in the hazard assessment process follow the principles outlined by the National Academy of Sciences in *Drinking Water and Health* (1977) and the guidelines of the Carcinogen Assessment Group of the U.S. EPA.

A. Exposure

The exposure section of the health effects chapters reviews known information on current levels of human exposure to the individual pollutant from all sources. Much of the data was obtained from monitoring studies of air, water, food, soil, and human or animal tissue residues. The major purpose of this section is to provide background information on the contribution of water exposure relative to all other sources. Consequently, the exposure section includes subsections reviewing different routes of exposure including water and food ingestion, inhalation, and dermal contact.

Information on exposure can be valuable in developing and assessing a water quality criterion. In these documents exposure from consumption of contaminated water and contaminated fish and shellfish products is used in criterion formulation. Data for all modes of exposure are useful in relating total intake to the expected contribution from contaminated water, fish, and shellfish. In addition, information for all routes of exposure, not limited to drinking water and fish and shellfish ingestion, can be used to justify or assess the feasibility of the formulation of criteria for ambient water.

The use of fish consumption as an exposure factor requires the quantitation of pollutant residues in the edible portions of the ingested species. Accordingly, bioconcentration factors (BCFs) are used to relate pollutant residues in aquatic organisms to the pollutant concentration in the ambient waters in which they reside.

To estimate the average per capita intake of a pollutant due to consumption of contaminated fish and shellfish the results of a diet survey were analyzed to calculate the average consumption of freshwater and estuarine fish and shellfish (U.S. EPA, 1980). A species is considered to be a consumed freshwater or estuarine fish and shellfish species if at some stage in its life cycle, it is harvested from fresh or estuarine water for human consumption in significant quantities (Stephan, 1980).

Three different procedures are used to estimate the weighted average BCF depending upon the lipid solubility of the chemical and the availability of bioconcentration data.

For lipid-soluble compounds, the average BCF is calculated from the weighted average percent lipids in the edible portions of consumed freshwater and estuarine fish and shellfish which was calculated from data on consumption of each species and its corresponding percent lipids to be 3.0 percent (Stephan, 1980). Because the steady-state BCFs for lipid-soluble compounds are proportional to percent lipids, bioconcentration factors for fish and shellfish can be adjusted to the average percent lipids for aquatic organisms consumed by Americans. For many lipid-soluble pollutants, there exists at least one BCF for which the percent lipid value was measured for the tissues for which the BCF is determined.

With 3.0 percent as the weighted average percent lipids for freshwater and estuarine fish and shellfish in the average diet, a BCF, and a corresponding percent lipid value, the weighted average bioconcentration factor can be calculated.

Example:

Weighted average percent lipids for average diet = 3.0 percent

Measured BCF of 17 for trichloroethylene with bluegills at 4.8 percent lipids

Weighted average BCF for average diet equals

$$17 \times \frac{3.0\%}{4.8\%} = 10.6$$

As an estimate, 10.6 is used for the BCF.

In those cases where an appropriate bioconcentration factor is not available, the equation "Log BCF=(0.85 Log P)-0.70" can be used (Veith, et al. 1979) to estimate the BCF for aquatic organisms containing about 7.6 percent lipids (Veith, 1980) from the octanol/water partition coefficient P. An adjustment for percent lipids in the average diet versus 7.6 percent is made in order to derive the weighted average bioconcentration factor.

For non-lipid-soluble compounds, the available BCFs for the edible portion of consumed freshwater and estuarine fish and shellfish are weighted according to consumption factors to determine a weighted BCF representative of the average diet.

B. Pharmacokinetics

This section summarizes the available information on the absorption, distribution, metabolism, and elimination of the compound(s) in humans and experimental mammals. Conceptually, such information is useful in validation of inter- and intraspecies extrapolations, and in characterizing the modes of toxic action. Sufficient information on absorption and excretion in animals, together with a knowledge of ambient concentrations in water, food, and air, could be useful in estimating body burdens of chemicals in the human population. Distribution data which suggest target organs or tissues are desirable for interspecies comparison techniques. In terms of the derivation of criteria, pharmacokinetic data are essential to estimate equivalent oral doses based on data from inhalation or other routes of exposure.

C. Effects

This section summarizes information on biological effects in both humans and experimental mammals resulting in: acute, subacute, and chronic toxicity, synergism and/or antagonism, teratogenicity, mutagenicity, or carcinogenicity.

The major goal of this section is to survey the suitability of the data for use in assessment of hazard and to determine which biological end-point, i.e., non-threshold, threshold, or organoleptic, should be selected for use in criterion formulation.

Because this section attempts to assess potential human health effects, data on documented human effects are thoroughly evaluated. However, several factors inherent in human epidemiological studies usually preclude the use of such data in generating water quality criteria. These problems, as summarized by the National Academy of Sciences (NAS, 1977) are as follows:

1. Epidemiology cannot tell what effects a material will have until after humans have been exposed. One must not conduct what might be hazardous experiments on man.

2. If exposure has been ubiquitous, it may be impossible to assess the effects of a material, because there is no unexposed control group. Statistics of morbidity obtained before use of a new material can sometimes be useful, but when latent periods are variable and times of introduction and removal of materials overlap, historical data on chronic effects are usually unsatisfactory.

3. It is usually difficult to determine doses in human exposures.

4. Usually, it is hard to identify small changes in common effects, which may nonetheless be important if the population is large.

5. Interactions in a "nature-designed" experiment usually cannot be controlled.

Although these problems often prevent the use of epidemiological data in quantitative risk assessments, qualitative similarities or differences between documented effects in humans and observed effects in experimental mammals are extremely useful in testing the validity of animal-to-man extrapolations. Consequently, in each case, an attempt is made to identify and utilize both epidemiologic and animal dose-response data. Criteria derived from such a confirmed data base are considered to be reliable.

The decision to establish a criterion based on a non-threshold model is made after evaluating all available information on carcinogenicity and supportive information on mutagenicity. The approach and conditions for the qualitative decision of carcinogenicity are outlined in the U.S. EPA Interim Cancer Guidelines (41 FR 21402), in a report by Albert, et al. (1977), and in the Interagency Regulatory Liaison Group (IRLG) guidelines on carcinogenic risks (IRLG, 1979). It is assumed that a substance which induces a statistically significant carcinogenic response in animals has the capacity to cause cancer in humans. A chemical which has not induced a significant cancer response in humans or experimental animals is not identified as a carcinogen, even though its metabolites or close structural analogues might induce a carcinogenic response or it was shown to be mutagenic in an *in vitro* system.

It is recognized that some potential human carcinogens may not be identified by the guidelines given above. For example, compounds for which there is plausible but weak qualitative evidence of carcinogenicity in experimental animal systems (such as data from mouse skin painting or strain A mouse pulmonary adenoma) would be included in this category. The derivation of a criterion for human consumption from these studies in not valid, regardless of the qualitative outcome. In addition, there are certain compounds (e.g., nickel and beryllium) which were shown to be carcinogenic in humans after inhalation exposure by chemical form, but have induced thus far no response in animals or humans via ingesting their soluble salts. Nevertheless, a non-threshold criterion is developed for beryllium because tumors have been produced in animals at a site removed from the site of administration; in contrast, a threshold criterion is recommended for nickel because there is no evidence of tumors at sites distant resulting from administration of nickel solutions by either ingestion or injection.

For those compounds which were not reported to induce carcinogenic effects or for those compounds for which carcinogenic data are lacking or insufficient, an attempt is made to estimate a no-effect level. In many respects, the hazard evaluation from these studies is similar to that of bioassays for carcinogenicity. In order to more closely approximate conditions of human exposure, preference is given to chronic studies involving oral exposures in water or diet over a significant portion of the animal life span. Greatest confidence is placed in those studies which demonstrate dose-related adverse effects as well as no-effect levels.

There is considerable variability in the biological endpoints used to define a no-effect level. They may range from gross effects, such as mortality, to more subtle biochemical, physiological, or pathological changes. Teratogenicity, reproductive impairment, and behavioral effects are significant toxic consequences of environmental contamination. In instances where carcinogenic or other chronic effects occur at exposure levels below those causing teratogenicity, reproductive impairment, or behavioral effects, the former are used in deriving the criterion. For most of the compounds evaluated thus far, teratogenicity and reproductive impairment occur at doses near maximum tolerated levels with dose administration schedules well above estimated environmental exposure levels. Moreover, information on behavioral effects, which could be of

significance, is not available for most of the compounds under study. Consequently, most NOAELs derived from chronic studies are based either on gross toxic effects or on effects directly related to functional impairment or defined pathological lesions.

For compounds on which adequate chronic toxicity studies are not available, studies on acute and subacute toxicity assume greater significance. Acute toxicity studies usually involve single exposures at lethal or near lethal doses. Subacute studies often involve exposures exceeding 10 percent of the life span of the test organism, e.g., 90 days for the rat with an average life span of 30 months. Such studies are useful in establishing the nature of the compound's toxic effects and other parameters of compound toxicity, such as target organ effects, metabolic behavior, physiological/biochemical effects, and patterns of retention and tissue distribution. The utility of acute and subacute studies in deriving environmentally meaningful NOELs is uncertain, although McNamara (1976) has developed application factors for such derivations.

In some cases where adequate data are not available from studies utilizing oral routes of administration, no-effect levels for oral exposures may be estimated from dermal or inhalation studies. Such estimates involve approximations of the total dose administered based on assumptions about breathing rates and/or magnitude of absorption.

D. Criterion Rationale

This section reviews existing standards for the chemical(s), summarizes data on current levels of human exposure, attempts to identify special groups at risk, and defines the basis for the recommended criterion.

Information on existing standards is included primarily for comparison with the proposed water quality criteria. Some of the present standards, such as those recommended by the Occupational Safety and Health Administration (OSHA) or the American Conference of Governmental Industrial Hygienists (ACGIH), are based on toxicologic data but are intended as acceptable levels for occupational rather than environmental exposure. Other levels, such as those recommended by the National Academy of Sciences in *Drinking Water and Health* (1977) or in the U.S. EPA Interim Primary Drinking Water Standards, are more closely related to proposed water quality criteria. Emphasis is placed on detailing the basis for the existing standards wherever possible.

Summaries of current levels of human exposure, presented in this section, specifically address the suitability of the data to derive water quality criteria. The identification of special groups at risk, either because of geographical or occupational differences in exposure or biological differences in susceptibility to the compound(s), focuses on the impact that these groups should have on the development of water quality criteria.

The basis for the recommended criteria section summarizes and qualifies all of the data used in developing the criteria.

IV. Guidelines for Criteria Derivation

The derivation of water quality criteria from laboratory animal toxicity data is essentially a two-step procedure. First, a total daily intake for humans must be estimated which establishes either a defined level of risk for non-threshold effects or a no-effect level for threshold effects. Secondly, assumptions must be made about the contribution of contaminated water and the consumption of fish/shellfish to the total daily intake of the chemical. These estimates are then used to establish the tolerable daily intake and consequently the water quality criterion.

A. Non-Threshold Effects

After the decision has been made that a compound has the potential for causing cancers in humans and that data exist which permit the derivation of a criterion, the water concentration which is estimated to cause a lifetime carcinogenic risk of 10^{-5} is determined. The lifetime carcinogenicity risk is the probability that a person would get cancer sometime in his or her life assuming continuous exposure to the compound. The water concentration is calculated by using the low-dose extrapolation procedure proposed by Crump (1980). This procedure is an improvement on the multistage low dose extrapolation procedure by Crump, et al. (1977).

The data used for quantitative estimates are of two types: (1) lifetime animal studies, and (2) human studies where excess cancer risk has been associated with exposure to the agent. In animal studies it is assumed, unless evidence exists to the contrary, that if a carcinogenic response occurs at the dose levels used in the study, then proportionately lower responses will also occur at all lower doses, with an incidence determined by the extrapolation model discussed below.

1. Choice of Model.

There is no really solid scientific basis for any mathematical extrapolation model which relates carcinogen exposure to cancer risks at the extremely low levels of concentration that must be dealt with in evaluating the environmental hazards. For practical reasons, such low levels of risk cannot be measured directly either using animal experiments or epidemiologic studies. We must, therefore, depend on our current understanding of the mechanisms of carcinogenesis for guidance as to which risk model to use. At the present time, the dominant view of the carcinogenic process involves the concept that most agents which cause cancer also cause irreversible damage to DNA. This position is reflected by the fact that a very large proportion of agents which cause cancer are also mutagenic. There is reason to expect that the quantal type of biological response that is characteristic of mutagenesis is associated with a linear non-threshold dose-response relationship. Indeed, there is substantial evidence from mutagenesis studies with both ionizing radiation and with a wide variety of chemicals that this type of dose-response model is the appropriate one to use. This is particularly true at the lower end of the dose-response curve; at higher doses, there can be an upward curvature, probably reflecting the effects of multistage processes on the mutagenic response. The linear non-threshold dose-response relationship is also consistent with the relatively few epidemiological studies of cancer responses to specific agents that contain enough information to make the evaluation possible (e.g., radiation-induced leukemia, breast and thyroid cancer, skin cancer induced by arsenic in drinking water, and liver cancer induced by aflatoxin in the diet). There is also some evidence from animal experiments that is consistent with the linear non-threshold hypothesis (e.g., liver tumors induced in mice by 2-acetylaminofluorene in the large scale ED_{01} study at the National Center of Toxicological Research, and the initiation stage of the two-stage carcinogenesis model in the rat liver and the mouse skin).

Because it has the best, albeit limited, scientific basis of any of the current mathematical extrapolation models, the linear non-threshold model has been adopted as the primary basis for risk extrapolation to low levels of the dose-response relationship. The risk assessments made with this model should be regarded as conservative, representing the most plausible upper limit for the risk; i.e., the true risk is not likely to be higher than the estimate, but it could be smaller.

The mathematical formulation chosen to describe the linear, non-threshold dose-response relationship at low doses is the improved multistage model developed by Crump (1980). This model employs enough arbitrary constants to be able to fit almost any monotonically increasing dose-response data and it incorporates a procedure for estimating the largest possible linear slope (in the 95 percent confidence limit sense) at low extrapolated doses that is consistent with the data at all dose levels of the experiment. For this reason, it may be called a "linearized" multistage model.

2. Procedure of Low-Dose Extrapolation Based on Animal Carcinogenicity Data.

A. Description of the Extrapolation Model

Let P(d) represent the lifetime risk (probability) of cancer at dose d. The multistage model has the form

$$P(d)=1-\exp[-(q_0+q_1d+q_2d^2+\ldots+q_kd^k)]$$

where:

$q_i \geq 0$, and $i=0, 1, 2, \ldots, k$

Equivalently,

$$A(d)=1-\exp[-(q_1d+q_2d^2+\ldots+q_kd^k)]$$

where:

$$A(d)=\frac{P(d)-P(o)}{1-P(o)},$$

is the extra risk over background rate at dose d.

The point estimate of the coefficients q_i, $i=0, 1, 2, \ldots, k$, and consequently the extra risk function A(d) at any given dose d, is calculated by maximizing the likelihood function of the data.

The point estimate and the 95 percent upper confidence limit of the extra risk A(d) are calculated by using the computer program GLOBAL 79 developed by Crump and Watson (1979). Upper 95 percent confidence limits on the extra risk and lower 95 percent confidence limits on the dose producing a given risk are determined from a 95 percent upper confidence limit, q_1^*, on parameter q_1. Whenever $q_1 \neq 0$, at low doses extra risk A(d) has approximately the form $A(d)=q_1 \times d$. Therefore, $q_1 \times d$ is a 95 percent upper confidence limit on the extra risk and R/q_1^* is a 95 percent lower confidence limit on the dose producing an extra risk of R. Let L_0 be the maximum value of the log-likelihood function. The upper limit q_1^* is calculated buy increasing q_1 to a value q_1^* such that when the log-likelihood is again maximized subject to this fixed value q_1^* for the linear coefficient, the resulting maximum value of the log-likelihood L_1 satisfies the equation $2(L_0-L_1)=2.70554$ where 2.70554 is the cumulative 90 percent point of the chi-square distribution with one degree of freedom, which corresponds to a 95 percent upper limit (one-sided). This approach of computing the upper confidence limit for the extra risk A(d) is an improvement on the Crump, et al. (1977) model. The upper confidence limit for the extra risk calculated at low doses is always linear. This is conceptually consistent with the linear nonthreshold concept discussed earlier. The slope q_1^* is taken as an upper bound of the potency of the chemical in inducing cancer at low doses.

In fitting the dose-response model, the number of terms in the polynomial g is chosen equal to (h-1), where h is the number of dose groups in the experiment, including the control group.

Whenever the multistage model does not fit the data sufficiently, data at the highest dose is deleted and the model is refitted to the rest of the data. This is continued until an acceptable fit to the data is obtained. To determine whether or not a fit is acceptable, the chi-square statistic:

$$X^2=\sum_{i=1}^{h}\frac{(X_i-N_iP_i)^2}{N_iP_i(1-P_i)}$$

is calculated, where N_i is the number of animals in the i^{th} dose group, X_i is the number of animals in the i^{th} dose group with a tumor response, P_i is the probability of a response in the i^{th} dose group estimated by fitting the multistage model to the data, and h is the number of remaining groups.

The fit is determined to be unacceptable whenever chi-square (X^2) is larger than the cumulative 99 percent point of the chi-square distribution with f degrees of freedom, where f equals the number of dose groups minus the number of non-zero multistage coefficients.

3. Selection and Form of Data used to Estimate Parameters in the Extrapolation Model.

For some chemicals, several studies in different animal species, strains, and sexes each conducted at several doses and different routes of exposure are available. A choice must be made as to which of the data sets from several studies are to be used in the model. It is also necessary to correct for metabolism differences between species and for differences in absorption via different routes of administration. The procedures, listed below, used in evaluating these data are consistent with the estimate of a maximum-likely-risk.

a. The tumor incidence data are separated according to organ sites or tumor types. The set data (i.e., dose and tumor incidence) used in the model is set where the incidence is statistically significantly higher than the control for at least one test dose level and/or where the tumor incidence rate shows a statistically significant trend with respect to dose level. The data set which gives the highest estimate of lifetime carcinogenic risk q_1^* is selected in most cases. However, efforts are made to exclude data sets which produce spuriously high risk estimates because of a small number of animals. That is, if two sets of data show a similar dose-response relationship and one has a very small sample size, the set of data which has the larger sample size is selected for calculating the carcinogenic potency.

b. If there are two or more data sets of comparable size which are identical with respect to species, strain, sex, and tumor sites, the geometric mean of q_1^*, estimated from each of these data sets is used for risk assessment. The geometric mean of numbers $A_1, A_2, \ldots, A_m$ is defined as $(A_1 \times A_2 \times \ldots \times A_m)^{1/m}$

c. If sufficient data exist for two or more significant tumor sites in the same study, the number of animals with at least one of the specific tumor sites under consideration is used as incidence data in the model.

d. Following the suggestion of Mantel and Schneiderman (1975), we assume that mg/surface area/day is an equivalent dose between species. Since to a close approximation the surface area is proportional to the ⅔rds power of the weight as would be the case for a perfect sphere, the exposure in mg/⅔rds power of the body weight/day is similarly considered to be an equivalent exposure. In an animal experiment, this equivalent dose is computed in the following manner:

Let:

L_e = duration of experiment
l_e = duration of exposure
m = average dose per day in mg during administration of the agent (i.e., during l_e)
W = average weight of the experimental animal.

Then, the lifetime average exposure is

$$d=\frac{l_e \times m}{L_e \times W^{2/3}}$$

Often exposures are not given in units of mg/day, and it becomes necessary to convert the given exposures into mg/day. For example, in most feeding studies, exposure is expressed as ppm in the diet. In this case the exposure (mg/day) is derived by: $m=ppm \times F \times r$

where ppm is parts per million of the carcinogenic agent in the diet, F is the weight of the food consumed per day in kgms, and r is the absorption fraction.

In the absence of any data to the contrary, r is assumed to be one. For a uniform diet the weight of the food consumed is proportional to the calories required, which, in turn, is proportional to the surface area or the ⅔rds power of the weight, so that: $m \alpha ppm \times W^{2/3} \times r$ or

$$\frac{m}{rW^{2/3}} \alpha ppm$$

As a result, ppm in the diet is often assumed to be an equivalent exposure between species. However, we feel that this is not justified since the calories/kg of food is significantly different in the diet of man vs. laboratory animals, primarily due to moisture content differences. Instead, we use an empirically derived food factor, f=F/W, which is the fraction of a species body weight that is consumed per day as food. We use the rates given below.

Species	W	f
Man	70	0.028
Rat	0.35	0.05
Mice	0.03	0.13

Thus, when the exposure is given as a certain dietary concentration in ppm, the exposure in $mg/W^{2/3}$ is

$$\frac{m}{r \times W^{2/3}} = \frac{ppm \times F}{W^{2/3}} =$$

$$\frac{ppm \times f \times W}{W^{2/3}} = ppm \times f \times W^{1/3}$$

When exposure is given in terms of mg/kg/day=m/Wr=s the conversion is simply:

$$\frac{m}{rW^{2/3}} = s \times W^{1/3}$$

When exposure is via inhalation, the calculation of dose can be considered for two cases where (1) the carcinogenic agent is either a completely water-soluble gas or an aerosol and is absorbed proportionally to the amount of air breathed in, and (2) where the carcinogen is a poorly water-soluble gas which reaches an equilibrium between the air breathed and the body compartments. After equilibrium is reached, the rate of absorption of these agents is expected to be proportional to metabolic rate, which in turn is proportional to the rate of oxygen consumption, which in turn is a function of surface area.

Case 1

Agents that are in the form of particulate matter or virtually completely absorbed gases such as SO_2 can reasonably be expected to be absorbed proportional to the breathing rate. In this case the exposure in mg/day may be expressed as: $m=I \times v \times r$ where I is inhalation rate per day in m^3, v is mg/m^3 of the agent in air, and r is the absorption fraction.

The inhalation rates, I, for various species can be calculated from the observation (FASEB, 1974) that 25 gm mice breathe 34.5 liters/day and 113 gm rats breathe 105 liters/day. For mice and rats of other weights, W, (expressed in kg), the surface area proportionality can be used to determine breathing rates (in m^3/day) as follows:

For mice, $I=0.0345\ (W/0.025)^{2/3} m^3$/day

For rats, $I=0.105\ (W/0.113)^{2/3} m^3$/day

For humans, the values of 20 m^3/day [a] is adopted as a standard breathing rate (ICRP, 1977).

The equivalent exposure in $mg/W^{2/3}$ for these agents can be derived from the air intake data in a way analogous to the food intake data. The empirical factors for the air intake per kg per day, i=I/W based upon the previously stated relationships, are as tabulated below:

Species	W	i=I/W
Man	70	0.29
Rat	0.35	0.64
Mice	0.03	1.3

Therefore, for particulates or completely absorbed gases, the equivalent exposure in $mg/W^{2/3}$ is:

$$\frac{m}{W^{2/3}} = \frac{Ivr}{W^{2/3}} = \frac{iWvr}{W^{2/3}} = iW^{1/3}\,vr$$

In the absence of empirical data or a sound theoretical argument to the contrary, the fraction absorbed, r, is assumed to be the same for all species.

Case 2

The dose in mg/day of partially soluble vapors is proportional to the O_2 consumption which in turn is proportional to $W^{2/3}$ and to the solubility of gas in body fluids, which can be expressed as an absorption coefficient r for the gas. Therefore, when expressing the O_2 consumption as $O_2=k\,W^{2/3}$, where k is a constant independent of species, it follows that $m=k\,W^{2/3} \times v \times r$ or

$$d = \frac{m}{W^{2/3}} = kvr$$

As with Case 1, in the absence of experimental information or a sound theoretical argument to the contrary, the absorption fraction, r, is assumed to be the same for all species. Therefore, for these substances a certain concentration in ppm or μ/m^3 in experimental animals is equivalent to the same concentration in humans. This is supported by the observation that the minimum alveolar concentration, necessary to produce a given "stage" of anesthesia, is similar in man and animals (Dripps, et al. 1977). When the animals were exposed via the oral route and human exposure is via inhalation or vice-versa, the assumption is made, unless there is pharmacokinetic evidence to the contrary, that absorption is equal by either exposure route.

e. If the duration of experiment (L_e) is less than the natural life span of the test animal (L), the slope q_1^*, or more generally the exponent g(d), is increased by multiplying a factor $(L/L_e)^3$. We assume that if the average dose, d, is continued, the age specific rate of cancer will continue to increase as a constant function of the background rate. The age specific rates for humans increase at least by the 2nd power of the age and often by a considerably higher power, as demonstrated by Doll (1971). Thus, we would expect the cumulative tumor rate to increase by at least the 3rd power of age. Using this fact, we assume that the slope q_1^*, or more generally, the exponent g(d), would also increase by at least the 3rd power of age. As a result, if the slope q_1^* [or g(d)] is calculated at age L_e, we would expect that if the experiment had been continued for the full life span, L, at the given average exposure, the slope q_1^* [or g(d)] would have been increased by at least $(L/L_e)^3$.

This adjustment is conceptually consistent to the proportional hazard model proposed by Cox (1972) and the time-to-tumor model considered by Crump, et al. (1977) where the probability of cancer at age t and dose d is given by $P(d,t)=1-\exp[-f(t) \times g(d)]$

4. Calculation of Carcinogenic Potency Based on Human Data. If human epidemiology studies and sufficiently valid exposure information are available for the compound, they are always used in some way. If they show a carcinogenic effect, the data are analyzed to give an estimate of the linear dependence of cancer rates on lifetime average dose, which is equivalent to the factor q_1^*. If they show

[a] From "Recommendation of the International Commission on Radiological Protection," page 9, the average breathing rate is 10^7 cm^3 per 8-hour work day and 2×10^7 cm^3 in 24 hours.

no carcinogenic effect when positive animal evidence is available, then it is assumed that a risk does exist but it is smaller than could have been observed in the epidemiologic study, and an upper limit of the cancer incidence is calculated assuming hypothetically that the true incidence is just below the level of detection in the cohort studied, which is determined largely by the cohort size. Whenever possible, human data are used in perference to animal bioassay data.

In human studies, the response is measured in terms of the relative risk of the exposed cohort of individuals compared to the control group. In the analysis of this data, it is assumed that the excess risk, or relative risk minus one, $R(X)-1$, is proportional to the lifetime average exposure, X, and that it is the same for all ages. It follows that the carcinogenic potency is equal to $[R(X)-1]/X$ multiplied by the lifetime risk at that site in the general population. Except for an unusually well-documented human study, the confidence limit for the excess risk is not calculated, due to the difficulty in accounting for the uncertainty inherent in the data (exposure and cancer response).

5. Calculation of Water Quality Criteria. After the value of q_1^* in $(mg/kg/day)^{-1}$ has been determined, the lifetime risk, P, from an average daily exposure of x mg/kg/day is found from the equation $P=q_1^*x$. Therefore, if the lifetime risk is set at $P=10^{-5}$ for calculation purposes, the intake, I, in mg/day for a 70 kg person can be found by the equation: $I=70\times10^{-5}/q_1^*$ The intake of the agent from ambient water is assumed to come from two sources: (1) drinking an average of 2 liters of water per day, and (2) ingesting an average of 6.5 grams of fish per day. Because of accumulation of residues in fish, the amount of the pollutant in fish (mg/kg of edible fish) is equal to a factor R times the water concentration (mg/kg of water). Therefore, the total intake I can be written as sum of two terms: $I(mg/day)=C(mg/l)\times R(l/kg\ fish)\times 0.0065\ kg\ fish/day+C(mg/l\times 2l/day=C(2+0.0065R)$ where C is the water concentration in mg/l. Therefore, the water concentration in mg/l corresponding to a lifetime risk of 10^{-5} for a 70 kg person is calculated by the formula:

$$C = \frac{70 \times 10^{-5}}{q_1^*(2 + 0.0065\ R)}$$

B. Threshold Effects

1. Use of Animal Toxicity Data (Oral). In developing guidelines for deriving criteria based on noncarcinogenic responses, five types of response levels are considered:

NOEL—No-Observed-Effect-Level
NOAEL—No-Observed-Adverse-Effect-Level
LOEL—Lowest-Observed-Effect-Level
LOAEL—Lowest-Observed-Adverse-Effect-Level
FEL—Frank-Effect-Level

Adverse effects are defined as any effects which result in functional impairment and/or pathological lesions which may affect the performance of the whole organism, or which reduce an organism's ability to respond to an additional challenge.

One of the major problems encountered in consideration of these concepts regards the reporting of "observed effect levels" as contrasted to "observed adverse effect levels". The terms "adverse" vs. "not adverse" are at times satisfactorily defined, but due to increasingly sophisticated testing protocols, more subtle responses are being identified, resulting in a need for judgment regarding the exact definition of adversity.

The concepts listed above (NOEL, NOAEL, LOEL, LOAEL) have received much attention because they represent landmarks which help to define the threshold region in specific experiments. Thus, if a single experiment yields a NOEL, a NOAEL, a LOAEL, and a clearly defined FEL in relatively closely spaced doses, the threshold region has been relatively well defined; such data are very useful for the purpose of deriving a criterion. On the other hand, a clearly defined FEL has little utility in establishing criteria when it stands alone, because such a level gives no indication how far removed the data point is from the threshold region. Similarly, a free-standing NOEL has little utility, because there is no indication of its proximity to the LOEL, since a free-standing NOEL may be many orders of magnitude below the threshold region.

Based on the above dose-response classification system, the following guidelines for deriving criteria have been adopted:

a. A free-standing FEL is unsuitable for the derivation of criteria.

b. A free-standing NOEL is unsuitable for the derivation of criteria. If multiple NOELs are available without additional data on LOELs, NOAELs, or LOAELs, the highest NOEL should be used to derive a criterion.

c. A NOAEL, LOEL, or LOAEL can be suitable for criteria derivation. A well-defined NOAEL from a chronic (at least 90-day) study may be used directly, applying the appropriate uncertainty factor. For a LOEL, a judgment needs to be made whether it actually corresponds to a NOAEL or a LOAEL. In the case of a LOAEL, an additional uncertainty factor is applied; the magnitude of the additional uncertainty factor is judgmental and should lie in the range of 1 to 10. Caution must be exercised not to substitute "Frank-Effect-Levels" for "Lowest-Observable-Adverse-Effect-Levels".

d. If for reasonably closely spaced doses only a NOEL and a LOAEL of equal quality are available, then the appropriate uncertainty factor is applied to the NOEL.

In using this approach, the selection and justification of uncertainty factors are critical. The basic definition and guidelines for using uncertainty factors has been given by the National Academy of Sciences (1977). "Safety Factor" or "Uncertainty Factor" is defined as a number that reflects the degree or amount of uncertainty that must be considered when experimental data in animals are extrapolated to man. When the quality and quantity of experimental data are satisfactory, a low uncertainty factor is used; when data is judged to be inadequate or equivocal, a larger uncertainty factor is used. The following general guidelines have been adopted in establishing the uncertainty factors:

a. Valid experimental results from studies on prolonged ingestion by man, with no indication of carcinogenicity. Uncertainty Factor=10

b. Experimental results of studies of human ingestion not available or scanty (e.g., acute exposure only) with valid results of long-term feeding studies on experimental animals, or in the absence of human studies, valid animal studies on one or more species. No indication of carcinogenicity. Uncertainty Factor=100

c. No long-term or acute human data. Scanty results on experimental animals with no indication of carcinogenicity. Uncertainty Factor=1,000

Considerable judgment must be used in selecting the appropriate safety factors for deriving a criterion. In those cases where the data do not completely fulfill the conditions for one category and appear to be intermediate between two categories an intermediate uncertainty factor is used. Such an intermediate uncertainty factor may be developed based on a logarithmic scale (e.g., 33, being halfway between 10 and 100 on a logarithmic scale).

In determining the appropriate use of the uncertainty factors, the phrase "no

indication of carcinogenicity" is interpreted as the absence of carcinogenicity data from animal experimental studies or human epidemiology. Available short-term carcinogenicity screening tests are reported in the criteria documents, but they are not used either for derivation of numerical criteria nor to rule out the uncertainty factor approach.

Because of the high degree of judgment involved in the selection of a safety factor, the criterion derivation section of each document should provide a detailed discussion and justification for both the selection of the safety factor and the data to which it is applied. This discussion should reflect a critical review of the available data base. Factors to be considered include number of animals, species, and parameters tested; quality of controls; dose levels; route; and dosing schedules. An effort should be made to differentiate between results which constitute a toxicologically sufficient data base and data which may be spurious in nature.

2. Use of Acceptable Daily Intake (ADI). For carcinogens, the assumption of low dose linearity precludes the necessity for defining total exposure in the estimation of increased incremental risk. For non-carcinogens, ADIs and criteria derived therefrom are calculated from total exposure data that include contributions from the diet and air. The equation used to derive the criterion (C) is: $C=ADI-(DT+IN)/[2\ l+(0.0065\ kg \times R)]$ where 2 l is assumed daily water consumption, 0.0065 kg is assumed daily fish consumption, R is bioconcentration factor in units of l/kg, DT is estimated non-fish dietary intake, and IN is estimated daily intake by inhalation.

If estimates of IN and DT cannot be provided from experimental data, an assumption must be made concerning total exposure. It is recognized that either the inability to estimate DT and IN due to lack of data or the wide variability in DT and IN in different states may add an additional element of uncertainty to the criterion formulation process. In terms of scientific validity, the accurate estimate of the Acceptable Daily Intake is the major factor in satisfactory derivation of water quality criteria.

3. Use of Threshold Limit Values or Animal Inhalation Studies. Threshold Limit Values (TLVs) are established by the American Conference of Governmental and Industrial Hygienists (ACGIH) and represent 8-hour time-weighted average concentrations in air that are intended to protect workers from various adverse health effects over a normal working lifetime. Similar values are set by NIOSH (criteria) and OSHA (standards) for 10- and 8-hour exposures, respectively. To the extent that these values are based on sound toxicologic assessments and have been protective in the work environment, they provide useful information for deriving or evaluating water quality criteria. However, each TLV must be carefully examined to determine if the basis of the TLV contains data which can be used directly to derive a water quality criterion using the uncertainty factor approach. In addition, the history of each TLV must be examined to assess the extent to which it has assured worker safety. In each case, the types of effects against which TLVs are designed to protect are examined in terms of their relevance to exposure from water. It must be demonstrated that the chemical is not a localized irritant and that there is no significant effect at the site of entry irrespective of the routes of exposure (i.e., oral or inhalation).

If the TLV or similar value is recommended as the basis of the criterion, consideration of the above points is explicitly stated in the criterion derivation section of the document. Particular emphasis is placed on the quality of the TLV relative to the available toxicity data that normally is given priority over TLVs or similar established values. If the TLV can be justified as the basis for the cirterion, then the problems associated with the estimation of acceptable oral doses from inhalation data must be addressed.

Estimating equivalencies of dose-response relationships from one route of exposure to another introduces an additional element of uncertainty in the derivation of criteria. Consequently, whenever possible, ambient water quality criteria should be based on data involving oral exposures. if oral data are insufficient, data from other routes of exposure may be useful in the criterion derivation process.

Inhalation data, including TLVs or similar values, are the most common alternatives to oral data. Estimates of equivalent doses can be based upon: (1) available pharmacokinetic data for oral and inhalation routes, (2) measurements of absorption efficiency from ingested or inhaled chemicals, or (3) comparative excretion data when the associated metabolic pathways are equivalent to those following oral ingestion or inhalation. Given that sufficient pharmacokinetic data are available, the use of accepted pharmacokinetic models provides the most satisfactory approach for dose conversions. However, if available pharmacokinetic data are marginal or of questionable quality, pharmacokinetic modeling is inappropriate.

The Stokinger and Woodward (1958) approach, or similar models based on assumptions of breathing rate and absorption efficiency, represents possible alternatives when data are not sufficient to justify pharmacokinetic modeling. Such alternative approaches, however, provide less satisfactory approximations because they are not based on pharmacokinetic data. Consequently, in using the Stokinger and Woodward or related models, the uncertainties inherent in each of the assumptions and the basis of each assumption must be clearly stated in the derivation of the criterion.

The use of data pertaining to other routes of exposure to derive water quality criteria may also be considered. As with inhalation data, an attempt is made to use accepted toxicologic and pharmacokinetic principles to estimate equivalent oral doses. If simplifying assumptions are used, their bases and limitations must be clearly specified.

Because of the uncertainties involved in extrapolating from one route of exposure to another and the consequent limitations that this may place on the derived criterion, the decision to disallow such extrapolation and recommend no criterion is highly judgmental and must be made on a case-by-case basis. A decision for or against criteria derivation must balance the quantity and quality of the available data against a perceived risk to the human population.

If the Stokinger and Woodward (1958) approach is used to calculate an ADI from a TLV, the general equation is:
$ADI=TLV\times BR\times DE\times d\times A_A/(A_O\times SF)$
where:

ADI = Acceptable daily intake in mg
TLV = Concentration in air in mg/m^3
DE = Duration of exposure in hours per day
d = 5 days/7 days
A_A = Efficiency of absorption from air
A_O = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above
BR = Amount of air breathed per day; assume 10 m^3

For deriving an ADI from animal toxicity data, the equation is:
$ADI=C_A\times D_E\times d\times A_A\times BR\times 70\ kg/(BW_A\times A_O\times SF)$
where:

ADI = Acceptable daily intake in mg
C_A = Concentration in air in mg/m^3
D_E = Duration of exposure in hours per day
d = Number of days exposed/number of days observed
A_A = Efficiency of absorption from air
BR = Volume of air breathed per day in m^3
70 kg = Assumed human body weight
BW_A = Body weight of experimental animals in kg

A_o = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above.

More formal pharmacokinetic models must be developed on a compound-by-compound basis.

It should be noted that the safety factors used in the above formulae are intended to account for species variability. Consequently, the mg/surface area/day conversion factor is not used in the derivation of toxicity based criterion.

C. Organoleptic Criteria

Organoleptic criteria define concentrations of materials which impart undesirable taste and/or odor to water. In developing and utilizing such criteria two factors must be appreciated: the limitations of most organoleptic data and the human health significance of organoleptic properties.

The publications which report taste and odor thresholds are, with very few exceptions, cryptic in their descriptions of test methodologies, number of subjects tested, concentration: response relationships, and sensory characteristics at specific concentrations above threshold. Thus, the quality of organoleptic data is often significantly less than that of toxicologic data used in establishing other criteria. Consequently, a critical evaluation of the available organoleptic data must be made and the selection of the most appropriate data base for the criterion must be based on sound scientific judgment.

Organoleptic criteria are not based on toxicologic information and have no direct relationship to potential adverse human health effects. Although sufficiently intense organoleptic characteristics could result in depressed fluid intake which, in turn, might aggravate a variety of functional disease states (i.e., kidney and circulatory diseases), such effects are not used in the derivation process of organoleptic criteria unless available data would indicate an indirect human health effect via decreased fluid consumption, criteria derived solely from organoleptic data are based upon aesthetic qualities only.

Since organoleptic and human health effects criteria are based on different endpoints, a distinction must be made between these two sets of information. In criteria summaries involving both types of data, the following format is used:

For comparison purposes, two approaches were used to derive criterion levels for ———. Based on available toxicity data, for the protection of public health the derived level is ——. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water the estimated level is ——. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have no demonstrated relationship to potential adverse human health effects.

In those instances where a level to limit toxicity cannot be derived, the following statement is to be appropriately inserted:

Sufficient data are not available for ——— to derive a level which would protect against the potential toxicity of this compound.

D. Criteria for Chemical Classes

A chemical class is broadly defined as any group of chemical compounds which are reviewed in a single risk assessment document. In criterion derivation, isomers should be regarded as a part of a chemical class rather than as a single compound. A class criterion is an estimate of risk/safety which applies to more than one member of a class. It involves the use of available data on one or more chemicals of a class to derive criteria for other compounds of the same class in the event that there are insufficient data available to derive compound-specific criteria.

A class criterion usually applies to each member of a class rather than to the sum of the compounds within the class. While the potential hazards of multiple toxicant exposure are not to be minimized, a criterion, by definition, most often applies to an individual compound. Exceptions may be made for complex mixtures which are produced, released, and toxicologically tested as mixtures (e.g., toxaphene and PCBs). For such exceptions, some attempt is made to assess the effects of environmental partitioning (i.e., different patterns of environmental transport and degradation) on the validity of the criterion. If these effects cannot be assessed, an appropriate statement of uncertainty should accompany the criterion.

Since relatively minor structural changes within a class of compounds can have pronounced effects on their biological activities, reliance on class criteria should be minimized. Whenever sufficient toxicologic data are available on a chemical within a class, a compound-specific criterion should be derived. Nonetheless, for some chemical classes, scientific judgment may suggest a sufficient degree of similarity among chemicals within a class to justify a class criterion applicable to some of all members of a class.

The development of a class criterion takes into consideration the following:

1. A detailed review of the chemical and physical properties of chemicals within the group should be made. A close relationship within the class with respect to chemical acitivity would suggest a similar potential to reach common biological sites within tissue. Likewise, similar lipid solubilities would suggest the possibility of comparable absorption and tissue distribution.

2. Qualitative and quantitative data for chemicals within the group are examined. Adequate toxicologic data on a number of compounds within a group provides a more reasonable basis for extrapolation to other chemicals of the same class than minimal data on one chemical or a few chemicals within the group.

3. Similarities in the nature of the toxicologic response to chemicals in the class provides additional support for the prediction that the response to other members of the class may be similar. In contrast, where the biological response has been shown to differ markedly on a qualitative and quantitative basis for chemicals within a class, the extrapolation of a criterion to other members of that class is not appropriate.

4. Additional support for the validity of extrapolation of a criterion to other members of a class could be provided by evidence of similar metabolic and pharmacokinetic data for some members of the class.

Based on the above considerations, it may be reasonable in some cases to divide a chemical class into various subclasses. Such divisions could be based on biological endpoints (e.g., carcinogens/non-carcinogens), potency, and/or sufficiency of data (e.g., a criterion for some members of a class but no criterion for others). While no *a priori* limits can be placed on the extent of subclassification, each subclassification must be explicitly justified by the available data.

Class criteria, if properly derived and supported, can constitute valid scientific assessments of potential risk/safety. Conversely, the development of a class criterion from an insufficient data base can lead to serious errors in underestimating or overestimating risk/safety and should be rigorously avoided. Although scientific judgment has a proper role in the development of class criteria, such criteria are useful and defensible only if they are based on adequate data and scientific reasoning. The definition of sufficient data on similarities in physical, chemical, pharmacokinetic, or toxicologic properties to justify a class criterion may vary markedly depending on the degree of structural similarity and the gravity of the perceived risk. Consequently, it is imperative that the criterion derivation section of each document in which a class criterion is recommended explicity address each of the key issues discussed above, and define, as clearly as possible, the

limitations of the proposed criterion as well as the type of data needed to generate a compound-specific criterion.

A class criterion should be abandoned when there is sufficient data availabe to derive a compound-specific criterion which protects against the biological effect of primary concern; e.g., the availability of a good subchronic study would not necessarily result in the abandonment of a class criterion based on potential carcinogenicity.

The inability to derive a valid class criterion does not, and should not, preclude regulation of a compound or group of compounds based on concern for potential human health effects. The failure to recommend a criterion is simply a statement that the degree of concern cannot be quantified based on the available data and risk assessment methodology.

E. Essential Elements

Some chemicals, particularly certain metals, are essential to biological organisms at low levels but may be toxic and/ or carcinogenic at high levels. Because of potential toxic effects, it is legitimate to establish criteria for such essential elements. However, criteria must consider essentiality and cannot be established at levels which would result in deficiency of the element in the human population.

Elements are accepted as essential if listed by NAS Food and Nutrition Board or a comparably qualified panel. Elements not yet determined to be essential but for which supportive data on essentiality exists need to be further reviewed by such a panel.

To modify the toxicity and carcinogenicity based criteria, essentiality must be quantified either as a "recommended daily allowance" (RDA) or "minimum daily requirement" (MDR). These levels are then compared to estimated daily doses associated with the adverse effect of primary concern. The difference between the RDA or MDR and the daily doses causing a specified risk level for carcinogens or ADIs for non-carcinogens defines the spread of daily doses from which the criterion may be derived. Because errors are inherent in defining both essential and maximum tolerable levels, the criterion is derived from dose levels near the center of such a dose range. The decision to use either the MDR or RDA is guided by the spread of the doses and the quality of the essentiality and toxicity estimates.

The modification of criteria by consideration of essentiality must take into account all routes of exposure. If water is a significant source of the MDR or RDA, the criterion must allow for attainment of essential intake. Conversely, even when essentiality may be attained from nonwater sources, standard criteria derivation methods may be adjusted if the derived criterion represents a small fraction of the ADI or MDR. On a case-by-case basis, the modification in the use of the guidelines may include the use of different safety factors for non-carcinogens or other modifications which can be explicitly justified.

F. Use of Existing Standards

For some chemicals for which criteria are to be established, drinking water standards already exist. These standards represent not only a critical assessment of literature, but also a body of human experience since their promulgation. Therefore, it is valid to accept the existing standard unless there is compelling evidence to the contrary. This decision should be made after considering the existing standards vs. new scientific evidence which has accumulated since the standards have been established. There are several instances where the peer review process recommended usage of the present drinking water standards.

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Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses

Introduction

Two versions of the Guidelines were published in the Federal Register for comment. The first version (43 FR 21506, May 18, 1978 and 43 FR 29028, July 5, 1979) was simply published for comment. The second (44 FR 15926, March 15, 1979) was published as part of the request for comments on the water quality criteria for 27 of the 65 pollutants. The second version was meant to be clearer and more detailed than the first, but very similar technically. Since the two versions were so similar, comments on both will be dealt with simultaneously.

Many comments were received that no draft water quality criteria for any of the 65 pollutants should have been issued for public comment until the comments on the first version of the Guidelines had been dealt with adequately and the Guidelines changed appropriately. The comments on the first version were read and the Guidelines were revised in an attempt to make the second version clearer and more detailed than the first. However, an extensive revision of the technical content of the Guidelines was not attempted between the first and second versions because the Agency was preparing water quality criteria based on the Guidelines. The Agency could have avoided this criticism simply by not publishing any version of the Guidelines for comment until March 15, 1979, but this would have greatly reduced the length of time available for people to consider the Guidelines and comment on them. As it was, some people commented that the comment period announced on March 15, 1979, was too short.

1. Comment—The procedures used to derive criteria in the "Red Book" were upheld in court and probably should still be used.

Response—The procedures used in the Guidelines are similar to some of the procedures used to develop criteria in the "Green Book", "Blue Book", and "Red Book". The Guidelines are designed to be more objective and systematic, to deal more adequately with residues, and to incorporate the concept of a minimum data base.

2. Comment—Criteria should be compilations of critically reviewed data with no synthesis or interpretation.

Response—Neither P.L. 92-500 nor the Consent Decree specify the form which a criterion must take. The Consent Decree (para. 11, p. 14) specifies that such criteria "shall state, *inter alia*, recommended maximum permissible concentrations". Adequate precedents have been set in the "Green Book", "Blue Book", and "Red Book" for the form of criteria used in the Guidelines.

3. Comment—The Guidelines and criteria should be developed by a consensus of aquatic toxicologists rather than by EPA personnel only.

Response—EPA certainly wants the Guidelines and the criteria to be as good as possible and as acceptable to as many interested people as possible. To this end, EPA has widely distributed draft versions of the Guidelines and the criteria documents, discussed them with many people, considered the comments received, and made many significant technical changes and editorial revisions. It is questionable whether or not a true consensus could have been reached by any means within the time available. In addition, EPA has a legislative responsibility which it should not delegate to someone else.

4. Comment—The Guidelines should be updated regularly.

Response—The Guidelines are not being promulgated as a regulation or directive. The purpose of presenting these Guidelines is to show how the water quality criteria for aquatic life were derived for the 65 pollutants. If EPA uses these Guidelines again, they will be revised to take into account new data, concepts, and ideas.

5. Comment—The objectives, purpose, and limitations of the Guidelines should be stated.

Response—The introductory portion of the Guidelines has been expanded to address these subjects more fully.

6. Comment—The Guidelines are too ambiguous.

Response—The Guidelines have been revised and rewritten, partly to improve clarity and provide additional details. It is not possible to provide explicit details on all items; in some areas only general guidance can be provided at this time.

EPA attempted to clearly and concisely deal with all issues which might significantly affect the resulting criteria without going into extreme detail on every potential problem. Because numerous judgments must be made, a reasonable amount of experience in aquatic toxicology will be necessary for a person to utilize the Guidelines effectively.

7. Comment—The Guidelines are too complex.

Response—Deriving a water quality criterion is a complex exercise because several different kinds of data and a wide variety of organisms need to be considered. In addition, because data have been generated using various procedures, numerous individual decisions need to be made and the Guidelines attempt to provide guidance concerning decisions that seem to need to be made frequently. The Guidelines are more complex than initially envisioned to help insure that criteria for different pollutants are derived in a reasonably comparable manner. Although the process of deriving a water quality criterion for aquatic life is complex, the Guidelines help organize the process into logical components and steps.

8. Comment—The Guidelines should be more flexible.

Response—The Guidelines are meant to provide guidance and at the same time allow reasonable flexibility. They have been used with quite a variety of pollutants for which the requirements of the minimum data base are satisfied, and they seem to be reasonably appropriate in all cases because the experiences with these substances were a major part of the basis for the Guidelines. If sound scientific evidence indicates that a particular aspect of the Guidelines is not appropriate for a specific substance, then some other more appropriate procedure should be used. However, the Guidelines should not be changed based on individual whim or personal preference.

9. Comment—The Guidelines should take into account synergism and antagonism by a wide variety of factors and the effect of the pollutant on important ecological relationships.

Response—Very little practically useful information is available on these factors in connection with the effects of pollutants on aquatic organisms. Synergism and antagonism are possible between numerous combination of two or more pollutants, and some data indicate that such interactions are not only species specific, but also vary with the ratios and absolute concentrations of the pollutants and the life stage of the species. Pollutants may affect the structure and function of aquatic ecosystems separate from their effects on individual species, but practical applications of such ideas seem very tenuous at this time. Little information is available concerning such effects, and the significance of the available data is questionable. An obviously important ecological relationship is the dependence of higher organisms on lower organisns for food. Even here, the existence of numerous lower species and their adaptability reduces the importance of any individual food species.

10. Comment—The Guidelines should take into account all identifiable effects—beneficial as well as harmful.

Response—Few tests have been conducted to identify beneficial effects of individual pollutants on aquatic organisms. However, beneficial effects are sometimes observed in chronic toxicity tests at concentrations below those that cause adverse effects. Usually in such cases the organisms in low concentrations of the pollutant are longer or heavier or reproduce more that do the controls. Even if such effects are statistically significant, they are not judged as adverse or harmful. On the other hand, a beneficial effect on one species may ultimately be to the detriment of a community if a balance between species is disturbed. Also, a concentration that benefits one species may harm a more sensitive species.

11. Comment—The Guidelines should take into account analytical methodology.

Response—The Guidelines do take into account analytical methodology in the definition of the substance, when necessary, but not in deriving the numerical value of the criterion. Concentrations which cannot be routinely measured accurately can often be measured accurately by nonroutine methods and, more importantly, do sometimes adversely affect aquatic organisms. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods, not to underprotect aquatic life. One use of criteria should be to identify needs in analytical chemistry.

12. Comment—The Guidelines should take into account (a) production and usage patterns, (b) chemical, physical and biological factors pertaining to degradation and fate of pollutants, including properties such as solubility in water, decay rate, persistence, and transformation pathways, and (c) whether or not a criterion is needed for the substance.

Response—Items included in (a) and (b) may be important in deciding whether a criterion is needed for a substance, but the Guidelines are intended to be used after the decision has been made that a criterion is needed. EPA is presently developing principles that can be used to decide whether or not a criterion is needed for a substance and items such as those listed above are probably some of the factors that should be considered when deciding whether or not a criterion is needed. If the toxicity of the chemical is used to evaluate the need for a criterion, the Guidelines may be useful in the collection and interpretation of the available toxicity data.

13. Comment—The Guidelines should take into account costs to states and industries, technological feasibility, and such characteristics of bodies of water as assimilative capacity, dispersal, dissipative factors, dilution, hydrology, mixing zones, and sediment.

Response—Factors such as these should be considered in developing standards, but not in deriving criteria. EPA is presently developing an implementation policy which will describe which of the above factors and which characteristics of the pollutant should be used, and how they should be used, in developing standards.

14. Comment—The Guidelines are not appropriate for establishing a concentration which may be present in an effluent.

Response—The Guidelines are for deriving water quality criteria, not effluent standards nor mixing zone standards nor water quality standards. Water quality criteria will probably be one factor taken into account in the development of water quality standards and toxicity-based effluent standards, but not technology-based effluent standards. EPA is presently developing policies concerning proper use of water quality criteria in various regulatory activities.

15. Comment—The derivation of criteria should be fundamentally a scientific exercise and should not employ subjective judgments.

Response—No exercise which involves the use and interpretation of data can avoid subjective judgment. Indeed, even the generation of scientific data requires subjective judgment, such as how many test organisms to use, what temperature to use, etc. One may decide to accept the recommendations of experts, but this is usually still a subjective decision. In statistics the subjective decisions are made on the basis of probability statements but the final decisions are still subjective judgments. Although the development of the Guidelines and the derivation of criteria cannot avoid subjective

decisions, gross extrapolations, wild assumptions, and novel judgments can be avoided. One can also avoid using large safety factors to "make up" for insufficient data. When some agreement exists between experts, such as on test temperature and duration of tests, the collective opinion can usually be used. EPA feels that the Guidelines do not go too far beyond the state-of-the-art and do not produce criteria by extrapolating far beyond the usefulness of the data.

16. Comment—The Guidelines should not use unproven extrapolations.

Response—EPA feels that the extrapolations used in the Guidelines are reasonable for most pollutants. Probably the most questionable extrapolation is the acute-chronic ratio, but even here an arbitrary ratio is not used. Indeed, the ratio used is usually a mean of experimentally determined acute-chronic ratios for at least three, not just one, species. In addition, the species must include at least one fish and one invertebrate. Even this amount of data does not "prove" the validity of the extrapolation, but it should provide reasonable evidence for or against the use of the ratio with any particular substance. To achieve reasonable criteria without using any extrapolations would require acute and chronic tests with many more species. This would be a high price to pay for disallowing any use of scientific inference in deriving criteria.

The early versions of the Guidelines used adjustment factors and sensitivity factors which were averages derived from data for a wide variety of substances and thus were attempts to make some extrapolations across all substances. The present version of the Guidelines is based on a minimum data base for each individual pollutant and the calculations are essentially pollutant-specific. Thus no extrapolations are made from one pollutant to another.

17. Comment—Laboratory tests overestimate the toxicity of materials because the test organisms are stressed by the artifical conditions.

Response—Laboratory conditions certainly are artificial, but they do not necessarily stress the test organisms. Organisms which survive, grow, and reproduce well in the laboratory cannot be stressed too much. Organisms in a laboratory might be considered pampered because they do not have to compete for food and are not subject to stress due to predators and changing and extreme conditions of turbidity, temperature, flow, and water quality. Also, laboratory organisms are rarely subject to stress from pollutants. Some species probably have longer average life spans in laboratories than they do in field situations.

18. Comment—Laboratory tests underestimate the toxicity of materials because the tests are usually conducted with species which are hardy, adaptable, and insensitive.

Response—Species which are readily adaptable to laboratory conditions are not necessarily insensitive as evidenced by the great range of sensitivities obtained in laboratory tests for some individual pollutants with different species. In fact, once the the proper techniques are developed, a wide variety of species can survive, grow, and reproduce well in laboratories. When the proper techniques are discovered and a species changes form "difficult" to "easy", its sensitivity does not change. Also, some species and life stages which are fragile and must be handled with great care are not particularly sensitive. On the other hand, because so few species have actually been tested in laboratories, species which are more sensitive than any of those tested in laboratories, species which are more sensitive than any of those tested probably exist for most substances.

19. Comment—Laboratory tests are artificial and contrived and do not represent the real world.

Response—Laboratory tests are indeed artificial but they are not contrived to give results that are unnecessarily high or low. Organisms in a laboratory are generally acclimated to water and conditions of constant and desirable quality, whereas in the field they are often subjected to fluctuations and extremes. Organisms in a laboratory do not have to compete for food and are not subject to predators or pollution. Organisms in the field are often exposed to more than one pollutant at a time, with the combinations and concentrations changing often.

It is true that aquatic organisms are usually exposed to instantaneous high concentrations in laboratory tests, but in field situations organisms are often not given much chance to acclimate to spills or short-term discharges. Also, some ameliorating effects occur in field, but not laboratory, situations, but such effects are not always dependable over long periods of time. The concentrations of mitigating anions, suspended solids, and complexing agents are relatively constant in some bodies of water, but not in others. Suspended solids probably do sorb and detoxify significant amounts of some pollutants, but high concentrations of suspended solids also stress some aquatic organisms. In addition, organisms are usually fed in chronic tests, so the test solution contains suspended solids and dissolved organic carbon from the food and fecal matter. Degradation and other transformations are more likely in field situations than in laboratory situations, but degradation products are not always less toxic than the undegraded material. On the other hand, many of these kinds of considerations will probably be taken into account when site-specific criteria and standards are developed under the implementation policy which is being developed by EPA.

20. Comment—Laboratory tests are poor predictors of what will happen in field situations.

Response—If conditions are comparable, laboratory toxicity tests are useful predictors of what will happen in field situations. The usefulness of such predictions will depend on how carefully one accounts for differences between species, water quality, and the form of the pollutant. Extrapolations are much more difficult for some pollutants than for others. Water quality affects the toxicity of some pollutants much more than others, and species differences, even within families, are much greater for some pollutants than for others. If such factors are taken into account, useful predictions are possible. In what is probably the most extensive comparison available of laboratory and field data (Geckler, J. R., et al. 1976. Validity of Laboratory Tests for Predicting Copper Toxicity in Streams. EPA–600/3–76–116. U.S. EPA. Duluth, MN 208 pp.), it was found that effects observed in laboratory exposures were also observed in field exposures. However, avoidance, which was not studied in laboratory exposures, was observed in the field exposures. Laboratory to field comparisons are not simple because several factors must be taken into account, the laboratory test must be conducted well and the field observations and measurements must be extensive. Although adverse effects observed in laboratory tests will usually occur in similar field situations, a problem exists with the bioaccumulation of some persistent substances. For example, PCB's seem to bioaccumulate to much higher levels in some bodies of water than they do in laboratory tests.

21. Comment—The Guidelines should place more emphasis on field information than on laboratory information.

Response—Field information on effects of pollutants on natural populations is acceptable, but the collection of definitive information of this type is high risk and costly. Few studies on the effects of pollution on natural populations provide definitive information because of the multitude of

variables that need to be taken into account. The major advantage of field studies is that conditions are natural (i.e., conditions are not controlled), but this is also the major problem with field studies. With uncontrolled conditions, numerous variables must be taken into account, because any individual variable or combination of variables may affect the results or indeed may be the cause of the results. Therefore, field studies on natural populations usually must last over several seasons and possibly over more than one year to be reasonably sure that proposed cause-and-effect relationships are real.

Another problem with field studies that are based on statistically significant differences is the power of the test. Because natural biological, spacial, and temporal variability is often rather great, a large number of samples is usually required to detect even a moderate change. A field study which purports to show that no change occurred is of no value if the power of the test calculated from the experimental design and observed variability was not high enough.

Because field studies are high cost-high risk ventures, well-designed laboratory tests are usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species and (2) the effect of various water quality characteristics on toxicity. Laboratory tests have been shown to generally be useful predictors of what happens in a field situation, and so it makes little sense to conduct high risk, high cost field studies rather than laboratory tests. Even definitive field studies rarely provide enough information to allow extrapolation of results to other situations, so field studies are more useful in reviewing criteria than in deriving criteria.

22. Comment—Field verification of laboratory tests and of the Guidelines are needed.

Response—Field verification of laboratory tests and of the Guidelines are certainly desirable and provide information that cannot be obtained in a laboratory. Field verification studies do not need to be as risky or as costly as studies on the effects of a pollutant on natural populations because verification studies can be designed (1) as a side-by-side comparison of the results of laboratory tests and field tests or (2) based on existing results of laboratory tests.

23. Comment—EPA should allow criteria to be derived using on-site acute toxicity tests and an application factor.

Response—This approach is usually suggested for developing effluent standards but may be just as applicable to deriving water quality criteria under certain conditions. This approach cannot be used with pollutants whose most sensitive adverse effect is due to residues. Also, it can only be used when the application factor has already been acceptably determined. Finally, acute tests must be determined with either an appropriate range of species or with an appropriate sensitive species. The implementation policy presently being developed by EPA will probably allow the use of appropriate on-site toxicity tests in the development of site-specific criteria and standards.

24. Comment—It is not clear what level of protection is intended.

Response—EPA feels that it is not possible to specify a minimum level of protection that is necessary to "protect aquatic life" or even to protect a particular species for such reasons as:

a. There are so many untested species.

b. Little practically useful information is available concerning synergism, antagonism, ecological relationships, and avoidance.

c. The effect of factors such as temperature on toxicity seems to be species-specific for at least some substances.

d. Information is not available concerning what amount of any effect would be ecologically significant and whether the amount is species-specific.

One possible conclusion is that to protect aquatic life, all species must be adequately protected. A possible extension of this would be that all criteria should be zero because any amount of any pollutant may affect some aquatic organism. Indeed, the assimilative capacity of body of water largely depends on the ability of aquatic life to "process" pollutants and to some extent, any organism which "processes" a pollutant is in some way affected by it.

The apparent level of protection is different for each kind of effect (acute toxicity to animals, chronic toxicity to animals, toxicity to plants, and bioaccumulation) because of the quality and quantity of the available information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. Thus it was felt that with regards to toxicity to animals it was probably not necessary to protect all of the species all of the time, but it certainly seems appropriate to protect most of the species most of the time and to protect important species.

On the other hand, the data base on toxicity to aquatic plants is usually very small and a variety of tests and endpoints have been used, especially with algae. Also, little information is available concerning the ecological relevance of the results of any toxicity test with algae in a concentrated test medium, especially because so many species of algae exist in each body of water.

The results of bioconcentration tests with organic chemicals, but not with inorganic chemicals, can apparently be extrapolated reasonably well based on percent lipids from one aquatic animal species to another, at least within commercially and recreationally important species. In addition, the limits on acceptable concentrations in tissue are reasonably well defined in some cases.

These kinds of considerations merely illustrate the complexity of the problem and the necessity for making decisions about each kind of effect individually. In addition, it is important to distinguish between the apparent level of protection provided by the Guidelines and the actual level of protection which will result in a field situation from the use of the implementation policy.

No attempt was made to develop Guidelines which would achieve a predetermined numerical level of protection. For each effect much desirable information is not available, and so it would be misleading to imply a level of sophistication that is not currently possible. EPA believes that the present state-of-the-art in aquatic toxicology does allow some useful conclusions about the ability of a substance to adversely affect aquatic organisms and their uses whenever the requirements of the minimum data base are satisfied, with the full realization that the resulting criterion may be somewhat overprotective or underprotective.

In almost all cases more data would be desirable and so an attempt to reach the "golden mean" will sometimes result incriteria being to high and sometimes too low. One alternative is to derive no criteria until all desirable data are available; this is unacceptable because it will almost always result in no criteria and no protection. The other alternative is to apply safety or uncertainty factors that are inversely proportional to the adequacy of the data base. In the long run this approach would encourage the generation of useful data where it was most needed, but in the short run would require many significant subjective decisions beyond the current state-of-the-art.

25. Comment—The Guidelines should not base criteria on "worst case" assumptions.

Response—The phrase "worst case assumptions" usually refers to the assumption that both the worst water quality and the most sensitive life stage occur at all times. These two assumptions are a natural result of the two concepts that criteria should be constant throughout the year and that aquatic life is not adequatley protected if it is not adequately protected throughout the year. The implementation policy being developed by EPA will determine whether site-specific criteria must be constant throughout the year. If not, then the "worst case assumptions" will not apply. Although the Guidelines might be viewed as making the "worst case assumptions", the implementation policy will determine whether the site-specific water quality criteria and standards will be based on these assumptions.

26. Comment—Safety factors should be used to protect against such things as potential subtle, but important, long term effects.

Response—Pollutants may cause many direct and indirect adverse effects which have not been studied adequately. For instance, some substances may make aquatic organisms more susceptible to disease or other stresses. In spite of such possibilities, the available information indicates that the major possible adverse effects are covered in the Guidelines and that adequate protection will usually be achieved without the use of safety factors. Safety factors would certainly offer additional protection, but the available information does not show that significant additional protection is needed.

Safety factors of from 10 to 1000 are often used to protect people mainly because people feel that people are more important than aquatic organisms and because humans are usually protected on the basis of tests with other species of animals, thus resulting in a greater uncertainty in the applicability of the results. Complete protection can only be achieved by setting all criteria at zero. Unfortunately, even "Mother Nature" sometimes seriously harms large groups of aquatic organisms, such as during droughts or severe winter freezes. EPA feels that complete protection is neither feasible, desirable, nor possible. In addition, aquatic ecosystems can recover from some adverse effects.

27. Comment—The Guidelines do not provide for an adequate margin of safety.

Response—If "margin of safety" is interpreted to mean "safety factor", then the Guidelines do not provide a margin of safety. If the Guidelines are viewed as deriving criteria for a constant quality water, then they provide a margin of safety during those portions of the year during which the most sensitive life stage does not occur. Although some species may occasionally be adversely affected, EPA feels that the Guidelines provide adequate safety because aquatic communities and their uses should not incur any substantial or permanent damage. Whether or not site-specific criteria will have a margin of safety will depend on how they are derived.

28. Comment—Criteria should be set at the least restrictive concentration and states can then apply more restrictive concentrations when necessary.

Response—It is unclear what is meant by the "least restrictive concentration" but presumably it would be a concentration which would not protect very many aquatic communities and their uses. This is contradictory to the concept that criteria are to protect aquatic life and its uses. The implementation policy being developed by EPA will allow site-specific criteria to be higher or lower than the criteria derived using the Guidelines, when adequate information is available.

29. Comment—The Guidelines should produce criteria in the form of a concentration-risk curve with appropriate confidence limits for each kind of effect.

Response—EPA feels that a risk analysis approach is certainly desirable, but far beyond the state-of-the-art at this time. When dealing with safety to humans, only one species is being protected and extrapolations are made far outside the limits of the actual test results, such as to 1 death in 100,000 people. With aquatic life, numerous species need to be protected and extrapolation far beyond the actual data is not readily accepted. In addition, safety or uncertainty factors are more readily accepted when protecting people than when protecting aquatic organisms.

Most aquatic toxicologists are not willing to let criteria for the protection of aquatic life be as dependent on mathematical models, assumptions, and manipulations as on the actual test results. Most people with experience in aquatic toxicology have an intuitive "feel" about how data should be interpreted and the Guidelines are merely an attempt to formalize a resaonable approach. The Guidelines could be written as mathematical algorithms and some approach such as error models could be developed in order to derive confidence limits. However, the algorithms and models would contain many unproven assumptions and, to be worthwhile, would undoubtedly require more data than are usually available. Although such models and algorithms would be acceptable to many statisticians and may be an appropriate future goal, the current Guidelines need to be useable by and comprehensible to current aquatic toxicologists. Most experienced aquatic toxicologists will judge the reasonableness of any set of Guidelines by comparing the resulting criteria for various pollutants with the data available for those pollutants using a "common sense" interpretation of data.

30. Comment—The Guidelines should not use unsound statistical procedures or misuse sound statistical procedures.

Response—EPA has tried to make sure that no statistical procedures are misused in the Guidelines, that no unsound statistical procedures are used, and that the purposes of the calculations are explained adequately.

31. Comment—It appears that geometric means were used instead of arithmetic means in the Guidelines to obtain lower values.

Response—Decisions such as this were made throughout the Guidelines on a case-by-case basis, and none were based on whether the resulting criteria would be higher or lower. The selection of the procedure used to calculate the mean could be based on the distribution of the values in the individual data set. Unfortunately, with small data sets rarely is it possible to reject many possible distributions and with large data sets all possible distributions are often rejected. Because many of the data sets of interest in the Guidelines are small, a reasonable approach is to base the selection of a procedure for calculating the mean on some general principles such as:

a. Sets of ratios and quotients are likely to be closer to lognormal than normal distributions. Thus geometric means, rather than arithmetic means, are used for acute-chronic ratios and for bioconcentration factors.

b. When there are numerous independent possible sources of error for each datum in a set, the error tends to be multiplicative rather than additive. Thus when the acute or chronic toxicity of a substance to a particular species is determined in different laboratories using different batches of organisms, different waters, etc, the geometric means should be used to calculate the species mean value rather than the arithmetic mean.

c. If a set of numbers approximates a lognormal distribution, the logarithms of the numbers will approximate a normal distribution.

d. The distribution of the sensitivities of individual organisms in a toxicity test

is likely to be closer to a lognormal distribution than a normal distribution. Thus the geometric mean, rather than the arithemetic mean, of the upper and lower chronic limits is used.

32. Comment—There should not be any criteria which apply to all bodies of water. Criteria should be specific for individual states, regions, other geographic areas, or bodies of water.

Response—The Guidelines are designed to provide guidance in the collection and interpretation of data concerning the effects of pollutants on aquatic life and its uses. The uses of the resulting criteria will be described by EPA in various regulations. If desired, the Guidelines can be appropriately modified and used to derive a criterion specific to one or more bodies of water or geographic areas if an appropriate data base is available. The critical literature reviews on which the criteria are based will be available for use in the derivation of local, state, or regional criteria. The latitude allowed for deriving local, state, or regional criteria and standards will be determined by the implementation policy presently being developed by EPA.

33. Comment—The Guidelines should result in criteria that are specific for individual species or groups of species (e.g., warmwater and coldwater).

Response—If the necessary data were available, criteria could be derived for any particular species or group of species. It was impractical for EPA to derive criteria for many such groups, but a relatively simple division is freshwater and saltwater organisms because these two groups rarely coexist. Most other possible general divisions of species are faced with the problem that species coexist in various combinations unless the groups are very narrow. In addition, toxicity data are rarely available for very many individual species and so data for representative species must be used, unless appropriate new data are generated. Also, the available data sometimes show wide differences within families so extrapolations from one species to another are often tenuous. Because of these problems, deriving criteria for individual species or groups of species was deemed impractical.

34. Comment—A criterion should be one number, not two.

Response—The two-number criterion is an acknowledgement that aquatic organisms can tolerate short exposures to concentrations that are higher than those they can tolerate continuously. In a two-number criterion, the higher number can assure that short-term fluctuations above the average are not too high, whereas the lower number can assure that the long-term average is not too high. A one-number criterion could be derived by using the existing 24-hour average as an instantaneous maximum. This would certainly provide additional protection, but would provide unnecessary overprotection in most cases. Because a one-number criterion would be more of an approximation than a two-number criterion, one-number criteria would be too high or too low more often and to a greater degree than two-number criteria.

35. Comment—The criteria should not specify sampling schemes.

Response—Criteria should state numerical concentration limits in terms of exposure durations because, everything else being constant, the amount of adverse effect depends on both the concentration of the pollutant and the duration of exposure. Criteria in the Green Book, Blue Book, and Red Book were usually stated as single numbers with no duration expressly stated. The implication was that the criteria were never to be exceeded at any time. Each criterion was apparently and instantaneous maximum. In practice, however, standards derived from these criteria were usually enforced on the basis of 24-hour composite samples. To avoid any ambiguity, the Guidelines specify that a criterion should be explicitly stated in terms of two time frames: an instantaneous maximum and a 24-hour average. However, this is not a specification for a sampling scheme. Standards developed from such a criterion should probably specify a sampling scheme for compliance monitoring, but it would not necessarily be in terms of point measurements and 24-hour averages.

Any sampling scheme used to determine whether or not an ambient concentration exceeds a water quality criterion or a comparable water quality standard should take into account such things as the ratio of the instantaneous maximum and the 24-hour average and the retention time of the body of water because these will primarily determine which portion of the criterion is most limiting in any specific situation. The sampling scheme should probably also take into account the cost of the analyses and results of any past analyses.

36. Comment—The criteria should be stated in terms of time frames longer that an instantaneous maximum and a 24-hour average.

Response—These two time frames were chosen because they would allow the derivation of a criterion which would be less restrictive than, but just as protective as, the previous one-number criterion. These two specific time frames were chosen because they match two kinds of samples that are commonly collected: grab samples and 24-hour composite samples. These specific time frames could probably be changed somewhat without much practical effect, but EPA saw no particular advantage to anyone to introducing novel time periods. For example, for all practical purposes in most situations a 10-minutes average is probably about the same as an instantaneous maximum.

Large increases in the time frames, however, would not provide the same amount of protection. If the instantaneous maximum were changed to a 24- or 96-hour average, and the 24-hour average were changed to a 7- or 30-day average with no change in the numerical limits, the amount of protection afforded aquatic life would fall to an unacceptable level. The longer the time span for the average, the higher the instantaneous concentration could be for short periods of time within that span. Although most chronic tests last for 28-days or longer, some chronic effects may be caused by short exposures of sensitive life stages. If the acute-chronic ratio is small, fluctuations in the instantaneous concentration may even cause acute toxicity, especially for cumulative pollutants, because for some substances the 24-, 48-, and 96-hour acute values do not differ too much.

37. Comment—A two-number criterion will be difficult to enforce.

Response—Criteria are not enforceable. Standards are enforceable. When standards to protect aquatic life are developed, they may or may not be in the same format as the criteria for aquatic life. Few standards are adequately enforced because of the high cost of continuous monitoring. The real value of many criteria and standards is in the design of waste treatment facilities; a two-number criterion should be a better basis for design than a one-number criterion.

38. Comment—The criteria should be expressed to one significant figure, not two.

Response—EPA acknowledges that there is much variability in some of the data and that the range of sensitivites is often great. When the requirements of the minimum data base are satisfied and the data agree reasonably well, two significant figures are not unreasonable. Rounding off to one significant figure could arbitrarily raise or lower the criterion by up to forty percent with no apparent consistent benefits to dischargers, regulators, or aquatic life.

39. Comment—The Guidelines should only use data for species that ought to be protected.

Response—In order to protect commercially and recreationally important species, a wide variety of "unimportant" species must also be protected. Such so-called "unimportant" species include the food organisms all the way to the bottom of the food chain. The "important" species in an aquatic community cannot maintain themselves without the help of primary producers, primary consumers, nitrifiers, dentrifiers, detritivores and saprophytes.

40. Comment—Criteria should not be based on sensitive, short-lived invertebrates.

Response—Many species of invertebrates are short-lived and are not widely distributed. However, these numerous short-lived, local species do serve important functions and should be represented in the data base. This group of organisms needs to be protected even if no one species can be considered important.

41. Comment—Criteria should protect endangered species.

Response—EPA agrees that criteria should protect endangered aquatic species. However, very few toxicity tests have been conducted with endangered species, and it does not appear feasible to require tests with such species. Endangered species are some of the many untested species which should be protected by criteria derived from available data using the Guidelines.

42. Comment—Migratory species are a special problem.

Response—Migratory species should usually be protected by criteria derived using the Guidelines unless such species are unusually sensitive. Migratory species may be especially susceptible to avoidance, but few data are available to compare species on this basis. Avoidance may be a serious latent problem because it might apply to all motile species, rather than just migratory species, and it has not been studied very much.

43. Comment—Estuarine species were ignored.

Response—The term "saltwater organisms" is meant to include estuarine species as well as true marine species.

44. Comment—The classification "invertebrates" includes species that are too dissimilar to be grouped together. These species should be separated into phyla or classes.

Response—The never-ending arguments between the "lumpers" and the "splitters" can only be resolved by considering the advantages and disadvantages of each approach in each situation. The "splitters" can usually argue that obvious differences should be taken into account and it is certainly true that shrimp are different from insects and both are different from worms. It can also be argued that there are significant differences within phyla, classes, and families. Each species could be considered a separate group, if differences between stains are arbitrarily ignored. After the species are split into separate groups, the problem then would be whether to recombine the data to derive one criterion for all species or to derive one criterion for each group. If numerous criteria are derived for a pollutant, how are these to be used to develop standards? Another problem is that unless more data are generated, the greater the number of groups, the less information there is available per group.

The basic question is "What are the important differences that need to be taken into account and how should this be done?" Because there are differences between taxonomic groups, the Guidelines require data on a number of species from a varitety of taxonomic groups. The information of each separate species is treated individually. This approach preserves the differences between species and allows all species to be considered in the development of the criterion. The number of data points is increased and the range of the data is readily apparent. Because "invertebrates" is already a large diverse group and because the range of sensitivities of fish usually overlaps that of invertebrates, little justification exists for not combining all aquatic animals.

45. Comment—Do not extrapolate from freshwater organisms to saltwater organisms or vice versa.

Response—Criteria and absolute toxicity values were not extrapolated from fresh water to salt water, but some relative data were, when it did not appear that factors such as salinity affected the data. The toxicity of some substances apparently is significantly affected by salinity, but most substances seem to have overlapping ranges of toxicity to freshwater and saltwater organisms. However, because these two kinds of organisms rarely inhabit the same body of water simultaneously, separate criteria were derived for each. Even though these two kinds of organisms are physiologically different, they do not seem to be too different toxicologically. Bioconcentration factors and acute-chronic ratios seem to be fairly similar for many freshwater and saltwater species for many pollutants, particularly organic chemicals.

46. Comment—The Guidelines base the criteria only on sensitive species and do not take into account insensitive species.

Response—The Guidelines do not necessarily base the criteria on the data for the most sensitive species. However, an aquatic ecosystem cannot be protected by protecting only the species which are insensitive. Protecting half the species will probably not protect the community. To offer reasonable protection to aquatic life and its uses, each major kind of organism and each major use must be given reasonable protection. In some cases it may in fact be necessary to protect the most sensitive species if it is a highly desirable species.

47. Comment—Species should be tested at their environmental extremes.

Response—Toxicity tests with each pollutant could indeeed be conducted with some or all species under a variety of extreme conditions and the lowest result obtained with a species could be used instead of a mean result. On the other hand, differences between results with different species seem to be much greater, and therefore more important, than the differences between results obtained with one species under different conditions. Furthermore, criteria need not necessarily protect species from all stress under the most extreme conditions, because aquatic communities and populations of individual species can recover from some perturbations.

48. Comment—Only data for species that are widely distributed, representative, critical, indigenous, important, ecologically relevant and sensitive should be used.

Response—Few species would satisfy all of the requirements that have been suggested. As more and more data are obtained with a wider variety of species for any one pollutant, it becomes more obvious that few if any species are atypically sensitive, although that may not be true for aquatic communities which contain very few species. No data exist to show that species in any one key role are toxicologically more sensitive than other kinds of species. Ecologically relevant species and species that have key roles or are relevant to the overall functioning of viable ecosystems are not necessarily toxicologically different from other species. EPA feels that if the available data cover an adequate number and variety of species, it is not necessary to try to identify and conduct tests with all important, sensitive species. In addition, the derivation of a criterion should not be based only on sensitive species, because a knowledge of the range of sensitivities may be useful. For instance, elevated concentrations of a pollutant that produces a narow range of species sensitivities are likely to cause more

damage than elevated concentrations of a pollutant that produces a wide range of species sensitivities.

49. Comment—The distinction between ionizable and unionizable compounds is not very good because some chemicals ionize and reach chemical equilibrium very slowly and others very rapidly.

Response—Most chemicals can readily be classified into one of three groups:

A. Chemicals that ionize, including hydrolyze, at least 90% and reach 90% of equilibrium in less than 8 hours in most surface waters.

B. Chemicals that ionize, including hydrolyze, less than 10% in 30 days in most surface waters.

C. Chemicals that do not fit into either one of the above categories.

For the purpose of the Guidelines, chemicals in the A group should be considered ionizable, chemicals in the B group should be considered non-ionizable, and chemicals in the C group should be classified on a case-by-case basis. Although the distinction between ionizable and unionizable may not be perfect, it is very useful for most chemicals.

50. Comment—Each individual organic compound should be considered separately.

Response—The vast majority of organic chemicals will be considered separately according to the Guidelines except for structurally similar organic compounds that meet all three specifications given in the Guidelines, such as polychlorinated biphenyls and toxaphene.

51. Comment—In-stream water quality criteria are meaningless for substances that are highly insoluble.

Response—The concentration of some substances in sediment may be important separate from the concentration of the substance in the ambient water and for these compounds a sediment quality criterion may be necessary. Generally such compounds can also cause adverse effects if the concentration in the ambient water is too high even if the concentration in the sediment is low. Thus for such compounds both kinds of criteria may be necessary rather than just one or the other.

52. Comment—If a substance is not dissolved, it is not biologically or toxicologically available.

Response—Although this may usually be true, it certainly does not apply to elemental mercury which can be oxidized and methylated to form a very toxic compound. Some organic acids and phenols and hydroxide and carbonate salts of metals have solubilities which differ substantially from one body of water to another.

53. Comment—Criteria for metals should not be for total metal.

Response—Criteria for metals will generally not be based on total metal. Most will be based on total recoverable metal because forms of metals that are not measured in the total recoverable procedure probably are not, and will not become, toxic. A major problem is that some people use a procedure for total recorverable, but report the results as total, metal. In many situations the two results are about the same, but in some cases the results are quite different.

54. Comment—The Guidelines should give more guidance for distinguishing between acceptable and unacceptable data.

Response—The Guidelines contain as much detail on this subject as EPA believes is currently feasible. Items such as the maximum acceptable control mortality and minimum number of test organisms are based on what many aquatic toxicologists generally feel are acceptable, as expressed in published methods. No data should be used in the derivation of a criteria until their quality and acceptability had been reviewed by a competent person. Competent people will occasionally disagree, but that is a fundamental property of subjective decisions.

55. Comment—Only published data should be used.

Response—Peer review is one of many concepts that is better in theory than in practice. Some poor quality data are published and some high quality data are rejected. In addition, publication is not a particularly rapid process. Whether or not data are used should depend on the applicability and quality of the data, not on whether they have been published. Data that are not published should be made readily available if they are used to derive water quality criteria.

56. Comment—All static test are unacceptable

Response—In general, high quality flow-through acute tests are preferable to high quality static acute tests, but static tests are by no means unacceptable. Few data are available to show whether static tests consistently produce acute values lower or higher or different than flow-through tests. Whereas degradation, violatilization, and buildup of metabolic products are more likely to be a problem in static tests, operator and mechanical errors are more likely in flow-through tests. Static acute tests are certainly not unacceptable for most pollutants, but static chronic tests generally are unacceptable because of changes in the toxicant concentrations and the quality of the dilution water during the test.

57. Comment—Data obtained using test organisms that were previously exposed to the pollutant should be used.

Response—Comparisons of results obtained with unexposed and previously exposed organisms should indicate whether or not acclimation has occurred. Generally, data obtained with acclimated organisms should not be used in deriving criteria because acclimated organisms are the exception rather than the norm. Rarely, if ever, can acclimation be depended on to protect organisms in a field situation because concentrations often fluctuate and motile organisms do not stay in one location very long. Data obtained with acclimated organisms may be acceptable for use in deriving some site-specific criteria.

58. Comment—Foreign species should be used to expand the data base.

Response—Foreign species may be representative of indigenous species, but some of them are quite unusual. Data obtained with foreign species may give good indications of indigenous speceis that should be used in tests on some pollutants and may identify some potential problems that should be investigated.

59. Comment—If data for brine shrimp are not used, the criteria should not apply to saline waters.

Response—Data obtained using brine shrimp are not used because these organisms are atypical. Although they may not be usually sensitive or insensitive to various pollutants, the species found in North America and used for testing only survive in the Great Salt Lake and in salt ponds near San Francisco Bay. These two habitats are unlike any others in the United States. If criteria were to be derived specifically for the Great Salt Lake or for salt ponds, then data for brine shrimp should be used.

60. Comment—Structure-activity relationships should not be used unless proven.

Response—No provision is made in the Guidelines for the use of structure-activity relationships. Such relationships may soon be well enough understood that they can be used in deriving water quality criteria.

61. Comment—A criterion should not be derived for a pollutant until data are available for a broad range of commercially, recreationally, and ecologically important species. Each species should be acutely and chronically tested under a variety of conditions in a number of different waters.

Response—Except for those people who merely want to stop EPA from deriving any water quality criteria, most people will admit that there must be some reasonable limit as to how much information is necessary concerning any regulatory action. This is as true for deriving water quality criteria, as it is for issuing NPDES permits, submitting PMNs, registering pesticides, etc. All of these regulatory activities deal with potentially significant adverse effects on aquatic organisms and should take into account many of the same possible kinds of adverse effects. Therefore, the data needs for these various activities should probably be somewhat similar, but for each regulatory activity the minimum data requirements also need to take into account the special aspects of the program and practical considerations. Unrealistic data requirements will benefit no one. It is not necessary that all questions be answered before any action is taken. It is only necessary that enough data be available to allow reasonable confidence that the water quality criteria will generally not be too high or too low.

EPA has developed minimum data requirements that describe the amounts and kinds of information that should usually be available if a criterion is to be derived using the Guidelines. When the minimum data requirements are satisfied, it should usually be possible to derive a useful criterion. The requirements take into account many things such as:

a. The existence of some species which are commerically or recreationally important and generally sensitive to some broad classes of pollutants;

b. The range of species for which data are available;

c. The cost of obtaining additional data and the usefulness of the data; and

d. The reasonableness of extrapolations from one species to another within and between groups.

The requirements set forth in the minimum data base are indeed minimal, considering the great varitey of species which exist in most aquatic ecosystems. However, EPA feels that based on the availavble information the routine requirement of more data would probably not improve criteria enough to justify the additional cost.

62. Comment—The mimimum data requirements should depend on the nature of the pollutant.

Response—EPA feels that such an approach may be feasible some time in the future, but would be an unwarrented level of sophistication at this time. For a few pollutants, it may be possible to relax some of the data requirements, but in general this can only be determined after enough data are available to indicate that a special case exists. In other cases the minimum data may indicate that additional data are highly desirable.

63. Comment—Criteria should not be derived if enough data are not available. The alternative procedures which were proposed should not be used.

Response—EPA agrees that a numerical criterion should not be derived if enough appropriate data are not available, except in some special cases. EPA also agrees that the alternative procedures which were proposed should not be used to develop numerical criteria at the present time. However, EPA feels that when a numerical criterion is not derived, a descriptive criterion can be used to accurately reflect the latest scientific knowledge.

64. Comment—The guidelines should give more guidance on relating a criterion to a water quality characteristic.

Response—More detail on this subject has been written into the Guidelines.

65. Comment—If data on the relation of toxicity and water quality are not available, no criterion should be derived.

Response—The purpose of a criterion is to present the best available information, not to ensure that all desirable information is available. Any water quality characteristic may affect the toxicity of each pollutant to some degree and it is never going to be possible to investigate all such interactions for even a few species and pollutants. EPA has adopted a minimum data base requirement for deriving a criterion, but there must be practical limits or no criterion will ever be possible. When the minimum data base requirements are satisfied, a criterion should be derived regardless of speculation that some unstudied relationship exist. When enough good data demonstrate a relation between toxicity and a water quality characteristic, an attempt should be made to use this information in the derivation of a criterion. A major purpose of site-specific criteria is to take into account the effect of local water quality conditions on toxicity.

66. Comment—Do not specify the form that a relationship between toxicity and water quality must take.

Response—The Guidelines allow the use of any set of transformations that fit the data well. The log-log model is given as an example because it seems to fit most of the available data concerning the relationship between hardness and toxicity of metals (the only such relationship for which much quantitative data are available) reasonably well.

67. Comment—The toxicity of metals should not be related to "hardness".

Response—EPA has tried to derive criteria in a form that will (a) adequately protect aquatic organisms and (b) be practically useful. Hardness is used as an easily measured surrogate for a number of interrelated water quality characteristics, such as pH, alkalinity, calcium, and magnesium. Various combinations of these probably affect individual metals differently, but these are all reasonably well correlated with hardness in a wide variety of natural waters. Some waters, such as those impacted by acid mine drainage, obviously are special cases, but they have special problems of their own.

68. Comment—Do not extrapolate slopes for toxicity vs. water quality from fish to invertebrates or from acute values to chronic values.

Response—The Guidelines do not now assume that the acute slope and the chronic slope are similar for a pollutant. On the other hand, there is no reason to believe that invertebrates are more similar than are fish and invertebrates. As explained earlier, the group "invertebrates" does not consist of a collection of species that are similar taxonomically or toxicologically. Some water quality characteristics apparently affect the toxicity of the pollutant, rather than the sensitivity of the organisms. For these kinds of factors, slopes should be the same for different species. Even factors that affect such things as the permeability of membranes may produce similar slopes for a wide variety of species. If each species must be treated separately, no criteria will ever be possible.

69. Comment—Relationships based on only two points should not be used.

Response—Two points certainly do not provide very much information about the shape, slope and position of a line. However, if other information or a reasonable assumption is available concerning the shape of the line, two good data points, spaced at a reasonable interval, can provide very useful information concerning the slope and position of the line. Three appropriately spaced points would certainly be better, and four points would be an ideal minimum.

70. Comment—Do not combine relationships that are and are not statistically significant.

Response—The Guidelines do now specify that relationships should be tested for statistical signficance. A test for statistical significance may be one indication of whether or not a slope is

useful, but such a test cannot be used with just two points and does not take into account such things as the comparability of the data, the quality of the test, and the range of the independent variable. A relationship based on six points may not be as significant as it seems if five of the points are tightly grouped.

71. Comment—The Guidelines should not combine 96-hr LC50 values and 48-hr EC50 values.

Response—Both LC50 values and EC50 values are used to measure acute toxicity of a substance to aquatic organisms. In general, an EC50 can be based on a wide variety of effects, but the Guidelines specify that the only effects to be used for deriving criteria are incomplete shell development, immobilization, and loss of equilibrium. All of these are certainly drastic effects. In a field situation these effects probably often lead to death. Just as the endpoint may be specific for the species, so may be the length of the test. The generally accepted length of an acute test with daphnids is 48 hours, whereas for most species of fish, it is 96 hours. Thus the Guidelines use both 48-hr EC50 values and 96-hr LC50 values because they are the widely accepted durations and endpoints used to measure acute toxicity to specific species.

72. Comment—Shell deposition tests are chronic tests and should not be equated with lethality tests.

Response—"Acute" implies "short" not "death". Many acute toxicity tests do use death for the effect, but many also use non-lethal effects. The shell deposition test is one of many non-lethal acute tests and is generally accepted as a short test compared to the average life span of oysters.

73. Comment—Adjustment factors should not be used to adjust for the length of the test, the technique, and unmeasured concentrations.

Response—All three kinds of adjustment factors have been deleted from the Guidelines. The factor for the length of the test was found to be unnecessary because most tests had been conducted for the standard times usually specified for the individual species. Thus the Guidelines now specify that only data from tests conducted for the time specified for the species should be used to calculate the Final Acute Value.

EPA has found that on the average flow-through acute tests give results slightly lower than do static tests, but the relationship does not seem to be too consistent and may vary from species to species for some pollutants. In addition, on the average results based on measured concerntrations do not seem to be much different from those based on unmeasured concentrations.

However, the results of flow-through tests based on measured concentrations are generally accepted as being better measures of acute toxicity than the results of flow-through tests based on unmeasured concentrations or the results of any static or renewal tests.Therefore, whenever the results of flow-through acute tests in which the concentrations were measured are available, the results of all other kinds of acute tests with that species and pollutant are not used in the calculation of the species mean acute value.

74. Comment—Species sensitivity factors should be pollutant-specific; and average factor should not be calculated for a variety of substances.

Response—EPA agrees. The requirement for acute values for at least eight different species was developed in part to allow for a reasonably good calculation of a mean acute value and a species sensitivity factor for each individual pollutant. A better way of using the acute values for the individual species has been developed, but no extrapolations are made from one pollutant to another.

75. Comment—The distribution of species mean acute values for a pollutant will be truncated if the species cannot be killed or affected by concentrations above solubility.

Response—Some species are so resistant to some pollutants that they cannot be killed or affected in acute tests even by concentrations which are much above solubility. Such "greater than" values cannot be used in the calculation of means and variances for pollutants. When the "greater than" values are for insensitive species and are at or above solubility, the values can be used in the calculation of the Final Acute Value by adjusting the cumulative proportions for all the speices with quantitative values. The shape of the curve at the high end cannot be determined, but the Final Acute Value is more dependent on the species mean acute values and the cumulative probabilities at the low end.

76. Comment—Early life-stage tests with fish should be used interchangeably with life-cycle and partial life-cycle tests with fish.

Response—EPA agrees that early life-stage tests with fish generally give about the same results as comparable life-cycle and partial life-cycle tests. However, because the shorter test is merely a predictor of the longer tests, whenever both kinds of results are available, the results of life-cycle and partial life-cycle tests should be used instead of the results of early life-stage tests.

77. Comment—Appropriate measures of chronic toxicity and appropriate lengths of exposure should be defined.

Response—The descriptions of appropriate chronic tests have been clarified.

78. Comment—The factor of 0.44 should not be used.

Response—It is not now used.

79. Comment—The Final Chronic Value should not be lower than the lowest measured species chronic value, even if chronic data are not available for sensitive species.

Response—Aquatic ecosystems cannot be protected from chronic toxicity by protecting only the insensitive species from chronic toxicity. In the past both arbitrary and experimentally determined application factors have been used to relate acute and chronic toxicity. For a variety of reasons the Guidelines do not use an application factor, but instead use the acute-chronic ratio, which is similar to the inverse of an application factor. Thus the acute-chronic ratio should normally be greater than one. The acute-chronic ratio is to be used with invertebrates as well as fish and is to be an experimentally determined value for each individual pollutant. The acute-chronic ratio should also avoid the confusion as to whether a large application factor is one that is close to unity or one that has a denominator that is much larger than the numerator. The acute-chronic ratio is calculated by dividing the appropriate measure of acute toxicity for the species (as specified in the Guidelines) by the appropriate measure of chronic toxicity for the same species (as specified in the Guidelines).

Some people have confused application factors and safety factors and use of the term "acute-chronic ratio" should help avoid this problem. Acute-chronic ratios are a way of estimating the chronic sensitivity of a species for which no chronic toxicity data are available. Safety factors would provide an extra margin of safety beyond the sensitivity of the species. Safety or uncertainty factors are intended to reduce the possibility of underprotection, whereas acute-chronic ratios are intended to estimate the actual chronic sensitivity of the species to the pollutant. This estimate is just as likely to be too high as it is to be too low. A mean acute-chronic ratio will in fact be too high for half the species and too low for the other half.

When three or more acute-chronic ratios have been determined for a pollutant with both fish and

invertebrates, three patterns have been observed when the individual species are listed in order of their species mean acute values:

a. The ratios randomly differ by a factor of ten or more.

b. The ratio appears to be about the same (within a factor of ten) for all species.

c. Species with higher acute values also have higher acute-chronic ratios.

The available data indicate that fish and invertebrates do not consistently have different acute-chronic ratios and that for some pollutants freshwater and saltwater species have similar acute-chronic ratios.

80. Comment—No application factor should be used unless it is specific for the pollutant, species, and water.

Response—There is no point in using an application factor or acute-chronic ratio or any concept if it does not allow some generalization or extrapolation from one species to another or from one water to another. Not allowing any generalizations or extrapolations would require that much data be generated for each species and each pollutant in each water in which a criterion is necessary. When enough supporting data are available, extrapolations using such things as acute-chronic ratios are cost-effective and scientifically sound.

81. Comment—Additional development of methodology for toxicity tests with aquatic plants is needed.

Response—This is most certainly true. Much other research also is needed, and generally is considered higher priority. EPA hopes that someday all of the additional research that needs to be done will be done. Few pollutants seem to affect aquatic plants at concentrations which do not chronically affect aquatic animals, and it is hoped that this is not an artifact of the test methods currently used.

82. Comment—Data on toxicity to plants should not be used for deriving criteria because plants are more site-specific than animals.

Response—Numerous species of plants, especially algae, exist in most bodies of water. On the other hand, EPA knows of no data to support the contention that the sensitivities of aquatic plants are any more site-specific than those of aquatic animals, or that the range of sensitivities between plants is as great as that for animals. One species may or may not be representative of other species. After the methodology for toxicity tests with aquatic plants is better developed, tests with a wider variety of species would certainly be desirable.

83. Comment—The Final Plant Value should not be the lowest available plant value based on measured concentrations.

Response—EPA adopted the procedure described in the Guidelines for obtaining the Final Plant Value for several reasons including:

a. The methodology for toxicity tests with aquatic plants is not well developed.

b. For only a few pollutants have toxicity tests been conducted with more than a very few species of plants.

c. Little is known about the range of sensitivities of various species of aquatic plants.

d. Based on available data, almost no pollutants are toxic to aquatic plants at the lowest concentrations which are chronically toxic to aquatic animals or cause unacceptable residues.

84. Comment—Residue accumulation in any part of an aquatic ecosystem should be prevented as much as possible.

Response—Accumulation of residues in aquatic organisms only becomes a problem if the concentration of residue is high enough to adversely affect either (a) the organism itself, (b) a consumer of the organism, or (c) the marketability of the organism. Adverse effects on the aquatic organism itself will be detected in acute and chronic toxicity tests. The use of FDA action levels and chronic feeding studies with wildlife are designed to protect the uses and consumers of aquatic organisms.

85. Comment—Bioconcentration factors (BCFs) derived from field data should not be used.

Response—EPA feels that BCFs derived from adequate data, whether they be laboratory data or field data, should be used. More data are necessary to document a BCF from a field exposure than a laboratory exposure, as specified in the Guidelines, but if enough data are available, field BCFs should be used.

86. Comment—Kinetically derived bioconcentration factors (BCFs) should be used.

Response—Kinetically derived BCFs should be used if the bioconcentration test lasted long enough, *i.e.*, to apparent steady-state, to verify that the model (assumptions) used in the calculations actually fits the data for the individual pollutant.

87. Comment—Bioconcentration factors (BCFs) should not be estimated from octanol-water partition coefficients.

Response—The available data seem to indicate a reasonably good relationship for lipid-soluble substances between steady-state BCFs and octanol-water partition coefficients. BCFs estimated from partition coefficients are not used in the Guidelines because measured BCFs are available for all pollutants for which a maximum permissible tissue concentration is available.

88. Comment—Bioconcentration factors (BCFs) are dependent on temperature, food, salinity, stress, and other things.

Response—Many things such as these probably do affect BCFs. Until data are available to show that such effects are important and are not species-specific, little needs to be, or can be, done to take such factors into account when deriving water quality criteria.

89. Comment—Bioconcentration factors (BCFs) should be based only on tissues that are actually eaten.

Response—Although people usually only eat muscle tissue of fish, wildlife usually eat the whole body of fish. The tissues used in the determination of BCFs must be appropriate to the kind of consumer organism or regulatory action. On the other hand, since the BCF for a lipid-soluble substance seems to be proportional to percent lipids, extrapolations can be made on the basis of percent lipids regardless of the tissue.

90. Comment—Chronic toxicity tests with rats and mice should not be used as representative of tests on mammalian wildlife.

Response—Because results of tests on a variety of species are extrapolated to man, it should be just as reasonable to extrapolate from one mammalian species to another mammalian species within certain limits. However, such extrapolations are not now used in the Guidelines; only the results of chronic toxicity tests with wildlife are used to protect wildlife consumers of aquatic life.

91. Comment—Information concerning bioconcentration should only be used if such information is used to protect aquatic organisms, not to protect the marketability of aquatic organisms.

Response—Protection of aquatic organisms must include not only the protection of the existence of aquatic organisms, but also protection of the common uses of aquatic organisms. Commercially important aquatic organisms cannot be considered adequately protected if they cannot be sold. The Guidelines do not use any data pertaining to safety to humans in an attempt to protect human consumers of aquatic organisms. Instead, the Guidelines merely attempt to ensure that residues in aquatic organisms do not exceed FDA action levels so that the uses of commercially and recreationally important species are not restricted by the Food and Drug Administration.

49 FR 43906-01
PROPOSED RULES
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 61
[AD-FRL 2694-2]

National Emission Standards for Hazardous Air Pollutants; Regulation of Radionuclides

Wednesday, October 31, 1984

***43906** AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed standards.

SUMMARY: On April 6, 1983, the Environmental Protection Agency, pursuant to section 112 of the Clean Air Act, proposed standards for sources of emissions of radionuclides in four categories: (1) Elemental phosphorus plants; (2) Department of Energy (DOE) facilities; (3) Nuclear Regulatory Commission (NRC)-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. In addition, the Agency decided not to propose standards for the following source categories of radionuclide emissions: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction industries; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators. The Agency is announcing the withdrawal of its four proposed standards for radionuclide emissions under Section 112 of the Clear Air Act and affirms its original decision not to regulate emissions from the other five source categories considered. The U.S. District Court for the Northern District of California has ordered EPA to take final action on its proposed standards by October 23, 1984.
DATE: This withdrawal is effective October 31, 1984.

ADDRESS: The rulemaking record is contained in Docket No. A-79-11. This docket is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery One, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: James M. Hardin, Environmental Standards Branch (ANR-460), Criteria and Standards Division, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-8977.

SUPPLEMENTARY INFORMATION:

I. Supporting Documents

A final Background Information Document has been prepared and single copies may be obtained by writing the Program Management Office, Office of Radiation Programs (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351. Please refer to “NESHAPS-Radionuclides: Background Information Document for Final Rules, Volumes 1 and 2 [EPA 520/1-84-022-1, EPA 520/1-84-022-2], October 1984. These documents comprise the integrated risk assessment performed to provide the scientific basis for this rulemaking. Volume 1 of the Background Information Document contains a complete description of the Agency's methodology used in its risk assessment of the hazards associated with airborne emissions of radionuclides. Volume 2 is devoted to a detailed description of how the Agency applied this methodology to each source category considered in this rulemaking. For each source category, this document describes the radionuclide emissions, estimated doses and risks to nearby individuals and to populations, description of current emission control technology, and descriptions and cost estimates of additional emission control technology.

The Agency's written responses to oral and written comments on the proposed standards have been placed in Docket No. A-79-11. Single copies of the Agency's responses may be obtained by writing the Program Management Office, Office

of Radiation Programs (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351. Please refer to "NESHAPS-Radionuclides: Response to Comments for Final Rules, Volumes 1 and 2" [EPA 520/1-84-023-1, EPA 520/1-84-023-2], October 1984.

II. History of Standards Development

In 1977, Congress amended the Clean Air Act (the Act) to adddress airborne emissions of radioactive materials. Before 1977, these emissions were either unregulated or were regulated under the Atomic Energy Act. Section 122 of the Act required the Administrator of EPA, after providing public notice and opportunity for public hearings (44 FR 21704, April 11, 1979), to determine whether emissions of radioactive pollutants "cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health." On December 27, 1979, EPA published a notice in the Federal Register listing radionuclides as a hazardous air pollutant under section 112 of the Act (44 FR 76738). This action was based on the Agency's finding that studies of the biological effects of ionizing radiation indicated that exposure to radionuclides increases the risk of human cancer and genetic damage. In addition, the Agency found that emissions data indicated that radionuclides are released into air from many different sources with the result that millions of people are exposed. To support these findings, EPA issued a report entitled "Radiological Impact Caused By Emissions oof Radionuclides into Air in the United States, Preliminary Report," [EPA 520/7-79-006], Office of Radiation Programs, U.S. EPA, Washington, D.C., August 1979.

Section 122(c)(2) of the Act directed that, after having listed radionuclides as a hazardous air pollutant, EPA enter into an interagency agreement with the Nuclear Regulatory Commission with respect to those facilities under NRC jurisdiction. Such a memorandum of understanding was effected on October 24, 1980, and was subsequently published in the Federal Register (45 FR 72980, November 3, 1980). When EPA began developing standards for Department of Energy facilities, a similar memorandum of understanding was negotiated with DOE and signed in October 1982. Copies of both these memoranda have been placed in the Docket for public review.

On April 6, 1983, EPA announced its proposed standards for sources of emissions of radionuclides from four categories: (1) Elemental phosphorus plants; (2) DOE facilities; (3) NRC-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. Several additional source categories emitting radionuclides were identified in the notice. However, the Agency concluded that good reasons existed to propose not to regulate these categories, which included: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction industries; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators (48 FR 15076, April 6, 1983). At the time of proposal, it was thought that these nine source categories were all that potentially released radionuclides to air at levels that could warrant regulatory attention. In support of these proposed standards and determinations, EPA published a draft report entitled "Background Information Document, Proposed Standards for Radionuclides," [EPA 520/1-83-001], Office of Radiation Programs, U.S. EPA, Washington, D.C., March 1983.

Following publication of the proposed standards, EPA conducted an informal public hearing in Washington, D.C., on April 28 and 29, 1983. The comment period was held open an additional 30 days to receive written comments. Subsequently, EPA received a number of ***43907** requests to extend the time for submission of public comments and to conduct a public hearing outside of Washington, D.C., on the proposed standards to accommodate those were unable to attend the first hearing. In response to these requests, EPA extended the comment period by an additional 45 days and held another informal public hearing in Denver, Colorado, on June 14, 1983 (48 FR 23665, May 26, 1983).

EPA has considered and responded to all written and oral comments; a copy of the Agency's responses is in the Docket. The Background Information Document has been revised and published in final form. In addition, a final economic analysis of the impact of the proposed standards for elemental phosphorus plants has been completed and placed in the Docket (Refer to "Regulatory Impact Analysis of Emission Standards for Elemental Phosphorus Plants," October 1984). The final report on control technology for radionuclide emissions to air at Department of Energy facilities has been published and a copy is available int he Docket. (Refer to "Control Technology for Radioactive Emissions to the Atmosphere at U.S. Department of Energy Facilities," [PNL-4621], October 1984).

In response to requests for wider scientific review of the Agency's risk assessment, the Administrator in December 1983, formed a Subcommittee on Risk Assessment for Radionuclides within the Agency's Science Advisory Board (SAB) to review the scientific basis for the proposed standards. This review is discussed in more detail in Section IV of this notice. On the basis of the Subcommittee's review, the final Background Information Document has been rewritten to incorporate recommendations made by the Subcommittee. The revised Background Information Document presents an integrated risk assessment following the format and methodology suggested by the Subcommittee, to the extent possible.

On February 17, 1984, the Sierra Club filed suit to compel final action in the U.S District Court for the Northern District of California, pursuant to the citizens' suit provision of the Act (Sierra Club v. Ruckelshaus, No. 84-0656 WHO). In August 1984, the Court granted the Sierra Club's summary judgment motion and ordered EPA to take final action on its proposed standards by October 23, 1984. On September 14, 1984, the Administrator requested that the Court delay its deadline until January 1985 to him enable him to personally evaluate the merits of the criticisms and suggestions presented by the Subcommittee. This request was denied.

On August 24, 1984, EPA announced in the Federal Register the availability of new technical information (49 FR 33695). The public was encouraged to comment on this new information which included the Final Report of the SAB Subcommittee, transcripts of all public meetings of the Subcommittee, information presented to the Subcommittee, and technical information relevant to elemental phosphorus plants and underground uranium mines. This new information was available in the Docket on September 7, 1984. The Agency's responses to these comments are included in Volume 2 of “NESHAPS-Radionuclides: Response to Comments for Final Rules.”

III. Summary of the Final Actions.

On April 6, 1983, the Agency proposed standards for sources of emissions of radionuclides in four categories: (1) Elemental phosphorus plants; (2) DOE facilities; (3) NRC-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. For DOE facilities, the Agency proposed an emission limit not to exceed an amount that causes a dose equivalent rate of 10 mrem/y to the whole body and 30 mrem/y to any organ of any individual living nearby. For NRC-licensees and non-DOE Federal facilities, the Agency proposed an emission limit not to exceed an amount that causes a dose equivalent rate of 10 mrem/y to any organ of any member of the public. The emission limit proposed for elemental phosphorus plants was 1 Ci/y of polonium-210.

For all three of these source categories, the Administrator has determined that current practice provides an ample margin of safety in protecting the public health from the hazards associated with exposure to airborne radionuclides, and has therefore decided to withdraw the proposed standards.

In the case of underground uranium mines, the Agency proposed a standard to limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/1 above background in any unrestricted area. The Agency is also withdrawing this proposed standard beacause it has concluded, for the reasons discussed below, that it did not meet the legal requirements of Section 112. The Agency has received additional technical information that suggests the possibility of using bulkheading and other techniques to control radon emissions. However, pursuing this course of action was not advocated or even suggested in the proposal. Indeed, the information available to EPA at the time of proposal indicated that these techniques were costly and “not very effective” and the Agency dismissed these techniques as the basis for an emission standard (48 FR 15083, col. 3). Since that time, new information suggests that conclusion may be erroneous. Technical information on which the base of final regulation or a proposal is not yet available; further work is needed to demonstrate how to set such a regulation at some future time. Therefore, the Agency is publishing, simultaneously with this notice, an Advance Notice of Proposed Rulemaking for Radon-222 Emissions from Underground Uranium Mines to solicit additional information on control methods, such as bulkheading and other forms of operational controls for radon-222 emissions from these mines. Such an approach could avoid many of the technical and legal difficulties pose by EPA's proposed standards.

In addition to the four source categories for which EPA did propose standards, the Agency has made a final determination not to regulate the following five source categories: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction facilities; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators. The Agency did not receive any new information during the public comment period that convinced it of a need for regulation of any of these five categories. Therefore, the Administrator affirms the original decision not to regulate these sources, believing that adequate public health protection exists to satisfy the requirements of the Clean Air Act.

When the Agency promulgated its standards for active uranium mill tailings (40 CFR 192, Subparts D and E), it decided that the control of the radon-222 emissions from the active uranium mill tailings piles could more appropriately be considered under the Clean Air Act, rather than the Uranium Mill Tailings Radiation Control Act. The preamble to the final uranium mill tailings standards noted that work practice standards were probably the most practical way to control radon emissions at active uranium mills. Consequently, EPA is issuing, simultaneously with this notice, an Advance Notice of Proposed Rulemaking for Radon-222 Emissions from Licensed Uranium Mills.

***43908** The withdrawal of the proposed standards for elemental phosphorus plants, Department of Energy facilities, Nuclear Regulatory Commission-licensed facilities and non-DOE Federal facilities, and underground uranium mines are final actions. Also, the decision not to establish radionuclide emission standards for coal-fired boilers; the phosphate industry, other extraction industries; uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and low energy accelerators are final actions. Judicial review is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit within 60 days of today's publication date.

III. Major Issues Raised in Public Comments

Many commenters expressed considerable dissatisfaction with the proposed standards. Operators of facilities for which standards were proposed objected vigorously to the stringency of the proposed standards; other groups objected on the grounds that the proposed actions were not sufficiently protective of public health. Both groups criticized the proposed standards for not meeting the intent of the Clean Air Act.

A number of comments were made which apply to all of the source categories considered and which address the bases of the standards-setting process. The following is a summary of the most significant comments and the Agency's responses:

Comment: Radionuclides should not be considered a hazardous air pollutant under section 112 of the Clean Air Act because ambient levels do not pose a significant risk to human health. One commenter petitioned for reconsideration of EPA's listing of radionuclides as a section 112 pollutant, on the basis that the Agency had not justified its conclusion that radionuclides are hazardous air pollutants within the meaning of section 112.

Responses: EPA has concluded that existing radionuclide emissions from some stationary sources can represent a significant risk of fatal and nonfatal cancers to exposed populations. There is no scientific doubt that radionuclides are carcinogens. This conclusion is based on extensive scientific evidence derived from studies of populations of humans and animals exposed to radiation at various levels ranging from very high doses to doses only slightly greater than environmental levels.

Both this conclusion and EPA's specific risk esitmates are based on the widely used assumption that there is no threshold below which exposure to radiation does not pose some risk to human health. Based on this premise, EPA concludes that exposure to radionuclides at low levels in the ambient air presents a risk of fatal and nonfatal cancers, as well as genetic damage.

In addition, section 112 requires not only a finding that the pollutant at issue is hazardous in the abstract, but also that it poses a public health risk in its form as an air pollutant. EPA has evaluated the air pollution risk of radionuclide emissions based on the magnitude of such emissions from stationary sources to the ambient air, on observed and estimated ambient concentrations of radionuclides, on the proximity of large populations to emitting sources, on estimates of health risks to exposed populations, and on considerations of uncertainties associated with risk estimates.

Based on this analysis, EPA has concluded that the present record does not support regulation of any of the source categories for which regulation was proposed. This conclusion, however, does not support delisting of radionuclides, because, in the case of uranium mines, the risks appear sufficient to warrant future regulatory action under section 112. It is only because regulation of the appropriate type is impossible at this time, due to the need for further work on the technical issues and the need to provide an opportunity for notice and comment on any proposed action, that no rules for uranium mines are being included in this decision.[FN1]

Therefore, with respect to the petition for reconsideration of the listing of radionuclides as a hazardous air pollutant, EPA has considered this option and has rejected it, believing that the original decision to list under section 112 is still appropriate.

Comment: The EPA standards are unnecesary because current administrative or regulatory standards of 500 mrem/y to the whole body and 1500 mrem/y to any organ (Federal Radiation Council guidance and NRC regulatory values), coupled with directives to keep emissions as low as practicable, are adequately protective of the public health. Other commenters felt that the proposed standards were too lax and that the Agency should set an emission limit of zero, with exceptions allowed only after a case-by-case examination.

Response: EPA does not believe that current Federal Radiation Council guidance and NRC policy of limiting exposure to individuals to 500 mrem/y to the whole body and 1500 mrem/y to any organ protects public health with an ample margin of safety, as required by the Clean Air Act. EPA estimates that a person receiving 500 mrem/y to the whole body over a lifetime would have an added potential risk of developing a fatal cancer of about one in one hundred due to the radiation exposure. In addition, that same person would face an approximately equal level of risk of nonfatal cancer and of passing on nonfatal genetic effects to succeeding generations.

However, EPA recognizes that the “as low as reasonably achievable” (ALARA) emissions policy had led to generally low emissions of radionuclides from most facilities. The Agency expects that this current policy will continue in the future and does not anticipate an increase in the emission level or the associated risks. Therefore, the Agency believes that in cases in which a vigorous and well-implemented ALARA program has achieved low emissions, such practice can provide an ample margin of safety for public health protection.

The Agency does not agree with the approach of establishing an emission limit of zero. The implementation of such a standard for the source categories considered would be extremely burdensome, and would result in little improvement in public health. More important, however, is the Administrator's determination that public health is currently protected to a degree which satisfies the requirement of Section 112 of the Act.

Comment: EPA is required to promulgate standards under all of its applicable authorities in order to fulfill the intent of its Congressional mandates. For example, the Agency must regulate air emissions from uranium fuel cycle facilities under the Clean Air Act, as well as under the Atomic Energy Act.

Response: The Agency believes that its primary objective is to provide reasonable public health protection, but that it was not the intent of Congress that the Agency issue duplicative regulations to achieve this goal. In light of the limited resources in both the ***43909** public and private sector, it would be inefficient and unnecessarily complicated to require sources to comply with a standard they already meet, or alternatively, to meet several comparable standards set by one Agency under different statutory authorities.

Comment: Some commenters stated that the standards should be based on cost analyses, and if not cost-effective, they should not be promulated. Others felt that costs should not be considered at all.

Response: The Agency believes that giving equal weight to costs and benefits is inappropriate in developing standards under Section 112 of the Clean Air Act. Congress clearly intended that public health protection considerations be primary and that cost be secondary.

The Agency did consider, in developing these rules, the availability and practicality of control equipment. While this was not a primary consideration, knowledge of the availability of control technology is necessary when making judgments on the need for and level of emission standards. EPA believes these considerations are within the Administrator's discretion in determining what level of protection is adequate. The Agency considered costs to a limited degree consistent with this overall perspective in reaching its decisions on coal-fired boilers and elemental phosphorus plants, but otherwise today's action does not rest on cost considerations.

Comment: Some commenters stated that the Clean Air Act requires standards for all source categories releasing significant amounts of radionuclides into the air. Determinations that standards are not needed are not allowed for any reason. Others supported EPA's determinations that standards for some categories are unnecessary.

Response: The comment that every stack emitting radionuclides to air must be subject to an emission limit established under the Clean Air Act must be considered in light of the fact that every stack in the United States discharges at least minute quantities of radionuclides. These radionuclides include certain kinds of carbon and potassium atoms and other naturally-occurring radionuclides. Because these emissions are so small, the risk to nearby individuals and the total population group is minimal. To regulate these sources would not significantly improve the public health.

Section 112 of the Act requires the Administrator to assure public health protection with an ample margin of safety. A negative determination of the need for standards is permissible within the context of the Act, so long as this criterion is met. With respect to eight of the source categories considered in this rulemaking, the Agency has concluded that the public health is adequately protected under current practice, and therefore has met the requirements of the Act. For the uranium mines category, the Agency concludes that risks are significant; however, there is presently no feasible way to establish an emission standard. The Agency will consider such a standard, together with alternative design, equipment, work practice and operational standards, for future proposal.

Comment: There has not been sufficient review outside the Agency of EPA's methods and procedures for risk assessment. Specifically, EPA's Science Advisory Board should review the scientific basis of the proposed standards for radionuclides.

Response: The Agency agrees with this comment (see section V below).

Comment: The proposed standards should not be promulgated because they cannot be implemented with reasonable procedures. Compliance with indirect emission standards (dose or concentration limits at site boundary) must be determined by environmental measurements at the site boundary. Because the proposed standards are so restrictive, this is either very expensive or altogether impractical.

Response: Questions concerning the implementations of standards for airborne radionuclide emissions are moot in light of the Administrator's decision to withdraw the proposed rules.

Comment: Standards should be consistent with established international and national policies and regulations governing radiation protection, as well as among each source category.

Response: The Agency agrees with this comment and has based its decision to withdraw the proposed standards, in part, on the fact that current practices in radiation protection do provide adequate public health protection.

Comment: Standards should allow for greater operational flexibility in selecting control technology.

Response: Questions concerning the amount of operational flexibility necessary to comply with standards for airborne radionuclide emissions are moot in light of the Administrator's decision to withdraw the proposed rules.

V. Technical Review by the Science Advisory Board

In response to criticism that the Agency did not have sufficient outside review of its methods used to assess risk due to radionuclides, the Administrator formed a subcommittee of the Agency's Science Advisory Board to review the scientific basis of the proposed standards for radionuclides. The Subcommittee held three public meetings: the first on January 16, 1984, the second on February 21-22, 1984, and the third on March 22, 1984. At these meetings, the Subcommittee was briefed by Agency staff on the methods used in estimating risks caused by airborne radionuclides. The panel heard from members of the public on the Agency's risk assessments, as well. The Subcommittee also held executive sessions to consider the information presented by the Agency and the public.

Transcripts of the public meetings are available in the Docket. The Subcommittee's final report, entitled “Report on the Scientific Basis of EPA's Proposed National Emission Standards for Hazardous Air Pollutants for Radionuclides,” was transmitted to the Administrator on August 17, 1984. A copy of this report and the Agency's response are available in the Docket.

In the Executive Summary of its report, the Subcommittee noted that its activities could be viewed as addressing two interrelated questions. First, did the Agency's staff collect the scientifically relevant data and use scientifically defensible approaches in modeling the transport of radionuclides through the environment from airborne releases, in calculating the doses received by persons inhaling or ingesting this radioactivity and in estimating the potential cancer and genetic risks of the calculated doses? Second, are the individual facts, calculational operations, scientific judgments, and estimates of uncertainty documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e., standard-setting? With regard to the first question, the Subcommittee concluded that EPA had gathered the appropriate scientific information needed for a risk assessment in a technically proficient manner.

The Subcommittee made several technical suggestions on how EPA could improve its assumptions, models, and methods for estimating risks. Most of these technical suggestions have been incorporated into EPA's risk assessment procedures. The risk assessment for the final rule reflects these modifications. Some of these technical suggestions involve additonal research to improve future risk assessment methods. Those ***43910** suggestions will be used as EPA conducts new studies.

The Subcommittee's greatest criticism in its report was related to the second question. They concluded that EPA had not assembled and integrated the available scientific data in the format of a risk assessment that provides an adequate basis for regulatory decisions. The panel suggested the need for an intermediate step between the collection of the relevant technical information and the selection of regulatory options. Specifically, they encouraged the Agency to assemble an intergrated risk assessment document that would lead a decisionmaker step-by-step from the identification of emission sources, through the calculation of radiation doses and the associated degree of uncertainty, to a variety of regulatory options from which to choose. Only in this way did the Subcommittee feel that a policymaker could be presented with all the facts necessary to make a responsible regulatory decision. Further, this analysis would enable the scientific community and the public to understand the rationale and basis for the Agency's actions.

The Agency recognizes and is concerned about the adverse criticism of its processes by its own Science Advisory Board. EPA does believe that, on balance, its risk estimates for specific sources of radionuclide emissions are accurate within the limitations inherent in making such estimates. It acknowledges, however, that the criticism of the Board does cloud the rulemaking record, and that the Subcommittee's concerns, by their very nature, cannot be fully addressed within the time available for this decision. Nevertheless, the final Background Information Document has been greatly modified to encompass the format and suggestions of the Subcommittee to the extent possible. However, the Subcommittee has not reviewed this revised document.

The Science Advisory Board also made several procedural suggestions for improving the Agency's risk assessment methods. These recommedations will be incorporated into the Agency's procedures and processes. Detailed responses to the Science Advisory Board's recommendations can be found in Volume 2 of “NESHAPS-Radionuclides: Response to Comments for Fiscal Rule.”

VI. **Perspectives on Risk Assessment**

Today's decision is based on a developing body of science and policy concerning the treatment of one particular class of hazardous substances, namely materials that cause, or are thought to cause, cancer. In some cases, scientific evidence indicates that a given substance is hazardous at high levels or exposure, but has no effect below a certain level. For most carcinogenic substances, however, scientists are unable to identify such a threshold below which no effects occur; moreover, to the extent scientists understand the process of carcinogenesis, there is some reason to believe such thresholds may not exist. For these kinds of substances, EPA and other Federal agencies have taken the position that any level of exposure may pose some risks of adverse effects, with the risks increasing as the exposure increases.

EPA's approach to risk assessment for suspected carcinogens may be divided into several steps. The first is qualitative evaluation of the evidence to determine whether a substance should be considered a human carcinogen for regulatory purposes. This was done for radionuclides before they were listed as a hazardous air pollutant in 1979. The second step is quantitative: how large is the risk of cancer at various levels of exposure? The result of this examination is a dose-response function which gives the lifetime risk per unit of exposure (or “potency”). The third step is to estimate how many people are exposed to the sources of radiation, and at what levels. These exposure estimates then are combined with the dose-response function to obtain estimates of the risk caused by emissions of the pollutant, in this case radionuclides, into the environment.

Exposure levels for each specific source category are derived using emissions estimates, dispersion modeling, and population data. For any given level of emissions, dispersion models predict concentrations at different distances from the emission source. By combining those estimated concentrations with census data on population densities, the number of people exposed at different levels can be estimated. Several factors suggest that actual exposure levels will be lower than those estimated. In estimating exposure, the most exposed individuals are hypothetically subjected to the maximum annual average concentration of the emissions for 24 hours every day for 70 years (roughly a lifetime). This does not take into account indoor vs. outdoor air, for instance, or the fact that most people in their daily routines move in and out of the specific areas where the emission concentration are the highest.

The final risk estimates are the product of the exposure levels and the estimated unit-risk factor. Two summary measures are of particular interest: “nearby individual risk” and “total population impact.” The former refers to the estimated increased lifetime risk from a source that is faced by individuals who spent their entire life at the point where predicted concentrations of the pollutant are highest. Nearby individual risk is expressed as a probability; a risk of one in one thousand, for example, means that a person spending a lifetime at the point of maximum exposure faces an estimated increased risk of cancer of one in one thousand. (For comparison, the average lifetime risk of dying of cancer in the United States is about 165 in 1,000, so eliminating a risk of one in one thousand reduces the overall lifetime risk of contracting cancer by less than 0.6 percent.) Estimates of nearby individual risk must be interpreted cautiously, however, since generally few people reside at the points of maximum concentrations and spend their whole lives at such locations.

The second measure, “total population impact,” considers people exposed at all concentrations, low as well as high. It is expressed in terms of annual number of cancer cases, and provides a measure of the overall impact on public health. A total population impact of 0.05 fatal cancer per year, for example, means that emissions of the specific pollutant from the source category are expected to cause one case of cancer every 20 years. Such figures should not be viewed as precise estimates of the likely effects. Together with the estimates of maximum individual risk, they are intended to give an indication of a reasonable upper-limit situation.

The two estimates together provide a better description of the magnitude and distribution of risk in a community than either number alone. “Nearby individual risk” tells us the highest risk, but not how many people bear that risk. “Total population impact” describes the overall health impact on the entire exposed population, but not how much risk the most exposed persons bear. Two sources of radionuclide or chemical emissions could have similar population impacts, but very different maximum individual risks, or vice versa. Any sensible “risk management” system cannot rely on either measure alone; both are important.

Much more is known about the risks from exposure to radiation than exposure to most chemicals. While there is uncertainty in risk estimates from assessments of chemical emissions and radionuclide emissions, there is likely to be much less uncertainty in estimates of ***43911** risk from radionuclide emissions because of the extensive data base on human exposure to radiation. Therefore, a risk estimate of one in one thousand resulting from radionuclide emissions is likely to be more accurate than the same estimate for chemical releases. The situation for estimating risk from radionuclides is much less likely to reflect hypothetical maximum potential estimates than are estimates made for chemical emissions.

To provide general perspective regarding radiation exposure, everyone is exposed to background radiation due to cosmic radiation, and radioactivity in minerals, soils, and even our own bodies. Background radiation levels vary across the U.S., but average about 100 mrem/y for each person. There is very little that people can do to control exposure to background radiation. Over a lifetime this exposure is estimated to contribute to a fatal cancer risk of about one or two cases for every one thousand people.

VII. Withdrawal of Proposed Standards

A. Alternatives

In determining the appropriate course of action for the proposed standards, EPA considered the following alternatives.

1. Withdraw the Proposed Standards

This alternative is based on the finding that current and future emissions at the facilities under consideration are anticipated to be at levels that would protect the public with an ample margin of safety, as required by section 112 of the Act. This alternative is also appropriate if implementation of the proposed standards is infeasible.

2. Promulgate the Proposed Standards

This alternative is based on the conclusion that the findings made in the proposed rule were correct and that the proposed standards are necessary to adequately protect the public health.

3. Promulgate a Standard for Each Category at a Level That Would Limit Dose to 25 mrem/y to the Whole Body and 75 mrem/y to Any Organ

This alternative is based on the conclusion that the need for standards for each category for which the Agency proposed rules was correct, but that EPA could establish the standards at these recommended levels and still provide an ample margin of safety. Establishing the standards at these levels would also respond to several comments regarding consistency among the categories and with the recommendations of recognized national and international radiation protection groups, and regarding the need for greater operator flexibility in selecting control technology and methods of demonstrating compliance.

B. Elemental Phosphorus Plants

One of the decisions presented by this rulemaking concerns emission for elemental phosphorus plants. Risks from these plants are higher than for any other source category in this rulemaking except uranium mines. Moreover, technology to reduce these risks is available. Nevertheless, after consideration of the proposed rule, the public comments, the Science Advisory Board report, the risk assessment, and other pertinent information, it is the Administrator's judgment that the present record does

not support a conclusion that regulation of elemental phosphorus plants is necessary to protect the public health, within the meaning of the Clean Air Act. Therefore, the proposed rule is withdrawn. This decision presents difficult questions and the Agency is undertaking a number of nonregulatory actions, explained below, that may lead to reexamination of this decision at some future date.

EPA estimates the total risk to human populations posed by radionuclide emissions from elemental phosphorus plants to be 0.06 fatal cancer per year, or approximately one case every seventeen years. This risk is similar to other risks that EPA has considered insufficient to warrant Federal regulation in comparable Section 112 proceedings. About 80% of the total risk presented by the industry is accounted for by two plants, the FMC plant in Pocatello, Idaho, and the Monsanto plant in Soda Springs, Idaho.

In the case of one of the plants, EPA estimates the dose rate to individuals at the location of highest air concentrations to be about 600 mrem/y to the lung. The chance of getting cancer from a lifetime of exposure at this location is calculated to be about one in one thousand. If risk to the “most exposed individuals” were the only criterion for judgment, this relatively high risk might well have led to a decision to regulate.

However, this risk must be weighed against both the low aggregate risk described earlier and against other factors. Our studies indicate that present emission controls on these plants are not efficient in removing radionuclides and could be improved. However, adding such additional controls will be expensive measured against the limited public health benefits provided.

Finally, the SAB Subcommittee's report harshly criticized EPA's analysis in support of its proposed standards. That alone would not justify a decision not to regulate, but in the context of the limited aggregate risk and other factors described earlier it contributes to such a decision, particularly given the Science Advisory Board's statutory role as the Agency's science advisor.

Over the next several years, EPA will work with the Science Advisory Board to satisfy its concerns regarding the scientific basis of regulations such as this. Undertaking this effort will also allow the development of answers to the following two questions that may have a bearing on any future EPA action.

1. EPA is curently reconsidering its ambient air quality standard for particulates, and may shift its emphasis toward regulating the smaller-sized particles. Since the two elemental phosphorus plants being considered here emit large amounts of these smallar particles, they may require additional controls based on these new standards. Limiting emissions of these smaller particulates would also control some of the radionuclide emissions from the plants.

2. The area surrounding these two plants is characterized by high total levels of radiation from a variety of sources. The storage and widespread use of slag and possibly other waste products from these plants have significantly increased the natural background radiation levels in parts of the communities. In particular, phosphate slag from these plants has been widely used as aggregate in road and house construction in these areas. EPA and the State of Idaho intend to perform a total assessement of the various sources and will investigate ways to reduce or prevent risks from growing. This assessment may find more effective ways to control the overall risks than by controlling the emissions at issue here.

C. Department of Energy (DOE) Facilities

It is also the Administrator's judgment that the present record does not support a conclusion that regulation of DOE facilities for radio-nuclide emissions to air is necessary to protect the public health with an ample margin of safety, within the meaning of the Clean Air Act. Therefore, the proposed rule is withdrawn and the rulemaking is terminated.

EPA estimates the total risk to exposed human populations by all DOE facilities for which regulation was proposed as 0.08 potential fatal cancer ***43912** per year, or one case every 13 years. This risk is comparable to risks that EPA has considered insufficient to warrant regulation in similar Section 112 proceedings.

Dose rates from the four DOE facilities with the greatest radionuclide emissions range from 50 mrem/y to 88 mrem/y to the lung; one of these facilities delivers a dose rate of 34 mrem/y to the whole body. EPA estimates the chances of fatal cancer from a lifetime of exposure to these plants' most concentrated emissions are about one to eight in ten thousand, somewhat lower than the maximum risks elemental phosphorus plants. Once again, this risk to nearby individuals must be weighed both against the low aggregate risks and the Science Advisory Board report described earlier.

The DOE currently has a program to keep exposure to the public to levels that are as low as reasonably achievable. This program is operated by the Department in keeping with the longstanding recommendations of the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, and the Federal Radiation Council to avoid radiation exposure where practical. While the Agency recognizes that DOE facilities maintain very large quantities of radionuclides in their inventories at many of their facilities, there has been a general trend at most facilities for radionuclide emissions to be reduced over the years. Emissions should not significantly increase in the future. EPA intends to continue its oversight of emissions from DOE facilities and should this change, the Agency will reexamine its decision not to regulate.

As previously noted, EPA currently has a Memorandum of Understanding (MOU) with DOE regarding the development and implementation of standards under section 112. EPA intends to coordinate with DOE to seek to modify the Memorandum of Understanding as appropriate.

D. Nuclear Regulatory Commission (NRC)-Licensed Facilities and Non-DOE Federal Facilities

It is also the Administrator's judgment that the present record does not support a conclusion that regulation of NRC-licensed facilities and Federal facilities other than DOE facilities is necessary to protect the public health with an ample margin of safety, within the meaning of section 112. Therefore, the proposed rule is withdrawn and the rulemaking is terminated.

EPA estimates the total risk to human populations posed by NRC-licensed facilities and non-DOE Federal facilities for which regulations were proposed to be no more than 0.02 fatal cancer per year, or less than one case every fifty years. This risk is comparable to other risks that EPA has considered insufficient to warrant regulation in similar Section 112 proceedings.

EPA calculates the changes of developing fatal cancer from a lifetime of exposure to the most concentrated emissions from the NCR facilitiy with the greatest dose rate at no more than two in ten thousands. EPA believes that the Nuclear Regulatory Commission and other Federal facilities will continue to implement programs to keep exposure of the public to levels that are as low as reasonably achievable, and adequate to protect the public against significant adverse effects from radiation. Emissions should not significantly increase in the future. EPA will continue its oversight of emissions from these facilities, and should this change, the Agency will reexamine its decision not to regulate.

As previously noted EPA currently has a Memorandum of Understanding (MOU) with NRC regarding the development and implementation of standards under section 112. EPA intends to coordinate with NRC to seek to modify the Memorandum of Understanding as appropriate.

E. Underground Uranimum Mines

The Agency proposed a standard for underground uranimum mines that would limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/1 above background in any unrestricted area. The standard was expected to be met by one of the following procedures: (1) Reducing the precentage of time the mine operates, (2) increasing the effective height of the release, and (3) controlling additional land. EPA expected that mine operators would most likely try to control land within about 2 kilometers of the mine vents in order to comply with the standard. EPA did not issue a direct emission standard for radon from underground uranium mines because, as the proposal explained, available information suggested that radon could not be collected by available pollution control equipment before being released from the vents, reductions afforded by better bulkheading or sealants were highly uncertain, and reducing the volume of air flow was not feasible due to the effect

on occupational exposure. Comments on the proposed rule indicated that controlling a sufficient amount of land might not be feasible because private owners of land surrounding the mine might be unwilling to make their land available to the mine owners.

Several comments were received starting that EPA had overestimated the risks from radon-222 emissions from underground uranium mines. It was suggested that the Agency had used overly conservative assumptions in the dispersion and risk calculations and that it used greater risk coefficients than recommended by other recognized radiation experts. EPA has considered these comments in establishing its parameters for emission rates, plume rise, and equilibrium ratios in the revised risk assessment. The most recent estimates of the lifetime risks to individuals living near these mine range from one in one thousand to one in one hundred. The potential exists for even higher risks in some situations, e.g., a person living very close to several horizontal mines vents or in areas influenced by multiple mine emissions. Lifetime risks in these situations could be as high as one in ten. EPA estimates the fatal cancer risk to the total population to be about five fatal cancers per year. The Agency considers these risks to be significant and believes action is needed to protect populations and individuals living near underground uranium mines.

Analysis of the likely reduction in health risks afforded by the proposed standards showed that while risks to nearly individuals were reduced by a factor of about ten, the risks to the total population were only negligibly reduced. The lack of population risk reduction is due to the fact that radon releases would not be reduced by the proposed rule, they would only be more widely dispersed.

EPA has concluded that its proposed standard was legally flawed in two ways. First, because it would not have limited radionuclide emissions on a continuous basis, but was primarily based on the use of dispersion technology to reduce risks to nearby people, it did not qualify an “emission standard” within the meaning of section 112 (See Clean Air Act, section 302(k)). EPA also believes such dispersion techniques cannot qualify in this context as a “design, equipment, work practice or operational standard” within the meaning of section 112(e). EPA believes that for such standards to be valid, they must also have an emission limiting effect. (See Clear Air Act, sections 112(e)(3) and (e)(4).) Second, because this standard would not reduce the aggregate population risk appreciably, when such risk was high, if failed to ***43913** meet the public health protection purposes of the Act.

Because radon-222 is a noble gas and the volume of air discharged through mine vents is very large, there is no practical method to remove radon-222 from the mine exhaust air. Adsorption onto activated charcoal is the most widely used method for removing noble gases from a low volume air stream. However, application of this method to the removal of radon-222 from mine ventilation air at the volumes of air which must be treated would require large, complex, unproven systems which would be extremely costly (i.e., at least $18-44/lb of U3 08 produced).

Since proposal, EPA has received additional technical information in a report prepared for the U.S. Bureau of Mines, indicating that work practices, such as bulkheading abandoned sections of mines to trap the radon before it is vented, may be more feasible and cost-effective than previously thought. This information, which is of a preliminary nature, suggests that bulkheading, even without the use of charcoal filters, could reduce emissions of radon-222 by 10-60% from typical mines at a cost ranging from $4-$60 per curie reduced or about $0.01-0.05/lb of U3 08 produced.

Uranium mines are widely diverse in their characteristics. They differ in configuration; for example, some mines have very few side tunnels and cross cuts whereas others may have many side areas. Consequently, they have a wide variety of surface areas where radon can be generated. In addition, mines differ in the geologic strata, mining techniques, and uranium and radium concentrations. All of these factors tend to decrease the number of common characteristics among mines that can be used to make general predictions of the effectiveness of specific control measures. Therefore, considerable additional work is needed to establish whether these results can be realized consistently for an appreciable segment of the industry, and to determine methods of bulkheading that might potentially produce any such consistently acceptable results. Only after these facts have been established would EPA be able to propose a standard based on these techniques. In any event, no such rule can be promulgated

on the present record because the original proposal considered the use of this form of control and explicitly dismised it as a basis for the standard.

Because the Agency is convinced that the health risks posed by underground uranium mines are significant, EPA has decided to begin developing an emission, design, equipment, work practice, or operational standard to control radon releases from underground uranium mines. An Advance Notice of Proposed Rulemaking announcing this decision is being published simultaneously with this notice.

VIII. Final Determination for Sources EPA Proposed Not To Regulate

EPA previously identified several source categories that emit radionuclides to air but proposed not to regulate them. Final decisions on the need for emission standards for these categories, and the reasons for these decisions, are discussed in the following paragraphs.

A. Coal-Fired Boilers

Large coal-fired boilers are used by utilities and industry to generate electricity and to make process steam and hot water for space heaters and industrial processes. When operating, these boilers emit trace amounts of uranium, radium, thorium, and their decay products found in the feed coal. These radionuclides become incorporated into fly ash and are carried into the air along with the particulate matter these boilers emit. Technology that removes particulates will also limit radionuclide emissions.

Particulate emissions from new utility and new large industrial boilers are controlled by new source performance standards issued under Section 111 of the Clean Air Act reflecting best demonstrated technology. EPA has also proposed new source performance standards for smaller industrial boilers. Existing utility and industrial boilers are regulated for particulate emissions by State implementation plans as required by the Clean Air Act.

EPA proposed not to regulate coal-fired boilers because these existing particulate emission standards also limit radionuclide releases, and result in relatively insignificant risks to nearby individuals and to populations due to radionuclides. The highest dose resulting from this source category is 1 mrem/y to the lung. This is equivalent to an individual lifetime risk of fatal cancer of one in one million. Population risk is estimated to be about two fatal cancers per year, spread over the entire U.S. population. The cost to further reduce radionuclide emissions is greater in comparison to the additional public health protection achieved. In addition, radionuclide emissions will decrease as old plants are replaced with new ones having improved particulate emission controls as required by the Clean Air Act.

Many commenters, mostly industrial groups, strongly supported the determination not to propose regulations for this source category. Several commenters stated that the risks from coal-fired boilers were so low that this fact alone indicated that standards are not needed. The Agency's decision not to regulate is based on both a consideration of the level of risk and on a consideration of total cost and practicality of additional control equipment. Some commenters stated costs should not be considered under section 112 of the Clean Air Act. EPA believes it is not reasonable to avoid considering cost and practicality of control technology; however, the protection of public health was the primary consideration in reaching this decision.

Some commenters raised the question of whether there are some boilers that might burn coal with high uranium content, leading to emission levels far greater than those considered in making this determination. EPA asked for comment on this point and contracted with Los Alamos National Laboratory to investigate the existence of such boilers. The Agency was unable to find boilers with radionuclide emission rates significantly greater than the model facility we studied in detail. In fact, the majority of boilers can be demonstrated to have emissions much lower.

Some commenters stated that the requirements of the Clean Air Act dictate that EPA must propose an emission standard specifically for radionuclides, regardless of other Clean Air Act regulations limiting particulate emissions. EPA believes that to issue a standard that duplicates current regulations is unreasonable. As a practical matter, Clean Air Act regulations limiting

particulate emissions from these boilers also limit radionuclide emissions. Hence, these existing regulations protect the public health with an ample margin of safety as far as radionuclide emissions are concerned.

After carefully considering all comments, EPA has decided not to regulate radionuclide emissions from coal-fired boilers at this time. This decision will be periodically reviewed as additional information on the total impact of all hazardous air pollutants from coal-fired boilers becomes available.

B. Phosphate Industry

The phosphate industry processes phosphate rock to produce fertilizers, detergents, animal feeds, and other products. The production of fertilizer ***43914** uses approximately 80 percent of the phosphate rock mined in the United States. Phosphate deposits contain elevated quantities of natural radioactivity, principally uranium-238 and members of its decay series. Uranium concentrations in phosphate deposits range from ten to one hundred times the concentration of uranium in other natural rocks and soils.

Phosphate Rock Processing Plants

The processing of phosphate rock in dryers, grinders, and fertilizer plants results in the release of radionuclides into the air in the form of dust particles. Control techniques that remove particulates will also control radionuclide emissions.

Particulate emissions from new or modified phosphate rock drying, grinding, and fertilizer plants are controlled by new source performance standards issued under Section 111 of the Clean Air Act. In the case of fertilizer plants, the new source performance standard for fluoride also provides for effective control of particulates. Existing drying, grinding, and fertilizer plants are regulated for particulate emissions by State implementation plans as required by the Clean Air Act. EPA proposed not to regulate phosphate rock processing facilities because the existing particulate and fluoride emission standards also limit radionuclide releases. The risks to nearby individuals and the total population risks due to radionuclide emissions from these three types of facilities are insignificant. The highest doses resulting from emissions from these facilities are 15 mrem/y to the bone and 7 mrem/y to the lung. This is equivalent to a lifetime individual risk of fatal cancer of one in one hundred thousand. Population risk is from all of these facilities about to 0.02 fatal cancer per year. In addition, there is no potential for emissions to increase; rather, they should decrease as older plants are replaced with new ones subject to new source performance standards.

Comments from the phosphate industry strongly supported EPA's proposal not to regulate phosphate rock processing facilities and further stated that EPA had overestimated the radionuclide emissions from these facilities. EPA agrees that its estimates of radionuclide emissions from these facilities were based on some conservative assumptions and has concluded that this serves to reinforce its decision not to regulate these facilities.

Several commenters stated that standards were needed for phosphate rock processing facilities and that cost should not be considered in reaching a decision on the need for these standards. Even without considering costs, EPA does not agree that standards are needed for these facilities for the reasons just stated.

EPA did not previously make any determination regarding radionuclide standards for phosphate rock calciners at wet process fertilizer plants because information on emissions from these facilities was not available. EPA requested comments on these emissions and asked whether standards were needed. In addition, the Agency conducted emission tests at two of these facilities. EPA has not yet completed its analysis of these emission tests or carried out a risk assessment for these calciners. Therefore, no determination of the need for standards for phosphate rock calciners at wet process fertilizer plants is made at this time.

After considering all comments, EPA has decided to affirm and make final its decision not to regulate radionuclide emissions from phosphate rock processing plants, other than phosphate rock calciners at wet process fertilizer plants. A decision regarding the need for standards for this latter source will be made after completion of the Agency's analyses of emissions and risks from these facilities.

Phosphogypsum Piles

Several comments were received requesting EPA to issue standards under the Clean Air Act for radionuclide emissions from phosphogypsum piles (fertilizer plant waste material). EPA did not propose radionuclide standards for this source because it believed that such wastes would be more appropriately regulated under the Resource Conservation and Recovery Act (Pub. L. 94-580).

After considering all comments, EPA is reevaluating the need for radionuclide standards for this source. Preliminary risk estimates indicate that individual lifetime risks from exposure to air emissions from these piles may be as high as eight in ten thousand. Population risks may be on the order of one fatal cancer per year. The Agency will continue its examination of the need for a standard for this source category.

C. Other Extraction Industries

Almost all industrial operations involving removal and processing of soils and rocks to recover mineral resources release some radionuclides into the air. EPA has conducted studies of airborne radioactive emissions from the mining, milling, and smelting of iron, copper, zinc, clay, limestone, fluorspar, and bauxite. These are relatively large industries and are considered to have the greatest potential for air emissions of radionuclides.

EPA proposed not to regulate these extraction industries because the available data showed that the risks to individuals and populations from radionuclide emissions from these facilities are insignificant. Individual lifetime risks range from one in one hundred million to one in ten thousand. Population risks range from 0.000001 to 0.01 fatal cancer per year.

Most of the comments received were from industry representatives who concurred with EPA's proposal not to regulate these facilities. In their opinion, emissions, doses, and risks were so small that a regulation was unnecessary. No new information was provided to the Agency during the public comment period which indicated a need for standards. Additional Agency studies have confirmed that radionuclide emissions from these sources are low.

After considering all comments, EPA has decided to affirm and make final its decision not to regulate radionuclide emissions from extraction industry facilities.

D. Uranium Fuel Cycle Facilities, Uranium Mill Tailings, and Management of High-Level Radioactive Waste

The uranium fuel cycle consists of operations associated with production of commercial electric power by light water reactors using uranium fuel. It includes nuclear power plants and facilities that mill uranium ore, process uranium, and fabricate and reprocess uranium fuel. EPA has promulgated emission standards for normal operations of the uranium fuel cycle under the Atomic Energy Act (40 CFR Part 190). These standards limit the annual dose equivalent from radionuclide emissions to 25 mrem/y to the whole body and to any organ, with the exception of the thyroid, which may receive 75 mrem/y. EPA standards and their implementation by the NRC require the use of available technology which results in low doses to individuals and populations.

Many commenters, both government and industry, supported EPA's decision not to issue emission standards for this source category. Other commenters felt that the Clean Air Act requires EPA to set emission standards for uranium fuel cycle facilities, regardless of any other standards in force.

The Agency believes that current EPA standards for the uranium fuel cycle provide a level of protection which ***43915** satisfies the requirements of the Clean Air Act. An emission standard promulgated under the Clean Air Act would be duplicative with the uranium fuel cycle standard and would not offer any additional public health protection. During the Agency's upcoming review of 40 CFR Part 190, this issue will be reexamined.

Uranium mill tailings remain after uranium is removed from the ore. Many thousands of acres of these tailings exist at both inactive and active uranium mill sites, located mostly in the West. The high concentration of radium-226 in the tailings can result in significant emission or radon-222, a radioactive gas. Under current EPA disposal standards which require long term stabilization of the tailings piles, 95% or more of the random emissions will be controlled. These standards, issued under the authority of the Uranium Mill Tailings Radiation Control Act of 1978 (Pub. L. 95-604), provide a level of public health protection comparable to an air emission standard.

However, commenters noted that randon emissions from the tailings piles at licensed uranium mills are exempted from the requirements of 40 CFR Part 190. They are controlled, instead, by NRC regulations which allow a concentration of 3pCi/1 of radon-222 in unrestricted areas. This value represents a level of risk that may be significant. EPA is publishing, simultaneously with this notice, and Advance Notice of Proposed Rulemaking to consider the need for an emission standard for radon emission from licensed uranium mills.

Highly radioactive liquid or solid wastes from reprocessing spent nuclear fuel, or the spent fuel elements themselves if they are disposed of without reprocessing, are considered high-level radioactive waste. EPA has proposed standards under the Atomic Energy Act to limit public exposure to the radionuclides in this waste prior to disposal and has proposed that operations be conducted to reduce exposures below the standard to the extent reasonably achievable. The Agency expects its standards for the management of high-level radioactive waste to be promulgated in the near future. These standards will control emissions during the operational phase of the disposal site to a level which results in a dose equivalent no greater than 25 mrem/y to the whole body or to any organ, except the thyroid, which may receive a dose as high as 75 mrem/y. These standards will provide a level of public health protection comparable to an emission standard issued under the Clean Air Act.

After consideration of all comments, EPA affirms and makes final its decision not to issue separate standards under the Clean Air Act for radionuclide emissions from the uranium fuel cycle, uranium mill tailings, and management of high-level radioactive waste.

E. Low Energy Accelerators

Accelerators impart energy to charged particles, such as electrons, alpha particles, protons, and neutrons. They are used for a wide variety of applications, including radiography, activation analysis, food sterilization and preservation, and radiation therapy and research. Accelerators, other than those owned by the DOE, operate at comparatively low energy levels and therefore emit very small quantities of radionuclides. The doses and health risks associated with these emissions are extremely low. Lifetime individual risks range from one in ten trillion to one in one billion. Further, there is no potential for the emissions from these facilities to increase significantly.

The Agency proposed not to regulate this category. No comments were received on this proposal, and the Agency is not aware of any new information indicating a need for a standard. Therefore, the Agency affirms and makes final its decision not to regulate radionuclide emissions from low energy accelerators.

IX. Miscellaneous

Docket

The docket is an organized and complete file of all information considered by EPA in this rulemaking. It is a dynamic file, since material is added throughout the rulemaking process. The docket allows interested persons to identify and locate documents so they can effectively participate in the rulemaking process, and it also serves as the record for judicial review.

Transcripts of the hearings, all written statements, the Agency's responses to comments, and other relevant documents have been placed in the docket and are available for inspection and copying during normal working hours.

Dated: October 23, 1984.

William D. Ruckelshaus,

Administrator.

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Footnotes

1 The Administrator believes, based on an analysis by EPA's Office of General Counsel, that today's actions are consistent with the statute and the court order governing today's decision. EPA acknowledges, however, that an argument exists that the only proper way to procedurally express the substantive conclusions set forth in today's rulemaking is by delisting the particular pollutant involved. Though EPA does not presently accept that position, it stands ready to amend this package promptly along these lines if the Court should so direct.

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NOTICES
ENVIRONMENTAL PROTECTION AGENCY
[OPP-260052; -FRL-3388-3]

Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement

Wednesday, October 19, 1988

***41104** AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice announces a change in the position EPA will take in rulemaking proceedings under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) concerning certain pesticides intended for use in food production. EPA's position will be that the section 409's so-called Delaney Clause—which, read literally, purports to bar absolutely the issuance of a food additive regulation for a food additive that has been found to induce cancer in test animals—is subject to a de minimis exception where the human dietary risk from residues of the pesticide is at most negligible. This change in position is intended to foster greater consistency in actions EPA will take with respect to the registrations of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and tolerances for pesticide residues on food under sections 408 and 409 of the FFDCA. Elsewhere in this issue of the Federal Register, the Agency is proposing new procedural rules for establishing, modifying, and revoking section 409 food additive regulations, as well as procedural rules governing the filing of objections, requests for hearings, and the holding of hearings under sections 408 and 409. This Notice also discusses how EPA plans to approach the issue of what risks might be considered “negligible.” This Notice provides the Agency's response to the recommendations of the recent National Academy of Sciences report entitled “Regulating Pesticides in Food: The Delaney Paradox”. Public comment is invited on this Notice.

ADDRESS: Comments should bear the document control number “OPP-260052”, and be submitted in triplicate to: Public Docket and Freedom of Information Section, Field Operations Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:By mail: William L. Jordan, Policy and Special Projects Office, Office of Pesticide Programs (TS-766C), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Office location and telephone number: Room 1115, CM 2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-7102).

SUPPLEMENTARY INFORMATION:

I. Introduction

The Environmental Protection Agency is responsible for regulating the sale and use of pesticide products under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), (7 U.S.C. 136 et seq). FIFRA contains a standard for registration that allows EPA to take both the risks and the benefits of a pesticide's use into account.

The Agency also regulates pesticide residues on food under sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, and 348). Food is “adulterated” and subject to seizure under the FFDCA if it is found to bear pesticide residues that are not permitted by appropriate section 408 and 409 tolerances. Section 408 of the FFDCA, like the FIFRA, gives the Agency authority to balance risks and benefits in reaching regulatory decisions with respect to pesticide residues on raw agricultural commodities section 409 of the FFDCA governs the establishment of food additive regulations (often called 409 tolerances) in processed food and feed. EPA interprets section 409 to also allow EPA to consider benefits to food consumers in reaching its decisions unless the Delaney Clause applies. However, the Delaney Clause of section 409, if

read literally, is a risk-only standard that bars the establishment of any food additive regulation that would authorize residues in or on processed food or feed of any pesticide that has been found to induce cancer when ingested by man or test animals, with certain limited exceptions.

The difference in the standards of these two statutes presents EPA with a major problem in regulating certain pesticide chemicals which have been found to induce cancer in test animals. Such pesticides may be ineligible for food additive regulations under the FFDCA even if they have been found to pose no unreasonable risk to humans and qualify for registration under FIFRA. This problem may arise in three situations: (1) When a food additive regulation is sought for a new pesticide chemical (or a new use of a currently registered chemical) that induces cancer in animals; (2) when new residue data indicate a need for a food additive regulation for a registered pesticide known to induce cancer in animals; or (3) when new toxicity data show that a registered pesticide for which food additive regulations have been established induces cancer in animals.

In the first situation, the issue is whether to allow the pesticide to enter the market or to be marketed initially for a particular food use. EPA's current regulations prohibit FIFRA registration until the issuance of any needed tolerances and food additive regulations associated with the pesticide's use. The second and third situations require EPA to decide whether to make unlawful the marketing of a pesticide for those previously-approved food uses subject to section 409. The number of uses in these latter two categories is increasing as EPA receives more and more toxicity and residue data. Of significant concern are the differences in the standards now applied to old and new pesticides. Under current Agency practice, as described more fully later in this Notice, a new pesticide that poses a relatively low risk of cancer may be barred from registration because of Delaney Clause constraints, while an old pesticide that poses a higher risk and that is used for the same purposes might remain on the market.

To address these issues, in February 1985 the Agency commissioned the Board on Agriculture of the National Research Council/ National Academy of Sciences (“NAS”) to examine the impact of the Delaney Clause on the tolerance-setting process and on EPA decision-making. The NAS committee formed to conduct this study included experts in agricultural pest control, pesticide development, agricultural economics, cancer risk assessment, public health, food science, regulatory decision making, and law.

The detailed report prepared by the NAS, entitled “Regulating Pesticides in Food: The Delaney Paradox,” was issued on May 20, 1987. The report set forth four main recommendations:

1. Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current law and regulations governing residues in raw and processed foods are inconsistent with this goal.

2. A negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits.

3. EPA should focus its energies on reducing risk from the most worrisome pesticides on the most-consumed crops.

4. The EPA should develop improved tools and methods to more systematically estimate the overall ***41105** impact of prospective regulatory actions on health, the environment, and food production.

The Agency has evaluated the recommendations of the NAS, and as discussed later in this document, has reached conclusions about what would be an ideal policy, one that would be based on the NAS recommendations. In summary under this ideal policy, the Agency would apply a uniform set of criteria to all FIFRA registration decisions and all FFDCA section 408 tolerance and section 409 food additive regulation decisions. If a pesticide's use would pose no risk or only a negligible risk, the pesticide's use would be approved under both Acts without any particular scrutiny of benefits. This has for some time been EPA's practice with respect to decisions on pesticides that pose only non-cancer risks, and with respect to decisions under FIFRA and under FFDCA section 408 on pesticides that may pose cancer risks. (EPA has assumed that an applicant's willingness to expend the sums required to obtain registration of a pesticide, in the expectation of recovering those sums by sales of the pesticide,

indicates that the pesticide's use will yield benefits that are greater than negligible.) Under the ideal policy, registrations and the associated tolerances and food additive regulations similarly would be granted for pesticides that pose at most a negligible risk of cancer to humans (and meet the other requirements of FIFRA and the FFDCA). For those pesticides deemed to pose a greater-than-negligible risk, a risk/benefit evaluation would determine the appropriateness of FIFRA registration and FFDCA clearances under sections 408 and 409. The greater the degree of risk, the greater the benefits that would have to be shown to justify approval, and the more intensive would be the benefits evaluation required to reach a regulatory decision.

Implementation of this ideal policy, however, is subject to the constraints imposed by the Delaney Clause. In the case of a use of a pesticide that requires a section 409 clearance and that poses a cancer risk that is greater than negligible, the Delaney Clause ordinarily bars approval of the use; the Agency is unaware of any legal theory that would justify a change in its current practice of refusing to issue new food additive regulations in such situations (with certain exceptions discussed in detail later in this Notice). However, for pesticides that pose at most a negligible risk of cancer and whose use requires section 409 clearances, EPA will change its current practice to the extent that, in the future, EPA will propose to issue food additive regulations on the basis of the de minimis doctrine, described in Unit II of this Notice.

The Agency wishes to make it clear that the interpretations and policy changes it is announcing today have no final effect with respect to any individual pesticide. This Notice relates primarily to the regulatory treatment of some pesticides under FFDCA section 409. Any food additive regulation that EPA may issue in reliance on the de minimis doctrine discussed in this Notice will be preceded by issuance of a proposed rule, and also will be referred to the FIFRA Scientific Advisory Panel. Section 409(b) and 409(h) allow “any person” to petition EPA to issue, modify, or revoke a section 409 food additive regulation, and section 409(c) says that EPA must act on such a petition. Under section 409(f), any “adversely affected person” (a term that has been given a very inclusive reading by the courts) may object to an EPA action taken either in response to a section 409(b) petition or at EPA's own initiative under section 409(d). EPA must rule on the objection; if factual matters are at issue, EPA first must hold a formal evidentiary hearing to produce a record upon which the ruling must be based. Although this Notice sets forth positions that the Agency expects to take initially in relevant proceedings arising under FFDCA section 409, EPA decisional officials will be open to all arguments presented in those proceedings and will base their final decisions on the merits of the arguments presented. See McLouth Steel Products Corp. v. Thomas, 838 F. 2d 1317 (D.C. Cir. 1988). Judicial review of rulings on individual objections under FFDCA section 409 is available only in the manner described by section 409(g). EPA will take the position that this Notice is not itself properly the subject of judicial review because it lacks the requisite finality.

A detailed discussion of the policy changes involved is set forth in Unit III. of this Notice.

II. Legal and Regulatory Background

EPA often must apply four different and sometimes conflicting statutory standards in deciding whether a particular pesticide may be used in food production: one under the FIFRA and three under the FFDCA.

A. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

The sale, distribution, and use of pesticides in the United States are governed directly by the FIFRA and are also influenced heavily by the FFDCA. FIFRA requires that all pesticides which are sold or distributed in the United States be registered in accordance with the statutory standard for registration set forth in FIFRA. That standard requires, among other thing, that the pesticide perform its intended function without causing “unreasonable adverse effects on the environment.” (FIFRA section 3(c)(5)). The term “unreasonable adverse effects on the environment” is defined as “any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide,” (FIFRA section 2(bb)). Under FIFRA section 6, EPA may cancel the registration of a use of a pesticide [FN1] (or require modifications in the terms and conditions of registration in lieu of cancellation) if the Agency determines that the risks of use of the pesticide outweigh the benefits of the use.

EPA regulations (40 CFR 162.7(d)(2)(iii)(E)) and 162.167(a)(4), redesignated as 40 CFR 152.112, 152.113, and 152.114, see 53 FR 15952, May 4, 1988) provide that a registration may not be granted if "the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in residues of the pesticide becoming a component of food or feed," unless the necessary sections 408 and 409 clearances have been issued.

This requirement assures that a pesticide use will not be registered for a food crop unless the Agency has determined that the resulting pesticide residues in or on the crop will not exceed a safe level. Moreover, by examining the pesticide use under the statutory scheme as a whole and assuring that the criteria of both FIFRA and FFDCA are met, the Agency avoids the potential for residues that are illegal under the FFDCA appearing in or on foods as a result of pesticide use that is legal under FIFRA. It has been EPA's belief that pesticide users and food processors should be able to safely assume that a pesticide registered under FIFRA has the appropriate clearances under the FFDCA for the food uses listed on the FIFRA label.

B. Sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA)

Under FFDCA section 402, a raw agricultural commodity is adulterated if ***41106** it contains a pesticide residue not authorized by a FFDCA section 408 tolerance (maximum permissible level) or an exemption from the requirement of a tolerance. An adulterated commodity sold or distributed in interstate commerce is subject to seizure by the Food and Drug Administration (FDA).[FN2]

To establish a tolerance or exemption regulation under section 408, the Agency must find that the regulation would "protect the public health." (FFDCA section 408(b)). In reaching this determination, the Agency is directed to consider, among "other relevant factors," the necessity for the production of an adequate, wholesome, and economical food supply, and the other ways in which the consumer may be affected by the pesticide. Thus, in the Agency's view, section 408 of the FFDCA expressly gives the Agency the authority to balance risks against benefits in determining appropriate tolerance levels.

Under FFDCA section 402, food is adulterated (and hence subject to seizure) if it contains any food additive (including any pesticide residue) not authorized by a section 409 food additive regulation. An important exception to this provision is that a processed food containing pesticide residues resulting from the "carryover" from treatment at the raw agricultural commodity stage is not regarded as adulterated if the residue level in such a food is no greater than that allowed by the section 408 tolerance established for the raw agricultural commodity.

The establishement of a food additive regulation under section 409 requires a finding under the "general safety clause" in section 409(c)(3) that the use of the pesticide "will be safe." The only direct guidance given by the Act as to the meaning of the term "safe" is that the term "has reference to the health of man or animal," (FFDCA section 201(u)). Factors to be considered in making this "general safety clause" determination are (1) the probable consumption of the pesticide or its metabolites; (2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; (3) appropriate safety factors to relate the animal data to the human risk evaluation; and (4) "other relevant factors." FFDCA Section 409(c)(5)).

Appendix A contains a discussion of the procedures followed by the Agency in evaluating safe residue levels for tolerances and food additive regulations.

The general safety clause in section 409(c)(3) has been construed by the Agency to allow the weighing of benefits and risks when issuing food additive regulations. The legislative history indicates that section 409 was intended to permit the use of food additives "which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted * * * as safe," and that "the test which should determine whether or not a particular additive may be used in a specific percentage of relationship of the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal." (S. Rep. No. 2422, 85th Cong. 2d Sess., August 18, 1958, at 2-3). In EPA's view, the determination of whether use of a pesticidal food additive is "not harmful" or is "safe" should take into account the net effects of use of the additive on the food supply, including the benefit (or to put it another way the

avoidance of harm) to an adequate, wholesome, and economical supply of food that may result from a pesticide's use as well as any harm to the food supply that may result from the pesticide's use. At least for residues of pesticide chemicals, EPA believes that this kind of benefit should be regarded as one of the "relevant factors" EPA may consider under FFDCA section 409(c)(5), even though it is not listed specifically there as it is in section 408(b). A risk/benefit reading of the general safety clause also was adopted by the one court that has addressed the issue.[FN3] FDA, however, has tended to interpret the section 409 general safety clause as a criterion that focuses solely on the risks to the food supply caused by the food additive, as opposed to the risks avoided, and this view has considerable support in the legislative history of section 409 and in scholarly journals.

C. The Delaney Clause

The one clear exception to the Agency's latitude to balance risks and benefits for food additives under section 409 is the "Delaney Clause" in section 409(c)(3). The Delaney Clause states that a food additive shall not be deemed safe "if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." Because FFDCA section 408 contains no counterpart to the Delaney Clause, the Agency has the authority to evaluate the risk posed by the presence of residues of a carcinogenic pesticide in a raw agricultural commodity, and to establish a section 408 tolerance at a level which will protect the public health, taking benefits to the food supply into account. As long as the processed food does not contain residues above the level allowed in the raw agricultural commodity, residues of that carcinogenic pesticide may legally be present in such processed food. However, where residues of the chemical concentrate above the section 408 tolerance level during processing, or result from use of a pesticide during or after processing, a food additive regulation might not be appropriate because of the Delaney Clause bar. The Delaney Clause contains an express exception (the "DES provisio") that allows a carcinogenic ingredient of animal feed to be found "safe" if such ingredient will not adversely affect the animal and if "no residue" of the substance will be found, by an Agency-approved method, in any edible food yielded or derived from the treated animal. FDA has concluded that the provision should be implemented by a "sensitivity-of-method" approach that allows a carcinogenic ingredient to be added to animal feed if "no residues" of that ingredient are detectable by an FDA-approved analytical method that is sensitive enough to detect any level of residue representing a lifetime excess human cancer risk of more than one in a million (44 FR 17070).[FN4] The FDA ***41107** approach incorporates a series of conservative assumptions for calculating the allowable residue levels in individual food items and in the total diet.

EPA has used the sensitivity-of-method approach in two actions establishing food additive regulations, one concerning thiodicarb and its possibly oncogenic metabolite acetamide on the animal feeds cottonseed hulls and soybean hulls (50 FR 27452, July 3, 1985; 50 FR 41341, October 10, 1985), and another concerning cyromazine and its possibly oncogenic metabolite melamine in or on poultry feed (49 FR 18120, April 27, 1984; 50 FR 20370, May 15, 1985).

If the chemcial induced cancer in animal studies in which the route of exposure was other than ingestion, the Delaney Clause by its own terms applies only if the tests in question "are appropriate for the evaluation of the safety of food additives." The Agency thus has discretion to decide whether a test showing cancer induction as a result of, e.g., dermal exposure to a chemical is "appropriate" for Delaney Clause purposes.

Two administratives doctrines, the "constituents policy" and the de minimis approach, also in EPA's view allow the establishment of food additive regulations in appropriate situations. The "consituents policy," developed by FDA, relies on the fact that the prohibitory language of the Delaney Clause pertains to any food additive, that has been shown to induce cancer in animals, but does not bar approval where an unwanted impurity (a "constituent") of the additive, tested by itself, is found to induce cancer. Thus, under the constituents policy, a food additive regulation may be established if the food additive as a whole does not cause cancer, even though the additive contains an undesired, nonfunctional constituent which is itself a carcinogen. In this situation, the impurity is judged under the general safety provisions of the applicable section of the FFDCA, using risk assessment as one of the decision-making tools. The Sixth Circuit Court of Appeals has upheld FDA's use of the constituents policy to interpret the color additives Delaney Clause provision in section 706(b)(5)(B) of the statute. (Scott v. FDA, 728 F. 2d 322 (6th Cir. 1984)). This provision contains a prohibition closely similar to that found in the section 409 Delaney Clause.

EPA has used the constituents policy in a rulemaking establishing a food additive regulation for dicamba in sugarcane molasses. Dicamba itself is not thought to be oncogenic; however, the pesticide formulation contains small amounts of a carcinogenic nitrosamine contaminant. EPA found the potential risk attributable to the presence of this contaminant to be very small, i.e., with an upper limit in the 10-9 range. Accordingly, the agency concluded that the requirements of section 409 were satisfied. (48 FR 11119, March 16, 1983; 48 FR 34024, July 27, 1983; 48 FR 50528, November 2, 1983).

In discussing its use of the "constituents policy" approach for dicamba, EPA noted that it does not regard deliberately added active or inert ingredients, or metabolites thereof, as potential candidates for clearance under the constituents policy. Rather, the Agency said it would only consider applying the rationale to unwanted impurities resulting from the manufacture of the pesticide (intermediates, residual reactants, products of side reactions, and chemical degradates). Furthermore, the Agency said that it would consider using this rationale in issuing a food additive regulation only where the potential risk from the impurity is extremely low, and that in estimating this risk, the Agency would rely on very conservative risk estimation methodology. (48 FR 34024, July 27, 1983).

Finally, the de minimis approach derives from case law holding that an administrative agency ordinarily has the inherent authority to avoid applying the terms of a statute literally when to do so would yield pointless results.[FN5] Two conditions are necessary to allow an agency to invoke the de minimis doctrine. First, the problem that would be addressed by regulation must be trivial in fact, such that no real benefit would result from regulation. Second, the legislative design must allow the Agency not to apply the statute literally in such a case.

In a recent case addressing the Delaney Clause contained in the color additive provisions of the FFDCA enacted in 1960 (Public Citizen v. Young, 831 F.2nd 1108 (D.C. Cir. 1987), cert. denied, 108 S.Ct. 1470), FDA argued that the establishment of a de minimis exception to the Delaney Clause is consistent with the legislative design, and that conservatively-assessed risks of one in a million (10 -6) or less should be regarded as trivial and thus subject to the exception. FDA relied on legislative history indicating that the Delaney Clause should be applied in a reasonable way. But the court rejected FDA's argument that the legislative history of the FFDCA color additive provisions does not preclude the use of the de minimis exception. The court held that "the Delaney Clause of the Color Additive Amendments does not contain an implicit de minimis exception for carcinogenic dyes with trivial risks to humans" because "Congress adopted an 'extraordinarily rigid' position, denying the FDA authority to list a dye once it found it to 'induce cancer in * * * animals'." (831 F.2nd at 1122). In the court's view, the proper mechanism for obtaining relief from the Delaney Clause with respect to color additives whose risk is trivial is to request that Congress make appropriate modifications to the statute. The food additive Delaney Clause in section 409, adopted in 1958, was not at issue in the case. Indeed, the court noted that the context of the section 409 provision was entirely different from that of the color additive Delaney Clause, and that "the operation of the food additive Delaney Clause raises complex issues distinct from those of this appeal" (id. at 1120, 1118 n. 13). The court suggested, moreover, that the legislative history of the section 409 Delaney Clause might lead to a different result (id. at 1120).

The Delaney Clause has long been regarded as allowing the administering agency to exercise scientific judgment and discretion in deciding whether a food additive "induces cancer" in animals.[FN6] EPA has generally assumed that, for purposes of the Delaney Clause, a substance "induces cancer" in animals if, in a well-conducted animal feeding study, a statistically significant increase in the incidence of histologically related tumors (benign, malignant, or combined) ***41108** is observed in treated animals compared to concurrent control animals, unless there is a reason to conclude that the observed increase is unrelated to the ingestion of the test substance. Under this approach, a pesticide may be found to "induce cancer" in animals despite the fact that increased tumor incidence occurs only at high doses, or that only benign tumors occur, and despite negative results in other animal feeding studies. FDA has taken a similar approach in assessing data for the purposes of the Delaney Clause.[FN7]

There is at least "limited evidence" of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 food-use pesticides already approved for use, under the classification scheme set forth in EPA's "Guidelines for Carcinogen Risk Assessment," (51 FR 33992, September 24, 1986), described in Appendix A. EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides.[FN8] A substantial portion of these pesticides require

section 409 food additive regulations for one or more of their uses. Appendix B lists those pesticides which currently have been identified by the Agency as potential carcinogens and indicates which ones have, or have recently been determined to need, section 409 food additive regulations.

D. Current Policy Has Been Constrained by the Delaney Clause

From the foregoing discussion, it is apparent that if EPA determines that a pesticide poses a cancer risk that is greater than negligible and that outweighs the pesticide's benefits, the pesticide's FIFRA registration should be cancelled and its FFDCA sections 408 and 409 clearances should be revoked. There is no conflict between the various standards in such a case, and EPA's current practice reflects this lack of conflict.

Difficulties arise in the two remaining situations. A pesticide may pose only a negligible cancer risk, or it may pose a cancer risk that is greater than negligible but nonetheless is not so great as to outweigh the pesticide's benefits to the food supply. In both of the latter situations, EPA views FIFRA, FFDCA section 408, and FFDCA section 409's general safety clause as allowing the registration or continued registration of the pesticide and the issuance or continuation of needed FFDCA clearances. But the Delaney Clause of FFDCA section 409 arguably bars the issuance of new section 409 clearances for pesticides in either of the latter two situations, and thus concomitantly calls into question the status of such pesticides under FFDCA section 408 and FIFRA. Due to the constraints dictated by the literal approach to the Delaney Clause, the Agency has not been willing to register a carcinogenic pesticide for a new food use which requires a section 409 food additive regulation, even though that pesticide meets the risk/benefit standards in the other statutory provisions. And since there is often no practical way to assure that the raw agricultural commodity at issue will not be processed, the Agency generally does not grant a section 408 tolerance for residues of the pesticide on a raw agricultural commodity in a situation where an associated section 409 food additive regulation is needed but cannot be issued. As noted earlier, EPA's regulations currently provide that before a pesticide may be registered under FIFRA for a food or feed use, there must exist appropriate clearances under FFDCA sections 408 and 409 for the pesticide residues.

However, if the pesticide is to be used on a type of raw agricultural commodity which is not processed or if concentration of the raw-commodity residues does not occur during processing, and if the pesticides is not added during or after processing, no food additive regulation is needed. If the pesticide use passes the risk/benefit test under FIFRA and FFDCA section 408, a registration can be granted. This is true even if the estimated dietary cancer risk to the public is the same as or higher than the risk posed by an analogous pesticide use for which a food additive regulation is required. Thus, very similar risk situations have been treated quite differently because of the inconsistent statutory provisions. This approach has not necessarily resulted in lower health risks for the public. In fact, there is a strong argument that in some cases the constraints of the Delaney Clause paradoxically may have led to greater risks to the public. New pesticides that pose lower cancer risks than pesticides currently on the market have been denied registration while older, more hazardous pesticides remained in use.

The Agency's treatment of established food additive regulations for registered pesticide chemicals shown by new data to induce cancer in test animals has been quite different than the just-described treatment of requests for new food additive regulations. To date, the Agency has not taken action based on the Delaney Clause to revoke established food additive regulations. In many instances, taking such action would require EPA either to revoke the associated 408 tolerances and cancel the FIFRA registration (despite the risk/benefit criteria that would govern such actions), or to abandon its long-standing policy that the lawful application of a pesticide should not result in illegal pesticide residues. Many of these pesticides appear to pose low or negligible risks and to have substantial benefits for the production of food in this country.

The Agency has deferred action in such cases, while studying the dilemma posed by the statutory scheme. Section 409(h), which authorizes EPA to issue regulations establishing procedures for amending or repealing food additive regulations, does not expressly require repeal of food additive regulations when new data indicate that the pesticide induces cancer.[FN9] The Agency arguably has the latitude to assess the safety of established food additive regulations under any standard it chooses to adopt that is not arbitrary and capricious within the meaning of the Administrative Procedure Act; it arguably could adopt a standard based on the general safety clause of section 409(c)(3), or on a non-FFDCA standard, such as the FIFRA risk/

benefit standard. ***41109** Thus, the Agency could conclude that a previously-approved use of a pesticide is "safe" or not "unreasonable," even though the potential risk is greater than "negligible," if the benefits of the use to the food supply outweigh its risks. On the other hand, if the Agency concluded that the presence of residues in the processed food or feed posed a risk that is "unreasonable" within the meaning of FIFRA or not "safe" within the meaning of the general safety clause of FFDCA section 409, considering the balance of risks and benefits, the Agency would be under an obligation to take action to repeal the regulation (or, in appropriate situations, to amend the regulation to allow a lower residue level determined to be "safe" or "reasonable") and to cancel or modify the terms and conditions of the related FIFRA registration as necessary to assure that the use of the pesticide did not cause unreasonable adverse effects on the environment. This approach would allow EPA to reconcile the FIFRA and FFDCA standards.

The contrary argument would rest on the assumption that Congress must have intended any reevaluation of an existing food additive regulation to be based on the section 409(c) criteria for establishing new regulations, and that the Delaney Clause is an integral part of section 409(c). This view of section 409 thus would incorporate section 409(c)—including the Delaney Clause—into section 409(h) of the statute. Under this reading, a food additive regulation would have to be revoked if new information should indicate that the Delaney Clause would have barred issuance of the regulation had that information been available originally.[FN10]

Such an approach might result in the cancellation of pesticide registrations for uses that meet the risk/benefit standard of FIFRA, FFDCA section 408, and FFDCA section 409's general safety clause, but that cannot conform to the risk-only, zero-risk standard of the Delaney Clause. Once the food additive regulation had been repealed, the presence of residues of that pesticide in the processed food in question would be illegal under the FFDCA, and the wisdom of allowing the pesticide to be sold under the FIFRA registration for use in producing that food would be questionable. To be consistent, many related section 408 tolerances also would have to be repealed under this approach, because such tolerances arguably would be inappropriate where residues could concentrate during processing to an unapproved level higher than the tolerance for the raw agricultural commodity. This approach, carried to its logical conclusion, might end many valuable uses of pesticide chemicals and might result in significant adverse consequences to food production, while resulting in little or no risk reduction. It should be noted that a registrant of a pesticide faced with a proposed FIFRA cancellation based entirely or primarily on the fact that the pesticide's residues are not thought to be "safe" within the meaning of FFDCA section 409 might assert that a FIFRA cancellation cannot be based on criteria imported from the FFDCA, and might succeed (see Continental Chemists Corp.v. Ruckelshaus, 461 F. 2d 331 (1972)). If the approach described in this paragraph were successful, however, there again would be no dichotomy in the treatment of old and new pesticides.

The system that has been used by EPA so far has the added undesirable feature of placing new pesticides that are barred from registration because of the strict reading of the Delaney Clause at a disadvantage relative to old products that are shown by new data to pose comparable or higher risks. Given the high costs of data development, there is little incentive to develop a new food use pesticide that shows carcinogenic potential—even if the risk it would pose would be minimal, and even if it could replace an old product that poses a higher risk—if initial registration is likely to be barred by Delaney Clause considerations. Thus, the development of new, lower-risk chemicals to replace old, higher-risk pesticides may have been retarded by the Agency's past implementation of the Delaney Clause.

A reassessment of the data in support of the tolerances for a particular pesticide chemical may present another serious concern. The data review by the Agency may reveal, with respect to a chemical that induces cancer in animal studies, that not all the necessary section 409 tolerances are in place. New residue data or a new review of old data may lead the Agency to determine that residues concentrate during processing and that section 409 food additive regulations have not been promulgated to cover this situation. If the Agency cannot promulgate such regulations because of the Delaney Clause ban, these processed commodities would contain illegal residues and would be subject to seizure by FDA. To prevent the presence of these residues in the processed commodities, the Agency would have to attempt to revoke the corresponding FIFRA registrations and FFDCA section 408 tolerances (unless appropriate use restrictions on the pesticide labeling could be developed to prevent the use of the pesticide on commodities destined for processing). Such action could profoundly limit the use of many beneficial pesticide chemicals.

The Agency is facing the issues discussed here with an ever-increasing number of old pesticide chemicals. (Appendix D discusses certain examples of pesticide chemicals currently or recently under review which give an overview of the practical dimensions of the problem.) EPA's decision on whether to attempt to apply the section 409(c) criteria retrospectively under section 409(h) may depend on whether its approach to negligible-risk situations, set forth in unit III of this document, is upheld.

E. Potential for Legislative Solution

The administrative approaches discussed so far in this document would solve only some of the problems the Agency faces in this area. Moreover, implementing those approaches will be controversial and might involve the Agency in protracted litigation that could cause uncertainty and make it difficult for businesses to make plans about pesticide development and pesticide use. A legislative solution, stating clearly that the Agency has the authority to grant food additive regulations for pesticide residues posing at most a negligible risk, clearly would be desirable. Additional legislative changes would be required to allow the Agency to fully reconcile FFDCA and FIFRA. Such legislation ideally would give the EPA the latitude to establish tolerances and food additive regulations for pesticides under a risk/benefit standard compatible with FIFRA, with a definitive statement that clearances for both raw and processed foods are to be established under a risk/benefit approach.

Hearings have been held recently in the House of Representatives on two bills that would address these issues. H.R. 4739, introduced by Congressman Waxman, would provide for the regulation of pesticide residues exclusively under comprehensively rewritten FFDCA section 408; H.R. 4937, introduced by Congressmen Brown and Roberts, would also provide for regulating pesticide residues under section 408, but would make only minor changes in the substance of that section.

*41110 III. Response to First and Second NAS Recommendations

A. Introduction

The Agency agrees completely with the NAS Report's most important conclusion—that a consistent approach ideally should be followed in the regulation of pesticides for food uses, regardless of whether the pesticides are new or old or whether the foods are raw or processed. As the NAS Report points out, there is no scientific reason to regulate pesticide residues in raw commodities differently from those in processed commodities. For risk assessment purposes, what is critical is not the type of food or feed commodity on which residues are present, but rather the identity and magnitude of the residues in the food and the associated consumption pattern. Likewise, EPA agrees with NAS that pesticides should be regulated consistently whether they are newly developed or have been on the market for many years.

Use of regulatory criteria that reflected those two NAS recommendations would allow the Agency to regulate high-risk pesticides more stringently than those that pose low risks, and permit the registration of new pesticides that offer substantial benefits and pose relatively insignificant risks. Riskier pesticides could then be replaced, and the total dietary risk reduced, with only minor adverse impacts on food production. This approach would be eminently sensible and desirable.

B. Policy for Achieving Greater Consistency in Evaluating Pesticides Under FIFRA and the FFDCA

The Agency believes that the most desirable way to achieve consistency in regulating potentially carcinogenic food-use pesticides would be to evaluate them under the same risk/benefit standard for both registration and tolerance purposes. However, if a section 409 regulation is required for a chemical to which the Delaney Clause applies, EPA believes that current law allows this approach to be used only to the extent that the de minimis doctrine allows Delaney Clause considerations to be dismissed. The following Table I outlines the regulatory outcomes that EPA would propose in response to various types of findings with respect to the cancer risk posed by new chemicals (or new uses of old chemicals). For clarity, Table I ignores non-cancer risks, and also ignores non-dietary cancer risks; in practice EPA would of course consider all risks.[FN11]]

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***41112** The following sections discuss how the new approach will affect pesticides in various regulatory categories.

1. Pesticides That Have no Carcinogenic Effect or That Pose Only a Negligible Risk of Carcinogenicity

For pesticides that are the subjects of applications for intitial registration or for registration for new uses, and that either do not induce cancer in test animals or pose only a negligible human cancer risk (generally a quantitative risk of 10 -6 or less), EPA will propose to establish section 408 tolerances and section 409 food additive regulations, where necessary, and thereafter to approve the applications for registration. Very little scrutiny will be given to the benefits of such non-carcinogenic or negligible-risk pesticides. As it has in the past, the Agency will assume the presence of benefits that outweigh the negligible risk. A list of pesticides that are potential candidates for consideration under the negligible-risk approach is provided in Appendix E.

2. Pesticides That Pose a Caracinogenic Risk That Is Greater Than Negligible

Some pesticides may pose a risk of carcinogenicity that is greater than negligible. Generally, such pesticides will be those with quantified upper-bound risks greater than 10-6 . (Some pesticides with quantified upper-bound risks greater than 10-6 may, however, fall into the negligible risk category for qualitative reasons, as discussed in Unit III.B.3.) For pesticide uses not requiring FFDCA section 409 clearances, EPA will continue its current practice of granting FIFRA registrations and the associated FFDCA section 408 tolerances for pesticides whose carcinogenic risk is greater than negligible only if the benefits are determined to outweigh the risks based on a careful scrutiny of the projected benefits compared to other available means of pest control. Benefits evaluations will be performed for such pesticides; the higher the risk, the more thorough the benefits evaluation that will be necessary. The risks of the available alternative pesticides will also be taken into account to determine if the total risk picture could be reduced by allowing the pesticide on the market. This approach accords with past practice.

But for the Delaney Clause, the Agency would propose to apply the same approach to pesticides in this category that require section 409 regulations. However, the Agency is not aware of any legal theory that would allow use of this approach under section 409 as it is currently written.

3. Treatment of Group C Chemicals

As explained in the EPA Guidelines for Carcinogen Risk Assessment, (51 FR 33992, September 24, 1986), there is great variability from one chemical to another in the amount and persuasiveness of evidence tending to show whether or not a chemical may cause cancer in humans. The EPA Guidelines represent the Agency's scheme for categorizing chemicals in terms of the weight of the evidence relating to their potential for human carcinogenicity. In general, the approach of the Guidelines is (1) to place a chemical in one of the groups (A through E) on the basis of the strength of the qualitative evidence of carcinogenicity from human epidemiology studies and animal tests and (2) for those chemicals showing some evidence of carcinogenicity, to set forth separately a quantitative upper bound on the risk that would be posed to humans if the substance in fact were a human carcinogen (see Appendix A). This information is useful to Agency officials and the public, since it provides a way to compare the risks of chemicals and to determine how consistently chemicals are regulated under the several statutory programs administered by the Agency.

The chemicals that pose the greatest difficulty in determining the proper regulatory response generally are those that fall into Group C (“possible human carcinogens”) under the Guidelines. A chemical is placed in Group C if there is some evidence of potential carcinogenicity from animal studies, but that evidence is so limited that the chemical cannot be assigned to a higher category.

The Guidelines state that is some cases the Agency will not calculate a quantitative risk ceiling for a Group C chemical. Although it is always possible to calculate a quantitative risk number, the Agency believes that in some cases such quantitative estimates may suggest that the chemical definitely poses a risk to humans, even though in fact the Agency is quite unsure whether the chemical poses human risk. Appendix F lists a number of Group C pesticides and states whether quantitation of risk was deemed appropriate for each.

The Delaney Clause, of course, makes no provision for the weighing of animal-test evidence in terms of its pertience to human risk. If a chemical is found to induce cancer when ingested by animals or in other appropriate tests, the chemical is deemed "unsafe" under section 409 (unless the de minimis doctrine or one of the other previously-discussed exceptions applies). This absolute criterion presents special difficulties with respect to Group C pesticides.

The Agency's treatment for Delaney Clause purposes of a pesticide that falls in Group C will very. For example, many chemicals fall into Group C merely because the evidence of carcinogenicity comes from only one study. When the evidence from that study clearly indicates a carcinogenic effect in the animal tested, the Agency ordinarily treats the chemical as falling within the "high" end of the C category range and quantifies the risk. A tolerance decision for such a chemical will be based on the quantitative risk number, and the Delaney Clause will be deemed to apply unless the quantitative upper bound risk level is so low that the chemical's risk may be ignored under the de minimis doctrine. Conversely, a pesticide may be classified in Group C because the data on whether the chemical is an animal carcinogen are limited or uncertain, e.g., if the data are equivocal, unreliable, or subject to significant doubt, or if only benign tumors occurred. If the Agency determines that the weight of the evidence does not support treating the chemical as an animal carcinogen, the Agency will not treat the chemical as falling within the Delaney Clause bar. The Agency will, of course, in any such determination, set forth the reasons for its judgment. For example, a pesticide may be classified as belonging in Group C because the pesticide is associated with an increase in tumors in only one sex of one species with a lack of a clear dose/reponse relationship. Assuming that mutagenic data are negative and that structure/activity analysis shows no association with known carcinogens, the Agency generally would consider such a pesticide to be at the "low" end of the Group C range. It is doubtful that the Agency would require a quantification of the carcinogenic risk, and in such a case, the Delaney Clause would not be deemed applicable.

A pesticide may also fall into Group C, not because of any doubt about whether the chemical induces cancer in certain animal tests, but because of uncertainties as to the relevance of the finding to human risk. Reasons for questioning the relevance of the animal data to human risk could include, among other things, know variations in response between the test species and humans, or mechanistic considerations, e.g., a showing that cancer was induced in animals only as a secondly effect of an organic change in the animals induced by very high doses of the chemical and a showing that this effect would not occur at the low levels of human exposure. If a convincing ***41113** explanation exists for why the chemical poses no risk of cancer for humans, despite the fact that it has been shown to be an animal carcinogen in a feeding study or other appropriate study and has a theoretical upper bound risk greater than 10-6 calculated using a no-threshold model, EPA would propose to treat the chemical as falling into the negligible risk or de minimis category for Delaney Clause purposes because of the qualitative reasons for discounting the animal test results as a predictor of human risk. Given the limited knowledge about interspecies response differences and mechanisms of action for cancer, EPA anticipates that very few pesticides would qualify for de minimis treatment on this qualitative basis in the near future.

A Group C carcinogen would be regarded as subject to the Delaney Clause if it did not fall into the quantitative or qualitative de minimis exception described in this Notice.

The following Table II summarizes the Agency's proposed treatment of Group C carcinogens:

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***41115** If the Agency determines that the Delaney Clause does not apply to a pesticide despite limited evidence of the pesticide's oncogenicity, the Agency will examine all toxicological effects of possible concern in determining the limit of acceptable dietary exposure. The Agency will then determine the no-observed-effect level (NOEL) for the most sensitive effect, which in turn will be used in setting the allowable daily intake (ADI) used in calculating the maximum permissible level of residues. (See Appendix A of this document.)

4. Currently Registered Pesticides

EPA's position with respect to currently registered pesticides that pose at most a negligible dietary risk of cancer will parallel that described earlier for proposed new food uses of pesticides, and the regulatory status of registered pesticides that pose such risks will not be changed as a result of this Notice. At the other end of the spectrum, EPA is not changing its policy of attempting to cancel FIFRA registrations and revoke FFDCA clearances for pesticides that pose risks of cancer (or other adverse effects) that outweigh their benefits. Finally, EPA has not determined how to proceed with respect to a pesticide that poses an upper-bound cancer risk that is greater than negligible but that is outweighed by the benefits of the pesticide.

5. Section 18 Exemptions

Section 18 of FIFRA allows EPA to exempt State and Federal agencies from the provisions of the Act if the Agency finds that emergency conditions exist that warrant the exemption. The changes in the Agency's approach to the issuance of food additive regulations already described in this document would result in conforming changes in the implementation of the emergency exemption program. The Agency will apply the negligible risk standard in evaluating emergency exemption requests in a manner similar to other regulatory decisions concerning pesticides which are carcinogens. If associated dietary risks are greater than negligible, the Agency would consider granting the exemption only if the benefits are so great that they outweigh the risks. In this connection, EPA considers, among other things, whether use of the unregistered pesticide would present a lower dietary risk than currently registered alternatives.

Generally, an emergency exemption will not be granted if adequate progress is not being made toward full registration of the pesticide use. In the recent past, the Agency has treated the need for a section 409 tolerance as an automatic bar to a request for an exemption to allow emergency use of a substance that has been found to induce cancer in appropriate animal studies, on the assumption that no section 409 clearance could be issued and accordingly there would be no possibility of registration. In the future, however, the Agency will not consider the need for a 409 tolerance, per se, as blocking progress toward registration of such a pesticide. Rather it would consider whether it is likely the pesticide may subsequently be registered according to the policies outlined in this document.

6. Minor Uses

FIFRA directs the Agency to make the registration process more flexible for minor use pesticides. Use of the approaches set forth in this Notice should favor minor uses because they ordinarily involve lower exposures than uses of chemicals on major crops such as wheat or corn.

As with section 18 requests, the need for a section 409 tolerance will no longer be treated as an absolute bar to further consideration of a potentially carcinogenic minor use pesticide. In fact, a number of the pesticides listed in Table V of this document as eligible for reconsideration under the negligible risk standard are intended for minor uses.

IV. Response to the Third Recommendation of the NAS

The NAS has recommended that EPA focus on one major crop at a time and evaluate the risks posed by all the major pesticides registered for that crop rather than evaluating individual pesticides according to current procedures. The Agency's historical

approach to reregistration has been to divide pesticides into “clusters” according to their predominant uses. A cluster is a group of chemicals and a group of sites that are closely correlated.

This approach was described in a Federal Register notice (45 FR 75488, November 14, 1980). The clusters were then ranked so that higher priority for review was given to those clusters that have significant use on food crops or were already known to pose special problems. Each individual pesticide chemical within the cluster is then evaluated, one at a time, for all of its uses. Thus, most of the major pesticides used on the 15 “high-consumption” crops identified by the NAS Report have had a recent comprehensive review or are scheduled for one in the near future. Appendix D of this document provides a status report on the Agency's review of 10 chemicals which have been identified as posing certain theoretical risks.

The NAS committee's recommended modification of EPA's approach is designed to ensure that final Agency decisions actually reduce dietary risk, help to preserve benefits of pesticide uses that pose low risks, and help to conserve limited Agency resources. The Agency agrees that this approach has merit in certain cases where the apparent risks are high and sufficient information is available to make comparative risk/benefit assessments. It also allows greater certainty that the final result will improve public health by comparing the risks and the benefits of the major alternatives at the same time.

Given the progress already made in the reregistration process, it is likey that the Agency will have the needed data on the major pesticides at approximately the same time so that comparative assessments can be done, at least for some crop/chemical combinations. During 1988, in fact, the Agency will be able to complete risk assessments for all but one of the six major fungicides (the exception is folpet, whose food use is relatively minor) and to compare the risks and benefits for these chemicals as recommended by the NAS.

There are, however, some problems associated with this approach. Timeliness will certainly be sacrificed in many cases. There will be more data to evaluate, and decisions will be more complex. Comparison of benefits may be difficult: available efficacy data are not designed to permit sophisticated benefits comparisons, and knowledge of all practical alternatives to a given pesticide may be limited and hard for the Agency to identify. For example, a pesticide might be effective for certain uses and yet might never have been registered for those uses because of a registrant's marketing strategy. Finally, it would not be advisable or protective of the public health to delay consideration of significant risks associated with a pesticide just because other pesticides used on the same crops cannot be evaluated at the same time due to the lack of key data. Consequently, the Agency expects to continue with its basic reregistration scheme for scheduling initial Registration Standards. However, adjustments will be made to allow consideration of alternatives whenever sufficient information is available and it appears to improve our ability to focus on high risk chemical/crop combinations.

Because of the Agency's basic priority scheme for Registration Standards, complete data bases for pesticides used on similar crops should be available at ***41116** roughly the same time, as in the case with the fungicides discussed in Appendix D. The sophistication of the comparative analyses may vary significantly, however, depending on the level of risk associated with the pesticide under review. In the case of cyanazine, for example, the final decision document discusses the known effects and the regulatory status of major alternatives briefly, but does not provide an extensive analysis because the Agency had concluded that the continued use of cyanazine did not pose unreasonable risks. It is likely, nevertheless, that the Agency will find it increasingly possible to make critical comparisons of pesticides which may substitute for each other.

V. Response to the Fourth Recommendation of the NAS

EPA is taking steps to implement the NAS recommendation to develop improved tools and methods to estimate more systematically the overall impact of prospective regulatory actions on health, the environment, and food production. A major new analytical tool that allows the Agency greater sophistication in the assessment of dietary risk is the computerized Tolerance Assessment System (TAS). TAS contains information on toxicology and residue date for particular pesticides, as well as food consumption information. Consumption information for various foods is based on a 1977-1978 nationwide survey of food consumption for different subgroups conducted by the U.S. Department of Agriculture (USDA). The TAS can be used to estimate dietary levels of pesticide residues for the average individual, as well as for 22 population subgroups, including various

age and ethnic groups, infants, pregnant women, and nursing mothers. The system can also be used to differentiate overall consumption patterns by season and by region.

One option offered by the TAS is the calculation of separate TMRCs (Theoretical Maximum Residue Contribution, see Appendix A) for each of the 22 subgroups, based on the assumption that residues will be present at tolerance level and that 100 percent of the crop is treated. Alternatively, the TAS may be used to calculate an "Anticipated Residue Contribution" (ARC) where verifiable data are available on the actual distribution of residues on treated crops, the dissipation or concentration of residues during the storage, transport, and processing of food commodities, and/or the percentage of the total crop actually treated with a pesticide.

Since 1986, the TAS has been used to determine if there are particular dietary concerns for pesticides undergoing reevaluation in the Registration Standard Process, for new chemicals and new uses of old chemicals, and for any other pesticide for which the Agency has a special dietary concern.

To solicit guidance on the scientific criteria that EPA should consider in developing its policy regarding the use of the TAS, the Agency presented a paper entitled "Briefing Paper on the Tolerance Assessment System (TAS) for Presentation to the FIFRA Science Advisory Panel" to that Panel in March 1987 to address a number of specific issues. A copy of that paper and the Report of SAP Recommendations is available on request from the Office of Pesticide Programs. In particular, the Agency requested advice on the scientific criteria the Agency should consider for the use of population subgroups in a dietary exposure analysis, and for the use of percentiles of exposure within a particular population in estimations of dietary risk. The Agency also asked the Panel to address the appropriate margins of safety which the Agency should use for determining acceptable exposures for subgroups or percentiles of exposure within a subgroup. Finally, the Agency requested guidance on the scientific criteria that should be used in identifying appropriate residue levels for use in dietary exposure estimations, and on data presentation.

In response, the SAP noted that the TAS will enable the Agency to predict exposure levels for population subgroups with far greater precision than the current system and thus represents an improved approach. On the issue of the appropriate use of population subgroups, the Panel, noting that the focus of the TAS is on exposure rather than on toxicity, commented that calculations based on body weight, will tend to overstate the risk to infants where there is no toxicological basis for increased susceptibility. To correct for this factor, the Panel recommended that the Agency explore the use of body surface rather than body weight as a basis for comparison. On the safety factor issue, the Panel did not recommend any changes to the traditionally-used one-hundred fold safety factor. The Panel also suggested that the use of a controlled field study would be more likely to provide useful data for the TAS than monitoring data. Finally, the Panel recommended that data should be presented in such a way as to indicate the reliance of the approach on exposure, rather than on toxicity, and the Agency should indicate how relevance, biological significance, and other issues could be introduced into the process. The Agency will work to refine the TAS, as recommended by the Panel, and will seek to develop additional tools and methods to improve its risk/benefit assessment capabilities.

VI. Related Agency Activities

The Agency is working on a number of other initiatives and program improvements which are related to the issues discussed here.

A. FFDCA Section 408/409 Procedural Rules

The Agency has made considerable progress in developing consistent procedural rules pertaining to section 408 and 409 tolerances. Elsewhere in this issue of the Federal Register, the Agency is proposing new procedural rules for establishing, modifying, and revoking section 409 food additive regulations, as well as procedural rules governing the filing of objections, requests for hearings, and the holding of hearings under sections 408 and 409. These proposed rules not only will modernize out-of-date hearing rules, but also will restate and update practices that have not necessarily been codified. The next step in the regulatory process will be to expand the regulations to include (1) substantive interpretations and criteria for determining

when tolerances and food additive regulations are required and what data are required in support of them and (2) the criteria and assumptions to be used by EPA in determining whether a tolerance or food additive regulation should be established, modified or revoked.

B. Encouraging Safer Pesticides

The Agency plans to take steps to encourage the development of safer pesticides. The Agency expects to publish a Federal Register notice detailing this plan in the near future.

C. Promoting Innovation in Pest Control

Despite gaps in current data bases, there are indications that human health and/or environmental risks exist for many currently registered nematicides and fungicides. In the case of nonfumigant nematicides, product efficacy depends largely on solubility. Solubility, however, increases soil mobility, giving rise to concern regarding ground and surface water contamination. Certain of the fumigant nematicides also are currently under Agency scrutiny because of potential chronic risks which may be incurred by workers. Of the registered fungicides, 12 ***41117** are currently undergoing Special Review, and additional classes of fungicides may be placed in Special Review in the near future.

The Agency is working with the Agricultural Research Service and the Cooperative State Research Service to focus USDA research efforts on development of alternative controls for nematodes and plant disease. The Agency has identified a particular need for alternative controls for nematodes on citrus and potatoes and for plant diseases on tomatoes, grapes, leafy vegetables, and pome fruits. The Agency is also considering what incentives can be introduced into the registration process to encourage development of alternative controls. These may include waivers of tolerance fees and registration fees for new pesticides that fall into specified categories for which alternative controls are desirable.

The agency has also joined with USDA, FDA, and private industry to establish a National Pest Management Task Force. The Task Force will identify those pests of economic significance for which effective chemical controls are no longer available or for which little or no research or registration effort is underway. The Task Force will develop, in conjunction with member agencies and private associations, mechanisms fostering the development of acceptable control technologies.

D. Revision of Product Performance Guidelines

To improve the efficacy data base, the Agency is in the process of revising its Product Performance Guidelines to require the development of “comparative product performance data.” In the past, product performance data requirements have concentrated on efficacy data that demonstrate how well a pesticide controls the pests listed on the label. The proposed revisions will require that registrants develop and maintain data which will provide information on performance of a pesticide compared to alternative pesticides, non-chemical techniques, and untreated controls.

E. Updating Food Consumption Data and Other TAS Improvements

Resources permitting, EPA hopes to update the food consumption data as part of our overall effort to implement TAS fully. Results of the latest USDA dietary survey should start coming in later this year, and the Agency plans to begin updating the TAS data in 1989. Subsequently, EPA hopes to update TAS every 10 years as results of a new USDA survey become available. The Agency also hopes to be able to enhance the analytical capabilities of TAS and to develop statistical guidelines and computer support for the incorporation of more accurate anticipated residue data based on actual residue studies.

F. Updating Animal Feed Data

Like human food consumption estimates, animal food consumption estimates also need updating. The Agency is currently working on a project to determine whether by-products from food processing plants are significant components of animal feeds. Once these significant feed items are identified, percent of diet figures for these new feed items will be determined.

G. Guidelines and Protocol Improvements

To provide for improved data for use in risk assessments, the Agency is developing guidelines and standard evaluation procedures for the use of registrants and food producers in the generation and submission of data to show actual pesticide residues in food. The Agency will also be working with the food industry to develop protocols for processing studies designed to show what happens to pesticide residues during processing.

H. Reclassification of Raw Versus Processed Commodities

The Agency intends to develop new criteria for classification of commodities as raw or processed in order to update and eliminate inconsistent 408/409 commodity classifications.

I. Factoring in Drinking Water Exposure to Pesticides

The Agency is concerned about human intake of pesticides via routes other than food, particularly drinking water. Historically, the Agency has based its decisions on tolerances only on dietary exposure from foods treated with pesticides. More recently the Office of Pesticides Programs (OPP) and the Office of Drinking Water (ODW) have begun focusing on drinking water as a potential source of pesticide residues in the diet. The Agency has recently made significant progress in its efforts to integrate activities or OPP and ODW with respect to pesticides in groundwater. All Health Advisories for pesticides in drinking water are now developed jointly by ODW and OPP, using the same data base and the same reference dose.

As a part of EPA's implementation of its Agricultural Chemicals in Groundwater Strategy, the Agency will be considering the extent to which pesticide residues in drinking water are a significant factor in dietary exposure to pesticide residues. This may be difficult in some cases, but is necessary in order to get a more complete picture of exposure. In cases where pesticides do reach drinking water supplies, it is necessary to factor this exposure into tolerance decisions.

For example, exposure to aldicarb through drinking water as a result of its presence in groundwater is being considered in the tolerance assessment in the special review of aldicarb. This is a case in which the data are available, and it is clear that drinking water is a potential route of exposure.

VII. Conclusion

In conclusion, the Agency believes that he recommendations of the NAS offer the Agency very useful guidance in improving and refining the process of evaluating pesticides for registration and tolerance purposes. Consistency between the criteria EPA uses in registering pesticides under FIFRA and in setting tolerances for pesticide residues on food under sections 408 and 409 of the FFDCA is a clearly desirable goal. A negligible risk approach to the pesticide regulatory process would allow the Agency to move in the direction of greater consistency, and allow the registration of new pesticides that pose lower risks than certain currently registered products.

The Agency also believes it would be desirable to have the authority to review all food additive regulations, as well as tolerances and registration actions, under a risk/benefit standard. Only by using a risk/benefit standard for all pesticide decisions will the Agency be able to achieve real consistency, and have the latitude to properly exercise its judgment based on a consideration of all relevant factors. Such an approach, over the long run, will be most likely to reduce the total risk attributable to pesticide use. As discussed in this document, the Agency cannot fully implement this goal without legislative change.

Nevertheless, the Agency will propose to follow the negligible-risk approach to the extent possible in future rulemakings on individual pesticides.

With regard to the other recommendations of the NAS, the Agency is focusing its energies on reviewing chemicals under a prioritization scheme in order to reduce risks attributable to pesticide use. Finally, the Agency is engaged in developing tools such as the Tolerance Assessment System to refine its ability to make regulatory decisions.

***41118** Dated: October 11, 1988.

Victor J. Kimm,

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Appendix A—Procedures Followed by the Agency in Determining Allowable Residue Levels for Tolerances and Food Additive Regulations

In setting tolerances, EPA reviews residue chemistry data and toxicology data. The required data are essentially the same as those necessary to support the registration of a pesticide product used on food. To be acceptable, a tolerance level must be both high enough to cover residues likely to be left when the pesticide is used in accordance with its labeling, and low enough to be safe.

The Agency estimates the level of daily exposure which is not expected to cause appreciable risks during the human lifetime. With regard to risks other than cancer, this level is called the Accpetable Daily Intake (ADI) or Reference Dose (RfD). The ADI is calculated by dividing the no-observed effect level (NOEL) (the dosage level at which any adverse effects observed at higher dose levels are absent) from the most senstivie test showing adverse effects by an appropriate safety factor. This calculation is based on the concept that the risks of concern other than cancer are threshold effects—i.e., below the ADI there will be no adverse effect.

EPA also calculates the theoretical maximum residue contribution (TMRC), which represents the maximum amount of residue of a pesticide which a typical human could ingest by consuming food that bears the maximum level of the residue allowable under all existing and proposed tolerances. The TMRC is calculated by multiplying the tolerance level for each food by the amount of that in the typical American diet (according to available statistics on food consumption patterns) and totalling the values for all foods which may bear residues of that pesticide.

The TMRC is then compared with the ADI, and the tolerance is established (assuming no other concerns) if the TMRC is less than the ADI. A tolerance may be established in certain situations where the TMRC is higher than the ADI if residue data establish that the actual human exposure is not likely to exceed the ADI. For pesticides which may induce cancer, in addition to performing the ADI calculations discussed above for the effects of concern other than cancer, the Agency usually performs a quantitative risk assessment for the cancer risk. Cancer ordinarily is treated as a non threshold effect, because of a lack of evidence to refute the assumption that the carcinogenic response in humans to low doses is approximately proportional to the response in animals to high dose. Thus, some risk presumptively could result even at very low levels of exposure.

EPA's current carcinogencity testing scheme requires the use of several test doses (up to a level at or near the maximum tolerated dose) in at least two animal species, in order to magnify the likelihood of detection of a carcinogenic response in an economical, practically-sized animal test population (50 animals per sex per dose level) animal test population. At the present time, there is not better way to assess practically the potential carcinogenicity of a pesticide to which the entire U.S. population may be exposed. The animal data, and any available human epidemiology data, are assessed in accordance with EPA's “Cancer Assessment Guildelines, designed for use by all Agency programs in implementing a number of statutes designed to protect the public health, provide a qualititative classification scheme regarding human carcinogenicity based on a weight-of-the-eveidence analysis of the available data. Chemicals are classified into five groups, as follows:

1. Group A
Human Carcinogen: (Sufficient evidence of cancer causality from human epidemiologic studies).

2. Group B
Probable Human Carcinogen B1 limited evidence of carcinogenicity from human epidemiologic studies B2 sufficient evidence of carcinogenicity from animal studies.

3. Group C
Possible Human Carcinogen: Limited evidence of carcinogenicity in animals in the absence of human data, including malignant tumor response in a single well-conducted experiment not meeting conditions for sufficient evidence, tumor responses of marginal statistical significance in studies having inadequate design or reporting, benign tumors where short-term mutagenicity tests are negative, and responses of marginal statistical significance in a tissue with high background rate.

4. Group D
Not classifiable as to Human Carcinogenicity: Either inadequate evidence of carcinogenicity or absence of data.

5. Group E
Evidence of Non-Carcinogenicity for Humans: No evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies.

A weight-of-the-evidence determination may involve consideration of, among other things, (1) the particular bioassay test system(s) used, (2) the evaluation of the histopathological and other results of the test(s), (3) the weight to be given to benign tumors, (4) mechanistic considerations, e.g., a situation where the chemical itself does not cause the tumor, but rather the effect the chemical causes at high doses of administration is the tumor-causing agent, and this effect would not occur at the lower doses of human exposure, and (5) the extent to which the overall quality and conduct of the tests accords with good laboratory practices.

Quantitative risk assessments are routinely performed for Category A and B carcinogens. In the case of pesticides classified as Category C, the Agency decides on a case-by-case basis whether the qualitative evidence is sufficient to warrrant a quantitative risk assessment, bearing in mind the possibility that publishing a risk number may create in the public mind an assumption of the reality of a risk to humans that is not supported by the qualitative data from animal studies.

To estimate the cancer risk posed by a pesticide from animal data, the Agency typically uses the linearized multistage model to extrapolate from the results seen at the high doses of the animal study to predict worst case risks at the much lower levels of estimated or actual human exposure. Using this model, a potency factor (Q1 *, called the “Q-star”) is calculated from the 95 percent confidence limit of the slope of the linearized portion of the dose response curve. This potency factor represents a plausible, statistically-derived upper limit to the carcinogenic potency of the potential carcinogen at doses relevant to human exposure, and when multiplied by human exposure, yields an upper bound estimate of the risk. Such an estimate does not represent the actual risk, which may, in fact, be considerably lower or even as low as zero. Estimates of the upper limit on lifetime dietary risk from consumption of residues of a carcinogenic pesticide are calculated by multiplying the Q1 * by the average human dietary exposure, using food factors derived from USDA data on food consumption patterns. Unless data are available on the actual level of ***41119** residues in particular food commodities, a worst-case risk will be calculated based on the assumption that all treated food bears residues at the tolerance level and that 100 percent of the crops are treated.

EPA's current method of deriving these worst-case risk estimates for a carcinogenic chemical from animal data is based on somewhat more conservative premises than the approach of FDA. FDA assumes that humans and animals are equally sensitive

to the test chemical on an equivalent body weight basis. EPA, on the other hand, bases its assessment on the premise that different sized animals are not equally sensitive to equal concentrations of a chemical, and makes a surface area adjustment to account for this difference.[FN1] The effect of this adjustment is to increase the estimate of human risk by about thirteen fold where data are derived from mice, and about 6[FN12] fold when the data source is the rat as the test animal. Accordingly, EPA's risk numbers represent about an order of magnitude of risk greater than would be calculated using FDA methodology.

Appendix B—Food Use Pesticides With Evidence of Carcinogenicity

Active Ingredient Group [FN1]	409	409 Needs [FN2]		
Tolerances	Tolerances	409		
food	feed	tolerances		
1,3-dichloropropene [FN3,6]	B2			
2,4-D	D	x	x	
Acephate	C	x	x	
Acifluorfen	B2			x
Alachlor 6	B2			x
Aliette (fosetyl al)	C			
Amdro	B2			
Amitraz	C			x
Arsenic acid (orthoarsenic acid)	A			
Asulam	C			
Atrazine	C			
Azinphos-methyl	D			x
Benomyl [FN4]	C	x		
Bifenthrin 5	C			
Bromacil				
Calcium arsenate				
Captafol	B2			
Captan 6	B2	x	x	
Chlordimeform & hydrochloride	B2			
Chlorobenzilate				
Chlorothalonil	B2			
Copper arsenate				
Cypermethrin				
Cyromazine 4			x	
Daminozide 6	B2	x	x	
Diallate				
Dicamba 7		x	x	
Dichlorvos (DDVP)	B2	x		
Diclofop methyl				
Dicofol	B2	x		
Dimethipin (Harvade)	C			x
Dinoseb	C			
EDB	B2			
Ethalfluralin			x	
Ethylene oxide 6		x		
Folpet	B2			
Gardona	C	x	x	
Glyphosate	D	x	x	
Lactofen 5	B2			
Lead arsenate				x
Lindane	D			x
Linuron 6	C			

Mancozeb 4, 6	B2	x		
Magnesium arsenate				
Maneb 4,6	B2			x
Methanearsenic acid			x	
Methidathion	C			x
Methomyl 4				x
Metiram 4 6	B2			
Metolachlor	C			
Oryzalin	C	x		
Oxadiazon	C			
O-phenylphenol				
Paraquat	E	x	x	
Parathion	C			
PCNB (pentachloronitrobenzene)	D			
Permethrin				x
Phosmet	C	x		
Pronamide	C			
Propazine	C			
Propiconazole 5	C			
P-dichlorobenzene 3	C			
Sodium arsenate				
Sodium arsenite				
Terbutryn	C			
Tetrachlorvinphos		x		
Thiodicarb 4				x
Thiophanate methyl 4				x
Toxaphene			x	
Triadimenol (Baytan)	C			
Tridiphane	C			
Trifluralin	C	x		
Zineb 4 6	B2			

Notes:
1 Classification in accordance with EPA's Cancer Assessment Guidelines (see Appendix A) for those chemicals for which a weight-of-the-evidence determination has been made.
2 Chemical has recently been determined to require a 409 tolerance.
3 Registered uses (formerly not considered to be food uses) which have recently been defined as food uses.
4 Included due to potentially oncogenic metabolite.
5 Recently added to list because of newly registered food uses.
6 Currently in Special Review for dietary concerns.
7 Included because a contaminant is an oncogen.

Appendix C—Active Ingredients for Which Registration Standards Have Been Issued or are Scheduled for Next Year

Active ingredient	Calendar year of issue
4-aminophyridine	1980
Acephate	1987
ADBAC	1985
Alachlor	1984
Aldicarb	1984
Aldrin	1986
Aliette (fosetyl al)	1983
[FN1]	1986
Amitraz	1987

Amitrole 1984
Ammonium sulfamate 1981
[FN1] 1987
Anilazine 1983
Arsenic acid (orthoarsenic acid) 1986
Aspon 1980
Asulam 1988
Atrazine 1983
[FN1] 1989
Azinphos-methyl 1986
Bacillus thuringiensis 1988
Barium metaborate 1983
Bendiocarb 1987
Benefin 1989
Benomyl 1987
Bentazon/sodium bentazon 1985
Bifenox 1981
Bifenox (SRR) 1989
Bioallethrin 1988
BKLFI-2 1981
Boron (incl. borax & boric acid) 1983
Bromacil 1982
[FN1] 1989
Bromoxynil 1989
Butoxicarboxime 1981
Butylate 1983
[FN1] 1989
Captafol 1984
Captan 1986
Carbaryl 1984
[FN1] 1988
Carbofuran 1984
Carbophenothion 1984
Carboxin 1981
Chloramben 1981
[FN1] 1989
Chlordane 1986
Chlordimeform hydrochloride 1985
Chlorobenzilate 1983
[FN1] 1989
Chloroneb 1980
[FN1] 1989
Chlorophacinone 1989
Chloropicrin 1982
Chlorpropham 1987
Chlorothalonil 1984
[FN1] 1988
Chlorpyrifos 1984
[FN1] 1989
Chlorsulfuron 1982
Chromated arsenicals 1986
Coal tar/creosote 1986
Copper chloride/nitrates 1987
Copper sulfate 1986
Coumaphos 1981
[FN1] 1989
Cryolite 1983
[FN1] 1988

Cyanazine 1984
Cycloate 1989
Cycloheximide 1982
Cyhexatin 1985
2,4-D 1988
2,4-DB 1988
2,4-DP 1988
Dacthal 1988
Dalapon 1987
Daminozide 1984
DCNA 1983
Deet 1980
Demeton 1985
Dialifor 1981
Diallate 1983
Diazinon 1988
3,5-dibromosalicylanilide 1985
Dicamba 1983
[FN1] 1989
Dichlobenil 1987
Dichlone 1981
1,3-dichloropropene 1986
Dichlorvos (DDVP) 1987
Dicrotophos 1982
Difenzoquat 1988
Diflubenzuron 1985
Dimethoate 1983
[FN1] 1989
Dioxathion 1983
Diphacinone 1989
Diphenamid 1987
Dipropetryn 1985
Diquat dibromide 1986
Disulfoton 1985
Diuron 1983
Dodine 1987
Endosulfan 1982
EPN 1987
EPTC 1983
[FN1] 1989
Ethephon 1988
Ethion 1982
[FN1] 1989
Ethoprop 1983
[FN1] 1988
Ethoxyquin 1981
Ethyl parathion 1986
2-ethyl-1,3-hexanediol 1981
Fenamiphos 1987
Fenaminosulf 1983
Fenitrothion 1987
Fensulfothion 1983
Fenthion 1988
Fluchloralin 1985
Fluometuron 1985
Folpet 1987
Fonofos 1984
Formaldehyde 1986

Formetanate hydrochloride 1983
[FN1] 1989
Fumarin 1980
Glyphosate 1986
Heliothis NPV 1984
Heptachlor 1986
Hexazinone 1982
[FN1] 1988
Isocyanurates 1987
Isopropalin 1981
Lindane 1985
Linuron 1984
MCPA 1982
[FN1] 1988
MCPB 1989
Magnesium & aluminum phosphide 1986
Malathion 1988
Maleic hydrazide 1988
Mancozeb 1987
Maneb 1988
Mecoprop 1989
Methiocarb 1987
Metalaxyl 1981
[FN1] 1988
Metaldehyde 1989
Methamidophos 1982
Methidathion 1981
[FN1] 1988
Methomyl 1982
[FN1] 1988
Methoprene 1982
Methoxychlor 1989
Methyl bromide 1986
Methyl parathion 1986
Methylene bis thiocyanate 1989
Metiram 1988
Metolachlor 1980
[FN1] 1987
Metribuzin 1985
Mevinphos 1988
Monocrotophos 1985
Monuron 1983
Monuron TCA 1983
Nabam 1987
Naled 1983
Napropamide 1989
Napthalene 1981
Naphthalene acetic acid & salts 1981
Naptalam 1985
Nitrapyrin 1985
Norflurazon 1984
[FN1] 1989
OBPA 1981
O-phenylphenol 1989
Oryzalin 1987
Oxamyl 1987
Oxydemeton methyl 1987
Oxytetracycline 1988

Paraquat 1987
PCNB (pentachloronitrobenzene) 1987
Pendimethalin 1985
Perfluidone 1985
Phenmedipham 1987
Phorate 1984
Phorate (SRR) 1988
Phosalone 1981
[FN1] 1987
Phosmet 1986
Phosphamidon 1987
Picloram 1985
[FN1] 1988
Piperonyl butoxide 1989
Potassium bromide 1984
Potassium permanganate 1985
Prometryn 1987
Pronamide 1986
Propachlor 1985
Propanil 1987
Propargite 1986
Propazine 1989
Propham 1987
Resmethrin 1988
Rotenone 1988
Simazine 1984
[FN1] 1989
Sodium & calcium hypochloride 1986
Sodium omadine 1985
Streptomycin 1988
Sulfur 1982
Sulfuryl fluoride 1985
Sulfotepp 1988
Sulprofos 1981
Sumithrin 1987
Tebuthiuron 1987
Temephos 1981
Terbacil 1982
[FN1] 1989
Terbufos 1983
Terbutryn 1986
Terrazole 1980
[FN1] 1989
Tetrachlorvinphos 1988
Thiophanate ethyl 1985
Thiophanate methyl 1988
Thiram 1984
TPTH 1984
Trichlorfon 1984
Trifluralin 1987
Trimethacarb 1985
Vendex 1987
Warfarin 1981
[FN1] 1989
Zinc phosphide 1982

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1 Second round of review of the earlier registration standards.

***41120 Appendix D—Examples of Pesticide Chemicals With Tolerance Issues Currently or Recently Under Review**

1. Benomyl

Benomyl is a broad spectrum systemic fungicide that controls a wide variety of plant diseases in field and vegetable crops, rice, tree fruit and nut crops, greenhouse, ornamentals, and turf sites. It is also used as a postharvest dip for fruits. In the Registration Standard issued for benomyl on March 31, 1986, the Agency concluded that benomyl and its major metabolite, 4-methyl benzimidazole carbamate (MBC), were possible human carcinogens (Group C), based on a significant increase in hepatocellular carcinomas in closely related strains of mice. Based on the established tolerances and the percent of crop treated, the Agency estimated any potential oncogenic risk from dietary exposure to be in the range of 10-5. The Agency noted, however, that this quantitative assessment should not be accorded much weight since the evidence for oncogenicity is limited, but could be taken to represent a worst-case upper limit for risk. The Registration Standard also reassessed the residue data base supporting the established tolerance and food additive regulations for benomyl and concluded that additional data were required to fill the identified data gaps. A conclusion was also reached that additional food ***41121** additive regulations under section 409 may be required to cover residues in the processed fractions of citrus, tomatoes, grapes, and soybeans.

The additional residue data required by the Standard were received in the summer of 1987 and are under review. When general metabolism data (due July 1989) are received, EPA will be able to complete the tolerance reassessment for benomyl.

If the new data indicate that additional section 409 regulations are necessary, the Agency could establish such regulations under a de minimis approach if weight-of-the-evidence considerations lead to a conclusion that the risk to humans is negligible.

2. Captafol

Captafol, which was originally registered in 1962, is used as a fungicide on various vegetable and fruit crops. The Registration Standard for captafol, completed in September 1984, estimated a dietary risk of 10-4 based on tolerance levels, and required registrants to produce data on actual residues in food crops and additional oncogenicity data. A Special Review was also initiated. In early 1987, EPA classified captafol as a B2 (probable human) oncogen. The major registrant, Chevron Chemical Company, voluntarily cancelled its captafol registrations in March 1987. Formulators followed suit the next month. On August 22, 1988, the Agency terminated the Special Review because all registrations of captafol products had been cancelled. Also, the Agency plans to initiate action during 1989 to revoke the remaining tolerances for captafol.

3. Captan

Captan (N-trichloromethylthio-4-cyclohexane-1,2-dicarboximide) is a widely used agricultural fungicide, currently registered for use on a number of fruits and vegetables, small grains, cotton, grasses, flowers, and numerous household uses. The chemical has been the subject of a recent Registration Standard (issued in March 1986) and a Special Review. The Agency has found that the dietary intake of captan resulted in an increased incidence of uncommon adenomas and adenocarcinomas of the upper gastrointestinal tract in the Charles River CD-1 mouse, an increased incidence of these GI tumors in B6C3F1 mice, and a small dose-related increased incidence of kidney tumors in Charles River CD-1 rats. The Agency also noted positive mutagenic activity in gene mutation and chromosomal aberration assays, and a structural relationship to other compounds that demonstrated oncogenic effects.

In the Standard, the Agency requested residue data, including field trials to generate data for raw agricultural commodities treated at the maximum permitted rate, and studies to show the effect of washing, peeling, cooking, and processing on residue levels. Section 408 tolerances are currently established for a number of commodities which are subjected to processing, namely potatoes, soybeans, tomatoes, oranges, grapes, sweet corn, cottonseed, and pineapples. Section 409 tolerances for captan exist for washed raisins at 50 ppm (21 CFR 193.40; 21 CFR 193.40 redesignated as 40 CFR 185.500 at 53 FR 24666, June 29, 1988) and detreated corn seed at 100 ppm (21 CFR 561.65; 21 CFR 561.65 redesignated as 40 CFR 186.500 at 53 FR 24668, June 29,

1988). However, the 409 tolerance for detreated corn seed is in the process of being revoked for failure to submit supporting data. Section 409 tolerances must be set for some commodities, such as dried prunes and dry apple pomace.

In the Preliminary Determination of the Special Review, issued on June 2, 1985, the Agency determined that the dietary risk could be as high as 10-4 based on the assumption that residues are present at tolerance levels. The new data will allow the Agency to refine its risk assessment, and determine whether the currently established tolerances and food additive regulations should be revoked.

4. Chlordimeform

Chlordimeform was previously registered for a number of fruit and vegetable insecticide uses; however, most food uses were withdrawn by the registrants in 1976 because preliminary results of a mouse study suggested that chlordimeform caused malignant blood vessel tumors. In 1978, chlordimeform was registered for use on cotton with new restrictions to reduce applicator exposure. A Registration Standard was published for chlordimeform in January 1986, and the chemical has been referred to Special Review because of worker exposure concerns. In conducting the Registration Standard review, the Agency assessed dietary risks from the cotton use, using data on the percent of cotton crops actually treated (between 10 percent and 12 percent), and actual residue data showing chlordimeform residues ranging from 1 to 2 orders of magnitude lower than tolerance levels. Dietary risk from actual residues of chlordimeform occurring in commodities derived from treated cotton was estimated at 10-7. Under the de minimis approach, the food additive regulations on commodities processed from cotton would be retained.

Very recently, the two registrants of the technical product have offered to voluntarily cancel the remaining cotton use, effective within the next year.

5. Chlorothalonil

Chlorothalonil is a fungicide used on numerous crops such as fruits, vegetables, and peanuts, as well as on ornamental turf. The chlorothalonil Registration Standard, issued in September 1984, identified significant data gaps; data have been submitted in response to the requirements set forth in the Standard. Based on such data, EPA has classified chlorothalonil as a B2 (probable human) oncogen. There are no existing 409 food additive regulations for this chemical; residue data required in the Standard will allow the Agency to determine if such regulations are necessary. A Revised Registration Standard and Tolerance Reassessment is scheduled for completion in September 1988. The Agency will assess during the Standard review whether the chemical should be referred to Special Review.

6. EBDCs

The EBDCs (ethylene bisdithiocarbamates) are a group of six fungicides (maneb, mancozeb, amobam, nabam, metiram, and zineb) with a common contaminant, metabolite, and degradation product called ethylene-thiourea (ETU). In 1984, a data call-in imposed extensive data requirements on the registrants of the EBDCs to enable the Agency to perform a comprehensive risk assessment. In response, registrants of amobam cancelled their products, and registrants of nabam deleted all food uses from their labels. Based on data received in response to the data call-in, the Agency has classified ETU and the EBDCs as B2 (probable human) oncogens. As set forth in the Registration Standard issued in April 1987, the dietary risk for mancozeb is estimated to be 10-4 based on actual residue data. The total dietary risks resulting from the use of all the EBDCs is likely to be higher. Residue data on maneb and metiram were received in March 1988. For zineb, which represents only 5 percent of total EBDC usage, residue data will not be available until 1991.

All the EBDCs have been placed in Special Review; the Preliminary Determination is scheduled for early 1989. The Agency expects to conduct a risk assessment of the dietary risk posed by these chemicals in the summer and fall of 1988, and then to conduct a comparative risk/benefit assessment of the major fungicides (EBDCs, captan, ***41122** chlorothalonil and benomyl) before making a regulatory decision on any one of them. As part of that review, the Agency will also determine what action

to take with respect to the existing tolerances and food additive regulations. There are several food additive regulations for mancozeb, and data may indicate the need for such regulations for maneb, metiram, and zineb.

7. Folpet

Folpet is a broad spectrum fungicide which, in the past, has been used on both food and nonfood crops and as an industrial fungicide in the manufacture of coatings and plastics. Non-agricultural uses and home and garden uses have accounted for approximately 86 percent of its total usage. A Registration Standard was issued for folpet in June 1987, and additional residue data (due in 1991) were requested. Currently, all food uses have been suspended for failure to provide data. Current indications are that the only food use which is likely to be supported by data is the use on avocadoes.

The chemical has been classified as a B2 (probable human) oncogen. Prior to the recent suspensions, theoretical dietary risks, based on the assumption that residues would be present at tolerance levels, were in the 10-4 range, but the Agency believes that, if actual residue data and percent of crop treated were factored into the risk calculation, risks would be likely to be in the 10-6 range. There are no existing section 409 food additive regulations for folpet. If any food uses are reinstituted, and if residue data show that there is a concentration effect during processing, such regulations would be necessary. If the data indicate that the risk is in fact in the 10-6 range, the de minimis approach could be followed in establishing such regulations.

8. Linuron

Linuron, a herbicide used for pre- and post-emergent control of annual grasses and broadleaf weeds, was initially registered in 1966, and a number of tolerances have been established since then for its use on soybeans, corn, cotton, sorghum, wheat, asparagus, carrots, celery, parsnips. and potatoes. There are no section 409 food or feed additive regulations for linuron. However, the Agency has requested processing data to demonstrate whether the chemical does concentrate in processed commodities.

In 1984, a Registration Standard was issued for linuron and additional residue and chronic effects data required. At the time of the Standard, the Agency estimated dietary oncogenic risk in the range of 10-4 (based on residues at tolerance levels with some adjustment for percent of crop treated). However, since the time the Special Review was initiated, the Agency has issued its oncogenicity classification guidelines and has concluded that linuron is a group C (possible human) oncogen. Because only benign tumors are formed, these tumors occur only late in life, and there is no evidence of mutagenic activity, the Agency has concluded that linuron's human carcinogenic potential is low. Therefore the Agency has recently terminated the Special Review based on oncogenicity.

9. Permethrin

Permethrin is an insecticide first registered in 1979 for use on cotton, with a wide variety of other uses, including vegetables and pears (registered in 1982). The toxicology data base for permethrin is complete. The Agency has classified permethrin as a Group C oncogen, based on the induction of lung and liver tumors in female mice. Based on the very weak evidence of oncogenicity observed, the Agency determined that a quantitative risk assessment for this chemical is inappropriate because the likelihood of oncogenic effects in humans from low levels of permethrin is non-existent or extremely low. The Agency has, however, regulated this chemical as a possible oncogen for Delaney Clause purposes, and has declined to set 409 food additive regulations.

A tolerance for tomatoes, a commodity which is usually subject to processing, was established for Florida tomatoes, subject to a restriction that the tomatoes only be used for the fresh market. This approach was believed to be feasible for permethrin because of the unique circumstances of tomato production in Florida, i.e., 98 percent of the tomatoes were for the fresh market, and the limited number of canneries in the area agreed not to process tomatoes into a form which would result in concentrated residues (such as paste, puree, or ketchup). However, the Agency subsequently was informed that a cannery in Florida was

processing permethrin-treated tomatoes into puree and paste. This incident demonstrates the impracticality of expecting growers and processors to distinguish between permethrin-treated tomatoes and untreated tomatoes.

In addition, the Agency is still seeking processing data to clarify whether residues will concentrate in any of the other processed commodities produced by Florida canneries. If the Agency were to follow the de minimis approach, permethrin would be a potential candidate for section 409 food additive regulations for additional uses in which concentration of the residues occurs during processing.

10. Trifluralin

Trifluralin is a selective preemergent herbicide registered for use on a variety of crops for the control of annual grasses and certain broad leaf weeds. This pesticide has been classified as a Group C carcinogen based on a significant increase in the incidence of malignant tumors of the renal pelvis, of the kidney and thyroid gland of male rats, and in the incidence of combined malignant and benign urinary bladder tumors in female rats at the highest dietary concentration tested. The Agency indicated in its August 1986 Registration Standard that processing data is being required for potatoes, sugar beets, soybeans, citrus fruits, sorghum, barley, corn and wheat grain, alfalfa hay, flax seed, cottonseed, peanuts, spent peppermint and spearmint hay, sugarcane, and sunflower seed. These data could indicate that additional food additive regulations are necessary to support current use patterns. Such regulations could be established under a de minimis approach if risks are found to be sufficiently low. Otherwise, if the Agency takes the approach that such regulations would be barred by the Delaney Clause, the corresponding section 408 tolerances might be subject to revocation, thereby eliminating many of the beneficial uses of this pesticide.

Appendix E—Candidates for Negligible Risk Consideration

Chemical	Type	Status	Proposed Use	Group
Aliette	Fungicide	New Use	Hops	C
Amitraz	Insecticide	New Use	Apples	C
Apollo	Insecticide	New Chemical	Apples	C
Cypermethrin corn	Insecticide	New Uses	Soybeans	C
Dicamba [FN1]	Herbicide	New Use	Cotton	Not classified.
Glyphosate	Herbicide	New Use	Wheat	C/D
Harvade	Herbicide	New Use	Sunflowers	C
Methomyl [FN2]	Insecticide	New Use	Hops	Not classified.
Metolachlor	Herbicide	New Uses	Apples, flax, sunflowers	C
Permethrin corn	Insecticide	New Uses	Soybeans, apples, tomatoes	Treated as C
Savey	Insecticide	New Chemical	Apples	C
Verdict	Herbicide	New Chemical	Soybeans	In review

1 A nitrosoamine contaminant of dicamba is an oncogen.
2 Acetamide is an oncogen and an animal metabolite of methomyl.

***41123 Appendix F Group C Carcinogens' Status Re Risk Quantification**

The decision as to whether or not quantification of risk for Group C chemicals is appropriate is subject to change as the Agency analyzes new data or reevaluate existing data. The following lists indicate those chemicals for which, as of August 1988, the Agency has determined a quantified risk number should or should not be used. There are a few other Group C chemicals for which this decision is still pending.

Risk Quantification Deemed Inappropriate

acephate

Aliette (fosetyl al)

amitraz

asulam

benomyl

bifenthrin

cypermethrin

dimethipin (Harvade)

fomesafan

gardona

linuron

methidathion

metolachlor

oryzalin

oxadiazon

parathion

permethion

phosmet

pronamide

propiconazole

triadimenol (Baytan)

tridiphane

trifluralin

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Footnotes

1 The decision to cancel a pesticide can result from a Special Review, an intensive review of the risks and benefits of a pesticide which meets or exceeds risk criteria set forth in 40 CFR Part 154. The Agency also can take action to cancel (and, if necessary, to suspend during the cancellation proceedings) the registration of a pesticide whose risks appear to exceed its benefits, without first going through the Special Review process.

2 Under Reorganization Plan No. 3 of 1970, which established EPA, the authority to set tolerances for pesticide chemicals in raw agricultural commodities and processed food under FFDCA sections 408 and 409 respectively, was transferred from FDA to EPA. FDA enforces most of the pesticide tolerances and food additive regulations that EPA issues, along with the many non-pesticide food additive regulations that FDA issues. The U.S. Department of Agriculture enforces the tolerances and food additive regulations with respect to meat, poultry, and egg products.

3 In Continental Chemiste Corp. v. Ruckelshaus, 461 F.2d 331, 340-341 (7th Cir. 1972), a case dealing with the relationship of FIFRA and FFDCA, the court stated that "[t]he test of safety [contained in the general safety clause of section 409] was intended to take into account the broader concepts of safety under the intended conditions of use; the benefits of the additive were to be evaluated rather than merely its potential for harm. In short, in making its ultimate determination whether new additives, or food containing them, may be marketed, [the FFDCA] employs the kind of substantive standard of product safety embodied in [the pre-1972] FIFRA's injury to man' concept, rather than a narrow consideration of the character of the additive itself." In discussing this "injury to man" concept, the court noted that "the substantive standards, phrased in terms of protection of the public and impact on living man, require consideration of the aggregate effect of a product's use upon the environment, including not only its potential for harm, but also the benefits which would be lost by removing it from the market." Id. at 336.

4 FDA has analyzed the meaning of the DES proviso in proposed regulations published in the Federal Register of March 20, 1979 (44 FR 17070), and February 11, 1983 (48 FR 6361). FDA's final rule establishing procedures implementing this sensitivity-of-method approach was published on December 31, 1987 (52 FR 49572).

5 See Alabama Power Co. v. Costle, 636 F.2d 323, 360 (D.C. Cir. 1979); District of Columbia v. Orleans, 406 F.2d 957, 959 (D.C. Cir. 1968); Environmental Defense Fund, Inc. v. EPA, 636 F.2d 1267, 1284 n. 46 (D.C. Cir. 1980).

6 See, e.g., the 1960 statement by Arthur S. Fleming, Secretary of Health, Education and Welfare, that the Delaney Clause "allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals," cited with approval in the Report of the House Committee on Interstate and Foreign Commerce on the Color Additive Amendments of 1960 (H.R. Rep. No. 1761, 85th Cong. 2d Sess., June 7, 1960) at 14. See also the May 1960 report of the President's Science Advisory Committee, noting that "[t]he definition of a carcinogen implicit in the language of section 409(c) requires discretion in its interpretation because so may variables enter into a judgment as to whether a particular substance is or is not carcinogenic," cited with approval in the Senate floor debate on reconsideration of the Delaney Clause in the Color Additive Amendments of 1960. Congressional Record 15380 (July 1, 1960).

FN7 See 52 FR 49572, 49577 (December 31, 1987) for a statement of FDA's current policy. See also 51 FR 28331, 28340 (August 7, 1986), where FDA specifically noted that "any chemical shown to induce cancer even in only one strain, gender, and species, at one dose in one experiment, is an animal carcinogen." The evidence as a whole may lead FDA to conclude that a substance that only causes benign tumors should be regulated as a carcinogen under the Delaney Clause. (52 FR 49577, December 31, 1987). However, a finding of only benign tumors does not of necessity lead FDA to conclude that the chemical "induces cancer" under the Delaney Clause.

8 In recent years, the Agency has been conducting a systematic review of currently registered pesticides under the Registration Standards process. This review determines the sufficiency of the data base for these chemicals in light of current data requirements, and evaluates the current terms of registration to see if modifications are appropriate. During the development of a Standard, data gaps are identified and data call-in notices sent to registrants pursuant to FIFRA section 3(c)(2)(B), which gives the Agency authority to require the submission of data necessary to support existing registrations. The Agency evaluates the adequacy of existing tolerances and food additive regulations for chemicals registered for food uses during the Registration Standard review. Appendix C lists those food use pesticides for which Registration Standards have been developed or are scheduled for FY 1988.

9 Section 409(h) states: "[The Administrator] shall by regulation prescribe the procedure by which regulations under (section 409) shall be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulation." The interpretation that revocation is not expressly required is based on giving the term "procedure" its normal meaning, rather than reading into the term the substantive criteria of section 409.

10 FDA appears to interpret the Delaney Clause as applying to food additives established prior to any indication of carcinogenic effect for such chemicals. See, for example, the discussion in the proposed FDA determination not to ban the use of methylene chloride in decaffeinated coffee (50 FR 51551, 51555 December 18, 1985).

11 Discussions in this document of risks resulting from pesticide use are limited to cancer risks due to dietary exposure. It is important for the reader to keep in mind that the Agency's reviews and decisions encompass many other risks as well. Table I proceeds from the assumption that all other risk criteria have been satisfied.

1 Theoretically, this assumption is based on the premise that smaller animals, which eliminate heat from the body (an indication of metabolism) more efficiently than larger animals, are more efficient metabolically at detoxifying a chemical than larger animals. This difference in heat elimination has been related to the ratio of the surface area to the volume of the organism. Mathematically, the correction for surface area differences is made by dividing the dose in the animal study by the ratio of human body weight to test animal body weight to the two-thirds power.

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[SWH-FRL-3601-1; EPA/OSW-FR-89-026]
RIN 2050-AA78

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revisions

Thursday, March 29, 1990

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On June 13, 1986, the Environmental Protection Agency (EPA) proposed to revise the existing toxicity characteristics, which are used to identify those wastes defined as hazardous and which are subject to regulation under subtitle C of the Resource Conservation and Recovery Act (RCRA) due to their potential to leach significant concentrations of specific toxic constituents. The proposed rule was designed to refine and broaden the scope of the hazardous waste regulatory program and to fulfill specific statutory mandates under the Hazardous and Solid Waste Amendments of 1984 (HSWA).

EPA is today promulgating the Toxicity Characteristics (TC). Today's rule retains many of the features of the original proposal: It replaces the Extraction Procedure (EP) leach test with the Toxicity Characteristic Leaching Procedure (TCLP); it adds 25 organic chemicals to the list of toxic constituents of concern; and it establishes regulatory levels for these organic chemicals based on health-based concentration thresholds and a dilution/attenuation factor that was developed using a subsurface fate and transport model. In response to comments received on the proposed rule and related notices, the final rule incorporates a number of modifications in the leaching procedure, the list of toxicants, the chronic toxicity reference levels, and the fate and transport model.

The overall effect of today's action will be to subject additional wastes to regulatory control under subtitle C of RCRA, thereby providing for further protection of human health and the environment.

DATES: Effective Date: September 25, 1990.
Compliance Dates: Large quantity generators: September 25, 1990. Small quantity generators (SQGs): March 29, 1991. Any person that would like to use the Toxicity Characteristic Leaching Procedure (TCLP) before the effective date may do so in order to determine whether the eight heavy metals and six pesticides that are currently regulated under the Extraction Procedure (EP) Toxicity Characteristic leach at levels of regulatory concern.

ADDRESSES: The official record for this rulemaking (Docket Number F-90-TCF-FFFFF) is located in the EPA RCRA Docket (Second Floor, Rm 2427), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding federal holidays. The public must make an appointment to review docket materials by calling (202) 475-9327. The public may copy material at a cost of $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information about this rulemaking, contact the RCRA/Superfund Hotline at (800) 424-9346 (toll free) or (202) 382-3000 in the Washington, DC metropolitan area. For information on specific

aspects of this rule, contact Steve Cochran, Office of Solid Waste (OS-332), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 475-8551.

SUPPLEMENTARY INFORMATION

Preamble Outline

b. Bis(2-chloroethyl) Ether

c. Toxaphene

d. Phenol

e. Pentachlorophenol

5. Specific Inorganic Constituents

a. Silver

b. Chromium

c. Nickel and Thallium

C. Chronic Toxicity Reference Levels

1. Maximum Contaminant Levels

2. Risk-Specific Doses for Carcinogenic Constituents

3. Apportionment of Health Limits

D. Use of Generic Dilution/Attenuation Factors (DAFs)

E. Application of a Subsurface Fate and Transport Model

1. Introduction

a. June 13, 1986, Proposed Rule (51 FR 21648)

b. August 1, 1988, Notice of Data Availability and Request for Comments; Supplement to Proposed Rule (52 FR 28892)

2. Modifications of the Subsurface Fate and Transport Model (EPASMOD) in Response to Comments

a. General Modifications

i. Unsaturated Zone

ii. Source Characterization

iii. Treatment of Dilution from Recharge

iv. Location of the Receptor Well

v. Dispersivity Values

vi. Hydraulic Conductivity

vii. Hydrolysis

viii. Steady-State Assumption

ix. Biodegradation

a. Risk Levels and Frequency Interval

b. Treatment Standards for TC Wastes

c. Schedule for LDR Determinations

3. RCRA Corrective Action and Closure Requirements

4. Minimum Technology Requirements

***11799** a. Applicability

b. Scope of Minimum Technology Requirements

1. Permitted Facilities

2. Interim Status Facilities

c. Compliance with Minimum Technology Requirements

5. RCRA Subtitle D (Solid Wastes)

a. Municipal Waste Combustion Ash

b. Impact on Wastes Excluded from Subtitle C Regulation

6. RCRA Subtitle I (Underground Storage Tanks)

a. Scope of the Underground Storage Tank Program

b. Deferral for Petroleum-Contaminated Media and Debris Subject to Part 280 Corrective Action Requirements

7. RCRA Section 3004(n) Air Regulations

J. Relationship to Other Regulatory Authorities

1. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

2. Clean Water Act

a. Conflict with NPDES Effluent Guidelines and Pretreatment Standards

b. Permit Requirements for Wastewater Treatment Facilities

c. Sludges from Publicly Owned Treatment Works (POTW)

3. Safe Drinking Water Act

4. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

a. Pesticide Wastes

b. Treated Wood Wastes

5. Food, Drug, and Cosmetic Act (FDCA)

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I. Authority

The amendments to the hazardous waste regulations in 40 CFR parts 261 and 271 are being promulgated under the authority of sections 1006, 2002(a), 3001, 3002, and 3006 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921, 6922, and 6926). The amendments to the list of hazardous substances and reportable quantities in 40 CFR part 302 are being promulgated under the authority of section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9602), as amended, and sections 311 and 501(a) of the Federal Water Pollution Control Act (33 U.S.C. 1321 and 1361).

II. Background

A. Definition of Hazardous Waste

Subtitle C of the Resource Conservation and Recovery Act (RCRA), as amended, establishes a federal program for the comprehensive regulation of hazardous waste. Section 1004(5) of RCRA defines hazardous waste, among other things, as solid waste that may ". . . pose a substantial present or potential hazard to human health and the environment when improperly treated, stored, transported, disposed, or otherwise managed." Under RCRA Section 3001, EPA is charged with defining which

solid wastes are hazardous by either identifying the characteristics of hazardous waste or listing particular hazardous wastes. Identifying characteristics of hazardous waste and listing hazardous wastes are distinct and fundamentally different mechanisms for defining hazardous wastes.

The hazardous waste characteristics promulgated by EPA designate broad classes of wastes which are clearly hazardous by virtue of an inherent property. In the May 19, 1980 final rule (45 FR 33084) that instituted EPA's general framework for identifying hazardous waste, the Agency established two basic criteria for identifying hazardous waste characteristics: (1) The characteristic should be capable of being defined in terms of physical, chemical, or other properties which cause the waste to meet the statutory definition of hazardous waste; and (2) the properties defining the characteristic must be measurable by standardized and available testing protocols or reasonably detected by generators through their knowledge of the waste (40 CFR 261.10). In the May 19, 1980 final rule, EPA stated that it adopted the second criterion in recognition that the primary responsibility for determining whether wastes exhibit hazardous characteristics rests with generators, for whom standardization and availability of testing protocols are essential.

The approach EPA uses to establish hazardous waste characteristics is to determine which properties of a waste would result in harm to human health or the environment if a waste is mismanaged. The Agency then establishes test methods and regulatory levels for each characteristic property; solid waste that exceeds the regulatory level for any characteristic property is a hazardous waste.

The regulatory levels for characteristics that have been established provide a high degree of certainty that wastes exceeding those regulatory levels would pose hazards to human health and the environment if improperly managed and therefore require regulation under subtitle C. Wastes that do not exhibit hazardous waste characteristics are not necessarily nonhazardous. The Agency may ***11800** evaluate wastes from either specific or nonspecific sources and decide to list them as hazardous wastes based on criteria defined in 40 CFR 261.11.

To list a waste as hazardous, EPA conducts a detailed industry or process study involving literature reviews, engineering analyses, surveys and questionnaires, site visits, and waste sampling. For listing, the Agency places particular emphasis on hazardous constituents contained in specific wastes generated by the industry or process being studied (See 40 CFR 261.11(a)(3)). However, EPA uses a comparatively flexible approach when deciding to list wastes as hazardous; the approach includes consideration of factors such as type of threat posed, plausible ways that the waste might be mismanaged, migration potential and persistence in the environment, waste quantity, and actions of other regulatory programs. The Agency also promulgated two other rules for identifying solid wastes as hazardous wastes—the mixture and derived-from rules. The mixture rule says that any mixture of a listed hazardous waste and a solid waste is the listed hazardous waste (40 CFR 261.3(a)(2)(iii)-(iv)); the derived-from rule says that any solid waste derived from the treatment, storage, or disposal of a listed hazardous waste is considered the listed hazardous waste (40 CFR 261.3(c)-(d)).

B. Existing Extraction Procedure Toxicity Characteristic

The Extraction Procedure (EP) toxicity characteristic is one of four existing hazardous waste characteristics (along with ignitability, corrosivity, and reactivity) that EPA has identified and promulgated (40 CFR 261.24). The Extraction Procedure Toxicity Characteristic (EPTC) defines the toxicity of a waste by measuring the potential for the toxic constituents in the waste not subject to subtitle C controls to leach out and contaminate ground water at levels of health or environmental concern. To determine if a waste exhibits the EPTC, constituents are extracted in a procedure that simulates the leaching action that occurs in municipal landfills. Because a “hazardous waste” is defined as a waste that may pose a substantial hazard “when mismanaged,” the EP was designed based on the assumption that wastes not subject to subtitle C controls would be co-disposed with municipal waste in an actively decomposing landfill that overlies an aquifer. Thus, the EP identifies wastes that are likely to leach hazardous concentrations of particular toxic constituents to ground water under conditions of improper management.

The Agency recognized that not all wastes are managed according to the mismanagement scenario postulated for the EP. However, it is necessary to make assumptions about management practices for unregulated wastes in order to determine whether

a waste poses a threat to human health and the environment and thus meets the statutory definition of hazardous waste. In addition, the Agency believed that a reasonably conservative mismanagement scenario was warranted in light of the statutory mandate to protect human health and the environment.

Under the existing EPTC, the liquid waste extract obtained from the EP is analyzed to determine whether it possesses any of 14 toxic contaminants that were identified in the National Interim Primary Drinking Water Standards (NIPDWS): eight metals (arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver), four insecticides (endrin, lindane, methoxychlor, and toxaphene), and two herbicides (2,4-D and 2,4,5-TP). NIPDWS levels are used as health-based concentration limits. At the time of promulgation of the EPTC, the NIPDWS were the only available benchmarks for toxicity that were scientifically recognized and that also addressed chronic exposure.

The regulatory levels established for the EPTC were 100 times the NIPDWS. The 100-fold factor is a dilution and attenuation factor (DAF) that estimates the dilution and attenuation of the toxic constituents in a waste as they travel through the subsurface from the point of leachate generation (i.e., the landfill) to the point of human or environmental exposure (i.e., at a drinking-water well). The Agency had originally proposed a DAF of 10 for use in the EP. In light of the fact that there were few empirical data on which to base the DAF and other considerations, the Agency adopted a DAF of 100 in the final rule (45 FR 33084, May 19, 1980). EPA was confident that any waste which exhibited the EPTC using the 100-fold factor would have the potential to present a substantial hazard regardless of the actual site-specific attenuation mechanisms. The Agency also noted that it would adjust the DAF if future studies indicated that another DAF was more appropriate.

C. The Hazardous and Solid Waste Amendments of 1984

On November 8, 1984, the Hazardous and Solid Waste Amendments of 1984 (HSWA) were enacted: these amendments have had far-reaching ramifications for EPA's hazardous waste regulatory program. RCRA sections 3001 (g) and (h), which were among the many provisions added by HSWA, direct EPA to examine and revise the EP Toxicity Characteristic and to identify additional hazardous waste characteristics, including measures of toxicity. Today's rule fulfills these mandates by promulgating an improved leaching procedure that better predicts leaching and an expansion of the Toxicity Characteristics (TC) list to include additional toxicants.

RCRA section 3001(g) specifically directs EPA to examine the EP leach procedure as a predictor of the leaching potential of waste and to make changes necessary to ensure that it accurately predicts the leaching potential of wastes that may pose a threat to human health and the environment when mismanaged. The legislative history for this provision indicates that Congress was specifically concerned about the EP's ability to accurately represent the mobility of toxicants under a wide variety of conditions. The legislative history also suggests that Congress intended for EPA to develop a more aggressive leaching medium for the test and noted that the EP only evaluated the mobility of elemental toxicants and not the mobility of organic toxicants.

Concerned that some wastes posing a threat to human health and the environment were not being brought into the hazardous waste system, Congress adopted RCRA section 3001(h), which directs EPA to promulgate additional characteristics. Of specific concern to Congress was the fact that the existing characteristics did not identify wastes that were hazardous due to toxic levels of organic constituents. Although Congress recognized that the development of such a characteristic would entail technical problems, Congress urged the Agency to make reasonable assumptions for purposes of regulation, rather than await definitive technical answers. In response to the 3001(g) and 3001(h) mandates, EPA issued a proposed rule to revise and expand the TC (51 FR 21648, June 13, 1986) which is discussed below in Section II.D.

D. Previous Federal Register Notices

As indicated above, EPA published a Federal Register notice (June 13, 1986) proposing to expand the existing TC. The proposal specifically identified 52 compounds that could cause a waste to be hazardous via toxicity, including the existing 14 EPTC compounds and 38 additional organic compounds. In ***11801** addition, it described the Toxicity Characteristic

Leaching Procedure (TCLP), a new version of the EP. The TCLP is designed to more accurately address the leaching of organic compounds and to improve upon technical aspects of the testing protocol.

The June 13 proposal used a subsurface fate and transport model to determine compound-specific dilution and attenuation factors (DAFs) as a basis for establishing the regulatory levels. (As mentioned above, the existing TC used a generic DAF of 100 which was not derived from modeling, but rather was an estimated factor indicating the potential for substantial hazard.) The extract from the second-generation extraction procedure, the TCLP, was analyzed for the presence of the 52 constituents at the proposed regulatory levels. In choosing the 38 new toxicants, the Agency identified those Appendix VIII constituents for which appropriate chronic toxicity reference levels were available and for which there existed adequate fate and transport data to establish a compound-specific DAF. (Appendix VIII of 40 CFR part 261 is the list of hazardous constituents that the Agency considers in evaluating the potential hazard posed by wastes; these constituents have been shown to have toxic, carcinogenic, mutagenic, or teratogenic effects.)

Chronic toxicity reference levels are those levels below which chronic exposure for individual toxicants in drinking water is considered safe or considered to pose minimal risk (in the case of carcinogens). The Agency decided to use, when possible, human health criteria and standards that have been proposed or promulgated for substances in particular media, because these have already received Agency and public review and evaluation. EPA proposed the continued use of the Drinking Water Standards (DWS) for the 14 existing EP toxicants and use of Recommended Maximum Contaminant Levels (RMCLs) for eight of the constituents being added to the TC list. For the remaining newly added constituents, EPA proposed to establish chronic toxicity reference levels using Reference Doses (RfDs) for non-carcinogens and Risk-Specific Doses (RSDs) for carcinogens.

The RfD is an estimate of the daily dose of a substance that will result in no adverse effect even after a lifetime of exposure to the substance at that dose. In order to account for toxicant exposure from sources other than water (i.e., air and food), the Agency proposed to apportion the RfD based on proportionate compound-specific exposure routes, as is done in developing drinking water standards.

The RSD is the daily dose of a carcinogen over a lifetime that will result in an incidence of cancer equal to a specific risk level. EPA proposed a weight-of-evidence approach, which involves categorizing carcinogens according to the quality and adequacy of the supporting toxicological studies, to establish the risk levels most appropriate for setting chronic toxicity reference levels for carcinogens.

The Agency proposed using a subsurface fate and transport model to calculate constituent-specific DAFs. This model incorporated compound-specific hydrolysis and soil adsorption data, coupled with parameters describing an underground environment (e.g., ground water flow rate, soil porosity, ground water pH). Values for parameters were selected based on review of geological conditions at existing landfills. Since the model was specifically developed to simulate transport of organics and a model for inorganics could not be completed in time for the June 13 proposal, EPA proposed to retain the existing EP levels for the eight inorganic toxicants.

The proposed rule introduced the TCLP as a second-generation leaching procedure to replace the existing EP. The main impetus behind the development of the TCLP was the need to address the leaching of organic compounds. However, the Agency also recognized that the EP protocol could be improved in certain ways. The TCLP was described in detail as a proposed revision to Appendix II of part 261. Further supporting information on the TCLP was provided through notices of availability of reports on July 9, 1986 (51 FR 24856) and September 19, 1986 (51 FR 33297). After the TC proposal, the Land Disposal Restrictions final rule (51 FR 40572, November 7, 1986) promulgated the TCLP for monitoring compliance with treatment standards for certain spent solvent wastes and dioxin-contaminated wastes. See Section II.E below for further discussion of these notices.

E. Other Notices Relating to the Proposal

Today's rule is based on three fundamental analytic components that were set forth in the original June 13 proposal: a set of chronic toxicity reference levels, a subsurface fate and transport model, and the TCLP. In addition to the June 13, 1986 proposed

rule described in the preceding section of this preamble, EPA has published several other notices in the Federal Register dealing with these three components. These notices are listed in Table II.1 and are summarized in this section. A more detailed discussion is presented on several of these notices in other sections of this preamble, as identified in Table II.1.

Table II.1--Related Federal Register Notices Discussing One or More of the Analytical Components of the Revised TC

Federal Register Notice	Analytic Component			Relevant preamble section of today's rule
	CTRLs [FN1]	Model [FN2]	TCLP [FN3]	
Jan. 14, 1986, 51 FR 1602 (Proposed LDR framework)	...	----------	X	III.E, III.I
Nov. 7, 1986, 51 FR 40572 (Final LDR approach)	.....	----------	----------	III.F
May 18, 1987, 52 FR 18583 (Consideration of separate wastewater TC)	.....	----------	X	III.A, III.H
May 19, 1988, 53 FR 18024 (CTRLs updated, two-tiered DAF alternative proposed)	..	X	X	III.C, III.D
May 24, 1988, 53 FR 18792 (Proposal to replace particle reduction)	.....	----------	----------	III.F
Aug. 1, 1988, 53 FR 28892 (Proposed modifications to ground water model)	.....	----------	X	III.E

1 Chronic Toxicity Reference Levels.
2 Ground water fate and transport model.
3 Toxicity Characteristic Leaching Procedure.

***11802** EPA's first discussion of the development of regulatory levels through the use of chronic toxicity reference levels in combination with a subsurface fate and transport model was in the proposed rule governing land disposal restrictions for solvents and dioxins (51 FR 1602, January 14, 1986). This proposal introduced the concept involved in “back-calculating” regulatory levels (i.e., multiplying chronic toxicity reference levels by dilution/ attenuation factors) and also discussed the Agency's plan for revising the EP. In the final rule on land disposal restrictions for solvents and dioxins (51 FR 40572, November 7, 1986), EPA decided not to use the “back-calculation approach” for the LDR program in favor of an engineering determination based on the best demonstrated available technology (BDAT). However, the Agency did promulgate the revised TCLP as the leaching procedure to be used in the land disposal restrictions program. Specifically, the TCLP is used to demonstrate that certain wastes meet the best demonstrated available technology standards.

On May 18, 1987, EPA published a Supplemental Notice of Proposed Rulemaking (52 FR 18583) in response to numerous comments on the June 1986 proposal concerning the application of the revised TC to wastewaters. The commenters' main concern was that it may be inappropriate to apply the TC mismanagement scenario (co-disposal of wastes with municipal wastes in an unlined landfill) to wastewaters managed in surface impoundments. The commenters believe that such an approach would result in inappropriately low regulatory levels. The Supplemental Notice outlined several alternatives for the application of the TC to wastewaters that would result in a separate set of regulatory levels for these wastes. The alternative scenario for wastewaters assumed that subject wastes are managed in an unlined impoundment instead of being co-disposed in a municipal

landfill. Sections III.A.2, III.E., and III.H provide further discussion of the Supplemental Notice for wastewaters and related issues.

The Agency then published a Notice of Data Availability and Request for Comments on May 19, 1988 (53 FR 18024), as a result of its concern about uncertainties and technical difficulties involved with developing sufficiently representative dilution/attenuation factors (DAFs) for specific constituents. In that notice, the Agency proposed an alternative to the constituent-specific DAFs in the proposed TC. The Agency presented a two-phased approach to implementing DAFs for the TC. In the first phase, the Agency would use generic DAFs for all 38 new TC organic constituents while the development of constituent-specific DAFs proceeded; once the development of the constituent-specific DAFs was completed, these DAFs would be implemented in the second phase. The Agency specifically requested comment on the use of a generic DAF that would initially bring into the hazardous waste regulatory system the most toxic of the wastes subject to the June 1986 proposal. The Agency also updated the chronic toxicity reference levels for a number of constituents based on newly available information. Section III.C discusses the incorporation of the new information into the chronic toxicity reference levels for specific constituents and Section III.D describes in more detail the two-tiered DAF approach.

In response to numerous comments expressing concern as to whether the particle reduction requirement in the TCLP was appropriate, EPA published a proposal (53 FR 18792, May 24, 1988) requesting comment on modifications to the TCLP as promulgated on November 7, 1986. Based on further experimental evaluation of the original testing methodology, the Agency proposed to modify the TCLP to include a cage insert requirement in place of the particle reduction step for certain materials. The specific revisions discussed in the proposal are presented in detail in section III.F of this preamble, and the TCLP protocol is presented in Section VIII of today's final rule. Today's rule does not include a cage requirement, but rather retains the particle reduction step for monolithic or fixated wastes.

In addition to the above-mentioned modifications, on August 1, 1988, the Agency published a Supplemental Notice (53 FR 28892) introducing potential modifications to the subsurface fate and transport model used to calculate constituent-specific DAFs in the proposed TC. In addition, the Agency presented currently available hydrogeological data on municipal waste landfills and proposed to modify the subsurface fate and transport model to more accurately reflect conditions in the universe of municipal waste landfills. Section III.E presents a more detailed description of the subsurface fate and transport model and the modifications made during its development.

F. Pollution Prevention

In section 1003(b) of RCRA, Congress declared waste minimization to be a national policy. Similarly, EPA has made pollution prevention an Agency objective, in both regulatory and nonregulatory programs. (See EPA's policy statement emphasizing the importance of pollution prevention (54 FR 3845, January 26, 1989).) This policy places highest priority on source reduction (i.e., reducing the volume or toxicity of wastes generated) and use of all pollutants for all sectors of society. A reduction in the amount of waste which must be managed (i.e., by source reduction and recycling) provides direct benefits related to protecting human health and the environment from the mismanagement of hazardous wastes. Pollution prevention measures can also reduce waste treatment and disposal costs, decrease costs for raw materials, minimize liability and regulatory burdens for waste generators, and may enhance efficiency, product quality, and public image. The Agency encourages industries affected by this rule to consider achieving compliance through pollution prevention.

The Agency has taken several steps to create pollution prevention incentives. First, EPA is developing institutional structures within each of its offices to ensure that the pollution prevention philosophy is incorporated into every feasible aspect of internal EPA planning and decision-making. Second, EPA is making technical information available to help firms reduce waste generation. EPA is developing the Pollution Prevention Information Clearinghouse (PPIC), a network of people and resources throughout the United States that have direct experience in many industries. PPIC includes the Electronic Information Exchange System (EIES), and a database of bulletins, programs, contacts, and reports related to pollution prevention. Third, the Agency is supporting the development of state programs to assist generators in their waste reduction efforts. Many states are already providing such help. For example, the Alaska Health Project has published technical assistance packets for specific

industries; North Carolina has a pollution prevention bibliography; and Oregon conducts a hazardous waste reduction program. Finally, EPA has initiated specific regulatory requirements addressing waste minimization. Under the Resource Conservation and Recovery Act (RCRA) regulations, hazardous waste generators are required to certify on their hazardous waste manifests and annual permit reports that they have a program in place to reduce the volume or quantity and toxicity of their hazardous wastes as much as economically practical. RCRA regulations also require ***11803** generators to describe on their RCRA biennial reports the efforts they have undertaken during the year to reduce the volume and toxicity of their hazardous waste and to compare these efforts to previous years.

As important as the efforts just described is the Agency's commitment to ensuring that regulations under development encourage pollution prevention, whenever possible. The TC (TC), we believe, provides significant incentives for pollution prevention. Currently, there is little incentive for industries to implement pollution prevention efforts for unregulated solid wastes. In particular, there are few controls on units handling solid wastes that have the potential for releases of hazardous constituents to groundwater. Large quantities of solid wastes containing TC constituents currently are managed in unregulated land-based units, such as surface impoundments and landfills. Many of these units are in states that are either highly dependent on groundwater for public water supply or where groundwater is hydraulically connected to surface water, or both. By subjecting management of TC wastes to subtitle C regulation, EPA is in effect requiring that waste managers rethink their practices for solid wastes that contain hazardous constituents. EPA's experience has been that hazardous waste regulations provide significant incentives for pollution prevention. For example, some listed wastestreams (e.g., bottoms from tetrachloroethylene production) are now completely recycled.

The characteristic mechanism used by EPA to identify hazardous waste is especially effective in encouraging pollution prevention because it sets a concentration level or criteria (e.g. test) that determines the point at which the waste is no longer regulated as characteristically hazardous. Because of the high cost of compliance with RCRA subtitle C requirements, members of the regulated community will have significant new incentives to reduce TC waste generation as a result of today's rule. Industries will consider substitutes for the specific chemicals on the TC list of toxicants of concern. Where substitutes are not used, there will be incentive to reduce the use of hazardous substances or otherwise limit their concentrations in wastes, in order to keep concentrations of hazardous chemicals below regulatory levels.

Pollution prevention options range from simple good housekeeping practices, e.g., keeping solvents and oils separate to facilitate recycling of each, to more extensive process reconfigurations and/or raw material substitutions. Even in cases where pollution prevention can not eliminate the need for treatment or disposal of hazardous wastes, it may reduce the generation of waste. For example, tank capacity is constrained by land area, engineering considerations, and cost. Managers of TC wastewaters that switch from surface impoundments to exempt tanks will almost certainly have to reduce volumes of hazardous waste generated, or segregate hazardous portions of their wastestreams.

In order to enhance the pollution preventions effects of this rule, EPA is incorporating pollution prevention into the communication strategy for the TC regulation. EPA will provide information targeted to small businesses specifically and industry in general through pamphlets, industry publications and conferences, on the mechanisms described above. We have found that many small businesses are turning to pollution prevention as a result of implementation of the small quantity generator regulations (see 51 FR 10146, March 24, 1986). For example, PPIC documents relate how one drycleaning operation reduced its solvent wastes to a level well below national industry standards by regularly checking for and sealing any system leaks, and installing a conditioning system and a carbon adsorption unit to recover additional solvent. With the new setup, the plant can clean four times as many clothes per drum of solvent. The Agency believes that other industries may have the potential to substitute less toxic source materials in their processes. EPA will consider whether any technical assistance could aid industry in these efforts. EPA would also be interested in suggestions from industries affected by the TC in ways that the Agency might facilitate these efforts. Inquiries should be directed to the Pollution Prevention Office, U.S. EPA, Washington, DC 20460.

In summary, the TC will alter the management of wastes that contain toxicant at hazardous levels by ending management in unregulated land-based units. As industries reassess their waste generation and management practices, many are likely to seriously consider pollution prevention options, and EPA will take steps to facilitate such efforts.

G. Summary of Final Rule

Today's rule retains many of the features of the June 1986 proposal: it replaces the EP with the TCLP; it adds 25 new organic constituents to the list of toxic constituents of concern; and it establishes regulatory levels for the organic constituents based on health-based concentration limits and a DAF developed using the subsurface fate and transport model. In response to comments received on the proposed rule and related notices, the final rule incorporates a number of modifications to the list of constituents, the leaching procedure, the chronic toxicity reference levels, the subsurface fate and transport model, and the schedule for compliance with the TC rule.

With respect to the list of constituents, the final rule includes 25 of the 38 constituents proposed in 1986. One group that has been excluded in the final rule are constituents that appreciably hydrolyze. EPA has been able to develop scientifically valid DAFs for nondegrading constituents but is still improving its approach for developing DAFs for constituents that are expected to hydrolyze appreciably during transport. In particular, the Agency does not yet have a procedure to address toxic hydrolysis byproducts that may be formed.

Second, in response to comments, the Agency has also evaluated the applicability of the steady-state condition assumed in the subsurface fate and transport model, and has determined that the assumption is valid for most of the originally proposed constituents. However, several of the original proposed constituents have been deferred from the final rule while the Agency continues to evaluate the extent to which the steady-state solution is appropriate in determining their fate and transport.

As a result, all the constituents newly regulated under today's rule are nonhydrolyzing or minimally hydrolyzing constituents, and all are constituents for which the steady-state solution is appropriate. For all these constituents, EPA has determined, based on the results of its subsurface fate and transport model, that use of a DAF of 100 is appropriate for setting regulatory levels. This DAF is sufficient to capture only those wastes that are clearly hazardous. As a result of the Agency's decision to regulate only nonhydrolyzing or minimally hydrolyzing constituents and those for which the steady-state solution is appropriate, 25 additional constituents are being regulated rather than the originally proposed 38. Regulatory levels for hydrolyzing constituents, as well as those constituents for which there remain questions as to whether the steady-state solution is appropriate, will be discussed in future notices.

The list of constituents regulated in today's rule and their respective regulatory levels are presented in Table II.2. As in the proposed rule, where the ***11804** calculated regulatory level (i.e., the chronic toxicity reference level multiplied by the DAF) is below the analytical quantitation limit, the quantitation limit is the final regulatory level. Note that the list of constituents in Table II.2 contains the 14 constituents currently regulated under the existing EPTC. As specified in today's rule, these constituents will continue to be regulated at their current levels.

Table II.2.--Toxicity Characteristic Constituents and Regulatory Levels

EPA HW No. [FN1]	Constituent [FN2]	CAS No.	Chronic toxicity reference level (mg/L)	Regulatory level (mg/L)
D004	Arsenic	7440-38-2	0.05	5.0
D005	Barium	7440-39-3	1.0	100.0
D018	Benzene	71-43-2	0.005	0.5
D006	Cadmium	7440-43-9	0.01	1.0

D019 ..... Carbon tetrachloride 56-23-5 0.005 0.5
D020 ..... Chlordane 57-74-9 0.0003 0.03
D021 ..... Chlorobenzene 108-90-7 1 100.0
D022 ..... Chloroform 67-66-3 0.06 6.0
D007 ..... Chromium 7440-47-3 0.05 5.0
D023 ..... o-Cresol ..... 95-48-7 2 [FN4] 200.0
D024 ..... m-Cresol ..... 108-39-4 2 [FN4] 200.0
D025 ..... p-Cresol ..... 106-44-5 2 [FN4] 200.0
D026 ..... Cresol ..... ---------- 2 [FN4] 200.0
D016 ..... 2,4-D 94-75-7 0.1 10.0
D027 ..... 1,4-Dichlorobenzene 106-46-7 0.075 7.5
D028 ..... 1,2-Dichloroethane 107-06-2 0.005 0.5
D029 ..... 1,1-Dichloroethylene 75-35-4 0.007 0.7
D030 ..... 2,4-Dinitrotoluene ..... 121-14-2 0.0005 [FN3] 0.13
D012 ..... Endrin 72-20-8 0.0002 0.02
D031 ..... Heptachlor (and its
hydroxide) 76-44-8 0.00008 0.008
D032 ..... Hexachlorobenzene ..... 118-74-1 0.0002 [FN3] 0.13
D033 ..... Hexachloro-1,3-butadiene 87-68-3 0.005 0.5
D034 ..... Hexachloroethane 67-72-1 0.03 3.0
D008 ..... Lead 7439-92-1 0.05 5.0
D013 ..... Lindane 58-89-9 0.004 0.4
D009 ..... Mercury 7439-97-6 0.002 0.2
D014 ..... Methoxychlor 72-43-5 0.1 10.0
D035 ..... Methyl ethyl ketone 78-93-3 2 200.0
D036 ..... Nitrobenzene 98-95-3 0.02 2.0
D037 ..... Pentachlorophenol 87-86-5 1 100.0
D038 ..... Pyridine ..... 110-86-1 0.04 [FN3] 5.0
D010 ..... Selenium 7782-49 2 0.01 1.0
D011 ..... Silver 7440-22-4 0.05 5.0
D039 ..... Tetrachloroethylene 127-18-4 0.007 0.7
D015 ..... Toxaphene 8001-35-2 0.005 0.5
D040 ..... Trichloroethylene 79-01-6 0.005 0.5
D041 ..... 2,4,5-Trichlorophenol 95-95-4 4 400.0
D042 ..... 2,4,6-Trichlorophenol 88-06-2 0.02 2.0
D017 ..... 2,4,5-TP (Silvex) 93-72-1 0.01 1.0
D043 ..... Vinyl chloride 75-01-4 0.002 0.2

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1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The quantitation limit therefore becomes the regulatory level.
4 If o-, m-, and p-cresol concentrations cannot be differentiated, the total cresol (D026) concentration is used. The regulatory level for total cresol is 200 mg/l.

The regulatory levels reflect modifications to some chronic toxicity reference levels since the original proposal. EPA has revised some of the Maximum Contaminant Levels, Risk-Specific Doses, and Reference Doses to reflect new data and better methods. In response to comments received, EPA has decided not to apportion reference doses of noncarcinogens to account for multiple routes of exposure, as was originally proposed (51 FR 21648). See section III.C for further discussion of comments on apportionment and the Agency's reasons for not including apportionment of reference doses in the final rule. Today's rule also promulgates the TCLP to replace the EP. The TCLP represents an improvement over the EP in that it more accurately addresses leaching potential for use in evaluating wastes containing organic constituents, and also corrects several minor technical deficiencies in the original EP. The version of the TCLP promulgated today reflects additional improvements and modifications made to the TCLP since the original proposal. The TCLP promulgated today will also replace the earlier version of the TCLP promulgated as part of the land disposal restrictions program.

Today's rule incorporates a schedule for compliance that classifies the universe of potentially affected TC waste handlers into two groups: (1) All generators of greater than 100 kg/month and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with the subtitle C requirements for management of their TC waste within 1 year; and (2) all generators of 1,000 kg/month or more of hazardous waste are required to comply with all subtitle C requirements for TC wastes within 6 months. The phased schedule for compliance is further discussed in section V.

Wastes identified as hazardous under the Toxicity Characteristic will also become hazardous substances under section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. Today's rule amends the list of reportable quantities (RQs) in 40 CFR part 302 by adding appropriate values for each of the new 25 TC toxicants. All of the newly- ***11805** designated TC toxicants are already listed as CERCLA hazardous substances. The RQs being promulgated are the same as those that already apply to all materials containing these hazardous substances.

Today's rule defers applicability of the TC to one type of waste and exempts another. First, the Agency is deferring the applicability of the TC to petroleum-contaminated media and debris at sites subject to the RCRA Underground Storage Tank (UST) cleanup regulations under part 280. (See section III.I.6.) Second, EPA has decided to exempt from today's rule certain polychlorinated biphenyl (PCB) wastes that are fully regulated under the Toxic Substances and Control Act (TSCA) and would be identified as hazardous because of today's rule (See section III.J.7.).

In portions of the existing codified waste regulation of title 40, chapter I, parts 261 through 265, the EPTC is named. Today's action of promulgating the TC necessitates amendment of these references to the EPTC. This amendment which replaces references to the EPTC with the words “Toxicity Characteristic” applies to the following sections of 40 CFR: 261.4(b)(6)(i) not (A)(B)(C); 261.4(b)(9), 264.301(e)(1), 265.221(d)(1) and 265.273(a).

In §§ 264.301(e)(1) and 265.221(d)(1), in addition to amending reference to the EPTC, the universe of constituents remains the same as the EPTC. To accomplish this, the constituents D004-D017, the EPTC constituents, are specifically named as those constituents which would not render the waste hazardous by the TC.

As discussed below, the Agency will continue to refine the TC in order to provide greater accuracy and comprehensiveness in identifying hazardous waste based on the waste's toxic constituents. However, the Agency believes that today's rule fulfills the statutory mandates under sections 3001(g) and 3001(h).

III. Response to Major Comments and Analysis of Issues

The Agency received many comments on the June 13, 1986 proposed rule and in response to subsequent notices. The Agency has carefully considered all comments in the preparation of this final rule. To facilitate the evaluation and response to comments, the Agency grouped the comments into ten categories. The categories are as follows:

A. General Approach

B. Constituents of Concern

C. Chronic Toxicity Reference Levels

D. Use of Generic DAFs

E. Application of a Subsurface Fate and Transport Model

F. The TCLP

G. Testing and Recordkeeping Requirements

H. Applicability to Wastes Managed in Surface Impoundments

I. Relationship to Other RCRA Regulations

J. Relationship to Other Regulatory Authorities

In this preamble, the Agency provides summaries of and responses to major comments. Readers are invited to refer to background documents (Refs. 1, 2, 3, and 4) for complete summaries and responses to all comments.

A. General Approach

1. Expanded Use of Hazardous Waste Characteristics.

The TC revisions specified in today's rule refine and expand the EPTC. Most commenters stated that increased reliance on hazardous waste characteristics is a reasonable approach to defining hazardous waste. Some commenters stated a preference for the hazardous waste characteristic mechanism over the alternative listing mechanism for identifying hazardous wastes. They noted that the characteristics are designed to measure directly the risks that subtitle C regulations are meant to control. Another advantage mentioned by commenters is that hazardous waste characteristics apply uniformly to all wastes, regardless of source.

A few commenters, however, objected to the expanded use of hazardous waste characteristics. Some of these commenters questioned the Agency's authority to develop the TC. One commenter asserted that RCRA section 3001(h) does not authorize EPA to take the action of adding the proposed organic constituents to the list of TC constituents. Another argued that the legislative history of HSWA indicates that changes in the leaching procedure should address the leaching of toxic metals only. This commenter claimed that the Agency had exceeded its statutory mandate by modifying the TC to include organics.

EPA strongly disagrees with those commenters who argued that the Agency lacks authority to expand the TC. The Agency's approach to identifying hazardous wastes through a self-implementing characteristics procedure was well established in 1984, when Congress passed HSWA. HSWA not only confirmed the validity of EPA's approach to identifying hazardous wastes by characteristics, but also directed the Agency to expand the scope of the TC. RCRA section 3001(h) states "* * * the Administrator shall promulgate regulations under this section identifying additional characteristics of hazardous waste, including measures or indicators of toxicity." Thus, the plain language of the statute authorizes EPA to broaden the TC.

Other commenters acknowledged EPA's authority to expand the TC, but offered policy arguments against the use of this mechanism for identifying hazardous wastes. Most commenters who argued against expanded use of characteristics favored use of the listing mechanism instead of an expanded TC. Some of these commenters noted that listings do not present the same technical problems of precision and accuracy as the characteristics. Others stated that listings are more easily enforced since they are not dependent upon use of a leaching procedure. Finally, some commenters claimed that by expanding the toxicity characteristic instead of listing additional wastes, EPA is unfairly shifting the burden for identifying hazardous wastes onto the shoulders of the regulated community.

The Agency maintains that the expanded use of characteristics, in addition to being consistent with the statutory mandate, offers advantages over listing for identifying broad categories of clearly hazardous waste. Establishing a characteristic allows the Agency to identify through one rule those wastes which are reasonably certain to pose a threat to human health and the environment by virtue of an inherent characteristic without expending vast Federal resources to study, characterize, and list numerous individual wastestreams. Since the Agency sets regulatory levels high enough to assure that wastes exhibiting the characteristic are hazardous, the characteristic approach does not bring wastes into the subtitle C system which do not present a substantial present or potential hazard to human health and the environment. By contrast, a listing, since it applies to all wastes that meet a listing description, may capture some individual wastestreams that do not actually pose a threat to human health and the environment. Generators may petition for delisting if this occurs; however, the delisting process can be burdensome to the petitioner and to EPA.

The Agency believes that the characteristic approach has the following advantages. First, it is less burdensome for the regulated community because the characteristic approach limits over-inclusiveness. ***11806** Second, reducing the potential of including wastes that do not, in fact, present a threat conserves hazardous waste management capacity and Agency administrative and enforcement resources for waste management activities that warrant priority attention. Finally, if necessary, a characteristic can be adapted quickly to possible future changes in science or technology, such as lower quantitation limits.

EPA acknowledges that there are also some advantages in using the listing mechanism for identifying hazardous wastes, particularly with respect to ease of implementation; the Agency thus will retain the listing approach as an alternative mechanism for identifying hazardous wastes. The Agency continues to believe that both the characteristic and listing approaches are valid and useful tools in identifying hazardous wastes that are subject to subtitle C regulation.

Finally, the Agency disagrees with commenters who contend that characteristics impose an unfair burden on the regulated community. Since the establishment of the hazardous waste identification framework in 1980, EPA has recognized that the primary responsibility for determining whether wastes exhibit hazardous waste characteristics rests with generators. In accordance with this, one of two criteria for establishing new characteristics is that they must be measurable by standardized and available testing protocols or reasonably detected by generators through their knowledge of the waste (see 40 CFR 261.10). Further, the regulations do not require testing; a generator may apply knowledge of the waste to determine if it is hazardous (40 CFR 262.11).

2. Mismanagement Scenario

Hazardous waste characteristics are designed to identify solid wastes that pose a threat to human health and the environment when improperly managed (RCRA section 1004(5)). Therefore, in developing the TC, EPA's first task was to determine how wastes might plausibly be mismanaged. The mismanagement scenario that both was reasonably realistic and presented the greatest environmental risks could then be chosen as the reasonable worst-case scenario and used as the basis for the revised characteristic. Specifically, the characteristic would be designed to identify any wastes from which toxic constituents would be likely to pose a threat to human health and the environment when managed in accordance with the selected scenario. In this way, EPA ensured that wastes would be adequately controlled, regardless of the manner in which they are actually managed.

In the June 13, 1986 proposal, EPA considered several alternative mismanagement scenarios for use in the development of the TC rule, including segregated management, co-disposal with municipal solid waste (the mismanagement scenario evaluated in the existing Toxicity Characteristic), co-disposal with industrial waste in a landfill subject to subtitle D requirements, and co-disposal with industrial waste in a landfill subject to subtitle C requirements that suffers some form of containment-system failure. The Agency rejected the subtitle C scenario as unrealistic because it is unlikely that waste generators would dispose of their wastes in the more expensive subtitle C landfills unless required to do so. Thus, it would not be a realistic scenario.

EPA determined that each of the remaining options was a plausible mismanagement scenario since most wastes are or may be managed in these types of land disposal facilities. The Agency rejected the segregated management or “monofill” scenario on the grounds that it did not represent a realistic worst-case practice. Facilities dedicated to the management of only one waste or the wastes of only one generator (i.e., a “monofill”) are likely to pose less of a hazard than general municipal or industrial landfills because the design and operation problems for a monofill are simpler and the operators generally have considerably more information on the properties of the wastes that are managed. Also, industrial monofills generally do not generate organic acids that result in an aggressive leaching medium, as is the case for municipal landfills. Thus, industrial monofills pose less of a potential hazard than municipal solid waste (MSW) landfills. EPA also rejected the general (as opposed to “monofill”) industrial landfill scenario on similar grounds (i.e., the generated leaching medium may not, in some cases, be as aggressive as in a municipal landfill). The Agency therefore retained the municipal landfill scenario as the reasonable worst-case mismanagement scenario for the revised TC.

a. Extent to Which Scenario is Reasonable. Several commenters challenged the municipal landfill scenario, claiming that it is based on an unreasonable assumption about the way in which industrial solid wastes are managed. These commenters claimed

that industrial wastes are rarely disposed in MSW landfills. If landfilled at all, these wastes are more likely to be disposed in industrial landfills. In addition, industrial wastes are frequently managed in ways other than landfill disposal (e.g., incineration, recycling, treatment on the land, or treatment in surface impoundments). Thus, commenters argued, it is inappropriate to base the TC on the municipal landfill scenario.

EPA fully recognizes that not all industrial wastes are managed in MSW landfills. Nevertheless, the Agency continues to believe that the MSW landfill scenario is reasonable because such landfills have traditionally accepted unregulated industrial wastes. It is for this reason that the MSW landfill scenario was originally established as the basis for the EPTC (see 45 FR 33112, May 19, 1980). Although fewer types of industrial wastes are being disposed in municipal landfills now as compared to a few years ago, EPA's information confirms the continued appropriateness of this scenario. The “State Subtitle D Regulations on Solid Waste Landfills” (Ref. 5), and the “National Survey of Solid Waste (Municipal) Landfill Facilities” (Ref. 6) indicate that most states impose few restrictions, if any, on the types of nonhazardous wastes accepted at these facilities; moreover, a substantial quantity of the wastes received (typically five to eight percent) are industrial wastes. Thus, EPA continues to believe that the municipal solid waste landfill scenario represents the most appropriate reasonable worst-case mismanagement scenario.

Many commenters suggested that EPA grant exceptions or variances for wastes that are not co-disposed with MSW. In this way, the TC would apply only to those wastes that are actually managed in accordance with the underlying mismanagement scenario. The commenters noted that EPA could separately develop alternative characteristics for wastes managed in other ways to ensure adequate protection of human health and the environment.

After careful consideration, EPA has decided not to adopt this suggestion for various reasons. Applying the TC only to wastes actually managed as suggested in the mismanagement scenario would involve the creation of a management-based approach to identifying hazardous wastes. EPA's current approach to establishing characteristics which identify certain wastes as hazardous is not contingent upon the way individual wastes are actually managed. Rather, consistent with the RCRA Section 1004(5) definition of hazardous waste, EPA is ***11807** identifying waste “* * * that may pose a substantial present or potential hazard to human health and the environment when improperly * * * managed” (emphasis added).

EPA has considered the possibility of developing management-based characteristics, i.e., different characteristics for categories of waste depending on how they are typically managed. However, the Agency believes that such an approach would present a number of difficulties. For instance, a management-based approach to hazardous waste identification could substantially complicate effective implementation of the RCRA regulations. In particular, it is not always possible to determine—at the point of generation, during transport, or even as a waste enters a treatment, storage, or disposal facility—how a solid waste will ultimately be managed. EPA believes that the most effective and appropriate approach is to identify hazardous waste characteristics, not according to the ways in which individual wastes are managed, but by identifying properties of wastes that would pose a threat to human health and the environment if improperly managed. The Agency maintains that co-disposal with MSW is a mismanagement scenario that is reasonably realistic for most industrial solid wastes.

Another group of commenters suggested that EPA exempt broad classes of wastes that, because of their volume or physical properties, cannot reasonably be placed in a municipal landfill. Commenters specifically mentioned wastewaters, mining wastes, and municipal waste combustion ash. They noted that separate characteristics could be developed for each class of wastes that is excluded from the TC, based on the most appropriate mismanagement scenario for each individual category of waste.

After careful consideration of these comments, the Agency agreed that one category of wastes, wastewaters, might warrant special consideration based on the fact that the mismanagement scenario may not be reasonably applicable. Thus, EPA published a Supplemental Notice of Proposed Rulemaking on May 18, 1987 (52 FR 18583), which asked for comment on the development of separate regulatory levels for wastewaters. EPA received considerable information in response to this notice, and reviewed additional information on management of wastewaters in surface impoundments. After analysis of the waste management techniques, attenuative mechanisms, and hydrogeologic processes that govern constituent transport from surface impoundments, the Agency concluded that the DAFs for nondegrading constituents managed in surface impoundments were

similar to those for the same constituents managed in landfills. Thus, for today's rule, the Agency determined that there is no technical basis for setting separate regulatory levels for wastewaters. This issue is discussed in more detail in subsection C, and further in sections III.E (Application of a Subsurface Fate and Transport Model) and III.H (Applicability to Wastes Managed in Surface Impoundments).

The Agency also does not agree that the mismanagement scenario is unreasonable for either non-exempt mineral processing wastes or municipal combustion ash. Although large volume wastes from the extraction, beneficiation and processing of ores and minerals are currently exempt from subtitle C regulation and will not be affected by the TC rule, small volume mineral processing wastes which may be subject to subtitle C regulation (see 54 FR 36592) can plausibly be disposed in municipal landfills. Municipal waste combustion ash can also be disposed in municipal landfills; in fact, the Agency estimates that only about 30 percent of municipal waste combustion facilities utilize ash monofills, and rely principally on municipal landfills for ash disposal. Issues related to the regulation of municipal waste combustion ash are discussed further in section III.I.5.

b. Worst-Case Scenario Selection. A few commenters agreed with EPA that the municipal landfill scenario is reasonable, but they claimed that the scenario does not represent a reasonable worst case. Most of these commenters asserted that co-disposal in a subtitle D industrial landfill poses more of a threat to human health and the environment than disposal in an MSW landfill. They pointed out, for example, that the regulatory standards for subtitle D industrial waste landfills are generally no more stringent than those for municipal landfills. The commenters further claimed that the leaching media in industrial landfills are frequently more aggressive than those in municipal landfills, especially when acids, bases, and solvents are present. Finally, the commenters noted that wastes placed in industrial landfills are not diluted with domestic wastes, as they are in a municipal landfill. The commenters concluded that because the TC proposal was based on a scenario that was less than worst-case, it would not adequately protect human health and the environment.

The Agency believes that the leaching media in a subtitle D municipal landfill is typically more aggressive than leaching media generated in industrial landfills due to the formation of acids during decomposition of putrescible wastes. “State Subtitle D Regulations on Solid Waste Landfills” (Ref. 5) shows that putrescible wastes are accepted at most subtitle D municipal landfills, while “Summary of Data on Industrial Non-Hazardous Waste Disposal Practices” (Ref. 7) shows solvents, acids, and bases (which can also increase the aggressiveness of leachate) are generally not disposed of in subtitle D industrial landfills. The potential for the formation of acids from decomposition of putrescibles in a subtitle D municipal landfill is greater than the potential of acids, bases, or solvents being present in a subtitle D industrial landfill, therefore supporting the municipal landfill scenario as a reasonable worst-case.

EPA acknowledges that, in certain circumstances, industrial wastes may pose more of a threat when placed in a subtitle D industrial landfill than when placed in a subtitle D municipal landfill. However, EPA believes that this situation will only occur in certain circumstances and thus represents a worst case rather than a reasonable worst case. Should the occurrence of this situation increase in frequency, the Agency will reconsider its approach for regulating these wastes in the future.

c. Extent to Which the Mismanagement Scenario for Wastes Managed in Surface Impoundments is Appropriate. In the May 18, 1987 notice, the Agency stated that it is considering developing a separate mismanagement scenario applicable to wastes that are managed in unlined surface impoundments. Developing a surface impoundment scenario, in addition to the landfill scenario, would mean that the TC would have two different sets of regulatory levels. Waste generators would first have to determine which scenario is appropriate and then would be responsible for evaluating whether their waste exceeded the applicable regulatory levels.

In the notice, the Agency requested comments on the appropriate criteria to be used in determining whether the characteristic should apply to a particular waste. The Notice suggested three possible approaches:

1. The “management-based” approach, which would apply only to those wastes actually managed in impoundments;

***11808** 2. The “physical property-based” approach, which would apply to those wastes having a certain physical property indicating that they are likely to be managed in surface impoundments (e.g., percent solids less than 5 percent); and

3. The “definition-based” approach, which would apply to those discharged wastewaters that are subject to regulation under either section 402 or section 307(b) of the Clean Water Act.

Commenters from various industries generally supported a separate mismanagement scenario because they do not believe that the landfill mismanagement scenario is appropriate for aqueous wastes managed in surface impoundments. Most of these commenters requested that EPA adopt either the management-based approach or the definition-based approach.

Other commenters, however, opposed a separate mismanagement scenario for wastes managed in surface impoundments. These commenters contended that the surface impoundment mismanagement scenario would not be a reasonable worst-case scenario, particularly if the scenario modeled biodegradation, because significant biodegradation does not occur in all impoundments. In addition, the commenters stated that if the development of a surface impoundment mismanagement scenario results in two sets of regulatory levels, requirements for storage, handling, and transportation of a waste would be based on the management practice that the generator assumes or expects will actually occur. These commenters were opposed to this result and noted that wastes may not always be ultimately disposed in the manner originally intended by the generator.

After receiving these comments, the Agency decided to revisit the issue of whether or not a separate mismanagement scenario is necessary for surface impoundments due to inappropriately low regulatory levels. As described in section III.E.2, the Agency believes that evaluation of the physical phenomena that affect dilution/attenuation factors (DAFs) indicates that the DAFs generated for landfills are similar, if not greater than, DAFs for surface impoundments (i.e., the regulatory levels for surface impoundments would be equal to or more stringent than those for landfills). To confirm this conclusion, EPA then investigated whether results from modeling a surface impoundment scenario would in fact be significantly different from modeling a landfill scenario. As described later in this preamble, for nondegrading constituents, EPA calculated the 85th and 90th percentile DAFs for landfills (which ranged from 134 to 47) and the 85th and 90th percentile DAFs for surface impoundments (which ranged from 111 to 51). The surface impoundment results were obtained by using the updated model (EPACML) for the landfill scenario with leachate generation and environmental parameters (e.g., well distances, facility areas) derived from surface impoundment data.

As a result of this analysis, EPA is confident that the results from modeling of the landfill mismanagement scenario are also appropriate for wastes managed in surface impoundments (i.e., the DAFs are of the same order of magnitude). The Agency therefore does not plan to develop a separate surface impoundment mismanagement scenario at this time. Since the modeling results indicate that the dilution/attenuation factors for non- and minimally degrading constituents are all on the order of 100, the Agency has concluded that a single value of 100 is an appropriate choice for use in establishing the regulatory levels for all of the constituents addressed in today's rule. (See section III.E. of this preamble for an additional explanation of EPA's modeling efforts and choice of DAFs.)

3. Targeted Risks

Several commenters argued that, even if the co-disposal mismanagement scenario was appropriate, EPA improperly focused on a few selected risks from this scenario. Specifically, they claimed that the Agency restricted its consideration to human health risks resulting from ground water contamination. A number of commenters stated that the Agency should consider additional routes of human exposure, such as air volatilization, surface runoff, and direct contact. One commenter questioned why EPA was not employing the same multimedia risk and exposure models that were originally proposed for use in the land disposal restrictions program (see 51 FR 1602, January 14, 1986).

A few commenters further suggested that EPA take environmental risks (e.g., aquatic toxicity) into account, rather than concentrating exclusively on human health risks. They noted that RCRA section 3001(g), on which the TC rule is based, directs EPA to make changes in the EPTC so that it “accurately predicts the leaching potential of wastes which pose a threat to human health and the environment when mismanaged” (emphasis added).

EPA acknowledges that the characteristic being promulgated today focuses on human health risks from ground water contamination. However, the Agency does not believe that a single characteristic is capable of identifying all wastes that present a threat to human health and the environment. The present TC revisions are only the first step in a long-term strategy to refine and expand the hazardous waste identification program. Future characteristics may address hazards other than human health risks resulting from ground water contamination. EPA continues to believe, however, that ground water contamination, as a route of human exposure, is a priority concern.

4. Accuracy

Several commenters asserted that the proposed TC revisions failed to fulfill the statutory mandate to improve the “accuracy” of the characteristic as a predictor of the leaching potential of solid wastes. Specifically, these commenters argued that, even if EPA selected the proper mismanagement scenario, the Agency failed to model the targeted risks in a reasonable or appropriate manner. (Many of the commenters addressing this issue also focused on the accuracy of individual elements of the characteristic, such as the TCLP, the subsurface fate and transport model, or the chronic toxicity reference levels. These specific concerns are considered in sections III.B through III.F of today's preamble.)

A number of the commenters on the issue of accuracy concentrated on the interrelationship between the various elements of the TC. These commenters pointed out that EPA had employed conservative assumptions at each step in the development of the revised characteristic. They argued that even if these assumptions were reasonable in isolation, they would not be reasonable in combination. According to these commenters, the effect of compounding multiple conservative assumptions would be a characteristic that is unreasonably conservative, thereby resulting in costly overregulation.

Other commenters maintained the opposite position and stated that EPA had employed non-conservative assumptions for many elements of the characteristic. These commenters believe that these assumptions result in a characteristic that is not conservative enough and, thus, not sufficiently protective of human health and the environment.

The Agency disagrees with commenters' assertions that the elements of the TC are either too conservative or not conservative enough. The TC, in particular the fate ***11809** and transport model used to establish the dilution/attenuation factors (DAFs), requires the selection of numerical values for many parameters. Rather than selecting values for each parameter based upon isolated judgments as to what constitutes a “reasonable worst case” value, the Agency used the full range and distribution of values for all parameters for which such data was available. By implementing these data sets through a monte carlo simulation, the model output (i.e., the frequency distribution of DAFs) is as realistic as possible and spans the range of all possible outcomes rather than representing only the “best case,” “reasonable worst-case,” etc. That is, the model output represents all cases, arrayed according to their frequency of occurrence, and does not reflect any qualitative judgement as to what constitutes a “reasonable worst case” or any other “case.” Accordingly, the determination as to which DAF value represents any particular “case” is solely dependent upon the selection of the cumulative frequency level. The Agency's selection of the cumulative frequency level is discussed in section III.E.4.d.

EPA does agree with commenters who recommended that the originally proposed subsurface fate and transport model could be revised to more realistically represent land disposal settings. Accordingly, EPA has modified the original model (EPASMOD) and has collected and incorporated new data into the model. These modifications and data are described in greater detail below (section III.E). The reader is referred to the Response-to-Comments Background Document for the Subsurface Fate and Transport Module (Ref. 1), which presents in detail each of the technical issues raised by public comments on the model and the Agency's responses to these issues. EPA believes that with these changes, the final TC rule represents a reasonable approach to the identification of hazardous wastes.

5. Solvent Override

In the June 13, 1986 TC proposal, the Agency discussed the possibility of incorporating a solvent “override” criterion into the TC because the presence of large amounts of solvents in a waste may result in leachate from the waste mobilizing hazardous constituents from co-disposed nonhazardous waste. The Agency considered setting regulatory levels for solvents based on the total concentration of solvent found in the TCLP extract.

Many commenters claimed that mobilization of toxicants in municipal landfills by industrial solvents is improbable. Commenters argued that there are no data to support the hypothesis that industrial solvents would alter the solubility of hazardous constituents in municipal waste. These commenters asserted that, at levels below their solubility in water, organic solvents exert very little influence on the solubility of other organics. Given the low concentrations of solvent wastes permitted for land disposal, the commenters contended that there is little probability that mobilization will occur. Commenters emphasized that, in general, subtitle D landfills do not accept organic solvents or liquids. Most industrial solvents already are listed hazardous wastes under 40 CFR 261.32 and 261.33 and will be managed in subtitle C hazardous waste facilities. Also, commenters contended that the contribution that industrial solvents will have on the solvent power of a solid-waste-landfill leachate is small compared to the contribution from solvents in household and small quantity generator waste.

Other commenters, however, expressed their support for EPA's proposal to characterize a waste by its ability to leach hazardous constituents from co-disposed wastes. They urged that a method be devised to monitor the influence that solvents have on the solubility of other waste constituents. One commenter suggested that the TCLP leachate could be tested for its ability to dissolve hazardous waste.

After careful consideration of the comments on this issue, EPA has decided not to include a solvent override in today's revision of the TC. EPA is not convinced by commenters who stated conclusively that mobilization of toxicants in municipal landfills by industrial solvents is improbable. EPA also is not convinced that the solvent contribution of industrial wastes at municipal landfills is small compared to that of household waste and small quantity generator waste. Moreover, the comparison to household waste and small quantity generator waste is not relevant to the issue of whether industrial wastes should be regulated based on solvent properties. However, the Agency does agree that there is insufficient data concerning the degree to which industrial solvents would mobilize other hazardous constituents and the amount of solvent wastes that are actually land disposed. Given this lack of data, a solvent override has not been included in today's rule. However, an override may be considered in future rulemakings if information becomes available that indicates a characteristic based on solvent properties is warranted.

One commenter claimed that RCRA does not authorize the imposition of restrictions based on toxicity simply because a substance can mobilize other constituents. The commenter asserted that the authority may reside elsewhere in RCRA, but in that case, a separate rulemaking, not involving the TC, should take place.

EPA does not agree; RCRA clearly authorizes EPA to regulate a waste as hazardous on the basis of its ability to mobilize other constituents. Further, regulating a waste as hazardous based on its ability to mobilize other constituents could be appropriately achieved through the characteristic mechanism. A solid waste is defined as hazardous if its “physical” or “chemical” characteristics “may pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed” (RCRA section 1004(5)). The capacity to mobilize toxic constituents falls within the definition of a physical or chemical characteristic of a waste which may pose a substantial environmental or health hazard. Thus, EPA may incorporate this approach into its characteristic waste identification scheme in the future.

Related to the issue of solubilization, another commenter asserted that if a chemical's capacity for mobilization is considered, treatment implemented to prevent mobilization (e.g., stabilization, containment, and chemical conversion) should be given equal consideration.

The TCLP does consider immobilization in the context of the co-disposal mismanagement scenario. The TCLP was developed to simulate leaching in a municipal landfill, addressing the degree of mobility (or, conversely, immobility) of both organic and

inorganic compounds. Wastes that have been treated to prevent mobilization are less likely to leach toxic constituents. Such wastes may cease to exhibit the TC and would therefore no longer be considered hazardous wastes. Thus, the TCLP already accounts for immobilization of toxic constituents in a waste. However, if wastes that have been treated to prevent mobilization fail the TC, EPA believes that the wastes in question should be managed as hazardous wastes.

B. Constituents of Concern

As noted above, the proposed TC rule identified 52 constituents that, if present at specified levels in a waste extract, ***11810** would render the waste "hazardous" under RCRA subtitle C. Fourteen of the constituents were already encompassed by the existing EPTC. The selection of the remaining 38 constituents was based on the availability of adequate and verified data necessary for establishing (1) a chronic toxicity reference level and (2) a constituent-specific DAF. Thus, the Agency focused on those constituents for which there existed a promulgated or proposed Maximum Contaminant Level (MCL), a Reference Dose (RfD), or a Risk-Specific Dose (RSD), and for which there were sufficient data on environmental fate and transport processes to support modeling of a constituent-specific DAF. The June 13, 1986 proposal also announced EPA's intention to expand the list of TC constituents as additional data became available.

1. Final List of Constituents

The Agency is finalizing the regulatory levels for 25 of the proposed organic constituents (see Table B-1) that do not readily hydrolyze and for which a steady-state subsurface fate and transport model is appropriate. EPA may promulgate or repropose (as warranted) regulatory levels for the other organic constituents at a future date.

Table B-1.--List of Organic Constituents Included in the Expanded TC Rule

Benzene	Hexachloro-1,3-butadiene
Carbon tetrachloride	Hexachlorobenzene
Chlordane	Hexachloroethane
Chlorobenzene	Methyl ethyl ketone
Chloroform	Nitrobenzene
m-Cresol	Pentachlorophenol
o-Cresol	Pyridine
p-Cresol	Tetrachloroethylene
1,4-Dichlorobenzene	Trichloroethylene
1,2-Dichloroethane	2,4,5-Trichlorophenol
1,1-Dichloroethylene	2,4,6-Trichlorophenol
2,4-Dinitrotoluene	Vinyl chloride
Heptachlor (and its hydroxide)	----------

Constituents with regulatory levels established under the EPTC will continue to be regulated at previously established levels, but will require application of the new TCLP instead of the EP.

2. Toxicants Versus Indicator Parameters

A few commenters recommended that EPA abandon its current focus on individual toxicants and rely instead on such indicator parameters as total organic carbon or total organic halogens. The commenters argued that such an approach would broaden the effective scope of the rule and reduce the burdens associated with making hazardous waste determinations.

The Agency does not believe it would be appropriate to use indicators as part of the TC. Indicators generally are used as screening levels or to set priorities for further investigations. They do not achieve sufficient specificity for the regulatory purposes of the TC. For instance, the two indicators suggested by the commenters do not in any way reflect differences in toxicities among organic constituents. Consequently, use of these indicators could lead to both nonhazardous wastes registering as hazardous and wastes that are clearly hazardous registering as nonhazardous.

3. Method for Selecting Constituents

Several commenters questioned the manner in which EPA selected toxicants for inclusion in the TC proposal. Some of these commenters charged that the Agency's choice of toxicants was entirely arbitrary. Others claimed that EPA had based its selections solely on the availability of toxicologic and hydrogeologic data, without considering the magnitude of the hazards presented by the constituents.

The commenters, in general, encouraged EPA to develop specific procedures and criteria for deciding which constituents should be included in the TC. A few commenters offered particular suggestions for the types of factors that might be considered in evaluating toxicants. The recommended factors included (1) the mobility and persistence of the constituents, (2) the frequency with which particular constituents have been found in industrial wastes or leachates from such wastes, and (3) the extent to which various constituents have been detected in ground water supplies in concentrations capable of posing a threat to human health and the environment.

EPA believes that its method for selecting TC constituents is both rational and consistent with the statutory mandate. While selection of constituents in today's rule is in part based on available toxicological data, it should be noted that both the fate and transport of constituents and the magnitude of hazards posed were also given consideration. The toxicants for which regulatory levels are being promulgated today are persistent and can represent a substantial threat to human health and the environment. Because of the lack of reliable data on the frequency with which certain toxic pollutants are found in leachates or ground water, an approach relying on such information would not provide an accurate and valid basis for selecting constituents. Further, where data do exist concerning the frequency at which certain constituents are found in the environment, accompanying information about risk posed in the environment is often absent.

Although the Agency proposed levels only for toxicants for which it has adequate and verified data, generally these data are available because these toxicants do represent a substantial threat to human health and the environment. The Agency will consider adding constituents as additional toxicological data and other supporting data become available; in making such decisions, the Agency will consider the factors identified by the commenters. Until such data are available, there is no technical basis to determine at what level a waste is hazardous under the TC.

A number of commenters argued that EPA was needlessly “cluttering” the characteristic with low-priority constituents that are either not being produced in the United States or are primarily found in wastes that are already subject to regulation.

The Agency does not agree that a substance no longer manufactured in the U.S. will not pose a threat from waste disposal. Some such substances may be contained in products imported into the U.S. Also, wastes generated during cleanup at Superfund sites or RCRA corrective action sites may exhibit the TC due to the presence of these constituents in wastes disposed at some time in the past. Further, the constituents could be manufactured again in the future.

Several of the toxicants listed in today's rule also appear among the list of discarded commercial chemical products, off-specification products, and container and spill residues, as listed in 40 CFR 261.33. A group of commenters argued that it would be redundant to establish regulatory levels for these toxicants because they are already regulated as listed hazardous wastes. Similarly, several commenters argued that some other listed wastes are regulated as hazardous wastes primarily because they contain constituents that will be regulated under the new TC.

EPA does not agree that setting levels for the selected toxicants would be redundant. While it is true that many of the newly designated TC constituents are constituents in wastes that are specifically listed as RCRA hazardous wastes, the current listings do not cover all of the wastestreams that may contain the TC constituents. For example, the commercial chemical product listings in 40 CFR 261.33 primarily encompass ***11811** unused products and off-specification variants of products that are generically identified using the name of a single toxic constituent; however, the listings would not cover other wastestreams containing the same constituent. The listings in 40 CFR 261.32 specify only a limited number of wastestreams that contain TC constituents. As another example, the spent solvent listings in 40 CFR 261.31 cover only those solvents that are used for their

"solvent" properties (i.e., to solubilize or mobilize other constituents). The current listings do not encompass process wastes where solvent constituents are used as reactants or ingredients in the formulation of commercial chemical products. The Agency has previously stated that it is expanding the TC to bring these wastestreams into the hazardous waste management system (see 50 FR 53317, December 31, 1985). Thus, the Agency is appropriately promulgating TC regulatory levels for some constituents that have been used as the basis for listings.

One commenter argued that EPA's approach in selecting TC constituents was too restrictive, ensuring that many toxic constituents may never be regulated. The commenter emphasized that reliance on MCLs, RfDs, and RSDs does not provide a comprehensive list of constituents for which reliable toxicological data exist. In addition, the commenter noted that reliance on human health data does not necessarily address hazards to the environment.

EPA disagrees with the commenter's first point. Reliance on MCLs, RfDs, and RSDs uses the most sound toxicologic data base available to the Agency. At present, there are more than 365 constituents with verified toxicity levels available for EPA use. In regard to the second point, the Agency recognizes that factors other than human health effects are also important to the overall protection of the environment, but points out that the purpose of this characteristic is to identify wastes that pose hazards to human health via a ground water contamination route. In regard to the other factors, the Agency is supporting a research effort focusing on the determination of action levels for ecological effects and evaluating appropriate exposure assessment tools. When sufficient information concerning these ecological risks is available, the Agency will compare the ecological-risk-based levels to the TC regulatory levels to determine whether further revisions to these levels, based on ecological risk, are necessary.

4. Specific Organic Constituents

Many commenters expressed concern over several of the specific organic constituents that EPA proposed to include in the TC. The comments focusing on specific toxicants are discussed below.

a. Vinyl Chloride. A few commenters objected to the inclusion of vinyl chloride in the TC. They suggested that the constituent is already adequately regulated under the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, and the Food, Drug, and Cosmetic Act (for food contact applications).

The commenters are correct in stating that vinyl chloride and polyvinyl chloride are already regulated under other environmental health and safety statutes. However, none of these other regulatory authorities address the specific problem of ensuring against releases of vinyl chloride caused by the improper management of solid wastes containing this constituent. Most importantly, none of the authorities directly protect ground water supplies from vinyl chloride contamination. Because vinyl chloride is known to be toxic to humans and has been detected in ground water supplies, EPA believes that regulating the constituent under RCRA will add significantly to the protection of human health and the environment. An analysis completed as part of the Regulatory Impact Analysis (Ref. 8) of this regulation indicates that large quantities of wastes currently not regulated as hazardous contain concentrations of vinyl chloride above the regulatory levels. Therefore, the Agency believes that RCRA regulation under the TC is an important expansion of the overall regulatory coverage of this constituent which poses a threat to human health and the environment.

b. Bis(2-chloroethyl) Ether. One commenter questioned whether incorporating bis(2-chloroethyl) ether into the TC is appropriate, since only an extremely limited quantity of the constituent could potentially be released into the environment. The commenter noted that the constituent is used almost exclusively as an intermediate in the production of ionene polymers. Moreover, it is handled primarily by a single facility, which either recycles the material or destroys it by biodegradation prior to discharge under a National Pollutant Discharge Elimination System (NPDES) permit.

The Agency is not promulgating standards for bis(2-chloroethyl) ether today. As discussed in section III.E.2.a.7, bis(2-chloroethyl ether) is expected to hydrolyze significantly during transport. EPA does not have sufficient data to address the formation and toxicity of hydrolysis products. Thus, the Agency expects to address appropriate regulatory action for this constituent, along with the other hydrolyzing constituents, in a future Federal Register notice.

c. Toxaphene. One commenter questioned the need to include toxaphene in the list of TC analytes. The commenter argued that toxaphene has not been produced in the United States for several years and that generators should not be required to test their wastes for “phantom” constituents that are unlikely to be present.

EPA recognizes that toxaphene is no longer produced domestically. However, because previously generated toxaphene wastes are still being managed in treatment, storage, and disposal facilities there is still a potential threat to human health and the environment from improper management of wastes containing this constituent. Thus, wastes containing toxaphene above the regulatory level should be managed as hazardous wastes.

Moreover, toxaphene has been regulated as an EP constituent since 1980 and today's rule retains the existing regulatory level. Thus, today's rule does not alter any regulatory requirements with respect to toxaphene. The Agency does not believe that maintaining toxaphene as a TC constituent is unnecessarily burdensome to the regulated community. The final TC rule does not require solid waste generators to test their wastes. Instead, generators may continue to determine whether their wastes exhibit the hazardous waste characteristics by relying on their knowledge of the materials and processes that they employ (see 40 CFR 262.11(c)(2)). Accordingly, generators who have reason to believe that their wastes contain no toxaphene are not specifically required to test for that constituent.

d. Phenol. One commenter urged EPA to delete phenol from the list of TC constituents of concern because phenol biodegrades under both aerobic and anaerobic conditions.

The Agency is not including phenol in today's rule because the steady-state assumption used in the model to calculate DAFs in this final rule may not be appropriate for phenol. The Agency will promulgate a TC regulatory level for phenol at a later date.

The issue of biodegradation is discussed in section III.E.2.a.9 as it pertains to phenol and other constituents.

***11812** e. Pentachlorophenol. The Agency is considering revisions to the regulatory level for pentachlorophenol (PCP) because new health data indicate that PCP is more toxic than originally assumed. Two studies of different grades of PCP material were conducted by the National Toxicology Program, and the new data indicate that PCP is carcinogenic in male and female mice under the conditions of the bioassay. These studies were used to support the proposal to list additional wastes from the wood preserving industry (53 FR 53282, December 30, 1988).

The Agency is today finalizing the higher regulatory level for PCP although the Agency expects that the regulatory level will decrease in the future. EPA has determined that it is more prudent to effect control at a higher level during the period necessary to take comment on the appropriateness of modifying the TC level.

5. Specific Inorganic Constituents

As noted earlier, EPA did not propose to add any new inorganic TC constituents in the June 13, 1986 proposal. Nevertheless, the Agency received a large number of comments addressing the eight metallic species that were already covered by the EPTC. The Agency also received many comments on the possibility of proposing TC regulatory levels for nickel and thallium (mentioned in the June 13 proposal). The principal comments are discussed below.

a. Silver. A number of commenters urged EPA to delete silver from the list of TC constituents of concern. They pointed out that a variety of studies have demonstrated that the chief effect of silver on humans is argyria, a blue-gray discoloration of the skin and internal organs. The commenters also stated that argyria is generally considered a cosmetic effect, rather than a health effect, because it does not impair the functioning of the body. While the commenters acknowledged that free silver ions may be toxic to aquatic life, they claimed that such ions are rarely discharged into the environment. Moreover, they argued that even if such ions were discharged, they would quickly be converted into insoluble salts, such as chlorides, sulfides, and phosphates. Finally, the commenters asserted that deleting silver from the TC list would be consistent with current EPA policy. They pointed

out that the Agency has not proposed a Recommended Maximum Contaminant Level (RMCL) for silver in drinking water, on the grounds that silver does not cause adverse health effects.

EPA acknowledges that an RMCL (now referred to as a Maximum Contaminant Level Goal, or MCLG) has not been proposed for silver because the only known adverse effect from exposure to silver is argyria. However, the Agency has specifically requested comments on whether it is appropriate to consider argyria a cosmetic effect as opposed to a health effect (see 50 FR 40979, November 13, l985). EPA believes it would be inappropriate to remove silver from the list of TC constituents until this issue is resolved. If EPA determines, within the scope of the Safe Drinking Water Act rulemaking, that silver does not pose a threat to human health and the environment, the Agency will consider proposing the deletion of silver from the list of TC constituents.

b. Chromium. Several commenters objected to the inclusion of total chromium as a TC constituent of concern. They argued that only hexavalent chromium (Cr(VI)) has been demonstrated to pose a threat to human health and the environment. Although they acknowledged that trivalent chromium (Cr(III)) can be oxidized to hexavalent chromium under certain conditions, they contend that such conversion is unlikely to occur in ground water environments. The commenters, in fact, claimed that iron-bearing soils are likely to effect the opposite transformation, from Cr(VI) to Cr(III). Finally, they stated that even if the oxidation reaction did occur, the resulting Cr(VI) concentrations would be so low as not to present a significant danger to human health and the environment.

EPA continues to believe that total chromium concentrations should be considered in determining whether solid wastes qualify as characteristic hazardous wastes. The Agency has long been aware of the fact that trivalent chromium is less toxic than hexavalent chromium. Nevertheless, the Agency also has been concerned that trivalent chromium could be converted to the hexavalent form under certain plausible mismanagement conditions. It is for this reason as well as the fact that the NIPDWS was developed for total chromium that the regulatory level for chromium in the EPTC was originally established on the basis of total chromium concentrations (see 45 FR 33084, May 19, 1980).

The Agency later proposed to amend the EPTC so that it would apply to hexavalent chromium rather than total chromium (45 FR 72029, October 30, 1980; see also 48 FR 22170, May 17, 1983). This proposal was based on the fact that trivalent chromium has significantly lower migratory potential than hexavalent chromium and is less mobile if it does migrate from a waste matrix. At that time, the Agency also believed that there was little likelihood that Cr(III) could oxidize to Cr(VI) under most plausible types of improper waste management.

More recent evidence, however, suggests that the conversion from trivalent to hexavalent chromium may occur in a number of environmental situations (see 51 FR 26420, July 23, 1986, fn. 6). For example, Cr(III) has been found to oxidize readily to Cr(VI) under conditions found in many field soils. This reaction is catalyzed by manganese dioxide, which is commonly present in both soils and sediments. Moreover, it has been shown that water treatment involving chlorination will effectively transform Cr(III) to Cr(VI). The normal presence of residual oxidizing capacity in treated water is capable of maintaining dissolved chromium in the higher valence state (50 FR 46966, November 13, 1985). Thus, if trivalent chromium is present in high concentrations in well water, chlorination can result in correspondingly high concentrations of hexavalent chromium at the point of exposure (i.e., at the tap).

For these reasons, EPA's original concerns regarding the potential for trivalent chromium to be converted to hexavalent chromium remain. Thus, the Agency believes that the prudent course is to regulate total chromium concentrations under the TC. It should be noted that because of this, the Agency is considering proposing the deletion of the exclusion for specific chromium wastes that contain virtually no hexavalent chromium [see 40 CFR 261.4(b)(6)(i)]. Such a change would affect certain wastes from the leather tanning and finishing industry (as well as certain sludges from the production of TiO2 pigment using chromium-bearing ores by the chloride process).

c. Nickel and Thallium. Several commenters expressed support for incorporating nickel and thallium into the list of TC analytes. One commenter emphasized that unless such a step is taken, a major inequity will continue to exist in the regulation of listed and unlisted wastes that contain comparable levels of nickel. Many other commenters, however, objected to the inclusion of nickel and thallium in the TC. Most of these commenters doubted whether either element poses a threat to human health and the environment, noting that neither one is on the Primary or Secondary Drinking Water Standards list.

***11813** EPA has decided not to add more metals to the TC constituent list at this time because technical issues remain as to their subsurface fate and transport. The regulatory levels for the toxicity characteristic metals are not changed in this rule (i.e., EPA is retaining the regulatory levels set under the previous EP) pending further Agency validation and study of the fate and transport of metals. These validation and study efforts are focusing on the development of the metal speciation model (MINTEQ).

The Agency is developing MINTEQ for the evaluation of the mobility of arsenic, barium, cadmium, chromium, lead, mercury, nickel, selenium, silver, and thallium in ground water. A modified version of MINTEQ will be used in combination with a set of generic ground water specifications and subsurface conditions to determine metal solubility limitations. EPA will then use these results, in conjunction with the subsurface fate and transport model, to estimate dilution during transport to the down-gradient exposure point. (See discussion of the development of the subsurface fate and transport of metals at 51 FR 1653, January 14, 1986.) The Agency is not specifically proposing an approach for evaluating the fate and transport of metals in today's rule, but does expect to propose, at a later time, DAFs specific to metals, including nickel and thallium, and will address comments relating to the toxicity of nickel and thallium at that time.

C. Chronic Toxicity Reference Levels. The Agency proposed to use chronic toxicity reference levels (combined with DAFs) to calculate leachate concentration limits for individual constituents; a waste containing constituents equal to or above those levels would be a hazardous waste under the TC. Specifically, EPA proposed to use the MCLs promulgated as part of the National Interim Primary Drinking Water Standard (NIPDWS), where available, as the starting point for establishing the regulatory levels for each of the constituents. For those constituents for which no MCLs had been promulgated, the Agency proposed to use oral Reference Doses (RfDs) and Risk-Specific Doses (RSDs) to develop chronic toxicity reference levels for the noncarcinogens and carcinogens, respectively. Because exposure to toxic constituents can occur by multiple pathways, the Agency also proposed to apportion the acceptable health risk level of each noncarcinogenic constituent among the various possible routes of exposure. The Agency solicited public comment on: (1) Whether RfDs and RSDs are appropriate to use when MCLs are available; (2) the health levels proposed for RfDs and RSDs; (3) the associated risk levels; and (4) the assumptions used to apportion exposure to the different possible routes. The Agency's decisions regarding the health-related issues for which it solicited comments are presented below.

1. Maximum Contaminant Levels

The original toxicity characteristic—the EPTC (40 CFR 261.24)—used the NIPDWS developed under the Safe Drinking Water Act as the toxicity levels to derive the regulatory levels for the eight metals, four insecticides, and two herbicides then regulated. (For ease of discussion, the acronym “MCLs” will be used in subsequent sections to refer collectively to both MCLs and the existing NIPDWS.) EPA plans to continue this approach in the expanded TC for those constituents for which MCLs are available.

A number of commenters expressed support for the use of MCLs, when they exist, as the starting point for calculating regulatory levels for the TC. Most of these commenters argued that the MCLs provide adequate protection of human health. These commenters stated that MCLs are reliable, scientifically defensible, and recognized and understood by the general public.

Several commenters supported the use of MCLs because factors relating to cost and available treatment technology may be considered along with health effects in the development of the standards. These commenters asserted that MCLs represent a reasonable balance among the factors EPA must consider, while RfDs and RSDs are more limited. A number of commenters also felt that the use of MCLs provides a level of protection consistent with other regulatory programs.

In contrast, other commenters supported the use of RfDs and RSDs as the basis for the chronic toxicity reference levels even when MCLs are available for those constituents. These commenters stated that health-based levels are an appropriate starting point for the regulation. Because the MCLs consider other factors relating to technical and economic feasibility in addition to toxicity, they contend that the RfDs and RSDs are preferable. Many of these commenters also supported a consistent approach for all constituents regulated by the TC, rather than using MCLs for some and RfDs and RSDs for others.

Several commenters asserted that because the MCLs were developed for the purpose of regulating the concentrations of constituents in treated water “at the tap,” it is not appropriate to use the same standards for defining hazardous wastes. Several commenters also expressed concern that the MCLs developed under the Safe Drinking Water Act are potentially more stringent than RfDs and RSDs. This concern was most strongly expressed regarding carcinogens, for which Maximum Contaminant Level Goals (MCLGs), previously referred to as Recommended Maximum Contaminant Levels (RMCLs), are set at zero, and MCLs are set at technically achievable levels that most closely approach this zero goal.

EPA maintains that the MCLs, when they exist, are the most appropriate health criterion to use as the starting point for developing the regulatory levels. The exposure scenario developed for the TC is based on ingesting contaminated drinking water, and because MCLs are developed for regulation of drinking water, they clearly are relevant. In addition, the development of the MCLs follows a rigorous methodology in which all available health information is evaluated in establishing the MCLGs. The MCLs are set as close to the MCLGs as is feasible, and the Agency believes that MCLs are protective of human health.

It should be noted that EPA evaluates the health risks that are associated with various contaminant levels in order to insure that the MCL adequately protects the public health. For drinking water contaminants, EPA sets a reference risk range for carcinogens at 10-4 to 10-6 excess individual risk from lifetime exposure. Most regulatory actions in a variety of EPA programs have generally targeted this range using conservative models which are not likely to underestimate the risk. Since the underlying goal of the Safe Drinking Water Act is to protect the public from adverse effects due to drinking water contaminants, EPA seeks to insure that the health risks associated with MCLs for carcinogenic contaminants are in the general range of 10-4 to 10-6 .

EPA acknowledges that use of MCLs will, in some cases, result in chronic toxicity reference levels that are lower than those that would be calculated using the RfD methodology. For example, many of the non-carcinogenic compounds have MCLs which are approximately 10 to 20 percent of their respective RfDs because exposure sources other than contaminated drinking water are considered in setting the MCLs. On the other hand, the MCLs for some of the constituents addressed in the proposal are higher than the ***11814** levels that would be calculated using the RSD methodology. An example of this situation arises when the health criteria are at such low levels that analytical methods are not available to measure these levels. In cases where the MCL is higher than a purely health-based level, the Agency notes that use of the MCL is not inconsistent with today's rule since the purpose of the rule is to identify wastes that clearly pose hazards, not to identify the lowest level of hazard. However, regardless of whether they are higher or lower than the levels calculated using the RfD or RSD methodologies, EPA believes that MCLs are the appropriate starting point for developing regulatory levels for the TC.

For the constituents lacking MCLs, EPA must rely on the available methodologies to provide chronic toxicity reference levels that are scientifically defensible and protective of human health. EPA believes that the RfD and RSD methodologies meet these two criteria. EPA also realizes that inconsistencies will exist when different methodologies are employed for developing regulatory levels. The Agency intends to evaluate newly promulgated MCLs to determine on a case-by-case basis whether the TC regulatory level will change significantly if the new MCL is used, and to revise the regulatory levels, as appropriate. In the long run, this should provide internal consistency for the TC, as well as consistency with other regulatory programs.

Some commenters supported the use of MCLGs as the basis for chronic toxicity reference levels under the TC because the MCLGs are based on health effects alone, whereas the MCLs consider other factors as well, such as economic and technical feasibility.

EPA disagrees with the commenters who stated that MCLGs are more appropriate than MCLs for use in the TC. MCLGs are nonenforceable health goals for drinking water, which are to be set at levels that would result in no known or anticipated adverse health effects with an adequate margin of safety. The Agency has adopted the policy of setting the MCLGs for probable human carcinogens (Group A and B carcinogens) at zero. If the Agency were to use MCLGs rather than MCLs in the TC, the regulatory levels for defining a waste as hazardous would be based on health criteria that, at least for carcinogens, are more stringent than the criteria used to set concentrations acceptable for direct human ingestion of drinking water. In addition, the regulatory levels would be virtually impossible to detect analytically. This would mean that any waste that contains detectable levels of carcinogens would be hazardous regardless of the potency of the carcinogen or the risk presented by that waste. EPA believes that this is an inappropriate approach for the TC because it would result in the regulation of wastes which are not necessarily hazardous.

2. Risk-Specific Doses for Carcinogenic Constituents

For constituents for which no MCLs have been established, EPA uses oral RSDs to develop chronic toxicity reference levels for carcinogens. The RSD is an upper-bound estimate of the average daily dose of a carcinogenic substance that corresponds to a specified excess cancer risk for lifetime exposure. A predetermined risk level and the oral carcinogenic slope factor estimated by EPA's Carcinogen Risk Assessment Verification Endeavor (CRAVE) Workgroup or Carcinogen Assessment Group (CAG) are used to calculate the RSD.

The Agency proposed a risk level of concern based on the weight of evidence regarding carcinogenicity of each constituent. Constituents classified as known or probable human carcinogens (Group A or B) were assigned a risk level of 1 in 100,000 (i.e., 10-5), while constituents classified as possible human carcinogens (Group C) were assigned a risk level of 1 in 10,000 (i.e., 10-4).

The Agency received comments regarding both the weight-of-evidence approach for establishing risk levels and the risk levels selected. In particular, one commenter supported the Agency's proposal, stating that a single risk level is not appropriate for all constituents, and that use of the weight-of-evidence approach avoids making regulatory decisions based on insufficient data. Another commenter also supported the use of weight-of-evidence to assign risk levels, but stated that it is inappropriate to regulate both known and probable human carcinogens at the same level of risk. Alternatively, a third commenter asserted that the weight-of-evidence approach is inappropriate because (1) new information is constantly being developed on the health effects of toxic constituents, so the weight of evidence is constantly changing, and (2) the classification scheme does not take into account the potency of the carcinogenic risk.

The Agency also received specific comments regarding both the weight-of-evidence approach and the selection of specific risk levels. Several commenters addressed the risk level at which the Agency proposed to regulate carcinogens. Some commenters specifically expressed support for EPA's proposal to regulate Class A and B constituents at a 10-5 risk level and Class C constituents at a 10-4 risk level. One commenter stated that because the procedure for developing risk estimates is extremely conservative, the proposed risk levels would not adversely affect human health and the environment. Another commenter noted that the stated risk levels are estimates of the upper confidence bound of risk and not the maximum likelihood estimate; thus, the actual risk to the public would be less than the stated level.

Other commenters supported the use of a 10-6 risk level for all carcinogens. These commenters argued that the use of the proposed risk levels represents a serious weakening in EPA's regulation of carcinogens and is inconsistent with other policies in effect in other EPA programs.

With respect to the weight-of-evidence approach, the Agency has decided to establish a single risk level of concern for all potential carcinogens (i.e., the Agency will not assign a specific risk level to a specific weight-of-evidence carcinogenicity classification for this rulemaking). The weight-of-evidence approach for classifying a constituent as carcinogenic is based primarily on the amount and quality of data that are available rather than the strength of the toxic response in animals or humans. In effect, it is a qualitative assessment that takes into account the uncertainty in the data for determining whether an agent

is carcinogenic to humans. This means that the actual quantitative difference in risk between an “A” and “B” carcinogen as classified by the weight of evidence may either be zero or may be orders of magnitude. Thus, EPA believes that both the weight-of-evidence and the strength of the toxic response (i.e., potency) should be considered in making regulatory decisions within the context of the TC.

With regard to the specific risk level chosen, the Agency has decided to set the level for carcinogens (Groups A, B, and C) at 1 in 100,000 (i.e., 10-5) for the final rulemaking. Characteristics are established at levels at which the Agency has a very high level of certainty that a waste which exhibits these properties needs to be managed in a controlled manner (i.e., as a hazardous waste). The Agency realizes that not all wastes which exhibit properties at concentrations below the regulatory levels are necessarily safe for disposal as nonhazardous wastes. Rather, those wastes having properties lower than the ***11815** regulatory levels and which are demonstrated to pose a hazard to human health or the environment still remain subject to waste-specific evaluations under the hazardous waste listing program. Wastes which are determined to require controlled management after consideration of the factors identified in 40 CFR 261.11(a)(3) (e.g., the nature of the toxic constituents, toxicant mobility under various environmental management scenarios, volume of waste generated and potential method of management) are then specifically listed as hazardous wastes and subjected to the appropriate RCRA management controls. This reflects EPA's philosophy, first articulated in May of 1980, that the characteristic defines broad classes of wastes that are clearly hazardous, while the listing process defines some wastes that may not exhibit the characteristics but are nonetheless hazardous wastes (45 FR 33111, May 19, 1980).

The chosen risk level of 10-5 is at the midpoint of the reference risk range for carcinogens (10-4 to 10-6) targeted in setting MCLs. This risk level also lies within the reference risk range (10-4 to 10-6) generally used to evaluate CERCLA actions. Furthermore, by setting the risk level at 10-5 for TC carcinogens, EPA believes that this is the highest risk level that is likely to be experienced, and most if not all risk will be below this level due to the generally conservative nature of the exposure scenario and the underlying health criteria. For these reasons, the Agency regards a 10-5 risk level for Group A, B, and C carcinogens as adequate to delineate, under the TC, wastes that clearly pose a hazard when mismanaged.

3. Apportionment of Health Limits

EPA proposed to account for potential exposure from sources other than the TC scenario by apportioning the RfD-based chronic toxicity reference levels. The apportionment scheme effectively reduced each such chronic toxicity reference level to 50 percent of its original value, (i.e., 50 percent of the RfD). The Agency also proposed to estimate environmental partitioning of the apportioned health limits in air and water according to a simplified fractionation scheme using Henry's Law Constants (Hc) and octanol-water coefficients (Kow) for individual constituents. The Agency did not propose to apportion the chronic toxicity reference levels based on RSDs or MCLs.

Several commenters addressed the Agency's proposal to apportion the RfDs. Commenters that criticized the Agency's proposed apportionment scheme argued that it was arbitrary, overly conservative, and unnecessary. Several commenters recommended that EPA either use more realistic estimates of exposure based on the available constituent-specific data or not apportion at all.

After a review of comments on the proposed regulation and consideration of the available data, the Agency has decided not to apportion in this rulemaking. Although the concept of apportionment has some scientific basis in that individuals are exposed to many of the chemicals of concern through more than one route of exposure and from more than one source, the implementation of the concept is very difficult when adequate data on the amount of exposure and/or health effects from all routes of exposure do not exist. Thus, due to the lack of sufficient data to determine an appropriate apportionment factor for the various constituents, the Agency now concludes that its proposed apportionment scheme cannot be supported at the present time. Of course, the proposed apportionment would deal with uncertainty by erring on the side of safety; nevertheless the Agency believes that the conservative approach used to deal with uncertainty in the development of the RfD is sufficiently stringent to define those wastes that clearly pose hazards. This approach is in accordance with the Agency's treatment of noncarcinogens. The Agency therefore will not apportion the RfDs for this rulemaking.

A few commenters criticized the Agency's proposed method for fractionating the apportioned RfD between air and water. These commenters questioned the technical basis of the Agency's approach and/or recommended alternative schemes. The Agency agrees with commenters that the technical basis for supporting fractionation as proposed is inadequate to predict media-specific concentrations. The Agency is exploring the development of an appropriate model. Thus, EPA has decided not to apportion the RfD and not to fractionate the RfD between air and water in this rulemaking.

Other commenters addressed the apportionment of RSDs for carcinogenic constituents. Several of these commenters agreed with EPA's decision not to apportion RSDs, stating that doing so would result in very low regulatory thresholds for some constituents. The commenters also pointed out that many conservative assumptions are already incorporated into the development of the RSDs for carcinogens. Others commented that RSDs should be apportioned because humans are exposed to these constituents by multiple routes.

The Agency continues to believe that it is not appropriate to apportion the RSDs for carcinogenic constituents. RSDs are estimated by a procedure that must deal with unavoidable uncertainties and is therefore intentionally conservative. The Agency stated in the preamble to the proposed rule that a difference in dose of a factor of 2 is still well within the margin of uncertainty of the estimated RSD (51 FR 21667, June 13, 1986).

Table C-1 presents chronic toxicity reference levels for the constituents in today's rule. The Agency received a number of comments on specific chronic toxicity reference levels. In some cases, EPA responded to these comments in the notice of proposed changes to the health levels on May 19, 1988 (53 FR 18024). Other chemical specific comments are addressed in the background document (Ref. 3).

Table C-1.--Chronic Toxicity Reference Levels

Constituent	Chronic toxicity reference level (mg/L)	Basis
Arsenic	0.05	MCL
Barium	1.0	MCL
Benzene	0.005	MCL
Cadmium	0.01	MCL
Carbon tetrachloride	0.005	MCL
Chlordane	0.0003	RSD
Chlorobenzene	1	RfD
Chloroform	0.06	RSD
Chromium	0.05	MCL
o-Cresol	2	RfD
m-Cresol	2	RfD
p-Cresol	2	RfD
2,4-D	0.1	MCL
1,4-Dichlorobenzene	0.075	MCL
1,2-Dichloroethane	0.005	MCL
1,1-Dichloroethylene	0.007	MCL
2,4-Dinitrotoluene	0.0005	RSD
Endrin	0.0002	MCL
Heptachlor (and its hydroxide)	0.00008	RSD
Hexachlorobenzene	0.0002	RSD
Hexachloro-1,3-butadiene	0.005	RSD
Hexachloroethane	0.03	RSD
Lead	0.05	MCL
Lindane	0.004	MCL
Mercury	0.002	MCL
Methoxychlor	0.1	MCL
Methyl ethyl ketone	2	RfD

```
Nitrobenzene ..................................................... 0.02 RfD
Pentachlorophenol ................................................ 1 RfD
Pyridine ......................................................... 0.04 RfD
Selenium ......................................................... 0.01 MCL
Silver ........................................................... 0.05 MCL
Tetrachloroethylene ............................................... 0.007 RSD
Toxaphene ........................................................ 0.005 MCL
Trichloroethylene ................................................ 0.005 MCL
2,4,5-Trichlorophenol ............................................ 4 RfD
2,4,6-Trichlorophenol ............................................ 0.02 RSD
2,4,5-TP acid (Silvex) ............................................ 0.01 MCL
Vinyl chloride ................................................... 0.002 MCL
-------------------------------------------------------------------------------
All RSDs are calculated at the 10-5 risk level.
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11816** ***D. Use of Generic Dilution/Attenuation Factors (DAFs)

In the May 19, 1988 supplemental proposal, EPA requested comment on an alternative strategy for setting DAFs in the TC. The alternative involved setting DAFs for these constituents in two phases. The first phase would use a generic DAF in a manner similar to the existing EPTC, which uses a DAF of 100 for all EP constituents. In the second phase, the Agency would further address the manner in which the DAFs are calculated and would either: (1) Continue to use generic DAFs, (2) employ a subsurface fate and transport model to develop constituent-specific DAFs, or (3) use some combination of the two approaches. The Agency also specifically solicited comment on the use of a generic DAF of 100 or 500 in the first phase.

Many commenters recognized the need to expeditiously promulgate the TC; however, most opposed the two-phased approach, arguing that it would cause undue economic burden by: (1) Forcing industries to design new treatment programs for one group of wastes at certain regulatory levels, and a few years later to redesign in order to accommodate new levels and wastes, and (2) over-regulating certain chemical substances under the first generic-DAF phase that may then not be regulated under the second phase. Some commenters were concerned, on the other hand, that EPA would set the generic DAFs so high (to avoid overregulation) that some substances would be under-regulated.

Most commenters opposed the use of generic DAFs and urged EPA to retain the constituent-specific modeling approach. These commenters argued that a generic DAF would be arbitrary and not scientifically defensible; that use of the generic DAFs would violate the statutory requirements to develop a process that accurately assesses leaching ability and differentiates between hazardous and nonhazardous wastes; and that the diversity in dilution and attenuation attributes across the constituents would cause any generic DAF to either severely under-regulate or severely overregulate a large number of the constituents. Even those few commenters who supported the two-phased approach recommended that the Agency move rapidly to the second phase and employ the modeling approach to set DAFs.

EPA acknowledges that the problems noted by the commenters are important ones. The Agency requested comment on the generic DAF approach because of the likelihood that the issues surrounding the proposed fate and transport model for establishing constituent-specific DAFs would not be resolved in a timely manner. Since the Agency has been able to address the concerns regarding the subsurface fate and transport model for the constituents identified in today's regulation, the Agency has decided to use the model to develop DAFs. Consequently, the DAFs set in today's rule for nonhydrolyzing constituents for which the steady-state solution is appropriate are not viewed by EPA as interim and are supported by the subsurface fate and transport model. The Agency intends to establish DAFs for constituents not addressed in today's rule on a constituent-specific basis, and regulatory levels for those constituents will be proposed or promulgated (as warranted) at a later date.

E. Application of a Subsurface Fate and Transport Model

1. Introduction

On June 13, 1986, EPA proposed an approach (see 51 FR 21648) for estimating regulatory concentration levels in a waste leachate using chronic toxicity reference levels, combined with constituent-specific dilution/attenuation factors (DAFs) derived from the application of a subsurface fate and transport model. The model (EPASMOD) was first described for public comment on January 14, 1986 (51 FR 1602).

A DAF represents a reduction in the concentration of a constituent expected to occur during transport through ground water from the bottom of a disposal unit to a drinking-water source. In response to the proposal and supplemental notices (see Section II, Table II.1), the Agency received numerous comments on the subsurface fate and transport model used for the calculation of DAFs. This section describes the different proposals related to the use of the subsurface fate and transport model, the modifications to the model in response to public comments, and the results obtained with the use of the modified model.

a. June 13, 1986 Proposed Rule (51 FR 21648). The Agency's June 13, 1986 proposal used a subsurface fate and transport model (EPASMOD) to calculate specific DAFs for each of the 44 organic hazardous constituents (see Table E-1). The DAFs for each constituent were calculated using the model, incorporating compound-specific hydrolysis and soil adsorption data coupled with parameters describing the subsurface environment (e.g., ground water flow rate, hydraulic conductivity of the aquifer, ground water pH, etc.). The Agency proposed modeling a scenario of waste mismanagement at a subtitle D municipal landfill. Data were incorporated in the model using a monte carlo simulation.

[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a meaningful review of its contents. The table has been divided into multiple pieces with each piece containing information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

****

******** This is piece 1. -- It begins at character 1 of table line 1. ********

****

Table E-1.--Dilution

Constituent
Acrylonitrile .....
Benzene .....
Bis(2-chloroethyl)ether .
Carbon disulfide .....
Carbon tetrachloride ....
Chlordane .....
Chlorobenzene .....
Chloroform .....
o-Cresol .....
m-Cresol .....
p-Cresol .....
2,4-D .....
1,2-Dichlorobenzene .....
1,4-Dichlorobenzene .....
1,2-Dichloroethane .....
1,1-Dichloroethylene ....
2,4-Dinitrotoluene .....
Endrin .....
Heptachlor (and its hydroxide) .....
Hexachlorobenzene .....
Hexachlorobutadiene .....
Hexachloroethane .....
Isobutanol .....

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Lindane .................
Methoxychlor ............
Methylene chloride ......
Methyl ethyl ketone .....
Nitrobenzene ............
Pentachlorophenol .......
Phenol ..................
Pyridine ................
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
Tetrachloroethylene .....
2,3,4,6-Tetrachlorophenol
Toluene .................
Toxaphene ...............
1,1,1-Trichloroethane ...
1,1,2-Trichloroethane ...
Trichloroethylene .......
2,4,5-Trichlorophenol ...
2,4,6-Trichlorophenol ...
2,4,5-TP (Silvex) .......
Vinyl chloride ..........
-------------------------
1...#...10....#...20....#
********************************************************************************
******* This is piece 2. -- It begins at character 26 of table line 1. ********
********************************************************************************
Attenuation Factors for Toxicity Characteristic Organic
Constituents
-------------------------------------------------------------
LOG Kow Ka [FN2] Kb [FN2] Kn [FN2] D/A
[FN1] factor
[FN3]
-------------------------------------------------------------
........ 0.07 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
........ 2.13 NHYF [FN4] NHYF ...... NHYF ............ 14.4
........ 1.04 NH [FN5] .. NH ........ 8E-5/hr ......... 14.4
........ 2.16 NH ........ >10/yr .... NH .............. 14.4
........ 2.96 NH ........ NH ........ NH .............. 14.4
....... [FN7] NH ........ >10/yr .... NH .............. 14.4
5.48
........ 2.87 NH ........ 1E-6/hr ... NH .............. 14.4
........ 1.96 NH ........ 0.23/hr ... 3E-9/hr ......... 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.70 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 3.56 NH ........ 1E-5/hr ... NH .............. 14.4
........ 3.56 NLFG [FN6] NLFG ...... NLFG ............ 14.4
........ 1.40 NH ........ NH ........ 7.2E-5/hr ....... 75.0
........ 2.13 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 2.30 NLFG ...... NLFG ...... NLFG ............ 14.4
....... [FN7] >1/yr ..... >1/yr ..... >1/yr ........... 14.4
3.54
....... [FN7] NLFG ...... NLFG ...... NLFG ............ 14.4
4.61
........ 6.42 <1/yr ..... <1/yr ..... <1/yr ........... 14.4
........ 4.24 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 4.22 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
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........ 0.74 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
........ 3.40 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
....... [FN7] NH ........ 1.4/hr .... 7.5E-5/hr ....... 14.4
4.30
........ 1.26 NH ........ NH ........ 1.18E-8/hr ...... 14.4
........ 0.30 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 1.90 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 5.06 NH ........ >1E-4/hr .. NH ............... 14.4
........ 1.49 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 0.68 NLFG ...... NLFG ...... NLFG ............ 14.4
....... 2.81 NH ........ 1.3/hr .... 2.2E-7/hr ....... 14.4
....... 2.42 NH ........ 2.6E# 3/hr NH ............... 65.0
........ 3.03 NLFG ...... NLFG ...... NLFG ............ 14.4
....... 4.33 NH ........ 1E-5/hr ... NH ............... 14.4
........ 2.82 NHYF ...... NHYF ...... NHYF ............ 14.4
....... [FN7] NH ........ >10/yr .... NH ............... 14.4
5.30
........ 2.50 NH ........ NH ........ 1.1E-4/hr ...... 150.0
........ 1.91 NH ........ 13/hr ..... 4.3E-7/hr ....... 20.0
........ 2.28 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 3.86 NH ........ 1E-5/hr ... NH ............... 14.4
........ 3.58 NH ........ 1E-5/hr ... NH ............... 14.4
........ 3.45 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 1.38 NH ........ 1E-5/hr ... 1E-7/hr ......... 14.4
-------------------------------------------------------------
26.......#...40....#...50....#...60....#...70....#...80....#.
******************************************************************************
******* This is piece 3. -- It begins at character 1 of table line 59. ********
******************************************************************************
1 Logarithm of the octanol/water partition coefficient.
2 Acid, base and neutral hydrolysis rate constants.
3 Dilution/attenuation factor derived from ground water transport system.
4 NHYF = No Hydrolyzable Functional Group.
5 NH = Negligible Hydrolysis.
6 NLFG = No Liable Functional Group.
7 Estimated value.
1...#...10....#...20....#...30....#...40....#...50....#...60....#...70....#....
```

***11817** In the monte carlo simulation, values for each parameter are based upon the frequency distribution for each parameter (where such data exists) rather than the selection of a single value for each parameter. The model is then run a sufficient number of times (typically several thousand) to produce the frequency distribution of the model's output. This overall frequency distribution is, effectively, a combination of the frequency distributions for each individual parameter. This approach avoids the compounding effects of conservatism inherent in choosing single, reasonable-worst-case values for each parameter. Monte carlo simulation was chosen as the preferred method to analyze the full range of possible environmental conditions for the land disposal scenario. The wide range of environmental conditions (e.g., ground water velocities, pH, temperatures, exposure point locations) that can exist in locations across the nation where the wastes in question may be disposed precludes a priori specification of a reasonable worst case for these parameters. Another important reason to use the monte carlo method is the very complex manner in which the many model variables and parameters interact. Unless many (hundreds to thousands) combinations of variables are investigated, it is simply not possible to anticipate those physical settings that lead to unacceptably high exposure levels. Accordingly, the monte carlo method was chosen to ensure that a conservative but not physically unrealistic or impossible analysis was completed.

The EPASMOD, as described in the proposed rule, was based on a number of key assumptions pertaining to the features of ground water flow, properties of the porous medium, and the behavior of hazardous wastes in ground water. These assumptions included the following:

- Saturated soil conditions (no attenuation of chemicals in the unsaturated zone);

- Flow regions of infinite extent in the longitudinal direction, semi-infinite extent in the lateral direction, and finite in the vertical direction;

- Aquifer can be characterized by homogeneous and isotropic properties and the aquifer thickness is constant;

- Ground water flow is uniform and continuous in direction and velocity;

- Degradation is limited to hydrolysis and the by-products of hydrolysis are assumed to be nonhazardous;

- Contaminants follow a linear equilibrium adsorption isotherm;

- An infinite source supplies a constant mass flux of chemical into the aquifer;

- Recharge due to precipitation supplies water to the disposal unit and the aquifer;

- The ground water upstream of the disposal site is initially free of contamination;

- The receptor well is directly in line with the source and the ground water flow direction;

- The receptor well is located 500 feet from the unit; and

- Hydraulic conductivity does not vary with temperature.

In the June proposed rule, the Agency also proposed using the 85th cumulative percentile level of the back-calculated dilution attenuation factors obtained using the monte carlo simulation technique as an appropriate regulatory level for the TC. Selection of this level means that downgradient ***11818** concentrations will not exceed the allowable health-based concentrations in more than 15 percent of all possible analyzed settings of subtitle D disposal units. (This proposal referenced other proposals dealing with the ground water transport model, such as the January 14, l986 Land Disposal Restrictions notice, and notices published by the delisting program; relevant comments received in response to those notices are also discussed in this rulemaking.)

b. August 1, 1988 Notice of Data Availability and Request for Comments; Supplement to Proposed Rule (52 FR 28892). On August 1, 1988, the Agency presented new data related to subtitle D municipal landfills, soil characteristics, and chemical-specific hydrolysis rates to be used with the subsurface fate and transport model to calculate DAFs for each of the organic constituents in the TC. These new data became available to the Agency after the June 13, 1986 proposal. The August 1, 1988 Notice also requested comments on several major revisions to EPASMOD that were being considered by the Agency, subsequently referred to as EPA's Composite Model for Landfills (EPACML). As a result of comments received on the January 14, 1986, and June 13, 1986 proposals, as well as the August 1, 1988 Notice, the Agency has used EPACML to support the choice of appropriate DAFs for this rulemaking.

These modifications and data are described in greater detail below (section III.E.2). The reader is referred to the Response-to-Comments Background Document for the Subsurface Fate and Transport Module (Ref. 1), which presents, in detail, each of the technical issues addressed in the public comments on the model and the Agency's response to these issues.

2. Modifications of the Subsurface Fate and Transport Model (EPASMOD) in Response to Comments

In today's rule, the Agency has used EPACML to estimate the attenuation and dilution of specific constituents during their migration through the unsaturated zone beneath a municipal landfill and their transport through the saturated zone to a potential drinking water source (exposure point). EPACML accounts for dispersion in the longitudinal, lateral, and vertical

directions; one-dimensional steady and uniform advective flow; sorption; and chemical degradation from hydrolysis. The major enhancements that were made to EPASMOD to produce EPACML, the substantive comments that led to these changes, and important assumptions made to develop analytical solutions are described in subsection (a) below.

In addition, the Agency used the EPACML model to corroborate its conclusions on dilution/attenuation factors for surface impoundments. For this exercise, data inputs typical of surface impoundments rather than landfills were used. These procedures are described in subsection (b) below.

a. General Modifications—i. Unsaturated Zone. The EPASMOD model discussed in the June 13, 1986 proposal assumed that there was no unsaturated zone (i.e., the bottom of the landfill is directly connected to the top of the aquifer). Several commenters stated that the assumption that the facility is located directly at the top of the saturated zone is unrealistic because an unsaturated zone usually exists above the aquifer and that retardation, dilution, and degradation effects in the unsaturated zone should be considered. The commenters also suggested that, when incorporating the unsaturated zone, the depth to the water table should be incorporated as part of the monte carlo analysis.

The Agency is in agreement with the commenters and has now included an unsaturated zone as part of the subsurface model. The Agency believes that this modification to the model is reasonable, based in part on a survey of existing municipal landfills that indicated that an unsaturated zone exists beneath 95 percent of the surveyed landfills. Incorporating an unsaturated zone into the model accounts for any retardation and degradation of chemicals in the unsaturated zone and provides a more realistic scenario.

To account for the unsaturated zone, the Agency developed unsaturated zone flow and transport modules and implemented them using the monte carlo (probabilistic) framework that has already been used in conjunction with the saturated zone modeling approach in EPASMOD; these unsaturated zone modules are incorporated into EPACML. The input concentration to the unsaturated zone transport module of EPACML corresponds to the leachate concentration at the bottom of the landfill.

The unsaturated zone model was reviewed by EPA's Science Advisory Board (SAB). The SAB endorsed the use of the model for applications for the development of regulations; however, the SAB recommended that it not be used for site-specific applications because the model has limitations imposed by the simplifying assumptions (those necessary for regulatory use), and the limitations of the use of site-specific data. The unsaturated zone model consists of two modules: a flow component and solute transport component. These two components were developed in a form to allow for their incorporation in the monte carlo simulation. The major assumptions and consequences of the flow module are:

- Flow is steady in the vertical direction, and lateral and transverse movement of the leachate is negligible. Because there is little or no lateral flow in the unsaturated zone, these assumptions are appropriate. In any case, this procedure will tend to maximize the concentration of leachate leaving the unsaturated zone and therefore represents a conservative assumption.

- No vapor phase or immiscible liquid flow occurs, and the water phase is the only flowing material. EPA acknowledges that some constituents in some situations may undergo phase shifts and be emitted in vapors. Because this rule is essentially directed to risks from drinking water and because of the uncertainties in accurately computing emissions and their relationship to the currently available leaching tests, this conservative assumption was adopted. Under certain conditions, particularly very high constituent concentrations, immiscible liquid flow can occur. For such situations, the model's inability to account for the immiscible flow condition may lead to higher downgradient concentrations (i.e., the model would underestimate the receptor well concentrations).

- Flow is isothermal (not affected by temperature variations). In reality, temperature variations at any given site are not dramatic because the source of infiltrating liquid is precipitation. Thus, this assumption is not expected to influence the results to any appreciable degree.

- Effects of variations in the unsaturated zone hydraulic properties caused by alternating moisture conditions are negligible (i.e., hysteresis effects). Many soils, especially the more porous ones for which infiltration rates are high, do not present important hysteresis effects. In other cases, little and often no data are available to characterize the effects. Failure to include hysteresis is not expected to affect the results to any appreciable extent.

- The flow field is uniform and continuous in direction and velocity. Precipitation-driven infiltration can be a dynamic process where much of the vertical movement occurs during relatively short periods of time. Time- ***11819** averaged values of infiltration derived from dynamic water balance calculations (as described in the Background Technical Support Document) are often used to enable solution of analytical, steady-flow models. The unsteady-flow conditions could lead to higher downgradient concentrations than predicted by EPACML. However, the effect is expected to be significant only for rapidly degrading constituents. For the constituents regulated in this rule, no appreciable impact is expected because none of the constituents are expected to hydrolyze to any significant extent during transport.

- The unsaturated zone is homogeneous and isotropic. This assumption is typically required to enable mathematical solutions amenable to exhaustive sensitivity analyses and monte carlo implementation. In any one application (one model run) of this assumption, the result can either under- or over-predict downgradient concentrations. The monte carlo implementation, however, results in a very wide range of possible conditions, and thus the total analysis, when taken together, accounts for a wide variety of unsaturated zone conditions.

The major assumptions and consequences of the unsaturated zone transport module are:

- Chemical transport is vertical; lateral and transverse movement of the chemical is negligible. This follows from the first assumption for the flow module described above.

- Chemical sorption is modeled as a reversible, linear equilibrium process. This is a standard modeling assumption which is accurate for systems having relatively low solute concentrations, and conservative at higher concentrations.

- Degradation is limited to hydrolysis. This assumption was made to be consistent with the similar approach adopted for the saturated zone. Thus, the model includes only those degradation mechanisms that can be reliably characterized in laboratory studies of each individual constituent. This assumption remains a major conservative component of the overall model.

- Chemical transport in the vapor phase has been assumed to be negligible. This follows from the second assumption for the flow module described above.

- The unsaturated zone transport model is solved for the steady-state condition. This is a conservative assumption that has been investigated for its impact on all the originally proposed constituents. The extent to which this assumption is appropriate is discussed in section III.E.4(b)(iii).

The details of the unsaturated zone module are provided in the background documents (Ref. 1, 9), which also describe the data sources and analyses that were performed to obtain the data distributions.

ii. Source Characterization. In EPASMOD, the input leachate to the saturated zone was assumed to be instantaneously mixed in the vertical direction over a pre-specified depth of source penetration, and the concentration in the leachate was equal to the maximum source contaminant concentration in the saturated zone below the facility. Mass balance considerations required that the lateral extent of the leachate directly underneath the facility be adjusted to ensure that leachate was neither gained nor lost in the transition from the facility (or unsaturated zone) to the aquifer. A number of commenters criticized the treatment of the source. A major concern was that the method was inadequate because of an overly conservative assumption, which equated the concentration of the contaminant in the saturated zone to the landfill leachate concentration. Thus, commenters argued that EPA had not given adequate consideration to mixing and dispersion under the landfill. The commenters also pointed out that

this treatment of the source could result in modeling physically unrealistic boundary conditions (e.g., by modeling a source of small cross-sectional area with a very large width of the Gaussian source, and vice versa).

The Agency agrees with the commenters that the method used to characterize the source-boundary conditions for the saturated zone transport needed to be improved. Thus, the method has been revised to consider the mass balance requirements, geometrical configurations, and physical processes that are occurring in the mixing zone below the facility and within the saturated zone. An important characteristic of the revised method is the plume restriction in the lateral extent. That is, the method no longer permits physically unrealistic situations where the plume source width exceeds the facility width. In addition, the current method of computing the source-boundary conditions represents the mixing and dilution effect on the leachate below the source and ensures that the concentration of the contaminant in the saturated zone will be less than or equal to the landfill leachate concentration.

iii. Treatment of Dilution from Recharge. In EPASMOD, the dilution effect of ground water recharge on contaminant transport in the saturated zone was taken into account by including recharge as a dilution term in the governing equation. Dilution of leachate concentrations from recharge was calculated by dividing the infiltration (recharge) rate by the source penetration depth. A number of commenters were concerned that the influence of recharge on the ground water flow field had not been properly accounted for in the model. In addition, several commenters alerted the Agency to an error in the equation used to evaluate the recharge dilution parameter.

In response to these comments, the Agency has modified the model to calculate dilution from recharge by dividing the recharge rate by the total saturated thickness of the aquifer, the aquifer porosity, and the effective retardation factor in this zone. This revision represents a more realistic assessment of the dilution potential of recharge by considering changes in the entire volume of water in the contaminated aquifer and the effectiveness of contaminant and recharge flow and mixing in the aquifer.

The Agency recognizes that recharge effects on ground water flow fields are not rigorously considered in the model and that the assumption of uniform, constant, horizontal ground water velocity neglects the possible effects of local mounding of the water table underneath the land disposal unit. However, the constant velocity assumption can be interpreted as an averaging of the velocity field over the spatial area affected by recharge; in addition, the uniform, horizontal flow assumption was necessary to make the three-dimensional transport equation analytically solvable. The effect of recharge on ground water velocity is difficult to account for directly in the model. To assist in the analysis, EPA has conducted a sensitivity analysis comparing EPACML results with recharge effects as predicted by a two-dimensional numerical model that rigorously accounts for recharge. The results (which can be found in Ref. 9) indicated that as long as recharge values are significantly less than the natural flow velocity, there was no major effect on the ground water flow fields. Based on this analysis, and on evidence of typically low rates of ground water recharge, the Agency believes that the revised treatment of the dilution effect from recharge is reasonable. In addition, the error, as pointed out by several commenters, in the equation used to evaluate the recharge dilution ***11820** parameters was corrected, and the correction is included in EPACML.

iv. Location of the Receptor Well. In EPASMOD, the receptor well was assumed to be located downgradient from the landfill along the centerline of the plume (direction of ground water-flow) at a fixed distance of 500 feet (152.4 m). In addition, the receptor well was assumed to be tapping water from the top of the aquifer, and no mixing of water in the well or effects of drawdown in the well were considered in EPASMOD.

Many commenters argued that the assumptions concerning the location of the receptor well were too conservative and suggested that well locations should be considered in a probabilistic manner as part of the monte carlo simulation in the model. These commenters noted that well locations other than on the centerline should be considered. Several commenters also stated that the well locations should not be restricted to lying within the areal extent of the plume and suggested that wells located outside of the plume should be considered in the calculation of the dilution/attenuation factors.

The Agency agrees that the proposed location of the well was unrealistic and that affected wells located at points other than on the centerline should be considered. Therefore, the model now considers well locations anywhere within the areal extent of

the contaminant plume. In order to incorporate these locations, a distribution of distances to downgradient wells was developed based upon a subtitle D municipal landfill survey (Ref. 6). These distances were used as part of the monte carlo analysis. Also, to incorporate locations other than on the centerline, the Y values (see Figure 1) were selected randomly over a 180° domain but the X-Y pairs were constrained to values that were located within the areal extent of the plume.

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***11822** The Agency disagrees with those commenters who stated that well locations outside of the areal extent of the plume should be considered. The purpose of the Toxicity Characteristic is to answer the question "if the management of this waste continues to be uncontrolled, what are the consequences in terms of human exposure via ingestion of contaminated drinking water?" In performing the exposure assessment to answer this question, the Agency believes it appropriate to consider only wells that could be affected by the disposal of the waste. Wells that could not be affected by the migration of constituents from the wastes are obviously irrelevant to the exposure assessment and, thus, not considered.

Commenters also stated that it was unrealistic to assume that the well tapped water from only the uppermost point of the aquifer. These commenters stated that, in practice, the intake portion of a well is located below the top of the water table and that mixing and drawdown will occur.

The Agency agrees that the proposed well intake location was unrealistic and that it ignored the effects of vertical mixing and the possibility that the well intake would likely be at some point other than the top of the aquifer. In response, the assumptlon has been modified to consider well intake at any point throughout the depth of the aquifer. This modification largely takes into account the above-described mixing and drawdown effects.

In determining how to account for well drawdown more realistically in the model, the Agency considered the mechanics of well construction. Generally, wells are screened from near the top of the aquifer to a sufficient depth (into the aquifer) to allow delivery of the needed water supply. Thus, the ranges of values for the length of the screens and their locations relative to the top of the aquifer are very large. In recognition of this variability, especially in screen length, the Agency has employed a simplifying assumption that the concentrations of constituents at various depths of the aquifer represent the concentrations at the exposure point. That is, the concentration of constituents in the water drawn from the well is assumed to be equal to the concentration of the constituents at the depth which is selected in the monte carlo simulation. (The well depth is randomly selected from all points within the vertical range of the aquifer's thickness.)

To evaluate the model's sensitivity to this assumption, the Agency evaluated the case in which wells were assumed to be screened from the top of the aquifer to the monte-carlo-selected depth. The exposure point concentration was then calculated as the average concentration over the screened depth. This case is considered to be more representative of the most likely well design, although in many cases the well will not extend to the bottom of the aquifer nor will it always be constrained to intersect the plume as is implemented in the monte carlo simulation. This scenario is considered to be more conservative (i.e., resulting in lower DAFs) than the EPACML-as-implemented scenario. When one considers other possibilities like well location factors up gradient and outside the plume, the range of DAFs from the two scenarios can be expected to bound the actual exposures.

In evaluating the model predictions over the range of cumulative frequency values considered in interpreting the model's results in today's rule (see Section III.E.4—DAF Evaluation), the dilution/attenuation factors for the two scenarios are not sufficiently different to warrant separate conclusions regarding the appropriate value for use in today's rule. (Model results for the two scenarios are compared in the background document for the model—Ref. 9.)

v. Dispersivity Values. Dispersivity controls the degree of spreading of dissolved contaminants in the subsurface. The saturated-zone fate and transport model includes dispersion in the longitudinal, transverse (horizontal), and vertical directions. The model thus requires values of the longitudinal, transverse, and vertical dispersivities in the saturated zone. In EPASMOD, the distance x from the downgradient edge of the landfill to the receptor well was assumed to be fixed at 152 m (500 feet). Consequently, fixed values of the longitudinal and transverse dispersivities were used in the model. The values of vertical dispersivity were assumed to vary uniformly.

Several commenters criticized the assumption that dispersivity values did not vary and reflected only the fixed distance selected in the model. They also suggested that the ratio of longitudinal to transverse dispersivity used in the model was too low. The basis of their comments is that field values of dispersivities have been shown to depend on, and usually increase with, the travel distance.

The Agency agrees with the commenters and now calculates the three components of dispersivity based on a detailed analysis of data gathered from field tests (the model background document [Ref. 9] presents a detailed discussion on dispersivity values and provides references to the field data). The Agency believes that the revised approach, reflecting the distance-dependent nature of the dispersivity values and different relationships between the dimensional dispersivities, is more realistic and consistent with the available data.

EPACML also requires the specification of a dispersivity parameter for transport in the unsaturated zone. Since the transport equation in the unsaturated zone is one-dimensional, only the longitudinal (vertical) dispersivity value is required and is calculated as a function of the distance (i.e., the depth to water table) traveled in the unsaturated zone.

vi. Hydraulic Conductivity. In EPASMOD, the value of hydraulic conductivity in the saturated zone was estimated using the Kozeny-Carmen (Ref. 9) expression, which relates hydraulic conductivity to porosity, the mean particle diameter of the aquifer material, and the fluid properties (density and viscosity). This relationship was based on an assumed ground water temperature of 15 degrees C and did not reflect changes in the fluid properties with temperature.

Commenters expressed concern with this assumption because ground water temperature is known to typically range in temperature from 4 degrees C to 30 degrees C. A few commenters also expressed concern regarding the validity of using this empirical relationship.

In response to these comments, the Agency generalized the expression to include the effects of changes in temperature on fluid viscosity and fluid density. That is, the fluid viscosity and density are now considered as functions of temperature rather than as constants. The Agency realizes that the hydraulic conductivity also depends on physical properties, such as grain shape, grain size distribution, packing, and tortuosity of the porous media. Porosity measurements reflect the composite result of these textural characteristics on the structural arrangement of the porous media. The range of porosity values derived in EPACML indirectly reflect the impact of these properties. Therefore, in view of the Agency's objective to represent the wide variations expected from site to site, the Agency decided to retain the Kozeny-Carmen equation, except for the modification described above.

vii. Hydrolysis. As already discussed in section III.E.2., the EPACML model accounts for reduction in constituent concentrations due to hydrolysis. This results in higher DAFs for constituents that hydrolyze during transport than for ***11823** constituents that do not. The DAF predicted by the model for some of these constituents ranges up to one million. Thus, in some cases, wastes would not be considered hazardous unless they contain large amounts of these toxicants; still, in other cases, no amount of toxicant in the waste would define it as hazardous under this scenario. Therefore, the Agency did not believe it appropriate to include these constituents in the TC (see Table E-2 for list of constituents that appreciably hydrolyze). Furthermore, the model does not account for the degradation products that are produced as the original constituents hydrolyze. That is, while the decrease in the concentration of the original constituent is accounted for, the resultant increase in concentration

of the hydrolysis products is not. Several commenters stated that the toxicity and transport of the potential hydrolysis products should be considered to fully assess the hazards posed by the constituents that hydrolyze.

The Agency agrees with the commenters and is (1) determining which byproducts result from hydrolysis and (2) developing an appropriate protocol for predicting the concentration of hydrolysis byproducts (see Table E-2). Once this protocol is developed, the Agency will determine whether any of these toxicants should be added to the list of constituents. While the Agency considered including these constituents at a higher dilution and attenuation factor until this work was completed, the Agency does not have sufficient information at this time to determine which of the constituents listed in Table E-2 will eventually be added to the TC and at what level.

Table E-2--Hydrolyzing Constituents Listed in the June 13, 1986 Proposed Rule
Acrylonitrile
Bis(2-chloroethyl) ether
Methylene chloride
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
1,1,1-Trichloroethane
1,1,2-Trichloroethane

viii. Steady-State Assumption. As implemented for today's rule, EPACML was solved for the steady-state condition. Thus, the solution represents the case where leaching has occurred for a period of time that is sufficiently long to allow the concentration at the receptor well to become constant. Several commenters noted that, in certain circumstances, use of the steady-state solution would lead to unreasonably low DAFs. In particular, in situations where the mass of a constituent is relatively low in the source facility (i.e., the landfill has a very limited quantity of the constituent available to contaminate leachate), the steady-state model will continue to assume the existence of a very large quantity of the constituent and, hence, over-predict the resulting concentration at the downgradient well. Under such circumstances, the commenters argue, the Agency should accommodate this phenomenon by using a transient solution in deriving appropriate DAFs.

The Agency agrees with the commenters and has initiated a study to thoroughly investigate the problem described above. Based upon preliminary investigations already complete, however, the Agency continues to believe that application of the steady-state model to many constituents is appropriate and is promulgating regulatory levels for those constituents based upon the results of the steady-state model. The preliminary investigations have also led to a decision to postpone the promulgation of regulatory levels for constituents that are believed to be more appropriately evaluated with a transient solution. The Agency is continuing to refine the approach required to implement the transient solution but results to date suggest that this latter group of constituents require unreasonably large quantities in the source facility to insure that the steady-state solution is appropriate. For example, under some conditions even when the constituents exist at concentrations in excess of 1000 ppm of the solid waste within the entire volume of the landfill, the steady-state condition is not realized. Therefore, based upon the preliminary analysis, regulation of these constituents based upon the DAFs predicted by the steady-state model may not be appropriate.

Preliminary investigation of this condition was completed for all of the originally proposed constituents. All constituents were assumed to exist in the “tested” waste at 1000 ppm. Furthermore, the “tested” waste was assumed to occupy 100% of the available facility capacity (i.e., the “tested” waste is the only solid waste in the facility). As a reasonable worst case scenario, the DAF was derived by the transient model for each constituent under these conditions. Because the above assumptions are very conservative, most of the DAFs derived for the constituents were found to coincide with the steady-state values. That is, sufficient mass was available to insure that steady-state conditions were reached. Accordingly, regulatory levels for these constituents are being promulgated in this rule. For the following constituents, however, the steady-state condition was not achieved under this scenario:

phenol

1,2-dichlorobenzene

carbon disulfide

isobutanol

2,3,4,6-tetrachlorophenol

toluene

Accordingly, the Agency is postponing the promulgation of regulatory levels for these six constituents until such time as the investigations are complete. Once these investigations are completed, the Agency will take the appropriate action.
ix. Biodegradation. The subsurface fate and transport model does not account for biodegradation processes in the subsurface environment. EPA recognizes, however, that biodegradation is an important process that can reduce concentrations under either aerobic or anaerobic conditions. Accordingly, the EPA has constructed the model so that it can theoretically be modified to include these processes for experimentally derived biodegradation rates. Biodegradation processes have not been included because the data bases to support this portion of the model are currently insufficient.

The first major data deficiency is that the model incorporates many diverse subsurface environmental conditions where as constituent-specific biodegradation rate data typically exist for only a few (if any) subsurface environments. EPA also recognizes that although the kinetic equations describing the degradation of hazardous organic chemicals in many environments are available, these equations have not been sufficiently evaluated in the subsurface environment (Ref. 10, 11, 12). Second, the Agency considers data on the formation of transformation products to be insufficient. Third, the key processes that can affect the subsurface biodegradation rate are not well understood. These processes include sorption, pH, temperature, nutrient availability, toxicity, and others. For example, while nutrient levels in the environment are generally considered sufficient for low populations of microorganisms, the microorganic population at which the nutrient availability in the environment becomes a limiting factor is not known. Additionally, while sorption is well understood for hydrophobic compounds at low concentrations (Ref. 13), at concentrations where the compounds can form small droplets or become entrained in the micropores of the ***11824** subsurface matrix, sorption effects are not well understood. The effects of temperature have been characterized in innumerable studies of isolated microorganisms, but the kinetics of these effects have only recently been investigated in environmental samples (Ref. 14). Finally, the toxicity of hazardous chemicals to the microorganisms themselves is only now being investigated (Ref. 15).

Accordingly, the Agency is continuing to gather data to refine the modeling of biodegradation, but has not been able to include biodegradation in the ground water transport model at this time. In this regard, EPA has published guidelines for developing anaerobic microbiological biodegradation rate data for chemicals in the subsurface environment (see 40 CFR 795.54). Results developed under these guidelines will provide data on kinetic rates of degradation, and to a lesser extent, on the effects of pH and temperature on these rates. Similar guidelines have not been developed for aerobic systems at this time. Data developed under 40 CFR 795.54 may be considered for use in the model at some future time.

x. Summary of General Modifications. The Technical Background Document (Ref. 9) describes in detail the model revisions, including options developed but not implemented for the purposes of establishing the regulatory levels for today's rule. A summary of the major model options and procedures implemented for the rule follows:

- The model was run for the steady-state case. The initial condition was a constant concentration. The equations were solved for infinite time.

- The unsaturated zone module was included in the analysis.

- Concentrations can be predicted at wells placed at any position. The wells can be allowed to draw from any selected depth.

- The updated method of computing dispersivities as a function of random longitudinal well locations was used (designated in the model as the “Gelhar procedure”).

- The option implemented for setting the boundary conditions between the unsaturated zone and the aquifer was the one that limits the lateral extent of the plume to the downgradient facility width, computes vertical mixing and dispersion underneath the facility, and estimates the maximum source concentration within the plume based on mass balance requirements. Any combination of conditions that violated these requirements and, thus is not physically realistic, was rejected.

The above options and additional options are listed in the background document for the model (Ref. 9). Specifically, the model input and control variables, as required and accepted by the computer code, are listed for each computer run used to set regulatory levels in today's rule.

By incorporating these modifications, the EPACML, as applied to landfills, models the following basic features:

- The landfills are filled to capacity and covered with native soil.

- Caps are characterized as being in a failed or deteriorated state. Thus, permeabilities are set to be higher than would be typical of landfills with an undamaged cap. It is assumed that liners are not present.

- All wells (exposure points) are considered to be downgradient in every model run. The longitudinal distance parallel to the direction of ground water flow is determined from data described later in section III.E.3.

- Lateral well location is determined by allowing the position to uniformly vary at random within the plume width and with the additional constraint that the location also must be within an area defined by lines at 90-degree angles from the direction of ground water flow at the midpoint of the downgradient boundary of the facility.

- Vertical well location is determined by allowing the position of the well intake point to uniformly vary at random over the entire aquifer depth.

- The landfill storage capacity is assumed to be sufficient to accommodate sufficient mass of each constituent to allow a steady-state condition to exist. This produces an infinite source initial condition.

- Constituents contained within the landfill do not degrade.

- Infiltration rates are represented as annually averaged flows based on 20-year climatic records and concomitant water balance calculations.

b. Use of the EPACML for Surface Impoundments. Because some wastes are managed in surface impoundments rather than landfills, several commenters indicated the need to analyze and include the results obtained by considering a surface impoundment mismanagement scenario. They argued that dilution/attenuation factors (DAFs) generated by modeling a landfill scenario would be too stringent for wastes managed in surface impoundments. Based upon these comments, the Agency decided to investigate whether surface impoundment DAFs would be significantly different from landfill DAFs. EPA requested comment on the use of this data in the August 1, 1988 notice.

Based upon this investigation, the Agency has concluded that the use of DAFs based on a landfill scenario is appropriate in establishing the regulatory levels for wastes managed in surface impoundments. EPA used the EPACML model to confirm this analysis by modeling a surface impoundment mismanagement scenario.

This conclusion is based on the Agency's evaluation of the physical parameters that would lead to different DAFs for surface impoundments than for landfills. A key factor that could lead to differences in the DAFs from these two types of management units (surface impoundments and landfills) is the difference in total leachate infiltration rates. The infiltration rate is equal to the product of the leachate mass flux (mass per unit area per unit time) and the area of the management unit. For surface impoundments, the mass flux can be considerably greater than for landfills. However, to the extent that the area of surface impoundments is typically smaller than the area of landfills (although some atypical surface impoundments can be as large, if not larger than landfills), the effects of the greater leachate flux are somewhat offset. That is, while the flux is greater, the area is smaller, resulting in relatively similar leachate infiltration rates.

A second factor that affects the DAFs is the situation in which the leachate flux is large and the ground water velocity is relatively small. In these situations, a ground water mound may form below the management unit. This effect is more typically associated with surface impoundments because of their higher leachate fluxes; this effect should result in smaller DAFs (and, thus, more stringent regulatory levels) than would be predicted if the mounding did not occur. As a result of these factors, the Agency concluded that DAFs from a surface impoundment scenario would be equivalent to or less than DAFs from a landfill scenario.

To confirm this conclusion, EPA used EPACML to evaluate a surface impoundment scenario. The main features of the surface impoundment scenario, as simulated using EPACML, are as follows:

- The surface impoundments are filled to their fluid capacity and are assumed to operate on a continuous basis.

- Bottom layers are characterized as being in a more permeable state (typically ten times greater) than those found in field studies.

- Location rules for downgradient well positions and lateral and vertical ***11825** locations are identical to landfills. The data base for longitudinal distances is different, however.

- The operating life of the surface impoundment is assumed to be sufficient to accommodate a sufficient mass of constituent to allow a steady-state condition to exist. This assumption produces an infinite source initial condition.

- The leaching rate from a surface impoundment depends on, among other factors, the ponding depth in the impoundment and the characteristics of the bottom materials. The Hydrologic Evaluation of Landfill Performance (HELP) model used in evaluating the landfill data is inadequate to determine the leaching rates from surface impoundments. Therefore, the leaching rates from subtitle D surface impoundments were estimated by considering the relationship between the velocity in the vertical direction and the substrate's porosity and permeability and the solution of the nonlinear steady state flow problem. To be conservative, the Agency used a permeability value ten times higher than the value typically reported in field studies as an input for calculating leaching rates (the source of these data are discussed below).

- The Agency has not yet conducted a detailed survey for subtitle D surface impoundments, but the Agency conducted a review and analysis of data on subtitle D units in RCRA Facility Assessment (RFA) Reports (Ref 16). A set of data on subtitle D surface impoundments was obtained from this analysis and used as inputs to the EPACML. Additional data were compiled from aerial photographs by EPA's Environmental Photographic Interpretation Center (EPIC).

- The data extracted from RFSs included the area of the surface impoundments and the distance to downgradient drinking water wells as determined by EPIC.

- The ponding depth data for the subtitle D surface impoundments were reported by E. C. Jordan (Ref. 9). The hydraulic conductivity of the bottom materials was chosen as 1.0 E-6 cm/sec. This value reflects the effect of gradual settlement and compaction of sediments at the bottom, because surface impoundments tend to fill up with sediments over a period of about 20 years or so. The Agency believes that the hydraulic conductivity value of 1.0 E-6 cm/sec represents a reasonable worst-case value. These values were used in conjunction with EPACML to estimate DAFs for the surface impoundment data.

As expected, DAFs predicted for surface impoundments are somewhat smaller than the corresponding values for landfills (see section III.E.4). However, because the EPACML does not incorporate the mounding effect, the surface impoundment evaluation was restricted to include only those cases where mounding would be minimal and, thus, reasonably ignored. As a consequence of limiting the evaluation to these cases, the modeling results tend to omit some worst case scenarios. That is, if all possible cases were included, rather than just the “no mounding” cases, the DAFs for surface impoundments could be somewhat lower and, thus, the downgradient concentrations may be higher than those estimated by the EPACML model. The Agency thus believes that the omitted surface impoundment conditions should be further investigated and may result in more stringent regulatory levels. The Agency believes, however, that the DAFs produced by the EPACML analysis properly delineate wastes that are clearly hazardous wastes.

3. Newly Acquired Data

As previously described, the DAFs proposed on June 13, 1986, were calculated based on the subtitle D landfill scenario. However, subtitle D landfill data were not available to the Agency at that time, and instead, subtitle C landfill data were used.

Several commenters criticized the use of subtitle C (hazardous waste) landfill data. The Agency agreed with the commenters and has based the final rule on data from a survey of solid waste subtitle D landfills.

a. Landfill Data. The Agency conducted a survey of municipal solid waste landfills in the U.S. (Ref. 6). The survey used a stratified design based on facility size. The results were tabulated based on 1,102 completed questionnaires. The survey yielded data on area of landfills, distance to the nearest downgradient drinking water wells, and thickness of the unsaturated zone. These data are site-specific, corresponding to individual solid waste landfills located throughout the United States. The survey data were analyzed to develop distributions of these site-specific parameters and used as inputs to EPACML, as described in the model background document (Ref. 9). The input frequency distributions are also presented in the background document.

EPA also collected additional data on leachate generation at municipal landfills. EPASMOD requires, as input, the leachate distribution from the bottom of the landfill. The leaching rate distributions for the June 13, 1986, proposal were based on the use of a single soil type, loam, as the cover soil for the landfill. These distributions were estimated using climatologic data for a total of 30 cities nationwide, representing the median range for each of 18 climatological conditions or zones identified in the 48 contiguous states.

The assumptions of a single soil type and 18 climatic zones were criticized as not being realistic and resulting in an overly optimistic cap performance. The commenters suggested enhancing the data base by including simulation of different soil covers.

In response to these comments, the Agency has implemented a number of changes. The Agency believes that these modifications significantly improve the validity of the leachate flux distribution and make it more realistic.

Soil Type

The Soil Conservation Service (SCS) has a county-by-county soil mapping program underway. More than 90 percent of the land area in the U.S. has been mapped, and soil data representing approximately 51 percent of the total land area in the U.S. have been entered into a computer data base. Using this data base, the soil classifications were grouped according to the U.S. Department of Agriculture's definitions of coarse, medium, and fine textures. These three categories are represented in EPACML by soils equivalent in properties to sandy loam, silt loam, and silty clay loam for the landfill cover materials. The latest results show that coarse grained soils, medium grained soils, and fine grained soils represent 15.4, 56.6, and 28.0 percent, respectively, of the soils that have been mapped thus far.

Climatic Zones

The number of cities representing climatic variations that were used to develop frequency distributions for the leachate generation has been increased from 30 to 100. The reason for this change was to reduce the chance that any one city would provide an unrepresentative percolation rate in its climatic range.

The climatic data base used in EPACML was enhanced to include six precipitation ranges and five ranges of pan evaporation rates, thereby resulting in 30 climatic ranges as opposed to the 18 described in the earlier proposal. For the climatic ranges so defined, the percentage of the area of the 48 states represented by each range was calculated, and the percent areal average was used to weight the percolation (recharge and/or infiltration) rate estimated for the selected cities in each range according ***11826** to probable relative occurrence in the U.S. The effect of these changes is to provide more representative values of the overall national distribution of the leachate flux.

After the percolation data for the landfill were calculated using the HELP model (Ref. 9), the climatic ranges were further subdivided to account for wide variations in percolation within a range. This resulted in separate subranges being established for some California cities (Los Angeles, Sacramento, San Diego, and Santa Maria), and two Oregon cities (Medford and Astoria).

Percolation rates for each of the selected cities in the 48 contiguous states were determined using silt loam, sandy loam, and silty clay loam cover soils. These soils, based on data obtained from the SCS, appear to represent the most common soil types in the U.S., and thus the most common soil to be used as covers for landfills. They also span the range of likely cover soils, from fine-grained to coarse-grained, or from low to high percolation rates. Simulations were performed for each of these soil types, and the results weighted according to the frequency of occurrence for each type.

The leaching rate flux was determined by using the average, weighted percolation rate from the cities in each climatic range. The model background document (Ref. 9) presents the data used and the accompanying changes to the June 13, 1986 proposal runs.

b. Chemical-Specific Parameters. In the EPASMOD proposal, chemical parameters, such as hydrolysis rates, were used to calculate the relative retardation factors and degradation rates for selected compounds. Some of the chemical-specific parameters used in that model were estimated based on a brief review of the existing chemical data. Some commenters criticized some of the parameter values selected and used for that proposal as being nonrepresentative of the range of parameter values.

The Agency has an ongoing program for the measurement of constituent-specific parameters and for the review of new constituent-specific data as reported in the current scientific literature. Some hydrolysis rate constants and octanol-water partition coefficients used in the proposal have been revised to reflect the most recent laboratory measurements and recent values reported in the literature. The updated parameter values are given in the background document (Ref. 9) and represent either measured or best available values.

4. DAF Evaluation

a. Selection of an Appropriate Percentile. As described earlier, the EPACML was used to investigate the expected range of DAFs associated with mismanagement of solid wastes. As generated by EPACML, the DAF represents the expected reduction in the concentration of a constituent during transport through soil and ground water from the leachate release point (bottom of the waste management unit) to an exposure point (a well serving as a drinking-water supply). The wide range of possible environmental settings (e.g., ground water velocities, pH, temperatures, etc.) and the multitude of possible scenario configurations (e.g., facility area, distance to downgradient wells, etc.) result in an extremely wide range of DAFs. Monte carlo simulation was used to implement EPACML, and the resulting cumulative frequency distribution can be viewed as a ranked order of increasingly higher downgradient concentrations expected from the “best-case” situations (large DAFs) to the “worst-case” situations (small DAFs) for the scenario being investigated.

The Agency's proposed approach was to define DAFs representative of reasonable worst-case conditions as those corresponding to the 85th percentile of the cumulative frequency distribution. The Agency received numerous comments on the selection of the 85th percentile, which are addressed in Section d, following.

b. Resulting DAFs for Landfills. The DAF values corresponding to various cumulative frequency levels for landfills are as follows:

Percentile	80	85	90	95
All nondegrading constituents	328	134	47	12
Chloroform [FN1]	385	152	52	14

1 The DAFs for chloroform are slightly higher than for the other nondegrading constituents because chloroform is expected to hydrolyze slightly during transport.

The similar DAF values for nondegrading constituents and chloroform arises because all these constituents either do not degrade at all or only degrade slightly.

c. Resulting DAFs for Surface Impoundments. The DAF values corresponding to various cumulative frequency levels for the surface impoundment investigations described in E.2.b of this section are as follows:

Percentile	80	85	90	95
All nondegrading constituents	226	111	51	19
Chloroform	227	111	52	19

As with the landfills, the constant DAF for all constituents reflects the fact that nondegraders and very slow degraders have virtually identical environmental fate for the scenario investigated. As the resulting numbers indicate, within a reasonable degree of accuracy, the DAFs for waste managed in surface impoundments are equivalent to the corresponding landfill DAFs.

d. Final DAF Selection. The Agency's purpose in developing dilution/attenuation factors (DAFs) is to identify wastes whose leaching behavior indicates that they may pose a hazard to human health unless they are controlled under subtitle C management standards. Thus, the Agency developed a subsurface fate and transport model that simulates a subtitle D management unit (i.e., a municipal landfill) and the subsurface environment that would be encountered by toxic constituents as they migrate from the management unit to a drinking-water well. In order to make the model's output (DAFs) as realistic as possible, the Agency implemented the model using real-world distributions for parameter values (e.g., areas of landfills, properties of the subsurface environment, etc.) whenever possible. The monte carlo structure of the simulation allowed the modeling results to be presented as a cumulative frequency distribution or probability. That is, the model expresses the probability that a toxic constituent disposed of in a municipal solid waste landfill will undergo certain dilution/attenuation as it moves through a subsurface environment to an exposure point. Thus, there is a different DAF for each selected probability.

In its June 13, 1986 proposal notice, the Agency proposed the use of the DAF corresponding to the 85th percentile cumulative frequency level and requested comment on the use of other percentile levels. Comments were received urging the use of both higher and lower levels. Recommendations for using the 80th percentile cumulative frequency were justified by assertions that the assumptions used in the model were already unduly conservative. One commenter noted that EPA could still rely on the listing program to regulate wastes whose leachate concentrations would not exceed the regulatory levels derived from the lower percentile DAF but that are still considered hazardous. ***11827** Other commenters argued that the 85th percentile was not adequately protective of human health and the environment. One commenter, claiming that assumptions in the model were not conservative enough, recommended that the 95th percentile be used.

In selecting the appropriate level, the Agency recognizes that there is no consensus “correct” level for interpreting modeling results. This has resulted in a particular challenge in developing today's rule, wherein a quantitative approach is being used

for guidance in answering what is a partly qualitative question—namely, “what is the human health impact of unregulated management of certain types of wastes in a ‘reasonable worst-case’ disposal scenario?” While the Agency believes that the 85th percentile is an appropriate choice to represent a reasonable worst-case result, consideration of the relationship of the 85th percentile DAF to other percentile DAFs is also appropriate. That is, the Agency believes that the behavior, or shape, of the upper portion of the cumulative frequency distribution curve should also be evaluated in order to determine how critical the selection of a particular frequency level is to the DAF.

Another consideration in determining the appropriate DAF value, independent of the selected cumulative frequency level, is the accuracy inherent in the data set used. Given that there is some uncertainty associated with any data set used to represent possible values for any parameter, and that the model requires values for many parameters, the Agency believes that the selected DAF value should not imply an undue degree of accuracy.

After considering the above factors, the Agency has concluded that a DAF value of 100 is appropriate for establishing the regulatory levels for the constituents included in today's rule.[FN1] First, the Agency believes that, considering the number of parameters for which distributions of values were established (in order to represent a “generalized” scenario), a DAF with an order-of-magnitude precision is appropriate.[FN2] Second, in selecting this DAF value of 100, the Agency noted that the 80th and 90th percentile DAFs, as well as the 85th percentile DAFs, indicate that constituents migrating in the modeled disposal scenario will be diluted by approximately two orders of magnitude. This is also true of the predicted DAFs from the data used for surface impoundments. Thus, EPA believes that a DAF data used for indicating dilution by two orders of magnitude (i.e. 100) is appropriate. Moreover, as the data indicate, on an order-of-magnitude scale, the predicted DAF is not extremely sensitive to the exact cumulative frequency value that was selected.

The Agency points out that the considerations leading to the use of 100 to represent the model-predicted dilution/attenuation factors are unique to today's promulgation. In other cases, different conclusions may be more appropriate. For example, when parameter values can be more narrowly defined (as in site-specific evaluations), the higher degree of precision may be appropriately ascribed to the model-predicted DAFs. Likewise, where the program goals are different (i.e. other than to identify levels that are indicative of wastes that clearly are hazardous), the selection of a value that represents a cumulative frequency value other than the 85th percentile may be warranted.

F. Toxicity Characteristic Leaching Procedure (TCLP) (Method 1311)

1. Introduction

The development of the TCLP and the role of the test in identifying a waste as hazardous were discussed at length in the June 1986 proposal (51 FR 21648). Today, EPA is promulgating the TCLP, with some improvements and modifications, as a replacement to the EP for use in the identification of hazardous waste. (The revised TCLP is promulgated in Appendix II to 40 CFR part 261 and has been designated as EPA Method 1311 and will be incorporated in “Test Methods for Evaluating Solid Waste Physical/Chemical Methods—SW-846”.)

The Agency received numerous comments in response to the Federal Register notices (51 FR 1602, 51 FR 21648, 51 FR 24856, 51 FR 33297, 51 FR 40593, 51 FR 40643 and 53 FR 18792) related to the TCLP procedure. ln particular, EPA received close to 140 comments on the application of the TCLP in response to the June 1986 proposal. The comments covered general issues such as the relationship to the EP, the adequacy of research supporting TCLP development and specifically, the statistical treatment of data. Commenters also addressed technical issues including the suitability of the zero head space extraction (ZHE) vessel; the types of filters, reagents, and leaching media; the quality assurance requirements; and the multiple extraction and oily waste extraction procedures. In addition, comments were received on the use of quantitation limits for establishing regulatory levels. All the comments were categorized and summarized by issue and are presented in the technical background document along with the Agency's response to these comments (Ref. 4).

In this preamble, only certain comments are discussed, which include (a) the applicability of the TCLP to specific types of waste (i.e., solidified wastes); (b) the analytical difficulties encountered during the analysis of the TCLP extract for phenolic compounds and phenoxy acid herbicides; and (c) the use of quantitation limits. The first two comment issues are presented below while the last comment and the Agency's response is given in section IV.C. of this preamble.

2. Adoption in the LDR Rulemaking and Modification from the Proposed Rule

The TCLP was promulgated in Appendix I to 40 CFR part 268 on November 7, 1986 (51 FR 40593), as part of the Land Disposal Restrictions Rule for Solvents and Dioxins. The TCLP is used in the Land Disposal Restrictions (LDR) program to determine whether certain wastes require treatment prior to land disposal and to determine whether certain treated wastes meet the applicable treatment standards. In today's rule, the Agency has incorporated two other clarifications to the TCLP as proposed on May 24, 1988 (53 FR 18792) for use in both the LDR and the TC programs.

The Agency modified the proposed TCLP as a result of the Agency's own research and comments received on the January 14, 1986 (51 FR 1602) proposal for the LDR program and the June 13, 1986 (51 FR 21648) proposal for the TC. These modifications to the TCLP were promulgated on November 7, 1986 for the LDR program. On May 24, 1988, the Agency proposed additional modifications to the TCLP for both the LDR and the TC. In today's rule, the Agency has adopted two of these proposed changes, and is promulgating the revised TCLP for use in both the LDR and TC programs.

***11828** The first change is the insertion of a more detailed method flow chart to explain how analysts are to perform the test. Comments expressed confusion regarding the original flow chart (e.g., that it was difficult to follow), so the Agency has added this new chart to eliminate confusion. The second change is the addition of new equipment suppliers to provide more information on the availability of suitable testing equipment. The new equipment suppliers include two manufacturers of rotary agitation devices, Environmental Machine and Design, Inc., of Lynchburg, VA, and Millipore Corporation of Bedford, MA; two manufacturers of a zero-headspace extractor (ZHE) vessel, Lars Lande of Whitmore Lake, MI and Environmental Machine and Design, Inc., of Lynchburg, VA; and three manufacturers of filter media, Millipore Corporation of Bedford, MA; Nucleopore Corporation of Pleasanton, CA; and Micro Filtration Systems of Dublin, CA. These manufacturers are listed in Tables 2, 3, and 5, respectively, of the method (i.e., Appendix II of 40 CFR 261), along with company telephone numbers and equipment model numbers.

Another more substantial proposed modification, the addition of a stainless steel cage insert to the bottle extractor, will not be added by the Agency at this time for the reasons discussed below. The Agency had proposed this modification to eliminate the requirement for particle size reduction for certain types of wastes (e.g., solidified materials).

3. Applicability of TCLP to Solidified Wastes

Some commenters expressed reservations regarding the applicability of the TCLP to specific types of wastes. The wastes of concern were solidified wastes. Numerous commenters supported the reinstatement of the structural integrity procedure (SIP) or some other stability criterion for solidified wastes. They argued that particle size reduction (i.e., “grinding”) would be inappropriate in those instances where solidification of the waste is needed to meet the best demonstrated available technology (BDAT) provisions of the law and that grinding may not adequately represent the weathering process or the effect of vehicular traffic. Commenters recommended that the Agency retain the SIP. Others agreed that particle size reduction is inappropriate for stabilized monolithic wastes and produces unrepresentative results. Specifically, commenters stated that particle size reduction alters the physical character of many solidified wastes by destroying the cementitious property of these wastes in such a way that the leaching rate increases unrealistically. By increasing the surface area that is available to attack by a leaching medium, the amount and rate at which substances may be leached increases. Inasmuch as waste grinding is not normally employed in municipal landfills, particle size reduction renders the TCLP a less accurate model of leaching in a municipal landfill environment.

Since the June 13, 1986, proposal, the Agency has reviewed the use of the SIP, which uses a drop-hammer to test the integrity of the waste and to reduce its size if it fractures. The Agency found that although the SIP may simulate the potential of a monolithic waste to be degraded by vehicular traffic on a landfill, it cannot address certain other stresses acting on the waste (e.g., wet-dry and freeze-thaw cycles). In addition, the SIP can only be used for wastes that can be prepared in a sample of specified dimensions.

While evaluating the use of the SIP, the Agency found that dense, hard materials would occasionally break the glass extractor bottle. To prevent breakage of the bottles, the Agency developed a cage insert for the extractor bottle. The cage, which is designed to prevent contact between the hard sample and the sides of the bottle, is constructed of 0.25-inch stainless steel woven mesh. Experiments have shown that the use of the cage prevents bottle breakage.

While evaluating the utility of the cage, the Agency noticed that wastes that were believed to be well-solidified retained their monolithic nature in the cage during extraction, whereas wastes that were believed to be less well-stabilized (even though some of them had passed the SIP) were broken into small pieces during the extraction. Thus, these experiments led to the proposed use of the stainless steel wire cage in the extraction apparatus (53 FR 28792, May 24, 1988). The use of this device, the Agency believed, tested the physical integrity of the sample and reduces particle size appropriately.

Commenters expressed support for the cage modification—that it is a step in the appropriate direction toward a more realistic assessment of the environmental leaching potential of a solidified waste. However, commenters also had concerns that the cage was proposed prematurely—that not enough evaluation of waste samples using the cage had been done. Specifically, commenters argued that the cage could possibly leach significant quantities of nickel and chromium to contaminate metals analysis; that it would be difficult to collect representative samples in some cases; that there were problems with the configuration of the cage so that it could not be accommodated to fit a large array of bottles; that the cage's construction provided numerous crevices and a significant amount of surface area for waste residue to collect, making effective cage cleaning difficult; and that solidified samples could be molded into a shape that would cause less material to be sloughed off during extraction, leading to a less aggressive test. The Agency agrees with these commenters and has decided not to go forward with the cage modification at this time. The Agency currently has work underway to evaluate all these concerns, and will continue to evaluate modifications of the TCLP and will propose further improvements as they are developed.

4. Analytical Methods

Several comments addressed the analytical difficulties of analyzing the TCLP extract for phenolic compounds and phenoxy acid herbicides by gas chromatography/mass spectroscopy, SW-846 Method 8250 (GC/MS). These analytical difficulties include the interference of the acetate ion in the TCLP leach fluid with the column packing material of Method 8250. Removal of the acetate ion is often difficult, and equipment damage may result if the acetate is not removed (i.e., the acetate ion can destroy the column packing material).

The Agency agrees that analysis for acidic compounds by GC methods may be difficult, but not impossible. The Agency suggests the use of a bonded-phase capillary column (Method 8270) to reduce the interference from acetate. In addition, the Agency is investigating other methods for removal of the acetate ion from the extract before analysis for the phenolics and herbicide and welcomes alternative suggestions, especially when accompanied by supporting data.

The Agency had suggested the use of HPLC as an alternative to GC/MS analysis of phenolics and phenoxy acid herbicides. However, several commenters believed that an HPLC method is generally regarded as more expensive and not as readily available as GC/MS. In addition, some commenters indicated that GC/MS is a better method analytically than HPLC, and that HPLC would be more difficult to implement. The commenters expressed that, at the very least, a lengthy verification process would be ***11829** required to determine an HPLC method's ruggedness and reproducibility and to determine the most effective cleanup steps. The commenters further suggested that even if an effective HPLC cleanup procedure is developed and approved by the Agency, it is bound to increase the analytical costs and slow down the analytical throughput. Even without considering this restriction, the procedure of leaching the organics into an aqueous medium, followed by extraction, recovery,

and concentration, is bound to require more manpower and thus more money than a more direct solvent extraction of the solid itself. The commenters indicated that methods for analyzing solid waste for semi-volatile organics and phenoxyacid herbicides are already described in SW-846 and should be the preferred methods, both for practicality and as a way of providing a reliable test.

The Agency agrees that the GC/MS or GC/electron capture (GC/EC) analysis is more advantageous for the analysis of phenolics and phenoxy acid herbicides because the equipment is more readily and widely available than HPLC, despite the associated difficulties. HPLC methods for phenolic compounds are not included in the third edition of SW-846 because of a lack of validation data. The Agency will allow only the use of the GC/MS method until such time that the Agency proposes an HPLC method.

G. Testing and Recordkeeping Requirements

1. Existing Requirements for Generators

Under existing regulations, persons who generate solid waste are not specifically required to test their wastes to determine whether they exhibit the characteristic of EP toxicity or any other characteristic. Instead, solid waste generators are required to make a determination as to whether or not their wastes are hazardous (40 CFR 262.11).

If a waste is found to be excluded from regulation under § 261.4, or if it is found to be a listed hazardous waste under subpart D of 40 CFR part 261, no further determination of hazardousness is necessary. On the other hand, if a waste is neither excluded nor listed, the solid waste generator must determine whether it exhibits any of the hazardous waste characteristics in subpart C of 40 CFR part 261. This determination may be made by either testing the waste or applying knowledge of the waste, the raw materials, and the processes used in its generation.

If a waste is determined to be hazardous, the generator must keep records establishing the basis for that determination (40 CFR 262.40(c)). These records must be maintained for at least 3 years after the generator no longer handles the waste in question. Neither of these recordkeeping requirements, however, applies to solid waste generators who do not generate hazardous wastes.

Other provisions in the hazardous waste regulations make generators responsible for knowing the properties of their wastes and for documenting that knowledge. For example, generators who declare that their wastes are hazardous must nevertheless have sufficient knowledge of their wastes to complete the Uniform Hazardous Waste Manifest, to use proper labels, containers, and placards, and to satisfy all applicable reporting and recordkeeping requirements (see 45 FR 12728, February 26, 1980). In addition, all generators of hazardous waste are required under 40 CFR part 268 to determine whether their wastes are restricted from land disposal.

2. Changes Considered

In the June 13, 1986 proposal, EPA expressed concern that the current system for determining whether a solid waste is hazardous may be inadequate to ensure that wastes are characterized properly as hazardous or nonhazardous. Because of the importance of accurate hazard determinations to the RCRA subtitle C program, the Agency discussed the possibility of requiring solid waste generators to test their wastes periodically.

In the proposed rule, EPA identified three general approaches that might be adopted in the TC final rule. In the first approach, the Agency would retain the current approach, allowing generators to rely on their knowledge of materials and processes used in generating wastes as a basis for their determination. In the second approach, EPA would require the testing of wastes, at a frequency specified by regulation. Finally, in the third approach, the Agency would require testing but without specifying a particular testing frequency. Under this third approach, generators would be required to develop an appropriate testing frequency, based on Agency guidance, and to document the basis for their choice.

Commenters were heavily divided on the issue of testing and recordkeeping requirements. Many commenters, including waste management firms and a few generators, favored mandatory testing of solid wastes. Most of these commenters argued that generators typically lack sufficient information to determine accurately the composition of their wastes without testing. Indeed, one commenter claimed that with 52 constituents regulated at the part-per-million level or lower, a generator could never be sure whether a waste exhibits the TC without performing the TCLP test. The commenters concluded that testing is the only reliable method for ensuring that potentially hazardous wastes are properly identified and managed.

A few commenters offered somewhat different reasons for supporting testing requirements. For example, some commenters pointed out that mandatory testing would facilitate EPA enforcement efforts. Others claimed that mandatory testing would reduce uncertainty by making it clear to generators precisely what EPA expects of them with respect to performing hazardous waste determinations.

Another group of commenters, however, opposed the imposition of a formal testing requirement. These commenters argued that mandatory testing would place an inordinate burden on the regulated community without providing significant benefit for human health and the environment. In particular, the commenters claimed that mandatory testing is unlikely to identify wastes that were improperly characterized as nonhazardous when generators relied exclusively on their knowledge. According to these commenters, generators rely on their knowledge only when the wastes they produce are clearly hazardous or clearly nonhazardous. Whenever uncertainty exists, these commenters stated, generators either declare their wastes hazardous or perform appropriate tests. The commenters emphasized that this cautioned response results from generators' liability for making incorrect determinations, regardless of whether they test their wastes. The commenters concluded that requiring testing of all wastes would deplete resources and place a strain on limited laboratory capacity.

The Agency recognizes that there are many difficult issues related to the imposition of a testing requirement, both for the Toxicity Characteristic and the other hazardous waste characteristics. While the Agency believes that a testing requirement could improve the Agency's enforcement tools, the Agency believes that the current requirements for hazardous waste determinations are not ineffective because many generators do have sufficient knowledge to make a determination without a test. The Agency further believes that liability for incorrect determinations provides a strong incentive for not misclassifying hazardous wastes as non-hazardous. Although EPA thinks that the current ***11830** system set forth in 40 CFR 262.11 is effective, the Agency believes that imposing a testing requirement does have some merit, in that it could increase the accuracy of determinations, could clarify the responsibilities of generators, and could facilitate compliance monitoring.

The Agency will continue to evaluate the comments on this issue as well as explore other options for a testing requirement. At present, however, the Agency is not yet ready to go forward with a testing requirement based on any of the options it has evaluated thus far. Should the Agency decide that an appropriate approach is available, it will propose and solicit comment upon the details of that approach in a separate rulemaking. In the meantime, the Agency believes that the existing determination requirement (as specified at 40 CFR 262.11), as well as the liability for incorrect determinations, is effective and practical.

H. Applicability to Wastes Managed in Surface Impoundments

As discussed above, in response to the proposed TC, EPA received many comments questioning the validity of applying the TC to wastes, including wastewaters, likely to be managed in surface impoundments. In response to commenters' concerns, on May 18, 1987, EPA published a Supplemental Notice of Proposed Rulemaking in the Federal Register, which requested comments and data on several issues related to the regulation of wastes managed in surface impoundments under the TC rule. The Agency also requested comment (assuming such an approach) on: (1) The criteria to be used to determine whether the surface impoundment scenario should apply to a particular waste, (2) the point at which concentration measurements should be made (e.g., at the point of generation or within the impoundment), and (3) how multiple surface impoundments should be handled under the TC rule.

Comments received in response to the notice concerning the surface impoundment management scenario are summarized and addressed in section III.A.2.c. Comments received in response to the notice, which addressed sampling point and multiple impoundment issues, are discussed below.

1. Sampling Point

In the May 18, 1987 notice, EPA requested comments on whether evaluations of wastes managed in surface impoundments should be based on measurements of the concentration in the impoundment or at the inlet to the impoundment. In response, some commenters supported sampling at the inlet to the impoundment and stated that sampling the waste within the impoundment is not only contrary to Congressional intent, but conflicts with EPA's own regulations that require the determination of hazard to be made at the point of generation.

Other commenters, however, argued that wastes should be sampled within the impoundment or that the impoundment effluent should be sampled. Many of these commenters argued that measuring the concentrations in the impoundment more accurately represents the concentrations of hazardous constituents that pose a threat to ground water. Some commenters argued that evaluation of hazard should be based on impoundment effluent because concentrations of the wastewaters within the impoundment are approximately the same as the concentrations in the impoundment effluent.

If the Agency were to allow persons to make their determinations on the waste in the impoundment, it would raise questions that the Agency has not yet evaluated completely nor taken comment on. For example, in this situation, should the Agency actually require testing; if so, how often and what should be tested? Would such a result allow persons to land dispose of wastes that (but for the point of hazard determination) would be hazardous, contrary to Congressional intent? Would such a result allow persons to treat wastes without a permit and thus be inconsistent with Congressional intent? EPA concedes that, for some activities (e.g., closure), leachate quality may be more appropriately assessed by measuring concentrations at multiple sites within the impoundment.

The current rules require that the determination of whether a waste is hazardous be made at the point of generation (i.e., when the waste becomes a solid waste). (A waste must be a solid waste before it can be classified as a hazardous waste under RCRA.) EPA believes that determination of the regulatory status of a waste at the point of generation continues to be appropriate, especially since the Agency is not developing a separate mismanagement scenario or set of regulatory levels for wastewaters. To be consistent with other hazardous waste regulations and until the Agency addresses the above questions, EPA is retaining the existing approach of requiring sampling at the point of generation.

2. Multiple Surface Impoundments

In the May 18, 1987 notice, EPA requested comment on how multiple surface impoundments or “treatment trains” should be handled under the TC rule. Some commenters favored regulating all surface impoundments in a treatment train as a single unit—if the first impoundment treats a hazardous waste, all impoundments would be required to comply with the RCRA regulations for hazardous waste treatment facilities. Other commenters, however, suggested that each impoundment should be regulated individually. Still other commenters stated that owners and operators should be required to determine whether the most upstream surface impoundment is treating wastes that exhibit the TC, but they should only be required to evaluate downstream impoundments if an upstream impoundment exhibits the TC.

As discussed above, the Agency has decided not to develop a separate regulatory scheme for surface impoundments. Thus, the Agency will continue to regulate all surface impoundments as individual units and will not pursue any of the other options discussed by commenters. Currently, under 40 CFR part 261, each surface impoundment in a series of multiple surface impoundments is regulated separately. If a surface impoundment receives or generates a hazardous waste, the owner or operator of the impoundment is required to comply with the RCRA regulations governing hazardous waste treatment, storage, and disposal facilities. On the other hand, if a downstream impoundment is not treating or generating a characteristically hazardous

waste and upstream units have not managed, listed wastes, then the downstream unit is not subject to RCRA subtitle C requirements.

I. Relationship to Other RCRA Regulations

1. Hazardous Waste Identification Regulations

a. Hazardous Waste Listings. Under the June 13, 1986, proposal, the hazardous waste listings in subpart D of 40 CFR part 261 would not be affected. All the listings would remain in effect, including those listings that were based on the presence of TC constituents. It is EPA's intention that the hazardous waste listings would continue to complement the revised TC as they had the EPTC.

A number of commenters, however, argued that the TC should supersede certain hazardous waste listings. In ***11831** particular, they suggested that the TC should be the only basis for regulating wastes that have been identified as hazardous solely because of the presence of a TC constituent. Such an approach, according to the commenters, would establish a more rational basis for identifying hazardous wastes. Wastes failing the TC test would be regulated as hazardous wastes, whether or not they have previously been listed, because they have demonstrated the potential to pose a threat to human health and the environment. Wastes passing the TC test, in contrast, would not be subject to subtitle C regulation. The commenters claimed that, by definition, if the extract from a waste that was listed because of the presence of a TC constituent does not contain the constituent in a concentration greater than or equal to the regulatory level, the waste can safely be managed at a subtitle D facility.

EPA does not agree that the TC revisions justify elimination of any of the hazardous waste listings. The Agency has consistently maintained that individual waste streams may be listed regardless of whether the waste is defined as hazardous by the TC. Exhibiting a characteristic can constitute the basis for listing a waste. In fact, prior to today's action, approximately 25 listings were based on the presence of metals or pesticides covered by the EPTC.

There are a number of reasons for continuing this approach. First, listed wastes frequently contain hazardous constituents other than the ones cited in Appendix VII of 40 CFR part 261 as the basis for the listings. It is for this reason that Congress directed EPA, in evaluating delisting petitions, to consider constituents other than those for which the wastes were listed, assuming that there is a reasonable basis to believe that such constituents might render the wastes hazardous (see RCRA section 3001(f)). In many cases, the additional hazardous constituents that are present in a waste may not be on the list of TC constituents. The listings may therefore serve to identify wastes that pass the TC test but are nevertheless hazardous. Removing wastes from a hazardous waste listing without an evaluation of additional constituents would appear to be inconsistent with the intent of section 3001(f).

Another reason for retaining the hazardous waste listings is that TC constituents may continue to pose a threat to human health and the environment even when they are present in concentrations lower than the regulatory levels. The regulatory levels have not been designed to address the problems of phytotoxicity, aquatic toxicity, or bioaccumulation potential. Moreover, they have not been designed to identify the full range of wastes that may be toxic to human beings. Instead, the characteristic levels have been established at concentrations where there is a high degree of certainty that any wastes with constituents at levels equal to or exceeding the regulatory levels pose a potential threat to human health. Individual wastes may continue to be hazardous, despite the fact that they may contain TC constituents in concentrations below the regulatory levels. This is particularly true for wastes that have the potential to be exposed to more aggressive leaching conditions than those modeled in the TCLP. As a result, EPA believes that wastes previously listed as hazardous should continue to be considered hazardous, whether or not they exhibit the characteristic.

b. “Mixture” and “Derived From” Rules. Because the TC will not supersede the listings for hazardous wastes, it also will not affect the regulatory status of wastes that are hazardous by virtue of the “mixture” rule of 40 CFR 262.3(a)(2)(iv) or the “derived from” rule of 40 CFR 261.3(c). The “mixture” rule provides that any mixture of a listed hazardous waste and a solid waste is

itself a RCRA hazardous waste.[FN3] The “derived from” rule states that any waste derived from the treatment, storage, or disposal of a listed hazardous waste is hazardous.

Several commenters contended that the current regulatory scheme encompasses wastes that contain de minimis quantities of leachable organic chemicals. The commenters acknowledged that mixtures and treatment residues posing insignificant threats to human health and the environment may be excluded from regulation through the delisting process. However, they claimed that delisting is unduly expensive, time-consuming, and, in some cases, impractical. The commenters suggested as an alternative that mixtures and treatment residues from listed wastes containing TCLP constituents not be considered hazardous unless they fail the TC test. They contended that this approach would adequately protect human health and the environment. Moreover, it would be “self-implementing,” in the sense that it would eliminate the need for the current process of petitions and Agency review for delisting.

EPA recognizes that the “mixture” and “derived from” rules may create some inequities by including wastes that contain very small amounts of hazardous wastes that have been mixed so as to render them nonhazardous. However, the Agency has consistently maintained that the mixture and derived from rules are an appropriate regulatory approach for dealing with waste mixtures and treatment residues.

When the rules were promulgated in 1980, EPA stated that it was essential to regulate waste mixtures to prevent generators from evading subtitle C requirements by simply co-mingling listed wastes with nonhazardous wastes. The Agency also determined that because of the infinite potential combinations of listed wastes and other wastes, it was unable at that time to devise any workable, broadly applicable formula that was capable of distinguishing between hazardous and nonhazardous mixtures. The Agency acknowledged that the “mixture” rule might be overly broad, but noted that generators could avoid any inequities either by segregating their wastes or by obtaining a waste-specific exclusion under the delisting program (see 45 FR 33095, May 19, 1980).

EPA also believed that it was important to regulate wastes from the treatment, storage, or disposal of listed hazardous wastes on the basis that these “derived from” wastes might themselves be hazardous. Once again, however, the Agency found that because of the large number of listed wastes and treatment processes (some of which introduce new hazardous constituents into the treatment residues), it was unable to prescribe standards that could properly distinguish between hazardous and nonhazardous residues. (It should be noted that the definition of treatment is not confined to rendering a waste non-hazardous, but also includes any method designed to change the nature of a waste to render the waste (1) less hazardous; (2) safer to transport, store, or dispose; (3) amenable for recovery; or (4) reduced in volume (see 40 CFR 260.10).) Therefore, the Agency concluded that wastes generated during the treatment of listed wastes should be presumed to be hazardous. Delisting was provided as the mechanism for excluding these wastes from subtitle C regulation (45 FR 33096, May 19, 1980).

EPA is sympathetic to the commenters' concerns regarding use of delisting to exclude wastes that are ***11832** hazardous under the “mixture” and “derived from” rules. The Agency does not believe, however, that the alternative suggested by the commenters (i.e., relying on the TC to regulate mixtures and treatment residues) would adequately protect human health and the environment. As noted above, wastes that pass the characteristic test may nevertheless be hazardous, either because they contain listed constituents at concentrations below the TC regulatory levels but at levels and under circumstances that nevertheless render the waste hazardous or because they contain hazardous constituents that are not covered by the TC rule. As noted above, the TC regulatory levels are not threshold levels defining all hazardous waste, but are levels that are set to clearly define hazardous waste. Wastes containing constituents falling below these levels may still present a hazard in more limited situations.

Nevertheless, the Agency recognizes that some inequities may result by the application of the “mixture” and “derived from” rules to certain dilute listed wastes. The Agency therefore is considering proposing an amendment to the definition of hazardous waste which would establish self-implementing de minimis exemption levels for hazardous constituents found in listed wastes. Listed wastes that meet these exemption levels would no longer be listed hazardous wastes and thus would not need to be managed as hazardous wastes unless they exhibit a hazardous waste characteristic.

c. Mixture Rule Exemption. The mixture rule under 40 CFR 261.3(a)(2)(iv) provides an exemption from RCRA subtitle C regulation for mixtures of wastewaters and certain listed spent solvents. The mixture rule exemption is applicable only if the maximum weekly usage of the solvents (other than solvents that can be demonstrated not to be discharged to wastewater) divided by the average weekly flow of wastewater does not exceed specified values. The mixture rule exemption does not apply to wastewaters that exhibit a characteristic of hazardous waste or to wastewaters that contain listed hazardous wastes not specified in the mixture rule exemption.

A number of commenters claimed that the proposed TC conflicts with the mixture rule exemption. The commenters noted that the mixture rule exemption levels are higher than the corresponding TC regulatory levels for solvent constituents. Because of this difference in regulatory levels, the commenters stated that the proposed TC rule will bring large quantities of currently exempted wastewaters into the hazardous waste management system. In effect, the commenters argued that the TC rule will revoke the mixture rule exemption. Commenters disapproved of this result, stating that the mixture rule exemption was promulgated in recognition that small amounts of certain spent solvents are often most efficiently managed by being discharged to a plant's wastewater treatment system and that this method of management does not pose risks to human health and the environment.

EPA acknowledges that the TC rule may bring some currently exempted wastewaters into the subtitle C regulatory system; however, the mixture rule exemption is an exemption from the hazardous waste listings, not the characteristics. Thus, there is no inconsistency between this rule and the mixture rule exemption. In addition, it should be noted that the TC regulatory levels are based on state-of-the-art toxicological data and risk assessment methodologies. Consequently, EPA believes that the TC regulatory levels are the best measures available to identify wastewater mixtures that pose a threat to human health and the environment. In contrast, the mixture rule exemption levels are based upon less current risk information.

Even though some wastewaters presently covered by the mixture rule exemption will become hazardous wastes as a result of the TC rule, EPA believes that the exemption will continue to serve an important purpose by ensuring that mixtures of wastewaters and certain listed spent solvents will not be considered hazardous unless they exhibit a characteristic of hazardous waste. To clarify the mixture rule exemption and make it more consistent with current risk information, EPA is considering proposing in the future that the mixture rule exemption levels be reduced so that they are equivalent to the TC regulatory levels.

d. Delisting. While the June 13, 1986 proposal did not specifically address the effect that the TC might have on the hazardous waste delisting program under 40 CFR 260.22, a number of comments were received claiming that the TC rule would be inconsistent with existing EPA policies regarding case-by-case exclusions. In the August 1, 1988 proposal, however, the Agency solicited comment on the use of the EPACML model in the delisting program.

The commenters noted that each major element of the delisting program is different from the corresponding element in the original TC proposal. For example, the chronic toxicity reference levels that are used to establish “no hazard” levels under the delisting program appear to differ from the levels that were used to establish the proposed TC regulatory standards. In addition, the delisting program uses (as appropriate) a different ground water transport model (i.e., the Vertical and Horizontal Spread (VHS) Model), which generates generic DAFs rather than compound-specific factors. Finally, the delisting program employs (as appropriate) the Organic Leachate Model (OLM) rather than the EP or the TCLP to determine the degree to which various organic constituents are likely to leach from solid wastes. The commenters urged the Agency to use the same reference levels, DAFs, and leaching procedures in both the characteristic and delisting programs. A few commenters expressed a particular preference for adopting the delisting elements as part of the revised TC.

There were a number of differences between the various elements of the proposed TC and the corresponding elements in the delisting program. However, regarding Chronic Toxicity Reference Levels, the only difference between the levels used in the delisting program and those in the TC final rule is the use of different risk levels for the carcinogens (i.e., delisting uses a more conservative risk factor of 10-6 for carcinogens, compared to the use of a 10-5 risk factor in the TC rule). Many of the differences between the chronic toxicity reference levels used in the TC rule and those in the delisting program have been

eliminated as a result of decisions concerning risk levels and apportionment. Furthermore, the health-based levels used in the delisting program and in the TC rule have been updated to incorporate recent Agency evaluations (see 53 FR 18024).

EPA believes that the risk factors being used for each program are appropriate, and does not think that risk levels used to set regulatory levels should necessarily be the same in the two programs because each serves a separate purpose. Delisting evaluates the hazard posed by specific individual wastestreams that have been listed as hazardous. Characteristics identify broad classes of clearly hazardous wastes; specific wastes that may pose a substantial identified hazard in a lower risk range may be listed as hazardous. As discussed below, EPA believes it is appropriate that the delisting program is, in certain cases, more stringent than the characteristic program.

***11833** A number of commenters focused on the overall stringency of the characteristic and delisting programs. In particular, the commenters stated that the proposed TC regulatory levels were sometimes greater than and sometimes less than the concentration standards used by the Agency's delisting program in determining when listed wastes may properly be managed in subtitle D facilities. Most of the commenters argued that EPA, in the interest of consistency, should adopt the same concentration standards under the characteristic and delisting programs. Other commenters, however, urged the Agency to establish higher concentration standards under the revised characteristic. The latter group of commenters noted that characteristics are designed to identify broad classes of solid wastes that are “clearly” hazardous, while listings are designed to identify wastes that may not exhibit a characteristic, yet are nevertheless hazardous. The commenters concluded that, in light of the different functions of listings and characteristics, it should be more difficult for a waste to pass the delisting standards (i.e., to be eligible for delisting) than for the same waste to pass the characteristic test.

EPA does not agree with those commenters who argued that the Agency must use the same concentration standards in the characteristic and delisting programs or, that the concentration standards for characteristics must be higher than those for delisting. These programs have very different purposes. While hazardous waste characteristic levels are those equal to or above which a waste is clearly hazardous due to a particular property, delisting levels are those below which a waste is not hazardous. Thus, it is reasonable that these two levels may or may not coincide. Delisting decisions are based on an extensive evaluation of a particular waste which requires specific information on the waste. The characteristics approach to defining a hazardous waste is much more broad. Only one mismanagement scenario is used and it is based on “reasonable worse-case” assumptions resulting in a “generic” regulatory level to be applied to all solid waste. And, of course, section 260.22 of the RCRA regulations specifies that a waste may not be delisted if it exhibits a characteristic of hazardous waste (e.g., the characteristic of EP toxicity). Thus, the delisting program could never be less stringent than the characteristic program.

In regard to the use of different models in the delisting and characteristic programs, in the August 1, 1988 Federal Register notice, the Agency specifically solicited comment on the use of the Toxicity Characteristics model (EPACML) in place of the model currently used in the delisting program (the VHS model). All of the commenters supported the use of EPACML instead of the VHS model in the delisting program, although one commenter supported this only if it would not add complexity and thereby increase the time required for delisting petition evaluation. Another commenter stated that the EPACML model should be used in the delisting program but that petition evaluations should not be restricted to the use of any single specific model. Finally, several of the commenters stated that the Agency should present details as to how the EPACML model would be used for delisting in a separate Federal Register notice.

In response to these comments, the Agency will use the EPACML model and the TCLP in the delisting program. Also, as suggested, the Agency will explain how the model and the TCLP will be used in a future Federal Register notice.

A few commenters expressed concern about the applicability of the TC to wastes that have previously been delisted. The commenters argued that once EPA has ruled (through the waste-specific delisting process) that a particular waste stream poses no threat to human health and the environment, the Agency should be barred from using a generic rule to declare the same waste as being “clearly” hazardous. One commenter claimed that it would be especially unfair to alter the regulatory status of

a waste stream after the person managing it has been granted an exclusion and has acted in reliance on that exclusion (e.g., by changing the production process or waste management practices).

EPA has consistently maintained that wastes "excluded" from subtitle C regulation under the delisting program may nevertheless be hazardous if they exhibit a characteristic of hazardous waste (see 40 CFR 260.22). While the TC rule will apply to previously delisted waste, EPA does not, in general, expect that such wastes will become hazardous because of application of the revised TC. The Agency believes that, because delisting levels are more stringent than the final TC levels, the impact of the TC rule on previously delisted wastes will be minimal. Nevertheless, if a previously delisted waste exhibits the TC, it will again be subject to subtitle C requirements (i.e., delisted wastes are treated no differently than any other solid waste).

2. Land Disposal Restrictions

a. Risk Levels and Frequency Interval. The approach used to develop regulatory levels in the proposed TC rule was similar to the original approach suggested for developing treatment standards in the proposed Land Disposal Restrictions (LDR) rule (51 FR 1602, January 14, 1986). Both proposals began with health-based concentration thresholds at the point of exposure and used subsurface fate and transport models to back-calculate allowable constituent concentrations in the leachate. In the June 13, 1986 TC proposal, the Agency requested comments on whether the risk levels and cumulative frequency level used in the TC should be the same as those used to develop the treatment standards in the proposed LDR rule.

Several commenters supported the use of different risk levels and cumulative frequency levels in the two proposals. These commenters stressed that different statutory mandates for the two rules and the entirely different functions of the TC regulatory levels and the LDR treatment standards warranted different approaches. However, other commenters contended that the frequency level and risk levels in the TC rule should be the same as or more stringent than those used in the LDR proposal. Some of these commenters argued that the more stringent risk levels and frequency level in the LDR proposal provided a more appropriate degree of protection for human health and the environment than the corresponding levels and frequency interval in the TC proposal.

The issue of consistency of risk levels and frequency level for the TC and the LDR program is now moot. The LDR final rule (51 FR 40572, November 7, 1986) abandoned the use of screening levels based on risk methodology and subsurface fate and transport modeling, and promulgated an approach to establishing treatment standards based entirely on technology-based standards expressed as Best Demonstrated Available Technology (BDAT). Today's rule continues to be based upon health-based concentration levels and dilution/attenuation factors, the values for which are based upon the predictions of a subsurface fate and transport model.

b. Treatment Standards for TC Wastes. Under RCRA section 3004(g)(4), EPA is required to make an LDR determination for all TC wastes within 6 months of today's action, as discussed in the following section. Several commenters were concerned that the LDR treatment standards that will ***11834** eventually be established for the TC wastes may be inconsistent with TC regulatory levels. Some of these commenters noted that the proposed LDR treatment standards for listed spent solvents were in many cases lower than the proposed TC regulatory levels for the identical constituents in unlisted characteristic wastes. The commenters feared that if LDR treatment standards are applied to unlisted TC wastes in the same manner as they are applied to similar listed wastes, the characteristic wastes may require treatment to below the TC level before subtitle C land disposal is permissible. This means that unlisted wastes no longer exhibiting the TC must continue to be managed as hazardous wastes. Some commenters who voiced concerns over potential differences between TC regulatory levels and LDR treatment standards suggested that there should be a clear continuum of regulatory levels, with the higher standards being those that deem a waste hazardous in the first place (i.e., the TC regulatory levels).

Wastes deemed hazardous under the TC will not immediately become subject to the LDR program on the effective date of the TC rule, except perhaps by operation of the California List restrictions (i.e., halogenated organic compounds are subject to the LDR if they exhibit a characteristic, see 52 FR 25770, July 8, 1987). However, the Agency has not yet determined whether the existing LDR California List restrictions should be applicable to newly identified TC wastes. The Agency specifically

requested comment on the appropriateness of applying the California List prohibitions to newly identified hazardous wastes in the November 22, 1989 proposed rule for the "Third Third" of scheduled wastes (54 FR 48499). The Agency will fully address this issue as part of the "Third Third" final rule.

Since the Agency is not today proposing LDR treatment standards for the TC wastes, the Agency believes that it is more appropriate to address these comments when the LDR treatment standards are proposed. However, in response to comments that proposed treatment standards for listed solvents were lower than proposed TC levels, the Agency would like to point out that the treatment standards for TC wastes will not necessarily be the same as the corresponding LDR treatment standards for spent solvents. Indeed, if the TC wastes belong to a different treatability group, one can expect that the treatment standards will be different.

c. Schedule for LDR Determinations. For wastes already listed or identified at the time of enactment of HSWA, the Agency must make LDR determinations according to the schedule set forth in RCRA section 3004(g)(4). If EPA fails to make the determinations by the established schedule, the wastes are automatically subject to the land disposal restrictions on the scheduled date. EPA must also make LDR determinations for all wastes that are identified or listed as hazardous after November 1984 (when HSWA was enacted) within six months after the wastes are identified or listed.

On November 22, 1989 (54 FR 48372), EPA proposed treatment standards for those wastes that exhibit the EPTC, as well as any of the other characteristics. Upon the effective date of today's rule, the TC will include the 14 EPTC constituents in addition to the 25 organics, and the TCLP will replace the EP. EPA proposed that the BDAT levels for wastes that exhibit the EPTC for the 14 constituents remain the same when the TC becomes effective. By May 8, 1990 the Agency will establish the final BDAT levels for the 14 constituent currently identified by the EPTC. Newly identified TC wastes are subject to the six-month listing deadline. However, wastes are not automatically prohibited from land disposal if EPA fails to make this required determination within six months.

Some commenters argued that the six-month deadline would accelerate the LDR determinations for listed wastes that contain TC constituents. For example, some commercial chemical products are currently scheduled to be reviewed by May 8, 1990 (51 FR 19300, May 28, 1986). However, these wastes also may exhibit the TC. Commenters were concerned that these wastes may be subject to the six-month deadline and claimed that this would effectively accelerate the determinations in a manner that would be contrary to Congressional intent.

Wastes that are newly identified as hazardous by today's rule will be subject to the six-month deadline for LDR determinations. However, even if EPA were to complete LDR determinations for TC wastes before May, 1990, the Agency disagrees with commenters that this has the potential to accelerate the determinations in a manner that would be contrary to Congressional intent. The dates set forth in RCRA section 3004(g)(4) are deadlines by which EPA must make LDR determinations or the wastes are automatically restricted from land disposal. EPA is in no way prevented or discouraged by the statute from making LDR determinations before any of its deadlines (RCRA section 3004(g)(5), "Not later than * * *"). lndeed, other determinations are being made ahead of schedule; the final rule for restricting "second third" wastes includes treatment standards and prohibitions for some "third third" wastes (54 FR 26594).

3. RCRA Corrective Action and Closure Requirements

Today's rule will have no direct effect on either the action levels of RCRA corrective action or the cleanup standards of RCRA closure requirements. However, to the extent that the TC brings more facilities under the RCRA program as hazardous waste management facilities, additional facilities will be newly subject to the subtitle C corrective action and closure requirements.

Although the corrective action program under subtitle C addresses remediation of releases of hazardous constituents from waste at facilities subject to RCRA permitting, the TC levels will be neither action levels (i.e., concentrations that, if exceeded, signal the need for corrective action) nor cleanup standards. Rather, corrective action, as a process, encompasses trigger levels and

cleanup standards that are developed from site-specific information gathered during the investigatory and evaluative phases of the process (i.e., the RCRA Facility Investigation and the Corrective Measures Study).

Thus, the levels or concentrations associated with today's TC rule are largely independent from levels associated with corrective action. Similarly, the closure requirements are unaffected by today's rule. The TC is not used to determine whether a facility has met the requirements for clean closure. However, it must be noted that solid wastes generated as a result of remediation of releases or in pursuance of closure requirements that exhibit the TC must be handled as a hazardous waste.

4. Minimum Technology Requirements

a. Applicability. HSWA added section 3004(o) to RCRA which imposes minimum technology requirements on owners and operators of certain landfills and surface impoundments seeking permits. HSWA also added a new section 3015 imposing similar requirements on certain interim status waste piles, landfills, and surface impoundments. Finally, HSWA section 3005(j) requires surface impoundments to be retrofitted to meet minimum technology requirements. EPA codified the statutory language in the Agency's ***11835** Codification Rule promulgated on July 25, 1985 (50 FR 28705). Facilities that will face new RCRA regulation following the promulgation of the TC will need to comply with the minimum technology requirements in order to remain in operation.

b. Scope of Minimum Technology Requirements—1. Permitted Facilities. Section 3004(o)(1)(A) requires that after November 8, 1984, certain landfills and surface impoundments must meet minimum technology requirements. The minimum technology requirements for 1andfills and surface impoundments appear in 40 CFR 264.301(c) and 264.221(c), respectively. They require the owner or operator of each new unit and each replacement unit or lateral expansion of an existing unit to install two or more liners and a leachate collection system between and, for landfills, above the liners.

2. Interim Status Facilities. Section 3015 of RCRA requires that certain waste piles, landfills, and surface impoundments meet minimum technology requirements. The minimum technology requirements for interim status waste piles, landfills, and surface impoundments appear in 40 CFR 265.254, 265.301, and 265.221, respectively. They require that the owner or operator of each new unit, replacement of an existing unit, or lateral expansion of an existing unit that is within the area identified in the part A permit application install liners and a leachate collection system or equivalent protection. Existing surface impoundments (i.e., surface impoundments regulated under subtitle C prior to November 8, 1984) had to be retrofitted to meet the minimum technology requirements by November 8, 1988.

c. Compliance with Minimum Technology Requirements. Facilities or units newly regulated as a result of the TC will have to meet the minimum technology requirements of sections 3004(o) and 3015 if and when they add a new unit, replace an existing unit, or laterally expand an existing unit. Surface impoundments must comply with the retrofitting requirement in section 3005(j)(6)(A), which requires the owner or operator of a newly-regulated surface impoundment to retrofit that impoundment 4 years from the date of promulgation of the additional listings or characteristics, that made it subject to regulation. Thus, surface impoundments that become regulated under subtitle C because of the TC will need to meet the minimum technology requirements on March 29, 1994. (However, retrofitting may be expedited due to the minimum technology requirements imposed under the capacity variance for land disposal under section 3004.) This extension applies only to those impoundments that contain solely the newly listed/characteristic wastes. Any impoundments that already contained listed/characteristic wastes currently are subject to RCRA regulations, including the minimum technology requirements. Other existing land disposal units (besides surface impoundments) that already contained wastes that exhibit the TC will not require retrofitting unless they are expanded or are replacement units.

5. RCRA Subtitle D (Solid Wastes)

a. Municipal Waste Combustion Ash. Several commenters requested that ash from municipal waste combustion (MWC) units be exempt from regulation under the TC. Many of these commenters argued that the regulation of MWC ash would be in direct conflict with RCRA section 3001(i), which provides that resource recovery facilities engaging in MWC “shall not be

deemed to be treating, storing, disposing of, or otherwise managing hazardous wastes." Other commenters indicated that the high costs associated with subtitle C regulation would discourage the recovery of energy values from MSW. They claimed that this result would run counter to the clear Congressional intent to encourage resource recovery as a beneficial alternative to the landfilling of MSW.

EPA articulated its position on the scope of section 3001(i) when the Agency codified the 1984 HSWA (see 50 FR 28725, July 15, 1985). However, two recent Court decisions have rejected EPA's 1985 interpretation. EDF v. City of Chicago, No. 88C769 (N.D. Ill.) (slip op. Nov. 29, 1989) and EDF v. Wheelabrator Technologies Inc., No. 88Civ.0560 (S.D. N.Y.) (slip op. Nov. 21, 1989). The Agency is considering the appropriate response to these two decisions.

b. Impact on Wastes Excluded from Subtitle C Regulation. Another group of commenters asked for assurances that the TC rule would not affect the existing exclusions for specific wastes under 40 CFR 261.4(b). One commenter expressed particular concern about the exclusion for mixtures of household and other nonhazardous solid wastes. Another commenter raised questions about applying the TC to wastes that are usually considered to be non-hazardous solid wastes. Other commenters focused on the exemptions for "special wastes," primarily mining and mineral processing wastes and oil and gas production wastes. A utility company consortium addressed the exemption for wood treated with arsenic, commonly used as a fungicide for utility poles. The commenter noted that cresols and pentachlorophenol, also used as fungicides for wood, are proposed as TC constituents; the commenter asserted that the exemption for arsenic-treated wood should be extended to creosote- and pentachlorophenol-treated wood as well.

The TC rule will not apply to wastes that are already excluded from subtitle C regulation under § 261.4(b). These wastes will continue to be exempt from regulation as hazardous wastes, even if they would exhibit the TC. Likewise, the TC rule does not add any exclusions to the applicability of previously promulgated hazardous waste characteristics. With respect to the issue of creosote- and pentachlorophenol-treated wood, EPA does not at this time intend to expand the list of exemptions under § 261.4(b) to include these wastes. This is discussed further in section III.J.4.b.

It should be noted, however, that the special waste exclusions are currently being reevaluated in accordance with the criteria and procedures mandated by Congress. After completing the studies required by RCRA section 8002, EPA may determine that one or more special wastes should be regulated under RCRA subtitle C (see RCRA section 3001(b)). Such wastes would then be listed or the generators required to determine whether the wastes exhibit a hazardous waste characteristic.

A few commenters argued that even if special wastes are brought into the subtitle C system, they should not be subject to the TC. These commenters claimed that codisposal of special wastes with MSW is implausible because special wastes, by definition, are generated in very large quantities. The commenters recommended that EPA develop a separate mismanagement scenario and leaching procedure for special wastes.

At this time, the Agency cannot agree that the TC should not be applicable to special wastes; rather, the applicability to these wastes will be determined on a case-by-case basis. If EPA makes a determination that any special wastes should be regulated under RCRA subtitle C, the Agency will at that time make a separate determination concerning the applicability of the TC to such wastes.

6. RCRA Subtitle I (Underground Storage Tanks)

a. Scope of the Underground Storage Tank Program. Subtitle I of RCRA provides for the establishment of a ***11836** regulatory program for underground storage tanks containing "regulated substances." Regulated substances are defined under RCRA section 9001(2) as (1) petroleum and (2) hazardous substances listed under section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), excluding hazardous wastes regulated under subtitle C of RCRA.

Except as discussed below, today's action will change the regulatory status of TC wastes that were previously subject to RCRA subtitle I. Because these wastes will be RCRA hazardous wastes, they are excluded from regulation under subtitle I (see 40 CFR part 280.10(b)(1)). For this reason, underground storage tanks that contain TC wastes will be subject to the subtitle C tank requirements rather than those promulgated under subtitle I.

b. Deferral for Petroleum-Contaminated Media and Debris Subject to Part 280 Corrective Action Requirements. As part of its underground storage tank (UST) program, the Agency has recently promulgated regulations which address releases from USTs containing petroleum (see 53 FR 37082, September 23, 1988 and 53 FR 43322, October 26, 1988). Among other requirements, these rules require petroleum UST owners and operators to install leak detection, to report leaks from their tanks and piping, to undertake corrective action to address such releases, and to demonstrate financial assurance for corrective action and third party liability resulting from such releases. These requirements started going into effect in December, 1988, and the Agency estimates that over the next few years more than 300,000 petroleum UST releases will be discovered and be subject to the subtitle I corrective action requirements. In addition, the Agency has, through cooperative agreements, provided funding to states from the Leaking Underground Storage Tank (LUST) Trust Fund under RCRA to undertake the necessary response actions where petroleum UST owners and operators are unable or unwilling to do so. Hundreds of petroleum UST cleanups have been initiated to date under this program.

As noted in the preamble to the final UST rules, due to the large regulated community affected by the UST regulations, the UST program is based on self-implementing requirements and is highly dependent upon voluntary compliance to attain the environmental performance objectives of the program. However, because petroleum contains several of the hazardous constituents for which regulatory levels are being established today (e.g., benzene) some of the petroleum-contaminated media and debris may exhibit the Toxicity Characteristic under today's rule. While the amount and type of media and debris that may exhibit the characteristic at any particular UST site will depend upon the petroleum product, soil type, and the size of the release, it is likely that many sites where petroleum UST releases have occurred will contain some media that exhibits the Toxicity Characteristic. The management of any such media and debris would be subject to subtitle C requirements for hazardous waste management.

The Agency has insufficient information concerning the full impact of this rule on UST cleanups, but the information available to date suggests that the impact may be severe in terms of the administrative feasibility of both the subtitle C and subtitle I programs. Thus, the Agency has decided to defer a final decision on the application of the TC to media and debris contaminated with petroleum from USTs subject to the part 280 requirements. The application of today's rule to these cleanups will be delayed while the Agency evaluates the extent and nature of this impact and alternative administrative mechanisms for implementing the UST cleanups in accordance with subtitle C requirements. The Agency believes that the UST regulations governing cleanups at these sites will be adequate in the interim to protect human health and the environment.

The deferral of a final decision concerning application of this rule to UST cleanups is necessary for several reasons. First, while the actual number of sites and amount of media and debris at each site that would exhibit the toxicity characteristic under today's rule is unclear, based on a preliminary assessment, the number and amount could be extremely high. As noted above, EPA expects hundreds of thousands of UST releases to be uncovered in the next few years. Subjecting each of these sites to subtitle C requirements could overwhelm the hazardous waste permitting program and the capacity of existing hazardous waste treatment, storage, and disposal facilities. Imposition of the subtitle C requirements is also likely to delay cleanups significantly and severely discourage the self-monitoring and voluntary reporting essential to implementation of the UST program. Moreover, the UST cleanup activities involving the most contaminated media and debris are also likely to involve free product recovery. Free product recovery would not be subject to subtitle C requirements because the material being recovered is not a waste.

Because of the uncertainties of the impacts on the UST cleanups as a result of this rule, including the amount of contaminated media that would become hazardous waste and the type of management feasible and appropriate for such waste (i.e., on-site treatment, off-site disposal), EPA cannot determine whether the application of this rule to these cleanups will have the severe consequences on implementation of these RCRA programs that preliminary information suggests. Also, because this issue did

not come to the Agency's attention until late in the development of this rulemaking, the Agency has not had an opportunity to obtain public input on this issue, the implications of the subtitle C requirements when applied to UST cleanups, or any alternative regulatory mechanisms to make feasible the implementation of UST cleanups while meeting subtitle C hazardous waste requirements. Thus, the Agency believes that further evaluation of the impacts of applying the TC to soils and ground water contaminated by petroleum from USTs and subject to the subtitle I program is necessary in order to determine whether an exemption for such materials is warranted or whether additional regulatory or administrative changes can or should be made in order to make the application of the TC to UST cleanups feasible.

In order to make a final decision concerning the applicability of this rule to UST sites, the Agency intends to undertake several activities. First, the Agency will attempt to more specifically define the impact of the TC through studies of petroleum UST sites, focusing upon the potential hazard from these sites. More specifically, the Agency will study the characteristics of UST sites (number of UST sites by media type, volumes of media and debris typically removed, fraction of this media and debris that exhibits the TC, if any, etc.), current practices and requirements for management of these media and debris, and how contaminated media and debris from these sites are managed under the new subtitle I state programs. As currently envisioned, these studies will include: (1) A survey of tank vendors, contractors, and others knowledgeable about UST site characteristics and contaminated media and debris management practices; (2) a survey of current state and local programs; and (3) a sampling program conducted in conjunction with one or ***11837** more selected states. The Agency also plans to evaluate the impact that subtitle C management of petroleum-contaminated media and debris from USTs would have on the Agency's and states' hazardous waste management programs. In addition, the inclusion of these media and debris in the subtitle C management system will be evaluated in comparison to the available capacity for commercial hazardous waste treatment, storage, and disposal.

Second, the Agency will evaluate whether and how the subtitle C requirements can be feasibly implemented for UST cleanups. This evaluation will include an investigation of regulatory streamlining, phased compliance, or other administrative changes to increase the feasibility of implementing UST cleanups in accordance with subtitle C requirements. As part of this effort and the larger issue of the application of subtitle C requirements to contaminated media, EPA intends to convene a public forum to discuss the relationship between subtitle C and subtitle I requirements, the impacts of the subtitle C program on UST cleanups, and how the subtitle C requirements can feasibly be applied to the UST cleanups.

EPA requests data and comment from the public on these issues. Upon completion of the evaluations described above, EPA will determine whether to retain the temporary exemption for UST cleanups provided in this rule or to remove the exemption and make the TC fully applicable to corrective actions under subtitle I.

7. RCRA Section 3004(n) Air Regulations

In HSWA, Congress directed EPA to "* * * promulgate such regulations for the monitoring and control of air emissions at hazardous waste treatment, storage, and disposal facilities, including but not limited to open tanks, surface impoundments, and landfills, as may be necessary to protect human health and the environment." This provision was added as section 3004(n) of RCRA. In response, the Agency proposed the first of a multi-phased set of air regulations for TSDFs on February 5, 1987 (53 FR 3748). This first phase is intended to apply to equipment that would be used to treat wastes that would first be subject to the Land Disposal Restrictions (LDR) standards to ensure that the LDR treatment did not result in cross-media transfer of hazardous constituents to the air (see III.I.2., above, for a discussion of the LDR program). This first phase is to be followed by proposals for more comprehensive air regulations for TSDFs. Once these air standards are promulgated, they are expected to apply to many of the wastes newly regulated by today's rule.

The February 5, 1987 proposal would limit air emissions of organics as a class from certain treatment units. The proposed rule would apply to specified equipment that contains or is in contact with certain hazardous wastes, which are identified based upon their potential to emit organics. The proposed standards contain two major features. First, a 95% reduction in process emissions from units distilling or stripping (air or steam) organic wastes would be required. Second, leak detection and repair programs would be required for certain valves, pumps, compressors, pressure relief devices, and closed-vent systems. If wastes

that exhibit the TC also have concentrations of organic constituents exceeding the regulatory threshold, they will be subject to this first phase of regulation for air emissions.

J. Relationship to Other Regulatory Authorities

1. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Although promulgated in fulfillment of a RCRA mandate, today's rule may affect, to varying degrees, remediations performed under CERCLA authority. Such effects or interactions, when they arise, will be associated with section 121(d) of CERCLA, which requires CERCLA remedial actions to comply with all applicable or relevant and appropriate requirements (ARARs) of other federal and state laws, including RCRA.

Several commenters questioned the applicability of the TC to CERCLA sites and argued that the TC would constrain the discretion of Remedial Project Managers and On-Scene Coordinators. However, CERCLA section 121(d) is clear that CERCLA remediations must comply with Federal and State ARARs. Accordingly, RCRA regulations, including today's TC, are incorporated into the CERCLA decision-making and remediation process to augment controls already in place under the CERCLA program.

In addition, a few commenters argued that as a result of today's rule, a greater number of hazardous waste determinations would be made during CERCLA remediations. Consequently, “thousands of additional Superfund sites” would be created, attributable in large part, one commenter notes, to petroleum and petrochemical waste that will exceed TC levels. The Agency disagrees with the commenters. While it is clear that CERCLA remediations must comply with Federal and State ARARs, the TC is not used by CERCLA to determine whether or not to undertake a clean-up action. Rather, the TC will apply to decisions concerning the management of solid wastes (e.g., soil and debris) generated during cleanup activities.

2. Clean Water Act

a. Conflict with NPDES Effluent Guidelines and Pretreatment Standards. Many commenters argued that the regulatory levels in the proposed TC conflict with NPDES effluent guidelines and pretreatment standards under the Clean Water Act (CWA). Several commenters stated that in many cases, the proposed TC regulatory levels are lower than the concentrations allowed in wastewaters directly discharged to surface waters in compliance with NPDES effluent guidelines. Commenters also stated that many wastewaters that are indirectly discharged to publicly owned treatment works in compliance with pretreatment standards will exhibit the TC.

Most of the commenters argued that it would be difficult to justify labeling a wastewater as “hazardous” under RCRA, but “safe” under the CWA. One commenter claimed that differential treatment of identical wastewaters is particularly difficult to justify because leaks from on-site wastewater management operations normally migrate to the same bodies of water that receive NPDES-permitted discharges.

EPA acknowledges the possibility that some wastewaters that meet NPDES effluent guidelines or pretreatment standards may exhibit the TC. However, because the statutory bases for setting regulatory levels are different under the CWA and RCRA, the treatment standards and effluent limitations established under the CWA are not inconsistent with the TC rule. The CWA requires EPA to set effluent limitations to control discharges of toxic pollutants “* * * which shall require application of the best available technology economically achievable * * *” and to set more stringent effluent limitations where necessary to meet applicable water quality standards (see CWA section 301(b)). RCRA, however, mandates that EPA identify wastes which may be a threat to human health or the environment. The criteria for the identification and listing of hazardous waste requires EPA to take into account “* * * toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous ***11838** characteristics” (see RCRA section 3001(a)). These criteria are different from those used under the CWA.

Accordingly, the two statutory programs have different goals. EPA believes that the TC regulatory levels represent concentrations above which a wastewater poses a potential hazard to human health and the environment, if mismanaged, even if it has been treated to some degree. Therefore, owners and operators of wastewater treatment facilities that treat wastewaters exhibiting the TC will be required to comply with all applicable regulations under RCRA and the CWA.

b. Permit Requirements for Wastewater Treatment Facilities. Many commenters stated that under the proposed TC, many wastewater treatment facilities will become hazardous waste treatment facilities subject to full RCRA permitting requirements. These commenters were concerned that the costs to industry of preparing permit applications and complying with RCRA regulations for hazardous waste treatment facilities will be prohibitive. Some commenters argued that EPA has insufficient resources to process permit applications from all of the wastewater treatment facilities that will require permits.

Although owners and operators of some wastewater treatment facilities that use newly-regulated surface impoundments could be subject to RCRA permitting requirements, EPA believes that the actual number of facilities requiring permits will not be large. The Regulatory Impact Analysis for this rule indicates that other options available to wastewater treatment facilities treating wastewaters exhibiting the TC are likely to be more cost-effective than obtaining an RCRA permit (see section VI. B for a more detailed discussion). In particular, an alternative that the Agency expects may be attractive to many owners and operators is the replacement of surface impoundments with tanks. Retrofitting existing surface impoundments to meet RCRA requirements for hazardous waste management facilities will often be more expensive than building tanks that are subject to CWA requirements in lieu of RCRA permitting requirements. (“Wastewater treatment units” are exempt from the hazardous waste management standards under 40 CFR 264.1(g)(6) and 265.1(c)(10). Similarly, “totally enclosed treatment facilities” are exempt under 40 CFR 264.1(g)(5) and 265.1(c)(9).) Thus, there are options available to owners/operators for whom RCRA standards may be too costly.

There may be some wastewater treatment facilities that opt to continue using surface impoundments to manage wastewaters exhibiting the TC, and these facilities will enter the RCRA permitting system. However, the Agency does not believe that there will be such a large number of facilities that it will overwhelm the Agency's permitting capabilities.

c. Sludges from Publicly Owned Treatment Works (POTW). The preamble to the June 13, 1986 proposed rule requested comments on the regulation of sewage sludge under RCRA and under the CWA. The preamble stated that EPA was considering an exemption from RCRA regulation for sludges from publicly owned treatment works (POTW sludges) upon the promulgation of sewage sludge management standards pursuant to section 405(d) of the CWA.

A number of commenters, including many municipalities, responded to this request for comments. Although a few commenters opposed an exemption from RCRA for POTW sludges, the commenting municipalities supported an exemption from RCRA. These municipalities stated that sewage sludge management regulations, in addition to pretreatment standards, are sufficient to protect human health and the environment without additional regulation under RCRA. Commenters stated that regulating POTW sludge under RCRA will place a significant economic burden on municipalities and will cause municipalities and EPA to face duplicative administrative costs and regulatory confusion.

EPA does not agree with commenters that regulation of POTW sludge under RCRA will place a significant economic burden on municipalities or increase the burden of implementation. EPA's office of Water tested 18 POTW sludge samples using the TCLP; none of the samples tested exhibited the TC at the proposed regulatory levels (Ref. 18). Because the final TC regulatory levels are higher than the proposed regulatory levels, the Agency believes that few, if any, POTW sludges will exhibit the TC. Thus, most POTW sludges will not be classified as hazardous waste under RCRA.

Although EPA does not believe it is necessary to exempt POTW sludges from RCRA at this time, the Agency may reconsider this decision after the sewage sludge management regulations are promulgated. In the unlikely event that a particular POTW sludge does exhibit the TC, the municipality may use the pretreatment program under the CWA to eliminate the indirect discharges of the pollutants that are causing the sludge to exhibit the TC.

3. Safe Drinking Water Act

Several commenters noted that the proposed regulatory level for chloroform is lower than the primary drinking water standard for trihalomethanes (a class of organic chemicals that includes chloroform) established under the Safe Drinking Water Act (SDWA). Most of these commenters consequently declared that the regulatory level had been set too low, and they argued that it would be unreasonable to regulate ordinary drinking water as a hazardous waste. Some commenters asserted that an industrial facility taking water from a public water supplier (a facility supplying drinking water in compliance with the SDWA rules) could find that its noncontact cooling water becomes a hazardous waste after it is passed through the plant and is disposed.

In today's final rule, the regulatory level for chloroform has been raised from that proposed in the June 13, 1986, notice of proposed rulemaking. The change is because of two modifications to the data originally used to set the regulatory level: first, the chronic toxicity reference level for chloroform is roughly 12 times higher than when originally proposed (see 53 FR 18024) and, second, due to the changes in the model, the DAF is about 7 times higher than the one originally proposed. Together, these two changes result in a regulatory level that is higher than both the original regulatory level and the SDWA standard for trihalomethanes. Non-contact cooling water or other wastewaters derived from public water supplies complying with the SDWA thus should not exhibit the TC for chloroform unless these wastewaters are contaminated by other sources.

4. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

a. Pesticide Wastes. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA regulation of pesticide sale, distribution, use, and disposal. Since RCRA regulations cover solid wastes which include pesticide product wastes, these wastes may be regulated under both FIFRA and RCRA.

Until recently, pesticide disposal under FIFRA was primarily controlled by mandating that product labeling include instructions for the proper disposal of the pesticide and its container. Recent amendments to FIFRA, effective October 25, 1988, authorize the Administrator to impose additional requirements relating to storage, transportation, and disposal of certain pesticides. For example, EPA under FIFRA may issue requirements ***11839** and procedures for the storage, transportation, and disposal of suspended or cancelled pesticides and of rinsates or containers associated with the pesticides. Also, EPA may require that applicants for registration of a pesticide submit information regarding methods for safe storage and disposal of the pesticide, and that applicants for registration provide evidence of sufficient financial resources to provide for disposal in the event of suspension or cancellation.

A number of pesticide-related wastes are listed as hazardous under 40 CFR part 261. The listings include four groups: The first, at § 261.31, includes certain discarded unused pesticide formulations containing tri-, tetra-, and pentachlorophenols (F027) or certain compounds derived from the chlorophenols; these are listed as acute hazardous waste. This listing includes approximately 20 phenoxy pesticides and their salts and esters. Today's rule will add the constituent 2,4,6-trichlorophenol, which is used as an active ingredient in pesticide products, to the TC list. Because products containing this constituent are separately listed under F027, the promulgation of specific toxicity limits will not affect their regulation under RCRA (i.e., they will continue to be regulated as acute hazardous wastes at all concentrations, both above and below the TC level).

The second group, at § 262.32, consists of “K” wastes from the production of specific pesticides, such as wastewater treatment sludges from the production of the pesticide chlordane (K032); these are listed as toxic wastes. Again, however, because these wastes are listed, they will not be affected by the regulatory levels of the TC, but will continue to be subject to regulation regardless of concentration levels.

The third grouping, at § 261.33 (e) and (f), consists of “P” and “U” wastes. Section 261.33 lists certain commercial chemical products as hazardous when discarded or intended for discard. Approximately 50 pesticide active ingredients are listed as acute hazardous wastes under § 261.33(e), while 83 pesticide active ingredients are listed under § 261.33(f) as toxic hazardous wastes. Pesticide products containing these chemicals as sole active ingredients or the pure or technical grade of these chemicals are

regulated under both RCRA and FIFRA when they become wastes. Generally, products containing these ingredients as one of multiple active ingredients are not regulated (at this time) as hazardous wastes under subtitle C of RCRA unless they meet one of the characteristics; their disposal is still subject to any applicable FIFRA and RCRA subtitle D requirements. For the majority of the 133 listed pesticides, today's rule will not change their status under RCRA; waste pesticides that are either pure, technical grade, or sole active ingredient products will continue to be subject to regulation as hazardous at all concentrations under RCRA subtitle C. Wastes from multiple active ingredient products that do not exhibit a characteristic will still be regulated under any applicable FIFRA and RCRA subtitle D requirements.

Six pesticide wastes that are currently regulated on a concentration basis under the existing EPTC at § 261.24, form the fourth group. These six pesticides (endrin, lindane, methoxychlor, toxaphene, 2,4-D, and silvex) will be retained in the new rule with their current concentration limits, which are based on a DAF of 100. The significant difference between the listings and the TC is that, while multiple active ingredient products are not covered by the listings, they are covered under the characteristic. Thus, increasing the number of pesticidal constituents encompassed by the TC (whether or not they are also listed), brings more multiple active ingredient formulations into the subtitle C system. Consequently, today's rule is expanding regulation of pesticide wastes under RCRA.

Although EPA is adding pesticides to the TC list of constituents, today's rule will not have a significant effect on many pesticide users who generate wastes. RCRA regulations contain special requirements that affect the extent to which pesticide users will become subject to additional RCRA regulation:

- Household pesticide wastes are, like other household wastes, exempt from RCRA.

- Farmers who triple rinse their containers and dispose of the rinsate on their own farm in a manner consistent with 40 CFR 262.51 and label instructions are exempt from RCRA requirements.

- Other small quantity generators under § 261.5 need comply only with reduced requirements. Many pesticide users are small quantity generators.

- Under § 261.7, properly emptied containers may be exempted from further RCRA requirements. Thus, many pesticide containers may not be subject to regulation as hazardous wastes.

As a result, the principal effects of today's final rule will be felt by commercial applicators, such as aerial applicators and pest control operators, who are not eligible for the special requirements applicable to farmers and who may use sufficiently large volumes of pesticides that they exceed the small quantity generator limitations. If they use large quantities of multiple active ingredient pesticide products that have not previously been regulated, such commercial applicators may be newly subject to the RCRA hazardous waste management requirements.

b. Treated Wood Wastes. The Agency is promulgating TC regulatory levels for certain chemicals—for example, cresols and pentachlorophenol—that are commonly used as wood preservatives. In its review of wood preservative chemicals under FIFRA, EPA concluded that these wood preservatives may continue to be used under certain circumstances, and the Agency decided to allow disposal of treated wood by means of ordinary trash collection, burial, or incineration (49 FR 28666, July 13, 1984, and 51 FR 1334, January 10, 1986). However, the mandates of FIFRA and RCRA are different. EPA has previously stated that even if it were determined that certain ground uses of treated wood did not pose unreasonable risks, wood wastes might still be regulated under RCRA subtitle C (45 FR 78531, November 25, 1980). Under FIFRA, the Agency may determine that the economic benefits of continued use of a pesticide outweigh any potential risks posed by the pesticide. This does not mean, however, that materials treated with pesticides should not be managed in a controlled manner under RCRA at the end of their useful lives, to ensure that long-term risks are minimized.

Some treated wood that is hazardous solely because it fails the EP toxicity test for arsenic which is not a hazardous waste for any other reason or reasons is exempt from regulation as hazardous (40 CFR 261.4(b)(9)). The exemption is limited to wood wastes generated by persons who use wood products for their intended end use. Several commenters claimed that large quantities of treated wood wastes will be newly regulated as hazardous under the TC, and they argued that this result is inconsistent with other EPA policies and regulations. Most of these commenters recommended that EPA expand the existing exemption for arsenic-treated wood waste to encompass all treated wood that exhibits the TC.

EPA has decided not to expand the existing exemption for arsenic-treated wood. If a wood waste does exhibit the TC for a constituent other than arsenic, or if the waste is hazardous waste for any other reasons or reasons, the ***11840** Agency believes that the waste should be regulated as hazardous, in order to protect human health and the environment. The arsenic-treated wood exemption is not being revoked at this time, but it may be reevaluated in the future.

5. Food, Drug, and Cosmetic Act (FDCA)

a. Food Wastes. Several commenters noted that allowable levels set by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetics Act (FDCA) are, in some cases, higher than the proposed TC regulatory levels for the same chemicals. Most of these commenters then asserted that if it is safe to consume substances containing pesticides or additives, it must also be safe to place such substances in municipal landfills. Some commenters expressed concern that food wastes that comply with FDCA pesticide tolerance or action levels may nevertheless have to be handled as hazardous wastes as a result of the TC. One food processing industry trade association requested that the final TC rule state that any waste from food already in compliance with a tolerance or action level set by EPA or FDA is nonhazardous.

The Agency acknowledges that for certain chemicals in waste, it proposed TC regulatory levels lower than FDCA tolerances or action levels in food. However, it is inappropriate to make a direct comparison of these two sets of levels. FDCA levels are set for concentrations in food products, while TC levels apply to concentrations in the leachate from waste materials. Because not all toxic constituents leach from the waste, levels in the leachate are lower than in the waste material itself. Accordingly, for a food waste to be hazardous, the waste would have to have constituent concentrations higher than the TC levels. The Agency is unaware of any food-related wastes that will be regulated as hazardous under the TC rule. (In addition, unlike the FDCA, RCRA does not allow consideration of economic factors in establishing regulatory levels of concern.)

If any food waste does exhibit the TC, it may be subject to lesser requirements as household waste (40 CFR 261.4(b)(1)) or under the small quantity generator provisions (40 CFR 261.5). For non-household food wastes that fail the TC (i.e., leachate from the waste contains contaminants in levels equal to or above the regulatory levels promulgated in today's rule) and that are generated in large quantities, it is appropriate that they be managed in a controlled manner to protect human health and the environment. Because EPA sees no conflict between the TC rule and tolerance or action levels under FDCA, this rule contains no exemption for wastes that meet the FDCA standards.

b. Pharmaceutical and Cosmetic Wastes. Several commenters, arguing that the proposed TC levels were too low, pointed out that the proposed regulatory levels are lower than FDCA-allowed levels for the same chemicals in drugs or cosmetics.

Although the proposed TC regulatory levels for certain chemicals were lower than the FDCA levels for the same chemicals in drug and cosmetic products, the levels are higher in the final rule. Moreover, it is clear that different factors must be taken into account when regulating these constituents in drugs and cosmetics rather than in solid wastes, as confirmed by different statutory mandates. The constituents in drugs and cosmetics products, often used in very small quantities, serve a useful function and may be therapeutic in certain quantities and under proper circumstances. However, this does not mean that these same constituents should not be controlled where found at TC levels in waste materials.

Of course, drug and cosmetic wastes generated in households are not subject to subtitle C regulation (40 CFR 261.4(b)(1)) nor are wastes generated by small quantity generators (less than 100 kg/mo of non-acute hazardous waste—see 40 CFR 261.5). However, drug and cosmetic products when discarded may present risks to human health and the environment if disposed

in large volumes. Thus, EPA maintains that regulation of large quantities of drug or cosmetic wastes exhibiting the TC is appropriate and not in conflict with the existing FDCA program.

6. Used Oil Recycling Act

The Used Oil Recycling Act of 1980 (UORA), which amended RCRA, was intended to increase safe recycling and reuse of used oil. It established that it is in the national interest to recycle used oil in a manner that both protects public health and the environment and conserves energy and materials. The UORA has been incorporated in section 3014 of RCRA.

Section 3014 of RCRA, as amended by HSWA, requires EPA to make a determination of whether to list or identify used oil as a hazardous waste (see RCRA section 3014(b)). In response to this statutory directive, EPA proposed to list most types of used oil, including recycled used oil, as a hazardous waste on November 29, 1985 (see 50 FR 49258). EPA subsequently decided in November, 1986 not to list used oil because the Agency believed that the listing would discourage recycling of used oil and could result in an increase in the amount of used oil that is disposed of or illegally dumped. The Agency decided to continue to study whether used oil that is disposed should be listed as a hazardous waste under RCRA or regulated under different statutes (see 51 FR 41900 (November 19, 1986)). EPA's decision to withdraw the proposed listing of used oils was invalidated by the D.C. Circuit Court of Appeals in 1988. The Agency was directed by the Court to reconsider the listing of used oil as a hazardous waste based on the technical criteria contained in RCRA section 3001.

Some commenters claimed that used oil would be brought into the subtitle C system under the TC proposal. They stated that used oil is likely to fail the TC test for both aromatic hydrocarbons (e.g., benzene) and chlorinated solvents (e.g., trichloroethylene and tetrachloroethylene). The commenters argued that regulating used oil as a hazardous waste would be inconsistent with the intent of the UORA, as well as with current Agency policies regarding used oil.

Under today's rule, used oil will be regulated as a hazardous waste only: (1) If it exhibits one or more of the hazardous waste characteristics defined in subpart C of 40 CFR part 261 (including the TC as finalized today) and (2) if it is disposed of (rather that recycled). On the other hand, used oil that exhibits one or more of the hazardous waste characteristics and is recycled is exempt from regulation (see 40 CFR 261.6(a)(3)(iii)) except as provided in subpart E of 40 CFR part 266. In addition, RCRA prohibits the use of used oil as a dust suppressant or for road treatment if it is contaminated with dioxin or mixed with a hazardous waste. Thus, used oil that exhibits one or more of the characteristics (except for ignitability) cannot be used as a dust suppressant. ln particular, the regulations have the following effect:

- Solid waste that is hazardous waste because it fails a characteristic and that is recycled (except by burning or use as a dust suppressant) is exempt from regulation.

- Characteristically hazardous used oil that is disposed of (or incinerated without recovery of energy value) is subject to full RCRA subtitle C regulation.

- Characteristically hazardous used oil that is being burned for energy recovery is subject to subpart E of part 266—i.e., off-specification used oil is subject to certain administrative requirements, while specification used ***11841** oil is subject only to the analysis and recordkeeping requirements of 40 CFR 266.43(b) (1) and (6).

- Characteristically hazardous used oil is prohibited from being used as a dust suppressant, unless it is hazardous solely for exhibiting the ignitability characteristic (see 40 CFR 266.23(b)).

- Characteristically hazardous used oil that is recycled in any manner other than being burned for energy recovery (e.g., by being rerefined) is exempt from subtitle C regulation.

Therefore, today's rule will not affect the regulatory status of most recycled used oil. In fact, today's rule should encourage the recycling of used oil, and not discourage its recycling as suggested by some commenters. It should also be noted that some percentage of used oil already is defined as hazardous (i.e., exhibits one or more of the hazardous waste characteristics and is disposed). Consequently, the amount of used oil that is affected by this rule and is either disposed of or recycled by being burned for energy recovery or used as a dust suppressant will be even less.
The Agency is currently determining how best to deal with used oil listing and management issues. Section 3014 of RCRA also requires EPA to promulgate management standards for used oil that is recycled. Standards for controlling used oil which is recycled were proposed on November 29, 1985 (50 FR 49212), but have not been finalized. The Agency will be addressing these issues as well as addressing the listing determination in the near future.

7. Toxic Substances Control Act (TSCA)
EPA has decided to exempt from the application of this rule certain polychlorinated biphenyl (PCB) wastes that are regulated under the Toxic Substances Control Act (TSCA) and would be identified as hazardous because of today's rule. Specifically, PCB-containing dielectric fluids removed from electrical transformers, capacitors, and associated PCB-contaminated electrical equipment may exhibit the TC, and thus become hazardous wastes when disposed, not because they contain PCBs (which are not among the constituents regulated under the TC) but because they may contain other TC constituents, such as chlorinated benzenes. The Agency has decided to exempt such wastes from the subtitle C management standards because new regulation of these wastes under RCRA may be disruptive to the mandatory phaseout of PCBs in certain electrical transformers and capacitors. In addition, the Agency believes that the regulation of these wastes under TSCA is adequate to protect human health and the environment. However, the exemption applies only to those dielectric fluids (as described above) that are fully regulated under TSCA. Other PCB-containing wastes that are hazardous (i.e., listed or exhibit a hazardous waste characteristic including the existing EPTC wastes—waste codes D004 through D017) are subject to all applicable subtitle C standards. Furthermore, these non-TC hazardous wastes that are (1) liquids containing PCBs at concentration greater than 50 ppm, or (2) solids containing PCBs listed in Appendix III of part 268 at concentrations greater than 1000 mg/Kg, are prohibited from land disposal under 40 CFR part 268.

The disposal and storage of PCB wastes is regulated under TSCA section 6(e)(1) authority rather than under subtitle C of RCRA. Since the enactment of TSCA, the manufacture, processing, and distribution in commerce of PCBs (without an exemption) has been banned and the use of PCB without authorization has been banned. In addition, EPA has developed comprehensive PCB disposal regulations under TSCA. This regulatory framework includes specific disposal requirements for defined classes of PCB wastes, specific marking requirements for PCB items, facility recordkeeping requirements, approval requirements for disposers, and a proposed notification and manifesting system modeled on the subtitle C “cradle to grave” tracking system.

One commenter stated that utility transformer dielectric fluids are likely to exhibit the revised TC and urged the Agency to exempt PCB-containing utility transformer dielectric fluids from the rule. The commenter noted that the regulation of PCBs is unique because the manufacture of PCBs (without an exemption) has been banned. Thus, the critical regulatory concern with respect to these PCB wastes is the need to expedite safe disposal of the chemical. The commenter stressed that if PCB wastes were to be regulated now under RCRA as well as under TSCA, serious legal, practical and administrative complications could result.

The Agency agrees with the commenter. The most significant potential negative impact of dual regulation of these wastes under both RCRA subtitle C and TSCA results from the unique scope and timing of PCB disposal. The Agency estimates that approximately 312 million pounds of PCBs are dispersed among nearly 30 million discrete units of electrical equipment. The TSCA regulations require the phaseout of certain PCB-containing electrical transformers, and EPA expects that the TSCA mandatory phaseout requirements and restrictions will render the next three years a peak period for PCB disposal. Under the authority of the TSCA mandatory phaseout, by October 1, 1990, owners of secondary network higher voltage transformers located in or near commercial buildings are required to either remove or reclassify these transformers. (Reclassification necessitates draining of all PCB fluids from the unit, and replacing them with non-PCB fluids or low concentration PCB

fluids, and keeping the transformer in full service, under loaded conditions, for a minimum of three months.) In addition, the phaseout restrictions affect lower secondary voltage network units of PCB-containing electrical transformers located in or near commercial buildings; by October 1, 1993, such transformers must either be removed or be reclassified, or an alternative option for lower voltage units allows for providing enhanced electrical protection on such units by October 1, 1990. Radial PCB-containing electrical transformers must either have enhanced electrical protection or be removed.

The TSCA program, with which the regulated community is familiar, is specifically tailored to deal with the problem of widely dispersed waste generation and the timely disposal of a chemical that is no longer commercially produced. The confusion that could result from the addition of requirements under a separate regulatory disposal system, and the RCRA disincentives to waste production, would cause significant disruption to the expeditious disposal of large quantities of these PCB wastes if these wastes were to become subject to the RCRA hazardous waste regulations.

In addition, the Agency believes that the existing system for PCB disposal, including the existing TSCA disposal regulations and recent additions to the program (e.g., the proposed notification and manifesting rule, published at 53 FR 37436), are adequate to protect human health and the environment with respect to the disposal of these wastes. Thus, further regulation under RCRA for PCB-containing dielectric fluids and associated PCB-contaminated electrical equipment does not appear to be necessary at this time. The Agency will also evaluate the integration of the TSCA PCB regulations with the RCRA hazardous waste regulations for other PCB-containing wastes which are identified or listed as hazardous.

11842** ***K. Implementation Issues

EPA received many comments concerning implementation of the TC rule. The comments addressed issues including the schedule for companies and municipalities to come into compliance with subtitle C requirements, exemptions and applicability, implications for permit modifications, and administrative requirements. Major comments on implementation are summarized and addressed below. Section V of this preamble further discusses how the Agency will implement today's rule.

1. Notification

In the June 13, 1986 Federal Register notice, EPA proposed to waive the RCRA section 3010 notification requirement for persons who manage TC wastes and have already: (1) Notified the Agency that they manage other hazardous wastes and (2) received an EPA identification number. Virtually all commenters who addressed the notification requirement supported EPA's proposal. However, one state agency opposed the proposal, on the grounds that a waiver would hinder efforts to develop a more accurate and complete understanding of hazardous waste management practices within the United States.

EPA has decided, as proposed, to waive the notification requirement for TC waste handlers that have already notified the Agency that they manage hazardous wastes and have received an EPA identification number. The Agency believes that, given the vast scope of the TC rule, a notification requirement for persons already identified within the hazardous waste management universe would present an administrative burden without providing any significant benefits to human health and the environment.

2. Effective Date

Several commenters claimed that the 6-month effective date of the TC rule would not provide them with sufficient time to come into compliance with the full array of hazardous waste regulations. Some commenters argued that it would be impossible for generators of TC wastes to test their wastes, obtain EPA identification numbers, arrange for transport and off-site management of their wastes, modify their short-term storage (i.e., accumulation) practices, and institute the necessary recordkeeping and reporting procedures within a 6-month time frame. The commenters stated that the time constraints are especially unreasonable in light of the shortages of laboratory and TSDF capacity that can be expected to result from the TC revisions. Other commenters claimed that TSDFs will require more than 6 months to come into compliance with the interim status standards of 40 CFR part 265 (e.g., personnel training, contingency planning, and financial responsibility).

EPA appreciates the concerns of the commenters, and the Agency is aware that all of the commenters addressing the effective date for the TC rule encouraged EPA to adopt a delayed effective date for most, if not all, requirements. However, RCRA section 3010(b) requires that hazardous waste regulations become effective 6 months after the date of promulgation unless EPA has good cause to establish an earlier effective date. Thus, the effective date for the final TC rule will be 6 months from the date of promulgation.

However, EPA is promulgating different compliance dates for two different categories of waste generators: (1) All generators of more than 100 and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with subtitle C requirements for management of their TC waste within one year of today; and (2) all generators of 1,000 kg/month or more of hazardous waste are required to comply with all subtitle C requirements for TC wastes within six months of today, on the effective date of the rule.

All generators of over 1,000 kg/month of hazardous waste are required to comply with all applicable RCRA regulations for their TC wastes on the effective date of this rule. (The generator quantity refers to all of a generator's hazardous waste, not just newly hazardous TC waste.) The Agency recognizes that this compliance category will include two groups of generators: current hazardous waste generators, including small quantity hazardous waste generators who will be generating additional hazardous wastes and generators of large quantities of solid wastes who will be regulated as hazardous waste generators for the first time. EPA believes that both of these groups of generators should predominantly be large businesses and either be familiar with the waste management regulations or be in a position to come into compliance with the requirements within the six month period. These persons should have been aware of the Agency's statutory commitment and have had ample notice of the impending TC rule through the proposed rule and supplemental notices.

On the other hand, the Agency is allowing an additional six months from the effective date (i.e., one year from today) for generators of greater than 100 but less than 1,000 kg/month of hazardous waste (small quantity generators) to comply with all applicable subtitle C regulations. (As with the over 1,000 kg/month category, this quantity refers to the total quantity of a generator's hazardous waste, not just newly hazardous TC waste.) The TC has the potential to affect an extremely large number of handlers that never before have been subject to the hazardous waste regulations; many of these firms are small businesses. Handlers that will assume small quantity generator status as a result of the TC rule are most likely not regulated under subtitle C at the present time. Thus, these handlers are less likely to be familiar with the waste management regulations, or because of their small business status, will need more than six months to come into compliance with the regulations.

As already indicated, these handlers are likely to be small entities and may be unaware that their practices, which were not regulated in the past, will now be regulated as a result of today's rule. The Agency recognizes that these new handlers of small quantities of TC wastes (over 100 but less than 1,000 kg/month) may have to test their wastes, obtain EPA identification numbers, arrange for transport and off-site management of their wastes, modify their short-term storage (i.e., accumulation) practices, and institute the necessary recordkeeping and reporting procedures. As recognized by the Agency in establishing special requirements for small quantity generators, the burden of initial compliance may fall relatively harder on these generators (see 51 FR 10146, March 24, 1986). Thus, to lessen the burden on the handlers of small quantities of TC wastes, the Agency has developed an outreach program targeted for the small quantity generators which will inform new generators of the required steps necessary to enter the hazardous waste management system. Effective program outreach, however, will take more than 6 months.

In amending RCRA in 1984, Congress, in requiring EPA to promulgate regulations for small quantity generators, indicated that the Agency should consider the impacts on small businesses, while still providing protection to human health and the environment. While this rule is not promulgated pursuant to this provision, we believe the intent of Congress is for the Agency (in promulgating any rule substantially affecting small quantity ***11843** generators) to consider such impacts and to provide procedural adjustments where appropriate. EPA believes that extending the compliance date for this group of generators will allow the Agency time to provide necessary assistance and outreach to these generators and will allow sufficient time for small quantity generators to comply with the full range of applicable subtitle C requirements. Finally, by delaying the effective date of

the TC for small quantity generators, the Agency will be able to concentrate its initial implementation efforts on large quantity generators, who will generate the vast majority of waste brought into the RCRA subtitle C system under this rule. Thus, because the delayed compliance date for small quantity generators enables the Agency to focus its attention on the waste generators expected to produce the largest volumes of waste, it maximizes protection of human health and the environment.

In summary, the Agency believes that allowing an additional six months for small quantity generators to come into full compliance with the TC will serve two purposes. First, it will allow the Agency time to educate small quantity generators on the RCRA rules, while at the same time, allowing the Agency to focus immediate implementation efforts on large generators of hazardous waste. Second, it will provide the necessary time for small quantity generators to comply with subtitle C requirements as a result of the TC.

3. Permitting

Several commenters expressed concern that they would not be able to submit required permit modifications before the effective date of the rule. Some commenters also expressed concern that the TC revisions could place a significant burden on the system for permitting hazardous waste treatment, storage, and disposal facilities.

The commenters recommended a number of different mechanisms for reducing the prospective burdens on the permitting system, such as (1) Allowing permitted facilities to operate under interim status with respect to newly regulated wastes; (2) handling requests from permitted facilities to manage TC wastes as minor permit modifications, rather than as major permit modifications (especially in the case of facilities that are already permitted to manage listed wastes containing TC constituents); (3) requiring permitted facilities to apply for major permit modifications by the effective date of the TC rule, but not requiring them to actually obtain the modification until a later date; or (4) delaying the effective date of the final rule.

EPA has promulgated amendments to the procedures for permit modifications for treatment, storage, and disposal facilities on September 28, 1988 (53 FR 37934). These changes to the regulations should generally allay the concerns expressed by the commenters. Although the new permit modifications rule will not automatically be effective in authorized states, EPA expects that many authorized states will adopt the provisions and EPA plans to use the new permit modification procedures to implement the TC. The new permit modification procedures are further explained in section V.

IV. Regulatory Levels

The regulatory levels established in today's rule are based on two elements—the toxicity of each constituent and the expected fate of the constituent when released into the environment. The latter element is expressed as a dilution/attenuation factor (DAF), which, when multiplied by the toxicity value, results in the regulatory level. It is this level that, when compared to the results of the TCLP, defines a waste as hazardous. If the waste leachate generated through the TCLP contains constituents equal to or above the regulatory levels in today's rule, the waste is a hazardous waste.

This section summarizes the Agency's basis for selecting the final list of constituents and the regulatory levels that are being promulgated in today's rule.

A. List of Constituents

1. Proposed List

The Agency initially proposed regulatory levels for 38 new organic constituents, proposed to modify the regulatory levels for the six organic constituents that are regulated under the existing EPTC, and proposed to retain the existing levels for the eight inorganic constituents regulated in the existing EPTC (see Table IV-1).

2. Constituents for Which Final Regulatory Levels Are Not Now Being Promulgated

The model used to predict DAFs for today's rule accounts for hydrolysis, which may occur during the transport of a constituent through the environment. If a constituent hydrolyzes during transport, its concentration will decrease more rapidly than it would if it were influenced by dispersion alone. Therefore, the DAF for a constituent that hydrolyzes during transport will be higher than that for a constituent that does not hydrolyze. However, the products that are formed because of hydrolysis of the constituent also may be toxic.

Table IV-1.--TC Constituents and Regulatory Levels Proposed June 13, 1986

HWNO [FN1]	Constituents	CASNO [FN2]	Regulatory level (mg/L)
D016	Acrylonitrile	107-13-1	5.0
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D019	Benzene	71-43-2	0.07
D020	Bis(2-chloroethyl) ether	111-44-4	0.05
D006	Cadmium	7440-43-9	1.0
D021	Carbon disulfide	75-15-0	14.4
D022	Carbon tetrachloride	58-23-5	0.07
D023	Chlordane	57-74-9	0.03
D024	Chlorobenzene	108-90-7	1.4
D025	Chloroform	67-66-3	0.07
D007	Chromium	1333-82-0	5.0
D026	o-Cresol	95-46-7	10.0
D027	m-Cresol	106-39-4	10.0
D028	p-Cresol	106-44-5	10.0
D016	2,4-D	94-75-7	1.4
D029	1,2-Dichlorobenzene	96-50-1	4.3
D030	1,4-Dichlorobenzene	106-46-7	10.8
D031	1,2-Dichloroethane	107-08-2	0.40
D032	1,1-Dichloroethylene	75-35-4	0.1
D033	2,4-Dinitrotoluene	121-14-2	0.13
D012	Endrin	72-20-8	0.003
D034	Heptachlor (and its hydroxide)	76-44-2	0.001
D035	Hexachlorobenzene	118-74-1	0.13
D036	Hexachlorobutadiene	87-68-3	0.72
D037	Hexachloroethane	67-72-1	4.3
D038	Isobutanol	78-83-1	36.0
D008	Lead	7439-92-1	5.0
D013	Lindane	58-89-9	0.06
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	72-43-5	1.4
D039	Methylene chloride	75-09-2	8.6
D040	Methyl ethyl ketone	78-93-3	7.2
D041	Nitrobenzene	96-95-3	0.13
D042	Pentachlorophenol	87-86-5	3.6
D043	Phenol	106-95-2	14.4
D044	Pyridine	110-86-1	5.0
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D045	1,1,2,2-Tetrachloroethane	630-20-6	10.0
D046	1,1,2,2-Tetrachloroethane	79-34-5	1.3
D047	Tetrachloroethylene	127-18-4	0.1
D048	2,3,4,6-Tetrachlorophenol	58-90-2	1.5
D049	Toluene	106-88-3	14.4
D015	Toxaphene	8001-35-2	0.07
D050	1,1,1-Trichloroethane	71-55-6	30.0

```
D051 ..... 1,1,2-Trichloroethane ................. 79-00-5 1.2
D052 ..... Trichloroethylene ..................... 79-01-6 0.07
D053 ..... 2,4,5-Trichlorophenol ................. 95-95-4 5.8
D054 ..... 2,4,6-Trichlorophenol ................. 88-06-2 0.30
D017 ..... 2,4,5-TP (Silvex) ..................... 93-76-5 0.14
D066 ..... Vinyl chloride ....................... 75-01-4 0.05
--------------------------------------------------------------------------------
1 EPA Hazardous Waste Code Number.
2 Chemical Abstracts Service number.
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***11844** As explained in section III.E.2.a.vii, the Agency does not have sufficient data to address the formation and toxicity of hydrolysis products. Therefore, in today's rule, the Agency is not establishing regulatory levels for those new organic constituents that are expected to appreciably hydrolyze and thereby form potentially toxic by-products. Rather, the Agency expects to address these constituents in a future Federal Register notice.

Three of the organic constituents currently regulated by the EPTC may hydrolyze to a significant extent. However, due to uncertainties associated with this mechanism, the Agency believes that it would not be prudent to remove these constituents from regulation on a temporary basis (i.e., until their hydrolysis products can be assessed). Therefore, these constituents (endrin, methoxychlor, and toxaphene) will continue to be regulated at the existing EPTC levels in the interim.

Also, as explained in section III.E.2.a, the Agency has concluded that the steady-state assumption used in the ground water transport model may not be appropriate for all constituents. The constituents for which a steady-state solution may not be appropriate are being deferred from the list of proposed constituents. EPA will promulgate or repropose (as warranted) regulatory levels for these constituents in a future Federal Register notice.

3. Final List of Constituents

a. Organic Constituents. The organic constituents for which the Agency is today establishing regulatory levels (i.e., those that are on the current EP list, and those that do not appreciably hydrolyze and for which a steady-state assumption is appropriate) are presented in Table IV-2.

Table IV-2.--Organic Constituents

EPA HW number [FN1]	Contaminant	CAS number [FN2]
D018	Benzene	71-43-2
D019	Carbon tetrachloride	56-23-5
D020	Chlordane	57-74-9
D021	Chlorobenzene	106-90-7
D022	Chloroform	67-66-3
D023	o-Cresol	95-46-7
D024	m-Cresol	106-39-4
D025	p-Cresol	106-44-5
D016	2,4-D	94-75-7
D027	1,4-Dichlorobenzene	106-46-7
D028	1,2-Dichloroethane	107-06-2
D029	1,1-Dichloroethylene	75-35-4
D030	2,4-Dinitrotoluene	121-14-2
D012	Endrin	72-20-8
D031	Heptachlor (and its hydroxide)	76-44-2
D032	Hexachlorobenzene	118-74-1
D033	Hexachloro-1,3-butadiene	87-68-3
D034	Hexachloroethane	67-72-1
D013	Lindane	58-89-9
D014	Methoxychlor	72-43-5

D035	Methyl ethyl ketone	78-93-3
D036	Nitrobenzene	96-95-3
D037	Pentachlorophenol	87-86-5
D038	Pyridine	110-86-1
D039	Tetrachloroethylene	127-18-4
D015	Toxaphene	8001-35-2
D040	Trichloroethylene	79-01-6
D041	2,4,5-Trichlorophenol	95-95-4
D042	2,4,6-Trichlorophenol	88-06-2
D017	2,4,5-TP (Silvex)	93-76-5
D043	Vinyl chloride	75-01-4

1 Hazardous waste number.
2 Chemical abstracts service number.

b. Inorganic Constituents. Among the constituents that were proposed for inclusion in the TC were eight inorganic constituents that are currently regulated in the EPTC. Because EPACML does not currently accommodate metallic species, it cannot be used to predict DAFs for these constituents. Therefore, the Agency is today retaining the regulatory ***11845** levels for these constituents at their current levels. When the MINTEQ model (see III.B.5.c) is available to accommodate these constituents, the Agency will reconsider their regulatory levels and propose new ones, if so warranted.

B. Selection of DAFs

The selection of the appropriate DAF for the constituents addressed in today's rule is based on the municipal landfill scenario, as proposed. However, based on comments on fate processes that were not appropriately considered in the model, several constituents have been omitted from the proposed list of constituents—specifically, those that may hydrolyze to more than a negligible extent and those for which the steady-state assumption may not be appropriate.

For the remaining constituents, the Agency believes that a DAF of 100 is appropriate for establishing regulatory levels in today's rule. The basis for this conclusion is explained in Section III.E.4.d.

C. Analytical Constraints

The regulatory levels for the compounds proposed for inclusion in the TC span approximately five orders of magnitude (i.e., from the low parts per billion to 100 parts per million). The calculated regulatory levels for three of these compounds (2,4-dinitrotoluene, hexachlorobenzene, and pyridine) are below the concentrations measurable using currently available methods.

EPA believes that the appropriate way to deal with a calculated regulatory level that is below the analytical detection limit is to use (for the regulatory level) the lowest level of detection that can be attained. The lowest level of a particular chemical that can be reliably measured within acceptable limits of precision and accuracy under routine laboratory operating conditions is that chemical's "quantitation limit." A quantitation limit is determined through such studies as method performance evaluations.

If data from interlaboratory studies are unavailable, quantitation limits are estimated based on the detection limits and an estimated multiplier that represents a practical and routinely achievable level with relatively high certainty that the reported value is reliable. EPA proposed to use a value of five times the analytical detection limit as the quantitation limit and to set the regulatory level at the quantitation limit for those compounds for which the calculated regulatory level is below the quantitation limit, and interlaboratory studies were not available.

Because TCLP extracts are aqueous in nature, the quantitation limits used in this rule are based on the presence of these compounds in a water matrix. The Agency received many comments on the use of the quantitation limit as the regulatory level for the three compounds with health-based thresholds below that level. Most commenters expressed concern that quantitation limits based on analysis of the constituent in a water matrix may not be achievable in more complex samples. The comments

discussed potential complications that could hamper analysis of various kinds of wastes and recommended that EPA work toward determining actual quantitation limits on real wastes.

The Agency agrees that the ability to achieve the quantitation levels listed in the proposed rule is strongly influenced by the type of waste that is being analyzed. However, determination of a matrix-dependent quantitation limit would require analysis of a wide variety of wastes. EPA believes that it would be impractical to perform such waste-specific analyses at this time. Therefore, EPA has chosen to use the proposed definition (i.e., five times the method detection limit) for the quantitation limit.

A number of commenters addressed the issue of the generic multiplier used to derive the quantitation limit. Several commenters recommended using 10 to 25 times the detection limit as the regulatory level, while a few commenters supported setting the regulatory level at the detection limit itself, to provide what they believe would be greater environmental protection.

The Agency is working to improve the sensitivity of analytical methods to provide increased protection of human health and the environment. Analytical detection limits are, by definition, not routinely achievable under average laboratory conditions. Thus, a regulatory level set at the detection limit would be difficult for the Agency to enforce and would make it difficult for the regulated community to demonstrate compliance. To provide a consistently enforceable regulatory limit while providing assurance that those wastes that clearly pose hazards are subject to subtitle C requirements, the Agency will set the regulatory level at five times the detection limit. The Agency has a high degree of confidence in setting the regulatory level at the quantitation limit (i.e., five times the detection limit) because other programs within the Agency have successfully used this method in the past to set regulatory levels (e.g., the Contract Laboratory Program under the Superfund Program).

Comments on the use of the quantitation limit are addressed more extensively in the testing methods background document.

D. Final Regulatory Levels

The regulatory levels being promulgated today are equal to the product of each constituent's toxicity threshold and the DAF or the quantitation limit. These regulatory levels are presented in Table IV-3. These levels are designed to identify wastes that clearly pose a hazard and define those wastes as hazardous. However, it should be noted that wastes that do not exhibit this characteristic (e.g., result in TCLP levels that are less than the regulatory levels) are not necessarily nonhazardous and may be listed as a hazardous waste or become hazardous under other hazardous waste characteristics.

Table IV-3.--Toxicity Characteristic Constituents and Regulatory Levels

EPA HW number [FN1]	Constituent	CAS Number	Regulatory level (mg/L) [FN2]
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	[FN4] 200.0
D024	m-Cresol	108-39-4	[FN4] 200.0
D025	p-Cresol	106-44-5	[FN4] 200.0
D026	Cresol	----------	[FN4] 200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7

D030 ..... 2,4-Dinitrotoluene ..... 121-14-2 [FN3] 0.13
D012 ..... Endrin 72-20-8 0.02
D031 ..... Heptachlor (and its
hydroxide) 76-44-8 0.008
D032 ..... Hexachlorobenzene ..... 118-74-1 [FN3] 0.13
D033 ..... Hexachloro-1,3-butadiene 87-68-3 0.5
D034 ..... Hexachloroethane 67-72-1 3.0
D008 ..... Lead 7439-92-1 5.0
D013 ..... Lindane 58-89-9 0.4
D009 ..... Mercury 7439-97-6 0.2
D014 ..... Methoxychlor 72-43-5 10.0
D035 ..... Methyl ethyl ketone 78-93-3 200.0
D036 ..... Nitrobenzene 98-95-3 2.0
D037 ..... Pentachlorophenol 87-86-5 100.0
D038 ..... Pyridine ..... 110-86-1 [FN3] 5.0
D010 ..... Selenium 7782-49-2 1.0
D011 ..... Silver 7440-22-4 5.0
D039 ..... Tetrachloroethylene 127-18-4 0.7
D015 ..... Toxaphene 8001-35-2 0.5
D040 ..... Trichloroethylene 79-01-6 0.5
D041 ..... 2,4,5-Trichlorophenol 95-95-4 400.0
D042 ..... 2,4,6-Trichlorophenol 88-06-2 2.0
D017 ..... 2,4,5-TP (Silvex) 93-72-1 1.0
D043 ..... Vinyl chloride 75-01-4 0.2

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1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The quantitation limit therefore becomes the regulatory level.
4 If o-m-, and p-cresol concentrations cannot be differentiated, the total cresol (D026) concentration is used. The regulatory level for total cresol is 200 mg/l.

***11846 V. Implementation**

This section is intended to assist the regulated community in understanding their regulatory obligations for managing TC wastes. Responses to comments and an analysis of issues related to implementation were presented in section III.K.

The first step in a solid waste generator's decision making process must be to determine whether or not particular wastes are hazardous (40 CFR 262.11). If a waste is excluded from regulation under 40 CFR 261.4, or if it is a listed hazardous waste under subpart D of 40 CFR part 261, then no further determination is necessary. If a waste is neither excluded nor listed, a generator must determine whether the waste exhibits any of the characteristics of hazardous waste; the Toxicity Characteristic is one such characteristic of hazardous waste. A generator may determine if a waste exhibits a characteristic either by testing the waste or applying knowledge of the waste, the raw materials, and the processes used in its generation.

When a waste is determined to be hazardous, handlers of that waste must comply with any applicable standards in parts 262, 263, 264, 265, 266, 267, 268 and 270 of chapter 40. Table V-1 presents an implementation timeline for the TC. The remainder of this section illuminates five implementation concerns: state authority, integration of today's TC with the existing EPTC, notification, permitting, and compliance date.

Table V-1.—IMPLEMENTATION TIMELINE FOR THE TOXICITY CHARACTERISTIC

0 Months: Publication in the Federal Register.

3 Months:

Generators of 1000 kg/mo or more and TSDFs who have not previously notified submit 3010 Notification to EPA.

6 Months:

Facilities wishing to avoid entering the RCRA program cease managing newly regulated TC hazardous wastes. Units that were receiving TC hazardous wastes must cease further receipt in order to avoid regulation under Subtitle C.

Large quantity generators begin to comply with all applicable Subtitle C regulations for newly regulated TC wastes.

Newly regulated facilities.

—Submit Part A permit application.

Already regulated facilities.

—Interim Status Facilities: submit amended Part A permit application.

—Permitted TSDFs: submit Class 1 permit modification.

12 Months:

Small quantity generators begin to comply with all applicable Subtitle C regulations for newly regulated TC wastes.

Already regulated facilities.

—Permitted TSDFs: submit Class 2 or Class 3 permit modifications.

18 Months:

Newly regulated land disposal units: submit Part B permit application and certifications to EPA—Interim Status terminates for those land disposal units that did not submit their Part B permit application and certifications by this date.

A. State Authority

1. Applicability of Final Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified states to ***11847** administer and enforce the RCRA program within the state (see 40 CFR part 271 for the standards and requirements for authorization). Following authorization, EPA retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized states have primary enforcement responsibility. Prior to HSWA, a state with final authorization administered its hazardous waste program entirely in lieu of the federal program. The federal requirements no longer applied in the authorized state, and EPA could not issue permits for any facilities in a state that was authorized to issue permits. When new, more stringent federal requirements were promulgated or enacted, the state was obligated to enact equivalent authority within specified time frames. New federal requirements did not take effect in an authorized state until the state adopted the requirements as state law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by HSWA take effect in authorized states at the same time that they take effect in nonauthorized states. EPA is directed to carry out those requirements and prohibitions in authorized states, including the issuance of permits, until the state is granted authorization to

do so. While states must still adopt HSWA-related provisions as state law to retain final authorization, the HSWA requirements are implemented by EPA in authorized states in the interim.

Today's rule is promulgated pursuant to RCRA section 3001(g) and (h). These provisions were added by HSWA. Therefore, the Agency is adding the requirement to Table 1 in § 271.1(j), which identifies the federal program requirements that are promulgated pursuant to HSWA and that take effect in all states, regardless of their authorization status. States may apply for either interim of final authorization for the HSWA provisions identified in Table 1, as discussed in the following section of this preamble.

2. Effect on State Authorization

As noted above, EPA will implement today's rule in authorized states until they modify their programs to adopt these rules and the modifications are approved by EPA. Because the rule is promulgated pursuant to HSWA, a state submitting a program modification may apply to receive either interim or final authorization under section 3006(g)(2) or 3006(b), respectively, on the basis of requirements that are substantially equivalent or equivalent to EPA's. The procedures and schedule for state program modifications for either interim or final authorization are described in 40 CFR 271.21. It should be noted that all HSWA interim authorizations will expire January 1, 1993 (see 40 CFR 271.24(c)).

40 CFR 271.21(e)(2) requires that states with final authorization must modify their programs to reflect federal program changes, and they must subsequently submit the modifications to EPA for approval. The deadline for state program modifications for this rule is July 1, 1991 (or July 1, 1992, if a state statutory change is needed). These deadlines can be extended in certain cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the state requirements become subtitle C RCRA requirements. States with authorized RCRA programs may already have requirements similar to those in today's rule. These state regulations have not been assessed against the federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a state is not authorized to implement these requirements in lieu of EPA until the state program modification is approved. Of course, states with existing standards may continue to administer and enforce their standards as a matter of state law. In implementing the federal program, EPA will work with states under cooperative agreements to minimize duplication of efforts. In many cases, EPA will be able to defer to the states in their program implementation efforts, rather than take separate actions under federal authority.

States that submit their official applications for final authorization less than 12 months after the effective date of these standards are not required to include standards equivalent to these standards in their application. However, the state must modify its program by the deadline set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of these standards must include standards equivalent to these standards in their application. The process and schedule for final state authorization applications is described in 40 CFR 271.3.

B. Integration of Today's Final Rule with Existing EPTC

As explained above, because this rule is promulgated pursuant to HSWA, it will be effective six months from today in both authorized and unauthorized states and will be implemented by EPA until states receive authorization for this rule. Thus, beginning on the effective date, large quantity generators that generate TC waste in all states are responsible for complying with the appropriate requirements. However, the rule promulgated today also revises an existing RCRA rule defining hazardous wastes that authorized states have been implementing for some time. The two principal changes in the rule are the revision to the leaching procedure, by replacing the EP with the TCLP, and the addition of constituents for which the leachate will be analyzed. The discussion below and Table V-2 describe how state implementation of the existing EPTC will be integrated with EPA implementation of the TC as promulgated today.

1. Facilities Located in Authorized States

There are three types of facilities located in authorized states which are affected by today's rule: facilities which are already operating under a RCRA permit, facilities which are already operating under interim status, and facilities which are subject to RCRA permit requirements for the first time as a result of today's rule. Permitted and interim status facilities can also be affected by today's rule in three distinct ways: (1) The facility may already be managing wastes that are hazardous under the existing EPTC, (2) the facility may already be managing wastes that are hazardous under the existing EPTC but which also exhibit the toxicity characteristic for a new constituent(s) under today's rule (and thus the waste would have a new waste code), or (3) the facility may be managing a solid waste which is newly subject to regulation as a result of today's revision of the TC. Table V-2 summarizes the initial filing requirements and applicable standards for each category of facility.

[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a meaningful review of its contents. The table has been divided into multiple pieces with each piece containing information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

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Table V-2.--Integration of TC With Existing EPTC

Status of State authorization	Facility status	Type of waste	What to file	Where to file
I. Authorized State	A. Permitted	1. Regulated EPA waste w/no new constituents under revised TC	NA	NA
		2. Regulated EP waste w/new constituents	Class 1 permit modification under 40 CFR 270.42	EPA Regional Office and State
		3. Previously unregulated waste in:	... Class 1 permit modification under 40 CFR 270.42.	[FN1] EPA Regional Office and State
		-Already regulated unit		
		-Previously		

unregulated
unit ..... ---------- ----------
B. Interim Status 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulated
EP waste
w/new
constituents
under
revised TC .. Revised Part A
under 40 CFR
270.72 ..... EPA
Regional
Office
and
State ...
---------- 3. Previously
unregulated
waste ..... Revised Part A
under 40 CFR
270.72.
[FN2] ..... EPA
Regional
Office
and
State ...
C.
Newly-regulated ---------- Part A and
3010 under
40 CFR
270.70.
[FN3] ..... EPA
Regional
Office ..
II.
Nonauthorized
State ..... A. Permitted ..... 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulate EP
waste w/new
constituents
under
revised TC .. Class 1 permit
modification
under 40 CFR
270.42 ..... EPA
Regional
Office ..
---------- 3. Previously
unregulated

waste in: ... Class 1 permit
modification
under 40 CFR
270.42.
[FN1] ..... EPA
Regional
Office ..
---------- -Already
regulated
unit ..... ---------- ----------
---------- -Previously
unregulated
unit ..... ---------- ----------
B. Interim Status 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulated
EP waste
w/new
constituents
under
revised TC .. Revised Part A
under 40 CFR
270.72 ..... EPA
Regional
Office ..
---------- 3. Previously
unregulated
waste ..... Revised Part A
under 40 CFR
270.72.
[FN2] ..... EPA
Regional
Office ..
C.
Newly-regulated ---------- Part A and
3010 under
40 CFR
270.70.
[FN3] ..... EPA
Regional
Office ..
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1 Facility may also need to receive a Class 2 or Class 3 modification under CFR 270.42.

2 If newly regulated waste is being managed in a land disposal unit, facility may need to submit certification of compliance within one year under 40 CFR 270.73.

3 If facility is a land disposal facility, Part B permit application and certfication of compliance must be submitted within one year under RCRA Section 3005(e)(3) and 40 CFR 270.73.

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Applicable
permitting
standards
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State permit
standards.
State permit
standards.
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State permit
standards.
40 CFR Part
265.
State interim
status
standards.
State interim
status
standards.
40 CFR Part
265.
40 CFR Part
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40 CFR Part
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40 CFR Part
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40 CFR Part
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265.
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80..#...90....#.
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***11848** For facilities which have been managing EPTC wastes under an authorized state program and the constituents exhibited by the wastes are unchanged under today's rule, (i.e., no waste code change is necessary), such interim status and permitted facilities have no changes to file with permitting authorities. Similarly, since the regulatory status of the waste is unchanged, management of that waste will continue to be regulated under the authorized state standards. The only effect of today's rule on such facilities is that the facility must use the TCLP when testing for toxic constituents. However, use of the EP in addition to the TCLP may continue to be required as a matter of state law.

For facilities which have been managing EPTC wastes under an authorized state program and the constituents exhibited by the wastes have changed as a result of today's rule, the facility will need to change the waste code assigned to its TC wastes. Permitted facilities must submit permit modifications to EPA reflecting the new wastes codes. Because EPA must implement this rule until the state is authorized to do so, the permittee must comply with federal permit modification procedures under 40 CFR 270.42 rather than state permit modification procedures. However, because the permit undergoing modification is most likely a joint EPA-state RCRA permit, a copy of the modification request should also be submitted to the authorized state.

Similarly, interim status facilities must submit a revised part A permit application to EPA pursuant to 40 CFR 270.72, with a copy to state permitting authorities. Although these facilities must make appropriate waste code modifications to reflect the new TC constituents, the wastes are already regulated as EP wastes under the authorized state program. Accordingly, such wastes are not subject to any new management requirements as a result of this rule and must continue to comply with appropriate authorized state ***11849** requirements for management of these wastes.

Some permitted and interim status facilities in authorized states will be managing wastes which will become hazardous as a result of today's rule. These facilities must also submit permit modifications or part A permit application revisions to EPA. However, because these wastes were previously unregulated under RCRA, they also were not regulated under the authorized state program. As a result, if these wastes are in a previously unregulated unit, they will be subject to the self-implementing Federal standards for hazardous wastes management at 40 CFR part 265 until permit issuance (for interim status facilities) or modification (for permitted facilities). After permit issuance or modification, the Federal permitting standards at 40 CFR part 264 will apply to these wastes (or the state permitting standards if the permit is ultimately issued or modified by a state authorized for the TC). However, if the wastes are at a permitted facility in a unit that is already regulated, that unit will continue to comply with the applicable 40 CFR part 264 (or state equivalent) standards.

Facilities in authorized states which are newly subject to RCRA permit requirements as a result of today's rule must obtain an EPA identification number and submit their part A permit application and section 3010 notification to EPA in order to obtain interim status (see 40 CFR 270.70). Such facilities are subject to regulation under 40 CFR part 265 until a permit is issued by EPA or a state authorized for the TC.

2. Facilities Located in Unauthorized States

There are also three types of facilities located in unauthorized states which are affected by today's rule: already permitted facilities, facilities operating under interim status, and facilities newly subject to RCRA permit requirements under today's rule. As in authorized states, some of the permitted and interim status facilities have been managing EPTC wastes.

For interim status and permitted facilities which have been managing EPTC wastes that will exhibit no new constituents as a result of the replacement of the EP with the TCLP and the addition of constituents to the TC, there will be no waste code changes. Accordingly, such facilities do not need to submit permit modifications or revised permit applications to EPA and will continue to be subject to the applicable federal standards for hazardous waste management.

Facilities which have been managing EPTC wastes which exhibit the toxicity characteristic for new constituents as a result of today's changes to the TC must notify EPA of the waste code changes for its TC wastes. Permitted facilities must submit permit modifications to EPA as required under 40 CFR 270.42 that reflect the new wastes codes. Interim status facilities must submit revised part A permit applications in accordance with 40 CFR 270.72. These facilities must continue to comply with the applicable federal standards for hazardous waste management.

Permitted and interim status facilities which manage waste that is newly defined as hazardous waste as a result of today's rule must also submit permit modification requests or part A permit application revisions to EPA. Facilities must manage these wastes in accordance with 40 CFR part 265 or 40 CFR part 264 until permit modification or issuance, depending on whether the waste is managed in a newly regulated or previously regulated unit.

Facilities which are newly subject to RCRA permit requirements as a result of today's rule must get an EPA identification number and a part A permit application to EPA in order to obtain interim status. Such facilities are subject to regulation under 40 CFR part 265 until a permit is issued.

C. Notification

Pursuant to RCRA section 3010, the Administrator may require all persons who handle hazardous wastes to notify EPA of their hazardous waste management activities within 90 days after the wastes are identified or listed as hazardous. This requirement may be applied even to those generators, transporters, and TSDFs who have previously notified EPA with respect to the management of other hazardous wastes.

In the June 13, 1986, Federal Register notice, EPA proposed to waive the notification requirement for persons who manage TC wastes and have already (1) notified the Agency that they manage other hazardous wastes and (2) received an EPA identification number. EPA has decided to waive the notification requirement as proposed. The Agency believes that, given the vast scope of the TC rule, a notification requirement for persons already identified within the hazardous waste management universe is unnecessary.

EPA is not waiving the notification requirement for TC waste handlers that have neither notified the Agency that they manage hazardous wastes nor received an EPA identification number. Those persons must notify EPA no later than June 27, 1990 of these activities pursuant to section 3010 of RCRA. Notification instructions are set forth in 45 FR 12746, February 26, 1980.

D. Permitting

Currently permitted facilities that manage TC wastes must submit Class 1 permit modifications if they are to continue managing the newly regulated wastes in units that require a permit. The facilities must obtain the necessary modification by the effective date of the rule, or they will be prohibited from accepting additional TC wastes.

Interim status facilities that manage TC wastes in units that require a permit must file an amended part A permit application under 40 CFR 270.10(g) if they are to continue managing newly regulated wastes. The facilities must file the necessary amendments by the effective date of the rule, or they will not receive interim status with respect to the TC wastes (i.e., they will be prohibited from accepting additional TC wastes until permitted).

Newly regulated facilities (i.e., facilities at which the only hazardous wastes that are managed are newly regulated TC wastes) must qualify for interim status by the compliance date of the rule in order to continue managing TC wastes prior to receiving a permit. Under 40 CFR 270.70, an existing facility may obtain interim status by getting an EPA identification number and submitting a part A permit application. To retain interim status, a newly-regulated land disposal facility must submit a part B permit application within one year after the effective date of the rule and certify that the facility is in compliance with all applicable ground water monitoring and financial responsibility requirements (see RCRA section 3005(e)(3)).

EPA recently promulgated amendments to the procedures for permit modifications for treatment, storage, and disposal facilities (see 53 FR 37934, September 28, 1988). The following discussion assumes implementation in accordance with the new rule. EPA will implement the TC by using the new permit modification procedures, consistent with EPA policy (see 53 FR 37933, September 28, 1988).

Under the new regulation in § 270.42, there are now three classes of permit modifications with different submittal and public participation requirements for each class. In § 270.42(g), which concerns newly listed or identified wastes, a permitted facility that is “in existence” as a hazardous waste facility for the newly listed or identified waste on the effective date of the notice must ***11850** submit a Class 1 modification by that date. Essentially, this modification is a notification to the Agency that the facility is handling the waste. As part of the procedure, the permittee must also notify the public within 90 days of submittal to the Agency.

Next, within 180 days of the effective date, the permittee must submit a Class 2 or 3 modification to the Agency. A permittee may submit a Class 2 modification if the newly regulated waste will be disposed in existing TSD units and will not require additional or different management practices from those authorized in the permit. A Class 2 modification requires public notice by the facility owner of the modification request, a 60 day public comment period, and an informal meeting between the owner and the public within the 60 day period. The rule includes a “default provision,” so that for Class 2 modifications, if the Agency

does not make a decision within 120 days, the modification is automatically authorized for 180 days. If the Agency does not reach a decision by the end of that period, the modification is permanently authorized. If the newly regulated waste requires additional or different management practices, a Class 3 modification is required. The initial public notification and public meeting requirements are the same as for Class 2. However, after the end of the public comment period, the Agency will develop a draft permit modification, open a public comment period of 45 days and hold a public hearing.

E. Compliance Date

The Agency is promulgating two different compliance dates for two different categories of TC waste generators: (1) All generators of greater than 100 and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with subtitle C requirements for management of their TC waste within one year from today; and (2) all generators of 1,000 kg/month or more of hazardous waste and TSDFs are required to comply with all subtitle C requirements for TC wastes within six months from today, on the effective date of the rule. Thus the EPTC remains in effect until six months after today's date for large quantity generators and TSDFs, and remains in effect for 12 months after today's date for small quantity generators. The generator quantity refers to all of a generator's hazardous waste, not just newly hazardous TC waste.

Further discussion of the Agency's reasons for promulgating an extended compliance date for small-quantity generators is provided in section III.K of this preamble. In summary, the Agency believes that allowing an additional six months for small quantity generators to come into full compliance with the TC will serve two purposes. First, it will allow the Agency time to educate small quantity generators on the RCRA rules while, at the same time, allowing the Agency to focus immediate implementation efforts on large volumes of hazardous waste. Second, it will provide the necessary time for small quantity generators to comply with subtitle C requirements as a result of the TC.

VI. Regulatory Requirements

A. Introduction

This portion of the preamble discusses the analyses required by Executive Order No. 12291 and the Regulatory Flexibility Act. The Agency is required under the Executive Order to estimate the costs, economic impacts, and benefits of “major” rules by conducting a regulatory impact analysis (RIA). Recognizing the potential of the Toxicity Characteristic (TC) rule to affect a broad spectrum of American industry, EPA prepared an RIA comparing several regulatory alternatives. Based on the results of this analysis, the Agency concluded that this final regulation is a major rule. Section VI.B presents the methodology and results of the RIA.

The Regulatory Flexibility Act requires the Agency to assess small business impacts resulting from regulations. The analysis of small business impacts indicated that the TC rule would not have a significant impact on small businesses, and therefore a formal regulatory flexibility analysis was not prepared. Section VI.C addresses potential effects on small businesses.

The Agency received many comments on the RIA for the June 13, 1986 proposal. A summary of comments, along with Agency responses, is included as section VI.D. Section VI.E discusses requirements under the Paperwork Reduction Act.

Details of the regulatory impact analysis and small business analysis are available in the RIA document for the final rule (Ref. 8). This final rule was submitted to the Office of Management and Budget for review as required by E.O. No. 12291.

B. Regulatory lmpact Analysis

1. Executive Order No. 12291

Executive Order No. 12291 requires EPA to assess the effect of Agency actions during the development of regulations. Such an assessment consists of a quantification of the potential costs, economic impacts, and benefits of a rule, as well as a description of any beneficial or adverse effects that cannot be quantified in monetary terms. ln addition, Executive Order No. 12291 requires

that regulatory agencies prepare a regulatory impact analysis (RlA) for major rules. Major rules are defined as those likely to result in (1) an annual cost to the economy of $100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, employment, investment, innovation, or international trade.

EPA prepared an RIA comparing the final TC rule with several regulatory alternatives. Based on the RIA, EPA estimates that the final TC rule is a major rule with annual compliance costs of between $130 million and $400 million. The analysis was conducted based on the Office of Management and Budget's “Interim Regulatory Impact Analysis Guidance” and EPA's “Guidelines for Performing Regulatory Impact Analyses.”

2. Basic Approach

In the final rule, EPA is amending its hazardous waste identification regulations under Subtitle C of the Resource Conservation and Recovery Act (RCRA) by refining and expanding the existing Extraction Procedure Toxicity Characteristic (EPTC). The resulting TC includes a new extraction procedure (the Toxicity Characteristic Leaching Procedure or TCLP) and 25 new organic constituents in addition to the 14 existing EPTC constituents. Wastes exhibiting the TC, based on concentrations of constituents in the TCLP extract, are designated as hazardous wastes and are brought under subtitle C regulation.

EPA estimated the costs, economic impacts, and benefits of the final rule and of a number of major regulatory alternatives to the rule. Only the anticipated effects of the final rule are presented in this preamble; results for the regulatory alternatives are discussed in the RIA. In presenting the results of the analysis, the Agency has presented range estimates for costs, economic impacts, and benefits to express the uncertainty associated with certain analytical assumptions.

In order to gauge the effects of the final rule, EPA first identified wastes and industries which would be affected by the rule. Incremental costs for affected facilities were estimated based on the change in waste management practices which would be required once ***11851** the wastes became hazardous. These incremental costs were aggregated to estimate national costs of the rule.

Economic impacts on facilities were based on a comparison of facility compliance costs with costs of production and cash from operations. The potential for facility closures was also examined.

Benefits, like costs, were based on required changes in waste management practices. Benefit measures included human health risk reduction, resource damage reduction, and cleanup costs avoided. Facility-level benefit estimates were aggregated to obtain national benefits.

Section VI.B.3, below, presents the methodology used to estimate costs, economic impacts, and benefits. It also briefly describes the sensitivity analyses that were conducted to determine the significance of key analytical assumptions; these sensitivity analyses are discussed in more detail in the RIA. Limitations of the analytical approach (e.g., assumptions which are likely to overstate, understate, or create uncertainty in results) are discussed in the RIA. Results of the analysis of costs, economic impacts, and benefits are provided in section VI.B.4.

3. Methodology

The methodology for the RIA is presented in several parts. First, the procedure for identifying wastes and facilities affected by the TC is discussed. Next, the development of national cost estimates is presented. The section on economic impact methodology describes the criteria used in gauging impacts on the regulated community. Following that is a section that presents several alternative measures of benefits of the rule. The last section describes the methodology for analysis of used oil.

a. Determination of Affected Wastes and Facilities. The first step in estimating the impacts of the rule was to determine which wastes and facilities would be affected by the rule, based on waste characteristics, quantities, and management practices. No

single data source contained all of this information, and none of the data were facility-specific. Therefore, the Agency assembled aggregated data (e.g., by industrial sector) from separate sources and used it to draw inferences on facility-level impacts.

Data on waste characterization and volume came primarily from a series of TC industry studies. (Ref. 19 through 29) These studies were conducted for major industrial categories identified as likely to generate significant quantities of TC wastes; other sectors, generating smaller quantities of potentially affected waste, were not addressed. Standard Industrial Classifications (SICs) for the industrial sectors studied range between the two-digit and four-digit levels. The industries profiled are shown in Table VI-1.

Table VI-1.--Potentially Affected Industries Considered in RIAs for the Proposed and Final TC Rules

Industry	SIC [FN1]	Proposed	Final
Textile Mills [FN2]	22		X
Lumber and Wood Products. [FN2]	2421, 2499		X
Pulp and Paper [FN2]	261, 262, 263, 266		X
Printing and Publishing	27		X
Plastics Materials and Resins. [FN2]	2821	X	X
Synthetic Rubber. [FN2]	2822	X	X
Synthetic Fibers. [FN2]	2823, 2824		X
Pharmaceuticals. [FN2]	283	X	X
Soaps and Other Detergents	2841	X	
Surface Active Agents	2843	X	
Paints and Allied Products	2851	X	
Organic Chemicals. [FN2]	2865, 2869	X	X
Agricultural Chemicals	2879	X	
Petroleum Refining. [FN2]	2911	X	X
Miscellaneous Petroleum and Coal Products. [FN2]	2992		X
Rubber and Miscellaneous Plastics Products. [FN2]	30		X
Non-Ferrous Wire Drawing and Insulation	3357	X	
Machinery and Mechanical Products	34 through 39		X
Pipelines, except Natural Gas. [FN2]	461		X
Electrical Services	4911		X
Wholesale Petroleum Marketing. [FN2]	517		X

1 SICs listed are those defining the group considered in this analysis. SICs given at the two-digit or three-digit SIC level indicate that the analysis applies to all four-digit SICs contained within the broader category

2 Included in detailed quantitative analysis for the final RIA.

The industry studies provided data including waste type (wastewater, sludge, solid process residual, or organic liquid), waste quantity, constituent concentration ranges and distributions, and number of generating facilities. The data in the studies were based primarily on EPA's effluent guidelines reports, supplemented by best engineering judgement and data received in comments on the proposed rule or in follow-up correspondence (Refs. 30 and 31). Most of the wastes which were included were related to wastewater treatment; there was relatively little data on process residuals. Wastes which were already hazardous by virtue of a listing or characteristic (e.g., the EPTC) were not included. Due to lack of data, certain types of wastes were not included in the analysis (e.g., contaminated soil, off-spec products, contaminated debris).

It is particularly difficult to predict the behavior of oily wastes in the TCLP test. For the purpose of deriving upper bound estimates of costs, economic impacts, and benefits, one assumption that EPA adopted was that oily non-liquid wastes would

not present filtration problems in the TCLP (i.e., that the oily phase passes through the filter and hazardous constituents in the oil phase leach to the test extract) and that if extract concentrations exceeded regulatory levels, these wastes would fail the TC. As a basis for lower bound estimates for costs, economic impacts and benefits, the Agency assumed that no oily wastes will be caught by TC regulation because the oily phase (and corresponding high levels of toxic constituents) would not filter through to the extract in the TCLP.

Due to the lack of facility-specific waste generation data, certain assumptions had to be made to derive the quantity of each wastestream per facility. First, potentially affected facilities within each industrial sector were split between small (with less than 50 employees) and large (with 50 employees or more) facility size categories based on 1982 Census of Manufacturers data on the number of facilities by size category. (The 1982 Census data were the most recent available.) Second, the total quantity of potentially affected waste was distributed between small and large facilities based on Census of Manufacturers data on the value of shipments for the small and large size categories. Using the distribution of facilities and of total waste quantity between small and large size categories, EPA estimated wastestream quantity per facility for small and large facilities.

EPA conducted a sensitivity analysis in order to test the sensitivity of results to the assumed distribution of wastes based on value of shipments. Since the division of waste quantities based on value of shipments resulted in most waste being generated by large facilities, EPA tested the alternative assumption that waste quantities were split evenly between the large and small facility size categories in each industry. (Results of sensitivity analyses are presented in section VI.B.4.)

***11852** Baseline management practices (i.e., management practices in the absence of the regulation) were derived primarily from the Screening Survey of Industrial subtitle D Establishments. (Ref. 16.) This survey provided information on the percent of facilities, by industrial sector, which manage non-hazardous wastes on-site in landfills, surface impoundments, waste piles, and land application units. Other baseline management practices were not specifically identified in the survey; therefore, EPA had to use knowledge of potentially affected TC wastes to identify these other practices and estimate the percentage of facilities using them.

In the case of non-wastewaters, the other practices considered included management in off-site landfills and land application units. For wastewaters, the other baseline practices included management in tanks as part of a wastewater treatment system, direct discharge under a NPDES permit, or indirect discharge to a Publicly Owned Treatment Works. These other wastewater management practices were assumed to be permissible under subtitle C; therefore it was assumed that facilities using these practices for wastes which were identified as hazardous by the TC would not be affected by the TC rule. EPA examined the sensitivity of results to this assumption by assuming, alternatively, that all wastewaters were managed on site in subtitle D surface impoundments.

For organic liquids, EPA determined, based on the Office of Solid Waste's Industry Studies Database, that the most likely baseline management practices were recycling and burning. EPA assumed that incremental management costs for these wastes would not be significant and therefore did not include the wastes in the analysis.

By combining the waste characterization and volume data with the management practice data, it was possible to estimate, by industrial sector, the amount of waste and the number of facilities potentially affected by the TC.

In order to determine the quantity of each wastestream which would be affected by the TC, the regulatory levels for constituents in the waste were compared with the estimated concentration distributions, derived from the TC industry studies, for constituents in the waste leachate. The constituent which caused the largest percentage of the wastestream to fail the TC was designated as the “cost-driving” constituent, and the quantity exhibiting the TC due to the presence of that constituent was used as the affected quantity. EPA tested the sensitivity of results to the assumption that waste would fail for a single driving constituent by adding the percentages failing for all constituents (up to 100 percent).

Due to the lack of facility-specific data, it was assumed that the percentage of facilities affected by the TC for a particular wastestream would equal the percentage of the total waste failing the TC. (For example, if 25 percent of a wastestream failed, it was assumed that 25 percent of the facilities generating the waste would be affected and that all of the wastestream at each affected facility would fail.) In order to test the importance of this assumption, EPA adopted two alternative assumptions as sensitivity analyses: for any percentage of waste failing (except for 0 and 100 percent, where clearly no facilities or all facilities would be affected), the percentage of facilities affected would be 10 percent or, alternatively, 90 percent.

The effects of potential production process changes in response to the rule were not addressed.

b. Cost Methodology. EPA estimated both the social costs and the compliance costs of the final rule. Social costs do not include transfer payments between different parties within society (i.e., they do not include tax payments or above-average profits); the social costs therefore represent the real resource costs imposed by the rule on society as a whole. Compliance costs, which include the effects of taxes and above-average profits, more accurately reflect the effect of the rule on particular entities within society.

1. Social Costs

EPA estimated the national social costs of the final rule by calculating before-tax incremental management costs for affected wastes at model facilities and then summing the facility costs across industrial sectors.

Before-tax incremental costs were calculated by subtracting baseline management costs from post-regulatory costs. Baseline management practices were determined as discussed previously. Post-regulatory management practices were developed based on waste types and quantities; the least-cost practice among those feasible for a waste was chosen as discussed below. The post-regulatory practices did not include potential waste treatment practices under the land disposal restrictions program since land disposal restrictions requirements for TC wastes will not come into effect until after the TC rule is promulgated. Possible post-regulatory management practices, as well as baseline practices, for TC wastes are shown in Table VI-2.

Table VI-2.--Baseline and Post-Regulatory Management Practices

Waste type	Baseline practice	Post-regulatory practice
Wastewater	On-site Subtitle D surface impoundment	On-site tank exempt from Subtitle C, Subtitle C surface impoundment. [FN1] or Practice permissible under Subtitle. [FN2] .....
Same as baseline. [FN3]		
Non-wastewater	On-site Subtitle D landfill or land application unit or off-site Subtitle D landfill	On-site or off-site Subtitle C landfill or land application unit.
Organic liquid	Burning, recycling	Same as baseline. [FN3]

1 Dilution and deep-well injection were also considered as post-regulatory practices but were found to be more expensive than tank management.
2 Includes management in Subtitle C-exempt tanks, direct discharge under a NPDES permit, or indirect discharge to a Publicly Owned Treatment Works.
3 Since the post-regulatory practice was the same as the baseline practice, the rule would not affect management of these wastes.

To estimate before-tax baseline and post-regulatory costs for wastes, EPA first estimated the cost per metric ton for the different on-site and off-site waste management practices. Before-tax costs for on-site management units include operation and maintenance (O&M) and capital costs. O&M costs are incurred annually for operation and maintenance of waste treatment or disposal units. Capital costs include costs for construction of the unit and for depreciable assets; these costs, which assumed an average operating life of 20 years, were restated as annual values by using a capital recovery factor based on a discount rate of three percent. RCRA-related costs such as personnel training, financial assurance, and liability insurance were included as indirect capital costs.

For the subset of subtitle D facilities which could potentially become subtitle C TSDFs in order to manage TC wastes on-site, post-regulatory costs for on-site management also included corrective action costs. Corrective action costs for units were based on data from the to-be-proposed corrective action subpart S rule RIA, which indicated the probability of a unit requiring a RCRA facility assessment, RCRA facility investigation, and corrective action cleanup. Corrective action costs were ***11853** not assigned to facilities which were determined to already be subtitle C treatment, storage, and disposal facilities, since units at these facilities would already be subject to corrective action requirements under subparts S and F. Like capital costs, corrective action costs were converted to annual values.

The annualized capital and (as appropriate) corrective action costs were added to yearly O&M costs to derive overall annualized costs for on-site units of various sizes. These annualized costs were then divided by the waste management capacities of the units to obtain the costs per metric ton for on-site management in different units.

Off-site management costs were based on commercial hazardous waste management prices, adjusted for the effects of above-average profits. Shipping costs were included for wastes sent off-site. Neither the on-site nor off-site costs included the cost of waste testing.

Since no data were available on the combinations of wastestreams generated at particular facilities, EPA used an algorithm to create model facilities. In estimating costs for the model facilities, wastes that were amenable to co-management were grouped to identify economies of scale.

Once the costs per metric ton for different types of on-site and off-site management had been developed and waste quantities for the model facilities had been determined, EPA estimated each facility's baseline cost based on the quantities of waste and the cost per metric ton for the baseline management practices identified for the wastes. The post-regulatory cost for each facility was estimated in a similar way. The post-regulatory management practices for facilities were selected by comparing the cost per metric ton for different feasible post-regulatory practices for wastes and selecting the least expensive alternative. (This comparison was made based on compliance costs, rather than social costs, as discussed below). EPA then subtracted baseline costs from post-regulatory costs to obtain the before-tax incremental cost for each facility. These before-tax incremental costs were then added across industrial sectors to obtain the total (national) social costs of the rule.

EPA examined the possibility that some facilities managing wastewaters would incur costs over and above the cost of switching from management in unlined surface impoundments to management in wastewater treatment tanks that are exempt from subtitle C. To calculate upper bound costs, the Agency assumed that facilities generating large quantities of TC wastewater (over 400,000 metric tons per year) would not be able to convert existing non-hazardous surface impoundments to tanks by the effective date of the rule (i.e., October 1, 1990) and therefore would become interim status facilities under RCRA and subject to subtitle C closure of any impoundments. The upper bound cost estimates included costs for subtitle C “landfill closure” of the surface impoundments currently used to manage TC waste. Costs for surface impoundment subtitle C closure included pumping of free liquid, solidification of sludges, construction of a cover system, installation of upgradient and downgradient ground water monitoring wells, closure certification, and potential corrective action costs triggered by bringing facilities with TC surface impoundments into the subtitle C system.

2. Compliance Costs

EPA used the same basic approach to estimate compliance costs that was used to estimate social costs except that the after-tax costs (or revenue requirements) of management practices were used rather than the before-tax costs, and the price of off-site management was used rather than the cost of off-site management (to address above-average profits). Since the compliance costs reflect the cost of the rule for particular entities within society more accurately than the social costs do, compliance costs were used in determining whether it would be less expensive for facilities to use on-site or off-site post-regulatory management practices.

Based on the cost analysis discussed above, EPA estimated the number of existing subtitle C treatment, storage, and disposal facilities (TSDFs) electing to manage TC non-wastewaters on site and the number of subtitle D facilities which would be likely to become subtitle C TSDFs in order to manage their non-wastewaters on-site. (The focus was on on-site management of non-wastewaters, since it was assumed that most facilities would be able to manage wastewaters on site without becoming subtitle C TSDFs.) This was done by first determining the number of facilities that would be likely to choose on-site management as the least-cost management practice for non-wastewaters and then estimating how many of these would be likely to already be subtitle C TSDFs. EPA also estimated the number of new subtitle C generators, by determining how many facilities would generate in excess of 100 kilograms per month of TC waste and then calculating how many of these facilities would be likely to already be subtitle C generators.

c. Economic Impact Methodology. To gauge impacts, EPA compared compliance costs (discussed previously) with average facility costs of production and with cash from operations. Financial data were obtained primarily from the Census and Annual Survey of Manufacturers (U.S. Department of Commerce, Bureau of Census) and were organized by Standard Industrial Classification (SIC) code and facility size. Impacts were estimated at the facility level rather than the firm level, due to lack of data on specific facilities and the firms owning them.

Two ratios were used to identify facilities likely to experience adverse economic effects: compliance cost divided by cost of production (the COP ratio) and cash from operations divided by compliance cost (the CFO ratio). These ratios bound possible effects on individual facilities by examining impacts assuming complete pass-through of compliance costs to customers, on the one hand, and assuming no pass-through of costs, on the other. The COP ratio represents the percentage product price increase for facility output that would be necessary if the entire compliance cost, accompanied by facility profit, were to be passed through to customers in the form of higher prices. A change exceeding five percent is considered an indication of a significant adverse economic impact on a facility. The CFO ratio represents the number of times that a facility's gross margin (profit) would cover the compliance cost if the facility were to fully absorb the cost. For this ratio, a value of less than 20 is considered to represent a significant adverse impact.

EPA then performed an analysis on the facilities experiencing significant economic impacts to identify the potential for facility closures. Those facilities for which the CFO ratio was less than two were considered likely to close.

Impacts on significantly affected product markets were addressed qualitatively by examining market structure and the ability of facilities to pass compliance costs on to customers.

d. Benefits Methodology. The benefits of the final rule were evaluated by considering the reduction in human health risk, the reduction in resource damage, and future cleanup costs avoided that would result from required changes in management practices for affected wastes. These benefits ***11854** measures centered primarily on the exposure to contaminants via the ground water medium, since this was the route of exposure addressed by the TC rule; however, a screening analysis of risks via air, due to emissions from surface impoundments, was also conducted to gauge the significance of these risks.

It is important to point out that the benefits measures should not be added. The measures provide alternative ways of evaluating benefits of the rule, and significant overlap between measures does occur.

EPA estimated benefits on a wastestream-by-wastestream basis. To simplify the analysis of benefits, EPA employed a screening analysis to identify two “risk-driving” constituents in each wastestream, one a carcinogen and one a non-carcinogen. These constituents were then used in developing benefit estimates.

A Monte Carlo modeling approach was used to simulate fate and transport of the constituents and subsequent exposure to them under a variety of waste characterizations, hydrogeologic settings, and exposure scenarios. Based on data from EPA's National Survey of Solid Waste Municipal Landfill Facilities (the “Municipal Landfill Survey”), it was assumed that only 46 percent of facilities had down-gradient wells. EPA examined the sensitivity of results to this assumption by assuming, alternatively, that all facilities had down-gradient wells.

Due to the way in which fate and transport of constituents was modeled (using an infinite source, steady-state model), benefits estimates were primarily a function of the number of facilities estimated to manage each wastestream and constituent concentrations in the waste; wastestream volumes did not affect benefits estimates. In contrast, cost analysis results were a function of the number of facilities, waste constituent concentrations, and wastestream volumes.

Worst-case estimates of baseline risk, resource damage, and cleanup costs were developed by assuming that the baseline management practice for both wastewaters and non-wastewaters was an unlined, non-hazardous waste landfill. This is the same assumption that was employed by the Agency in determining regulatory levels for TC constituents. Post-regulatory risk, resource damage, and cleanup costs were estimated by assuming that the wastes managed as hazardous under the TC would be effectively prevented from contaminating ground water and would therefore result in no risk, resource damage, or cleanup costs; only those wastes continuing to be managed as non-hazardous would pose a threat to human health or the environment.

For wastewaters, the baseline risk, resource damage, and cleanup cost due to ground water contamination were based on concentrations of constituents in the influents to waste management units. Consequently, since volatilization of constituents from waste management units was not accounted for, benefits due to reduction in ground water contamination may be overstated.

The three benefits measures used in this analysis are discussed separately below.

1. Human Health Risk Reduction

EPA estimated two types of human health risk: risk to the most exposed individual (MEI) and population risk. Human health risk is defined herein as the probability of injury, disease, or death over a given time (70 years) due to responses to doses of disease-causing agents. The human health risk posed by a waste management practice is a function of the toxicity of the chemical constituents in the wastestream and the extent of human exposure to the constituents. The likelihood of exposure is dictated by hydrogeologic and climatic settings at land disposal units and by the fate and transport of chemical constituents in environmental media.

a. MEI Risk Reduction. MEI risk was based on exposure to the risk-driving constituents. Concentrations of the risk-driving constituents in the waste leachate were selected randomly from the constituents' concentration distributions. A dilution-attenuation factor (DAF), derived from EPA's subsurface fate and transport model (EPACML), was then randomly selected and used to model the fate and transport of the constituents in ground water. (The DAFs were developed using data from the Municipal Landfill Survey on landfill size, hydrogeology, and distance from the unit to the closest drinking water well; see section III.E for further discussion of the model.) By dividing the initial leachate concentrations of the risk-driving constituents by the DAF, exposure concentrations at a down-gradient well were estimated. Risks from ingestion of contaminated ground water were then calculated. The carcinogenic MEI risk was expressed as the probability of the MEI contracting cancer over a 70-year lifetime, and the non-carcinogenic MEI risk was expressed as an exceedance of the health-effects threshold.

Risk estimates were developed in this way for baseline conditions and for the final rule. The difference between the final rule and baseline risk estimates yielded the MEI risk reduction (or benefit).

EPA conducted a separate screening analysis of baseline MEI risks due to air emissions from surface impoundments in order to assess whether potential air risks were significant. This was done by assuming that constituents in wastewaters would potentially volatilize to the air rather than leach to ground water. EPA's Liner Location Model (Ref. 32) was used to estimate concentrations of constituents at an exposure point 200 meters from the edge of the surface impoundment. Both carcinogenic and non-carcinogenic risks were estimated.

b. Population Risk Reduction. Population risk was estimated in much the same way as MEI risk, with the exception that ground water plume areas for risk-driving constituents were used to model the exposure of populations located downgradient from units. The plume areas were developed for a representative hydrogeologic environment, based on data from the Municipal Landfill Survey.

Each plume area contained a gradient of exposure concentrations, with the highest concentration near the unit boundary and the lowest concentration near the outside edge of the plume. By assuming a uniform population density of 1.6 persons per acre, based on the Municipal Landfill Survey, it was possible to estimate the number of persons exposed to each of the concentration levels within each plume.

The population risk for the carcinogenic constituent, based on the constituent's risk-specific dose (RSD), was expressed as the number of cancer cases over a 70-year lifetime. The population risk for the non-carcinogenic constituent, based on the constituent's reference dose (RfD), was expressed as the number of persons exposed to average daily concentrations exceeding the RfD over a 70-year period.

2. Resource Damage Avoided

Resource damage measures the cost associated with replacing contaminated ground water that had been used as a source of drinking water. Resource damage was assumed to result from any contamination of ground water which would render it unsuitable for human consumption; other potential foregone uses, such as industrial or agricultural uses, were not addressed.

If the concentration of a constituent in ground water exceeded a maximum contaminant level (MCL), the ground water was assumed to be damaged. If ***11855** the contaminant did not have an MCL but the concentration exceeded a taste and odor threshold or a health effects threshold, the ground water was also assumed to be damaged. Areas of damaged ground water were derived based on a comparison of the constituent's concentration within the plume with the constituent's MCL, taste and odor threshold, or health-based number, in an approach similar to that used to estimate plume areas for population risk.

To place a value on the damaged resource, EPA assumed that an alternative water supply system would have to be built to provide water to persons living above the area of the damaged ground water. The costs of constructing the water supply system included capital and O&M costs; these costs were discounted to the present at a rate of three percent to obtain the resource damage per facility. Addition of resource damage across facilities provided a national estimate.

3. Cleanup Costs Avoided

As an alternative measure of benefits, EPA estimated the cleanup costs avoided as a result of the TC rule. Costs of cleanup of contaminated ground water were estimated by assuming that sites with resource damage in the baseline would eventually require cleanups. To develop an upper bound estimate, it was assumed that sites with resource damage greater than $1,000,000 (present value) would require cleanup.

Cleanup costs were based on an average cost of $15 million per site, with cleanups beginning in 15 years. EPA estimated the average cost of cleanup by examining recent Superfund records of decision (RODs) for sites contaminated with TC constituents that required substantial ground water cleanup efforts. Costs were discounted to present values using a discount rate of three percent.

e. Used Oil Methodology. EPA addressed the impacts of the TC on used oil separately from other wastes for several reasons. First, used oil is generated across a wide variety of industrial sectors. Second, unlike other wastes, it has economic value and can be sold in intermediate or end-use markets; this complicates any analysis of the costs of regulating it as a hazardous waste. Also, data on used oil are quite limited. Finally, it is difficult to accurately estimate quantities of used oil that may exhibit the TC because in practice TCLP filtration is sample-specific and difficult to predict.

The analysis of costs, economic impacts, and benefits associated with used oil was qualitative in nature; no attempt was made to develop national estimates. In determining the quantity of used oil potentially affected, EPA excluded used oil that was: (1) Already hazardous because it exhibits a hazardous waste characteristic (e.g., ignitability); (2) recycled; or (3) generated by "do-it-yourselfers" (i.e., auto owners disposing of crankcase oil). In order to develop worst-case estimates of impacts on used oil, it was assumed that used oil would filter in the TCLP. It was also assumed that the facilities managing used oil were subtitle D facilities. Finally, estimated impacts on used oil did not account for the possible stigma associated with management of used oil as a hazardous waste.

4. Results

Results of the RIA are presented below. These results are approximations that are intended to identify the most significant impacts of the TC rule. As discussed previously, there were no data on the waste types and quantities generated by specific facilities in the different industrial sectors. Therefore, EPA used more aggregated data and focused on those industrial sectors which were most likely to generate significant quantities of TC wastes.

a. Affected Wastes and Facilities. EPA estimated the amount of waste and the number of facilities that would be "affected" by the rule, i.e., that would incur any incremental costs due to required changes in management practices for newly hazardous wastes.

1. Affected Wastes

The overall quantity of waste affected by the TC was driven by wastewaters. EPA estimated the quantity of affected wastewaters to be approximately 730 million metric tons (MMT) per year and the quantity of affected non-wastewaters (sludges and solids) would range from approximately 0.85 MMT/year to 1.8 MMT/year. It should be noted that the affected wastewaters, which would be hazardous wastes, are assumed to be exempt from subtitle C regulation in the post-regulatory scenario due to their management in exempt tanks. However, they would be affected wastes because a change in management practice (from surface impoundments to tanks) would be required.

The industrial sectors with the largest quantities of affected wastewaters were Petroleum Refining (SIC 2911), Organic Chemicals (SIC 286), Synthetic Rubber (SIC 2822), and Cellulosic and Non-Cellulosic Synthetic Fibers (SICs 2823 and 2824). For the lower bound estimate of 0.85 MMT/year of non-wastewaters affected, the sectors with the largest quantities of affected non-wastewaters were Pulp and Paper (SIC 26), Synthetic Fibers, Organic Chemicals, and Pharmaceuticals (SIC 283). For the upper bound estimate of 1.8 MMT/year, industry sectors generating the largest quantities of affected non-wastewaters were Petroleum Refining, Pulp and Paper, Synthetic Fibers, Organic Chemicals, and Wholesale Petroleum Marketing (SIC 517). Certain sectors generate significant quantities of both wastewaters and non-wastewaters due to the wastewater treatment sludges associated with wastewater streams. Most of the affected wastewaters and non-wastewaters are believed to be generated by large facilities.

A total of twelve constituents appeared as "cost-driving" constituents in the analysis. However, benzene was the driving constituent for over 60 percent of the affected waste quantity. Other volume-driving constituents include chloroform (25%), vinyl chloride (17%), and trichloroethylene (15%).

2. Affected Facilities

EPA estimated that between 15,000 and 17,000 generators would be affected by the rule. Costs and additional requirements among these affected facilities will vary (e.g., some may already be RCRA generators or TSDFs, others may need to apply for RCRA permits or send wastes off-site). Over 90 percent of these were small facilities (with fewer than 50 employees). The industries with the most affected large facilities were Hosiery and Knit Fabric Finishing (SIC 225), Wholesale Petroleum Marketing, Organic Chemicals, Petroleum Refining, and Plastics Materials and Resins (SIC 2821). The industries with the most affected small facilities were Wholesale Petroleum Marketing, Hosiery and Knit Fabric Finishing, Miscellaneous Petroleum and Coal Products (SIC 2992), Organic Chemicals, and Plastics Materials and Resins.

3. Sensitivity Analysis of Affected Wastes and Facilities

Changes in certain analytical assumptions had significant effects on the quantity of waste and number of facilities affected by the TC final rule. (Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected cost and benefit results, as discussed below under cost results and benefit results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would have a very significant effect on the quantity of non- ***11856** wastewaters affected by the TC. This effect can be seen in the difference between lower bound (assuming oily wastes do not filter) and upper bound (assuming oily wastes filter without complications) estimates of affected quantities of non-wastewaters. Nearly all of the non-wastewaters from Petroleum Refining (including a very large-volume primary treatment sludge), Wholesale Petroleum Marketing, and Petroleum Pipelines are oily wastes.

Assuming that all wastewaters were managed in surface impoundments, rather than some portion being managed by practices exempt under subtitle C, increased affected wastewater quantity significantly to approximately 1,900 MMT/year. lt also increased the number of facilities affected in certain sectors.

Finally, assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced the number of facilities affected by the TC in most industrial sectors.

b. Cost Results—1. Social Costs and Compliance Costs. EPA estimated the total social costs of the TC rule (excluding taxes and above-average profits) to be approximately $90 million to $310 million per year (present value $1.3 billion to $5.7 billion); this does not include costs associated with used oil. Compliance costs (which include taxes and above-average profits) ranged from $130 million to $400 million per year (present value $1.9 billion to $6.0 billion). While affected waste quantities were driven by wastewaters, compliance costs (for the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred) were driven by non-wastewaters due to the significantly higher incremental costs of managing non-wastewaters. Non-wastewaters accounted for over 95 percent of compliance costs.

For the lower bound cost estimate, the industrial sectors with the largest compliance costs were Pulp and Paper, Synthetic Fibers, Organic Chemicals, and Synthetic Rubber. For the upper bound cost estimate, the industrial sectors with the largest compliance costs were Petroleum Refining, Pulp and Paper, Synthetic Fibers, Wholesale Petroleum Marketing, and Organic Chemicals. Constituents driving the cost results were: benzene, chloroform, trichloroethylene, vinyl chloride, and carbon tetrachloride.

Approximately 90 percent of the compliance costs (for the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred) were incurred by large facilities and 10 percent by small facilities across industrial sectors. A relatively small number of large facilities incurs the majority of compliance costs because large facilities are believed to have much greater waste generation rates than small facilities.

The estimated number of subtitle D facilities seeking permits to become non-commercial subtitle C TSDFs was 40 to 250; this does not include facilities seeking permits for storage or treatment only. Most of the expected permit applicants were in the Pulp and Paper Industry in the lower bound estimate. Most of these new TSDFs in the upper bound estimate were in Petroleum Refining.

The number of existing subtitle C non-commercial TSDFs expected to seek permit modifications to handle TC wastes was between 45 and 220, depending on whether permits are considered for only disposal or for treatment, storage, and disposal. Most of these facilities in the upper bound estimate were in the Wholesale Petroleum Marketing and Petroleum Refining industries.

The number of subtitle C commercial TSDFs (SIC 4953) seeking permit modifications or changes to interim status could be as high as 360, the estimated number of existing commercial TSDFs. Many of these commercial TSDFs are primarily storage facilities.

In addition, the TC rule would result in as many as 15,000 new subtitle C generators. Most of the new generators would be in Wholesale Petroleum Marketing and Hosiery and Knit Fabric Finishing.

2. Sensitivity Analysis of Costs. Changes in certain analytical assumptions had significant effects on the social costs and compliance costs of the TC final rule. (Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected benefit results, as discussed below under benefits results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would have a significant effect on both social costs and compliance costs. The Agency estimated, as a lower bound assuming that no oily wastes will fail the TC test, social costs of about $90 million per year and compliance costs of about $130 million per year. By comparison, if it were assumed for the purpose of predicting TCLP results that oily wastes behave like other non-liquid wastes, social costs would be $190 million per year and compliance costs would be $250 million per year.

Assuming that not all facilities would be able to convert within six months from surface impoundments to tanks for management of their TC wastewaters, rather than assuming that all facilities would be able to convert, significantly increased the cost of the rule. Based on landfill closure of impoundments, this assumption added approximately $120 million to annual social costs and $140 million to annual compliance costs.

Splitting wastestream quantity evenly between small and large facility size categories, rather than based on value of shipments, shifted wastes from large to small facilities. While this did not affect the overall costs greatly, it significantly decreased compliance costs for large facilities and increased them for small facilities.

Finally, assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced social costs and compliance costs due to the larger quantities of waste being managed at a smaller number of facilities and the resultant economies of scale. The estimated number of new subtitle0 C TSDFs, existing TSDFs seeking permit modifications, and new subtitle C generators also decreased significantly.

c. Economic Impact Results—1. Significantly Affected Facilities. Based on the economic impact criteria discussed previously the estimated total number of significantly affected facilities was 65 to 81, of which most (51 to 66) are large. The fact that most of the significantly affected facilities are large can be partially explained by the fact that data indicate there are no small facilities in certain sectors (e.g., Cellulosic Synthetic Fibers). Another reason for the preponderance of significantly affected large facilities is that for some wastes, total compliance costs are less for small facilities than for large facilities because large facilities are believed to generate significantly more waste.

In the lower bound estimates, significantly affected facilities were expected in four industrial sectors: Pulp and Paper, Synthetic Rubber, Synthetic Fibers, and Organic Chemicals. In the lower bound estimates the Pulp and Paper industry was predicted to have the greatest number of significantly affected facilities (35), of which 30 are large facilities. The synthetic rubber industry had the highest number of significantly affected small facilities (8), out of a total of 14 significantly affected small facilities. None of the industries examined were expected to suffer facility closures as a result of the TC.

***11857** In the upper bound estimates, significantly affected facilities were expected in seven industries: Pulp and Paper, Synthetic Rubber, Synthetic Fibers, Organic Chemicals, Textiles, Pharmaceuticals, and Plastics and Resins. Pulp and paper had the largest number of significantly affected facilities—36 out of 80 for all facilities.

2. Effects on Product and Capital Markets

The industries with significantly affected facilities have very little potential to pass compliance costs on to consumers in the form of higher prices. These industries produce primarily intermediate goods (e.g., rubber, paper, fibers, and chemicals) which are used in a number of subsequent processes (e.g., manufacturing and fabrication) before they reach consumer markets. The users of these intermediate products have access to similar or identical products from U.S. suppliers that are not significantly affected by the TC and from foreign suppliers; because substitutes are available, these users would not be forced to pay higher prices for the intermediate products.

While results suggest that prices in product markets will not be affected, at least some impact is likely on capital markets. Because affected facilities will not be able to pass compliance costs through to buyers in the form of higher prices, they will experience lower profits. Lower profits will reduce the value of capital tied up in these facilities. However, as most of the affected facilities are part of integrated production systems and are owned by large firms with significant asset holdings, the effect on capital markets (i.e., stock prices and bond ratings) should be relatively small.

3. Sensitivity Analysis of Economic Impacts.

A change in one of the analytical assumptions had significant effects on economic impacts due to the TC final rule. Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.

Splitting wastestream quantity evenly between small and large facility size categories, rather than based on value of shipments, shifted wastes from large to small facilities. Under the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred, this resulted in nearly 40 additional small facilities with significant economic impacts and 10 small facility closures.

d. Benefits Results. EPA estimated the benefits of regulating TC wastes on a wastestream by wastestream basis; results of this analysis are presented in Table VI-3. As discussed in the benefits methodology section, results for different benefit measures (human health risk, resource damage, and cleanup costs avoided) are likely to overlap and should not be added.

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Table VI-3.--Benefits of the TC Rule
Reduction in MEI Risk:
- Reduction in Carcinogenic Risk (number of facilities with risk
greater than 1x10E-5 at down-gradient well) ..................... 370 to
780.
- Reduction in Non-Carcinogenic Risk (number of facilities with
exposure above a health-based threshold at downgradient well) ..... 8.
Reduction in Population Risk:
- Reduction in Carcinogenic Risk (number of cancer cases over 70
years) ........................................................... 6.
- Reduction in Non-Carcinogenic Risk (number of persons with
exposure above a health-based threshold at downgradient wells) ..... 320.
Reduction in Resource Damage (present value, millions of 1988
dollars) ....................................................... 3,800.
Cleanup Costs Avoided (present value, millions of 1988 dollars) ..... Up to
15,000.
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1. MEI Risk

As can be seen from the table, there is a potentially significant reduction under the final rule in the carcinogenic risk to the most exposed individual (MEI). There are from 370-780 fewer facilities managing wastes that present risks to the most exposed individual (MEI) greater than 1x10E-5 under the final rule than there were under baseline conditions. The industrial sectors driving these benefits include Wholesale Petroleum Marketing (SIC 517) and Miscellaneous Plastics Products (SIC 3079). The constituent driving most of these benefits is benzene. The difference between the lower and upper bounds results from certain oily wastes that are unregulated in the lower bound.

For non-carcinogenic MEI risk, there are 8 fewer facilities managing wastewaters where the exposure to a non-carcinogenic constituent exceeds the reference dose (RfD) under the final rule than under baseline conditions. Wastes from Wholesale Petroleum Marketing drive these benefits results. Cresols are the risk-driving constituents.

The Wholesale Petroleum Marketing sector presents significant risks due to the large number of facilities managing wastewaters and non-wastewaters. The number of facilities in this sector estimated to manage wastewaters and non-wastewaters are 1,290 and 1,050 facilities, respectively; this compares with 1,900 and 8,600 facilities, respectively, managing affected wastewaters and non-wastewaters across all industrial sectors.

A screening analysis of MEI risks due to air emissions from surface impoundments was conducted to gauge the potential risk via the air medium. This analysis indicated that in sectors other than Wholesale Petroleum Marketing approximately 20 percent of modeled facilities had carcinogenic risks greater than 1x10E-5 and 5 percent had non-carcinogenic doses greater than the RfD; MEI air risks from Wholesale Petroleum Marketing were less than 1x10E-6. Benzene contributed most of the carcinogenic risks while phenol was responsible for most of the non-carcinogenic risks.

The industries generating wastes with high MEI air risks differ to some extent from those generating wastes with high MEI ground water risks. The industries generating wastes with high MEI air risks include Pulp and Paper, Plastics Materials and Resins, Synthetic Rubber, Cellulosic and Non-Cellulosic Synthetic Fibers (SICs 2823 and 2824), and Organic Chemicals.

There is some potential overlap in estimates of air and ground water risk. The wastewater MEI risks via ground water were based on the assumption that all the constituent mass was available for leaching to ground water; in contrast, the air risks assumed some percentage of constituent mass would volatilize from impoundments. As a result, the wastewater MEI risks via ground water are likely to be overstated.

2. Population Risk

Based on a very limited analysis of population risk, EPA estimates that there would be six fewer cancer cases over the 70-year modeling period due to the final rule. Wholesale Petroleum Marketing (constituent: benzene) and Plastics and Resins (SIC 2821) (constituent: vinyl chloride) drive these benefits. The reduction in number of persons exposed to non-carcinogens at concentrations greater than the RfDs was estimated to be 320 over a 70-year period. Sawmills and Planing Mills (SIC 2421) and Organic Chemicals (pentachlorophenol and methyl ethyl keytone) drive these results.

3. Resource Damage

The total reduction in resource damage would be approximately $3.8 billion (present value). Wholesale Petroleum Marketing and Miscellaneous Plastics Products are the industrial sectors driving resource damage benefits. Benzene is the driving constituent.

***11858 4. Cleanup Costs Avoided**

Estimated cleanup costs avoided due to the final rule ranged up to $15 billion (present value). Under the assumption that all sites with significant resource damage (i.e., resource damage greater than $1,000,000 (present value)) would require cleanup, approximately 1,600 facilities would require cleanup.

5. Sensitivity Analysis of Benefits

Changes in certain analytical assumptions had significant effects on the benefits of the TC final rule. (Refer to sections VI.B.3. a and d for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected cost results, as discussed under cost results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would reduce the benefits associated with non-wastewaters, as can be seen in the lower bound estimates indicated in the results above. This would result primarily from the significant reduction in the number of facilities managing non-wastewaters in Wholesale Petroleum Marketing.

Assuming that all wastewaters were managed in surface impoundments, rather than some portion being managed by practices exempt under subtitle C, would increase the number of facilities affected in many sectors and increase benefits significantly. Benefits for wastewaters could increase by approximately 10 times since there would be 10 times as many facilities with surface impoundments.

Assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced the number of facilities affected by the TC in all industrial sectors. This would significantly reduce benefits as a result, since fewer facilities would be managing wastes.

Assuming that all facilities have down-gradient wells, rather than assuming only 46% have down-gradient wells, would increase benefit results by a factor of approximately two.

e. Cost-Effectiveness. The Agency estimated the cost-effectiveness of the final rule and of several regulatory alternatives. This discussion is presented in the regulatory impact analysis document, which is part of the public docket for the rule.

f. Used Oil Results. Used oil is generated across a wide variety of industrial sectors. Some generators manage or dispose of their used oil directly while others provide their used oil to the used oil management system (UOMS), a system of intermediate collectors and processors (Ref. 33). Firms in the UOMS then re-refine or process the used oil and/or sell it for various end uses.

Under the worst-case assumption that used oil would not create TCLP filtration problems, EPA found based on constituent concentration data (see Ref. 8), that virtually all used oil would fail the TC. EPA determined that three end-use management practices for used oil would be affected: landfilling/incineration, dumping, and road oiling.

Once used oil became TC hazardous, it would have to be shifted to other end-use management practices. Much of the used oil that is currently dumped or applied directly to roads by generators would probably be collected and sold to the UOMS. Firms in the UOMS that currently sell used oil for road oiling would generally shift this oil to other management practices, such as re-refining or burning as a fuel. Used oil that is managed by landfilling or incineration in subtitle D units would likely be shifted to management in subtitle C units.

The shift in management practices would impose costs on used oil generators, the UOMS, and end-users of used oil. Used oil generators currently providing used oil to the UOMS would be likely to pay somewhat higher collection costs due to pass-through of compliance costs by firms in the UOMS. Generators that currently manage their wastes by road oiling would incur storage and collection costs for their used oil as well as costs for a road-oiling substitute. Generators directly managing their wastes by dumping would incur costs for storage and collection. Firms in the UOMS that sell used oil for road oiling would be forced to sell the oil in less profitable markets, and some firms could close if unable to enter another market. Firms in the UOMS could also incur costs for disposal of low quality used oil and related wastes in subtitle C (rather than subtitle D) units if these wastes were TC hazardous; as discussed above, some of these costs could be passed on to used oil generators. Firms that

re-refine used oil could benefit from the TC rule, since a greater volume of used oil would potentially be available at a lower price. Finally, end-users that purchase used oil for road oiling would incur costs for an alternative dust suppressant.

The shift in management practices could also result in certain benefits. A previous study of carcinogenic risks from used oil management practices (Ref. 34) indicates that dumping of used oil may present significant risks relative to other management practices (with the possible exception of burning in boilers, where risks are more comparable). Road oiling appears to present more significant risks than recycling and comparable or fewer risks relative to burning in boilers or landfill disposal. It is difficult to draw definitive conclusions concerning benefits due to the different constituent profiles and population densities associated with each of the management practices in the risk analysis.

C. Regulatory Flexibility Analysis

1. Approach

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires that whenever an agency publishes a notice of rulemaking, it must prepare a Regulatory Flexibility Analysis (RFA) that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). An RFA is unnecessary, however, if the Agency's administrator certifies that the rule will not have a significant economic effect on a substantial number of small entities.

EPA examined the final rule's potential effects on small entities as required by the Regulatory Flexibility Act. Three measures, based on EPA guidelines for conducting an RFA, were used to determine whether the rule would have a “significant economic effect” on small entities: the ratio of compliance cost to cost of production, the ratio of compliance cost to value of sales, and the ratio of cash from operations to compliance cost (the last ratio being used to assess potential closures). Two of the three criteria, the ratio of compliance cost to cost of production and the ratio of cash from operations to compliance cost, are discussed in section VI.B.3.c. The third, the ratio of compliance cost to value of sales, was estimated for small and large facilities; if the difference between these ratios was greater than ten percent, this indicated a significant impact.

The guidelines for conducting RFAs are somewhat ambiguous with respect to evaluating impacts based on the third criterion. Determining whether the difference between ratios exceeds ten percent can be done by subtracting the large facility ratio from the small facility ratio or by dividing the small facility ratio by the large facility ratio. Dividing the small facility ratio by the large facility ratio may incorrectly indicate siqnificant impacts on small facilities when both ratios are very small but the small facility ratio is larger than the large facility ratio. (For example, a small ***11859** facility ratio of 0.00002 divided by a large facility ratio of 0.00001 would indicate a significant impact on small businesses based on the division approach, despite the fact that the very low ratio of compliance cost to value of sales for small facilities indicates little impact on small facilities.) Therefore, the division approach must be interpreted with caution.

A “substantial number” of small entities was assumed to be 20 percent or more of the population of small businesses, small organizations, or small government jurisdictions within the universe of facilities affected by the rule.

The Agency defined a small business as a business employing 50 employees or less. (Standard Small Business Administration criterion is 500 employees.) EPA decided to use the 50 employee definition of a small business because the RIA estimates facility-level impacts, and the SBA definition applies to entire firms. The SBA definition would designate most of the facilities in the examined industries as small businesses, which would obscure differential impacts on smaller facilities.

Impacts on small businesses related to costs of compliance for used oil and contaminated soils were not examined due to lack of data on the facilities experiencing those costs.

2. Results

The only entities found to be affected by the final rule were small businesses, defined here as businesses employing fewer than 50 persons. No small organizations or small government jurisdictions were identified as potential TC waste generators in the TC industry studies which form the foundation for this analysis.

The Agency did not identify any industries in which 20 percent or more of the small businesses were significantly affected based on the ratio of compliance cost to cost of production, the ratio of cash from operations to compliance cost, or the ratio of compliance cost to value of sales (using the subtraction approach). Using the division approach for the ratio of compliance cost to value of sales indicated that small businesses in four sectors (including Pulp and Paper, Synthetic Rubber, Organic Chemicals, and Wholesale Petroleum Marketing) would be significantly affected. However, since the small facility and large facility ratios were both quite small (small facility ratios were less than 0.03), the Agency does not expect significant small business impacts in these sectors. Based on these results, EPA has concluded that today's final rule will not have a significant effect on a substantial number of small entities. As a result of this finding, EPA has not prepared a formal RFA in support of the rule. More detailed information on small business impacts is available in the RIA for this rule.

D. Response to Comments on RIA for June 13, 1986 Proposal

EPA received many comments on the RIA for the proposed TC rule. This section presents a general summary and analysis of the public comments concerning the original RIA; all of the comments are addressed in the background document for this final rule. Major issues addressed by commenters included consideration of particular industries, specific aspects of cost and benefit methodologies, cost and benefit estimates, and the assessment of small business impacts.

1. Industries Included in the Analysis

The majority of comments on the RIA for the proposed rule concerned the absence of specific industrial sectors from the group examined for potential impacts. Other commenters criticized the RIA for not considering the effects of the TC on end users of products and on facilities such as Publicly Owned Treatment Works and Municipal Landfills.

Industries that commenters suggested should have been evaluated included natural gas production, manufacturing of a variety of products, including forest products, pharmaceuticals, automobiles, plastics, metals, polyvinyl chloride, semi-conductors, wire and cables, and waste management. The Agency agrees with commenters that a number of industrial sectors were not addressed in the RIA for the proposed rule. The Agency notes, however, that several of the wastestreams that commenters believed should have been included in the RIA (based upon the proposed regulatory levels) are not expected to be defined as hazardous based upon the final regulatory levels being promulgated today. One of the fundamental problems with determining which industries would potentially be affected by the TC is lack of data on currently non-hazardous wastes. Since these wastes are currently outside the subtitle C system, requirements for information gathering related to them are minimal.

The Agency made extensive efforts, in preparing the RIA for the TC final rule, to obtain data on the industrial sectors potentially affected by the TC. These data were derived from a variety of sources. The Agency contacted numerous trade associations and individual facilities and collected pertinent EPA and other government publications. In addition, EPA prepared a series of TC industry study reports on those sectors most likely to generate significant quantities of TC wastes.

In preparing its TC industry studies, EPA first conducted preliminary studies which examined a large number of industries, with emphasis on identifying whether or not TC constituents would be likely to be present in industry wastes. Based on the preliminary studies, EPA completed detailed profiles of potentially affected industries for use in the final RIA. The Agency examined the potential for impacts on a number of industries that were not considered in the RIA for the proposed rule, as well as reconsidering some that were addressed in that RIA. Table VI-1 in section VI.B compares the coverage of industries for both the proposed rule RIA and the final rule RIA and indicates the industries for which detailed quantitative analysis was conducted.

Commenters also criticized the proposed rule RIA for not considering effects on end-users of products containing TC constituents. Examples of such end-user industries include agricultural chemical users, transporters, automotive maintenance

facilities, petroleum retailers, medical facilities, and research laboratories. The Agency recognizes that TC toxicants exist in a variety of substances, and that end-users as well as producers of products containing TC constituents could be affected by the rule. Some end-users not identified in the RIA may be affected, but there is no information to quantify these potential impacts. The Agency believes that some of the impacts on affected end users may be mitigated by small quantity generator regulations under 40 CFR 261.5.

Finally, several commenters questioned EPA's assessment of impacts on Publicly Owned Treatment Works (POTWs), resource recovery facilities, public water suppliers, municipal landfills, the electrical services industry, and currently regulated RCRA facilities. As discussed previously in section III.K.2, the Agency has tested a number of POTW sludges to determine whether or not these sludges would be considered hazardous under the TC; the data generally indicate that these wastes would not be affected by the TC (Ref. 8). Because the final regulatory level for chloroform is significantly higher than originally proposed, EPA believes that public water suppliers also are unlikely to generate TC wastes. The Agency analyzed wastestreams generated by the Electrical Services ***11860** industry. These wastes were excluded from the RIA because they are fossil fuel combustion wastes, which are exempt from subtitle C regulation until a determination is made as to whether they should be regulated as hazardous. The Agency acknowledges that some waste generated by waste management facilities may exhibit the TC; however, most of these wastestreams that commenters believed should be included are not expected to exhibit the TC under the final regulatory levels. Finally, impacts on currently regulated RCRA facilities (in the industries included in the RIA) were addressed in the RIA.

2. Estimation of Costs and Economic Impacts

Many commenters expressed concern that the compliance cost estimates for facilities included in the economic impact analysis did not capture many of the expenditures faced by handlers of hazardous waste. The most common criticism was directed at the omission of the cost for actually performing the TCLP. Other commenters mentioned insurance costs and costs associated with RCRA permit applications. Another large group of comments concerned the costs for permitting and retrofitting the large universe of surface impoundments containing wastewaters which would exhibit the TC. In addition, a number of commenters contended that the RIA significantly underestimated potential economic impacts of the TC.

Other commenters claimed that the expense of the highly sophisticated equipment and specially trained personnel necessary for the testing of wastes would pose a significant burden on many firms, especially those without on-site laboratory facilities. The Agency recognizes that testing of wastes could pose a significant expense for firms that choose to test their wastes. On the other hand, there is currently no RCRA requirement for generators to test their wastes; the determination of hazardousness may be made based on either laboratory analysis of the waste or on knowledge of the waste, raw materials, and production processes. The Agency expects that many generators will rely on the latter method, and elect not to perform the TCLP. The Agency is still considering promulgating a testing requirement at a future date. If a testing requirement is proposed, potential costs of testing will be analyzed in detail.

Recognizing that administrative and insurance costs can constitute a significant portion of waste management costs, the Agency considered these in cost estimates in the final RIA. In addition, the cost of preparing RCRA permit applications is considered in the cost of subtitle C waste management, as are items such as liability insurance, personnel training, and contingency planning.

In response to comments that surface impoundment impacts were understated, the Agency examined the effect of the TC rule on wastewaters and estimated the costs of compliance with subtitle C requirements. The Agency assumed in the final RIA that, based on least-cost management practices, surface impoundments would not have to be retrofitted. Instead, it was assumed that affected wastewaters would be segregated and treated in a separate tank system, while remaining non-hazardous wastewaters could continue to be managed in the impoundments. In deriving an upper bound estimate of costs, it was assumed that some impoundments would have to undergo subtitle C clean closure.

Given the broad scope of the TC rule and the general lack of data on industries and facilities managing currently non-hazardous wastes, the Agency agrees that economic impacts on certain sectors may have been underestimated in the RIA for the proposed

rule. As discussed above, the Agency has made significant efforts in the final RIA to more accurately characterize the sectors potentially affected by the TC and to estimate the actual impacts on affected facilities.

3. Estimation of Benefits

Several commenters remarked on the original methodology used for the estimation of benefits. The most frequent target of criticism was the assumption that all contaminated aquifers would be cleaned up as a result of the TC. Commenters also questioned the validity of assuming that ground water resource conditions in North Carolina were representative of conditions across the entire United States.

Commenters on the use of aquifer cleanup as the basis for estimating benefits of the proposed rule asked for justification of the assumption that all aquifers would be cleaned up and an explanation of the benefits to human health and the environment which would result from the cleanup. The Agency used a different methodology to estimate benefits for the final RIA than was used for the original RIA. For the final RIA, EPA examined three potential types of benefits: human health risk reduction, resource damage avoided, and cleanup costs avoided. The assumption that all aquifers would be cleaned up was not used in the final RIA. In estimating benefits based on cleanup costs avoided through controlled subtitle C management of TC wastes, EPA assumed in the RIA for the final rule that, for the near term, the subtitle D facilities with down-gradient wells and with at least some resource damage (as predicted by the resource damage analysis) would be the most likely candidates for cleanup.

The Agency agrees with the comments that ground water resource conditions in North Carolina may not be representative of conditions across the entire United States. As a result, in the final RIA EPA used distributions of hydrogeologic parameters which were representative of nationwide conditions, rather than relying on hydrogeologic information from one state.

4. Cost-Benefit Comparisons

In general, commenters argued that the RIA overestimated likely benefits of the proposed rule while underestimating the potential impacts. Commenters believed that the TC would bring large quantities of waste into the subtitle C system with little or no attendant environmental or health benefit. One commenter claimed that, after all indirect impacts are considered, the net benefits of the rule could be negative. Another commenter, however, stated that benefits were actually underestimated because of assumptions in the baseline scenario.

The Agency has used an improved methodology and additional data in the final RIA. EPA believes that the final RIA provides reasonable estimates of the potential costs and benefits of the rule. As presented in this section, the final RIA does indicate that the TC will bring relatively large quantities of waste into the subtitle C system, and also indicates that there will be attendant benefits. The Agency used cost and benefit estimates to compare relative costs and benefits of the various regulatory options. The analyses were conducted separately using approaches constructed to make the best possible use of available data. The separate analyses were not meant to be used to produce absolute measures of cost effectiveness. The RIA contains discussion of the Agency's evaluation and comparison of cost and benefit results.

5. Small Business Analysis

The Agency received many comments on its assessment of the effects of the proposed TC on small businesses. One group of comments focused on the definition chosen by EPA for small businesses. The Agency was also criticized for its threshold for ***11861** determining if a “substantial number” of small businesses would suffer significant economic impacts, and therefore necessitate the preparation of a full Regulatory Flexibility Analysis. Finally, many commenters felt that the analysis severely underestimated the impact of the rule on small businesses.

Commenters asked why the Agency did not use the standard Small Business Administration (SBA) criterion of 500 employees to define a small business. The Agency decided to use the 50 employee definition of a small business because the RIA estimates facility-level impacts, and the SBA definition applies to entire firms. In the absence of data to estimate firm-level impacts,

the Agency chose the 50 employee cutoff as an appropriate small facility definition for the RIA. The SBA definition would designate most of the establishments in most of the examined industries as small facilities, which would obscure differential impacts on smaller facilities.

The Agency was criticized for using a 20 percent threshold for determining if a "substantial number" of small businesses would be significantly affected. Commenters claimed that it was arbitrary to consider the small business impact negligible if "only 19.9 percent" of small business were significantly affected. The Agency recognizes that, for an individual facility, the magnitude of impacts is not altered by the number of other facilities which are significantly affected. Nevertheless, the Agency believes that 20 percent is a reasonable benchmark for defining a "substantial number" of small businesses. The 20 percent threshold is commonly applied in RIAs conducted by EPA.

A large number of commenters criticized the overall conclusions of the small business analysis, declaring that the analysis severely underestimated the economic effects of the TC on small businesses. Commenters maintained that the universe of small businesses was inadequately addressed. Examples of small businesses not included in the analysis which commenters felt should have been considered included service stations and vehicle maintenance facilities. Commenters also mentioned the expense of performing the TCLP, claiming that it was an especially significant hardship for small businesses.

As explained in the general discussion of the industrial sectors included in the RIA, the Agency made extensive efforts to identify and include sectors potentially affected by the TC rule, including end users of products. And, as discussed under the comments on incorporating testing costs, these costs were not included since generators are not currently required to test their wastes. Although EPA maintains that a full RFA is not necessary for the TC rule, it realizes that the impact of the rule could be significant for individual small enterprises.

E. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paper Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned the following OMB control numbers: 2050-0007, Land Disposal Permitting Standards; 2050-0008, RCRA Closure/Post-Closure; 2050-0009, Hazardous Waste Storage and Treatment Facilities; 2050-0011, Contingency Plans for Hazardous Waste Facilities; 2050-0012, General Facility Operating Requirements; 2050-0013, Operating Record for Hazardous Waste Facilities; 2050-0028, Notification of a Hazardous Waste Activity; 2050-0033, Reporting, Recordkeeping, and Planning for Ground-Water Monitoring; 2050-0034, RCRA Hazardous Waste Permit Application Part A; 2050-0036, RCRA Financial Assurance Requirements; 2050-0037, Recordkeeping and Reporting for RCRA Permitees; and 2050-0039, Uniform Hazardous Waste Manifest for Generators and Transporters.

VII. References

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List of Subjects in 40 CFR Parts 261, 264, 265, 268, 271, and 302

Administrative practice and procedure, Air pollution control, Chemicals, Confidential business information, Hazardous materials transportation, Hazardous substances, Hazardous waste, Indian lands, Intergovernmental relations, Natural resources, Nuclear materials, Penalties, Pesticides and pests, Radioactive materials, Recycling, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply, Waste treatment and disposal.

Dated: March 5, 1990.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6922.

2. Section 261.4 is amended by revising paragraphs (b)(6)(i) introductory text, and (b)(9) and by adding paragraph (b)(10) to read as follows:

§ 261.4 Exclusions.

* * * * *

(b) * * *

(6)(i) Wastes which fail the test for the Toxicity Characteristic because chromium is present or are listed in subpart D due to the presence of chromium, which do not fail the test for the Toxicity Characteristic for any other constituent or are not listed due to the presence of any other constituent, and which do not fail the test for any other characteristic, if it is shown by a waste generator or by waste generators that:

* * * * *

(9) Solid waste which consists of discarded wood or wood products which fails the test for the Toxicity Characteristic solely for arsenic and which is not a hazardous waste for any other reason or reasons, if the waste is generated by persons who utilize the arsenical-treated wood and wood products for these materials' intended end use.

(10) Petroleum-contaminated media and debris that fail the test for the Toxicity Characteristic of § 261.24 and are subject to the corrective action regulations under part 280 of this chapter.

3. Section 261.8 is added to subpart A to read as follows:

§ 261.8 PCB Wastes Regulated Under Toxic Substance Control Act

The disposal of PCB-containing dielectric fluid and electric equipment containing such fluid authorized for use and regulated under part 761 of this chapter and that are hazardous only because they fail the test for the Toxicity Characteristic (Hazardous Waste Codes D018 through D043 only) are exempt from regulation under parts 261 through 265, and parts 268, 270, and 124 of this chapter, and the notification requirements of section 3010 of RCRA.

4. Section 261.24 is revised to read as follows:

§ 261.24 Toxicity characteristic.

(a) A solid waste exhibits the characteristic of toxicity if, using the test methods described in Appendix II or equivalent methods approved by the Administrator under the procedures set forth in §§ 260.20 and 260.21, the extract from a representative sample of the waste contains any of the contaminants listed in Table 1 at the concentration equal to or greater than the respective value given in that Table. Where the waste contains less than 0.5 percent filterable solids, the waste itself, after filtering using the methodology outlined in Appendix II, is considered to be the extract for the purpose of this section.

(b) A solid waste that exhibits the characteristic of toxicity, but is not listed as a hazardous waste in subpart D, has the EPA Hazardous Waste Number specified in Table 1 which corresponds to the toxic contaminant causing it to be hazardous.

Table 1.--Maximum Concentration of Contaminants for the Toxicity Characteristic

EPA HW No. [FN1]	Contaminant	CAS No. [FN2]	Regulatory Level (mg/L)
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0.
D023	o-Cresol	95-48-7 [FN4]	200.0
D024	m-Cresol	108-39-4 [FN4]	200.0
D025	p-Cresol	106-44-5 [FN4]	200.0
D026	Cresol	---------- [FN4]	200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7
D030	2,4-Dinitrotoluene	121-14-2 [FN3]	0.13
D012	Endrin	72-20-8	0.02
D031	Heptachlor (and its hydroxide)	76-44-8	0.008
D032	Hexachlorobenzene	118-74-1 [FN3]	0.13
D033	Hexachlorobutadiene	87-68-3	0.5

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D034 ..... Hexachloroethane ..... 67-72-1 3.0
D008 ..... Lead ..... 7439-92-1 5.0
D013 ..... Lindane ..... 58-89-9 0.4
D009 ..... Mercury ..... 7439-97-6 0.2
D014 ..... Methoxychlor ..... 72-43-5 10.0
D035 ..... Methyl ethyl ketone ..... 78-93-3 200.0
D036 ..... Nitrobenzene ..... 98-95-3 2.0
D037 ..... Pentrachlorophenol ..... 87-86-5 100.0
D038 ..... Pyridine ..... 110-86-1 [FN3] 5.0
D010 ..... Selenium ..... 7782-49-2 1.0
D011 ..... Silver ..... 7440-22-4 5.0
D039 ..... Tetrachloroethylene ..... 127-18-4 0.7
D015 ..... Toxaphene ..... 8001-35-2 0.5
D040 ..... Trichloroethylene ..... 79-01-6 0.5
D041 ..... 2,4,5-Trichlorophenol ..... 95-95-4 400.0
D042 ..... 2,4,6-Trichlorophenol ..... 88-06-2 2.0
D017 ..... 2,4,5-TP (Silvex) ..... 93-72-1 1.0
D043 ..... Vinyl chloride ..... 75-01-4 0.2
--------------------------------------------------------------------------------
1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The
quantitation limit therefore becomes the regulatory level.
4 If o-, m-, and p-Cresol concentrations cannot be differentiated, the total
cresol (D026) concentration is used. The regulatory level of total cresol is
200 mg/l.
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***11863** 5. Section 261.30 is amended by revising paragraph (b) to read as follows:

§ 261.30 General.

* * * * *

(b) The Administrator will indicate his basis for listing the classes or types of wastes listed in this subpart by employing one or more of the following Hazard Codes:

```
Ignitable Waste ..... (I)
Corrosive Waste ..... (C)
Reactive Waste ..... (R)
Toxicity Characteristic Waste ..... (E)
Acute Hazardous Waste ..... (H)
Toxic Waste ..... (T)
```

Appendix VII identifies the constituent which caused the Administrator to list the waste as a Toxicity Characteristic Waste (E) or Toxic Waste (T) in §§ 261.31 and 261.32.

* * * * *

6. Appendix II of part 261 is revised to read as follows:

Appendix II—Method 1311 Toxicity Characteristic Leaching Procedure (TCLP)

1.0 Scope and Application

1.1 The TCLP is designed to determine the mobility of both organic and inorganic contaminants present in liquid, solid, and multiphasic wastes.

1.2 If a total analysis of the waste demonstrates that individual contaminants are not present in the waste, or that they are present but at such low concentrations that the appropriate regulatory thresholds could not possibly be exceeded, the TCLP need not be run.

1.3 If an analysis of any one of the liquid fractions of the TCLP extract indicates that a regulated compound is present at such high levels that even after accounting for dilution from the other fractions of the extract the concentration would be above the regulatory threshold for that compound, then the waste is hazardous and it is not necessary to analyze the remaining fractions of the extract.

1.4 If an analysis of extract obtained using a bottle extractor shows that the concentration of any regulated volatile contaminant exceeds the regulatory threshold for that compound, then the waste is hazardous and extraction using the ZHE is not necessary. However, extract from a bottle extractor cannot be used to demonstrate that the concentration of volatile compounds is below the regulatory threshold.

2.0 Summary of Method (see Figure 1)

2.1 For liquid wastes (i.e., those containing less than 0.5 percent dry solid material), the waste, after filtration through a 0.6 to 0.8-um glass fiber filter, is defined as the TCLP extract.

2.2 For wastes containing greater than or equal to 0.5 percent solids, the liquid, if any, is separated from the solid phase and stored for later analysis; the solid phase, if necessary, is reduced in particle size. The solid phase is extracted with an amount of extraction fluid equal to 20 times the weight of the solid phase. The extraction fluid employed is a function of the alkalinity of the solid phase of the waste. A special extractor vessel is used when testing for volatile contaminants (see Table 1 for a list of volatile compounds). Following extraction, the liquid extract is separated from the solid phase by filtration through a 0.6 to 0.8-um glass fiber filter.

BILLING CODE 6560-50-M

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

BILLING CODE 6560-50-C

Table 1.--Volatile Contaminants [FN1]

Compound	CAS no.
Acetone	67-64-1
Benzene	71-43-2
n-Butyl alcohol	71-36-3
Carbon disulfide	75-15-0
Carbon tetrachloride	56-23-5
Chlorobenzene	108-90-7
Chloroform	67-66-3
1,2-Dichloroethane	107-06-2
1,1-Dichloroethylene	75-35-4
Ethyl acetate	141-78-6
Ethyl benzene	100-41-4
Ethyl ether	60-29-7
lsobutanol	78-83-1
Methanol	67-56-1
Methylene chloride	75-09-2
Methyl ethyl ketone	78-93-3
Methyl isobutyl ketone	108-10-1

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Tetrachloroethylene ..................................................... 127-18-4
Toluene ................................................................. 108-88-3
1,1,1-Trichloroethane ................................................... 71-55-6
Trichloroethylene ....................................................... 79-01-6
Trichlorofluoromethane .................................................. 75-69-4
1,1,2-Trichloro-1,2,2-trifluoroethane ................................... 76-13-1
Vinyl chloride .......................................................... 75-01-4
Xylene ................................................................ 1330-20-7
--------------------------------------------------------------------------------
1 When testing for any or all of these contaminants, the zero-headspace
extractor vessel shall be used instead of the bottle extractor.
```

2.3 If compatible (i.e., multiple phases will not form on combination), the initial liquid phase of the waste is added to the liquid extract, and these are analyzed together. If incompatible, the liquids are analyzed separately and the results are mathematically combined to yield a volume-weighted average concentration.

3.0 Interferences

3.1 Potential interferences that may be encountered during analysis are discussed in the individual analytical methods.

4.0 Apparatus and Materials

4.1 Agitation apparatus: The agitation apparatus must be capable of rotating the extraction vessel in an end-over-end fashion (see Figure 2) at 30 +2 rpm. Suitable devices known to EPA are identified in Table 2.

4.2 Extraction Vessel:

4.2.1 Zero-Headspace Extraction Vessel (ZHE). This device is for use only when the waste is being tested for the mobility of volatile constituents (i.e., those listed in Table 1). The ZHE (depicted in Figure 3) allows for liquid/solid separation within the device, and effectively precludes headspace. This type of vessel allows for initial liquid/solid separation, extraction, and final extract filtration without opening the vessel (see step 4.3.1). The vessels shall have an internal volume of 500-600 mL and be equipped to accommodate a 90-110 mm filter. The devices contain VITON R [FN1] O-rings which should be replaced frequently. Suitable ZHE devices known to EPA are identified in Table 3.

BILLING CODE 6560-50-M

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

BILLING CODE 6560-50-C

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Table 2.--Suitable Rotary Agitation Apparatus [FN1]
--------------------------------------------------------------------------------
Company Location Model no.
--------------------------------------------------------------------------------
Analytical Testing and
Consulting Services,
Inc ................. Warrington, PA (215)
343-4490 .......... 2-ZHE or 4-bottle extractor
(DC20S); 4-ZHE or 8-bottle
extractor (DC20); 6-ZHE or
12-bottle extractor (DC20B).
Associated Design and
Manufacturing
Company ............. Alexandria, VA (703)
549-5999 .......... 2-vessel (3740-2). 4-vessel
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(3740-4). 6-vessel (3740-6).
8-vessel (3740-8). 12-vessel
(3740-12). 24-vessel (3740-24).
Environmental Machine
and Design, Inc ..... Lynchburg, VA (804)
845-6424 ..... 8-vessel (08-00-00). 4-vessel
(04-00-00).
IRA Machine Shop and
Laboratory ..... Santurce, PR (809)
752-4004 ..... 8-vessel (011001).
Lars Lande
Manufacturing ..... Whitmore Lake, MI
(313) 449-4116 .... 10-vessel (10VRE). 5-vessel (5
VRE).
Millipore Corp..... Bedford, MA (800)
225-3384 ..... 4-ZHE or 4 1-liter bottle
extractor (YT30ORAHW).

---

1 Any device that rotates the extraction vessel in an end-over-end fashion at
30 #2 rpm is acceptable.

BILLING CODE 6560-50-M

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

BILLING CODE 6560-50-C

Table 3.--Suitable Zero-Headspace Extractor Vessels [FN1]

Company Location Model no.

Analytical Testing &
Consulting Services, Inc Warrington, PA (215)
343-4490 ..... C102, Mechanical Pressure
Device.
Associated Design and
Manufacturing Company ... Alexandria, VA (703)
549-5999 ..... 3745-ZHE, Gas Pressure
Device.
Lars Lande Manufacturing
[FN2] ..... Whitmore Lake, MI (313)
449-4116 ..... ZHE-11, Gas Pressure
Device.
Millipore Corporation ..... Bedford, MA (800)
225-3384 ..... YT3009OHW, Gas Pressure
Device.
Environmental Machine and
Design, Inc ..... Lynchburg, VA (804)
845-6424 ..... VOLA-TOX1, Gas Gas
Pressure Device.

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1 Any device that meets the specifications listed in Section 4.2.1 of the
method is suitable.
2 This device uses a 110 mm filter.

For the ZHE to be acceptable for use, the piston within the ZHE should be able to be moved with approximately 15 psi or less. If it takes more pressure to move the piston, the O-rings in the device should be replaced. If this does not solve the problem, the ZHE is unacceptable for TCLP analyses and the manufacturer should be contacted.

The ZHE should be checked for leaks after every extraction. If the device contains a built-in pressure gauge, pressurize the device to 50 psi, allow it to stand unattended for 1 hour, and recheck the pressure. If the device does not have a built-in pressure gauge, pressurize the device to 50 psi, submerge it in water, and check for the presence of air bubbles escaping from any of the fittings. If pressure is lost, check all fittings and inspect and replace O-rings, if necessary. Retest the device. If leakage problems cannot be solved, the manufacturer should be contacted.

Some ZHEs use gas pressure to actuate the ZHE piston, while others use mechanical pressure (see Table 3). Whereas the volatiles procedure (see section 9.0) refers to pounds-per-square-inch (psi), for the mechanically actuated piston, the pressure applied is measured in torque-inch-pounds. Refer to the manufacturer's instructions as to the proper conversion.

4.2.2 Bottle Extraction Vessel. When the waste is being evaluated using the nonvolatile extraction, a jar with sufficient capacity to hold the sample and the extraction fluid is needed. Headspace is allowed in this vessel.

The extraction bottles may be constructed from various materials, depending on the contaminants to be analyzed and the nature of the waste (see Step 4.3.3). It is recommended that borosilicate glass bottles be used instead of other types of glass, especially when inorganics are of concern. Plastic bottles, other than polytetrafluoro-ethylene, shall not be used if organics are to be investigated. Bottles are available from a number of laboratory suppliers. When this type of extraction vessel is used, the filtration device discussed in Step 4.3.2 is used for initial liquid/solid separation and final extract filtration.

4.3 Filtration Devices: It is recommended that all filtrations be performed in a hood.

4.3.1 Zero-Headspace Extractor Vessel (ZHE): When the waste is evaluated for volatiles, the zero-headspace extraction vessel described in section 4.2.1 is used for filtration. The device shall be capable of supporting and keeping in place the glass fiber filter and be able to withstand the pressure needed to accomplish separation (50 psi).

Note: When it is suspected that the glass fiber filter has been ruptured, an in-line glass fiber filter may be used to filter the material within the ZHE.

4.3.2 Filter Holder: When the waste is evaluated for other than volatile compounds, any filter holder capable of supporting a glass fiber filter and able to withstand the pressure needed to accomplish separation may be used. Suitable filter holders range from simple vacuum units to relatively complex systems capable of exerting pressures of up to 50 psi or more. The type of filter holder used depends on the properties of the material to be filtered (see Step 4.3.3). These devices shall have a minimum internal volume of 300 mL and be equipped to accommodate a minimum filter size of 47 mm (filter holders having an internal capacity of 1.5 L or greater and equipped to accommodate a 142 mm diameter filter are recommended). Vacuum filtration can only be used for wastes with low solids content (<10 percent) and for highly granular liquid-containing wastes. All other types of wastes should be filtered using positive pressure filtration. Suitable filter holders known to EPA are shown in Table 4.

4.3.3 Materials of Construction: Extraction vessels and filtration devices shall be made of inert materials which will not leach or absorb waste components. Glass, polytetrafluoroethylene (PTFE), or type 316 stainless steel equipment may be used when evaluating the mobility of both organic and inorganic components. Devices made of high-density polyethylene (HDPE), polypropylene, or polyvinyl chloride may be used only when evaluating the mobility of metals. Borosilicate glass bottles are recommended for use over other types of glass bottles, especially when inorganics are constituents of concern.

Table 4.--Suitable Filter Holders [FN1]

Company	Location	Model/Catalogue no.	Size (um)
Nucleopore Corporation	..... Pleasanton, CA	(800)	

882-7711 ..... 425910 410400 142 mm 47 mm
Micro Filtration
Systems ..... Dublin, CA (800)
334-7132 (415)
828-6010 ..... 302400 311400 142 mm 47 mm
Millipore
Corporation ..... Bedford, MA (800)
225-3384 ..... YT30142HW XX1004700 . 142 mm 47 mm

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1 Any device capable of separating the liquid from the solid phase of the waste is suitable, providing that it is chemically compatible with the waste and the constituents to be analyzed. Plastic devices (not listed above) may be used when only inorganic contaminants are of concern. The 142 mm size filter holder is recommended.

4.4 Filters: Filters shall be made of borosilicate glass fiber, shall contain no binder materials, and shall have an effective pore size of 0.6 to 0.8-um or equivalent. Filters known to EPA which meet these specifications are identified in Table 5. Pre-filters must not be used. When evaluating the mobility of metals, filters shall be acid-washed prior to use by rinsing with 1N nitric acid followed by three consecutive rinses with deionized distilled water (a minimum of 1-L per rinse is recommended). Glass fiber filters are fragile and should be handled with care.

4.5 pH meters: The meter should be accurate to +0.05 units at 25 °C.

Table 5.--Suitable Filter Media [FN1]

Company Location Model Pore size

Millipore Corporation ... Bedford, MA (800) 225-3384 . AP40 ..... 0.7
Nucleopore Corporation .. Pleasanton, CA (415)
463-2530 ..... 211625 0.7
Whatman Laboratory
Products, Inc ..... Clifton, NJ (201) 773-5800 . GFF 0.7
Micro Filtration Systems Dublin, CA (800) 334-7132
(415) 828-6010 ..... GF75 ..... 0.7

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1 Any filter that meets the specifications in Section 4.4 of the Method is suitable.

***11870** 4.6 ZHE extract collection devices: TEDLARR[FN2] bags or glass, stainless steel or PTFE gas-tight syringes are used to collect the initial liquid phase and the final extract of the waste when using the ZHE device. The devices listed are recommended for use under the following conditions:

4.6.1 If a waste contains an aqueous liquid phase or if a waste does not contain a significant amount of nonaqueous liquid (i.e., <1 percent of total waste), the TEDLARR bag or a 600 mL syringe should be used to collect and combine the initial liquid and solid extract.

4.6.2 If a waste contains a significant amount of nonaqueous liquid in the initial liquid phase (i.e., >1 percent of total waste), the syringe or the TEDLARR bag may be used for both the initial solid/liquid separation and the final extract filtration. However, analysts should use one or the other, not both.

4.6.3 If the waste contains no initial liquid phase (is 100 percent solid) or has no significant solid phase (is 100 percent liquid), either the TEDLARR bag or the syringe may be used. If the syringe is used, discard the first 5 mL of liquid expressed from the device. The remaining aliquots are used for analysis.

4.7 ZHE extraction fluid transfer devices: Any device capable of transferring the extraction fluid into the ZHE without changing the nature of the extraction fluid is acceptable (e.g., a positive displacement or peristaltic pump, a gas tight syringe, pressure filtration unit (See Step 4.3.2), or other ZHE device).

4.8 Laboratory balance: Any laboratory balance accurate to within +0.01 grams may be used (all weight measurements are to be within +0.1 grams).

5.0 Reagents

5.1 Reagent water. Reagent water is defined as water in which an interferant is not observed at or above the methods detection limit of the analyte(s) of interest. For nonvolatile extractions, ASTM Type II water or equivalent meets the definition of reagent water. For volatile extractions, it is recommended that reagent water be generated by any of the following methods. Reagent water should be monitored periodically for impurities.

5.1.1 Reagent water for volatile extractions may be generated by passing tap water through a carbon filter bed containing about 500 grams of activated carbon (Calgon Corp., Filtrasorb-300 or equivalent).

5.1.2 A water purification system (Millipore Super-Q or equivalent) may also be used to generate reagent water for volatile extractions.

5.1.3 Reagent water for volatile extractions may also be prepared by boiling water for 15 minutes. Subsequently, while maintaining the water temperature at 90 +5 °C, bubble a contaminant-free inert gas (e.g., nitrogen) through the water for 1 hour. While still hot, transfer the water to a narrow mouth screw-cap bottle under zero-headspace and seal with a Teflon-lined septum and cap.

5.2 Hydrochloric acid (1N), HCl, made from ACS reagent grade.

5.3 Nitric acid (1N), HNO3 , made from ACS reagent grade.

5.4 Sodium hydroxide (1N), NaOH, made from ACS reagent grade.

5.5 Glacial acetic acid, HOAc, ACS reagent grade.

5.6 Extraction fluid.

5.6.1 Extraction fluid 1: Add 5.7 mL glacial HOAc to 500 mL of the appropriate water (See Step 5.1), add 64.3 mL of 1N NaOH, and dilute to a volume of 1 liter. When correctly prepared, the pH of this fluid will be 4.93 +0.05.

5.6.2 Extraction fluid 2: Dilute 5.7 mL glacial HOAc with ASTM Type II water (See Step 5.1) to a volume of 1 liter. When correctly prepared, the pH of this fluid will be 2.88+0.05.

Note: These extraction fluids should be monitored frequently for impurities. The pH should be checked prior to use to ensure that these fluids are made up accurately. If impurities are found or the pH is not within the above specifications, the fluid shall be discarded and fresh extraction fluid prepared.

5.7 Analytical standards prepared according to the appropriate analytical method.

6.0 Sample Collection, Preservation, and Handling

6.1 All samples shall be collected using an appropriate sampling plan.

6.2 The TCLP may place requirements on the minimal size of the field sample depending upon the physical state or states of the waste and the contaminants of concern. An aliquot is needed for preliminary evaluation of which extraction fluid is to be used for the nonvolatile contaminant extraction procedure. Another aliquot may be needed to actually conduct the nonvolatile extraction (see section 1.4 concerning the use of this extract for volatile organics). If volatile organics are of concern, another aliquot may be needed. Quality control measures may require additional aliquots. Further, it is always wise to collect more sample just in case something goes wrong with the initial attempt to conduct the test.

6.3 Preservatives shall not be added to samples.

6.4 Samples may be refrigerated unless refrigeration results in irreversible physical change to the waste. If precipitation occurs, the entire sample (including precipitate) should be extracted.

6.5 When the waste is to be evaluated for volatile contaminants, care shall be taken to minimize the loss of volatiles. Samples shall be taken and stored in a manner to prevent the loss of volatile contaminants (e.g., samples should be collected in Teflon-lined septum capped vials and stored at 4 °C, until ready to be opened prior to extraction).

6.6 TCLP extracts should be prepared for analysis and analyzed as soon as possible following extraction. Extracts or portions of extracts for metallic contaminant determinations must be acidified with nitric acid to a pH <2, unless precipitation occurs (see section 8.14 if precipitation occurs). Extracts or portions of extracts for organic contaminant determinations shall not be allowed to come into contact with the atmosphere (i.e., no headspace) to prevent losses. See section 10.0 (QA requirements) for acceptable sample and extract holding times.

7.0 Preliminary Evaluations

Perform preliminary TCLP evaluations on a minimum 100 gram aliqout of waste. This aliquot may not actually undergo TCLP extraction. These preliminary evaluations include: (1) determination of the percent solids; (2) determination of whether the waste contains insignificant solids and is, therefore, its own extract after filtration; (3) determination of whether the solid portion of the waste requires particle size reduction; and (4) determination of which of the two extraction fluids are to be used for the nonvolatile TCLP extraction of the waste.

7.1 Preliminary determination of percent solids: Percent solids is defined as that fraction of a waste sample (as a percentage of the total sample) from which no liquid may be forced out by an applied pressure, as described below.

7.1.1 If the waste will obviously yield no free liquid when subjected to pressure filtration (i.e., is 100% solids) proceed to Step 7.3.

7.1.2 If the sample is liquid or multiphasic, liquid/solid separation to make a preliminary determination of percent solids is required. This involves the filtration device described in Step 4.3.2 and is outlined in Steps 7.1.3 through 7.1.9.

7.1.3 Pre-weigh the filter and the container that will receive the filtrate.

7.1.4 Assemble the filter holder and filter following the manufacturer's instructions. Place the filter on the support screen and secure.

***11871** 7.1.5 Weigh out a subsample of the waste (100 gram minimum) and record the weight.

7.1.6 0Allow slurries to stand to permit the solid phase to settle. Wastes that settle slowly may be centrifuged prior to filtration. Centrifugation is to be used only as an aid to filtration. If used, the liquid should be decanted and filtered followed by filtration of the solid portion of the waste through the same filtration system.

7.1.7 Quantitatively transfer the waste sample to the filter holder (liquid and solid phases). Spread the waste sample evenly over the surface of the filter. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature then allow the sample to warm up to room temperature in the device before filtering.

Note: If waste material (>1 percent of original sample weight) has obviously adhered to the container used to transfer the sample to the filtration apparatus, determine the weight of this residue and subtract it from the sample weight determined in Step 7.1.5 to determine the weight of the waste sample that will be filtered.

Gradually apply vacuum or gentle pressure of 1-10 psi, until air or pressurizing gas moves through the filter. If this point is not reached under 10 psi, and if no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10-psi, if the pressurizing gas has not moved through the filter, and if no additional liquid has passed through the filter in any 2-minute interval, proceed to the next 10-psi increment. When the pressurizing gas begins to move through the filter, or when liquid flow has ceased at 50 psi (i.e., filtration does not result in any additional filtrate within any 2-minute period), stop the filtration.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

7.1.8 The material in the filter holder is defined as the solid phase of the waste, and the filtrate is defined as the liquid phase.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying vacuum or pressure filtration, as outlined in Step 7.1.7, this material may not filter. If this is the case, the material within the filtration device is defined as a solid. Do not replace the original filter with a fresh filter under any circumstances. Use only one filter.

7.1.9 Determine the weight of the liquid phase by subtracting the weight of the filtrate container (see Step 7.1.3) from the total weight of the filtrate-filled container. Determine the weight of the solid phase of the waste sample by subtracting the weight of the liquid phase from the weight of the total waste sample, as determined in Step 7.1.5 or 7.1.7.

Record the weight of the liquid and solid phases. Calculate the percent solids as follows:

```
Percent = Weight of solid (Step 7.1.9) X 100
solids
--------------------------------
Total weight of waste (Step 7.1.5
or 7.1.7)
```

7.2 If the percent solids determined in Step 7.1.9 is equal to or greater than 0.5%, then proceed either to Step 7.3 to determine whether the solid material requires particle size reduction or to Step 7.2.1 if it is noticed that a small amount of the filtrate is entrained in wetting of the filter. If the percent solids determined in Step 7.1.9 is less than 0.5%, then proceed to Step 8.9 if the nonvolatile TCLP is to be performed and to section 9.0 with a fresh portion of the waste if the volatile TCLP is to be performed.

7.2.1 Remove the solid phase and filter from the filtration apparatus.

7.2.2 Dry the filter and solid phase at 100 +20 °C until two successive weighing yield the same value within +1 percent. Record the final weight.

Note: Caution should be taken to ensure that the subject solid will not flash upon heating. It is recommended that the drying oven be vented to a hood or other appropriate device.

7.2.3 Calculate the percent dry solids as follows:

```
Percent dry = (Weight of dry X 100
solids waste#filter)-tared weight of
filter
--------------------------------
Initial weight of waste (Step
7.1.5 or 7.1.7)
```

7.2.4 lf the percent dry solids is less than 0.5 percent, then proceed to Step 8.9 if the nonvolatile TCLP is to be performed, and to Section 9.0 if the volatile TCLP is to be performed. If the percent dry solids is greater than or equal to 0.5%, and if the nonvolatile TCLP is to be performed, return to the beginning of this Section (7.0) and, with a fresh portion of waste, determine whether particle size reduction is necessary (Step 7.3) and determine the appropriate extraction fluid (Step 7.4). If only the volatile TCLP is to be performed, see the note in Step 7.4.

7.3 Determination of whether the waste requires particle-size reduction (particle-size is reduced during this step): Using the solid portion of the waste, evaluate the solid for particle size. Particle-size reduction is required, unless the solid has a surface area per gram of material equal to or greater than 3.1 cm2 , or is smaller than l cm in its narrowest dimension (i.e., is capable of passing through a 9.5 mm (0.375 inch) standard sieve). If the surface area is smaller or the particle size larger than described above, prepare the solid portion of the waste for extraction by crushing, cutting, or grinding the waste to a surface area or particle-size as described above. If the solids are prepared for organic volatiles extraction, special precautions must be taken, see Step 9.6.

Note: Surface area criteria are meant for filamentous (e.g., paper, cloth, and similar) waste materials. Actual measurement of surface area is not required, nor is it recommended. For materials that do not obviously meet the criteria, sample-specific methods would need to be developed and employed to measure the surface area. Such methodology is currently not available.

7.4 Determination of appropriate extraction fluid: If the solid content of the waste is greater than or equal to 0.5 percent and if TCLP extraction for nonvolatile constituents will take place (Section 8.0), perform the determination of the appropriate fluid (Step 5.6) to use for the nonvolatiles extraction as follows:

Note: TCLP extraction for volatile constituents uses only extraction fluid 1 (Step 5.6.1). Therefore, if TCLP extraction for nonvolatiles is not required, proceed to Section 9.0.

7.4.1 Weigh out a small subsample of the solid phase of the waste, reduce the solid (if necessary) to a particle-size of approximately 1 mm in diameter or less, and transfer 5.0 grams of the solid phase of the waste to a 500-mL beaker or Erlenmeyer flask.

7.4.2 Add 96.5 mL of reagent water (ASTM Type II) to the beaker, cover with a watchglass, and stir vigorously for 5 minutes using a magnetic stirrer. Measure and record the pH. If the pH is <5.0, use extraction fluid 1. Proceed to Section 8.0.

7.4.3 If the pH from Step 7.4.2 is >5.0, add 3.5 mL 1N HCl, slurry briefly, cover with a watchglass, heat to 50 °C, and hold at 50 °C for 10 minutes.

7.4.4 Let the solution cool to room temperature and record the pH. If the pH is <5.0, use extraction fluid 1. If the pH is >5.0, use extraction fluid 2. Proceed to Section 8.0.

7.5 If the aliquot of the waste used for the preliminary evaluation (Steps 7.1-7.4) was determined to be 100% solid at Step 7.1.1, then it can be used for the Section 8.0 extraction (assuming at least 100 grams ***11872** remain), and the section 9.0 extraction (assuming at least 25 grams remain). If the aliquot was subjected to the procedure in Step 7.1.7, then another aliquot shall be used for the volatile extraction procedure in Section 9.0. The aliquot of the waste subjected to the procedure in Step 7.1.7 might be appropriate for use for the section 8.0 extraction if an adequate amount of solid (as determined by Step 7.1.9) was

obtained. The amount of solid necessary is dependent upon whether a sufficient amount of extract will be produced to support the analyses. If an adequate amount of solid remains, proceed to Step 8.10 of the nonvolatile TCLP extraction.

8.0 Procedure When Volatiles Are Not Involved

A minimum sample size of 100 grams (solid and liquid phases) is required. In some cases, a larger sample size may be appropriate, depending on the solids content of the waste sample (percent solids, See Step 7.1), whether the initial liquid phase of the waste will be miscible with the aqueous extract of the solid, and whether inorganics, semivolatile organics, pesticides, and herbicides are all analytes of concern. Enough solids should be generated for extraction such that the volume of TCLP extract will be sufficient to support all of the analyses required. If the amount of extract generated by a single TCLP extraction will not be sufficient to perform all of the analyses, more than one extraction may be performed and the extracts from each combined and aliquoted for analysis.

8.1 If the waste will obviously yield no liquid when subjected to pressure filtration (i.e., is 100 percent solid, see Step 7.1), weigh out a subsample of the waste (100 gram minimum) and proceed to Step 8.9.

8.2 If the sample is liquid or multiphasic, liquid/solid separation is required. This involves the filtration device described in Step 4.3.2 and is outlined in Steps 8.3 to 8.8.

8.3 Pre-weigh the container that will receive the filtrate.

8.4 Assemble the filter holder and filter following the manufacturer's instructions. Place the filter on the support screen and secure. Acid wash the filter if evaluating the mobility of metals (see Step 4.4).

Note: Acid washed filters may be used for all nonvolatile extractions even when metals are not of concern.

8.5 Weigh out a subsample of the waste (100 gram minimum) and record the weight. If the waste contains <0.5 percent dry solids (Step 7.2), the liquid portion of the waste, after filtration, is defined as the TCLP extract. Therefore, enough of the sample should be filtered so that the amount of filtered liquid will support all of the analyses required of the TCLP extract. For wastes containing >0.5 percent dry solids (Step 7.1 or 7.2), use the percent solids information obtained in Step 7.1 to determine the optimum sample size (100 gram minimum) for filtration. Enough solids should be generated by filtration to support the analyses to be performed on the TCLP extract.

8.6 Allow slurries to stand to permit the solid phase to settle. Wastes that settle slowly may be centrifuged prior to filtration. Use centrifugation only as an aid to filtration. If the waste is centrifuged, the liquid should be decanted and filtered followed by filtration of the solid portion of the waste through the same filtration system.

8.7 Quantitatively transfer the waste sample (liquid and solid phases) to the filter holder (see Step 4.3.2). Spread the waste sample evenly over the surface of the filter. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature, then allow the sample to warm up to room temperature in the device before filtering.

Note: If waste material (>1 percent of the original sample weight) has obviously adhered to the container used to transfer the sample to the filtration apparatus, determine the weight of this residue and subtract it from the sample weight determined in Step 8.5, to determine the weight of the waste sample that will be filtered.

Gradually apply vacuum or gentle pressure of 1-10 psi, until air or pressurizing gas moves through the filter. If this point is not reached under 10 psi, and if no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10 psi, if the pressurizing gas has not moved through the filter, and if no additional liquid has passed through the filter in any 2-minute interval, proceed to the

next 10-psi increment. When the pressurizing gas begins to move through the filter, or when the liquid flow has ceased at 50 psi (i.e., filtration does not result in any additional filtrate within a 2-minute period), stop the filtration.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

8.8 The material in the filter holder is defined as the solid phase of the waste, and the filtrate is defined as the liquid phase. Weigh the filtrate. The liquid phase may now be either analyzed (See Step 8.12) or stored at 4 °C until time of analysis.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying vacuum or pressure filtration, as outlined in Step 8.7, this material may not filter. If this is the case, the material within the filtration device is defined as a solid and is carried through the extraction as a solid. Do not replace the original filter with a fresh filter under any circumstances. Use only one filter.

8.9 If the waste contains <0.5 percent dry solids (see Step 7.2), proceed to Step 8.13. If the waste contains >0.5 percent dry solids (see Step 7.1 or 7.2), and if particle-size reduction of the solid was needed in Step 7.3, proceed to Step 8.10. If the waste as received passes a 9.5 mm sieve, quantitatively transfer the solid material into the extractor bottle along with the filter used to separate the initial liquid from the solid phase, and proceed to Step 8.11.

8.10 Prepare the solid portion of the waste for extraction by crushing, cutting, or grinding the waste to a surface area or particle-size as described in Step 7.3. When the surface area or particle-size has been appropriately altered, quantitatively transfer the solid material into an extractor bottle. Include the filter used to separate the initial liquid from the solid phase.

Note: Sieving of the waste is not normally required. Surface area requirements are meant for filamentous (e.g., paper, cloth) and similar waste materials. Actual measurement of surface area is not recommended. If sieving is necessary, a Teflon-coated sieve should be used to avoid contamination of the sample.

8.11 Determine the amount of extraction fluid to add to the extractor vessel as follows:

```
Weight of = 20 X percent solids (Step 7.1) weight of
extraction waste filtered (Step 8.5 or 8.7)
fluid
-----------------------------------------
100
```

Slowly add this amount of appropriate extraction fluid (see Step 7.4) to the extractor vessel. Close the extractor bottle tightly (it is recommended that Teflon tape be used to ensure a tight seal), secure in rotary agitation device, and rotate at 30+2 rpm for 18+2 hours. Ambient temperature (i.e., temperature of room in which extraction takes place) shall be maintained at 22 +3 °C during the extraction period.

Note: As agitation continues, pressure may build up within the extractor bottle for some types of wastes (e.g., limed or calcium carbonate containing waste may evolve gases such as carbon dioxide). To relieve excess pressure, the extractor bottle may be periodically opened (e.g., after 15 minutes, 30 minutes, and 1 hour) and vented into a hood.

8.12 Following the 18+2 hour extraction, separate the material in the extractor vessel into its component liquid and solid phases by filtering through a new glass fiber filter, as outlined in Step 8.7. For final filtration of the TCLP extract, the glass fiber filter may be changed, if necessary, to facilitate filtration. Filter(s) shall be acid-washed (see Step 4.4) if evaluating the mobility of metals.

8.13 Prepare the TCLP extract as follows:

8.13.1 If the waste contained no initial liquid phase, the filtered liquid material obtained from Step 8.12 is defined as the TCLP extract. Proceed to Step 8.14.

***11873** 8.13.2 If compatible (e.g., multiple phases will not result on combination), combine the filtered liquid resulting from Step 8.12 with the initial liquid phase of the waste obtained in Step 8.7. This combined liquid is defined as the TCLP extract. Proceed to Step 8.14.

8.13.3 If the initial liquid phase of the waste, as obtained from Step 8.7, is not or may not be compatible with the filtered liquid resulting from Step 8.12, do not combine these liquids. Analyze these liquids, collectively defined as the TCLP extract, and combine the results mathematically, as described in Step 8.14.

8.14 Following collection of the TCLP extract, the pH of the extract should be recorded. Immediately aliquot and preserve the extract for analysis. Metals aliquots must be acidified with nitric acid to pH<2. If precipitation is observed upon addition of nitric acid to a small aliquot of the extract, then the remaining portion of the extract for metals analyses shall not be acidified and the extract shall be analyzed as soon as possible. All other aliquots must be stored under refrigeration (4 °C) until analyzed. The TCLP extract shall be prepared and analyzed according to appropriate analytical methods. TCLP extracts to be analyzed for metals shall be acid digested except in those instances where digestion causes loss of metallic contaminants. If an analysis of the undigested extract shows that the concentration of any regulated metallic contaminant exceeds the regulatory level, then the waste is hazardous and digestion of the extract is not necessary. However, data on undigested extracts alone cannot be used to demonstrate that the waste is not hazardous. If the individual phases are to be analyzed separately, determine the volume of the individual phases (to +0.5 percent), conduct the appropriate analyses, and combine the results mathematically by using a simple volume-weighted average:

```
Final analyte concentration = (V1)(C1) (V2)(C2)
----------------------
V1 V2
```

where:

V1 =The volume of the first phase (L).

C1 =The concentration of the contaminant of concern in the first phase (mg/L).

V2 =The volume of the second phase (L).

C2 =The concentration of the contaminant of concern in the second phase (mg/L).
8.15 Compare the contaminant concentrations in the TCLP extract with the thresholds identified in the appropriate regulations. Refer to § 10.0 for quality assurance requirements.

9.0 Procedure When Volatiles Are Involved
Use the ZHE device to obtain TCLP extract for analysis of volatile compounds only. Extract resulting from the use of the ZHE shall not be used to evaluate the mobility of nonvolatile analytes (e.g., metals, pesticides, etc.).

The ZHE device has approximately a 500-mL internal capacity. The ZHE can thus accommodate a maximum of 25 grams of solid (defined as that fraction of a sample from which no additional liquid may be forced out by an applied pressure of 50 psi), due to the need to add an amount of extraction fluid equal to 20 times the weight of the solid phase.

Charge the ZHE with sample only once and do not open the device until the final extract (of the solid) has been collected. Repeated filling of the ZHE to obtain 25 grams of solid is not permitted.

Do not allow the waste, the initial liquid phase, or the extract to be exposed to the atmosphere for any more time than is absolutely necessary. Any manipulation of these materials should be done when cold (4 °C) to minimize loss of volatiles.

9.1 Pre-weigh the (evacuated) filtrate collection container (See Step 4.6) and set aside. If using a TEDLARR bag, express all liquid from the ZHE device into the bag, whether for the initial or final liquid/solid separation, and take an aliquot from the liquid in the bag for analysis. The containers listed in Step 4.6 are recommended for use under the conditions stated in 4.6.1-4.6.3.

9.2 Place the ZHE piston within the body of the ZHE (it may be helpful first to moisten the piston O-rings slightly with extraction fluid). Adjust the piston within the ZHE body to a height that will minimize the distance the piston will have to move once the ZHE is charged with sample (based upon sample size requirements determined from Section 9.0, Step 7.1 and/or 7.2). Secure the gas inlet/outlet flange (bottom flange) onto the ZHE body in accordance with the manufacturer's instructions. Secure the glass fiber filter between the support screens and set aside. Set liquid inlet/outlet flange (top flange) aside.

9.3 If the waste is 100 percent solid (see Step 7.1), weigh out a subsample (25 gram maximum) of the waste, record weight, and proceed to Step 9.5.

9.4 If the waste contains <0.5 percent dry solids (Step 7.2), the liquid portion of waste, after filtration, is defined as the TCLP extract. Filter enough of the sample so that the amount of filtered liquid will support all of the volatile analyses required. For wastes containing >0.5 percent dry solids (Steps 7.1 and/or 7.2), use the percent solids information obtained in Step 7.1 to determine the optimum sample size to charge into the ZHE. The recommended sample size is as follows:

9.4.1 For wastes containing <0.5 percent solids (see Step 7.1), weigh out a 500-gram subsample of waste and record the weight.

9.4.2 For wastes containing >0.5 percent solids (see Step 7.1), determine the amount of waste to charge into the ZHE as follows:

```
Weight of waste to = 25 X 100
change ZHE
-------------------------
Percent solids (Step 7.1)
```

Weigh out a subsample of the waste of the appropriate size and record the weight.

9.5 If particle-size reduction of the solid portion of the waste was required in Step 7.3, proceed to Step 9.6. If particle-size reduction was not required in Step 7.3, proceed to Step 9.7.

9.6 Prepare the waste for extraction by crushing, cutting, or grinding the solid portion of the waste to a surface area or particle-size as described in Step 7.3.1. Wastes and appropriate reduction equipment should be refrigerated, if possible, to 4 °C prior to particle-size reduction. The means used to effect particle-size reduction must not generate heat in and of itself. If reduction of the solid phase of the waste is necessary, exposure of the waste to the atmosphere should be avoided to the extent possible.

Note: Sieving of the waste is not recommended due to the possibility that volatiles may be lost. The use of an appropriately graduated ruler is recommended as an acceptable alternative. Surface area requirements are meant for filamentous (e.g., paper, cloth) and similar waste materials. Actual measurement of surface area is not recommended.

When the surface area or particle-size has been appropriately altered, proceed to Step 9.7.

9.7 Waste slurries need not be allowed to stand to permit the solid phase to settle. Do not centrifuge wastes prior to filtration.

9.8 Quantitatively transfer the entire sample (liquid and solid phases) quickly to the ZHE. Secure the filter and support screens onto the top flange of the device and secure the top flange to the ZHE body in accordance with the manufacturer's instructions.

Tighten all ZHE fittings and place the device in the vertical position (gas inlet/outlet flange on the bottom). Do not attach the extract collection device to the top plate.

Note: If waste material (>1% of original sample weight) has obviously adhered to the container used to transfer the sample to the ZHE, determine the weight of this residue and subtract it from the sample weight determined in Step 9.4 to determine the weight of the waste sample that will be filtered.

Attach a gas line to the gas inlet/outlet valve (bottom flange) and, with the liquid ***11874** inlet/outlet valve (top flange) open, begin applying gentle pressure of 1-10 psi (or more if necessary) to force all headspace slowly out of the ZHE device into a hood. At the first appearance of liquid from the liquid inlet/outlet valve, quickly close the valve and discontinue pressure. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature, then allow the sample to warm up to room temperature in the device before filtering. If the waste is 100 percent solid (see Step 7.1), slowly increase the pressure to a maximum of 50 psi to force most of the headspace out of the device and proceed to Step 9.12.

9.9 Attach the evacuated pre-weighed filtrate collection container to the liquid inlet/outlet valve and open the valve. Begin applying gentle pressure of 1-10 psi to force the liquid phase of the sample into the filtrate collection container. If no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10 psi, if no additional liquid has passed through the filter in any 2-minute interval, proceed to the next 10-psi increment. When liquid flow has ceased such that continued pressure filtration at 50 psi does not result in any additional filtrate within a 2-minute period, stop the filtration. Close the liquid inlet/outlet valve, discontinue pressure to the piston, and disconnect and weigh the filtrate collection container.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

9.10 The material in the ZHE is defined as the solid phase of the waste and the filtrate is defined as the liquid phase.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying pressure filtration, this material will not filter. If this is the case, the material within the filtration device is defined as a solid and is carried through the TCLP extraction as a solid.

If the original waste contained <0.5 percent dry solids (see Step 7.2), this filtrate is defined as the TCLP extract and is analyzed directly. Proceed to Step 9.15.

9.11 The liquid phase may now be either analyzed immediately (See Steps 9.13 through 9.15) or stored at 4 °C under minimal headspace conditions until time of analysis. Determine the weight of extraction fluid 1 to add to the ZHE as follows:

```
Weight of = 20 X percent solids (Step 7.1) weight of
extraction waste filtered (Step 9.4 or 9.8)
fluid
-------------------------------------------
100
```

9.12 The following steps detail how to add the appropriate amount of extraction fluid to the solid material within the ZHE and agitation of the ZHE vessel. Extraction fluid 1 is used in all cases (See Step 5.6).

9.12.1 With the ZHE in the vertical position, attach a line from the extraction fluid reservoir to the liquid inlet/outlet valve. The line used shall contain fresh extraction fluid and should be preflushed with fluid to eliminate any air pockets in the line. Release gas pressure on the ZHE piston (from the gas inlet/outlet valve), open the liquid inlet/outlet valve, and begin transferring extraction fluid (by pumping or similar means) into the ZHE. Continue pumping extraction fluid into the ZHE until the appropriate amount of fluid has been introduced into the device.

9.12.2 After the extraction fluid has been added, immediately close the liquid inlet/outlet valve and disconnect the extraction fluid line. Check the ZHE to ensure that all valves are in their closed positions. Manually rotate the device in an end-over-end fashion 2 or 3 times. Reposition the ZHE in the vertical position with the liquid inlet/outlet valve on top. Pressurize the ZHE to 5-10 psi (if necessary) and slowly open the liquid inlet/outlet valve to bleed out any headspace (into a hood) that may have been introduced due to the addition of extraction fluid. This bleeding shall be done quickly and shall be stopped at the first appearance of liquid from the valve. Re-pressurize the ZHE with 5-10 psi and check all ZHE fittings to ensure that they are closed.

9.12.3 Place the ZHE in the rotary agitation apparatus (if it is not already there) and rotate at 30+2 rpm for 18+2 hours. Ambient temperature (i.e., temperature of room in which extraction occurs) shall be maintained at 22+3 °C during agitation.

9.13 Following the 18 +2 hour agitation period, check the pressure behind the ZHE piston by quickly opening and closing the gas inlet/outlet valve and noting the escape of gas. If the pressure has not been maintained (i.e., no gas release observed), the device is leaking. Check the ZHE for leaking as specified in Step 4.2.1, and perform the extraction again with a new sample of waste. If the pressure within the device has been maintained, the material in the extractor vessel is once again separated into its component liquid and solid phases. If the waste contained an initial liquid phase, the liquid may be filtered directly into the same filtrate collection container (i.e., TEDLARR bag) holding the initial liquid phase of the waste. A separate filtrate collection container must be used if combining would create multiple phases, or there is not enough volume left within the filtrate collection container. Filter through the glass fiber filter, using the ZHE device as discussed in Step 9.9. All extract shall be filtered and collected if the TEDLARR bag is used, if the extract is multiphasic, or if the waste contained an initial liquid phase (see Steps 4.6 and 9.1).

Note: An in-line glass fiber filter may be used to filter the material within the ZHE if it is suspected that the glass fiber filter has been ruptured.

9.14 If the original waste contained no initial liquid phase, the filtered liquid material obtained from step 9.13 is defined as the TCLP extract. If the waste contained an initial liquid phase, the filtered liquid material obtained from Step 9.13 and the initial liquid phase (Step 9.9) are collectively defined as the TCLP extract.

9.15 Following collection of the TCLP extract, immediately prepare the extract for analysis and store with minimal headspace at 4 °C until analyzed. Analyze the TCLP extract according to the appropriate analytical methods. If the individual phases are to be analyzed separately (i.e., are not miscible), determine the volume of the individual phases (to 0.5%), conduct the appropriate analyses, and combine the results mathematically by using a simple volume-weighted average:

```
Final analyte concentration (V1)(C1) (V2)(C2)
----------------------
V1 V2
```

***11875** where:

V1 =The volume of the first phases (l).

C1 =The concentration of the contaminant of concern in the first phase (mg/l).

V2 =The volume of the second phase (l).

C2 =The concentration of the contaminant of concern in the second phase (mg/l).

9.16 Compare the contaminant concentrations in the TCLP extract with the thresholds identified in the appropriate regulations. Refer to section 10.0 for quality assurance requirements.

10.0 Quality Assurance Requirements

10.1 Maintain all data, including quality assurance data, and keep it available for reference or inspection.

10.2 A minimum of one blank (extraction fluid 1) for every 10 extractions that have been conducted in an extraction vessel shall be employed as a check to determine if any memory effects from the extraction equipment are occurring.

10.3 A matrix spike shall be performed for each waste unless the result exceeds the regulatory level and the data is being used solely to demonstrate that the waste property exceeds the regulatory level. If more than one sample of the same waste is being tested, a matrix spike needs to be performed for every twenty samples and the average percent recovery applied to the waste characterization.

10.3.1 Matrix spikes are to be added after filtration of the TCLP extract and before preservation. Matrix spikes should not be added prior to TCLP extraction of the sample.

10.3.2 Matrix spike levels should be made at the appropriate regulatory threshold limits. However, if the extract contaminant concentration is less than one half the threshold limit, the spike level may be one half the contaminant concentration but not less than the quantitation limit or a fifth of the threshold limit.

10.3.3 The purpose of the matrix spike is to monitor the adequacy of the analytical methods used on the TCLP extract and to determine whether matrix interferences exist in analyte detection. If the matrix spike recoveries are less than 50%, then the analytical methods are not performing adequately or use of the methods is inadequate. Use of internal calibration quantitation methods, modification of the analytical methods, or use of alternate analytical methods may be needed to accurately measure the contaminant concentration in the TCLP extract.

10.3.4 Use of internal quantitation methods is also required when the contaminant concentration is within 20% of the regulatory level. (See section 10.5 concerning the use of internal calibration methods.)

10.3.5 Matrix spike recoveries are calculated by the following formula:

```
Percent recovery = A-B X 100%
--------
C
```

where A=the concentration of the spiked sample,

B=the concentration of the unspiked sample, and

C=the spike level

10.4 All quality control measures described in the appropriate analytical methods shall be followed.

10.5 The use of internal calibration quantitation methods shall be employed for a contaminant if: (1) Recovery of the contaminant from the TCLP extract is not at least 50% and the concentration does not exceed the regulatory level, and (2) The concentration of the contaminant measured in the extract is within 20% of the appropriate regulatory level.

10.5.1 The method of standard additions shall be employed as the internal calibration quantitation method for each metallic contaminant.

10.5.1.1 The method of standard additions requires preparing calibration standards in the sample matrix rather than reagent water or blank solution. It requires taking four identical aliquots of the solution and adding known amounts of standard to three of these aliquots. The fourth aliquot is the unknown. Preferably, the first addition should be prepared so that the resulting concentration is approximately 50% of the expected concentration of the sample. The second and third additions should be

prepared so that the concentrations are approximately 100% and 150% of the expected concentration of the sample. All four aliquots are maintained at the same final volume by adding reagent water or a blank solution, and may need dilution adjustment to maintain the signals in the linear range of the instrumental technique. All four aliquots are analyzed.

10.5.1.2 Prepare a plot, or subject data to linear regression, of instrumental signals or external-calibration-derived concentrations as the dependent variable (y-axis) versus concentrations of the additions of standard as the independent variable (x-axis). Solve for the intercept of the abscissa (the independent variable, x-axis) which is the concentration in the unknown.

10.5.1.3 Alternately, subtract the instrumental signal or external-calibration-derived concentration of the unknown (unspiked) sample from the instrumental signals or external-calibration-derived concentrations of the standard additions. Plot or subject data to linear regression of the corrected instrumental signals or external-calibration-derived concentrations as the dependent variable versus the independent variable. Derive concentrations for unknowns using the internal calibration curve as if it were an external calibration curve.

10.6 Samples must undergo TCLP extraction within the following time periods:

Sample Maximum Holding Times [Days]			
From: Field collection To: TCLP extraction	From: TCLP extraction To: Preparative extraction	From: Preparative extraction To: Determinative analysis	Total elapsed time
Volatiles	14	NA	14 28
Semi-volatiles	7	7 40	54
Mercury	28	NA	28 56
Metals, except mercury	180	NA	180 360

NA = Not applicable.

If sample holding times are exceeded, the values obtained will be considered minimal concentrations. Exceeding the holding time is not acceptable in establishing that a waste does not exceed the regulatory level. Exceeding the holding time will not invalidate characterization if the waste exceeds the regulatory level.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

7. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, and 6925.

8. Section 264.301 is amended by revising paragraph (e)(1) to read as follows:

§ 264.301 Design and operating requirements.

* * * * *

***11876** (e) * * *

(1) The monofill contains only hazardous wastes from foundry furnace emission controls or metal casting molding sand, and such wastes do not contain constituents which would render the wastes hazardous for reasons other than the Toxicity Characteristic in § 261.24 of this chapter, with EPA Hazardous Waste Numbers D004 through D017; and

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT STORAGE, AND DISPOSAL FACILITIES

9. The authority citation of part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6935.

10. Section 265.221 is amended by revising paragraph (d)(1) to read as follows:

§ 265.221 Design requirements.

* * * * *

(d) * * *

(1) The monofill contains only hazardous wastes from foundry furnace emission controls or metal casting molding sand, and such wastes do not contain constituents which would render the wastes hazardous for reasons other than the Toxicity Characteristic in § 261.24 of this chapter, with EPA Hazardous Waste Numbers D004 through D017; and

* * * * *

11. Section 265.273 is amended by revising paragraph (a) to read as follows:

§ 265.273 Waste analysis.

* * * * *

(a) Determine the concentrations in the waste of any substances which equal or exceed the maximum concentrations contained in Table 1 of § 261.24 of this chapter that cause a waste to exhibit the Toxicity Characteristic;

* * * * *

PART 268—LAND DISPOSAL RESTRICTIONS

12. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

13. Appendix I of part 268 is revised to read as follows:

Appendix I—Toxicity Characteristic Leaching Procedure (TCLP)

Note: The TCLP is published in Appendix II of part 261.

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

14. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), and 6926.

15. Section 271.1, paragraph (j), the heading of Table 1 is republished, and Table 1 is amended by adding the following entry in chronological order by date of promulgation to read as follows:

§ 271.1 Purpose and scope.

* * * * *

(j) * * *

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[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a
meaningful review of its contents. The table has been divided into multiple pieces with each piece containing
information to help you assemble a printout of the table. The information for each piece includes: (1) a
three line message preceding the tabular data showing by line # and character # the position of the upper
left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric
scale following the tabular data displaying the character positions.]
******************************************************************************
******** This is piece 1. -- It begins at character 1 of table line 1. ********
******************************************************************************
Table 1.--Regulations Implementing the Hazardous and Solid Waste
-----------------------------------------------------------------
Promulgation date Title of regulation Federal Register
reference
-----------------------------------------------------------------
* * * *
March 29, 1990 ..... Toxicity
characteristic .... [Insert FR
reference on date
of publication] ..
-----------------------------------------------------------------
1...#...10....#...20....#...30....#...40....#...50....#...60....
******************************************************************************
******* This is piece 2. -- It begins at character 65 of table line 1. ********
******************************************************************************
Amendments of 1984
--------------------
Effective date
--------------------
*
September 25, 1990
--------------------
65..70....#...80....
```

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

16. The authority citation for part 302 continues to read as follows:

Authority: 42 U.S.C. 9602; 33 U.S.C. 1321 and 1361.

17. Section 302.4 is amended by revising under the column Hazardous Substance the entry “Unlisted Hazardous Wastes Characteristic of EP Toxicity” to read “Unlisted Hazardous Wastes Characteristics:” and by revising the entry “Characteristic of EP Toxicity” and its sub entries to read as follows:

§ 302.4 Designation of hazardous substances.

* * * * *

```
[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a
meaningful review of its contents. The table has been divided into multiple pieces with each piece containing
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information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

****

******** This is piece 1. -- It begins at character 1 of table line 1. ********

****

Table 302.4.--List of Hazardous Substances

Hazardous substance	CASRN	Regulatory synonyms	RQ
* * * * *			
Characteristic of Toxicity:			
Arsenic (D004)	N.A.		*1
Barium (D005)	N.A.		*1
Benzene (D018)	N.A.		1000
Cadmium (D006)	N.A.		*1
Carbon tetrachloride (D019)	N.A.		5,000
Chlordane (D020)	N.A.		1
Chlorobenzene (D021)	N.A.		100
Chloroform (D022)	N.A.		5,000
Chromium (D007)	N.A.		*1
o-Cresol (D023)	N.A.		1,000
m-Cresol (D024)	N.A.		1,000
p-Cresol (D025)	N.A.		1,000
Cresol (D026)	N.A.		1,000
2,4-D (D016)	N.A.		100
1,4-Dichlorobenzene (D027)	N.A.		100
1,2-Dichloroethane (D028)	N.A.		5,000
1,1-Dichloroethylene (D029)	N.A.		5,000
2,4-Dinitrotoluene (D030)	N.A.		1,000
Endrin (D012)	N.A.		1
Heptachlor (and hydroxide) (D031)	N.A.		1
Hexachlorobenzene (D032)	N.A.		*1
Hexachlorobutadiene (D033)	N.A.		*1
Hexachloroethane (D034)	N.A.		*1
Lead (D008)	N.A.		*1
Lindane (D013)	N.A.		1
Mercury (D009)	N.A.		*1
Methoxychlor (D014)	N.A.		1
Methyl ethyl ketone (D035)	N.A.		*1
Nitrobenzene (D036)	N.A.		1,000
Pentachlorophenol (D037)	N.A.		10
Pyridine (D038)	N.A.		*1
Selenium (D010)	N.A.		*1
Silver (D011)	N.A.		*1
Tetrachloroethylene			

```
(D039) ................. N.A....... --------------- *1
Toxaphene (D015) ......... N.A....... --------------- 1
Thrichloroethylene (D040) N.A....... --------------- 1000
2,4,5-Trichloroethylene
(D041) ................. N.A....... --------------- 10
2,4,6-Trichlorophenol
(D042) ................. N.A....... --------------- 10
2,4,5-TP (D017) .......... N.A....... --------------- 100
Vinyl chloride (D043) .... N.A....... --------------- *1
* * * *
*
------------------------------------------------------------
1...#...10....#...20....#...30....#...40....#...50....#...60..
********************************************************************************
******* This is piece 2. -- It begins at character 63 of table line 1. ********
********************************************************************************
and Reportable Quantities
-------------------------------------------
Statutory Final RQ
-------------------------------------------
Code RCRA Category Pounds (Kg)
waste
number
-------------------------------------------
* * -
4 D004 ..... X ............ 1 (0.454)
4 D005 ..... C .......... 1,000 (454)
1, 2, D018 ..... A ............ 10 (4.54)
3, 4
4 D006 ..... A ............ 10 (4.54)
1, 2, 4 D019 ..... A ............ 10 (4.54)
1, 2, 4 D020 ..... X ............ 1 (0.454)
1, 2, 4 D021 ..... B ............ 100 (45.4)
1, 2, 4 D022 ..... A ............ 10 (4.54)
4 D007 ..... A ............ 10 (4.54)
1, 4 D023 ..... C .......... 1,000 (454)
1, 4 D024 ..... C .......... 1,000 (454)
1, 4 D025 ..... C .......... 1,000 (454)
1, 4 D026 ..... C .......... 1,000 (454)
1, 4 D016 ..... B ............ 100 (45.4)
1, 2, 4 D027 ..... B ............ 100 (45.4)
1, 2, 4 D028 ..... B ............ 100 (45.4)
1, 2, 4 D029 ..... B ............ 100 (45.4)
1, 2, 4 D030 ..... A ............ 10 (4.54)
1, 4 D012 ..... X ............ 1 (0.454)
1, 2, 4 D031 ..... X ............ 1 (0.454)
2, 4 D032 ..... A ............ 10 (4.54)
2, 4 D033 ..... X ............ 1 (0.454)
2, 4 D034 ..... B ............ 100 (45.4)
4 D008 ..... ---------- ()
1, 4 D013 ..... X ............ 1 (0.454)
4 D009 ..... X ............ 1 (0.454)
1, 4 D014 ..... X ............ 1 (0.454)
4 D035 ..... D ................ 5,000
(2270)
1, 2, 4 D036 ..... C .......... 1,000 (454)
1, 2, 4 D037 ..... A ............ 10 (4.54)
4 D038 ..... C .......... 1,000 (454)
```

```
4 D010 ..... A ............ 10 (4.54)
4 D011 ..... X ............ 1 (0.454)
2, 4 D039 ..... B ........... 100 (45.4)
1, 4 D015 ..... X ............ 1 (0.454)
1, 2, 4 D040 ..... B ........... 100 (45.4)
1, 4 D041 ..... A ............ 10 (4.54)
1, 2, 4 D042 ..... A ............ 10 (4.54)
1, 4 D017 ..... B ........... 100 (45.4)
2, 3, 4 D043 ..... X ............ 1 (0.454)
* * -
*
-------------------------------------------
63....70....#...80....#...90....#....0....#...
*******************************************************************************
******* This is piece 3. -- It begins at character 1 of table line 68. ********
*******************************************************************************
--indicates the statutory source as defined by 1, 2, 3, or 4 below.
*1 --indicates that the 1-pound RQ is a CERCLA statutory RQ.
--indicates that the RQ is subject to change when the assessment of potential
carcinogenicity is completed.
1...#...10....#...20....#...30....#...40....#...50....#...60....#...70....#....
```

***11877** [FR Doc. 90-6104 Filed 3-28-90; 8:45 am]

BILLING CODE 6560-50-M

Footnotes

1 As explained previously, the Agency is not, in today's rule, promulgating regulatory levels for several of the constituents for which regulatory levels were proposed. These constituents include those that are expected to hydrolyze appreciably and those for which it has not yet been determined whether the steady-state solution to the subsurface fate and transport model is appropriate. Once the issues associated with these constituents are resolved, the Agency will promulgate or repropose (as warranted) regulatory levels for these constituents. For cases where regulatory levels are reproposed, they may incorporate dilution/ attenuation factors other than 100. FN2 The health data is only valid to one order of magnitude precision and thus may control the total number of significant figures.

3 The exception to this rule is a mixture of solid waste and a waste that is listed solely because it exhibits a characteristic of hazardous waste. If such a mixture does not exhibit any characteristic of hazardous waste, the mixture is not defined as hazardous [40 CFR 261.3(a)(2)(iii)].

1 VITON R is a trademark of Du Pont.

2 TEDLARR is a registered trademark of Du Pont.

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57 FR 22888-01
NOTICES
ENVIRONMENTAL PROTECTION AGENCYI41(FRL-4129-5)

Guidelines for Exposure Assessment

*22888 Friday, May 29, 1992

AGENCY: U.S. Environmental Protection Agency

ACTION: Final guidelines for exposure assessment

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today issuing final guidelines for exposure assessment. The Guidelines for Exposure Assessment (hereafter "Guidelines") are intended for risk assessors in EPA, and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. In addition, publication of these Guidelines makes information on the principles, concepts, and methods used by the Agency available to all interested members of the public. These Guidelines supersede and replace both the Guidelines for Estimating Exposures published September 24, 1986 (51 FR 34042-34054) (hereafter "1986 Guidelines") and the Proposed Guidelines for Exposure-Related Measurements published for comment on December 2, 1988 (53 FR 48830-48853) (hereafter "1988 Proposed Guidelines"). In response to recommendations from the Science Advisory Board (SAB) and the public, the 1986 Guidelines were updated and combined with the 1988 Proposed Guidelines and retitled as the current Guidelines for Exposure Assessment.

These Guidelines establish a broad framework for Agency exposure assessments by describing the general concepts of exposure assessment including definitions and associated units, and by providing guidance on the planning and conducting of an exposure assessment. Guidance is also provided on presenting the results of the exposure assessment and characterizing uncertainty. Although these Guidelines focus on exposures of humans to chemical substances, much of the guidance contained herein also pertains to assessing wildlife exposure to chemicals, or to human exposures to biological, noise, or radiological agents. Since these latter four areas present unique challenges, assessments on these topics must consider additional factors beyond the scope of these Guidelines. The Agency may, at a future date, issue additional specific guidelines in these areas.

EFFECTIVE DATE: The Guidelines will be effective May 29, 1992.

FOR FURTHER INFORMATION CONTACT: Michael A. Callahan, Director, Exposure Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-260-8909.

SUPPLEMENTARY INFORMATION: In its 1983 book Risk Assessment in the Federal Government: Managing the Process, the National Academy of Sciences recommended that Federal regulatory agencies establish "inference guidelines" to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and estimating exposures. Following extensive scientific and public review, these guidelines were issued on September 24, 1986 (51 FR 33992-34054). Subsequent work resulted in the publishing of four additional proposals (one of which has recently become final): Proposed Guidelines for Assessing Female Reproductive Risk (53 FR 24834-24847), Proposed Guidelines for Assessing Male Reproductive Risk (53 FR 24850-24869), Proposed Guidelines for Exposure-Related Measurements (53 FR 48830-48853), and Proposed Amendments to the Guidelines for the Health Assessment of Suspect

Developmental Toxicants (54 FR 9386-9403). The final Guidelines for Developmental Toxicity Risk Assessment, published December 5, 1991 (56 FR 63798-63826), supersede and replace the proposed amendments.

The Guidelines issued today continue the guidelines development process initiated in 1984. Like the guidelines issued in 1986, the Guidelines issued today set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments and to inform Agency decision makers and the public about these procedures. In particular, the Guidelines standardize terminology used by the Agency in exposure assessment and in many areas outline the limits of sound scientific practice. They emphasize that exposure assessments done as part of a risk assessment need to consider the hazard identification and dose-response parts of the risk assessment in the planning stages of the exposure assessment so that these three parts can be smoothly integrated into the risk characterization. The Guidelines discuss and reference a number of approaches and tools for exposure assessment, along with discussion of their appropriate use. The Guidelines also stress that exposure estimates along with supporting information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Work on these Guidelines began soon after publication of the 1986 Guidelines. At that time, the SAB recommended that the Agency develop supplementary guidelines for conducting exposure studies. This supplementary guidance was developed by an Agency work group composed of scientists from throughout the Agency, a draft was peer reviewed by experienced professionals from environmental groups, industry, academia, and other governmental agencies, and proposed for comment on December 2, 1988 (as Proposed Guidelines for Exposure-Related Measurements). In the public notice, the Agency asked for comment on whether the proposed guidelines should be combined with the 1986 guidelines in order to have a single Agency guideline for exposure assessment. Comments from the public and the SAB were heavily in favor of combining the two guidelines.

Since proposal, the Agency has reformatted the 1988 Proposed Guidelines to allow incorporation of the information in the 1986 Guidelines, and incorporated revisions resulting from additional public and SAB comments, to establish the current Guidelines. The current Guidelines were reviewed by the Risk Assessment Forum and the Risk Assessment Council, subjected to an external peer review, and presented to the SAB on September 12, 1991 for final comment (EPA-SAB-IAQC-92-015). In addition, the Guidelines were reviewed by the Working Party on Exposure Assessment, an interagency working group under the Subcommittee on Risk Assessment of the Federal Coordinating Committee on Science, Engineering and Technology. Comments of these groups have been considered in the revision of these Guidelines. The full text of the final Guidelines for Exposure Assessment is published here.

These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Risk Assessment Forum and the Office of Health and Environmental Assessment in the Agency's Office of Research and ***22889** Development. The Agency is continuing to study risk assessment issues raised in these Guidelines, and will revise them in line with new information as appropriate.

Following this preamble are two parts: Part A is the Guidelines and Part B is the Response to the Public and Science Advisory Board comments submitted in response to the 1988 Proposed Guidelines.

References, supporting documents, and comments received on the 1988 Proposed Guidelines, as well as a copy of these final Guidelines for Exposure Assessment are available for inspection at the ORD Public Information Shelf, EPA Headquarters Library (202-260-5926), 401 M Street, SW., Washington, DC, between the hours of 8 a.m. and 4:30 p.m.

Dated: April 28, 1992.

William K. Reilly,

Administrator.

Table of Contents

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Figures

Tables

Abbreviations and Acronyms

ADD—Average daily dose

AF—Absorption fraction

AT—Averaging time

BW—Body weight

C—Exposure concentration

C(t)—Exposure concentration as a function of time

CO—Carbon monoxide

CT—Contact time

D—Dose

D_{app}—Applied dose

D_{int}—Internal dose

D_{pot}—Potential dose

DQO—Data quality objective

E—Exposure

ED—Exposure duration

EPA—U.S. Environmental Protection Agency

F_{adh}—Adherence factor for soil

f(t)—Absorption function

IR—Intake rate (also ingestion or inhalation rate)

J—Flux

K_p—Permeability coefficient

***22890** LADD—Lifetime average daily dose

LOAEL—Lowest observable adverse effect level

LOD—Limit of detection

LT—Lifetime

M_{medium}—Amount (mass) of carrier medium material applied to the skin

MDL—Method detection limit

MEI—Maximally exposed individual or most exposed individual

ND—Not detected

PMN—Premanufacture notice

QA—Quality assurance

QAP_jP—Quality assurance project plan

QC—Quality control

QL—Quantification limit

RfC—Reference concentration

RfD—Reference dose

SA—Surface area

SAB—Science Advisory Board

TEAM—Total exposure assessment methodology

TUBE—Theoretical upper bounding estimate

UCL—Upper confidence limit (often used to refer to the upper confidence limit of the mean)

UR—Uptake rate

Part A: Guidelines for Exposure Assessment

1. Introduction

In 1984, the U. S. Environmental Protection Agency (EPA) initiated a program to ensure scientific quality and technical consistency of Agency risk assessments. One of the goals of the program was to develop risk assessment guidelines that would be used Agencywide. The guidelines development process includes a public review and comment period for all proposed guidelines as well as Agency Science Advisory Board review. Following the review process, the guidelines are revised if needed and then issued as final guidelines. The Guidelines for Estimating Exposures (hereafter "1986 Guidelines") were one of five guidelines issued as final in 1986 (U.S. EPA, 1986a). In 1988, the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") were published in the Federal Register for public review and comment (U.S. EPA, 1988a). The 1988 Proposed Guidelines were intended to be a companion and supplement to the 1986 Guidelines.

When proposing the 1988 guidelines, the Agency asked both the EPA Science Advisory Board (SAB) and the public for comments on combining the 1986 and 1988 exposure guidelines into a larger, more comprehensive guideline; the majority of comments received were in favor of doing so. Thus, these 1992 Guidelines for Exposure Assessment (hereafter "Guidelines") combine, reformat, and substantially update the earlier guidelines. These guidelines make use of developments in the exposure assessment field since 1988, both revising the previous work and adding several topics not covered in the 1986 or 1988 guidelines. Therefore, the 1992 guidelines are being issued by the Agency as a replacement for both the 1986 Guidelines and the 1988 Proposed Guidelines.

1.1. Intended Audience

This document is intended for exposure and risk assessors in the Agency and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. Risk managers in the Agency may also benefit from this document since it clarifies the terminology and methods used by assessors, which in some cases could strengthen the basis for decisions. In addition, publication of these guidelines makes information on the principles, concepts, and methods used by the Agency available to other agencies, States, industry, academia, and all interested members of the public.

1.2. Purpose and Scope of the Guidelines

There are a number of different purposes for exposure assessments, including their use in risk assessments, status and trends analysis, and epidemiology. These Guidelines are intended to convey the general principles of exposure assessment, not to serve as a detailed instructional guide. The technical documents cited here provide more specific information for individual exposure assessment situations. As the Agency performs more exposure assessments and incorporates new approaches, these Guidelines will be revised.

Agency risk assessors should use these Guidelines in conjunction with published guidelines for assessing health effects such as cancer (U.S. EPA, 1986b), developmental toxicity (U.S. EPA, 1991a), mutagenic effects (U.S. EPA, 1986c), and reproductive effects (U.S. EPA, 1988b; U.S. EPA, 1988c). These exposure assessment guidelines focus on human exposure to chemical substances. Much of the guidance contained herein also applies to wildlife exposure to chemicals, or human exposure to biological, physical (i.e., noise), or radiological agents. Since these areas present unique challenges, however, assessments on these topics must consider additional factors beyond the scope of these Guidelines.

For example, ecological exposure and risk assessment may deal with many species which are interconnected via complex food webs, while these guidelines deal with one species, humans. While these guidelines discuss human exposure on the individual and population levels, ecological exposure and risk assessments may need to address community, ecosystem, and landscape levels, also. Whereas chemical agents may degrade or be transformed in the environment, biological agents may of course grow and multiply, an area not covered in these guidelines. The Agency may, at a future date, issue specific guidelines in these areas.

Persons subject to these Guidelines should use the terms associated with chemical exposure assessment in a manner consistent with the glossary in Section 8. Throughout the public comment and SAB review process, the Agency has sought definitions that have consensus within the scientific community, especially those definitions common to several scientific fields. The Agency is aware that certain well understood and widely accepted concepts and definitions in the area of health physics (such as the definition of exposure) differ from the definitions in this glossary. The definitions in this glossary are not meant to replace such basic definitions used in another field of science. It was not possible, however, to reconcile all the definitions used in various fields of science, and the ones used in the glossary are thought to be the most appropriate for the field of chemical exposure assessment.

The Agency may, from time to time, issue updates of or revisions to these Guidelines.

1.3. Organization of the Guidelines

These Guidelines are arranged in an order that assessors commonly use in preparing exposure assessments. Section 2 deals with general concepts, section 3 with planning, section 4 with data development, section 5 with calculating exposures, section 6 with uncertainty evaluation, and section 7 with presenting the results. In addition, these Guidelines include a glossary of terms (section 8) and references to other documents (section 9).

2. General Concepts in Exposure Assessment

Exposure assessment in various forms dates back at least to the early twentieth century, and perhaps before, particularly in the fields of epidemiology (World Health Organization (WHO), 1983), industrial hygiene (Cook, 1969; Paustenbach, 1985), and health physics (Upton, 1988). Epidemiology is the study of disease occurrence and the causes of disease, while the latter fields deal primarily with occupational exposure. ***22891** Exposure assessment combines elements of all three disciplines. This has become increasingly important since the early 1970s due to greater public, academic, industrial, and governmental awareness of chemical pollution problems.

Because there is no agreed-upon definition of the point on or in the body where exposure takes place, the terminology used in the current exposure assessment literature is inconsistent. Although there is reasonable agreement that human exposure means contact with the chemical or agent (Allaby, 1983; Environ Corporation, 1988; Hodgson et al., 1988; U.S. EPA, 1986a), there has not yet been widespread agreement as to whether this means contact with (a) the visible exterior of the person (skin and openings into the body such as mouth and nostrils), or (b) the so-called exchange boundaries where absorption takes place (skin, lung, gastrointestinal tract). [FN1] These different definitions have led to some ambiguity in the use of terms and units for quantifying exposure.[FN2]

Comments on the 1986 Guidelines and the 1988 Proposed Guidelines suggested that EPA examine how exposure and dose were defined in Agency assessments and include guidance on appropriate definitions and units. After internal discussions and external

peer review, it is the Agency's position that defining exposure as taking place at the visible external boundary, as in (a) above, is less ambiguous and more consistent with nomenclature in other scientific fields. This is a change from the 1986 Guidelines.

Under this definition, it is helpful to think of the human body as having a hypothetical outer boundary separating inside the body from outside the body. This outer boundary of the body is the skin and the openings into the body such as the mouth, the nostrils, and punctures and lesions in the skin. As used in these Guidelines, exposure to a chemical is the contact of that chemical with the outer boundary. An exposure assessment is the quantitative or qualitative evaluation of that contact; it describes the intensity, frequency, and duration of contact, and often evaluates the rates at which the chemical crosses the boundary (chemical intake or uptake rates), the route by which it crosses the boundary (exposure route; e.g., dermal, oral, or respiratory), and the resulting amount of the chemical that actually crosses the boundary (a dose) and the amount absorbed (internal dose).

Depending on the purpose for which an exposure assessment will be used, the numerical output of an exposure assessment may be an estimate of either exposure or dose. If exposure assessments are being done as part of a risk assessment that uses a dose-response relationship, the output usually includes an estimate of dose. [FN3] Other risk assessments, for example many of those done as part of epidemiologic studies, use empirically derived exposure-response relationships, and may characterize risk without the intermediate step of estimating dose.

2.1. Concepts of Exposure, Intake, Uptake, and Dose

The process of a chemical entering the body can be described in two steps: contact (exposure), followed by actual entry (crossing the boundary). Absorption, either upon crossing the boundary or subsequently, leads to the availability of an amount of the chemical to biologically significant sites within the body (internal dose[FN4]). Although the description of contact with the outer boundary is simple conceptually, the description of a chemical crossing this boundary is somewhat more complex.

There are two major processes by which a chemical can cross the boundary from outside to inside the body. Intake involves physically moving the chemical in question through an opening in the outer boundary (usually the mouth or nose), typically via inhalation, eating, or drinking. Normally the chemical is contained in a medium such as air, food, or water; the estimate of how much of the chemical enters into the body focuses on how much of the carrier medium enters. In this process, mass transfer occurs by bulk flow, and the amount of the chemical itself crossing the boundary can be described as a chemical intake rate. The chemical intake rate is the amount of chemical crossing the outer boundary per unit time, and is the product of the exposure concentration times the ingestion or inhalation rate. Ingestion and inhalation rates are the amount of the carrier medium crossing the boundary per unit time, such as m3 air breathed/hour, kg food ingested/day, or liters of water consumed/day. Ingestion or inhalation rates typically are not constant over time, but often can be observed to vary within known limits. [FN5]

The second process by which a chemical can cross the boundary from outside to inside the body is uptake. Uptake involves absorption of the chemical through the skin or other exposed tissue such as the eye. Although the chemical is often contained in a carrier medium, the medium itself typically is not absorbed at the same rate as the chemical, so estimates of the amount of the chemical crossing the boundary cannot be made in the same way as for intake (see section 2.1.3.). Dermal absorption is an example of direct uptake across the outer boundary of the body.[FN6] A chemical uptake rate is the amount of chemical absorbed per unit time. In this process, mass transfer occurs by diffusion, so uptake can depend on the concentration gradient across the boundary, permeability of the barrier, and other factors. Chemical uptake rates can be expressed as a function of the exposure concentration, permeability coefficient, and surface area exposed, or as a flux (see section 2.1.4.).

The conceptual process of contact, then entry and absorption, can be used to derive the equations for exposure and dose for all routes of exposure.

2.1.1. Exposure

The condition of a chemical contacting the outer boundary of a human is exposure. Most of the time, the chemical is contained in air, water, soil, a product, or a transport or carrier medium; the chemical concentration at the point of contact is the exposure

***22892** concentration. Exposure over a period of time can be represented by a time-dependent profile of the exposure concentration. The area under the curve of this profile is the magnitude of the exposure, in concentration-time units (Lioy, 1990; NRC, 1990):

where E is the magnitude of exposure, C(t) is the exposure concentration as a function of time, and t is time, t_2- t_1 being the exposure duration (ED). If ED is a continuous period of time (e.g., a day, week, year, etc.), then C(t) may be zero during part of this time. [FN7] Integrated exposures are done typically for a single individual, a specific chemical, and a particular pathway or exposure route over a given time period. [FN8]

The integrated exposures for a number of different individuals (a population or population segment, for example), may then be displayed in a histogram or curve (usually, with integrated exposure increasing along the abscissa or x-axis, and the number of individuals at that integrated exposure increasing along the ordinate or y-axis). This histogram or curve is a presentation of an exposure distribution for that population or population segment. The utility of both individual exposure profiles and population exposure distributions is discussed in Section 2.3.

2.1.2. Applied Dose and Potential Dose

Applied dose is the amount of a chemical at the absorption barrier (skin, lung, gastrointestinal tract) available for absorption. It is useful to know the applied dose if a relationship can be established between applied dose and internal dose, a relationship that can sometimes be established experimentally. Usually, it is very difficult to measure the applied dose directly, as many of the absorption barriers are internal to the human and are not localized in such a way to make measurement easy. An approximation of applied dose can be made, however, using the concept of potential dose[FN9] (Lioy, 1990; NRC, 1990).

Potential dose is simply the amount of the chemical ingested, inhaled, or in material applied to the skin. It is a useful term or concept for those instances in which there is exposure to a discrete amount of chemical or transport medium, such as eating a certain amount of food or applying a certain amount of material to the skin. [FN10]

The potential dose for ingestion and inhalation is analogous to the administered dose in a dose-response experiment. Human exposure to environmental chemicals is generally inadvertent rather than administered, so in these Guidelines it is termed potential dose rather than administered dose. Potential dose can be used for dose-response relationships based on administered dose.

For the dermal route, potential dose is the amount of chemical applied, or the amount of chemical in the medium applied, for example as a small amount of particulate deposited on the skin. Note that as all of the chemical in the particulate is not contacting the skin, this differs from exposure (the concentration in the particulate times the time of contact) and applied dose (the amount in the layer actually touching the skin).

The applied dose, or the amount that reaches the exchange boundaries of the skin, lung, or gastrointestinal tract, may often be less than the potential dose if the material is only partly bioavailable. Where data on bioavailability are known, adjustments to the potential dose to convert it to applied dose and internal dose may be made. [FN11]

2.1.3. Internal Dose

The amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors is called the internal dose. Once absorbed, the chemical can undergo metabolism, storage, excretion, or transport within the body. The amount transported to an individual organ, tissue, or fluid of interest is termed the delivered dose. The delivered dose may be only a small part of the total internal dose. The biologically effective dose, or the amount that actually reaches cells, sites, or membranes where adverse effects occur (NRC, 1990, p. 29), may only be a part of the delivered dose, but it is obviously the crucial part. Currently, most risk assessments dealing with environmental chemicals (as opposed to pharmaceutical assessments) use dose-response relationships based on potential (administered) dose or internal dose, since the pharmacokinetics necessary

to base relationships on the delivered dose or biologically effective doses are not available for most chemicals. This may change in the future, as more becomes known about the pharmacokinetics of environmental chemicals.

Doses are often presented as dose rates, or the amount of a chemical dose (applied or internal) per unit time (e.g., mg/day), or as dose rates on a per-unit-body-weight basis (e.g., mg/kg/day).

Distributions of individual doses within a population or population segment may be displayed in a histogram or curve analogous to the exposure distributions described in section 2.1.1. The utility of individual dose profiles, as well as the utility of population distributions of dose are described more fully in section 2.3.

2.1.4. Exposure and Dose Relationships

Depending on the use of the exposure assessment, estimates of exposure and dose in various forms may be required.

- Exposure concentrations are useful when comparing peak exposures to levels of concern such as short-term exposure limits (STELs). They are typically expressed in units such as MUg/m3, mg/m3, mg/kg, MUg/L, mg/L, ppb, or ppm.

- Exposure or dose profiles describe the exposure concentration or dose as a function of time. Concentration and time are used to depict exposure, while amount and time characterize dose; ***22893** graphical or tabular presentations may be used for either type of profile.

Such profiles are very important for use in risk assessment where the severity of effect is dependent on the pattern by which the exposure occurs rather than the total (integrated) exposure. For example, a developmental toxin may only produce effects if exposure occurs during a particular stage of development. Similarly, a single acute exposure to very high contaminant levels may induce adverse effects even if the average exposure is much lower than apparent no-effect levels. Such profiles will become increasingly important as biologically based dose-response models become available.

- Integrated exposures are useful when a total exposure for a particular route (i.e., the total for various pathways leading to exposure via the same route) is needed. Units of integrated exposure are concentration times time. The integrated exposure is the total area under the curve of the exposure profile (Equation 2-1). Note that an exposure profile (a picture of exposure concentration over time) contains more information than an integrated exposure (a number), including the duration and periodicity of exposure, the peak exposure, and the shape of the area under the time-concentration curve.

- Time-weighted averages are widely used in exposure assessments, especially as part of a carcinogen risk assessment. A time-weighted average exposure concentration (units of concentration) is the integrated exposure divided by the period where exposure occurs, and is useful in some of the equations discussed below in estimating dose. A time-weighted average dose rate is the total dose divided by the time period of dosing, usually expressed in units of mass per unit time, or mass/time normalized to body weight (e.g., mg/kg/day). Time-weighted average dose rates such as the lifetime average daily dose (LADD) are often used in dose-response equations to estimate effects or risk. [FN12]

The discussion in the next three sections focuses on exposure via inhalation, oral intake, and dermal absorption. Other exposure routes are possible, however, including direct introduction into the bloodstream via injection or transfusion, contamination of exposed lesions, placental transfer, or use of suppositories. The exposures and doses for these routes can be calculated in a similar manner, depending on whether an intake or uptake process is involved.

Although equations for calculating exposure, dose, and their various averages are in widespread use in exposure assessment, the assessor should consider the implications of the assumptions used to derive the equations. Simplifying assumptions used in deriving the equations may mean that variations in exposure concentration, ingestion or inhalation rate, permeability coefficient, surface area exposed, and absorption fraction can introduce error into the estimate of dose if average values are used, and this must be considered in the evaluation of uncertainty (section 6).

2.1.4.1. Calculating Potential Dose for Intake Processes

The general equation for potential dose for intake processes, e.g., inhalation and ingestion (see Figure 2-1 for illustration of various exposures and doses) is simply the integration of the chemical intake rate (concentration of the chemical in the medium times the intake rate of the medium, C times IR) over time:

where D_{pot} is potential dose and IR(t) is the ingestion or inhalation rate.

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***22895** The quantity t_2-t_1, as before, represents the period of time over which exposure is being examined, or the exposure duration (ED). The exposure duration may contain times where the chemical is in contact with the person, and also times when C(t) is zero. Contact time represents the actual time period where the chemical is in contact with the person. For cases such as ingestion, where actual contact with food or water is intermittent, and consequently the actual contact time may be small, the intake rate is usually expressed in terms of a frequency of events (e.g., 8 glasses of water consumed per day) times the intake per event (e.g., 250 mL of water/glass of water consumed). Intermittent air exposures (e.g., 8 hours exposed/day times one cubic meter of air inhaled/hour) can also be expressed easily using exposure duration rather than contact time. Hereafter, the term exposure duration will be used in the examples below to refer to the term t_2-t_1, since it occurs frequently in exposure assessments and it is often easier to use.

Equation 2-2 can also be expressed in discrete form as a summation of the doses received during various events i:

where ED_i is the exposure duration for event i. If C and IR are nearly constant (which is a good approximation if the contact time is very short), Equation 2-3 becomes:

where ED is the sum of the exposure durations for all events, and C#8 and IR#8 are the average values for these parameters. Equation 2-4 will not necessarily hold in cases where C and IR vary considerably. In those cases, Equation 2-3 can be used if the exposure can be broken out into segments where C and IR are approximately constant. If even this condition cannot be met, Equation 2-2 may be used.

For risk assessment purposes, estimates of dose should be expressed in a manner that can be compared with available dose-response data. Frequently, dose-response relationships are based on potential dose (called administered dose in animal studies), although dose-response relationships are sometimes based on internal dose.

Doses may be expressed in several different ways. Solving Equations 2-2, 2-3, or 2-4, for example, gives a total dose accumulated over the time in question. The dose per unit time is the dose rate, which has units of mass/time (e.g., mg/day). Because intake and uptake can vary, dose rate is not necessarily constant. An average dose rate over a period of time is a useful number for many risk assessments.

Exposure assessments should take into account the time scale related to the biological response studied unless the assessment is intended to provide data on the range of biological responses (NRC, 1990, p. 28). For many noncancer effects, risk assessments consider the period of time over which the exposure occurred, and often, if there are no excursions in exposure that would lead to acute effects, average exposures or doses over the period of exposure are sufficient for the assessment. These averages are often in the form of average daily doses (ADDs).

An ADD can be calculated from Equation 2-2 by averaging D_{pot} over body weight and an averaging time, provided the dosing pattern is known so the integral can be solved. It is unusual to have such data for human exposure and intake over extended periods of time, so some simplifying assumptions are commonly used. Using Equation 2-4 instead of 2-2 or 2-3 involves making steady-state assumptions about C and IR, but this makes the equation for ADD easier to solve.[FN13] For intake processes, then, using Equation 2-4, this becomes:

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where ADD_{pot} is the average daily potential dose, BW is body weight, and AT is the time period over which the dose is averaged (converted to days). As with Equation 2-4, the exposure concentration C#8 is best expressed as an estimate of the arithmetic mean regardless of the distribution of the data. Again, using average values for C and IR in Equation 2-5 assumes that C and IR are approximately constant.

For effects such as cancer, where the biological response is usually described in terms of lifetime probabilities, even though exposure does not occur over the entire lifetime, doses are often presented as lifetime average daily doses (LADDs). The LADD takes the form of Equation 2-5, with lifetime (LT) replacing the averaging time (AT):

The LADD is a very common term used in carcinogen risk assessment where linear nonthreshold models are employed.

2.1.4.2. Calculating Internal Dose for Uptake Processes (Especially via the Dermal Route)

For absorption processes, there are two methods generally in use for calculating internal dose. The first, commonly used for dermal absorption from a liquid where at least partial immersion occurs, is derived from the equation for internal dose, D_{int}, which is analogous to Equation 2-2 except that the chemical uptake rate (C - Kp - SA) replaces the chemical intake rate (C - IR). Thus,

***22896** where K_p is the permeability coefficient, and SA is the surface area exposed. Both C and SA will vary over time, and although K_p may not vary over time, it may vary over different parts of the body. Unlike the intake processes, where the rate of the carrier medium crossing the boundary can be observed or measured, the carrier may or may not cross the absorption barrier; the equations must be in terms of the chemical itself crossing. The flow of the chemical across the barrier (or flux, J) is not directly measurable, and is dependent on many factors including the nature of the chemical, the nature of the barrier, active transport versus passive diffusion processes, and the concentration of the chemical contacting the barrier. The relationship between the flux and the exposure concentration[FN14] is usually expressed as a permeability coefficient, K_p, which is experimentally measurable.[FN15] The internal dose that is analogous to the potential dose in Equation 2-4 would be:

where SA#8 is the average surface area exposed and the ADD_{int} (average daily internal dose) becomes:

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(The corresponding $LADD_{int}$ would be obtained by substituting LT for AT.) This is the method to use when calculating internal dose for a swimmer. The total body surface area (SA) is assumed to be exposed to a layer of water with an average chemical concentration C#8 for a period of time (ED). It is not necessary to know the mass of the chemical that comes in contact with the skin. The assumptions necessary in going from Equation 2-7 to Equation 2-9 are comparable to those made in deriving Equation 2-5. Recall that both C and SA will vary over time, and K_p may not be constant over different parts of the body. If the assumption used to derive Equation 2-5 (that these variables are nearly constant) does not hold, a different form of the equation having several terms must be used.

The second method of calculating internal dose uses empirical observations or estimates of the rate that a chemical is absorbed when a dose is administered or applied. It is useful when a small or known amount of material (such as a particulate) or a chemical (such as a pesticide) contacts the skin. The potential dose of a chemical to the skin, D_{pot}, can often be calculated from knowing the concentration (C) and the amount of carrier medium applied (M_{medium}), either as a whole or on a unit surface area basis. For example, potential dose from dermal contact with soil can be calculated using the following equation:

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where D_{pot} is potential dose, M_{medium} is amount of soil applied, and F_{adh} is the adherence factor for soil (the amount of soil applied to and adhering to the skin on a unit surface area per unit time).
The relationship between potential dose and applied dose for dermal exposures is that potential dose includes the amount of the chemical in the total amount of medium contacting the skin, e.g., the amount of chemical in the soil whether or not all the chemical itself ever comes in direct contact, and applied dose includes only that amount of the chemical which actually directly touches the skin. Theoretically, the relationship between the applied dose (D_{app}) and the internal (or absorbed) dose (D_{int}) can be thought of as:

where f(t) is a complicated nonlinear absorption function, usually not measurable, having the dimensions of mass absorbed per mass applied per unit time. The absorption function will vary due to a number of factors (concentration gradient of chemical, carrier medium, type of skin, skin moisture, skin condition, etc.). If f(t) could be integrated over time from the start of exposure until time T, it would yield the absorption fraction, AF, which is the fraction of the applied dose that is absorbed after time T. The absorption fraction is a cumulative number and can increase with time to a possible maximum of 1 (or 100% absorption), but due to competing processes may reach steady state long before reaching 100% absorption. Equation 2-11 then becomes:

***22897** where AF is the absorption fraction in units of mass absorbed/mass applied (dimensionless).
If one assumes that all the chemical contained in the bulk material will eventually come in contact with the skin, then D_{app} equals D_{pot} and using Equation 2-12, the D_{int} equation becomes:

and (using Equations 2-9 and 2-10) consequently:

where M_{medium} is the mass of the bulk material applied to the skin. For reasons explained below, this approximation will by no means always give credible results. The key is whether all the chemical contained in the bulk medium can actually contact the skin. Although with certain liquids or small amounts of material, the applied dose may be approximately equal to the potential dose, in cases where there is contact with more than a minimal amount of soil, there is research that indicates that using this approximation may cause serious error (Yang et al., 1989). When this approximation does not hold, the assessor must make assumptions about how much of the bulk material actually contacts the skin, or use the first method of estimating internal dose outlined above.
Unfortunately, almost no data are available concerning the relationship between potential dose and applied dose for dermal exposures. Experimental data on absorption fractions derived for soil commonly use potential dose rather than applied dose, which may make the experimental data at least in part dependent on experimental conditions such as how much soil was applied. If the exposure assessment conditions are similar to those in the experiment, this would not usually introduce much error, but if the conditions vary widely, the error introduced may be difficult to determine.

As a practical matter, estimates of absorption fraction are often crude approximations and may be difficult to refine even if some data from experiments are available in the published literature. Typically, absorption experiments report results as an absorption fraction after a given time (e.g., 50% after 24 hours). Since absorption fraction is a function of several variables such as skin temperature, pH, moisture content, and exposed surface area, as well as characteristics of the matrix in which the

chemical occurs (e.g., soil particle size distribution, organic matter content, and moisture content), it is often difficult to make comparisons between experimental data and conditions being considered for an assessment.

With single data points, it may not be clear whether the experiment reached steady state. If several data points are available from different times in the experiment, a plot of absorption fraction vs. time may be instructive. For chemicals where data are available for steady-state conditions, the steady-state value will probably be a good approximation to use in assessments where exposure duration is at least this long, provided the conditions in the experiment are similar to those of the case being assessed. Assessors should be very cautious in applying absorption fractions for moderately absorbed chemicals (where observed experimental absorption fractions are not in the steady-state part of the cumulative curve), or in using experimental data for estimates of absorption over a much shorter duration than in the experiment.

In almost all cases, the absorption fraction method of estimating internal dose from applied dose gives only an approximation of the internal dose. The interested reader is referred to U.S. EPA (1992b) for more thorough guidance on dermal exposure assessment.

2.1.4.3. Calculating Internal Dose for Intake Processes (Especially via Respiratory and Oral Routes)

Chemicals in air, food, or drinking water normally enter the body through intake processes, then are subsequently absorbed through internal uptake processes in the lung or gastrointestinal tract. Sometimes it is necessary to estimate resulting internal dose, D_{int}, after intake. In addition, if enough is known about the pharmacokinetics of the chemical to make addition of doses across routes a meaningful exercise, the doses must be added as internal dose, not applied dose, potential dose, or exposure.

Theoretically, one could calculate D_{int} in these cases by using an equation similar to Equation 2-7; but C in that equation would become the concentration of the chemical in the lung or gastrointestinal tract, SA would be the internal surface area involved, and K_p would be the permeability coefficient of the lung or gastrointestinal tract lining. Although data from the pharmaceutical field may be helpful in determining, for example, internal surface areas, all of the data mentioned above are not known, nor are they measurable with current instrumentation.

Because Equations 2-2 through 2-4 estimate the potential dose D_{pot}, which is the amount ingested or inhaled, and Equations 2-11 and 2-12 provide relationships between the applied dose (D_{app}) and internal dose (D_{int}), all that is necessary is a relationship between potential dose and applied dose for intake processes. Again, data on this topic are virtually nonexistent, so a common assumption is that for intake processes, the potential dose equals the applied dose. Although arguments can be made that this assumption is likely to be more nearly accurate than for the case of soil contact, the validity of this assumption is unknown at this point. Essentially, the assumption of equality means that whatever is eaten, drunk, or inhaled touches an absorption barrier inside the person.

Assuming potential dose and applied dose are approximately equal, the internal dose after intake can be estimated by combining Equations 2-2 or 2-3 and 2-10 or 2-11. Using Equations 2-3 and 2-11, this becomes:

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***22898** The ADD_{int} for the two-step intake/uptake process becomes:

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Using average values for C#8 and IR#8 in Equations 2-15 and 2-16 involves the same assumptions and cautions as were discussed in deriving the ADD and LADD equations in the previous two sections, and of course, the same cautions apply to the use of the absorption fraction as were outlined in section 2.1.4.2.

2.1.5. Summary of Exposure and Dose Terms With Example Units

Table 2-1 provides a summary of the exposure and dose terms discussed in section 2.1, along with examples of units commonly used.

Table 2-1.—Explanation of Exposure and Dose Terms.

Term	Refers to	Generic units	Specific example units
Exposure	Contact of chemical with outer boundary of a person, e.g., skin, nose, mouth	Concentration x time	Dermal: (mg chem/L water) x (hrs of contact) (mg chem/kg soil) x (hrs of contact) Respiratory: (ppm chem in air) x (hrs of contact) (MUg/m^3 air) x (days of contact) Oral: (mg chem/L water) x (min of contact) (mg chem/kg food) (min of contact)
Potential Dose	Amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin	Mass of the chemical: Dose rate is mass of the chemical/time; The dose rate is sometimes normalized to body weight: mass of chemical/unit body weight x time	Dermal: (mg chem/kg soil) x (kg soil on skin) = mg chem in soil applied to skin Respiratory: (MUg chem/m3 air) x (m3 air breathed/min) x (min exposed) = MUg chemical in air breathed Oral: (mg chem/L water) x (L water consumed/day) x days exposed = mg chemical ingested in water (also dose rate: mg/day)
Applied Dose	Amount of chemical in contact with the primary	As above	Dermal: (mg chem/kg soil) x (kg soil directly touching

	absorption boundaries (e.g., skin, lungs, gastrointestinal tract) and available for absorption		skin) x (% of chem in soil actually touching skin) = mg chem actually touching skin Respiratory: (MUg chem/ m^3 air) x (m^3 air directly touching lung) (% of chemical actually touching lung) = mg chemical actually touching lung absorption barrier Oral:(mg chem/kg food) x (kg food consumed/day) x (% of chemical touching g.i. tract) = mg chemical actually touching g.i. tract absorption barrier (also absorbed dose rate: mg/day) chemical available to organ or cell (dose rate: mg chemical available to organ/day)
Internal (Absorbed) Dose	The amount of a chemical penetrating across an absorption barrier or exchange boundary via either physical or biological processes	As above	Dermal: mg chemical absorbed through skin Respiratory: mg chemical absorbed via lung Oral: mg chemical absorbed via g.i. tract (dose rate: mg chemical absorbed/day or mg/kg x day)
Delivered Dose	Amount of chemical available for interaction with any particular organ or cell	As above	mg chemical available to organ or cell (dose rate: mg chemical available to organ/day)

2.2. Approaches to Quantification of Exposure

Although exposure assessments are done for a variety of reasons (see Section 3), the quantitative exposure estimate can be approached from three different ways:[FN16]

***22899** 1. The exposure can be measured at the point of contact (the outer boundary of the body) while it is taking place, measuring both exposure concentration and time of contact and integrating them (point-of-contact measurement),

2. The exposure can be estimated by separately evaluating the exposure concentration and the time of contact, then combining this information (scenario evaluation),

3. The exposure can be estimated from dose, which in turn can be reconstructed through internal indicators (biomarkers,[FN17] body burden, excretion levels, etc.) after the exposure has taken place (reconstruction).

These three approaches to quantification of exposure (or dose) are independent, as each is based on different data. The independence of the three methods is a useful concept in verifying or validating results. Each of the three has strengths and weaknesses; using them in combination can considerably strengthen the credibility of an exposure or risk assessment. Sections 2.2.1 through 2.2.3 briefly describe some of the strengths and weaknesses of each approach.

2.2.1. Measurement of Exposure at the Point-of-Contact

Point-of-contact exposure measurement evaluates the exposure as it occurs, by measuring the chemical concentrations at the interface between the person and the environment as a function of time, resulting in an exposure profile. The best known example of the point-of-contact measurement is the radiation dosimeter. This small badge-like device measures exposure to radiation as it occurs and provides an integrated estimate of exposure for the period of time over which the measurement has been taken. Another example is the Total Exposure Assessment Methodology (TEAM) studies (U.S. EPA, 1987a) conducted by the EPA. In the TEAM studies, a small pump with a collector and absorbent was attached to a person's clothing to measure his or her exposure to airborne solvents or other pollutants as it occurred. A third example is the carbon monoxide (CO) point-of-contact measurement studies where subjects carried a small CO measuring device for several days (U.S. EPA, 1984a). Dermal patch studies and duplicate meal studies are also point-of-contact measurement studies. In all of these examples, the measurements are taken at the interface between the person and the environment while exposure is occurring. Use of these data for estimating exposures or doses for periods that differ from those for which the data are collected (e.g., for estimates of lifetime exposures) will require some assumptions, as discussed in Section 5.3.1.

The strength of this method is that it measures exposure directly, and providing that the measurement devices are accurate, is likely to give the most accurate exposure value for the period of time over which the measurement was taken. It is often expensive, however, and measurement devices and techniques do not currently exist for all chemicals. This method may also require assumptions to be made concerning the relationship between short-term sampling and long-term exposures, if appropriate. This method is also not source-specific, a limitation when particular sources will need to be addressed by risk managers.

2.2.2. Estimates of Exposure from Scenario Evaluation

In exposure scenario evaluation, the assessor attempts to determine the concentrations of chemicals in a medium or location and link this information with the time that individuals or populations contact the chemical. The set of assumptions about how this contact takes place is an exposure scenario. In evaluating exposure scenarios, the assessor usually characterizes the chemical concentration and the time of contact separately. This may be done for a series of events, e.g., by using Equation 2-3, or using a steady-state approximation, e.g., using Equation 2-4.

The goal of chemical concentration characterization is to develop estimates of exposure concentration. This is typically accomplished indirectly by measuring, modeling, or using existing data on concentrations in the bulk media, rather than at the point of contact. Assuming the concentration in the bulk medium is the same as the exposure concentration is a clear source of potential error in the exposure estimate and must be discussed in the uncertainty analysis. Generally, the closer the medium can be measured to the point of contact (in both space and time), the less uncertainty there is in the characterization of exposure concentration.

The goal of characterizing time of contact is to identify who is exposed and to develop estimates of the frequency and duration of exposure. Like chemical concentration characterization, this is usually done indirectly by use of demographic data, survey statistics, behavior observation, activity diaries, activity models, or, in the absence of more substantive information, assumptions about behavior.

The chemical concentration and population characterizations are ultimately combined in an exposure scenario, and there are various ways to accomplish this. One of the major problems in evaluating dose equations such as Equations 2-4 through 2-6 is that the limiting assumptions or boundary conditions used to derive them (e.g., steady-state assumptions; see section 2.1.4.) do not always hold true. Two major approaches to this problem are (1) to evaluate the exposure or dose equation under conditions where the limiting assumptions do hold true, or (2) to deal with the uncertainty caused by the divergence from the boundary conditions. As an example of the first way, the microenvironment method, usually used for evaluating air exposures, evaluates segments of time and location where the assumption of constant concentration is approximately true, then sums over all such time segments for a total exposure for the respiratory route, effectively removing some of the boundary conditions by falling back to the more general Equation 2-3. While estimates of exposure concentration and time-of-contact are still derived indirectly by this method, the concentration and time-of-contact estimates can be measured for each microenvironment. This avoids much of the error due to using average values in cases where concentration varies widely along with time of contact.ng18ng

As examples of the second approach, there are various tools used to describe uncertainty caused by parameter variation, such as Monte Carlo analysis (see section 5). Section 6 discusses some of these techniques in more detail.

One strength of the scenario evaluation approach is that it is usually the least expensive method of the three. ***22900** Also, it is particularly suited to analysis of the risk consequences of proposed actions. It is both a strength and a weakness of scenario development that the evaluation can be performed with little or no data; it is a technique that is best used when some knowledge exists about the soundness, validity, and uncertainty of the underlying assumptions.

2.2.3. Exposure Estimation by Reconstruction of Internal Dose

Exposure can also be estimated after it has taken place. If a total dose is known, or can be reconstructed, and information about intake and uptake rates is available, an average past exposure rate can be estimated. Reconstruction of dose relies on measuring internal body indicators after exposure and intake and uptake have already occurred, and using these measurements to back-calculate dose. However, the data on body burden levels or biomarkers cannot be used directly unless a relationship can be established between these levels or biomarker indications and internal dose, and interfering reactions (e.g., metabolism of unrelated chemicals) can be accounted for or ruled out. Biological tissue or fluid measurements that reveal the presence of a chemical may indicate directly that an exposure has occurred, provided the chemical is not a metabolite of other chemicals.

Biological monitoring can be used to evaluate the amount of a chemical in the body by measuring one or more of the following items. Not all of these can be measured for every chemical:

- The concentration of the chemical itself in biological tissues or sera (blood, urine, breath, hair, adipose tissue, etc.),

- The concentration of the chemical's metabolite(s),

- The biological effect that occurs as a result of human exposure to the chemical (e.g., alkylated hemoglobin or changes in enzyme induction), or

- The amount of a chemical or its metabolites bound to target molecules.

The results of biomonitoring can be used to estimate chemical uptake during a specific interval if background levels do not mask the marker and the relationships between uptake and the marker selected are known. The time of sampling for biomarkers

can be critical. Establishing a correlation between exposure and the measurement of the marker, including pharmacokinetics, can help optimize the sampling conditions.

The strengths of this method are that it demonstrates that exposure to and absorption of the chemical has actually taken place, and it theoretically can give a good indication of past exposure. The drawbacks are that it will not work for every chemical due to interferences or the reactive nature of the chemical, it has not been methodologically established for very many chemicals, data relating internal dose to exposure are needed, and it may be expensive.

2.3. Relationships of Exposure and Dose to Risk

Exposure and dose information are often combined with exposure-response or dose-response relationships to estimate risk, the probability of an adverse effect occurring. There are a variety of risk models, with various mathematical relationships between risk and dose or (less frequently) exposure. A major function of the exposure assessment as part of a risk assessment is to provide the exposure or dose values, and their interpretations.

The exposure and dose information available will often allow estimates of individual risk or population risk, or both. Presentation of risks in a risk assessment involves more than merely a numerical value, however. Risks can be described or characterized in a number of different ways. This section discusses the relationships between exposure and dose and a series of risk descriptors.

In preparing exposure information for use in a risk assessment, the use of several descriptors, including descriptors of both individual and population risk, often provides more useful information to the risk manager than a single descriptor or risk value. Developing several descriptors may require the exposure assessor to analyze and evaluate the exposure and dose information in several different ways. The exposure assessor should be aware of the purpose, scope, and level of detail of the assessment (see Sections 3.1 through 3.3) before gathering data, since the types and amounts of data needed may differ. The questions that need to be addressed as a result of the purpose of the assessment determine the type of risk descriptors used in the assessment.

2.3.1. Individual Risk

Individual risk is risk borne by individual persons within a population. Risk assessments almost always deal with more than a single individual. Frequently, individual risks are calculated for some or all of the persons in the population being studied, and are then put into the context of where they fall in the distribution of risks for the entire population. Descriptions of individual risk can take various forms, depending on the questions being addressed. For the risk manager, there are often key questions in mapping out a strategy for dealing with individual risk. For cancer (or when possible, noncancer) assessments, the risk manager may need answers to questions such as:

- Are individuals at risk from exposure to the substances under study? Although for substances, such as carcinogens, that are assumed to have no threshold, only a zero dose would result in no excess risk; for noncarcinogens, this question can often be addressed. In the case of the use of hazard indices, where exposures or doses are compared to a reference dose or some other acceptable level, the risk descriptor would be a statement based on the ratio between the dose incurred and the reference dose.

- To what risk levels are the persons at the highest risk subjected?

- Who are these people, what are they doing, where do they live, etc., and what might be putting them at this higher risk?

- Can people with a high degree of susceptibility be identified?

- What is the average individual risk?

In addressing these questions, risk descriptors may take any of several forms:

- An estimate of the probability that an individual in the high end of the distribution may suffer an adverse effect, along with an explanation (to the extent known) of the (exposure or susceptibility) factors which result in their being in the high end;

- An estimate of the probability that an individual at the average or median risk may suffer an adverse effect; or

- An estimate of the probability that an individual will suffer an adverse effect given a specific set of exposure circumstances.

Individuals at the high end of the risk distribution are often of interest to risk managers when considering various actions to mitigate risk. These individuals often are either more susceptible to the adverse health effect than others in the population or are highly exposed individuals, or both.

Higher susceptibility may be the result of a clear difference in the way the chemical is processed by the body, or it may be the result of being in the extreme part of the normal range in metabolism for a population. It may not always be possible to identify persons or subgroups who are more susceptible than the general population. If groups of individuals who have clearly different susceptibility characteristics can be identified, they can be treated as a separate subpopulation, and the risk assessment for this subgroup may require a different dose-response relationship from the one used for the ***22901** general population. When highly susceptible individuals can be identified, but when a different dose-response relationship is not appropriate or feasible to develop, the risks for these individuals are usually treated as part of the variability of the general population.

Highly exposed individuals have been described in the literature using many different terms. Due to unclear definitions, terms such as most exposed individual,[FN19] worst case exposure,[FN20] and reasonable worst case exposure [FN21] have sometimes been applied to a variety of ad hoc estimates with unclear target ranges. The term most exposed individual has often been used synonymously with worst case exposure, that is, to estimate the exposure of the individual with the highest actual or possible exposure. An accurate estimate of the exposure of the person in the distribution with the highest exposure is extremely difficult to develop; uncertainty in the estimate usually increases greatly as the more extreme ends of the distribution are approached. Even using techniques such as Monte Carlo simulations can result in high uncertainty about whether the estimate is within, or above, the actual exposure distribution.

For the purpose of these guidelines, a high end exposure estimate is a plausible estimate of the individual exposure for those persons at the upper end of an exposure distribution. The intent of this designation is to convey an estimate of exposures in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, the high end of the distribution means above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. High-end dose estimates are described analogously.

The concept of the high end exposure, as used in this guidance, is fundamentally different from terms such as worst case, in that the estimate is by definition intended to fall on the actual (or in the case of scenarios dealing with future exposures, probable) exposure distribution.

Key Point: The primary objective when developing an estimate of high-end exposure or dose is to arrive at an estimate that will fall within the actual distribution, rather than above it. (Estimates above the distribution are bounding estimates; see section 5.3.4.1.) Often this requires professional judgment when data are sparse, but the primary objective of this type of estimator is to be within this fairly wide conceptual target range.

The relationship between answering the questions about high-end individual risk and what the exposure assessor must do to develop the descriptors is discussed in section 3.4. Individual risk descriptors will generally require the assessor to make estimates of high-end exposure or dose, and sometimes additional estimates (e.g., estimates of central tendency such as average or median exposure or dose).

Another type of individual risk descriptor results from specific sets of circumstances that can be hypothesized as part of a scenario, for example:

- What if a homeowner lives at the edge of this site for his entire life?

- What if a pesticide applicator applies this pesticide without using protective equipment?

- What if a consumer uses this product every day for ten years? Once a month? Once a week?

- What risk level will occur if we set the standard at 100 ppb?

The assumptions made in answering these assessment-specific postulated questions should not be confused with the approximations made in developing an exposure estimate for an existing population or with the adjustments in parameter values made in performing a sensitivity analysis. The assumptions in these specific questions address a purer “if/then” relationship and, as such, are more helpful in answering specific hypothetical or anecdotal questions. The answers to these postulated questions do not give information about how likely the combination of values might be in the actual population or about how many (if any) persons might actually be subjected to the calculated risk.

Exposure scenarios employing these types of postulated questions are encountered often in risk assessments, especially in those where actual exposure data are incomplete or nonexistent. Although the estimates of individual exposure derived from these assumptions provide numerical values for calculating risk, they do so more as a matter of context than a determination of actual exposure. They are not the same types of estimates as high-end exposure or risk, where some statement must be made about the likelihood of their falling within a specified range in the actual exposure or risk distribution.

2.3.2. Population Risk

Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. Risk managers may need questions addressed such as the following:

- How many cases of a particular health effect might be probabilistically estimated for a population of interest during a specified time period?

- For noncarcinogens, what portion of the population exceeds the reference dose (RfD), the reference concentration (RfC), or other health concern level?

- For carcinogens, how many persons are above a certain risk level such as 10^{-6} or a series of risk levels such as 10^{-5}, 10^{-4}, etc?

- How do various subgroups fall within the distributions of exposure, dose, and risk?

- What is the risk for a particular population segment?

- Do any particular subgroups experience a high exposure, dose, or risk?

The risk descriptors for population risk can take any of several forms:

- A probabilistic projection of the estimated extent of occurrence of a particular effect for a population or segment (sometimes called “number of cases” of effect);

- A description of what part of the population (or population segment) is above a certain risk value of interest; or

- A description of the distribution of risk among various segments or subgroups of the population.

In theory, an estimate of the extent of effects a population might incur (e.g., the number of individual cases that might occur during a specified time) can be calculated by summing the individual risks for all individuals within the population or population segment of interest. The ability to calculate this estimate depends on whether the individual risks are in terms of probabilities for each individual, rather than a hazard index or other ***22902** nonprobabilistic risk. The calculation also requires a great deal more information than is normally available.

For some assessments, an alternate method is used, provided certain conditions hold. An arithmetic mean dose is usually much easier to estimate than the individual doses of each person in the population or population segment, but calculating the hypothetical number of cases by using mean doses, slope factors, and population size must be done with considerable caution. If the risk varies linearly with dose, and there is no threshold below which no effect ever occurs, an estimate of the number of cases that might occur can be derived from the definition of arithmetic mean. If A = T/n, where A is the arithmetic mean of n numbers, and T is the sum of the same n numbers, simple rearrangement gives T = A x n. If the arithmetic mean risk for the population (A) can be estimated, and the size of the population (n) is known, then this relationship can be used to calculate a probabilistic estimate of the extent of effects (T).[FN22] Even so, several other cautions apply when using this method.

Individual risks are usually expressed on an upper bound basis, and the resulting number of cases estimated in this manner will normally be an upper bound estimate due to the nature of the risk model used. This method will not work at all for nonlinear dose-response models, such as many noncancer effects or for nonlinear carcinogenic dose-response models.

In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate predictions of real (or actuarial) cases of disease. The estimate's value lies in framing hypothetical risk in an understandable way rather than in any literal interpretation of the term “cases.”

Another population risk descriptor is a statement regarding how many people are thought to be above a certain risk level or other point of demarcation. For carcinogens, this might be an excess risk level such as 10^{-6} (or a series of levels, i.e., 10^{-5}, 10^{-4}, etc.). For noncarcinogenic risk, it might be the portion of the population that exceeds the RfD (a dose), the RfC (an exposure concentration), an effect-based level such as a lowest observed adverse effect level (LOAEL), etc. For the exposure assessor, this type of descriptor usually requires detailed information about the distribution of exposures or doses.

Other population risk descriptors address the way the risk burden is distributed among various segments of the subject population. The segments (or subgroups) could be divided by geographic location, age, sex, ethnic background, lifestyle, economic factors, or other demographic variables, or they could represent groups of persons with a typical sensitivity or susceptibility, such as asthmatics.

For assessors, this means that data may need to be evaluated for both highly exposed population segments and highly sensitive population segments. In cases involving a highly exposed population segment, the assessor might approach this question by having this segment of the population in mind when developing the descriptors of high-end exposure or dose. Usually, however, these segments are identified (either a priori or from inspection of the data) and then treated as separate, unique populations in themselves, with segment-specific risk descriptors (population, individual, etc.) analogous to those used for the larger population.

2.3.3. Risk Descriptors

In summary, exposure and dose information developed as part of an exposure assessment may be used in constructing risk descriptors. These are statements to convey information about risk to users of that information, primarily risk managers. Risk descriptors can be grouped as descriptors of individual risk or population risk, and within these broad categories, there are several types of descriptors. Not all descriptors are applicable to all assessments. As a matter of policy, the Agency or individual program offices within the Agency may require one or more of these descriptors to be included in specific risk assessments. Because the type of descriptor translates fairly directly into the type of analysis the exposure assessor must perform, the exposure assessor needs to be aware of these policies. Additional information on calculating and presenting exposure estimates and risk descriptors is found in sections 5 and 7 of these Guidelines.

3. Planning an Exposure Assessment

Exposure assessments are done for a variety of purposes, and for that reason, cannot easily be regimented into a set format or protocol. Each assessment, however, uses a similar set of planning questions, and by addressing these questions the assessor will be better able to decide what is needed to perform the assessment and how to obtain and use the information required. To facilitate this planning, the exposure assessor should consider some basic questions:

Purpose: Why is the study being conducted? What questions will the study address and how will the results be used?

Scope: Where does the study area begin and end? Will inferences be made on a national, regional, or local scale? Who or what is to be monitored? What chemicals and what media will be measured, and for which individuals, populations, or population segments will estimates of exposure and dose be developed?

Level of Detail: How accurate must the exposure or dose estimate be to achieve the purpose? How detailed must the assessment be to properly account for the biological link between exposure, dose, effect, and risk, if necessary? How is the depth of the assessment limited by resources (time and money), and what is the most effective use of those resources in terms of level of detail of the various parts of the assessment?

Approach: How will exposure or dose be measured or estimated, and are these methods appropriate given the biological links among exposure, dose, effect, and risk? How will populations be characterized? How will exposure concentrations be estimated? What is known about the environmental and biological fate of the substance? What are the important exposure pathways? What is known about expected concentrations, analytical methods, and detection limits? Are the presently available analytical methods capable of detecting the chemical of interest and can they achieve the level of quality needed in the assessment? How many samples are needed? When will the samples be collected? How frequently? How will the data be handled, analyzed, and interpreted?

By addressing each of these questions, the exposure assessor will develop a clear and concise definition of study ***22903** objectives that will form the basis for further planning.

3.1. Purpose of the Exposure Assessment

The particular purpose for which an exposure assessment will be used will often have significant implications for the scope, level of detail, and approach of the assessment. Because of the complex nature of exposure assessments, a multidisciplinary approach that encompasses the expertise of a variety of scientists is necessary. Exposure assessors should seek assistance from other scientists when they lack the expertise necessary in certain areas of the assessment.

3.1.1. Using Exposure Assessments in Risk Assessment

The National Research Council (NRC, 1983) described exposure assessment as one of the four major areas of risk assessment (the others are hazard identification, dose-response assessment, and risk characterization). The primary purpose of an exposure assessment in this application is often to estimate dose, which is combined with chemical-specific dose-response data (usually

from animal studies) in order to estimate risk. Depending on the purpose of the risk assessment, the exposure assessment will need to emphasize certain areas in addition to quantification of exposure and dose.

If the exposure assessment is part of a risk assessment to support regulations for specific chemical sources, such as point emission sources, consumer products, or pesticides, then the link between the source and the exposed or potentially exposed population is important. In this case, it is often necessary to trace chemicals from the source to the point of exposure by using source and fate models and exposure scenarios. By examining the individual components of a scenario, assessors can focus their efforts on the factors that contribute the most to exposure, and perhaps use the exposure assessment to select possible actions to reduce risk. For example, exposure assessments are often used to compare and select control or cleanup options. Most often the scenario evaluation is employed to estimate the residual risk associated with each of the alternatives under consideration. These estimates are compared to the baseline risk to determine the relative risk reduction of each alternative. These types of assessments can also be employed to make screening decisions about whether to further investigate a particular chemical. These assessments can also benefit from verification through the use of personal or biological monitoring techniques.

If the exposure assessment is part of a risk assessment performed to set standards for environmental media, usually the concentration levels in the medium that pose a particular risk level are important. Normally, these assessments place less emphasis on the ultimate source of the chemical and more emphasis on linking concentration levels in the medium with exposure and dose levels of those exposed. A combination of media measurements and personal exposure monitoring could be very helpful in assessments for this purpose, since what is being sought is the relationship between the two. Modeling may also support or supplement these assessments.

If the exposure assessment is part of a risk assessment used to determine the need to remediate a waste site or chemical spill, the emphasis is on calculating the risk to an individual or small group, comparing that risk to an acceptable risk level, and if necessary determining appropriate cleanup actions to reach an acceptable risk. The source of chemical contamination may or may not be known. Although personal exposure monitoring can give a good indication of the exposure or dose at the present time, often the risk manager must make a decision that will protect health in the future. For this reason, modeling and scenario development are the primary techniques used in this type of assessment. Emphasis is usually placed on linking sources with the exposed individuals. Biological monitoring may also be helpful (in cases where the methodology is established) in determining if exposure actually results in a dose, since some chemicals are not bioavailable even if intake occurs.

If the exposure assessment is part of a risk assessment used as a screening device for setting priorities, the emphasis is more on the comparative risk levels, perhaps with the risk estimates falling into broad categories (e.g., semi-quantitative categories such as high, medium, and low). For such quick-sorting exercises, rarely are any techniques used other than modeling and scenario development. Decisions made in such cases rarely involve direct cleanup or regulatory action without further refinement of the risk assessment, so the scenario development approach can be a cost-effective way to set general priorities for future investigation of worst risk first.

If the exposure assessment is part of a risk assessment that is wholly predictive in nature, such as for the premanufacture notice (PMN) program, a modeling and scenario development approach is recommended. In such cases, measurement of chemicals yet to be manufactured or in the environment is not possible. In this case again, the link between source and exposed individuals is emphasized.

Not only are risk assessments done for a variety of purposes, but the toxic endpoints being assessed (e.g., cancer, reproductive effects, neurotoxic effects) can also vary widely. Endpoints and other aspects of the hazard identification and dose-response relationships can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. This is discussed in more detail in section 3.5.1.

3.1.2. Using Exposure Assessments for Status and Trends

Exposure assessments can also be used to determine whether exposure occurs and to monitor status and trends. The emphasis in these exposure assessments is on what the actual exposure (or dose) is at one particular time, and how the exposure changes over time. Examples of this type of assessment are occupational studies. Characteristics and special considerations for occupational studies have been discussed by the National Institute for Occupational Safety and Health (NIOSH, 1988).

Exposure status is the snapshot of exposure at a given time, usually the exposure profile of a population or population segment (perhaps a segment or statistical sample that can be studied periodically). Exposure trends show how this profile changes with time. Normally, status and trends studies make use of statistical sampling strategies to assure that changes can be interpreted meaningfully. These data are particularly useful if actions for risk amelioration and demonstration of the effectiveness of these actions can be made through exposure trend measurements.

Measurement is critical to such assessments. Personal monitoring can give the most accurate picture of exposure, but biological or media monitoring can indicate exposure levels, provided a strong link is established between the biological or media levels and the exposure levels. Usually this link is established first by correlating biological or media levels with personal monitoring data for the same population over the same period.

22904** ***3.1.3. Using Exposure Assessments in Epidemiologic Studies

Exposure assessments can also be important components of epidemiologic studies, where the emphasis is on using the exposure assessment to establish exposure-incidence (or dose-effect) relationships. For this purpose, personal monitoring, biological monitoring, and scenario development have all been used. If the population under study is being currently exposed, personal monitoring or biological monitoring may be particularly helpful in establishing exposure or dose levels. If the exposure took place in the past, biological monitoring may provide useful data, provided the chemical is amenable to detection without interference or degradation, and the pharmacokinetics are known. More often, however, scenario development techniques are used to estimate exposure in the past, and often the accuracy of the estimate is limited to classifying exposure as high, medium, or low. This type of categorization is rather common, but sometimes it is very difficult to determine who belongs in a category, and to interpret the results of the study. Although epidemiologic protocols are beyond the scope of these Guidelines, the use of exposure assessment for epidemiology has been described by the World Health Organization (WHO, 1983).

3.2. Scope of the Assessment

The scope of an assessment refers to its comprehensiveness. For example, an important limitation in many exposure assessments relates to the specific chemical(s) to be evaluated. Although this seems obvious, where exposure to multiple chemicals or mixtures is possible, it is not always clear whether assessing “all” chemicals will result in a different risk value than if only certain significant chemicals are assessed and the others assumed to contribute only a minor amount to the risk. This may also be true for cases where degradation products have equal or greater toxicological concerns. In these cases, a preliminary investigation may be necessary to determine which chemicals are likely to be in high enough concentrations to cause concern, with the possibile contribution of the others discussed in the uncertainty assessment. The assessor must also determine geographical boundaries, population exposed, environmental media to be considered, and exposure pathways and routes of concern.

The purpose of the exposure assessment will usually help define the scope. There are characteristics that are unique to national exposure assessments as opposed to industry-wide or local exposure assessments. For example, exposure assessments in support of national regulations must be national in scope; exposure assessments to support cleanup decisions at a site will be local in scope. Exposure assessments to support standards for a particular medium will often concentrate on that medium's concentration levels and typical exposure pathways and routes, although the other pathways and routes are also often estimated for perspective.

3.3. Level of Detail of the Assessment

The level of detail, or depth of the assessment, is measured by the amount and resolution of the data used, and the sophistication of the analysis employed. It is determined by the purpose of the exposure assessment and the resources available to perform

the assessment. Although in theory the level of detail needed can be established by determining the accuracy of the estimate required, this is rarely the case in practice. To conserve resources, most assessments are done in an iterative fashion, with a screening done first; successive iterations add more detail and sophistication. After each iteration, the question is asked, is this level of detail or degree of confidence good enough to achieve the purpose of the assessment? If the answer is no, successive iterations continue until the answer is affirmative, new input data are generated, or as is the case for many assessments, the available data, time, or resources are depleted. Resource-limited assessments should be evaluated in terms of what part of the original objectives have been accomplished, and how this affects the use of the results.

The level of detail of an exposure assessment can also be influenced by the level of sophistication or uncertainty in the assessment of health effects to be used for a risk assessment. If only very weak health information is available, a detailed, costly, and in-depth exposure assessment will in most cases be wasteful, since the most detailed information will not add significantly to the certainty of the risk assessment.

3.4. Determining the Approach for the Exposure Assessment

The intended use of the exposure assessment will generally favor one approach to quantifying exposure over the others, or suggest that two or more approaches be combined. These approaches to exposure assessment can be viewed as different ways of estimating the same exposure or dose. Each has its own unique characteristics, strengths, and weaknesses, but the estimate should theoretically be the same, independent of the approach taken.

The point-of-contact approach requires measurements of chemical concentrations at the point where they contact the exposed individuals, and a record of the length of time of contact at each concentration. Some integrative techniques are inexpensive and easy to use (radiation badges), while others are costly and may present logistical challenges (personal continuous-sampling devices), and require public cooperation.

The scenario evaluation approach requires chemical concentration and time-of-contact data, as well as information on the exposed persons. Chemical concentration may be determined by sampling and analysis or by use of fate and transport models (including simple dilution models). Models can be particularly helpful when some analytical data are available, but resources for additional sampling are limited. Information on human behavior and physical characteristics may be assumed or obtained by interviews or other techniques from individuals who represent the population of interest.

For the reconstruction of dose approach, the exposure assessor usually uses measured body burden or specific biomarker data, and selects or constructs a biological model that uses these data to account for the chemical's behavior in the body. If a pharmacokinetic model is used, additional data on metabolic processes will be required (as well as model validation information). Information on exposure routes and relative source strengths is also helpful.

One of the goals in selecting the approach should include developing an estimate having an acceptable amount of uncertainty. In general, estimates based on quality-assured measurement data, gathered to directly answer the questions of the assessment, are likely to have less uncertainty than estimates based on indirect information. The approach selected for the assessment will determine which data are needed. All three approaches also require data on intake and uptake rates if the final product of the assessment is a calculated dose.

Sometimes more than one approach is used to estimate exposure. For example, the TEAM study combines point-of-contact measurement with the microenvironment (scenario evaluation) approach and breath measurements for the reconstruction of dose approach (U.S. EPA, 1987a). If more than one ***22905** approach is used, the assessor should consider how using each approach separately can verify or validate the others. In particular, point-of-contact measurements can be used as a check on assessments made by scenario evaluation.

3.5. Establishing the Exposure Assessment Plan

Before starting work on an exposure assessment, the assessor should have determined the purpose, scope, level of detail, and approach for the assessment, and should be able to translate these into a set of objectives. These objectives will be the foundation for the exposure assessment plan. The exposure assessment plan need not be a lengthy or formal document, especially for assessments that have a narrow scope and little detail. For more complex exposure assessments, however, it is helpful to have a written plan.

For exposure assessments being done as part of a risk assessment, the exposure assessment plan should reflect (in addition to the objectives) an understanding of how the results of the exposure assessment will be used in the risk assessment. For some assessments, three additional components may be needed: the sampling strategy (section 3.5.2), the modeling strategy (section 3.5.3), and the communications strategy (section 7.1.3).

3.5.1. Planning an Exposure Assessment as Part of a Risk Assessment

For risk assessments, exposure information must be clearly linked to the hazard identification and dose-response relationship (or exposure-response relationship; see section 3.5.4). The toxic endpoints (e.g., cancer, reproductive effects, neurotoxic effects) can vary widely, and along with other aspects of the hazard identification and dose-response relationships, can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. Some of these aspects include implications of limited versus repeated exposures, dose-rate considerations, reversibility of toxicological processes, and composition of the exposed population.

- Limited versus Repeated Exposures. Current carcinogen risk models often use lifetime time-weighted average doses in the dose-response relationships owing to their derivation from lifetime animal studies. This does not mean cancer cannot occur after single exposures (witness the A-bomb experience), merely that exposure information must be consonant with the source of the model. Some toxic effects, however, occur after a single or a limited number of exposures, including acute reactions such as anesthetic effects and respiratory depression or certain developmental effects following exposure during pregnancy. For developmental effects, for example, lifetime time-weighted averages have little relevance, so different types of data must be collected, in this case usually shorter-term exposure profile data during a particular time window. Consequently, the exposure assessors and scientists who conduct monitoring studies need to collaborate with those scientists who evaluate a chemical's hazard potential to assure the development of a meaningful risk assessment. If short-term peak exposures are related to the effect, then instruments used should be able to measure short-term peak concentrations. If cumulative exposure is related to the effect, long-term average sampling strategies will probably be more appropriate.

- Dose-Rate Effects. The use of average daily dose values (e.g., ADD, LADD) in a dose-response relationship assumes that within some limits, increments of C times T (exposure concentration times time) that are equal in magnitude are equivalent in their potential to cause an effect, regardless of the pattern of exposure (the so-called Haber's Rule; see Atherley, 1985). In those cases where toxicity depends on the dose rate, one may need a more precise determination of the time people are exposed to various concentrations and the sequence in which these exposures occur.

- Reversibility of Toxicological Processes. The averaging process for daily exposure assumes that repeated dosing continues to add to the risk potential. In some cases, after cessation of exposure, toxicological processes are reversible over time. In these cases, exposure assessments must provide enough information so that the risk assessor can account for the potential influence of episodic exposures.

- Composition of the Exposed Population. For some substances, the type of health effect may vary as a function of age or sex. Likewise, certain behaviors (e.g., smoking), diseases (e.g., asthma), and genetic traits (e.g., glucose-6-phosphate dehydrogenase deficiency) may affect the response of a person to a chemical substance. Special population segments, such as children, may also call for a specialized approach to data collection (WHO, 1986).

3.5.2. Establishing the Sampling Strategy

If the objectives of the assessment are to be met using measurements, it is important to establish the sampling strategy before samples are actually taken. The sampling strategy includes setting data quality objectives, developing the sampling plan and design, using spiked and blank samples, assessing background levels, developing quality assurance project plans, validating previously generated data, and selecting and validating analytical methods.

3.5.2.1. Data Quality Objectives

All measurements are subject to uncertainty because of the inherent variability in the quantities being measured (e.g., spatial and temporal variability) and analytical measurement variability introduced during the measurement process through sampling and analysis. Some sources of variability can be expressed quantitatively, but others can only be described qualitatively. The larger the variability associated with individual measurements, the lower the data quality, and the greater the probability of errors in interpretation. Data quality objectives (DQOs) describe the degree of uncertainty that an exposure assessor and other scientists and management are willing to accept.

Realistic DQOs are essential. Data of insufficient quality will have little value for problem solving, while data of quality vastly in excess of what is needed to answer the questions asked provide few, if any, additional advantages. DQOs should consider data needs, cost-effectiveness, and the capability of the measurement process. The amount of data required depends on the level of detail necessary for the purpose of the assessment. Estimates of the number of samples to be taken and measurements to be made should account for expected sample variability. Finally, DQOs help clarify study objectives by compelling the exposure assessor to establish how the data will be used before they are collected.

The exposure assessor establishes data criteria by proposing limits (based on best judgment or perhaps a pilot study) on the acceptable level of uncertainty for each conclusion to be drawn from new data, considering the resources available for the study. DQOs should include:

- A clear statement of study objectives, to include an estimation of the key study parameters, identifying the hypotheses being tested, the specific aims of the study, and how the results will be used.

- The scope of study objectives, to include the minimum size of subsamples from which separate results may be calculated, and the largest unit (area, ***22906** time period, or group of people) the data will represent.

- A description of the data to be obtained, the media to be sampled, and the capabilities of the analytical methodologies.

- The acceptable probabilities and uncertainties associated with false positive and false negative statements.

- A discussion of statistics used to summarize the data; any standards, reference values, or action levels used for comparison; and a description and rationale for any mathematical or statistical procedures used.

- An estimate of the resources needed.

3.5.2.2. Sampling Plan

The sampling plan specifies how a sample is to be selected and handled. An inadequate plan will often lead to biased, unreliable, or meaningless results. Good planning, on the other hand, makes optimal use of limited resources and is more likely to produce valid results.

The sampling design specifies the number and types of samples needed to achieve DQOs. Factors to be considered in developing the sampling design include study objectives, sources of variability (e.g., temporal and spatial heterogeneity, analytical differences) and their relative magnitudes, relative costs, and practical limitations of time, cost, and personnel.

Sampling design considers the need for temporal and spatial replication, compositing (combining several samples prior to analysis), and multiple determinations on a single sample. A statistical or environmental process model may be used to allocate sampling effort in the most efficient manner.

Data may be collected using a survey or an experimental approach. It may be desirable to stratify the sample if it is suspected that differences exist between segments of the statistical population being sampled. In such cases, the stratified sampling plan assures representative samples of the obviously different parts of the sample population while reducing variance in the sample data. The survey approach estimates population exposure based on the measured exposure of a statistically representative sample of the population. In some situations the study objectives are better served by an experimental approach; this approach involves experiments designed to determine the relationship between two or more factors, (e.g., between house construction and a particular indoor air pollutant). In the experimental approach, experimental units are selected to cover a range of situations (e.g., different housing types), but do not reflect the frequency of those units in the population of interest. An understanding of the relationship between factors gained from an experiment can be combined with other data (e.g., distribution of housing types) to estimate exposure. An advantage of the experimental approach is that it may provide more insight into underlying mechanisms which may be important in targeting regulatory action. However, as in all experimental work, one must argue that the relationships revealed apply beyond that particular experiment.

A study may use a combination of survey and experimental techniques and involve a variety of sampling procedures. A summary of methods for measuring worker exposure is found in Lynch (1985). Smith et al. (1987) provide guidance for field sampling of pesticides. Relevant EPA reference documents include Survey Management Handbook, Volumes I and II (U.S. EPA, 1984b); Soil Sampling Quality Assurance User's Guide (U.S. EPA, 1990a); and A Rationale for the Assessment of Errors in the Sampling of Soils (U.S. EPA, 1989a). A detailed description of methods for enumerating and characterizing populations exposed to chemical substances is contained in Methods for Assessing Exposure to Chemical Substances, Volume 4 (U.S. EPA, 1985a).

Factors to be considered in selecting sampling locations include population density, historical sampling results, patterns of environmental contamination and environmental characteristics such as stream flow or prevailing wind direction, access to the sample site, types of samples, and health and safety requirements.

The frequency and duration of sample collection will depend on whether the risk assessor is concerned with acute or chronic exposures, how rapidly contamination patterns are changing, ways in which chemicals are released into the environment, and whether and to what degree physical conditions are expected to vary in the future.

There are many sources of information on methods for selecting sampling locations. Schweitzer and Black (1985) and Schweitzer and Santolucito (1984) give statistical methods for selecting sampling locations for ground water, soil, and hazardous wastes. A practical guide for ground-water sampling (U.S. EPA, 1985b) and a handbook for stream sampling (U.S. EPA, 1986d) are also available.

The type of sample to be taken and the physical and chemical properties of the chemical of concern usually dictate the sampling frequency. For example, determining the concentration of a volatile chemical in surface water requires a higher sampling frequency than necessary for ground water because the chemical concentration of the surface water changes more rapidly. Sampling frequency might also depend on whether the health effects of concern result from acute or chronic exposures. More frequent sampling may be needed to determine peak exposures versus average exposure.

A preliminary survey is often used to estimate the optimum number, spacing, and sampling frequency. Factors to be considered include technical objectives, resources, program schedule, types of analyses, and the constituents to be evaluated. Shaw et al. (1984), Sanders and Adrian (1978), and Nelson and Ward (1981) discuss statistical techniques for determining the optimal number of samples.

Sampling duration depends on the analytical method chosen, the limits of detection, the physical and chemical properties of the analyte, chemical concentration, and knowledge of transport and transformation mechanisms. Sampling duration may be extended to ensure adequate collection of a chemical at low concentration or curtailed to prevent the breakthrough of one at high concentration. Sampling duration is directly related to selection of statistical procedures, such as trend or cross-sectional analyses.

Storage stability studies with periodic sample analysis should normally be run concurrently with the storage of treated samples. However, in certain situations where chemicals are prone to break down or have high volatility, it is advisable to run a storage stability study in advance so that proper storage and maximum time of storage can be determined prior to sample collection and storage. Unless storage stability has been previously documented, samples should be analyzed as soon as possible after collection to avoid storage stability problems. Individual programs may have specific time limits on storage, depending on the types of samples being analyzed.

3.5.2.3. Quality Assurance Samples

Sampling should be planned to ensure that the samples are not biased by the introduction of field or laboratory contaminants. If sample validity is in question, all associated analytical data will be suspect. Field- and laboratory-spiked samples and blank samples should be analyzed concurrently to validate results. The plan should provide instructions clear enough so that ***22907** each worker can collect, prepare, preserve, and analyze samples according to established protocols.

Any data not significantly greater than blank sample levels should be used with considerable caution. All values should be reported as measured by the laboratory, but with appropriate caveats on blank sample levels. The method for interpreting and using the results from blank samples depends on the analyte and should be specified in the sampling plan. The following guidance is recommended:

- For volatiles and semivolatiles, no positive sample results should be reported unless the concentration of the compound in the sample exceeds 10 times the amount in any blank for the common laboratory contaminants methylene chloride, acetone, toluene, 2-butanone, and common phthalate esters. The amount for other volatiles and semivolatiles should exceed 5 times the amount in the blank (U.S. EPA, 1988d).

- For pesticides and polychlorinated biphenyls (PCBs) no positive sample results should be reported unless the concentration in the sample exceeds 5 times that in the blank (U.S. EPA, 1988d). If a pesticide or PCB is found in a blank but not in a sample, no action is taken.

- For inorganics, no positive sample results should be reported if the results are less than 5 times the amount in any blank (U.S. EPA, 1988e).

3.5.2.4. Background Level

Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

When differences between a background (control area) and a target site are to be determined experimentally, the control area must be sampled with the same detail and care as the target.

3.5.2.5. Quality Assurance and Quality Control

Quality assurance (QA) assures that a product meets defined standards of quality with a stated level of confidence. QA includes quality control.

Quality assurance begins with the establishment of DQOs and continues throughout the measurement process. Each laboratory should have a QA program and, for each study, a detailed quality assurance project plan, with language clear enough to preclude confusion and misunderstanding. The plan should list the DQOs and fully describe the analytes, all materials, methods, and procedures used, and the responsibilities of project participants. The EPA has prepared a guidance document (U.S. EPA, 1980) that describes all these elements and provides complete guidance for plan preparation.

Quality control (QC) ensures a product or service is satisfactory, dependable, and economical. A QC program should include development and strict adherence to principles of good laboratory practice, consistent use of standard operational procedures, and carefully-designed protocols for each measurement effort. The program should ensure that errors have been statistically characterized and reduced to acceptable levels.

3.5.2.6. Quality Assurance and Quality Control for Previously Generated Data

Previously generated data may be used by the exposure assessor to fulfill current needs. Any data developed through previous studies should be validated with respect to both quality and extrapolation to current use. One should consider how long ago the data were collected and whether they are still representative. The criteria for method selection and validation should also be followed when analyzing existing data. Other points considered in data evaluation include the collection protocol, analytical methods, detection limits, laboratory performance, and sample handling.

3.5.2.7. Selection and Validation of Analytical Methods

There are several major steps in the method selection and validation process. First, the assessor establishes methods requirements. Next, existing methods are reviewed for suitability to the current application. If a net method must be developed, it is subjected to field and laboratory testing to determine its performance; these tests are then repeated by other laboratories using a round robin test. Finally, the method is revised as indicated by laboratory testing. The reader is referred to Guidance for Data Useability in Risk Assessment (U.S. EPA, 1990b) for extensive discussion of this topic.

3.5.3. Establishing the Modeling Strategy

Often the most critical element of the assessment is the estimation of pollutant concentrations at exposure points. This is usually carried out by a combination of field data and mathematical modeling results. In the absence of field data, this process often relies on the results of mathematical models (U.S. EPA, 1986e, 1987b, 1987c, 1988f, 1991b). EPA's Science Advisory Board (U.S. EPA, 1989b) has concluded that, ideally, modeling should be linked with monitoring data in regulatory assessments, although this is not always possible (e.g., for new chemicals).

A modeling strategy has several aspects, including setting objectives, model selection, obtaining and installing the code, calibrating and running the computer model, and validation and verification. Many of these aspects are analogous to the QA/QC measures applied to measurements.

3.5.3.1. Setting the Modeling Study Objectives

The first step in using a model to estimate concentrations and exposure is to clearly define the goal of the exposure assessment and how the model can help address the questions or hypotheses of the assessment. This includes a clear statement of what information the model will help estimate, and how this estimate will be used. The approach must be consistent with known project constraints (i.e., schedule, budget, and other resources).

3.5.3.2. Characterization and Model Selection

Regardless of whether models are extensively used in an assessment and a formal modeling strategy is documented in the exposure assessment plan, when computer simulation models such as fate and transport models and exposure models are used

in exposure assessments, the assessor must be aware of the performance characteristics of the model and state how the exposure assessment requirements are satisfied by the model.

If models are to be used to simulate pollutant behavior at a specific site, the site must be characterized. Site characterization for any modeling study includes examining all data on the site such as source characterization, dimensions and topography of the site, location of receptor populations, meteorology, soils, geohydrology, and ranges and distributions of chemical concentrations. For exposure models that simulate both chemical concentration and time of exposure (through behavior patterns) data on these two parameters must be evaluated.

For all models, the modeler must determine if databases are available to support the site, chemical, or population characterization, and that all parameters required by the model can be obtained or reasonable default values are ***22908** available. The assessment goals and the results of the characterization step provide the technical basis for model selection.

Criteria are provided in U.S. EPA (1987b, 1988f) for selection of surface water models and ground-water models respectively; the reader is referred to these documents for details. Similar selection criteria exist for air dispersion models (U.S. EPA, 1986e, 1987c, 1991b).

A primary consideration in selecting a model is whether to perform a screening study or to perform a detailed study. A screening study makes a preliminary evaluation of a site or a general comparison between several sites. It may be generic to a type of site (i.e., an industrial segment or a climatic region) or may pertain to a specific site for which sufficient data are not available to properly characterize the site. Screening studies can help direct data collection at the site by, for example, providing an indication of the level of detection and quantification that would be required and the distances and directions from a point of release where chemical concentrations might be expected to be highest.

The value of the screening-level analysis is that it is simple to perform and may indicate that no significant contamination problem exists. Screening-level models are frequently used to get a first approximation of the concentrations that may be present. Often these models use very conservative assumptions; that is, they tend to overpredict concentrations or exposures. If the results of a conservative screening procedure indicate that predicted concentrations or exposures are less than some predetermined no-concern level, then a more detailed analysis is probably not necessary. If the screening estimates are above that level, refinement of the assumptions or a more sophisticated model are necessary for a more realistic estimate.

Screening-level models also help the user conceptualize the physical system, identify important processes, and locate available data. The assumptions used in the preliminary analysis should represent conservative conditions, such that the predicted results overestimate potential conditions, limiting false negatives. If the limited field measurements or screening analyses indicate that a contamination problem may exist, then a detailed modeling study may be useful.

A detailed study is one in which the purpose is to make a detailed evaluation of a specific site. The approach is to use the best data available to make the best estimate of spatial and temporal distributions of chemicals. Detailed studies typically require much more data of higher quality and models of greater sophistication.

3.5.3.3. Obtaining and Installing the Computer Code

It may be necessary to obtain and install the computer code for a model on a specific computer system. Modern computer systems and software have a variety of differences that require changes to the source code being installed. It is essential to verify that these modifications do not change the way the model works or the results it provides. If the model is already installed and supported on a computer system to which the user has access, this step is simplified greatly.

Criteria for using a model include its demonstrated acceptability and the ease with which the model can be obtained. Factors include availability of specific models and their documentation, verification, and validation. These so-called implementation

criteria relate to the practical considerations of model use and may be used to further narrow the selection of technically acceptable models.

3.5.3.4. Calibrating and Running the Model

Calibration is the process of adjusting selected model parameters within an expected range until the differences between model predictions and field observations are within selected criteria. Calibration is highly recommended for all operational, deterministic models. Calibration accounts for spatial variations not represented by the model formulation; functional dependencies of parameters that are either nonquantifiable, unknown, or not included in the model algorithms; or extrapolation of laboratory measurements to field conditions. Extrapolation of laboratory measurements to field conditions requires considerable care since many unknown factors may cause differences between laboratory and field.

The final step in the modeling portion of an exposure assessment is to run the model and generate the data needed to answer the questions posed in the study objectives.

Experience and familiarity with a model can also be important. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements. It frequently takes months to years of experience to fully comprehend all aspects of a model. Consequently, it is suggested that an exposure assessor select a familiar model if it possesses all the selection criteria, or seek the help of experienced exposure modelers.

3.5.3.5. Model Validation

Model validation is a process by which the accuracy of model results is compared with actual data from the system being simulated. There are numerous levels of validation of an environmental fate model, for example, such as verifying that the transport and transformation concepts are appropriately represented in the mathematical equations, verifying that the computer code is free from error, testing the model against laboratory microcosms, running field tests under controlled conditions, running general field tests, and repeatedly comparing field data to the modeling results under a variety of conditions and chemicals. In essence, validation is an independent test of how well the model (with its calibrated parameters) represents the important processes occurring in the natural system. Although field and environmental conditions are often different during the validation step, parameters fixed as a result of calibration are not readjusted during validation.[FN23]

The performance of models (their ability to represent measured data) is often dramatically influenced by site characterization and how models represent such characteristics. Characterizing complex, heterogenous physical systems presents major challenges; modeling representations of such systems must be evaluated in light of that difficulty. In many cases, the apparent inability to model a system is caused by incomplete physical characterization of the system. In other cases the uncertainties cannot be readily apportioned between the model per se and the model's input data.

In addition to comparing model results with actual data (thus illustrating accuracy, bias, etc.), the model validation process provides information about conditions under which a simulation will be acceptable and accurate, and under what conditions it should not be used at all. All models have specific ranges of application and specific classes of chemicals for which they are appropriate. Assessors should be aware of these limitations as they develop modeling strategies.

22909** ***3.5.4. Planning an Exposure Assessment to Assess Past Exposures

In addition to the considerations discussed in sections 3.5.1 through 3.5.3, if the data are being collected to assess past exposures, such as in epidemiologic studies, they need to be representative of the past exposure conditions, which may have changed with time. The scope and level of detail of the assessment depends greatly on the availability and quality of past data. Several approaches for determining and estimating past exposure are provided in the literature (Waxweiler et al., 1988; Stern et al., 1986; NIOSH, 1988; Greife et al., 1988; Hornung and Meinhardt, 1987).

4. Gatherring and Developing Data for Exposure Assessments

The information needed to perform an exposure assessment will depend on the approach(es) selected in the planning stage (section 3). For those assessments using point-of-contact measurements, the information includes:

- Measured exposure concentrations and duration of contact.

For assessments using the scenario evaluation method for estimating exposures, the needed information includes:

- Information on chemical concentrations in media, usually desirable in the format of a concentration-time-location profile.

- Information on persons who are exposed and the duration of contact with various concentrations.

For assessments estimating exposure from dose, the information includes:

- Biomarker data.

- Pharmacokinetic relationships, including the data to support pharmacokinetic models.

If dose is to be calculated, data are needed on:

- Intake and uptake, usually in the form of rates.

Information on both natural and anthropogenic sources is usually helpful. If the agent has natural sources, the contribution of these to environmental concentrations may be relevant. These background concentrations may be particularly important when the results of toxicity tests show a threshold or distinctly nonlinear dose-response relationship. In a situation where only relative or additional risk is considered, background levels may not be relevant.

4.1. Measurement Data for Point-of-Contact Assessments

This approach requires that chemical concentrations be measured at the interface between the person and the environment, usually through the use of personal monitors; there are currently no models to assist in the process of obtaining the concentration-time data itself. The chemical concentrations contacted in the media are measured by sampling the individual's breathing zone, food, and water. These methodologies were originally developed for occupational monitoring; they may have to be modified for exposures outside the workplace. An example of this is the development of a small pump and collector used in the TEAM studies (U.S. EPA, 1987a). In order to conduct these studies, a monitoring device had to be developed that was sufficiently small and lightweight so that it could be worn by the subjects.

The Total Human Exposure and Indoor Air Quality (U.S. EPA, 1988h) report is a useful bibliography covering models, field data, and emerging research methodologies, as well as new techniques for accurately determining exposure at nonoccupational levels.

New data for a particular exposure assessment may be developed through the use of point-of-contact methods, or data from prior studies can sometimes be used. In determining whether existing point-of-contact monitoring data can be used in another assessment, the assessor must consider the factors that existed in the original study and that influenced the exposure levels measured. Some of these factors are proximity to sources, activities of the studied individuals, time of day, season, and weather conditions.

Point-of-contact data are valuable in evaluating overall population exposure and checking the credibility of exposure estimates generated by other methods.

4.2. Obtaining Chemical Concentration Information

The distribution of chemical concentrations is used to estimate the concentration that comes in contact with the individual(s) at any given time and place. This can be done through personal monitoring, but for a variety of reasons, in a given assessment, personal monitoring may not be feasible. Alternative methods involve measuring the concentration in the media, or modeling the concentration distribution based on source strength, media transport, and chemical transformation processes. For exposure scenario evaluation, measurements and modeling of media concentrations are often used together.

Many types of measurements can be used to help determine the distribution of chemical concentrations in media. They can be measurements of the concentrations in the media themselves, measurements of source strength, or measurements of environmental fate processes which will allow the assessor to use a model to estimate the concentration in the media at the point of contact. Table 4-1 illustrates some of the types of measurements used by exposure assessors, along with notes concerning what additional information is usually needed to use these measurements in estimating exposure or dose. For epidemiologic studies, questionnaires are often used when data are not measureable or are otherwise unavailable.

Table 4-1.—Examples of types of measurements to characterize exposure-related media and parameters. [a]

Type of measurement (sample)	Usually attempts to characterize (whole)	Examples	Typical information needed to characterize exposure
A. For Use in Exposure Scenario Evaluation:			
1. Fixed-Location Monitoring	Environmental medium; samples used to establish long-term indications of media quality and trends	National Stream Quality Accounting Network (NASQAN), [b] water quality networks, air quality networks	Population location and activities relative to monitoring locations; fate of pollutants over distance between monitoring and point of exposure; time variation of pollutant concentration at point of exposure
2. Short-Term Media Monitoring	Environmental or ambient medium; samples used to establish a snapshot of quality of medium over relatively short time	Special studies of environmental media, indoor air	Population location and activities (this is critical since it must be closely matched to variations in concentrations due to short period of study); fate of pollutants between measurement point and point of exposure; time variation of pollutant concentration at point of exposure.
3. Source Monitoring of Facilities	Release rates to the environment from sources (facilities). Often given in terms of relationships between release amounts and	Stack sampling, effluent sampling, leachate sampling from landfills, incinerator ash sampling, fugitive emissions sampling,	Fate of pollutants from point of entry into the environment to point of exposure; population location and activities; time variation of release.

	various operating parameters of the facilities	pollution control device sampling	
4. Food Samples (also see #11 below)	Concentrations of contaminants in food supply	FDA Total Diet Study Program, [c] market basket studies, shelf studies, cooked-food diet sampling	Dietary habits of various age, sex, or cultural groups. Relationship between food items sampled and groups (geographic, ethnic, demographic) studied. Relationships between concentrations in uncooked versus prepared food.
5. Drinking Water Samples	Concentrations of pollutants in drinking water supply	Ground Water Supply Survey, [d] Community Water Supply Survey, [e] tap water	Fate and distribution of pollutants from point of sample to point of consumption. Population served by specific facilities and consumption rates. For exposure due to other uses (e.g., cooking and showering), need to know activity patterns and volatilization rates.
6. Consumer Products	Concentration levels of various products	Shelf surveys, e.g., solvent concentration in household cleaners [f]	Establish use patterns and/or market share of particular products, individual exposure at various usage levels, extent of passive exposure.
7. Breathing Zone Measurements	Exposure to airborne chemicals	Industrial hygiene studies, occupational surveys, indoor air studies.	Location, activities, and time spent relative to monitoring locations. Protective measures/avoidance.
8. Microenvironmental Studies	Ambient medium in a defined area, e.g., kitchen, automobile interior, office setting, parking lot	Special studies of indoor air, house dust, contaminated surfaces, radon measurements, office building studies	Activities of study populations relative to monitoring locations and time exposed.
9. Surface Soil Sample	Degree of contamination of soil available for contact	Soil samples at contaminated sites	Fate of pollution on/in soil; activities of potentially exposed populations.
10. Soil Core	Soil including pollution available for ground-water contamination; can be an indication of quality and trends over time	Soil sampling at hazardous waste sites	Fate of substance in soil; speciation and bioavailability, contact and ingestion rates as a function of activity patterns and age.
11. Fish Tissue	Extent of contamination of edible fish tissue	National Shellfish Survey [g]	Relationship of samples to food supply for individuals or population of interest; consumption habits; preparation habits.

B. For Use in Point-of-Contact Measurement			
1. Air Pump/Particulates and Vapors	Exposure of an individual or population via the air medium	TEAM study, [h] carbon monoxide study. [i] Breathing zone sampling in industrial settings	Direct measurement of individual exposure during time sampled. In order to characterize exposure to population, relationships between individuals and the population must be established as well as relationships between times sampled and other times for the same individuals, and relationships between sampled individuals and other populations. In order to make these links, activities of the sampled individuals compared to populations characterized are needed in some detail.
2. Passive Vapor Sampling	Same as above	Same as above	Same as above.
3. Split Sample Food/Split Sample Drinking Water	Exposures of an individual or population via ingestion.	TEAM study [j]	Same as above.
4. Skin Patch Samples	Dermal exposure of an individual or population	Pesticide Applicator Survey [k]	(1) Same as above. (2) Skin penetration.
C. For Use in Exposure Estimation from Reconstructed Dose:			
1. Breath	Total internal dose for individuals or population (usually indicative of relatively recent exposures)	Measurement of volatile organic chemicals (VOCs), alcohol. (Usually limited to volatile compounds)	(1) Relationship between individuals and population; exposure history (i.e., steady-state or not) pharmacokinetics (chemical half-life), possible storage reservoirs within the body. (2) Relationship between breath content and body burden.
2. Blood	Total internal dose for individuals or population (may be indicative of either relatively recent exposures to fat-soluble organics or long term body burden for metals)	Lead studies, pesticides, heavy metals (usually best for soluble compounds, although blood lipid analysis may reveal lipophilic compounds)	(1) Same as above.

			(2) Relationship between blood content and body burden.
3. Adipose	Total internal dose for individuals or population (usually indicative of long-term averages for fat-soluble organics).	NHATS,[l] dioxin studies, PCBs (usually limited to lipophilic compounds)	1) Same as above.
			(2) Relationship between adipose content and body burden.
4. Nails, Hair	Total internal dose for individuals or population (usually indicative of past exposure in weeks to months range; can sometimes be used to evaluate exposure patterns)	Heavy metal studies (usually limited to metals)	(1) Same as above.
			(2) Relationship between nails, hair content and body burden.
5. Urine	Total internal dose for individuals or population (usually indicative of elimination rates); time from exposure to appearance in urine may vary, depending on chemical	Studies of tetrachloroethylene[m] and trichloroethylene[n]	(1) Same as above.
			(2) Relationship between urine content and body burden.

22911** ***4.2.1. Concentration Measurements in Environmental Media

Measured concentration data can be generated for the exposure assessment by a new field study, or by evaluating concentration data from completed field study results and using them to estimate concentrations. Media measurements taken close to the point of contact with the individual(s) in space and time are preferable to measurements far removed geographically or temporally. As the distance from the point of contact increases, the certainty of the data at the point of contact usually decreases, and the obligation for the assessor to show relevance of the data to the assessment at hand becomes greater. For example, an outdoor air measurement, no matter how close it is taken to the point of contact, cannot by itself adequately characterize indoor exposure.

Concentrations can vary considerably from place to place, seasonally, and over time due to changing emission and use patterns. This needs to be considered not only when designing studies to collect new data, but especially when evaluating the applicability of existing measurements as estimates of exposure concentrations in a new assessment. It is a particular concern when the measurement data will be used to extrapolate to long time periods such as a lifetime. Transport and dispersion models are frequently used to help answer these questions.

The exposure assessor is likely to encounter several different types of measurements. One type of measurement used for general indications and trends of concentrations is outdoor fixed-location monitoring. This measurement is used by EPA and other

groups to provide a record of pollutant concentration at one place over time. Nationwide air and water monitoring programs have been established so that baseline values in these environmental media can be documented. Although it is not practical to set up a national monitoring network to gather data for a particular exposure assessment, the data from existing networks can be evaluated for relevance to an exposure assessment. These data are usually somewhat removed, and often far removed, from the point of contact. Adapting data from previous studies usually presents challenges similar to those encountered when using network data. If new data are needed for the assessment, studies measuring specific chemicals at specific locations and times can be conducted.

Contaminant concentrations in indoor air can vary as much or more than those in outdoor air. Consequently, indoor exposure is best represented by measurements taken at the point of contact. However, because pollutants such as carbon monoxide can exhibit substantial indoor penetration, indoor exposure estimates should consider potential outdoor as well as indoor sources of the contaminant(s) under evaluation.

Food and drinking water measurements can also be made. General characterization of these media, such as market basket studies (where representative diets are characterized), shelf studies (where foodstuffs are taken from store shelves and analyzed), or drinking water quality surveys, are usually far removed from the point of contact for an individual, but may be useful in evaluating exposure concentrations over a large population. Closer to the point of contact would be measurements of tap water or foodstuffs in a home, and how they are used. In evaluating the relevance of data from previous studies, variations in the distribution systems must be considered as well as the space-time proximity.

Consumer or industrial product analysis is sometimes done to characterize the concentrations of chemicals in products. The formulation of products can change substantially over time, similar products do not ***22912** necessarily have similar formulations, and regional differences in product formulation can also occur. These should be considered when determining relevance of extant data and when setting up sampling plans to gather new data.

Another type of concentration measurement is the microenvironmental measurement. Rather than using measurements to characterize the entire medium, this approach defines specific zones in which the concentration in the medium of interest is thought to be relatively homogenous, then characterizes the concentration in that zone. Typical microenvironments include the home or parts of the home, office, automobile, or other indoor settings. Microenvironments can also be divided into time segments (e.g., kitchen-day, kitchen-night). This approach can produce measurements that are closely linked with the point of contact both in location and time, especially when new data are generated for a particular exposure assessment. The more specific the microenvironment, however, the greater the burden on the exposure assessor to establish that the measurements are representative of the population of interest. Adapting existing data bases in this area to a particular exposure assessment requires the usual evaluation discussed throughout this section.

The concentration measurement that provides the closest link to the actual point of contact uses personal monitoring, which is discussed in section 4.3.

4.2.2. Use of Models for Concentration Estimation

If concentrations in the media cannot be measured, they can frequently be estimated indirectly by using related measurements and models. To accomplish this, source and fate information are usually needed. Source characterization data are used as input to transport and transformation models (environmental fate models). These models use a combination of general relationships and situation-specific information to estimate concentrations. In exposure assessments, mathematical models are used extensively to calculate environmental fate and transport, concentrations of chemicals in different environmental media, the distribution of concentrations over space and time, indoor air levels of chemicals, concentrations in foods, etc. In determining the relevance of this type of model for estimating concentrations, the same rules apply as for the measurements of concentrations discussed in the previous section. When concentrations in the media are available, models can be used to interpolate concentrations between measurements. Because models rely on indirect measurements and data remote from the point of contact, statistically valid

analytical measurements take precedence when discrepancies arise. When it is necessary to estimate contributions of individual sources to overall concentrations, models are commonly used.

Source characterization measurements usually determine the rate of release of chemicals into the environment from a point of emission such as an incinerator, landfill, industrial facility, or other source. Often these measurements are used to estimate emission factors, or a relationship between releases and facility operations. Since emission factors are usually averages over time, the assessor must determine whether given emission factors from previous work are relevant to the time specificity and source type needed for the exposure assessment. Generally, emission factors are more useful for long-term average emission calculations, and become less useful when applied to intermittent or short-term exposures.

Environmental fate measurements can be either field measurements (field degradation studies, for example) or laboratory measurements (partition coefficients, hydrolysis, or biodegradation rates, etc.). Approximations for these can sometimes also be calculated (Lyman et al., 1982).

Environmental fate models calculate estimated concentrations in media that in turn are linked to the concentrations at the point of contact. The use of estimated properties or rates adds to the uncertainty in the exposure concentration estimate. When assessors use these methods to estimate exposures, uncertainties attributable to the model and the validation status of the model must be clearly discussed in the uncertainty section (see discussion in section 6).

4.2.3. Selection of Models for Environmental Concentrations

Selection of an appropriate model is essential for successful simulation of chemical concentrations. In most cases assessors will be able to choose between several models, any of which could be used to estimate environmental concentrations. There is no right model; there may not even be a best model. There are, however, several factors that will help in selecting an appropriate model for the study. The assessor should consider the objectives of the study, the technical capabilities of the models, how readily the models can be obtained, and how difficult each is to use (U.S. EPA, 1987b, 1988f, 1991b).

The primary consideration in selecting a model is the objective of the exposure assessment. The associated schedule, budget, and other resource constraints will also affect model selection options. Models are available to support both screening-level and detailed, site-specific studies. Screening models can provide quick, easy, and cost-effective estimates of environmental concentrations. They can support data collection efforts at the site by indicating the required level of detection and quantification and the locations where chemical concentrations are expected to be highest. They are also used to interpolate chemical concentrations between measurements. Where study objectives require the best estimates of spatial and temporal distributions of chemicals, more sophisticated models are available. These models require more and better data to characterize the site, and therefore site-specific data may be needed in order to use them.

The technical capabilities of a model are expressed in its ability to simulate site-specific contaminant transport and transformation processes. The model must be able to simulate the relevant processes occurring within the specified environmental setting. It must adequately represent the physical setting (e.g., the geometric configuration of hydrogeological systems, river widths and depths, soil profiles, meteorological patterns, etc.) and the chemical transformation processes. Field data from the area where doses are to be estimated are necessary to define the input parameters required to use the models. In cases in which these data are not available, parameter values representative of field conditions should be used as defaults. Assumptions of homogeneity and simplification of site geometry may allow use of simpler models.

In addition, it is important to thoroughly understand the performance characteristics of the model used. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements.

4.3. Estimating Duration of Contact

As discussed in section 2, the duration of contact is linked to a particular exposure concentration to estimate exposure. Depending on the purpose of the assessment and the confidence ***22913** needed in the accuracy of the final estimate, several approaches for obtaining estimates of duration of contact can be used.

Ideally, the time that the individual is in contact with a chemical would be observed and recorded, and linked to the concentrations of the chemical during those time segments. Although it is sometimes feasible to do this (by point-of-contact measurement, see section 4.1.), many times it is not. In those cases, as in concentration characterization, the duration of contact must be estimated by using data that may be somewhat removed from the actual point of contact, and assumptions must be made as to the relevance of the data.

It is common for the estimate of duration of contact at a given concentration to be the single largest source of uncertainty in an exposure assessment. [FN24] The exposure assessor, in developing or selecting data for making estimates of duration of contact, must often assume that the available data adequately represent exposure.

4.3.1. Observation and Survey Data

Observation and recording of activities, including location-time data, are likely to be the types of data collection closest to the point of contact. This can be done by an observer or the person(s) being evaluated for exposure, and can be done for an individual, a population segment, or a population. The usual method for obtaining these data for population segments or populations is survey questionnaires. Surveys can be performed as part of the data-gathering efforts of the exposure assessment, or existing survey data can be used if appropriate.

There are several approaches used in activity surveys, including diaries, respondent or third-party estimates, momentary sampling, videomonitoring, and behavioral meters. The diary approach, probably the most powerful method for developing activity patterns, provides a sequential record of a person's activities during a specified time period. Typical time-diary studies are done across a day or a week. Diary forms are designed to have respondents report all their activities and locations for that period. Carefully designed forms are especially important for diary studies to ensure that data reported by each individual are comparable. The resulting time budget is a sample of activity that can be used to characterize an individual's behavior, activities, or other features during the observation period. Sequential activity monitoring forms the basis of an activity profile.

Several studies have demonstrated the reliability of the diary method in terms of its ability to produce similar estimates. One study (Robinson, 1977) found a 0.85 correlation between diary estimates using the yesterday and tomorrow approaches and a 0.86 correlation between overall estimates. However, no definitive study has established the validity of time-diary data.

Questionnaires are used for direct questions to collect the basic data needed. Questionnaire design is a complex and subtle process, and should only be attempted with the help of professionals well-versed in survey techniques. A useful set of guidelines is provided in the Survey Management Handbook (U.S. EPA, 1984b).

Respondent estimates are the least expensive and most commonly used questionnaire alternative. Respondents are simply asked to estimate the time they spend at a particular activity. Basically, the question is, how many hours did you spend doing this activity (or in this location or using a certain product)? In exposure studies, respondents may be asked how often they use a chemical or product of interest or perform a specific activity. These data are less precise and likely to be somewhat less accurate than a carefully conducted diary approach.

At a less demanding level, respondents may be asked whether their homes contain items of interest (pesticides, etc.). Since this information is not time-of-activity data, it is more useful in characterizing whether the chemical of interest is present. It does, however, give the assessor some indication that use may occur.

Estimates from other respondents (third parties) use essentially the same approach, except that other informants respond for that individual. Here the question is how many hours per week does the target person spend doing this activity?

Momentary (beeper) sampling or telephone-coincidental techniques ask respondents to give only brief reports for a specific moment — usually the moment the respondent's home telephone or beeper sounds. This approach is limited to times when people are at home or able to carry beepers with them.

Methods that use behavioral meter or monitoring devices are probably the most expensive approach, since they require the use or development of equipment, respondent agreement to use such equipment, and technical help to install or adjust the equipment.

The Exposure Factors Handbook (U.S. EPA, 1989c) contains a summary of published data on activity patterns along with citations. Note that the summary data and the mean values cited are for the data sets included in the Handbook, and may or may not be appropriate for any given assessment.

4.3.2. Developing Other Estimates of Duration of Contact

When activity surveys cannot be used to estimate duration of contact, it may be estimated from more indirect data. This is the least expensive and most commonly used approach for generating estimates of duration of contact; it is also the least accurate. But for some situations, such as assessing the risk to new chemicals being introduced into the marketplace or in assessing future possible uses of contaminated sites, it is the only approach that can be used.

In general, the methods used to make these estimates fall into two areas: (1) those where the time it takes to perform an activity is itself estimated, and (2) those where an average duration of contact is estimated by combining the time of a unit activity with data on the use of a product or commodity.

Methods that try to estimate the time of a particular activity include general time-and-motion studies that might be adapted for use in an exposure assessment, general marketing data which include time of use, anecdotal information, personal experience, and assumptions about the amount of time it takes to perform an activity.

Methods that estimate average times for activities from product or commodity use usually interpret data on product sales or marketing surveys, water use, general food sales, etc. Information on use can be combined with an estimate of the number of persons using the product to estimate the average consumption of the product. If an estimate of the duration of contact with one unit (product, gallon of water, etc.) can be made, this can then be multiplied by the average number of units consumed to arrive at an estimate of average duration of contact for each individual.

Duration-of-contact estimates based on data collected close to the actual point of contact are preferable to those based on indirect measurements; both of these are preferred to estimates based on assumptions alone. This hierarchy is ***22914** useful in both the data-gathering process and uncertainty analysis.

4.4. Obtaining Data on Body Burden or Biomarkers

Body burden or biomarker data denote the presence of the chemical inside the body of exposed individuals. In a reconstructive assessment, these data, in conjunction with other environmental monitoring data, may provide a better estimate of exposure.

A biomarker of exposure has been defined as an exogenous substance or its metabolite or the product of an interaction between a xenobiotic agent and some target molecule or cell that is measured in a compartment within an organism (NRC, 1989a). Examples of simple direct biomarkers include the chemical itself in body fluid, tissue, or breath. Measurable changes in the physiology of the organism can also constitute markers of exposure. Examples include changes in a particular enzyme synthesis and activity. The interaction of xenobiotic compounds with physiological receptors can produce measurable complexes which also serve as exposure biomarkers. Other markers of exposure include xenobiotic species adducted to protein or DNA, as well as a variety of genotoxicity endpoints, such as micronuclei and mutation. Some biomarkers are specific to a given chemical while others may result from exposure to numerous individual or classes of compounds.

Biomarker data alone do not usually constitute a complete exposure assessment, since these data must be associated with external exposures. However, biomarker data complement other environmental monitoring data and modeling activities in estimating exposure.

4.5. Obtaining Data for Pharmacokinetic Relationships

To estimate dose from exposure, one must understand the pharmacokinetics of the chemical of interest. This is particularly true when comparing risks resulting from different exposure situations. Two widely different exposure profiles for the same chemical may have the same integrated exposure (area under the curve), but may not result in the same internal dose due to variations in disposition of the chemical under the two profiles. For example, enzymes that normally could metabolize low concentrations of a chemical may be saturated when the chemical is absorbed in high doses, resulting in a higher dose delivered to target tissues. The result of these two exposures may even be a different toxicological endpoint, if pharmacokinetic sensitivities are severe enough.

An iterative approach, including both monitoring and modeling, is necessary for proper data generation and analysis. Data collection includes monitoring of environmental media, personal exposure, biomarkers, and pharmacokinetic data. It may involve monitoring for the chemical, metabolites, or the target biomarker. Monitoring activities must be designed to yield data that are useful for model formulation and validation. Modeling activities must be designed to simulate processes that can be monitored with available techniques. The pharmacokinetic data necessary for model development are usually obtained from laboratory studies with animals. The data are generated in experiments designed to estimate such model parameters as the time course of the process, absorption, distribution, metabolism, and elimination of the chemical. These data, and the pharmacokinetic models developed from them, are necessary to interpret field biomarker data.

4.6. Obtaining Data on Intake and Uptake

The Exposure Factors Handbook (U.S. EPA, 1989c) presents statistical data on many of the factors used in assessing exposure, including intake rates, and provides citations for the primary references. Some of these data were developed by researchers using approaches discussed in Section 4.2.1 (for example, Pao et al. (1982) used the diary approach in a study of food consumption). Intake factors included are:

- Drinking water consumption rates;

- Consumption rates for homegrown fruits, vegetables, beef, and dairy products;

- Consumption rates for recreationally caught fish and shellfish;

- Incidental soil ingestion rates;

- Pulmonary ventilation rates; and

- Surface areas of various parts of the human body.

The Exposure Factors Handbook is being updated to encompass additional factors and to include new research data on the factors currently covered. It also provides default parameter values that can be used when site-specific data are not available. Obviously, general default values should not be used in place of known, valid data that are more relevant to the assessment being done.

5. Using Data to Determine or Estimate Exposure and Dose

Collecting and assembling data, as discussed in the previous section, is often an iterative process. Once the data are assembled, inferences can be made about exposure concentrations, times of contact, and exposures to persons other than those for whom data are available. During this process, there usually will be gaps in information that can be filled by making a series of assumptions. If these gaps are in areas critical to the accuracy of the assessment, further data collection may be necessary.

Once an acceptable data set[FN25] is available, the assessor can calculate exposure or dose. Depending on the method used to quantify exposure, there are several ways to calculate exposure and dose. This chapter will discuss making inferences (section 5.1), assumptions (section 5.2), and calculations (section 5.3).

5.1. Use of Data in Making Inferences for Exposure Assessments

Inferences are generalizations that go beyond the information contained in a data set. The credibility of an inference is often related to the method used to make it and the supporting data. Anecdotal information is the source of one type of inference, but the assessor has only limited knowledge of how well one anecdote represents the realm of possibilities, so anecdotes as a basis for inference should be used only with considerable caution. Professional judgment is usually preferred to anecdotes assuming that it is based on experience representing a variety of conditions. Statistical inferences also are generalizations that go beyond the data set. They may take any of several forms (see any statistics textbook for examples), but unlike those described above, a statistical inference will usually include a measure of how certain it is. For that reason, statistical inferences are often preferable to anecdotes or professional judgment provided the data are shown to be relevant and adequate.

As discussed above, the primary use of data from exposure-related measurements is to infer more general information about exposure concentrations, contact times, exposures, or doses. For example, measured concentrations in a medium can be used to infer what the concentration might be at the point of contact, which may not have been measured directly. Point-of-contact measurement data for one group of people may be used to infer the ***22915** exposures of a similar group, or to infer what the exposures of the same group might be at different times.

In all cases, the exposure assessor must have a clear picture of the relationship between the data at hand and what is being characterized by inference. For example, surface water concentration data alone, although essential for characterizing the medium itself, are not necessarily useful for inferring exposures from surface water, since other information is necessary to complete the link between surface water and exposure. But the medium's characteristics (over space and time) can be used, along with the location and activities of individuals or populations, to estimate exposures. Samples taken for exposure assessment may be designed to characterize different aspects (or components) of exposure. For example, a sample taken as a point-of-contact exposure measurement is qualitatively different from a sample of an environmental medium or body fluid.

Different measurements taken under the general category of exposure-related measurements cannot necessarily all be used in the same way. The exposure assessor must explain the relationship between the sample data and the inferences or conclusions being drawn from them. In order to do this, data relevance, adequacy, and uncertainty must be evaluated.

5.1.1. Relevance of Data for the Intended Exposure Assessment

When making inferences from a data set, the assessor must establish a clear link between the data and the inference. When statistically based sampling is used to generate data, relevance is a function of how well the sample represents the medium or parameter being characterized. When planning data collection for an exposure assessment, the assessor can use information about the inferences that will be made to select the best measurement techniques. In many cases data are also available from earlier studies. The assessor must determine (and state) how relevant the available data are to the current assessment; this is usually easier for new data than for previously collected information.

5.1.2. Adequacy of Data for the Intended Assessment

Table 4-1 in the previous section illustrated how different types of measurements may be used to characterize a variety of concentrations, contact times, and intake or uptake parameters. Nevertheless, just because certain types of measurements generally can be used to make certain inferences, there is no guarantee that this can always be done. The adequacy of the data to make inferences is determined by evaluating the amount of data available and the accuracy of the data. Evaluation of the adequacy of data will ensure that the exposure assessment is conducted with data of known quality.

In general, inadequate data should not be used, but when it can be demonstrated that the inadequacies do not affect results, it is sometimes possible to use such data. In these cases, an explanation should be given as to why the inadequacies do not invalidate conclusions drawn from them. In some cases, even seriously inadequate or only partially relevant data may be the only data available, and some information may be gained from their consideration. It may not be possible to discard these data entirely unless better data are available. If these data are used, the uncertainties and resulting limitations of the inferences should be clearly stated. If data are rejected for use in favor of better data, the rationale for rejection should be clearly stated and the basis for retaining the selected data should be documented. QA/QC considerations are paramount in considerations of which data to keep and which to discard.

Outliers should not be eliminated from data analysis procedures unless it can be shown that an error has occurred in the sample collection or analysis phases of the study. Very often outliers provide much information to the study evaluators. Statistical tests such as the Dixon test exist to determine the presence of outliers (Dixon, 1950, 1951, 1953, 1960).

5.1.2.1. Evaluation of Analytical Methods

Analytical methods are evaluated in order to develop a data set based on validated analytical methods and appropriate QA/QC procedures. In a larger sense, analytical methods can be evaluated to determine the strength of the inferences made from them, and in turn, the confidence in the exposure assessment itself. Consequently, it is just as important to evaluate analytical methods used for data generated under another study as it is to evaluate the methods used to generate new data.

The EPA has established extensive QA/QC procedures (U.S. EPA, 1980). Before measurement data are used in the assessment, they should be evaluated against these procedures and the results stated. If this is not possible, the assessor must consider what effect the unknown quality of the data has on the confidence placed on the inferences and conclusions of the assessment.

5.1.2.2. Evaluation of Analytical Data Reports

An assortment of qualifiers is often used in data validation. These qualifiers are used to indicate QA/QC problems such as uncertain chemical identity or difficulty in determining chemical concentration. Qualifiers usually appear on a laboratory analysis report as a letter of the alphabet next to the analytical result. Some examples of data qualifiers, applied by U.S. EPA regional reviewers for Contract Laboratory Program (CLP) data include:

B (blank)—the analyte was found in blank samples;

J (judgment)—the compound is present but the concentration value is estimated;

U (undetected)—the chemical was analyzed for but not detected at the detection limit;

R (reject)—the quality control indicates that the data are unusable.

The exposure assessor may contact the laboratory or the person who validated the data if the definitions of the qualifiers are unclear. Since the exposure assessment is only as good as the data supporting it, it is essential to interpret these types of data properly to avoid misrepresenting the data set or biasing the results.

5.1.2.2.1. Evaluation of Censored Data Sets

Exposure assessors commonly encounter data sets containing values that are lower than limits deemed reliable enough to report as numerical values (i.e., quantification limits (QL)). These data points are often reported as nondetected and are referred to as censored. The level of censoring is based on the confidence with which the analytical signal can be discerned from the noise. While the concentration may be highly uncertain for substances below the reporting limit, it does not necessarily mean that the concentration is zero. As a result the exposure assessor is often faced with the problem of having to estimate values for the censored data. Although a variety of techniques have been described in the literature, no one procedure is appropriate under all exposure assessment circumstances; thus, the exposure assessor will need to decide on the appropriate method for a given situation. Techniques for analyzing censored data sets can be grouped into three classes (Helsel, 1990): Simple substitution methods, distributional methods, and robust methods.

Simple substitution methods, the most commonly encountered technique, ***22916** involve substitution of a single value as a proxy for each nondetected data value. Frequently used values have included zero, the QL, QL/2, and

QL/§2.[FN26]

In the worst-case approach, all nondetects are assigned the value of the QL, which is the lowest level at which a chemical may be accurately and reproducibly quantitated. This approach biases the mean upward. On the other hand, assigning all nondetects the value of zero biases the mean downward. The degree to which the results are biased will depend on the relative number of detects and nondetects in the data set and the difference between the reporting limit and the measured values above it.

In an effort to minimize the obvious bias introduced by choosing either zero or the QL as the proxy, two other values have been suggested, i.e., QL/2 and QL/§2. Assigning all nondetects as QL/2 (Nehls and Akland, 1973) assumes that all values between the QL and zero are equally likely; therefore, an average value would result if many samples in this range were measured. Hornung and Reed (1990) discuss the merits of assigning a value of QL/§2 for nondetects rather than QL/2 if the data are not highly skewed (geometric standard deviation < 3.0); otherwise they suggest using QL/2.

Based on reported analyses of simulated data sets that have been censored to varying degrees (Gleit, 1985; Horning and Reed, 1990; Gilliom and Helsel, 1986; Helsel and Cohn, 1988), it can be concluded that substitution with QL/2 or QL/§ 2 for nondetects will be adequate for most exposure assessments provided that the nondetects do not exceed 10% to 15% of the data set or the data are not highly skewed. When such situations arise, the additional effort to make use of more sophisticated methods as discussed below is recommended. On the other hand, the exposure assessor may encounter situations in which the purpose of the assessment is only to serve as a screen to determine if a health concern has been triggered or if a more detailed study is required, then assigning the value of the QL to all nondetect values can be justified. If, when using this conservative approach, no concern is indicated, then no further effort is warranted. This method cannot be used to prove an unacceptable risk exists, and any exposure values calculated using this method should be caveated and clearly presented as “less than” estimates.

Distributional methods, unlike simple substitution methods, make use of the data above the reporting limit to extrapolate below it. One such technique is the use of log-probit analysis. This approach assumes a lognormal probability distribution of the data. In the probit analysis, the detected values are plotted on the scale and the nondetectable values are treated as unknowns, but their percentages are accounted for. The geometric mean is determined from the 50th percentile. As discussed by Travis and Land (1990), limitations of the method have been pointed out, but it is less biased and more accurate than the frequently used substitution methods. This method is useful in situations where the data set contains enough data points above the reporting limit to define the distribution function for the exposure values (i.e., lognormal) with an acceptable degree of confidence. The treatment of the nondetectable samples is then straightforward, assuming the nondetectable samples follow the same distribution as those above the reporting limit.

Robust methods have an advantage over distributional methods in so far as they do not assume that the data above the reporting limit follow a defined distribution (e.g., lognormal) and they are not subject to transformation bias in going from logarithms

back to original units. Gilliom and Helsel (1986) have described the application of several approaches to data sets of varying sample size and degree of censoring. These methods involve somewhat more data manipulation than the log-probit method discussed earlier in this Section, but they may be more appropriate to use when the observed data do not fit a lognormal distribution. Generally, these methods only assume a distributional form for the censored values rather than the entire data set, and extrapolation from the uncensored data is done by using regression techniques.

In summary, when dealing with censored data sets, a variety of approaches can be used by the exposure assessor. Selecting the appropriate method requires consideration of the degree of censoring, the goals of the exposure assessment, and the accuracy required. Regardless of the method selected, the assessor should explain the choice made and how it may affect the summary statistics. Presenting only the summary statistics developed by one of these methods should be avoided. It is always useful to include a characterization of the data by the percentage of detects and nondetects in language such as "in 37% of the samples the chemical was detected above the quantitation limit; of these 37%, the mean concentration was 47 ppm, the standard deviation was 5 ppm, etc."

5.1.2.2.2. Blanks and Recovery

Blank samples should be compared with the results from their corresponding samples. When comparing blank samples to the data set, the following rules should be followed (outlined in section 3):

- Sample results should be reported only if the concentrations in the sample exceed 10 times the maximum amount detected in the blank for common laboratory contaminants. Common laboratory contaminants include: acetone, 2-butanone (or methyl ethyl ketone), methylene chloride, toluene, and phthalate esters.

- Sample results should be reported only if the concentrations in the sample exceed 5 times the maximum amount detected in a blank for chemicals that are not common laboratory contaminants.

In general, for other types of qualifiers, the exposure assessor may include the data with qualifiers if they indicate that a chemical's concentration is uncertain, but its identity is known. If possible, the uncertainties associated with the qualifier should be noted.

Chemical spike samples that show abnormally high or low recoveries may result in qualified or rejected data. Assessors should not use rejected data; these samples should be treated as if the samples were not taken, since the resulting data are unreliable. Typically, analytical results are reported from the laboratory unadjusted for recovery, with the recovery percentage also reported. The assessor must determine how these data should be used to calculate exposures. If recovery is near 100%, concentrations are not normally adjusted (although the implicit assumption of 100% recovery should be mentioned in the uncertainty section). However, the assessor may need to adjust the data to account for consistent, but abnormally high or low recovery. The rationale for such adjustments should be clearly explained; individual program offices may develop guidance on the acceptable percent recovery limits before data adjustment or rejection is necessary.

5.1.3. Combining Measurement Data Sets from Various Studies

Combining data from several sources into a single data set must be done cautiously. The circumstances under which each set of data was collected (target population, sampling design, ***22917** location, time, etc.) and quality (precision, accuracy, representativeness, completeness, etc.) must be evaluated. Combining summary statistics of the data sets (e.g., means) into a single set may be more appropriate than combining the original values. Statistical methods are available for combining results from individual statistical tests. For example, it is sometimes possible to use several studies with marginally significant results to justify an overall conclusion of a statistically significant effect.

The best way to report data is to provide sufficient background information to explain what was done and why, including clear documentation of the source of the data and including any references.

5.1.4. Combining Measurement Data and Modeling Results

Combining model results with measurement data must be done with an understanding of how this affects the resulting inferences, conclusions, or exposure estimates. If model results are used in lieu of additional data points, they must be evaluated for accuracy and representativeness as if they were additional data, and the uncertainty associated with this data combination must be described fully, as discussed in section 5.1.3.

On the other hand, measurement data are often used within the context of the model itself, as calibration and verification points, or as a check on the plausibility of the model results. If measurements are used within the model, the uncertainty in these measurements affects the uncertainty of the model results, and should be discussed as part of the uncertainty of the model results.

5.2. Dealing With Data Gaps

Even after supplementing existing measurement data with model results, there are likely to be gaps in the information base to be used for calculating exposures and doses. There are several ways to deal with data gaps. None are entirely satisfactory in all situations, but they can be useful depending on the purposes of the assessment and the resources available. The following options can be used singly or in combination:

- New data can be collected. This may be beyond the reach of the assessor's resources, but promises the best chance for getting an accurate answer. It is most likely to be a useful option if the new data are quick and easy to obtain.

- The scope of the assessment can be narrowed. This is possible if the data gaps are in one pathway or exposure route, and the others have adequate data. It may be a viable option if the pathway or route has values below certain bounds, and those bounds are small relative to the other pathways being evaluated. This is unlikely to be satisfactory if the part of the assessment deleted is an important exposure pathway or route and must be evaluated.

- Conservative[FN27] assumptions can be used. This option is useful for establishing bounds on exposure parameters, but limits how the resulting exposures and doses can be expressed. For example, if one were to assume that a person stays at home 24 hours a day as a conservative assumption, and used this value in calculations, the resulting contact time would have to be expressed as an upper limit rather than a best estimate. When making conservative assumptions, the assessor must be aware of (and explain) how many of these are made in the assessment, and how they influence the final conclusions of the assessment.[FN28]

- Models may be used in some cases, not only to estimate values for concentrations or exposures, but also to check on how conservative certain assumptions are.

- Surrogate data may also be used in some cases. For example, for pesticide applicators' exposure to pesticides, the EPA Office of Pesticide Programs (U.S. EPA, 1987d) assumes that the general parameters of application (such as the human activity that leads to exposure) are more important than the properties of the pesticide in determining the level of exposure.[FN29] This option assumes that surrogate data are available and that the differences between the chemical and the surrogate are small. If a clear relationship can be determined between the concentration of a chemical and the surrogate (usually termed an indicator chemical) in a medium, this relationship could also be used to fill data gaps. In any case, the strength and character of the relationship between the chemical and the surrogate must be explained.

- Professional judgment can be used. The utility of this option depends on the confidence placed in the estimate. Expert opinion based on years of observation of similar circumstances usually carries more weight than anecdotal information. The assessor must discuss the implications of these estimates in the uncertainty analysis.

5.3. Calculating Exposure and Dose

Depending on the approach used to quantify exposure and dose, various types of data will have been assembled. In calculating exposures and doses from these data, the assessor needs to direct attention specifically to certain aspects of the data. These aspects include the use of short-term data for long-term projections, the role of personal monitoring data, and the particular way the data might be used to construct scenarios. Each of these aspects is covered in turn below.

5.3.1. Short-Term Versus Long-Term Data for Population Exposures

Short-term data, for the purposes of this discussion, are data representing a short period of time measured (or modeled) relative to the time period covered in the exposure assessment. For example, a 3-day sampling period would produce short-term data if the exposure assessment covered a period of several years to a lifetime. The same 3-day sampling period would not be considered short-term if the assessment covered, say, a few days to a week.

Short-term data can provide a snapshot of concentrations or exposures during that time, and an inference must be made about what that means for the longer term if the exposure assessment covers a long period. The assessor must determine how well the short-term data represent the longer period.

Even when short-term population data are statistically representative (i.e., they describe the shape of the distribution, the mean, and other statistics), use of these short-term data to infer long-term exposures and risks must be done with caution. Using short-term data to estimate long-term exposures has a tendency to underestimate the number of people exposed, but to overestimate the exposure levels to the upper end of the distribution, even though the mean will remain the same.[FN30] Both ***22918** concentration variation at a single point and population mobility will drive the estimates of the levels of exposure for the upper tail of the distribution toward the mean. If short-term data are used for long-term exposure or dose estimates, the implications of this on the estimated exposures must be discussed in the assessment. Likewise, use of long-term monitoring data for specific short-term assessments can miss significant variations due to short-term conditions or activities. Long-term data should be used cautiously when estimating short-term exposures or doses, and the implications should be discussed in the assessment.

5.3.2. Using Point-of-Contact Data to Calculate Exposure and Dose

Point-of-contact exposure assessments are often done with the intent of protecting the individuals, often in an occupational setting. When exposures are being evaluated to determine whether they exceed an action level or other benchmark, point-of-contact measurements are the most relevant data.

Typically, point-of-contact measurement data reflect exposures over periods of minutes to perhaps a week or so. For individuals whose exposures have been measured, these data may be used directly as an indication of their exposure during the sampling period, provided they are of adequate quality, measure the appropriate chemical, and actually measure exposure while it occurs. This is the only case in which measurement data may be used directly as exposure data.

When using point-of-contact measurements, even with statistically based data, several inferences still must be made to calculate exposure or dose:

- Inferences must be made to apply short-term measurements of exposure to long-term estimates of exposure; these are subject to the cautions outlined in section 5.3.1.

- Inferences must be made about the representativeness of the individual or persons sampled for the individual or population segment for which the assessment is done.

- Inferences must be made about the factors converting measured exposure to potential or internal dose for use in a risk assessment.

- If the assessment requires it, inferences must be made about the relationship between the measured chemical exposures and the presence and relative contribution of various sources of the chemical.

5.3.3. The Role of Exposure Scenarios in Exposure Assessment

Exposure scenarios have several functions in exposure and risk assessments. First, they are calculational tools to help the assessor develop estimates of exposure, dose, and risk. Whatever combination of data and models is used, the scenario will help the assessor to picture how the exposure is taking place, and will help organize the data and calculations. Second, the estimates derived from scenarios are used to develop a series of exposure and risk descriptors, which were discussed in section 2.3. Finally, exposure scenarios can often help risk managers make estimates of the potential impact of possible control actions. This is usually done by changing the assumptions in the exposure scenario to the conditions as they would exist after the contemplated action is implemented, and reassessing the exposure and risk. These three uses of exposure assessments are explained in sections 5.3.3.1, 5.3.3.2, and 5.3.3.3, respectively.

An exposure scenario is the set of information about how exposure takes place. An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about the following:

- The physical setting where exposure takes place (exposure setting)

- The exposure pathway(s) from source(s) to exposed individual(s) (exposure pathways)

- The characterization of the chemical, i.e., amounts, locations, time variation of concentrations, source strength, environmental pathways from source to exposed individuals, fate of the chemical in the environment, etc. (characterization of the chemical)

- Identification of the individual(s) or population(s) exposed, and the profile of contact with the chemical based on behavior, location as a function of time, characteristics of the individuals, etc. (characterization of the exposed population)

- If the dose is to be estimated, assumptions about the transfer of the chemical across the boundary, i.e., ingestion rates, respiration rates, absorption rates, etc. (intake and uptake rates)

It usually is necessary to know whether the effect of concern is chronic, acute, or dependent on a particular exposure time pattern.

The risk characterization, the link between the development of the assessment and the use of the assessment, is usually communicated in part to the risk manager by means of a series of “risk descriptors,” which are merely different ways to describe the risk. Section 2.3 outlined two broad types of descriptors: individual risk descriptors and population risk descriptors, with several variations for each. To the exposure or risk assessor, different types of risk information require different risk descriptors and different analyses of the data. The following paragraphs discuss some of the aspects of developing and using exposure scenarios in various functions for exposure assessment.

5.3.3.1. Scenarios as a Means to Quantify Exposure and Dose

When using exposure scenario evaluation as a means to quantify exposure and dose, it is possible to accumulate a large volume of data and estimated values, and both the amount and type of information can vary widely. The exposure scenario also contains the information needed to calculate exposure, since the last three bullets above (section 5.3.3) are the primary variables in most exposure and dose equations.

As an example, consider Equation 2-5, the equation for lifetime average daily potential dose ($LADD_{pot}$). This equation uses the variables of exposure concentration (C), intake rate (IR), and exposure duration (ED) as the three primary variables. Body weight (BW) and averaging time (AT) (in this case, lifetime, LT) are not related to the exposure or dose per se, but are averaging variables used to put the resulting dose in convenient units of lifetime average exposure or dose per kg of body weight.

In looking at the three primary variables (C, IR, and ED), the exposure assessor must determine what value to use for each to solve the equation. In actuality, the information available for a variable like C may consist of measurements of various points in an environmental medium, source and fate characterizations, and model results. There will be uncertainty in the values for C for any individual; there will also be variability among individuals. Each ***22919** of these primary variables will be represented by a range of values, even though at times, the boundaries of this range will be unknown. How exposure or dose is calculated depends on how these ranges are treated.

In dealing with these ranges in trying to solve the equation for LADD, the assessor has at least two choices. First, statistical tools, such as the Monte Carlo analysis, can be used to enter the values as frequency distributions, which results in a frequency distribution for the LADD. This is an appropriate strategy when the frequency distributions are known for C, IR, and ED (or for the uptake analogs, C, K_p, SA, and ED introduced in section 2), and when these variables are independent.

A second approach is to select or estimate discrete values from the ranges of each of the variables and use these values to solve the LADD equation. This approach usually results in a less certain estimate, but may be easier to do. Which values are used determines how the resulting estimate will be described. Several terms for describing such estimates are discussed in section 5.3.3.2.

Since exposure to chemicals occurs through a variety of different pathways, contact patterns, and settings, sufficient perspective must be provided to the users of the assessment (usually risk managers) to help them make an informed decision. Providing this perspective and insight would be relatively straightforward if complete and accurate information were known about the exposure, dose, and risk for each and every person within the population of interest. In this hypothetical situation, these individual data could actually be arrayed next to the name of each person in the population, or the data could be compiled into frequency distribution curves. From such distributions, the average, median, maximum, or other statistical values could easily be read off the curves and presented to the risk manager. In addition, accurate information could be provided about how many persons are above certain exposure, dose, or risk levels as well as information about where various subgroups fall within the subject distribution.

Unfortunately, an assessor rarely has these kinds of data; the reality an assessor faces usually falls far short of this ideal. But it is precisely this kind of information about the distribution of exposure, dose, and risk that is needed many times by the risk assessor to characterize risk, and by the risk manager to deal with risk-related issues.

In the absence of comprehensive data, or if the scenario being evaluated is a possible future use or post-control scenario, an assessor must make assumptions in order to estimate what the distribution would look like if better data were available, or if the possible future use becomes a reality. Communicating this estimated distribution to the risk manager can be difficult. The assessor must not only estimate exposure, dose, and risk levels, but must also estimate where those levels might fall on the actual distributions or estimated distributions for potential future situations. To help communicate where on the distribution the estimate might fall, loosely defined terms such as reasonable worst case, worst case, and maximally exposed individual have been used by assessors. Although these terms have been used to help describe the exposure assessor's perceptions of where estimated exposures fall on the actual or potential distribution for the future use, the ad hoc nature of the historical definitions used has led to some inconsistency. One of the goals of these Guidelines is to promote greater consistency in the use of terms describing exposure and risk. 5.3.3.2. Exposure Scenarios and Exposure Estimators as Input to Risk Descriptors

As discussed in section 2.3, risk descriptors convey information about risk to users of that information, primarily risk managers. This information usually takes the form of answers to a relatively short set of questions, not all of which are applicable to all assessments. Section 5.3.5 provides more detail on how the exposure assessor's analysis leads to construction of the risk descriptors.

5.3.3.3. Exposure Scenarios as a Tool for Option Evaluation

A third important use for exposure scenarios is as a tool for evaluating proposed options for action. Risk managers often have a number of choices for dealing with environmental problems, from taking no action on one extreme to a number of different actions, each with different costs, on the other. Often the exposure scenarios developed as part of the baseline risk assessment provide a powerful tool to evaluate the potential reduction of exposure and risk for these various options, and consequently are quite useful in many cost-benefit analyses.

There are several additional related uses of exposure scenarios for risk managers. They may help establish a range of options for cleanup by showing the sensitivity of the risk estimates to the changes in assumed source or exposure levels. The exposure assessor can use the sensitivity analysis of the exposure scenario to help evaluate and communicate the uncertainty of the assumptions, and what can be done to reduce that uncertainty. Well-crafted and soundly based exposure scenarios may also help communicate risks and possible options to community groups.

Although it is beyond the scope of these Guidelines to detail the methods used for option evaluation and selection, the assessor should be aware of this potential use. Discussing strategy (and specific information needs) with risk managers is usually prudent before large resource expenditures are made in the risk assessment area.

5.3.4. General Methods for Estimating Exposure and Dose

A variety of methods are used to obtain estimates of dose necessary for risk characterization. These range from quick screening level calculations and rules of thumb to more sophisticated techniques. The technique to be used in a given case is a matter of the amount of information available and the purpose of the assessment. Several of the methods are outlined in the following sections.

Normally it is neither practical nor advisable to immediately develop detailed information on all the potential pathways, since not all may contribute significantly to the outcome of the assessment.[FN31] Rather, evaluation of the scenario is done in an iterative manner. First, screening or bounding techniques are used to ascertain which pathways are unimportant, then the information for the remaining pathways is refined, iteratively becoming more accurate, until the quantitative objectives of the assessment are met (or resources are depleted).

In beginning the evaluation phase of any assessment, the assessor should have a scenario's basic assumptions (setting, scope, etc.) well identified, one or more applicable exposure pathways defined, an equation for evaluating the exposure or dose for each of those exposure pathways, and the data and information requirements pertinent to solving the equations. Quality and quantity of data and information needed to substitute quantitative values or ***22920** ranges into the parameters of the exposure equation will often vary widely, from postulated assumptions to actual high-quality measurements. Many times, there are several exposure pathways identified within the scenario, and the quality of the data and information may vary for each.

A common approach to estimating exposure and dose is to do a preliminary evaluation, or screening step, during which bounding estimates are used, and then to proceed to refine the estimates for those pathways that cannot be eliminated as of trivial importance.

5.3.4.1. Preliminary Evaluation and Bounding Estimates

The first step that experienced assessors usually take in evaluating the scenario involves making bounding estimates for the individual exposure pathways. The purpose of this is to eliminate further work on refining estimates for pathways that are clearly not important.

The method used for bounding estimates is to postulate a set of values for the parameters in the exposure or dose equation that will result in an exposure or dose higher than any exposure or dose expected to occur in the actual population. The estimate of

exposure or dose calculated by this method is clearly outside of (and higher than) the distribution of actual exposures or doses. If the value of this bounding estimate is not significant, the pathway can be eliminated from further refinement.[FN32]

The theoretical upper bounding estimate (TUBE) is a type of bounding estimate that can be easily calculated and is designed to estimate exposure, dose, and risk levels that are expected to exceed the levels experienced by all individuals in the actual distribution. The TUBE is calculated by assuming limits for all the variables used to calculate exposure and dose that, when combined, will result in the mathematically highest exposure or dose (highest concentration, highest intake rate, lowest body weight, etc.). The theoretical upper bound is a bounding estimate that should, if the limits of the parameters used are known, ensure that the estimate is above the actual exposures received by all individuals in the population. It is not necessary to go to the formality of the TUBE to assure that the exposure or dose calculated is above the actual distribution, however, since any combination that results in a value clearly higher than the actual distribution can serve as a suitable upper bound.

The bounding estimate (a limit of individual exposure, dose or risk) is most often used only to eliminate pathways from further consideration. This is often done in screening-level assessments, where bounding estimates of exposure, dose, or risk provide a quick and relatively easy check on whether the levels to be assessed are trivial relative to a level that would cause concern. If acceptably lower than the concern level, then additional assessment work is not necessary.

Bounding estimates also are used in other types of assessments. They can be used for deregulation of chemicals when pathways or concentrations can be shown to present insignificant or de minimis risk. They can be used to determine whether more information is needed to determine whether a pathway is significant; if the pathway's significance cannot be ruled out by a bounding estimate, test data may be needed to refine the estimate.

There are two important points about bounding estimates. First, the only thing the bounding estimate can establish is a level to eliminate pathways from further consideration. It cannot be used to make a determination that a pathway is significant (that can only be done after more information is obtained and a refinement of the estimate is made), and it certainly cannot be used for an estimate of actual exposure (since by definition it is clearly outside the actual distribution). Second, when an exposure scenario is presented in an assessment, it is likely that the amount of refinement of the data, information, and estimates will vary by pathway, some having been eliminated by bounding estimates, some eliminated after further refinement, and others fully developed and quantified. This is an efficient way to evaluate scenarios. In such cases, bounding estimates must not be considered to be equally as sophisticated as an estimate of a fully developed pathway, and should not be described as such.

Experienced assessors can often eliminate some obvious pathways more or less by inspection as they may have evaluated these pathways many times before.[FN33] In these cases, the assessor must still explain why the pathway is being eliminated. For less experienced assessors, developing bounding estimates for all pathways is instructive and will be easier to defend.

5.3.4.2. Refining the Estimates of Exposure and Dose

For those pathways not eliminated by bounding estimates or judged trivial, the assessor will then evaluate the resulting exposure or dose. At this point, the assessor will make estimates of exposure or dose that are designed to fall on the actual distribution. The important point here is that unlike a bounding estimate, these estimates of exposure or dose should focus on points in the actual distribution. Both estimates of central tendency and estimates of the upper end of the distribution curve are useful in crafting risk descriptors.

Consider Equation 2-6 for the lifetime average daily potential dose ($LADD_{pot}$), an equation often used for linear, nonthreshold carcinogen risk models. The assessor will use the data, ranges of data, distributions of data, and assumptions about each of the factors needed to solve the equation for dose. Generally, both central estimates and high-end estimates are performed. Each of these estimates has uncertainty (perhaps unquantifiable uncertainty), and the better the quality and comprehensiveness of data used as input to the equation, the less uncertainty.

After solving the equation, the assessor will determine whether the uncertainty associated with the answer is sufficiently narrow to allow the risk descriptors to be developed (see section 3.4) and to answer satisfactorily the questions posed in the exposure assessment statement of purpose. Evaluating whether the data, uncertainty, risk descriptors, and answers to the questions are good enough is usually a joint responsibility of the risk assessor and the risk manager.

Should the estimates of exposure or dose have sufficiently narrow uncertainty, the assessor can then proceed to develop the descriptors and finish the assessment. If not, the data or assumptions used usually will have to be refined, if resources allow, in an attempt to bring the estimated exposure or dose closer to what the assessor believes are the actual values in the population. Refining the estimates usually requires that new data be brought into consideration [FN34]; this new ***22921** information can be other studies from the literature, information previously developed for another, related purpose that can be adapted, or new survey, laboratory, or field data. The decision about which particular parts of the information base to refine should be based both on which data will most significantly reduce the uncertainty of the overall exposure or dose estimate, and on which data are in fact obtainable either technologically or within resource constraints.

After refinement of the estimate, the assessor and risk manager again determine whether the estimates provided will be sufficient to answer the questions posed to an acceptable degree, given the uncertainties that may be associated with those estimates. Refinements proceed iteratively until the assessment provides an adequate answer within the resources available.

5.3.5. Using Estimates for Developing Descriptors

Risk assessors and risk managers are encouraged to explore a range of ways to describe exposure and risk information, depending on the purpose of the assessment and the questions for which the risk manager must have answers. Section 2.3 outlines a series of risk descriptors; in the sections below, these are discussed in the context of how an exposure assessor's analysis of the data would lead to various descriptors for risk.

5.3.5.1. Individual Exposure, Dose, and Risk

Questions about individual risk are an important component of any assessment, especially an estimate of the high end of the distribution. Section 5.3.4.1 indicated that bounding estimates are actually a useful but limited form of individual risk estimate, a form which is by definition beyond the highest point on the population distribution. This section deals with estimates that are actually on the distribution of exposure, dose, or risk.

There are several approaches for arriving at an individual risk estimate. Since calculation of risk involves using information from fields other than exposure assessment, the reader is advised to consult other Agency guidelines for more detailed discussions (e.g., U.S. EPA, 1986b, 1986c, 1988b, 1988c, 1991a). The uncertainty in the risk estimate will depend heavily on the quality of the information used. There are several steps in the process:

First, the question of unusual susceptibility of part of the population must be addressed. If equal doses result in widely different responses in two individuals, it may be necessary to consult with scientists familiar with the derivation of the dose-response relationship for the chemical in question in order to ascertain whether this is normal variability among members of a population. Normal variability should have been considered as part of the development of the dose-response relationship; unusual susceptibility may not have been. If such a highly susceptible subgroup can be identified, it is often useful to assess their risk separately from the general population. It will not be common, given the current data availability, to clearly identify such susceptible subgroups. If none can be identified, the default has usually been to assume the dose-response relationship applies to all members of the population being assessed. Where no information shows the contrary, this assumption may be used provided it is highlighted as a source of uncertainty.

Second, after the population or population segment can be represented by a single dose-response relationship, the appropriate dose for use in the dose-response relationship (absorbed/internal dose, potential dose, applied dose, effective dose) must be identified. For dose-response relationships based on administered dose in animal studies, potential dose will usually be the

human analogue. If the dose-response relationship is based on internal dose, then that is the most appropriate human dose. If the estimates of exposure and dose from the exposure assessment are in an inappropriate form (say, potential dose rather than internal dose), they must be converted before they are used for risk calculations. This may involve analysis of bioavailability, absorption rates as a function of form of the chemical and route, etc. If these data are not available, the default has been to assume the entire potential dose becomes the internal dose.[FN35] As more data become available concerning absorption for different chemicals, this conservative assumption may not always be the best, or even a credible, default. Whatever assumption is made concerning absorption (or the relationships among any of the different dose terms if used, for that matter), it should be highlighted in the uncertainty section.

Once the first two steps have been done, and the dose-response relationship and type of dose have been identified, the exposure and dose information needs to be put in the appropriate form. Ideally, this would be a distribution of doses of the appropriate type across the population or population subgroup of interest. This may involve converting exposures into potential doses or converting potential doses into internal, delivered, or biologically effective doses. Once this is accomplished, the high-end estimate of dose will often (but not always) lead fairly directly to the high-end estimate of risk. The method used to develop the high-end estimate for dose depends on the data available. Because of the skewed nature of exposure data, there is no exact formula that will guarantee an estimate will fall into this range in the actual population if only sparse data are available.

The high-end risk is a plausible estimate of the individual risk for those persons at the upper end of the risk distribution. The intent of this descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, high-end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk. This descriptor is intended to estimate the risks that are expected to occur in small but definable high-end segments of the subject population. The use of “above the 90th percentile” in the definition is not meant to precisely define the range of this descriptor, but rather to clarify what is meant conceptually by high end.

The high-end segments of the exposure, dose, and risk populations may represent different individuals. Since the location of individuals on the exposure, dose, and risk distributions may vary depending on the distributions of bioavailability, absorption, intake rates, susceptability, and other variables, a high exposure does not necessarily result in a high dose or risk, although logically one would expect a moderate to highly positive correlation among exposure, dose, and risk.

When the complete data on the population distributions of exposures and doses are available, and the significance of the factors above (bioavailability, etc.) are known to the ***22922** extent to allow a risk distribution to be constructed, the highend risk estimate can be represented by reporting risks at selected percentiles of the distributions, such as the 90th, 95th, or 98th percentile. When the complete distributions are not available, the assessor should conceptually target something above the 90th percentile on the actual distribution.

In developing estimates of high-end individual exposure and dose, the following conditions must be met:

- The estimated exposure or dose is on the expected distribution, not above the value one would expect for the person with the highest estimated risk in the population. This means that when constructing this estimate from a series of factors (environmental concentrations, intake rates, individual activities, etc.), not all factors should be set to values that maximize exposure or dose, since this will almost always lead to an estimate that is much too conservative.

- The combination of values assigned to the exposure and dose factors can be expected to be found in the actual population. In estimating high-end exposures or doses for future use or post-control scenarios, the criterion to be used should be that it is expected to be on the distribution provided the future use or control measure occurs.[FN36]

Some of the alternative methods for determining a high-end estimate of dose are:

- If sufficient data on the distribution of doses are available, take the value directly for the percentile(s) of interest within the high end. If possible, the actual percentile(s) should be stated, or the number of persons determined in the high end above the estimate, in order to give the risk manager an idea of where within the high end-range the estimate falls.

- If data on the distribution of doses are not available, but data on the parameters used to calculate the dose are available, a simulation (such as an exposure model or Monte Carlo simulation) can sometimes be made of the distribution. In this case, the assessor may take the estimate from the simulated distribution. As in the method above, the risk manager should be told where in the high-end range the estimate falls by stating the percentile or the number of persons above this estimate.

The assessor and risk manager should be cautioned that unless a great deal is known about exposures or doses at the high end of the distribution, simulated distributions may not be able to differentiate between bounding estimates and high-end estimates. Simulations often include low-probability estimates at the upper end that are higher than those actually experienced in a given population, due to improbability of finding these exposures or doses in a specific population of limited size, or due to nonobvious correlations among parameters at the high ends of their ranges.[FN37] Using the highest estimate from a Monte Carlo simulation may therefore overestimate the exposure or dose for a specific population, and it is advisable to use values somewhat less than the highest Monte Carlo estimated value if one is to defend the estimate as being within the actual population distribution and not above it.

Simulations using finite ranges for parameters will result in a simulated distribution with a calculable finite maximum exposure, and the maximum exposures calculated in repeated simulations will not exceed this theoretical maximum.[FN38] When unbounded default distributions, such as lognormal distributions, are used for input parameters to generate the simulated exposure distributions, there will not be a finite maximum exposure limit for the simulation, so the maximum value of the resulting simulated distribution will vary with repeated simulations. The EPA's Science Advisory Board (SAB) (U.S. EPA, 1992a) has recommended that values above a certain percentile in these simulations be treated as if they were bounding estimates, not estimates of high-end exposures (see Figure 5-1). The SAB noted that for large populations, simulated exposures, doses, and risks above the 99.9th percentile may not be meaningful when unbounded lognormal distributions are used as a default.

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

***22923** Although the Agency has not specifically set policy on this matter, exposure assessors should observe the following caution when using simulated distributions. The actual percentile cutoff above which a simulation should be considered a bounding estimate may be expected to vary depending on the size of the population. Since bounding estimates are established to develop statements that exposures, doses, and risks are “not greater than . . .,” it is prudent that the percentile cutoff bound expected exposures for the size of the population being evaluated. For example, if there are 100 persons in the population, it may be prudent to consider simulated exposures above the 1 in 500 level or 1 in 1000 level (i.e., above the 99.5^{th} or 99.9^{th} percentile, respectively) to be bounding estimates. Due to uncertainties in simulated distributions, assessors should be cautious about using estimates above the 99.9^{th} percentile for estimates of high-end exposure regardless of the size of the population. The Agency or individual program offices may issue more direct policy for setting the exact cutoff value for use as high-end and bounding estimates in simulations.

- If some information on the distribution of the variables making up the exposure or dose equation (e.g., concentration, exposure duration, intake or uptake rates) is available, the assessor may estimate a value which falls into the high end by meeting the defining criteria of “high end”: An estimate that will be within the distribution, but high enough so that less than 1 out of 10 in the distribution will be as high. The assessor often constructs such an estimate by using maximum or near-maximum values for one or more of the most sensitive ***22924** variables, leaving others at their mean values. [FN39] The exact method used to calculate the estimate of high-end exposure or dose is not critical; it is very important that the exposure assessor explain why the estimate, in his or her opinion, falls into the appropriate range, not above or below it.

- If almost no data are available, it will be difficult, if not impossible, to estimate exposures or doses in the high end. One method that has been used, especially in screening-level assessments, is to start with a bounding estimate and back off the limits used until the combination of parameter values is, in the judgment of the assessor, clearly in the distribution of exposure or dose. Obviously, this method results in a large uncertainty. The availability of pertinent data will determine how easily and defensibly the high-end estimate can be developed by simply adjusting or backing off from the ultra conservative assumptions used in the bounding estimates. This estimate must still meet the defining criteria of "high end," and the assessor should be ready to explain why the estimate is thought to meet the defining criteria.

A descriptor of central tendency may be either the arithmetic mean risk (average estimate) or the median risk (median estimate), but should be clearly labeled as such. Where both the arithmetic mean and the median are available, but differ substantially, it is helpful to present both.

Exposure and dose profiles often fall in a skewed distribution that many times appears to be approximately lognormally distributed, although statistical tests for lognormality may fail. The arithmetic mean and the median are the same in a normal distribution, but exposure data are rarely normally distributed. As the typical skewness in the distribution increases, the exposure or dose distribution comes to resemble a lognormal curve where the arithmetic mean will be higher than the median. It is not unusual for the arithmetic mean to be located at the 75^{th} percentile of the distribution or higher. Thus, the arithmetic mean is not necessarily a good indicator of the midpoint (median, 50_{th} percentile) of a distribution.

The average estimate, used to describe the arithmetic mean, can be approximated by using average values for all the factors making up the exposure or dose equation. It does not necessarily represent a particular individual on the distribution, but will fall within the range of the actual distribution. Historically, this calculation has been referred to as the average case, but as with other ad hoc descriptors, definitions have varied widely in individual assessments.

When the data are highly skewed, it is sometimes instructive to approximate the median exposure or dose, or median estimate. This is usually done by calculating the geometric mean of the exposure or dose distribution, and historically this has often been referred to as the typical case, although again, definitions have varied widely. Both the average estimate and median estimate are measures of the central tendency of the exposure or dose distribution, but they must be clearly differentiated when presenting the results.

It will often be useful to provide additional specific individual risk information to provide perspective for the risk manager. This specific information may take the form of answers to what if questions, such as, what if a consumer should use this product without adequate ventilation? For the risk manager, these questions are likely to put bounds on various aspects of the risk question. For the assessor, these are much less complicated problems than trying to estimate baseline exposure or dose in an actual population, since the answers to these questions involve choosing values for various parameters in the exposure or risk equations and solving them for the estimate.

This type of risk descriptor is a calculation of risk to specific hypothetical or actual combinations of factors postulated within the exposure assessment. It is often valuable to ask and answer specific questions of the "what if" nature to add perspective to the risk assessment.

Each assessment may have none, one, or several of these specific types of descriptors. The answers to these questions might be a point estimate or a range, but are usually fairly simple to calculate. The answers to these types of postulated questions, however, do not directly give information about how likely that combination of values might be in the actual population, so there are some limits to the applicability of these descriptors.

5.3.5.2. Population Exposure, Dose, and Risk

Questions about population exposure, dose, and risk are central to any risk assessment. Ideally, given the time and methods, the assessor might strive to construct a picture of exposure, dose, and risk in which each individual exposure, dose and risk is known. These data could then be displayed in a frequency distribution.

The risk manager, perhaps considering what action might be necessary for this particular situation, might ask how many cases of the particular effect might be probabilistically estimated in a population during a specific time period, or what percentage of the population is (or how many people are) above a certain exposure, dose, or risk level.

For those who do the assessments, answering these questions requires some knowledge of the population frequency distribution. This information can be obtained or estimated in several ways, leading to two descriptors of population risk.

The first is the probabilistic number of health effect cases estimated in the population of interest over a specified time period. This descriptor can be obtained either by summing the individual risks over all the individuals in the population, or by multiplying the slope factor obtained from a carcinogen dose-response relationship, the arithmetic mean of the dose, and the size of the population. The latter approach may be used only if the risk model assumes a single linear, nonthreshold response to dose, and then only with some caution.[FN40] If risk varies ***22925** linearly with dose, knowing the arithmetic mean risk and the population size can lead to an estimate of the extent of harm for the population as a whole, excluding sensitive subgroups for which a different dose-response curve may need to be used. For noncarcinogens, or for nonlinear, nonthreshold carcinogen models, using the arithmetic mean exposure or dose, multiplying by a slope factor to calculate an average risk, and multiplying by the population size is not appropriate, and risks should be summed over individuals.[FN41]

Obviously, the more relevant information one has, the less uncertain this descriptor, but in any case, the estimate used to develop the descriptor is also limited by the inherent uncertainties in risk assessment methodology, e.g., the risk estimates often being upper confidence level bounds. With the current state of the science, this descriptor should not be confused with an actuarial prediction of cases in the population (which is a statistical prediction based on a great deal of empirical data).

The second type of population risk descriptor is an estimate of the percentage of the population, or the number of persons, above a specified level of risk, RfD, RfC, LOAEL, or other specific level of interest. This descriptor must be obtained by measuring or simulating the population distribution, which can be done in several ways.

First, if the population being studied is small enough, it may be possible to measure the distribution of exposure or dose. Usually, this approach can be moderately to highly costly, but it may be the most accurate. Possible problems with this approach are lack of measuring techniques for the chemical of interest, the availability of a suitable population subset to monitor, and the problem of extrapolating short-term measurements to long-term exposures.

Second, the distribution itself may be simulated from a model such as an exposure model (a model that reports exposures or doses by linking concentrations with contact times for subsets of the population, such as those living various distances from a source) or a Monte Carlo simulation. Although this may be considerably less costly than measurements, it will probably be less accurate, especially near the high end of the distribution. Although models and statistical simulations can be fairly accurate if the proper input data are available, these data are often difficult to obtain and assumptions must be made; use of assumptions may reduce the certainty of the estimated results.

Third, it may be possible to estimate how many people are above a certain exposure, dose, or risk level by identifying and enumerating certain population segments known to be at higher exposure, dose, sensitivity, or risk than the level of interest.

For those who use the assessments, this descriptor can be used in the evaluation of options if a level can be identified as an exposure, dose, or risk level of concern. The options can then be evaluated by estimating how many persons would go from the higher category to the lower category after the option is implemented.

Questions about the distribution of exposure, dose, and risk often require the use of additional risk descriptors. In considering the risks posed by the particular situation being evaluated, a risk manager might want to know how various subgroups fall within the distribution, and if there are any particular subgroups at disproportionately high risk.

It is often helpful for the risk assessor to describe risk by an identification, and if possible, characterization and quantification of the magnitude of the risk for specific highly exposed subgroups within the population. This descriptor is useful when there is (or is expected to be) a subgroup experiencing significantly different exposures or doses from that of the larger population.

It is also helpful to describe risk by an identification, and if possible, characterization and quantification of the magnitude of risk for specific highly sensitive or highly susceptible subgroups within the population. This descriptor is useful when the sensitivity or susceptibility to the effect for specific subgroups within the population is (or is expected to be) significantly different from that of the larger population. In order to calculate risk for these subgroups, it will sometimes be necessary to use a different dose-response relationship.

Generally, selection of the subgroups or population segments is a matter of either a priori interest in the subgroup, in which case the risk manager and risk assessor can jointly agree on which subgroups to highlight, or a matter of discovery of a subgroup during the assessment process. In either case, the subgroup can be treated as a population in itself and characterized the same way as the larger population using the descriptors for population and individual risk.

Exposures and doses for highly-exposed subpopulations can be calculated by defining the population segment as a population, then estimating the doses as for a population. The assessor must make it clear exactly which population was considered.

A special case of a subpopulation is that of children. For exposures that take place during childhood, when low body weight results in a higher dose rate than would be calculated using the $LADD_{pot}$ (Equation 2-6), it is appropriate to average the dose rate (intake rate/body weight) rather than dose. The $LADD_{pot}$ equation then becomes

where $LADD_{pot}$ is the lifetime average daily potential dose, ED_i is the exposure duration (time over which the contact actually takes place), $C\#8_i$ is the average exposure concentration during period of calendar time ED_i, IR_i is the average ingestion or inhalation rate during ED_i, BW_i is body weight during exposure duration ED_i, and LT is the averaging time, in this case, a lifetime (converted to days). This form of the $LADD_{pot}$ equation, if applied to an exposure that occurs primarily in childhood (for example, inadvertent soil ingestion), may result in an $LADD_{pot}$ calculation somewhat higher than that obtained by using Equation 2-6, but there is some evidence that it is more defensible (Kodell et al., 1987; additional discussion in memorandum from Hugh McKinnon, EPA, to Michael Callahan, EPA, November 9, 1990).

6. Assessing Uncertainty

Assessing uncertainty may involve simple or very sophisticated techniques, depending on the requirements of the assessment. Uncertainty characterization and uncertainty assessment are two activities that lead to different degrees of sophistication in describing uncertainty. Uncertainty characterization generally involves a qualitative discussion of the thought processes that lead to the selection and rejection of specific data, estimates, scenarios, etc. For simple exposure assessments, where not much quantitative information is available, uncertainty characterization may be all that is necessary.

The uncertainty assessment is more quantitative. The process begins with simpler measures (i.e., ranges) and simpler analytical techniques (i.e., sensitivity analysis), and progresses, to the extent needed to support the decision for which the exposure ***22926** assessment is conducted, to more complex measures and techniques. The development and implementation of an appropriate uncertainty assessment strategy can be viewed as a decision process. Decisions are made about ways to characterize and analyze uncertainties, and whether to proceed to increasingly more complex levels of uncertainty assessment.

6.1. Role of Uncertainty Analysis in Exposure Assessment

Exposure assessment uses a wide array of information sources and techniques. Even where actual exposure-related measurements exist, assumptions or inferences will still be required (see section 5.2). Most likely, data will not be available for all aspects of the exposure assessment and those data that are available may be of questionable or unknown quality. In these situations, the exposure assessor will have to rely on a combination of professional judgment, inferences based on analogy with similar chemicals and conditions, estimation techniques, and the like. The net result is that the exposure assessment will be based on a number of assumptions with varying degrees of uncertainty.

The decision analysis literature has focused on the importance of explicitly incorporating and quantifying scientific uncertainty in risk assessments (Morgan, 1983; Finkel, 1990). Reasons for addressing uncertainties in exposure assessments include:

- Uncertain information from different sources of different quality must be combined.

- A decision must be made about whether and how to expend resources to acquire additional information (e.g., production, use, and emissions data; environmental fate information; monitoring data; population data) to reduce the uncertainty.

- There is considerable empirical evidence that biases may result in so-called best estimates that are not actually very accurate. Even if all that is needed is a best-estimate answer, the quality of that answer may be improved by an analysis that incorporates a frank discussion of uncertainty.

- Exposure assessment is an iterative process. The search for an adequate and robust methodology to handle the problem at hand may proceed more effectively, and to a more certain conclusion, if the associated uncertainty is explicitly included and can be used as a guide in the process of refinement.

- A decision is rarely made on the basis of a single piece of analysis. Further, it is rare for there to be one discrete decision; a process of multiple decisions spread over time is the more common occurrence. Chemicals of concern may go through several levels of risk assessment before a final decision is made. Within this process, decisions may be made based on exposure considerations. An exposure analysis that attempts to characterize the associated uncertainty allows the user or decision-maker to better evaluate it in the context of the other factors being considered.

- Exposure assessors have a responsibility to present not just numbers but also a clear and explicit explanation of the implications and limitations of their analyses. Uncertainty characterization helps carry out this responsibility.

Essentially, the construction of scientifically sound exposure assessments and the analysis of uncertainty go hand in hand. The reward for analyzing uncertainties is knowing that the results have integrity or that significant gaps exist in available information that can make decision-making a tenuous process.

6.2. Types of Uncertainty

Uncertainty in exposure assessment can be classified into three broad categories:

1. Uncertainty regarding missing or incomplete information needed to fully define the exposure and dose (scenario uncertainty).

2. Uncertainty regarding some parameter (parameter uncertainty).

3. Uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (model uncertainty).

Identification of the sources of uncertainty in an exposure assessment is the first step toward eventually determining the type of action necessary to reduce that uncertainty. The three types of uncertainty mentioned above can be further defined by examining some principal causes for each.

Exposure assessments often are developed in a phased approach. The initial phase usually involves some type of broad-based screening in which the scenarios that are not expected to pose a risk to the receptor are eliminated from a more detailed, resource-intensive review, usually through developing bounding estimates. These screening-level scenarios often are constructed to represent exposures that would fall beyond the extreme upper end of the expected exposure distribution. Because the screening-level assessments for these nonproblem scenarios usually are included in the final exposure assessment document, this final document may contain scenarios that differ quite markedly in level of sophistication, quality of data, and amenability to quantitative expressions of uncertainty. These also can apply to the input parameters used to construct detailed exposure scenarios.

The following sections will discuss sources, characterization, and methods for analyzing the different types of uncertainty.

6.2.1. Scenario Uncertainty

The sources of scenario uncertainty include descriptive errors, aggregation errors, errors in professional judgment, and incomplete analysis.

Descriptive errors include errors in information, such as the current producers of the chemical and its industrial, commercial, and consumer uses. Information of this type is the foundation for the eventual development of exposure pathways, scenarios, exposed populations, and exposure estimates.

Aggregation errors arise as a result of lumping approximations. Included among these are assumptions of homogeneous populations, and spatial and temporal approximations such as assumptions of steady-state conditions.

Professional judgment comes into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposure scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc. Errors in professional judgment also are a source of uncertainty.

A potentially serious source of uncertainty in exposure assessments arises from incomplete analysis. For example, the exposure assessor may overlook an important consumer exposure due to lack of information regarding the use of a chemical in a particular product. Although this source of uncertainty is essentially unquantifiable, it should not be overlooked by the assessor. At a minimum, the rationale for excluding particular exposure scenarios should be described and the uncertainty in those decisions should be characterized as high, medium, or low. The exposure assessor should discuss whether these decisions were based on actual data, analogues, or professional judgment. For situations in which the uncertainty is high, one should perform a reality check where credible upper limits on the exposure are established by a “what if” analysis.

Characterization of the uncertainty associated with nonnumeric assumptions (often relating to setting the assessment's direction and scope) will ***22827** generally involve a qualitative discussion of the rationale used in selecting specific scenarios. The discussion should allow the reader to make an independent judgment about the validity of the conclusions reached by the assessor by describing the uncertainty associated with any inferences, extrapolations, and analogies used and the weight of evidence that led the assessor to particular conclusions.

6.2.2. Parameter Uncertainty

Sources of parameter uncertainty include measurement errors, sampling errors, variability, and use of generic or surrogate data.

Measurement errors can be random or systematic. Random error results from imprecision in the measurement process. Systematic error is a bias or tendency away from the true value.

Sampling errors concern sample representativeness. The purpose of sampling is to make an inference about the nature of the whole from a measurement of a subset of the total population. If the exposure assessment uses data that were generated for another purpose, for example, consumer product preference surveys or compliance monitoring surveys, uncertainty will arise if the data do not represent the exposure scenario being analyzed.

The inability to characterize the inherent variability in environmental and exposure-related parameters is a major source of uncertainty. For example, meteorological and hydrological conditions may vary seasonally at a given location, soil conditions can have large spatial variability, and human activity patterns can vary substantially depending on age, sex, and geographical location.

The use of generic or surrogate data is common when site-specific data are not available. Examples include standard emission factors for industrial processes, generalized descriptions of environmental settings, and data pertaining to structurally related chemicals as surrogates for the chemical of interest. This is an additional source of uncertainty, and should be avoided if actual data can be obtained.

The approach to characterizing uncertainty in parameter values will vary. It can involve an order-of-magnitude bounding of the parameter range when uncertainty is high, or a description of the range for each of the parameters including the lower- and upper-bound and the best estimate values and justification for these based on available data or professional judgment. In some circumstances, characterization can take the form of a probabilistic description of the parameter range. The appropriate characterization will depend on several factors, including whether a sensitivity analysis indicates that the results are significantly affected by variations within the range. When the results are significantly affected by a particular parameter, the exposure assessor should attempt to reduce the uncertainty by developing a description of the likely occurrence of particular values within the range. If enough data are available, standard statistical methods can be used to obtain a meaningful representation. If available data are inadequate, then expert judgments can be used to develop a subjective probabilistic representation. Expert judgments should be developed in a consistent, well-documented manner. Examples of techniques to solicit expert judgments have been described (Morgan et al., 1979; Morgan et al., 1984; Rish, 1988).

Most approaches for analyzing uncertainty have focused on techniques that examine how uncertainty in parameter values translates into overall uncertainty in the assessment. Several published reports (Cox and Baybutt, 1981; U.S. EPA, 1985f; Inman and Helton, 1988; Seller, 1987; Rish and Marnicio, 1988) have reviewed the many techniques available; the assessor should consult these for details. In general, these approaches can be described, in order of increasing complexity and data requirements, as either sensitivity analysis, analytical uncertainty propagation, probabilistic uncertainty analysis, or classical statistical methods.

Sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. The procedure involves fixing each uncertain quantity, one at a time, at its credible lower-bound and then its upper-bound (holding all others at their medians), and then computing the outcomes for each combination of values. These results are useful to identify the variables that have the greatest effect on exposure and to help focus further information gathering. The results do not provide any information about the probability of a quantity's value being at any level within the range; therefore, this approach is most useful at the screening level when deciding about the need and direction of further analyses.

Analytical uncertainty propagation involves examining how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment. Intuitively, it seems clear that uncertainty in a specific parameter may propagate very differently through a model than another variable having approximately the same uncertainty. Some parameters are more important than others, and the model structure is designed to account for the relative sensitivity. Thus, uncertainty propagation is a function of both the data and the model structure. Accordingly, both model sensitivity and input variances are evaluated in this procedure.

Application of this approach to exposure assessment requires explicit mathematical expressions of exposure, estimates of the variances for each of the variables of interest, and the ability either analytically or numerically to obtain a mathematical derivative of the exposure equation.

Although uncertainty propagation is a powerful tool, it should be applied with caution, and the assessor should consider several points. It is difficult to generate and solve the equations for the sensitivity coefficients. In addition, the technique is most accurate for linear equations, so any departure from linearity must be carefully evaluated. Assumptions, such as independence of variables and normality of errors in the variables, need to be checked. Finally, this approach requires estimates of parameter variance, and the information to support these may not be readily available.

Probabilistic uncertainty analysis is generally considered the next level of refinement. The most common example is the Monte Carlo technique where probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values results that reflects the overall uncertainty in the inputs to the calculation.

The principal advantage of the Monte Carlo method is its very general applicability. There is no restriction on the form of the input distributions or the nature of the relationship between input and output; computations are also straightforward. There are some disadvantages as well as inconveniences, however. The exposure assessor should only consider using this technique when there are credible distribution data (or ranges) for most key variables. Even if these distributions are known, it may not be necessary to apply this technique. For example, if only average exposure values are needed, these can often be computed as accurately by using average values for each of the input parameters. Another ***22928** inconvenience is that the sensitivity of the results to the input distributions is somewhat cumbersome to assess. Changing the distribution of only one value requires rerunning the entire calculation (typically, several hundreds or thousands of times). Finally, Monte Carlo results do not tell the assessor which variables are the most important contributors to output uncertainty. This is a disadvantage since most analyses of uncertainty are performed to find effective ways to reduce uncertainty.

Classical statistical methods can be used to analyze uncertainty in measured exposures. Given a data set of measured exposure values for a series of individuals, the population distribution may be estimated directly, provided that the sample design was developed properly to capture a representative sample. The measured exposure values also may be used to directly compute confidence interval estimates for percentiles of the exposure distribution (American Chemical Society, 1988). When the exposure distribution is estimated from measured exposures for a probability sample of population members, confidence interval estimates for percentiles of the exposure distribution are the primary uncertainty characterization. Data collection survey design should also be discussed, as well as accuracy and precision of the measurement techniques.

Often the observed exposure distribution is skewed; many sample members have exposure distributions at or below the detection limit. In this situation, estimates of the exposure distribution may require a very large sample size. Fitting the data to a distribution type can be problematic in this situation because data are usually scant in the low probability areas (the tails) where numerical values vary widely. As a consequence, for data sets for which the sampling has been completed, means and standard deviations may be determined to a good approximation, but characterization of the tails of the distribution will have much greater uncertainty. This difference should be brought out in the discussion. For data sets for which sampling is still practical, stratification of the statistical population to oversample the tail may give more precision and confidence in the information in the tail area of the distribution.

6.2.3. Model Uncertainty

At a minimum, the exposure assessor should describe in qualitative terms the rationale for selection of any conceptual and mathematical models. This discussion should address the status of these approaches and any plausible alternatives in terms of their acceptance by the scientific community, how well the model(s) represents the situation being assessed, e.g., high end estimate, and to what extent verification and validation have been done. Relationship errors and modeling errors are the primary sources of modeling uncertainty.

Relationship errors include errors in correlations between chemical properties, structure-reactivity correlations, and environmental fate models. In choosing to use these tools, the exposure assessor must decide among the many possible functional forms available. Even though statistics on the performance of the methodology for a given test set of chemicals may be available and can help guide in the selection process, the exposure assessor must decide on the most appropriate methodology for the chemical of interest based on the goals of the assessment.

Modeling errors are due to models being simplified representations of reality, for example approximating a three-dimensional aquifer with a two-dimensional mathematical model. Even after the exposure assessor has selected the most appropriate model for the purpose at hand, one is still faced with the question of how well the model represents the real situation. This question is compounded by the overlap between modeling uncertainties and other uncertainties, e.g., natural variability in environmental inputs, representativeness of the modeling scenario, and aggregation errors. The dilemma facing exposure assessors is that many existing models (particularly the very complex ones) and the hypotheses contained within them cannot be fully tested (Beck, 1987), although certain components of the model may be tested. Even when a model has been validated under a particular set of conditions, uncertainty will exist in its application to situations beyond the test system.

A variety of approaches can be used to quantitatively characterize the uncertainty associated with model constructs. One approach is to use different modeling formulations (including the preferred and plausible alternatives) and consider the range of the outputs to be representative of the uncertainty range. This strategy is most useful when no clear best approach can be identified due to the lack of supporting data or when the situations being assessed require extrapolation beyond the conditions for which the models were originally designed.

Where the data base is sufficient, the exposure assessor should characterize the uncertainty in the selected model by describing the validation and verification efforts. Validation is the process of examining the performance of the model compared to actual observations under situations representative of those being assessed. Approaches for model validation have been discussed (U.S. EPA 1985e). Verification is the process of confirming that the model computer code is producing the proper numerical output. In most situations, only partial validation is possible due to data deficiencies or model complexity.

6.3. Variability Within a Population Versus Uncertainty in the Estimate

For clarity, it should be emphasized that variability (the receipt of different levels of exposure by different individuals) is being distinguished from uncertainty (the lack of knowledge about the correct value for a specific exposure measure or estimate). Most of the exposure and risk descriptors discussed in this report deal with variability directly, but estimates must also be made of the uncertainty of these descriptors. [FN42] This may be done qualitatively or quantitatively, and it is beyond the scope of this report to discuss the mechanics of uncertainty analysis in detail. It is an important distinction, however, since the risk assessor and risk manager need to know if the numbers being reported for exposures take variability, uncertainty, or both, into consideration.

Not all approaches historically used to construct measures or estimates of exposure attempted to distinguish variability and uncertainty. In particular, in many cases in which estimates were termed worst case, focusing on the high end of the exposed population and also selection of high-end values for uncertain physical quantities resulted in values that were seen to be quite conservative. By using both the high-end individuals (variability) and upper confidence bounds[FN43] on data or physical parameters ***22929** (uncertainty), these estimates might be interpreted as “not exceeding an upper bound on exposures received by certain high-end individuals.”

Note that this approach will provide an estimate that considers both variability and uncertainty, but by only reporting the upper confidence bound, it appears to be merely a more conservative estimate of the variability. High end estimates which include consideration of uncertainty should be presented with both the upper and lower uncertainty bounds on the high end estimate. This provides the necessary information to the risk manager. Without specific discussion of what was done, risk managers may view the results as not having dealt with uncertainty. It is fundamental to exposure assessment that assessors have a clear

distinction between the variability of exposures received by individuals in a population, and the uncertainty of the data and physical parameters used in calculating exposure.

The discussion of estimating exposure and dose presented in Section 5.3.4 addresses the rationale and approaches for constructing a range of measures or estimates of exposure, with emphasis on how these can be used for exposure or risk characterization. The distinction between these measures or estimates (e.g., average versus high end) is often a difference in anticipated variability in the exposures received by individuals (i.e., average exposure integrates exposures across all individuals, while high-end exposure focuses on the upper percentiles of the exposed group being assessed.) Although several measures can be used to characterize risk in different ways, this does not address which of these measures or characterizations is used for decisions. The selection of the point or measure of exposure or risk upon which regulatory decisions are made is a risk management decision governed by programmatic policy, and is therefore beyond the scope of these guidelines.

7. Presenting the Results of the Exposure Assessment

One of the most important aspects of the exposure assessment is presenting the results. It is here that the assessment ultimately succeeds or fails in meeting the objectives laid out in the planning as discussed in section 3. This section discusses communication of the results, format considerations, and suggested tips for reviewing exposure assessments either as a final check or as a review of work done by others.

7.1. Communicating the Results of the Assessment

Communicating the results of an exposure assessment is more than a simple summary of conclusions and quantitative estimates for the various pathways and routes of exposure. The most important part of an exposure assessment is the overall narrative exposure characterization, without which the assessment is merely a collection of data, calculations, and estimates. This exposure characterization should consist of discussion, analysis, and conclusions that synthesize the results from the earlier portions of the document, present a balanced representation of the available data and its relevancy to the health effects of concern, and identify key assumptions and major areas of uncertainty. Section 7.1.1 discusses the exposure characterization, and section 7.1.2 discusses how this is used in the risk characterization step of a risk assessment.

7.1.1. Exposure Characterization

The exposure characterization is the summary explanation of the exposure assessment. In this final step, the exposure characterization:

- Provides a statement of purpose, scope, level of detail, and approach used in the assessment, including key assumptions;

- Presents the estimates of exposure and dose by pathway and route for individuals, population segments, and populations in a manner appropriate for the intended risk characterization;

- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of exposure and dose and the conclusions drawn;

- Interprets the data and results; and

- Communicates results of the exposure assessment to the risk assessor, who can then use the exposure characterization, along with characterizations of the other risk assessment elements, to develop a risk characterization.

As part of the statement of purpose, the exposure characterization explains why the assessment was done and what questions were asked. It also reaches a conclusion as to whether the questions posed were in fact answered, and with what degree

of confidence. It should also note whether the exposure assessment brought to light additional or perhaps more appropriate questions, if these were answered, and if so, with what degree of confidence.

The statement of scope discusses the geographical or demographic boundaries of the assessment. The specific populations and population segments that were the subjects of the assessment are clearly identified, and the reasons for their selection and any exclusions are discussed. Especially sensitive groups or groups that may experience unusual exposure patterns are highlighted.

The characterization also discusses whether the scope and level of detail of the assessment were ideal for answering the questions of the assessment and whether limitations in scope and level of detail were made because of technical, practical, or financial reasons, and the implications of these limitations on the quality of the conclusions.

The methods used to quantify exposure and dose are clearly stated in the exposure characterization. If models are used, the basis for their selection and validation status is described. If measurement data are used, the quality of the data is discussed. The strengths and weaknesses of the particular methods used to quantify exposure and dose are described, along with comparison and contrast to alternate methods, if appropriate.

In presenting the exposure and dose estimates, the important sources, pathways, and routes of exposure are identified and quantified, and reasons for excluding any from the assessment are discussed.

A variety of risk descriptors, and where possible, the full population distribution is presented. Risk managers should be given some sense of how exposure is distributed over the population and how variability in population activities influences this distribution. Ideally, the exposure characterization links the purpose of the assessment with specific risk descriptors, which in turn are presented in such a way as to facilitate construction of a risk characterization.

A discussion of the quality of the exposure and dose estimates is critical to the credibility of the assessment. This may be based in part on a quantitative uncertainty analysis, but the exposure characterization must explain the results of any such analysis in terms of the degree of confidence to be placed in the estimates and conclusions drawn.

Finally, a description of additional research and data needed to improve the exposure assessment is often helpful to risk managers in making decisions about improving the quality of the assessment. For this reason, the exposure characterization should identify key data gaps that can help ***22930** focus further efforts to reduce uncertainty.

Additional guidance on communicating the results of an exposure assessment can be found in the proceedings of a recent workshop on risk communication (American Industrial Health Council, 1989).

7.1.2. Risk Characterization

Most exposure assessments will be done as part of a risk assessment, and the exposure characterization must be useful to the risk assessor in constructing a risk characterization. Risk characterization is the integration of information from hazard identification, dose-response assessment, and exposure assessment into a coherent picture. A risk characterization is a necessary part of any Agency report on risk whether the report is a preliminary one prepared to support allocation of resources toward further study or a comprehensive one prepared to support regulatory decisions.

Risk characterization is the culmination of the risk assessment process. In this final step, the risk characterization:

- Integrates the individual characterizations from the hazard identification, dose-response, and exposure assessments;

- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of risk and conclusions drawn;

- Describes risks to individuals and populations in terms of extent and severity of probable harm; and

- Communicates results of the risk assessment to the risk manager.

It provides a scientific interpretation of the assessment. The risk manager can then use the risk assessment, along with other risk management elements, to make public health decisions. The following sections describe these four aspects of the risk characterization in more detail.

7.1.2.1. Integration of Hazard Identification, Dose-Response, and Exposure Assessments

In developing the hazard identification, dose-response, and exposure portions of the risk assessment, the assessor makes many judgments concerning the relevance and appropriateness of data and methodology. These judgments are summarized in the individual characterizations for hazard identification, dose-response, and exposure. In integrating the parts of the assessment, the risk assessor determines if some of these judgments have implications for other parts of the assessment, and whether the parts of the assessment are compatible. For example, if the hazard identification assessment determines that a chemical is a developmental toxicant but not a carcinogen, the dose-response and exposure information is presented accordingly; this differs greatly from the way the presentation is made if the chemical is a carcinogen but not a developmental toxicant.

The risk characterization not only examines these judgments, but also explains the constraints of available data and the state of knowledge about the phenomena studied in making them, including:

- The qualitative, weight-of-evidence conclusions about the likelihood that the chemical may pose a specific hazard (or hazards) to human health, the nature and severity of the observed effects, and by what route(s) these effects are seen to occur. These judgments affect both the dose-response and exposure assessments;

- For noncancer effects, a discussion of the dose-response behavior of the critical effect(s), data such as the shapes and slopes of the dose-response curves for the various other toxic endpoints, and how this information was used to determine the appropriate dose-response assessment technique; and

- The estimates of the magnitude of the exposure, the route, duration and pattern of the exposure, relevant pharmacokinetics, and the number and characteristics of the population exposed. This information must be compatible with both the hazard identification and dose-response assessments.

The presentation of the integrated results of the assessment draws from and highlights key points of the individual characterizations of hazard, dose-response, and exposure analysis performed separately under these Guidelines. The summary integrates these component characterizations into an overall risk characterization.

7.1.2.2. Quality of the Assessment and Degree of Confidence

The risk characterization summarizes the data brought together in the analysis and the reasoning upon which the assessment is based. The description also conveys the major strengths and weaknesses of the assessment that arise from data availability and the current limits of understanding of toxicity mechanisms.

Confidence in the results of a risk assessment is consequently a function of confidence in the results of analysis of each element: hazard, dose-response, and exposure. Each of these three elements has its own characterization associated with it. For example, the exposure assessment component includes an exposure characterization. Within each characterization, the important uncertainties of the analysis and interpretation of data are explained so that the risk manager is given a clear picture of any consensus or lack thereof about significant aspects of the assessment. For example, whenever more than one view of dose-response assessment is supported by the data and by the policies of these Guidelines, and choosing between them is difficult,

the views are presented together. If one has been selected over another, the rationale is given; if not, then both are presented as plausible alternatives.

If a quantitative uncertainty analysis is appropriate, it is summarized in the risk characterization; in any case a qualitative discussion of important uncertainties is appropriate. If other organizations, such as other Federal agencies, have published risk assessments, or prior EPA assessments have been done on the substance or an analogous substance and have relevant similarities or differences, these too are described.

7.1.2.3. Descriptors of Risk

There are a number of different ways to describe risk in quantitative or qualitative terms. Section 2.3 explains how risk descriptors are used. It is important to explain what aspect of the risk is being described, and how the exposure data and estimates are used to develop the particular descriptor.

7.1.2.4. Communicating Results of a Risk Assessment to the Risk Manager

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization, technologic factors, and socioeconomic considerations in reaching a regulatory decision. Because of the way these risk management factors may impact different cases, consistent, but not necessarily identical, risk management decisions must be made on a case-by-case basis. Consequently, it is entirely possible and appropriate that a chemical with a specific risk characterization may be regulated differently under different statutes. These Guidelines are not intended to give guidance on the nonscientific aspects of risk management decisions.

***22931** *7.1.3. Establishing the Communication Strategy*

For assessments that must be explained to the general public, a communication strategy is often required. Although risk communication is often considered a part of risk management, it involves input from the exposure and risk assessors; early planning for a communication strategy can be very helpful to the ultimate risk communication.

The EPA has guidance on preparing communication strategies (U.S. EPA, 1988g). Additional sources of information are the New Jersey Department of Environmental Protection (1988a, 1988b) and the NRC (1989b). These documents, and the sources listed within them, are valuable resources for all who will be involved with the sensitive issues of explaining environmental health risks. The NRC (1989b, p. 148) states:

“It is a mistake to simply consider risk communication to be an add-on activity for either scientific or public affairs staffs; both elements should be involved. There are clear dangers if risk messages are formulated ad hoc by public relations personnel in isolation from available technical expertise; neither can they be prepared by risk analysts as a casual extension of their analytic duties.”

7.2. Format for Exposure Assessment Reports

The Agency does not require a set format for exposure assessment reports, but individual program offices within the Agency may have specific format requirements. Section 3 illustrates that exposure assessments are performed for a variety of purposes, scopes, and levels of detail, and use a variety of approaches. While it is impractical for the Agency to specify an outline format for all types of assessments being performed within the Agency, program offices are encouraged to use consistent formats for similar types of assessments within their own purview.

All exposure assessments must, at a minimum, contain a narrative exposure characterization section that contains the types of information discussed in section 7.1. For the purpose of consistency, this section should be titled exposure characterization.

Placement of this section within the assessment is optional, but it is strongly suggested that it be prominently featured in the assessment. It is not, however, an executive summary and should not be used interchangeably with one.

7.3. Reviewing Exposure Assessments

This section provides some suggestions on how to effectively review an exposure assessment and highlights some of the common pitfalls. The emphasis in these Guidelines has been on how to properly conduct exposure assessments; this section can serve as a final checklist in reviewing the completed assessment. An exposure assessor also may be called upon to critically review and evaluate exposure assessments conducted by others; these suggestions should be helpful in this regard.

Reviewers of exposure assessments are usually asked to identify inconsistences with the underlying science and with Agency-developed guidelines, factors, and methodologies, and to determine the effect these inconsistences might have on the results and conclusions of the exposure assessment. Often the reviewer can only describe whether these inconsistencies or deficiencies might underestimate or overestimate exposure.

Some of the questions a reviewer should ask to identify the more common pitfalls that tend to underestimate exposure are:

Has the pathways analysis been broad enough to avoid overlooking a significant pathway?

For example, in evaluating exposure to soil contaminated with PCBs, the exposure assessment should not be limited only to evaluating the dermal contact pathway. Other pathways, such as inhalation of dust and vapors or the ingestion of contaminated gamefish from an adjacent stream receiving surface runoff containing contaminated soil, should also be evaluated as they could contribute higher levels of exposure from the same source.

Have all the contaminants of concern in a mixture been evaluated?

Since risks resulting from exposures to complex mixtures of chemicals with the same mode of toxic action are generally treated as additive (by summing the risks) in a risk assessment, failure to evaluate one or more of the constituents would neglect its contribution to the total exposure and risk. This is especially critical for relatively toxic or potent chemicals that tend to drive risk estimates even when present in relatively low quantities.

Have exposure levels or concentration measurements been compared with appropriate background levels?

Contaminant concentrations or exposure levels should not be compared with other contaminated media or exposed populations. When comparing with background levels, the exposure assessor must determine whether these concentrations or exposure levels are also affected by contamination from anthropogenic activities.

Were the detection limits sensitive enough to make interpretations about exposures at levels corresponding to health concerns? Were the data interpreted correctly?

Because values reported as not detected (ND) mean only that the chemical of interest was not found at the particular detection limit used in the laboratory analysis, ND does not rule out the possibility that the chemical may be present in significant concentrations. Depending on the purpose and the degree of conservatism warranted in the exposure assessment, results reported as ND should be handled as discussed in Section 5.

Has the possibility of additive pathways been considered for the population being studied?

If the purpose of the exposure assessment is to evaluate the total exposure and risk of a population, then exposures from individual pathways within the same route may be summed in cases which concurrent exposures can realistically be expected to occur.

Some questions a reviewer should ask to avoid the more prevalent errors that generally tend to overestimate exposure are:

Have unrealistically conservative exposure parameters been used in the scenarios?

The exposure assessor must conduct a reality check to ensure that the exposure cases used in the scenario(s) (except bounding estimates) could actually occur.

Have potential exposures been presented as existing exposures?

In many situations, especially when the scenario evaluation approach is used, the objective of the assessment is to estimate potential exposures. (That is, if a person were to be exposed to these chemicals under these conditions, then the resultant exposure would be this much.) In determining the need and urgency for regulatory action, risk managers often weigh actual exposures more heavily than higher levels of potential exposures. Therefore, the exposure assessment should clearly note whether the results represent actual or potential exposures.

Have exposures derived from “not detected” levels been presented as actual exposures?

For some exposure assessments it may be appropriate to assume that a chemical reported as not detected is present at either the detection limit or ***22932** one-half the detection limit. The exposure estimates derived from these nondetects, however, should be clearly labeled as hypothetical since they are based on the conservative assumption that chemicals are present at or below the detection limit, when, in fact, they may not be present at all. Exposures, doses, or risks estimated from data using substituting values of detection limits for “not detected” samples must be reported as “less than” the resulting exposure, dose, or risk estimate.

Questions a reviewer should ask to identify common errors that may underestimate or overestimate exposure are:

Are the results presented with an appropriate number of significant figures?

The number of significant figures should reflect the uncertainty of the numeric estimate. If the likely range of the results spans several orders of magnitude, then using more than one significant figure implies more confidence in the results than is warranted.

Have the calculations been checked for computational errors?

Obviously, calculations should be checked for arithmetic errors and mistakes in converting units. This is overlooked more often than one might expect.

Are the factors for intake rates, etc. used appropriately?

Exposure factors should be checked to ensure that they correspond to the site or situation being evaluated.

Have the uncertainties been adequately addressed?

Exposure assessment is an inexact science, and the confidence in the results may vary tremendously. It is essential the exposure assessment include an uncertainty assessment that places these uncertainties in perspective.

If Monte Carlo simulations were used, were correlations among input distributions known and properly accounted for? Is the maximum value simulated by this method in fact a bounding estimate? Was Monte Carlo simulation necessary?

(A Monte Carlo simulation randomly selects the values from the input parameters to simulate an individual. If data already exist to show the relationship between variables for the actual individuals, it makes little sense to use Monte Carlo simulation, since one already has the answer to the question of how the variables are related for each individual. A simulation is unnecessary.)

8. Glossary of Terms

Absorbed dose—See internal dose.

Absorption barrier—Any of the exchange barriers of the body that allow differential diffusion of various substances across a boundary. Examples of absorption barriers are the skin, lung tissue, and gastrointestinal tract wall.

Accuracy—The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Administered dose—The amount of a substance given to a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation. In exposure assessment, since exposure to chemicals is usually inadvertent, this quantity is called potential dose.

Agent—A chemical, physical, mineralogical, or biological entity that may cause deleterious effects in an organism after the organism is exposed to it.

Ambient—The conditions surrounding a person, sampling location, etc.

Ambient measurement—A measurement (usually of the concentration of a chemical or pollutant) taken in an ambient medium, normally with the intent of relating the measured value to the exposure of an organism that contacts that medium).

Ambient medium—One of the basic categories of material surrounding or contacting an organism, e.g., outdoor air, indoor air, water, or soil, through which chemicals or pollutants can move and reach the organism. (See also biological medium, environmental medium)

Applied dose—The amount of a substance in contact with the primary absorption boundaries of an organism (e.g., skin, lung, gastrointestinal tract) and available for absorption.

Arithmetic mean—The sum of all the measurements in a data set divided by the number of measurements in the data set.

Background level (environmental)—The concentration of substance in a defined control area during a fixed period of time before, during, or after a data-gathering operation.

Breathing zone—A zone of air in the vicinity of an organism from which respired air is drawn. Personal monitors are often used to measure pollutants in the breathing zone.

Bias—A systematic error inherent in a method or caused by some feature of the measurement system.

Bioavailability—The state of being capable of being absorbed and available to interact with the metabolic processes of an organism. Bioavailability is typically a function of chemical properties, physical state of the material to which an organism is exposed, and the ability of the individual organism to physiologically take up the chemical.

Biological marker of exposure (sometimes referred to as a biomarker of exposure)—Exogenous chemicals, their metabolites, or products of interactions between a xenobiotic chemical and some target molecule or cell that is measured in a compartment within an organism.

Biological measurement—A measurement taken in a biological medium. For the purpose of exposure assessment via reconstruction of dose, the measurement is usually of the concentration of a chemical/metabolite or the status of a biomarker, normally with the intent of relating the measured value to the internal dose of a chemical at some time in the past. (Biological measurements are also taken for purposes of monitoring health status and predicting effects of exposure.) (See also ambient measurement)

Biological medium—One of the major categories of material within an organism, e.g., blood, adipose tissue, or breath, through which chemicals can move, be stored, or be biologically, physically, or chemically transformed. (See also ambient medium, environmental medium)

Biologically effective dose—The amount of a deposited or absorbed chemical that reaches the cells or target site where an adverse effect occurs, or where that chemical interacts with a membrane surface.

Blank (blank sample)—An unexposed sampling medium, or an aliquot of the reagents used in an analytical procedure, in the absence of added analyte. The measured value of a blank sample is the blank value.

Body burden—The amount of a particular chemical stored in the body at a particular time, especially a potentially toxic chemical in the body as a result of exposure. Body burdens can be the result of long-term or short-term storage, for example, the amount of a metal in bone, the amount of a lipophilic substance such as PCB in adipose tissue, or the amount of carbon monoxide (as carboxyhemoglobin) in the blood.

Bounding estimate—An estimate of exposure, dose, or risk that is higher than that incurred by the person in the population with the highest exposure, dose, or risk. Bounding estimates are useful in developing statements that exposures, doses, or risks are “not greater than” the estimated value.

Comparability—The ability to describe likenesses and differences in the quality and relevance of two or more data sets.

***22933** Data quality objectives (DQO)—Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Dose—The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose rate—Dose per unit time, for example in mg/day, sometimes also called dosage. Dose rates are often expressed on a per-unit-body-weight basis, yielding units such as mg/kg/day (mg/kg-day). They are also often expressed as averages over some time period, for example a lifetime.

Dose-response assessment—The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Dose-response curve—A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent.

Dose-response relationship—The resulting biological responses in an organ or organism expressed as a function of a series of different doses.

Dosimeter—Instrument to measure dose; many so-called dosimeters actually measure exposure rather than dose.

Dosimetry—Process of measuring or estimating dose.

Ecological exposure—Exposure of a nonhuman receptor or organism to a chemical, or a radiological or biological agent.

Effluent—Waste material being discharged into the environment, either treated or untreated. Effluent generally is used to describe water discharges to the environment, although it can refer to stack emissions or other material flowing into the environment.

Environmental fate—The destiny of a chemical or biological pollutant after release into the environment. Environmental fate involves temporal and spatial considerations of transport, transfer, storage, and transformation.

Environmental fate model—In the context of exposure assessment, any mathematical abstraction of a physical system used to predict the concentration of specific chemicals as a function of space and time subject to transport, intermedia transfer, storage, and degradation in the environment.

Environmental medium—One of the major categories of material found in the physical environment that surrounds or contacts organisms, e.g., surface water, ground water, soil, or air, and through which chemicals or pollutants can move and reach the organisms. (See ambient medium, biological medium)

Exposure— Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of that contact.

Exposure assessment—The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure concentration—The concentration of a chemical in its transport or carrier medium at the point of contact.

Exposure pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Exposure route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Exposure scenario—A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.

Fixed-location monitoring—Sampling of an environmental or ambient medium for pollutant concentration at one location continuously or repeatedly over some length of time.

Geometric mean—The nth root of the product of n values.

Guidelines—Principles and procedures to set basic requirements for general limits of acceptability for assessments.

Hazard identification—A description of the potential health effects attributable to a specific chemical or physical agent. For carcinogen assessments, the hazard identification phase of a risk assessment is also used to determine whether a particular agent or chemical is, or is not, causally linked to cancer in humans.

High-end exposure (dose) estimate—A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure or dose.

High-end Risk Descriptor—A plausible estimate of the individual risk for those persons at the upper end of the risk distribution, conceptually above the 90th percentile but not higher than the individual in the population with the highest risk. Note that persons in the high end of the risk distribution have high risk due to high exposure, high susceptibility, or other reasons, and therefore persons in the high end of the exposure or dose distribution are not necessarily the same individuals as those in the high end of the risk distribution.

Intake—The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation. (See also potential dose)

Internal dose—The amount of a substance penetrating across the absorption barriers (the exchange boundaries) of an organism, via either physical or biological processes. For the purpose of these Guidelines, this term is synonymous with absorbed dose.

Limit of detection (LOD) (or Method detection limit (MDL))—The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

Matrix—A specific type of medium (e.g., surface water, drinking water) in which the analyte of interest may be contained.

Maximally exposed individual (MEI)—The single individual with the highest exposure in a given population (also, most exposed individual). This term has historically been defined various ways, including as defined here and also synonymously with worst case or bounding estimate. Assessors are cautioned to look for contextual ***22934** definitions when encountering this term in the literature.

Maximum exposure range—A semiquantitative term referring to the extreme uppermost portion of the distribution of exposures. For consistency, this term (and the dose or risk analogues) should refer to the portion of the individual exposure distribution that conceptually falls above about the 98th percentile of the distribution, but is not higher than the individual with the highest exposure.

Median value—The value in a measurement data set such that half the measured values are greater and half are less.

Microenvironment method—A method used in predictive exposure assessments to estimate exposures by sequentially assessing exposure for a series of areas (microenvironments) that can be approximated by constant or well-characterized concentrations of a chemical or other agent.

Microenvironments—Well-defined surroundings such as the home, office, automobile, kitchen, store, etc. that can be treated as homogeneous (or well characterized) in the concentrations of a chemical or other agent.

Mode—The value in the data set that occurs most frequently.

Monte Carlo technique—A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population.

Nonparametric statistical methods—Methods that do not assume a functional form with identifiable parameters for the statistical distribution of interest (distribution-free methods).

Pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Personal measurement—A measurement collected from an individual's immediate environment using active or passive devices to collect the samples.

Pharmacokinetics—The study of the time course of absorption, distribution, metabolism, and excretion of a foreign substance (e.g., a drug or pollutant) in an organism's body.

Point-of-contact measurement of exposure—An approach to quantifying exposure by taking measurements of concentration over time at or near the point of contact between the chemical and an organism while the exposure is taking place.

Potential dose—The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.

Precision—A measure of the reproducibility of a measured value under a given set of conditions.

Probability samples—Samples selected from a statistical population such that each sample has a known probability of being selected.

Quality assurance (QA)—An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality control (QC)—The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quantification limit (QL)—The concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99%.

Random samples—Samples selected from a statistical population such that each sample has an equal probability of being selected.

Range—The difference between the largest and smallest values in a measurement data set.

Reasonable worst case—A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case, and assessors are cautioned to look for contextual definitions when encountering this term in the literature. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile. (compare maximum exposure range, worst case).

Reconstruction of dose—An approach to quantifying exposure from internal dose, which is in turn reconstructed after exposure has occurred, from evidence within an organism such as chemical levels in tissues or fluids or from evidence of other biomarkers of exposure.

Representativeness—The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.

Risk—The probability of deleterious health or environmental effects.

Risk characterization—The description of the nature and often the magnitude of human or nonhuman risk, including attendant uncertainty.

Route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sample—A small part of something designed to show the nature or quality of the whole. Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.

Sampling frequency—The time interval between the collection of successive samples.

Sampling plan—A set of rules or procedures specifying how a sample is to be selected and handled.

Scenario evaluation—An approach to quantifying exposure by measurement or estimation of both the amount of a substance contacted, and the frequency/duration of contact, and subsequently linking these together to estimate exposure or dose.

Source characterization measurements—Measurements made to characterize the rate of release of agents into the environment from a source of emission such as an incinerator, landfill, industrial or municipal facility, consumer product, etc.

Standard operating procedure (SOP)—A procedure adopted for repetitive use when performing a specific measurement or sampling operation.

Statistical control—The process by which the variability of measurements or of data outputs of a system is controlled to the extent necessary to produce stable and reproducible results. To say that measurements are under statistical control means that there is statistical evidence that the critical variables in the measurement process are being controlled to such an extent that the system yields data that are reproducible within well-defined limits.

Statistical significance—An inference that the probability is low that the observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves. The inference that an observed difference is statistically significant is typically based on a test to reject one hypothesis and accept another.

Surrogate data—Substitute data or measurements on one substance used to ***22935** estimate analogous or corresponding values of another substance.

Uptake—The process by which a substance crosses an absorption barrier and is absorbed into the body.

Worst case—A semiquantitative term referring to the maximum possible exposure, dose, or risk, that can conceivably occur, whether or not this exposure, dose, or risk actually occurs or is observed in a specific population. Historically, this term has been loosely defined in an ad hoc way in the literature, so assessors are cautioned to look for contextual definitions when encountering this term. It should refer to a hypothetical situation in which everything that can plausibly happen to maximize exposure, dose, or risk does in fact happen. This worst case may occur (or even be observed) in a given population, but since it is usually a very unlikely set of circumstances, in most cases, a worst-case estimate will be somewhat higher than occurs in a specific population. As in other fields, the worst-case scenario is a useful device when low probability events may result in

a catastrophe that must be avoided even at great cost, but in most health risk assessments, a worst-case scenario is essentially a type of bounding estimate.

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Part B: Response to Public and Science Advisory Board Comments

1. Introduction

This section summarizes the major issues raised in public comments on the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") published December 2, 1988 (53 FR 48830-48853). In addition to general comments, reviewers were requested to comment specifically on the guidance for interpreting contaminated blanks versus field data, the interpretation of data at or near the limit of detection, approaches to assessing uncertainty, and the Glossary of Terms. Comment was also invited on the following questions: Should the 1988 Proposed Guidelines be combined with the 1986 Guidelines for Estimating Exposures (hereafter "1986 Guidelines")? Is the current state-of-the-art in making measurements of population activities for the purpose of exposure assessment advanced to the point where the Agency can construct guidelines in this area? Given that EPA Guidelines are not protocols or detailed literature reviews, is the level of detail useful and appropriate, especially in the area of statistics?

The Science Advisory Board (SAB) met on December 2, 1988, and provided written comments in a May, 1989 letter to the EPA Administrator (EPA-SAB-EETFC-89-020). The public comment period extended until March 2, 1989. Comments were received from 17 individuals or organizations.

After the SAB and public comment, Agency staff prepared summaries of the comments and analyses of major issues presented by the commentors. These were considered in the development of these final Guidelines. In response to the comments, the Agency has modified or clarified most of the sections of the Guidelines. For the purposes of this discussion, only the most significant issues reflected by the public and SAB comments are discussed. Several minor recommendations, which do not warrant discussion here, were considered and adopted by the Agency in the revision of these Guidelines.

The EPA revised the 1988 Proposed Guidelines in accordance with the public and SAB comments, retitling them Guidelines for Exposure Assessment (hereafter "Guidelines"). The Agency presented the draft final Guidelines to the SAB at a public meeting on September 12, 1991, at which time the SAB invited public comment for a period of 30 days on the draft. The SAB discussed the final draft in a January 13, 1992 letter to the Administrator of the EPA (EPA-SAB-IAQC-92-015). There were no additional public comments received.

2. Response to General Comments

In general, the reviewers were complementary regarding the overall quality of the 1988 Proposed Guidelines. Several reviewers requested that the ***22938** Agency better define the focus and intended audiences and refine the Guidelines with regard to treatment of nonhuman exposure. The Agency has refined its approach and coverage in these Guidelines. Although these Guidelines deal specifically with human exposures to chemicals, additional supplemental guidance may be developed

for ecological exposures, and exposures to biological or radiological entities. The Agency is currently developing separate guidelines for ecological risk assessment.

Concerns were expressed about the Agency's use of the terms exposure and dose. Consequently, the Agency reviewed its definitions and uses of these terms and evaluated their use elsewhere in the scientific community. The Agency has changed its definitions and uses of these terms from that in both the 1986 Guidelines and the 1988 Proposed Guidelines. It is believed that the definitions contained in the current Guidelines are now in concert with the definitions suggested by the National Academy of Sciences and others in the scientific field.

Many reviewers urged the Agency to be more explicit in its recommendations regarding uncertainty in statistics, limits of detection, censored data sets, and the use of models. Some reviewers felt the level of detail was appropriate for statistical uncertainty while others wanted additional methods for dealing with censored data. Several commended the Agency for its acknowledgement of uncertainty in exposure assessments and the call for its explicit description in all exposure assessments, while others expressed concern for lack of acknowledgement of model uncertainty. Accordingly, these areas have been revised and an entire section has been devoted to uncertainty. We agree with the reviewers that much more work remains to be done in this area, particularly with evaluating overall exposure assessment uncertainty, not only with models but also with the distributions of exposure parameters. The Agency may issue additional guidance in this area in the future.

Some reviewers submitted extensive documentation regarding detection limits and statistical representations. Several submitted comments arguing against data reporting conventions that result in censored data sets and recommended that the Agency issue a guidance document for establishing total system detection limits. The Agency found the documentation to be helpful and has revised the sections of the Guidelines accordingly. Unfortunately, several of the other suggestions go beyond the scope of this document.

The reviewers generally commented that the glossary was useful, presenting many technical terms and defining them in an appropriate manner. The glossary has been expanded to include the key terms used in the Guidelines, while at the same time correcting some definitions that were inconsistent or unclear. In particular, the definitions for exposure and dose have been revised.

3. Response to Comments on the Specific Questions

3.1. Should the 1988 Proposed Guidelines Be combined with the 1986 Guidelines?

The SAB and several other commentors recommended that the 1986 Guidelines and the 1988 Proposed Guidelines be combined into an integrated document. The Agency agrees with this recommendation and has made an effort to produce a single guideline that progresses logically from start to finish. This was accomplished through an extensive reformatting of the two sets of guidelines as an integrated document, rather than a simple joining together of the previous versions.

In integrating the two previous guidelines, the Agency has revised and updated the section in the 1986 Guidelines that suggests an outline for an exposure assessment. A more complete section (section 7 of the current Guidelines) now discusses how assessments should be presented and suggests a series of points to consider in reviewing assessments.

The Agency has also expanded the section in the 1986 Guidelines that discussed exposure scenarios, partly by incorporating material from the 1988 Proposed Guidelines, and partly as a result of comments requesting clarification of the appropriate use of certain types of scenario (e.g., “worst case”). Section 5.3 of the current Guidelines extensively discusses the appropriateness of using various scenarios, estimates, and risk descriptors, and defines certain scenario-related terms for use in exposure assessments.

3.2. Is the Current State-of-the-Art in Making Measurements of Population Activities for the Purpose of Exposure Assessment Advanced to the Point Where the Agency Can Construct Guidelines in This Area?

Both the SAB and public comments recommended the inclusion of demographics, population dynamics, and population activity patterns in the exposure assessment process. In response, the Agency has included additional discussion on use of activity patterns in the current Guidelines, while recognizing that more research has to be done in this area.

3.3. Is the Level of Detail of the Guidelines Useful and Appropriate, Especially in the Area of Statistics?

As might be expected, there was no clear consensus of opinion on what constitutes appropriate coverage. Regarding quality assurance (QA) and quality control (QC), it was felt that a strong statement on the need for QA/QC followed by reference to appropriate EPA documents was a suitable level of detail. Statistical analyses, sampling issues, limit of detection, and other analytical issues all elicited many thoughtful comments. Where the recommendations did not exceed the scope of the document or the role of EPA, the Agency has attempted to blend the various recommendations into the current Guidelines. In all these areas, therefore, the previous sections have been revised in accordance with comments.

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Footnotes

1 A third, less common, scheme is that exposure is contact with any boundary outside or inside of the body, including internal boundaries around organs, etc. This scheme is alluded to, for example, in an article prepared by the National Research Council (NRC, 1985, p. 91). One could then speak of exposure to the whole person or exposure to certain internal organs.

FN2 For example, the amount of food ingested would be a dose under scheme (a) and an exposure under scheme (b). Since the amount ingested in an animal toxicology study is usually termed administered dose, this leads to the use of both exposure and dose for the same quantity under scheme (b). There are several such ambiguities in any of the currently used schemes. Brown (1987) provides a discussion of various units used to describe exposures due to multiple schemes.

3 The National Research Council's 1983 report Risk Assessment in the Federal Government: Managing the Process often addresses the output of an exposure assessment as an exposure or a dose (NRC 1983, pp. 32, 35-36).

4 These guidelines use the term internal dose to refer to the amount of a chemical absorbed across the exchange boundaries, such as the skin, lung, or gastrointestinal tract. The term absorbed dose is often used synonymously for internal dose, although the connotation for the term absorbed dose seems to be more related to a specific boundary (the amount absorbed across a membrane in an experiment, for example), while the term internal dose seems to connote a more general sense of the amount absorbed across one or more specific sites. For the purpose of these guidelines, the term internal dose is used for both connotations. The term internal dose as used here is also consistent with how it is generally applied to a discussion of biomarkers (NRC, 1989a). It is also one of the terms used in epidemiology (NRC, 1985).

5 Ingestion of food or water is an intermittent rather than continuous process, and can be expressed as (amount of medium per event) x (events per unit clock or calendar time) (the frequency of contact); (e.g., 250 mL of water/glass of water ingested x 8 glasses of water ingested/day).

6 Uptake through the lung, gastrointestinal tract, or other internal barriers also can occur following intake through ingestion or inhalation.

7 Contact time (CT) is that part of the exposure duration where C(t) does not equal zero; that is, the actual time periods (events, episodes) during which actual exposure is taking place. The exposure duration as defined here, on the other hand, is a time interval of interest for assessment purposes during which exposure occurs, either continuously or intermittently.

FN8 An exposure pathway is the course a chemical takes from its source to the person being contacted. An exposure route is the particular means of entry into the body, e.g., inhalation, ingestion, or dermal absorption.

9 Potential dose is the potential amount of the chemical that could be absorbed if it were 100% bioavailable. Note, however, that this does not imply that 100% bioavailability or 100% absorption is assumed when using potential dose. The equations and discussion in this chapter use potential dose as a measurable quantity that can then be converted to applied or absorbed dose by the use of the

appropriate factors. Potential dose is a general term referring to any of the exposure routes. The terms respiratory dose, oral dose, or dermal dose are sometimes used to refer to the route-specific potential doses.

10 It is not useful to calculate potential doses in cases where there is partial or total immersion in a fluid such as air or water. In these cases, it is more useful to describe the situation in terms of exposure (concentration of the chemical in the medium times the time of contact) or absorbed dose. For cases such as contact with water in a swimming pool, the person is not really exposed to the entire mass of the chemical that would be described by a potential dose. Nor is it useful to calculate dermal applied doses because the boundary layer is being constantly renewed. The use of alternate ways to calculate a dose that might occur while swimming is discussed in Section 2.1.4.2., in conjunction with Equations 2-7 and 2-8.

11 This may be done by adding a bioavailability factor (range: 0 to 1) to the dose equation. The bioavailability factor would then take into account the ability of the chemical to be extracted from the matrix, absorption through the exchange boundary, and any other losses between ingestion and contact with the lung or gastrointestinal tract. When no data or information are available to indicate otherwise, the bioavailability factor is usually assumed to be 1.

12 Current carcinogen risk models, such as the linearized multistage procedure and other linear nonthreshold models, use lifetime exposures to develop the dose-response relationships, and therefore use lifetime time-weighted average exposures to estimate risks. Within the range of linearity for risk, this procedure effectively treats exposures and doses as a series of “units,” with each unit of dose being equal to any other unit of dose in terms of risk potential without respect to prior exposure or dose patterns. Current research in the field of dose-response modeling is focusing on biologically based dose-response models which may take into account the effects of the exposure or dose patterns, making use of all of the information in an exposure or dose profile. For a more indepth discussion on the implications of the use of time-weighted averages, see Atherley (1985).

13 The assessor should keep in mind that this steady state assumption has been made when using Equation 2-5, and should be able to discuss what effect using average values for C, IR, and ED has on the resulting estimate.

14 This relationship is described by Fick's Law, where $J = K_p \cdot C$ where C represents the steady-state concentration of the chemical, J is the steady-state flux, and K_p is the permeability coefficient.

FN15 The permeability coefficient, K_p, can be experimentally calculated for a chemical and a particular barrier (e.g., skin type) by observing the flux rate in vitro (typical units: mg chemical crossing/sec-cm 2), and dividing it by the concentration of the chemical in the medium in contact with the barrier (typical units: mg chemical/cm ^{3}). This allows the relationship between bulk concentration and the crossing of the chemical itself to be made. K_p has the advantage of being fairly constant over a range of concentrations and can be used for concentrations other than the one used in the experiment. The chemical uptake rate, relating the crossing of the barrier of the chemical itself in terms of the bulk concentration, then becomes C times K_p times the surface area exposed (SA).

16 These three ways are approaches for arriving at a quantitative estimate of exposure. Sometimes the approaches to assessing exposure are described in terms of “direct measures” and “indirect measures” of exposure (e.g., NRC, 1990). Measurements that actually involve sampling on or within a person, for example, use of personal monitors and biomarkers, are termed “direct measures” of exposure. Use of models, microenvironmental measurements, and questionnaires, where measurements do not actually involve personal measurements, are termed “indirect measures” of exposure. The direct/indirect nomenclature focuses on the type of measurements being made; the scenario evaluation/point-of-contact/reconstruction nomenclature focuses on how the data are used to develop the dose estimate. The three-term nomenclature is used in these guidelines to highlight the point that three independent estimates of dose can be developed.

17 Biomarkers can be used to study exposure, effects, or susceptibility. The discussion of biomarkers in these guidelines is limited to their use in indicating exposure.

18 This technique still may not deal effectively with the problem of short-term “peak concentrations” exceeding some threshold leading to an acute effect. Even the averaging process used in a microenvironment may miss significant concentration spikes and average them out to lower concentrations which are apparently less toxicologically significant. A similar problem exists when evaluating sources; a “peak release” of a toxic chemical for a short time may cause serious acute effects, even though the average concentration over a longer period of time might not indicate serious chronic effects.

19 The uppermost portion of the high-end exposure range has generally been the target for terms such as “most exposed individual,” although actual usage has varied.

FN20 The term “worst case exposure” has historically meant the maximum possible exposure, or where everything that can plausibly happen to maximize exposure, happens. While in actuality, this worst case exposure may fall on the uppermost point of the population distribution, in most cases, it will be somewhat higher than the individual in the population with the highest exposure. The worst case represents a hypothetical individual and an extreme set of conditions; this will usually not be observed in an actual population. The worst case and the so-called maximum exposed individual are therefore not synonymous, the former describing a statistical possibility that may or may not occur in the population, and the latter ostensibly describing an individual that does, or is thought to, exist in the population.

FN21 The lower part of the high-end exposure range, e.g., conceptually above the 90th percentile but below about the 98th percentile, has generally been the target used by those employing the term “reasonable worst case exposure.” Above about the 98th percentile has been termed the “maximum exposure” range. Note that both these terms should refer to estimates of exposure on the actual distribution, not above it.

22 Since the geometric mean (G) is defined differently, use of the geometric mean individual risk (where G does not equal A, such as is often found in environmental situations) in the above relationship will obviously give an erroneous (usually low) estimate of the total. Geometric means have appropriate uses in exposure and risk assessment, but estimating population risk in this way is not one of them.

23 In other words, a fundamental rule is that a model should not be validated using data that were already used to generate or calibrate the model, since doing so would not be an independent test.

a To characterize dose, intake or uptake information is also needed (see Section 2). U.S. EPA (1985c).

[e f] c U.S. EPA (1986f). U.S. EPA (1985c). U.S. EPA (1985d). U.S. EPA (1985a).

[i j] g U.S. EPA (1986f). U.S. EPA (1987a). U.S. EPA (1987a). U.S. EPA (1987a).

[m n] k U.S. EPA (1987d). U.S. EPA (1986g). U.S. EPA (1986h). U.S. EPA (1987e).

24 Conversely, it may be stated that the largest source of uncertainty is the concentration for a given exposure duration. Often, however, the concentration in the media is known with more certainty than the activities of the individual(s) exposed.

25 An acceptable data set is one that is consistent with the scope, depth, and purpose of the assessment, and is both relevant and adequate as discussed in Section 5.1.

26 Some programs, such as the U.S. Department of Energy (1991), do not recommend this procedure at all, if it can be avoided.

27 “Conservative” assumptions are those which tend to maximize estimates of exposure or dose, such as choosing a value near the high end of the concentration or intake rate range.

FN28 Obviously, the mathematical product of several conservative assumptions is more conservative than any single assumption alone. Ultimately, this could lead to unrealistically conservative bounding estimates (see section 5.3).

29 Note that when using a passive dosimetry monitoring method, what is measured is the amount of chemical impinging on the skin surface or available for inhalation, that is, exposure, not the actual dose received. Factors such as dermal penetration, are, of course, expected to be highly chemical dependent.

30 Consider, for example, a hypothetical set of 100 rooms (microenvironments) where the concentration of a particular pollutant is zero in 50 of them, and ranges stepwise from 1 to 50 (nominal concentration units) in the remainder. If one person were in each room, short-term “snapshot” monitoring would show that 50 people were unexposed and the others were exposed to concentrations ranging from 1 to 50. If the concentration in each room remained constant and people were allowed to visit any room at random, long-term monitoring would indicate that all 100 were exposed to a mean concentration of 12.75. The short-term data would tend to overestimate concentration and underestimate the number of persons exposed if applied to long-term exposures. If only average values were available, the long-term data would tend to underestimate concentration and overestimate the number exposed if applied to short-term exposures. Because populations are not randomly mobile or static, the exposure assessor should determine what effect this has on the exposure estimate.

31 There are some important exceptions to this statement. First, the public or other concerned groups may express particular interest in certain pathways, which will not normally be dropped entirely at this point. Second, for routine repetitive assessments using a certain standard scenario for many chemicals, once the general bounding has been done on the various possible pathways, it may become standard operating procedure to immediately begin developing information for particular pathways as new chemicals are assessed.

32 “Not significant” can mean either that it is so small relative to other pathways that it will not add perceptibly to the total exposure being evaluated or that it falls so far below a level of concern that even when added to other results from other pathways, it will be trivial. Note that a “level of concern” is a risk management term, and the assessor must discuss and establish any such levels of concern with risk managers (and in some cases, concerned groups such as the local community) before eliminating pathways as not significant.

33 Experienced assessors may also be able to determine quickly that a pathway requires refined estimation.

34 It also can involve new methods or additional methods for analyzing the old data.

35 The unstated assumption is often made that the relationship between administered dose and absorbed dose in the animal is the same as that between potential dose and internal dose in humans, provided a correction is made for body weight/surface area. In other words, the bioavailability and absorption fractions are assumed to be the same in the human as in the animal experiment. If no correction is made for absorption, this leads to the assumption that the absorption percent is the same as in the animal experiment from which the dose-response relationship was derived. Note this uncorrected conversion of potential dose to internal dose does not assume “100% absorption” unless there was 100% absorption in the animal study.

36 This means that estimates of high-end exposure or dose for future uses are limited to the same conceptual range as current uses. Although a “worst-case” combination of future conditions or events may result in an exposure that is conceivably possible, the

assessor should not merely use a worst-case combination as an estimate of high-end exposure for possible future uses. Rather, the assessor must use judgment as to what the range of exposures or doses would plausibly be, given the population size and probability of certain events happening.

37 For example, although concentration breathed, frequency, duration, and breathing rate may be independent for a consumer painting rooms in a house under most normal circumstances, if the concentration is high enough, it may affect the other parameters such as duration or breathing rate. These types of high-end correlations are difficult to quantify, and techniques such as Monte Carlo simulations will not consider them unless relationships are known and taken into account in the simulation. If extreme concentration in this case resulted in lower breathing rate or duration, a non-corrected Monte Carlo simulation could overestimate the exposure or dose at the high end. Far less likely, due to self-preservation processes, would seem the case where high concentration increases duration or intake rate, although this theoretically might also occur.

38 This maximum is the theoretical upper bounding estimate (TUBE).

39 Maximizing all variables, as is done in bounding estimates, will result in virtually all cases in an estimate that is above the bounds of this range, that is, above the actual values seen in the population.

40 For example, when calculating risks using doses and “slope factors,” the risk is approximately linear with dose until relatively high individual risks (about 10^{-1}) are attained, after which the relationship is no longer even approximately linear. This results from the fact that no matter how high the dose, the individual risk cannot exceed 1, and the dose-risk curve approaches 1 asymptotically. This can result in artifacts when calculating population risk from average individual doses and population size if there are individuals in the population in this nonlinear risk range. Consider a population of five persons, only one of whom is exposed. As an example, assume a lifetime average daily dose of 100 mg/kg/day corresponds to an individual risk of 4×10^{-1}. Increasing the dose fivefold, to 500 mg/kg/day, would result in a higher individual risk for that individual, but due to the nonlinearity of the dose-risk curve, not yet a risk of 1. The average dose for the five persons in the population would then be 100 mg/kg/day. Multiplying the “average risk” of 4×10^{-1} by the population size of five results in an estimate of two cases, even though in actuality only one person is exposed. Although calculating average individual dose, estimating individual risk from it, and multiplying by the population size is a useful approximation if all members of the population are within the approximately linear range of the dose-risk curve, this method should not be used if some members of the population have calculated individual risks higher than about 10^{-1}, since it will overestimate the number of cases.

FN41 In these cases, a significant problem can be the lack of a constant (or nearly constant) “slope factor” that would be appropriate over a wide exposure/dose range, since the dose-response curve may have thresholds, windows, or other discontinuities.

42 Each measure or estimate of exposure will have its associated uncertainty which should be addressed both qualitatively and quantitatively. For example, if population mean exposure is being addressed by use of direct personal monitoring data, qualitative issues will include the representativeness of the population monitored to the full population, the representativeness of the period selected for monitoring, and confidence that there were not systematic errors in the measured data. Quantitative uncertainty could be addressed through the use of confidence intervals for the actual mean population exposure.

43 The confidence interval is interpreted as the range of values within which the assessor knows the true measure lies, with specified statistical confidence. The upper bound confidence limit is the higher of the two ends of the confidence interval.

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Final Water Quality Guidance for the Great Lakes System

Thursday, March 23, 1995

***15366** AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is publishing Final Water Quality Guidance for the Great Lakes System. Great Lakes States and Tribes will use the water quality criteria, methodologies, policies, and procedures in the Guidance to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them.

The Guidance was initially developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem. It will affect all types of pollutants, but will target especially the types of long-lasting pollutants that accumulate in the food web of large lakes.

The Guidance consists of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that can be allowed to reach the Lakes and their tributaries from all sources; and antidegradation policies and procedures.

Under the Clean Water Act, the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin must adopt provisions into their water quality standards and NPDES permit programs within two years (by March 23, 1997) that are consistent with the Guidance, or EPA will promulgate the provisions for them. The Guidance for the Great Lakes System will help establish consistent, enforceable, long-term protection from all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The Guidance includes minimum water quality criteria, antidegradation policies, and implementation procedures that provide a coordinated ecosystem approach for addressing existing and possible pollutant problems and improves consistency in water quality standards and permitting procedures in the Great Lakes System. In addition, the Guidance provisions help establish consistent goals or minimum requirements for Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs) that are critical to the success of international multi-media efforts to protect and restore the Great Lakes ecosystem.

EFFECTIVE DATE: April 24, 1995.

ADDRESSES: The public docket for this rulemaking, including applicable Federal Register documents, public comments in response to these documents, the Final Water Quality Guidance for the Great Lakes System, Response to Comments Document, other major supporting documents, and the index to the docket are available for inspection and copying at U.S. EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604 by appointment only. Appointments may be made by calling Wendy Schumacher (telephone 312-886-0142).

Information concerning the Great Lakes Initiative (GLI) Clearinghouse is available from Ken Fenner, Water Quality Branch Chief, (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

Copies of the Information Collection Request for the Guidance are available by writing or calling Sandy Farmer, Information Policy Branch, EPA, 401 M St., S.W. (Mail Code 2136), Washington, DC 20460 (202-260-2740).

Selected documents supporting the Guidance are also available for viewing by the public at locations listed in section XI of the preamble.

Selected documents supporting the Guidance are available by mail upon request for a fee. Selected documents are also available in electronic format at no incremental cost to users of the Internet. See section XI of the preamble for additional information.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

SUPPLEMENTARY INFORMATION

Preamble Outline

I. Introduction

Section 118(c)(2) of the Clean Water Act (CWA) (Pub. L. 92-500 as amended by the Great Lakes Critical Programs Act of 1990 (CPA), Pub. L. 101-596, November 16, 1990) required EPA to publish proposed and final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. In response to these requirements, EPA published the Proposed Water Quality Guidance for the Great Lakes System (proposed Guidance) in the Federal Register on April 16, 1993 (58 FR 20802). EPA also published four subsequent documents in the Federal Register identifying corrections and requesting comments on additional related materials (April 16, 1993, 58 FR 21046; August 9, 1993, 58 FR 42266; September 13, 1993, 58 FR 47845; and August 30, 1994, 59 FR 44678). EPA received over 26,500 pages of comments, data, and information from over 6,000 commenters in response to ***15367** these documents and from meetings with members of the public.

After reviewing and analyzing the information in the proposal and these comments, EPA has developed the Final Water Quality Guidance for the Great Lakes System (final Guidance), published in this document and codified in 40 CFR part 132, which includes six appendixes of detailed methodologies, policies, and procedures. This preamble describes the background and purpose of the final Guidance, and briefly summarizes the major provisions. Detailed discussion of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance, are provided in “Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document” (SID), (EPA, 1995, 820-B-95-001) and in additional technical and supporting documents which are available in the docket for this rulemaking. Copies of the SID and other supporting documents are also available from EPA in electronic format, or in printed form for a fee upon request; see section XI of this preamble.

II. Background

The Great Lakes are one of the outstanding natural resources of the world. They have played a vital role in the history and development of the United States and Canada, and have physical, chemical, and biological characteristics that make them a unique ecosystem. The Great Lakes themselves—Lakes Superior, Huron, Michigan, Erie and Ontario and their connecting channels—plus all of the streams, rivers, lakes and other bodies of water that are within the drainage basin of the Lakes collectively comprise the Great Lakes System.

The System spans over 750 miles across eight States—New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota—and the Province of Ontario. The Lakes contain approximately 18 percent of the world's and 95 percent of the United States' fresh surface water supply. The Great Lakes are a source of drinking water and energy, and are used for recreational, transportation, agricultural and industrial purposes by the more than 46 million Americans and Canadians who inhabit the Great Lakes region, including 29 Native American tribes. Over 1,000 industries and millions of jobs are dependent upon water from the Great Lakes. The Great Lakes System also supports hundreds of species of aquatic life, wildlife and plants along more than 4,500 miles of coastline which boast six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and hundreds of State parks, forests and sanctuaries.

Because of their unique features, the Great Lakes are viewed as important to the residents of the region, and to the Nation as a whole. The natural resources of the region have contributed to the development of its economy. The Lakes' natural beauty and aquatic resources form the basis for heavy recreational activity. The Great Lakes Basin Ecosystem—the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin—is a remarkably diverse and unique ecosystem important in the global ecology.

In the past few decades, the presence of environmental contaminants in the Great Lakes has been of significant concern. In spite of the fact that the Great Lakes contain 5,500 cubic miles of water that cover a total surface area of 94,000 square miles, they have proved to be sensitive to the effects of pollutants that accumulate in them. The internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times cause pollutants to recycle between biota, sediments and the water column.

The first major basin-wide environmental problem in the Great Lakes emerged in the late 1960s, when increased nutrients had dramatically stimulated the growth of green plants and algae, reduced dissolved oxygen levels, and accelerated the process of eutrophication. As oxygen levels continued to drop, certain species of insects and fish were displaced from affected areas of the Great Lakes Basin Ecosystem. Environmental managers determined that a lakewide approach was necessary to adequately control accelerated eutrophication. From the late 1960s through the late 1970s, United States and Canadian regulatory agencies agreed on measures to limit the loadings of phosphorus, including effluent limits on all major municipal sewage treatment facilities, limitations on the phosphorus content in household detergents, and reductions in nonpoint source runoff loadings. As a result of all of these efforts, open lake phosphorus concentrations have declined, and phosphorus loadings from municipal sewage treatment facilities have been reduced by an estimated 80 to 90 percent. These reductions have resulted in dramatic improvements in nearshore water quality and measurable improvements in open lake conditions.

More recently, scientists and public leaders have reached a general consensus that the presence of environmentally persistent, bioaccumulative contaminants is a serious environmental threat to the Great Lakes Basin Ecosystem. Beginning in 1963, adverse environmental impacts in the form of poor reproductive success and high levels of the pesticide DDT were observed in herring gulls in Lake Michigan. Through ongoing research, scientists have detected 362 contaminants in the Great Lakes System. Of these, approximately one third have toxicological data showing that they can have acute or chronic toxic effects on aquatic life, wildlife and/or human health. Chemicals that have been found to bioaccumulate at levels of concern in the Great Lakes include, but are not limited to, polychlorinated biphenyls (PCBs), mercury, DDT, dioxin, chlordane, and mirex. The main route of exposure to these chemicals for humans is through the consumption of Great Lakes fish.

Potential adverse human health effects by these pollutants resulting from the consumption of fish include both the increased risk of cancer and the potential for systemic or noncancer risks such as kidney damage. EPA has calculated health risks to populations in the Great Lakes basin from consumption of contaminated fish based on exposure to eight bioaccumulative pollutants: chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations from the Great Lakes.

Based on these data, EPA estimates that the lifetime cancer risks for Native Americans in the Great Lakes System due to ingestion of contaminated fish at current concentrations range from $1.8\ 10^{-3}$ (Lake Superior) (1.8 in one thousand) to $3.7\ 10^{-2}$ (Lake Michigan) (3.7 in 100). Estimated risks to low income minority sport anglers range from $2.5\ 10^{-3}$ (2.5 in one thousand) (Lake Superior) to $1.2\ 10^{-2}$ (1.2 in 100) (Lake Michigan). Estimated risks for other sport anglers range from $9.7\ 10^{-4}$ (9.7 in ten thousand) (Lake Superior) to $4.5\ 10^{-3}$ (4.5 in one thousand) (Lake Michigan). (See section I.B.2.a of the SID.) In comparison, EPA has long maintained that $1\ 10^{-4}$ (one in ten thousand) to $1\ 10^{-6}$ (one in 1 million) is an appropriate range of risk to protect human health.

***15368** EPA also estimates a high potential risk of systemic (noncancer) injury to populations in the Great Lakes basin due to ingestion of fish contaminated with these pollutants at current concentrations. The systemic adverse health effects associated with the assessed contaminants are described in section I.B of the SID.

Although the Great Lakes States and EPA have moved forward to deal with these problems, control of persistent, bioaccumulative pollutants proved to be more complex and difficult than dealing with nutrients. As a result, inconsistencies began to be apparent in the ways various States developed and implemented controls for the pollutants. By the mid-1980s, such inconsistencies became of increasing concern to EPA and State environmental managers.

EPA began the Great Lakes Water Quality Initiative (“Initiative”) in cooperation with the Great Lakes States to establish a consistent level of environmental protection for the Great Lakes ecosystem, particularly in the area of State water quality standards and the National Pollutant Discharge Elimination System (NPDES) programs. In the spring of 1989, the Council of Great Lakes Governors unanimously agreed to participate in the Initiative with EPA, because the Initiative supported the principles and goals of the Great Lakes Toxic Substances Control Agreement (Governors' Agreement). Signed in 1986 by the Governors of all eight Great Lakes States, the Governors' Agreement affirmed the Governors' intention to manage and protect the resources of the Great Lakes basin through the joint pursuit of unified and cooperative principles, policies and programs enacted and adhered to by each Great Lakes State.

The Initiative provided a forum for a regional dialogue to establish minimum requirements that would reduce disparities between State water quality controls in the Great Lakes basin. The scope of the Initiative included development of proposed Great Lakes water quality guidance—Great Lakes-specific water quality criteria and methodologies to protect aquatic life, wildlife and human health, procedures to implement water quality criteria, and an antidegradation policy.

Three committees were formed to oversee the Initiative. A Steering Committee (composed of directors of water programs from the Great Lakes States' environmental agencies and EPA's National and Regional Offices) discussed policy, scientific, and technical issues, directed the work of the Technical Work Group and ratified final proposals. The Technical Work Group (consisting of technical staff from the Great Lakes States' environmental agencies, EPA, the U.S. Fish and Wildlife Service, and the National Park Service) prepared proposals on elements of the Guidance for consideration by the Steering Committee. The Public Participation Group (consisting of representatives from environmental groups, municipalities, industry and academia) observed the deliberations of the other two committees, advised them of the public's concerns, and kept its various constituencies apprised of ongoing activities and issues. These three groups were collectively known as the Initiative Committees. From the start, one goal of the Initiative Committees was to develop the Guidance elements in an open public forum, drawing upon the extensive expertise and interest of individuals and groups within the Great Lakes community.

The Initiative efforts were well underway when Congress amended section 118 of the CWA in 1990 through the CPA. The general purpose of these amendments was to improve the effectiveness of EPA's existing programs in the Great Lakes by identifying key treaty provisions agreed to by the United States and Canada in the Great Lakes Water Quality Agreement (GLWQA), imposing statutory deadlines for the implementation of these key activities, and increasing Federal resources for program operations in the Great Lakes System.

Section 118(c)(2) requires EPA to publish proposed and final water quality guidance for the Great Lakes System. This Guidance must conform with the objectives and provisions of the GLWQA (a binational agreement establishing common water quality objectives for the Great Lakes) and be no less restrictive than provisions of the CWA and National water quality criteria and guidance. The Guidance must specify minimum requirements for the waters in the Great Lakes System in three areas: (1) water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife); (2) antidegradation policies; and (3) implementation procedures.

The Great Lakes States must adopt water quality standards, antidegradation policies and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of EPA's publication. In the absence of such action, EPA is required to promulgate any necessary requirements within that two-year period. In addition, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

On December 6, 1991, the Initiative Steering Committee unanimously recommended that EPA publish the draft Guidance ratified by that group in the Federal Register for public review and comment. The agreement that the draft Great Lakes Guidance was ready for public notice did not represent an endorsement by every State of all of the specific proposals. Rather, all parties agreed on the importance of proceeding to publish the draft Great Lakes Guidance in order to further solicit public comment. State Steering Committee members indicated their intent to develop and submit specific comments on the proposed Guidance during the public comment period. EPA worked to convert the agreements reached in principle by the Steering Committee into a formal package suitable for publication in the Federal Register as proposed Guidance. EPA generally used the draft proposal ratified by the Steering Committee as the basis for preparing the Federal Register proposal package. Modifications were necessary, however, to reflect statutory and regulatory requirements and EPA policy considerations, to propose procedures for State and Tribal adoption of the final Guidance, to provide suitable discussion of various alternative options, and to accommodate necessary format changes. Where modifications were made, the preamble to the proposal described both the modification and the original Steering Committee-approved guidelines, and invited public comment on both. All elements approved by the Steering Committee were either incorporated in the proposed rule or discussed in the preamble to the proposal.

III. Purpose of the Guidance

The final Guidance represents a milestone in the 30 years of effort described above on the part of the Great Lakes stakeholders to define and apply innovative, comprehensive environmental programs in protecting and restoring the Great Lakes. In particular, this publication of the final Guidance culminates six years of intensive, cooperative effort that included participation by the eight Great Lakes States, the environmental community, academia, industry, municipalities and EPA Regional and National offices.

***15369** The final Guidance will help establish consistent, enforceable, long-term protection with respect to all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The final Guidance will establish goals and minimum requirements that will further the next phase of Great Lakes programs, including the Great Lakes Toxic Reduction Effort's integrated, multi-media ecosystem approach.

EPA and State development of the Guidance—from drafting through proposal and now final publication—was guided by several general principles that are discussed below.

A. Use the Best Available Science to Protect Human Health, Aquatic Life, and Wildlife

EPA and the Initiative Committees have been committed throughout the Initiative to using the best available science to develop programs to protect the Great Lakes System. In the 1986 Governors' Agreement, the Governors of the Great Lakes States recognized that the problem of persistent toxic substances was the foremost environmental issue confronting the Great Lakes. They also recognized that the regulation of toxic contaminants was scientifically complex because the pollutants are numerous, their pathways into the Lakes are varied, and their effects on the environment, aquatic life and human health are not completely understood. Based on the importance of the Great Lakes Basin Ecosystem and the documented adverse effects from toxic contamination, however, the Governors directed their environmental administrators to jointly develop an agreement and procedure for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes basin.

As discussed further above, the Initiative was subsequently created to begin work on these goals. EPA and the Great Lakes States, with input from interested parties in the basin, began collecting and analyzing data, comparing regulatory requirements and technical guidance in their various jurisdictions, and drafting specific methodologies and procedures to control the discharge of toxic contaminants. The provisions of the final Guidance were based in large part on these prior efforts of the Initiative Committees, and incorporate the best available science to protect human health, wildlife and aquatic life in the Great Lakes System. For example, the final Guidance includes new criteria and a methodology developed by the Initiative Committees to specifically protect wildlife; incorporates recent data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporates Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and provides a methodology to determine the bioaccumulation properties of individual pollutants. Additionally, EPA understands that the science of risk assessment is rapidly improving. Therefore, in order to ensure that the scientific basis for the criteria methodologies is always current and peer reviewed, EPA will review the methodologies and revise them as appropriate every three years.

B. Recognize the Unique Nature of the Great Lakes Basin Ecosystem

The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants. The Initiative Committees devoted considerable effort to identifying the chemicals of most concern to the Great Lakes System —persistent, bioaccumulative pollutants termed “bioaccumulative chemicals of concern (BCCs)”—and developing the most appropriate criteria, methodologies, policies, and procedures to address them. The special provisions for BCCs, initially developed by the Initiative Committees and incorporated into the final Guidance, include antidegradation procedures, to ensure that future problems are minimized; general phase-out and elimination of mixing zones for BCCs, except in limited circumstances, to reduce their overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not under-regulated for lack of data; and development of water quality criteria that will protect wildlife that feed on aquatic prey.

The final Guidance is designed not only to begin to address existing problems, but also to prevent emerging and potential problems posed by additional chemicals in the future which may damage the overall health of the Great Lakes. The experience with such pollutants as DDT and PCBs indicates that it takes many decades to overcome the damage to the ecosystem caused by even short-term discharges, and that prevention would have been dramatically less costly than clean-up. Issuance of the final Guidance alone will not solve the existing long-term problems in the Great Lakes System from these contaminants. Full implementation of provisions consistent with the final Guidance will, however, provide a coordinated ecosystem approach for addressing possible pollutant problems before they produce adverse and long-lasting basin-wide impacts, rather than waiting to see what the future impacts of the pollutants might be before acting to control them. The comprehensive approach used in the development of the final Guidance provides regulatory authorities with both remedial and preventive ways of gauging the actions and potential effects of chemical stressors upon the Great Lakes Basin Ecosystem. The methodologies, policies and procedures contained in the final Guidance provide mechanisms for appropriately addressing both pollutants that have been or may in the future be documented as chemicals of concern.

C. Promote Consistency in Standards and Implementation Procedures While Allowing Appropriate Flexibility to States and Tribes

Promoting consistency in standards and implementation procedures while providing for appropriate State flexibility was the third principle in State and EPA development of the final Guidance. The underlying rationale for the Governors' Agreement, the Initiative, and the requirements set forth in the CPA was a recognition of the need to promote consistency through adoption of minimum water quality standards, antidegradation policies, and implementation procedures by Great Lakes States and Tribes to protect human health, aquatic life and wildlife. Although provisions in the CWA provide for the adoption of and periodic revisions to State water quality criteria, such provisions do not necessarily ensure that water quality criteria of adjoining States are consistent within a shared water body. For example, ambient water quality criteria in place in six of the eight Great Lakes States to protect aquatic life from acute effects range from 1.79 MUg/L to 15.0 MUg/L for cadmium, and from 0.21 MUg/L to 1.33 MUg/L for dieldrin. Other examples of variations in acute aquatic life criteria include nickel, which ranges from 290.30 MUg/L to 852.669 MUg/L; lindane, ***15370** with a range of no criteria in place to 1.32 MUg/L; and mercury, ranging from 0.5 MUg/L to 2.4 MUg/L. Similar ranges and disparities exist for chronic aquatic life criteria, and for water quality criteria to protect human health.

Disparities also exist among State procedures to translate water quality criteria into individual discharge permits. Wide variations exist, for example, in procedures for the granting of mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for pollutants discharged in mixtures with other pollutants. Additionally, when addressing the accumulation of chemicals by fish that will be consumed by humans and wildlife, some States consider accumulation through multiple steps in the food chain (bioaccumulation) while others consider only the single step of concentration from the water column (bioconcentration). Further disparities exist in different translator methodologies in deriving numeric values for implementing narrative water quality criteria; different assumptions when calculating total maximum daily loads (TMDLs) and wasteload allocations (WLAs), including different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate; and different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

These inconsistencies in State standards and implementation procedures have resulted in the disparate regulation of point source discharges. In the Governors' Agreement, the Governors recognized that the water resources of the basin transcend political boundaries and committed to taking steps to manage the Great Lakes as an integrated ecosystem. The Great Lakes States, as participants in the Initiative Committees, recommended provisions, based on their extensive experience in administering State water programs and knowledge of the significant differences in these programs within the basin, that were ultimately included in the proposed Guidance. The final Guidance incorporates the work begun by the Initiative Committees to identify these disparities and improve consistency in water quality standards and permit procedures in the Great Lakes System.

Although improved consistency in State water programs is a primary goal of the final Guidance, it is also necessary to provide appropriate flexibility to States and Tribes in the development and implementation of water programs. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate site-specific situations and unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. Many commenters, including the Great Lakes States, urged EPA to evaluate the appropriate level of flexibility provided to States and Tribes in the proposed Guidance provisions. EPA reviewed all sections of the proposed Guidance and all comments received to determine the appropriate level of flexibility needed to address these concerns while still providing a minimum level of consistency between the State and Tribal programs. Based on this review, the final Guidance provides flexibility for State and Tribal adoption and implementation of provisions consistent with the final Guidance in many areas, including the following:

—Antidegradation: Great Lakes States and Tribes may develop their own approaches for implementing the prohibition against deliberate actions of dischargers that increase the mass loading of BCCs without an approved antidegradation demonstration. Furthermore, States and Tribes have flexibility in adopting antidegradation provisions regarding non-BCCs.

—TMDLs: Great Lakes States and Tribes may use assessment and remediation plans for the purposes of appendix F to part 132 if the State or Tribe certifies that the assessment and remediation plan meets certain TMDL-related provisions in the final Guidance and public participation requirements applicable to TMDLs, and if EPA approves such plan. Thus, States have the flexibility in many cases to use LAMPs, RAPs and State Water Quality Management Plans in lieu of TMDLs.

—Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits (WQBELs) in accordance with procedure 5 of appendix F.

—Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria and bioaccumulation factors (BAFs) based on site-specific circumstances specified in procedure 1 of appendix F. All criteria, however, must be sufficient not to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act.

—Variances: Great Lakes States and Tribes may grant variances from water quality standards based on the factors identified in procedure 2 of appendix F.

—Compliance Schedules: Great Lakes States and Tribes may allow existing Great Lakes dischargers additional time to comply with permit limits in order to collect data to derive new or revised Tier I criteria and Tier II values in accordance with procedure 9 of appendix F.

—Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after the 10-year phase-out period in accordance with procedure 3.B of appendix F, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations.

—Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision is in §132.4(h) of the final Guidance.

—Reduced Detail: In many instances, EPA has revised the proposed Guidance to reduce the amount of detail in the provisions without sacrificing the objectives of the provisions. Examples of such revisions include simplification of procedures for developing TMDLs in procedure 3 of appendix F, and simplification of procedures for determining reasonable potential to exceed water quality standards in procedure 5.B of appendix F.

—Other Provisions: Flexibility is also present in provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions in the final Guidance including: determining the appropriate uncertainty factors in the human health and wildlife criteria methodologies; selection of data sets for establishing water quality criteria; identifying reasonable and prudent ***15371** measures in antidegradation provisions; and specifying appropriate margins of safety when developing TMDLs. In all cases, of course, State and Tribal provisions would need to be scientifically defensible and consistent with all applicable regulatory requirements.

D. Establish Equitable Strategies to Control Pollution Sources

Many commenters argued that the proposed Guidance unfairly focused on point source discharges. They asserted that nonpoint sources or diffuse sources of pollution, such as air emissions, are responsible for most of the loadings of some pollutants of concern in the Great Lakes, that increased regulation of point sources will be inequitable and expensive, and that the final Guidance will not result in any environmental improvement given the large, continuing contribution of toxic pollutants by nonpoint sources.

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from toxic pollutants in the Great Lakes. In addition to discharges from point sources, toxic pollutants are also contributed to the Great Lakes from industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, urban and agricultural runoff, hazardous waste and Superfund sites, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in all of these areas. EPA, Canada and the Great Lakes States and Tribes are currently implementing or developing many voluntary and regulatory programs to address these and other nonpoint sources of environmental contaminants in the Great Lakes.

Additionally, EPA intends to use the scientific data developed in the final Guidance and new or revised water quality criteria subsequently adopted by Great Lakes States and Tribes in evaluating and determining appropriate levels of control in other environmental programs. For example, EPA's future biennial reports under section 112(m) of the Clean Air Act will consider the extent to which air discharges cause or contribute to exceedances of water quality criteria in assessing whether additional air emission standards or control measures are necessary to prevent serious adverse effects. Similarly, once provisions consistent with the final Guidance are adopted by the Great Lakes States or Tribes, they will serve as applicable or relevant and appropriate requirements (ARARs) for on-site responses under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). EPA will also consider the data and criteria developed for the final Guidance, including the information on BCCs, in developing or evaluating LaMPs and RAPs under section 118 of the CWA and Article VI, Annex 2 of the GLWQA; determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act; new or existing chemical reviews under the Toxic Substances Control Act (TSCA); pesticide reviews under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and reporting requirements for toxic releases under the Emergency Planning and Community Right-to-Know Act (EPCRA).

The final Guidance also includes provisions to address the contribution of pollutants by nonpoint sources. First, the water quality criteria to protect human health, wildlife and aquatic life, and the antidegradation provisions apply to the waters in the Great Lakes System regardless of whether discharges to the water are from point or nonpoint sources. Accordingly, any regulatory programs for nonpoint sources that require compliance with water quality standards would also be subject to the criteria and antidegradation provisions of the final Guidance once they are adopted into State or Tribal standards.

Second, several elements of the final Guidance would, after State, Tribal or Federal promulgation, require or allow permitting authorities to consider the presence of pollutants in ambient waters—including pollutants from nonpoint source dischargers—in establishing WQBELs for point sources. For example, permit authorities may consider the presence of other point or nonpoint source discharges when evaluating whether to grant a variance from water quality criteria. Additionally, the provisions for TMDLs address nonpoint sources by specifying that the loading capacity of a receiving water that does not meet water quality standards for a particular pollutant be allocated, where appropriate, among nonpoint as well as point sources of the pollutant, including, at a minimum, a margin of safety to account for technical uncertainties in establishing the TMDL.

The development of TMDLs is the preferred mechanism for addressing equitable division of the loading capacities of these nonattained waters. Because TMDLs have not been completed for most nonattained waters, however, the final Guidance promotes the development of TMDLs through a phased approach, where appropriate, and provides for short-term regulatory relief to point source dischargers in the absence of TMDLs through intake credits, variances, and other water quality permitting procedures.

EPA received numerous comments on the problem posed in controlling mercury in particular. Many commenters stated that since the primary source of mercury is now atmospheric deposition, point sources contribute only a minor portion of the total loading of mercury to the Great Lakes System and further restriction of point source discharges would have no apparent effect in improving water quality. Although EPA believes that there is sufficient flexibility in the Guidance to handle the unique problems posed by mercury (e.g., water quality variances, phased TMDLs, intake credits), EPA is committed to developing a mercury permitting strategy to provide a holistic, comprehensive approach for dealing with this pollutant. EPA will publish this strategy no later than two years following publication of this Guidance.

There are also many ongoing voluntary and regulatory activities that address nonpoint sources of toxic pollutants to the Great Lakes System, including activities taken under the Clean Air Act Amendments of 1990 (CAAA), the CWA, and State regulatory and voluntary programs. Some of these activities are summarized in the preamble to the proposed Guidance (58 FR 20826-32) and section I.D of the SID.

In addition to the many ongoing activities, EPA and the Great Lakes States, Tribes, and other federal agencies are pursuing a multi-media program to prevent and to further reduce toxic loadings from all sources of pollution to the Great Lakes System, with an emphasis on nonpoint sources. This second phase of the Great Lakes Water Quality Initiative, called the Great Lakes Toxic Reduction Effort (GLTRE), will build on the open, participative public dialogue established during the development of the final Guidance. Through the GLTRE, the Federal, State, and Tribal agencies intend to coordinate and enhance the effectiveness of ongoing actions and existing tools to prevent and reduce nonpoint source and wet-weather point source contributions of toxic pollutants in the Great Lakes System. A special emphasis will be placed on BCCs identified in the final Guidance.

A partial list of ongoing actions that are being or could be focused on BCCs includes: implementation of the CAAA to reduce atmospheric deposition of toxics; Resource Conservation and Recovery Act and CERCLA remedial actions to reduce loadings of toxics from ***15372** hazardous waste sites; increased focus (through the GLTRE) on toxic pollutants emanating from combined sewer overflows and stormwater outfalls; application in the Great Lakes basin of the National Contaminated Sediment Management Strategy; implementation of spill prevention planning practices to minimize this potential source of loadings to the Great Lakes; improved reporting of toxic pollutants under the Toxic Release Inventory; public education on the dangers of mercury and other BCCs; pesticide registration and re-registration processes; development of a "mass balance" model for fate and transport of pollutants in the Great Lakes; and, development of a "virtual elimination strategy." These programs will prevent and further reduce mass loadings of pollutants and facilitate equitable division of the costs of any necessary control measures between point and nonpoint sources.

In addition to the GLTRE, which is basin-wide in scope, a primary vehicle for coordinating Federal and State programs at the local level for meeting water quality standards and restoring beneficial uses for the open waters of the Great Lakes are LaMPS. LaMPs will define media specific program actions to further reduce loadings of toxic substances, assess whether these programs will ensure restoration and attainment of water quality standards and designated beneficial uses, and recommend any media-specific program enhancements as necessary. Additionally, LaMPs will be periodically updated and revised to assess progress in implementing media-specific programs, assess the reductions in toxic loadings to the Great Lakes System through these programs, incorporate advances in the understanding of the System based on new data and information, and recommend specific adjustments to media programs as appropriate.

E. Promote Pollution Prevention Practices

The final Guidance also promotes pollution prevention practices consistent with EPA's National Pollution Prevention Strategy and the Pollution Prevention Action Plan for the Great Lakes. The Pollution Prevention Act of 1990 declares as National policy that reducing the sources of pollution is the preferred approach to environmental protection. When source reductions are not possible, however, recycling, treating and properly disposing of pollutants in an environmentally safe manner complete the hierarchy of management options designed to prevent pollution from entering the environment.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Great Lakes Pollution Prevention Action Plan highlights how EPA, in partnership with the States, will incorporate pollution prevention into actions designed to reduce the use and release of toxic substances in the Great Lakes basin.

The final Guidance builds upon these two components of the Great Lakes program by promoting the development of pollution prevention analysis and activities in the level of detection, mixing zone, and antidegradation sections of the final Guidance. Also, the decision to provide special provisions for BCCs implements EPA's commitment to pollution prevention by reducing the discharge of these pollutants in the future. This preventive step not only makes good environmental management sense, but is appropriate based on the documented adverse effects that the past and present discharge of these pollutants has produced in the Great Lakes basin.

F. Provide Accurate Assessment of Costs and Benefits

In developing the final Guidance, EPA identified and carefully evaluated the anticipated costs and benefits from implementation of the major provisions. EPA received many comments on the draft cost and benefit studies conducted as part of the proposed Regulatory Impact Analysis (RIA) required by Executive Order 12291, and its successor, Executive Order 12866. Based upon consideration of those comments and further analysis, EPA has revised the RIA. The results of this analysis are summarized in section V of this preamble.

IV. Summary of the Final Guidance

The final Guidance will establish minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Pennsylvania, Ohio and Wisconsin, including waters within the jurisdiction of Indian Tribes. Specifically, the final Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provides methodologies to derive numeric criteria for additional pollutants discharged to these waters. The final Guidance also contains minimum procedures to translate the proposed ambient water quality criteria into enforceable controls on discharges of pollutants, and a final antidegradation policy.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. The Great Lakes States and Tribes must adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System consistent with the (as protective as) final Guidance or be subject to EPA promulgation. Great Lakes Tribes include any Tribe within the Great Lakes basin for which EPA has approved water quality standards under section 303 or has authorized to administer a NPDES program under section 402 of the CWA. No Indian Tribe has been authorized to administer these water programs in the Great Lakes basin as of this time. If a Great Lakes State fails to adopt provisions consistent with the final Guidance within two years of this publication in the Federal Register (that is, by March 23, 1997), EPA will publish a final rule at the end of that time period identifying the provisions of the final Guidance that will apply to waters and discharges within that jurisdiction. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

The following sections provide a brief summary of the provisions of the final Guidance. A more complete discussion of the final Guidance, including EPA's analysis of major comments, issues, and a description of specific changes made to the proposed Guidance, are contained in the SID.

The parenthetical note at the beginning of each section provides references to the primary provisions in the final Guidance being discussed in the section, and to discussions in the SID. The final Guidance is codified as 40 CFR 132, including appendixes A through F. Note that appendix F consists of procedures 1 through 9. For ease of reference, sections in appendix F may be referred to by appending the section designation to the procedure number. For example, section A.1 of procedure 1 may be referred to as procedure 1.A.1 of appendix F.

15373** ***A. Water Quality Criteria and Methodologies

1. Protection of Aquatic Life
(§§132.3(a), 132.3(b), 132.4(a)(2); Tables 1 and 2 to part 132; appendix A to part 132; section III, SID)

The final Guidance contains numeric criteria to protect aquatic life for 15 pollutants, and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System. Aquatic life criteria are derived to establish ambient concentrations for pollutants, which, if not exceeded in the Great Lakes System, will protect fish, invertebrates, and other aquatic life from adverse effects due to that pollutant. The final Guidance includes both acute and chronic criteria to protect aquatic life from acute and chronic exposures to pollutants.

Tier I aquatic life criteria for each chemical are based on laboratory toxicity data for a variety of aquatic species (e.g., fish and invertebrates) which are representative of species in the freshwater aquatic environment as a whole. The Guidance also includes a Tier II methodology to be used in the absence of the full set of data needed to meet Tier I data requirements. For pollutants for which Tier I criteria have not been adopted into State or Tribal water quality standards, States must use methodologies consistent with either the Tier I or Tier II methodologies, depending on the data available, in conjunction with whole effluent toxicity requirements in the final Guidance (see section IV.B.5 of this preamble), to implement their existing narrative water quality criteria that prohibit toxic pollutants in toxic amounts in all waters. The Great Lakes States and Tribes are not required to use the Tier II methodology to adopt numeric criteria into their water quality standards.

Use of the two-tiered final Guidance methodologies in these situations will enable regulatory authorities to translate narrative criteria to derive TMDLs and individual NPDES permit limits on a more uniform basis. EPA and the States determined that there is a need to regulate pollutants more consistently in the Great Lakes System when faced with limited numbers of criteria. Many of the Great Lakes States are already employing procedures similar to the approach in the final Guidance to implement narrative criteria. EPA determined the Tier II approach improves upon existing mechanisms by utilizing all available data.

The two-tiered methodology allows the application of the final Guidance to all pollutants, except those listed in Table 5 of part 132 (see section IV.E of this preamble). The Tier I aquatic life methodology includes data requirements very similar to those used in current guidelines for developing National water quality criteria guidance under section 304(a) of the CWA. For example, both require that acceptable toxicity data for aquatic species in at least eight different families representing differing habitats and taxonomic groups must exist before a Tier I numeric criterion can be derived. The Tier II aquatic life methodology is used to derive Tier II values which can be calculated with fewer toxicity data than Tier I. Tier II values can, in certain instances, be based on toxicity data from a single taxonomic family, provided the data are acceptable. The Tier II methodology generally produces more stringent values than the Tier I methodology, to reflect greater uncertainty in the absence of additional toxicity data. As more data become available, the derived Tier II values tend to become less conservative. That is, they more closely approximate Tier I numeric criteria. EPA and the States believe it is desirable to continue to supplement toxicity data to ultimately derive Tier I numeric criteria.

One difference from the existing National water quality criteria guidelines is that the final Guidance methodology for aquatic life deletes the provision in the National guidelines to use a Final Residue Value (FRV) in deriving a criterion. The FRV is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting wildlife that consume them by preventing the exceedance of applicable Food

and Drug Administration action levels and concentrations that affect wildlife. The final Guidance provides specific, separate methodologies to protect wildlife and human health (discussed below) which EPA believes will provide more accurate and appropriate levels of protection than the FRVs.

For pollutants without Tier I criteria but with enough data to derive Tier II values for aquatic life, the proposal would have required permittees to meet permit limits based on both Tier II values and whole effluent toxicity (WET) testing. In response to comments, the final Guidance clarifies that States and Tribes may adopt provisions allowing use of indicator parameter limits consistent with 40 CFR 122.44(d)(1)(vi)(C). When deriving limits to meet narrative criteria, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. If use of an indicator parameter is allowed, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality standard that protects aquatic life.

Finally, the aquatic criteria for metals in the proposed Guidance were expressed as total recoverable concentrations. The final Guidance expresses the criteria for metals in dissolved form because the dissolved metal more closely approximates the bioavailable fraction of metal in the water column than does the total recoverable metal. The dissolved criteria are obtained by multiplying the chronic and/or acute criterion by appropriate conversion factors in Table 1 or 2. This is consistent with many comments on the issue and with the policy on metals detailed in "Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (October 1, 1993). A document describing the methodology to convert total recoverable metals criteria to dissolved metals criteria was published in the Federal Register on August 30, 1994 (59 FR 44678). If a State or Tribe fails to adopt approvable aquatic life criteria for metals, EPA will promulgate criteria expressed as dissolved concentrations.

EPA Region 5, in cooperation with EPA Regions 2 and 3 and Headquarters offices, and the Great Lakes States and Tribes, will establish a Great Lakes Initiative (GLI) Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria for aquatic life, human health and wildlife and Tier II water quality values for aquatic life and human health. As additional toxicological data and exposure data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes. EPA believes operation of the GLI Clearinghouse will help ensure consistency during implementation of the final Guidance.

2. Protection of Human Health
(§§132.3(c), 132.4(a)(4); Table 3 to part 132; appendix C to part 132; section V of the SID)

The final Guidance contains numeric human health criteria for 18 pollutants, and includes Tier I and Tier II methodologies to derive cancer and ***15374** non-cancer human health criteria for additional pollutants. The proposed Guidance contained numeric criteria for 20 pollutants, but two pollutants were deleted because they do not meet the more restrictive minimum data requirements for BAFs used in the final Guidance.

Tier I human health criteria are derived to establish ambient concentrations of chemicals which, if not exceeded in the Great Lakes System, will protect individuals from adverse health impacts from that chemical due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities in the Great Lakes System. For each chemical, chronic criteria are derived to reflect long-term consumption of food and water from the Great Lakes System. Tier II values are intended to provide a conservative, interim level of protection in the establishment of a permit limit, and are distinguished from the Tier I approach by the amount and quality of data used for derivation.

The final Guidance differs from current National water quality criteria guidelines when calculating the assumed human exposure through consumption of aquatic organisms. The final Guidance uses BAFs predicted from biota-sediment accumulation factors (BSAFs) in addition to field-measured BAFs, and uses a food chain multiplier (FCM) to account for biomagnification when using measured or predicted bioconcentration factors (BCFs). BAFs are discussed further in section IV.A.4. of this preamble.

Human health water quality criteria for carcinogens are typically expressed in concentrations associated with a plausible upper bound of increased risk of developing cancer. In practice, the level of cancer risk generally accepted by EPA and the States typically ranges between 10^{4} (one in one thousand) and 10^{6} (one in one million). In contrast, as discussed in section II above, the cancer risk from ingestion of contaminated fish at current concentrations in the Great Lakes System are as high as 1.2 10^{2} (1.2 in 100). The proposed and final Guidance establishes 10^{5} (one in one hundred thousand) as the risk level used for deriving criteria and values for individual carcinogens. This is within the range historically used in EPA actions, and approved for State actions, designed to protect human health. The majority of the Great Lakes States use 10^{5} as a baseline risk level in establishing their water quality standards.

The methodology is designed to protect humans who drink water or consume fish from the Great Lakes System. The portion of the methodology addressing fish consumption includes a factor describing how much fish humans consume per day. The final Guidance includes a Great Lakes-specific fish consumption rate of 15 grams per day, based upon several fish consumption surveys from the Great Lakes, including a recent study by West et al. that was discussed in a Federal Register document on August 30, 1994 (59 FR 44678). This rate differs from the 6.5 grams per day rate which is used in the National water quality criteria guidelines as a National average consumption value. The 15 grams per day represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing population.

Commenters argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 FR 7629). EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations. In carrying out regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{4} to 10^{6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{5}. Therefore, if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{4} risk level. Available data indicate that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day. The final Guidance requires, moreover, that States and Tribes modify the human health criteria on a site-specific basis to provide additional protection appropriate for highly exposed sub-populations. Thus, where a State or Tribe finds that a population of high-end consumers would not be adequately protected by criteria derived using the 15 gram per day assumption (e.g., where the risk was greater than 10^{4}), the State or Tribe would be required to modify the criteria to provide appropriate additional protection. The final Guidance also requires States and Tribes to adopt provisions to protect human health from the potential adverse effects of mixtures of pollutants in effluents, specifically including mixtures of carcinogens. Understood in the larger context of the human health methodology and the final Guidance as a whole, therefore, EPA believes that the 15 gram per day fish consumption rate provides adequate health protection for the public, including highly exposed populations, and that the final Guidance is therefore consistent with Executive Order 12898.

In developing bioaccumulation factors, the proposed Guidance used a 5.0 percent lipid value for fish consumed by humans, based on Great Lakes-specific data. The current National methodology uses a 3.0 percent lipid value. The final Guidance uses a 3.10 percent lipid value for trophic level 4 fish and 1.82 for trophic level 3 fish. These percent lipid values are based on an analysis of the West et al. study cited above and data from State fish contaminant monitoring programs.

The final Guidance contains specific technical guidelines concerning the range of uncertainty factors that may be applied by the State and Tribal agencies on the basis of their best professional judgment. The final Guidance places a cap of 30,000 on the combined product of uncertainty factors that may be applied in the derivation of non-cancer Tier II values and a combined

uncertainty factor of 10,000 for Tier I criteria. The likely maximum combined uncertainty factor for Tier I criteria in most cases is 3,000. The SID discusses further the use of the uncertainty factors in the derivation of human health criteria and values.

The proposed Guidance used an 80 percent relative source contribution (RSC) from surface water pathways for BCCs, and a 100 percent RSC for all other pollutants, in deriving noncancer criteria. The RSC concept is applied in the National drinking water regulations and is intended to account, at least in part, for exposures from other sources for those bioaccumulative pollutants for which surface water pathways are likely to be major contributors to human exposure. The final Guidance uses the more protective 80 percent RSC for all pollutants in deriving noncancer criteria. This change was made because of concern that for non-BCCs as well as ***15375** BCCs, there may be other sources of exposures for noncarcinogens.

3. Protection of Wildlife

(§§132.3(d), 132.4(a)(5); Table 4 to part 132; appendix D to part 132; section VI of the SID)

The final Guidance contains numeric criteria to protect wildlife for four pollutants and a methodology to derive Tier I criteria for additional BCCs. Wildlife criteria are derived to establish ambient concentrations of chemicals which, if not exceeded, will protect mammals and birds from adverse impacts from that chemical due to consumption of food and/or water from the Great Lakes System.

These are EPA's first water quality criteria specifically for the protection of wildlife. The methodology is based largely on the noncancer human health paradigm. It focuses, however, on endpoints related to reproduction and population survival rather than the survival of individual members of a species. The methodology incorporates pollutant-specific effect data for a variety of mammals and birds and species-specific exposure parameters for two mammals and three birds representative of mammals and birds resident in the Great Lakes basin which are likely to experience significant exposure to bioaccumulative contaminants through the aquatic food web.

In the proposal, EPA included a two-tiered approach similar to that for aquatic life and human health. In response to comments, the final Guidance requires States and Tribes to adopt provisions consistent with only the Tier I wildlife methodology, and only to apply this methodology for BCCs (see section IV.A.4 below). The TSD provides discretionary guidelines for the use of Tier I and Tier II methodologies for other pollutants. The wildlife methodology was limited to the BCCs because these are the chemicals of greatest concern to the higher trophic level wildlife species feeding from the aquatic food web in the Great Lakes basin. This decision is consistent with comments made by the EPA Science Advisory Board (SAB) who agreed that the initial focus for wildlife criteria development should be on persistent, bioaccumulative organic contaminants (USEPA, 1994, EPA-SAB-EPEC-ADV-94-001).

Numerous commenters were concerned that the mercury criterion for wildlife was not scientifically appropriate. After review of all comments and a reevaluation of all the data, the mercury criterion for wildlife has been increased from 180 pg/L to 1300 pg/L. EPA believes the 1300 pg/L is protective of wildlife in the Great Lakes System.

In developing bioaccumulation factors, the proposed Guidance used a 7.9 percent lipid value for fish consumed by wildlife. The final Guidance uses a 10.31 percent lipid value for trophic level 4 fish and 6.46 for trophic level 3 fish. These percent lipid values are based on the actual prey species consumed by the representative wildlife species specified in the methodology, and are used to estimate the BAFs for the trophic levels which those species consume. The percent lipid is based on the preferential consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid. This approach is a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

4. Bioaccumulation Methodology

(§132.4(a)(3); appendix B to part 132; section IV of the SID)

The proposed Guidance incorporated BAFs in the derivation of criteria and values to protect human health and wildlife. Bioaccumulation refers to the uptake and retention of a substance by an aquatic organism from its surrounding medium and from food. For certain chemicals, uptake through the aquatic food chain is the most important route of exposure for wildlife and humans. The wildlife criteria and the human health criteria and values incorporate appropriate BAFs in order to more accurately account for the total exposure to a chemical. Current EPA guidelines for the derivation of human health water quality criteria use BCFs, which measure only uptake from water, when field-measured BAFs are not available. EPA believes, however, that the BAF is a better predictor of the concentration of a chemical within fish tissues in the Great Lakes System because it includes consideration of the uptake of contaminants from all routes of exposure.

The proposed Guidance included a hierarchy of three methods for deriving BAFs for non-polar organic chemicals: field-measured BAFs; predicted BAFs derived by multiplying a laboratory-measured BCF by a food-chain multiplier; and BAFs predicted by multiplying a BCF calculated from the log K_{ow} by a food-chain multiplier. For inorganic chemicals, the proposal would have required either a field-measured BAF or laboratory-measured BCF. On August 30, 1994, EPA published a document in the Federal Register (59 FR 44678) requesting comments on revising the hierarchy of methods for deriving BAFs for organic chemicals, and issues pertaining to the model used to assist in predicting BAFs when a field-measured BAF is not available. Based on the comments received, the final Guidance modifies the proposed hierarchy by adding a predicted BAF based on a BSAF as the second method in the hierarchy. BSAFs may be used for predicting BAFs from concentrations of chemicals in surface sediments. In addition, the final Guidance uses a model to assist in predicting BAFs that includes both benthic and pelagic food chains thereby incorporating exposures of organisms to chemicals from both the sediment and the water column. The model used in the proposal only included the pelagic food chain, and therefore, did not account for exposure to aquatic organisms from sediment.

The proposed Guidance used the total concentration of a chemical in the ambient water when deriving BAFs for organic chemicals. In the preamble to the proposed Guidance and in the Federal Register document cited above, EPA requested comments on deriving BAFs in terms of the freely dissolved concentration of the chemical in the ambient water. Based on comments received from the proposal and the document, the final Guidance uses the freely dissolved concentration of a chemical instead of the total concentration in the derivation of BAFs for organic chemicals. Use of the freely dissolved concentration will improve the accuracy of extrapolations between water bodies.

Finally, as discussed in section II of this preamble, bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem. Because of these concerns, the proposed Guidance would have required that pollutants with human health BAFs greater than 1000 receive increased attention and more stringent controls within the Great Lakes System. These pollutants are termed BCCs. EPA identified 28 BCCs in the proposed Guidance. The additional controls for BCCs are specified in certain of the implementation procedures and the antidegradation procedures, and are discussed further in the SID. The final Guidance continues to include increased attention on and more stringent controls for BCCs within the Great Lakes System. The final Guidance identifies 22 BCCs that are targeted for special controls instead of the 28 in the proposed Guidance. Six BCCs were deleted from the proposed list because of concern that the methods used to estimate the BAFs may not ***15376** account for the metabolism or degradation of the pollutants in the environment. States and Tribes may identify more BCCs as additional BAF data become available. The final Guidance designates as BCCs only those chemicals with human health BAFs greater than 1000 that were derived from either a field-measured BAF or a predicted BAF based on a field-measured BSAF (for non-metals) or from a field-measured BAF or a laboratory-measured BCF (for metals). Field-measured BAFs and BSAFs, unlike BAFs based only on laboratory analyses or calculations, account for the effects of metabolism.

B. Implementation Procedures

(§§132.4(a)(7), 132.4(e); appendix F to part 132; section VIII of the SID)
This section of the preamble discusses nine specific procedures contained in the final Guidance for implementing water quality standards and developing NPDES permits to attain the standards.

1. Site-Specific Modifications

(Procedure 1 of appendix F to part 132; section VIII.A of the SID)
The proposed Guidance would have allowed States and Tribes to adopt site-specific modifications to water quality criteria and values under certain circumstances. States and Tribes could modify aquatic life criteria to be either more stringent or less stringent when local water quality characteristics altered the biological availability or toxicity of a pollutant, or where local species' sensitivities differed from tested species. Less stringent modifications to chronic aquatic life criteria could also be made to reflect local physical and hydrological conditions. States and Tribes could also modify BAFs and human health and wildlife criteria to be more stringent, but not less stringent than the final Guidance.

The final Guidance retains most of the above provisions, but in addition allows less stringent modifications to acute aquatic life criteria and values to reflect local physical and hydrological conditions, less stringent modifications to BAFs in developing human health and wildlife criteria, and the use of fish consumption rates lower than 15 grams per day if justified. The final Guidance also specifies that site-specific modifications must be made to prevent water quality that would cause jeopardy to endangered or threatened species that are listed or proposed under the ESA, and prohibits any less-stringent site-specific modifications that would cause such jeopardy. Other issues related to the ESA are discussed in section IX of this preamble.

2. Variances from Water Quality Standards for Point Sources

(Procedure 2 of appendix F to part 132; section VIII.B of the SID)
The final Guidance allows Great Lakes States and Tribes to adopt variances from water quality standards, applicable to individual existing Great Lakes dischargers for up to five years, where specified conditions exist. For example, a variance may be granted when compliance with a criterion would result in substantial and widespread social and economic impacts or where certain stream conditions prevent the attainment of the criterion. No significant changes were made in this section from the proposed Guidance.

3. TMDLs and Mixing Zones

(Procedure 3 of appendix F to part 132; section VIII.C of the SID)
Section 303(d) of the CWA and implementing regulations at 40 CFR 130.7 require the establishment of TMDLs for waters not attaining water quality standards after implementation of existing or planned pollution controls. The TMDL quantifies the maximum allowable loading of a pollutant to a water body and allocates the loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards for that pollutant will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve single point sources or multiple sources (e.g., point sources and nonpoint sources) and may be established for geographic areas that range in size from large watersheds to relatively small water body segments.

The proposal attempted to develop a single, consistent approach for developing TMDLs to be used by all States and Tribes in the Great Lakes System. Current practice in the eight Great Lakes States includes distinct technical procedures and program approaches that differ in scale, emphasis, scope and level of detail. Two options for TMDL development were proposed. One, Option A, focused on first evaluating the basin as a whole and then conducting individual site-by-site adjustments as necessary to ensure attainment of water quality standards at each location in the basin. The other, Option B, focused on evaluating limits needed for individual point sources with supplemental emphasis on basin-wide considerations as necessary. Both approaches are consistent with the CWA, but result in different methodologies for TMDL development.

Both options proposed that within 10 years of the effective date of the final Guidance (i.e., two five-year NPDES permit terms), mixing zones would be prohibited for BCCs for existing point source discharges to the Great Lakes System. Further, both proposed that mixing zones be denied for new point source discharges of BCCs as of the effective date of the final Guidance.

Both options also specified procedures for determining background levels of pollutants present in ambient waters. In addition, the proposal would have tightened the relationship between TMDL development and NPDES permit issuance by providing that TMDLs be established for each pollutant causing an impairment in a water body prior to the issuance or reissuance of any NPDES permits for that pollutant.

The final Guidance merges both Options A and B into one single set of minimum regulatory requirements for TMDL development. In general, the final TMDL procedures are less detailed than the proposal, and offer more flexibility for States and Tribes in establishing TMDLs. The final TMDL procedures contain elements from both Options A and B that were deemed critical for a minimum level of consistency among the Great Lakes States and Tribes. These critical elements include: mixing zone specifications, design flows, and procedures for determining background concentrations.

The final Guidance also includes a prohibition on mixing zones for BCCs after 12 years in most circumstances. Maintaining these restrictions on the availability of mixing zones is consistent with both the Steering Committee's policy views and the bi-national GLWQA goal of virtual elimination of persistent, bioaccumulative toxics. Because of the unique nature of the Great Lakes ecosystem, documented ecological impacts, and the need for consistency, EPA believes that the general prohibition on mixing zones for BCCs is reasonable and appropriate. However, a new exception is allowed if a facility with an existing BCC discharge can demonstrate that it is reducing that discharge to the maximum extent feasible (considering technical and economic factors) but cannot meet WQBELs for that discharge without a mixing zone. EPA, in conjunction with stakeholders within the Great Lakes Basin, will develop guidance for use by ***15377** States and Tribes in exercising the exception provision with special focus on the technical and economic feasibility criteria. This guidance will also consider the notice, public hearing, monitoring and pollution prevention demonstration elements of the exception criteria.

The final Guidance also retains many of the proposed provisions for calculating background concentrations used in TMDLs and WLAs established in the absence of TMDLs. The procedure addressing data points below the level of detection, however, has been modified so that it no longer specifies the use of default values (i.e., half of the level of detection).

The final TMDL procedures do not require that TMDLs be established for point sources prior to the issuance/reissuance of NPDES permits. The final Guidance defers to the existing National program for determining when a TMDL is required. Lastly, the final Guidance allows assessment and remediation plans that are approved by EPA under 40 CFR 130.6 to be used in lieu of a TMDL for purposes of appendix F as long as they meet the general conditions of a TMDL as outlined by procedure 3 of appendix F, and the public participation requirements applicable to TMDLs.

4. Additivity

(Procedure 4 of appendix F to part 132; section VIII.D of the SID)
EPA has traditionally developed numeric water quality criteria on a single pollutant basis. While some potential environmental hazards involve significant exposure to only a single compound, most instances of contamination in surface waters involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life and wildlife. WET tests are available to generally address interactive effects of mixtures on aquatic organisms. EPA's 1986 “Guidelines for the Health Risk Assessment of Chemical Mixtures” set forth principles and procedures for human health risk assessment of chemical mixtures. There are currently no technical guidelines on how to assess effects on wildlife from chemical mixtures.

The preamble for the proposed Guidance discussed several possible approaches to address additive effects from multiple pollutants. Proposed regulatory language was provided for two specific options, each with separate provisions related to aquatic life, wildlife and human health. One approach was developed by the Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife. The other approach was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. In the absence of contrary data, both approaches recommended that the risk

to human health from individual carcinogens in a mixture be considered additive, and that a 10^{-5} risk level be adopted as a cap for the cancer risk associated with mixtures. Both approaches also proposed using TEFs to assess the risk to humans and wildlife from certain chemical classes. The TEF approach converts the concentration of individual components in a mixture of chemicals to an "equivalent" concentration expressed in terms of a reference chemical. Both approaches used the 17 TEFs for dioxins and furans identified in the 1989 EPA document, "Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans," and the 1989 update.

The final Guidance includes a general requirement for States and Tribes to adopt an additivity provision consistent with procedure 4 of appendix F to protect human health from the potential additive adverse effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. The final Guidance also requires the use of the 17 TEFs included in the proposed Guidance to protect human health from the potential additive adverse effects in effluents.

5. Determining the Need for WQBELs (Reasonable Potential)

(Procedure 5 of appendix F to part 132; section VIII.E of the SID)
EPA's existing regulations require NPDES permits to include WQBELs to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause or contribute to an excursion of any applicable water quality standard. If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric water quality criterion, it must include a WQBEL for the individual pollutant in the permit. In the absence of an adopted numeric water quality criterion for an individual pollutant, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by either calculating a numeric criterion for the pollutant; applying EPA's water quality criteria developed under section 304(a) of the CWA, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant. See 40 CFR 122.44(d)(1).

The final Guidance implements these National requirements by specifying procedures for determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of Tier I criteria or Tier II values based on facility-specific effluent data. The final Guidance also specifies procedures for determining whether permitting authorities must generate or require permittees to generate data sufficient to calculate Tier II values when specified pollutants of concern in the Great Lakes System are known or suspected of being discharged, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. EPA believes that the data necessary to calculate Tier II values for aquatic life, wildlife and human health currently exists for most of the specified pollutants of concern.

The final Guidance maintains all the basic requirements from the proposed procedure. Some minor changes are that the procedure no longer includes a special provision for effluent dominated streams, and the procedure allows a broader range of statistical approaches to be used when evaluating effluent data, which provides added simplicity and flexibility to States and Tribes.

Another change from the proposal is the relationship in the final Guidance between the reasonable potential and TMDL procedures. Numerous commenters pointed out that the proposed Guidance indicated that TMDLs would be required for any water receiving effluent from a discharger found to exhibit reasonable potential. Given the fact that there are many waterbodies in the Great Lakes basin for which TMDLs have not been developed, and the obvious need for permitting to proceed in the interim until TMDLs are completed, the final Guidance provides that the permitting authority can establish waste load allocations and WQBELs in the absence of a TMDL or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F. A more detailed discussion of the assessment and remediation plan and its relationship to a TMDL can be found in section VIII.C.2 of the SID. Procedures for establishing such WLAs are therefore addressed in the final Guidance.

***15378 6. Intake Pollutants**

(Procedures 5.D and 5.E of appendix F to part 132; section VIII.E of the SID)
The proposed Guidance allowed a permitting authority to determine that the return of an identified intake water pollutant to the same body of water under specified circumstances does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards, and therefore, that a WQBEL would not be required for that pollutant. Under the proposal, this "pass through" of intake water pollutants would be allowed if the facility returns the intake water containing the pollutant of concern to the same waterbody; does not contribute additional mass of pollutant; does not increase the concentration of the intake water pollutant; and does not discharge at a time or location, or alter the pollutant in a manner which would cause adverse impacts to occur that would not occur if the pollutant were left in-stream.

EPA received numerous comments on the proposal. Some commenters argued that the proposed provision was too narrow because relief would not be available if the facility added any amount of the pollutant to the discharge, even where the facility was not contributing any additional mass or concentration to the waterbody than was contained in the intake water. After consideration of public comments, EPA decided to expand the intake pollutant provisions to include not only a reasonable potential procedure like the one contained in the proposal, but also a provision that allows the permitting authority to take into account the presence of pollutants in intake water in deriving WQBELs. Specifically, the final Guidance authorizes the permitting authority to establish limits based on a principle of "no net addition" (i.e., the limit would allow the mass and concentration of the pollutant in the discharge up to the mass and concentration of the pollutant in the intake water). This provision would be available where the facility's discharge is to the same body of water as the intake water, and could be applied for up to 12 years after publication of the final Guidance. After that time, if a TMDL or comparable plan that meets the requirements of procedure 3 of appendix F has not been completed, the facility's WQBEL must be established in accordance with the "baseline" provisions in procedure 5.F.2 of appendix F. This time limit provides a period of relief for dischargers that are not causing increased impacts on the waterbody by virtue of their discharge that would not have occurred had the pollutant remained in-stream, while maintaining the incentive for development of a comprehensive assessment and remediation plan for achieving attainment of water quality standards, which EPA believes is a critical element of the final Guidance for addressing pollutants for which a large contributor to non-attainment is nonpoint source pollution.

The final Guidance allows States and Tribes to address intake pollutants in a manner consistent with assessment and remediation plans that have been developed through mechanisms other than TMDLs in order to provide flexibility where such plans comprehensively address the point and non-point sources of non-attainment in a waterbody and the means for attaining compliance with standards.

EPA believes that 12 years provides sufficient time for States to develop and complete the water quality assessments that would serve as the basis for establishing effluent limits (including "no net addition" limits, where appropriate) under procedure 3.A of appendix F. However, EPA also recognizes that unforeseen events could delay State completion of these assessments, and therefore will, at 7 years following promulgation, in consultation with the States, evaluate the progress of the assessments. If this evaluation shows that completion of the assessments may not be accomplished by the 12 year date, EPA will revisit these provisions, and consider proposing extensions if appropriate.

Under the final Guidance, the permitting authority can permit the discharge of intake pollutants to a different body of water that is in non-attainment provided limitations require the discharge to meet a WQBEL for the pollutant equal to the pollutant's water quality criterion. Because inter-waterbody transfers of pollutants introduce pollutants to the receiving water that would not be present in that waterbody in the absence of the facility's discharge, EPA does not believe that relief for such pollutants comparable to the "no net addition" approach would be appropriate. However, to address the concern raised by commenters about facilities with multiple sources of intake water, the permitting authority may use a flow-weighted combination of these approaches when the facility has co-mingled sources of intake water from the same and different bodies of water.

EPA maintains that the preferred approach to deal with non-attainment waters, particularly when multiple sources contribute a pollutant for which the receiving water exceeds the applicable criterion, is development of a TMDL or comparable assessment and remediation plan. The above “no net addition” permitting approach provides additional flexibility in situations where a TMDL or comparable plan has not yet been developed. Other existing relief mechanisms include variances to water quality standards, removal of non-existing uses, and site-specific criteria.

7. WET

(Procedure 6 of appendix F to part 132; section VIII.F of the SID)
Existing EPA regulations define WET as “the aggregate toxic effect of an effluent measured directly by a toxicity test.” These regulations require WET limits to be included in permits in most circumstances in which the WET of a discharge has the reasonable potential to cause or contribute to an in-stream excursion above either a State's numeric criteria for toxicity or narrative criteria for water quality (40 CFR 122.2, 122.44(d)(1)). The regulations allow States and Tribes the flexibility to control for WET with either numeric or narrative criteria. Current technical guidelines recommend that no discharge should exceed 0.3 acute toxic units (TUa = 100/LC50) at the edge of an acute mixing zone and 1.0 chronic toxic units (TUc = 100/NOEC, the No Observed Effect Concentration) at the edge of a chronic mixing zone.

The proposed Guidance would have continued to allow States and Tribes the flexibility to choose to control WET with either numeric or narrative criteria, but specified that no discharge could exceed 1.0 TU_a at the point of discharge (i.e., no acute mixing zones) and 1.0 TU_c at the edge of a chronic mixing zone (with some exceptions). In addition, the proposal contained minimum requirements for appropriate test methods to measure WET and for permit conditions, and procedures for determining whether or not limits for WET are necessary.

The final Guidance differs principally from the proposal in requiring States and Tribes to adopt 0.3 TU_a and 1.0 TU_c either as numeric criteria or as an equivalent numeric interpretation of narrative criteria. The final Guidance also allows the use of acute mixing zones for the application of the acute criterion. This approach will promote consistency among States and Tribes in controlling WET, while still permitting considerable flexibility regarding implementation measures, consistent with current National policies and guidelines.

***15379 8. Loading Limits**

(Procedure 9 of appendix F to part 132; section VIII.G of the SID)
The final Guidance provides that WQBELs be expressed in terms of both concentration and mass loading rate, except for those pollutants that cannot appropriately be expressed in terms of mass. These provisions clarify the application of existing Federal regulations at 40 CFR 122.45(f), and are consistent with current EPA guidance which requires the inclusion of any limits determined necessary based on best professional judgment to meet water quality standards, including, where appropriate, mass loading rate limits. They are also consistent with the antidegradation policy for the Great Lakes System in appendix E of the final Guidance.

9. Levels of Quantification

(Procedure 8 of appendix F to part 132; section VIII.H of the SID)
Many of the pollutants of concern in the Great Lakes System cause unacceptable toxic effects at very low concentrations. This results in instances where WQBELs are below levels of reliable quantification. When this occurs, the permitting authority may not be able to determine whether the pollutant concentration is above or below the WQBEL. The final Guidance requires adoption of pollutant minimization programs (PMPs) for such permits to increase the likelihood that the concentration of the pollutant is as close to the effluent limit as possible. The PMP is an ongoing, iterative process that requires, among other things,

internal wastestream monitoring and submission of status reports. The use of PMPs for facilities with pollutants below the level of quantification is consistent with existing EPA guidance.

Unlike the proposal, however, the final Guidance eliminates additional minimum requirements for BCCs. For example, the final Guidance recommends but does not require bio-uptake studies that had been proposed to assess impacts to the receiving water and evaluate the effectiveness of the PMP.

10. Compliance Schedules

(Procedure 9 of appendix F to part 132; section VIII.I of the SID)
The final Guidance includes a procedure that allows Great Lakes States and Tribes to include schedules of compliance in permits for existing Great Lakes dischargers for effluent limitations based on new water quality criteria and certain other requirements. Generally, compliance schedules may provide for up to five years to comply with the effluent limitation in question and may, in specified cases, allow the compliance schedule to go beyond the term of the permit. Existing Great Lakes dischargers are those whose construction commenced before March 23, 1997. Thus the term, existing Great Lakes discharges, covers expanding dischargers who were ineligible for compliance schedules under the proposal. The final Guidance also provides the opportunity for States and Tribes to allow dischargers additional time to comply with effluent limitations based on Tier II values while conducting studies to justify modifications of those limitations.

C. Antidegradation Provisions

(§132.4(a)(6); appendix E to part 132; section VII of the SID)
EPA's existing regulations, at 40 CFR 131.6, establish an antidegradation policy as one of the minimum requirements of an acceptable water quality standards submittal. Section 131.12 describes the required elements of an antidegradation policy. These are: protection of water quality necessary to maintain existing uses, protection of high quality waters (those where water quality exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the waters) and protection of water quality in those water bodies identified as outstanding National resources.

The proposed Guidance provided detailed procedures for implementing antidegradation that were not part of the existing regulations. The detailed implementation procedures were intended to result in greater consistency in how antidegradation was applied throughout the Great Lakes System. The proposed Guidance specified, among other things, how high quality waters should be identified, what activities should and should not require review under antidegradation, and the information necessary to support a request to lower water quality and the procedures to be followed by a Tribe or State in making a decision whether or not to allow a lowering of water quality.

The final Guidance maintains the overall structure of the proposed Guidance while allowing Tribes and States greater flexibility in how antidegradation is implemented. As in the proposal, the final Guidance is composed of an antidegradation standard, antidegradation implementation procedures, antidegradation demonstration and antidegradation decision. However, many of the detailed requirements found in the proposed Guidance appear in the SID accompanying the final Guidance as nonbinding guidelines, including provisions specific to non-BCCs.

Key elements of the proposed Guidance that are retained in the final Guidance for BCCs include: identification of high quality waters on a pollutant-by-pollutant basis; requirements for States and Tribes to adopt an antidegradation standard consistent with the final Guidance for BCCs; minimum requirements for conducting an antidegradation review of any activity expected to result in a significant lowering of water quality due to BCCs, minimum requirements for notifying permitting authorities of increases in discharges of BCCs; and, minimum requirements for an antidegradation demonstration consisting of a pollution prevention analysis, an alternative treatment analysis and a showing that the significant lowering of water quality will allow for important social and economic development. Significant changes from the proposed Guidance include: encouraging, but not

requiring, States and Tribes to adopt provisions consistent with the antidegradation standard and implementation procedures for non-BCCs; replacement of numeric existing effluent quality-based (EEQ) limits as a means of implementing antidegradation for BCCs with a narrative description of the types of activities that will trigger an antidegradation review; and greater flexibility in the implementation, demonstration and decision components. A detailed discussion of the basis for each of the changes is provided in Section VII the SID.

D. Regulatory Requirements

(Part 132; Tables 5 and 6 to part 132; section II of the SID)
The Great Lakes States must adopt water quality standards, anti-degradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of this publication. If a Great Lakes State fails to adopt such standards, policies, and procedures, section 118(c)(2)(C) of the CWA requires EPA to promulgate them not later than the end of that two-year period. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into its water program.

Part 132 establishes requirements and procedures to implement section 118(c)(2)(C). Sections 132.3 and 132.4 ***15380** require Great Lakes States and Tribes to adopt criteria, methodologies, policies, and procedures consistent with the criteria, methodologies, policies, and procedures contained in part 132—that is, the definitions in §132.2, the numeric criteria in Tables 1 through 4, the criteria development methodologies in appendixes A through D, the antidegradation policy in appendix E, and the implementation procedures in appendix F. Section 132.5 specifies the procedures for States and Tribes to make their submissions to EPA, and for EPA to approve or disapprove the submissions. The section specifies that in reviewing submissions, EPA will consider provisions of State and Tribal submissions to be "consistent with" the final Guidance if each provision is as protective as the corresponding provision of the final Guidance. If a State or Tribe fails to make a submission, or if provisions of the submission are not consistent with the final Guidance, §132.5 provides that EPA will publish a final rule in the Federal Register identifying the final Guidance provisions that will apply to discharges within the particular State or Federal Indian Reservation.

Section 132.4 specifies that water quality criteria adopted by States and Tribes consistent with the final Guidance will apply to all waters of the Great Lakes System, regardless of designated uses of the waters in most cases, with some variations in human health criteria depending on whether the waters are designated for drinking water use. Section 132.4 also contains certain exceptions in applying the final Guidance methodologies and procedures. First, States and Tribes do not have to adopt and apply the final Guidance methodologies and procedures for the 14 pollutants listed in Table 5 of part 132. EPA believes that some or all of the methodologies and procedures are not scientifically appropriate for these pollutants. Second, if a State or Tribe demonstrates that the final Guidance methodologies or procedures are not scientifically defensible for a particular pollutant, the State or Tribe may use alternate methodologies or procedures so long as they meet all applicable Federal, State, and Tribal laws. Third, §132.4 specifies that for wet-weather point sources, States and Tribes generally do not have to adopt and apply the final Guidance implementation procedures. The exception is the TMDL general condition for wet weather events. Fourth, pursuant to section 510 of the CWA, part 132 specifies that nothing in the final Guidance prohibits States or Tribes from adopting provisions more stringent than the final Guidance.

As discussed further in section IX of this preamble, §132.4 also provides that State and Tribal submissions will need to include any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation with the U.S. Fish and Wildlife Service (FWS) under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to any endangered or threatened species listed under the ESA.

Part 132 extends the requirements of section 118(c)(2)(C) to Indian Tribes within the Great Lakes basin for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA. EPA believes that inclusion of Great Lakes Tribes in this way is necessary and appropriate to be

consistent with section 518 of the CWA. The reasons for EPA's proposal are discussed further in the preamble to the proposed Guidance (58 FR 20834), and section II.D.3 of the SID. As a practical matter, no Great Lakes Tribes currently have approved water quality standards or authorized NPDES programs, so the submission requirements of part 132 do not apply to any Great Lakes Tribes. Tribes that are approved or authorized in the future, however, will need to adopt provisions consistent with the final Guidance in their water programs.

V. Costs, Cost-Effectiveness and Benefits

(Section IX of the SID)
Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it raises novel policy issues arising out of the development of a comprehensive ecosystem-based approach for a large geographic area involving several States, Tribal governments, local governments, and a large number of regulated dischargers. This approach, including the Great Lakes Water Quality Initiative which developed the core concepts of the final Guidance, is a unique and precedential approach to the implementation of environmental programs. As such, this action was submitted to OMB for review pursuant to Executive Order 12866. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

The following is a summary of major elements of the "Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance" (RIA) (EPA 820-B-95-011) that has been prepared in compliance with Executive Order 12866. Further discussion is included in section IX of the SID, and in the full RIA, which is available in the docket for this rulemaking.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. Therefore, this publication of the final Guidance does not have an immediate effect on dischargers. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect on any dischargers. For the purposes of the RIA, EPA's analysis of costs and benefits assumes that either State or EPA promulgations occur consistent with the final Guidance within the next two years.

Under the CWA, costs cannot be a basis for adopting water quality criteria that will not be protective of designated uses. If a range of scientifically defensible criteria that are protective can be identified, however, costs may be considered in selecting a particular criterion within that range. Costs may also be relevant under the antidegradation standard as applied to high quality waters.

EPA has assessed compliance costs for facilities that could be affected by provisions adopted by States or Tribes consistent with the final Guidance. EPA has also assessed basin-wide risk reduction benefits to sport anglers and Native American subsistence

anglers in the basin, and benefits for three case study sites in the Great Lakes System. ***15381** The methodology used in each assessment and the results of these assessments are discussed below.

EPA solicited public comment and supporting data on the RIA methodology used to estimate both costs and benefits for implementation of the proposed Guidance. EPA evaluated these comments and supporting data as well as comments provided by OMB and revised the RIA methodology prior to performing these assessments for the final Guidance.

A. Costs

Based on the information provided by each State and a review of the permit files, EPA identified about 3,800 direct dischargers that could be affected by State or Tribal adoption or subsequent EPA promulgation, if necessary, of requirements consistent with the final Guidance. Of these, about 590 are major dischargers and the remaining 3,210 are minor dischargers. Of the 590 majors, about 275 are industrial facilities and 315 are publicly owned treatment works (POTWs). Out of these dischargers, EPA used a stratified random sampling procedure to select 59 facilities (50 major and nine minor) that it considered representative of all types and sizes of facilities in the basin.

EPA divided the major facilities into nine industrial categories and a category for POTWs. The nine industrial categories are: mining, food and food products, pulp and paper, inorganic chemical manufacturing, organic chemical manufacturing/petroleum refining, metals manufacturing, electroplating/metal fabrication, steam electric power plants, and miscellaneous facilities.

For each major and minor facility in the sample, EPA estimated incremental costs to comply with subsequently promulgated provisions consistent with the final Guidance, using a baseline of compliance with the requirements of section 303(c)(2)(B) of the CWA. Using a decision matrix, costs were developed for two different scenarios—a “low-end” cost scenario and a “high-end” cost scenario—to account for the range of regulatory flexibility available to States and Tribes when adopting and implementing provisions consistent with the final Guidance. In addition, the decision matrix specified assumptions used for selection of control options in the cost analysis such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and “end of pipe” effluent treatment.

The annualized costs for direct and indirect dischargers to implement the final Guidance are estimated to be between $60 million (low end) and $380 million (high end) (first quarter 1994 dollars). EPA believes the costs for implementing the final Guidance, which balance pollution prevention, “end-of-pipe” treatment and regulatory flexibility, will approach the low end of the cost range. Costs are unlikely to reach the high end of the cost range because State and Tribal authorities are likely to choose implementation options that provide some degree of relief to point source dischargers, especially because in many cases the nonpoint source contributions will be significant. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because in cases where the final Guidance provides States and Tribes flexibility in selecting less costly approaches when implementing provisions consistent with the final Guidance, the most costly approach was used to estimate the costs. This approach was used to reduce uncertainty in the cost analysis for the final Guidance.

Under the low-end cost scenario, major industrial facilities and POTWs would account for about 65 percent of the costs, indirect dischargers about 33 percent, and minor dischargers about two percent. Among the major dischargers three categories would account for most of the costs—POTWs (39 percent), pulp and paper (14 percent), and miscellaneous (eight percent). The average per plant costs for different industry categories range from zero to $168,000. The two highest average cost categories are pulp and paper ($151,000) and miscellaneous ($168,000). Although major POTWs make up a large portion of the total cost, the average cost per plant under the low-end scenario is not among the highest at $75,000 per facility. About half of the low-end costs are associated with pollution prevention activities, and about half are for capital and operating costs for wastewater treatment.

For the high-end cost scenario, direct dischargers account for 98 percent of the total estimated cost, and indirect dischargers account for two percent. This shift in proportion of costs between direct and indirect dischargers and between the low and the high estimates are due to the assumption that more direct dischargers will need to use end-of-pipe treatment under the high-end

scenario. In addition, it was assumed that a smaller proportion of indirect dischargers (10 percent) would be impacted under the high-end scenario, since municipalities are adding end-of-pipe treatment which should reduce the need for source controls (i.e., reduce the need for increased pretreatment program efforts) by indirect discharges. Less than 10 percent of the high-end costs are associated with pollution prevention activities, and over 90 percent are for capital and operating costs for wastewater treatment.

Under the high-end scenario for the direct dischargers, municipal major dischargers are expected to incur just under 70 percent of total costs, and industrial major dischargers account for 29 percent of total costs. Minor direct dischargers are estimated to incur less than one percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (23 percent of total) and miscellaneous (three percent) categories. The food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

Under the high-end scenario, the average annual cost per major municipal facility is just over $822,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for pulp and paper ($1,583,000 per plant) and miscellaneous ($433,700 per plant) categories. Regardless of the scenario, the average costs for minor facilities are negligible at an estimated $500 per facility.

The costs described above account for the costs of eliminating mixing zones for BCCs except in narrow circumstances, costs related to implementation of Tier II values, and specific calculated costs related to intake credits. The cost assessment also projects the potential cost savings across the different scenarios that facilities may realize if States or Tribes use existing regulatory relief mechanisms to modify or eliminate the need for a WQBEL for an identified pollutant (e.g., variances, TMDLs, site-specific modifications to criteria, and changes in designated uses).

In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a “lost opportunity” cost for facilities impacted by the antidegradation requirements. This cost could result in the addition of about $22 million each year.

B. Cost-Effectiveness

EPA estimated the cost-effectiveness of the final Guidance in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness (cost per pound removed) is derived by dividing the annualized costs of implementing the final ***15382** Guidance by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

It is estimated that implementation of provisions consistent with the final Guidance would be responsible for the reduction of about six to eight million toxic pounds per year, or 16 to 22 percent of the toxic-weighted baseline for the low- and high-end scenarios, respectively. The cost-effectiveness of the scenarios, over the baseline, is quite good, ranging from $10 to $50 per pound-equivalent.

Approximately 80 percent of the pollutant load reduction from implementation of the final Guidance, regardless of the scenario, is attributable to reducing BCCs as a result of PMPs and end-of-pipe treatment. The largest pollutant load reductions occur for chlordane, dieldrin, heptachlor, lead, and pentachlorobenzene.

In a separate analysis, EPA also investigated the cost-effectiveness of regulating point and nonpoint sources of mercury and PCBs, two contaminants associated with fish advisories in the Great Lakes basin. Although data and resource constraints limited the findings from these analyses, the preliminary results indicate that point sources may factor cost-effectively into pollutant reduction scenarios. For both contaminants, the cost-effectiveness of point and nonpoint source controls are likely to be highly site-specific.

C. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of implementation of provisions adopted by States and Tribes consistent with the final Guidance. To the extent feasible, empirical estimates of the potential magnitude of the benefits are developed and then compared to the estimated costs of implementing provisions adopted by States and Tribes consistent with the final Guidance.

The benefits analysis is based on a case study approach, using benefits transfer applied to three case studies. The case study approach was used because it is more amenable to meaningful benefit-cost analyses than are studies of larger aggregate areas. Although the results obtained for a case study site may not apply uniformly to the entire Great Lakes basin, the case study approach does provide a pragmatic and realistic perspective of how implementation of the final Guidance can generate benefits, the types of benefits anticipated, and how these benefits compare to costs.

The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio. The case studies were selected from a list of candidate sites (i.e., designated Areas of Concern (AOCs) in the Great Lakes basin) on the basis of data availability and the relevance of the water quality problems to the final Guidance (i.e., areas in which problems were more likely to be associated with on-going point source discharges rather than historic loadings from Superfund sites and other sources). Geographic diversity was also considered in selecting the sites so that the analyses might better promote a broad perspective of the final Guidance's benefits and costs.

For each of the three case studies, EPA estimated future toxics-oriented water quality benefits, and then attributed a percentage of these benefits to implementation of the final Guidance. The attribution of benefits was based only on the estimated reduction in loadings from point sources at the case study sites and information on the relative contribution of point sources to total loadings in the basin. EPA did not attempt to calculate the longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water.

In the Fox River and Green Bay case study, total annual undiscounted benefits attributable to the final Guidance range from $0.3 million to $8.5 million (first quarter 1994 dollars). Human health benefits account for between 29 percent and 72 percent of the estimated benefits, recreational fishing accounts for between eight percent and 45 percent, and nonuse/ecologic benefits account for between nine percent and 23 percent. Municipal and industrial dischargers in this case study are estimated to incur annualized costs of about $3.6 million.

In the Saginaw River/Bay case study, total annual undiscounted benefits range from $0.2 million to $7.7 million. Recreational fishing benefits account for between 36 percent and 60 percent of the estimated benefits, non-use benefits account for between 18 percent and 30 percent, and human health benefits account for between eight percent and 36 percent. Total annualized costs to municipal and industrial dischargers are estimated to be about $2.6 million.

In the Black River case study, total annual undiscounted benefits range from $0.4 million to $1.5 million. Recreational fishing benefits account for between 48 percent and 63 percent of the estimated benefits, and nonuse benefits account for between 32 percent and 44 percent. Total annualized costs to municipal and industrial dischargers are estimated to be $2.1 million.

An inherent limitation of the case study approach is the inability to extrapolate from a limited set of river-based sites to the Great Lakes basin as a whole. Accordingly, extrapolation of the case study results to the Great Lakes basin is not recommended. However, as noted above, the three case studies were selected on the basis of data availability, the relative importance of point source discharges to the watersheds' problems, and an attempt to portray spatial diversity throughout the Great Lakes basin. Thus, there is no reason to conclude that the selected sites are not reflective of the basin, even though benefits (and costs) tend to be highly site-specific. In addition, the benefits extend from the case study rivers into the larger, open-water environment of the Great Lakes.

The representativeness of the case study sites was assessed by comparing the percentage of total benefits estimated to accrue in the case study areas to the percentage of basin-wide costs incurred by the case study sites. Benefits-related measures (such as population, recreational angling days, and nonconsumptive recreation days) were used in place of total benefits for this analysis because there is no estimate of benefits for the entire Great Lakes basin. The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e., basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest). Thus, the three case studies may represent a reasonably proportionate share of costs and benefits.

In addition to the case study analyses, a basin-wide risk assessment was conducted for Great Lakes anglers. EPA collected data and information on the consumption of Great Lakes basin fish to estimate baseline risk levels and reductions in risks due to implementation of the final Guidance for two populations at risk: Great Lakes sport anglers (including minority and ***15383** low-income anglers) and Native Americans engaged in subsistence fishing in the basin. For sport anglers, EPA estimated that the projected reduction in loadings from point sources based on controls consistent with the final Guidance would result in a reduction of annual excess lifetime cancer cases (potential cancer cases assuming a 70-year lifetime exposure period) of 2.2 to 4.1 for low-income minorities in lakeshore counties; 0.4 to 0.8 for other minorities in lakeshore counties; and 21.9 to 41.9 for all other sport anglers. For Native American subsistence anglers, EPA estimated that reductions from point source loadings attributable to the final Guidance would result in a reduction of excess lifetime cancer cases of between 0.1 and 0.3 using a low fish ingestion scenario and 0.5 to 1.1 using a high fish ingestion scenario. Note that these estimates do not include the long-term benefits (including reduced cancer cases) that will result once the final Guidance provisions are fully implemented and the minimum protection levels are attained in the ambient water.

In total, using the most conservative consumption scenario for Native Americans, these reductions represent between 0.35 and 0.67 excess cancer cases per year, and potential basin-wide benefits of the final Guidance for this one benefits category of between $0.7 million and $6.7 million per year, based on the estimated value of a statistical life of between $2.0 million and $10.0 million. Comparison to case study results, which were based on a more comprehensive sample of facilities within case study areas than was possible for the entire basin, indicates these values likely underestimate the potential risk reduction benefits of the final Guidance at the basin level. For example, if the average percentage load reduction for PCBs for the three case studies is used to reflect reductions in PCBs for the basin, the reduction in excess cancer cases increases to between three and six cases per year, and potential benefits increase to between $6.6 and $60 million per year.

The reduction in pollutant loadings for PCBs was likely understated in the basin-wide analysis because the analysis did not count pollutant load reduction benefits when the current State-based permit limit and the final Guidance-based permit limit were both below the pollutant analytical method detection limit (MDL). Only three sample facilities in the population of 59 sample facilities used to project basin-wide costs and human health benefits had State-based permit limits for PCBs. Since the current State-based permit limit and the final Guidance-based permit limit were below the MDL in all three facilities, “zero” reduction in PCB loadings for the basin was estimated. This, of course, is an artifact of the methodology and the size of the sample population selected for the analysis, and would not occur, as demonstrated in the case study analysis, if a larger sample population had been used.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), EPA generally is required to conduct a final regulatory flexibility analysis (FRFA) describing the impact of the regulatory action on small entities as part of the final rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a FRFA.

Implementation of the final Guidance is dependent upon future promulgation of provisions consistent with it by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions, or equally protective provisions consistent with the final Guidance, there will be no economic effect of this rule on any entities, large or small. For

that reason, and pursuant to Section 605(b) of the RFA, EPA is certifying that this rule itself will not have a significant economic impact on a substantial number of small entities.

Although EPA is certifying that this rule will not have a significant economic impact on a substantial number of small entities, and therefore is not required to prepare a FRFA, it is nevertheless including for public information in the RIA a discussion of the possible economic effects to small entities that could result from State or Tribal adoption of provisions consistent with the final Guidance or subsequent EPA promulgation, if necessary. As discussed above, small facilities are projected to incur costs of only approximately $500 per facility to comply with subsequently promulgated requirements that are consistent with the final Guidance. Accordingly, EPA believes there will be no significant economic impact on a substantial number of small entities as a result of State or Tribal implementation of the final Guidance.

VII. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875 (58 FR 58093, October 28, 1993), EPA has involved State, Tribal, and local governments in the development of the final Guidance.

As described in section II above, the core elements of the final Guidance were developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem over a five-year period through the Initiative. The Initiative process marks the first time that EPA has developed a major rulemaking effort in the water program through a regional public forum. The Initiative process is described further in the preamble to the proposed Guidance (58 FR 20820-23) and section II of this preamble.

In addition to the participation by State and local governments in the initial development of the proposed Guidance and in the public comment process, several activities have been carried out since the publication of the proposed Guidance. These include:

(1) On April 26, 1994, EPA held a public meeting to solicit additional information from interested parties on the proposed Guidance. As part of EPA's outreach efforts to State, Tribal and local governments, a special invitation was sent inviting elected officials and other State, Tribal and local representatives to participate in the public meeting. EPA specifically welcomed Tribal and local officials and opened the floor to them to hear and discuss their specific concerns and views on the final Guidance.

(2) A series of meetings and teleconferences were held with Great Lakes States in early 1994 to discuss their comments on several issues, including development of water quality criteria, State adoption requirements, WET, BAFs, additivity, compliance schedules, anti-backsliding, nonpoint sources, and international concerns.

(3) In October, 1994, EPA met with each individual State in the Great Lakes basin to discuss the nature, form, and scope of the proposed Guidance, and State concerns with implementation of the provisions under consideration. The following issues were discussed at each of the meetings: intake credits, antidegradation and EEQ, wildlife criteria, excluded pollutants (e.g., ammonia and chlorine), elimination of mixing zones, site-specific modifications, fish consumption, appropriate degrees of flexibility for implementation (e.g., guidance vs. regulation), and implementation procedures.

(4) In 1994 and 1995, EPA met with representatives of the National Wildlife Federation to discuss EPA's activities in developing the final Guidance in ***15384** accordance with the terms of a consent decree governing the schedule for development of the final Guidance.

(5) In 1994, EPA also met with elected officials and other representatives from several local communities in the Great Lakes basin to discuss issues regarding the economic impact of the proposed Guidance on local communities and POTWs. Issues discussed include cost impacts associated with implementing water quality criteria, methodologies, and implementation procedures; dealing with pollution from nonpoint sources; public outreach to control pollutants such as mercury instead of costly end-of-pipe treatment; and applicability of provisions in the final Guidance to the National water quality program.

(6) EPA held an additional 18 consultations with the regulated community throughout 1994. Such meetings allowed representatives of dischargers to share additional data, which has been placed in the docket for this rulemaking, and concerns about a range of issues, including cost concerns, that the dischargers expect to arise in implementation of the final Guidance.

(7) In 1994, EPA met with State representatives to conduct initial planning for implementation of the GLI Clearinghouse. All Great Lakes States agreed to participate in this effort, which will involve the sharing of toxicological and other data to assist in the development of additional water quality criteria and values.

The results of the above efforts have assisted in the development of the final Guidance through broad communication with a full range of interested parties, sharing of additional information, and incorporation of features to improve the implementation of the final Guidance.

EPA has estimated the total annual State government burden to implement the final Guidance as approximately 5,886 hours, resulting in a State government cost of $175,992 annually. Such burden and costs were estimated based upon the burden and costs associated with developing water quality criteria, review of antidegradation policy demonstrations, review of approvable control strategies and BCC monitoring data, and review of variance requests. The total annual local government burden is estimated to be 42,296 hours with an associated cost of $2,008,624. All of the burden and costs to local governments are associated with being a regulated entity as an operator of a POTW.

VIII. Paperwork Reduction Act

The information collection requirements in this final Guidance have been approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned OMB control number 2040-0180. EPA has prepared an Information Collection Request (ICR) document (ICR No. 1639.02). A copy of ICR 1639.02 may be obtained by writing to Ms. Sandy Farmer, Information Policy Branch, EPA 2136, Washington, D.C. 20460, or by calling (202) 260-2740.

The annual public reporting and record keeping burden for this regulation is estimated to be 128,787 hours for the affected 3,795 permittees, or an average of 34 hours. This includes the total annual burden to local governments as POTW operators, estimated to be 45,296 hours. The total annual burden to State governments is estimated to be 5,886 hours. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

In this rulemaking EPA is also amending the table of currently approved ICR control numbers issued by OMB for various regulations into 40 CFR 9.1. This amendment updates the table to accurately display those information requirements promulgated under the CWA. The affected regulations are codified at 40 CFR parts 122, 123, 131, and 132. EPA will continue to present OMB control numbers in a consolidated table format. The table will be codified in 40 CFR part 9 of EPA's regulations and in each 40 CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

The ICR for this rulemaking was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is “good cause” under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

IX. Endangered Species Act

Pursuant to section 7(a)(2) of the ESA, EPA consulted with the FWS concerning EPA's publication of the final Guidance. EPA and the FWS have now completed both informal and formal consultation conducted over a two-year period.

As a result of the consultation, as well as an analysis of comments, EPA modified several provisions of the final Guidance. The procedure for site-specific modifications provides that Great Lakes States and Tribes must make site-specific modifications to criteria and values where necessary to ensure the resulting water quality does not cause jeopardy to listed or proposed species. Similarly, the antidegradation policy and implementation procedures restrict certain actions States and Tribes may take to allow lowering of water quality in high quality waters, or to adopt variances or mixing zones. Additionally, the regulatory requirements were modified to require Great Lakes States and Tribes to include in their part 132 submissions any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to listed species. EPA and the FWS also agreed on how further consultations will be conducted as the final Guidance is implemented. The two agencies also agreed that EPA will undertake a review of water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA.

During the consultation, two issues were identified that required formal consultation, as defined in 40 CFR part 402. These issues were: the absence of toxicological data concerning effects of contaminants on three species of freshwater mussels in the Great Lakes basin, and the adequacy of the wildlife criteria methodology to protect three endangered or threatened wildlife species in the basin. On February 21, 1995, the FWS provided EPA with a written Biological Opinion (Opinion) on these issues. The Opinion is available in the docket for this rulemaking. On both issues, the FWS concluded that the water quality resulting from implementation of the final Guidance will not cause jeopardy to the listed species. To minimize the amount or extent of any incidental take that might ***15385** occur, the FWS consulted closely with EPA to develop a coordinated approach. The final Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact. EPA has agreed to implement the measures, and the FWS and EPA will continue to work cooperatively during the implementation.

X. Judicial Review of Provisions Not Amended

In some situations, EPA has renumbered or included other editorial changes to regulations that have been promulgated in past rulemakings. Additionally, to provide for ease in reading changes to existing regulations, EPA has in some cases repeated entire sections, including portions not changed. The promulgation of this final rule, however, does not provide another opportunity to seek judicial review on the substance of the existing regulations.

XI. Supporting Documents

All documents that are referenced in this preamble are available for inspection and photocopying in the docket for this rulemaking at the address listed at the beginning of this preamble. A reasonable fee will be charged for photocopies.

Selected documents supporting the final Guidance are also available for viewing by the public at locations listed below:

Illinois: Illinois State Library, 300 South 2nd Street, Springfield, IL 62701 (217-785-5600)

Indiana: Indiana Department of Environmental Management, Office of Water Management, 100 North Senate Street, Indianapolis, IN 46204 (317-232-8671)

Michigan: Library of Michigan, Government Documents Service, 717 West Allegan, Lansing, MI 48909 (517-373-1300); Detroit Public Library, Sociology and Economics Department, 5201 Woodward Avenue, Detroit, MI 48902 (313-833-1440)

Minnesota: Minnesota Pollution Control Agency, Library, 520 Lafayette, St. Paul, MN (612-296-7719)

New York: U.S. EPA Region 2 Library, Room 402, 26 Federal Plaza, New York, NY 10278 (212-264-2881); U.S. EPA Public Information Office, Carborundum Center, Suite 530, 345 Third Street, Niagara Falls, NY 14303 (716-285-8842); New York State Department of Environmental Conservation (NYSDEC), Room 310, 50 Wolf Road, Albany, NY 12333 (518-457-7463); NYSDEC, Region 6, 7th Floor, State Office Building, 317 Washington Street, Watertown, NY 13602 (315-785-2513); NYSDEC, Region 7, 615 Erie Boulevard West, Syracuse, NY 13204 (315-426-7400); NYSDEC, Region 8, 6274 East Avon-Lima Road, Avon, NY 14414 (716-226-2466); NYSDEC, Region 9, 270 Michigan Avenue, Buffalo, NY 14203 (716-851-7070)

Ohio: Ohio Environmental Protection Agency Library—Central District Office, 1800 Watermark Road, Columbus, OH 43215 (614-644-3024); U.S. EPA Eastern District Office, 25809 Central Ridge Road, Westlake, OH 44145 (216-522-7260)

Pennsylvania: Pennsylvania Department of Environmental Resources, 230 Chestnut Street, Meadville, PA 16335 (814-332-6945); U.S. EPA Region 3 Library, 8th Floor, 841 Chestnut Building, Philadelphia, PA 19107-4431 (215-597-7904)

Wisconsin: Water Resources Center, University of Wisconsin-Madison, 2nd Floor, 1975 Willow Drive, Madison, WI (608-262-3069)

EPA is also making a number of documents available in electronic format at no incremental cost to users of the Internet. These documents include the contents of this Federal Register document, the SID, many documents listed below, and other supporting materials.

The documents listed below are also available for a fee upon written request or telephone call to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161 (telephone 800-553-6847 or 703-487-4650). Alternatively, copies may be obtained for a fee upon written request or telephone call to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, OH 43212 (614-292-6717). When ordering, please include the NTIS or ERIC/CSMEE accession number.

A. Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID). NTIS Number: PB95187266. ERIC Number: D046.

B. Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water. NTIS Number: PB95187282. ERIC Number: D048.

C. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. NTIS Number: PB95187290. ERIC Number: D049.

D. Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. NTIS Number: PB95187308. ERIC Number: D050.

E. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values. NTIS Number: PB95187316. ERIC Number: D051.

F. Great Lakes Water Quality Initiative Criteria Document for the Protection of Wildlife: DDT; Mercury; 2,3,7,8-TCDD; PCBs. NTIS Number: PB95187324. ERIC Number: D052.

G. Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria. NTIS Number: PB95187332. ERIC Number: D053.

H. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187340. ERIC Number: D054.

I. Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187357. ERIC Number: D055.

List of Subjects

40 CFR Part 9
Reporting and recordkeeping requirements.

40 CFR Part 122
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 131
Great Lakes, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 132
Administrative practice and procedure, Great Lakes, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 13, 1995.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 9, 122, 123, and 131 are amended, and part 132 is added as follows:

***15386 PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**
1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.
40 CFR § 9.1

2. Section 9.1 is amended as follows:

a. By adding in numerical order the entry “122.44(r)” under the heading “EPA Administered Permit Programs: The National Pollutant Discharge Elimination System”.

b. By revising the entries under the heading “State Permit Requirements”;

c. By adding in numerical order the entries “131.1” and “131.5” and by revising the entries “131.20”, “131.21” and “131.22” under the heading “Water Quality Standards Regulations”; and

d. By adding in numerical order a new heading and new entries for “Water Quality Guidance for the Great Lakes System” to read as follows:

40 CFR § 9.1

§9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
EPA Administered Permit Programs: The National Pollutant Discharge Elimination System	
* * * * *	
122.44(r)	2040-0180
* * * * *	
State Permit Requirements	
123.21-123.24	2040-0057, 2040-0170
123.25	2040-0004, 2040-0110, 2040-0170, 2040-0180
123.26-123.29	2040-0057, 2040-0170
123.43	2040-0057, 2040-0170
123.44	2040-0057, 2040-0170, 2040-0180

123.45	2040-0057, 2040-0170
123.62	2040-0057, 2040-0170, 2040-0180
123.63	2040-0057, 2040-0170, 2040-0180
123.64	2040-0057, 2040-0170

Water Quality Standards Regulation

131.1	2040-0180
131.5	2040-0180

* * * * *

131.20	2040-0049
131.21	2040-0049, 2040-0180
131.22	2040-0049

* * * * *

Water Quality Guidance for the Great Lakes System

132.1	2040-0180
132.2	2040-0180
132.3	2040-0180
132.4	2040-0180
132.5	2040-0180
Appendix A	2040-0180
Appendix B	2040-0180
Appendix C	2040-0180
Appendix D	2040-0180

Appendix E	2040-0180
Appendix F	2040-0180

* * * * *

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

3. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 122.44

4. Section 122.44 is amended by adding a new paragraph (r) to read as follows:

40 CFR § 122.44

§122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see §123.25).

* * * * *

(r) Great Lakes. When a permit is issued to a facility that discharges into the Great Lakes System (as defined in 40 CFR 132.2), conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

PART 123—STATE PROGRAM REQUIREMENTS

5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 123.25

6. Section 123.25 is amended by removing “and” at the end of paragraph (a)(36), removing the period at the end of paragraph (a)(37) and adding “; and” in its place, and adding a new paragraph (a)(38) to read as follows:

40 CFR § 123.25

§123.25 Requirements for permitting.

(a) * * *

(38) For a Great Lakes State or Tribe (as defined in 40 CFR 132.2), 40 CFR part 132 (NPDES permitting implementation procedures only).

* * * * *40 CFR § 123.44

7. Section 123.44 is amended by adding a new paragraph (c)(9) to read as follows:

40 CFR § 123.44

§123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(9) For a permit issued by a Great Lakes State or Tribe (as defined in 40 CFR 132.2), the permit does not satisfy the conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

* * * * *40 CFR § 123.62

8. Section 123.62 is amended by adding a new paragraph (f) to read as follows:

40 CFR § 123.62

§123.62 Procedures for revision of State programs.

* * * * *

(f) Revision of a State program by a Great Lakes State or Tribe (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132 shall be accomplished pursuant to 40 CFR part 132.

40 CFR § 123.63

9. Section 123.63 is amended by adding a new paragraph (a)(6) and adding and reserving paragraph (b) to read as follows:

40 CFR § 123.63

§123.63 Criteria for withdrawal of State programs.

(a) * * *

(6) Where a Great Lakes State or Tribe (as defined in 40 CFR 132.2) fails to adequately incorporate the NPDES permitting implementation procedures promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132 into individual permits.

(b) [Reserved]

PART 131—WATER QUALITY STANDARDS

10. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 131.1

11. Section 131.1 is revised to read as follows:

40 CFR § 131.1

§131.1 Scope.

40 CFR § 132.2

This part describes the requirements and procedures for developing, reviewing, revising, and approving water quality standards by the States as authorized by section 303(c) of the Clean Water Act. Additional specific procedures for developing, reviewing, revising, and approving water quality standards for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the ***15387** Clean Water Act and 40 CFR part 132, are provided in 40 CFR part 132.

40 CFR § 131.5

12. Section 131.5 is amended by revising paragraph (a)(5), by redesignating paragraph (b) as paragraph (c), and by adding a new paragraph (b) to read as follows:

40 CFR § 131.5

§131.5 EPA Authority.

(a) * * *

(5) Whether the State submission meets the requirements included in §131.6 of this part and, for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the Act, the requirements of 40 CFR part 132.

(b) If EPA determines that the State's or Tribe's water quality standards are consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *40 CFR § 131.21

13. Section 131.21 is amended by revising paragraph (b) to read as follows:

40 CFR § 131.21

§131.21 EPA review and approval of water quality standards.

* * * * *

(b) The Regional Administrator's approval or disapproval of a State water quality standard shall be based on the requirements of the Act as described in §§131.5 and 131.6, and, with respect to Great Lakes States or Tribes (as defined in 40 CFR 132.2), 40 CFR part 132.

* * * * *

14. Part 132 is added as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

Tables to Part 132

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 132.1

§132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System (Guidance) required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 et seq.) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101-596, 104 Stat. 3000 et seq.). The Guidance in this part identifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) The U.S. Environmental Protection Agency, Great Lakes States, and Great Lakes Tribes will use the Guidance in this part to evaluate the water quality programs of the States and Tribes to assure that they are protective of water quality. State and Tribal programs do not need to be identical to the Guidance in this part, but must contain provisions that are consistent with (as protective as) the Guidance in this part. The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the preamble, Supplementary Information Document, Technical Support Documents,

and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing the State and Tribal water quality programs in the Great Lakes for consistency with this part.

(c) The Great Lakes States and Tribes must adopt provisions consistent with the Guidance in this part applicable to waters in the Great Lakes System or be subject to EPA promulgation of its terms pursuant to this part.

(d) EPA understands that the science of risk assessment is rapidly improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D are always current and peer reviewed, EPA will review the methodologies and revise them, as appropriate, every 3 years.

(e) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.
40 CFR § 132.2

§132.2 Definitions.
The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act and EPA implementing regulations.

Acute-chronic ratio (ACR) is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

Acute toxicity is concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Bioaccumulation is the net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time.

Bioaccumulative chemical of concern (BCC) is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation ***15388** product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

Bioconcentration is the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF) is the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Carcinogen is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Chronic toxicity is concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

Criterion maximum concentration (CMC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.

Endangered or threatened species are those species that are listed as endangered or threatened under section 4 of the Endangered Species Act.

Existing Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, that is not a new Great Lakes discharger.

Federal Indian reservation, Indian reservation, or reservation means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher GMAVs, or (b) the SMAV of an important and/or critical species, if the SMAV is lower than the calculated estimate.

Final chronic value (FCV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, (b) the quotient of an FAV divided by an appropriate acute-chronic ratio, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Final plant value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important.

Genus mean acute value (GMAV) is the geometric mean of the SMAVs for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the SMCVs for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian Tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the Clean Water Act or which EPA has authorized to administer an NPDES program under section 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes within the United States.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Indian Tribe or Tribe means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is a statistically or graphically estimated concentration that is expected ***15389** to be lethal to 50 percent of a group of organisms under specified conditions.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future nonpoint sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is the lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

Method detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth in appendix B of 40 CFR part 136.

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed.

New Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, the construction of which commenced after March 23, 1997.

No observed adverse effect level (NOAEL) is the highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

No observed effect concentration (NOEC) is the highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

Open waters of the Great Lakes (OWGLs) means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in (mg/kg)/day which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Species mean acute value (SMAV) is the geometric mean of the results of all acceptable flow-through acute toxicity tests (for which the concentrations of the test material were measured) with the most sensitive tested life stage of the species. For a species for which no such result is available for the most sensitive tested life stage, the SMAV is the geometric mean of the results of all acceptable acute toxicity tests with the most sensitive tested life stage.

Species mean chronic value (SMCV) is the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests.

Stream design flow is the stream flow that represents critical conditions, upstream from the source, for protection of aquatic life, human health, or wildlife.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are numeric values derived by use of the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

Uncertainty factor (UF) is one of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

Uptake is acquisition of a substance from the environment by an organism as a result of any active or passive process.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h). In the absence of a TMDL approved by EPA pursuant to 40 CFR 130.7 or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F of this part, a WLA is the allocation for an individual point source, that ensures that the level of water quality to be achieved by the point source is derived from and complies with all applicable water quality standards.

Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, ***15390** commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the Clean Water Act. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

40 CFR § 132.3

§132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with §132.4(d) that are consistent with:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

40 CFR § 132.4

§132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in §132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodology for Development of Wildlife Criteria in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies and procedures consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric criteria and values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply implementation procedures consistent with the procedures in appendix F of this part for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures consistent with procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply an antidegradation policy consistent with the policy in appendix E for all applicable purposes under the Clean Water Act, including 40 CFR 131.12.

(g) For pollutants listed in Table 5 of this part, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or

(2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

(i) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values specified in §132.3 or that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part, or to adopt antidegradation standards and implementation procedures more ***15391** stringent than those set forth in appendixes E and F of this part.
40 CFR § 132.5

§132.5 Procedures for adoption and EPA review.

(a) Except as provided in paragraph (c) of this section, the Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than September 23, 1996.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of National Pollutant Discharge Elimination System (NPDES) program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) The Regional Administrator may extend the deadline for the submission required in paragraph (a) of this section if the Regional Administrator believes that the submission will be consistent with the requirements of this part and can be reviewed and approved pursuant to this section no later than March 23, 1997.

(d) If a Great Lakes State or Tribe makes no submission pursuant to this part to EPA for review, the requirements of this part shall apply to discharges to waters of the Great Lakes System located within the State or Federal Indian reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(e) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review that contain substantial modifications of the State or Tribal NPDES program, EPA shall issue public notice and provide a minimum of 30 days for public comment on such modifications. The public notice shall conform with the requirements of 40 CFR 123.62.

(f) After review of State or Tribal submissions under this section, and following the public comment period in subparagraph (e) of this section, if any, EPA shall either:

(1) Publish notice of approval of the submission in the Federal Register within 90 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the Federal Register identifying the approved and disapproved elements of the submission and a final rule in the Federal Register identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian reservation.

(g) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA's determination whether the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part will be based on whether:

(1) For pollutants listed in Tables 1, 2, 3, and 4 of this part. The Great Lakes State or Tribe has adopted numeric water quality criteria as protective as each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) For pollutants other than those listed in Tables 1, 2, 3, 4, and 5 of this part. The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are as protective as or more protective than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures in accordance with procedure 1 of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more protective of:

(A) Numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997; or

(B) Water quality criteria and values derived pursuant to §132.4(c); and

(3) For methodologies, policies, and procedures. The Great Lakes State or Tribe has adopted methodologies, policies, and procedures as protective as the corresponding methodology, policy, or procedure in §132.4. The Great Lakes State or Tribe may adopt provisions that are more protective than those contained in this part. Adoption of a more protective element in one provision may be used to offset a less protective element in the same provision as long as the adopted provision is as protective as the corresponding provision in this part; adoption of a more protective element in one provision, however, is not justification for adoption of a less protective element in another provision of this part.

(h) A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

(i) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.
40 CFR § 132.6

§132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CMC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 339.8	1.000

Chromium (VI)	[a,b] 16.02		0.982
Cyanide	[c] 22	n/a	
Dieldrin	[d] 0.24	n/a	
Endrin	[d] 0.086	n/a	
Lindane	[d] 0.95	n/a	
Mercury (II)	[a,b] 1.694		0.85
Parathion	[d] 0.065	n/a	
Selenium	[a,b] 19.34		0.922

***15392** (b)

Chemical	m_A	b_A	Conversion factor (CF)
Cadmium [a,b]	1.128	3.6867	0.85
Chromium (III) [a,b]	0.819	+3.7256	0.316
Copper [a,b]	0.9422	1.700	0.960
Nickel [a,b]	0.846	+2.255	0.998
Pentachlorophenol [c]	1.005	4.869	n/a
Zinc [a,b]	0.8473	+0.884	0.978

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CCC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 147.9	1.000
Chromium (VI)	[a,b] 10.98	0.962

Cyanide	[c] 5.2	n/a	
Dieldrin	[d] 0.056	n/a	
Endrin	[d] 0.036	n/a	
Mercury (II)	[a,b] 0.9081		0.85
Parathion	[d] 0.013	n/a	
Selenium	[a,b] 5		0.922

(b)

Chemical	m_c	b_c	Conversion factor (CF)
Cadmium [a,b]	0.7852	2.715	0.850
Chromium (III) [a,b]	0.819	+0.6848	0.860
Copper [a,b]	0.8545	1.702	0.960
Nickel [a,b]	0.846	+0.0584	0.997
Pentachlorophenol [c]	1.005	5.134	n/a
Zinc [a,b]	0.8473	+0.884	0.986

Table 3.—Water Quality Criteria for Protection of Human Health

Chemical	HNV (MUg/L)		HCV (MUg/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	1.9E1	5.1E2	1.2E1	3.1E2
Chlordane	1.4E-3	1.4E-3	2.5E-4	2.5E-4
Chlorobenzene	4.7E2	3.2E3		
Cyanides	6.0E2	4.8E4		
DDT	2.0E-3	2.0E-3	1.5E-4	1.5E-4
Dieldrin	4.1E-4	4.1E-4	6.5E-6	6.5E-6
2,4-Dimethylphenol	4.5E2	8.7E3		
2,4-Dinitrophenol	5.5E1	2.8E3		

Hexachlorobenzene	4.6E-2	4.6E-2	4.5E-4	4.5E-4	
Hexachloroethane	6.0	7.6	5.3	6.7	
Lindane	4.7E-1	5.0E-1			
Mercury [1]	1.8E-3	1.8E-3			
Methylene chloride	1.6E3	9.0E4	4.7E1	2.6E3	
PCBs (class)	.....		3.9E-6	3.9E-6	
2,3,7,8-TCDD	6.7E-8	6.7E-8	8.6E-9	8.6E-9	
Toluene	5.6E3	5.1E4			
Toxaphene	.....		6.8E-5	6.8E-5	
Trichloroethylene	.....		2.9E1	3.7E2	

Table 4.—Water Quality Criteria for Protection of Wildlife

Chemical	Criteria (MUg/L)
DDT and metabolites	1.1E-5
Mercury (including methylmercury)	1.3E-3
PCBs (class)	7.4E-5
2,3,7,8-TCDD	3.1E-9

***15393** Table 5.—Pollutants Subject to Federal, State, and Tribal Requirements
Alkalinity

Ammonia

Bacteria

Biochemical oxygen demand (BOD)

Chlorine

Color

Dissolved oxygen

Dissolved solids

pH

Phosphorus

Salinity

Temperature

Total and suspended solids

Turbidity

Table 6.—Pollutants of Initial Focus in the Great Lakes Water Quality Initiative
A. Pollutants that are bioaccumulative chemicals of concern (BCCs):

Chlordane

4,4#-DDD; p,p#-DDD; 4,4#-TDE; p,p#-TDE

4,4#-DDE; p,p#-DDE

4,4#-DDT; p,p#-DDT

Dieldrin

Hexachlorobenzene

Hexachlorobutadiene; hexachloro-1, 3-butadiene

Hexachlorocyclohexanes; BHCs

alpha-Hexachlorocyclohexane; alpha-BHC

beta-Hexachlorocyclohexane; beta-BHC

delta-Hexachlorocyclohexane; delta-BHC

Lindane; gamma-hexachlorocyclohexane; gamma-BHC

Mercury

Mirex

Octachlorostyrene

PCBs; polychlorinated biphenyls

Pentachlorobenzene

Photomirex

2,3,7,8-TCDD; dioxin

1,2,3,4-Tetrachlorobenzene

1,2,4,5-Tetrachlorobenzene Toxaphene

B. Pollutants that are not bioaccumulative chemicals of concern:

Acenaphthene

Acenaphthylene

Acrolein; 2-propenal

Acrylonitrile

Aldrin

Aluminum

Anthracene

Antimony

Arsenic

Asbestos

1,2-Benzanthracene; benz[a]anthracene

Benzene

Benzidine

Benzo[a]pyrene; 3,4-benzopyrene

3,4-Benzofluoranthene; benzo[b]fluoranthene

11,12-Benzofluoranthene; benzo[k]fluoranthene

1,12-Benzoperylene; benzo[ghi]perylene

Beryllium

Bis(2-chloroethoxy) methane

Bis(2-chloroethyl) ether

Bis(2-chloroisopropyl) ether

Bromoform; tribomomethane

4-Bromophenyl phenyl ether

Butyl benzyl phthalate

Cadmium

Carbon tetrachloride; tetrachloromethane

Chlorobenzene

p-Chloro-m-cresol; 4-chloro-3-methylphenol

Chlorodibromomethane

Chlorethane

2-Chloroethyl vinyl ether

Chloroform; trichloromethane

2-Chloronaphthalene

2-Chlorophenol

4-Chlorophenyl phenyl ether

Chlorpyrifos

Chromium

Chrysene

Copper

Cyanide

2,4-D; 2,4-Dichlorophenoxyacetic acid

DEHP; di(2-ethylhexyl) phthalate

Diazinon

1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene

Dibutyl phthalate; di-n-butyl phthalate

1,2-Dichlorobenzene

1,3-Dichlorobenzene

1,4-Dichlorobenzene

3,3#-Dichlorobenzidine

Dichlorobromomethane; bromodichloromethane

1,1-Dichloroethane

1,2-Dichloroethane

1,1-Dichloroethylene; vinylidene chloride

1,2-trans-Dichloroethylene

2,4-Dichlorophenol

1,2-Dichloropropane

1,3-Dichloropropene; 1,3-dichloropropylene

Diethyl phthalate

2,4-Dimethylphenol; 2,4-xylenol

Dimethyl phthalate

4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol

2,4-Dinitrophenol

2,4-Dinitrotoluene

2,6-Dinitrotoluene

Dioctyl phthalate; di-n-octyl phthalate

1,2-Diphenylhydrazine

Endosulfan; thiodan

alpha-Endosulfan

beta-Endosulfan

Endosulfan sulfate

Endrin

Endrin aldehyde

Ethylbenzene

Fluoranthene

Fluorene; 9H-fluorene

Fluoride

Guthion

Heptachlor

Heptachlor epoxide

Hexachlorocyclopentadiene

Hexachloroethane

Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene

Isophorone

Lead

Malathion

Methoxychlor

Methyl bromide; bromomethane

Methyl chloride; chloromethane

Methylene chloride; dichloromethane

Napthalene

Nickel

Nitrobenzene

2-Nitrophenol

4-Nitrophenol

N-Nitrosodimethylamine

N-Nitrosodiphenylamine

N-Nitrosodipropylamine; N-nitrosodi-n-propylamine

Parathion

Pentachlorophenol

Phenanthrene

Phenol

Iron

Pyrene

Selenium

Silver

1,1,2,2-Tetrachloroethane

Tetrachloroethylene

Thallium

Toluene; methylbenzene

1,2,4-Trichlorobenzene

1,1,1-Trichloroethane

1,1,2-Trichloroethane

Trichloroethylene; trichloroethene

2,4,6-Trichlorophenol

Vinyl chloride; chloroethylene; chloroethene

Zinc

Appendix A to part 132—Great Lakes Water Quality Initiative Methodologies for Developments of Aquatic Life Criteria and Values

Methodology for Deriving Aquatic Life Criteria: Tier I

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

15394** ***I. Definitions

A. Material of Concern. When defining the material of concern the following should be considered:

1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g., some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloid), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material of concern should include an operational analytical component. Identification of a material simply as “sodium,” for example, implies “total sodium,” but leaves room for doubt. If “total” is meant, it must be explicitly stated. Even “total” has different operational definitions, some of which do not necessarily measure “all that is there” in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

a. The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses. Toxicity is the property of a material, or combination of materials, to adversely affect organisms.

b. Because an ideal analytical measurement will rarely be available, an appropriate compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. What is an appropriate measurement in one situation might not be appropriate for another. For example, because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is appropriate for analyzing an effluent might not be appropriate for expressing a criterion, and vice versa. A criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

Note: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods.

4. It is now the policy of EPA that the use of dissolved metal to set and measure compliance with water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of metal in the water column that does total recoverable metal. One reason is that a primary mechanism for water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. Reasons for the consideration of total recoverable metals criteria include risk management considerations not covered by evaluation of water column toxicity. A risk manager may consider sediments and food chain effects and may decide to take a conservative approach for metals, considering that metals are very persistent chemicals. This approach could include the use of total recoverable metal in water quality standards. A range of different risk management decisions can be justified. EPA recommends that State water quality standards be based on dissolved metal. EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable under this program.

B. Acute Toxicity. Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism. (Concurrent toxicity is an adverse effect to an organism that results from, and occurs during, its exposure to one or more test materials.) Exposure constitutes contact with a chemical or physical agent. Acute exposure, however, is exposure of an organism for any short period which usually does not constitute a substantial portion of its life span.

C. Chronic Toxicity. Concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure. Chronic exposure is exposure of an organism for any long period or for a substantial portion of its life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (e.g., publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. In some cases, it might be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it might be appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods. A flow-through test is a test with aquatic organisms in which test solutions flow into constant-volume test chambers either intermittently (e.g., every few minutes) or continuously, with the excess flowing out.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios. An ACR is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with species non-resident to North America or previously exposed organisms may be used to provide auxiliary information but must not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. An adverse effect is a change in an organism that is harmful to the organism. Exposure means contact with a chemical or physical agent. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are usually available because procedures for conducting tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute (or chronic) tests (see section IV or VI of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

***15395** a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish);

c. A third family in the phylum Chordata (e.g., fish, amphibian);

d. A planktonic crustacean (e.g., a cladoceran, copepod);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with at least one species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived except in special cases. For example, derivation of a chronic criterion might not be possible if the available ACRs vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix), more data will be required.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value (FAV). The calculated Final Acute Value is a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher Genus Mean Acute Values (GMAVs). An acute test is a comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span. However, in some cases, the Species Mean Acute Value (SMAV) of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FAV, then the SMAV replaces the calculated FAV in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 729, Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed should not be used, unless data indicate that the food did not affect the toxicity of the test material. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges must be started with second or third instar larvae. It is preferred that the results should be the 48-hour EC50 based on the total percentage of organisms killed and immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test. An EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. An LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.

2. It is preferred that the results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on the percentage of organisms with incompletely developed shells plus the percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48-hour to 96-hour LC50s. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

3. It is preferred that the result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should

be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as “greater than” values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing circumstances.

H. If the available data indicate that one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the SMAV because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the SMAV shall be calculated as the geometric mean of the results of all acceptable flow-through acute toxicity tests in which the concentrations of test material were measured with the most sensitive tested life stage of the species. For a species for which no such result is available, the SMAV shall be calculated as the geometric mean of all acceptable acute toxicity tests with the most sensitive tested life stage, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material. A renewal test is a test with aquatic organisms in which either the test solution in a test chamber is removed and replaced at least once during the test or the test organisms are transferred into a new test solution of the same composition at least once during the test. A static test is a test with aquatic organisms in which the solution ***15396** and organisms that are in a test chamber at the beginning of the test remain in the chamber until the end of the test, except for removal of dead test organisms.

Note 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must not be rounded off to fewer than four significant digits.

Note 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

Note 3: Geometric means, rather than arithmetic means, are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for ACRs because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the GMAV shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are fewer than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the four selected GMAVs, and Ps, calculate

Note: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through V.G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus should not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing justification. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too

few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. For each species, calculate the geometric mean of the available acute values and then divide each of the acute values for the species by the geometric mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually using the same procedure as above.

F. Individually for each species perform a least squares regression of the normalized ***15397** acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section V.B. of this appendix. If, however, the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections V.D and V.E of this appendix).

I. For each species, calculate the logarithm, Y, of the SMAV at a selected value, Z, of the water quality characteristic using the equation:

Y=ln WV(ln Xln Z)
J. For each species calculate the SMAV at X using the equation:

$SMAV=e^{Y}$
Note: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the FAV at Z by using the procedure described in sections IV.J through IV.O of this appendix.

L. If, for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow-through tests in which the concentrations of the test material were measured is lower than the FAV at Z, then the geometric mean must be used as the FAV instead of the FAV.

M. The Final Acute Equation is written as:

$FAV=e^{(V[\ln(\text{water quality characteristic})]+AV[\ln Z])}$,
where:

V=pooled acute slope, and A=ln(FAV at Z).
Because V, A, and Z are known, the FAV can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value (FCV) can be calculated in the same manner as the FAV or by dividing the FAV by the Final Acute-Chronic Ratio (FACR). In some cases, it might not be possible to calculate a FCV. The FCV is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, or (b) the quotient of an FAV divided by an appropriate ACR, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Note: As the name implies, the ACR is a way of relating acute and chronic toxicities.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test. A chronic test is a comparative study in which organisms, that are subjected to different treatments, are observed for a long period or a substantial portion of their life span.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for ceriodaphnids not less than seven days. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 1193 Guide for conducting renewal life-cycle toxicity tests with Daphnia magna and ASTM Standard E 1295 Guide for conducting three-brood, renewal toxicity tests with Ceriodaphnia dubia. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. A life-cycle test is a comparative study in which organisms, that are subjected to different treatments, are observed at least from a life stage in one generation to the same life-stage in the next generation. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and

analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

Note: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and,

c. Above which all tested concentrations also caused such an effect.

Note: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related ***15398** to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a SMCV shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests. Appropriate GMCVs shall also be calculated. A GMCV is the geometric mean of the SMCVs for the genus. The FCV shall be obtained using the procedure described in sections IV.J through IV.O of this appendix, substituting SMCV and GMCV for SMAV and GMAV respectively. See section VI.M of this appendix.

Note: Section VI.I through VI.L are for use when chronic values are not available for species in eight taxonomic families as described in section III.B.1 of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an ACR, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests were not conducted as part of the same study, but were conducted as part of a different study in the same laboratory and dilution water, then they may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an ACR shall not be calculated.

J. For each species, calculate the SMACR as the geometric mean of all ACRs available for that species. If the minimum ACR data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used along with the freshwater data.

K. For some materials, the ACR seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the SMAV increases. Thus the FACR can be obtained in three ways, depending on the data available:

1. If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the FAV.

2. If no major trend is apparent and the ACRs for all species are within a factor of ten, the FACR shall be calculated as the geometric mean of all of the SMACRs.

3. If the most appropriate SMACRs are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the FACR should be assumed to be two, so that the FCV is equal to the Criterion Maximum Concentration (CMC). (See section X.B of this appendix.)

If the available SMACRs do not fit one of these cases, a FACR may not be obtained and a Tier I FCV probably cannot be calculated.

L. Calculate the FCV by dividing the FAV by the FACR.

FCV=FAV+FACR

If there is a Final Acute Equation rather than a FAV, see also section V of this appendix.
M. If the SMCV of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV, then that SMCV must be used as the FCV instead of the calculated FCV.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If ACRs are available for enough species at enough values of the water quality characteristic to indicate that the ACR appears to be the same for all species and appears to be independent of the water quality characteristic, calculate the FACR as the geometric mean of the available SMACRs.

2. Calculate the FCV at the selected value Z of the water quality characteristic by dividing the FAV at Z (see section V.M of this appendix) by the FACR.

3. Use V=pooled acute slope (see section V.M of this appendix), and

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic, the relationship should be taken into account as described in sections C through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus in most cases should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is, in most cases, absent countervailing circumstances, appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the ACR is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species, calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species, perform a least squares regression of the normalized chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

***15399** I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the SMCV at a selected value, Z, of the water quality characteristic using the equation:

Q=ln M—L(ln Pln Z)
Note: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section V of this appendix.

K. For each species, calculate a SMCV at Z using the equation:

$SMCV=e^{Q}$
Note: Alternatively, the SMCV at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z, and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted chronic values for each species.

L. Obtain the FCV at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the SMCV at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV at Z, then that SMCV shall be used as the FCV at Z instead of the calculated FCV.

N. The Final Chronic Equation is written as:

$FCV=e^{(L[\ln(\text{water quality characteristic})]+\ln SL[\ln Z])}$

Where:

L=pooled chronic slope and S = FCV at Z.
Because L, S, and Z are known, the FCV can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. A Final Plant Value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will, in most cases, also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

Note: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 mg/L should be considered excessive.

C. The FPV shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Delayed toxicity is an adverse effect to an organism that results from, and occurs after the end of, its exposure to one or more test materials. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F.3 of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the CMC and the Criterion Continuous Concentration (CCC).

B. The CMC is equal to one-half the FAV. The CMC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

C. The CCC is equal to the lowest of the FCV or the FPV (if available) unless other data (see section IX of this appendix) show that a lower value should be used. The CCC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or FPV (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a commercially or recreationally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration

of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the CCC

(3) = insert the CMC

If the CMC averaging period of one hour or the CCC averaging period of four days is inappropriate for the pollutant, or if the once-in-three-year allowable excursion frequency is inappropriate for the pollutant or for the sites to which a criterion is applied, then the State may specify alternative averaging periods or frequencies. The choice of an alternative averaging period or frequency shall be justified by a scientifically defensible analysis demonstrating that the alternative values will protect the aquatic life uses of the water. Appropriate laboratory data and/or well-designed field biological surveys shall be submitted to EPA as justification for differing averaging periods and/or frequencies of exceedance.

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance in this part. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?

2. Are all required data available?

3. Is the range of acute values for any species greater than a factor of 10?

4. Is the range of SMAVs for any genus greater than a factor of 10?

5. Is there more than a factor of 10 difference between the four lowest GMAVs?

6. Are any of the lowest GMAVs questionable?

7. Is the FAV reasonable in comparison with the SMAVs and GMAVs?

8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the FAV?

9. Are any of the chronic values used questionable?

10. Are any chronic values available for acutely sensitive species?

11. Is the range of acute-chronic ratios greater than a factor of 10?

12. Is the FCV reasonable in comparison with the available acute and chronic data?

13. Is the measured or predicted chronic value for any commercially or recreationally important species of the Great Lakes System below the FCV?

14. Are any of the other data important?

15. Do any data look like they might be outliers?

16. Are there any deviations from the Guidance in this part? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived consistent with the Guidance in this part.

Methodology for Deriving Aquatic Life Values: Tier II

15400** ***XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes System shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A-1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). (Requirements for definitions, data collection and data review, contained in sections I, II, and IV shall be applied to calculation of a SAV.) If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—Ceriodaphnia sp., Daphnia sp., or Simocephalus sp.

If appropriate, the SAV shall be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined ACRs, meeting the data collection and review requirements of Section VI of this appendix, are available for the chemical, determine the FACR using the procedure described in Section VI. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined ACRs are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values or chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV or SCV, then that geometric mean must be used as the SAV or SCV instead of the calculated SAV or SCV.

XVI. Tier II Value

A. A Tier II value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (see section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or FPV, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The Tier II value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the SCC

(3) = insert the SMC
As discussed above, States and Tribes have the discretion to specify alternative averaging periods or frequencies (see section X.E. of this appendix).

XVII. Appropriate Modifications
On the basis of all available pertinent laboratory and field information, determine if the Tier II value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, shall be derived consistent with the Guidance in this part.

Table A-1.— Secondary Acute Factors

Number of minimum data requirements satisfied	Adjustment factor
1	21.9
2	13.0
3	8.0
4	7.0
5	6.1
6	5.2
7	4.3

Appendix B to Part 132—Great Lakes Water Quality Initiative

Methodology for Deriving Bioaccumulation Factors

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. The purpose of this methodology is to describe procedures for deriving bioaccumulation factors (BAFs) to be used in the calculation of Great Lakes Water Quality Guidance (Guidance) human health Tier I criteria and Tier II values and wildlife Tier I criteria. A subset of the human health BAFs are also used to identify the chemicals that are considered bioaccumulative chemicals of concern (BCCs).

B. Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes (i.e., ambient water and food), as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only through the ambient water. Both BAFs and bioconcentration factors (BCFs) are proportionality constants that describe the relationship between the concentration of a substance in aquatic organisms and its concentration in the ambient water. For the Guidance in this part, BAFs, rather than BCFs, are used to calculate Tier I criteria for human health and wildlife and Tier II values for human health because they better account for the total exposure of aquatic organisms to chemicals.

C. For organic chemicals, baseline BAFs can be derived using four methods. Measured baseline BAFs are derived from field-measured BAFs; predicted baseline BAFs are derived using biota-sediment accumulation factors (BSAFs) or are derived by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier (FCM). The lipid content of the aquatic organisms is used to account for partitioning of organic chemicals within organisms so that data from different ***15401** tissues and species can be integrated. In addition, the baseline BAF is based on the concentration of freely dissolved organic chemicals in the ambient water to facilitate extrapolation from one water to another.

D. For inorganic chemicals, baseline BAFs can be derived using two of the four methods. Baseline BAFs are derived using either field-measured BAFs or by multiplying laboratory-measured BCFs by a FCM. For inorganic chemicals, BAFs are assumed to equal BCFs (i.e., the FCM is 1.0), unless chemical-specific biomagnification data support using a FCM other than 1.0.

E. Because both humans and wildlife consume fish from both trophic levels 3 and 4, two baseline BAFs are needed to calculate either a human health criterion or value or a wildlife criterion for a chemical. When appropriate, ingestion through consumption of invertebrates, plants, mammals, and birds in the diet of wildlife species to be protected may be taken into account.

II. Definitions

Baseline BAF. For organic chemicals, a BAF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BAF that is based on the wet weight of the tissue.

Baseline BCF. For organic chemicals, a BCF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BCF that is based on the wet weight of the tissue.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to and the ratio does not change substantially over time.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF). The ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food-chain multiplier (FCM). The ratio of a BAF to an appropriate BCF.

Octanol-water partition coefficient (K_{OW}). The ration of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{OW}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Uptake. Acquisition of a substance from the environment by an organism as a result of any active or passive process.

III. Review and Selection of Data

A. Data Sources. Measured BAFs, BSAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.

2. Published scientific literature.

3. Reports issued by EPA or other reliable sources.

4. Unpublished data.

One useful source of references is the Aquatic Toxicity Information Retrieval (AQUIRE) database.

B. Field-Measured BAFs. The following procedural and quality assurance requirements shall be met for field-measured BAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. The trophic level of the fish species shall be determined.

3. The site of the field study should not be so unique that the BAF cannot be extrapolated to other locations where the criteria and values will apply.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

5. The concentration of the chemical in the water shall be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.

6. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water shall be either measured or reliably estimated.

7. For inorganic and organic chemicals, BAFs shall be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

C. Field-Measured BSAFs. The following procedural and quality assurance requirements shall be met for field-measured BSAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. Samples of surface sediments (0-1 cm is ideal) shall be from locations in which there is net deposition of fine sediment and is representative of average surface sediment in the vicinity of the organism.

3. The K_{ow}s used shall be acceptable quality as described in section III.F below.

4. The site of the field study should not be so unique that the resulting BAF cannot be extrapolated to other locations where the criteria and values will apply.

5. The tropic level of the fish species shall be determined.

6. The percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

D. Laboratory-Measured BCFs. The following procedural and quality assurance requirements shall be met for laboratory-measured BCFs:

1. The test organism shall not be diseased, unhealthy, or adversely affected by the concentration of the chemical.

2. The total concentration of the chemical in the water shall be measured and should be relatively constant during the steady-state time period.

3. The organisms shall be exposed to the chemical using a flow-through or renewal procedure.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BCF.

5. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the test solution shall be either measured or reliably estimated.

6. Laboratory-measured BCFs should be determined using fish species, but BCFs determined with molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, a baseline BCF determined for such a chemical using invertebrates is expected to be higher than a comparable baseline BCF determined using fish.

7. If laboratory-measured BCFs increase or decrease as the concentration of the chemical increases in the test solutions in a bioconcentration test, the BCF measured at the lowest test concentration that is above concentrations existing in the control water shall be used (i.e., a BCF should be calculated from a control treatment). The concentrations of an inorganic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccummulation of an inorganic chemical might be overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

8. For inorganic and organic chemicals, BCFs shall be used only if they are expressed on a wet weight basis. BCFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

9. BCFs for organic chemicals may be based on measurement or radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

10. The calculation of the BCF must appropriately address growth dilution.

11. Other aspects of the methodology used should be similar to those described by ASTM (1990).

***15402** E. Predicted BCFs. The following procedural and quality assurance requirements shall be met for predicted BCFs:

1. The K_{ow} used shall be of acceptable quality as described in section III.F below.

2. The predicted baseline BCF shall be calculated using the equation: predicted baseline BCF = K_{ow}

where:

K_{ow} = octanol-water partition coefficient.

F. Octanol-Water Partition Coefficient (K_{ow}). 1. The value of K_{ow} used for an organic chemical shall be determined by giving priority to the experimental and computational techniques used as follows:

Log K_{ow} < 4:

Priority	Technique
1	Slow-stir.
1	Generator-column.
1	Shake-flask.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Calculated by the CLOGP program.

Log K_{ow} > 4:

Priority	Technique
1	Slow Stir.
1	Generator-column.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Shake-flask.
5	Calculated by the CLOGP program.

2. The CLOGP program is a computer program available from Pomona College. A value of K_{ow} that seems to be different from the others should be considered an outlier and not used. The value of K_{ow} used for an organic chemical shall be the geometric mean of the available K_{ow}s with highest priority or can be calculated from the arithmetic mean of the available log K_{ow} with the highest priority. Because it is an intermediate value in the derivation of a BAF, the value used for the K_{ow} of a chemical should not be rounded to fewer than three significant digits and a value for log K_{ow} should not be rounded to fewer than three significant digits after the decimal point.

G. This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF, BSAF, BCF or K_{ow}. The amount of uncertainty in a baseline BAF depends on both the quality of data available and the method used to derive the BAF.

H. Hereinafter in this methodology, the terms BAF, BSAF, BCF and K_{ow} refer to ones that are consistent with the procedural and quality assurance requirements given above.

IV. Four Methods for Deriving Baseline BAFs

Baseline BAFs shall be derived using the following four methods, which are listed from most preferred to least preferred:

A. A measured baseline BAF for an organic or inorganic chemical derived from a field study of acceptable quality.

B. A predicted baseline BAF for an organic chemical derived using field-measured BSAFs of acceptable quality.

C. A predicted baseline BAF for an organic or inorganic chemical derived from a BCF measured in a laboratory study of acceptable quality and a FCM.

D. A predicted baseline BAF for an organic chemical derived from a K_{ow} of acceptable quality and a FCM.

For comparative purposes, baseline BAFs should be derived for each chemical by as many of the four methods as available data allow.

V. Calculation of Baseline BAFs for Organic Chemicals

A. Lipid Normalization. 1. It is assumed that BAFs and BCFs for organic chemicals can be extrapolated on the basis of percent lipid from one tissue to another and from one aquatic species to another in most cases.

2. Because BAFs and BCFs for organic chemicals are related to the percent lipid, it does not make any difference whether the tissue sample is whole body or edible portion, but both the BAF (or BCF) and the percent lipid must be determined for the same tissue. The percent lipid of the tissue should be measured during the BAF or BCF study, but in some cases it can be reliably estimated from measurements on tissue from other organisms. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same or a comparable laboratory population of test organisms that were used in the original study may be used.

3. The lipid-normalized concentration, C_l, of a chemical in tissue is defined using the following equation:

Where:

C_B=concentration of the organic chemical in the tissue of aquatic biota (either whole organism or specified tissue) (MUg/g).

f_l=fraction of the tissue that is lipid.

B. Bioavailability. By definition, baseline BAFs and BCFs for organic chemicals, whether measured or predicted are based on the concentration of the chemical that is freely dissolved in the ambient water in order to account for bioavailability. For the purposes of this Guidance in this part, the relationship between the total concentration of the chemical in the water (i.e., that which is freely dissolved plus that which is sorbed to particulate organic carbon or to dissolved organic carbon) to the freely dissolved concentration of the chemical in the ambient water shall be calculated using the following equation:

Where:

C^{fd}_w=freely dissolved concentration of the organic chemical in the ambient water;

C^{t}_w=total concentration of the organic chemical in the ambient water;

f_{fd}=fraction of the total chemical in the ambient water that is freely dissolved.

The fraction of the total chemical in the ambient water that is freely dissolved, f_{fd}, shall be calculated using the following equation:

Where:

DOC=concentration of dissolved organic carbon, kg of dissolved organic carbon/L of water.

K_{OW}=octanol-water partition coefficient of the chemical.

POC=concentration of particulate organic carbon, kg of particulate organic carbon/L of water.

C. Food-Chain Multiplier. In the absence of a field-measured BAF or a predicted BAF derived from a BSAF, a FCM shall be used to calculate the baseline BAF for trophic levels 3 and 4 from a laboratory-measured or predicted BCF. For an organic chemical, the FCM used shall be derived from Table B-1 using the chemical's log K_{OW} and linear interpolation. A FCM greater than 1.0 applies to most organic chemicals with a log K_{OW} of four or more. The trophic level used shall take into account the age or size of the fish species consumed by the human, avian or mammalian predator because, for some species of fish, the young are in trophic level 3 whereas the adults are in trophic level 4.

D. Calculation of a Baseline BAF from a Field-Measured BAF. A baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

***15403** Where:

BAF^{t}_{T}=BAF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured baseline BAF is available for a given species. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be calculated. If a baseline BAF based on a measured BAF is available for either trophic level 3 or 4, but not both, a measured baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.
E. Calculation of a Baseline BAF from a Field-Measured BSAF. 1. A baseline BAF for organic chemical “i” shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

Where:

$(BSAF)_i$=BSAF for chemical “i”.

$(BSAF)_r$=BSAF for the reference chemical “r”.

$(K_{OW})_i$=octanol-water partition coefficient for chemical “i”.

$(K_{OW})_r$=octanol-water partition coefficient for the reference chemical “r”.
2. A BSAF shall be calculated using the following equation:

Where:

C_t=the lipid-normalized concentration of the chemical in tissue.

C_{SOC}=the organic carbon-normalized concentration of the chemical in sediment.
3. The organic carbon-normalized concentration of a chemical in sediment, C_{SOC}, shall be calculated using the following equation:

Where:

C_S=concentration of chemical in sediment (mg/g sediment).

f_{OC}=fraction of the sediment that is organic carbon.
4. Predicting BAFs from BSAFs requires data from a steady-state (or near steady-state) condition between sediment and ambient water for both a reference chemical “r” with a field-measured BAF_l^{fd} and other chemicals “n=i” for which BSAFs are to be determined.

5. The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF. For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from BSAFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs derived using BSAFs shall be calculated.

6. If a baseline BAF based on a measured BSAF is available for either trophic level 3 or 4, but not both, a baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.

F. Calculation of a Baseline BAF from a Laboratory-Measured BCF. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

Where:

$BCF^{t}T$=BCF based on total concentration in tissue and water.

fl=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical in the test water that is freely dissolved.

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from laboratory-measured BCFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs based on laboratory-measured BCFs shall be calculated.

G. Calculation of a Baseline BAF from an Octanol-Water Partition Coefficient. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

Baseline BAF=(FCM) (predicted baseline BCF)=(FCM) (K_{OW})

Where:

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW}=octanol-water partition coefficient.

VI. Human Health and Wildlife BAFs for Organic Chemicals

A. To calculate human health and wildlife BAFs for an organic chemical, the K_{OW} of the ***15404** y15404[chemical shall be used with a POC concentration of 0.00000004 kg/L and a DOC concentration of 0.000002 kg/L to yield the fraction freely dissolved:

B. The human health BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0182 and 0.0310 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive human health criteria and values for the GLI.

C. The wildlife BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0646 and 0.1031 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive wildlife criteria for the GLI.

VII. Human Health and Wildlife BAFs for Inorganic Chemicals

A. For inorganic chemicals, the baseline BAFs for trophic levels 3 and 4 are both assumed to equal the BCF determined for the chemical with fish, i.e., the FCM is assumed to be 1 for both trophic levels 3 and 4. However, a FCM greater than 1 might be applicable to some metals, such as mercury, if, for example, an organometallic form of the metal biomagnifies.

B. BAFs for Human Health Criteria and Values.

1. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals shall be based on edible tissue (e.g., muscle) of freshwater fish unless it is demonstrated that whole-body BAFs or BCFs are similar to edible-tissue BAFs or BCFs. BCFs and BAFs based on measurements of aquatic plants and invertebrates should not be used in the derivation of human health criteria and values.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with the muscle of fish:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species; and

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the human health BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable edible-portion laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the human health BAF for that chemical.

C. BAFs for Wildlife Criteria.

1. Measured BAFs and BCFs used to determine wildlife BAFs for inorganic chemicals shall be based on whole-body freshwater fish and invertebrate data unless it is demonstrated that edible-tissue BAFs or BCFs are similar to whole-body BAFs or BCFs.

***15405** 2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with whole body of fish or invertebrates:

2. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species.

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the wildlife BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable whole-body laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the wildlife BAF for that chemical.

VIII. Final Review

For both organic and inorganic chemicals, human health and wildlife BAFs for both trophic levels shall be reviewed for consistency with all available data concerning the bioaccumulation, bioconcentration, and metabolism of the chemical. For example, information concerning octanol-water partitioning, molecular size, or other physicochemical properties that might enhance or inhibit bioaccumulation should be considered for organic chemicals. BAFs derived in accordance with this methodology should be modified if changes are justified by available data.

IX. Literature Cited

ASTM. 1990. Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. Standard E 1022. American Society for Testing and Materials, Philadelphia, PA.

Table B-1.—Food-Chain Multipliers for Trophic Levels 2, 3 & 4

Log K_{ow}	Trophic level 2	Trophic [1] level 3	Trophic level 4
2.0	1.000	1.005	1.000
2.5	1.000	1.010	1.002
3.0	1.000	1.028	1.007
3.1	1.000	1.034	1.007
3.2	1.000	1.042	1.009
3.3	1.000	1.053	1.012
3.4	1.000	1.067	1.014
3.5	1.000	1.083	1.019
3.6	1.000	1.103	1.023
3.7	1.000	1.128	1.033
3.8	1.000	1.161	1.042
3.9	1.000	1.202	1.054

4.0	1.000	1.253	1.072
4.1	1.000	1.315	1.096
4.2	1.000	1.380	1.130
4.3	1.000	1.491	1.178
4.4	1.000	1.614	1.242
4.5	1.000	1.766	1.334
4.6	1.000	1.950	1.459
4.7	1.000	2.175	1.633
4.8	1.000	2.452	1.871
4.9	1.000	2.780	2.193
5.0	1.000	3.181	2.612
5.1	1.000	3.643	3.162
5.2	1.000	4.188	3.873
5.3	1.000	4.803	4.742
5.4	1.000	5.502	5.821
5.5	1.000	6.266	7.079
5.6	1.000	7.096	8.551
5.7	1.000	7.962	10.209
5.8	1.000	8.841	12.050
5.9	1.000	9.716	13.964
6.0	1.000	10.556	15.996
6.1	1.000	11.337	17.783
6.2	1.000	12.064	19.907
6.3	1.000	12.691	21.677
6.4	1.000	13.228	23.281
6.5	1.000	13.662	24.604
6.6	1.000	13.980	25.645
6.7	1.000	14.223	26.363
6.8	1.000	14.355	26.669

6.9	1.000	14.388		26.669
7.0	1.000	14.305		26.242
7.1	1.000	14.142		25.468
7.2	1.000	13.852		24.322
7.3	1.000	13.474		22.856
7.4	1.000	12.987		21.038
7.5	1.000	12.517		18.967
7.6	1.000	11.708		16.749
7.7	1.000	10.914		14.388
7.8	1.000	10.069		12.050
7.9	1.000	9.162		9.840
8.0	1.000	8.222		7.798
8.1	1.000	7.278	6.012	
8.2	1.000	6.361		4.519
8.3	1.000	5.489		3.311
8.4	1.000	4.683		2.371
8.5	1.000	3.949		1.663
8.6	1.000	3.296		1.146
8.7	1.000	2.732		0.778
8.8	1.000	2.246		0.521
8.9	1.000	1.837		0.345
9.0	1.000	1.493		0.226

***15406 Appendix C to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Human Health Criteria and Values**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

Great Lakes States and Tribes shall adopt provisions consistent with this appendix C to ensure protection of human health.

A. Goal. The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. Definitions.

Acceptable daily exposure (ADE). An estimate of the maximum daily dose of a substance which is not expected to result in adverse noncancer effects to the general human population, including sensitive subgroups.

Adverse effect. Any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Carcinogen. A substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Human cancer criterion (HCC). A Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C.

Human cancer value (HCV). The maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC). A Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV). The maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health criteria and Values in appendix C of this part.

Linearized multi-stage model. A conservative mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer.

Lowest observed adverse effect level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No observed adverse effect level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Quantitative structure activity relationship (OSAR) or structure activity relationship (SAR). A mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Relative source contribution (RSC). The factor (percentage) used in calculating an HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD). A dose of a known or presumed carcinogenic substance in (mg/kg/day) which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Slope factor. Also known as q_1*, slope factor is the incremental rate of cancer development calculated through use of a linearized multistage model or other appropriate model. It is expressed in (mg/kg/day) of exposure to the chemical in question.

Threshold effect. An effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Uncertainty factor (UF). One of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

C. Level of Protection. The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or noncarcinogenic effects. Criteria are a function of the level of designated risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime upper-bound incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

D. Two-tiered Classification. Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels and the quantity and quality of data on bioaccumulation.

II. Minimum Data Requirements

The best available toxicity data on the adverse health effects of a chemical and the best data on bioaccumulation factors shall be used when developing human health Tier I criteria or Tier II values. The best available toxicity data shall include data from well ***15407** -conducted epidemiologic and/or animal studies which provide, in the case of carcinogens, an adequate weight of evidence of potential human carcinogenicity and, in the case of noncarcinogens, a dose-response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS. When deviations from IRIS are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or the Cancer Risk Assessment Verification Endeavor (CRAVE) workgroup immediately. The best available bioaccumulation data shall include data from field studies and well-conducted laboratory studies.

A. Carcinogens. Tier I criteria and Tier II values shall be derived using the methodologies described in section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists. Carcinogens are classified, depending on the weight of evidence, as either human carcinogens, probable human carcinogens, or possible human carcinogens. The human evidence is considered inadequate and therefore the chemical cannot be classified as a human carcinogen, if one of two conditions exists: (a) there are few pertinent data, or (b) the available studies, while showing evidence of association, do not exclude chance, bias, or confounding and therefore a casual interpretation is not credible. The animal evidence is considered inadequate, and therefore the chemical cannot

be classified as a probable or possible human carcinogen, when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

Chemicals are described as “human carcinogens” when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the chemicals and cancer. Chemicals described as “probable human carcinogens” include chemicals for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Limited human evidence is that which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, cannot adequately be excluded. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Sufficient animal evidence is data which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (a) in multiple species or strains; (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests (such as mutagenicity/genotoxicity tests which help determine whether the chemical interacts directly with DNA) or on chemical structure, metabolism or mode of action.

“Possible human carcinogens” are chemicals with limited evidence of carcinogenicity in animals in the absence of human data. Limited animal evidence is defined as data which suggests a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the studies indicate an increase in the incidence of benign tumors only. More specifically, this group can include a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

1. Tier I: Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I HCC shall generally include human carcinogens, probable human carcinogens and can include, on a case-by-case basis, possible human carcinogens if studies have been well-conducted albeit based on limited evidence, when compared to studies used in classifying human and probable human carcinogens. The decision to use data on a possible human carcinogen for deriving Tier I criteria shall be a case-by-case determination. In determining whether to derive a Tier I HCC, additional evidence that shall be considered includes but is not limited to available information on mode of action, such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity, and metabolism.

2. Tier II: Weight of evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens for which there are at a minimum, data sufficient for quantitative risk assessment, but for which data are inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship. In determining whether to derive Tier II human cancer values, additional evidence that shall be considered includes but is not limited to available information on mode of action such as mutagenicity/ genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity and metabolism. As with the use of data on possible human carcinogens in developing Tier I criteria, the decision to use data on possible human carcinogens to derive Tier II values shall be made on a case-by-case basis.

B. Noncarcinogens. All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality

and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database with which to develop Tier I criteria or Tier II values. The following represent the minimum data sets necessary for this procedure.

1. Tier I: The minimum data set sufficient to derive a Tier I human HNC shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I HNC must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to ***15408** effects at higher doses. This does not preclude the use of a LOAEL from a study (of chronic duration) with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. Tier II: When the minimum data for deriving Tier I criteria are not available to meet the Tier I data requirements, a more limited database may be considered for deriving Tier II values. As with Tier I criteria, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less extensive data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for a less extensive database, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies (greater than 28 days) may be more appropriate in some cases for derivation of Tier II values. Use of a LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study.

C. Bioaccumulation factors (BAFs).

1. Tier I for Carcinogens and Noncarcinogens: To be considered a Tier I cancer or noncancer human health criterion, along with satisfying the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix, a chemical must have the following minimum bioaccumulation data. For all organic chemicals either: (a) a field-measured BAF; (b) a BAF derived using the BSAF methodology; or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, either: (a) a field-measured BAF or (b) a laboratory-measured BCF.

2. Tier II for Carcinogens and Noncarcinogens: A chemical is considered a Tier II cancer or noncancer human health value if it does not meet either the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix or the minimum bioaccumulation data requirements of section II.C.1 of this appendix.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. Carcinogens.

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that is considered most biologically relevant to humans (i.e., responds most like humans) is preferred where all other considerations regarding quality of data are equal. In the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g., Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986), which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which are more appropriate to the available data may be used where scientifically justified.

4. If the duration of the study is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed (e.g., U.S. EPA, 1980) In the absence of alternative approaches which compensate for study durations significantly less than lifetime, the permitting authority may use the process described in the 1980 National Guidelines (see 45 FR 79352).

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 2/3 power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the RAD shall be calculated using the following equation:

Where:

RAD=risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (110^{5})=incremental risk of developing cancer equal to one in 100,000.

q_1*=slope factor $(mg/kg/day)^{1}$.

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may, on a case-by-case basis, be calculated using a method which assumes a threshold mechanism is operative.

B. Noncarcinogens.

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. To the maximum extent possible, data most specific to the environmentally relevant route of exposure shall be used. Oral exposure data should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), should generally be used.

***15409** 3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the LOAEL from studies satisfying the provisions of section II.B of this appendix may be used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic (e.g., 90 days or more in length), or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional UF of up to 10-fold for less than chronic, but greater than subchronic, studies.

d. An UF of up to 3000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than subchronic (e.g., 28 days). In comparison to b above, this represents an additional UF of up to 30-fold for less than

subchronic studies (e.g., 28-day). The level of additional uncertainty applied for less than chronic exposures depends on the duration of the study used relative to the lifetime of the experimental animal.

e. An additional UF of between one and ten may be used when deriving a criterion from a LOAEL. This UF accounts for the lack of an identifiable NOAEL. The level of additional uncertainty applied may depend upon the severity and the incidence of the observed adverse effect.

f. An additional UF of between one and ten may be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data (e.g., reproductive/developmental data). The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

g. When deriving an UF in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of sections 4.a through f, cited above, shall not exceed 10,000 for Tier I criteria and 30,000 for Tier II values.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses shall be adjusted for continuous exposure (i.e., seven days/week, 24 hours/day, etc.).

C. Criteria and Value Derivation.

1. Standard Exposure Assumptions. The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to Clean Water Act (CWA) section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

BW = body weight of an average human (BW = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

—or—

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015kg/day (0.0036 kg/day for trophic level 3 and 0.0114 kg/day for trophic level 4).

BAF = bioaccumulation factor for trophic level 3 and trophic level 4, as derived using the BAF methodology in appendix B to part 132.

2. Carcinogens. The Tier I human cancer criteria or Tier II values shall be calculated as follows:

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to one in 100,000.

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

FC_{TL3}=mean consumption of trophic level 3 of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=bioaccumulation factor for trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=bioaccumulation factor for trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.
3. Noncarcinogens. The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8. An RSC derived from actual exposure data may be developed using the methodology outlined by the 1980 National Guidelines (see 45 FR 79354).

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

***15410** FC_{TL3}=mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.

IV. References

A. Howe, R.B., K.S. Crump and C. Van Landingham. 1986. Computer Program to Extrapolate Quantitative Animal Toxicity Data to Low Doses. Prepared for EPA under subcontract #2-251U-2745 to Research Triangle Institute.

B. U.S. Environmental Protection Agency. 1980. Water Quality Criteria Availability, Appendix C Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

C. U.S. Environmental Protection Agency. 1986. Guidelines for Carcinogen Risk Assessment. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. A Great Lakes Water Quality Wildlife Criterion (GLWC) is the concentration of a substance which is likely to, if not exceeded, protect avian and mammalian wildlife populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the Great Lakes System. These criteria are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Since toxicological and exposure data for individual wildlife species are limited, a GLWC is derived using a methodology similar to that used to derive noncancer human health criteria (Barnes and Dourson, 1988; NAS, 1977; NAS, 1980; U.S. EPA, 1980). Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative Great Lakes basin wildlife species. The wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience the highest exposures to bioaccumulative contaminants through the aquatic food web; they are the bald eagle, herring gull, belted kingfisher, mink, and river otter.

B. This appendix establishes a methodology which is required when developing Tier I wildlife criteria for bioaccumulative chemicals of concern (BCCs). The use of the equation provided in the methodology is encouraged, but not required, for the development of Tier I criteria or Tier II values for pollutants other than those identified in Table 6-A for which Tier I criteria or Tier II values are determined to be necessary for the protection of wildlife in the Great Lakes basin. A discussion of the methodology for deriving Tier II values can be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria (Wildlife TSD).

C. In the event that this methodology is used to develop criteria for pollutants other than BCCs, or in the event that the Tier II methodology described in the Wildlife TSD is used to derive Tier II values, the methodology for deriving bioaccumulation factors under appendix B to part 132 must be used in either derivation. For chemicals which do not biomagnify to the extent of BCCs, it may be appropriate to select different representative species which are better examples of species with the highest exposures for the given chemical. The equation presented in this methodology, however, is still encouraged. In addition, procedure 1 of appendix F of this part describes the procedures for calculating site-specific wildlife criteria.

D. The term “wildlife value” (WV) is used to denote the value for each representative species which results from using the equation presented below, the value obtained from averaging species values within a class, or any value derived from application of the site-specific procedure provided in procedure 1 of appendix F of this part. The WVs calculated for the representative species are used to calculate taxonomic class-specific WVs. The WV is the concentration of a substance which, if not exceeded, should better protect the taxon in question.

E. “Tier I wildlife criterion,” or “Tier I criterion” is used to denote the number derived from data meeting the Tier I minimum database requirements, and which will be protective of the two classes of wildlife. It is synonymous with the term “GLWC,” and the two are used interchangeably.

II. Calculation of Wildlife Values for Tier I Criteria

Table 4 of Part 132 and Table D-1 of this appendix contain criteria calculated by EPA using the methodology provided below.

A. Equation for Avian and Mammalian Wildlife Values. Tier I wildlife values for the pollutants designated BCCs pursuant to part 132 are to be calculated using the equation presented below.

Where:

WV=Wildlife Value in milligrams of substance per liter (mg/L).

TD=Test Dose (TD) in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A=Uncertainty Factor (UF) for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_S=UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L=UF for LOAEL to NOAEL extrapolations (unitless).

Wt=Average weight in kilograms (kg) for the representative species.

W=Average daily volume of water consumed in liters per day (L/d) by the representative species.

F_{TLi}=Average daily amount of food consumed from trophic level i in kilograms per day (kg/d) by the representative species.

BAF^{WL}_{TLi}=Bioaccumulation factor (BAF) for wildlife food in trophic level i in liters per kilogram (L/kg), developed using the BAF methodology in appendix B to part 132, Methodology for Development of Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

B. Identification of Representative Species for Protection. For bioaccumulative chemicals, piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Wildlife TSD. This analysis identifies three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) as representative species for protection. The TD obtained from toxicity data for each taxonomic class is used to calculate WVs for each of the five representative species.

C. Calculation of Avian and Mammalian Wildlife Values and GLWC Derivation. The avian WV is the geometric mean of the WVs calculated for the three representative avian species. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species. The lower of the mammalian and avian WVs must be selected as the GLWC.

III. Parameters of the Effect Component of the Wildlife Criteria Methodology

A. Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology.

Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect reproductive or developmental success, organismal viability or growth, or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

***15411** Chronic effect. An adverse effect that is measured by assessing an acceptable endpoint, and results from continual exposure over several generations, or at least over a significant part of the test species' projected life span or life stage.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Subchronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

B. Minimum Toxicity Database for Tier I Criteria Development. A TD value is required for criterion calculation. To derive a Tier I criterion for wildlife, the data set shall provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species. In reviewing the toxicity data available which meet the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species take precedence over other types of studies, where such studies are of adequate quality. An acceptable field study must be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, or determined to be of inadequate quality, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. All available laboratory data and field studies shall be reviewed to corroborate the final GLWC, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any UFs which are applied. When evaluating the studies from which a test dose is derived in general, the following requirements must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 70 days or greater designed to observe subchronic or chronic effects as defined in this document.

3. In reviewing the studies from which a TD is derived for use in calculating a WV, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

4. In assessing the studies which meet the minimum data requirements, preference should be given to studies which assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained. The Wildlife TSD provides additional discussion on the selection of an appropriate toxicity study.

C. Selection of TD Data. In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in Section III.A of this appendix, will be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of the Ufs which are applied.

1. If more than one TD value is available within a taxonomic class, based on different endpoints of toxicity, that TD, which is likely to reflect best potential impacts to wildlife populations through resultant changes in mortality or fecundity rates, shall be used for the calculation of WVs.

2. If more than one TD is available within a taxonomic class, based on the same endpoint of toxicity, the TD from the most sensitive species shall be used.

3. If more than one TD based on the same endpoint of toxicity is available for a given species, the TD for that species shall be calculated using the geometric mean of those TDs.

D. Exposure Assumptions in the Determination of the TD. 1. In those cases in which a TD is available in units other than milligrams of substance per kilograms per day (mg/kg/d), the following procedures shall be used to convert the TD to the appropriate units prior to calculating a WV.

2. If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the TD shall be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).

3. If the TD is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the TD shall be multiplied by the average amount of food in kilograms consumed daily by the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).

E. Drinking and Feeding Rates. 1. When drinking and feeding rates and body weight are needed to express the TD in milligrams of substance per kilograms per day (mg/kg/d), they are obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

2. If the study does not provide the needed values, the values shall be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH), or Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988) should be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations from Calder and Braun (1983) and Nagy (1987), which are presented below, or the exposure estimation methods presented in Chapter 4 of the Wildlife Exposure Factors Handbook (U.S. EPA, 1993), should be applied to approximate the needed feeding or drinking rates. Additional discussion and recommendations are provided in the Wildlife TSD. The choice of the methods described above is at the discretion of the State or Tribe.

3. For mammalian species, the general allometric equations are:

a. $F = 0.0687 (Wt)^{0.82}$

Where:

F = Feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.

b. $W = 0.099 (Wt)^{0.90}$

Where:

W = Drinking rate of mammalian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
4. For avian species, the general allometric equations are:

a. $F = 0.0582 (Wt)^{0.65}$

Where:

F = Feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.
b. $W = 0.059 (Wt)^{0.67}$

Where:

W = Drinking rate of avian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
F. LOAEL to NOAEL Extrapolations (UF_L). In those cases in which a NOAEL is unavailable as the TD and a LOAEL is available, the LOAEL may be used to estimate the NOAEL. If used, the LOAEL shall be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF shall not be less than one and should not exceed 10, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in Section II.A of this appendix. Guidance for selecting an appropriate UF_L, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

G. Subchronic to Chronic Extrapolations (US_S). In instances where only subchronic data are available, the TD may be derived from subchronic data. In such cases, the TD shall be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF shall not be less than one and should not exceed 10, and is represented by UF_S in the equation expressed in Section II.A of this appendix. This factor is to be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length ***15412** underestimates chronic effects. Guidance for selecting an appropriate UF_S, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

H. Interspecies Extrapolations (UF_A). 1. The selection of the UF_A shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic, and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is an UF that is intended to account for differences in toxicological sensitivity among species. Guidance for selecting an appropriate UF_A, based on a review of available wildlife toxicity data, is available in the Wildlife TSD. Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria may be useful in determining the appropriate value for UF_A.

2. For the derivation of Tier I criteria, a UF_A shall not be less than one and should not exceed 100, and shall be applied to each of the five representative species, based on existing data and best professional judgment. The value of UF_A may differ for each of the representative species.

3. For Tier I wildlife criteria, the UF_A shall be used only for extrapolating toxicity data across species within a taxonomic class, except as provided below. The Tier I UF_A is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation

employing a UF_A may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considering acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Drinking and Feeding Rates of Representative Species. The body weights (Wt), feeding rates (F_{Tli}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and percent in diet) for each of the five representative species are presented in Table D-2 of this appendix. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD.

B. BAFs. The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. Trophic level 3 and 4 BAFs are used to derive Wvs because these are the trophic levels at which the representative species feed.

V. References

A. Barnes, D.G. and M. Dourson. 1988. Reference Dose (RfD): Description and Use in Health Risk Assessments. Regul. Toxicol. Pharmacol. 8:471-486.

B. Calder III, W.A. and E.J. Braun. 1983. Scaling of Osmotic Regulation in Mammals and Birds. American Journal of Physiology. 244:601-606.

C. Nagy, K.A. 1987. Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds. Ecological Monographs. 57(2):111-128.

D. National Academy of Sciences. 1977. Chemical Contaminants: Safety and Risk Assessment, in Drinking Water and Health, Volume 1. National Academy Press.

E. National Academy of Sciences. 1980. Problems of Risk Estimation, in Drinking Water and Health, Volume 3. National Academy Press.

F. National Institute for Occupational Safety and Health. Latest edition. Registry of Toxic Effects of Chemical Substances. Division of Standards Development and Technology Transfer. (Available only on microfiche or as an electronic database.)

G. U.S. EPA. 1980. Appendix C. Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, pp. 79347-79357 in Water Quality Criteria Documents; Availability. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St. SW, Washington, DC 20460.

H. U.S. EPA. 1988. Recommendations for, and documentation of, biological values for use in risk assessment. NTIS-PB88-179874.

I. U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. EPA/600/R-93/187a and b.

Tables to Appendix D to Part 132

Table D-1.—Tier I Great Lakes Wildlife Criteria

Substance	Criterion (MUg/L)

DDT & Metabolites	1.1E-5
Mercury	1.3E-3
PCBs (total)	7.4E-5
2,3,7,8-TCDD	3.1E-9

Table D-2.—Exposure Parameters for the Five Representative Species Identified for Protection

Species (units)	Adult body weight (kg)	Water ingestion rate (L/day)	Food ingestion rate of prey in each trophic level (kg/day)	Trophic level of prey (percent of diet)
Mink	0.80	0.081	TL3: 0.159; Other: 0.0177	TL3: 90; Other: 10.
Otter	7.4	0.600	TL3: 0.977; TL4: 0.244	TL3: 80; TL4: 20.
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100.
Herring gull	1.1	0.063	TL3: 0.192; TL4: 0.0480	Fish: 90—TL3: 80; TL4: 20.
	.....	.....	Other: 0.0267	Other: 10.
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929	Fish: 92—TL3: 80; TL4: 20.
	.....	.....	PB: 00283; Other: 0.0121	Birds: 8—PB: 70; non-aquatic: 30.

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) appendix E to part 132.

The State or Tribe shall adopt an antidegradation standard applicable to all waters of the Great Lakes System and identify the methods for implementing such a standard. Consistent with 40 CFR 131.12, an acceptable antidegradation standard and implementation procedure are required elements of a State's or Tribe's water quality standards program. Consistent with 40 CFR 131.6, a complete water quality standards submission needs to include both an antidegradation standard and antidegradation implementation procedures. At a minimum, States and Tribes shall adopt provisions in their antidegradation standard and implementation methods consistent with sections I, II, III and IV of this appendix, applicable to pollutants identified as bioaccumulative chemicals of concern (BCCs).

I. Antidegradation Standard

This antidegradation standard shall be applicable to any action or activity by any source, point or nonpoint, of pollutants that is anticipated to result in an increased loading of BCCs to surface waters of the Great Lakes System and for which independent regulatory authority exists requiring compliance with water quality standards. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR 131, and the level of water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the waterbody are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the quality of the waters exceed levels necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter consistent

with the definition of high quality water found at section II.A of this appendix and that quality ***15413** shall be maintained and protected unless the State or Tribe finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's or Tribe's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State or Tribe shall assure water quality adequate to protect existing uses fully. Further, the State or Tribe shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control. The State or Tribe shall utilize the Antidegradation Implementation Procedures adopted pursuant to the requirements of this regulation in determining if any lowering of water quality will be allowed;

C. Where high quality waters constitute an outstanding national resource, such as waters of national and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act (CWA).

II. Antidegradation Implementation Procedures

A. Definitions.

Control Document. Any authorization issued by a State, Tribal or Federal agency to any source of pollutants to waters under its jurisdiction that specifies conditions under which the source is allowed to operate.

High quality waters. High quality waters are water bodies in which, on a parameter by parameter basis, the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water.

Lake Superior Basin—Outstanding International Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to ensure that any new or increased discharges of Lake Superior bioaccumulative substances of immediate concern are subject to best technology in process and treatment requirements.

Lake Superior Basin—Outstanding National Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2, 3, 7, 8-TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following States' or Tribes' assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Those waters designated as such by a Tribe or State. The State or Tribal designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Waters that may be considered for designation as Outstanding National Resource Waters include, but are not limited to, water bodies that are recognized as:

Important because of protection through official action, such as Federal or State law, Presidential or secretarial action, international treaty, or interstate compact;

Having exceptional recreational significance;

Having exceptional ecological significance;

Having other special environmental, recreational, or ecological attributes; or waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of other waters so designated.

Significant Lowering of Water Quality. A significant lowering of water quality occurs when there is a new or increased loading of any BCC from any regulated existing or new facility, either point source or nonpoint source for which there is a control document or reviewable action, as a result of any activity including, but not limited to:

(1) Construction of a new regulated facility or modification of an existing regulated facility such that a new or modified control document is required;

(2) Modification of an existing regulated facility operating under a current control document such that the production capacity of the facility is increased;

(3) Addition of a new source of untreated or pretreated effluent containing or expected to contain any BCC to an existing wastewater treatment works, whether public or private;

(4) A request for an increased limit in an applicable control document;

(5) Other deliberate activities that, based on the information available, could be reasonably expected to result in an increased loading of any BCC to any waters of the Great Lakes System.

b. Notwithstanding the above, changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review. These changes include, but are not limited to:

(1) Normal operational variability;

(2) Changes in intake water pollutants;

(3) Increasing the production hours of the facility, (e.g., adding a second shift); or

(4) Increasing the rate of production.

C. Also, excluded from an antidegradation review are new effluent limits based on improved monitoring data or new water quality criteria or values that are not a result of changes in pollutant loading.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a waterbody or ambient pollutant concentrations exceed water quality criteria applicable to that waterbody, the Director shall not allow a lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (i.e., weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no action resulting in a lowering of water quality occurs unless an antidegradation demonstration has been completed pursuant to section III of this appendix and the information thus provided is determined by the Director pursuant to section IV of this appendix to adequately support the lowering of water quality.

1. The Director shall establish conditions in the control document applicable to the regulated facility that prohibit the regulated facility from undertaking any deliberate action, such that there would be an increase in the rate of mass loading of any BCC, unless an antidegradation demonstration is provided to the Director and approved pursuant to section IV of this appendix prior to commencement of the action. Imposition of limits due to improved monitoring data or new water quality criteria or values, or changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review.

2. For BCCs known or believed to be present in a discharge, from a point or nonpoint source, a monitoring requirement shall be included in the control document. The control document shall also include a provision requiring the source to notify the Director or any increased loadings. Upon notification, the Director shall require actions as necessary to reduce or eliminate the increased loading.

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall reflect any conditions developed under sections II.D.1 or II.D.2 of this appendix and included in a permit.

E. Special Provisions for Lake Superior.The following conditions apply in addition to those specified in section II.B through II.C of this appendix for waters of Lake Superior so designated.

1. A State or Tribe may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States and Tribes may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of ***15414** Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.B of this appendix.

F. Exemptions. Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected waterbody is an Outstanding National Resource Water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (i.e., weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended, or similar Federal, State or Tribal authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. States and Tribes should tailor the level of detail and documentation in antidegradation reviews, to the specific circumstances encountered. The antidegradation demonstration shall include the following:

A. Pollution Prevention Alternatives Analysis. Identify any cost-effective pollution prevention alternatives and techniques that are available to the entity, that would eliminate or significantly reduce the extent to which the increased loading results in a lowering of water quality.

B. Alternative or Enhanced Treatment Analysis. Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the lowering of water quality and their costs relative to the cost of treatment necessary to achieve applicable effluent limitations.

C. Lake Superior. If the States or Tribes designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. Important Social or Economic Development Analysis. Identify the social or economic development and the benefits to the area in which the waters are located that will be foregone if the lowering of water quality is not allowed.

E. Special Provision for Remedial Actions. Entities proposing remedial actions pursuant to the CERCLA, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity proposing to increase loadings is administratively complete, the Director shall use that information to determine whether or not the lowering of water quality is necessary, and, if it is necessary, whether or not the lowering of water quality will support important social and economic development in the area. If the proposed lowering of water quality is either not necessary, or will not support important social and economic development, the Director shall deny the request to lower water quality. If the lowering of water quality is necessary, and will support important social and economic development, the Director may allow all or part of the proposed lowering to occur as necessary to accommodate the important social and economic development. In no event may the decision reached under this section allow water quality to be lowered below the minimum level required to fully support existing and designated uses. The decision of the Director shall be subject to the public participation requirements of 40 CFR 25.

B. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Procedure 1: Site-specific Modifications to Criteria and Values

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

A. Requirements for Site-specific Modifications to Criteria and Values. Criteria and values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be protective of designated uses and aquatic life, wildlife or human health and be submitted to EPA for approval. In addition, any site-specific modifications that result in less stringent criteria must be based on a sound scientific rationale and shall not be likely to jeopardize the continued existence of endangered or threatened species listed or proposed under section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications shall be developed to protect endangered or threatened species listed or proposed under section 4 of the ESA, where such modifications are necessary to ensure that water quality is not likely to jeopardize the continued existence of such species or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications may also be developed to protect candidate (C1) species being considered by the U.S. Fish and Wildlife Service (FWS) for listing under section 4 of the ESA, where such modifications are necessary to protect such species.

1. Aquatic Life.

a. Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act (CWA) section 510.

Guidance on developing site-specific criteria in these instances is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

b. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality characteristics such as Ph, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or

ii. The sensitivity of the aquatic organisms species that “occur at the site” differs from the species actually tested in developing the criteria. The phrase “occur at the site” includes the species, genera, families, orders, classes, and phyla that: are usually present at the site; are present at the site only seasonally due to migration; are present intermittently because they periodically return to or extend their ranges into the site; were present at the site in the past, are not currently present at the site due to degraded conditions, and are expected to return to the site when conditions improve; are present in nearby bodies of water, are not currently present at the site due to degraded conditions, and are expected to be present at the site when conditions improve. The taxa that “occur at the site” cannot be determined merely by sampling downstream and/or upstream of the site at one point in time. “Occur at the site” does not include taxa that were once present at the site but cannot exist at the site now due to permanent physical alteration of the habitat at the site resulting, for example, from dams, etc.

c. Less stringent modifications also may be developed to acute and chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

Guidance on developing site-specific criteria is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

***15415** d. Any modifications to protect threatened or endangered aquatic species required by procedure 1.A of this appendix may be accomplished using either of the two following procedures:

i. If the Species Mean Acute Value (SMAV) for a listed or proposed species, or for a surrogate of such species, is lower than the calculated Final Acute Value (FAV), such lower SMAV may be used instead of the calculated FAV in developing site-specific modified criteria; or,

ii. The site-specific criteria may be calculated using the recalculation procedure for site-specific modifications described in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

2. Wildlife.

a. Wildlife water quality criteria may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510.

b. Less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part. The modification must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed. In addition, there must be a showing that:

i. Any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations; and

ii. Wildlife populations utilizing the site or downstream waters will continue to be fully protected.

c. Any modification to protect endangered or threatened wildlife species required by procedure 1.A of this appendix must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed, and may be accomplished by using the following recommended method.

i. The methodology presented in appendix D to part 132 is used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

ii. An interspecies uncertainty factor of 1 should be used where epidemiological data are available for the species in question. If necessary, species-specific exposure parameters can be derived as presented in Appendix D of this part;

iii. An intraspecies uncertainty factor (to account for protection of individuals within a wildlife population) should be applied in the denominator of the effect part of the wildlife equation in appendix D of this part in a manner consistent with the other uncertainty factors described in appendix D of this part; and

iv. The resulting wildlife value for the species in question should be compared to the two class-specific wildlife values which were previously calculated, and the lowest of the three shall be selected as the site-specific modification.

Note: Further discussion on the use of this methodology may be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria.

3. BAFs.

a. BAFs may be modified on a site-specific basis to larger values, pursuant to the authority reserved to the States and Tribes under CWA section 510, where reliable data show that local bioaccumulation is greater than the system-wide value.

b. BAFs may be modified on a site-specific basis to lower values, where scientifically defensible, if:

i. The fraction of the total chemical that is freely dissolved in the ambient water is different than that used to derive the system-wide BAFs (i.e., the concentrations of particulate organic carbon and the dissolved organic carbon are different than those used to derive the system-wide BAFs);

ii. Input parameters of the Gobas model, such as the structure of the aquatic food web and the disequilibrium constant, are different at the site than those used to derive the system-wide BAFs;

iii. The percent lipid of aquatic organisms that are consumed and occur at the site is different than that used to derive the system-wide BAFs; or

iv. Site-specific field-measured BAFs or biota-sediment accumulation factor (BSAFs) are determined.

If site-specific BAFs are derived, they shall be derived using the methodology in appendix B of this part.

c. Any more stringent modifications to protect threatened or endangered species required by procedure 1.A of this appendix shall be derived using procedures set forth in the methodology in appendix B of this part.

4. Human Health.

a. Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

b. Less stringent site-specific modifications to human health criteria or values may be developed when:

i. local fish consumption rates are lower than the rate used in deriving human health criteria or values under appendix C of this part; and/or

ii. a site-specific BAF is derived which is lower than that used in deriving human health criteria or values under appendix C of this part.

B. Notification Requirements. When a State proposes a site-specific modification to a criterion or value as allowed in section 4.A above, the State should notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. References.

U.S. EPA. 1984. Water Quality Standards Handbook—Revised. Chapter 3 and Appendices. U.S. Environmental Protection Agency, Office of Water Resource Center (RC-4100), 401 M Street, SW., Washington, DC 20960.

Procedure 2: Variances from Water Quality Standards for Point Sources

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources pursuant to such procedures. Variance procedures shall be consistent with (as protective as) the provisions in this procedure.

A. Applicability. A State or Tribe may grant a variance to a WQS which is the basis of a water quality-based effluent limitation included in a National Pollutant Discharge Elimination System (NPDES) permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the State or Tribe to modify, the corresponding water quality standard for the waterbody as a whole.

1. This provision shall not apply to new Great Lakes dischargers or recommencing dischargers.

2. A variance to a water quality standard shall not be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under Section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat.

3. A WQS variance shall not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act (CWA) and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

B. Maximum Timeframe for Variances. A WQS variance shall not exceed five years or the term of the NPDES permit, whichever is less. A State or Tribe shall review, and modify as necessary, WQS variances as part of each water quality standards review pursuant to section 303(c) of the CWA.

C. Conditions to Grant a Variance. A variance may be granted if:

1. The permittee demonstrates to the State or Tribe that attaining the WQS is not feasible because:

a. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

b. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable WQS to be met without violating State or Tribal water conservation requirements;

c. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied, or would cause more environmental damage to correct than to leave in place;

d. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

e. Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of WQS; or

***15416** f. Controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact.

2. In addition to the requirements of C.1, above, the permittee shall also:

a. Show that the variance requested conforms to the requirements of the State's or Tribe's antidegradation procedures; and

b. Characterize the extent of any increased risk to human health and the environment associated with granting the variance compared with compliance with WQS absent the variance, such that the State or Tribe is able to conclude that any such increased risk is consistent with the protection of the public health, safety and welfare.

D. Submittal of Variance Application. The permittee shall submit an application for a variance to the regulatory authority issuing the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in section C.1 of this procedure; and,

2. All relevant information demonstrating compliance with the conditions in section C.2 of this procedure.

E. Public Notice of Preliminary Decision. Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the State or Tribe shall public notice the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedures Act and shall notify the other Great Lakes States and Tribes of the preliminary decision. This public notice requirement may be satisfied by including the supporting information for the variance and the preliminary decision in the public notice of a draft NPDES permit.

F. Final Decision on Variance Request. The State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall include all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, and which is no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the waterbody as a whole through appropriate conditions;

3. When the duration of a variance is shorter than the duration of a permit, compliance with an effluent limitation sufficient to meet the underlying water quality standard, upon the expiration of said variance; and

4. A provision that allows the permitting authority to reopen and modify the permit based on any State or Tribal triennial water quality standards revisions to the variance.

The State shall deny a variance request if the permittee fails to make the demonstrations required under section C of this procedure.

G. Incorporating Variance into Permit. The State or Tribe shall establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. Renewal of Variance. A variance may be renewed, subject to the requirements of sections A through G of this procedure. As part of any renewal application, the permittee shall again demonstrate that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the original variance pursuant to sections F and G of this procedure. Renewal of a variance may be denied if the permittee did not comply with the conditions of the original variance.

I. EPA Approval. All variances and supporting information shall be submitted by the State or Tribe to the appropriate EPA regional office and shall include:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and records of any public hearings pursuant to section E of this procedure;

3. The final decision pursuant to section F of this procedure; and,

4. NPDES permits issued pursuant to section G of this procedure.

5. Items required by sections I.1 through I.3. of this procedure shall be submitted by the State within 30 days of the date of the final variance decision. The item required by section I.4 of this procedure shall be submitted in accordance with the State or Tribe Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.
40 CFR § 123.4440 CFR § 131.21
6. EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. State WQS Revisions. All variances shall be appended to the State or Tribe WQS rules.

Procedure 3: Total Maximum Daily Loads, Wasteload Allocations for Point Sources, Load Allocations for Nonpoint Sources, Wasteload Allocations in the Absence of a TMDL, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure 3 for the purpose of developing Total Maximum Daily Loads (TMDLs), Wasteload Allocations (WLAs) in the Absence of TMDLs, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits (WQBELs), except as specifically provided.

A. Where a State or Tribe develops an assessment and remediation plan that the State or Tribe certifies meets the requirements of sections B through F of this procedure and public participation requirements applicable to TMDLs, and that has been approved by EPA as meeting those requirements under 40 CFR 130.6, the assessment and remediation plan may be used in lieu of a TMDL for purposes of appendix F to part 132. Assessment and remediation plans under this procedure may include, but are not limited to, Lakewide Management Plans, Remedial Action Plans, and State Water Quality Management Plans. Also, any part of an assessment and remediation plan that also satisfies one or more requirements under Clean Water Act (CWA) section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. Assessment and remediation plans under this section should be tailored to the level of detail and magnitude for the watershed and pollutant being assessed.

B. General Conditions of Application. Except as provided in §132.4, the following are conditions applicable to establishing TMDLs for all pollutants and pollutant parameters in the Great Lakes System, with the exception of whole effluent toxicity, unless otherwise provided in procedure 6 of appendix F. Where specified, these conditions also apply to wasteload allocations (WLAs) calculated in the absence of TMDLs and to preliminary WLAs for purposes of determining the needs for WQBELs under procedure 5 of appendix F.

1. TMDLs Required. TMDLs shall, at a minimum, be established in accordance with the listing and priority setting process established in section 303(d) of the CWA and at 40 CFR 130.7. Where water quality standards cannot be attained immediately, TMDLs must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. Some TMDLs may be based on attaining water quality standards over a period of time, with specific controls on individual sources being implemented in stages. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination considering a number of factors including, but not limited to: receiving water characteristics; persistence, behavior and ubiquity of pollutants of concern; type of remediation activities necessary; available regulatory and non-regulatory controls; and individual State or Tribal requirements for attainment of water quality standards.

2. Attainment of Water Quality Standards. A TMDL must ensure attainment of applicable water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values for each pollutant or pollutants for which a TMDL is established.

3. TMDL Allocations.

a. TMDLs shall include WLAs for point sources and load allocations (LAs) for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant(s) addressed by the TMDL, minus the sum of a specified margin of safety (MOS) and any capacity reserved for future growth.

b. Nonpoint source LAs shall be based on:

i. Existing pollutant loadings if changes in loadings are not reasonably anticipated to occur;

ii. Increases in pollutant loadings that are reasonably anticipated to occur;

***15417** iii. Anticipated decreases in pollutant loadings if such decreased loadings are technically feasible and are reasonably anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether anticipated decreases in pollutant loadings are technically feasible and can reasonably be expected to occur within a reasonable period of time, technical and institutional factors shall be considered. These decisions are case-specific and should reflect the particular TMDL under consideration.

c. WLAs. The portion of the loading capacity not assigned to nonpoint sources including background, or to an MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include effluent limitations consistent with WLAs in EPA-approved or EPA-established TMDLs.

d. Monitoring. For LAs established on the basis of subsection b.iii above, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to varify anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and LAs as necessary to ensure that water quality standards will be achieved within the time-period established in the TMDL.

4. WLA Values. If separate EPA-approved or EPA-established TMDLs are prepared for different segments of the same watershed, and the separate TMDLs each include WLAs for the same pollutant for one or more of the same point sources, then WQBELs for that pollutant for the point source(s) shall be consistent with the most stringent of those WLAs in order to ensure attainment of all applicable water quality standards.

5. Margin of Safety (MOS). Each TMDL shall include a MOS sufficient to account for technical uncertainties in establishing the TMDL and shall describe the manner in which the MOS is determined and incorporated into the TMDL. The MOS may be provided by leaving a portion of the loading capacity unallocated or by using conservative modeling assumptions to establish WLAs and LAs. If a portion of the loading capacity is left unallocated to provide a MOS, the amount left unallocated shall be described. If conservative modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

6. More Stringent Requirements. States and Tribes may exercise authority reserved to them under section 510 of the CWA to develop more stringent TMDLs (including WLAs and LAs) than are required herein, provided that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time-period as a result of implementing nonpoint source controls.

7. Accumulation in Sediments. TMDLs shall reflect, where appropriate and where sufficient data are available, contributions to the water column from sediments inside and outside of any applicable mixing zones. TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life.

8. Wet Weather Events. Notwithstanding the exception provided for the establishment of controls on wet weather point sources in §132.4(e)(1), TMDLs shall reflect, where appropriate and where sufficient data are available, discharges resulting from wet

weather events. This procedure does not provide specific procedures for considering discharges resulting from wet weather events. However, some of the provisions of procedure 3 may be deemed appropriate for considering wet weather events on a case-by-case basis.

9. Background Concentration of Pollutants. The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs, WLAs calculated in the absence of a TMDL, or preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F. Background loadings may be accounted for in a TMDL through an allocation to a single “background” category or through individual allocations to the various background sources.

a. Definition of Background. “Background” represents all loadings that: (1) flow from upstream waters into the specified watershed, waterbody or waterbody segment for which a TMDL, WLA in the absence of a TMDL or preliminary WLA for the purpose of determining the need for a WQBEL is being developed; (2) enter the specified watershed, waterbody or waterbody segment through atmospheric deposition or sediment release or resuspension; or (3) occur within the watershed, waterbody or waterbody segment as a result of chemical reactions.

b. Data considerations. When determining what available data are acceptable for use in calculating background, the State or Tribe should use best professional judgment, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels. When data in more than one of the data sets or categories described in section B.9.c.i through B.9.c.iii below exist, best professional judgment should be used to select the one data set that most accurately reflects or estimates background concentrations. Pollutant degradation and transport information may be considered when utilizing pollutant loading data.

c. Calculation requirements. Except as provided below, the representative background concentration for a pollutant in the specified watershed, waterbody or waterbody segment shall be established on a case-by-case basis as the geometric mean of:

i. Acceptable available water column data; or

ii. Water column concentrations estimated through use of acceptable available caged or resident fish tissue data; or

iii. Water column concentrations estimated through use of acceptable available or projected pollutant loading data.

d. Detection considerations.

i. Commonly accepted statistical techniques shall be used to evaluate data sets consisting of values both above and below the detection level.

ii. When all of the acceptable available data in a data set or category, such as water column, caged or resident fish tissue or pollutant loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

10. Effluent Flow. If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. Reserved Allocations. TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, any increased loadings of the pollutant for which the TMDL was developed that are due to a new or expanded discharge shall not be allowed unless the TMDL is revised in accordance with these proceudres to include an allocation for the new or expanded discharge.

C. Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs). The following requirements shall be applied in establishing TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, for BCCs:

1. Beginning on March 23, 1997, there shall be no mixing available for new discharges of BCCs to the Great Lakes System. WLAs established through TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs for new discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

2. For purposes of section C of procedure 3 of appendix F, new discharges are defined as: (1) discharges from new Great Lakes dischargers; or (2) new or expanded discharges from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges.

3. Up until March 23, 2007, mixing zones for BCCs may be allowed for existing discharges to the Great Lakes System pursuant to the procedures specified in sections D and E of this procedure.

4. Except as provided in sections C.5 and C.6 of this procedure, permits issued on or after March 23, 1997 shall not authorize mixing zones for existing discharges of BCCs to the Great Lakes System after March 23, 2007. After March 23, 2007, WLAs established through TMDLs, WLAs established in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F for existing dischrges of BCCs to the Great Lakes System shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

5. Exception for Water Conservation. States and Tribes may grant mixing zones for any existing discharge of BCCs to the Great Lakes ***15418** System beyond the dates specified in sections C.3 and C.4 of this procedure, where it can be demonstrated, on a case-by-case basis, that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections D and E of this procedure.

6. Exception for Technical and Economic Considerations. States and Tribes may grant mixing zones beyond the dates specified in sections C.3 and C.4 of this procedure for any existing discharges of a BCC to the Great Lakes System upon the request of a discharger subject to the limited circumstances specified in sections C.6.a through C.6.d below. Such mixing zones shall also be consistent with sections D and E of this procedure.

a. The permitting authority must determine that:

i. The discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of CWA sections 301, 302, 304, 306, 307, 401, and 402, and is in compliance with its existing NPDES water quality-based effluent limitations, including those based on a mixing zone; and

ii. The discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested to the maximum extent possible.

b. In making the determination in section C.6.a above, the State or Tribal authority should consider:

i. The availability and feasibility, including cost effectiveness, of additional controls or pollution prevention measures for reducing and ultimately eliminating BCCs for that discharger, including those used by similar dischargers;

ii. Whether the discharger or affected communities will suffer unreasonable economic effects if the mixing zone is eliminated;

iii. The extent to which the discharger will implement an ambient monitoring plan to ensure compliance with water quality criteria at the edge of any authorized mixing zone or to ensure consistency with any applicable TMDL or such other strategy consistent with section A of this procedure; and,

iv. Other information the State or Tribe deems appropriate.

c. Any exceptions to the mixing zone elimination provision for existing discharges of BCCs granted pursuant to this section shall:

i. Not result in any less stringent limitations than those existing March 23, 1997;

ii. Not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

iii. Be limited to one permit term unless the permitting authority makes a new determination in accordance with this section for each successive permit application in which a mixing zone for the BCC(s) is sought;

iv. Reflect all information relevant to the size of the mixing zone considered by the State or Tribe under subsection b above;

v. Protect all designated and existing uses of the receiving water;

vi. Meet all applicable aquatic life, wildlife and human health criteria and values at the edge of the mixing zone and, as appropriate, within the mixing zone or be consistent with any appropriate TMDL or such other strategy consistent with section A of this procedure;

vii. Ensure the discharger has developed and conducted a pollutant minimization program for the BCC(s) if required to do so under regulations adopted consistent with procedure 8 of appendix F; and

viii. Ensure that alternative means for reducing BCCs elsewhere in the watershed are evaluated.

d. For each draft NPDES permit that would allow a mixing zone for one or more BCCs after March 23, 2007, the fact sheet or statement of basis for the draft permit, required to be made available through public notice under 40 CFR 124.6(e), shall:

i. Specify the mixing provisions used in calculating the permit limits; and

ii. Identify each BCC for which a mixing zone is proposed.

D. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources: WLAs in the Absence of a TMDL; and Preliminary WLAs for Purposes of Determining the Need for WQBELs for OWGL. This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. State and Tribal procedures to derive TMDLs under this section must be consistent with (as protective as) the general conditions in section B of this procedure, CWA section 303(d), existing regulations (40 CFR 130.7), section C of this procedure, and sections D.1. through D.4 below. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F must be consistent with sections B.9, C.1, C3 through C.6, and D. 1 through D.4 of this procedure.

1. Individual point source WLAs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution than one part effluent to 10 parts receiving water for implementation of numeric

and narrative chronic criteria and values (including, but not limited to human cancer criteria, human cancer values, human noncancer values, human noncancer criteria, wildlife criteria, and chronic aquatic life criteria and values) unless an alternative mixing zone is demonstrated as appropriate in a mixing zone demonstration conducted pursuant to section F of this procedure. In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State or Tribal requirements, on a case-by-case basis.

3. WLAs and preliminary WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value (FAV), unless a mixing zone demonstration is conducted and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where acute mixing zones overlap.

4. In no case shall a mixing zone be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

E. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources; WLAs in the Absence of a TMDL; and Preliminary WLAs for the Purposes of Determining the Need for WQBELs for Great Lakes Systems Tributaries and Connecting Channels. This section describes conditions for deriving TMDLs for tributaries and connecting channels of the Great Lakes System that exhibit appreciable flows relative to their volumes. State and Tribal procedures to derive TMDLs must be consistent with the general conditions listed in section B of this procedure, section C of this procedure, existing TMDL regulations (40 CFR 130.7) and specific conditions E.1 through E.5. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of this appendix for discharges to tributaries and connecting channels must be consistent with sections B.9, C.1, C.3 through C.6, and E.1 through E.5 of this procedure.

1. Stream Design. These design flows must be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. For purposes of calculating a TMDL, WLAs in the absence of a TMDL, or preliminary WLAs for the purposes of determining reasonable potential under procedure 5 of this appendix, using a steady-state model, the stream design flows shall be:

a. The 7-day, 10-year stream design flow (7Q10), or the 4-day, 3-year biologically-based stream design flow for chronic aquatic life criteria or values;

b. The 1-day, 10-year stream design flow (1Q10), for acute aquatic life criteria or values;

c. The harmonic mean flow for human health criteria or values;

d. The 90-day, 10-year flow (90Q10) for wildlife criteria.

e. TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for the purpose of determining the need for WQBELs calculated using dynamic modelling do not need to incorporate the stream design flows specified in sections E.1.a through E.1.d of this procedure.

2. Loading Capacity. The loading capacity is the greatest amount of loading that a water can receive without violating water quality standards. The loading capacity is initially calculated at the farthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of each applicable numeric ***15419** criterion or value for a given pollutant is determined by multiplying the applicable criterion or value by the flow at the farthest downstream location in the tributary basin at the design flow condition described above. This loading is then compared to the loadings at

sites within the basin to assure that applicable numeric criteria or values for a given pollutant are not exceeded at all applicable sites. The lowest load is then selected as the loading capacity.

3. Polluant Degradation. TMDLs, WLAs in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall be based on the assumption that a pollutant does not degrade. However, the regulatory authority may take into account degradation of the pollutant if each of the following conditions are met.

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered;

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. Acute Aquatic Life Criteria and Values. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purpose of determining the need for WQBELs based on acute aquatic life criteria or values shall not exceed the FAV, unless a mixing zone demonstration is completed and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where any applicable acute mixing zones overlap. This acute WLA review shall include, but not be limited to, consideration of:

a. The expected dilution under all effluent flow and concentration conditions at stream design flow;

b. Maintenance of a zone of passage for aquatic organisms; and

c. Protection of critical aquatic habitat.

In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

5. Chronic Mixing Zones. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purposes of determining the need for WQBELs for protection of aquatic life, wildlife and human health from chronic effects shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration pursuant to section F of this procedure is conducted and approved. A demonstration for a larger mixing zone may be provided, if approved and implemented in accordance with section F of this procedure. In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

F. Mixing Zone Demonstration Requirements.

1. For purposes of establishing a mixing zone other than as specified in sections D and E above, a mixing zone demonstration must:

a. Describe the amount of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. For sources discharging to the open waters of the Great Lakes (OWGLs), define the location at which discharge-induced mixing ceases;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone will be allowed only to the extent that the level of the pollutant permitted in the waterbody would not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

f. Show that the mixing zone does not extend to drinking water intakes;

g. Show that the mixing zone would not otherwise interfere with the designated or existing uses of the receiving water or downstream waters;

h. Document background water quality concentrations;

i. Show that the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

j. Provide that by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced; and

iii. Objectionable color, odor, taste or turbidity will not be produced.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character; and

c. Whether the habitat supports endemic or naturally occurring species.

3. The mixing zone demonstration must be submitted to EPA for approval. Following approval of a mixing zone demonstration consistent with sections F.1 and F.2, adjustment to the dilution ratio specified in section D.1 of this procedure shall be limited to the dilution available in the area where discharger-induced mixing occurs.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, unless:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered; and

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

Procedure 4: Additivity

The Great Lakes States and Tribes shall adopt additivity provisions consistent with (as protective as) this procedure.

A. The Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. For the chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) listed in Table 1, potential adverse additive effects in effluents shall be accounted for in accordance with section B of this procedure.

B. Toxicity Equivalency Factors (TEFs)/Bioaccumulation Equivalency Factors (BEFs).

1. The TEFs in Table 1 and BEFs in Table 2 shall be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

where:

$(TEC)_{tcdd}$=2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$=concentration of total chemical x in effluent

$(TEF)_x$=TCDD toxicity equivalency factor for x

$(BEF)_x$=TCDD bioaccumulation equivalency factor for x

2. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent shall be used when developing waste load allocations under procedure 3, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5, and for purposes of establishing effluent quality limits under procedure 5.

Table 1.—Toxicity Equivalency Factors for CDDs and CDFs

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5

1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Table 2.—Bioaccumulation Equivalency Factors for CDDs and CDFs

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

***15420 Procedure 5: Reasonable Potential To Exceed Water Quality Standards**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure. If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations (PEL) and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In all cases, the permitting authority shall use any valid, relevant, representative information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source.

1. The permitting authority shall develop preliminary wasteload allocations (WLAs) for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion nor sufficient data to calculate a Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant for the protection of human health, and aquatic life and the preliminary WLAs shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section C of this procedure to determine whether data must be generated to calculate a Tier II value.

2. The following provisions in procedure 3 of appendix F shall be used as the basis for determining preliminary WLAs in accordance with section 1 of this procedure: procedure 3.B.9, Background Concentrations of Pollutants; procedure 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs), procedures 3.C.1, and 3.C.3 through 3.C.6; procedure 3.D, Deriving TMDLs for Discharges to Lakes (when the receiving water is an open water of the Great Lakes (OWGL), an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume); procedure 3.E, Deriving TMDLs, WLAs and Preliminary WLAs, and load allocations (LAs) for Discharges to Great Lakes System Tributaries (when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume); and procedure 3.F, Mixing Zone Demonstration Requirements.

3. The permitting authority shall develop PELs consistent with the preliminary WLAs developed pursuant to sections A.1 and A.2 of this procedure, and in accordance with existing State or Tribal procedures for converting WLAs into WQBELs. At a minimum:

a. The PELs based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The PELs based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The PELs based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. Determining Reasonable Potential Using Effluent Pollutant Concentration Data.

If representative, facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:

1. The permitting authority shall specify the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent

concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the PELs developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in a NPDES permit for such pollutant.

2. In lieu of following the procedures under section B.1 of this procedure, the permitting authority may apply procedures consistent with the following:

a. The permitting authority shall specify the PEQ as the 95th percentile of the distribution of the projected population of daily values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term daily variability of the effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of monthly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the monthly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of weekly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the weekly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A.3 of this procedure, the permitting ***15421** authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. Developing Necessary Data to Calculate Tier II Values Where Such Data Does Not Currently Exist.
40 CFR § 122.44
1. Except as provided in sections C.2, C.4, or D of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent, and for which pollutant data sufficient to calculate Tier II values for non-cancer human health, acute aquatic life and chronic aquatic life do not exist, the permitting authority shall take the following actions:

a. The permitting authority shall use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects.

b. Using the procedures specified in sections A.1 and A.2 of this procedure, the permitting authority shall develop preliminary WLAs for the discharge of the pollutant from the point source to protect human health, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop PELs in accordance with section A.3 of this procedure, which are consistent with the preliminary WLAs developed in accordance with section C.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in section B of this procedure to the PELs developed in accordance with section C.1.c of this procedure. If the PEQ exceeds any of the PELs, the permitting authority shall generate or require the permittee to generate the data necessary to derive Tier II values for noncancer human health, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section C.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure. The calculated Tier II value shall be used in calculating the preliminary WLA and PEL under section A of this procedure, for purposes of determining whether a WQBEL must be included in the permit. If the permitting authority finds that the PEQ exceeds the calculated PEL, a WQBEL for the pollutant or a permit limit on an indicator parameter consistent with 40 CFR 122.44(d)(1)(vi)(C) must be included in the permit.

2. With the exception of bioaccumulative chemicals of concern (BCCs), a permitting authority is not required to apply the procedures set forth in section C.1 of this procedure or include WQBELs to protect aquatic life for any pollutant listed in Table 6 of part 132 discharged by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections C.1 or C.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative criterion for water quality; and

b. Incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a WQBEL consistent with section C.3 of this procedure, and the permitting authority demonstrates that the WQBEL developed under section C.3 of this procedure is at least as stringent as a WQBEL that would have been based upon the Tier II value or values for that pollutant, the permitting authority shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

D. Consideration of Intake Pollutants in Determining Reasonable Potential.
40 CFR § 122.44
1. General.

a. Any procedures adopted by a State or Tribe for considering intake pollutants in water quality-based permitting shall be consistent with this section and section E.

b. The determinations under this section and section E shall be made on a pollutant-by-pollutant, outfall-by-outfall, basis.

c. This section and section E apply only in the absence of a TMDL applicable to the discharge prepared by the State or Tribe and approved by EPA, or prepared by EPA pursuant to 40 CFR 130.7(d), or in the absence of an assessment and remediation

plan submitted and approved in accordance with procedure 3.A. of appendix F. This section and section E do not alter the permitting authority's obligation under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations consistent with the assumptions and requirements of any available WLA for the discharge, which is part of a TMDL prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7, or prepared by EPA pursuant to 40 CFR 130.7(d).

2. Definition of Same Body of Water.

a. This definition applies to this section and section E of this procedure.

b. An intake pollutant is considered to be from the same body of water as the discharge if the permitting authority finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

i. The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

ii. There is a direct hydrological connection between the intake and discharge points; and

iii. Water quality characteristics (e.g., temperature, Ph, hardness) are similar in the intake and receiving waters.

c. The permitting authority may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

d. An intake pollutant from groundwater may be considered to be from the same body of water if the permitting authority determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to human activity, such as industrial, commercial, or municipal operations, disposed actions, or treatment processes.

e. An intake pollutant is the amount of a pollutant that is present in waters of the United States (including groundwater as provided in section D.2.d of this procedure) at the time it is withdrawn from such waters by the discharger or other facility (e.g., public water supply) supplying the discharger with intake water.

3. Reasonable Potential Determination.

a. The permitting authority may use the procedure described in this section of procedure 5 in lieu of procedures 5.A through C provided the conditions specified below are met.

b. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within an applicable water quality standard where a discharger demonstrates to the satisfaction of the permitting authority (based upon information provided in the permit application or other information deemed necessary by the permitting authority) that:

i. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

ii. The facility does not contribute any additional mass of the identified intake pollutant to its wastewater;

iii. The facility does not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream;

iv. The facility does not increase the identified intake pollutant concentration, as defined by the permitting authority, at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water, unless the increased concentration does not cause or contribute to an excursion above an applicable water quality standard; and

v. The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

c. Upon a finding under section D.3.b of this procedure that a pollutant in the ***15422** discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority is not required to include a WQBEL for the identified intake pollutant in the facility's permit, provided:

i. The NPDES permit fact sheet or statement of basis includes a specific determination that there is no reasonable potential for the discharge of an identified intake pollutant to cause or contribute to an excursion above an applicable narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

ii. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section D.3.b of this procedure are maintained during the permit term; and

iii. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section D.3.b of this procedure.

d. Absent a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority shall use the procedures under sections 5.A through C of this procedure to determine whether a discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable narrative or numeric water quality criterion.

E. Consideration of Intake Pollutants in Establishing WQBELs.

1. General. This section applies only when the concentration of the pollutant of concern upstream of the discharge (as determined using the provisions in procedure 3.B.9 of appendix F) exceeds the most stringent applicable water quality criterion for that pollutant.

2. The requirements of sections D.1-D.2 of this procedure shall also apply to this section.

3. Intake Pollutants from the Same Body of Water.

a. In cases where a facility meets the conditions in sections D.3.b.i and D.3.b.iii through D.3.b.v of this procedure, the permitting authority may establish effluent limitations allowing the facility to discharge a mass and concentration of the pollutant that are no greater than the mass and concentration of the pollutant identified in the facility's intake water (“no net addition limitations”). The permit shall specify how compliance with mass and concentration limitations shall be assessed. No permit may authorize “no net addition limitations” which are effective after March 23, 2007. After that date, WQBELs shall be established in accordance with procedure 5.F.2 of appendix F.

b. Where proper operation and maintenance of a facility's treatment system results in removal of a pollutant, the permitting authority may establish limitations that reflect the lower mass and/or concentration of the pollutant achieved by such treatment, taking into account the feasibility of establishing such limits.

c. For pollutants contained in intake water provided by a water system, the concentration of the intake pollutant shall be determined at the point where the raw water supply is removed from the same body of water, except that it shall be the point where the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. Mass shall be determined by multiplying the concentration of the pollutant determined in accordance with this paragraph by the volume of the facility's intake flow received from the water system.

4. Intake Pollutants from a Different Body of Water. Where the pollutant in a facility's discharge originates from a water of the United States that is not the same body of water as the receiving water (as determined in accordance with section D.2 of this procedure), WQBELs shall be established based upon the most stringent applicable water quality criterion for that pollutant.

5. Multiple Sources of Intake Pollutants. Where a facility discharges intake pollutants that originate in part from the same body of water, and in part from a different body of water, the permitting authority may apply the procedures of sections E.3 and E.4 of this procedure to derive an effluent limitation reflecting the flow-weighted average of each source of the pollutant, provided that adequate monitoring to determine compliance can be established and is included in the permit.

F. Other Applicable Conditions.

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. Once the permitting authority has determined in accordance with this procedure that a WQBEL must be included in an NPDES permit, the permitting authority shall:

a. Rely upon the WLA established for the point source either as part of any TMDL prepared under procedure 3 of this appendix and approved by EPA pursuant to 40 CFR 130.7, or as part of an assessment and remediation plan developed and approved in accordance with procedure 3.A of this appendix, or, in the absence of such TMDL or plan, calculate WLAs for the protection of acute and chronic aquatic life, wildlife and human health consistent with the provisions referenced in section A.1 of this procedure for developing preliminary wasteload allocations, and

b. Develop effluent limitations consistent with these WLAs in accordance with existing State or Tribal procedures for converting WLAs into WQBELs.

3. When determining whether WQBELs are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

4. If the geometric mean of a pollutant in fish tissue samples collected from a waterbody exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant to that water has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

Procedure 6: Whole Effluent Toxicity Requirements

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 6 of appendix F of part 132.

The following definitions apply to this part:

Acute toxic unit (TU_a). $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to 50 percent of the test organisms.

Chronic toxic unit (TU_c). 100/NOEC or $100/IC_{25}$, where the NOEC and IC_{25} are expressed as a percent effluent in the test medium.

Inhibition concentration 25 (IC_{25}). the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant that would cause a 25 percent reduction in mean young per female or in growth for the test population.

No observed effect concentration (NOEC). The highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

A. Whole Effluent Toxicity Requirements. The Great Lakes States and Tribes shall adopt whole effluent toxicity provisions consistent with the following:

1. A numeric acute WET criterion of 0.3 acute toxic units (TU_a) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that 0.3 TU_a measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from acute effects of WET. At the discretion of the permitting authority, the foregoing requirement shall not apply in an acute mixing zone that is sized in accordance with EPA-approved State and Tribal methods.

2. A numeric chronic WET criterion of one chronic toxicity unit (TU_c) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that one TU_c measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from the chronic effects of WET. At the discretion of the permitting authority, the foregoing requirements shall not apply within a chronic mixing zone consistent with: (a) procedures 3.D.1 and 3.D.4, for discharges to the open of the Great Lakes (OWGL), inland ***15423** lakes and other waters of the Great Lakes System with no appreciable flow relative to their volume, or (b) procedure 3.E.5 for discharges to tributaries and connecting channels of the Great Lakes System.

B. WET Test Methods. All WET tests performed to implement or ascertain compliance with this procedure shall be performed in accordance with methods established in 40 CFR part 136.

C. Permit Conditions.

40 CFR § 122.44

1. Where a permitting authority determines pursuant to section D of this procedure that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority:

a. Shall (except as provided in section C.1.e of this procedure) establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET consistent with section C.1.b of this procedure;

b. Shall calculate WQBELs pursuant to section C.1.a. of this procedure to ensure attainment of the State's or Tribe's chronic WET criteria under receiving water flow conditions described in procedures 3.E.1.a (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, and with mixing zones no larger than allowed pursuant to section A.2. of this procedure. Shall calculate WQBELs to ensure attainment of the State's or Tribe's acute WET criteria under receiving water flow conditions described in procedure 3.E.1.b (or where applicable, with procedure 3.E.1.e) for Great Lakes System

tributaries and connecting channels, with an allowance for mixing zones no greater than specified pursuant to section A.1 of this procedure.

c. May specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation.

d. May allow with respect to any WQBEL established pursuant to section C.1.a of this procedure an appropriate schedule of compliance consistent with procedure 9 of appendix F; and

e. May decide on a case-by-case basis that a WQBEL for WET is not necessary if the State's or Tribe's water quality standards do not contain a numeric criterion for WET, and the permitting authority demonstrates in accordance with 40 CFR 122.44(d)(1)(v) that chemical-specific effluent limits are sufficient to ensure compliance with applicable criteria.

2. Where a permitting authority lacks sufficient information to determine pursuant to section D of this procedure whether the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, then the permitting authority should consider including in the NPDES permit appropriate conditions to require generation of additional data and to control toxicity if found, such as:

a. WET testing requirements to generate the data needed to adequately characterize the toxicity of the effluent to aquatic life;

b. Language requiring a permit reopener clause to establish WET limits if any toxicity testing data required pursuant to section C.2.a of this procedure indicate that the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.
40 CFR § 122.44
3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that the WET of an effluent neither is nor may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority may include conditions and limitations described in section C.2 of this procedure at its discretion.

D. Reasonable Potential Determinations. The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) and, where representative facility-specific WET effluent data are available, apply the following requirements in determining whether the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Either averaging or using the maximum of acute toxicity values collected within the same day for each species to represent one daily value. The maximum of all daily values for the most sensitive species tested is used for reasonable potential determinations;

b. Either averaging or using the maximum of chronic toxicity values collected within the same calendar month for each species to represent one monthly value. The maximum of such values, for the most sensitive species tested, is used for reasonable potential determinations:

c. Estimating the toxicity values for the missing endpoint using a default acute-chronic ratio (ACR) of 10, when data exist for either acute WET or chronic WET, but not for both endpoints.

2. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_a effluent) (B) (effluent flow/(Qad+effluent flow))>AC

Where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary wasteload allocations (WLAs) for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of this procedure and expressed in TU_a, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow(s) for tributaries and connecting channels in section C.1.b of this procedure, or where appropriate procedure 3.E.1.e of appendix F, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a coefficient of variation (CV) or 0.6. Where there are 10 or more individual WET tests, the multiplying factor taken from Table F6-1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

3. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_c effluent) (B) (effluent flow/Qad+effluent flow))>CC

Where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with section D.1.b. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of this procedure and expressed in TU_c, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.e of appendix F, and in accordance with the provisions of procedure 3.E.5 for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 for discharges to the OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV of 0.6. Where there are 10 more individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

Table F6-1.— Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of Samples	Coefficient of variation																			
0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0		
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1

3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

***15424 Procedure 7: Loading Limits**

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

Whenever a water quality-based effluent limitation (WQBEL) is developed, the WQBEL shall be expressed as both a concentration value and a corresponding mass loading rate.

A. Both mass and concentration limits shall be based on the same permit averaging periods such as daily, weekly, or monthly averages, or in other appropriate permit averaging periods.

B. The mass loading rates shall be calculated using effluent flow rates that are consistent with those used in establishing the WQBELs expressed in concentration.

Procedure 8: Water Quality-based Effluent Limitations Below the Quantification Level

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

When a water quality-based effluent limitation (WQBEL) for a pollutant is calculated to be less than the quantification level:

A. Permit Limits. The permitting authority shall designate as the limit in the NPDES permit the WQBEL exactly as calculated.

B. Analytical Method and Quantification Level.

1. The permitting authority shall specify in the permit the most sensitive, applicable, analytical method, specified in or approved under 40 CFR part 136, or other appropriate method if one is not available under 40 CFR part 136, to be used to monitor for the presence and amount in an effluent of the pollutant for which the WQBEL is established; and shall specify in accordance with section B.2 of this procedure, the quantification level that can be achieved by use of the specified analytical method.

2. The quantification level shall be the minimum level (ML) specified in or approved under 40 CFR part 136 for the method for that pollutant. If no such ML exists, or if the method is not specified or approved under 40 CFR part 136, the quantification level shall be the lowest quantifiable level practicable. The permitting authority may specify a higher quantification level if the permittee demonstrates that a higher quantification level is appropriate because of effluent-specific matrix interference.

3. The permit shall state that, for the purpose of compliance assessment, the analytical method specified in the permit shall be used to monitor the amount of pollutant in an effluent down to the quantification level, provided that the analyst has complied with the specified quality assurance/quality control procedures in the relevant method.

4. The permitting authority shall use applicable State and Tribal procedures to average and account for monitoring data. The permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level.

C. Special Conditions. The permit shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates that presence of the pollutant in the discharge at levels above the WQBEL. Special conditions that may be included in the permit include, but are not limited to, fish tissue sampling, whole effluent toxicity (WET) tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameters. Data generated as a result of special conditions can be used to reopen the permit to establish more stringent effluent limits or conditions, if necessary.

D. Pollutant Minimization Program. The permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program for each pollutant with a WQBEL below the quantification level. The goal of the pollutant minimization program shall be to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL. In addition, States and Tribes may consider cost-effectiveness when establishing the requirements of a PMP. The pollutant minimization program shall include, but is not limited to, the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant, which may include fish tissue monitoring and other bio-uptake sampling;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL;

4. When the sources of the pollutant are discovered, appropriate cost-effective control ***15425** measures shall be implemented, consistent with the control strategy; and

5. An annual status report that shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. A summary of all action taken to reduce or eliminate the identified sources of the pollutant.
40 CFR § 122.44
6. Any information generated as a result of procedure 8.D can be used to support a request for subsequent permit modifications, including revisions to (e.g., more or less frequent monitoring), or removal of the requirements of procedure 8.D, consistent with 40 CFR 122.44, 122.62 and 122.63.

Procedure 9: Compliance Schedules
The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 9 of appendix F of part 132.

A. Limitations for New Great Lakes Dischargers. When a permit issued on or after March 23, 1997 to a new Great Lakes discharger (defined in Part 132.2) contains a water quality-based effluent limitation (WQBEL), the permittee shall comply with such a limitation upon the commencement of the discharge.

B. Limitations for Existing Great Lakes Dischargers.

1. Any existing permit that is reissued or modified on or after March 23, 1997 to contain a new or more restrictive WQBEL may allow a reasonable period of time, up to five years from the date of permit issuance or modification, for the permittee to comply with that limit, provided that the Tier I criterion or whole effluent toxicity (WET) criterion was adopted (or, in the case of a narrative criterion, Tier II value, or Tier I criterion derived pursuant to the methodology in appendix A of part 132, was newly derived) after July 1, 1977.

2. When the compliance schedule established under paragraph 1 goes beyond the term of the permit, an interim permit limit effective upon the expiration date shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect the final limit and its compliance date.

3. If a permit establishes a schedule of compliance under paragraph 1 which exceeds one year from the date of permit issuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The time between such interim dates may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of any interim requirements.

C. Delayed Effectiveness of Tier II Limitations for Existing Great Lakes Discharges.

1. Whenever a limit (calculated in accordance with Procedure 3) based upon a Tier II value is included in a reissued or modified permit for an existing Great Lakes discharger, the permit may provide a reasonable period of time, up to two years, in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation within a reasonable period of time, no later than five years after permit issuance or modification, and contain a reopener clause.

2. The reopener clause shall authorize permit modifications if specified studies have been completed by the permittee or provided by a third-party during the time allowed to conduct the specified studies, and the permittee or a third-party demonstrates, through such studies, that a revised limit is appropriate. Such a revised limit shall be incorporated through a permit modification and a reasonable time period, up to five years, shall be allowed for compliance. If incorporated prior to the compliance date of the original Tier II limitation, any such revised limit shall not be considered less-stringent for purposes of the anti-backsliding provisions of section 402(o) of the Clean Water Act.

3. If the specified studies have been completed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide a reasonable additional period of time, not to exceed five years with which to achieve compliance with the original effluent limitation.

4. Where a permit is modified to include new or more stringent limitations, on a date within five years of the permit expiration date, such compliance schedules may extend beyond the term of a permit consistent with section B.2 of this procedure.

5. If future studies (other than those conducted under paragraphs 1, 2, or 3 above) result in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of a Tier II-based limit, the existing Tier II-based limit may be revised to be less stringent if:

(a) It complies with sections 402(o) (2) and (3) of the CWA; or,

(b) In non-attainment waters, where the existing Tier II limit was based on procedure 3, the cumulative effect of revised effluent limitation based on procedure 3 of this appendix will assure compliance with water quality standards; or,

(c) In attained waters, the revised effluent limitation complies with the State or Tribes' antidegradation policy and procedures.

[FR Doc. 95-6671 Filed 3-22-95; 8:45 am]

BILLING CODE 6560-50-P

Footnotes

tr a CMC=CMC.

d $^{tr\ d}$b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

c CMC should be considered free cyanide as CN.

t d CMC=CMC.

Notes:

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr $_{AA}$a CMC=exp { m [ln (hardness)]+b}.

d [tr d]b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

t [AA t]c CMC=exp m { [pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr a CCC=CCC.

d [tr d]b CCC=(CCC) CF. The CCC shall be rounded to two significant digits.

c CCC should be considered free cyanide as CN.

t d CCC=CCC.

Notes:

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

tr [cc]a CCC=exp {m[ln (hardness)]+b}.

[d tr d]b CCC=(CCC) (CF). The CCC shall be rounded to two significant digits.

t [AA t]c CMC=exp {m[pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

1 Includes methylmercury.

1 The FCMs for trophic level 3 are the geometric mean of the FCMs for sculpin and alewife.

Note: TL3=trophic level three fish; TL4=trophic level four fish; PB =piscivorous birds; Other=non-aquatic birds and mammals.

End of Document

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ENVIRONMENTAL PROTECTION AGENCY

[FRL 1623-3]

Water Quality Criteria Documents; Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of Water Quality Criteria Documents.

SUMMARY: EPA announces the availability and provides summaries of water quality criteria documents for 64 toxic pollutants or pollutant categories. These criteria are published pursuant to section 304(a)(1) of the Clean Water Act.

AVAILABILITY OF DOCUMENTS: Summaries of both aquatic-based and health-based criteria from the documents are published below. Copies of the complete documents for individual pollutants may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650). A list of the NTIS publication order numbers for all 64 criteria documents is published below. These documents are also available for public inspection and copying during normal business hours at: Public Information Reference Unit, U.S. Environmental Protection Agency, Room 2404 (rear), 401 M St., S.W., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services. Copies of these documents are also available for review in the EPA Regional Office libraries.

Copies of the documents are not available from the EPA office listed below. Requests sent to that office will be forwarded to NTIS or returned to the sender.

1. Acenaphthene, PB81-117269.
2. Acrolein, PB81-117277.
3. Acrylonitrile, PB81-117285.
4. Aldrin/Dieldrin, PB81-117301.
5. Antimony, PB81-117319.
6. Arsenic, PB81-117327.
7. Asbestos, PB81-117335.
8. Benzene, PB81-117293.
9. Benzidine, PB81-117343.
10. Beryllium, PB81-117350.
11. Cadmium, PB81-117368.
12. Carbon Tetrachloride, PB81-117376.
13. Chlordane, PB81-117384.
14. Chlorinated benzenes, PB81-117392.
15. Chlorinated ethanes, PB81-117400.
16. Chloroalkyl ethers, PB81-117418.
17. Chlorinated naphthalene, PB81-117426.
18. Chlorinated phenols, PB81-117434.
19. Chloroform, PB81-117442.
20. 2-chlorophenol, PB81-117459.
21. Chromium, PB81-117467.
22. Copper, PB81-117475.
23. Cyanides, PB81-117483.
24. DDT, PB81-117491.
25. Dichlorobenzenes, PB81-117509.
26. Dichlorobenzidine, PB81-117517.
27. Dichloroethylenes, PB81-117525.
28. 2,4-dichlorophenol, PB81-117533.
29. Dichloropropanes/propenes, PB81-117541.
30. 2,4-dimethylphenol, PB81-117558.
31. Dinitrotoluene, PB81-117566.
32. Diphenylhydrazine, PB81-117731.
33. Endosulfan, PB81-117574.
34. Endrin, PB81-117582.
35. Ethylbenzene, PB81-117590.
36. Fluoranthene, PB81-117608.
37. Haloethers, PB81-117616.
38. Halomethanes, PB81-117624.
39. Heptachlor, PB81-117632.
40. Hexachlorobutadiene, PB81-117640.
41. Hexachlorocyclohexane, PB81-117657.
42. Hexachlorocyclopentadiene, PB81-117665.
43. Isophorone, PB81-117673.
44. Lead, PB81-117681.
45. Mercury, PB81-117699.
46. Naphthalene, PB81-117707.
47. Nickel, PB81-117715.
48. Nitrobenzene, PB81-117723.
49. Nitrophenols, PB81-117749.
50. Nitrosamines, PB81-117756.
51. Pentachlorophenol, PB81-117764.
52. Phenol, PB81-117772.
53. Phthalate esters, PB81-117780.
54. Polychlorinated biphenyls (PCBs), PB81-117798.
55. Polynuclear aromatic hydrocarbons, PB81-117806.
56. Selenium, PB81-117814.
57. Silver, PB81-117822.
58. Tetrachloroethylene, PB81-117830.
59. Thallium, PB81-117848.
60. Toluene, PB81-117855.
61. Toxaphene, PB81-117863.
62. Trichloroethylene, PB81-117871.
63. Vinyl chloride, PB81-117889.
64. Zinc, PB81-117897.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Gostomski, Criteria and Standards Division (WH-585), United States Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 245-3042.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 304(a)(1) of the Clean Water Act, 33 U.S.C. 1314(a)(1), EPA is required to periodically review and publish criteria for water quality accurately reflecting the latest scientific knowledge:

(A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including groundwater, (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

EPA is today announcing the availability of criteria documents for 64 of the 65 pollutants designated as toxic under section 307(a)(1) of the Act. The document on TCDD (Dioxin) will be published within the next month after review of recent studies. Criteria for the section 307(a)(1) toxic pollutants being published today will replace the criteria for those same pollutants found in the EPA publication, *Quality Criteria for Water*, (the "Red Book.") Criteria for all other pollutants and water constituents found in the "Red Book" remain valid. The criteria published today have been derived using revised methodologies for determining pollutant concentrations that will, when not exceeded, reasonably protect human health and aquatic life. Draft criteria documents were made available for public comment (44 FR 15926, March 15, 1979, 44 FR 43660, July 25, 1979, 44 FR 56628, October 1, 1979). These final criteria have been derived after consideration of all comments received.

These criteria documents are also issued in satisfaction of the Settlement Agreement in *Natural Resources Defense Council, et al.* v. *Train*, 8 E.R.C. 2120 (1976), modified, 12 E.R.C. 1833 (D.D.C. 1979). Pursuant to paragraph 11 of that agreement, EPA is required to publish criteria documents for the 65 pollutants which Congress, in the 1977 amendments to the Act, designated as toxic under section 307(a)(1). These documents contain recommended maximum permissible pollutant concentrations consistent with the protection of aquatic organisms, human health, and some recreational activities. Although paragraph 11 imposes certain obligations on the Agency, it does not create additional authority.

The Development of Water Quality Criteria

Section 304(a)(1) criteria contain two essential types of information: (1) discussions of available scientific data on the effects of pollutants on public health and welfare, aquatic life and recreation, and (2) quantitative concentrations or qualitative assessments of the pollutants in water which will generally ensure water

section 304(a)(1) criteria codified in the "Red Book." Presumptive applicability meant that a State had to adopt a criterion for a particular water quality parameter at least as stringent as the recommendation in the Red Book unless the State was able to justify a less stringent criterion based on: natural background conditions, more recent scientific evidence, or local, site-specific information. EPA is rescinding the policy of presumptive applicability because it has proven to be too inflexible in actual practice.

Although the section 304(a)(1) criteria represent a reasonable estimate of pollutant concentrations consistent with the maintenance of designated water uses, States may appropriately modify these values to reflect local conditions. In certain circumstances, the criteria may not accurately reflect the toxicity of a pollutant because of the effect of local water quality characteristics or varying sensitivities of local populations. For example, in some cases, ecosystem adaptation may enable a viable, balanced aquatic population to exist in waters with high natural background levels of certain pollutants. Similarly, certain compounds may be more or less toxic in some waters because of differences in alkalinity, temperature, hardness, and other factors.

Methods for adjusting the section 304(a)(1) criteria to reflect these local differences are discussed below.

Relationship of Section 304(a)(1) Criteria to Designated Water Uses:

The criteria published today can be used to support the designated uses which are generally found in State standards. The following section discusses the relationship between the criteria and individual use classifications. Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use should be applied.

1. *Recreation:* Recreational uses of water include such activities as swimming, wading, boating and fishing. Although insufficient data exist on the effects of toxic pollutants resulting from exposure through such primary contact as swimming, section 304(a)(1) criteria based on human health effects may be used to support this designated use where fishing is included in the State definition of "recreation." In this situation only the portion of the criterion based on fish consumption should be used.

2. *Protection and Propagation of Fish and Other Aquatic Life:* The section 304(a)(1) criteria based on toxicity to aquatic life may be used directly to support this designated use.

3. *Agricultural and Industrial Uses:* The section 304(a)(1) criteria were not specifically developed to reflect the impact of pollutants on agricultural and industrial uses. However, the criteria developed for human health and aquatic life are sufficiently stringent to protect these other uses. States may establish criteria specifically designed to protect these uses.

4. *Public Water Supply:* The drinking water exposure component of the human health effects criteria can apply directly to this use classification or may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control, and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of toxic pollutants in finished ("end-of-tap") drinking water. A brief description of relevant sections of this Act is necessary to explain how the SDWA will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water.

Pursuant to section 1412 of the SDWA, EPA has promulgated "National Interim Primary Drinking Water Standards" for certain organic and inorganic substances. These standards establish "maximum contaminant levels" ("MCLs") which specify the maximum permissible level of a contaminant in water which may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also technological and economic feasibility of the contaminants' removal from the supply. EPA is required to establish revised primary drinking water regulations based on the effects of a contaminant on human health, and include treatment capability, monitoring availability, and costs. Under Section 1401(1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water which may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "end of tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria may be analogous to the recommended maximum contaminant levels (RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allows an adequate margin of safety". RMCLs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the RMCLs. Specific mandates of the SDWA such as the consideration of multi-media exposure, as well as different methods for setting maximum contaminant levels under the two Acts, may result in differences between the two numbers.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment and the fact that only a relatively small number of MCLs have been developed, ambient water criteria may be used by the States as a supplement to SDWA regulations. States will have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria or controls more stringent than these three to protect against the effects of toxic pollutants by ingestion from drinking water.

For untreated drinking water supplies, States may control toxics in the ambient water through either use of MCLs (if they exist for the pollutants of concern), section 304(a)(1) human health effects criteria, or a more strigent contaminant level than the former two options.

For treated drinking water supplies serving less than 25 people, States may choose toxics control through application of MCLs (if they exist for the pollutants of concern and are attainable by the type of treatment) in the finished drinking water. States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment procedure reduces the level of pollutants, or a more stringent contaminant level than the former three options.

For treated drinking water supplies serving 25 people or greater, States *must* control toxics down to levels at least as stringent as MCLs (where they exist for

probably some untested species, will have sensitivities below the maximum value or the 24-hour average under some conditions and would be adversely affected if the highest allowable pollutant concentrations and the worst conditions existed for a long time. In actual practice, such a situation is not likely to occur and thus the aquatic community as a whole will normally be protected if the criteria are not exceeded. In any aquatic community there is a wide range of individual species sensitivities to the effects of toxic pollutants. A criterion adequate to protect the most susceptible life stage of the most sensitive species would in many cases be more stringent than necessary to protect the overall aquatic community.

The aquatic life criteria specify both maximum and 24-hour average values. The combination of the two values is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity and bioconcentration without being as restrictive as a one-number criterion would have to be to provide the same amount of protection. A time period of 24 hours was chosen in order to ensure that concentrations not reach harmful levels for unacceptably long periods. Averaging for longer periods, such as a week or a month for example, could permit high concentrations to persist long enough to produce significant adverse effects. A 24-hour period was chosen instead of a slightly longer or shorter period in recognition of daily fluctuations in waste discharges and of the influence of daily cycles of sunlight and darkness and temperature on both pollutants and aquatic organisms.

The maximum value, which is derived from acute toxicity data, prevents significant risk of adverse impact to organisms exposed to concentrations above the 24-hour average. Merely specifying the average value over a specified time period is insufficient because concentrations of chemicals higher than the average value can kill or cause irreparable damage in short periods. Furthermore, for some chemicals the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed. The two-number criterion is intended to describe the highest average ambient water concentration which will produce a water quality generally suited to the maintenance of aquatic life while restricting the extent and duration of the excursions over that average to levels which will not cause harm. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

Since some substances may be more toxic in freshwater than in saltwater, or vice versa, provision is made for deriving separate water quality criteria for freshwater and for saltwater for each substance. However, for some substances sufficient data may not be available to derive one or both of these criteria using the Guidelines.

Specific aquatic life criteria have not been developed for all of the 65 toxic pollutants. In those cases where there were insufficient data to allow the derivation of a criterion, narrative descriptions of apparent threshold levels for acute and/or chronic effects based on the available data are presented. These descriptions are intended to convey a sense of the degree of toxicity of the pollutant in the absence of a criterion recommendation.

Summary of the Aquatic Life Guidelines

The Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and its Uses were developed to describe an objective, internally consistent, and appropriate way of ensuring that water quality criteria for aquatic life would provide, on the average, a reasonable amount of protection without an unreasonable amount of overprotection or underprotection. The resulting criteria are not intended to provide 100 percent protection of all species and all uses of aquatic life all of the time, but they are intended to protect most species in a balanced, healthy aquatic community. The Guidelines are published as Appendix B of this Notice. Responses to public comments on these Guidelines are attached as Appendix D.

Minimum data requirements are identified in four areas: acute toxicity to animals (eight data points), chronic toxicity to animals (three data points), toxicity to plants, and residues. Guidance is also given for discarding poor quality data.

Data on acute toxicity are needed for a variety of fish and invertebrate species and are used to derive a Final Acute Value. By taking into account the number and relative sensitivities of the tested species, the Final Acute Value is designed to protect most, but not necessarily all, of the tested and untested species.

Data on chronic toxicity to animals can be used to derive a Final Chronic Value by two different means. If chronic values are available for a specified number and array of species, a final chronic value can be calculated directly. If not, an acute-chronic ratio is derived and then used with the Final Acute Value to obtain the Final Chronic Value.

The Final Plant Value is obtained by selecting the lowest plant toxicity value based on measured concentrations.

The Final Residue Value is intended to protect wildlife which consume aquatic organisms and the marketability of aquatic organisms. Protection of the marketability of aquatic organisms is, in actuality, protection of a use of that water body ("commercial fishery"). Two kinds of data are necessary to calculate the Final Residue Value: a bioconcentration factor (BCF) and a maximum permissible tissue concentration, which can be an FDA action level or can be the result of a chronic wildlife feeding study. For lipid soluble pollutants, the BCF is normalized for percent lipids and then the Final Residue Value is calculated by dividing the maximum permissible tissue concentration by the normalized BCF and by an appropriate percent lipid value. BCFs are normalized for percent lipids since the BCF measured for any individual aquatic species is generally proportional to the percent lipids in that species.

If sufficient data are available to demonstrate that one or more of the final values should be related to a water quality characteristic, such as salinity, hardness, or suspended solids, the final value(s) are expressed as a function of that characteristic.

After the four final values (Final Acute Value, Final Chronic Value, Final Plant Value, and Final Residue Value) have been obtained, the criterion is established with the Final Acute Value becoming the maximum value and the lowest of the other three values becoming the 24-hour average value. All of the data used to calculate the four final values and any additional pertinent information are then reviewed to determine if the criterion is reasonable. If sound scientific evidence indicates that the criterion should be raised or lowered, appropriate changes are made as necessary.

The present Guidelines have been revised from the earlier published versions (43 FR 21506, May 18, 1978; 43 FR 29028, July 5, 1978; 44 FR 15926, March 15, 1979). Details have been added in many places and the concept of a minimum data base has been incorporated. In addition, three adjustment factors and the species sensitivity factor have been deleted. These modifications were the result of the Agency's analysis of public comments and comments received from the Science Advisory Board on earlier

human epidemiology studies using the following basic exposure assumptions: a 70-kilogram male person (*Report of the Task Group on Reference Man*, International Commission for Radiation Protection, November 23, 1957) as the exposed individual; the average daily consumption of freshwater and estuarine fish and shellfish products equal to 6.5 grams/day; and the average ingestion of two liters/day of water (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977). Criteria based on these assumptions are estimated to be protective of an adult male who experiences average exposure conditions.

Two basic methods were used to formulate health criteria, depending on whether the prominent adverse effect was cancer or other toxic manifestations. The following sections detail these methods.

Carcinogens

Extrapolation of cancer responses from high to low doses and subsequent risk estimation from animal data is performed using a linearized multi-stage model. This procedure is flexible enough to fit all monotonically-increasing dose response data, since it incorporates several adjustable parameters. The multi-stage model is a linear non-threshold model as was the "one-hit" model originally used in the proposed criteria documents. The linearized multi-stage model and its characteristics are described fully in Appendix C. The linear non-threshold concept has been endorsed by the four agencies in the Interagency Regulatory Liaison Group and is less likely to underestimate risk at the low doses typical of environmental exposure than other models that could be used. Because of the uncertainties associated with dose response, animal-to-human extrapolation and other unknown factors, because of the use of average exposure assumptions, and because of the serious public health consequences that could result if risk were underestimated, EPA believes that it is prudent to use conservative methods to estimate risk in the water quality criteria program. The linearized multistage model is more systematic and invokes fewer arbitrary assumptions than the "one-hit" procedure previously used.

It should be noted that extrapolation models provide estimates of risk since a variety of assumptions are built into any model. Models using widely different assumptions may produce estimates ranging over several orders of magnitude. Since there is at present no way to demonstrate the scientific validity of any model, the use of risk extrapolation models is a subject of debate in the scientific community. However, risk extrapolation is generally recognized as the only tool available at this time for estimating the magnitude of health hazards associated with non-threshold toxicants and has been endorsed by numerous Federal agencies and scientific organizations, including EPA's Carcinogen Assessment Group, the National Academy of Sciences, and the Interagency Regulatory Liaison Group as a useful means of assessing the risks of exposure to various carcinogenic pollutants.

Non-Carcinogens

Health criteria based on toxic effects of pollutants other than carcinogenicity are estimates of concentrations which are not expected to produce adverse effects in humans. They are based upon Acceptable Daily Intake (ADI) levels and are generally derived using no-observed-adverse-effect-level (NOAEL) data from animal studies although human data are used wherever available. The ADI is calculated using safety factors to account for uncertainties inherent in extrapolation from animal to man. In accordance with the National Research Council recommendations (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977), safety factors of 10, 100, or 1,000 are used depending on the quality and quantity of data. In some instances extrapolations are made from inhalation studies or limits to approximate a human response from ingestion using the Stokinger-Woodward model (Journal of American Water Works Association, 1958). Calculations of criteria from ADIs are made using the standard exposure assumptions (2 liters of water, 6.5 grams of edible aquatic products, and an average body weight of 70 kg).

Dated: October 24, 1980.

Douglas M. Costle,

Administrator.

Appendix A—Summary of Water Quality Criteria

Acenaphthene

Freshwater Aquatic Life

The available data for acenaphthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,700 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acenaphthene to sensitive freshwater aquatic animals but toxicity to freshwater algae occur at concentrations as low as 520 μg/l.

Saltwater Aquatic Life

The available data for acenaphthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 970 and 710 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 500 μg/l.

Human Health

Sufficient data is not available for acenaphthene to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Acrolein

Freshwater Aquatic Life

The available data for acrolein indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 68 and 21 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for acrolein indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 55 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acrolein to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of acrolein ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 320 μg/l.

For the protection of human health from the toxic properties of acrolein ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 780 μg/l.

Acrylonitrile

Freshwater Aquatic Life

The available data for acrylonitrile indicate that acute toxicity to freshwater aquatic life occurs at concentrations as

estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 22 ng/l, 2.2 ng/l, and .22 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 175 ng/l, 17.5 ng/l, and 1.75 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Asbestos

Freshwater Aquatic Life

No freshwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of asbestos through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 300,000 fibers/1,30,000 fibers/1, and 3,000 fibers/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzene

Freshwater Aquatic Life

The available data for benzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,300 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for benzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of benzene to sensitive saltwater aquatic life, but adverse effects occur at concentrations as low as 700 μg/l with a fish species exposed for 168 days.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.6 μg/l, .66 μg/l, and .066 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 400 μg/l, 40.0 μg/l, and 4.0 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzidine

Freshwater Aquatic Life

The available data for benzidine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzidine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with benzidine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.2 ng/1, .12 ng/1, and .01 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.3 ng/1, .53 ng/1, and .05 ng/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Beryllium

Freshwater Aquatic Life

The available data for beryllium indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 130 and 5.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Hardness has a substantial effect on acute toxicity.

Salt water Aquatic Life

The limited saltwater data base available for beryllium does not permit any statement concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beryllium through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 37 ng/l, 3.7 ng/l, and .37 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 641 ng/l, 64.1 ng/l, and 6.41 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Cadmium

Freshwater Aquatic Life

For total recoverable cadmium the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given

this time due to the insufficiency in the available data for trichlorobenzene.

For comparison purposes, two approaches were used to derive criterion levels for monochlorobenzene. Based on available toxicity data, for the protection of public health, the derived level is 488 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Chlorinated Ethanes

Freshwater Aquatic Life

The available freshwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination, and that acute toxicity occurs at concentrations as low as 118,000 μg/l for 1,2-dichloroethane, 18,000 μg/l for two trichloroethanes, 9,320 μg/l for two tetrachloroethanes, 7,240 μg/l for pentachloroethane, and 980 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 20,000 μg/l for 1,2-dichloroethane, 3400 μg/l for 1,1,2-trichloroethane, 2,400 μg/l for 1,1,2,2,-tetrachloroethane, 1,100 μg/l for pentachloroethane, and 540 μg/l for hexachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination and that acute toxicity to fish and invertebrate species occurs at concentrations as low as 113,000 μg/l for 1,2-dichloroethane, 31,200 μg/l for 1,1,1-trichloroethane, 9,020 μg/l for 1,1,2,2-tetrachloroethane, 390 μg/l for pentachloroethane, and 940 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 201 μg/l for pentachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-dichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 9.4 μg/l, .94 μg/l, and .094 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2,430 μg/l, 243 μg/l, and 24.3 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of 1,1,1-trichloroethane ingested through water and contaminated aquatic organism, the ambient water criterion is determined to be 18.4 mg/l.

For the protection of human health from the toxic properties of 1,1,1,-trichloroethane ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.03 g/l.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2-trichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.0 μg/l, .6 μg/l, and .06 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 418 μg/l, 41.8 μg/l, and 4.18 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2,2-tetrachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.7 μg/l, .17 μg/l, and .017 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 107 μg/l, 10.7 μg/l, and 1.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 19 μg/l, 1.9 μg/l, and .19 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 87.4 μg/l, 8.74 μg/l, and .87 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for monochloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,-dichloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,1,2-tetrachloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for pentachloroethane.

Chlorinated Naphthalenes

Freshwater Aquatic Life

The available data for chlorinated naphthalenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,600 μg/l and would occur at lower concentrations among species that are

recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-4-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 3000 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-6-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Chloroalkyl Ethers

Freshwater Aquatic Life

The available data for chloroalkyl ethers indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 238,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of chloroalkyl ethers to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with any chloroalkyl ether and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis-(chloromethyl)-ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .038 ng/l, .0038 ng/l, and .00038 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.4 ng/l, 1.84 ng/l, and .184 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis (2-chloroethyl) ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .3 μg/l, .03 μg/l, and .003 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 13.6 μg/l, 1.36 μg/l, and .136 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34.7 μg/l.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 4.36 mg/l.

Chloroform

Freshwater Aquatic Life

The available data for choloroform indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 28,900 μg/l, and would occur at lower concentrations among species that are more sensitive than the three tested species. Twenty-seven-day LC50 values indicate that chronic toxicity occurs at concentrations as low as 1,240 μg/l, and could occur at lower concentrations among species or other life stages that are more sensitive than the earliest life cycle stage of the rainbow trout.

Saltwater Aquatic Life

The data base for saltwater species is limited to one test and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloroform through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.90 μg/l, .19 μg/l, and .019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

2-Chlorophenol

Freshwater Aquatic Life

The availabe data for 2-chlorophenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 4,380 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No definitive data are available concerning the chronic toxicity of 2-chlorophenol to sensitive freshwater aquatic life but flavor impairment occurs in one species of fish at concentrations as low as 2,000 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2-chlorophenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data is not available for 2-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no

chronic toxicity of TDE to sensitive saltwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 14 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of DDT through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment of an "acceptable" risk level.

Dichlorobenzenes

Freshwater Aquatic Life

The available data for dichlorobenzenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 1,120 and 763 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichlorobenzenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 1,970 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichlorobenzenes to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 400 μg/l.

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.6 mg/l.

Dichlorobenzidines

Freshwater Aquatic Life

The data base available for dichlorobenzidines and freshwater organisms is limited to one test on bioconcentration of 3,3'-dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dichlorobenzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero base on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .103 μg/l, .0103 μg/l, and .00103 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .204 μg/l, .0204 μg/l, and .00204 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Dichloroethylenes

Freshwater Aquatic Life

The available data for dichloroethylenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,600 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of dichlorethylenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for dichlorethylenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 224,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity dichloroethylenes to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1-dichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .33 μg/l, .033 μg/l, and .0033 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.5 μg/l, 1.85 μg/l, and .185 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficency in the available data for 1,2-dichloroethylene.

2,4-Dichlorophenol

Freshwater Aquatic Life

The available data for 2,4-dichlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 2,020 and 365 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive that those tested. Mortality to early life stages of one species of fish occurs at concentrations as low as 70 μg/l.

Saltwater Aquatic Life

Only one test has been conducted with saltwater organisms on 2,4-dichlorophenol and no statement can be made concerning acute or chronic toxicity.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for 2,4-dichlorophenol.

epresent an Agency judgment on an "acceptable" risk level.

Endosulfan

Freshwater Aquatic Life

For endosulfan the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.056 μg/l as a 24-hour average and the concentration should not exceed 0.22 μg/l at any time.

Saltwater Aquatic Life

For endosulfan the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0087 μg/l as a 24-hour average and the concentration should not exceed 0.034 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of endosulfan ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of endosulfan ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 159 μg/l.

Endrin

Freshwater Aquatic Life

For endrin the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.18 μg/l at any time.

Saltwater Aquatic Life

For endrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.037 μg/l at any time.

Human Health

The ambient water quality criterion for endrin is recommended to be identical to the existing drinking water standard which is 1 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Ethylbenzene

Freshwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 32,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of ethylbenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 430 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of ethylbenzene to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of ethylbenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 1.4 mg/l.

For the protection of human health from the toxic properties of ethylbenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3.28 mg/l.

Fluoranthene

Freshwater Aquatic Life

The available data for fluoranthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 3980 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of fluoranthene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for fluoranthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 40 and 16 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of fluoranthene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 42 μg/l.

For the protection of human health from the toxic properties of fluoranthene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 54 μg/l.

Haloethers

Freshwater Aquatic Life

The available data for haloethers indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 360 and 122 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

No saltwater organisms have been tested with any haloether and no statement can be made concerning acute or chronic toxicity.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for haloethers.

Halomethanes

Freshwater Aquatic Life

The available data for halomethanes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of halomethanes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for halomethanes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 12,000 and 6,400 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. A decrease in algal cell numbers occurs at concentrations as low as 11,500 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloromethane, bromomethane, dichloromethane, bromodichloromethane, tribromomethane, dichlorodifluoromethane, trichlorofluoromethane, or combinations of these chemicals through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are

represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tech-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 123 ng/l, 12.3 ng/l, and 1.23 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 414 ng/l, 41.4 ng/l, and 4.14 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of gamma-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentrations should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 186 ng/l, 18.6 ng/l, and 1.86 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 625 ng/l, 62.5 ng/l, 6.25 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for delta-HCH.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for epsilon-HCH.

Hexachlorocyclopentadiene

Freshwater Aquatic Life

The available data for hexachlorocyclopentadiene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 7.0 and 5.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data to hexachlorocyclopentadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.0 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of hexachlorocyclopentadiene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for hexachlorocyclopentadiene. Based on available toxicity data, for the protection of public health, the derived level is 206 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Isophorone

Freshwater Aquatic Life

The available data for isophorone indicate that acute toxicity to freshwater aquatic life ocurs at concentrations as low as 117,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for isophorone indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 12,900 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of isophorone ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 5.2 mg/l.

For the protection of human health from the toxic properties of isophorone ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 520 mg/l.

Lead

Freshwater Aquatic Life

For total recoverable lead the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(2.35[ln(hardness)]-9.48) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(1.22[ln(hardness)]-0.47) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.75, 3.8, and 20 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 74, 170, and 400 μg/l, respectively, at any time.

Saltwater Aquatic Life

The available data for total recoverable lead indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 668 and 25 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for lead is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective to human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Mercury

Freshwater Aquatic Life

For total recoverable mercury the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.00057 μg/l as a 24-hour average and the concentration should not exceed 0.0017 μg/l at any time.

Saltwater Aquatic Life

For total recoverable mercury the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.025 μg/l as a 24-hour average and the concentration should not exceed 3.7 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of mercury

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodimethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 14 ng/l, 1.4 ng/l, and .14 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 160,000 ng/l, 16,000 ng/l, and 1,600 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodiethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 ng/l, 0.8 ng/l, and 0.08 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 12,400 ng/l, 1,240 ng/l, and 124 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodi-n-butylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 64 ng/l 6.4 ng/l and .064 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,868 ng/l, 587 ng/l, and 58.7 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodiphenylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 49,000 ng/l 4,900 ng/l and 490 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 161,000 ng/l, 16,100 ng/l, and 1,610 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosopyrrolidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 160 ng/l 16.0 ng/l and 1.60 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 919,000 ng/l, 91,900 ng/l, and 9,190 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Pentachlorophenol

Freshwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 55 and 3.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 53 and 34 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for pentachlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 1.01 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phenol

Freshwater Aquatic Life

The available data for phenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 10,200 and 2,560 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phenol indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,800 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phenol to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for phenol. Based on available toxicity data, for the protection of public health, the derived level is 3.5 mg/l. Using available organoleptic data, for controlling

than those tested. No data are available concerning the chronic toxicity of inorganic selenate to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect saltwater aquatic life as derived using the Guidelines is 54 μg/l as a 24-hour average and the concentration should not exceed 410 μg/l at any time.

No data are available concerning the toxicity of inorganic selenate to saltwater aquatic life.

Human Health

The ambient water quality criterion for selenium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Silver

Freshwater Aquatic Life

For freshwater aquatic life the concentration (in μg/l) of total recoverable silver should not exceed the numerical value given by "e[1.72(ln (hardness)-6.52)]" at any time. For example, at hardnesses of 50, 100, 200 mg/l as $CaCO_3$ the concentration of total recoverable silver should not exceed 1.2, 4.1, and 13 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life may occur at concentrations as low as 0.12 μg/l.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of total recoverable silver should not exceed 2.3 μg/l at any time. No data are available concerning the chronic toxicity of silver to sensitive saltwater aquatic life.

Human Health

The ambient water quality criterion for silver is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Tetrachloroethylene

Freshwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 5,280 and 840 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations low as 10,200 and 450 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tetrachloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 μg/l, .8 μg/l, and .08 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 88.5 μg/l, 8.85 μg/l, and .88 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Thallium

Freshwater Aquatic Life

The available data for thallium indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 1,400 and 40 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to one species of fish occurs at concentrations as low as 20 μg/l after 2,600 hours of exposure.

Saltwater Aquatic Life

The available data for thallium indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,130 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of thallium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of thallium ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13 μg/l.

For the protection of human health from the toxic properties of thallium ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

Toluene

Freshwater Aquatic Life

The available data for toluene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 17,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of toluene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for toluene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 6,300 and 5,000 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of toluene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 14.3 mg/l.

For the protection of human health from the toxic properties of toluene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 424 mg/l.

Toxaphene

Freshwater Aquatic Life

For toxaphene the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.013 μg/l as a 24-hour average and the concentration should not exceed 1.6 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of toxaphene should not exceed 0.070 μg/l at any time. No data

necessarily all of the species all of the time. Aquatic communities can tolerate some stress and occasional adverse effects on a few species, and so total protection of all of the species all of the time is not necessary. Rather, the Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of considerable overprotection or underprotection. Within these constraints, it seems appropriate to err on the side of overprotection.

The numerical aquatic life criteria derived using the Guidelines are expressed as two numbers, rather than the traditional one number, so that the criteria can more accurately reflect toxicological and practical realities. The combination of both a maximum value and a 24-hour average value is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity to animals, toxicity to plants and bioconcentration by aquatic organisms without being as restrictive as a one-number criterion would have to be to provide the same amout of protection. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

The two-number criterion is intended to identify an average pollutant concentration which will produce a water qualtiy generally suited to the maintenance of aquatic life and its uses while restricting the extent and duration of excursions over the average so that the total exposure will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient, unless the period of time is rather short, because of concentration higher than the average value can kill or cause substantial damage in short periods. Furthermore, for some substances the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed, especially when the maximum value is not much higher than the average value. For some substances the maximum may be so much higher than the 24-hour average that in any real-world situation the maximum will never be reached if the 24-hour average is achieved. In such cases the 24-hour average will be limiting and the maximum will have no practical significance, except to indicate that elevated concentrations are acceptable as long as the 24-hour average is achieved.

These Guidelines have been developed on the assumption that the results of laboratory tests are generally useful for predicting what will happen in field situations. The resulting criteria are meant to apply to most bodies of water in the United States, except for the Great Salt Lake. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available, with at least one specific exception. This exception is the accumulation of residues of organic compounds in the siscowet subspecies of lake trout which occurs in Lake Superior and contains up to 67% fat in the fillets (Thurston, C.E., 1962, Physical Characteristics and Chemical Composition of Two Subspecies of Lake Trout, J. Fish. Res. Bd. Canada 19:39–44). Neither siscowet nor organisms in the Great Salt Lake are intentionally protected by these Guidelines because both may be too atypical.

With appropriate modifications these Guidelines can be used to derive criteria for any specified geographical area, body of water (such as the Great Salt Lake), or group of similar bodies of water. Thus with appropriate modifications the Guidelines can be used to derive national, state, or local criteria if adequate information is available concerning the effects of the substance of concern on appropriate species and their uses. However, the basic concepts described in the Guidelines should be modified only when sound scientific evidence indicates that a criterion produced using the Guidelines would probably significantly overprotect or underprotect the presence or uses of aquatic life.

Criteria produced by these Guidelines are not enforceable numbers. They may be used in developing enforceable numbers, such as water quality standards and effluent standards. However, the development of standards may take into account additional factors such as social, legal, economic, and hydrological considerations, the environmental and analytical chemistry of the substance, the extrapolation from laboratory data to field situations, and the relationship between the species for which data are available and the species which are to be protected.

Because fresh water and salt water (including both estuarine and marine waters) have basically different chemical compositions and because freshwater and saltwater species rarely inhabit the same water simultaneously, separate criteria should be derived for these two kinds of waters. However, for some substances sufficient data may not be available to allow derivation of one or both of these criteria using the Guidelines.

These Guidelines are meant to be used after a decision is made that a criterion is needed for a substance. The Guidelines do not address the rationale for making that decision. If the potential for adverse effects on aquatic life and its uses are part of the basis for deciding whether or not a criterion is needed for a substance, these Guidelines may be helpful in the collection and interpretation of relevant data.

I. Define the Substance for Which the Criterion Is To Be Derived

A. Each separate chemical which would not ionize significantly in most natural bodies of water should usually be considered a separate substance, except possibly for structurally similar organic compounds that only differ in the number and location of atoms of a specific halogen, and only exist in large quantities as commercial mixtures of the various compounds, and apparently have similar chemical, biological, and toxicological properties.

B. For chemicals, which would ionize significantly in most natural bodies of water, such as inorganic salts, organic acids and phenols, all forms that would be in chemical equilibrium should usually be considered one substance. For metals, each different valence and each different covalently bonded organometallic compound should usually be considered a separate substance.

C. The definition of the substance may also need to take into account the analytical chemistry and fate of the substance.

II. Collect and Review Available Data

A. Collect all available data on the substance concerning (1) toxicity to, and bioaccumulation by, aquatic animals and plants, (2) FDA action levels, and (3) chronic feeding studies with wildlife.

B. Discard all data that are not available in hard copy (publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. Do not assume that all published data are acceptable.

C. Discard questionable data. For example, discard data from tests for which no control treatment existed, in which too many organisms in the control treatment died or showed signs of stress or disease, or in which distilled or deionized water was used as the dilution water for aquatic organisms. Discard data on formulated mixtures and emulsifiable concentrates of the

xposure to toxicant or for whom the cute adverse effect of the exposure cannot be adequately measured. Such freshwater and saltwater animals include air-breathing molluscs, unionid clams, operculate snails, and bivalve molluscs, except for some species that cannot "close up" and thus prevent exposure to toxicant, such as the bay scallop (*Argopecten irradians*).

F. For the use of LC50 or EC50 values for durations shorter and longer than those listed above, see Section X.

G. If the acute toxicity of the substance to aquatic animals has been shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Acute Equation should be derived based on that water quality characteristic. Go to Section V.

H. If the acute toxicity of the substance has not been adequately shown to be related to a water quality characteristic, for each species for which at least one acute value is available, calculate the geometric mean of the results of all flow-through tests in which the toxicant concentrations were measured. For a species for which no such result is available, calculate the geometric mean of all available acute values, i.e., results of flow-through tests in which the toxicant concentrations were not measured and results of static and renewal tests based on initial total toxicant concentrations.

Note.—The geometric mean of N numbers is obtained by taking the N^{th} root of the product of N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers can also be calculated as the square root of the product of the two numbers. The geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithm used.

I. Count the number=N of species for which a species mean acute value is available.

J. Order the species mean acute values from low to high. Take the common logarithms of the N values (log mean values).

K. The intervals (cell widths) for the lower cumulative proportion calculations are 0.11 common log units apart, starting from the lowest log value. The value of 0.11 is an estimate of average precision and was calculated from replicate species acute values.

L. Starting with the lowest log mean value, separate the N values into intervals (or cells) calculated in Step IV. K.

M. Calculate cumulative proportions for each non-empty interval by summing the number of values in the present and all lower intervals and dividing by N. These calculations only need to be done for the first three non-empty intervals (or cells).

N. Calculate the arithmetic mean of the log mean values for each of the three intervals.

O. Using the two interval mean acute values and cumulative proportions closest to 0.05, linearly extrapolate or interpolate to the 0.05 log concentration. The Final Acute Value is the antilog of the 0.05 concentration.

In other words, where

Prop(1) and conc(1) are the cumulative proportion and mean log value for the lowest non-empty interval.

Prop(2) and conc(2) are the cumulative proportion and mean log value for the second lowest non-empty interval.

A=Slope of the cumulative proportions

B=The 0.05 log value

Then:

$A=[0.05-Prop(1)]/[Prop(2)-Prop(1)]$

$B=conc(1)+A\,[conc(2)-conc(1)]$

Final Acute Value $=10^B$

P. If for an important species, such as a recreationally or commercially important species, the geometric mean of the acute values from flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Value, then that geometric mean should be used as the Final Acute Value.

Q. Go to Section VI.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly affected by a water quality characteristic, this effect can be taken into account as described below. Pooled regression analysis should produce similar results, although data available for individual species would be weighted differently.

B. For each species for which comparable acute toxicity values are available at two or more different values of a water quality characteristic which apparently affects toxicity, perform a least squares regression of the natural logarithms of the acute toxicity values on the natural logarithms of the values of the water quality characteristic. [Natural logarithms [logarithms to the base e, denoted as ln] are used herein merely because they are easier to use on some hand calculators and computers than common logarithms [logarithms to the base 10]. Consistent use of either will produce the same result.] No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section.

C. Determine whether or not each acute slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If meaningful slopes are not available for at least two species or if the available slopes are not similar, return to Section IV. H., using the results of tests conducted under conditions and in water similar to those commonly used for toxicity tests with the species.

D. Calculate the mean acute slope (V) as the arithmetic average of all the meaningful acute slopes for individual species.

E. For each species calculate the geometric mean (W) of the acute toxicity values and the geometric mean (X) of the related values of the water quality characteristic.

F. For each species calculate the logarithmic intercept (Y) using the equation: $Y=\ln W-V(\ln X)$.

G. For each species calculate the species mean acute intercept as the antilog of Y.

H. Obtain the Final Acute Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

I. If for an important species, such as a recreationally or commercially important species, the intercept calculated only from results of flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Intercept, then that intercept should be used as the Final Acute Intercept.

J. The Final Acute Equation is written as $e^{(V[\ln(\text{water quality characteristic})]+\ln Z)}$, where V=mean acute slope and Z=Final Acute Intercept.

VI. Final Chronic Value

A. The Final Chronic Value can be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio, depending on the data available. In some cases it will not be possible to calculate a Final Chronic Value.

B. Use only the results of flow-through (except renewal is acceptable for

meaningful chronic slope is not available for at least one species, return to Section VI. H.

C. Calculate the mean chronic slope (L) as the arithmetic average of all the meaningful chronic slopes for individual species.

D. For each species calculate the geometric mean (M) of the toxicity values and the geometric mean (P) of the related values of the water quality characteristic.

E. For each species calculate the logarithmic intercept (Q) using the equation: $Q = \ln M - L(\ln P)$.

F. For each species calculate a species mean chronic intercept as the antilog of Q.

G. Obtain the Final Chronic Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

H. If the species mean chronic intercept of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Intercept, then that species mean chronic intercept should be used as the Final Chronic Intercept.

I. The Final Chronic Equation is written as $e^{(L[\ln(\text{Water quality characteristic})]+\ln R)}$, where L = mean chronic slope and R = Final Chronic Intercept.

VIII. Final Plant Value

A. Appropriate measures of the toxicity of the substance to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals.

B. A value is a concentration which decreased growth (as measured by dry weight, chlorophyll, etc.) in a 96-hr or longer test with an alga or in a chronic test with an aquatic vascular plant.

C. Obtain the Final Plant Value by selecting the lowest plant value from a test in which the toxicant concentrations were measured.

IX. Final Residue Value

A. The Final Residue Value is derived in order to (1) prevent commercially or recreationally important aquatic organisms from exceeding relevant FDA action levels and (2) protect wildlife, including fishes and birds, that eat aquatic organisms from demonstrated adverse effects. A residue value is calculated by dividing a maximum permissible tissue concentration by an appropriate bioconcentration factor (BCF), where the BCF is the quotient of the concentration of a substance in all or part of an aquatic organism divided by the concentration in water to which the organism has been exposed. A maximum permissible tissue concentration is either (1) an action level from the FDA Administrative Guidelines Manual for fish oil or for the edible portion of fish or shellfish, or (2) a maximum acceptable dietary intake based on observations on survival, growth or reproduction in a chronic wildlife feeding study. If no maximum permissible tissue concentration is available, go to Section X because no Final Residue Value can be derived.

B. 1. A BCF determined in a laboratory test should be used only if it was calculated based on measured concentrations of the substance in the test solution and was based on an exposure that continued until either steady-state or 28-days was reached. Steady-state is reached when the BCF does not change significantly over a period of time, such as two days or 16 percent of the length of the exposure, whichever is longer. If a steady-state BCF is not available for a species, the available BCF for the longest exposure over 28 days should be used for that species.

2. A BCF from a field exposure should be used only when it is known that the concentration of the substance was reasonably constant for a long enough period of time over the range of territory inhabited by the organisms.

3. If BCF values from field exposures are consistently lower or higher than those from laboratory exposures, then only those values from field exposures should be used if possible.

4. A BCF should be calculated based on the concentration of the substance and its metabolites, which are structurally similar and are not much more soluble in water than the parent compound, in appropriate tissue and should be corrected for the concentration in the organisms at the beginning of the test.

5. A BCF value obtained from a laboratory or field exposure that caused an observable adverse effect on the test organism may be used only if it is similar to that obtained with unaffected organisms at lower concentrations in the same test.

6. Whenever a BCF is determined for a lipid-soluble substance, the percent lipids should also be determined in the tissue for which the BCF was calculated.

C. A BCF calculated using dry tissue weights must be converted to a wet tissue weight basis by multiplying the dry weight BCF value by 0.1 for plankton and by 0.2 for individual species of fishes and invertebrates.

Note.—The values of 0.2 and 0.1 were derived from data published in:

McDiffett, W. F., 1970. Ecology 51:975–988.
Brocksen, R. W., et al. 1968. J. Wildlife Management 32:52–75.
Cummins, K. W., et al. 1973. Ecology 54: 336–345.
Pesticide Analytical Manual, Volume I. Food and Drug Administration, 1969.
Love, R. M., 1957. In The Physiology of Fishes, Vol. I, M. E. Brown, ed. Academic Press, New York. p. 411.
Ruttner, F., 1963. Fundamentals of Limnology. 3rd ed. Trans. by D. G. Frey and F. E. J. Fry. Univ. of Toronto Press, Toronto.

Some additional values can be found in:

Sculthorpe, C. D., 1967. The Biology of Aquatic Vascular Plants. Arnold Publishing Ltd., London.

D. If enough pertinent data exist, several residue values can be calculated by dividing maximum permissible tissue concentrations by appropriate BCF values.

1. For each available maximum acceptable dietary intake derived from a chronic feeding study with wildlife, including birds and aquatic organisms, the appropriate BCF is based on the whole body of aquatic species which constitute or represent a major portion of the diet of the tested wildlife species.

2. For an FDA action level, the appropriate BCF is the highest geometric mean species BCF for the edible portion (muscle for decapods, muscle with or without skin for fishes, adductor muscle for scallops and total living tissue for other bivalve molluscs) of a consumed species. The highest species BCF is used because FDA action levels are applied on a species-by-species basis.

E. For lipid-soluble substances, it may be possible to calculate additional residue values. Because steady-state BCF values for a lipid-soluble chemical seem to be proportional to percent lipids from one tissue to another and from one species to another, extrapolations can be made from tested tissues or species to untested tissues or species on the basis of percent lipids.

1. For each BCF for which the percent lipids is known for the same tissue for which the BCF was measured, the BCF should be normalized to a one percent lipid basis by dividing the BCF by the percent lipids. This adjustment to a one percent lipid basis makes all the measured BCF values comparable regardless of the species or tissue for which the BCF was measured.

2. Calculate the geometric mean normalized BCF. Data for both saltwater and freshwater species can be used to determine the mean normalized BCF, because the normalized BCF seems to be about the same for both kinds of organisms.

3. Residue values can then be calculated by dividing the maximum permissible tissue concentrations by the mean normalized BCF and by a percent lipids value appropriate to the maximum permissible tissue concentration, *i.e.*,

riteria for carcinogens are presented as a range of pollutant concentrations associated with corresponding incremental risks.

For compounds which do not manifest any apparent carcinogenic effect, the threshold assumption is used in deriving a criterion. This assumption is based on the premise that a physiological reserve capacity exists within the organism which is thought to be depleted before clinical disease ensues. Alternatively, it may be assumed that the rate of damage will be insignificant over the life span of the organism. Thus, ambient water quality criteria are derived for non-carcinogenic chemicals, and presumably result in no observable-adverse-effect levels (NOAELs) in the exposed human population.

In some instances, criteria are based on organoleptic characteristics, i.e., thresholds for taste or odor. Such criteria are established when insufficient information is available on toxicologic effects or when the estimate of the level of the pollutant in ambient water based on organoleptic effects is lower than the level calculated from toxicologic data. It should be recognized that criteria based solely on organoleptic effects do not necessarily represent approximations of acceptable risk levels for human health.

Several ambient water quality criteria documents deal with classes of compounds which include chemicals exhibiting varying degrees of structural similarity. Because prediction of biological effects based solely on structural parameters is difficult, the derivation of compound-specific criteria is preferable to a class criterion. A compound-specific criterion is defined as a level derived from data on each individual subject compound that does not represent a significant risk to the public. For some chemical classes, however, a compound-specific criterion cannot be derived for each member of a class. In such instances, it is sometimes justifiable to derive a class criterion in which available data on one member of a class may be used to estimate criteria for other chemicals of the class because a sufficient data base is not available for those compounds.

For some chemicals and chemical classes, the data base was judged to be insufficient for the derivation of a criterion. In those cases, deficiencies in the available information are detailed.

III. Approach

The human health effects chapters attempt to summarize all information on the individual chemicals or classes of chemicals which might be useful in the risk assessment process to develop water quality criteria. Although primary emphasis is placed on identifying epidemiologic and toxicologic data, these assessments typically contain discussions on four topics: existing levels of human exposure, pharmacokinetics, toxic effects, and criterion formulation.

For all documents, an attempt is made to include the known relevant information. Review articles and reports are often used in the process of data evaluation and synthesis. Scientific judgment is exercised in the review and evaluation of the data in each document and in the identification of the adverse effects against which protective criteria are sought. In addition, each of these documents is reviewed by a peer committee of scientists familiar with the specific compound(s). These work groups evaluate the quality of the available data, the completeness of the data summary, and the validity of the derived criterion.

In the analysis and organization of the data, an attempt is made to be consistent with respect to the format and the application of acceptable scientific principles. Evaluation procedures used in the hazard assessment process follow the principles outlined by the National Academy of Sciences in *Drinking Water and Health* (1977) and the guidelines of the Carcinogen Assessment Group of the U.S. EPA.

A. Exposure

The exposure section of the health effects chapters reviews known information on current levels of human exposure to the individual pollutant from all sources. Much of the data was obtained from monitoring studies of air, water, food, soil, and human or animal tissue residues. The major purpose of this section is to provide background information on the contribution of water exposure relative to all other sources. Consequently, the exposure section includes subsections reviewing different routes of exposure including water and food ingestion, inhalation, and dermal contact.

Information on exposure can be valuable in developing and assessing a water quality criterion. In these documents exposure from consumption of contaminated water and contaminated fish and shellfish products is used in criterion formulation. Data for all modes of exposure are useful in relating total intake to the expected contribution from contaminated water, fish, and shellfish. In addition, information for all routes of exposure, not limited to drinking water and fish and shellfish ingestion, can be used to justify or assess the feasibility of the formulation of criteria for ambient water.

The use of fish consumption as an exposure factor requires the quantitation of pollutant residues in the edible portions of the ingested species. Accordingly, bioconcentration factors (BCFs) are used to relate pollutant residues in aquatic organisms to the pollutant concentration in the ambient waters in which they reside.

To estimate the average per capita intake of a pollutant due to consumption of contaminated fish and shellfish the results of a diet survey were analyzed to calculate the average consumption of freshwater and estuarine fish and shellfish (U.S. EPA, 1980). A species is considered to be a consumed freshwater or estuarine fish and shellfish species if at some stage in its life cycle, it is harvested from fresh or estuarine water for human consumption in significant quantities (Stephan, 1980).

Three different procedures are used to estimate the weighted average BCF depending upon the lipid solubility of the chemical and the availability of bioconcentration data.

For lipid-soluble compounds, the average BCF is calculated from the weighted average percent lipids in the edible portions of consumed freshwater and estuarine fish and shellfish which was calculated from data on consumption of each species and its corresponding percent lipids to be 3.0 percent (Stephan, 1980). Because the steady-state BCFs for lipid-soluble compounds are proportional to percent lipids, bioconcentration factors for fish and shellfish can be adjusted to the average percent lipids for aquatic organisms consumed by Americans. For many lipid-soluble pollutants, there exists at least one BCF for which the percent lipid value was measured for the tissues for which the BCF is determined.

With 3.0 percent as the weighted average percent lipids for freshwater and estuarine fish and shellfish in the average diet, a BCF, and a corresponding percent lipid value, the weighted average bioconcentration factor can be calculated.

Example:

Weighted average percent lipids for average diet = 3.0 percent

Measured BCF of 17 for trichloroethylene with bluegills at 4.8 percent lipids

Weighted average BCF for average diet equals

$$17 \times \frac{3.0\%}{4.8\%} = 10.6$$

significance, is not available for most of the compounds under study. Consequently, most NOAELs derived from chronic studies are based either on gross toxic effects or on effects directly related to functional impairment or defined pathological lesions.

For compounds on which adequate chronic toxicity studies are not available, studies on acute and subacute toxicity assume greater significance. Acute toxicity studies usually involve single exposures at lethal or near lethal doses. Subacute studies often involve exposures exceeding 10 percent of the life span of the test organism, e.g., 90 days for the rat with an average life span of 30 months. Such studies are useful in establishing the nature of the compound's toxic effects and other parameters of compound toxicity, such as target organ effects, metabolic behavior, physiological/biochemical effects, and patterns of retention and tissue distribution. The utility of acute and subacute studies in deriving environmentally meaningful NOELs is uncertain, although McNamara (1976) has developed application factors for such derivations.

In some cases where adequate data are not available from studies utilizing oral routes of administration, no-effect levels for oral exposures may be estimated from dermal or inhalation studies. Such estimates involve approximations of the total dose administered based on assumptions about breathing rates and/or magnitude of absorption.

D. Criterion Rationale

This section reviews existing standards for the chemical(s), summarizes data on current levels of human exposure, attempts to identify special groups at risk, and defines the basis for the recommended criterion.

Information on existing standards is included primarily for comparison with the proposed water quality criteria. Some of the present standards, such as those recommended by the Occupational Safety and Health Administration (OSHA) or the American Conference of Governmental Industrial Hygienists (ACGIH), are based on toxicologic data but are intended as acceptable levels for occupational rather than environmental exposure. Other levels, such as those recommended by the National Academy of Sciences in *Drinking Water and Health* (1977) or in the U.S. EPA Interim Primary Drinking Water Standards, are more closely related to proposed water quality criteria. Emphasis is placed on detailing the basis for the existing standards wherever possible.

Summaries of current levels of human exposure, presented in this section, specifically address the suitability of the data to derive water quality criteria. The identification of special groups at risk, either because of geographical or occupational differences in exposure or biological differences in susceptibility to the compound(s), focuses on the impact that these groups should have on the development of water quality criteria.

The basis for the recommended criteria section summarizes and qualifies all of the data used in developing the criteria.

IV. Guidelines for Criteria Derivation

The derivation of water quality criteria from laboratory animal toxicity data is essentially a two-step procedure. First, a total daily intake for humans must be estimated which establishes either a defined level of risk for non-threshold effects or a no-effect level for threshold effects. Secondly, assumptions must be made about the contribution of contaminated water and the consumption of fish/shellfish to the total daily intake of the chemical. These estimates are then used to establish the tolerable daily intake and consequently the water quality criterion.

A. Non-Threshold Effects

After the decision has been made that a compound has the potential for causing cancers in humans and that data exist which permit the derivation of a criterion, the water concentration which is estimated to cause a lifetime carcinogenic risk of 10^{-5} is determined. The lifetime carcinogenicity risk is the probability that a person would get cancer sometime in his or her life assuming continuous exposure to the compound. The water concentration is calculated by using the low-dose extrapolation procedure proposed by Crump (1980). This procedure is an improvement on the multistage low dose extrapolation procedure by Crump, et al. (1977).

The data used for quantitative estimates are of two types: (1) lifetime animal studies, and (2) human studies where excess cancer risk has been associated with exposure to the agent. In animal studies it is assumed, unless evidence exists to the contrary, that if a carcinogenic response occurs at the dose levels used in the study, then proportionately lower responses will also occur at all lower doses, with an incidence determined by the extrapolation model discussed below.

1. Choice of Model.

There is no really solid scientific basis for any mathematical extrapolation model which relates carcinogen exposure to cancer risks at the extremely low levels of concentration that must be dealt with in evaluating the environmental hazards. For practical reasons, such low levels of risk cannot be measured directly either using animal experiments or epidemiologic studies. We must, therefore, depend on our current understanding of the mechanisms of carcinogenesis for guidance as to which risk model to use. At the present time, the dominant view of the carcinogenic process involves the concept that most agents which cause cancer also cause irreversible damage to DNA. This position is reflected by the fact that a very large proportion of agents which cause cancer are also mutagenic. There is reason to expect that the quantal type of biological response that is characteristic of mutagenesis is associated with a linear non-threshold dose-response relationship. Indeed, there is substantial evidence from mutagenesis studies with both ionizing radiation and with a wide variety of chemicals that this type of dose-response model is the appropriate one to use. This is particularly true at the lower end of the dose-response curve; at higher doses, there can be an upward curvature, probably reflecting the effects of multistage processes on the mutagenic response. The linear non-threshold dose-response relationship is also consistent with the relatively few epidemiological studies of cancer responses to specific agents that contain enough information to make the evaluation possible (e.g., radiation-induced leukemia, breast and thyroid cancer, skin cancer induced by arsenic in drinking water, and liver cancer induced by aflatoxin in the diet). There is also some evidence from animal experiments that is consistent with the linear non-threshold hypothesis (e.g., liver tumors induced in mice by 2-acetylaminofluorene in the large scale ED_{01} study at the National Center of Toxicological Research, and the initiation stage of the two-stage carcinogenesis model in the rat liver and the mouse skin).

Because it has the best, albeit limited, scientific basis of any of the current mathematical extrapolation models, the linear non-threshold model has been adopted as the primary basis for risk extrapolation to low levels of the dose-response relationship. The risk assessments made with this model should be regarded as conservative, representing the most plausible upper limit for the risk; i.e., the true risk is not likely to be higher than the estimate, but it could be smaller.

where ppm is parts per million of the carcinogenic agent in the diet, F is the weight of the food consumed per day in kgms, and r is the absorption fraction.

In the absence of any data to the contrary, r is assumed to be one. For a uniform diet the weight of the food consumed is proportional to the calories required, which, in turn, is proportional to the surface area or the ⅔rds power of the weight, so that: $m \alpha ppm \times W^{2/3} \times r$ or

$$\frac{m}{rW^{2/3}} \alpha ppm$$

As a result, ppm in the diet is often assumed to be an equivalent exposure between species. However, we feel that this is not justified since the calories/kg of food is significantly different in the diet of man vs. laboratory animals, primarily due to moisture content differences. Instead, we use an empirically derived food factor, f=F/W, which is the fraction of a species body weight that is consumed per day as food. We use the rates given below.

Species	W	f
Man	70	0.028
Rat	0.35	0.05
Mice	0.03	0.13

Thus, when the exposure is given as a certain dietary concentration in ppm, the exposure in $mg/W^{2/3}$ is

$$\frac{m}{r \times W^{2/3}} = \frac{ppm \times F}{W^{2/3}} =$$

$$\frac{ppm \times fxW}{W^{2/3}} = ppm \times f \times W^{1/3}$$

When exposure is given in terms of mg/kg/day=m/Wr=s the conversion is simply:

$$\frac{m}{rW^{2/3}} = s \times W^{1/3}$$

When exposure is via inhalation, the calculation of dose can be considered for two cases where (1) the carcinogenic agent is either a completely water-soluble gas or an aerosol and is absorbed proportionally to the amount of air breathed in, and (2) where the carcinogen is a poorly water-soluble gas which reaches an equilibrium between the air breathed and the body compartments. After equilibrium is reached, the rate of absorption of these agents is expected to be proportional to metabolic rate, which in turn is proportional to the rate of oxygen consumption, which in turn is a function of surface area.

Case 1

Agents that are in the form of particulate matter or virtually completely absorbed gases such as SO_x can reasonably be expected to be absorbed proportional to the breathing rate. In this case the exposure in mg/day may be expressed as: $m=I \times v \times r$ where I is inhalation rate per day in m^3, v is mg/m^3 of the agent in air, and r is the absorption fraction.

The inhalation rates, I, for various species can be calculated from the observation (FASEB, 1974) that 25 gm mice breathe 34.5 liters/day and 113 gm rats breathe 105 liters/day. For mice and rats of other weights, W, (expressed in kg), the surface area proportionality can be used to determine breathing rates (in m^3/day) as follows:

For mice, $I=0.0345\ (W/0.025)^{2/3} m^3$/day

For rats, $I=0.105\ (W/0.113)^{2/3} m^3$/day

For humans, the values of 20 m^3/day [a] is adopted as a standard breathing rate (ICRP, 1977).

The equivalent exposure in $mg/W^{2/3}$ for these agents can be derived from the air intake data in a way analogous to the food intake data. The empirical factors for the air intake per kg per day, i=I/W based upon the previously stated relationships, are as tabulated below:

Species	W	i=I/W
Man	70	0.29
Rat	0.35	0.64
Mice	0.03	1.3

Therefore, for particulates or completely absorbed gases, the equivalent exposure in $mg/W^{2/3}$ is:

$$\frac{m}{W^{2/3}} = \frac{Ivr}{W^{2/3}} = \frac{iWvr}{W^{2/3}} = iW^{1/3}\,vr$$

In the absence of empirical data or a sound theoretical argument to the contrary, the fraction absorbed, r, is assumed to be the same for all species.

Case 2

The dose in mg/day of partially soluble vapors is proportional to the O_2 consumption which in turn is proportional to $W^{2/3}$ and to the solubility of gas in body fluids, which can be expressed as an absorption coefficient r for the gas. Therefore, when expressing the O_2 consumption as $O_2=k\,W^{2/3}$, where k is a constant independent of species, it follows that $m=k\,W^{2/3} \times v \times r$ or

$$d = \frac{m}{W^{2/3}} = kvr$$

As with Case 1, in the absence of experimental information or a sound theoretical argument to the contrary, the absorption fraction, r, is assumed to be the same for all species. Therefore, for these substances a certain concentration in ppm or μ/m^3 in experimental animals is equivalent to the same concentration in humans. This is supported by the observation that the minimum alveolar concentration, necessary to produce a given "stage" of anesthesia, is similar in man and animals (Dripps, et al. 1977). When the animals were exposed via the oral route and human exposure is via inhalation or vice-versa, the assumption is made, unless there is pharmacokinetic evidence to the contrary, that absorption is equal by either exposure route.

e. If the duration of experiment (L_e) is less than the natural life span of the test animal (L), the slope q_1^*, or more generally the exponent g(d), is increased by multiplying a factor $(L/L_e)^3$. We assume that if the average dose, d, is continued, the age specific rate of cancer will continue to increase as a constant function of the background rate. The age specific rates for humans increase at least by the 2nd power of the age and often by a considerably higher power, as demonstrated by Doll (1971). Thus, we would expect the cumulative tumor rate to increase by at least the 3rd power of age. Using this fact, we assume that the slope q_1^*, or more generally, the exponent g(d), would also increase by at least the 3rd power of age. As a result, if the slope q_1^* [or g(d)] is calculated at age L_e, we would expect that if the experiment had been continued for the full life span, L, at the given average exposure, the slope q_1^* [or g(d)] would have been increased by at least $(L/L_e)^3$.

This adjustment is conceptually consistent to the proportional hazard model proposed by Cox (1972) and the time-to-tumor model considered by Crump, et al. (1977) where the probability of cancer at age t and dose d is given by $P(d,t)=1-\exp[-f(t) \times g(d)]$

4. Calculation of Carcinogenic Potency Based on Human Data. If human epidemiology studies and sufficiently valid exposure information are available for the compound, they are always used in some way. If they show a carcinogenic effect, the data are analyzed to give an estimate of the linear dependence of cancer rates on lifetime average dose, which is equivalent to the factor q_1^*. If they show

[a] From "Recommendation of the International Commission on Radiological Protection," page 9, the average breathing rate is 10^7 cm^3 per 8-hour work day and 2×10^7 cm^3 in 24 hours.

"ndication of carcinogenicity" is interpreted as the absence of carcinogenicity data from animal experimental studies or human epidemiology. Available short-term carcinogenicity screening tests are reported in the criteria documents, but they are not used either for derivation of numerical criteria nor to rule out the uncertainty factor approach.

Because of the high degree of judgment involved in the selection of a safety factor, the criterion derivation section of each document should provide a detailed discussion and justification for both the selection of the safety factor and the data to which it is applied. This discussion should reflect a critical review of the available data base. Factors to be considered include number of animals, species, and parameters tested; quality of controls; dose levels; route; and dosing schedules. An effort should be made to differentiate between results which constitute a toxicologically sufficient data base and data which may be spurious in nature.

2. Use of Acceptable Daily Intake (ADI). For carcinogens, the assumption of low dose linearity precludes the necessity for defining total exposure in the estimation of increased incremental risk. For non-carcinogens, ADIs and criteria derived therefrom are calculated from total exposure data that include contributions from the diet and air. The equation used to derive the criterion (C) is: $C=ADI-(DT+IN)/[2\ l+(0.0065\ kg \times R)]$ where 2 l is assumed daily water consumption, 0.0065 kg is assumed daily fish consumption, R is bioconcentration factor in units of l/kg, DT is estimated non-fish dietary intake, and IN is estimated daily intake by inhalation.

If estimates of IN and DT cannot be provided from experimental data, an assumption must be made concerning total exposure. It is recognized that either the inability to estimate DT and IN due to lack of data or the wide variability in DT and IN in different states may add an additional element of uncertainty to the criterion formulation process. In terms of scientific validity, the accurate estimate of the Acceptable Daily Intake is the major factor in satisfactory derivation of water quality criteria.

3. Use of Threshold Limit Values or Animal Inhalation Studies. Threshold Limit Values (TLVs) are established by the American Conference of Governmental and Industrial Hygienists (ACGIH) and represent 8-hour time-weighted average concentrations in air that are intended to protect workers from various adverse health effects over a normal working lifetime. Similar values are set by NIOSH (criteria) and OSHA (standards) for 10- and 8-hour exposures, respectively. To the extent that these values are based on sound toxicologic assessments and have been protective in the work environment, they provide useful information for deriving or evaluating water quality criteria. However, each TLV must be carefully examined to determine if the basis of the TLV contains data which can be used directly to derive a water quality criterion using the uncertainty factor approach. In addition, the history of each TLV must be examined to assess the extent to which it has assured worker safety. In each case, the types of effects against which TLVs are designed to protect are examined in terms of their relevance to exposure from water. It must be demonstrated that the chemical is not a localized irritant and that there is no significant effect at the site of entry irrespective of the routes of exposure (i.e., oral or inhalation).

If the TLV or similar value is recommended as the basis of the criterion, consideration of the above points is explicitly stated in the criterion derivation section of the document. Particular emphasis is placed on the quality of the TLV relative to the available toxicity data that normally is given priority over TLVs or similar established values. If the TLV can be justified as the basis for the cirterion, then the problems associated with the estimation of acceptable oral doses from inhalation data must be addressed.

Estimating equivalencies of dose-response relationships from one route of exposure to another introduces an additional element of uncertainty in the derivation of criteria. Consequently, whenever possible, ambient water quality criteria should be based on data involving oral exposures. if oral data are insufficient, data from other routes of exposure may be useful in the criterion derivation process.

Inhalation data, including TLVs or similar values, are the most common alternatives to oral data. Estimates of equivalent doses can be based upon: (1) available pharmacokinetic data for oral and inhalation routes, (2) measurements of absorption efficiency from ingested or inhaled chemicals, or (3) comparative excretion data when the associated metabolic pathways are equivalent to those following oral ingestion or inhalation. Given that sufficient pharmacokinetic data are available, the use of accepted pharmacokinetic models provides the most satisfactory approach for dose conversions. However, if available pharmacokinetic data are marginal or of questionable quality, pharmacokinetic modeling is inappropriate.

The Stokinger and Woodward (1958) approach, or similar models based on assumptions of breathing rate and absorption efficiency, represents possible alternatives when data are not sufficient to justify pharmacokinetic modeling. Such alternative approaches, however, provide less satisfactory approximations because they are not based on pharmacokinetic data. Consequently, in using the Stokinger and Woodward or related models, the uncertainties inherent in each of the assumptions and the basis of each assumption must be clearly stated in the derivation of the criterion.

The use of data pertaining to other routes of exposure to derive water quality criteria may also be considered. As with inhalation data, an attempt is made to use accepted toxicologic and pharmacokinetic principles to estimate equivalent oral doses. If simplifying assumptions are used, their bases and limitations must be clearly specified.

Because of the uncertainties involved in extrapolating from one route of exposure to another and the consequent limitations that this may place on the derived criterion, the decision to disallow such extrapolation and recommend no criterion is highly judgmental and must be made on a case-by-case basis. A decision for or against criteria derivation must balance the quantity and quality of the available data against a perceived risk to the human population.

If the Stokinger and Woodward (1958) approach is used to calculate an ADI from a TLV, the general equation is:

$ADI=TLV\times BR\times DE\times d\times A_A/(A_O\times SF)$

where:

ADI = Acceptable daily intake in mg
TLV = Concentration in air in mg/m³
DE = Duration of exposure in hours per day
d = 5 days/7 days
A_A = Efficiency of absorption from air
A_O = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above
BR = Amount of air breathed per day; assume 10 m³

For deriving an ADI from animal toxicity data, the equation is:

$ADI=C_A\times D_E\times d\times A_A\times BR\times 70\ kg/(BW_A\times A_O\times SF)$

where:

ADI = Acceptable daily intake in mg
C_A = Concentration in air in mg/m³
D_E = Duration of exposure in hours per day
d = Number of days exposed/number of days observed
A_A = Efficiency of absorption from air
BR = Volume of air breathed per day in m³
70 kg = Assumed human body weight
BW_A = Body weight of experimental animals in kg

limitations of the proposed criterion as well as the type of data needed to generate a compound-specific criterion.

A class criterion should be abandoned when there is sufficient data availabe to derive a compound-specific criterion which protects against the biological effect of primary concern; e.g., the availability of a good subchronic study would not necessarily result in the abandonment of a class criterion based on potential carcinogenicity.

The inability to derive a valid class criterion does not, and should not, preclude regulation of a compound or group of compounds based on concern for potential human health effects. The failure to recommend a criterion is simply a statement that the degree of concern cannot be quantified based on the available data and risk assessment methodology.

E. Essential Elements

Some chemicals, particularly certain metals, are essential to biological organisms at low levels but may be toxic and/ or carcinogenic at high levels. Because of potential toxic effects, it is legitimate to establish criteria for such essential elements. However, criteria must consider essentiality and cannot be established at levels which would result in deficiency of the element in the human population.

Elements are accepted as essential if listed by NAS Food and Nutrition Board or a comparably qualified panel. Elements not yet determined to be essential but for which supportive data on essentiality exists need to be further reviewed by such a panel.

To modify the toxicity and carcinogenicity based criteria, essentiality must be quantified either as a "recommended daily allowance" (RDA) or "minimum daily requirement" (MDR). These levels are then compared to estimated daily doses associated with the adverse effect of primary concern. The difference between the RDA or MDR and the daily doses causing a specified risk level for carcinogens or ADIs for non-carcinogens defines the spread of daily doses from which the criterion may be derived. Because errors are inherent in defining both essential and maximum tolerable levels, the criterion is derived from dose levels near the center of such a dose range. The decision to use either the MDR or RDA is guided by the spread of the doses and the quality of the essentiality and toxicity estimates.

The modification of criteria by consideration of essentiality must take into account all routes of exposure. If water is a significant source of the MDR or RDA, the criterion must allow for attainment of essential intake. Conversely, even when essentiality may be attained from nonwater sources, standard criteria derivation methods may be adjusted if the derived criterion represents a small fraction of the ADI or MDR. On a case-by-case basis, the modification in the use of the guidelines may include the use of different safety factors for non-carcinogens or other modifications which can be explicitly justified.

F. Use of Existing Standards

For some chemicals for which criteria are to be established, drinking water standards already exist. These standards represent not only a critical assessment of literature, but also a body of human experience since their promulgation. Therefore, it is valid to accept the existing standard unless there is compelling evidence to the contrary. This decision should be made after considering the existing standards vs. new scientific evidence which has accumulated since the standards have been established. There are several instances where the peer review process recommended usage of the present drinking water standards.

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01762

EPA attempted to clearly and concisely deal with all issues which might significantly affect the resulting criteria without going into extreme detail on every potential problem. Because numerous judgments must be made, a reasonable amount of experience in aquatic toxicology will be necessary for a person to utilize the Guidelines effectively.

7. Comment—The Guidelines are too complex.

Response—Deriving a water quality criterion is a complex exercise because several different kinds of data and a wide variety of organisms need to be considered. In addition, because data have been generated using various procedures, numerous individual decisions need to be made and the Guidelines attempt to provide guidance concerning decisions that seem to need to be made frequently. The Guidelines are more complex than initially envisioned to help insure that criteria for different pollutants are derived in a reasonably comparable manner. Although the process of deriving a water quality criterion for aquatic life is complex, the Guidelines help organize the process into logical components and steps.

8. Comment—The Guidelines should be more flexible.

Response—The Guidelines are meant to provide guidance and at the same time allow reasonable flexibility. They have been used with quite a variety of pollutants for which the requirements of the minimum data base are satisfied, and they seem to be reasonably appropriate in all cases because the experiences with these substances were a major part of the basis for the Guidelines. If sound scientific evidence indicates that a particular aspect of the Guidelines is not appropriate for a specific substance, then some other more appropriate procedure should be used. However, the Guidelines should not be changed based on individual whim or personal preference.

9. Comment—The Guidelines should take into account synergism and antagonism by a wide variety of factors and the effect of the pollutant on important ecological relationships.

Response—Very little practically useful information is available on these factors in connection with the effects of pollutants on aquatic organisms. Synergism and antagonism are possible between numerous combination of two or more pollutants, and some data indicate that such interactions are not only species specific, but also vary with the ratios and absolute concentrations of the pollutants and the life stage of the species. Pollutants may affect the structure and function of aquatic ecosystems separate from their effects on individual species, but practical applications of such ideas seem very tenuous at this time. Little information is available concerning such effects, and the significance of the available data is questionable. An obviously important ecological relationship is the dependence of higher organisms on lower organisns for food. Even here, the existence of numerous lower species and their adaptability reduces the importance of any individual food species.

10. Comment—The Guidelines should take into account all identifiable effects—beneficial as well as harmful.

Response—Few tests have been conducted to identify beneficial effects of individual pollutants on aquatic organisms. However, beneficial effects are sometimes observed in chronic toxicity tests at concentrations below those that cause adverse effects. Usually in such cases the organisms in low concentrations of the pollutant are longer or heavier or reproduce more that do the controls. Even if such effects are statistically significant, they are not judged as adverse or harmful. On the other hand, a beneficial effect on one species may ultimately be to the detriment of a community if a balance between species is disturbed. Also, a concentration that benefits one species may harm a more sensitive species.

11. Comment—The Guidelines should take into account analytical methodology.

Response—The Guidelines do take into account analytical methodology in the definition of the substance, when necessary, but not in deriving the numerical value of the criterion. Concentrations which cannot be routinely measured accurately can often be measured accurately by nonroutine methods and, more importantly, do sometimes adversely affect aquatic organisms. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods, not to underprotect aquatic life. One use of criteria should be to identify needs in analytical chemistry.

12. Comment—The Guidelines should take into account (a) production and usage patterns, (b) chemical, physical and biological factors pertaining to degradation and fate of pollutants, including properties such as solubility in water, decay rate, persistence, and transformation pathways, and (c) whether or not a criterion is needed for the substance.

Response—Items included in (a) and (b) may be important in deciding whether a criterion is needed for a substance, but the Guidelines are intended to be used after the decision has been made that a criterion is needed. EPA is presently developing principles that can be used to decide whether or not a criterion is needed for a substance and items such as those listed above are probably some of the factors that should be considered when deciding whether or not a criterion is needed. If the toxicity of the chemical is used to evaluate the need for a criterion, the Guidelines may be useful in the collection and interpretation of the available toxicity data.

13. Comment—The Guidelines should take into account costs to states and industries, technological feasibility, and such characteristics of bodies of water as assimilative capacity, dispersal, dissipative factors, dilution, hydrology, mixing zones, and sediment.

Response—Factors such as these should be considered in developing standards, but not in deriving criteria. EPA is presently developing an implementation policy which will describe which of the above factors and which characteristics of the pollutant should be used, and how they should be used, in developing standards.

14. Comment—The Guidelines are not appropriate for establishing a concentration which may be present in an effluent.

Response—The Guidelines are for deriving water quality criteria, not effluent standards nor mixing zone standards nor water quality standards. Water quality criteria will probably be one factor taken into account in the development of water quality standards and toxicity-based effluent standards, but not technology-based effluent standards. EPA is presently developing policies concerning proper use of water quality criteria in various regulatory activities.

15. Comment—The derivation of criteria should be fundamentally a scientific exercise and should not employ subjective judgments.

Response—No exercise which involves the use and interpretation of data can avoid subjective judgment. Indeed, even the generation of scientific data requires subjective judgment, such as how many test organisms to use, what temperature to use, etc. One may decide to accept the recommendations of experts, but this is usually still a subjective decision. In statistics the subjective decisions are made on the basis of probability statements but the final decisions are still subjective judgments. Although the development of the Guidelines and the derivation of criteria cannot avoid subjective

variables that need to be taken into account. The major advantage of field studies is that conditions are natural (i.e., conditions are not controlled), but this is also the major problem with field studies. With uncontrolled conditions, numerous variables must be taken into account, because any individual variable or combination of variables may affect the results or indeed may be the cause of the results. Therefore, field studies on natural populations usually must last over several seasons and possibly over more than one year to be reasonably sure that proposed cause-and-effect relationships are real.

Another problem with field studies that are based on statistically significant differences is the power of the test. Because natural biological, spacial, and temporal variability is often rather great, a large number of samples is usually required to detect even a moderate change. A field study which purports to show that no change occurred is of no value if the power of the test calculated from the experimental design and observed variability was not high enough.

Because field studies are high cost-high risk ventures, well-designed laboratory tests are usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species and (2) the effect of various water quality characteristics on toxicity. Laboratory tests have been shown to generally be useful predictors of what happens in a field situation, and so it makes little sense to conduct high risk, high cost field studies rather than laboratory tests. Even definitive field studies rarely provide enough information to allow extrapolation of results to other situations, so field studies are more useful in reviewing criteria than in deriving criteria.

22. Comment—Field verification of laboratory tests and of the Guidelines are needed.

Response—Field verification of laboratory tests and of the Guidelines are certainly desirable and provide information that cannot be obtained in a laboratory. Field verification studies do not need to be as risky or as costly as studies on the effects of a pollutant on natural populations because verification studies can be designed (1) as a side-by-side comparison of the results of laboratory tests and field tests or (2) based on existing results of laboratory tests.

23. Comment—EPA should allow criteria to be derived using on-site acute toxicity tests and an application factor.

Response—This approach is usually suggested for developing effluent standards but may be just as applicable to deriving water quality criteria under certain conditions. This approach cannot be used with pollutants whose most sensitive adverse effect is due to residues. Also, it can only be used when the application factor has already been acceptably determined. Finally, acute tests must be determined with either an appropriate range of species or with an appropriate sensitive species. The implementation policy presently being developed by EPA will probably allow the use of appropriate on-site toxicity tests in the development of site-specific criteria and standards.

24. Comment—It is not clear what level of protection is intended.

Response—EPA feels that it is not possible to specify a minimum level of protection that is necessary to "protect aquatic life" or even to protect a particular species for such reasons as:

a. There are so many untested species.

b. Little practically useful information is available concerning synergism, antagonism, ecological relationships, and avoidance.

c. The effect of factors such as temperature on toxicity seems to be species-specific for at least some substances.

d. Information is not available concerning what amount of any effect would be ecologically significant and whether the amount is species-specific.

One possible conclusion is that to protect aquatic life, all species must be adequately protected. A possible extension of this would be that all criteria should be zero because any amount of any pollutant may affect some aquatic organism. Indeed, the assimilative capacity of body of water largely depends on the ability of aquatic life to "process" pollutants and to some extent, any organism which "processes" a pollutant is in some way affected by it.

The apparent level of protection is different for each kind of effect (acute toxicity to animals, chronic toxicity to animals, toxicity to plants, and bioaccumulation) because of the quality and quantity of the available information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. Thus it was felt that with regards to toxicity to animals it was probably not necessary to protect all of the species all of the time, but it certainly seems appropriate to protect most of the species most of the time and to protect important species.

On the other hand, the data base on toxicity to aquatic plants is usually very small and a variety of tests and endpoints have been used, especially with algae. Also, little information is available concerning the ecological relevance of the results of any toxicity test with algae in a concentrated test medium, especially because so many species of algae exist in each body of water.

The results of bioconcentration tests with organic chemicals, but not with inorganic chemicals, can apparently be extrapolated reasonably well based on percent lipids from one aquatic animal species to another, at least within commercially and recreationally important species. In addition, the limits on acceptable concentrations in tissue are reasonably well defined in some cases.

These kinds of considerations merely illustrate the complexity of the problem and the necessity for making decisions about each kind of effect individually. In addition, it is important to distinguish between the apparent level of protection provided by the Guidelines and the actual level of protection which will result in a field situation from the use of the implementation policy.

No attempt was made to develop Guidelines which would achieve a predetermined numerical level of protection. For each effect much desirable information is not available, and so it would be misleading to imply a level of sophistication that is not currently possible. EPA believes that the present state-of-the-art in aquatic toxicology does allow some useful conclusions about the ability of a substance to adversely affect aquatic organisms and their uses whenever the requirements of the minimum data base are satisfied, with the full realization that the resulting criterion may be somewhat overprotective or underprotective.

In almost all cases more data would be desirable and so an attempt to reach the "golden mean" will sometimes result incriteria being to high and sometimes too low. One alternative is to derive no criteria until all desirable data are available; this is unacceptable because it will almost always result in no criteria and no protection. The other alternative is to apply safety or uncertainty factors that are inversely proportional to the adequacy of the data base. In the long run this approach would encourage the generation of useful data where it was most needed, but in the short run would require many significant subjective decisions beyond the current state-of-the-art.

25. Comment—The Guidelines should not base criteria on "worst case" assumptions.

is likely to be closer to a lognormal distribution than a normal distribution. Thus the geometric mean, rather than the arithemetic mean, of the upper and lower chronic limits is used.

32. Comment—There should not be any criteria which apply to all bodies of water. Criteria should be specific for individual states, regions, other geographic areas, or bodies of water.

Response—The Guidelines are designed to provide guidance in the collection and interpretation of data concerning the effects of pollutants on aquatic life and its uses. The uses of the resulting criteria will be described by EPA in various regulations. If desired, the Guidelines can be appropriately modified and used to derive a criterion specific to one or more bodies of water or geographic areas if an appropriate data base is available. The critical literature reviews on which the criteria are based will be available for use in the derivation of local, state, or regional criteria. The latitude allowed for deriving local, state, or regional criteria and standards will be determined by the implementation policy presently being developed by EPA.

33. Comment—The Guidelines should result in criteria that are specific for individual species or groups of species (e.g., warmwater and coldwater).

Response—If the necessary data were available, criteria could be derived for any particular species or group of species. It was impractical for EPA to derive criteria for many such groups, but a relatively simple division is freshwater and saltwater organisms because these two groups rarely coexist. Most other possible general divisions of species are faced with the problem that species coexist in various combinations unless the groups are very narrow. In addition, toxicity data are rarely available for very many individual species and so data for representative species must be used, unless appropriate new data are generated. Also, the available data sometimes show wide differences within families so extrapolations from one species to another are often tenuous. Because of these problems, deriving criteria for individual species or groups of species was deemed impractical.

34. Comment—A criterion should be one number, not two.

Response—The two-number criterion is an acknowledgement that aquatic organisms can tolerate short exposures to concentrations that are higher than those they can tolerate continuously. In a two-number criterion, the higher number can assure that short-term fluctuations above the average are not too high, whereas the lower number can assure that the long-term average is not too high. A one-number criterion could be derived by using the existing 24-hour average as an instantaneous maximum. This would certainly provide additional protection, but would provide unnecessary overprotection in most cases. Because a one-number criterion would be more of an approximation than a two-number criterion, one-number criteria would be too high or too low more often and to a greater degree than two-number criteria.

35. Comment—The criteria should not specify sampling schemes.

Response—Criteria should state numerical concentration limits in terms of exposure durations because, everything else being constant, the amount of adverse effect depends on both the concentration of the pollutant and the duration of exposure. Criteria in the Green Book, Blue Book, and Red Book were usually stated as single numbers with no duration expressly stated. The implication was that the criteria were never to be exceeded at any time. Each criterion was apparently and instantaneous maximum. In practice, however, standards derived from these criteria were usually enforced on the basis of 24-hour composite samples. To avoid any ambiguity, the Guidelines specify that a criterion should be explicitly stated in terms of two time frames: an instantaneous maximum and a 24-hour average. However, this is not a specification for a sampling scheme. Standards developed from such a criterion should probably specify a sampling scheme for compliance monitoring, but it would not necessarily be in terms of point measurements and 24-hour averages.

Any sampling scheme used to determine whether or not an ambient concentration exceeds a water quality criterion or a comparable water quality standard should take into account such things as the ratio of the instantaneous maximum and the 24-hour average and the retention time of the body of water because these will primarily determine which portion of the criterion is most limiting in any specific situation. The sampling scheme should probably also take into account the cost of the analyses and results of any past analyses.

36. Comment—The criteria should be stated in terms of time frames longer that an instantaneous maximum and a 24-hour average.

Response—These two time frames were chosen because they would allow the derivation of a criterion which would be less restrictive than, but just as protective as, the previous one-number criterion. These two specific time frames were chosen because they match two kinds of samples that are commonly collected: grab samples and 24-hour composite samples. These specific time frames could probably be changed somewhat without much practical effect, but EPA saw no particular advantage to anyone to introducing novel time periods. For example, for all practical purposes in most situations a 10-minutes average is probably about the same as an instantaneous maximum.

Large increases in the time frames, however, would not provide the same amount of protection. If the instantaneous maximum were changed to a 24- or 96-hour average, and the 24-hour average were changed to a 7- or 30-day average with no change in the numerical limits, the amount of protection afforded aquatic life would fall to an unacceptable level. The longer the time span for the average, the higher the instantaneous concentration could be for short periods of time within that span. Although most chronic tests last for 28-days or longer, some chronic effects may be caused by short exposures of sensitive life stages. If the acute-chronic ratio is small, fluctuations in the instantaneous concentration may even cause acute toxicity, especially for cumulative pollutants, because for some substances the 24-, 48-, and 96-hour acute values do not differ too much.

37. Comment—A two-number criterion will be difficult to enforce.

Response—Criteria are not enforceable. Standards are enforceable. When standards to protect aquatic life are developed, they may or may not be in the same format as the criteria for aquatic life. Few standards are adequately enforced because of the high cost of continuous monitoring. The real value of many criteria and standards is in the design of waste treatment facilities; a two-number criterion should be a better basis for design than a one-number criterion.

38. Comment—The criteria should be expressed to one significant figure, not two.

Response—EPA acknowledges that there is much variability in some of the data and that the range of sensitivites is often great. When the requirements of the minimum data base are satisfied and the data agree reasonably well, two significant figures are not unreasonable. Rounding off to one significant figure could arbitrarily raise or lower the criterion by up to forty percent with no apparent consistent benefits to dischargers, regulators, or aquatic life.

39. Comment—The Guidelines should only use data for species that ought to be protected.

damage than elevated concentrations of a pollutant that produces a wide range of species sensitivities.

49. Comment—The distinction between ionizable and unionizable compounds is not very good because some chemicals ionize and reach chemical equilibrium very slowly and others very rapidly.

Response—Most chemicals can readily be classified into one of three groups:

A. Chemicals that ionize, including hydrolyze, at least 90% and reach 90% of equilibrium in less than 8 hours in most surface waters.

B. Chemicals that ionize, including hydrolyze, less than 10% in 30 days in most surface waters.

C. Chemicals that do not fit into either one of the above categories.

For the purpose of the Guidelines, chemicals in the A group should be considered ionizable, chemicals in the B group should be considered non-ionizable, and chemicals in the C group should be classified on a case-by-case basis. Although the distinction between ionizable and unionizable may not be perfect, it is very useful for most chemicals.

50. Comment—Each individual organic compound should be considered separately.

Response—The vast majority of organic chemicals will be considered separately according to the Guidelines except for structurally similar organic compounds that meet all three specifications given in the Guidelines, such as polychlorinated biphenyls and toxaphene.

51. Comment—In-stream water quality criteria are meaningless for substances that are highly insoluble.

Response—The concentration of some substances in sediment may be important separate from the concentration of the substance in the ambient water and for these compounds a sediment quality criterion may be necessary. Generally such compounds can also cause adverse effects if the concentration in the ambient water is too high even if the concentration in the sediment is low. Thus for such compounds both kinds of criteria may be necessary rather than just one or the other.

52. Comment—If a substance is not dissolved, it is not biologically or toxicologically available.

Response—Although this may usually be true, it certainly does not apply to elemental mercury which can be oxidized and methylated to form a very toxic compound. Some organic acids and phenols and hydroxide and carbonate salts of metals have solubilities which differ substantially from one body of water to another.

53. Comment—Criteria for metals should not be for total metal.

Response—Criteria for metals will generally not be based on total metal. Most will be based on total recoverable metal because forms of metals that are not measured in the total recoverable procedure probably are not, and will not become, toxic. A major problem is that some people use a procedure for total recoverable, but report the results as total, metal. In many situations the two results are about the same, but in some cases the results are quite different.

54. Comment—The Guidelines should give more guidance for distinguishing between acceptable and unacceptable data.

Response—The Guidelines contain as much detail on this subject as EPA believes is currently feasible. Items such as the maximum acceptable control mortality and minimum number of test organisms are based on what many aquatic toxicologists generally feel are acceptable, as expressed in published methods. No data should be used in the derivation of a criteria until their quality and acceptability had been reviewed by a competent person. Competent people will occasionally disagree, but that is a fundamental property of subjective decisions.

55. Comment—Only published data should be used.

Response—Peer review is one of many concepts that is better in theory than in practice. Some poor quality data are published and some high quality data are rejected. In addition, publication is not a particularly rapid process. Whether or not data are used should depend on the applicability and quality of the data, not on whether they have been published. Data that are not published should be made readily available if they are used to derive water quality criteria.

56. Comment—All static test are unacceptable

Response—In general, high quality flow-through acute tests are preferable to high quality static acute tests, but static tests are by no means unacceptable. Few data are available to show whether static tests consistently produce acute values lower or higher or different than flow-through tests. Whereas degradation, violatilization, and buildup of metabolic products are more likely to be a problem in static tests, operator and mechanical errors are more likely in flow-through tests. Static acute tests are certainly not unacceptable for most pollutants, but static chronic tests generally are unacceptable because of changes in the toxicant concentrations and the quality of the dilution water during the test.

57. Comment—Data obtained using test organisms that were previously exposed to the pollutant should be used.

Response—Comparisons of results obtained with unexposed and previously exposed organisms should indicate whether or not acclimation has occurred. Generally, data obtained with acclimated organisms should not be used in deriving criteria because acclimated organisms are the exception rather than the norm. Rarely, if ever, can acclimation be depended on to protect organisms in a field situation because concentrations often fluctuate and motile organisms do not stay in one location very long. Data obtained with acclimated organisms may be acceptable for use in deriving some site-specific criteria.

58. Comment—Foreign species should be used to expand the data base.

Response—Foreign species may be representative of indigenous species, but some of them are quite unusual. Data obtained with foreign species may give good indications of indigenous speceis that should be used in tests on some pollutants and may identify some potential problems that should be investigated.

59. Comment—If data for brine shrimp are not used, the criteria should not apply to saline waters.

Response—Data obtained using brine shrimp are not used because these organisms are atypical. Although they may not be usually sensitive or insensitive to various pollutants, the species found in North America and used for testing only survive in the Great Salt Lake and in salt ponds near San Francisco Bay. These two habitats are unlike any others in the United States. If criteria were to be derived specifically for the Great Salt Lake or for salt ponds, then data for brine shrimp should be used.

60. Comment—Structure-activity relationships should not be used unless proven.

Response—No provision is made in the Guidelines for the use of structure-activity relationships. Such relationships may soon be well enough understood that they can be used in deriving water quality criteria.

61. Comment—A criterion should not be derived for a pollutant until data are available for a broad range of commercially, recreationally, and ecologically important species. Each species should be acutely and chronically tested under a variety of conditions in a number of different waters.

useful, but such a test cannot be used with just two points and does not take into account such things as the comparability of the data, the quality of the test, and the range of the independent variable. A relationship based on six points may not be as significant as it seems if five of the points are tightly grouped.

71. Comment—The Guidelines should not combine 96-hr LC50 values and 48-hr EC50 values.

Response—Both LC50 values and EC50 values are used to measure acute toxicity of a substance to aquatic organisms. In general, an EC50 can be based on a wide variety of effects, but the Guidelines specify that the only effects to be used for deriving criteria are incomplete shell development, immobilization, and loss of equilibrium. All of these are certainly drastic effects. In a field situation these effects probably often lead to death. Just as the endpoint may be specific for the species, so may be the length of the test. The generally accepted length of an acute test with daphnids is 48 hours, whereas for most species of fish, it is 96 hours. Thus the Guidelines use both 48-hr EC50 values and 96-hr LC50 values because they are the widely accepted durations and endpoints used to measure acute toxicity to specific species.

72. Comment—Shell deposition tests are chronic tests and should not be equated with lethality tests.

Response—"Acute" implies "short" not "death". Many acute toxicity tests do use death for the effect, but many also use non-lethal effects. The shell deposition test is one of many non-lethal acute tests and is generally accepted as a short test compared to the average life span of oysters.

73. Comment—Adjustment factors should not be used to adjust for the length of the test, the technique, and unmeasured concentrations.

Response—All three kinds of adjustment factors have been deleted from the Guidelines. The factor for the length of the test was found to be unnecessary because most tests had been conducted for the standard times usually specified for the individual species. Thus the Guidelines now specify that only data from tests conducted for the time specified for the species should be used to calculate the Final Acute Value.

EPA has found that on the average flow-through acute tests give results slightly lower than do static tests, but the relationship does not seem to be too consistent and may vary from species to species for some pollutants. In addition, on the average results based on measured concerntrations do not seem to be much different from those based on unmeasured concentrations.

However, the results of flow-through tests based on measured concentrations are generally accepted as being better measures of acute toxicity than the results of flow-through tests based on unmeasured concentrations or the results of any static or renewal tests.Therefore, whenever the results of flow-through acute tests in which the concentrations were measured are available, the results of all other kinds of acute tests with that species and pollutant are not used in the calculation of the species mean acute value.

74. Comment—Species sensitivity factors should be pollutant-specific; and average factor should not be calculated for a variety of substances.

Response—EPA agrees. The requirement for acute values for at least eight different species was developed in part to allow for a reasonably good calculation of a mean acute value and a species sensitivity factor for each individual pollutant. A better way of using the acute values for the individual species has been developed, but no extrapolations are made from one pollutant to another.

75. Comment—The distribution of species mean acute values for a pollutant will be truncated if the species cannot be killed or affected by concentrations above solubility.

Response—Some species are so resistant to some pollutants that they cannot be killed or affected in acute tests even by concentrations which are much above solubility. Such "greater than" values cannot be used in the calculation of means and variances for pollutants. When the "greater than" values are for insensitive species and are at or above solubility, the values can be used in the calculation of the Final Acute Value by adjusting the cumulative proportions for all the speices with quantitative values. The shape of the curve at the high end cannot be determined, but the Final Acute Value is more dependent on the species mean acute values and the cumulative probabilities at the low end.

76. Comment—Early life-stage tests with fish should be used interchangeably with life-cycle and partial life-cycle tests with fish.

Response—EPA agrees that early life-stage tests with fish generally give about the same results as comparable life-cycle and partial life-cycle tests. However, because the shorter test is merely a predictor of the longer tests, whenever both kinds of results are available, the results of life-cycle and partial life-cycle tests should be used instead of the results of early life-stage tests.

77. Comment—Appropriate measures of chronic toxicity and appropriate lengths of exposure should be defined.

Response—The descriptions of appropriate chronic tests have been clarified.

78. Comment—The factor of 0.44 should not be used.

Response—It is not now used.

79. Comment—The Final Chronic Value should not be lower than the lowest measured species chronic value, even if chronic data are not available for sensitive species.

Response—Aquatic ecosystems cannot be protected from chronic toxicity by protecting only the insensitive species from chronic toxicity. In the past both arbitrary and experimentally determined application factors have been used to relate acute and chronic toxicity. For a variety of reasons the Guidelines do not use an application factor, but instead use the acute-chronic ratio, which is similar to the inverse of an application factor. Thus the acute-chronic ratio should normally be greater than one. The acute-chronic ratio is to be used with invertebrates as well as fish and is to be an experimentally determined value for each individual pollutant. The acute-chronic ratio should also avoid the confusion as to whether a large application factor is one that is close to unity or one that has a denominator that is much larger than the numerator. The acute-chronic ratio is calculated by dividing the appropriate measure of acute toxicity for the species (as specified in the Guidelines) by the appropriate measure of chronic toxicity for the same species (as specified in the Guidelines).

Some people have confused application factors and safety factors and use of the term "acute-chronic ratio" should help avoid this problem. Acute-chronic ratios are a way of estimating the chronic sensitivity of a species for which no chronic toxicity data are available. Safety factors would provide an extra margin of safety beyond the sensitivity of the species. Safety or uncertainty factors are intended to reduce the possibility of underprotection, whereas acute-chronic ratios are intended to estimate the actual chronic sensitivity of the species to the pollutant. This estimate is just as likely to be too high as it is to be too low. A mean acute-chronic ratio will in fact be too high for half the species and too low for the other half.

When three or more acute-chronic ratios have been determined for a pollutant with both fish and

79 FR 27303-01
NOTICES
ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-OW-2014-0135; FRL—9910-81-OW]

Updated National Recommended Water Quality Criteria for the Protection of Human Health

Tuesday, May 13, 2014

AGENCY: Environmental Protection Agency (EPA).

***27303** ACTION: Notice of Availability.

SUMMARY: EPA is announcing the availability of draft updated national recommended water quality criteria for the protection of human health for the purpose of obtaining public comments. EPA has updated its national recommended water quality criteria for human health for ninety-four chemical pollutants to reflect the latest scientific information and current EPA policies. This draft update is based on EPA's current methodology for deriving human health criteria as described in “Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)” and does not establish new policy. EPA's recommended water quality criteria provide technical information for States and authorized Tribes to establish water quality standards under the Clean Water Act to protect human health.

DATES: The public comment period begins on May 13, 2014 and ends on July 14, 2014. Technical comments should be submitted to the public EPA docket by July 14, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2014-0135, by one of the following methods:

• www.regulations.gov: Follow the on-line instructions for submitting comments.

• Mail: Water Docket, Environmental Protection Agency, 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Attention Docket ID No. EPA-HQ-OW-2014-0135.

• Hand Delivery: Water Docket, EPA Docket Center, EPA WJC West Building Room 3334, 1301 Constitution Ave. NW., Washington, DC, 20004, Attention Docket EPA-HQ-OW-2014-0135. Deliveries to the docket are accepted only during their normal hours of operation: 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, call (202) 566-2426, to schedule an appointment.

• Email: ow-docket@epa.gov; Attention Docket No. EPA-HQ-OW-2014-0135. To ensure that EPA can properly respond to comments, commenters should cite the section(s) or chemical(s) in draft updates to which each comment refers. Commenters should use a separate paragraph for each issue discussed, and must submit any references cited in their comments. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2014-0135. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov. The www.regulations.gov Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov your email address will be automatically

captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: Heidi Bethel at U.S. EPA, Office of Water, Health and Ecological Criteria Division (Mail Code 4304T), 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 566-2054; or email: bethel.heidi@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What should I consider as I prepare my comments for EPA?

In preparation for submitting comments for EPA on this action, please review the draft chemical-specific support documents EPA is publishing (1) in the public docket for this action under Docket ID No. EPA-HQ-OW-2014-0135, or (2) on EPA's Web site http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm. Provide EPA with comments regarding scientific views related to the draft updated national recommended water quality criteria for protecting human health. Include any recommended references for data or other scientific information to be considered by EPA.

II. What are recommended water quality criteria?

EPA's recommended water quality criteria are scientifically derived numeric values that protect aquatic life or human health from the deleterious effects of pollutants in ambient water.

***27304** Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish and, from time to time, revise, criteria for protection of water quality and human health that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended Section 304(a) criteria provide technical information to States and authorized Tribes in adopting water quality standards that ultimately provide a basis for assessing water body health and controlling discharges or releases of pollutants. Under the CWA and its implementing regulations, States and authorized Tribes are to adopt water quality criteria to protect designated uses (e.g., public water supply, aquatic life, recreational use, or industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

III. What are the updated criteria?

Today, EPA is publishing draft updated national recommended water quality criteria for the protection of human health for ninety-four chemical pollutants. These revisions are based on EPA's current methodology for deriving human health criteria

(See: Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), EPA-822-B-00-004, October 2000). The methodology describes EPA's current approach for deriving national recommended water quality criteria for the protection of human health.

The revision of these criteria represents a systematic update of EPA's national recommended 304(a) criteria. EPA has previously described its process for publishing revised criteria [see National Recommended Water Quality Criteria—Correction (64 FR 19781; or EPA 822-Z-99-001) or the Federal Register Notice for EPA's 2000 Methodology (65 FR 66444)]. EPA is announcing the availability of the updated human health criteria in today's Notice in order to solicit scientific views. EPA has updated the draft human health criteria using information sources and models that have previously undergone external peer review. A fact sheet and a summary of updated input parameters (e.g., cancer slope factor, reference dose, and bioaccumulation factors) used to derive the updated criteria was prepared to assist reviewers. EPA has also developed chemical-specific support documents for each of the ninety-four chemical pollutants. The support documents detail the latest scientific information supporting the updated draft human health criteria, particularly the updated toxicity and exposure input values. All of these documents are available in the docket (EPA-HQ-OW-2014-0135) and on EPA's Web site http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm.

IV. What is the relationship between the draft national recommended water quality criteria and your state or tribal water quality standards?

As part of the water quality standards triennial review process defined in section 303(c)(1) of the CWA, the States and authorized Tribes are responsible for maintaining and revising water quality standards. Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and may include general policies for application and implementation. Section 303(c)(1) requires States and authorized Tribes to review and modify, if appropriate, their water quality standards at least once every three years.

States and authorized Tribes must adopt water quality criteria that protect designated uses. Protective criteria are based on a sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. Criteria may be expressed in either narrative or numeric form. States and authorized Tribes have four options when adopting water quality criteria for which EPA has published section 304(a) criteria. They can:

(1) Establish numerical values based on recommended section 304(a) criteria;

(2) Adopt section 304(a) criteria modified to reflect site specific conditions;

(3) Adopt criteria derived using other scientifically defensible methods; or

(4) Establish narrative criteria where numeric criteria cannot be determined (40 CFR 131.11).

EPA believes that it is important for States and authorized Tribes to consider any new or updated 304(a) criteria as part of their triennial review to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These updated criteria recommendations may change based on scientific views shared in response to this notice, but once final they would supersede EPA's previous recommendations.

Consistent with 40 CFR 131.21, new or revised water quality criteria adopted into law or regulation by States and authorized Tribes on or after May 30, 2000 are in effect for CWA purposes only after EPA approval.

Dated: April 29, 2014.

Nancy K. Stoner,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2014-10963 Filed 5-12-14; 8:45 am]

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United States Environmental Protection Agency

Office of Water
4304T

EPA-820-F-14-003
May 2014

Human Health Ambient Water Quality Criteria: Draft 2014 Update

Summary

EPA is announcing in the Federal Register the availability of draft updated ambient water quality criteria for the protection of human health for the purpose of obtaining public comments. EPA has updated its national recommended water quality criteria for human health for 94 chemical pollutants to reflect the latest scientific information and EPA policies. EPA will accept written scientific views from the public on the draft updated human health criteria for 60 days. Once finalized, EPA water quality criteria provide recommendations to states and tribes authorized to establish water quality standards under the Clean Water Act.

Background

Ambient water quality criteria developed by EPA under the Clean Water Act represent specific levels of chemicals or conditions in a water body that are not expected to cause adverse effects to human health. EPA is required to develop and publish water quality criteria that reflect the latest scientific knowledge. These criteria are not rules, nor do they automatically become part of a state's water quality standards. States may adopt the criteria that EPA publishes, modify EPA's criteria to reflect site-specific conditions, or adopt different criteria based on other scientifically-defensible methods. EPA must, however, approve any new water quality standards adopted by a state before they can be used for Clean Water Act purposes.

In this 2014 update, EPA has revised 94 of the existing human health criteria to reflect the latest scientific information, including updated exposure factors (body weight, drinking water intake, fish consumption rate), bioaccumulation factors, and toxicity factors (reference dose, cancer slope factor). The criteria have also been updated to follow the current EPA methodology for deriving human health criteria (2000). Specific updates are described in detail below.

Due to outstanding technical issues, including new toxicity factors and bioaccumulation factors, EPA is *not* updating criteria for the following chemical pollutants at this time: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium (III or VI), copper, manganese, methylmercury, nickel, nitrates, nitrosamines, N-nitrosodibutylamine, N-nitrosodiethylamine, N-nitrosopyrrolidine, N-nitrosodimethylamine, N-nitrosodi-n-propylamine, N-nitrosodiphenylamine, polychlorinated biphenyls (PCBs), selenium, thallium, zinc, or 2,3,7,8-TCDD (dioxin).

Updated Exposure Assumptions

Body Weight

EPA has updated the default body weight assumption for human health criteria to 80 kilograms based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006. This represents the mean body weight for adults ages 21 and older. EPA's previously recommended body weight assumption was 70 kilograms, which was based on the mean body weight of adults from the NHANES III database (1988-1994).

Drinking Water

EPA has updated the default drinking water intake rate assumption to 3 liters per day based on NHANES data from 2003 to 2006 for all sources of water at the 90th percentile for adults ages 21 and older. This value is based on consumer-only estimates of direct and indirect water ingestion. EPA previously recommended a default drinking water intake rate of 2 liters per day, which represented the 86th percentile for adults surveyed in the US Department of Agriculture's 1994-1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis and the 88th percentile of adults in the National Cancer Institute study of the 1977-1978 Nationwide Food Consumption Survey.

Fish Consumption

EPA has updated the default fish consumption rate to 22 grams per day. This rate represents the 90th percentile consumption rate of freshwater and estuarine fish for the U.S. adult population 21 years of age and older, based on NHANES data from 2003 to 2010 (USEPA 2014). EPA's previously recommend rate of 17.5 grams per day was based on the 90th percentile consumption rate of freshwater and estuarine fish for the U.S. adult population and was derived from 1994-1996 CSFII data.

As described in EPA's human health criteria methodology (USEPA 2000), the level of fish intake in highly exposed populations varies by geographical location. Therefore, EPA suggests a four preference hierarchy for states and authorized tribes that encourages use of the best local, state, or regional data available to derive fish consumption rates. EPA recommends that states and authorized tribes consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/ population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.

Bioaccumulation Factors

EPA's national recommended water quality criteria for the protection of human health have been updated using bioaccumulation factors rather than bioconcentration factors, as recommended in EPA's human health criteria methodology (USEPA 2000). Unlike bioconcentration factors, bioaccumulation factors account for more exposure pathways than direct water contact. As a result, the updated criteria will better represent exposures to pollutants that affect human health. In order to account for the variation in bioaccumulation that is due to trophic position of the organism, EPA's human health criteria methodology (USEPA 2000) recommends that bioaccumulation factors be determined and applied to three trophic levels of fish. EPA used a peer-reviewed model called Estimation Program Interface Suite (EPI Suite) to develop bioaccumulation factors for each trophic level of fish.

Updated Health Risk Factors

EPA has updated the health risk factors using the most current toxicity information. EPA's Integrated Risk Information System (IRIS) is the primary recommended source for reference dose and cancer slope factor information. For some pollutants, more recent assessments may be found using other resources provided by EPA's Office of Water, EPA's Office of Pesticide Programs, and international or state agencies.

Relative Source Contribution

EPA has updated the human health criteria to reflect the recommended default relative source contribution (RSC) of 20 percent, as recommended in EPA's human health criteria methodology (USEPA 2000). The RSC component of the human health criteria calculation for non-carcinogens designates a percentage of the reference dose that accounts for exposures from water and fish (freshwater and estuarine), when there are other possible exposure routes. Other such routes include, but are not limited to, exposure to a particular pollutant from marine fish consumption, non-fish food consumption, dermal exposure, and respiratory exposure. For pollutants exhibiting threshold effects, the use of an RSC ensures that an individual's total exposure from all sources of a pollutant does not exceed that threshold level.

In accordance with EPA's human health criteria methodology (USEPA 2000), an alternative RSC may be used to derive human health criteria when there are sufficient data available to support a scientifically defensible alternative value.

For More Information

Contact: Heidi Bethel by telephone at (202) 566-2054, by email at bethel.heidi@epa.gov, or by mail at U.S. EPA, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460.
To access the Federal Register notice, the draft updated criteria, and supporting documents visit: http://water.epa.gov/scitech/swguidance/standards/criteria/health/.

References

USEPA (U.S. Environmental Protection Agency). 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Office of Water. Washington, DC. EPA-822-B-00-004.

USEPA (U.S. Environmental Protection Agency). 2003. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Technical Support Document Volume 2: Development of National Bioaccumulation Factors. Office of Water. Washington, DC. EPA-822-R-03-030.

USEPA (U.S. Environmental Protection Agency). 2011. Exposure Factors Handbook: 2011 Edition. Office of Research and Development. Washington, DC. EPA-600-R-09-052F.

USEPA (U.S. Environmental Protection Agency). 2012. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency, Washington, DC, USA.

USEPA (U.S. Environmental Protection Agency). 2014. Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010). United States Environmental Protection Agency, Washington, DC, USA. EPA 820-R-14-002.

60 FR 15366-01
RULES and REGULATIONS
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 9, 122, 123, 131, and 132
[FRL-5173-7]
RIN 2040-AC08

Final Water Quality Guidance for the Great Lakes System

Thursday, March 23, 1995

***15366** AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is publishing Final Water Quality Guidance for the Great Lakes System. Great Lakes States and Tribes will use the water quality criteria, methodologies, policies, and procedures in the Guidance to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them.

The Guidance was initially developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem. It will affect all types of pollutants, but will target especially the types of long-lasting pollutants that accumulate in the food web of large lakes.

The Guidance consists of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that can be allowed to reach the Lakes and their tributaries from all sources; and antidegradation policies and procedures.

Under the Clean Water Act, the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin must adopt provisions into their water quality standards and NPDES permit programs within two years (by March 23, 1997) that are consistent with the Guidance, or EPA will promulgate the provisions for them. The Guidance for the Great Lakes System will help establish consistent, enforceable, long-term protection from all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The Guidance includes minimum water quality criteria, antidegradation policies, and implementation procedures that provide a coordinated ecosystem approach for addressing existing and possible pollutant problems and improves consistency in water quality standards and permitting procedures in the Great Lakes System. In addition, the Guidance provisions help establish consistent goals or minimum requirements for Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs) that are critical to the success of international multi-media efforts to protect and restore the Great Lakes ecosystem.

EFFECTIVE DATE: April 24, 1995.

ADDRESSES: The public docket for this rulemaking, including applicable Federal Register documents, public comments in response to these documents, the Final Water Quality Guidance for the Great Lakes System, Response to Comments Document, other major supporting documents, and the index to the docket are available for inspection and copying at U.S. EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604 by appointment only. Appointments may be made by calling Wendy Schumacher (telephone 312-886-0142).

Information concerning the Great Lakes Initiative (GLI) Clearinghouse is available from Ken Fenner, Water Quality Branch Chief, (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

Copies of the Information Collection Request for the Guidance are available by writing or calling Sandy Farmer, Information Policy Branch, EPA, 401 M St., S.W. (Mail Code 2136), Washington, DC 20460 (202-260-2740).

Selected documents supporting the Guidance are also available for viewing by the public at locations listed in section XI of the preamble.

Selected documents supporting the Guidance are available by mail upon request for a fee. Selected documents are also available in electronic format at no incremental cost to users of the Internet. See section XI of the preamble for additional information.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

SUPPLEMENTARY INFORMATION

Preamble Outline

I. Introduction

Section 118(c)(2) of the Clean Water Act (CWA) (Pub. L. 92-500 as amended by the Great Lakes Critical Programs Act of 1990 (CPA), Pub. L. 101-596, November 16, 1990) required EPA to publish proposed and final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. In response to these requirements, EPA published the Proposed Water Quality Guidance for the Great Lakes System (proposed Guidance) in the Federal Register on April 16, 1993 (58 FR 20802). EPA also published four subsequent documents in the Federal Register identifying corrections and requesting comments on additional related materials (April 16, 1993, 58 FR 21046; August 9, 1993, 58 FR 42266; September 13, 1993, 58 FR 47845; and August 30, 1994, 59 FR 44678). EPA received over 26,500 pages of comments, data, and information from over 6,000 commenters in response to ***15367** these documents and from meetings with members of the public.

After reviewing and analyzing the information in the proposal and these comments, EPA has developed the Final Water Quality Guidance for the Great Lakes System (final Guidance), published in this document and codified in 40 CFR part 132, which includes six appendixes of detailed methodologies, policies, and procedures. This preamble describes the background and purpose of the final Guidance, and briefly summarizes the major provisions. Detailed discussion of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance, are provided in “Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document” (SID), (EPA, 1995, 820-B-95-001) and in additional technical and supporting documents which are available in the docket for this rulemaking. Copies of the SID and other supporting documents are also available from EPA in electronic format, or in printed form for a fee upon request; see section XI of this preamble.

II. Background

The Great Lakes are one of the outstanding natural resources of the world. They have played a vital role in the history and development of the United States and Canada, and have physical, chemical, and biological characteristics that make them a unique ecosystem. The Great Lakes themselves—Lakes Superior, Huron, Michigan, Erie and Ontario and their connecting channels—plus all of the streams, rivers, lakes and other bodies of water that are within the drainage basin of the Lakes collectively comprise the Great Lakes System.

The System spans over 750 miles across eight States—New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota—and the Province of Ontario. The Lakes contain approximately 18 percent of the world's and 95 percent of the United States' fresh surface water supply. The Great Lakes are a source of drinking water and energy, and are used for recreational, transportation, agricultural and industrial purposes by the more than 46 million Americans and Canadians who inhabit the Great Lakes region, including 29 Native American tribes. Over 1,000 industries and millions of jobs are dependent upon water from the Great Lakes. The Great Lakes System also supports hundreds of species of aquatic life, wildlife and plants along more than 4,500 miles of coastline which boast six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and hundreds of State parks, forests and sanctuaries.

Because of their unique features, the Great Lakes are viewed as important to the residents of the region, and to the Nation as a whole. The natural resources of the region have contributed to the development of its economy. The Lakes' natural beauty and aquatic resources form the basis for heavy recreational activity. The Great Lakes Basin Ecosystem—the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin—is a remarkably diverse and unique ecosystem important in the global ecology.

In the past few decades, the presence of environmental contaminants in the Great Lakes has been of significant concern. In spite of the fact that the Great Lakes contain 5,500 cubic miles of water that cover a total surface area of 94,000 square miles, they have proved to be sensitive to the effects of pollutants that accumulate in them. The internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times cause pollutants to recycle between biota, sediments and the water column.

The first major basin-wide environmental problem in the Great Lakes emerged in the late 1960s, when increased nutrients had dramatically stimulated the growth of green plants and algae, reduced dissolved oxygen levels, and accelerated the process of eutrophication. As oxygen levels continued to drop, certain species of insects and fish were displaced from affected areas of the Great Lakes Basin Ecosystem. Environmental managers determined that a lakewide approach was necessary to adequately control accelerated eutrophication. From the late 1960s through the late 1970s, United States and Canadian regulatory agencies agreed on measures to limit the loadings of phosphorus, including effluent limits on all major municipal sewage treatment facilities, limitations on the phosphorus content in household detergents, and reductions in nonpoint source runoff loadings. As a result of all of these efforts, open lake phosphorus concentrations have declined, and phosphorus loadings from municipal sewage treatment facilities have been reduced by an estimated 80 to 90 percent. These reductions have resulted in dramatic improvements in nearshore water quality and measurable improvements in open lake conditions.

More recently, scientists and public leaders have reached a general consensus that the presence of environmentally persistent, bioaccumulative contaminants is a serious environmental threat to the Great Lakes Basin Ecosystem. Beginning in 1963, adverse environmental impacts in the form of poor reproductive success and high levels of the pesticide DDT were observed in herring gulls in Lake Michigan. Through ongoing research, scientists have detected 362 contaminants in the Great Lakes System. Of these, approximately one third have toxicological data showing that they can have acute or chronic toxic effects on aquatic life, wildlife and/or human health. Chemicals that have been found to bioaccumulate at levels of concern in the Great Lakes include, but are not limited to, polychlorinated biphenyls (PCBs), mercury, DDT, dioxin, chlordane, and mirex. The main route of exposure to these chemicals for humans is through the consumption of Great Lakes fish.

Potential adverse human health effects by these pollutants resulting from the consumption of fish include both the increased risk of cancer and the potential for systemic or noncancer risks such as kidney damage. EPA has calculated health risks to populations in the Great Lakes basin from consumption of contaminated fish based on exposure to eight bioaccumulative pollutants: chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations from the Great Lakes.

Based on these data, EPA estimates that the lifetime cancer risks for Native Americans in the Great Lakes System due to ingestion of contaminated fish at current concentrations range from $1.8\ 10^{-3}$ (Lake Superior) (1.8 in one thousand) to $3.7\ 10^{-2}$ (Lake Michigan) (3.7 in 100). Estimated risks to low income minority sport anglers range from $2.5\ 10^{-3}$ (2.5 in one thousand) (Lake Superior) to $1.2\ 10^{-2}$ (1.2 in 100) (Lake Michigan). Estimated risks for other sport anglers range from $9.7\ 10^{-4}$ (9.7 in ten thousand) (Lake Superior) to $4.5\ 10^{-3}$ (4.5 in one thousand) (Lake Michigan). (See section I.B.2.a of the SID.) In comparison, EPA has long maintained that $1\ 10^{-4}$ (one in ten thousand) to $1\ 10^{-6}$ (one in 1 million) is an appropriate range of risk to protect human health.

***15368** EPA also estimates a high potential risk of systemic (noncancer) injury to populations in the Great Lakes basin due to ingestion of fish contaminated with these pollutants at current concentrations. The systemic adverse health effects associated with the assessed contaminants are described in section I.B of the SID.

Although the Great Lakes States and EPA have moved forward to deal with these problems, control of persistent, bioaccumulative pollutants proved to be more complex and difficult than dealing with nutrients. As a result, inconsistencies began to be apparent in the ways various States developed and implemented controls for the pollutants. By the mid-1980s, such inconsistencies became of increasing concern to EPA and State environmental managers.

EPA began the Great Lakes Water Quality Initiative (“Initiative”) in cooperation with the Great Lakes States to establish a consistent level of environmental protection for the Great Lakes ecosystem, particularly in the area of State water quality standards and the National Pollutant Discharge Elimination System (NPDES) programs. In the spring of 1989, the Council of Great Lakes Governors unanimously agreed to participate in the Initiative with EPA, because the Initiative supported the principles and goals of the Great Lakes Toxic Substances Control Agreement (Governors' Agreement). Signed in 1986 by the Governors of all eight Great Lakes States, the Governors' Agreement affirmed the Governors' intention to manage and protect the resources of the Great Lakes basin through the joint pursuit of unified and cooperative principles, policies and programs enacted and adhered to by each Great Lakes State.

The Initiative provided a forum for a regional dialogue to establish minimum requirements that would reduce disparities between State water quality controls in the Great Lakes basin. The scope of the Initiative included development of proposed Great Lakes water quality guidance—Great Lakes-specific water quality criteria and methodologies to protect aquatic life, wildlife and human health, procedures to implement water quality criteria, and an antidegradation policy.

Three committees were formed to oversee the Initiative. A Steering Committee (composed of directors of water programs from the Great Lakes States' environmental agencies and EPA's National and Regional Offices) discussed policy, scientific, and technical issues, directed the work of the Technical Work Group and ratified final proposals. The Technical Work Group (consisting of technical staff from the Great Lakes States' environmental agencies, EPA, the U.S. Fish and Wildlife Service, and the National Park Service) prepared proposals on elements of the Guidance for consideration by the Steering Committee. The Public Participation Group (consisting of representatives from environmental groups, municipalities, industry and academia) observed the deliberations of the other two committees, advised them of the public's concerns, and kept its various constituencies apprised of ongoing activities and issues. These three groups were collectively known as the Initiative Committees. From the start, one goal of the Initiative Committees was to develop the Guidance elements in an open public forum, drawing upon the extensive expertise and interest of individuals and groups within the Great Lakes community.

The Initiative efforts were well underway when Congress amended section 118 of the CWA in 1990 through the CPA. The general purpose of these amendments was to improve the effectiveness of EPA's existing programs in the Great Lakes by identifying key treaty provisions agreed to by the United States and Canada in the Great Lakes Water Quality Agreement (GLWQA), imposing statutory deadlines for the implementation of these key activities, and increasing Federal resources for program operations in the Great Lakes System.

Section 118(c)(2) requires EPA to publish proposed and final water quality guidance for the Great Lakes System. This Guidance must conform with the objectives and provisions of the GLWQA (a binational agreement establishing common water quality objectives for the Great Lakes) and be no less restrictive than provisions of the CWA and National water quality criteria and guidance. The Guidance must specify minimum requirements for the waters in the Great Lakes System in three areas: (1) water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife); (2) antidegradation policies; and (3) implementation procedures.

The Great Lakes States must adopt water quality standards, antidegradation policies and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of EPA's publication. In the absence of such action, EPA is required to promulgate any necessary requirements within that two-year period. In addition, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

On December 6, 1991, the Initiative Steering Committee unanimously recommended that EPA publish the draft Guidance ratified by that group in the Federal Register for public review and comment. The agreement that the draft Great Lakes Guidance was ready for public notice did not represent an endorsement by every State of all of the specific proposals. Rather, all parties agreed on the importance of proceeding to publish the draft Great Lakes Guidance in order to further solicit public comment. State Steering Committee members indicated their intent to develop and submit specific comments on the proposed Guidance during the public comment period. EPA worked to convert the agreements reached in principle by the Steering Committee into a formal package suitable for publication in the Federal Register as proposed Guidance. EPA generally used the draft proposal ratified by the Steering Committee as the basis for preparing the Federal Register proposal package. Modifications were necessary, however, to reflect statutory and regulatory requirements and EPA policy considerations, to propose procedures for State and Tribal adoption of the final Guidance, to provide suitable discussion of various alternative options, and to accommodate necessary format changes. Where modifications were made, the preamble to the proposal described both the modification and the original Steering Committee-approved guidelines, and invited public comment on both. All elements approved by the Steering Committee were either incorporated in the proposed rule or discussed in the preamble to the proposal.

III. Purpose of the Guidance

The final Guidance represents a milestone in the 30 years of effort described above on the part of the Great Lakes stakeholders to define and apply innovative, comprehensive environmental programs in protecting and restoring the Great Lakes. In particular, this publication of the final Guidance culminates six years of intensive, cooperative effort that included participation by the eight Great Lakes States, the environmental community, academia, industry, municipalities and EPA Regional and National offices.

***15369** The final Guidance will help establish consistent, enforceable, long-term protection with respect to all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The final Guidance will establish goals and minimum requirements that will further the next phase of Great Lakes programs, including the Great Lakes Toxic Reduction Effort's integrated, multi-media ecosystem approach.

EPA and State development of the Guidance—from drafting through proposal and now final publication—was guided by several general principles that are discussed below.

A. Use the Best Available Science to Protect Human Health, Aquatic Life, and Wildlife

EPA and the Initiative Committees have been committed throughout the Initiative to using the best available science to develop programs to protect the Great Lakes System. In the 1986 Governors' Agreement, the Governors of the Great Lakes States recognized that the problem of persistent toxic substances was the foremost environmental issue confronting the Great Lakes. They also recognized that the regulation of toxic contaminants was scientifically complex because the pollutants are numerous, their pathways into the Lakes are varied, and their effects on the environment, aquatic life and human health are not completely understood. Based on the importance of the Great Lakes Basin Ecosystem and the documented adverse effects from toxic contamination, however, the Governors directed their environmental administrators to jointly develop an agreement and procedure for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes basin.

As discussed further above, the Initiative was subsequently created to begin work on these goals. EPA and the Great Lakes States, with input from interested parties in the basin, began collecting and analyzing data, comparing regulatory requirements and technical guidance in their various jurisdictions, and drafting specific methodologies and procedures to control the discharge of toxic contaminants. The provisions of the final Guidance were based in large part on these prior efforts of the Initiative Committees, and incorporate the best available science to protect human health, wildlife and aquatic life in the Great Lakes System. For example, the final Guidance includes new criteria and a methodology developed by the Initiative Committees to specifically protect wildlife; incorporates recent data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporates Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and provides a methodology to determine the bioaccumulation properties of individual pollutants. Additionally, EPA understands that the science of risk assessment is rapidly improving. Therefore, in order to ensure that the scientific basis for the criteria methodologies is always current and peer reviewed, EPA will review the methodologies and revise them as appropriate every three years.

B. Recognize the Unique Nature of the Great Lakes Basin Ecosystem

The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants. The Initiative Committees devoted considerable effort to identifying the chemicals of most concern to the Great Lakes System —persistent, bioaccumulative pollutants termed “bioaccumulative chemicals of concern (BCCs)”—and developing the most appropriate criteria, methodologies, policies, and procedures to address them. The special provisions for BCCs, initially developed by the Initiative Committees and incorporated into the final Guidance, include antidegradation procedures, to ensure that future problems are minimized; general phase-out and elimination of mixing zones for BCCs, except in limited circumstances, to reduce their overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not under-regulated for lack of data; and development of water quality criteria that will protect wildlife that feed on aquatic prey.

The final Guidance is designed not only to begin to address existing problems, but also to prevent emerging and potential problems posed by additional chemicals in the future which may damage the overall health of the Great Lakes. The experience with such pollutants as DDT and PCBs indicates that it takes many decades to overcome the damage to the ecosystem caused by even short-term discharges, and that prevention would have been dramatically less costly than clean-up. Issuance of the final Guidance alone will not solve the existing long-term problems in the Great Lakes System from these contaminants. Full implementation of provisions consistent with the final Guidance will, however, provide a coordinated ecosystem approach for addressing possible pollutant problems before they produce adverse and long-lasting basin-wide impacts, rather than waiting to see what the future impacts of the pollutants might be before acting to control them. The comprehensive approach used in the development of the final Guidance provides regulatory authorities with both remedial and preventive ways of gauging the actions and potential effects of chemical stressors upon the Great Lakes Basin Ecosystem. The methodologies, policies and procedures contained in the final Guidance provide mechanisms for appropriately addressing both pollutants that have been or may in the future be documented as chemicals of concern.

C. Promote Consistency in Standards and Implementation Procedures While Allowing Appropriate Flexibility to States and Tribes

Promoting consistency in standards and implementation procedures while providing for appropriate State flexibility was the third principle in State and EPA development of the final Guidance. The underlying rationale for the Governors' Agreement, the Initiative, and the requirements set forth in the CPA was a recognition of the need to promote consistency through adoption of minimum water quality standards, antidegradation policies, and implementation procedures by Great Lakes States and Tribes to protect human health, aquatic life and wildlife. Although provisions in the CWA provide for the adoption of and periodic revisions to State water quality criteria, such provisions do not necessarily ensure that water quality criteria of adjoining States are consistent within a shared water body. For example, ambient water quality criteria in place in six of the eight Great Lakes States to protect aquatic life from acute effects range from 1.79 MUg/L to 15.0 MUg/L for cadmium, and from 0.21 MUg/L to 1.33 MUg/L for dieldrin. Other examples of variations in acute aquatic life criteria include nickel, which ranges from 290.30 MUg/L to 852.669 MUg/L; lindane, ***15370** with a range of no criteria in place to 1.32 MUg/L; and mercury, ranging from 0.5 MUg/L to 2.4 MUg/L. Similar ranges and disparities exist for chronic aquatic life criteria, and for water quality criteria to protect human health.

Disparities also exist among State procedures to translate water quality criteria into individual discharge permits. Wide variations exist, for example, in procedures for the granting of mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for pollutants discharged in mixtures with other pollutants. Additionally, when addressing the accumulation of chemicals by fish that will be consumed by humans and wildlife, some States consider accumulation through multiple steps in the food chain (bioaccumulation) while others consider only the single step of concentration from the water column (bioconcentration). Further disparities exist in different translator methodologies in deriving numeric values for implementing narrative water quality criteria; different assumptions when calculating total maximum daily loads (TMDLs) and wasteload allocations (WLAs), including different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate; and different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

These inconsistencies in State standards and implementation procedures have resulted in the disparate regulation of point source discharges. In the Governors' Agreement, the Governors recognized that the water resources of the basin transcend political boundaries and committed to taking steps to manage the Great Lakes as an integrated ecosystem. The Great Lakes States, as participants in the Initiative Committees, recommended provisions, based on their extensive experience in administering State water programs and knowledge of the significant differences in these programs within the basin, that were ultimately included in the proposed Guidance. The final Guidance incorporates the work begun by the Initiative Committees to identify these disparities and improve consistency in water quality standards and permit procedures in the Great Lakes System.

Although improved consistency in State water programs is a primary goal of the final Guidance, it is also necessary to provide appropriate flexibility to States and Tribes in the development and implementation of water programs. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate site-specific situations and unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. Many commenters, including the Great Lakes States, urged EPA to evaluate the appropriate level of flexibility provided to States and Tribes in the proposed Guidance provisions. EPA reviewed all sections of the proposed Guidance and all comments received to determine the appropriate level of flexibility needed to address these concerns while still providing a minimum level of consistency between the State and Tribal programs. Based on this review, the final Guidance provides flexibility for State and Tribal adoption and implementation of provisions consistent with the final Guidance in many areas, including the following:

—Antidegradation: Great Lakes States and Tribes may develop their own approaches for implementing the prohibition against deliberate actions of dischargers that increase the mass loading of BCCs without an approved antidegradation demonstration. Furthermore, States and Tribes have flexibility in adopting antidegradation provisions regarding non-BCCs.

—TMDLs: Great Lakes States and Tribes may use assessment and remediation plans for the purposes of appendix F to part 132 if the State or Tribe certifies that the assessment and remediation plan meets certain TMDL-related provisions in the final Guidance and public participation requirements applicable to TMDLs, and if EPA approves such plan. Thus, States have the flexibility in many cases to use LAMPs, RAPs and State Water Quality Management Plans in lieu of TMDLs.

—Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits (WQBELs) in accordance with procedure 5 of appendix F.

—Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria and bioaccumulation factors (BAFs) based on site-specific circumstances specified in procedure 1 of appendix F. All criteria, however, must be sufficient not to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act.

—Variances: Great Lakes States and Tribes may grant variances from water quality standards based on the factors identified in procedure 2 of appendix F.

—Compliance Schedules: Great Lakes States and Tribes may allow existing Great Lakes dischargers additional time to comply with permit limits in order to collect data to derive new or revised Tier I criteria and Tier II values in accordance with procedure 9 of appendix F.

—Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after the 10-year phase-out period in accordance with procedure 3.B of appendix F, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations.

—Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision is in §132.4(h) of the final Guidance.

—Reduced Detail: In many instances, EPA has revised the proposed Guidance to reduce the amount of detail in the provisions without sacrificing the objectives of the provisions. Examples of such revisions include simplification of procedures for developing TMDLs in procedure 3 of appendix F, and simplification of procedures for determining reasonable potential to exceed water quality standards in procedure 5.B of appendix F.

—Other Provisions: Flexibility is also present in provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions in the final Guidance including: determining the appropriate uncertainty factors in the human health and wildlife criteria methodologies; selection of data sets for establishing water quality criteria; identifying reasonable and prudent ***15371** measures in antidegradation provisions; and specifying appropriate margins of safety when developing TMDLs. In all cases, of course, State and Tribal provisions would need to be scientifically defensible and consistent with all applicable regulatory requirements.

D. Establish Equitable Strategies to Control Pollution Sources

Many commenters argued that the proposed Guidance unfairly focused on point source discharges. They asserted that nonpoint sources or diffuse sources of pollution, such as air emissions, are responsible for most of the loadings of some pollutants of concern in the Great Lakes, that increased regulation of point sources will be inequitable and expensive, and that the final Guidance will not result in any environmental improvement given the large, continuing contribution of toxic pollutants by nonpoint sources.

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from toxic pollutants in the Great Lakes. In addition to discharges from point sources, toxic pollutants are also contributed to the Great Lakes from industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, urban and agricultural runoff, hazardous waste and Superfund sites, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in all of these areas. EPA, Canada and the Great Lakes States and Tribes are currently implementing or developing many voluntary and regulatory programs to address these and other nonpoint sources of environmental contaminants in the Great Lakes.

Additionally, EPA intends to use the scientific data developed in the final Guidance and new or revised water quality criteria subsequently adopted by Great Lakes States and Tribes in evaluating and determining appropriate levels of control in other environmental programs. For example, EPA's future biennial reports under section 112(m) of the Clean Air Act will consider the extent to which air discharges cause or contribute to exceedances of water quality criteria in assessing whether additional air emission standards or control measures are necessary to prevent serious adverse effects. Similarly, once provisions consistent with the final Guidance are adopted by the Great Lakes States or Tribes, they will serve as applicable or relevant and appropriate requirements (ARARs) for on-site responses under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). EPA will also consider the data and criteria developed for the final Guidance, including the information on BCCs, in developing or evaluating LaMPs and RAPs under section 118 of the CWA and Article VI, Annex 2 of the GLWQA; determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act; new or existing chemical reviews under the Toxic Substances Control Act (TSCA); pesticide reviews under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and reporting requirements for toxic releases under the Emergency Planning and Community Right-to-Know Act (EPCRA).

The final Guidance also includes provisions to address the contribution of pollutants by nonpoint sources. First, the water quality criteria to protect human health, wildlife and aquatic life, and the antidegradation provisions apply to the waters in the Great Lakes System regardless of whether discharges to the water are from point or nonpoint sources. Accordingly, any regulatory programs for nonpoint sources that require compliance with water quality standards would also be subject to the criteria and antidegradation provisions of the final Guidance once they are adopted into State or Tribal standards.

Second, several elements of the final Guidance would, after State, Tribal or Federal promulgation, require or allow permitting authorities to consider the presence of pollutants in ambient waters—including pollutants from nonpoint source dischargers—in establishing WQBELs for point sources. For example, permit authorities may consider the presence of other point or nonpoint source discharges when evaluating whether to grant a variance from water quality criteria. Additionally, the provisions for TMDLs address nonpoint sources by specifying that the loading capacity of a receiving water that does not meet water quality standards for a particular pollutant be allocated, where appropriate, among nonpoint as well as point sources of the pollutant, including, at a minimum, a margin of safety to account for technical uncertainties in establishing the TMDL.

The development of TMDLs is the preferred mechanism for addressing equitable division of the loading capacities of these nonattained waters. Because TMDLs have not been completed for most nonattained waters, however, the final Guidance promotes the development of TMDLs through a phased approach, where appropriate, and provides for short-term regulatory relief to point source dischargers in the absence of TMDLs through intake credits, variances, and other water quality permitting procedures.

EPA received numerous comments on the problem posed in controlling mercury in particular. Many commenters stated that since the primary source of mercury is now atmospheric deposition, point sources contribute only a minor portion of the total loading of mercury to the Great Lakes System and further restriction of point source discharges would have no apparent effect in improving water quality. Although EPA believes that there is sufficient flexibility in the Guidance to handle the unique problems posed by mercury (e.g., water quality variances, phased TMDLs, intake credits), EPA is committed to developing a mercury permitting strategy to provide a holistic, comprehensive approach for dealing with this pollutant. EPA will publish this strategy no later than two years following publication of this Guidance.

There are also many ongoing voluntary and regulatory activities that address nonpoint sources of toxic pollutants to the Great Lakes System, including activities taken under the Clean Air Act Amendments of 1990 (CAAA), the CWA, and State regulatory and voluntary programs. Some of these activities are summarized in the preamble to the proposed Guidance (58 FR 20826-32) and section I.D of the SID.

In addition to the many ongoing activities, EPA and the Great Lakes States, Tribes, and other federal agencies are pursuing a multi-media program to prevent and to further reduce toxic loadings from all sources of pollution to the Great Lakes System, with an emphasis on nonpoint sources. This second phase of the Great Lakes Water Quality Initiative, called the Great Lakes Toxic Reduction Effort (GLTRE), will build on the open, participative public dialogue established during the development of the final Guidance. Through the GLTRE, the Federal, State, and Tribal agencies intend to coordinate and enhance the effectiveness of ongoing actions and existing tools to prevent and reduce nonpoint source and wet-weather point source contributions of toxic pollutants in the Great Lakes System. A special emphasis will be placed on BCCs identified in the final Guidance.

A partial list of ongoing actions that are being or could be focused on BCCs includes: implementation of the CAAA to reduce atmospheric deposition of toxics; Resource Conservation and Recovery Act and CERCLA remedial actions to reduce loadings of toxics from ***15372** hazardous waste sites; increased focus (through the GLTRE) on toxic pollutants emanating from combined sewer overflows and stormwater outfalls; application in the Great Lakes basin of the National Contaminated Sediment Management Strategy; implementation of spill prevention planning practices to minimize this potential source of loadings to the Great Lakes; improved reporting of toxic pollutants under the Toxic Release Inventory; public education on the dangers of mercury and other BCCs; pesticide registration and re-registration processes; development of a "mass balance" model for fate and transport of pollutants in the Great Lakes; and, development of a "virtual elimination strategy." These programs will prevent and further reduce mass loadings of pollutants and facilitate equitable division of the costs of any necessary control measures between point and nonpoint sources.

In addition to the GLTRE, which is basin-wide in scope, a primary vehicle for coordinating Federal and State programs at the local level for meeting water quality standards and restoring beneficial uses for the open waters of the Great Lakes are LaMPS. LaMPs will define media specific program actions to further reduce loadings of toxic substances, assess whether these programs will ensure restoration and attainment of water quality standards and designated beneficial uses, and recommend any media-specific program enhancements as necessary. Additionally, LaMPs will be periodically updated and revised to assess progress in implementing media-specific programs, assess the reductions in toxic loadings to the Great Lakes System through these programs, incorporate advances in the understanding of the System based on new data and information, and recommend specific adjustments to media programs as appropriate.

E. Promote Pollution Prevention Practices

The final Guidance also promotes pollution prevention practices consistent with EPA's National Pollution Prevention Strategy and the Pollution Prevention Action Plan for the Great Lakes. The Pollution Prevention Act of 1990 declares as National policy that reducing the sources of pollution is the preferred approach to environmental protection. When source reductions are not possible, however, recycling, treating and properly disposing of pollutants in an environmentally safe manner complete the hierarchy of management options designed to prevent pollution from entering the environment.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Great Lakes Pollution Prevention Action Plan highlights how EPA, in partnership with the States, will incorporate pollution prevention into actions designed to reduce the use and release of toxic substances in the Great Lakes basin.

The final Guidance builds upon these two components of the Great Lakes program by promoting the development of pollution prevention analysis and activities in the level of detection, mixing zone, and antidegradation sections of the final Guidance. Also, the decision to provide special provisions for BCCs implements EPA's commitment to pollution prevention by reducing the discharge of these pollutants in the future. This preventive step not only makes good environmental management sense, but is appropriate based on the documented adverse effects that the past and present discharge of these pollutants has produced in the Great Lakes basin.

F. Provide Accurate Assessment of Costs and Benefits

In developing the final Guidance, EPA identified and carefully evaluated the anticipated costs and benefits from implementation of the major provisions. EPA received many comments on the draft cost and benefit studies conducted as part of the proposed Regulatory Impact Analysis (RIA) required by Executive Order 12291, and its successor, Executive Order 12866. Based upon consideration of those comments and further analysis, EPA has revised the RIA. The results of this analysis are summarized in section V of this preamble.

IV. Summary of the Final Guidance

The final Guidance will establish minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Pennsylvania, Ohio and Wisconsin, including waters within the jurisdiction of Indian Tribes. Specifically, the final Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provides methodologies to derive numeric criteria for additional pollutants discharged to these waters. The final Guidance also contains minimum procedures to translate the proposed ambient water quality criteria into enforceable controls on discharges of pollutants, and a final antidegradation policy.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. The Great Lakes States and Tribes must adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System consistent with the (as protective as) final Guidance or be subject to EPA promulgation. Great Lakes Tribes include any Tribe within the Great Lakes basin for which EPA has approved water quality standards under section 303 or has authorized to administer a NPDES program under section 402 of the CWA. No Indian Tribe has been authorized to administer these water programs in the Great Lakes basin as of this time. If a Great Lakes State fails to adopt provisions consistent with the final Guidance within two years of this publication in the Federal Register (that is, by March 23, 1997), EPA will publish a final rule at the end of that time period identifying the provisions of the final Guidance that will apply to waters and discharges within that jurisdiction. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

The following sections provide a brief summary of the provisions of the final Guidance. A more complete discussion of the final Guidance, including EPA's analysis of major comments, issues, and a description of specific changes made to the proposed Guidance, are contained in the SID.

The parenthetical note at the beginning of each section provides references to the primary provisions in the final Guidance being discussed in the section, and to discussions in the SID. The final Guidance is codified as 40 CFR 132, including appendixes A through F. Note that appendix F consists of procedures 1 through 9. For ease of reference, sections in appendix F may be referred to by appending the section designation to the procedure number. For example, section A.1 of procedure 1 may be referred to as procedure 1.A.1 of appendix F.

15373** ***A. Water Quality Criteria and Methodologies

1. Protection of Aquatic Life
(§§132.3(a), 132.3(b), 132.4(a)(2); Tables 1 and 2 to part 132; appendix A to part 132; section III, SID)

The final Guidance contains numeric criteria to protect aquatic life for 15 pollutants, and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System. Aquatic life criteria are derived to establish ambient concentrations for pollutants, which, if not exceeded in the Great Lakes System, will protect fish, invertebrates, and other aquatic life from adverse effects due to that pollutant. The final Guidance includes both acute and chronic criteria to protect aquatic life from acute and chronic exposures to pollutants.

Tier I aquatic life criteria for each chemical are based on laboratory toxicity data for a variety of aquatic species (e.g., fish and invertebrates) which are representative of species in the freshwater aquatic environment as a whole. The Guidance also includes a Tier II methodology to be used in the absence of the full set of data needed to meet Tier I data requirements. For pollutants for which Tier I criteria have not been adopted into State or Tribal water quality standards, States must use methodologies consistent with either the Tier I or Tier II methodologies, depending on the data available, in conjunction with whole effluent toxicity requirements in the final Guidance (see section IV.B.5 of this preamble), to implement their existing narrative water quality criteria that prohibit toxic pollutants in toxic amounts in all waters. The Great Lakes States and Tribes are not required to use the Tier II methodology to adopt numeric criteria into their water quality standards.

Use of the two-tiered final Guidance methodologies in these situations will enable regulatory authorities to translate narrative criteria to derive TMDLs and individual NPDES permit limits on a more uniform basis. EPA and the States determined that there is a need to regulate pollutants more consistently in the Great Lakes System when faced with limited numbers of criteria. Many of the Great Lakes States are already employing procedures similar to the approach in the final Guidance to implement narrative criteria. EPA determined the Tier II approach improves upon existing mechanisms by utilizing all available data.

The two-tiered methodology allows the application of the final Guidance to all pollutants, except those listed in Table 5 of part 132 (see section IV.E of this preamble). The Tier I aquatic life methodology includes data requirements very similar to those used in current guidelines for developing National water quality criteria guidance under section 304(a) of the CWA. For example, both require that acceptable toxicity data for aquatic species in at least eight different families representing differing habitats and taxonomic groups must exist before a Tier I numeric criterion can be derived. The Tier II aquatic life methodology is used to derive Tier II values which can be calculated with fewer toxicity data than Tier I. Tier II values can, in certain instances, be based on toxicity data from a single taxonomic family, provided the data are acceptable. The Tier II methodology generally produces more stringent values than the Tier I methodology, to reflect greater uncertainty in the absence of additional toxicity data. As more data become available, the derived Tier II values tend to become less conservative. That is, they more closely approximate Tier I numeric criteria. EPA and the States believe it is desirable to continue to supplement toxicity data to ultimately derive Tier I numeric criteria.

One difference from the existing National water quality criteria guidelines is that the final Guidance methodology for aquatic life deletes the provision in the National guidelines to use a Final Residue Value (FRV) in deriving a criterion. The FRV is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting wildlife that consume them by preventing the exceedance of applicable Food

and Drug Administration action levels and concentrations that affect wildlife. The final Guidance provides specific, separate methodologies to protect wildlife and human health (discussed below) which EPA believes will provide more accurate and appropriate levels of protection than the FRVs.

For pollutants without Tier I criteria but with enough data to derive Tier II values for aquatic life, the proposal would have required permittees to meet permit limits based on both Tier II values and whole effluent toxicity (WET) testing. In response to comments, the final Guidance clarifies that States and Tribes may adopt provisions allowing use of indicator parameter limits consistent with 40 CFR 122.44(d)(1)(vi)(C). When deriving limits to meet narrative criteria, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. If use of an indicator parameter is allowed, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality standard that protects aquatic life.

Finally, the aquatic criteria for metals in the proposed Guidance were expressed as total recoverable concentrations. The final Guidance expresses the criteria for metals in dissolved form because the dissolved metal more closely approximates the bioavailable fraction of metal in the water column than does the total recoverable metal. The dissolved criteria are obtained by multiplying the chronic and/or acute criterion by appropriate conversion factors in Table 1 or 2. This is consistent with many comments on the issue and with the policy on metals detailed in "Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (October 1, 1993). A document describing the methodology to convert total recoverable metals criteria to dissolved metals criteria was published in the Federal Register on August 30, 1994 (59 FR 44678). If a State or Tribe fails to adopt approvable aquatic life criteria for metals, EPA will promulgate criteria expressed as dissolved concentrations.

EPA Region 5, in cooperation with EPA Regions 2 and 3 and Headquarters offices, and the Great Lakes States and Tribes, will establish a Great Lakes Initiative (GLI) Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria for aquatic life, human health and wildlife and Tier II water quality values for aquatic life and human health. As additional toxicological data and exposure data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes. EPA believes operation of the GLI Clearinghouse will help ensure consistency during implementation of the final Guidance.

2. Protection of Human Health
(§§132.3(c), 132.4(a)(4); Table 3 to part 132; appendix C to part 132; section V of the SID)

The final Guidance contains numeric human health criteria for 18 pollutants, and includes Tier I and Tier II methodologies to derive cancer and ***15374** non-cancer human health criteria for additional pollutants. The proposed Guidance contained numeric criteria for 20 pollutants, but two pollutants were deleted because they do not meet the more restrictive minimum data requirements for BAFs used in the final Guidance.

Tier I human health criteria are derived to establish ambient concentrations of chemicals which, if not exceeded in the Great Lakes System, will protect individuals from adverse health impacts from that chemical due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities in the Great Lakes System. For each chemical, chronic criteria are derived to reflect long-term consumption of food and water from the Great Lakes System. Tier II values are intended to provide a conservative, interim level of protection in the establishment of a permit limit, and are distinguished from the Tier I approach by the amount and quality of data used for derivation.

The final Guidance differs from current National water quality criteria guidelines when calculating the assumed human exposure through consumption of aquatic organisms. The final Guidance uses BAFs predicted from biota-sediment accumulation factors (BSAFs) in addition to field-measured BAFs, and uses a food chain multiplier (FCM) to account for biomagnification when using measured or predicted bioconcentration factors (BCFs). BAFs are discussed further in section IV.A.4. of this preamble.

Human health water quality criteria for carcinogens are typically expressed in concentrations associated with a plausible upper bound of increased risk of developing cancer. In practice, the level of cancer risk generally accepted by EPA and the States typically ranges between 10^{4} (one in one thousand) and 10^{6} (one in one million). In contrast, as discussed in section II above, the cancer risk from ingestion of contaminated fish at current concentrations in the Great Lakes System are as high as 1.2 10^{2} (1.2 in 100). The proposed and final Guidance establishes 10^{5} (one in one hundred thousand) as the risk level used for deriving criteria and values for individual carcinogens. This is within the range historically used in EPA actions, and approved for State actions, designed to protect human health. The majority of the Great Lakes States use 10^{5} as a baseline risk level in establishing their water quality standards.

The methodology is designed to protect humans who drink water or consume fish from the Great Lakes System. The portion of the methodology addressing fish consumption includes a factor describing how much fish humans consume per day. The final Guidance includes a Great Lakes-specific fish consumption rate of 15 grams per day, based upon several fish consumption surveys from the Great Lakes, including a recent study by West et al. that was discussed in a Federal Register document on August 30, 1994 (59 FR 44678). This rate differs from the 6.5 grams per day rate which is used in the National water quality criteria guidelines as a National average consumption value. The 15 grams per day represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing population.

Commenters argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 FR 7629). EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations. In carrying out regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{4} to 10^{6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{5}. Therefore, if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{4} risk level. Available data indicate that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day. The final Guidance requires, moreover, that States and Tribes modify the human health criteria on a site-specific basis to provide additional protection appropriate for highly exposed sub-populations. Thus, where a State or Tribe finds that a population of high-end consumers would not be adequately protected by criteria derived using the 15 gram per day assumption (e.g., where the risk was greater than 10^{4}), the State or Tribe would be required to modify the criteria to provide appropriate additional protection. The final Guidance also requires States and Tribes to adopt provisions to protect human health from the potential adverse effects of mixtures of pollutants in effluents, specifically including mixtures of carcinogens. Understood in the larger context of the human health methodology and the final Guidance as a whole, therefore, EPA believes that the 15 gram per day fish consumption rate provides adequate health protection for the public, including highly exposed populations, and that the final Guidance is therefore consistent with Executive Order 12898.

In developing bioaccumulation factors, the proposed Guidance used a 5.0 percent lipid value for fish consumed by humans, based on Great Lakes-specific data. The current National methodology uses a 3.0 percent lipid value. The final Guidance uses a 3.10 percent lipid value for trophic level 4 fish and 1.82 for trophic level 3 fish. These percent lipid values are based on an analysis of the West et al. study cited above and data from State fish contaminant monitoring programs.

The final Guidance contains specific technical guidelines concerning the range of uncertainty factors that may be applied by the State and Tribal agencies on the basis of their best professional judgment. The final Guidance places a cap of 30,000 on the combined product of uncertainty factors that may be applied in the derivation of non-cancer Tier II values and a combined

uncertainty factor of 10,000 for Tier I criteria. The likely maximum combined uncertainty factor for Tier I criteria in most cases is 3,000. The SID discusses further the use of the uncertainty factors in the derivation of human health criteria and values.

The proposed Guidance used an 80 percent relative source contribution (RSC) from surface water pathways for BCCs, and a 100 percent RSC for all other pollutants, in deriving noncancer criteria. The RSC concept is applied in the National drinking water regulations and is intended to account, at least in part, for exposures from other sources for those bioaccumulative pollutants for which surface water pathways are likely to be major contributors to human exposure. The final Guidance uses the more protective 80 percent RSC for all pollutants in deriving noncancer criteria. This change was made because of concern that for non-BCCs as well as ***15375** BCCs, there may be other sources of exposures for noncarcinogens.

3. Protection of Wildlife

(§§132.3(d), 132.4(a)(5); Table 4 to part 132; appendix D to part 132; section VI of the SID)

The final Guidance contains numeric criteria to protect wildlife for four pollutants and a methodology to derive Tier I criteria for additional BCCs. Wildlife criteria are derived to establish ambient concentrations of chemicals which, if not exceeded, will protect mammals and birds from adverse impacts from that chemical due to consumption of food and/or water from the Great Lakes System.

These are EPA's first water quality criteria specifically for the protection of wildlife. The methodology is based largely on the noncancer human health paradigm. It focuses, however, on endpoints related to reproduction and population survival rather than the survival of individual members of a species. The methodology incorporates pollutant-specific effect data for a variety of mammals and birds and species-specific exposure parameters for two mammals and three birds representative of mammals and birds resident in the Great Lakes basin which are likely to experience significant exposure to bioaccumulative contaminants through the aquatic food web.

In the proposal, EPA included a two-tiered approach similar to that for aquatic life and human health. In response to comments, the final Guidance requires States and Tribes to adopt provisions consistent with only the Tier I wildlife methodology, and only to apply this methodology for BCCs (see section IV.A.4 below). The TSD provides discretionary guidelines for the use of Tier I and Tier II methodologies for other pollutants. The wildlife methodology was limited to the BCCs because these are the chemicals of greatest concern to the higher trophic level wildlife species feeding from the aquatic food web in the Great Lakes basin. This decision is consistent with comments made by the EPA Science Advisory Board (SAB) who agreed that the initial focus for wildlife criteria development should be on persistent, bioaccumulative organic contaminants (USEPA, 1994, EPA-SAB-EPEC-ADV-94-001).

Numerous commenters were concerned that the mercury criterion for wildlife was not scientifically appropriate. After review of all comments and a reevaluation of all the data, the mercury criterion for wildlife has been increased from 180 pg/L to 1300 pg/L. EPA believes the 1300 pg/L is protective of wildlife in the Great Lakes System.

In developing bioaccumulation factors, the proposed Guidance used a 7.9 percent lipid value for fish consumed by wildlife. The final Guidance uses a 10.31 percent lipid value for trophic level 4 fish and 6.46 for trophic level 3 fish. These percent lipid values are based on the actual prey species consumed by the representative wildlife species specified in the methodology, and are used to estimate the BAFs for the trophic levels which those species consume. The percent lipid is based on the preferential consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid. This approach is a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

4. Bioaccumulation Methodology

(§132.4(a)(3); appendix B to part 132; section IV of the SID)

The proposed Guidance incorporated BAFs in the derivation of criteria and values to protect human health and wildlife. Bioaccumulation refers to the uptake and retention of a substance by an aquatic organism from its surrounding medium and from food. For certain chemicals, uptake through the aquatic food chain is the most important route of exposure for wildlife and humans. The wildlife criteria and the human health criteria and values incorporate appropriate BAFs in order to more accurately account for the total exposure to a chemical. Current EPA guidelines for the derivation of human health water quality criteria use BCFs, which measure only uptake from water, when field-measured BAFs are not available. EPA believes, however, that the BAF is a better predictor of the concentration of a chemical within fish tissues in the Great Lakes System because it includes consideration of the uptake of contaminants from all routes of exposure.

The proposed Guidance included a hierarchy of three methods for deriving BAFs for non-polar organic chemicals: field-measured BAFs; predicted BAFs derived by multiplying a laboratory-measured BCF by a food-chain multiplier; and BAFs predicted by multiplying a BCF calculated from the log K_{ow} by a food-chain multiplier. For inorganic chemicals, the proposal would have required either a field-measured BAF or laboratory-measured BCF. On August 30, 1994, EPA published a document in the Federal Register (59 FR 44678) requesting comments on revising the hierarchy of methods for deriving BAFs for organic chemicals, and issues pertaining to the model used to assist in predicting BAFs when a field-measured BAF is not available. Based on the comments received, the final Guidance modifies the proposed hierarchy by adding a predicted BAF based on a BSAF as the second method in the hierarchy. BSAFs may be used for predicting BAFs from concentrations of chemicals in surface sediments. In addition, the final Guidance uses a model to assist in predicting BAFs that includes both benthic and pelagic food chains thereby incorporating exposures of organisms to chemicals from both the sediment and the water column. The model used in the proposal only included the pelagic food chain, and therefore, did not account for exposure to aquatic organisms from sediment.

The proposed Guidance used the total concentration of a chemical in the ambient water when deriving BAFs for organic chemicals. In the preamble to the proposed Guidance and in the Federal Register document cited above, EPA requested comments on deriving BAFs in terms of the freely dissolved concentration of the chemical in the ambient water. Based on comments received from the proposal and the document, the final Guidance uses the freely dissolved concentration of a chemical instead of the total concentration in the derivation of BAFs for organic chemicals. Use of the freely dissolved concentration will improve the accuracy of extrapolations between water bodies.

Finally, as discussed in section II of this preamble, bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem. Because of these concerns, the proposed Guidance would have required that pollutants with human health BAFs greater than 1000 receive increased attention and more stringent controls within the Great Lakes System. These pollutants are termed BCCs. EPA identified 28 BCCs in the proposed Guidance. The additional controls for BCCs are specified in certain of the implementation procedures and the antidegradation procedures, and are discussed further in the SID. The final Guidance continues to include increased attention on and more stringent controls for BCCs within the Great Lakes System. The final Guidance identifies 22 BCCs that are targeted for special controls instead of the 28 in the proposed Guidance. Six BCCs were deleted from the proposed list because of concern that the methods used to estimate the BAFs may not ***15376** account for the metabolism or degradation of the pollutants in the environment. States and Tribes may identify more BCCs as additional BAF data become available. The final Guidance designates as BCCs only those chemicals with human health BAFs greater than 1000 that were derived from either a field-measured BAF or a predicted BAF based on a field-measured BSAF (for non-metals) or from a field-measured BAF or a laboratory-measured BCF (for metals). Field-measured BAFs and BSAFs, unlike BAFs based only on laboratory analyses or calculations, account for the effects of metabolism.

B. Implementation Procedures

(§§132.4(a)(7), 132.4(e); appendix F to part 132; section VIII of the SID)
This section of the preamble discusses nine specific procedures contained in the final Guidance for implementing water quality standards and developing NPDES permits to attain the standards.

1. Site-Specific Modifications

(Procedure 1 of appendix F to part 132; section VIII.A of the SID)
The proposed Guidance would have allowed States and Tribes to adopt site-specific modifications to water quality criteria and values under certain circumstances. States and Tribes could modify aquatic life criteria to be either more stringent or less stringent when local water quality characteristics altered the biological availability or toxicity of a pollutant, or where local species' sensitivities differed from tested species. Less stringent modifications to chronic aquatic life criteria could also be made to reflect local physical and hydrological conditions. States and Tribes could also modify BAFs and human health and wildlife criteria to be more stringent, but not less stringent than the final Guidance.

The final Guidance retains most of the above provisions, but in addition allows less stringent modifications to acute aquatic life criteria and values to reflect local physical and hydrological conditions, less stringent modifications to BAFs in developing human health and wildlife criteria, and the use of fish consumption rates lower than 15 grams per day if justified. The final Guidance also specifies that site-specific modifications must be made to prevent water quality that would cause jeopardy to endangered or threatened species that are listed or proposed under the ESA, and prohibits any less-stringent site-specific modifications that would cause such jeopardy. Other issues related to the ESA are discussed in section IX of this preamble.

2. Variances from Water Quality Standards for Point Sources

(Procedure 2 of appendix F to part 132; section VIII.B of the SID)
The final Guidance allows Great Lakes States and Tribes to adopt variances from water quality standards, applicable to individual existing Great Lakes dischargers for up to five years, where specified conditions exist. For example, a variance may be granted when compliance with a criterion would result in substantial and widespread social and economic impacts or where certain stream conditions prevent the attainment of the criterion. No significant changes were made in this section from the proposed Guidance.

3. TMDLs and Mixing Zones

(Procedure 3 of appendix F to part 132; section VIII.C of the SID)
Section 303(d) of the CWA and implementing regulations at 40 CFR 130.7 require the establishment of TMDLs for waters not attaining water quality standards after implementation of existing or planned pollution controls. The TMDL quantifies the maximum allowable loading of a pollutant to a water body and allocates the loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards for that pollutant will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve single point sources or multiple sources (e.g., point sources and nonpoint sources) and may be established for geographic areas that range in size from large watersheds to relatively small water body segments.

The proposal attempted to develop a single, consistent approach for developing TMDLs to be used by all States and Tribes in the Great Lakes System. Current practice in the eight Great Lakes States includes distinct technical procedures and program approaches that differ in scale, emphasis, scope and level of detail. Two options for TMDL development were proposed. One, Option A, focused on first evaluating the basin as a whole and then conducting individual site-by-site adjustments as necessary to ensure attainment of water quality standards at each location in the basin. The other, Option B, focused on evaluating limits needed for individual point sources with supplemental emphasis on basin-wide considerations as necessary. Both approaches are consistent with the CWA, but result in different methodologies for TMDL development.

Both options proposed that within 10 years of the effective date of the final Guidance (i.e., two five-year NPDES permit terms), mixing zones would be prohibited for BCCs for existing point source discharges to the Great Lakes System. Further, both proposed that mixing zones be denied for new point source discharges of BCCs as of the effective date of the final Guidance.

Both options also specified procedures for determining background levels of pollutants present in ambient waters. In addition, the proposal would have tightened the relationship between TMDL development and NPDES permit issuance by providing that TMDLs be established for each pollutant causing an impairment in a water body prior to the issuance or reissuance of any NPDES permits for that pollutant.

The final Guidance merges both Options A and B into one single set of minimum regulatory requirements for TMDL development. In general, the final TMDL procedures are less detailed than the proposal, and offer more flexibility for States and Tribes in establishing TMDLs. The final TMDL procedures contain elements from both Options A and B that were deemed critical for a minimum level of consistency among the Great Lakes States and Tribes. These critical elements include: mixing zone specifications, design flows, and procedures for determining background concentrations.

The final Guidance also includes a prohibition on mixing zones for BCCs after 12 years in most circumstances. Maintaining these restrictions on the availability of mixing zones is consistent with both the Steering Committee's policy views and the bi-national GLWQA goal of virtual elimination of persistent, bioaccumulative toxics. Because of the unique nature of the Great Lakes ecosystem, documented ecological impacts, and the need for consistency, EPA believes that the general prohibition on mixing zones for BCCs is reasonable and appropriate. However, a new exception is allowed if a facility with an existing BCC discharge can demonstrate that it is reducing that discharge to the maximum extent feasible (considering technical and economic factors) but cannot meet WQBELs for that discharge without a mixing zone. EPA, in conjunction with stakeholders within the Great Lakes Basin, will develop guidance for use by ***15377** States and Tribes in exercising the exception provision with special focus on the technical and economic feasibility criteria. This guidance will also consider the notice, public hearing, monitoring and pollution prevention demonstration elements of the exception criteria.

The final Guidance also retains many of the proposed provisions for calculating background concentrations used in TMDLs and WLAs established in the absence of TMDLs. The procedure addressing data points below the level of detection, however, has been modified so that it no longer specifies the use of default values (i.e., half of the level of detection).

The final TMDL procedures do not require that TMDLs be established for point sources prior to the issuance/reissuance of NPDES permits. The final Guidance defers to the existing National program for determining when a TMDL is required. Lastly, the final Guidance allows assessment and remediation plans that are approved by EPA under 40 CFR 130.6 to be used in lieu of a TMDL for purposes of appendix F as long as they meet the general conditions of a TMDL as outlined by procedure 3 of appendix F, and the public participation requirements applicable to TMDLs.

4. Additivity

(Procedure 4 of appendix F to part 132; section VIII.D of the SID)
EPA has traditionally developed numeric water quality criteria on a single pollutant basis. While some potential environmental hazards involve significant exposure to only a single compound, most instances of contamination in surface waters involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life and wildlife. WET tests are available to generally address interactive effects of mixtures on aquatic organisms. EPA's 1986 “Guidelines for the Health Risk Assessment of Chemical Mixtures” set forth principles and procedures for human health risk assessment of chemical mixtures. There are currently no technical guidelines on how to assess effects on wildlife from chemical mixtures.

The preamble for the proposed Guidance discussed several possible approaches to address additive effects from multiple pollutants. Proposed regulatory language was provided for two specific options, each with separate provisions related to aquatic life, wildlife and human health. One approach was developed by the Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife. The other approach was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. In the absence of contrary data, both approaches recommended that the risk

to human health from individual carcinogens in a mixture be considered additive, and that a 10^{-5} risk level be adopted as a cap for the cancer risk associated with mixtures. Both approaches also proposed using TEFs to assess the risk to humans and wildlife from certain chemical classes. The TEF approach converts the concentration of individual components in a mixture of chemicals to an "equivalent" concentration expressed in terms of a reference chemical. Both approaches used the 17 TEFs for dioxins and furans identified in the 1989 EPA document, "Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans," and the 1989 update.

The final Guidance includes a general requirement for States and Tribes to adopt an additivity provision consistent with procedure 4 of appendix F to protect human health from the potential additive adverse effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. The final Guidance also requires the use of the 17 TEFs included in the proposed Guidance to protect human health from the potential additive adverse effects in effluents.

5. Determining the Need for WQBELs (Reasonable Potential)

(Procedure 5 of appendix F to part 132; section VIII.E of the SID)
EPA's existing regulations require NPDES permits to include WQBELs to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause or contribute to an excursion of any applicable water quality standard. If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric water quality criterion, it must include a WQBEL for the individual pollutant in the permit. In the absence of an adopted numeric water quality criterion for an individual pollutant, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by either calculating a numeric criterion for the pollutant; applying EPA's water quality criteria developed under section 304(a) of the CWA, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant. See 40 CFR 122.44(d)(1).

The final Guidance implements these National requirements by specifying procedures for determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of Tier I criteria or Tier II values based on facility-specific effluent data. The final Guidance also specifies procedures for determining whether permitting authorities must generate or require permittees to generate data sufficient to calculate Tier II values when specified pollutants of concern in the Great Lakes System are known or suspected of being discharged, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. EPA believes that the data necessary to calculate Tier II values for aquatic life, wildlife and human health currently exists for most of the specified pollutants of concern.

The final Guidance maintains all the basic requirements from the proposed procedure. Some minor changes are that the procedure no longer includes a special provision for effluent dominated streams, and the procedure allows a broader range of statistical approaches to be used when evaluating effluent data, which provides added simplicity and flexibility to States and Tribes.

Another change from the proposal is the relationship in the final Guidance between the reasonable potential and TMDL procedures. Numerous commenters pointed out that the proposed Guidance indicated that TMDLs would be required for any water receiving effluent from a discharger found to exhibit reasonable potential. Given the fact that there are many waterbodies in the Great Lakes basin for which TMDLs have not been developed, and the obvious need for permitting to proceed in the interim until TMDLs are completed, the final Guidance provides that the permitting authority can establish waste load allocations and WQBELs in the absence of a TMDL or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F. A more detailed discussion of the assessment and remediation plan and its relationship to a TMDL can be found in section VIII.C.2 of the SID. Procedures for establishing such WLAs are therefore addressed in the final Guidance.

***15378 6. Intake Pollutants**

(Procedures 5.D and 5.E of appendix F to part 132; section VIII.E of the SID)
The proposed Guidance allowed a permitting authority to determine that the return of an identified intake water pollutant to the same body of water under specified circumstances does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards, and therefore, that a WQBEL would not be required for that pollutant. Under the proposal, this "pass through" of intake water pollutants would be allowed if the facility returns the intake water containing the pollutant of concern to the same waterbody; does not contribute additional mass of pollutant; does not increase the concentration of the intake water pollutant; and does not discharge at a time or location, or alter the pollutant in a manner which would cause adverse impacts to occur that would not occur if the pollutant were left in-stream.

EPA received numerous comments on the proposal. Some commenters argued that the proposed provision was too narrow because relief would not be available if the facility added any amount of the pollutant to the discharge, even where the facility was not contributing any additional mass or concentration to the waterbody than was contained in the intake water. After consideration of public comments, EPA decided to expand the intake pollutant provisions to include not only a reasonable potential procedure like the one contained in the proposal, but also a provision that allows the permitting authority to take into account the presence of pollutants in intake water in deriving WQBELs. Specifically, the final Guidance authorizes the permitting authority to establish limits based on a principle of "no net addition" (i.e., the limit would allow the mass and concentration of the pollutant in the discharge up to the mass and concentration of the pollutant in the intake water). This provision would be available where the facility's discharge is to the same body of water as the intake water, and could be applied for up to 12 years after publication of the final Guidance. After that time, if a TMDL or comparable plan that meets the requirements of procedure 3 of appendix F has not been completed, the facility's WQBEL must be established in accordance with the "baseline" provisions in procedure 5.F.2 of appendix F. This time limit provides a period of relief for dischargers that are not causing increased impacts on the waterbody by virtue of their discharge that would not have occurred had the pollutant remained in-stream, while maintaining the incentive for development of a comprehensive assessment and remediation plan for achieving attainment of water quality standards, which EPA believes is a critical element of the final Guidance for addressing pollutants for which a large contributor to non-attainment is nonpoint source pollution.

The final Guidance allows States and Tribes to address intake pollutants in a manner consistent with assessment and remediation plans that have been developed through mechanisms other than TMDLs in order to provide flexibility where such plans comprehensively address the point and non-point sources of non-attainment in a waterbody and the means for attaining compliance with standards.

EPA believes that 12 years provides sufficient time for States to develop and complete the water quality assessments that would serve as the basis for establishing effluent limits (including "no net addition" limits, where appropriate) under procedure 3.A of appendix F. However, EPA also recognizes that unforeseen events could delay State completion of these assessments, and therefore will, at 7 years following promulgation, in consultation with the States, evaluate the progress of the assessments. If this evaluation shows that completion of the assessments may not be accomplished by the 12 year date, EPA will revisit these provisions, and consider proposing extensions if appropriate.

Under the final Guidance, the permitting authority can permit the discharge of intake pollutants to a different body of water that is in non-attainment provided limitations require the discharge to meet a WQBEL for the pollutant equal to the pollutant's water quality criterion. Because inter-waterbody transfers of pollutants introduce pollutants to the receiving water that would not be present in that waterbody in the absence of the facility's discharge, EPA does not believe that relief for such pollutants comparable to the "no net addition" approach would be appropriate. However, to address the concern raised by commenters about facilities with multiple sources of intake water, the permitting authority may use a flow-weighted combination of these approaches when the facility has co-mingled sources of intake water from the same and different bodies of water.

EPA maintains that the preferred approach to deal with non-attainment waters, particularly when multiple sources contribute a pollutant for which the receiving water exceeds the applicable criterion, is development of a TMDL or comparable assessment and remediation plan. The above “no net addition” permitting approach provides additional flexibility in situations where a TMDL or comparable plan has not yet been developed. Other existing relief mechanisms include variances to water quality standards, removal of non-existing uses, and site-specific criteria.

7. WET

(Procedure 6 of appendix F to part 132; section VIII.F of the SID)
Existing EPA regulations define WET as “the aggregate toxic effect of an effluent measured directly by a toxicity test.” These regulations require WET limits to be included in permits in most circumstances in which the WET of a discharge has the reasonable potential to cause or contribute to an in-stream excursion above either a State's numeric criteria for toxicity or narrative criteria for water quality (40 CFR 122.2, 122.44(d)(1)). The regulations allow States and Tribes the flexibility to control for WET with either numeric or narrative criteria. Current technical guidelines recommend that no discharge should exceed 0.3 acute toxic units (TUa = 100/LC50) at the edge of an acute mixing zone and 1.0 chronic toxic units (TUc = 100/NOEC, the No Observed Effect Concentration) at the edge of a chronic mixing zone.

The proposed Guidance would have continued to allow States and Tribes the flexibility to choose to control WET with either numeric or narrative criteria, but specified that no discharge could exceed 1.0 TU_a at the point of discharge (i.e., no acute mixing zones) and 1.0 TU_c at the edge of a chronic mixing zone (with some exceptions). In addition, the proposal contained minimum requirements for appropriate test methods to measure WET and for permit conditions, and procedures for determining whether or not limits for WET are necessary.

The final Guidance differs principally from the proposal in requiring States and Tribes to adopt 0.3 TU_a and 1.0 TU_c either as numeric criteria or as an equivalent numeric interpretation of narrative criteria. The final Guidance also allows the use of acute mixing zones for the application of the acute criterion. This approach will promote consistency among States and Tribes in controlling WET, while still permitting considerable flexibility regarding implementation measures, consistent with current National policies and guidelines.

***15379 8. Loading Limits**

(Procedure 9 of appendix F to part 132; section VIII.G of the SID)
The final Guidance provides that WQBELs be expressed in terms of both concentration and mass loading rate, except for those pollutants that cannot appropriately be expressed in terms of mass. These provisions clarify the application of existing Federal regulations at 40 CFR 122.45(f), and are consistent with current EPA guidance which requires the inclusion of any limits determined necessary based on best professional judgment to meet water quality standards, including, where appropriate, mass loading rate limits. They are also consistent with the antidegradation policy for the Great Lakes System in appendix E of the final Guidance.

9. Levels of Quantification

(Procedure 8 of appendix F to part 132; section VIII.H of the SID)
Many of the pollutants of concern in the Great Lakes System cause unacceptable toxic effects at very low concentrations. This results in instances where WQBELs are below levels of reliable quantification. When this occurs, the permitting authority may not be able to determine whether the pollutant concentration is above or below the WQBEL. The final Guidance requires adoption of pollutant minimization programs (PMPs) for such permits to increase the likelihood that the concentration of the pollutant is as close to the effluent limit as possible. The PMP is an ongoing, iterative process that requires, among other things,

internal wastestream monitoring and submission of status reports. The use of PMPs for facilities with pollutants below the level of quantification is consistent with existing EPA guidance.

Unlike the proposal, however, the final Guidance eliminates additional minimum requirements for BCCs. For example, the final Guidance recommends but does not require bio-uptake studies that had been proposed to assess impacts to the receiving water and evaluate the effectiveness of the PMP.

10. Compliance Schedules

(Procedure 9 of appendix F to part 132; section VIII.I of the SID)
The final Guidance includes a procedure that allows Great Lakes States and Tribes to include schedules of compliance in permits for existing Great Lakes dischargers for effluent limitations based on new water quality criteria and certain other requirements. Generally, compliance schedules may provide for up to five years to comply with the effluent limitation in question and may, in specified cases, allow the compliance schedule to go beyond the term of the permit. Existing Great Lakes dischargers are those whose construction commenced before March 23, 1997. Thus the term, existing Great Lakes discharges, covers expanding dischargers who were ineligible for compliance schedules under the proposal. The final Guidance also provides the opportunity for States and Tribes to allow dischargers additional time to comply with effluent limitations based on Tier II values while conducting studies to justify modifications of those limitations.

C. Antidegradation Provisions

(§132.4(a)(6); appendix E to part 132; section VII of the SID)
EPA's existing regulations, at 40 CFR 131.6, establish an antidegradation policy as one of the minimum requirements of an acceptable water quality standards submittal. Section 131.12 describes the required elements of an antidegradation policy. These are: protection of water quality necessary to maintain existing uses, protection of high quality waters (those where water quality exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the waters) and protection of water quality in those water bodies identified as outstanding National resources.

The proposed Guidance provided detailed procedures for implementing antidegradation that were not part of the existing regulations. The detailed implementation procedures were intended to result in greater consistency in how antidegradation was applied throughout the Great Lakes System. The proposed Guidance specified, among other things, how high quality waters should be identified, what activities should and should not require review under antidegradation, and the information necessary to support a request to lower water quality and the procedures to be followed by a Tribe or State in making a decision whether or not to allow a lowering of water quality.

The final Guidance maintains the overall structure of the proposed Guidance while allowing Tribes and States greater flexibility in how antidegradation is implemented. As in the proposal, the final Guidance is composed of an antidegradation standard, antidegradation implementation procedures, antidegradation demonstration and antidegradation decision. However, many of the detailed requirements found in the proposed Guidance appear in the SID accompanying the final Guidance as nonbinding guidelines, including provisions specific to non-BCCs.

Key elements of the proposed Guidance that are retained in the final Guidance for BCCs include: identification of high quality waters on a pollutant-by-pollutant basis; requirements for States and Tribes to adopt an antidegradation standard consistent with the final Guidance for BCCs; minimum requirements for conducting an antidegradation review of any activity expected to result in a significant lowering of water quality due to BCCs, minimum requirements for notifying permitting authorities of increases in discharges of BCCs; and, minimum requirements for an antidegradation demonstration consisting of a pollution prevention analysis, an alternative treatment analysis and a showing that the significant lowering of water quality will allow for important social and economic development. Significant changes from the proposed Guidance include: encouraging, but not

requiring, States and Tribes to adopt provisions consistent with the antidegradation standard and implementation procedures for non-BCCs; replacement of numeric existing effluent quality-based (EEQ) limits as a means of implementing antidegradation for BCCs with a narrative description of the types of activities that will trigger an antidegradation review; and greater flexibility in the implementation, demonstration and decision components. A detailed discussion of the basis for each of the changes is provided in Section VII the SID.

D. Regulatory Requirements

(Part 132; Tables 5 and 6 to part 132; section II of the SID)
The Great Lakes States must adopt water quality standards, anti-degradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of this publication. If a Great Lakes State fails to adopt such standards, policies, and procedures, section 118(c)(2)(C) of the CWA requires EPA to promulgate them not later than the end of that two-year period. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into its water program.

Part 132 establishes requirements and procedures to implement section 118(c)(2)(C). Sections 132.3 and 132.4 ***15380** require Great Lakes States and Tribes to adopt criteria, methodologies, policies, and procedures consistent with the criteria, methodologies, policies, and procedures contained in part 132—that is, the definitions in §132.2, the numeric criteria in Tables 1 through 4, the criteria development methodologies in appendixes A through D, the antidegradation policy in appendix E, and the implementation procedures in appendix F. Section 132.5 specifies the procedures for States and Tribes to make their submissions to EPA, and for EPA to approve or disapprove the submissions. The section specifies that in reviewing submissions, EPA will consider provisions of State and Tribal submissions to be "consistent with" the final Guidance if each provision is as protective as the corresponding provision of the final Guidance. If a State or Tribe fails to make a submission, or if provisions of the submission are not consistent with the final Guidance, §132.5 provides that EPA will publish a final rule in the Federal Register identifying the final Guidance provisions that will apply to discharges within the particular State or Federal Indian Reservation.

Section 132.4 specifies that water quality criteria adopted by States and Tribes consistent with the final Guidance will apply to all waters of the Great Lakes System, regardless of designated uses of the waters in most cases, with some variations in human health criteria depending on whether the waters are designated for drinking water use. Section 132.4 also contains certain exceptions in applying the final Guidance methodologies and procedures. First, States and Tribes do not have to adopt and apply the final Guidance methodologies and procedures for the 14 pollutants listed in Table 5 of part 132. EPA believes that some or all of the methodologies and procedures are not scientifically appropriate for these pollutants. Second, if a State or Tribe demonstrates that the final Guidance methodologies or procedures are not scientifically defensible for a particular pollutant, the State or Tribe may use alternate methodologies or procedures so long as they meet all applicable Federal, State, and Tribal laws. Third, §132.4 specifies that for wet-weather point sources, States and Tribes generally do not have to adopt and apply the final Guidance implementation procedures. The exception is the TMDL general condition for wet weather events. Fourth, pursuant to section 510 of the CWA, part 132 specifies that nothing in the final Guidance prohibits States or Tribes from adopting provisions more stringent than the final Guidance.

As discussed further in section IX of this preamble, §132.4 also provides that State and Tribal submissions will need to include any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation with the U.S. Fish and Wildlife Service (FWS) under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to any endangered or threatened species listed under the ESA.

Part 132 extends the requirements of section 118(c)(2)(C) to Indian Tribes within the Great Lakes basin for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA. EPA believes that inclusion of Great Lakes Tribes in this way is necessary and appropriate to be

consistent with section 518 of the CWA. The reasons for EPA's proposal are discussed further in the preamble to the proposed Guidance (58 FR 20834), and section II.D.3 of the SID. As a practical matter, no Great Lakes Tribes currently have approved water quality standards or authorized NPDES programs, so the submission requirements of part 132 do not apply to any Great Lakes Tribes. Tribes that are approved or authorized in the future, however, will need to adopt provisions consistent with the final Guidance in their water programs.

V. Costs, Cost-Effectiveness and Benefits

(Section IX of the SID)
Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it raises novel policy issues arising out of the development of a comprehensive ecosystem-based approach for a large geographic area involving several States, Tribal governments, local governments, and a large number of regulated dischargers. This approach, including the Great Lakes Water Quality Initiative which developed the core concepts of the final Guidance, is a unique and precedential approach to the implementation of environmental programs. As such, this action was submitted to OMB for review pursuant to Executive Order 12866. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

The following is a summary of major elements of the "Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance" (RIA) (EPA 820-B-95-011) that has been prepared in compliance with Executive Order 12866. Further discussion is included in section IX of the SID, and in the full RIA, which is available in the docket for this rulemaking.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. Therefore, this publication of the final Guidance does not have an immediate effect on dischargers. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect on any dischargers. For the purposes of the RIA, EPA's analysis of costs and benefits assumes that either State or EPA promulgations occur consistent with the final Guidance within the next two years.

Under the CWA, costs cannot be a basis for adopting water quality criteria that will not be protective of designated uses. If a range of scientifically defensible criteria that are protective can be identified, however, costs may be considered in selecting a particular criterion within that range. Costs may also be relevant under the antidegradation standard as applied to high quality waters.

EPA has assessed compliance costs for facilities that could be affected by provisions adopted by States or Tribes consistent with the final Guidance. EPA has also assessed basin-wide risk reduction benefits to sport anglers and Native American subsistence

anglers in the basin, and benefits for three case study sites in the Great Lakes System. ***15381** The methodology used in each assessment and the results of these assessments are discussed below.

EPA solicited public comment and supporting data on the RIA methodology used to estimate both costs and benefits for implementation of the proposed Guidance. EPA evaluated these comments and supporting data as well as comments provided by OMB and revised the RIA methodology prior to performing these assessments for the final Guidance.

A. Costs

Based on the information provided by each State and a review of the permit files, EPA identified about 3,800 direct dischargers that could be affected by State or Tribal adoption or subsequent EPA promulgation, if necessary, of requirements consistent with the final Guidance. Of these, about 590 are major dischargers and the remaining 3,210 are minor dischargers. Of the 590 majors, about 275 are industrial facilities and 315 are publicly owned treatment works (POTWs). Out of these dischargers, EPA used a stratified random sampling procedure to select 59 facilities (50 major and nine minor) that it considered representative of all types and sizes of facilities in the basin.

EPA divided the major facilities into nine industrial categories and a category for POTWs. The nine industrial categories are: mining, food and food products, pulp and paper, inorganic chemical manufacturing, organic chemical manufacturing/petroleum refining, metals manufacturing, electroplating/metal fabrication, steam electric power plants, and miscellaneous facilities.

For each major and minor facility in the sample, EPA estimated incremental costs to comply with subsequently promulgated provisions consistent with the final Guidance, using a baseline of compliance with the requirements of section 303(c)(2)(B) of the CWA. Using a decision matrix, costs were developed for two different scenarios—a “low-end” cost scenario and a “high-end” cost scenario—to account for the range of regulatory flexibility available to States and Tribes when adopting and implementing provisions consistent with the final Guidance. In addition, the decision matrix specified assumptions used for selection of control options in the cost analysis such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and “end of pipe” effluent treatment.

The annualized costs for direct and indirect dischargers to implement the final Guidance are estimated to be between $60 million (low end) and $380 million (high end) (first quarter 1994 dollars). EPA believes the costs for implementing the final Guidance, which balance pollution prevention, “end-of-pipe” treatment and regulatory flexibility, will approach the low end of the cost range. Costs are unlikely to reach the high end of the cost range because State and Tribal authorities are likely to choose implementation options that provide some degree of relief to point source dischargers, especially because in many cases the nonpoint source contributions will be significant. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because in cases where the final Guidance provides States and Tribes flexibility in selecting less costly approaches when implementing provisions consistent with the final Guidance, the most costly approach was used to estimate the costs. This approach was used to reduce uncertainty in the cost analysis for the final Guidance.

Under the low-end cost scenario, major industrial facilities and POTWs would account for about 65 percent of the costs, indirect dischargers about 33 percent, and minor dischargers about two percent. Among the major dischargers three categories would account for most of the costs—POTWs (39 percent), pulp and paper (14 percent), and miscellaneous (eight percent). The average per plant costs for different industry categories range from zero to $168,000. The two highest average cost categories are pulp and paper ($151,000) and miscellaneous ($168,000). Although major POTWs make up a large portion of the total cost, the average cost per plant under the low-end scenario is not among the highest at $75,000 per facility. About half of the low-end costs are associated with pollution prevention activities, and about half are for capital and operating costs for wastewater treatment.

For the high-end cost scenario, direct dischargers account for 98 percent of the total estimated cost, and indirect dischargers account for two percent. This shift in proportion of costs between direct and indirect dischargers and between the low and the high estimates are due to the assumption that more direct dischargers will need to use end-of-pipe treatment under the high-end

scenario. In addition, it was assumed that a smaller proportion of indirect dischargers (10 percent) would be impacted under the high-end scenario, since municipalities are adding end-of-pipe treatment which should reduce the need for source controls (i.e., reduce the need for increased pretreatment program efforts) by indirect discharges. Less than 10 percent of the high-end costs are associated with pollution prevention activities, and over 90 percent are for capital and operating costs for wastewater treatment.

Under the high-end scenario for the direct dischargers, municipal major dischargers are expected to incur just under 70 percent of total costs, and industrial major dischargers account for 29 percent of total costs. Minor direct dischargers are estimated to incur less than one percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (23 percent of total) and miscellaneous (three percent) categories. The food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

Under the high-end scenario, the average annual cost per major municipal facility is just over $822,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for pulp and paper ($1,583,000 per plant) and miscellaneous ($433,700 per plant) categories. Regardless of the scenario, the average costs for minor facilities are negligible at an estimated $500 per facility.

The costs described above account for the costs of eliminating mixing zones for BCCs except in narrow circumstances, costs related to implementation of Tier II values, and specific calculated costs related to intake credits. The cost assessment also projects the potential cost savings across the different scenarios that facilities may realize if States or Tribes use existing regulatory relief mechanisms to modify or eliminate the need for a WQBEL for an identified pollutant (e.g., variances, TMDLs, site-specific modifications to criteria, and changes in designated uses).

In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a “lost opportunity” cost for facilities impacted by the antidegradation requirements. This cost could result in the addition of about $22 million each year.

B. Cost-Effectiveness

EPA estimated the cost-effectiveness of the final Guidance in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness (cost per pound removed) is derived by dividing the annualized costs of implementing the final ***15382** Guidance by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

It is estimated that implementation of provisions consistent with the final Guidance would be responsible for the reduction of about six to eight million toxic pounds per year, or 16 to 22 percent of the toxic-weighted baseline for the low- and high-end scenarios, respectively. The cost-effectiveness of the scenarios, over the baseline, is quite good, ranging from $10 to $50 per pound-equivalent.

Approximately 80 percent of the pollutant load reduction from implementation of the final Guidance, regardless of the scenario, is attributable to reducing BCCs as a result of PMPs and end-of-pipe treatment. The largest pollutant load reductions occur for chlordane, dieldrin, heptachlor, lead, and pentachlorobenzene.

In a separate analysis, EPA also investigated the cost-effectiveness of regulating point and nonpoint sources of mercury and PCBs, two contaminants associated with fish advisories in the Great Lakes basin. Although data and resource constraints limited the findings from these analyses, the preliminary results indicate that point sources may factor cost-effectively into pollutant reduction scenarios. For both contaminants, the cost-effectiveness of point and nonpoint source controls are likely to be highly site-specific.

C. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of implementation of provisions adopted by States and Tribes consistent with the final Guidance. To the extent feasible, empirical estimates of the potential magnitude of the benefits are developed and then compared to the estimated costs of implementing provisions adopted by States and Tribes consistent with the final Guidance.

The benefits analysis is based on a case study approach, using benefits transfer applied to three case studies. The case study approach was used because it is more amenable to meaningful benefit-cost analyses than are studies of larger aggregate areas. Although the results obtained for a case study site may not apply uniformly to the entire Great Lakes basin, the case study approach does provide a pragmatic and realistic perspective of how implementation of the final Guidance can generate benefits, the types of benefits anticipated, and how these benefits compare to costs.

The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio. The case studies were selected from a list of candidate sites (i.e., designated Areas of Concern (AOCs) in the Great Lakes basin) on the basis of data availability and the relevance of the water quality problems to the final Guidance (i.e., areas in which problems were more likely to be associated with on-going point source discharges rather than historic loadings from Superfund sites and other sources). Geographic diversity was also considered in selecting the sites so that the analyses might better promote a broad perspective of the final Guidance's benefits and costs.

For each of the three case studies, EPA estimated future toxics-oriented water quality benefits, and then attributed a percentage of these benefits to implementation of the final Guidance. The attribution of benefits was based only on the estimated reduction in loadings from point sources at the case study sites and information on the relative contribution of point sources to total loadings in the basin. EPA did not attempt to calculate the longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water.

In the Fox River and Green Bay case study, total annual undiscounted benefits attributable to the final Guidance range from $0.3 million to $8.5 million (first quarter 1994 dollars). Human health benefits account for between 29 percent and 72 percent of the estimated benefits, recreational fishing accounts for between eight percent and 45 percent, and nonuse/ecologic benefits account for between nine percent and 23 percent. Municipal and industrial dischargers in this case study are estimated to incur annualized costs of about $3.6 million.

In the Saginaw River/Bay case study, total annual undiscounted benefits range from $0.2 million to $7.7 million. Recreational fishing benefits account for between 36 percent and 60 percent of the estimated benefits, non-use benefits account for between 18 percent and 30 percent, and human health benefits account for between eight percent and 36 percent. Total annualized costs to municipal and industrial dischargers are estimated to be about $2.6 million.

In the Black River case study, total annual undiscounted benefits range from $0.4 million to $1.5 million. Recreational fishing benefits account for between 48 percent and 63 percent of the estimated benefits, and nonuse benefits account for between 32 percent and 44 percent. Total annualized costs to municipal and industrial dischargers are estimated to be $2.1 million.

An inherent limitation of the case study approach is the inability to extrapolate from a limited set of river-based sites to the Great Lakes basin as a whole. Accordingly, extrapolation of the case study results to the Great Lakes basin is not recommended. However, as noted above, the three case studies were selected on the basis of data availability, the relative importance of point source discharges to the watersheds' problems, and an attempt to portray spatial diversity throughout the Great Lakes basin. Thus, there is no reason to conclude that the selected sites are not reflective of the basin, even though benefits (and costs) tend to be highly site-specific. In addition, the benefits extend from the case study rivers into the larger, open-water environment of the Great Lakes.

The representativeness of the case study sites was assessed by comparing the percentage of total benefits estimated to accrue in the case study areas to the percentage of basin-wide costs incurred by the case study sites. Benefits-related measures (such as population, recreational angling days, and nonconsumptive recreation days) were used in place of total benefits for this analysis because there is no estimate of benefits for the entire Great Lakes basin. The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e., basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest). Thus, the three case studies may represent a reasonably proportionate share of costs and benefits.

In addition to the case study analyses, a basin-wide risk assessment was conducted for Great Lakes anglers. EPA collected data and information on the consumption of Great Lakes basin fish to estimate baseline risk levels and reductions in risks due to implementation of the final Guidance for two populations at risk: Great Lakes sport anglers (including minority and ***15383** low-income anglers) and Native Americans engaged in subsistence fishing in the basin. For sport anglers, EPA estimated that the projected reduction in loadings from point sources based on controls consistent with the final Guidance would result in a reduction of annual excess lifetime cancer cases (potential cancer cases assuming a 70-year lifetime exposure period) of 2.2 to 4.1 for low-income minorities in lakeshore counties; 0.4 to 0.8 for other minorities in lakeshore counties; and 21.9 to 41.9 for all other sport anglers. For Native American subsistence anglers, EPA estimated that reductions from point source loadings attributable to the final Guidance would result in a reduction of excess lifetime cancer cases of between 0.1 and 0.3 using a low fish ingestion scenario and 0.5 to 1.1 using a high fish ingestion scenario. Note that these estimates do not include the long-term benefits (including reduced cancer cases) that will result once the final Guidance provisions are fully implemented and the minimum protection levels are attained in the ambient water.

In total, using the most conservative consumption scenario for Native Americans, these reductions represent between 0.35 and 0.67 excess cancer cases per year, and potential basin-wide benefits of the final Guidance for this one benefits category of between $0.7 million and $6.7 million per year, based on the estimated value of a statistical life of between $2.0 million and $10.0 million. Comparison to case study results, which were based on a more comprehensive sample of facilities within case study areas than was possible for the entire basin, indicates these values likely underestimate the potential risk reduction benefits of the final Guidance at the basin level. For example, if the average percentage load reduction for PCBs for the three case studies is used to reflect reductions in PCBs for the basin, the reduction in excess cancer cases increases to between three and six cases per year, and potential benefits increase to between $6.6 and $60 million per year.

The reduction in pollutant loadings for PCBs was likely understated in the basin-wide analysis because the analysis did not count pollutant load reduction benefits when the current State-based permit limit and the final Guidance-based permit limit were both below the pollutant analytical method detection limit (MDL). Only three sample facilities in the population of 59 sample facilities used to project basin-wide costs and human health benefits had State-based permit limits for PCBs. Since the current State-based permit limit and the final Guidance-based permit limit were below the MDL in all three facilities, “zero” reduction in PCB loadings for the basin was estimated. This, of course, is an artifact of the methodology and the size of the sample population selected for the analysis, and would not occur, as demonstrated in the case study analysis, if a larger sample population had been used.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), EPA generally is required to conduct a final regulatory flexibility analysis (FRFA) describing the impact of the regulatory action on small entities as part of the final rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a FRFA.

Implementation of the final Guidance is dependent upon future promulgation of provisions consistent with it by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions, or equally protective provisions consistent with the final Guidance, there will be no economic effect of this rule on any entities, large or small. For

that reason, and pursuant to Section 605(b) of the RFA, EPA is certifying that this rule itself will not have a significant economic impact on a substantial number of small entities.

Although EPA is certifying that this rule will not have a significant economic impact on a substantial number of small entities, and therefore is not required to prepare a FRFA, it is nevertheless including for public information in the RIA a discussion of the possible economic effects to small entities that could result from State or Tribal adoption of provisions consistent with the final Guidance or subsequent EPA promulgation, if necessary. As discussed above, small facilities are projected to incur costs of only approximately $500 per facility to comply with subsequently promulgated requirements that are consistent with the final Guidance. Accordingly, EPA believes there will be no significant economic impact on a substantial number of small entities as a result of State or Tribal implementation of the final Guidance.

VII. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875 (58 FR 58093, October 28, 1993), EPA has involved State, Tribal, and local governments in the development of the final Guidance.

As described in section II above, the core elements of the final Guidance were developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem over a five-year period through the Initiative. The Initiative process marks the first time that EPA has developed a major rulemaking effort in the water program through a regional public forum. The Initiative process is described further in the preamble to the proposed Guidance (58 FR 20820-23) and section II of this preamble.

In addition to the participation by State and local governments in the initial development of the proposed Guidance and in the public comment process, several activities have been carried out since the publication of the proposed Guidance. These include:

(1) On April 26, 1994, EPA held a public meeting to solicit additional information from interested parties on the proposed Guidance. As part of EPA's outreach efforts to State, Tribal and local governments, a special invitation was sent inviting elected officials and other State, Tribal and local representatives to participate in the public meeting. EPA specifically welcomed Tribal and local officials and opened the floor to them to hear and discuss their specific concerns and views on the final Guidance.

(2) A series of meetings and teleconferences were held with Great Lakes States in early 1994 to discuss their comments on several issues, including development of water quality criteria, State adoption requirements, WET, BAFs, additivity, compliance schedules, anti-backsliding, nonpoint sources, and international concerns.

(3) In October, 1994, EPA met with each individual State in the Great Lakes basin to discuss the nature, form, and scope of the proposed Guidance, and State concerns with implementation of the provisions under consideration. The following issues were discussed at each of the meetings: intake credits, antidegradation and EEQ, wildlife criteria, excluded pollutants (e.g., ammonia and chlorine), elimination of mixing zones, site-specific modifications, fish consumption, appropriate degrees of flexibility for implementation (e.g., guidance vs. regulation), and implementation procedures.

(4) In 1994 and 1995, EPA met with representatives of the National Wildlife Federation to discuss EPA's activities in developing the final Guidance in ***15384** accordance with the terms of a consent decree governing the schedule for development of the final Guidance.

(5) In 1994, EPA also met with elected officials and other representatives from several local communities in the Great Lakes basin to discuss issues regarding the economic impact of the proposed Guidance on local communities and POTWs. Issues discussed include cost impacts associated with implementing water quality criteria, methodologies, and implementation procedures; dealing with pollution from nonpoint sources; public outreach to control pollutants such as mercury instead of costly end-of-pipe treatment; and applicability of provisions in the final Guidance to the National water quality program.

(6) EPA held an additional 18 consultations with the regulated community throughout 1994. Such meetings allowed representatives of dischargers to share additional data, which has been placed in the docket for this rulemaking, and concerns about a range of issues, including cost concerns, that the dischargers expect to arise in implementation of the final Guidance.

(7) In 1994, EPA met with State representatives to conduct initial planning for implementation of the GLI Clearinghouse. All Great Lakes States agreed to participate in this effort, which will involve the sharing of toxicological and other data to assist in the development of additional water quality criteria and values.

The results of the above efforts have assisted in the development of the final Guidance through broad communication with a full range of interested parties, sharing of additional information, and incorporation of features to improve the implementation of the final Guidance.

EPA has estimated the total annual State government burden to implement the final Guidance as approximately 5,886 hours, resulting in a State government cost of $175,992 annually. Such burden and costs were estimated based upon the burden and costs associated with developing water quality criteria, review of antidegradation policy demonstrations, review of approvable control strategies and BCC monitoring data, and review of variance requests. The total annual local government burden is estimated to be 42,296 hours with an associated cost of $2,008,624. All of the burden and costs to local governments are associated with being a regulated entity as an operator of a POTW.

VIII. Paperwork Reduction Act

The information collection requirements in this final Guidance have been approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned OMB control number 2040-0180. EPA has prepared an Information Collection Request (ICR) document (ICR No. 1639.02). A copy of ICR 1639.02 may be obtained by writing to Ms. Sandy Farmer, Information Policy Branch, EPA 2136, Washington, D.C. 20460, or by calling (202) 260-2740.

The annual public reporting and record keeping burden for this regulation is estimated to be 128,787 hours for the affected 3,795 permittees, or an average of 34 hours. This includes the total annual burden to local governments as POTW operators, estimated to be 45,296 hours. The total annual burden to State governments is estimated to be 5,886 hours. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

In this rulemaking EPA is also amending the table of currently approved ICR control numbers issued by OMB for various regulations into 40 CFR 9.1. This amendment updates the table to accurately display those information requirements promulgated under the CWA. The affected regulations are codified at 40 CFR parts 122, 123, 131, and 132. EPA will continue to present OMB control numbers in a consolidated table format. The table will be codified in 40 CFR part 9 of EPA's regulations and in each 40 CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

The ICR for this rulemaking was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is “good cause” under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

IX. Endangered Species Act

Pursuant to section 7(a)(2) of the ESA, EPA consulted with the FWS concerning EPA's publication of the final Guidance. EPA and the FWS have now completed both informal and formal consultation conducted over a two-year period.

As a result of the consultation, as well as an analysis of comments, EPA modified several provisions of the final Guidance. The procedure for site-specific modifications provides that Great Lakes States and Tribes must make site-specific modifications to criteria and values where necessary to ensure the resulting water quality does not cause jeopardy to listed or proposed species. Similarly, the antidegradation policy and implementation procedures restrict certain actions States and Tribes may take to allow lowering of water quality in high quality waters, or to adopt variances or mixing zones. Additionally, the regulatory requirements were modified to require Great Lakes States and Tribes to include in their part 132 submissions any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to listed species. EPA and the FWS also agreed on how further consultations will be conducted as the final Guidance is implemented. The two agencies also agreed that EPA will undertake a review of water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA.

During the consultation, two issues were identified that required formal consultation, as defined in 40 CFR part 402. These issues were: the absence of toxicological data concerning effects of contaminants on three species of freshwater mussels in the Great Lakes basin, and the adequacy of the wildlife criteria methodology to protect three endangered or threatened wildlife species in the basin. On February 21, 1995, the FWS provided EPA with a written Biological Opinion (Opinion) on these issues. The Opinion is available in the docket for this rulemaking. On both issues, the FWS concluded that the water quality resulting from implementation of the final Guidance will not cause jeopardy to the listed species. To minimize the amount or extent of any incidental take that might ***15385** occur, the FWS consulted closely with EPA to develop a coordinated approach. The final Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact. EPA has agreed to implement the measures, and the FWS and EPA will continue to work cooperatively during the implementation.

X. Judicial Review of Provisions Not Amended

In some situations, EPA has renumbered or included other editorial changes to regulations that have been promulgated in past rulemakings. Additionally, to provide for ease in reading changes to existing regulations, EPA has in some cases repeated entire sections, including portions not changed. The promulgation of this final rule, however, does not provide another opportunity to seek judicial review on the substance of the existing regulations.

XI. Supporting Documents

All documents that are referenced in this preamble are available for inspection and photocopying in the docket for this rulemaking at the address listed at the beginning of this preamble. A reasonable fee will be charged for photocopies.

Selected documents supporting the final Guidance are also available for viewing by the public at locations listed below:

Illinois: Illinois State Library, 300 South 2nd Street, Springfield, IL 62701 (217-785-5600)

Indiana: Indiana Department of Environmental Management, Office of Water Management, 100 North Senate Street, Indianapolis, IN 46204 (317-232-8671)

Michigan: Library of Michigan, Government Documents Service, 717 West Allegan, Lansing, MI 48909 (517-373-1300); Detroit Public Library, Sociology and Economics Department, 5201 Woodward Avenue, Detroit, MI 48902 (313-833-1440)

Minnesota: Minnesota Pollution Control Agency, Library, 520 Lafayette, St. Paul, MN (612-296-7719)

New York: U.S. EPA Region 2 Library, Room 402, 26 Federal Plaza, New York, NY 10278 (212-264-2881); U.S. EPA Public Information Office, Carborundum Center, Suite 530, 345 Third Street, Niagara Falls, NY 14303 (716-285-8842); New York State Department of Environmental Conservation (NYSDEC), Room 310, 50 Wolf Road, Albany, NY 12333 (518-457-7463); NYSDEC, Region 6, 7th Floor, State Office Building, 317 Washington Street, Watertown, NY 13602 (315-785-2513); NYSDEC, Region 7, 615 Erie Boulevard West, Syracuse, NY 13204 (315-426-7400); NYSDEC, Region 8, 6274 East Avon-Lima Road, Avon, NY 14414 (716-226-2466); NYSDEC, Region 9, 270 Michigan Avenue, Buffalo, NY 14203 (716-851-7070)

Ohio: Ohio Environmental Protection Agency Library—Central District Office, 1800 Watermark Road, Columbus, OH 43215 (614-644-3024); U.S. EPA Eastern District Office, 25809 Central Ridge Road, Westlake, OH 44145 (216-522-7260)

Pennsylvania: Pennsylvania Department of Environmental Resources, 230 Chestnut Street, Meadville, PA 16335 (814-332-6945); U.S. EPA Region 3 Library, 8th Floor, 841 Chestnut Building, Philadelphia, PA 19107-4431 (215-597-7904)

Wisconsin: Water Resources Center, University of Wisconsin-Madison, 2nd Floor, 1975 Willow Drive, Madison, WI (608-262-3069)

EPA is also making a number of documents available in electronic format at no incremental cost to users of the Internet. These documents include the contents of this Federal Register document, the SID, many documents listed below, and other supporting materials.

The documents listed below are also available for a fee upon written request or telephone call to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161 (telephone 800-553-6847 or 703-487-4650). Alternatively, copies may be obtained for a fee upon written request or telephone call to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, OH 43212 (614-292-6717). When ordering, please include the NTIS or ERIC/CSMEE accession number.

A. Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID). NTIS Number: PB95187266. ERIC Number: D046.

B. Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water. NTIS Number: PB95187282. ERIC Number: D048.

C. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. NTIS Number: PB95187290. ERIC Number: D049.

D. Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. NTIS Number: PB95187308. ERIC Number: D050.

E. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values. NTIS Number: PB95187316. ERIC Number: D051.

F. Great Lakes Water Quality Initiative Criteria Document for the Protection of Wildlife: DDT; Mercury; 2,3,7,8-TCDD; PCBs. NTIS Number: PB95187324. ERIC Number: D052.

G. Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria. NTIS Number: PB95187332. ERIC Number: D053.

H. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187340. ERIC Number: D054.

I. Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187357. ERIC Number: D055.

List of Subjects

40 CFR Part 9
Reporting and recordkeeping requirements.

40 CFR Part 122
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 131
Great Lakes, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 132
Administrative practice and procedure, Great Lakes, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 13, 1995.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 9, 122, 123, and 131 are amended, and part 132 is added as follows:

***15386 PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**
1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.
40 CFR § 9.1

2. Section 9.1 is amended as follows:

a. By adding in numerical order the entry “122.44(r)” under the heading “EPA Administered Permit Programs: The National Pollutant Discharge Elimination System”.

b. By revising the entries under the heading “State Permit Requirements”;

c. By adding in numerical order the entries “131.1” and “131.5” and by revising the entries “131.20”, “131.21” and “131.22” under the heading “Water Quality Standards Regulations”; and

d. By adding in numerical order a new heading and new entries for “Water Quality Guidance for the Great Lakes System” to read as follows:

40 CFR § 9.1

§9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
EPA Administered Permit Programs: The National Pollutant Discharge Elimination System	
* * * * *	
122.44(r)	2040-0180
* * * * *	
State Permit Requirements	
123.21-123.24	2040-0057, 2040-0170
123.25	2040-0004, 2040-0110, 2040-0170, 2040-0180
123.26-123.29	2040-0057, 2040-0170
123.43	2040-0057, 2040-0170
123.44	2040-0057, 2040-0170, 2040-0180

123.45	2040-0057, 2040-0170
123.62	2040-0057, 2040-0170, 2040-0180
123.63	2040-0057, 2040-0170, 2040-0180
123.64	2040-0057, 2040-0170

Water Quality Standards Regulation

131.1	2040-0180
131.5	2040-0180

* * * * *

131.20	2040-0049
131.21	2040-0049, 2040-0180
131.22	2040-0049

* * * * *

Water Quality Guidance for the Great Lakes System

132.1	2040-0180
132.2	2040-0180
132.3	2040-0180
132.4	2040-0180
132.5	2040-0180
Appendix A	2040-0180
Appendix B	2040-0180
Appendix C	2040-0180
Appendix D	2040-0180

Appendix E	2040-0180
Appendix F	2040-0180

* * * * *

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

3. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 122.44

4. Section 122.44 is amended by adding a new paragraph (r) to read as follows:

40 CFR § 122.44

§122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see §123.25).

* * * * *

(r) Great Lakes. When a permit is issued to a facility that discharges into the Great Lakes System (as defined in 40 CFR 132.2), conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

PART 123—STATE PROGRAM REQUIREMENTS

5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 123.25

6. Section 123.25 is amended by removing “and” at the end of paragraph (a)(36), removing the period at the end of paragraph (a)(37) and adding “; and” in its place, and adding a new paragraph (a)(38) to read as follows:

40 CFR § 123.25

§123.25 Requirements for permitting.

(a) * * *

(38) For a Great Lakes State or Tribe (as defined in 40 CFR 132.2), 40 CFR part 132 (NPDES permitting implementation procedures only).

* * * * *40 CFR § 123.44

7. Section 123.44 is amended by adding a new paragraph (c)(9) to read as follows:

40 CFR § 123.44

§123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(9) For a permit issued by a Great Lakes State or Tribe (as defined in 40 CFR 132.2), the permit does not satisfy the conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

* * * * *40 CFR § 123.62

8. Section 123.62 is amended by adding a new paragraph (f) to read as follows:

40 CFR § 123.62

§123.62 Procedures for revision of State programs.

* * * * *

(f) Revision of a State program by a Great Lakes State or Tribe (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132 shall be accomplished pursuant to 40 CFR part 132.

40 CFR § 123.63

9. Section 123.63 is amended by adding a new paragraph (a)(6) and adding and reserving paragraph (b) to read as follows:

40 CFR § 123.63

§123.63 Criteria for withdrawal of State programs.

(a) * * *

(6) Where a Great Lakes State or Tribe (as defined in 40 CFR 132.2) fails to adequately incorporate the NPDES permitting implementation procedures promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132 into individual permits.

(b) [Reserved]

PART 131—WATER QUALITY STANDARDS

10. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 131.1

11. Section 131.1 is revised to read as follows:

40 CFR § 131.1

§131.1 Scope.

40 CFR § 132.2

This part describes the requirements and procedures for developing, reviewing, revising, and approving water quality standards by the States as authorized by section 303(c) of the Clean Water Act. Additional specific procedures for developing, reviewing, revising, and approving water quality standards for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the ***15387** Clean Water Act and 40 CFR part 132, are provided in 40 CFR part 132.

40 CFR § 131.5

12. Section 131.5 is amended by revising paragraph (a)(5), by redesignating paragraph (b) as paragraph (c), and by adding a new paragraph (b) to read as follows:

40 CFR § 131.5

§131.5 EPA Authority.

(a) * * *

(5) Whether the State submission meets the requirements included in §131.6 of this part and, for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the Act, the requirements of 40 CFR part 132.

(b) If EPA determines that the State's or Tribe's water quality standards are consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *40 CFR § 131.21

13. Section 131.21 is amended by revising paragraph (b) to read as follows:

40 CFR § 131.21

§131.21 EPA review and approval of water quality standards.

* * * * *

(b) The Regional Administrator's approval or disapproval of a State water quality standard shall be based on the requirements of the Act as described in §§131.5 and 131.6, and, with respect to Great Lakes States or Tribes (as defined in 40 CFR 132.2), 40 CFR part 132.

* * * * *

14. Part 132 is added as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

Tables to Part 132

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 132.1

§132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System (Guidance) required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 et seq.) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101-596, 104 Stat. 3000 et seq.). The Guidance in this part identifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) The U.S. Environmental Protection Agency, Great Lakes States, and Great Lakes Tribes will use the Guidance in this part to evaluate the water quality programs of the States and Tribes to assure that they are protective of water quality. State and Tribal programs do not need to be identical to the Guidance in this part, but must contain provisions that are consistent with (as protective as) the Guidance in this part. The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the preamble, Supplementary Information Document, Technical Support Documents,

and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing the State and Tribal water quality programs in the Great Lakes for consistency with this part.

(c) The Great Lakes States and Tribes must adopt provisions consistent with the Guidance in this part applicable to waters in the Great Lakes System or be subject to EPA promulgation of its terms pursuant to this part.

(d) EPA understands that the science of risk assessment is rapidly improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D are always current and peer reviewed, EPA will review the methodologies and revise them, as appropriate, every 3 years.

(e) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.
40 CFR § 132.2

§132.2 Definitions.
The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act and EPA implementing regulations.

Acute-chronic ratio (ACR) is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

Acute toxicity is concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Bioaccumulation is the net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time.

Bioaccumulative chemical of concern (BCC) is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation ***15388** product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

Bioconcentration is the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF) is the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Carcinogen is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Chronic toxicity is concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

Criterion maximum concentration (CMC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.

Endangered or threatened species are those species that are listed as endangered or threatened under section 4 of the Endangered Species Act.

Existing Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, that is not a new Great Lakes discharger.

Federal Indian reservation, Indian reservation, or reservation means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher GMAVs, or (b) the SMAV of an important and/or critical species, if the SMAV is lower than the calculated estimate.

Final chronic value (FCV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, (b) the quotient of an FAV divided by an appropriate acute-chronic ratio, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Final plant value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important.

Genus mean acute value (GMAV) is the geometric mean of the SMAVs for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the SMCVs for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian Tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the Clean Water Act or which EPA has authorized to administer an NPDES program under section 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes within the United States.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Indian Tribe or Tribe means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is a statistically or graphically estimated concentration that is expected ***15389** to be lethal to 50 percent of a group of organisms under specified conditions.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future nonpoint sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is the lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

Method detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth in appendix B of 40 CFR part 136.

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed.

New Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, the construction of which commenced after March 23, 1997.

No observed adverse effect level (NOAEL) is the highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

No observed effect concentration (NOEC) is the highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

Open waters of the Great Lakes (OWGLs) means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in (mg/kg)/day which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Species mean acute value (SMAV) is the geometric mean of the results of all acceptable flow-through acute toxicity tests (for which the concentrations of the test material were measured) with the most sensitive tested life stage of the species. For a species for which no such result is available for the most sensitive tested life stage, the SMAV is the geometric mean of the results of all acceptable acute toxicity tests with the most sensitive tested life stage.

Species mean chronic value (SMCV) is the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests.

Stream design flow is the stream flow that represents critical conditions, upstream from the source, for protection of aquatic life, human health, or wildlife.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are numeric values derived by use of the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

Uncertainty factor (UF) is one of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

Uptake is acquisition of a substance from the environment by an organism as a result of any active or passive process.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h). In the absence of a TMDL approved by EPA pursuant to 40 CFR 130.7 or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F of this part, a WLA is the allocation for an individual point source, that ensures that the level of water quality to be achieved by the point source is derived from and complies with all applicable water quality standards.

Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, ***15390** commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the Clean Water Act. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

40 CFR § 132.3

§132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with §132.4(d) that are consistent with:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

40 CFR § 132.4

§132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in §132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodology for Development of Wildlife Criteria in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies and procedures consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric criteria and values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply implementation procedures consistent with the procedures in appendix F of this part for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures consistent with procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply an antidegradation policy consistent with the policy in appendix E for all applicable purposes under the Clean Water Act, including 40 CFR 131.12.

(g) For pollutants listed in Table 5 of this part, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or

(2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

(i) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values specified in §132.3 or that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part, or to adopt antidegradation standards and implementation procedures more ***15391** stringent than those set forth in appendixes E and F of this part.
40 CFR § 132.5

§132.5 Procedures for adoption and EPA review.

(a) Except as provided in paragraph (c) of this section, the Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than September 23, 1996.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of National Pollutant Discharge Elimination System (NPDES) program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) The Regional Administrator may extend the deadline for the submission required in paragraph (a) of this section if the Regional Administrator believes that the submission will be consistent with the requirements of this part and can be reviewed and approved pursuant to this section no later than March 23, 1997.

(d) If a Great Lakes State or Tribe makes no submission pursuant to this part to EPA for review, the requirements of this part shall apply to discharges to waters of the Great Lakes System located within the State or Federal Indian reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(e) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review that contain substantial modifications of the State or Tribal NPDES program, EPA shall issue public notice and provide a minimum of 30 days for public comment on such modifications. The public notice shall conform with the requirements of 40 CFR 123.62.

(f) After review of State or Tribal submissions under this section, and following the public comment period in subparagraph (e) of this section, if any, EPA shall either:

(1) Publish notice of approval of the submission in the Federal Register within 90 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the Federal Register identifying the approved and disapproved elements of the submission and a final rule in the Federal Register identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian reservation.

(g) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA's determination whether the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part will be based on whether:

(1) For pollutants listed in Tables 1, 2, 3, and 4 of this part. The Great Lakes State or Tribe has adopted numeric water quality criteria as protective as each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) For pollutants other than those listed in Tables 1, 2, 3, 4, and 5 of this part. The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are as protective as or more protective than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures in accordance with procedure 1 of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more protective of:

(A) Numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997; or

(B) Water quality criteria and values derived pursuant to §132.4(c); and

(3) For methodologies, policies, and procedures. The Great Lakes State or Tribe has adopted methodologies, policies, and procedures as protective as the corresponding methodology, policy, or procedure in §132.4. The Great Lakes State or Tribe may adopt provisions that are more protective than those contained in this part. Adoption of a more protective element in one provision may be used to offset a less protective element in the same provision as long as the adopted provision is as protective as the corresponding provision in this part; adoption of a more protective element in one provision, however, is not justification for adoption of a less protective element in another provision of this part.

(h) A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

(i) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.
40 CFR § 132.6

§132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CMC	Conversion factor (CF)
	(MUg/L)	
Arsenic (III)	[a,b] 339.8	1.000

Chromium (VI)	[a,b] 16.02		0.982
Cyanide	[c] 22	n/a	
Dieldrin	[d] 0.24	n/a	
Endrin	[d] 0.086	n/a	
Lindane	[d] 0.95	n/a	
Mercury (II)	[a,b] 1.694		0.85
Parathion	[d] 0.065	n/a	
Selenium	[a,b] 19.34		0.922

***15392** (b)

Chemical	m_A	b_A	Conversion factor (CF)
Cadmium [a,b]	1.128	3.6867	0.85
Chromium (III) [a,b]	0.819	+3.7256	0.316
Copper [a,b]	0.9422	1.700	0.960
Nickel [a,b]	0.846	+2.255	0.998
Pentachlorophenol [c]	1.005	4.869	n/a
Zinc [a,b]	0.8473	+0.884	0.978

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CCC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 147.9	1.000
Chromium (VI)	[a,b] 10.98	0.962

Cyanide	[c] 5.2	n/a	
Dieldrin	[d] 0.056	n/a	
Endrin	[d] 0.036	n/a	
Mercury (II)	[a,b] 0.9081		0.85
Parathion	[d] 0.013	n/a	
Selenium	[a,b] 5		0.922

(b)

Chemical	m_c	b_c	Conversion factor (CF)
Cadmium [a,b]	0.7852	2.715	0.850
Chromium (III) [a,b]	0.819	+0.6848	0.860
Copper [a,b]	0.8545	1.702	0.960
Nickel [a,b]	0.846	+0.0584	0.997
Pentachlorophenol [c]	1.005	5.134	n/a
Zinc [a,b]	0.8473	+0.884	0.986

Table 3.—Water Quality Criteria for Protection of Human Health

Chemical	HNV (MUg/L)		HCV (MUg/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	1.9E1	5.1E2	1.2E1	3.1E2
Chlordane	1.4E-3	1.4E-3	2.5E-4	2.5E-4
Chlorobenzene	4.7E2	3.2E3		
Cyanides	6.0E2	4.8E4		
DDT	2.0E-3	2.0E-3	1.5E-4	1.5E-4
Dieldrin	4.1E-4	4.1E-4	6.5E-6	6.5E-6
2,4-Dimethylphenol	4.5E2	8.7E3		
2,4-Dinitrophenol	5.5E1	2.8E3		

Hexachlorobenzene	4.6E-2	4.6E-2	4.5E-4	4.5E-4	
Hexachloroethane	6.0	7.6	5.3	6.7	
Lindane	4.7E-1	5.0E-1			
Mercury [1]	1.8E-3	1.8E-3			
Methylene chloride	1.6E3	9.0E4	4.7E1	2.6E3	
PCBs (class)	.....		3.9E-6	3.9E-6	
2,3,7,8-TCDD	6.7E-8	6.7E-8	8.6E-9	8.6E-9	
Toluene	5.6E3	5.1E4			
Toxaphene	.....		6.8E-5	6.8E-5	
Trichloroethylene	.....		2.9E1	3.7E2	

Table 4.—Water Quality Criteria for Protection of Wildlife

Chemical	Criteria (MUg/L)
DDT and metabolites	1.1E-5
Mercury (including methylmercury)	1.3E-3
PCBs (class)	7.4E-5
2,3,7,8-TCDD	3.1E-9

***15393** Table 5.—Pollutants Subject to Federal, State, and Tribal Requirements
Alkalinity

Ammonia

Bacteria

Biochemical oxygen demand (BOD)

Chlorine

Color

Dissolved oxygen

Dissolved solids

pH

Phosphorus

Salinity

Temperature

Total and suspended solids

Turbidity

Table 6.—Pollutants of Initial Focus in the Great Lakes Water Quality Initiative
A. Pollutants that are bioaccumulative chemicals of concern (BCCs):

Chlordane

4,4#-DDD; p,p#-DDD; 4,4#-TDE; p,p#-TDE

4,4#-DDE; p,p#-DDE

4,4#-DDT; p,p#-DDT

Dieldrin

Hexachlorobenzene

Hexachlorobutadiene; hexachloro-1, 3-butadiene

Hexachlorocyclohexanes; BHCs

alpha-Hexachlorocyclohexane; alpha-BHC

beta-Hexachlorocyclohexane; beta-BHC

delta-Hexachlorocyclohexane; delta-BHC

Lindane; gamma-hexachlorocyclohexane; gamma-BHC

Mercury

Mirex

Octachlorostyrene

PCBs; polychlorinated biphenyls

Pentachlorobenzene

Photomirex

2,3,7,8-TCDD; dioxin

1,2,3,4-Tetrachlorobenzene

1,2,4,5-Tetrachlorobenzene Toxaphene

B. Pollutants that are not bioaccumulative chemicals of concern:

Acenaphthene

Acenaphthylene

Acrolein; 2-propenal

Acrylonitrile

Aldrin

Aluminum

Anthracene

Antimony

Arsenic

Asbestos

1,2-Benzanthracene; benz[a]anthracene

Benzene

Benzidine

Benzo[a]pyrene; 3,4-benzopyrene

3,4-Benzofluoranthene; benzo[b]fluoranthene

11,12-Benzofluoranthene; benzo[k]fluoranthene

1,12-Benzoperylene; benzo[ghi]perylene

Beryllium

Bis(2-chloroethoxy) methane

Bis(2-chloroethyl) ether

Bis(2-chloroisopropyl) ether

Bromoform; tribomomethane

4-Bromophenyl phenyl ether

Butyl benzyl phthalate

Cadmium

Carbon tetrachloride; tetrachloromethane

Chlorobenzene

p-Chloro-m-cresol; 4-chloro-3-methylphenol

Chlorodibromomethane

Chlorethane

2-Chloroethyl vinyl ether

Chloroform; trichloromethane

2-Chloronaphthalene

2-Chlorophenol

4-Chlorophenyl phenyl ether

Chlorpyrifos

Chromium

Chrysene

Copper

Cyanide

2,4-D; 2,4-Dichlorophenoxyacetic acid

DEHP; di(2-ethylhexyl) phthalate

Diazinon

1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene

Dibutyl phthalate; di-n-butyl phthalate

1,2-Dichlorobenzene

1,3-Dichlorobenzene

1,4-Dichlorobenzene

3,3#-Dichlorobenzidine

Dichlorobromomethane; bromodichloromethane

1,1-Dichloroethane

1,2-Dichloroethane

1,1-Dichloroethylene; vinylidene chloride

1,2-trans-Dichloroethylene

2,4-Dichlorophenol

1,2-Dichloropropane

1,3-Dichloropropene; 1,3-dichloropropylene

Diethyl phthalate

2,4-Dimethylphenol; 2,4-xylenol

Dimethyl phthalate

4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol

2,4-Dinitrophenol

2,4-Dinitrotoluene

2,6-Dinitrotoluene

Dioctyl phthalate; di-n-octyl phthalate

1,2-Diphenylhydrazine

Endosulfan; thiodan

alpha-Endosulfan

beta-Endosulfan

Endosulfan sulfate

Endrin

Endrin aldehyde

Ethylbenzene

Fluoranthene

Fluorene; 9H-fluorene

Fluoride

Guthion

Heptachlor

Heptachlor epoxide

Hexachlorocyclopentadiene

Hexachloroethane

Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene

Isophorone

Lead

Malathion

Methoxychlor

Methyl bromide; bromomethane

Methyl chloride; chloromethane

Methylene chloride; dichloromethane

Napthalene

Nickel

Nitrobenzene

2-Nitrophenol

4-Nitrophenol

N-Nitrosodimethylamine

N-Nitrosodiphenylamine

N-Nitrosodipropylamine; N-nitrosodi-n-propylamine

Parathion

Pentachlorophenol

Phenanthrene

Phenol

Iron

Pyrene

Selenium

Silver

1,1,2,2-Tetrachloroethane

Tetrachloroethylene

Thallium

Toluene; methylbenzene

1,2,4-Trichlorobenzene

1,1,1-Trichloroethane

1,1,2-Trichloroethane

Trichloroethylene; trichloroethene

2,4,6-Trichlorophenol

Vinyl chloride; chloroethylene; chloroethene

Zinc

Appendix A to part 132—Great Lakes Water Quality Initiative Methodologies for Developments of Aquatic Life Criteria and Values

Methodology for Deriving Aquatic Life Criteria: Tier I

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

15394** ***I. Definitions

A. Material of Concern. When defining the material of concern the following should be considered:

1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g., some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloid), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material of concern should include an operational analytical component. Identification of a material simply as “sodium,” for example, implies “total sodium,” but leaves room for doubt. If “total” is meant, it must be explicitly stated. Even “total” has different operational definitions, some of which do not necessarily measure “all that is there” in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

a. The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses. Toxicity is the property of a material, or combination of materials, to adversely affect organisms.

b. Because an ideal analytical measurement will rarely be available, an appropriate compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. What is an appropriate measurement in one situation might not be appropriate for another. For example, because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is appropriate for analyzing an effluent might not be appropriate for expressing a criterion, and vice versa. A criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

Note: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods.

4. It is now the policy of EPA that the use of dissolved metal to set and measure compliance with water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of metal in the water column that does total recoverable metal. One reason is that a primary mechanism for water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. Reasons for the consideration of total recoverable metals criteria include risk management considerations not covered by evaluation of water column toxicity. A risk manager may consider sediments and food chain effects and may decide to take a conservative approach for metals, considering that metals are very persistent chemicals. This approach could include the use of total recoverable metal in water quality standards. A range of different risk management decisions can be justified. EPA recommends that State water quality standards be based on dissolved metal. EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable under this program.

B. Acute Toxicity. Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism. (Concurrent toxicity is an adverse effect to an organism that results from, and occurs during, its exposure to one or more test materials.) Exposure constitutes contact with a chemical or physical agent. Acute exposure, however, is exposure of an organism for any short period which usually does not constitute a substantial portion of its life span.

C. Chronic Toxicity. Concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure. Chronic exposure is exposure of an organism for any long period or for a substantial portion of its life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (e.g., publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. In some cases, it might be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it might be appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods. A flow-through test is a test with aquatic organisms in which test solutions flow into constant-volume test chambers either intermittently (e.g., every few minutes) or continuously, with the excess flowing out.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios. An ACR is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with species non-resident to North America or previously exposed organisms may be used to provide auxiliary information but must not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. An adverse effect is a change in an organism that is harmful to the organism. Exposure means contact with a chemical or physical agent. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are usually available because procedures for conducting tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute (or chronic) tests (see section IV or VI of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

***15395** a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish);

c. A third family in the phylum Chordata (e.g., fish, amphibian);

d. A planktonic crustacean (e.g., a cladoceran, copepod);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with at least one species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived except in special cases. For example, derivation of a chronic criterion might not be possible if the available ACRs vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix), more data will be required.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value (FAV). The calculated Final Acute Value is a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher Genus Mean Acute Values (GMAVs). An acute test is a comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span. However, in some cases, the Species Mean Acute Value (SMAV) of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FAV, then the SMAV replaces the calculated FAV in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 729, Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed should not be used, unless data indicate that the food did not affect the toxicity of the test material. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges must be started with second or third instar larvae. It is preferred that the results should be the 48-hour EC50 based on the total percentage of organisms killed and immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test. An EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. An LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.

2. It is preferred that the results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on the percentage of organisms with incompletely developed shells plus the percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48-hour to 96-hour LC50s. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

3. It is preferred that the result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should

be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as “greater than” values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing circumstances.

H. If the available data indicate that one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the SMAV because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the SMAV shall be calculated as the geometric mean of the results of all acceptable flow-through acute toxicity tests in which the concentrations of test material were measured with the most sensitive tested life stage of the species. For a species for which no such result is available, the SMAV shall be calculated as the geometric mean of all acceptable acute toxicity tests with the most sensitive tested life stage, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material. A renewal test is a test with aquatic organisms in which either the test solution in a test chamber is removed and replaced at least once during the test or the test organisms are transferred into a new test solution of the same composition at least once during the test. A static test is a test with aquatic organisms in which the solution ***15396** and organisms that are in a test chamber at the beginning of the test remain in the chamber until the end of the test, except for removal of dead test organisms.

Note 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must not be rounded off to fewer than four significant digits.

Note 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

Note 3: Geometric means, rather than arithmetic means, are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for ACRs because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the GMAV shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are fewer than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the four selected GMAVs, and Ps, calculate

Note: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through V.G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus should not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing justification. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too

few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. For each species, calculate the geometric mean of the available acute values and then divide each of the acute values for the species by the geometric mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually using the same procedure as above.

F. Individually for each species perform a least squares regression of the normalized ***15397** acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section V.B. of this appendix. If, however, the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections V.D and V.E of this appendix).

I. For each species, calculate the logarithm, Y, of the SMAV at a selected value, Z, of the water quality characteristic using the equation:

Y=ln WV(ln Xln Z)
J. For each species calculate the SMAV at X using the equation:

$SMAV=e^{Y}$
Note: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the FAV at Z by using the procedure described in sections IV.J through IV.O of this appendix.

L. If, for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow-through tests in which the concentrations of the test material were measured is lower than the FAV at Z, then the geometric mean must be used as the FAV instead of the FAV.

M. The Final Acute Equation is written as:

$FAV=e^{(V[\ln(\text{water quality characteristic})]+AV[\ln Z])}$,
where:

V=pooled acute slope, and A=ln(FAV at Z).
Because V, A, and Z are known, the FAV can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value (FCV) can be calculated in the same manner as the FAV or by dividing the FAV by the Final Acute-Chronic Ratio (FACR). In some cases, it might not be possible to calculate a FCV. The FCV is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, or (b) the quotient of an FAV divided by an appropriate ACR, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Note: As the name implies, the ACR is a way of relating acute and chronic toxicities.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test. A chronic test is a comparative study in which organisms, that are subjected to different treatments, are observed for a long period or a substantial portion of their life span.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for ceriodaphnids not less than seven days. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 1193 Guide for conducting renewal life-cycle toxicity tests with Daphnia magna and ASTM Standard E 1295 Guide for conducting three-brood, renewal toxicity tests with Ceriodaphnia dubia. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. A life-cycle test is a comparative study in which organisms, that are subjected to different treatments, are observed at least from a life stage in one generation to the same life-stage in the next generation. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and

analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

Note: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and,

c. Above which all tested concentrations also caused such an effect.

Note: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related ***15398** to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a SMCV shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests. Appropriate GMCVs shall also be calculated. A GMCV is the geometric mean of the SMCVs for the genus. The FCV shall be obtained using the procedure described in sections IV.J through IV.O of this appendix, substituting SMCV and GMCV for SMAV and GMAV respectively. See section VI.M of this appendix.

Note: Section VI.I through VI.L are for use when chronic values are not available for species in eight taxonomic families as described in section III.B.1 of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an ACR, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests were not conducted as part of the same study, but were conducted as part of a different study in the same laboratory and dilution water, then they may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an ACR shall not be calculated.

J. For each species, calculate the SMACR as the geometric mean of all ACRs available for that species. If the minimum ACR data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used along with the freshwater data.

K. For some materials, the ACR seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the SMAV increases. Thus the FACR can be obtained in three ways, depending on the data available:

1. If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the FAV.

2. If no major trend is apparent and the ACRs for all species are within a factor of ten, the FACR shall be calculated as the geometric mean of all of the SMACRs.

3. If the most appropriate SMACRs are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the FACR should be assumed to be two, so that the FCV is equal to the Criterion Maximum Concentration (CMC). (See section X.B of this appendix.)

If the available SMACRs do not fit one of these cases, a FACR may not be obtained and a Tier I FCV probably cannot be calculated.

L. Calculate the FCV by dividing the FAV by the FACR.

FCV=FAV+FACR

If there is a Final Acute Equation rather than a FAV, see also section V of this appendix.
M. If the SMCV of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV, then that SMCV must be used as the FCV instead of the calculated FCV.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If ACRs are available for enough species at enough values of the water quality characteristic to indicate that the ACR appears to be the same for all species and appears to be independent of the water quality characteristic, calculate the FACR as the geometric mean of the available SMACRs.

2. Calculate the FCV at the selected value Z of the water quality characteristic by dividing the FAV at Z (see section V.M of this appendix) by the FACR.

3. Use V=pooled acute slope (see section V.M of this appendix), and

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic, the relationship should be taken into account as described in sections C through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus in most cases should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is, in most cases, absent countervailing circumstances, appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the ACR is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species, calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species, perform a least squares regression of the normalized chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

***15399** I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the SMCV at a selected value, Z, of the water quality characteristic using the equation:

$$Q=\ln M—L(\ln P\ln Z)$$

Note: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section V of this appendix.

K. For each species, calculate a SMCV at Z using the equation:

$$SMCV=e^{Q}$$

Note: Alternatively, the SMCV at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z, and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted chronic values for each species.

L. Obtain the FCV at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the SMCV at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV at Z, then that SMCV shall be used as the FCV at Z instead of the calculated FCV.

N. The Final Chronic Equation is written as:

$$FCV=e^{(L[\ln(\text{water quality characteristic})]+\ln SL[\ln Z])}$$

Where:

L=pooled chronic slope and S = FCV at Z.
Because L, S, and Z are known, the FCV can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. A Final Plant Value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will, in most cases, also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

Note: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 mg/L should be considered excessive.

C. The FPV shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Delayed toxicity is an adverse effect to an organism that results from, and occurs after the end of, its exposure to one or more test materials. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F.3 of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the CMC and the Criterion Continuous Concentration (CCC).

B. The CMC is equal to one-half the FAV. The CMC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

C. The CCC is equal to the lowest of the FCV or the FPV (if available) unless other data (see section IX of this appendix) show that a lower value should be used. The CCC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or FPV (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a commercially or recreationally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration

of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the CCC

(3) = insert the CMC

If the CMC averaging period of one hour or the CCC averaging period of four days is inappropriate for the pollutant, or if the once-in-three-year allowable excursion frequency is inappropriate for the pollutant or for the sites to which a criterion is applied, then the State may specify alternative averaging periods or frequencies. The choice of an alternative averaging period or frequency shall be justified by a scientifically defensible analysis demonstrating that the alternative values will protect the aquatic life uses of the water. Appropriate laboratory data and/or well-designed field biological surveys shall be submitted to EPA as justification for differing averaging periods and/or frequencies of exceedance.

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance in this part. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?

2. Are all required data available?

3. Is the range of acute values for any species greater than a factor of 10?

4. Is the range of SMAVs for any genus greater than a factor of 10?

5. Is there more than a factor of 10 difference between the four lowest GMAVs?

6. Are any of the lowest GMAVs questionable?

7. Is the FAV reasonable in comparison with the SMAVs and GMAVs?

8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the FAV?

9. Are any of the chronic values used questionable?

10. Are any chronic values available for acutely sensitive species?

11. Is the range of acute-chronic ratios greater than a factor of 10?

12. Is the FCV reasonable in comparison with the available acute and chronic data?

13. Is the measured or predicted chronic value for any commercially or recreationally important species of the Great Lakes System below the FCV?

14. Are any of the other data important?

15. Do any data look like they might be outliers?

16. Are there any deviations from the Guidance in this part? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived consistent with the Guidance in this part.

Methodology for Deriving Aquatic Life Values: Tier II

15400** ***XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes System shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A-1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). (Requirements for definitions, data collection and data review, contained in sections I, II, and IV shall be applied to calculation of a SAV.) If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—Ceriodaphnia sp., Daphnia sp., or Simocephalus sp.

If appropriate, the SAV shall be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined ACRs, meeting the data collection and review requirements of Section VI of this appendix, are available for the chemical, determine the FACR using the procedure described in Section VI. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined ACRs are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values or chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV or SCV, then that geometric mean must be used as the SAV or SCV instead of the calculated SAV or SCV.

XVI. Tier II Value

A. A Tier II value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (see section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or FPV, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The Tier II value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the SCC

(3) = insert the SMC
As discussed above, States and Tribes have the discretion to specify alternative averaging periods or frequencies (see section X.E. of this appendix).

XVII. Appropriate Modifications
On the basis of all available pertinent laboratory and field information, determine if the Tier II value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, shall be derived consistent with the Guidance in this part.

Table A-1.— Secondary Acute Factors

Number of minimum data requirements satisfied	Adjustment factor
1	21.9
2	13.0
3	8.0
4	7.0
5	6.1
6	5.2
7	4.3

Appendix B to Part 132—Great Lakes Water Quality Initiative

Methodology for Deriving Bioaccumulation Factors

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. The purpose of this methodology is to describe procedures for deriving bioaccumulation factors (BAFs) to be used in the calculation of Great Lakes Water Quality Guidance (Guidance) human health Tier I criteria and Tier II values and wildlife Tier I criteria. A subset of the human health BAFs are also used to identify the chemicals that are considered bioaccumulative chemicals of concern (BCCs).

B. Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes (i.e., ambient water and food), as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only through the ambient water. Both BAFs and bioconcentration factors (BCFs) are proportionality constants that describe the relationship between the concentration of a substance in aquatic organisms and its concentration in the ambient water. For the Guidance in this part, BAFs, rather than BCFs, are used to calculate Tier I criteria for human health and wildlife and Tier II values for human health because they better account for the total exposure of aquatic organisms to chemicals.

C. For organic chemicals, baseline BAFs can be derived using four methods. Measured baseline BAFs are derived from field-measured BAFs; predicted baseline BAFs are derived using biota-sediment accumulation factors (BSAFs) or are derived by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier (FCM). The lipid content of the aquatic organisms is used to account for partitioning of organic chemicals within organisms so that data from different ***15401** tissues and species can be integrated. In addition, the baseline BAF is based on the concentration of freely dissolved organic chemicals in the ambient water to facilitate extrapolation from one water to another.

D. For inorganic chemicals, baseline BAFs can be derived using two of the four methods. Baseline BAFs are derived using either field-measured BAFs or by multiplying laboratory-measured BCFs by a FCM. For inorganic chemicals, BAFs are assumed to equal BCFs (i.e., the FCM is 1.0), unless chemical-specific biomagnification data support using a FCM other than 1.0.

E. Because both humans and wildlife consume fish from both trophic levels 3 and 4, two baseline BAFs are needed to calculate either a human health criterion or value or a wildlife criterion for a chemical. When appropriate, ingestion through consumption of invertebrates, plants, mammals, and birds in the diet of wildlife species to be protected may be taken into account.

II. Definitions

Baseline BAF. For organic chemicals, a BAF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BAF that is based on the wet weight of the tissue.

Baseline BCF. For organic chemicals, a BCF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BCF that is based on the wet weight of the tissue.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to and the ratio does not change substantially over time.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF). The ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food-chain multiplier (FCM). The ratio of a BAF to an appropriate BCF.

Octanol-water partition coefficient (K_{OW}). The ration of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{OW}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Uptake. Acquisition of a substance from the environment by an organism as a result of any active or passive process.

III. Review and Selection of Data

A. Data Sources. Measured BAFs, BSAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.

2. Published scientific literature.

3. Reports issued by EPA or other reliable sources.

4. Unpublished data.

One useful source of references is the Aquatic Toxicity Information Retrieval (AQUIRE) database.

B. Field-Measured BAFs. The following procedural and quality assurance requirements shall be met for field-measured BAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. The trophic level of the fish species shall be determined.

3. The site of the field study should not be so unique that the BAF cannot be extrapolated to other locations where the criteria and values will apply.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

5. The concentration of the chemical in the water shall be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.

6. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water shall be either measured or reliably estimated.

7. For inorganic and organic chemicals, BAFs shall be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

C. Field-Measured BSAFs. The following procedural and quality assurance requirements shall be met for field-measured BSAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. Samples of surface sediments (0-1 cm is ideal) shall be from locations in which there is net deposition of fine sediment and is representative of average surface sediment in the vicinity of the organism.

3. The K_{ow}s used shall be acceptable quality as described in section III.F below.

4. The site of the field study should not be so unique that the resulting BAF cannot be extrapolated to other locations where the criteria and values will apply.

5. The tropic level of the fish species shall be determined.

6. The percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

D. Laboratory-Measured BCFs. The following procedural and quality assurance requirements shall be met for laboratory-measured BCFs:

1. The test organism shall not be diseased, unhealthy, or adversely affected by the concentration of the chemical.

2. The total concentration of the chemical in the water shall be measured and should be relatively constant during the steady-state time period.

3. The organisms shall be exposed to the chemical using a flow-through or renewal procedure.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BCF.

5. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the test solution shall be either measured or reliably estimated.

6. Laboratory-measured BCFs should be determined using fish species, but BCFs determined with molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, a baseline BCF determined for such a chemical using invertebrates is expected to be higher than a comparable baseline BCF determined using fish.

7. If laboratory-measured BCFs increase or decrease as the concentration of the chemical increases in the test solutions in a bioconcentration test, the BCF measured at the lowest test concentration that is above concentrations existing in the control water shall be used (i.e., a BCF should be calculated from a control treatment). The concentrations of an inorganic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccummulation of an inorganic chemical might be overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

8. For inorganic and organic chemicals, BCFs shall be used only if they are expressed on a wet weight basis. BCFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

9. BCFs for organic chemicals may be based on measurement or radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

10. The calculation of the BCF must appropriately address growth dilution.

11. Other aspects of the methodology used should be similar to those described by ASTM (1990).

***15402** E. Predicted BCFs. The following procedural and quality assurance requirements shall be met for predicted BCFs:

1. The K_{ow} used shall be of acceptable quality as described in section III.F below.

2. The predicted baseline BCF shall be calculated using the equation: predicted baseline BCF = K_{ow}

where:

K_{ow} = octanol-water partition coefficient.

F. Octanol-Water Partition Coefficient (K_{ow}). 1. The value of K_{ow} used for an organic chemical shall be determined by giving priority to the experimental and computational techniques used as follows:

Log K_{ow} < 4:

Priority	Technique
1	Slow-stir.
1	Generator-column.
1	Shake-flask.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Calculated by the CLOGP program.

Log K_{ow} > 4:

Priority	Technique
1	Slow Stir.
1	Generator-column.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Shake-flask.
5	Calculated by the CLOGP program.

2. The CLOGP program is a computer program available from Pomona College. A value of K_{ow} that seems to be different from the others should be considered an outlier and not used. The value of K_{ow} used for an organic chemical shall be the geometric mean of the available K_{ow}s with highest priority or can be calculated from the arithmetic mean of the available log K_{ow} with the highest priority. Because it is an intermediate value in the derivation of a BAF, the value used for the K_{ow} of a chemical should not be rounded to fewer than three significant digits and a value for log K_{ow} should not be rounded to fewer than three significant digits after the decimal point.

G. This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF, BSAF, BCF or K_{ow}. The amount of uncertainty in a baseline BAF depends on both the quality of data available and the method used to derive the BAF.

H. Hereinafter in this methodology, the terms BAF, BSAF, BCF and K_{ow} refer to ones that are consistent with the procedural and quality assurance requirements given above.

IV. Four Methods for Deriving Baseline BAFs

Baseline BAFs shall be derived using the following four methods, which are listed from most preferred to least preferred:

A. A measured baseline BAF for an organic or inorganic chemical derived from a field study of acceptable quality.

B. A predicted baseline BAF for an organic chemical derived using field-measured BSAFs of acceptable quality.

C. A predicted baseline BAF for an organic or inorganic chemical derived from a BCF measured in a laboratory study of acceptable quality and a FCM.

D. A predicted baseline BAF for an organic chemical derived from a K_{ow} of acceptable quality and a FCM.

For comparative purposes, baseline BAFs should be derived for each chemical by as many of the four methods as available data allow.

V. Calculation of Baseline BAFs for Organic Chemicals

A. Lipid Normalization. 1. It is assumed that BAFs and BCFs for organic chemicals can be extrapolated on the basis of percent lipid from one tissue to another and from one aquatic species to another in most cases.

2. Because BAFs and BCFs for organic chemicals are related to the percent lipid, it does not make any difference whether the tissue sample is whole body or edible portion, but both the BAF (or BCF) and the percent lipid must be determined for the same tissue. The percent lipid of the tissue should be measured during the BAF or BCF study, but in some cases it can be reliably estimated from measurements on tissue from other organisms. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same or a comparable laboratory population of test organisms that were used in the original study may be used.

3. The lipid-normalized concentration, C_l, of a chemical in tissue is defined using the following equation:

Where:

C_B=concentration of the organic chemical in the tissue of aquatic biota (either whole organism or specified tissue) (MUg/g).

f_l=fraction of the tissue that is lipid.

B. Bioavailability. By definition, baseline BAFs and BCFs for organic chemicals, whether measured or predicted are based on the concentration of the chemical that is freely dissolved in the ambient water in order to account for bioavailability. For the purposes of this Guidance in this part, the relationship between the total concentration of the chemical in the water (i.e., that which is freely dissolved plus that which is sorbed to particulate organic carbon or to dissolved organic carbon) to the freely dissolved concentration of the chemical in the ambient water shall be calculated using the following equation:

Where:

C^{fd}_w=freely dissolved concentration of the organic chemical in the ambient water;

C^{t}_w=total concentration of the organic chemical in the ambient water;

f_{fd}=fraction of the total chemical in the ambient water that is freely dissolved.

The fraction of the total chemical in the ambient water that is freely dissolved, f_{fd}, shall be calculated using the following equation:

Where:

DOC=concentration of dissolved organic carbon, kg of dissolved organic carbon/L of water.

K_{OW}=octanol-water partition coefficient of the chemical.

POC=concentration of particulate organic carbon, kg of particulate organic carbon/L of water.

C. Food-Chain Multiplier. In the absence of a field-measured BAF or a predicted BAF derived from a BSAF, a FCM shall be used to calculate the baseline BAF for trophic levels 3 and 4 from a laboratory-measured or predicted BCF. For an organic chemical, the FCM used shall be derived from Table B-1 using the chemical's log K_{OW} and linear interpolation. A FCM greater than 1.0 applies to most organic chemicals with a log K_{OW} of four or more. The trophic level used shall take into account the age or size of the fish species consumed by the human, avian or mammalian predator because, for some species of fish, the young are in trophic level 3 whereas the adults are in trophic level 4.

D. Calculation of a Baseline BAF from a Field-Measured BAF. A baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

***15403** Where:

BAF^{t}_{T}=BAF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured baseline BAF is available for a given species. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be calculated. If a baseline BAF based on a measured BAF is available for either trophic level 3 or 4, but not both, a measured baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.
E. Calculation of a Baseline BAF from a Field-Measured BSAF. 1. A baseline BAF for organic chemical “i” shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

Where:

$(BSAF)_i$=BSAF for chemical “i”.

$(BSAF)_r$=BSAF for the reference chemical “r”.

$(K_{OW})_i$=octanol-water partition coefficient for chemical “i”.

$(K_{OW})_r$=octanol-water partition coefficient for the reference chemical “r”.
2. A BSAF shall be calculated using the following equation:

Where:

C_t=the lipid-normalized concentration of the chemical in tissue.

C_{SOC}=the organic carbon-normalized concentration of the chemical in sediment.
3. The organic carbon-normalized concentration of a chemical in sediment, C_{SOC}, shall be calculated using the following equation:

Where:

C_S=concentration of chemical in sediment (mg/g sediment).

f_{OC}=fraction of the sediment that is organic carbon.
4. Predicting BAFs from BSAFs requires data from a steady-state (or near steady-state) condition between sediment and ambient water for both a reference chemical “r” with a field-measured BAF_l^{fd} and other chemicals “n=i” for which BSAFs are to be determined.

5. The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF. For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from BSAFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs derived using BSAFs shall be calculated.

6. If a baseline BAF based on a measured BSAF is available for either trophic level 3 or 4, but not both, a baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.

F. Calculation of a Baseline BAF from a Laboratory-Measured BCF. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

Where:

$BCF^{t}T$=BCF based on total concentration in tissue and water.

fl=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical in the test water that is freely dissolved.

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from laboratory-measured BCFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs based on laboratory-measured BCFs shall be calculated.

G. Calculation of a Baseline BAF from an Octanol-Water Partition Coefficient. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

Baseline BAF=(FCM) (predicted baseline BCF)=(FCM) (K_{OW})

Where:

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW}=octanol-water partition coefficient.

VI. Human Health and Wildlife BAFs for Organic Chemicals

A. To calculate human health and wildlife BAFs for an organic chemical, the K_{OW} of the ***15404** y15404[chemical shall be used with a POC concentration of 0.00000004 kg/L and a DOC concentration of 0.000002 kg/L to yield the fraction freely dissolved:

B. The human health BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0182 and 0.0310 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive human health criteria and values for the GLI.

C. The wildlife BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0646 and 0.1031 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive wildlife criteria for the GLI.

VII. Human Health and Wildlife BAFs for Inorganic Chemicals

A. For inorganic chemicals, the baseline BAFs for trophic levels 3 and 4 are both assumed to equal the BCF determined for the chemical with fish, i.e., the FCM is assumed to be 1 for both trophic levels 3 and 4. However, a FCM greater than 1 might be applicable to some metals, such as mercury, if, for example, an organometallic form of the metal biomagnifies.

B. BAFs for Human Health Criteria and Values.

1. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals shall be based on edible tissue (e.g., muscle) of freshwater fish unless it is demonstrated that whole-body BAFs or BCFs are similar to edible-tissue BAFs or BCFs. BCFs and BAFs based on measurements of aquatic plants and invertebrates should not be used in the derivation of human health criteria and values.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with the muscle of fish:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species; and

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the human health BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable edible-portion laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the human health BAF for that chemical.

C. BAFs for Wildlife Criteria.

1. Measured BAFs and BCFs used to determine wildlife BAFs for inorganic chemicals shall be based on whole-body freshwater fish and invertebrate data unless it is demonstrated that edible-tissue BAFs or BCFs are similar to whole-body BAFs or BCFs.

***15405** 2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with whole body of fish or invertebrates:

2. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species.

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the wildlife BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable whole-body laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the wildlife BAF for that chemical.

VIII. Final Review

For both organic and inorganic chemicals, human health and wildlife BAFs for both trophic levels shall be reviewed for consistency with all available data concerning the bioaccumulation, bioconcentration, and metabolism of the chemical. For example, information concerning octanol-water partitioning, molecular size, or other physicochemical properties that might enhance or inhibit bioaccumulation should be considered for organic chemicals. BAFs derived in accordance with this methodology should be modified if changes are justified by available data.

IX. Literature Cited

ASTM. 1990. Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. Standard E 1022. American Society for Testing and Materials, Philadelphia, PA.

Table B-1.—Food-Chain Multipliers for Trophic Levels 2, 3 & 4

Log K_{ow}	Trophic level 2	Trophic [1] level 3	Trophic level 4
2.0	1.000	1.005	1.000
2.5	1.000	1.010	1.002
3.0	1.000	1.028	1.007
3.1	1.000	1.034	1.007
3.2	1.000	1.042	1.009
3.3	1.000	1.053	1.012
3.4	1.000	1.067	1.014
3.5	1.000	1.083	1.019
3.6	1.000	1.103	1.023
3.7	1.000	1.128	1.033
3.8	1.000	1.161	1.042
3.9	1.000	1.202	1.054

4.0	1.000	1.253	1.072
4.1	1.000	1.315	1.096
4.2	1.000	1.380	1.130
4.3	1.000	1.491	1.178
4.4	1.000	1.614	1.242
4.5	1.000	1.766	1.334
4.6	1.000	1.950	1.459
4.7	1.000	2.175	1.633
4.8	1.000	2.452	1.871
4.9	1.000	2.780	2.193
5.0	1.000	3.181	2.612
5.1	1.000	3.643	3.162
5.2	1.000	4.188	3.873
5.3	1.000	4.803	4.742
5.4	1.000	5.502	5.821
5.5	1.000	6.266	7.079
5.6	1.000	7.096	8.551
5.7	1.000	7.962	10.209
5.8	1.000	8.841	12.050
5.9	1.000	9.716	13.964
6.0	1.000	10.556	15.996
6.1	1.000	11.337	17.783
6.2	1.000	12.064	19.907
6.3	1.000	12.691	21.677
6.4	1.000	13.228	23.281
6.5	1.000	13.662	24.604
6.6	1.000	13.980	25.645
6.7	1.000	14.223	26.363
6.8	1.000	14.355	26.669

6.9	1.000	14.388		26.669
7.0	1.000	14.305		26.242
7.1	1.000	14.142		25.468
7.2	1.000	13.852		24.322
7.3	1.000	13.474		22.856
7.4	1.000	12.987		21.038
7.5	1.000	12.517		18.967
7.6	1.000	11.708		16.749
7.7	1.000	10.914		14.388
7.8	1.000	10.069		12.050
7.9	1.000	9.162		9.840
8.0	1.000	8.222		7.798
8.1	1.000	7.278	6.012	
8.2	1.000	6.361		4.519
8.3	1.000	5.489		3.311
8.4	1.000	4.683		2.371
8.5	1.000	3.949		1.663
8.6	1.000	3.296		1.146
8.7	1.000	2.732		0.778
8.8	1.000	2.246		0.521
8.9	1.000	1.837		0.345
9.0	1.000	1.493		0.226

***15406 Appendix C to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Human Health Criteria and Values**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

Great Lakes States and Tribes shall adopt provisions consistent with this appendix C to ensure protection of human health.

A. Goal. The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. Definitions.

Acceptable daily exposure (ADE). An estimate of the maximum daily dose of a substance which is not expected to result in adverse noncancer effects to the general human population, including sensitive subgroups.

Adverse effect. Any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Carcinogen. A substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Human cancer criterion (HCC). A Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C.

Human cancer value (HCV). The maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC). A Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV). The maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health criteria and Values in appendix C of this part.

Linearized multi-stage model. A conservative mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer.

Lowest observed adverse effect level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No observed adverse effect level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Quantitative structure activity relationship (OSAR) or structure activity relationship (SAR). A mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Relative source contribution (RSC). The factor (percentage) used in calculating an HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD). A dose of a known or presumed carcinogenic substance in (mg/kg/day) which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Slope factor. Also known as q_1*, slope factor is the incremental rate of cancer development calculated through use of a linearized multistage model or other appropriate model. It is expressed in (mg/kg/day) of exposure to the chemical in question.

Threshold effect. An effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Uncertainty factor (UF). One of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

C. Level of Protection. The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or noncarcinogenic effects. Criteria are a function of the level of designated risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime upper-bound incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

D. Two-tiered Classification. Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels and the quantity and quality of data on bioaccumulation.

II. Minimum Data Requirements

The best available toxicity data on the adverse health effects of a chemical and the best data on bioaccumulation factors shall be used when developing human health Tier I criteria or Tier II values. The best available toxicity data shall include data from well ***15407** -conducted epidemiologic and/or animal studies which provide, in the case of carcinogens, an adequate weight of evidence of potential human carcinogenicity and, in the case of noncarcinogens, a dose-response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS. When deviations from IRIS are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or the Cancer Risk Assessment Verification Endeavor (CRAVE) workgroup immediately. The best available bioaccumulation data shall include data from field studies and well-conducted laboratory studies.

A. Carcinogens. Tier I criteria and Tier II values shall be derived using the methodologies described in section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists. Carcinogens are classified, depending on the weight of evidence, as either human carcinogens, probable human carcinogens, or possible human carcinogens. The human evidence is considered inadequate and therefore the chemical cannot be classified as a human carcinogen, if one of two conditions exists: (a) there are few pertinent data, or (b) the available studies, while showing evidence of association, do not exclude chance, bias, or confounding and therefore a casual interpretation is not credible. The animal evidence is considered inadequate, and therefore the chemical cannot

be classified as a probable or possible human carcinogen, when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

Chemicals are described as “human carcinogens” when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the chemicals and cancer. Chemicals described as “probable human carcinogens” include chemicals for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Limited human evidence is that which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, cannot adequately be excluded. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Sufficient animal evidence is data which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (a) in multiple species or strains; (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests (such as mutagenicity/genotoxicity tests which help determine whether the chemical interacts directly with DNA) or on chemical structure, metabolism or mode of action.

“Possible human carcinogens” are chemicals with limited evidence of carcinogenicity in animals in the absence of human data. Limited animal evidence is defined as data which suggests a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the studies indicate an increase in the incidence of benign tumors only. More specifically, this group can include a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

1. Tier I: Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I HCC shall generally include human carcinogens, probable human carcinogens and can include, on a case-by-case basis, possible human carcinogens if studies have been well-conducted albeit based on limited evidence, when compared to studies used in classifying human and probable human carcinogens. The decision to use data on a possible human carcinogen for deriving Tier I criteria shall be a case-by-case determination. In determining whether to derive a Tier I HCC, additional evidence that shall be considered includes but is not limited to available information on mode of action, such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity, and metabolism.

2. Tier II: Weight of evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens for which there are at a minimum, data sufficient for quantitative risk assessment, but for which data are inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship. In determining whether to derive Tier II human cancer values, additional evidence that shall be considered includes but is not limited to available information on mode of action such as mutagenicity/ genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity and metabolism. As with the use of data on possible human carcinogens in developing Tier I criteria, the decision to use data on possible human carcinogens to derive Tier II values shall be made on a case-by-case basis.

B. Noncarcinogens. All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality

and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database with which to develop Tier I criteria or Tier II values. The following represent the minimum data sets necessary for this procedure.

1. Tier I: The minimum data set sufficient to derive a Tier I human HNC shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I HNC must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to ***15408** effects at higher doses. This does not preclude the use of a LOAEL from a study (of chronic duration) with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. Tier II: When the minimum data for deriving Tier I criteria are not available to meet the Tier I data requirements, a more limited database may be considered for deriving Tier II values. As with Tier I criteria, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less extensive data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for a less extensive database, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies (greater than 28 days) may be more appropriate in some cases for derivation of Tier II values. Use of a LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study.

C. Bioaccumulation factors (BAFs).

1. Tier I for Carcinogens and Noncarcinogens: To be considered a Tier I cancer or noncancer human health criterion, along with satisfying the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix, a chemical must have the following minimum bioaccumulation data. For all organic chemicals either: (a) a field-measured BAF; (b) a BAF derived using the BSAF methodology; or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, either: (a) a field-measured BAF or (b) a laboratory-measured BCF.

2. Tier II for Carcinogens and Noncarcinogens: A chemical is considered a Tier II cancer or noncancer human health value if it does not meet either the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix or the minimum bioaccumulation data requirements of section II.C.1 of this appendix.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. Carcinogens.

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that is considered most biologically relevant to humans (i.e., responds most like humans) is preferred where all other considerations regarding quality of data are equal. In the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g., Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986), which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which are more appropriate to the available data may be used where scientifically justified.

4. If the duration of the study is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed (e.g., U.S. EPA, 1980) In the absence of alternative approaches which compensate for study durations significantly less than lifetime, the permitting authority may use the process described in the 1980 National Guidelines (see 45 FR 79352).

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 2/3 power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the RAD shall be calculated using the following equation:

Where:

RAD=risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (110^{5})=incremental risk of developing cancer equal to one in 100,000.

q_1*=slope factor $(mg/kg/day)^{1}$.

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may, on a case-by-case basis, be calculated using a method which assumes a threshold mechanism is operative.

B. Noncarcinogens.

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. To the maximum extent possible, data most specific to the environmentally relevant route of exposure shall be used. Oral exposure data should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), should generally be used.

***15409** 3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the LOAEL from studies satisfying the provisions of section II.B of this appendix may be used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic (e.g., 90 days or more in length), or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional UF of up to 10-fold for less than chronic, but greater than subchronic, studies.

d. An UF of up to 3000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than subchronic (e.g., 28 days). In comparison to b above, this represents an additional UF of up to 30-fold for less than

subchronic studies (e.g., 28-day). The level of additional uncertainty applied for less than chronic exposures depends on the duration of the study used relative to the lifetime of the experimental animal.

e. An additional UF of between one and ten may be used when deriving a criterion from a LOAEL. This UF accounts for the lack of an identifiable NOAEL. The level of additional uncertainty applied may depend upon the severity and the incidence of the observed adverse effect.

f. An additional UF of between one and ten may be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data (e.g., reproductive/developmental data). The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

g. When deriving an UF in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of sections 4.a through f, cited above, shall not exceed 10,000 for Tier I criteria and 30,000 for Tier II values.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses shall be adjusted for continuous exposure (i.e., seven days/week, 24 hours/day, etc.).

C. Criteria and Value Derivation.

1. Standard Exposure Assumptions. The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to Clean Water Act (CWA) section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

BW = body weight of an average human (BW = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

—or—

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015kg/day (0.0036 kg/day for trophic level 3 and 0.0114 kg/day for trophic level 4).

BAF = bioaccumulation factor for trophic level 3 and trophic level 4, as derived using the BAF methodology in appendix B to part 132.

2. Carcinogens. The Tier I human cancer criteria or Tier II values shall be calculated as follows:

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to one in 100,000.

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

FC_{TL3}=mean consumption of trophic level 3 of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=bioaccumulation factor for trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=bioaccumulation factor for trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.
3. Noncarcinogens. The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8. An RSC derived from actual exposure data may be developed using the methodology outlined by the 1980 National Guidelines (see 45 FR 79354).

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

***15410** FC_{TL3}=mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.

IV. References

A. Howe, R.B., K.S. Crump and C. Van Landingham. 1986. Computer Program to Extrapolate Quantitative Animal Toxicity Data to Low Doses. Prepared for EPA under subcontract #2-251U-2745 to Research Triangle Institute.

B. U.S. Environmental Protection Agency. 1980. Water Quality Criteria Availability, Appendix C Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

C. U.S. Environmental Protection Agency. 1986. Guidelines for Carcinogen Risk Assessment. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. A Great Lakes Water Quality Wildlife Criterion (GLWC) is the concentration of a substance which is likely to, if not exceeded, protect avian and mammalian wildlife populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the Great Lakes System. These criteria are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Since toxicological and exposure data for individual wildlife species are limited, a GLWC is derived using a methodology similar to that used to derive noncancer human health criteria (Barnes and Dourson, 1988; NAS, 1977; NAS, 1980; U.S. EPA, 1980). Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative Great Lakes basin wildlife species. The wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience the highest exposures to bioaccumulative contaminants through the aquatic food web; they are the bald eagle, herring gull, belted kingfisher, mink, and river otter.

B. This appendix establishes a methodology which is required when developing Tier I wildlife criteria for bioaccumulative chemicals of concern (BCCs). The use of the equation provided in the methodology is encouraged, but not required, for the development of Tier I criteria or Tier II values for pollutants other than those identified in Table 6-A for which Tier I criteria or Tier II values are determined to be necessary for the protection of wildlife in the Great Lakes basin. A discussion of the methodology for deriving Tier II values can be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria (Wildlife TSD).

C. In the event that this methodology is used to develop criteria for pollutants other than BCCs, or in the event that the Tier II methodology described in the Wildlife TSD is used to derive Tier II values, the methodology for deriving bioaccumulation factors under appendix B to part 132 must be used in either derivation. For chemicals which do not biomagnify to the extent of BCCs, it may be appropriate to select different representative species which are better examples of species with the highest exposures for the given chemical. The equation presented in this methodology, however, is still encouraged. In addition, procedure 1 of appendix F of this part describes the procedures for calculating site-specific wildlife criteria.

D. The term “wildlife value” (WV) is used to denote the value for each representative species which results from using the equation presented below, the value obtained from averaging species values within a class, or any value derived from application of the site-specific procedure provided in procedure 1 of appendix F of this part. The WVs calculated for the representative species are used to calculate taxonomic class-specific WVs. The WV is the concentration of a substance which, if not exceeded, should better protect the taxon in question.

E. “Tier I wildlife criterion,” or “Tier I criterion” is used to denote the number derived from data meeting the Tier I minimum database requirements, and which will be protective of the two classes of wildlife. It is synonymous with the term “GLWC,” and the two are used interchangeably.

II. Calculation of Wildlife Values for Tier I Criteria

Table 4 of Part 132 and Table D-1 of this appendix contain criteria calculated by EPA using the methodology provided below.

A. Equation for Avian and Mammalian Wildlife Values. Tier I wildlife values for the pollutants designated BCCs pursuant to part 132 are to be calculated using the equation presented below.

Where:

WV=Wildlife Value in milligrams of substance per liter (mg/L).

TD=Test Dose (TD) in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A=Uncertainty Factor (UF) for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_S=UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L=UF for LOAEL to NOAEL extrapolations (unitless).

Wt=Average weight in kilograms (kg) for the representative species.

W=Average daily volume of water consumed in liters per day (L/d) by the representative species.

F_{TLi}=Average daily amount of food consumed from trophic level i in kilograms per day (kg/d) by the representative species.

BAF^{WL}_{TLi}=Bioaccumulation factor (BAF) for wildlife food in trophic level i in liters per kilogram (L/kg), developed using the BAF methodology in appendix B to part 132, Methodology for Development of Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

B. Identification of Representative Species for Protection. For bioaccumulative chemicals, piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Wildlife TSD. This analysis identifies three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) as representative species for protection. The TD obtained from toxicity data for each taxonomic class is used to calculate WVs for each of the five representative species.

C. Calculation of Avian and Mammalian Wildlife Values and GLWC Derivation. The avian WV is the geometric mean of the WVs calculated for the three representative avian species. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species. The lower of the mammalian and avian WVs must be selected as the GLWC.

III. Parameters of the Effect Component of the Wildlife Criteria Methodology

A. Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology.

Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect reproductive or developmental success, organismal viability or growth, or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

***15411** Chronic effect. An adverse effect that is measured by assessing an acceptable endpoint, and results from continual exposure over several generations, or at least over a significant part of the test species' projected life span or life stage.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Subchronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

B. Minimum Toxicity Database for Tier I Criteria Development. A TD value is required for criterion calculation. To derive a Tier I criterion for wildlife, the data set shall provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species. In reviewing the toxicity data available which meet the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species take precedence over other types of studies, where such studies are of adequate quality. An acceptable field study must be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, or determined to be of inadequate quality, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. All available laboratory data and field studies shall be reviewed to corroborate the final GLWC, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any UFs which are applied. When evaluating the studies from which a test dose is derived in general, the following requirements must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 70 days or greater designed to observe subchronic or chronic effects as defined in this document.

3. In reviewing the studies from which a TD is derived for use in calculating a WV, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

4. In assessing the studies which meet the minimum data requirements, preference should be given to studies which assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained. The Wildlife TSD provides additional discussion on the selection of an appropriate toxicity study.

C. Selection of TD Data. In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in Section III.A of this appendix, will be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of the Ufs which are applied.

1. If more than one TD value is available within a taxonomic class, based on different endpoints of toxicity, that TD, which is likely to reflect best potential impacts to wildlife populations through resultant changes in mortality or fecundity rates, shall be used for the calculation of WVs.

2. If more than one TD is available within a taxonomic class, based on the same endpoint of toxicity, the TD from the most sensitive species shall be used.

3. If more than one TD based on the same endpoint of toxicity is available for a given species, the TD for that species shall be calculated using the geometric mean of those TDs.

D. Exposure Assumptions in the Determination of the TD. 1. In those cases in which a TD is available in units other than milligrams of substance per kilograms per day (mg/kg/d), the following procedures shall be used to convert the TD to the appropriate units prior to calculating a WV.

2. If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the TD shall be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).

3. If the TD is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the TD shall be multiplied by the average amount of food in kilograms consumed daily by the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).

E. Drinking and Feeding Rates. 1. When drinking and feeding rates and body weight are needed to express the TD in milligrams of substance per kilograms per day (mg/kg/d), they are obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

2. If the study does not provide the needed values, the values shall be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH), or Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988) should be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations from Calder and Braun (1983) and Nagy (1987), which are presented below, or the exposure estimation methods presented in Chapter 4 of the Wildlife Exposure Factors Handbook (U.S. EPA, 1993), should be applied to approximate the needed feeding or drinking rates. Additional discussion and recommendations are provided in the Wildlife TSD. The choice of the methods described above is at the discretion of the State or Tribe.

3. For mammalian species, the general allometric equations are:

a. $F = 0.0687 (Wt)^{0.82}$

Where:

F = Feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.

b. $W = 0.099 (Wt)^{0.90}$

Where:

W = Drinking rate of mammalian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
4. For avian species, the general allometric equations are:

a. $F = 0.0582 (Wt)^{0.65}$

Where:

F = Feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.
b. $W = 0.059 (Wt)^{0.67}$

Where:

W = Drinking rate of avian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
F. LOAEL to NOAEL Extrapolations (UF_L). In those cases in which a NOAEL is unavailable as the TD and a LOAEL is available, the LOAEL may be used to estimate the NOAEL. If used, the LOAEL shall be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF shall not be less than one and should not exceed 10, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in Section II.A of this appendix. Guidance for selecting an appropriate UF_L, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

G. Subchronic to Chronic Extrapolations (US_S). In instances where only subchronic data are available, the TD may be derived from subchronic data. In such cases, the TD shall be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF shall not be less than one and should not exceed 10, and is represented by UF_S in the equation expressed in Section II.A of this appendix. This factor is to be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length ***15412** underestimates chronic effects. Guidance for selecting an appropriate UF_S, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

H. Interspecies Extrapolations (UF_A). 1. The selection of the UF_A shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic, and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is an UF that is intended to account for differences in toxicological sensitivity among species. Guidance for selecting an appropriate UF_A, based on a review of available wildlife toxicity data, is available in the Wildlife TSD. Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria may be useful in determining the appropriate value for UF_A.

2. For the derivation of Tier I criteria, a UF_A shall not be less than one and should not exceed 100, and shall be applied to each of the five representative species, based on existing data and best professional judgment. The value of UF_A may differ for each of the representative species.

3. For Tier I wildlife criteria, the UF_A shall be used only for extrapolating toxicity data across species within a taxonomic class, except as provided below. The Tier I UF_A is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation

employing a UF_A may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considering acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Drinking and Feeding Rates of Representative Species. The body weights (Wt), feeding rates (F_{Tli}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and percent in diet) for each of the five representative species are presented in Table D-2 of this appendix. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD.

B. BAFs. The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. Trophic level 3 and 4 BAFs are used to derive Wvs because these are the trophic levels at which the representative species feed.

V. References

A. Barnes, D.G. and M. Dourson. 1988. Reference Dose (RfD): Description and Use in Health Risk Assessments. Regul. Toxicol. Pharmacol. 8:471-486.

B. Calder III, W.A. and E.J. Braun. 1983. Scaling of Osmotic Regulation in Mammals and Birds. American Journal of Physiology. 244:601-606.

C. Nagy, K.A. 1987. Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds. Ecological Monographs. 57(2):111-128.

D. National Academy of Sciences. 1977. Chemical Contaminants: Safety and Risk Assessment, in Drinking Water and Health, Volume 1. National Academy Press.

E. National Academy of Sciences. 1980. Problems of Risk Estimation, in Drinking Water and Health, Volume 3. National Academy Press.

F. National Institute for Occupational Safety and Health. Latest edition. Registry of Toxic Effects of Chemical Substances. Division of Standards Development and Technology Transfer. (Available only on microfiche or as an electronic database.)

G. U.S. EPA. 1980. Appendix C. Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, pp. 79347-79357 in Water Quality Criteria Documents; Availability. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St. SW, Washington, DC 20460.

H. U.S. EPA. 1988. Recommendations for, and documentation of, biological values for use in risk assessment. NTIS-PB88-179874.

I. U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. EPA/600/R-93/187a and b.

Tables to Appendix D to Part 132

Table D-1.—Tier I Great Lakes Wildlife Criteria

Substance	Criterion (MUg/L)

DDT & Metabolites	1.1E-5
Mercury	1.3E-3
PCBs (total)	7.4E-5
2,3,7,8-TCDD	3.1E-9

Table D-2.—Exposure Parameters for the Five Representative Species Identified for Protection

Species (units)	Adult body weight (kg)	Water ingestion rate (L/day)	Food ingestion rate of prey in each trophic level (kg/day)	Trophic level of prey (percent of diet)
Mink	0.80	0.081	TL3: 0.159; Other: 0.0177	TL3: 90; Other: 10.
Otter	7.4	0.600	TL3: 0.977; TL4: 0.244	TL3: 80; TL4: 20.
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100.
Herring gull	1.1	0.063	TL3: 0.192; TL4: 0.0480	Fish: 90—TL3: 80; TL4: 20.
	.....	.....	Other: 0.0267	Other: 10.
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929	Fish: 92—TL3: 80; TL4: 20.
	.....	.....	PB: 00283; Other: 0.0121	Birds: 8—PB: 70; non-aquatic: 30.

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) appendix E to part 132.

The State or Tribe shall adopt an antidegradation standard applicable to all waters of the Great Lakes System and identify the methods for implementing such a standard. Consistent with 40 CFR 131.12, an acceptable antidegradation standard and implementation procedure are required elements of a State's or Tribe's water quality standards program. Consistent with 40 CFR 131.6, a complete water quality standards submission needs to include both an antidegradation standard and antidegradation implementation procedures. At a minimum, States and Tribes shall adopt provisions in their antidegradation standard and implementation methods consistent with sections I, II, III and IV of this appendix, applicable to pollutants identified as bioaccumulative chemicals of concern (BCCs).

I. Antidegradation Standard

This antidegradation standard shall be applicable to any action or activity by any source, point or nonpoint, of pollutants that is anticipated to result in an increased loading of BCCs to surface waters of the Great Lakes System and for which independent regulatory authority exists requiring compliance with water quality standards. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR 131, and the level of water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the waterbody are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the quality of the waters exceed levels necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter consistent

with the definition of high quality water found at section II.A of this appendix and that quality ***15413** shall be maintained and protected unless the State or Tribe finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's or Tribe's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State or Tribe shall assure water quality adequate to protect existing uses fully. Further, the State or Tribe shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control. The State or Tribe shall utilize the Antidegradation Implementation Procedures adopted pursuant to the requirements of this regulation in determining if any lowering of water quality will be allowed;

C. Where high quality waters constitute an outstanding national resource, such as waters of national and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act (CWA).

II. Antidegradation Implementation Procedures

A. Definitions.

Control Document. Any authorization issued by a State, Tribal or Federal agency to any source of pollutants to waters under its jurisdiction that specifies conditions under which the source is allowed to operate.

High quality waters. High quality waters are water bodies in which, on a parameter by parameter basis, the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water.

Lake Superior Basin—Outstanding International Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to ensure that any new or increased discharges of Lake Superior bioaccumulative substances of immediate concern are subject to best technology in process and treatment requirements.

Lake Superior Basin—Outstanding National Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2, 3, 7, 8-TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following States' or Tribes' assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Those waters designated as such by a Tribe or State. The State or Tribal designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Waters that may be considered for designation as Outstanding National Resource Waters include, but are not limited to, water bodies that are recognized as:

Important because of protection through official action, such as Federal or State law, Presidential or secretarial action, international treaty, or interstate compact;

Having exceptional recreational significance;

Having exceptional ecological significance;

Having other special environmental, recreational, or ecological attributes; or waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of other waters so designated.

Significant Lowering of Water Quality. A significant lowering of water quality occurs when there is a new or increased loading of any BCC from any regulated existing or new facility, either point source or nonpoint source for which there is a control document or reviewable action, as a result of any activity including, but not limited to:

(1) Construction of a new regulated facility or modification of an existing regulated facility such that a new or modified control document is required;

(2) Modification of an existing regulated facility operating under a current control document such that the production capacity of the facility is increased;

(3) Addition of a new source of untreated or pretreated effluent containing or expected to contain any BCC to an existing wastewater treatment works, whether public or private;

(4) A request for an increased limit in an applicable control document;

(5) Other deliberate activities that, based on the information available, could be reasonably expected to result in an increased loading of any BCC to any waters of the Great Lakes System.

b. Notwithstanding the above, changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review. These changes include, but are not limited to:

(1) Normal operational variability;

(2) Changes in intake water pollutants;

(3) Increasing the production hours of the facility, (e.g., adding a second shift); or

(4) Increasing the rate of production.

C. Also, excluded from an antidegradation review are new effluent limits based on improved monitoring data or new water quality criteria or values that are not a result of changes in pollutant loading.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a waterbody or ambient pollutant concentrations exceed water quality criteria applicable to that waterbody, the Director shall not allow a lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (i.e., weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no action resulting in a lowering of water quality occurs unless an antidegradation demonstration has been completed pursuant to section III of this appendix and the information thus provided is determined by the Director pursuant to section IV of this appendix to adequately support the lowering of water quality.

1. The Director shall establish conditions in the control document applicable to the regulated facility that prohibit the regulated facility from undertaking any deliberate action, such that there would be an increase in the rate of mass loading of any BCC, unless an antidegradation demonstration is provided to the Director and approved pursuant to section IV of this appendix prior to commencement of the action. Imposition of limits due to improved monitoring data or new water quality criteria or values, or changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review.

2. For BCCs known or believed to be present in a discharge, from a point or nonpoint source, a monitoring requirement shall be included in the control document. The control document shall also include a provision requiring the source to notify the Director or any increased loadings. Upon notification, the Director shall require actions as necessary to reduce or eliminate the increased loading.

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall reflect any conditions developed under sections II.D.1 or II.D.2 of this appendix and included in a permit.

E. Special Provisions for Lake Superior.The following conditions apply in addition to those specified in section II.B through II.C of this appendix for waters of Lake Superior so designated.

1. A State or Tribe may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States and Tribes may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of ***15414** Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.B of this appendix.

F. Exemptions. Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected waterbody is an Outstanding National Resource Water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (i.e., weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended, or similar Federal, State or Tribal authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. States and Tribes should tailor the level of detail and documentation in antidegradation reviews, to the specific circumstances encountered. The antidegradation demonstration shall include the following:

A. Pollution Prevention Alternatives Analysis. Identify any cost-effective pollution prevention alternatives and techniques that are available to the entity, that would eliminate or significantly reduce the extent to which the increased loading results in a lowering of water quality.

B. Alternative or Enhanced Treatment Analysis. Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the lowering of water quality and their costs relative to the cost of treatment necessary to achieve applicable effluent limitations.

C. Lake Superior. If the States or Tribes designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. Important Social or Economic Development Analysis. Identify the social or economic development and the benefits to the area in which the waters are located that will be foregone if the lowering of water quality is not allowed.

E. Special Provision for Remedial Actions. Entities proposing remedial actions pursuant to the CERCLA, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity proposing to increase loadings is administratively complete, the Director shall use that information to determine whether or not the lowering of water quality is necessary, and, if it is necessary, whether or not the lowering of water quality will support important social and economic development in the area. If the proposed lowering of water quality is either not necessary, or will not support important social and economic development, the Director shall deny the request to lower water quality. If the lowering of water quality is necessary, and will support important social and economic development, the Director may allow all or part of the proposed lowering to occur as necessary to accommodate the important social and economic development. In no event may the decision reached under this section allow water quality to be lowered below the minimum level required to fully support existing and designated uses. The decision of the Director shall be subject to the public participation requirements of 40 CFR 25.

B. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Procedure 1: Site-specific Modifications to Criteria and Values

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

A. Requirements for Site-specific Modifications to Criteria and Values. Criteria and values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be protective of designated uses and aquatic life, wildlife or human health and be submitted to EPA for approval. In addition, any site-specific modifications that result in less stringent criteria must be based on a sound scientific rationale and shall not be likely to jeopardize the continued existence of endangered or threatened species listed or proposed under section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications shall be developed to protect endangered or threatened species listed or proposed under section 4 of the ESA, where such modifications are necessary to ensure that water quality is not likely to jeopardize the continued existence of such species or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications may also be developed to protect candidate (C1) species being considered by the U.S. Fish and Wildlife Service (FWS) for listing under section 4 of the ESA, where such modifications are necessary to protect such species.

1. Aquatic Life.

a. Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act (CWA) section 510.

Guidance on developing site-specific criteria in these instances is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

b. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality characteristics such as Ph, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or

ii. The sensitivity of the aquatic organisms species that “occur at the site” differs from the species actually tested in developing the criteria. The phrase “occur at the site” includes the species, genera, families, orders, classes, and phyla that: are usually present at the site; are present at the site only seasonally due to migration; are present intermittently because they periodically return to or extend their ranges into the site; were present at the site in the past, are not currently present at the site due to degraded conditions, and are expected to return to the site when conditions improve; are present in nearby bodies of water, are not currently present at the site due to degraded conditions, and are expected to be present at the site when conditions improve. The taxa that “occur at the site” cannot be determined merely by sampling downstream and/or upstream of the site at one point in time. “Occur at the site” does not include taxa that were once present at the site but cannot exist at the site now due to permanent physical alteration of the habitat at the site resulting, for example, from dams, etc.

c. Less stringent modifications also may be developed to acute and chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

Guidance on developing site-specific criteria is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

***15415** d. Any modifications to protect threatened or endangered aquatic species required by procedure 1.A of this appendix may be accomplished using either of the two following procedures:

i. If the Species Mean Acute Value (SMAV) for a listed or proposed species, or for a surrogate of such species, is lower than the calculated Final Acute Value (FAV), such lower SMAV may be used instead of the calculated FAV in developing site-specific modified criteria; or,

ii. The site-specific criteria may be calculated using the recalculation procedure for site-specific modifications described in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

2. Wildlife.

a. Wildlife water quality criteria may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510.

b. Less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part. The modification must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed. In addition, there must be a showing that:

i. Any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations; and

ii. Wildlife populations utilizing the site or downstream waters will continue to be fully protected.

c. Any modification to protect endangered or threatened wildlife species required by procedure 1.A of this appendix must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed, and may be accomplished by using the following recommended method.

i. The methodology presented in appendix D to part 132 is used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

ii. An interspecies uncertainty factor of 1 should be used where epidemiological data are available for the species in question. If necessary, species-specific exposure parameters can be derived as presented in Appendix D of this part;

iii. An intraspecies uncertainty factor (to account for protection of individuals within a wildlife population) should be applied in the denominator of the effect part of the wildlife equation in appendix D of this part in a manner consistent with the other uncertainty factors described in appendix D of this part; and

iv. The resulting wildlife value for the species in question should be compared to the two class-specific wildlife values which were previously calculated, and the lowest of the three shall be selected as the site-specific modification.

Note: Further discussion on the use of this methodology may be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria.

3. BAFs.

a. BAFs may be modified on a site-specific basis to larger values, pursuant to the authority reserved to the States and Tribes under CWA section 510, where reliable data show that local bioaccumulation is greater than the system-wide value.

b. BAFs may be modified on a site-specific basis to lower values, where scientifically defensible, if:

i. The fraction of the total chemical that is freely dissolved in the ambient water is different than that used to derive the system-wide BAFs (i.e., the concentrations of particulate organic carbon and the dissolved organic carbon are different than those used to derive the system-wide BAFs);

ii. Input parameters of the Gobas model, such as the structure of the aquatic food web and the disequilibrium constant, are different at the site than those used to derive the system-wide BAFs;

iii. The percent lipid of aquatic organisms that are consumed and occur at the site is different than that used to derive the system-wide BAFs; or

iv. Site-specific field-measured BAFs or biota-sediment accumulation factor (BSAFs) are determined.

If site-specific BAFs are derived, they shall be derived using the methodology in appendix B of this part.

c. Any more stringent modifications to protect threatened or endangered species required by procedure 1.A of this appendix shall be derived using procedures set forth in the methodology in appendix B of this part.

4. Human Health.

a. Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

b. Less stringent site-specific modifications to human health criteria or values may be developed when:

i. local fish consumption rates are lower than the rate used in deriving human health criteria or values under appendix C of this part; and/or

ii. a site-specific BAF is derived which is lower than that used in deriving human health criteria or values under appendix C of this part.

B. Notification Requirements. When a State proposes a site-specific modification to a criterion or value as allowed in section 4.A above, the State should notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. References.

U.S. EPA. 1984. Water Quality Standards Handbook—Revised. Chapter 3 and Appendices. U.S. Environmental Protection Agency, Office of Water Resource Center (RC-4100), 401 M Street, SW., Washington, DC 20960.

Procedure 2: Variances from Water Quality Standards for Point Sources

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources pursuant to such procedures. Variance procedures shall be consistent with (as protective as) the provisions in this procedure.

A. Applicability. A State or Tribe may grant a variance to a WQS which is the basis of a water quality-based effluent limitation included in a National Pollutant Discharge Elimination System (NPDES) permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the State or Tribe to modify, the corresponding water quality standard for the waterbody as a whole.

1. This provision shall not apply to new Great Lakes dischargers or recommencing dischargers.

2. A variance to a water quality standard shall not be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under Section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat.

3. A WQS variance shall not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act (CWA) and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

B. Maximum Timeframe for Variances. A WQS variance shall not exceed five years or the term of the NPDES permit, whichever is less. A State or Tribe shall review, and modify as necessary, WQS variances as part of each water quality standards review pursuant to section 303(c) of the CWA.

C. Conditions to Grant a Variance. A variance may be granted if:

1. The permittee demonstrates to the State or Tribe that attaining the WQS is not feasible because:

a. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

b. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable WQS to be met without violating State or Tribal water conservation requirements;

c. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied, or would cause more environmental damage to correct than to leave in place;

d. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

e. Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of WQS; or

***15416** f. Controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact.

2. In addition to the requirements of C.1, above, the permittee shall also:

a. Show that the variance requested conforms to the requirements of the State's or Tribe's antidegradation procedures; and

b. Characterize the extent of any increased risk to human health and the environment associated with granting the variance compared with compliance with WQS absent the variance, such that the State or Tribe is able to conclude that any such increased risk is consistent with the protection of the public health, safety and welfare.

D. Submittal of Variance Application. The permittee shall submit an application for a variance to the regulatory authority issuing the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in section C.1 of this procedure; and,

2. All relevant information demonstrating compliance with the conditions in section C.2 of this procedure.

E. Public Notice of Preliminary Decision. Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the State or Tribe shall public notice the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedures Act and shall notify the other Great Lakes States and Tribes of the preliminary decision. This public notice requirement may be satisfied by including the supporting information for the variance and the preliminary decision in the public notice of a draft NPDES permit.

F. Final Decision on Variance Request. The State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall include all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, and which is no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the waterbody as a whole through appropriate conditions;

3. When the duration of a variance is shorter than the duration of a permit, compliance with an effluent limitation sufficient to meet the underlying water quality standard, upon the expiration of said variance; and

4. A provision that allows the permitting authority to reopen and modify the permit based on any State or Tribal triennial water quality standards revisions to the variance.

The State shall deny a variance request if the permittee fails to make the demonstrations required under section C of this procedure.

G. Incorporating Variance into Permit. The State or Tribe shall establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. Renewal of Variance. A variance may be renewed, subject to the requirements of sections A through G of this procedure. As part of any renewal application, the permittee shall again demonstrate that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the original variance pursuant to sections F and G of this procedure. Renewal of a variance may be denied if the permittee did not comply with the conditions of the original variance.

I. EPA Approval. All variances and supporting information shall be submitted by the State or Tribe to the appropriate EPA regional office and shall include:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and records of any public hearings pursuant to section E of this procedure;

3. The final decision pursuant to section F of this procedure; and,

4. NPDES permits issued pursuant to section G of this procedure.

5. Items required by sections I.1 through I.3. of this procedure shall be submitted by the State within 30 days of the date of the final variance decision. The item required by section I.4 of this procedure shall be submitted in accordance with the State or Tribe Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.
40 CFR § 123.4440 CFR § 131.21
6. EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. State WQS Revisions. All variances shall be appended to the State or Tribe WQS rules.

Procedure 3: Total Maximum Daily Loads, Wasteload Allocations for Point Sources, Load Allocations for Nonpoint Sources, Wasteload Allocations in the Absence of a TMDL, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure 3 for the purpose of developing Total Maximum Daily Loads (TMDLs), Wasteload Allocations (WLAs) in the Absence of TMDLs, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits (WQBELs), except as specifically provided.

A. Where a State or Tribe develops an assessment and remediation plan that the State or Tribe certifies meets the requirements of sections B through F of this procedure and public participation requirements applicable to TMDLs, and that has been approved by EPA as meeting those requirements under 40 CFR 130.6, the assessment and remediation plan may be used in lieu of a TMDL for purposes of appendix F to part 132. Assessment and remediation plans under this procedure may include, but are not limited to, Lakewide Management Plans, Remedial Action Plans, and State Water Quality Management Plans. Also, any part of an assessment and remediation plan that also satisfies one or more requirements under Clean Water Act (CWA) section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. Assessment and remediation plans under this section should be tailored to the level of detail and magnitude for the watershed and pollutant being assessed.

B. General Conditions of Application. Except as provided in §132.4, the following are conditions applicable to establishing TMDLs for all pollutants and pollutant parameters in the Great Lakes System, with the exception of whole effluent toxicity, unless otherwise provided in procedure 6 of appendix F. Where specified, these conditions also apply to wasteload allocations (WLAs) calculated in the absence of TMDLs and to preliminary WLAs for purposes of determining the needs for WQBELs under procedure 5 of appendix F.

1. TMDLs Required. TMDLs shall, at a minimum, be established in accordance with the listing and priority setting process established in section 303(d) of the CWA and at 40 CFR 130.7. Where water quality standards cannot be attained immediately, TMDLs must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. Some TMDLs may be based on attaining water quality standards over a period of time, with specific controls on individual sources being implemented in stages. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination considering a number of factors including, but not limited to: receiving water characteristics; persistence, behavior and ubiquity of pollutants of concern; type of remediation activities necessary; available regulatory and non-regulatory controls; and individual State or Tribal requirements for attainment of water quality standards.

2. Attainment of Water Quality Standards. A TMDL must ensure attainment of applicable water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values for each pollutant or pollutants for which a TMDL is established.

3. TMDL Allocations.

a. TMDLs shall include WLAs for point sources and load allocations (LAs) for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant(s) addressed by the TMDL, minus the sum of a specified margin of safety (MOS) and any capacity reserved for future growth.

b. Nonpoint source LAs shall be based on:

i. Existing pollutant loadings if changes in loadings are not reasonably anticipated to occur;

ii. Increases in pollutant loadings that are reasonably anticipated to occur;

***15417** iii. Anticipated decreases in pollutant loadings if such decreased loadings are technically feasible and are reasonably anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether anticipated decreases in pollutant loadings are technically feasible and can reasonably be expected to occur within a reasonable period of time, technical and institutional factors shall be considered. These decisions are case-specific and should reflect the particular TMDL under consideration.

c. WLAs. The portion of the loading capacity not assigned to nonpoint sources including background, or to an MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include effluent limitations consistent with WLAs in EPA-approved or EPA-established TMDLs.

d. Monitoring. For LAs established on the basis of subsection b.iii above, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to varify anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and LAs as necessary to ensure that water quality standards will be achieved within the time-period established in the TMDL.

4. WLA Values. If separate EPA-approved or EPA-established TMDLs are prepared for different segments of the same watershed, and the separate TMDLs each include WLAs for the same pollutant for one or more of the same point sources, then WQBELs for that pollutant for the point source(s) shall be consistent with the most stringent of those WLAs in order to ensure attainment of all applicable water quality standards.

5. Margin of Safety (MOS). Each TMDL shall include a MOS sufficient to account for technical uncertainties in establishing the TMDL and shall describe the manner in which the MOS is determined and incorporated into the TMDL. The MOS may be provided by leaving a portion of the loading capacity unallocated or by using conservative modeling assumptions to establish WLAs and LAs. If a portion of the loading capacity is left unallocated to provide a MOS, the amount left unallocated shall be described. If conservative modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

6. More Stringent Requirements. States and Tribes may exercise authority reserved to them under section 510 of the CWA to develop more stringent TMDLs (including WLAs and LAs) than are required herein, provided that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time-period as a result of implementing nonpoint source controls.

7. Accumulation in Sediments. TMDLs shall reflect, where appropriate and where sufficient data are available, contributions to the water column from sediments inside and outside of any applicable mixing zones. TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life.

8. Wet Weather Events. Notwithstanding the exception provided for the establishment of controls on wet weather point sources in §132.4(e)(1), TMDLs shall reflect, where appropriate and where sufficient data are available, discharges resulting from wet

weather events. This procedure does not provide specific procedures for considering discharges resulting from wet weather events. However, some of the provisions of procedure 3 may be deemed appropriate for considering wet weather events on a case-by-case basis.

9. Background Concentration of Pollutants. The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs, WLAs calculated in the absence of a TMDL, or preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F. Background loadings may be accounted for in a TMDL through an allocation to a single “background” category or through individual allocations to the various background sources.

a. Definition of Background. “Background” represents all loadings that: (1) flow from upstream waters into the specified watershed, waterbody or waterbody segment for which a TMDL, WLA in the absence of a TMDL or preliminary WLA for the purpose of determining the need for a WQBEL is being developed; (2) enter the specified watershed, waterbody or waterbody segment through atmospheric deposition or sediment release or resuspension; or (3) occur within the watershed, waterbody or waterbody segment as a result of chemical reactions.

b. Data considerations. When determining what available data are acceptable for use in calculating background, the State or Tribe should use best professional judgment, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels. When data in more than one of the data sets or categories described in section B.9.c.i through B.9.c.iii below exist, best professional judgment should be used to select the one data set that most accurately reflects or estimates background concentrations. Pollutant degradation and transport information may be considered when utilizing pollutant loading data.

c. Calculation requirements. Except as provided below, the representative background concentration for a pollutant in the specified watershed, waterbody or waterbody segment shall be established on a case-by-case basis as the geometric mean of:

i. Acceptable available water column data; or

ii. Water column concentrations estimated through use of acceptable available caged or resident fish tissue data; or

iii. Water column concentrations estimated through use of acceptable available or projected pollutant loading data.

d. Detection considerations.

i. Commonly accepted statistical techniques shall be used to evaluate data sets consisting of values both above and below the detection level.

ii. When all of the acceptable available data in a data set or category, such as water column, caged or resident fish tissue or pollutant loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

10. Effluent Flow. If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. Reserved Allocations. TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, any increased loadings of the pollutant for which the TMDL was developed that are due to a new or expanded discharge shall not be allowed unless the TMDL is revised in accordance with these proceudres to include an allocation for the new or expanded discharge.

C. Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs). The following requirements shall be applied in establishing TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, for BCCs:

1. Beginning on March 23, 1997, there shall be no mixing available for new discharges of BCCs to the Great Lakes System. WLAs established through TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs for new discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

2. For purposes of section C of procedure 3 of appendix F, new discharges are defined as: (1) discharges from new Great Lakes dischargers; or (2) new or expanded discharges from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges.

3. Up until March 23, 2007, mixing zones for BCCs may be allowed for existing discharges to the Great Lakes System pursuant to the procedures specified in sections D and E of this procedure.

4. Except as provided in sections C.5 and C.6 of this procedure, permits issued on or after March 23, 1997 shall not authorize mixing zones for existing discharges of BCCs to the Great Lakes System after March 23, 2007. After March 23, 2007, WLAs established through TMDLs, WLAs established in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F for existing dischrges of BCCs to the Great Lakes System shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

5. Exception for Water Conservation. States and Tribes may grant mixing zones for any existing discharge of BCCs to the Great Lakes ***15418** System beyond the dates specified in sections C.3 and C.4 of this procedure, where it can be demonstrated, on a case-by-case basis, that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections D and E of this procedure.

6. Exception for Technical and Economic Considerations. States and Tribes may grant mixing zones beyond the dates specified in sections C.3 and C.4 of this procedure for any existing discharges of a BCC to the Great Lakes System upon the request of a discharger subject to the limited circumstances specified in sections C.6.a through C.6.d below. Such mixing zones shall also be consistent with sections D and E of this procedure.

a. The permitting authority must determine that:

i. The discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of CWA sections 301, 302, 304, 306, 307, 401, and 402, and is in compliance with its existing NPDES water quality-based effluent limitations, including those based on a mixing zone; and

ii. The discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested to the maximum extent possible.

b. In making the determination in section C.6.a above, the State or Tribal authority should consider:

i. The availability and feasibility, including cost effectiveness, of additional controls or pollution prevention measures for reducing and ultimately eliminating BCCs for that discharger, including those used by similar dischargers;

ii. Whether the discharger or affected communities will suffer unreasonable economic effects if the mixing zone is eliminated;

iii. The extent to which the discharger will implement an ambient monitoring plan to ensure compliance with water quality criteria at the edge of any authorized mixing zone or to ensure consistency with any applicable TMDL or such other strategy consistent with section A of this procedure; and,

iv. Other information the State or Tribe deems appropriate.

c. Any exceptions to the mixing zone elimination provision for existing discharges of BCCs granted pursuant to this section shall:

i. Not result in any less stringent limitations than those existing March 23, 1997;

ii. Not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

iii. Be limited to one permit term unless the permitting authority makes a new determination in accordance with this section for each successive permit application in which a mixing zone for the BCC(s) is sought;

iv. Reflect all information relevant to the size of the mixing zone considered by the State or Tribe under subsection b above;

v. Protect all designated and existing uses of the receiving water;

vi. Meet all applicable aquatic life, wildlife and human health criteria and values at the edge of the mixing zone and, as appropriate, within the mixing zone or be consistent with any appropriate TMDL or such other strategy consistent with section A of this procedure;

vii. Ensure the discharger has developed and conducted a pollutant minimization program for the BCC(s) if required to do so under regulations adopted consistent with procedure 8 of appendix F; and

viii. Ensure that alternative means for reducing BCCs elsewhere in the watershed are evaluated.

d. For each draft NPDES permit that would allow a mixing zone for one or more BCCs after March 23, 2007, the fact sheet or statement of basis for the draft permit, required to be made available through public notice under 40 CFR 124.6(e), shall:

i. Specify the mixing provisions used in calculating the permit limits; and

ii. Identify each BCC for which a mixing zone is proposed.

D. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources: WLAs in the Absence of a TMDL; and Preliminary WLAs for Purposes of Determining the Need for WQBELs for OWGL. This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. State and Tribal procedures to derive TMDLs under this section must be consistent with (as protective as) the general conditions in section B of this procedure, CWA section 303(d), existing regulations (40 CFR 130.7), section C of this procedure, and sections D.1. through D.4 below. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F must be consistent with sections B.9, C.1, C3 through C.6, and D. 1 through D.4 of this procedure.

1. Individual point source WLAs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution than one part effluent to 10 parts receiving water for implementation of numeric

and narrative chronic criteria and values (including, but not limited to human cancer criteria, human cancer values, human noncancer values, human noncancer criteria, wildlife criteria, and chronic aquatic life criteria and values) unless an alternative mixing zone is demonstrated as appropriate in a mixing zone demonstration conducted pursuant to section F of this procedure. In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State or Tribal requirements, on a case-by-case basis.

3. WLAs and preliminary WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value (FAV), unless a mixing zone demonstration is conducted and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where acute mixing zones overlap.

4. In no case shall a mixing zone be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

E. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources; WLAs in the Absence of a TMDL; and Preliminary WLAs for the Purposes of Determining the Need for WQBELs for Great Lakes Systems Tributaries and Connecting Channels. This section describes conditions for deriving TMDLs for tributaries and connecting channels of the Great Lakes System that exhibit appreciable flows relative to their volumes. State and Tribal procedures to derive TMDLs must be consistent with the general conditions listed in section B of this procedure, section C of this procedure, existing TMDL regulations (40 CFR 130.7) and specific conditions E.1 through E.5. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of this appendix for discharges to tributaries and connecting channels must be consistent with sections B.9, C.1, C.3 through C.6, and E.1 through E.5 of this procedure.

1. Stream Design. These design flows must be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. For purposes of calculating a TMDL, WLAs in the absence of a TMDL, or preliminary WLAs for the purposes of determining reasonable potential under procedure 5 of this appendix, using a steady-state model, the stream design flows shall be:

a. The 7-day, 10-year stream design flow (7Q10), or the 4-day, 3-year biologically-based stream design flow for chronic aquatic life criteria or values;

b. The 1-day, 10-year stream design flow (1Q10), for acute aquatic life criteria or values;

c. The harmonic mean flow for human health criteria or values;

d. The 90-day, 10-year flow (90Q10) for wildlife criteria.

e. TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for the purpose of determining the need for WQBELs calculated using dynamic modelling do not need to incorporate the stream design flows specified in sections E.1.a through E.1.d of this procedure.

2. Loading Capacity. The loading capacity is the greatest amount of loading that a water can receive without violating water quality standards. The loading capacity is initially calculated at the farthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of each applicable numeric ***15419** criterion or value for a given pollutant is determined by multiplying the applicable criterion or value by the flow at the farthest downstream location in the tributary basin at the design flow condition described above. This loading is then compared to the loadings at

sites within the basin to assure that applicable numeric criteria or values for a given pollutant are not exceeded at all applicable sites. The lowest load is then selected as the loading capacity.

3. Polluant Degradation. TMDLs, WLAs in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall be based on the assumption that a pollutant does not degrade. However, the regulatory authority may take into account degradation of the pollutant if each of the following conditions are met.

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered;

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. Acute Aquatic Life Criteria and Values. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purpose of determining the need for WQBELs based on acute aquatic life criteria or values shall not exceed the FAV, unless a mixing zone demonstration is completed and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where any applicable acute mixing zones overlap. This acute WLA review shall include, but not be limited to, consideration of:

a. The expected dilution under all effluent flow and concentration conditions at stream design flow;

b. Maintenance of a zone of passage for aquatic organisms; and

c. Protection of critical aquatic habitat.

In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

5. Chronic Mixing Zones. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purposes of determining the need for WQBELs for protection of aquatic life, wildlife and human health from chronic effects shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration pursuant to section F of this procedure is conducted and approved. A demonstration for a larger mixing zone may be provided, if approved and implemented in accordance with section F of this procedure. In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

F. Mixing Zone Demonstration Requirements.

1. For purposes of establishing a mixing zone other than as specified in sections D and E above, a mixing zone demonstration must:

a. Describe the amount of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. For sources discharging to the open waters of the Great Lakes (OWGLs), define the location at which discharge-induced mixing ceases;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone will be allowed only to the extent that the level of the pollutant permitted in the waterbody would not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

f. Show that the mixing zone does not extend to drinking water intakes;

g. Show that the mixing zone would not otherwise interfere with the designated or existing uses of the receiving water or downstream waters;

h. Document background water quality concentrations;

i. Show that the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

j. Provide that by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced; and

iii. Objectionable color, odor, taste or turbidity will not be produced.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character; and

c. Whether the habitat supports endemic or naturally occurring species.

3. The mixing zone demonstration must be submitted to EPA for approval. Following approval of a mixing zone demonstration consistent with sections F.1 and F.2, adjustment to the dilution ratio specified in section D.1 of this procedure shall be limited to the dilution available in the area where discharger-induced mixing occurs.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, unless:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered; and

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

Procedure 4: Additivity

The Great Lakes States and Tribes shall adopt additivity provisions consistent with (as protective as) this procedure.

A. The Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. For the chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) listed in Table 1, potential adverse additive effects in effluents shall be accounted for in accordance with section B of this procedure.

B. Toxicity Equivalency Factors (TEFs)/Bioaccumulation Equivalency Factors (BEFs).

1. The TEFs in Table 1 and BEFs in Table 2 shall be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

where:

$(TEC)_{tcdd}$=2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$=concentration of total chemical x in effluent

$(TEF)_x$=TCDD toxicity equivalency factor for x

$(BEF)_x$=TCDD bioaccumulation equivalency factor for x

2. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent shall be used when developing waste load allocations under procedure 3, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5, and for purposes of establishing effluent quality limits under procedure 5.

Table 1.—Toxicity Equivalency Factors for CDDs and CDFs

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5

1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Table 2.—Bioaccumulation Equivalency Factors for CDDs and CDFs

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

***15420 Procedure 5: Reasonable Potential To Exceed Water Quality Standards**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure. If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations (PEL) and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In all cases, the permitting authority shall use any valid, relevant, representative information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source.

1. The permitting authority shall develop preliminary wasteload allocations (WLAs) for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion nor sufficient data to calculate a Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant for the protection of human health, and aquatic life and the preliminary WLAs shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section C of this procedure to determine whether data must be generated to calculate a Tier II value.

2. The following provisions in procedure 3 of appendix F shall be used as the basis for determining preliminary WLAs in accordance with section 1 of this procedure: procedure 3.B.9, Background Concentrations of Pollutants; procedure 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs), procedures 3.C.1, and 3.C.3 through 3.C.6; procedure 3.D, Deriving TMDLs for Discharges to Lakes (when the receiving water is an open water of the Great Lakes (OWGL), an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume); procedure 3.E, Deriving TMDLs, WLAs and Preliminary WLAs, and load allocations (LAs) for Discharges to Great Lakes System Tributaries (when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume); and procedure 3.F, Mixing Zone Demonstration Requirements.

3. The permitting authority shall develop PELs consistent with the preliminary WLAs developed pursuant to sections A.1 and A.2 of this procedure, and in accordance with existing State or Tribal procedures for converting WLAs into WQBELs. At a minimum:

a. The PELs based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The PELs based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The PELs based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. Determining Reasonable Potential Using Effluent Pollutant Concentration Data.

If representative, facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:

1. The permitting authority shall specify the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent

concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the PELs developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in a NPDES permit for such pollutant.

2. In lieu of following the procedures under section B.1 of this procedure, the permitting authority may apply procedures consistent with the following:

a. The permitting authority shall specify the PEQ as the 95th percentile of the distribution of the projected population of daily values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term daily variability of the effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of monthly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the monthly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of weekly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the weekly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A.3 of this procedure, the permitting ***15421** authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. Developing Necessary Data to Calculate Tier II Values Where Such Data Does Not Currently Exist.
40 CFR § 122.44
1. Except as provided in sections C.2, C.4, or D of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent, and for which pollutant data sufficient to calculate Tier II values for non-cancer human health, acute aquatic life and chronic aquatic life do not exist, the permitting authority shall take the following actions:

a. The permitting authority shall use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects.

b. Using the procedures specified in sections A.1 and A.2 of this procedure, the permitting authority shall develop preliminary WLAs for the discharge of the pollutant from the point source to protect human health, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop PELs in accordance with section A.3 of this procedure, which are consistent with the preliminary WLAs developed in accordance with section C.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in section B of this procedure to the PELs developed in accordance with section C.1.c of this procedure. If the PEQ exceeds any of the PELs, the permitting authority shall generate or require the permittee to generate the data necessary to derive Tier II values for noncancer human health, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section C.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure. The calculated Tier II value shall be used in calculating the preliminary WLA and PEL under section A of this procedure, for purposes of determining whether a WQBEL must be included in the permit. If the permitting authority finds that the PEQ exceeds the calculated PEL, a WQBEL for the pollutant or a permit limit on an indicator parameter consistent with 40 CFR 122.44(d)(1)(vi)(C) must be included in the permit.

2. With the exception of bioaccumulative chemicals of concern (BCCs), a permitting authority is not required to apply the procedures set forth in section C.1 of this procedure or include WQBELs to protect aquatic life for any pollutant listed in Table 6 of part 132 discharged by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections C.1 or C.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative criterion for water quality; and

b. Incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a WQBEL consistent with section C.3 of this procedure, and the permitting authority demonstrates that the WQBEL developed under section C.3 of this procedure is at least as stringent as a WQBEL that would have been based upon the Tier II value or values for that pollutant, the permitting authority shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

D. Consideration of Intake Pollutants in Determining Reasonable Potential.
40 CFR § 122.44
1. General.

a. Any procedures adopted by a State or Tribe for considering intake pollutants in water quality-based permitting shall be consistent with this section and section E.

b. The determinations under this section and section E shall be made on a pollutant-by-pollutant, outfall-by-outfall, basis.

c. This section and section E apply only in the absence of a TMDL applicable to the discharge prepared by the State or Tribe and approved by EPA, or prepared by EPA pursuant to 40 CFR 130.7(d), or in the absence of an assessment and remediation

plan submitted and approved in accordance with procedure 3.A. of appendix F. This section and section E do not alter the permitting authority's obligation under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations consistent with the assumptions and requirements of any available WLA for the discharge, which is part of a TMDL prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7, or prepared by EPA pursuant to 40 CFR 130.7(d).

2. Definition of Same Body of Water.

a. This definition applies to this section and section E of this procedure.

b. An intake pollutant is considered to be from the same body of water as the discharge if the permitting authority finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

i. The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

ii. There is a direct hydrological connection between the intake and discharge points; and

iii. Water quality characteristics (e.g., temperature, Ph, hardness) are similar in the intake and receiving waters.

c. The permitting authority may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

d. An intake pollutant from groundwater may be considered to be from the same body of water if the permitting authority determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to human activity, such as industrial, commercial, or municipal operations, disposed actions, or treatment processes.

e. An intake pollutant is the amount of a pollutant that is present in waters of the United States (including groundwater as provided in section D.2.d of this procedure) at the time it is withdrawn from such waters by the discharger or other facility (e.g., public water supply) supplying the discharger with intake water.

3. Reasonable Potential Determination.

a. The permitting authority may use the procedure described in this section of procedure 5 in lieu of procedures 5.A through C provided the conditions specified below are met.

b. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within an applicable water quality standard where a discharger demonstrates to the satisfaction of the permitting authority (based upon information provided in the permit application or other information deemed necessary by the permitting authority) that:

i. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

ii. The facility does not contribute any additional mass of the identified intake pollutant to its wastewater;

iii. The facility does not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream;

iv. The facility does not increase the identified intake pollutant concentration, as defined by the permitting authority, at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water, unless the increased concentration does not cause or contribute to an excursion above an applicable water quality standard; and

v. The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

c. Upon a finding under section D.3.b of this procedure that a pollutant in the ***15422** discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority is not required to include a WQBEL for the identified intake pollutant in the facility's permit, provided:

i. The NPDES permit fact sheet or statement of basis includes a specific determination that there is no reasonable potential for the discharge of an identified intake pollutant to cause or contribute to an excursion above an applicable narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

ii. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section D.3.b of this procedure are maintained during the permit term; and

iii. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section D.3.b of this procedure.

d. Absent a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority shall use the procedures under sections 5.A through C of this procedure to determine whether a discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable narrative or numeric water quality criterion.

E. Consideration of Intake Pollutants in Establishing WQBELs.

1. General. This section applies only when the concentration of the pollutant of concern upstream of the discharge (as determined using the provisions in procedure 3.B.9 of appendix F) exceeds the most stringent applicable water quality criterion for that pollutant.

2. The requirements of sections D.1-D.2 of this procedure shall also apply to this section.

3. Intake Pollutants from the Same Body of Water.

a. In cases where a facility meets the conditions in sections D.3.b.i and D.3.b.iii through D.3.b.v of this procedure, the permitting authority may establish effluent limitations allowing the facility to discharge a mass and concentration of the pollutant that are no greater than the mass and concentration of the pollutant identified in the facility's intake water (“no net addition limitations”). The permit shall specify how compliance with mass and concentration limitations shall be assessed. No permit may authorize “no net addition limitations” which are effective after March 23, 2007. After that date, WQBELs shall be established in accordance with procedure 5.F.2 of appendix F.

b. Where proper operation and maintenance of a facility's treatment system results in removal of a pollutant, the permitting authority may establish limitations that reflect the lower mass and/or concentration of the pollutant achieved by such treatment, taking into account the feasibility of establishing such limits.

c. For pollutants contained in intake water provided by a water system, the concentration of the intake pollutant shall be determined at the point where the raw water supply is removed from the same body of water, except that it shall be the point where the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. Mass shall be determined by multiplying the concentration of the pollutant determined in accordance with this paragraph by the volume of the facility's intake flow received from the water system.

4. Intake Pollutants from a Different Body of Water. Where the pollutant in a facility's discharge originates from a water of the United States that is not the same body of water as the receiving water (as determined in accordance with section D.2 of this procedure), WQBELs shall be established based upon the most stringent applicable water quality criterion for that pollutant.

5. Multiple Sources of Intake Pollutants. Where a facility discharges intake pollutants that originate in part from the same body of water, and in part from a different body of water, the permitting authority may apply the procedures of sections E.3 and E.4 of this procedure to derive an effluent limitation reflecting the flow-weighted average of each source of the pollutant, provided that adequate monitoring to determine compliance can be established and is included in the permit.

F. Other Applicable Conditions.

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. Once the permitting authority has determined in accordance with this procedure that a WQBEL must be included in an NPDES permit, the permitting authority shall:

a. Rely upon the WLA established for the point source either as part of any TMDL prepared under procedure 3 of this appendix and approved by EPA pursuant to 40 CFR 130.7, or as part of an assessment and remediation plan developed and approved in accordance with procedure 3.A of this appendix, or, in the absence of such TMDL or plan, calculate WLAs for the protection of acute and chronic aquatic life, wildlife and human health consistent with the provisions referenced in section A.1 of this procedure for developing preliminary wasteload allocations, and

b. Develop effluent limitations consistent with these WLAs in accordance with existing State or Tribal procedures for converting WLAs into WQBELs.

3. When determining whether WQBELs are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

4. If the geometric mean of a pollutant in fish tissue samples collected from a waterbody exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant to that water has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

Procedure 6: Whole Effluent Toxicity Requirements

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 6 of appendix F of part 132.

The following definitions apply to this part:

Acute toxic unit (TU_a). $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to 50 percent of the test organisms.

Chronic toxic unit (TU_c). 100/NOEC or $100/IC_{25}$, where the NOEC and IC_{25} are expressed as a percent effluent in the test medium.

Inhibition concentration 25 (IC_{25}). the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant that would cause a 25 percent reduction in mean young per female or in growth for the test population.

No observed effect concentration (NOEC). The highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

A. Whole Effluent Toxicity Requirements. The Great Lakes States and Tribes shall adopt whole effluent toxicity provisions consistent with the following:

1. A numeric acute WET criterion of 0.3 acute toxic units (TU_a) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that 0.3 TU_a measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from acute effects of WET. At the discretion of the permitting authority, the foregoing requirement shall not apply in an acute mixing zone that is sized in accordance with EPA-approved State and Tribal methods.

2. A numeric chronic WET criterion of one chronic toxicity unit (TU_c) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that one TU_c measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from the chronic effects of WET. At the discretion of the permitting authority, the foregoing requirements shall not apply within a chronic mixing zone consistent with: (a) procedures 3.D.1 and 3.D.4, for discharges to the open of the Great Lakes (OWGL), inland ***15423** lakes and other waters of the Great Lakes System with no appreciable flow relative to their volume, or (b) procedure 3.E.5 for discharges to tributaries and connecting channels of the Great Lakes System.

B. WET Test Methods. All WET tests performed to implement or ascertain compliance with this procedure shall be performed in accordance with methods established in 40 CFR part 136.

C. Permit Conditions.

40 CFR § 122.44

1. Where a permitting authority determines pursuant to section D of this procedure that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority:

a. Shall (except as provided in section C.1.e of this procedure) establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET consistent with section C.1.b of this procedure;

b. Shall calculate WQBELs pursuant to section C.1.a. of this procedure to ensure attainment of the State's or Tribe's chronic WET criteria under receiving water flow conditions described in procedures 3.E.1.a (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, and with mixing zones no larger than allowed pursuant to section A.2. of this procedure. Shall calculate WQBELs to ensure attainment of the State's or Tribe's acute WET criteria under receiving water flow conditions described in procedure 3.E.1.b (or where applicable, with procedure 3.E.1.e) for Great Lakes System

tributaries and connecting channels, with an allowance for mixing zones no greater than specified pursuant to section A.1 of this procedure.

c. May specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation.

d. May allow with respect to any WQBEL established pursuant to section C.1.a of this procedure an appropriate schedule of compliance consistent with procedure 9 of appendix F; and

e. May decide on a case-by-case basis that a WQBEL for WET is not necessary if the State's or Tribe's water quality standards do not contain a numeric criterion for WET, and the permitting authority demonstrates in accordance with 40 CFR 122.44(d)(1)(v) that chemical-specific effluent limits are sufficient to ensure compliance with applicable criteria.

2. Where a permitting authority lacks sufficient information to determine pursuant to section D of this procedure whether the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, then the permitting authority should consider including in the NPDES permit appropriate conditions to require generation of additional data and to control toxicity if found, such as:

a. WET testing requirements to generate the data needed to adequately characterize the toxicity of the effluent to aquatic life;

b. Language requiring a permit reopener clause to establish WET limits if any toxicity testing data required pursuant to section C.2.a of this procedure indicate that the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.
40 CFR § 122.44
3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that the WET of an effluent neither is nor may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority may include conditions and limitations described in section C.2 of this procedure at its discretion.

D. Reasonable Potential Determinations. The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) and, where representative facility-specific WET effluent data are available, apply the following requirements in determining whether the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Either averaging or using the maximum of acute toxicity values collected within the same day for each species to represent one daily value. The maximum of all daily values for the most sensitive species tested is used for reasonable potential determinations;

b. Either averaging or using the maximum of chronic toxicity values collected within the same calendar month for each species to represent one monthly value. The maximum of such values, for the most sensitive species tested, is used for reasonable potential determinations:

c. Estimating the toxicity values for the missing endpoint using a default acute-chronic ratio (ACR) of 10, when data exist for either acute WET or chronic WET, but not for both endpoints.

2. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_a effluent) (B) (effluent flow/(Qad+effluent flow))>AC

Where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary wasteload allocations (WLAs) for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of this procedure and expressed in TU_a, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow(s) for tributaries and connecting channels in section C.1.b of this procedure, or where appropriate procedure 3.E.1.e of appendix F, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a coefficient of variation (CV) or 0.6. Where there are 10 or more individual WET tests, the multiplying factor taken from Table F6-1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

3. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_c effluent) (B) (effluent flow/Qad+effluent flow))>CC

Where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with section D.1.b. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of this procedure and expressed in TU_c, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.e of appendix F, and in accordance with the provisions of procedure 3.E.5 for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 for discharges to the OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV of 0.6. Where there are 10 more individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

Table F6-1.— Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of Samples	Coefficient of variation																			
0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0		
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1

3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

***15424 Procedure 7: Loading Limits**

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

Whenever a water quality-based effluent limitation (WQBEL) is developed, the WQBEL shall be expressed as both a concentration value and a corresponding mass loading rate.

A. Both mass and concentration limits shall be based on the same permit averaging periods such as daily, weekly, or monthly averages, or in other appropriate permit averaging periods.

B. The mass loading rates shall be calculated using effluent flow rates that are consistent with those used in establishing the WQBELs expressed in concentration.

Procedure 8: Water Quality-based Effluent Limitations Below the Quantification Level

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

When a water quality-based effluent limitation (WQBEL) for a pollutant is calculated to be less than the quantification level:

A. Permit Limits. The permitting authority shall designate as the limit in the NPDES permit the WQBEL exactly as calculated.

B. Analytical Method and Quantification Level.

1. The permitting authority shall specify in the permit the most sensitive, applicable, analytical method, specified in or approved under 40 CFR part 136, or other appropriate method if one is not available under 40 CFR part 136, to be used to monitor for the presence and amount in an effluent of the pollutant for which the WQBEL is established; and shall specify in accordance with section B.2 of this procedure, the quantification level that can be achieved by use of the specified analytical method.

2. The quantification level shall be the minimum level (ML) specified in or approved under 40 CFR part 136 for the method for that pollutant. If no such ML exists, or if the method is not specified or approved under 40 CFR part 136, the quantification level shall be the lowest quantifiable level practicable. The permitting authority may specify a higher quantification level if the permittee demonstrates that a higher quantification level is appropriate because of effluent-specific matrix interference.

3. The permit shall state that, for the purpose of compliance assessment, the analytical method specified in the permit shall be used to monitor the amount of pollutant in an effluent down to the quantification level, provided that the analyst has complied with the specified quality assurance/quality control procedures in the relevant method.

4. The permitting authority shall use applicable State and Tribal procedures to average and account for monitoring data. The permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level.

C. Special Conditions. The permit shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates that presence of the pollutant in the discharge at levels above the WQBEL. Special conditions that may be included in the permit include, but are not limited to, fish tissue sampling, whole effluent toxicity (WET) tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameters. Data generated as a result of special conditions can be used to reopen the permit to establish more stringent effluent limits or conditions, if necessary.

D. Pollutant Minimization Program. The permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program for each pollutant with a WQBEL below the quantification level. The goal of the pollutant minimization program shall be to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL. In addition, States and Tribes may consider cost-effectiveness when establishing the requirements of a PMP. The pollutant minimization program shall include, but is not limited to, the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant, which may include fish tissue monitoring and other bio-uptake sampling;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL;

4. When the sources of the pollutant are discovered, appropriate cost-effective control ***15425** measures shall be implemented, consistent with the control strategy; and

5. An annual status report that shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. A summary of all action taken to reduce or eliminate the identified sources of the pollutant.
40 CFR § 122.44
6. Any information generated as a result of procedure 8.D can be used to support a request for subsequent permit modifications, including revisions to (e.g., more or less frequent monitoring), or removal of the requirements of procedure 8.D, consistent with 40 CFR 122.44, 122.62 and 122.63.

Procedure 9: Compliance Schedules
The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 9 of appendix F of part 132.

A. Limitations for New Great Lakes Dischargers. When a permit issued on or after March 23, 1997 to a new Great Lakes discharger (defined in Part 132.2) contains a water quality-based effluent limitation (WQBEL), the permittee shall comply with such a limitation upon the commencement of the discharge.

B. Limitations for Existing Great Lakes Dischargers.

1. Any existing permit that is reissued or modified on or after March 23, 1997 to contain a new or more restrictive WQBEL may allow a reasonable period of time, up to five years from the date of permit issuance or modification, for the permittee to comply with that limit, provided that the Tier I criterion or whole effluent toxicity (WET) criterion was adopted (or, in the case of a narrative criterion, Tier II value, or Tier I criterion derived pursuant to the methodology in appendix A of part 132, was newly derived) after July 1, 1977.

2. When the compliance schedule established under paragraph 1 goes beyond the term of the permit, an interim permit limit effective upon the expiration date shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect the final limit and its compliance date.

3. If a permit establishes a schedule of compliance under paragraph 1 which exceeds one year from the date of permit issuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The time between such interim dates may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of any interim requirements.

C. Delayed Effectiveness of Tier II Limitations for Existing Great Lakes Discharges.

1. Whenever a limit (calculated in accordance with Procedure 3) based upon a Tier II value is included in a reissued or modified permit for an existing Great Lakes discharger, the permit may provide a reasonable period of time, up to two years, in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation within a reasonable period of time, no later than five years after permit issuance or modification, and contain a reopener clause.

2. The reopener clause shall authorize permit modifications if specified studies have been completed by the permittee or provided by a third-party during the time allowed to conduct the specified studies, and the permittee or a third-party demonstrates, through such studies, that a revised limit is appropriate. Such a revised limit shall be incorporated through a permit modification and a reasonable time period, up to five years, shall be allowed for compliance. If incorporated prior to the compliance date of the original Tier II limitation, any such revised limit shall not be considered less-stringent for purposes of the anti-backsliding provisions of section 402(o) of the Clean Water Act.

3. If the specified studies have been completed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide a reasonable additional period of time, not to exceed five years with which to achieve compliance with the original effluent limitation.

4. Where a permit is modified to include new or more stringent limitations, on a date within five years of the permit expiration date, such compliance schedules may extend beyond the term of a permit consistent with section B.2 of this procedure.

5. If future studies (other than those conducted under paragraphs 1, 2, or 3 above) result in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of a Tier II-based limit, the existing Tier II-based limit may be revised to be less stringent if:

(a) It complies with sections 402(o) (2) and (3) of the CWA; or,

(b) In non-attainment waters, where the existing Tier II limit was based on procedure 3, the cumulative effect of revised effluent limitation based on procedure 3 of this appendix will assure compliance with water quality standards; or,

(c) In attained waters, the revised effluent limitation complies with the State or Tribes' antidegradation policy and procedures.

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BILLING CODE 6560-50-P

Footnotes

tr a CMC=CMC.

d $^{tr\ d}$b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

c CMC should be considered free cyanide as CN.

t d CMC=CMC.

Notes:

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr $_{AA}$a CMC=exp { m [ln (hardness)]+b}.

d [tr d]b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

t [AA t]c CMC=exp m { [pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr a CCC=CCC.

d [tr d]b CCC=(CCC) CF. The CCC shall be rounded to two significant digits.

c CCC should be considered free cyanide as CN.

t d CCC=CCC.

Notes:

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

tr [cc]a CCC=exp {m[ln (hardness)]+b}.

[d tr d]b CCC=(CCC) (CF). The CCC shall be rounded to two significant digits.

t [AA t]c CMC=exp {m[pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

1 Includes methylmercury.

1 The FCMs for trophic level 3 are the geometric mean of the FCMs for sculpin and alewife.

Note: TL3=trophic level three fish; TL4=trophic level four fish; PB =piscivorous birds; Other=non-aquatic birds and mammals.

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U.S. ENVIRONMENTAL PROTECTION AGENCY – REGION 10

Technical Support Document

for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011

October 17, 2011

Contents

TECHNICAL SUPPORT DOCUMENT

For Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011

I. INTRODUCTION

In consideration of current information relative to fish consumption in Oregon, the Oregon Department of Environmental Quality (ODEQ) proposed revisions to Oregon's water quality standards (WQS) located in Chapter 340, Division 41 of Oregon's Administrative Rules (OAR 340-041). ODEQ proposed new and revised human health water quality criteria for toxics and associated implementation provisions on December 21, 2010. ODEQ provided a formal public comment period on the proposed revisions and held nine public hearings. The public comment period extended from December 21, 2010 through March 21, 2011. 1,075 written comments were received and responded to by ODEQ. Revisions were adopted by the Oregon Environmental Quality Commission (EQC or Commission) on June 16, 2011, and filed with Oregon Secretary of State on July 13, 2011. Oregon's submittal included a letter dated July 20, 2011, from Larry Knudsen, Assistant Attorney General, certifying that the revisions were adopted in accordance with Oregon State law. In accordance with Section 303(c) of the Clean Water Act (CWA) ODEQ submitted these revisions to EPA for review and approval on July 21, 2011.

ODEQ revised their human health criteria for iron and manganese in a separate submittal dated January 18, 2011, which EPA approved on June 9, 2011. ODEQ also revised the human health criteria for arsenic in a separate submittal dated July 12, 2011, which EPA is now approving as part of this action. ODEQ accepted public comments on these revisions from August 25 to September 30, 2010, and held public hearings in Portland and Pendleton. ODEQ also conducted further public comment on the proposed rule, including revised proposed numeric criteria from February 1 to February 23, 2011. These revisions were adopted by the EQC on April 21, 2011 and became effective under State law upon filing with the Oregon Secretary of State on June 30, 2011. ODEQ submitted the revisions to the human health criteria for arsenic to EPA for review and approval on July 12, 2011. Oregon's submittal included a letter dated July 11, 2011, from Larry Knudsen, Assistant Attorney General, certifying that the revisions were adopted in accordance with Oregon State law.

The June 16, 2011 rule package adopted by the EQC included revisions to the States' Total Maximum Daily Load (TMDL) and National Pollutant Discharge Elimination System (NPDES) permitting regulations found in OAR 340-042 and 045. These are revisions to Oregon's implementation rules and are not water quality standards. Accordingly, Oregon did not include

them in the materials submitted for review under Section 303(c) of the CWA and EPA does not address them in today's action.

Revisions addressed in today's decision can be divided into the general categories described below.

1. ***New and revised human health criteria for carcinogens and non-carcinogens at OAR 340-041-0033.***
   ODEQ adopted new and revised human health criteria for 104 toxic pollutants (48 non-carcinogens and 56 carcinogens) based on a fish consumption rate of 175 grams per day. The criteria for these toxic pollutants are consistent with EPA's 304(a) recommended criteria values[1] and were derived using the methodology presented in EPA's 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*[2] and EPA's 2001 Methylmercury guidance.[3] The new and revised human health criteria for toxic pollutants are contained in Table 40.

   Additional revisions related to the human health criteria include:

   - The removal of 13 pollutants consistent with EPA's removal of 304(a) recommended criteria values for these same pollutants. Most of these recommended criteria were withdrawn since EPA developed individual criteria for the most toxic of chemicals in the family of chemicals represented by those 13 pollutants.
   - Several new, revised and withdrawn footnotes to the criteria in order to provide clarification.
   - Revisions to the water quality standards provision at OAR 340-041-0033 which revise regulatory citations and table numbers referencing the human health and aquatic life criteria tables.

2. ***Revised arsenic human health criteria.***
   ODEQ adopted revised human health criteria for arsenic and submitted the revised criteria separately to EPA on July 12, 2011.

3. ***New implementation provision entitled "Site-specific background pollutant criteria" at OAR 340-041-0033(6).***
   ODEQ adopted a new provision that allows it to develop a site-specific criteria for a portion of a waterbody in the vicinity of an NPDES permitted discharge in limited instances. The criteria is only applicable for criteria addressing carcinogenic effects on

[1] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf
[2] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[3] EPA. 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

human health and for pollutants that are taken into a facility through their intake water and discharged to the same waterbody at an equal or lower mass. The instream criterion concentration is limited to three percent above the ambient condition and may not exceed a 10^{-4} risk level as calculated using the same input variables as used to calculate the criteria in Table 40.

4. ***Revised variance provision at OAR 340-041-0059.***
   ODEQ has removed the variance authorizing procedure found at OAR 340-041-0061(2) and replaced it with a new procedure at OAR 340-041-0059. ODEQ's objective for these revisions was to ensure that variances and their accompanying pollutant reduction plans continue to ensure progress toward meeting standards, to streamline the administration process, and to require pollutant reduction plans with specific milestones that will result in water quality improvement, and add general clarification to the rule. All variances adopted under this provision require EPA approval.

5. ***A correction to a cross-reference in the bacteria provision found at OAR 340-041-0009(10).***
   ODEQ adopted a revision to correct the cross-reference in this provision to reflect rule numbering revisions in OAR 340-041-0061.

6. ***Revised rules explaining how the mechanisms for forestry and agricultural nonpoint sources work to meet water quality standards and the total maximum daily load (TMDL) load at OAR 340-041-0007(5) and OAR 340-041-0061(9)(a)(E), (10), and (11).***
   ODEQ adopted revisions to clarify how nonpoint sources will be addressed in TMDLs and how ODEQ will interact with the Departments of Forestry and Agriculture to ensure needed programs are in place to address these sources of pollution.

II. ORGANIZATION OF DOCUMENT

This document is organized in the following manner. Part III of this document contains background on ODEQ's process to adopt new and revised human health criteria and information regarding the July 12 and 21, 2011 submittals.

Part IV contains the basis for EPA's decisions under section 303(c) of the Clean Water Act (CWA) and implementing regulations found in the Code of Federal Regulations (CFR) at 40 CFR § 131.11 to approve Oregon's new and revised human health criteria. This section includes information regarding EPA's review of Oregon's human health criteria revisions which specifically evaluates the applicability of the human health criteria to Oregon's waters along with the methodology and input variables used by Oregon for their non-carcinogenic and carcinogenic criteria. This includes an evaluation of Oregon's revised fish consumption rate of 175 grams per day used to derive the State's new and revised human health criteria. Separate subsections include the EPA's action on Oregon's new methylmercury human health criteria and revised human health criteria for arsenic. Finally, this section outlines EPA's review and action on new, revised and withdrawn footnotes, withdrawn human health criteria which were replaced by more specific criteria and the Table 40 summary language.

Part V of this document contains EPA's review and action on revisions to Oregon's narrative statement at OAR 340-041-0033.

Parts VI and VII of the document contain EPA's review and approval of two implementation procedures included in the July 21, 2011 submittal – the background pollutant criteria and the revised variance provision.

Part VIII of this document includes EPA's review and action on a minor editorial change to Oregon's bacteria provision to correct a cross-referencing error.

Part IX discusses the revised rules regarding implementation of criteria by forestry and agricultural nonpoint sources. These provisions are not WQS under the CWA and therefore EPA is taking no action on them.

III. BACKGROUND

In 1999, ODEQ initiated a Water Quality Standards Review (triennial review) to update Oregon's criteria for toxic pollutants which were based on the 1986 EPA Gold Book[4] and that were contained in OAR 340-041-0033 and Table 20 of Oregon's water quality standards. This review was completed in 2003. During this review, ODEQ made significant revisions to both their aquatic life and human health criteria based on the updated EPA methodologies and science for deriving aquatic life and human health criteria that had occurred since the Gold Book had been published. The Commission adopted these new and revised water quality standards on May 20, 2004. Upon adoption, ODEQ submitted these criteria changes along with revisions to the narrative toxics provision to EPA on July 8, 2004.

One goal of Oregon's 1999-2003 WQS review was to update its human health criteria for toxic pollutants in order to reflect the latest scientific information and EPA's most recent national CWA § 304(a) human health criteria recommendations.[5] In 2000, EPA published a revised methodology for deriving § 304(a) human health criteria recommendations titled *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (hereinafter referred to as the "2000 Methodology").[6] In separate updates published in 2002 and 2003[7,8] along with 2009,[9] EPA updated the § 304(a) human health criteria recommendations to reflect this new methodology and to consider updated toxicological information in EPA's Integrated Risk Information System (IRIS).[10]

The new and revised human health criteria adopted by Oregon in 2004 were based on EPA's recommendations provided in these documents. The human health criteria were derived using a fish consumption rate of 17.5 grams per day (about 0.6 ounces per day or three 6-ounce meals per month), which represents the 90th percentile of consumption among consumers and non-consumers of fish nationwide. This is the national default fish consumption rate recommended

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[4] EPA. 1986. *Quality Criteria for Water* ("Gold Book"). U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 440/5-86-001. Available at: http://www.epa.gov/waterscience/criteria/library/goldbook.pdf

[5] ODEQ. 2003. *Toxic Compounds Criteria: 1999-2003 Water Quality Standards Review Issue Paper*. Oregon Department of Environmental Quality, Portland, Oregon. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/may2004/5.20.04.ItemB.AttchH.pdf

[6] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[7] EPA. 2002. *Revision of National Recommended Water Quality Criteria*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 67, Issue: 249, Page: 79091 (67 FR 79091), December 27, 2002. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2002/December/Day-27/w32770.htm

[8] EPA. 2003. *National Recommended Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 68, Issue: 250, Page: 75507 (68 FR 75507), December 31, 2003. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2003/December/Day-31/w32211.htm

[9] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[10] EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

by EPA in the 2000 Methodology for use when local, regional or other data is not available. During the public process Oregon received comment regarding concerns that the fish consumption rate used in the criteria may not accurately represent Oregonian's consumption patterns. Following review of these comments ODEQ recommended, and in 2004 the Commission adopted, criteria derived using a fish consumption rate of 17.5 grams per day. However, in recognition of this expressed public concern, the Commission requested that ODEQ seek resources to conduct a fish consumption rate study in Oregon.

Following Oregon's 2004 adoption of these criteria, the Confederated Tribes of the Umatilla Indian Reservation (Umatilla Tribe) and other tribal governments raised objections to EPA, stating that the criteria did not protect tribal members who eat higher amounts of fish and for whom fish consumption is a critical part of their cultural tradition and religion. In response, EPA evaluated the protectiveness of the criteria in light of local and regional fish consumption data and initiated discussions with Oregon regarding this issue. Local data was available from a study conducted by the Columbia River Inter-Tribal Fish Commission (CRITFC)[11] (hereinafter referred to as the "CRITFC Study"), which included surveys of four Columbia River Tribes, two of whom reside in Oregon, the Confederated Tribes of the Umatilla Indian Reservation (CTUIR or Umatilla Tribe) and the Confederated Tribes of the Warms Springs Reservation. In addition, several regional fish consumption studies were also available.

Oregon was not able to obtain funding for a study of Oregon fish consumption rates specific to Oregon but did agree to review available literature and data in collaboration with EPA and the Umatilla Tribe. In the fall of 2006, ODEQ launched the fish consumption rate review project involving seven public workshops and two workgroups. The workgroups were charged with providing ODEQ with information relative to the available science and the potential implementation and fiscal concerns that may be associated with criteria based on a higher fish consumption rate. The Human Health Focus Group (HHFG), made up of public health professionals and toxicologists, reviewed the available data on fish consumption patterns in the Pacific Northwest and elsewhere. The group wrote a report[12] summarizing the science and made recommendations about the quality and appropriate use of the available information. ODEQ considered the HHFG's analysis and the other information obtained during this project to select a fish consumption rate they felt appropriate for use in developing criteria for Oregon's waters.

Oregon addressed several issues during the process of determining an appropriate fish consumption rate for Oregon. These included:

- Which studies should be considered when developing a fish consumption rate for Oregon?
- Should the criteria be based on a fish consumption rate that includes Oregonians who

[11] Columbia River Inter-Tribal Fish Commission (CRITFC). October 1994. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin.* Technical Report 94.3. Available at: http://www.critfc.org/tech/94-3report.pdf

[12] ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf

eat large amounts of fish and shellfish for cultural, economic, health or other reasons, or a fish consumption rate reflective of Oregon's total (general) population, including people who do not eat fish or eat it rarely?

- What proportion or percentile of the population(s) should be protected by the criteria? (Within any group, whether Native-Americans, Asian-Americans, commercial fishermen or the general population, there will be some individuals who eat more than any chosen rate and some who eat less than that rate.)
- How should the consumption of salmon (an anadromous fish) and/or marine fish be considered when determining the rate to be used for freshwaters?
- Should the same rate be used for all waters of Oregon or should multiple rates be considered based on known consumption patterns?

Following review of all the information obtained during the fish consumption rate review project, ODEQ determined that a fish consumption rate of 175 grams per day was a reasonable and protective fish consumption rate to use when driving the human health criteria applicable to Oregon's surface waters. A fish consumption rate of 175 grams per day equals approximately 6.2 ounces per day (or approximately 23 8-oz fish or shellfish meals per month). This rate represents the 95th percentile value from the CRITFC study and is within the range of the 90th percentile values from various studies from the Northwest assembled by the HHFG.[13] ODEQ found the 175 grams per day rate to be consistent with the HHFG recommendation to use 90th or 95th percentile values to represent the proportion of the population the criteria should be designed to protect. ODEQ also found the rate to be consistent with HHFG recommendations to use a fish consumption rate that represents fish consumers only, rather than a rate derived from the overall population including both consumers and non-consumers of fish, and to include salmon and other marine species in the rate. Finally, ODEQ recommended that the rate be applied statewide.[14]

On October 23, 2008, ODEQ presented the EQC with a recommendation to revise Oregon's toxics criteria for human health using a FCR of 175 grams per day.[15] The Commission agreed with this recommendation and directed ODEQ to:

1. Revise Oregon's toxics criteria for human health based on a fish consumption rate of 175 grams per person per day;

[13] EPA. June 1, 2010. Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions Submitted on July 8, 2004. U.S. Environmental Protection Agency. See Appendix A for a summary of the studies considered by Oregon. Available at: http://www.epa.gov/region10/pdf/water/oregon-hhwqc-tsd_june2010.pdf

[14] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 8-10. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[15] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf

2. Propose rule language that will allow ODEQ to implement the standards in National Pollutant Discharge Elimination System (NPDES) permits and other Clean Water Act programs in an environmentally meaningful and cost-effective manner;
3. Propose rule language or develop other implementation strategies to reduce the adverse impacts of toxic substances in Oregon's waters that are the result of non-point source (not via a pipe) discharges or other sources not subject to section 402 of the Clean Water Act;
4. Develop a proposed rule and implementation methods that carefully consider the costs and benefits of the fish consumption rate and the data and scientific analysis already compiled or that is developed as part of the rulemaking proceeding.

Pursuant to this directive, ODEQ established a Rulemaking Workgroup in December 2008. The purpose of this group was to provide input and feedback to ODEQ as it developed its proposed rulemaking to revise human health criteria using the revised fish consumption rate and to address potential issues associated with implementing the revised criteria. The workgroup met on a monthly basis from December 2008 until October 2010. In addition, to address the third element of the EQC directive, ODEQ formed other workgroups to address the reduction of toxic pollution from sources not regulated by NPDES permits and to assist in the development of a comprehensive, cross media toxics reduction strategy.[16]

On December 21, 2010, ODEQ issued a proposed rule for public comment that included new and revised human health criteria for toxic pollutants, a revision to their variance rule, a new background pollutant provision and several proposed additions and revisions to rules relating to the implementation of the NPDES program and nonpoint source programs. As detailed in Section I, ODEQ revised the proposed rule in response to comments received, presented it to the Commission for adoption on June 16, 2011, and submitted it to EPA on July 21, 2011.

On June 1, 2010, consistent with a Consent Decree entered in the U.S. District Court in the District of Oregon,[17] EPA acted on the revised human health criteria which Oregon had submitted to EPA on July 8, 2004. As part of this action, EPA disapproved all of Oregon's new and revised human health criteria that were derived using a fish consumption rate of 17.5 grams per day as well as three footnotes associated with those criteria and footnote K insofar as it applies to the "organism only" human health criterion for manganese. EPA found that these human health criteria, derived using a fish consumption rate of 17.5 grams per day, were not protective of Oregon's designated use of fishing consistent with the Commission's October 2008 directive. In the June 1, 2010 letter to ODEQ, EPA stated that it "believe[d] that Oregon's adoption of human health criteria consistent with the Commission's Directive to develop criteria using a fish consumption rate of 175 grams per day statewide would be adequate to address EPA's disapproval of the new and revised human health criteria as well as [3 of the 4] footnotes."[18] As part of the 2010 action, EPA approved the human health criteria for asbestos

[16] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 8-9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[17] *Northwest Environmental Advocates v. U.S. EPA,* No. 06-479-HA (D. Or. 2006).
[18] EPA. June 1, 2010. Letter from Michael A. Bussell, Director, Office of Water and Watersheds, EPA Region 10 to Neil Mullane, Administrator, Water Quality Division, ODEQ, *Re: EPA's Action on New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions in Oregon's Water Quality*

and copper since those criteria value were not derived based on a fish consumption rate, footnote K as it applies to the "water + organism criteria for iron and manganese, the withdrawal of eight human health criteria, and revisions to the narrative toxic provisions at OAR 340-041-0033(1) and (2).

A. *ODEQ'S JULY 12 AND JULY 21, 2011 SUBMITTALS*

In order to address the Commission's October 2008 directive and EPA's June 1, 2010 disapproval action, on July 21, 2011 Oregon submitted new and revised numeric human health criteria and two WQS implementation provisions to EPA for action under CWA §303(c). This submission also contained a correction to a regulatory citation in the bacteria criteria provision and several other regulatory changes that are not WQS. Revised criteria for arsenic were adopted separately by the Commission on April 21, 2011 and submitted to EPA on July 12, 2011. All of the numeric criteria adopted in these actions were derived using a fish consumption rate of 175 grams per day.

The new and revised criteria, which serve as the basis for NPDES permit limits and other regulatory decisions, are located in Oregon's WQS in a new table called Table 40. ODEQ has consolidated the human health criteria which were previously contained in Tables 20, 33A and 33B into Table 40. The adoption of the new and revised human health criteria based on a fish consumption rate of 175 grams per day is ODEQ's remedy to EPA's disapproval of ODEQ's 2004 human health criteria based on a fish consumption rate of 17.5 grams per day.

Consistent with CWA §303(c)(2)(B), in adopting these new and revised human health criteria, Oregon has adopted human health criteria for all of the priority toxic pollutants for which EPA has published criteria under CWA §304(a). Forty-eight of the 104 pollutants for which Oregon adopted new or revised human health criteria are characterized as non-carcinogens (i.e., not having the potential to cause cancer). The remaining 56 pollutants are carcinogens (i.e., having the potential to cause cancer).

The calculations that Oregon used to derive the human health criteria for non-carcinogens and carcinogens differed depending upon the primary exposure pathway appropriate to the pollutant for which the criteria were derived and are further described separately in section IV below. Oregon's criteria were adopted to protect human health from chronic (lifetime) exposure to toxic substances through drinking water and eating fish[19] obtained from surface waters. Where the criteria are derived to protect human health from exposure through both drinking water and eating fish (in combination), Oregon has adopted "water + organism" criteria. Where the criteria are derived to protect human health from exposure through eating fish alone (not in combination with drinking water), Oregon has adopted "organism only" criteria. These two sets of criteria (i.e., "water + organism" and "organism only") are reflected in the column headings of Table 40

Standards. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/EPAHHLetter20100601.pdf
[19] As used throughout this technical support document, the term "fish" refers to finfish as well as shellfish.

in Oregon's WQS. Additional information can be found in ODEQ's Human Health Criteria Issue Paper.[20]

The criteria adopted by Oregon for methylmercury and arsenic were derived using variations to the methodology used for all other criteria. Thus, those two pollutants and the methods used to derive those criteria are addressed separately below.

Additional revisions related to the human health criteria, which are discussed below, include:

- The removal of 13 pollutants consistent with EPA's removal of 304(a) recommended criteria values for these same pollutants. Most of the previous criteria recommendations addressed families of pollutants for which the criteria recommendations were withdrawn when EPA developed criteria recommendations for the individual pollutants within each family of chemicals that present the greatest human health risk.
- Several new, revised and withdrawn footnotes to the criteria in order to provide clarification.
- Revisions to the water quality standards provision at OAR 340-041-0033 which provide narrative language explaining the human health and aquatic life criteria tables.

In response to the second, third and forth directives issued by the EQC on October 23, 2008, ODEQ also revised OAR 340-041 to include two WQS implementation provisions - a revised variance procedure and a site-specific background pollutant provision – and revised rule language addressing implementation for nonpoint sources. In addition, ODEQ adopted an intake credit rule (an NPDES permitting provision) and several changes to the TMDL rules in OAR 340-042 and 045. These latter changes were not submitted to EPA for consideration under CWA 303(c), are not WQS under the CWA, and are not addressed in this action.

[20] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

IV. ODEQ'S NEW AND REVISED HUMAN HEALTH CRITERIA

A. *EPA REVIEW OF OREGON'S HUMAN HEALTH CRITERIA REVISIONS*

This section contains the basis for EPA's decisions under section 303(c) of the CWA and implementing regulations found at 40 CFR § 131.11 to approve Oregon's new and revised human health criteria. This section includes information regarding EPA's review of Oregon's human health criteria revisions which specifically evaluates the applicability of the human health criteria to Oregon's waters along with the methodology and input variables used by Oregon for their non-carcinogenic and carcinogenic criteria. This includes an evaluation of Oregon's revised fish consumption rate of 175 grams per day. Separate subsections address EPA's action on Oregon's new methylmercury human health criteria and revised human health criteria for arsenic. Finally, this section outlines EPA's review and action on new, revised and withdrawn footnotes, withdrawn human health criteria which were replaced by more specific criteria and the Table 40 summary language.

1. Human Health Criteria Applicability to Oregon's Waters

Oregon's water quality standards designate beneficial uses for waters of the state for each basin in OAR 340-041-0101 to 0340 and Tables 101(A) through 340(A), incorporated into Oregon rule by reference. Oregon's designated uses consist of the following:

- Public Domestic Water Supply
- Private Domestic Water Supply
- Industrial Water Supply
- Irrigation
- Livestock Watering
- Fish and Aquatic Life
- Wildlife and Hunting
- Fishing
- Boating
- Water Contact Recreation
- Aesthetic Quality
- Hydro Power
- Commercial Navigation and Transportation

Oregon's human health criteria were developed to protect human health from long-term exposure to toxic pollutants in drinking water and through eating fish and shellfish containing these pollutants. Waters to be protected for drinking water are those designated as either "Public Domestic Water Supply" or "Private Domestic Water Supply." Waters to be protected for consumption of fish and shellfish are designated as "Fishing."

Oregon's "water + organism" criteria were established to limit the pollutant to levels that protect the safe consumption of drinking water and fish, including shellfish. These criteria are applied where Oregon has designated public or private domestic water supply, and fishing as beneficial uses. Table 1 below identifies those waters in Oregon that have both a fishing designated use and either a public domestic water supply or a private domestic water supply designated use. Both the "water + organism" criteria and the "organism only" criteria apply to these waters.

The "organism only" criteria apply where Oregon has designated a fishing use but not a domestic or private water supply use.[21] Table 2 below identifies those waters in Oregon that have a fishing designated use but neither a public domestic water supply nor a private domestic water supply designated use.

Table 1: Waters in Oregon that have both a fishing designated use as well as a public domestic water supply or a private domestic water supply designated use. Both the "water + organism" criteria and the "organism only" criteria apply to these waters.

OR WQS Table No.	Basin Name	Segment Names
101A	Mainstem Columbia River	Columbia River (Mouth to RM 86); and Columbia River (RM 86 to 309)
121A	Mainstem Snake River	Snake River (RM 176 to 409)
130A	Deschutes Basin	Deschutes River Main Stem from Mouth to Pelton Regulating Dam; Deschutes River Main Stem from Pelton Regulating Dam to Bend Diversion Dam and for the Crooked River Main Stem; Deschutes River Main Stem above Bend Diversion Dam and for the Metolious River Main Steam; and All Other Basin Stems
140A	Goose and Summer Lakes Basin	Freshwater Lakes and Reservoirs; and Freshwater Streams
151A	Grande Ronde Basin	Main Stem Grande Ronde River (RM 39 to 165) and All Other Basin Waters
160A	Hood Basin	Hood River Basin Streams
170A	John Day Basin	John Day River and All Tributaries
180A	Klamath Basin	Klamath River from Klamath Lake to Keno Dam (RM 255 to 232.5); Lost River (RM 5 to 65) and Lost River Diversion Channel; and All Other Basin Waters
190A	Malheur Lake Basin	All Rivers and Tributaries

[21] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper*. Oregon Department of Environmental Quality. page 11. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf Also described in ODEQ. 2004. *Toxic Compounds Criteria. 1999-2003 Water Quality Standards Review. Issue Paper.* May 20-21, 2004 EQC Meeting. Agenda Item B, Rule Adoption: Water Quality Standards, including Toxics Criteria. Attachment H. Oregon Department of Environmental Quality. pages H-14, H-17. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/may2004/5.20.04.ItemB.AttchH.pdf

OR WQS Table No.	Basin Name	Segment Names
201 A	Malheur River Basin	Malheur River from Namorf to Mouth; Malheur River from Beulah Dam and Warm Springs Dams to Namorf; Willow Creek from Brogan to Mouth; Willow Creek from Malheur Reservoir to Brogan; Bully Creek from Reservoir to Mouth; Malheur Reservoir, Bully Creek Reservoir, Beulah Reservoir, Warm Springs Reservoir; and Malheur River and Tributaries Upstream from Reservoirs
220A	Mid Coast Basin	Fresh Waters
230A	North Coast Basin	All Other Streams and Tributaries Thereto
250A	Owyhee Basin	Owyhee River (RM 0 to 18); Owyhee River (RM 18 to Dam); Antelope Reservoir, Cow Creek Reservoir, and Owyhee Reservoir; Owyhee River and Tributaries Upstream from Owyhee Reservoir; Main Stem of the South Fork of the Owyhee River from the Oregon-Idaho River border to Three Forks (the confluence of the North, Middle, and South Forks of Owyhee River); and Main Stem Owyhee River from Crooked Creek (RM 22) to the mouth of Birch Creek (RM 76)
260A	Powder/Burnt Basin	All Basin Waters
		Rogue River Main Stem from Estuary to Lost Creek Dam; Rogue River Main Stem above Lost Dam and Tributaries; and All Other Tributaries to Rogue River and Bear Creek
286A	Sandy Basin	Sandy River; and All Other Tributaries to Sandy River
300A	South Coast Basin	All Streams and Tributaries Thereto
310A	Umatilla Basin	Umatilla Sub-basin; Willow Creek Sub-basin; Umpqua River Main Stem from Head of Tidewater to Confluence of North and South Umpqua Rivers; North Umpqua River Main Stem; South Umpqua River Main Stem; and All Other Tributaries to Umpqua, North Umpqua, and South Umpqua Rivers
330A	Walla Walla Basin	Walla Walla River Main Stem from Confluence of North and South Forks to State Line; and All Other Basin Streams
340A	Willamette Basin	Main Stem Willamette River from Mouth to Willamette Falls, including Multnomah Channel; Main Stem Willamette River from Willamette Falls to Newberg; Main Stem Willamette River from Newberg to Salem; Main Stem Willamette River from Salem to Coast Fork; Clackamas River; Molalla River; Santiam River; McKenzie River; Tualatin River; and All Other Streams and Tributaries

Table 2: Waters in Oregon that have a fishing designated use but neither a public domestic water supply nor a private domestic water supply designated use. "Organism only" criteria apply to these waters.

OR WQS Table No.	Basin	Segment Name
140A	Goose and Summer Lakes Basin	Goose Lake; and Highly Alkaline and Saline Lakes
190A	Malheur Lake Basin	Natural Lakes
220A	Mid Coast Basin	Estuaries and Adjacent Marine Waters
230A	North Coast Basin	Estuaries and Adjacent Marine Waters
271A	Rogue Basin	Rogue River Estuary and Adjacent Marine Waters; and Bear Creek Main Stem
286A	Sandy Basin	Streams Forming Waterfalls Near Columbia River Highway
300A	South Coast Basin	Estuaries and Adjacent Marine Waters
320A	Umpqua Basin	Umpqua River Estuary to Head of Tidewater and Adjacent Marine Waters

Oregon's application of human health criteria is consistent with EPA's guidance to states and the methodology inherent in developing the criteria. EPA's *Water Quality Standards Handbook* recommends that states adopt human health criteria to protect waters designated for public water supply. In addition, for waters where fish ingestion is considered an important activity, EPA recommends that the criterion applicable to fish consumption be applied to protect the use.[22] Oregon's human health criteria are applied consistent with this recommendation.

EPA has published guidelines for developing criteria that protect human health endpoints and separate criteria guidance to protect aquatic life endpoints. Consistent with the science used to derive the criteria, EPA recommends that human health criteria be applied to uses where human health could be affected by exposure from consumption of water and/or aquatic life and aquatic life criteria be applied to uses associated with the protection of aquatic life. Thus, most states, including Oregon, have adopted two sets of criteria for toxic pollutants, one to address the effects to human health and the other to address the effects to aquatic life. For some pollutants, this results in a waterbody segment having multiple criteria for a single pollutant, in which case the WQS require the attainment of all of the applicable criteria.

Oregon's human health criteria are developed pursuant to methods presented in EPA's 2000 Human Health Methodology.[23] These criteria take into consideration the cancer potency or systemic toxicity of a pollutant, the exposure related to surface water exposure and a risk characterization. The criteria generated pursuant to the 2000 Human Health Methodology protect humans from toxicological effects from chronic exposure to a pollutant through drinking water or from eating fish living in a water body to which the criteria apply.

[22] EPA. 1994. *Water Quality Standards (WQS) Handbook: Second Edition.* August 1994. United States Environmental Protection Agency, Office of Water. EPA-823-B-94-005a. page 3-15. Available at http://water.epa.gov/scitech/swguidance/standards/handbook/index.cfm

[23] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

EPA's guidance for developing aquatic life criteria recommends that such criteria use toxicity information for aquatic life, establishing pollutant levels necessary for protection of aquatic life from both short and long term effects of the pollutant.[24] Toxicity tests are used to evaluate pollutant effects on survival, growth and reproduction of aquatic organisms.

EPA has reviewed Oregon's new and revised human health criteria in order to assess whether they are sufficient to protect Oregon's designated uses from human health impacts associated with the pollutants for which they were adopted. Other endpoints and uses (e.g., Fish and Aquatic Life) are addressed by other provisions in Oregon's WQS and are not before the Agency for review under § 303(c)(3) of the CWA as part of this action.

2. Non-Carcinogens: Criteria Methodology and Input Variables Used by Oregon[25]

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants.[26] Pursuant to Section 304(a) of the CWA, EPA has published a table of recommended criteria for use by states in adopting and revising criteria.[27] For each pollutant, this table also identifies whether EPA recommends the methodology specific to carcinogens or non-carcinogens, based on information relative to the human health endpoints of greatest significance.[28] For criteria recommendations for non-carcinogens, the values in this table reflect criteria derived using the 'national default' values identified in the 2000 Methodology: the reference dose (RfD) contained in the Integrated Risk Information System (IRIS) at the time of publication; the use of EPA's recommended bioconcentration factors (BCFs) (as opposed to site-specific bioaccumulation factors (BAFs)); and relative source concentration factors (RSC) as provided by the latest 304(a) recommendations.

While the 2000 Methodology provides national default values, it also provides guidance necessary to adjust criteria to reflect local conditions and encourages states to use the guidance to appropriately reflect local conditions and/or protect identifiable subpopulations.[29] Numerous states have adopted criteria derived through the use of site-specific input variables instead of the national default values, thus ensuring the criteria are protective of the human health uses

[24] EPA. 1985. *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses.* Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/upload/85guidelines.pdf
[25] For methylmercury, Oregon used an alternate approach that will be addressed in a separate section.
[26] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[27] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html
[28] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 1-3. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[29] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages iii, 1-11. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

designated in the waters where those criteria apply.

Criteria calculated pursuant to the 2000 Methodology are derived by applying a number of pollutant-specific and general risk-assessment values to an equation that generates a criteria protective of human health uses. Where a state uses this equation to develop criteria, the protectiveness of those criteria are dependent on whether the values used for each input variable are appropriate for protection of the uses specific to a pollutant and/or waterbody. With the exception of the methylmercury criterion, Oregon has directly applied this equation when deriving the new or revised human health criteria for the non-carcinogenic pollutants included in EPA's 2009 table of 304(a) criteria recommendations.[30] A simplified version of this equation is provided in Figure A below, followed by a discussion of the variables in the equation and the values utilized by Oregon to derive their new and revised criteria, and supporting information provided by Oregon. EPA's review of the protectiveness of the criteria is contained in a later subsection.

Figure A: Simplified version of the equation used by Oregon in deriving the human health criteria for non-carcinogens.

$$AWQC = RfD \bullet RSC \bullet \frac{(BW)}{[DI + (FCR \bullet BAF)]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
RfD	=	Reference dose for noncancer effects (milligrams per kilogram per day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure (unitless)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCR	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

a) Reference Done (RfD)

For non-carcinogens, EPA's 2000 Methodology recommends deriving human health criteria using a reference dose. A reference dose is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime."[31] In other words, individuals should not suffer from appreciable risks of deleterious effects if their exposure to a chemical is at or below the reference dose for that chemical. Thus,

[30] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[31] EPA. 1993. *Reference Dose (RfD): Description and Use in Health Risk Assessments. Integrated Risk Information System (IRIS).* Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, U.S. Environmental Protection Agency, Cincinnati, OH. Available at: http://www.epa.gov/ncea/iris/rfd.htm

the reference dose serves as a threshold level and is specific to each individual pollutant.

In deriving both the "water + organism" and "organism only" criteria for non-carcinogens, Oregon utilized the most recent reference doses recommended by EPA's current § 304(a) criteria.

b) Body Weight (BW)

Oregon used EPA's national default value of 70 kilograms for the body weight as recommended in the 2000 Methodology. The source of data for the human body weight value of 70 kilograms is the *National Health and Nutrition Examination Survey* (NHANES) conducted between 1988 and 1994 using a nationwide probability sample of over 30,000 persons. Body weights of 73 percent of those individuals included in the survey were carefully measured by survey staff (i.e., weights were not self-reported). The mean body weight value for men and women ages 18-74 years old from this survey was 75.6 kilograms. Another survey by the National Cancer Institute measured a mean body weigh value of 70.5 kilograms for adults aged 20-64 years old, and EPA's *Exposure Factors Handbook* recommends 71.8 kilograms for adults based on an earlier NHANES survey.[32] While these data are slightly higher than 70 kilograms, the derivation of cancer slope factors identified in EPA's IRIS database are based upon a body weight of 70 kilograms. Since consistency is advocated between the dose-response relationship and the exposure factors, a default value of 70 kilograms was recommended by EPA for use in deriving human health water quality criteria.[33]

c) Drinking Water Intake Rate (DI)

Oregon used EPA's national default value of two liters per day for the drinking water intake rate as recommended in the 2000 Methodology. This rate was based on the 1994-1996 *Continuing Survey of Food Intake by Individuals* (hereinafter referred to as the "CSFII survey") conducted by the U.S. Department of Agriculture. This rate represents the 86th percentile of drinking water intake data for adults collected from the CSFII survey.[34] While this rate was utilized for "water + organisms" criteria, a drinking water intake rate of zero liters per day was used for "organism only" criteria because the criteria are not intended to address human health effects from the consumption of drinking water.

d) Bioaccumulation/Bioconcentration Factor (BAF/BCF)

Bioconcentration factors (BCF) describe the uptake and retention of a pollutant by an aquatic organism from water only while bioaccumulation factors (BAF)describe the uptake and retention of a pollutant by an aquatic organism from all sources (e.g., water, ingestion, and sediment). The

[32] EPA. 1997. *Exposure Factors Handbook*. U.S. Environmental Protection Agency, National Center for Environmental Assessment, Office of Research and Development, Washington, D.C. EPA/600/P-95/002Fa. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464
[33] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 4-18 to 4-19. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[34] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 4-21 to 4-22. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

magnitude of bioconcentration or bioaccumulation by aquatic organisms varies widely depending upon the pollutant but can be extremely high for some highly persistent and hydrophobic pollutants. For highly bioaccumulative pollutants, concentrations in aquatic organisms may pose unacceptable human health risks from fish consumption even when concentrations in water are too low to cause unacceptable health risks from drinking water consumption alone. EPA's 2000 Human Health Methodology recommends the use of national BAFs in the calculation of ambient water quality criteria. However, to date, EPA has only provided guidance on the calculation of national BAFs. BAF values have not been calculated for individual pollutants. EPA uses bioconcentration factors in their nationally recommended criteria. As explained below, States have the option to use these BCFs or to calculate BAFs using guidance documents published by EPA.

EPA's 2000 Human Health Methodology provides guidance on developing bioaccumulation factors for the protection of human health.[35] A subsequent technical support document to the 2000 Methodology entitled *Technical Support Document Volume 2: Development of National Bioaccumulation Factors* (2003) provides added detail to the BAF calculation procedures outlined in the Methodology.[36] In 2009, EPA published the *Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors.* This document provides guidance on different approaches that investigators can take to develop site-specific BAFs, and the factors that should be considered when selecting an approach for a given situation.[37]

EPA recommends that states use these methods when adopting human health criteria. Neither of the bioaccumulation technical support documents should be used alone to derive BAFs but should be used in conjunction with the 2000 Human Health Methodology. The bioaccumulation methodology documents encourage developing site-specific BAFs because EPA recognizes that BAFs vary not only between chemicals and trophic levels, but also among different ecosystems and waterbodies. National average BAF values for a given chemical and trophic level may not provide the most accurate estimate of bioaccumulation for certain water bodies in the United States. At a given location, the BAF for a chemical may be higher or lower than the national BAF, depending on the nature and extent of site-specific influences.

While EPA's 2000 Human Health Methodology recommends the use of bioaccumulation factors in deriving human health criteria, development of bioaccumulation factors is a time and resource intensive process and BAFs can vary from site-to-site. Thus, it is difficult to develop BAFs on a national or statewide scale and this has rarely been done. Therefore, until such time as

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[35] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Section 5. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[36] EPA. December 2003. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).* Technical Support Document Volume 2: Development of National Bioaccumulation Factors. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_tsdvol2.pdf

[37] EPA. September 2009. *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health (2000).* Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors. Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/2008_07_01_criteria_human health_method_tsdvol3.pdf

bioaccumulation factors are developed, EPA's national CWA § 304(a) human health criteria guidance values continue to be based upon the use of bioconcentration factors which reflect the uptake and retention of a pollutant by an aquatic organism from water alone. Given the lack of any Oregon-specific BAFs and consistent with EPA guidance, Oregon utilized bioconcentration factors instead of bioaccumulation factors in deriving its new and revised human health criteria. The bioconcentration factors utilized by Oregon are pollutant-specific and are consistent with the bioconcentration factors recommended by EPA in the most recent national CWA § 304(a) human health criteria recommendations.

e) Fish Consumption Rate (FC)

When establishing a single value/criterion as a regulatory endpoint, States and EPA must make several policy decisions relative to the members of the population that will be protected when using the waters for activities protected by the designated uses and the established criteria. In EPA's 2000 Human Health Methodology, EPA provides guidance to the States on the use of local and regional data to develop an appropriate fish consumption rate for the use in criteria derivation and encourages the states to use this data to determine the level of protection appropriate for State waters.

Between 2006 and 2008 Oregon conducted extensive outreach and information gathering and consulted with a group of public health experts (the Human Health Focus Group (HHFG)) in order to inform their decision-making regarding an appropriate fish consumption rate for use in developing human health criteria for Oregon. Based on the information gathered in this effort and the review of available fish consumption studies, ODEQ concluded that a fish consumption rate of 175 grams per day (about 23, 8 ounce fish meals per month) is a protective rate to use as the basis for Oregon's human health criteria. Oregon found that this rate reflected the goal of providing sufficiently clean water in the state such that people who wish to regularly eat fish for cultural, health or economic reasons may do so without risk of adverse health effects due to contaminants contained in the fish.[38]

Further detail regarding Oregon's process, information considered and the decision to use a fish consumption rate of 175 grams per day is available in Oregon's Human Health Criteria Issue Paper and the Human Health Focus Group Report and outlined in a separate EPA memo.[39]

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[38] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. page 5. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2011june/C-WQStdsStaffRpt.pdf

[39] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. At: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf
ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf
EPA. October 17, 2011. Memorandum from Jannine Jennings to Record. *Fish Consumption Rate Analysis – Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011.*

f) Relative Source Contribution (RSC)

Criteria for pollutants that are non-carcinogens are based on a total cumulative dose over time that causes an observable effect. Because the human health water quality criteria address exposure only through drinking water and eating fish and not from other sources (e.g. skin absorption, inhalation, other foods and occupational exposure), a relative source contribution (RSC) factor is used to calculate the criteria. The RSC represents the proportion of exposure from water and fish relative to the total exposure (including water and fish - and other exposures such as air, food, dermal, etc.). This estimate allows for adjustment of the criteria value to reflect exposure from only water and fish. This is intended to make sure that the total exposure from all sources does not exceed the reference dose for lifetime exposure.

Developing an RSC value for a pollutant requires an evaluation of both the sources of potential exposure and quantifying the relative exposure from each source. EPA has derived RSC values for 17 of the pollutants with 304(a) recommended human health criteria. Most of these RSC values were developed by EPA's drinking water program under the Safe Drinking Water Act.

Oregon used 15 of the 17 RSC values recommended by EPA. These 15 RSC values are listed in table 5 below. Oregon chose to use RSC values that vary from those recommended by EPA for endrin (80% instead of 20%, discussed in more detail below) and methylmercury (a value of zero instead of 2.7×10^{-5} mg methylmercury/kg/day, discussed in the methylmercury section below).

Table 5: Criteria where Oregon applied EPA's recommended RSC values.

Pollutant	RSC Value
Antimony	40%
Chlorobenzene	20%
Chlorodibromomethane	80%
Cyanide	20%
Ethylbenzene	20%
gamma-BHC (Lindane)	20%
Hexachlorcyclopentadiene	20%
Thallium	20%
Toluene	20%
1,1,2-Trichloroethane	20%
1,1-Dichloroethylene	20%
1,2,4-Trichlorobenzene	20%
1,2-Dichlorobenzene(o)	20%
1,2-trans-Dichloroethylene	20%
1,4-Dichlorobenzene(p)	20%

RSC for Endrin

EPA's recommended RSC value of 20% for endrin was developed by the drinking water program and takes into account exposure through multiple pathways. Endrin is a pesticide that was banned under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in the 1980s, thus limiting current sources of exposure. Following the review of available data and

information, ODEQ determined that an RSC of 80% was appropriate for use in deriving the human health criteria for endrin.[40] Oregon's rationale is described below.

Due to the chemical properties of endrin and its prohibition by FIFRA in the 1980s, ODEQ believes it is unlikely that people in Oregon would gain only 20% of their exposure from water and fish while gaining 80% of their exposure from other sources identified in the RSC calculation performed by EPA and used in EPA's recommended 304(a) criteria.[41] The 80% RSC calculation for endrin used by Oregon accounts for the two main sources of exposure which they considered to have a potential to impact human health in Oregon: (1) drinking water and (2) the bioconcentration of endrin in aquatic organisms and thus potential accumulation in fish tissue. ODEQ found that the other sources or routes of exposure to endrin considered by EPA were not expected to occur in Oregon for the following reasons:

> 1) The use of endrin has been banned in the US since the 1980s. Endrin is not mobile in soil, it volatizes into the air rapidly, and has a conservative half life estimate in soil of 14 years.
>
> 2) The U.S. Food and Drug Administration concluded in 1995 that exposure to endrin through food products was no longer a concern, thus reducing concerns regarding exposure to endrin from food sources.
>
> 3) The one possible route of exposure to endrin that was identified in the literature was at hazardous waste sites where endrin has been detected in contaminated soils; however, no such sites were identified in Oregon. [42,43]

Based on the above considerations, Oregon found that human health exposure to endrin through routes other than fish tissue and drinking water is unlikely. In addition, although endrin bioconcentrates in aquatic organisms, it is not very soluble in water and therefore is not likely to be found in drinking water sources. Since the bioconcentration factor used to derive the human health criteria is very high (3970), the endrin criteria values for "water + organism" and "organism only" are the same when rounded to significant digits.[44] Therefore, Oregon concluded that the primary routes of exposure for endrin are anticipated to be through

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[40] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[41] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[42] U.S. Department of Health and Human Services. August 1996. *Toxicological Profile for Endrin.* Public Health Service. Agency for Toxic Substances and Disease Registry. Available at: http://www.atsdr.cdc.gov/toxprofiles/tp89.pdf

[43] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[44] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

bioconcentration in aquatic organisms and its accumulation in fish tissue. These two exposure routes have already been accounted for through the BCF and fish consumption rate.

The purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD.[45] Where a state reviews exposure data and develops an alternate RSC value, EPA recommends that the RSC not be lower than 20% or higher than 80%.[46] Where it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), EPA recommends a ceiling of 80%. This 80% ceiling is a way to provide adequate protection for those who experience exposures (from any or several sources) higher than available data may indicate.[47] Oregon adjusted the RSC value for endrin to 80% consistent with this guidance.[48]

3. Carcinogens: Criteria Methodology and Input Variables Used by Oregon[49]

As noted above, EPA's 2000 Methodology provides guidance for deriving human health criteria for toxic pollutants[50] and has published a table of recommended criteria for use by states in adopting and revising criteria.[51] For human health criteria, the values in this table reflect criteria derived using all of the 'national default' values identified in the 2000 Methodology, the reference dose (RfD) contained in the Integrated Risk Information System (IRIS) at the time of publication, the use of EPA's recommended bioconcentration factors (BCFs), relative source contribution factors (RSC) as provided by the latest 304(a) recommendations and a 10^{-6} carcinogenic risk factor. While the 2000 Methodology provides national default values, it also provides necessary guidance to adjust criteria to reflect local conditions and encourages states to use the guidance to appropriately reflect local conditions and/or protect identifiable subpopulations.[52] Numerous states have adopted criteria derived through the use of site-specific input variables or a carcinogenic risk level other than $1x10^{-6}$.

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[45] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[46] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[47] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[48] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf
[49] Note: For arsenic, Oregon used an alternate approach that will be addressed in section IV.E of this document.
[50] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[51] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html
[52] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages iii, 1-11. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

For carcinogens, EPA's 2000 Methodology recognizes that states have the flexibility to adopt human health criteria within a risk level range of 1×10^{-6} to 1×10^{-5}, as long as highly exposed populations would at least be protected at the 1×10^{-4} (1:10,000) risk level. Furthermore, the 2000 Methodology recognizes that states have the flexibility to adopt human health criteria that protect the general population at a more protective risk level or target the protection of a higher proportion of its population at the targeted risk level. Oregon's new and revised criteria for carcinogens (except arsenic) target the protection of high consumers at the 1×10^{-6} risk level through the use of a fish consumption rate representative of the 95th percentile consumption from a study of a highly exposed subpopulation.

EPA's 2000 Methodology describes procedures that can be used as guidance by states for deriving human health water criteria. The 2000 Methodology includes an equation that Oregon used in deriving the "water + organism" and "organism only" new and revised human health criteria for 56 carcinogens. A simplified version of this equation is provided below in Figure B. Descriptions of the variables included in these equations, and the values that Oregon utilized for each variable, are also provided below.

Figure B: Simplified version of the equation used by Oregon in deriving the human health criteria for carcinogens.

$$AWQC = \frac{(Risk\ Level \bullet BW)}{[CSF \bullet (DI + (FCR \bullet BAF))]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
Risk Level	=	Risk level (unitless)
CSF	=	Cancer slope factor (milligrams per kilogram per day)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCF	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

a) Body Weight, Drinking Water Intake Rate, Bioaccumulation/Bioconcentration Factor and Fish Consumption Rate

Four of the input variables used by Oregon in deriving its numeric human health water quality criteria for carcinogens are the same as those used by Oregon in deriving its numeric human health water quality criteria for non-carcinogens. A body weight of 70 kilograms and a drinking water intake of two liters per day were used, consistent with the default values that EPA utilized in deriving its national CWA § 304(a) human health criteria guidance values. Oregon also used bioconcentration factors consistent with those used by EPA in deriving its national CWA § 304(a) human health criteria guidance values.

Consistent with the criteria for non-carcinogens, a fish consumption rate of 175 grams per day was used in deriving the new and revised human health criteria for carcinogens. This value was

used by Oregon following an evaluation of local and regional data (discussed in greater detail above).

b) Cancer Slope Factor

For toxic pollutants identified as carcinogens and assumed to exhibit a linear dose-response relationship at low doses, EPA derives its national CWA § 304(a) human health criteria recommendations to correspond to incremental lifetime cancer risk levels, applying a risk management policy that ensures a reasonable level of protection for the general population.[53] Accordingly, a cancer slope factor is included in the calculation. A cancer slope factor expresses incremental, lifetime risk of cancer as a function of the rate of intake of the contaminant, and is combined with exposure assumptions to express that risk in terms of an ambient water concentration. Cancer slope factors are specific to individual pollutants. In deriving both the "water + organism" and "organism only" human health criteria for carcinogens, Oregon utilized the cancer slope factors recommended by EPA.

c) Carcinogenic Risk Level

EPA has identified a risk level range of 1 x 10^{-6} (1:1,000,000) to 1 x 10^{-5} (1:100,000) to be an appropriate risk management goal for the general population. EPA characterizes this acceptable risk range as the "upper-bound estimate of excess lifetime cancer risk," ranging from one case in a population of one million to one case in a population of one hundred thousand. The nationally recommended 304(a) criteria are intended to protect the general population at a cancer risk of 1 x 10^{-6}.

EPA's 2000 Methodology states that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} risk level. If a state does not find that the 1 x 10^{-6} risk level adequately protects highly exposed populations, it has the flexibility to adopt water quality criteria based on a more stringent risk level or at a level more representative of highly exposed population groups. This flexibility extends to all variables used to calculate the criteria. [54]

Except where specifically identified, Oregon's new and revised human health criteria for carcinogens are calculated using a risk level of 1 x 10^{-6} (1:1,000,000). As discussed earlier, these criteria include the use of a fish consumption rate of 175 grams per day, a level representative of high fish consumers in the state. Oregon's goal in adopting the criteria was to protect high end consumers (as opposed to the general population) at a risk level of 10^{-6}.

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[53] EPA. 2000. *Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 65, Issue: 214, page: 66443 (65 FR 66443), November 3, 2000. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm

[54] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

4. EPA Review of Input Variables for All New and Revised Human Health Criteria except Methylmercury and Arsenic[55]

As discussed above, EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA looked at the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review.

EPA has not identified any local or regional data to indicate that the national values used by Oregon for the reference dose, relative source contribution, body weight, drinking water intake rate, or bioaccumulation factors are inappropriate for use in Oregon.

EPA's review indicates that there is local and regional fish consumption data available and that it should be considered consistent with EPA's 2000 Methodology. The 2000 Methodology recognizes the variability of fish consumption rates among population groups and by geographic region. In employing the 2000 Methodology to derive criteria, EPA urges States and Tribes to use a fish intake level derived from local or regional data instead of the national default recommendation to ensure the fish intake level chosen is protective of highly exposed subpopulations. A four preference hierarchy concerning the use of fish consumption rate data is set forth: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rate.

As discussed in greater detail above, in 1996 Oregon initiated an extensive review of the fish consumption rate used for deriving its human health criteria. This process resulted in ODEQ and the Commission determining that a fish consumption rate of 175 grams per day was a reasonable and protective fish consumption rate to use as the basis for Oregon's human health criteria. EPA has reviewed the available information and the basis for ODEQ's determination and has found that Oregon has considered all relevant local and regional data, applied that data consistent with EPA's 2000 Methodology to select a fish consumption rate that would result in a level of protection consistent with that recommended by EPA in the 2000 Methodology. Thus, EPA finds that the FCR utilized to derive Oregon's criteria is consistent with EPA's recommendations in the 2000 Methodology.

B. *EPA ACTION ON ODEQ'S NEW HUMAN HEALTH CRITERIA*

ODEQ has adopted new human health criteria for 41 pollutants (excluding methylmercury which is discussed in further detail below). Previously, Oregon did not have EPA-approved values for these criteria in their WQS. These new criteria, found in Table 40 of Oregon's WQS, are

[55] Methylmercury and arsenic are addressed in sections IV.D and IV.E of this document.

consistent with EPA's current 304(a) criteria recommendations and utilize the 175 grams per day fish consumption rate.

Table 6: Oregon's new human health criteria.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
1	Acenaphthene		95	99
2	Anthracene		2900	4000
3	Benzo(a)anthracene	✓	0.0013	0.0018
4	Benzo (a)pyrene	✓	0.0013	0.0018
5	Benzo(b)fluoranthene 3,4	✓	0.0013	0.0018
6	Benzo(k)fluoranthene	✓	0.0013	0.0018
7	Bromoform	✓	3.3	14
8	Butylbenzyl phthalate		190	190
9	Chlorobenzene		74	160
10	Chlorodibromomethane	✓	0.31	1.3
11	Chloronaphthalene 2		150	160
12	Chlorophenol 2		14	15
13	Chrysene	✓	0.0013	0.0018
14	DDD 4,4'	✓	0.000031	0.000031
15	DDE 4,4'	✓	0.000022	0.000022
16	DDT 4,4'	✓	0.000022	0.000022
17	Dibenzo(a,h)anthracene	✓	0.0013	0.0018
18	Dichlorobenzene(o) 1,2		110	130
19	Dichlorobenzene(p) 1,4		16	19
20	Dichlorobromomethane	✓	0.42	1.7
21	Dichloroethylene 1,1		230	710
22	Dichloroethylene trans 1,2		120	1000
23	Dichloropropane 1,2	✓	0.38	1.5
24	Dimethylphenol 2,4		76	85
25	Dinitrophenol 2,4		62	530
26	Dinitrophenols		62	530
27	Diphenylhydrazine 1,2	✓	0.014	0.020
28	Endosulfan alpha		8.5	8.9
29	Endosulfan beta		8.5	8.9
30	Endosulfan sulfate		8.5	8.9
31	Endrin aldehyde		0.030	0.030
32	Fluorene		390	530
33	Heptachlor epoxide	✓	0.0000039	0.0000039
34	Indeno(1,2,3-cd)pyrene	✓	0.0013	0.0018
35	Methyl bromide		37	150
36	Methyl-4,6-dinitrophenol 2		9.2	28
37	Methylene chloride	✓	4.3	59
38	Nitrosodi-n-propylamine, N	✓	0.0046	0.051
39	Pyrene		290	400
40	Trichlorobenzene 1,2,4		6.4	7.0
41	Zinc		2100	2600

EPA Approval
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new human health toxic criteria for these 41 pollutants that are consistent with EPA's current CWA § 304(a) criteria recommendations because they are protective of Oregon's fishing and water supply designated uses.

EPA Rationale
EPA's WQS regulations at 40 C.F.R. 131 require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA looked at the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review. As discussed above EPA has found that ODEQ has appropriately considered local and regional data in selecting input variables for use in deriving the criteria identified in Table 6.

The 2000 Methodology document provides an extensive technical basis and justification as to how EPA's recommended human health criteria adequately protect human health uses. Oregon's new criteria were developed consistent with these recommendations, therefore, EPA has determined that Oregon's new criteria protect human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

C. *EPA ACTION ON ODEQ'S REVISED HUMAN HEALTH CRITERIA*

ODEQ has adopted revised human health criteria for 62 pollutants (excluding arsenic which is described in further detail below). These revised criteria, found in Table 40 of Oregon's WQS, are consistent with EPA's current 304(a) criteria recommendations and utilize the 175 grams per day fish consumption rate.

Table 7: Oregon's revised human health criteria.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
1	Acrolein[56]		0.88	0.93
2	Acrylonitrile	✓	0.018	0.025
3	Aldrin	✓	0.0000050	0.0000050
4	Antimony		5.1	64

[56] Based on June 10, 2009 updates to EPA's IRIS system, Oregon's previous ADI value of 15.6 ug/kgram per day was replaced with an RfD value of 5.0 x 10^{-4}. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
5	Benzene	✓	1.6	5.1
6	Benzidine	✓	0.000018	0.000020
7	BHC Alpha	✓	0.00045	0.00049
8	BHC Beta	✓	0.0016	0.0017
9	BHC Gamma (Lindane)		0.17	0.18
10	Carbon tetrachloride	✓	0.10	0.16
11	Chlordane	✓	0.000081	0.000081
12	Chloroethyl ether bis 2	✓	0.020	0.05
13	Chloroform[57]		260	1100
14	Chloroisopropyl ether bis 2		1200	6500
15	Chloromethyl ether, bis	✓	0.000024	0.000029
16	Cyanide[G]		130	130
17	Dichlorobenzene(m) 1,3		80	96
18	Dichlorobenzidine 3,3'	✓	0.0027	0.0028
19	Dichloroethane 1,2	✓	0.35	3.7
20	Dichlorophenol 2,4		23	29
21	Dichloropropene 1,3	✓	0.30	2.1
22	Dieldrin	✓	0.0000053	0.0000054
23	Diethyl phthalate		3800	4400
24	Dimethyl phthalate		84000	110000
25	Di-n-butyl phthalate		400	450
26	Dinitrotoluene 2,4	✓	0.084	0.34
27	Dioxin (2,3,7,8-TCDD)	✓	0.00000000051	0.00000000051
28	Endrin		0.024	0.024
29	Ethylbenzene		160	210
30	Ethylhexyl phthalate bis 2	✓	0.20	0.22
31	Fluoranthene		14	14
32	Heptachlor	✓	0.0000079	0.0000079
33	Hexachlorobenzene	✓	0.000029	0.000029
34	Hexachlorobutadiene	✓	0.36	1.8
35	Hexachlorocyclo-hexane-Technical	✓	0.0014	0.0015
36	Hexachlorocyclopentadiene		30	110
37	Hexachloroethane	✓	0.29	0.33
38	Isophorone	✓	27	96
39	Nickel[58]		140	170
40	Nitrobenzene		14	69
41	Nitrosamines	✓	0.00079	0.046

[57] Based on June 10, 2009 updates to EPA's IRIS system, Oregon's previous q1* value of 6.1 x 10^{-3} was replaced with an RfD value of 0.01 mg/kgrams per day. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

[58] Oregon's revised human health criteria for nickel are less stringent than Oregon's previous values despite Oregon's adoption of a 175 grams per day fish consumption rate. However, the equation used to calculate the revised criteria is consistent with EPA's current 304(a) recommendations. It is unclear how ODEQ derived their previous values for nickel. Nonetheless, EPA assessed protectiveness of the revised criteria using EPA's 304(a) recommendations and Oregon's human health designated uses.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
42	Nitrosodibutylamine, N	✓	0.0050	0.02
43	Nitrosodiethylamine, N	✓	0.00079	0.046
44	Nitrosodimethylamine, N	✓	0.00068	0.30
45	Nitrosodiphenylamine, N	✓	0.55	0.60
46	Nitrosopyrrolidine, N	✓	0.016	3.4
47	Pentachlorobenzene		0.15	0.15
48	Pentachlorophenol	✓	0.15	0.30
49	Phenol[59]		9400	86000
50	Polychlorinated biphenyls (PCBs)[L]	✓	0.0000064	0.0000064
51	Selenium[60]		120	420
52	Tetrachlorobenzene 1,2,4,5-		0.11	0.11
53	Tetrachloroethane 1,1,2,2	✓	0.12	0.40
54	Tetrachloroethylene	✓	0.24	0.33
55	Thallium		0.043	0.047
56	Toluene		720	1500
57	Toxaphene	✓	0.000028	0.000028
58	Trichloroethane 1,1,2	✓	0.44	1.6
59	Trichloroethylene	✓	1.4	3.0
60	Trichlorophenol 2,4,5-		330	360
61	Trichlorophenol 2,4,6	✓	0.23	0.24
62	Vinyl chloride	✓	0.02	0.24

Footnote G: They cyanide criterion is expressed as total cyanide (CN)/L
Footnote L: This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).

EPA Approval

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's revised human health toxic criteria for these 62 pollutants, consistent with EPA's current CWA § 304(a) criteria recommendations, because they are protective of fishing and water supply uses.

EPA Rationale

EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

[59] Based on updates to EPA's IRIS system, the RfD value of 6.0×10^{-1} was replaced by Oregon with an RfD value of 3.0×10^{-1}. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

[60] Oregon's revised human health criteria for selenium are less stringent than Oregon's previous values despite Oregon's adoption of a 175 grams per day fish consumption rate. However, the equation used to calculate the revised criteria is consistent with EPA's current 304(a) recommendations. It is unclear how ODEQ derived their previous values for these two pollutants. Nonetheless, EPA assessed protectiveness of the revised criteria using EPA's 304(a) recommendations and Oregon's human health designated uses.

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA reviewed the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review. As discussed above EPA has found that ODEQ has appropriately considered local and regional data in selecting input variables for use in deriving the criteria identified in Table 7.

EPA provides an extensive technical basis and justification as to how its recommended human health criteria adequately protect human health uses in EPA's 2000 Methodology document. Oregon's revised criteria were developed consistent with these recommendations, therefore, EPA has determined that Oregon's revised criteria protect human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

D. *METHYLMERCURY CRITERION*

1. Methylmercury: Criteria Methodology and Input Variables Used by Oregon

On January 8, 2001, EPA published[61] a new national CWA § 304(a) human health criterion recommendation for methylmercury[62] which replaced EPA's previous recommendations for total mercury. The new recommendation is expressed as a fish tissue value, thus reflecting the latest science that indicates consumption of contaminated fish and shellfish is the primary human route of exposure to methylmercury.

In 1980, EPA published a water quality criterion for total mercury. The criterion was partially updated in 1997 to incorporate a change in the reference dose (RfD). Consistent with Section 304(a) of the Clean Water Act, EPA periodically revises water quality criteria to reflect the latest scientific knowledge on the type and extent of identifiable effects on human health from the presence of pollutants in a waterbody. In 2001, EPA completed a review of the water quality criterion for protection of human health for methylmercury. This criterion recommendation considered the bioaccumulation of methylmercury as well as the latest science and data regarding health effects from intake of mercury and the primary routes of exposure. The new criterion for methylmercury was derived consistent with the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000). The 2001 recommendation

[61] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, page: 1344 (66 FR 1344). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[62] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

is expressed as a fish tissue concentration for methylmercury and replaces the water column concentration for mercury that was contained in EPA's previous recommendation.[63]

As part of the 2001 reevaluation of the mercury criterion, EPA evaluated the sources and form of mercury that humans are exposed to when eating fish or consuming water from the nation's waters. It was found that humans are exposed primarily to methylmercury rather than to inorganic mercury and that the dominant exposure pathway is through consumption of contaminated fish and shellfish rather than from ambient water.[64] EPA found that if a criterion addressed the potential health effects from methylmercury, it would protect humans from the most toxic form of mercury and the primary route of exposure. Thus, in considering the fate of mercury in the environment and available toxicological data, EPA concluded that it is more appropriate to derive a water quality criterion for methylmercury rather than inorganic mercury. In addition, "EPA believes that the latest data and science on methylmercury exposure, effects, and environmental fate support the derivation of a fish tissue residue criterion," instead of a water column criterion.[65]

"Methylmercury is highly bioaccumulative and is the form of mercury that bioaccumulates most efficiently in the aquatic food web. Methylation of mercury is a key step in the entrance of mercury into food chains. The biotransformation of inorganic mercury species to methylated organic species in water bodies can occur in the sediment and the water column. Inorganic mercury can be absorbed by aquatic organisms but is generally taken up at a slower rate and with lower efficiency than is methylmercury."[66]

"Methylmercury continues to accumulate in fish as they age. Predatory organisms at the top of aquatic and terrestrial food webs generally have higher methylmercury concentrations because methylmercury is typically not completely eliminated by organisms and is transferred up the food chain when predators feed on prey; for example, when a largemouth bass feeds on a bluegill sunfish, which fed on aquatic insects and smaller fish, all of which could contain some amount of methylmercury that gets transferred to the predator. Nearly 100 percent of the mercury that bioaccumulates in upper trophic level fish (predator) tissue is methylmercury (Bloom, 1992; Akagi, 1995; Kim, 1995; Becker and Bigham, 1995.)"[67]

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[63] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page 1-1. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[64] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1345. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[65] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page 1-2. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[66] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1348. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[67] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water,

In consideration of the environmental fate of mercury, a fish tissue residue water quality criterion was found to be appropriate for many reasons. "Such a criterion integrates spatial and temporal complexity that occurs in aquatic systems and that affects methylmercury bioaccumulation. A fish tissue residue water quality criterion is more closely tied to the CWA goal of protecting the public health because it is based directly on the dominant human exposure route for methylmercury. The concentration of methylmercury is also generally easier to quantify in fish tissue than in water and is less variable over the time periods in which water quality standards are typically implemented in water quality-based. Thus, the data used in permitting activities can be based on a more consistent and measurable endpoint. A fish tissue residue criterion is also consistent with how fish advisories are issued. Fish advisories for mercury are based on the amount of methylmercury in fish tissue that is considered acceptable, although they are usually issued for a certain fish or shellfish species in terms of a meal size. A fish tissue residue water quality criterion should enhance harmonization between these two approaches for protecting the public health."[68]

Consistent with EPA's 304(a) recommendation published in 2001, Oregon has replaced its "water + organism" and "organism only" water column human health criteria for total mercury with a new fish tissue-based "organism only" human health criterion for methylmercury. Similar to the 2000 Methodology, the computation of the methylmercury criterion uses several input variables, described in Figure C below.

Figure C: Simplified version of the equation used by Oregon in deriving its new fish tissue-based "organism only" human health criterion for methylmercury.

$$TRC = \frac{(RfD - RSC) \bullet (BW)}{(FCR)}$$

where:

TRC	=	Fish Tissue Residue Criterion (milligrams per kilogram)
RfD	=	Reference dose for noncancer effects (milligrams per kilogram per day) = 0.0001mg/kg-day
RSC	=	Relative source contribution factor to account for non-water sources of exposure (milligrams per kilogram per day) = 0
BW	=	Human body weight (kilograms) = 70 kg
FCR	=	Fish Consumption Rate (kg/day) = 175 g/day

In the 2001 methylmercury criteria document, EPA strongly encourages States and authorized Tribes to consider developing a criterion using local or regional data over the default values if they believe that appropriate for protection of the target population. EPA recommends that these

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Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1348. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[68] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page xv. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

adjustments be applied consistent with the guidance provided in the 2000 Human Health Methodology.[69]

Consistent with EPA's recommendation, Oregon replaced its "water + organism" and "organism only" water column human health criteria for total mercury with a new fish tissue-based "organism only" human health criterion for methylmercury equal to 0.040 micrograms per kilogram (mg/kg). In deriving this new criterion, Oregon used the equation below and the following values for each variable: reference dose equal to 0.0001 milligrams per kilogram per day; relative source contribution of 0; body weight equal to 70 kilograms and; fish consumption rate equal to 175 grams per day. As discussed in greater detail above, the reference dose and body weight are the values recommended by EPA and the fish consumption rate was derived using local and regional data. The RSC is discussed below.

a) Relative Source Contribution (RSC) for Methylmercury

Following review of available data and information specific to the exposure pathways for methylmercury, Oregon used EPA's subtraction method to derive an RSC of zero for use in deriving the human health criterion for methylmercury.[70]

In establishing a recommended RSC value, EPA found that the most significant source of exposure to methylmercury was the ingestion of marine fish. EPA also found that the estimated exposure from ambient water, drinking water, nonfish dietary foods, air, and soil were all, on average, at least several orders of magnitude less than those from marine fish ingestion. Therefore, these later exposure pathways were not factored into EPA's recommended RSC value. An RSC of 2.7×10^{-5} mg methylmercury/kg/day is recommended by EPA as an estimated exposure from marine fish intake.[71]

EPA's above recommendation is based on the assumption that the fish consumption rate does not include fish of marine origin (as would be the case for most inland states/waters and is true of EPA's national default value for fish consumptions of 17.5 grams per day). However, as part of Oregon's reevaluation of local and regional data and the selection of a fish consumption rate of 175 grams per day, Oregon did take into consideration the consumption of salmon (an anadromous species identified as marine in the CSFII study) and regional consumption rates that included estuarine finfish and shellfish. Therefore, in reviewing this information, Oregon determined that it was not necessary to provide additional protection from ingestion of marine fish through the use of an RSC value. As a result, Oregon subtracted out the exposure related to marine fish, resulting in an RSC of zero.

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[69] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001, page 7-2. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[70] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm

[71] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page xiv. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

EPA's 2000 Human Health Methodology recognizes that if States include marine fish in the fish consumption rate they may need to adjust the RSC consistent with this decision to appropriately represent overall exposure to a pollutant.

"States and Tribes need to ensure that when evaluating overall exposure to a contaminant, [and that] marine fish intake is not double-counted with the other dietary intake estimate used. Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., fresh/estuarine and marine species) is more appropriate for protecting the population of concern may do so, provided that the marine intake component is not double-counted with the RSC estimate." [72]

Oregon's use of the subtraction method for deriving the RSC for methylmercury is consistent with this guidance.

2. New human health criteria for methylmercury

Oregon has adopted the following new criterion for methylmercury:

Table 8: Oregon's criterion for methylmercury.

Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
Methylmercury (mg/kg)[J]		--	0.040 (mg/kg)

Footnote J: This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury.

Oregon's new criterion of 0.040 mg/kg is expressed as a fish tissue residue concentration, not a water column concentration as all other human health criteria adopted by Oregon. Thus, when applying the criterion, ODEQ may need to consider data collected from either the water column or fish tissue or express a limitation as a water column value (e.g. provide a discharger with an effluent limit in an NPDES permit that can be measured in their effluent). Recognizing this fact, EPA has encouraged "states and authorized tribes to develop a methylmercury criterion implementation plan to ensure environmentally protective and effective administration of all water quality related programs with respect to methylmercury". Furthermore, to assist the States in this process, in April 2010 EPA published recommended methods for implementing these criteria. [73] In recognition of this need, Oregon's Human Health Criteria Issue Paper states that "…DEQ intends to develop implementation procedures similar to EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion.*"[74]

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[72] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. page 4-25. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[73] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. pages 21-22. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html
[74] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. page 26. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

3. EPA Action and Rationale Regarding Oregon's Methylmercury Criterion

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new human health criterion for methylmercury, consistent with EPA's current CWA § 304(a) criteria recommendations, because it is protective of Oregon's fishing and water supply uses. EPA is also approving the first sentence of footnote J which states: *This value is expressed as the fish tissue concentration of methylmercury.*

EPA Rationale
EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

EPA's 2000 Human Health Methodology and 2001 Criteria Recommendations for Methylmercury provide guidance for deriving human health criteria for methylmercury. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA reviewed the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review.

For all input variables except for the fish consumption rate and the RSC value, Oregon used EPA's recommended 304(a) national default values for calculating the methylmercury criterion. EPA has not identified any local or regional data to indicate that the national values for the reference dose, body weight, or drinking water intake rate are inappropriate for use in Oregon.

Oregon has used local and regional data to develop the fish consumption rate and RSC values used to calculate the methylmercury criterion. EPA has reviewed the information used in developing these values and has found that ODEQ appropriately considered the available data and developed input values consistent with EPA guidance.

EPA's 2001 Methylmercury Criteria document provides an extensive technical basis and justification as to how EPA's recommended criterion adequately protects human health uses. Based on Oregon's consistency with EPA's recommendations in the 2001 Methylmercury Criteria document and as discussed above, EPA has determined that Oregon's new methylmercury criterion protects human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

In addition, EPA is approving the first sentence of footnote J which states: *This value is expressed as the fish tissue concentration of methylmercury.* This sentence of the footnote provides clarification that the human health criterion for methylmercury is expressed as a fish tissue concentration rather than as a water column concentration. Oregon's new footnote

language along with the human health criterion value for methylmercury are consistent with EPA's recommended 304(a) national default values for calculating the criterion. This sentence of the footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable expression of methylmercury is a component of the overall level of protection afforded by the criterion. Since this sentence of the footnote specifies the applicable expression of the methylmercury criterion Oregon adopted, EPA has approved this sentence of the footnote as a WQS.

EPA acknowledges the second sentence of footnote J which states: *Contaminated fish and shellfish is the primary human route of exposure to methylmercury.* This sentence of the footnote provides details on the primary route of human exposure to methylmercury, but does not establish a legally binding requirement under State law and it does not describe a desired ambient condition of a waterbody to support a particulate designated use. For this reason, this sentence of footnote J is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the second sentence of footnote J for methylmercury.

E. *INORGANIC ARSENIC CRITERIA*

1. Background

The Oregon Environmental Quality Commission directed ODEQ to revise Oregon's human health criteria for toxic pollutants based on an increased fish consumption rate of 175 grams per day as well as to carefully consider cost effective and environmentally meaningful implementation of the criteria and review the data and science behind the criteria for earth metals.[75] ODEQ reviewed the science supporting the EPA's recommended 304(a) arsenic criteria and considered the appropriateness of revising the criteria to more closely reflect the levels of arsenic that naturally occur in Oregon waters. Oregon's revised arsenic criteria, submitted to EPA on July 12, 2011 are the result of that review. Oregon's goal in reevaluating the criteria was to protect human health, reduce toxic pollutants and to achieve meaningful environmental results commensurate with the cost.[76]

Oregon made the following arsenic-related regulatory revisions (including some changes other than revisions to arsenic criteria):

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[75] Oregon Environmental Quality Commission (OEQC). October 23, 2008. *Oregon Environmental Quality Commission Minutes of the Three Hundred and Forty-sixth Meeting.* Available at: http://www.deq.state.or.us/about/eqc/minutes/2008/2008octEQCMinutes.htm

[76] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 1-2. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

- Revised the numeric criteria human health criteria for arsenic in OAR 340-04-0033 Table 20.
- Identified the form of arsenic addressed by the criteria as inorganic arsenic.
- Added footnote A which states "The arsenic criteria are expressed as total inorganic arsenic. The 'organism only' criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the 'water + organism' criterion is based on a risk level of 1.1 x 10^{-4}."[77]
- Revised the drinking water M.C.L. from 0.05 mg to 10 µg/l in Table 20 and added footnote 1 which states "The arsenic value is shown here for informational purposes only and is not a water quality criterion."
- Added a new provision, OAR 340-04-0033(2)(b), that states the arsenic criteria become effective for purposes of State law and the CWA at the time of EPA approval.[78]
- Added an arsenic reduction policy under State law to address the reduction of arsenic from some anthropogenic sources in the vicinity of public drinking water intake supplies.[79]

The revised arsenic criteria were adopted through a public notice and rulemaking action separate from that used to adopt the June 16, 2011 human health criteria revisions. This separate rulemaking process is described in Section III above.

ODEQ reviewed the available scientific literature on bioaccumulation of arsenic and the ratio of inorganic arsenic to total arsenic in freshwater and marine environments. ODEQ also reviewed data specific to waters in Oregon and used the information to derive arsenic criteria for Oregon's waters.

Arsenic is a known carcinogen that may cause cancer in skin or internal organs such as the liver, kidneys, lungs and bladder. Other potential health impacts from arsenic include cardiovascular, kidney, central nervous system and hyper-pigmentation or keratosis effects.[80] In its 304(a) criteria recommendations EPA states that arsenic criteria should be based on cancer endpoints and be applied as inorganic arsenic.

Naturally-occurring arsenic in Oregon comes from geologic sources. It is typically present at natural levels in fresh surface waters at background levels that range from less than 1 microgram per liter (µg/l) to 3 µg/l. ODEQ data indicate that much higher arsenic levels (greater than 5-10 µg/l) may be present in some south central and southeastern Oregon watersheds but it is not known whether these levels represent solely natural geologic sources or are elevated due to

[77] Footnote A for arsenic was established in Table 40 in ODEQ's July 21, 2011 submittal to EPA.
[78] This language was deleted as part of ODEQ's July 21, 2011 submittal to EPA since effective dates of the criteria are addressed in OAR 340-041-0033(1), which includes arsenic.
[79] To accommodate additional revisions associated with ODEQ's submittal to EPA on July 21, 2011 ODEQ moved the location of this rule from OAR 340-041-0033(4) to OAR 340-041-0033(7). However, the rule language was not revised.
[80] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

anthropogenic activity.[81] ODEQ's review of the scientific literature indicates natural total arsenic levels of the oceans to be in the range of 1 to 3 µg/l.[82]

EPA's current 304(a) human health criteria recommendations for arsenic, published in 1986, are derived using a fish consumption rate of 6.5 grams per day and a cancer slope factor of 1.75 and are recommended to be applied as inorganic arsenic.[83] As is the case for all pollutants, EPA's 2000 Human Health Methodology encourages states to use local and regional data when making risk management decisions inherent in developing criteria, including decisions inherent in selecting the appropriate fish consumption rate, target risk level and bioaccumulation factor.[84]

2. Numeric Criteria Revisions

Based on its review of current data and information, ODEQ found differences in the bioconcentration (BCF) of arsenic in freshwater and saltwater organisms. In addition, DEQ found the ratio of inorganic arsenic relative to total arsenic differs in the freshwater and marine environments. Based on these findings, Oregon adopted two sets of criteria, one applying to freshwater and the other to saltwater. The revised criteria and the input variables used to calculate the criteria are presented in Tables 9 and 10 below.

Oregon has adopted the following new criterion for inorganic arsenic:

Table 9: Oregon's revised arsenic criteria (as inorganic arsenic).

Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
Arsenic (inorganic)[A]	✓	2.1	2.1 (freshwater) 1.0 (saltwater)

Footnote A: The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.

Table 10. Input variables for Oregon's revised arsenic criteria.

	Water + organism: freshwater	Organism only: freshwater	Organism only: saltwater
Revised Criteria	2.1 µg/l	2.1 µg/l	1.0 µg/l
Input Variables	FCR=175	FCR=175	FCR=175

[81] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 6. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[82] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[83] EPA. May 1, 1986. *Quality Criteria for Water.* U.S. Environmental Protection Agency, Office of Water. 440/5-86-001. At: https://owpubauthor.epa.gov/scitech/swguidance/standards/upload/2009_01_13_criteria_goldbook.pdf
[84] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

	BCF=14 IF=10% CSF=1.5 Risk level=$1x10^{-4}$	BCF=14 IF=10% CSF=1.5 Risk level=$1.1x10^{-5}$	BCF=26 IF=10% CSF=1.5 Risk level=$1x10^{-5}$

FCR = Fish Consumption Rate
BCF = Bioconcentration Factor
IF = Inorganic Factor
CSF = Cancer Slope Factor

Oregon's arsenic criteria revisions were adopted into Table 20 (Water Quality Criteria Summary), OAR 340-04-0033. It should be noted that in Oregon's June 16, 2011 action, all human health criteria in Table 20 were moved to Table 40. Thus, the arsenic criteria are now located in Table 40.

Oregon's revised numeric criteria for arsenic were derived using the same general methodology and equation used to calculate EPA's current 304(a) criteria for carcinogens. However, based on its review of scientific studies and Oregon specific data,[85] Oregon applied an inorganic to total arsenic ratio in the criteria calculation because the arsenic criteria are expressed in terms of inorganic arsenic, but the toxicity data used to develop EPA's BCF are reported in the form of total arsenic. Therefore, Oregon applied the inorganic to organic arsenic ratio to the criteria calculated using BCF values they derived based on state-specific data. Oregon also applied a fish consumption rate based on state-specific data. Oregon used the cancer slope factor listed in EPA's IRIS database available at the time of criteria adoption (April 2011). The input variables used by Oregon to derive their revised criteria are listed in Table 10 above.

a) Freshwater Criteria

Body weight and drinking water intake rate

Oregon used EPA's recommended national default rates for body weight and drinking water intake rates. These are the same values that Oregon used to derive all other criteria addressed in this action. Further detail on these variables was provided above.

Fish consumption rate

A fish consumption rate of 175 grams per day was used to derive the freshwater arsenic criteria. This is the same fish consumption rate that Oregon used to derive all other criteria addressed in this action. As discussed in detail above, this rate was determined by ODEQ to be appropriate for use in Oregon's human health criteria following a thorough review of local and regional data.

The fish consumption rate of 175 grams per day was selected by Oregon to ensure protection of all people in Oregon who may consume fish and shellfish from state waters including those who traditionally consume large amounts of fish for subsistence, health, economic or other reasons.[86] It reflects the 95th percentile of tribal members surveyed as part of the CRITFC Survey and the

[85] For more detail, see previous description in this document of methodology for deriving criteria for carcinogens.
[86] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. page 7. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf

90th percentile of subsistence consumers surveyed in regional fish consumption studies. The Human Health Focus Group formed by ODEQ to provide technical recommendations for selecting a fish consumption rate appropriate for Oregon found that fish consumers generally eat a variety of species that are the most readily available geographically and seasonally and that the range of consumption rates among fish consumers tend to be comparable regardless of the species that are available at any given time.[87] Thus, Oregon determined the rate of 175 grams per day appropriate for protection of high consumers from both freshwater and saltwater environments throughout the state.

Bioconcentration factor

Limited data are available regarding bioaccumulation (BAF) and bioconcentration (BCF) of arsenic in aquatic species. As discussed above, EPA recommends bioaccumulation data be used when available in order to take into consideration all pathways of accumulation, not merely the concentration that is received from water as reflected in bioconcentration data. EPA review of the literature found no relevant BAF data was available and thus EPA recommended that BCF data be used by Oregon to determine appropriate BCFs for use in deriving their arsenic criteria.[88]

EPA reviewed the available literature that might be relevant to recalculating a BCF specific to Oregon's waters and provided that information to ODEQ.[89] Only six published studies were identified and only four of the studies were found suitable for use in recalculating a BCF. Limitations in the data reported in two of the studies resulted in EPA determining they were not appropriate for use and thus were not used in either ODEQ's recalculations or EPA's review of the recalculated BCFs. The four studies found to be appropriate for this purpose and thus used provided data for only three species. One data set is from a test of a saltwater mollusk, the eastern oyster, and the others tested two freshwater finfish, bluegill and rainbow trout. Additional information on these studies can be found in ODEQ's April 2011 review document.[90]

Oregon determined that a BCF of 14 was appropriate for use in developing arsenic human health criteria for freshwaters of the state based on their review of the data contained in the above mentioned studies. A BCF of 14 represents the geometric mean of the data available from the studies of freshwater organisms (two publications on rainbow trout[91] and one on bluegill[92]). Oregon determined that the BCF data for the eastern oyster, a marine mollusk, was not appropriate for use in deriving a freshwater BCF because the oyster was a marine organism and available data indicate marine organisms are more likely to bioaccumulate arsenic than freshwater organisms. Furthermore, DEQ stated that they were not aware of data showing

[87] ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. pages 18-19. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf
[88] EPA. November 2011. Oregon Arsenic BCF and 304(a) Calculations.
[89] EPA. November 2011. Oregon Arsenic BCF and 304(a) Calculations.
[90] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[91] McGeachy and Dixon, 1990. Canadian Journal of Fisheries and Aquatic Sciences. 47: 2228-2233; Rankin and Dixon, 1994. Canadian Journal of Fisheries and Aquatic Sciences. 51: 372-380.
[92] Barrows, et al. 1980. Ann Arbor Science Pub., Inc., Ann Arbor, MI. pages 379-392.

harvesting or consumption of mollusks or other shellfish from freshwaters in Oregon and thus, freshwater mollusks were not likely to comprise a significant portion of the fish consumed from freshwaters in Oregon. Thus Oregon assumed finfish would be the primary exposure route for arsenic ingested from freshwaters and therefore, used only the data from finfish studies to calculate the freshwater BCF.[93,94] Based on this evaluation, ODEQ found that a BCF of 14 was a reasonable and protective value to use in calculating the arsenic criteria for Oregon's freshwaters.

Cancer Slope Factor

Similar to all other criteria addressed in this action, for arsenic, ODEQ used the cancer slope factor identified in EPA's Integrated Risk Information System (IRIS) data base at the time of rule adoption (April 2011). For arsenic this value is 1.5 $(mg/kg/day)^{-1}$ and was last modified in 1998.

Inorganic Proportion Factor (Inorganic to Total Arsenic Ratio)

Arsenic is present in the environment and in fish tissue in both organic and inorganic forms. Inorganic arsenic, specifically arsenite (trivalent or As III), is the form that is most toxic to humans and used to develop toxicity data for cancer and other end points. Thus, EPA recommends that human health criteria for arsenic are developed specific to inorganic arsenic and apply to the inorganic portion of arsenic in the water column. The inorganic portion may be referred to as either "inorganic arsenic" or "total inorganic arsenic". When both inorganic and organic arsenic are included, it is referred to as "total arsenic".[95]

All of the bioconcentration studies identified by EPA and used by Oregon reported arsenic as total arsenic, not inorganic arsenic. In order to address this difference in form and toxicity, Oregon multiplied the BCF by an "inorganic proportion factor" that reflects the ratio of inorganic to total arsenic likely to be present in the water. The proportion varies geographically and between fresh and marine waters so must be determined using state or local data.

Only limited data are available relative to the ratio of inorganic to total arsenic in Oregon's freshwaters. Previous studies have reported the proportion of inorganic arsenic found in fish tissue collected in the Columbia and Willamette rivers to contain an average of 6.5% inorganic arsenic while the ratios reported for individual species of fish ranged from 0.5% to 9.2% inorganic arsenic.[96] ODEQ also found several other sources of information indicating that an

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[93] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 12-13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. pages 16-17. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf

[94] EPA's review of this decision is documented later in this subsection.

[95] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[96] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

inorganic proportion of 10% or less was typical of freshwater environments.[97] Based on these findings, Oregon determined that an inorganic factor of 10% was a conservative ratio and appropriate for use in deriving the arsenic criteria for Oregon's freshwaters.

To incorporate the inorganic factor (IF) into the calculation, ODEQ used the following revised equations:

$$\text{Water + fish ingestion Criterion } (\mu g/L) = 1000 \times \frac{RF \times BW}{q1^*[DW + (BCF \times FCR \times \mathbf{IF})]}$$

$$\text{Org Only Criterion } (\mu g/L) = 1000 \times \frac{RF \times BW}{q1^*[BCF \times FCR \times \mathbf{IF}]}$$

Carcinogenic Risk Level

In the 2000 Human Health Methodology EPA states that it believes States and authorized Tribes have the flexibility to adopt the carcinogenic risk level they find appropriate for protection of the designated uses as long as the general population is protected at a 10^{-5} or 10^{-6} risk level and highly exposed populations are protected at a risk level that does not exceed 10^{-4}.[98] With the exception of arsenic, Oregon has used a risk rate of 10^{-6} when developing water quality criteria for carcinogenic pollutants. However, due to the natural levels of arsenic in Oregon's waters and the exposure levels resulting from natural sources of arsenic, Oregon has chosen to use a risk level of 10^{-4} for the arsenic criteria. Oregon made this policy decision following consideration of several alternatives and consideration of public comments received on the proposed criteria. The lower level of protection afforded by the proposed criteria was clearly identified by ODEQ in the documents provided to the public during both public notice periods and in the materials presented to the EQC at the time the rule was adopted.[99] ODEQ has stated that they made this

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EPA. 2002. *Columbia River Basin Fish Contaminant Survey, 1996-1998*. U.S. Environmental Protection Agency, Region 10, Seattle, Washington. EPA 910-R-02-006. Available at: http://yosemite.epa.gov/r10/oea.nsf/0703bc6b0c5525b088256bdc0076fc44/c3a9164ed269353788256c09005d36b7/$FILE/Fish%20Study.PDF

EVS Environmental Consultants. November 21, 2000. *Human Health Risk Assessment of Chemical Contaminants in Four Fish Species from the Middle Willamette River, Oregon*. Prepared for the Oregon Department of Environmental Quality, Portland, Oregon. Available at: http://www.deq.state.or.us/wq/willamette/docs/studies/hhrarpt.pdf

[97]ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[98] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[99] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 1-2. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

decision because of the special circumstances associated with natural levels of arsenic but believed that the 10^{-6} risk level used to derive all other criteria continued to be appropriate.[100] In determining the acceptable risk level for the arsenic criteria, ODEQ considered the natural background levels of arsenic commonly found in Oregon and evaluated the likely risk associated with exposure to these levels for the general population and high fish consumers. As noted earlier, ODEQ found that naturally occurring arsenic in many surface waters of the state range from less than 1 µg/l up to 3 µg/l and may occur at much higher levels. Therefore, ODEQ evaluated the risks that would be associated with arsenic criteria of 2-3 µg/l.

Using the input variables identified above, Oregon determined that a freshwater water plus organism (water + org) criterion of 2.1µg/l would result in a carcinogenic risk of $1x10^{-4}$. Since this value would protect high fish consumers of the State (those consuming 175 grams of fish per day) at a 10^{-4} risk level, Oregon found this criterion would protect the human health uses in State waters at a level consistent with the risk levels recommended by EPA in the 2000 Human Health Methodology.[101] Thus, Oregon adopted an arsenic water plus organism criterion of 2.1 µg/l for freshwaters.

Oregon similarly evaluated the criterion for protection of waters where fish consumption was a designated use but drinking water was not a designated use (organism (org) only criterion). Using the same variables discussed above, Oregon determined that a criterion of 19 µg/l would protect at a $1x10^{-4}$ risk level while a criterion value of 1.9 µg/l would protect at a $1x10^{-5}$ risk level. Oregon noted that establishing the org only criterion at the same risk level as the water + org criterion would result in a criterion that was nearly an order of magnitude less stringent than the water + org criterion. Therefore, after reviewing several options Oregon established the organism only criterion at the same level as the water + org criterion (2.1 µg/l). Oregon's revised freshwater arsenic org only criterion of 2.1 µg/l represents a carcinogenic risk of 1.1 x 10^{-5} to high consumers of the State (at a fish consumption rate of 175 grams/day). Oregon found this level of protection appropriate as it was within the risk range identified in EPA's 2000 Human Health Methodology and took into consideration the natural levels of arsenic found in Oregon's waters.[102]

ODEQ. April 21, 2011. Recommended Revisions to Oregon's Human Health Criteria for Arsenic, Presentation to the EQC. See Action Item E audio presentation. Available at: http://www.deq.state.or.us/about/eqc/minutes/2011/2011aprEQCMinutes.htm

[100] ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. page 25. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf
ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 10-11. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 4-5. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

[101] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

[102] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon

b) Saltwater Criteria

Oregon's objectives in developing an arsenic criterion for saltwater was to protect those who consume fish and shellfish from Oregon's marine and estuarine waters to which a criterion applies, taking into consideration the presence of naturally occurring levels of arsenic in marine waters. Uncertainties in the scientific community's current knowledge of the various species of arsenic in the saltwater environment and in marine and estuarine species also were considered in the evaluation.[103]

Oregon has not designated any saltwaters of the state as a drinking water use. Consistent with this designation, the only human health criterion applicable to and derived for saltwaters in Oregon are the organism only criteria (i.e. developed to protect humans from health effects incurred while ingesting fish and shellfish). As identified in Table 9 above, Oregon adopted an organism only criterion of 1.0 µg/l inorganic arsenic for all saltwaters of the State. The following discusses the input variables used and the conclusions reached by ODEQ in establishing this criterion.

Body weight, fish consumption rate and cancer slope factor
The input variables used for body weight, fish consumption rate and the cancer slope factor to derive Oregon's arsenic human health water quality criteria applicable to saltwater are the same as those used to derive the freshwater criteria discussed above.

Bioconcentration factor and inorganic proportion factor
Oregon's arsenic criterion for saltwater was calculated using a BCF of 26 (the geometric mean of all BCFs for fresh and saltwater species combined) and an inorganic proportion factor of 10%.

As discussed in the freshwater section above, bioconcentration data for arsenic is limited. EPA's review of the literature found only four studies appropriate for use in calculating BCFs and only one of those tested an organism from a saltwater environment (eastern oyster).[104] When ODEQ reviewed the available studies, they found a large difference in BCF values found in the study of the Eastern oyster (BCF of 350) relative to those found in the freshwater finfish studies (BCFs of 4 to 27). Given the differences in the BCFs and recognizing that people consume both mollusks and finfish from the Oregon waters where this criterion would apply, ODEQ evaluated potential options for criteria using two scenarios (see Table 11 below). The first scenario considered criterion calculated using a BCF of 26, the geometric mean of all available BCF data (both saltwater and freshwater). The second evaluated options using a BCF of 350, the geometric mean from the one study of a saltwater organism. Under both scenarios, the criteria that would result from using inorganic proportion factors of 1% and 10% were calculated. Results of the various options were compared to levels of arsenic naturally present in estuarine and marine

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Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[103] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[104] Zaroogian and Hoffman. 1982. *Arsenic uptake and loss in the American oyster, Crassostrea virinica.* Environmental Monitoring and Assessment 1:345-358.

waters. Following analysis of the options generated under the two scenarios ODEQ evaluated the level of protection provided by each and compared the criteria to the concentrations of arsenic naturally present in estuarine and marine waters. Based on this analysis ODEQ determined that a criterion of 1.0 µg/L inorganic arsenic was appropriate for protection of the fish consumption use in Oregon's saltwaters.

Table 11. Scenarios evaluated by Oregon and/or EPA.

Scenario	**A**	**B**	**C**	**D**	**E**	**F**
Fish Consumption	175 g/day	175 g/day	175 g/day	175 g/day	175 g/day	
Bioconcentration	26	26	350	350	350	
Inorganic portion	10%	1%	1%	10%	7.3%	
Risk level	1×10^{-5}	1×10^{-6}	1×10^{-5}	1.3×10^{-5}	9.6×10^{-5}	
Natural ocean level						1 – 1.2 µg/l
Resultant Criterion	**1.0 µg/l**	**1.0 µg/l**	**0.8 µg/l**	**1.0 µg/l**	**1.0 µg/l**	**1.0 µg/l**

As part of this evaluation, ODEQ evaluated the appropriate species to be considered in deriving a BCF value, the ratio of inorganic to total arsenic in the ocean environment, and the natural level of arsenic in Oregon's salt waters. When evaluating BCF data, ODEQ found that bioconcentration of arsenic in the tissue of invertebrates tended to be higher than that for vertebrates. In particular, they found that crustaceans and mollusks tended to accumulate more inorganic arsenic in their tissue (the form toxic to humans) than anadromous or marine fish. While data specific to consumption levels of various species from Oregon's saltwaters was not available, ODEQ knew that both shellfish and finfish were harvested and consumed from saltwaters in Oregon. ODEQ's literature review also indicated that, for the general US population, estuarine and marine mollusks represent only a small percent (3-13%) of the total fish and shellfish consumption. Given the small percentage of shellfish consumption relative to fish consumption and the much higher bioconcentration rate in shellfish, ODEQ concluded that a criterion calculated using only the oyster data (BCF = 350) was likely to be overly conservative.[105]

Oregon's literature review found a growing body of literature indicating that while saltwater organisms may contain more total arsenic than freshwater fish, the predominant form of arsenic in marine species is organic arsenic (i.e. rather than inorganic arsenic).[106] One analysis of five types of ocean finfish and ocean shrimp found that inorganic arsenic in the organism's tissues was less than 0.1% of the total arsenic present in tissues.[107] Other literature reported values of less than 3% and more recent surveys report values less than 1%.[108] A summary of the data from

[105] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[106] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in EPA 2003; Neff 1997; Schoof and Yager 2007; Tanaka and Santosa 1995; TetraTech 1996, IN EPA 2002; and Williams et.al. 2006. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[107] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in Schoof et. al., 1999 in BorakandHosgood. 2007. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[108] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon

20 studies is provided below and indicates that the inorganic arsenic in tissues of marine fish and marine shellfish ranged from 0.0001% to 7.3% of the total arsenic present; anadromous fish ranged from 0.3% to 3.04% and freshwater fish tissue contained between 0.5% and 26.6% inorganic arsenic.[109]

Inorganic arsenic as a % of total arsenic in seafood measured as ng/g wet weight

	Mean	Range
Freshwater	7.2	0.5-26.6
Anadromous fish	1.1	0.03-3.04
Marine fish	1.0	0.001-6.9
Marine Crustaceans	1.3	0.001-7.3
Marine Mollusks	1.8	0.04-6.5

Based on the review of the above information, ODEQ concluded it appropriate to use an inorganic factor of 1% if used in association with a conservative BCF of 350. However, if using the less conservative BCF of 26, ODEQ used a more conservative inorganic factor of 10% in their initial scenarios. ODEQ found comparison of these scenarios was a reasonable approach to take into account the variability and uncertainty in both the BCFs and inorganic factors while not resulting in an overly conservative criterion.[110]

Natural ocean levels and complexities in the marine environment

Oregon's review of the literature found natural total arsenic levels of oceans waters to be in the range of 1 to 3 µg/l. Data cited from the Pacific Ocean indicated average concentrations of 1.1 – 1.2 µg/l.[111]

Oregon did not have any data from Oregon's marine waters where inorganic and total arsenic were measured simultaneously. Thus, they relied on the above literature for their conclusion that the natural concentrations of arsenic in Oregon salt waters contain 1.0 µg/l or more of inorganic arsenic and that a waterbody criterion of 1.0 µg/l should not present any greater human health risk than that naturally present.[112]

Department of Environmental Quality. pages 16-17 in Borak and Hosgood, 2007; EPA 2003; Neff, 1997. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[109] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in Schoof and Yager, 2007. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[110] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[111] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16 in Tanaka, Shigeru and Sri Juari Santosa. 1995. The concentration distribution and chemical form of arsenic compounds in sea water. Biogeochemical Processes and Ocean Flux in the Western Pacific, Eds. H. Sakai and Y. Nozake, page. 1590170. Terra Scientific Publishing Company, Tokyo. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[112] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

Carcinogenic Risk Level
For the saltwater organism only criterion of 1.0 µg/l inorganic arsenic represents a carcinogenic risk level of 10^{-5}. Since this value would protect high fish consumers of the State (those consuming 175 grams of fish per day) at a 10^{-5} risk level, Oregon found this criterion would protect the human health uses in State waters at a level consistent with the risk levels recommended by EPA in the 2000 Human Health Methodology.[113] Furthermore, ODEQ determined it was appropriate to use a different carcinogenic risk level for this criterion than that used for other criteria in the state (10^{-6}) since the resultant criterion concentration reflected that which naturally occurred in marine waters.[114] (See the discussion regarding carcinogenic risk level for the freshwater arsenic criteria for more detail regarding EPA's 2000 Human Health Methodology.)

Based on the above findings, Oregon considered the scenarios in Table 11 above when selecting an appropriate org only criterion for arsenic in Oregon's saltwaters. Based on the conservative nature of a BCF of 350, the variability in the data, the uncertainties in the scientific communities current knowledge and ODEQ's determination that "there does not appear that an unacceptable human health risk with eating fish from an unpolluted marine environment," Oregon revised the saltwater criterion for inorganic arsenic to 1.0 µg/l.

c) EPA Review of Oregon's Revised Arsenic Criteria

EPA has reviewed the information provided by Oregon regarding the literature considered during their review of the arsenic criteria. EPA determined that Oregon's review considered the relevant and available information relative to selecting appropriate input variables for deriving the arsenic criteria. EPA conducted a more detailed review of several of the variables used in deriving the criteria. This review is presented below.

(1) FRESHWATER CRITERIA

BCF for Freshwater Criteria
EPA has reviewed the literature used by Oregon to calculate a BCF and finds that all relevant studies were identified. The use of a geometric mean value from available studies is appropriate for deriving a single BCF value. As determined by Oregon, a BCF of 14 is representative of the available BCF data relative to freshwater species.

In EPA's review of the literature relative to bioaccumulation of arsenic in aquatic organisms, no BAF studies specific to bioaccumulation in Oregon or models which could readily produce

[113] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf
[114] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16 in Tanaka and Santosa. 1995 National Academy of Sciences, 1972 and EPA. 2003. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

bioaccumulation factors specific to Oregon's waters were found. Thus, ODEQ's use of a bioconcentration factor is appropriate in this situation.

In selecting the appropriate BCF for use in deriving freshwater criteria, Oregon reviewed the available data for both saltwater and freshwater organisms and considered whether that data was representative of organisms likely to be consumed from waters to which the criteria would apply. In evaluating the use of the data from a study of the eastern oyster, a saltwater mollusk, Oregon noted that saltwater mollusks are not present in freshwaters of Oregon and that they were "not aware of any mollusks or other shellfish harvested and consumed from Oregon's freshwaters".[115] In order to verify this assertion, EPA consulted the Oregon Department of Fish and Wildlife website.[116] According to the regulations posted on this site, Oregon prohibits the harvest or possession of all freshwater mussels or clams (except for Zebra mussels or Asian clams) except as authorized by a Scientific Take Permit.[117] Furthermore, EPA noted that no freshwater mussels or shellfish were included in the species identified in the CRITFC Fish Consumption Study. While this later fact does not speak to all mussels or shellfish from freshwaters of Oregon, it is one indication that traditional and cultural consumption of these organisms is not occurring in a large portion of Oregon. Based on this information, EPA finds the assumption made by Oregon as to type of organisms consumed from Oregon's freshwaters to be reasonable. While including BCF data from the eastern oyster in the calculations would have expanded the scope of represented species to include mollusks, it would have also contributed BCF data from a marine species into the calculation of freshwater criteria. EPA concludes that Oregon's decision not to include the BCF data from the eastern oyster was appropriate, in light of the above data with respect to the low likelihood of human consumption of freshwater mollusks in Oregon.

One commenter provided numerous comments relative to the use of a BCF instead of a site-specific BAF. In the 2000 Human Health Methodology EPA recommends using a BAF in cases where data are available. EPA's review of the literature indicates that data and models are not currently available to develop a state-specific BAF for waters in Oregon. Additional information on this topic can be found in the above description of the methodology used to develop criteria for noncarcinogens and in EPA's Response to Comments document developed in association with the recent June 1, 2010 action on Oregon's human health criteria adopted in 2004.[118] The same commenter noted that recent studies of arsenic bioaccumulation indicate use of a regression approach to developing arsenic criteria may be more appropriate than using a single criterion applicable to all waters. EPA reviewed the cited study and agrees that it is an approach that has been applied on a site-specific basis and could be applied by a state in developing criteria for arsenic. However, EPA has not developed a recommended approach for

[115] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[116] Oregon Department of Fish and Wildlife (ODFW). *Oregon Wildlife Species: Sport Fish Species of Oregon.* Available at: www.dfw.state.or.us/species/fish/index.asp
[117] Oregon Department of Fish and Wildlife (ODFW). *2011 Sport Fishing Regulations.* Available at: http://www.dfw.state.or.us/fish/docs/2011_Oregon_Fish_Regs.pdf
[118] EPA. June 1, 2010. Supplemental Response to Comments Submitted by Northwest Environmental Advocates (NWEA) as They Pertain to Oregon's New and Revised Human Health Water Quality Criteria for Toxics Submitted on July 8, 2004.

incorporating this approach into a water quality criterion and no state has used it to develop a water quality criterion. Utilization of a regression approach would result in a criterion expressed as an equation for calculating a criterion concentration which varies with the ambient level of arsenic present in a waterbody in order to take into account the fact that the fraction of total arsenic that is inorganic arsenic tends to decrease as the concentration in the tissues increase. Additional questions regarding whether the criteria would more appropriately be expressed as a water column or tissue concentration would also need to be addressed. While utilizing this approach to developing a state-wide criterion would result in a site-specific criterion that may more accurately reflect the desired level of protection at any particular site (i.e. a 10^{-5} risk level), it would not necessarily provide for a greater level of protection. Given that this level of detail is not needed to protect the use and that this method has never been applied to derive a water quality criterion, EPA finds that it was reasonable for Oregon to establish a single criterion concentration and not use this new approach in this rule revision.

Inorganic Proportion Factor for Freshwater Criteria

EPA's review of available information finds that an inorganic proportion factor of 10% represents a reasonable and conservative estimate of the proportion of total arsenic present in an inorganic form in the tissue of organisms collected from freshwaters in Oregon. EPA notes that this same value was used by EPA when conducting site-specific risk assessments in the Columbia and Willamette Rivers that considered the same data set. No additional data have become available since the EPA assessments.

Level of Protection Provided by the Freshwater Criteria

Oregon's arsenic criteria for fresh waters are established at a level that protect high fish consumers in Oregon at carcinogenic risks levels of between 1×10^{-4} to 1×10^{-5} (see more detailed discussion above). EPA's 2000 Human Health Methodology states that states have the flexibility to choose an appropriate risk level for use in deriving water quality criteria as long as it protects the use to the levels recommended by EPA. Those risk levels are a 10^{-5} or 10^{-6} risk level for the general population and a risk level that does not exceed 10^{-4} for highly exposed populations.

Oregon's criteria were established using a fish consumption rate of 175 grams per day, reflective of the 95th percentile of consumption in a high-consuming subpopulation in Oregon and the 90th percentile of data from regional surveys of high consuming subpopulations. Therefore, the criteria represent the level of exposure expected to occur in highly exposed populations of Oregon. As such, Oregon's freshwater arsenic criteria protect highly exposed populations of Oregon at a level consistent with EPA's recommendations (does not exceed 10^{-4} risk level).

EPA has recommended using a fish consumption rate for the general US population of 17.5 grams per day if no local or regional data is available. There is currently no available fish consumption data specific to the general population of Oregon. If one were to evaluate the protectiveness of Oregon's arsenic criteria at EPA's default fish consumption rate of 17.5 grams per day, the result would indicate a carcinogenic risk level between $1x10^{-6}$ and $1x10^{-5}$. This risk level is consistent with that recommended by EPA. Therefore, EPA finds that ODEQ's revised arsenic criteria for freshwater are established at a level protective of both the general population and high fish consuming populations consistent with the levels recommended by EPA in the

2000 Human Health Methodology.

(2) SALTWATER CRITERIA

BCF for Saltwater Criteria

EPA has reviewed the literature used by Oregon to calculate the BCF used to derive the saltwater criterion and finds that all relevant studies were identified. EPA also found the use of a geometric mean value to be appropriate for deriving a BCF. As considered by Oregon, a BCF of 26 is representative of all available BCF data for both saltwater and freshwater species (one study of a saltwater mollusk and three studies of freshwater finfish). A BCF of 350 reflects all of the available BCF data for saltwater species (one study of a saltwater mollusk). Oregon considered both of these BCF values when evaluating the protectiveness of the revised criterion.

As noted by Oregon, there is relatively little BCF data available for arsenic and only one study that addresses saltwater species. Given the limited data and the differences in BCF between the finfish and mollusk data, EPA finds Oregon's approach of comparing the outcomes of scenarios for both a BCF of 26 and a BCF of 350 in terms of protectiveness to be reasonable. (See Table 11 above). Given the limited data and the variability in the available data, EPA believes that evaluating the level of protection provided by a range of inorganic proportion factors in association with the different BCF values is also appropriate. EPA's evaluation of whether the criteria derived using these input values is protective of the use is provided below.

Inorganic Proportion Factor for Saltwater Criterion

EPA's review of the literature relative to the ratio of inorganic to total arsenic in the tissue of saltwater organisms indicated that ODEQ reviewed the available information on this subject. EPA concurs that the information is limited, especially specific to Oregon waters, but it does indicate that the ratio of inorganic to total arsenic in tissues of saltwater organisms is typically lower than that found in freshwater organisms. Thus, using the 10% inorganic ratio that is also used in the freshwater criteria serves to provide a conservative estimate of the ratio—i.e., one that is larger than the mean ratio values found in various studies (1 to 3%). Given the variability in these factors and in the BCF values discussed above, EPA believes it was appropriate for ODEQ to have considered several different exposure scenarios when developing this criterion and that ODEQ's use of inorganic factors of 10% and 1% in the scenarios was also reasonable. EPA's evaluation of whether the criteria derived using these input values is protective of the use is provided below.

Level of Protection Provided by the Saltwater Criteria

Oregon adopted a saltwater criterion of 1 µg/l and relied on multiple lines of evidence in determining it is protective of Oregon's human health uses. Consistent with Oregon's approach at evaluating scenarios, EPA has evaluated the level of protection provided by each scenario presented. As illustrated in Table 11 above, when the more conservative BCF (350) was paired with the less conservative inorganic proportion factor (1%), a criterion of 1.0 µg/L was found to protect high fish consuming populations (175 g/day) at a 1.3×10^{-5} risk level. When the less conservative BCF (26) was paired with the more conservative inorganic proportion factor (10%), a criterion of 1.0 µg/l was found to protect high consumers (175 g/day) at a 1.0×10^{-5} risk level. Both of these scenarios provide a level of protection consistent with that recommended by EPA

in the 2000 Human Health Methodology. However, when EPA evaluated the level of protection that would be provided using the more conservative of both factors (BCF of 350 and inorganic proportion factor of 10%), a criterion of 1.0 µg/l resulted in a 1.3 x 10^{-4} risk level. This level is a higher risk than that recommended by EPA in the 2000 Human Health Methodology. EPA notes that the highest ratio of inorganic to total arsenic in fish tissue of saltwater organisms identified by ODEQ was 7.3%. ODEQ used 10% as a conservative inorganic proportion value for marine criteria (incorporating data from freshwater species) but EPA believes 7.3% is also a conservative estimate for marine organisms as it is the highest data value reported. Combining an inorganic factor of 7.3% (not as conservative a value as selected by Oregon but still sufficiently conservative based on a reasonable assessment of the available data) with a BCF of 350 (more conservative than the value ultimately selected by Oregon), EPA calculated that a criterion of 1.0 µg/L would protect high fish consuming populations at a risk level of 9.6 x 10^{-5}. Thus, a criterion of 1.0 µg/l calculated using a conservative inorganic proportion factor of 7.3% would protect high fish consumers in Oregon at a level consistent with that recommended by EPA in the 2000 Human Health methodology.

Oregon has presented a reasonable scientific basis to not rely solely on the BCF from the eastern oyster (350) in calculating the saltwater criterion, and instead rely on a BCF that incorporates data from other species (26).[119] Furthermore, the percentage of total arsenic that occurs in an inorganic form that Oregon paired with this BCF (10%) was more than sufficiently conservative based on the available data. Based on the calculations discussed in the paragraph above and these additional considerations, EPA believes that Oregon's saltwater criterion for arsenic will protect human health consistent with the level recommended by EPA.

(3) GENERAL CONSIDERATIONS

Risk level applied to arsenic criteria relative to that applied to other criteria

EPA reviewed the information provided by Oregon related to establishing criteria for arsenic at a level different than that used for all other criteria in the State. EPA notes that ODEQ stated that they were addressing arsenic as a special case and clearly stated their reasons for evaluating risk management decisions relative to this pollutant. The public notice, memorandum presenting recommendations to the EQC and ODEQ's document presenting its review and recommendations for the arsenic criteria all clearly identify that the criteria recommendations were established at a level providing less protection than for other pollutants in Oregon. Thus, the Commission was made aware of the policy decision inherent in their decision to adopt the recommended criteria. Thus, EPA finds that Oregon was reasonably exercising its discretion when establishing an alternate risk level for the arsenic criteria.

Cancer Slope Factor

One commenter noted that a cancer slope factor of 1.75$(mg/kg/day)^{-1}$ was used by EPA to develop the current 304(a) criteria recommendation while another stated that EPA was currently

[119] Mollusks tend to accumulate arsenic to a greater extent than other species and mollusks represent only a small percent (3-13%) of the U.S. general population's total fish and shellfish consumption. A marine BCF that is only based on mollusk data is therefore not ideally representative of marine species overall. EPA concludes that it was reasonable for Oregon to incorporate data from non-mollusk species to arrive at a more representative BCF, even though those non-mollusk species were not marine species.

reviewing the science behind the cancer slope factor. Both of these assertions are correct. EPA's 304(a) criteria recommendations for arsenic were first published in 1986 and uses a cancer slope factor of $1.75(mg/kg/day)^{-1}$. This recommendation has not been updated to reflect the latest value identified in the IRIS database, in part because the science behind that number is currently under review. A draft document was circulated for public comment and peer review by the Science Advisory Board in 2010.[120] EPA is currently reviewing these comments and has yet to make a final determination on potential revisions to the cancer slope factor for arsenic. Thus, EPA does not believe it appropriate for ODEQ to use the draft value in revising these criteria. EPA expects to coordinate with ODEQ regarding the potential need for reevaluation of the criteria if a new value is established in IRIS and/or changes are made to EPA's 304(a) criteria recommendations for arsenic.

3. EPA Action and Rationale Regarding Oregon's Arsenic Criteria

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's revised human health toxic criteria for inorganic arsenic because they are protective of Oregon's fishing and water supply uses. EPA is also approving footnote A which states: *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.*

EPA Rationale
EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

As discussed in detail above, EPA has found that Oregon considered the available and relevant literature in revising Oregon's arsenic criteria. Oregon provided a reasonable basis for the decisions made in developing the criteria. All three of the criteria adopted by ODEQ were found to protect human health uses consistent with recommendations provided in EPA's 2000 Human Health Methodology.

Inorganic Arsenic and Footnote A in Table 40
EPA's current 304(a) human health criteria recommendations are specifically identified as criteria for inorganic arsenic. As noted above, inorganic arsenic is the form most toxic to humans. As such, EPA's recommendations relative to this criteria and the associated risk assessment input variables are expressed as inorganic arsenic. In this revision, Oregon specifically identified that the criteria as inorganic arsenic in Table 40 by placing the word "inorganic" in parentheses.

[120] February 19, 2010. *Federal Register*, Volume: 75, No.: 33, page: 7477 (78 FR 7477). Available at: http://www.gpo.gov/fdsys/pkg/FR-2010-02-19/pdf/FR-2010-02-19.pdf

In addition, EPA is approving footnote A to the arsenic criteria in Table 40 which states: *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.*

The first sentence of the footnote provides clarification that the human health criterion for arsenic is expressed as total inorganic. This new footnote language for arsenic is consistent with EPA's recommended 304(a) national default expression for the arsenic criterion. The second sentence of the footnote clearly articulates the input variables regarding risk levels that were used to derive the arsenic criteria. This footnote establishes a legally binding requirement under State law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable expression of arsenic associated risk level is a component of the overall level of protection afforded by the arsenic criteria. Therefore, EPA approves this footnote as a WQS.

Acknowledgement of Maximum Contaminant Level (MCL) in Table 20
ODEQ revised the drinking water MCL for arsenic from 0.05 mg to 10 µg/l in Table 20 and added footnote 1 which states: *The arsenic value is shown here for informational purposes only and is not a water quality criterion.*

Drinking water standards are regulations that EPA sets to control the level of contaminants in the nation's drinking water. In most cases, the standard is a MCL**,** the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. The Safe Drinking Water Act gives individual states and tribes the opportunity to set and enforce their own drinking water standards if the standards are at least as stringent as EPA's national standards. When making a determination to regulate, the Safe Drinking Water Act requires consideration of these three criteria:

- the potential adverse effects of the contaminant on the health of humans;
- the frequency and level of contaminant occurrence in public drinking water systems; and
- whether regulation of the contaminant presents a meaningful opportunity for reducing public health risks.

ODEQ revised their MCL value for arsenic from 0.05 mg to 10 µg/l in Table 20. This revision reflects the current level set under the Safe Drinking Water Act and is consistent with EPA recommended drinking water MCL.[121] ODEQ also added a clarifying footnote which explains that the MCL value is not a water quality criterion.

[121] January 22, 2001. *Federal Register*, Volume: 66, No.: 14, page: 6976 (66 FR 6976). *Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring Final Rule.* Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-22/w1668.htm
March 25, 2003. *Federal Register*, Volume: 68, No.: 57, page: 14501 (68 FR 14501). *Minor Clarification of National Primary Drinking Water Regulation for Arsenic; Final Rule.* Available at: http://www.gpo.gov/fdsys/pkg/FR-2003-03-25/html/03-7048.htm

Since Oregon has not adopted the arsenic MCL value as a water quality criterion, is not considered WQS under the CWA. Instead, the MCL is a value that the State uses to set the maximum permissible level of arsenic in drinking water delivered to the tap (after treatment) consistent with the Safe Drinking Water Act, not a value that surface waters of the State must meet. MCLs are enforceable standards under the Safe Drinking Water Act, and are not required under the Clean Water Act unless determined by the State to be needed to protect the designated uses. For these reasons, EPA is taking no action to approve or disapprove the revised MCL value for arsenic.

Based on the above, EPA has determined that Oregon's MCL value for arsenic is not a WQS subject to EPA review and approval under Section 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove this MCL value.

Provision Establishing the Effective Date for Arsenic at OAR 340-041-0033(2)(b)
The following language was added to Oregon's WQS at OAR340-041-0033 – Toxic Substances as part of Oregon's April 21, 2011 rule revisions submitted to EPA on July 12, 2011:

OAR 340-041-0033(2)(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

As part of Oregon's subsequent June 16, 2011 rule revisions submitted to EPA on July 21, 2011, Oregon removed and renumbered the provision cited above language at OAR 340-041-0033(3)(b) when it reformatted the toxics criteria tables, thus moving the arsenic criteria to Table 40. Since the deleted language was submitted to EPA as part of the June 16, 2011 rule revisions, the provision is no longer applicable under state law and there is no requirement for EPA to act on the provision under Section 303(c) of the CWA.
~~*OAR 340-041-0033(3)(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).*~~

Since ODEQ deleted the language l as part of the July 21, 2011 submittal to EPA, the provision is not applicable under State law and there is no requirement for EPA to evaluate the provision under Section 303(c) of the CWA.

In the July 21, 2011 submittal, ODEQ addressed the effective dates of the criteria, including arsenic, in the associated revisions at OAR 340-041-0033(1) which describe the dates when the toxics criteria in Tables 20, 33A, 33B and 40 become effective under State law and the Clean Water Act. EPA's rationale for approval of OAR 340-041-0033(1) is explained in section V of this document.

Acknowledgement of the Arsenic Reduction Policy at OAR 340-041-0033(7)
In conjunction with this rule and in recognition that the revised criteria provide a lower level of protection than other human health criteria in Oregon, an Arsenic Reduction Policy was adopted under State law at OAR 340-041-033(4). To accommodate additional revisions associated with the rulemaking submitted to EPA on July 21, ODEQ reorganized the location of the rule and

moved the arsenic reduction policy section to OAR 340-041-0033(7). However, ODEQ did not revise any of the rule language that was previously adopted. The policy was included in Oregon's WQS regulation in the same section as the arsenic criteria to help ensure it was applied where applicable. The policy requires that, in situations where water bodies have background levels below the arsenic criteria, dischargers with the potential to affect a drinking water supply develop an arsenic reduction plan and take feasible steps to reduce arsenic loading.

The new policy does not establish a legally binding ambient condition for a waterbody to support a particular designated use. Nor does it establish a binding process whereby the State would establish an alternate ambient condition for a waterbody following a public process. Rather, this policy outlines permitting requirements that the State will place on selected dischargers (those located in a surface water drinking water protection area as delineated under the Safe Drinking Water Act). These permitting requirements are not tied to what is necessary to protect the designated uses of Oregon's waters, but rather to what measures are "feasible" to reduce arsenic loading. The permitting requirements are to be used in association with other implementation tools to encourage further arsenic reductions below the established criteria, but they do not modify those criteria.

In the Response to Comments, ODEQ states that the arsenic reduction policy is an important component of Oregon's WQS but that the intent of the policy is not to alter the numeric criteria. Furthermore, ODEQ specifies that the policy applies to specific sources and circumstances and requires that feasible reduction steps be taken.[122]
Based on the above, EPA has determined that this policy is not a WQS subject to EPA review and approval under Section 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove this provision.

F. *NEW, REVISED AND WITHDRAWN FOOTNOTES*

As part of the July 21, 2011 submittal, ODEQ added, revised and withdrew several footnotes. In addition to footnote J (for methylmercury) and footnote A (for arsenic) which are discussed separately above with those individual criteria, these changed footnotes are described in further detail below.

1. New Footnotes

ODEQ has added new footnotes for the following three pollutants: barium, cyanide, and PCBs.

Footnote C: Barium
The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The

[122] ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. page 26. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf

"water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.

Footnote G: Cyanide
The cyanide criterion is expressed as total cyanide (CN)/L.

Footnote L: PCBs
This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).

Acknowledgement of Barium Footnote C
The new footnote C for barium clarifies the source of information upon which the criterion is based. However, the footnote does not establish a legally binding requirement under State law nor does it describe a desired ambient condition of a waterbody to support a particular designated use. Therefore this footnote is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the new footnote for barium. The underlying criterion for barium was unrevised and therefore EPA is not reviewing the underlying criterion as part of this action.

EPA acknowledges that the footnote provides accurate information respecting the human health criterion development for barium. The new footnote for barium explains that the criterion is based upon a Safe Drinking Water MCL value along with the rationale for why an "organism only" criterion does not exist. The human health criterion for barium was not derived using EPA's 2000 Methodology, but instead was based upon EPA's national 304(a) criteria recommendations in EPA's 1986 Gold Book.

EPA Approval of Footnotes for Cyanide (footnote G) and PCBs (footnote L)
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's addition of the two footnotes, Footnote G for cyanide and Footnote L for PCBs, as consistent with EPA's current CWA § 304(a) criteria recommendations.

EPA Rationale Regarding Footnotes for Cyanide (footnote G) and PCBs (footnote L)
Oregon's new footnote G for cyanide explains that the criterion is expressed as total cyanide (CN)/L. EPA has reviewed this footnote language and the 304(a) criteria recommendation, which states that the "recommended water quality criterion is expressed as total cyanide, even though the IRIS RfD used to derive the criterion is based on free cyanide. The multiple forms of cyanide that are present in ambient water have significant differences in toxicity due to their differing abilities to liberate the CN-moiety. Some complex cyanides require even more extreme conditions than refluxing with sulfuric acid to liberate the CN-moiety. Thus, these complex cyanides are expected to have little or no 'bioavailability' to humans. If a substantial fraction of the cyanide present in a water body is present in a complex form (e.g., $Fe_4[Fe(CN)_6]_3$), this criterion may be over conservative."[123] Oregon's new footnote language along with the human

[123] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Footnote jj. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html

health criterion values for cyanide are consistent with EPA's recommended 304(a) national default values for calculating the criterion.

This footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable form of cyanide is a component of the overall description of the level of protection afforded by the criterion. Since this footnote specifies the applicable form of the cyanide criterion Oregon adopted, EPA approves this footnote as a WQS. EPA is approving the associated numeric criteria for cyanide as discussed above in section IV.

Oregon's new footnote L for PCBs explains that the criterion applies to total PCBs. EPA has reviewed this footnote language and the 304(a) criteria recommendations, which states that the "criterion applies to total PCBs, (e.g., the sum of all congener or all isomer or homolog or Aroclor analyses.)"[124] Oregon's new footnote language along with the human health criterion values for PCBs are consistent with EPA's recommended 304(a) national default values for calculating the criterion.

This footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable form of PCBs is a component of the overall description of the level of protection afforded by the criterion. Since this footnote specifies the applicable form of the PCB criterion Oregon adopted, EPA approves this footnote as a WQS. EPA is approving the associated numeric criteria for PCBs as discussed above in section IV.

2. Revised Footnotes

ODEQ has revised the footnotes below for the following six pollutants: footnote B: asbestos, footnote D: chlorophenoxy herbicide (2,4,5,-TP), footnote E: chlorophenoxy herbicide (2,4,-D), footnote F: copper, footnote I: methoxychlor, and footnote K: nitrates.

Table 12: Revised Footnotes.

Id.	Pollutant	Previous Footnote	New Footnote
B	Asbestos	*Human health criteria for carcinogens reported for three risk levels. Value presented is the 10-6 risk level, which means the probability of one cancer case per million people at the stated concentration.*	*The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
D	Chlorophenoxy Herbicide (2,4,5,-TP)	*This value is based on a Drinking Water regulation.*	*The Chlorophenoxy Herbicide (2,4,5,-TP)criterion is the same as originally*

[124] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Footnote N. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html

			published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.
E	Chlorophenoxy Herbicide (2,4,-D)	*This value is based on a Drinking Water regulation.*	*The Chlorophenoxy Herbicide (2,4,-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
F	Copper	*This value is based on a Drinking Water regulation.*	*Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
I	Methoxychlor	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
K	Nitrates	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water +*

			organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.

EPA Review
All six of these revised footnotes clarify the sources of information upon which the criteria are based. The footnotes are not considered water quality standards because they do not establish legally binding requirements under State law and do not describe a desired ambient condition of a waterbody to support a particular designated use. Therefore they are not water quality standards subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the revised footnotes for these six pollutants.

The revised footnotes identified above explain in more detail than the previous footnotes that the criteria are based upon a Safe Drinking Water MCL value in addition to an explanation concerning the rationale for why an "organism only" criterion does not exist. These human health criteria were not derived using EPA's 2000 Methodology, but instead were based upon EPA's national 304(a) criteria recommendations in EPA's 1986 Gold Book and developed under the Safe Drinking Water Act. EPA has reviewed these footnotes and found them to be accurate regarding the human health criteria development for these six pollutants. The underlying toxics criteria for asbestos and copper were approved by EPA on June 1, 2010. The underlying toxics criteria for chlorophenoxy herbicide (2,4,5,-TP), chlorophenoxy herbicide (2,4,-D), methoxychlor, and nitrates have not been revised and thus are not addressed in this action. These values remain consistent with EPA's current 304(a) criteria recommendations.

3. Withdrawn Footnotes

ODEQ has removed the footnote below for the three pollutants to which it applied: hexachlorocyclo-hexane-technical, nitrosamines, and nitrosodiethylamine, N:
No BCF was available; therefore, this value is based on that published in the 1986 Gold Book.

EPA Review
EPA's current CWA 304(a) criteria recommendations include the following BCF values for these three pollutants:

- Hexachlorocyclo-hexane-technical: BCF value = 130
- Nitrosamines: BCF value = 0.20
- Nitrosodiethylamine, N: BCF value = 0.20

At the time of Oregon's previous adoption of human health criteria for these three pollutants, EPA's 304(a) criteria recommendations were not derived using a methodology that accounted for bioconcentration through the use of a BCF. EPA now recommends the use of the BCF values listed above. Consistent with EPA's recommended 304(a) national default values for calculating the human health criteria, ODEQ has updated the criteria for these three pollutants to include EPA's recommended BCF values and therefore the three footnotes are no longer accurate or relevant. EPA is approving Oregon's human health criteria for hexachlorocyclo-hexane-

technical, nitrosamines, and nitrosodiethylamine, N as discussed above in section IV as consistent with EPA's 304(a) guidance.

Therefore, as a result of updating the human health criteria for these three pollutants, the footnotes are no longer accurate and relevant and removing them is appropriate. Furthermore, these three footnotes were not water quality standards because they did not establish legally binding requirements under state law and they did not describe a desired ambient condition of a waterbody to support a particulate designated use. Rather, the footnotes clarified the source of information, EPA's 1986 Gold Book, upon which the criteria were based. For this reason, the footnotes were not considered WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the removal of the footnote as applied to hexachlorocyclo-hexane-technical, nitrosamines, and nitrosodiethylamine, N.

G. *WITHDRAWN HUMAN HEALTH CRITERIA WHICH WERE REPLACED BY MORE SPECIFIC CRITERIA*

During this rule revision, Oregon updated its numeric human health toxics criteria to reflect EPA's most recent science and refinements as published in EPA's current CWA § 304(a) criteria recommendations. Included in the refinements recommended by EPA was the removal of 13 general human health criteria developed for families of pollutants and the replacement of these criteria by other criteria that address the specific chemical(s) of concern for human health protection. The 13 chemicals that ODEQ has removed and replaced with criteria for specific chemical compounds are consistent with EPA's current 304(a) criteria recommendations. They are listed and explained in Table 13 below.

Table 13: Withdrawn human health criteria replaced with more specific criteria.

No.	Withdrawn Criteria	Replacement Criteria	Explanation[125]
1	Dinitrotoluene	*Dinitrotoluene 2,4*	More specific and more stringent of the two compounds was retained.
2	Dinitro-o-Cresol 2,4	Dinitrophenol 2,4; Dinitrophenols	Alternative compounds, including a synonym, in the same family identified.
3	Diphenylhydrazine	Diphenylhydrazine 1,2	More specific compound in the same family identified.
4	Endosulfan	Endosulfan Alpha; Endosulfan Beta; Endosulfan Sulfate	More specific compounds in the same family identified.
5	Halomethanes	Chlorodibromomethane; Dichlorobromomethane; Bromoform; *Chloroform*	More specific compounds in the same family identified.
6	Monochlorobenzene	Chlorobenzene	Identical compound, the two criteria names are synonyms.

[125] Explanations in the table were developed with information from EPA's "Gold Book". EPA. May 1, 1986. *Quality Criteria for Water*. U.S. Environmental Protection Agency, Office of Water. 440/5-86-001. Available at: https://owpubauthor.epa.gov/scitech/swguidance/standards/upload/2009_01_13_criteria_goldbook.pdf

7	Polynuclear Aromatic Hydrocarbons	Acenaphthene; Anthracene; Fluorene; *Fluoranthene;* Pyrene; Chyrsene; Dibenzo(a,h)anthracene; Benzo(a)anthracene; Benzo(a)pyrene; Benzo(b)fluorantehene 3,4; Benzo(k)fluoranthene; Indeno(1,2,3-cd)pyrene	More specific compounds in the same family identified.
8	Chlorinated Benzenes	Chlorobenzene	More specific compound in the same family identified.
9	DDT	DDD 4,4'; DDE 4,4'; DDT 4,4'	More specific compounds in the same family identified.
10	Dichlorobenzenes	*Dichlorobenzene(m) 1,3*; Dichlorobenzene(o)1,2; Dichlorobenzene(p) 1,4	More specific compounds in the same family identified.
11	Dichloroethylenes	Dichloroethylene 1,1; Dichloroethylene trans 1,2	More specific compounds in the same family identified.
12	Dichlorobenzidine	*Dichlorobenzidine 3,3'*	More specific and more sensitive of the two compounds was retained.
13	Dichloropropene	*Dichloropropene 1,3*	More specific and more sensitive of the two compounds was retained.

Note: Chemicals listed in *italics* are criteria that Oregon had previously adopted and which EPA had previously approved. EPA is taking no action on these criteria. All other pollutants listed in the replacement criteria column, new criteria have been adopted by Oregon and are approved by EPA as part of this action.

EPA Review

In 2000 and 2003 EPA refined its "priority" list of toxic pollutants and 304(a) human health criteria recommendations specific to a number of pollutants on that list.[126] The criteria for the 13 pollutants listed above have been refined in three ways:

1. EPA previously had established recommended criteria for large chemical families of pollutants. Advances in scientific information have allowed EPA to refine its criteria recommendations by developing criteria for specific chemical forms (i.e. isomers or congeners) of a pollutant within the larger chemical family. For example, while the *Gold Book* published only a single criterion for DDT, subsequent revisions (see EPA's 2004 *National Recommended Water Quality Criteria*) have resulted in multiple criteria for DDT and two metabolites: 4,4' DDT, 4,4' DDE and 4,4' DDD. Similarly, while the *Gold Book* recommended a single criterion for dichlorobenzenes in the *Gold Book,* EPA's 2004 *National Recommended Water Quality Criteria*, recommends criteria for 1,2-dichlorobenzene, 1,3-dichlorobenzene, and 1,4-dichlorobenezene;

[126] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, page: 66443 (65 FR 66443). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
December 31, 2003. *Federal Register*, Volume: 68, Issue: 250, page: 75507 (68 FR 75507). Available at: http://edocket.access.gpo.gov/2003/pdf/03-32211.pdf

2. EPA has replaced some of the toxic pollutant names with synonyms for specific chemicals.[127] For example, while the *Gold Book* contained criteria for hexachlorocyclohexane-alpha, hexachlorocyclohexane-beta, and hexachlorocyclohexane-gamma, these criteria are now listed under the synonyms alpha BHC, beta BHC and gamma BHC in EPA's *National Recommended Water Quality Criteria*; and
3. EPA has condensed certain pollutants from several chemical forms of a given compound into a single compound, such as recommending criteria for total arsenic in EPA's 2004 *National Recommended Water Quality Criteria* to replace the previously recommended criteria for arsenic (tri) and arsenic (pent) as published in the *Gold Book*.

In updating its numeric toxics human health criteria, Oregon revised the criteria consistent with EPA's most recent CWA § 304(a) criteria recommendations, including withdrawing and/or revising the criteria as recommended by the above changes. The criteria withdrawn based on these refinements in chemical names are identified in Table 13 above. The table further identifies the pollutants for which Oregon has adopted new criteria to address the human health impacts associated with these pollutants. EPA action on the new criteria were addressed previously as part of EPA's action on Oregon's new criteria in section IV.B.

EPA Approval

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the withdrawal of Oregon's human health criteria for the 13 pollutants identified in Table 13, coupled with EPA's approval of new criteria (in section IV.B), as protective of human health. These changes are consistent with EPA's current CWA § 304(a) criteria recommendations to replace the specified criteria with more specific criteria for associated pollutants consistent with the latest science. EPA has approved the more specific pollutant replacement criteria above as consistent with 40 C.F.R. part 131. Since these new criteria address the same human health affects as the withdrawn criteria, EPA finds the criteria for the 13 pollutants identified above are not necessary to protect Oregon's fishing and water supply uses.

EPA Rationale

The CWA requires that, whenever a state or authorized tribe revises or adopts new WQS, it adopt criteria for all toxic pollutants listed pursuant to CWA § 307(a)(1) for which EPA has developed recommended criteria under CWA § 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with the adopted designated uses (CWA § 303(c)(2)(B)). As noted above, Oregon has refined the list of criteria for which it has established human health criteria to reflect recent science incorporated by EPA into the § 304(a)

[127] In addition, the following pollutant names were modified by ODEQ from their previous human health criteria for consistency with EPA terminology. These compounds are synonyms.

1. Dibutylphthalate was changed to Di-n-butyl Phthalate
2. Di-2-ethylhexyl phthalate was changed to Ethylhexyl phthalate bis 2
3. Hexachlorocyclohexane-alpha was changed to BHC alpha
4. Hexachlorocyclohexane-beta was changed to BHC beta
5. Hexachlorocyclohexane-gamma was changed to BHC gamma (Lindane)

human health criteria recommendations, including the removal of several pollutants representing chemical families and replacing them with criteria for more specific chemical compounds within the same general family. As such, the changes in the pollutant names listed above and the criteria adopted for these pollutants represent a refinement of criteria for individual chemicals within families, not withdrawals of criteria identified for pollutants in CWA § 307(a). Therefore, Oregon's withdrawal of its previous human health water quality criteria for these 13 pollutants is consistent with CWA § 303(c)(2)(B).

As stated above, Oregon's removal of these 13 pollutants and the associated criteria is consistent with EPA's removal of 304(a) criteria recommendations. Although the criteria for these 13 pollutants have been withdrawn, Oregon has developed individual criteria for the most toxic of chemicals in that family or retained the more specific criteria or a synonym for the chemical compounds. Therefore, while withdrawing the criteria for these 13 pollutants, Oregon has adopted new criteria to protect the same human health endpoints which these criteria were originally developed to protect. Therefore, EPA has determined that the withdrawal of these criteria coupled with the adoption of new criteria for similar pollutants (approved above in section IV.B) will protect Oregon's human health uses in accordance with 40 C.F.R. part 131.11(a)(1).

H. *TABLE 40 HUMAN HEALTH CRITERIA SUMMARY*

Oregon has added the following summary language prior to the human health criteria in Table 40 which explains the purpose of the criteria, criteria derivation and the format of the table.

TABLE 40: Human Health Water Quality Criteria for Toxic Pollutants

Human Health Criteria Summary
The concentration for each pollutant listed in Table 40 was derived to protect Oregonians from potential adverse health impacts associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water. The "organism only" criteria are established to protect fish and shellfish consumption and apply to waters of the state designated for fishing. The "water + organism" criteria are established to protect the consumption of drinking water, fish, and shellfish, and apply where both fishing and domestic water supply (public and private) are designated uses. All criteria are expressed as micrograms per liter (µg/L), unless otherwise noted. Pollutants are listed in alphabetical order. Additional information includes the Chemical Abstract Service (CAS) number, whether the criterion is based on carcinogenic effects (can cause cancer in humans), and whether there is an aquatic life criterion for the pollutant (i.e. "y"= yes, "n" = no). All the human health criteria were calculated using a fish consumption rate of 175 grams per day unless otherwise noted. A fish consumption rate of 175 grams per day is approximately equal to 23 8-ounce fish meals per month. For pollutants categorized as carcinogens, values represent a cancer risk of one additional case of cancer in one million people (i.e. 10-6), unless otherwise noted. All metals criteria are for total metal concentration, unless otherwise noted. Italicized pollutants represent non-priority pollutants. The human health criteria revisions established by OAR 340-041-0033

and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

Acknowledgement of Table 40 Summary Language

The new introductory summary language for Table 40 explains the purpose of the criteria, criteria derivation and the format of the table. However, this language does not establish a legally binding requirement under State law and it does not describe a desired ambient condition of a waterbody to support a particular designated use it is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. EPA has addressed the new and revised underlying human health criteria in Table 40 and the narrative language at OAR 340-041-0033(4) in this technical support document. This summary language further explains how the state derived the criteria values in Table 40. EPA incorporated the explanatory information provided in this summary into its analysis of the individual criteria values in Table 40. But because this summary does not operate as an independent water quality standard, in isolation from the criteria values in Table 40 and the narrative language at OAR 340-041-0033(4) (which EPA acted on individually), EPA is taking no action to approve or disapprove this summary language.

V. NARRATIVE STATEMENT

Oregon's revisions to its narrative toxics provisions found at OAR 340-041-033(1), (3) and (4) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. Non-revised words are also provided below for context. Additionally, Oregon reorganized sections of OAR 340-041-0033, thus renumbering several of the provisions without substantively changing any of the regulatory language.

340-041-0033
Toxic Substances
(1) Amendments to sections (4) and (6) of this rule (OAR 340-041-0033) and associated revisions to Tables 20, 33A, 33B and 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality standards pursuant to 40 CFR 131.21 (4/27/2000).

(3) Aquatic Life Criteria. Levels of toxic substances in waters of the state may not exceed the applicable aquatic life criteria listed in Tables 20, 33A, and 33B. Tables 33A and 33B, adopted on May 20, 2004, update Table 20 as described in this section.

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the new and revised language at OAR 340-041-0033(1) and (3).

EPA Rationale
The new and revised provisions at OAR 340-041-0033(1) and (3) describe dates when the toxics criteria in Tables 20, 33A, 33B and 40 become effective under state law and the Clean Water Act. The effective date of WQS provisions under the CWA is determined by the date of EPA approval. These timing provisions are WQS that provide for the new and revised criteria to be immediately in effect at the time of EPA's approval action. EPA has addressed the new and revised underlying human health criteria in this technical support document. OAR 340-041-0033(3) clarifies that only aquatic life criteria remain in Tables 20, 33A and 33B. EPA will address the aquatic life criteria in these tables and their corresponding footnotes in a separate action.

(4) Human Health Criteria. The criteria for waters of the state listed in Table 40 are established to protect Oregonians from potential adverse health effects associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water.

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the new language at OAR 340-041-0033(4).

EPA Rationale

The new provision at OAR 340-041-0033(4) adopts the human health criteria in Table 40. EPA approves this language which adopts the criteria and describes the intent of the criteria to protect human health uses in Oregon. This language explains the purpose of the human health criteria and describes that the criteria in Table 40 are established to protect Oregonians from potential adverse health effects association with long-term exposure to toxic substances associated with fish, shellfish and water consumption. EPA's action on each individual criterion in Table 40 is described in detail above.

VI. BACKGROUND POLLUTANT CRITERIA PROVISION

A. *BACKGROUND*

As previously discussed, in October 2008, the Oregon Environmental Quality Commission directed ODEQ to revise the State's human health criteria to incorporate a fish consumption rate of 175 grams per day. The fish consumption rate of 175 grams per day was selected by Oregon to ensure protection of all people in Oregon who may consume fish and shellfish from State waters including those who traditionally consume high amounts of fish for subsistence, health, economic or other reasons.[128] The rate reflects the 95th percentile of tribal members surveyed as part of the CRITFC Survey[129] and the 90th percentile of subsistence consumers surveyed in regional fish consumption studies. When providing this direction, the Commission also directed ODEQ to "propose rule language that would allow [O]DEQ to implement the standards in NPDES permits and other Clean Water Act programs in an environmentally meaningful and cost-effective manner" and to carefully consider the costs and benefits associated with elements of the new rule. This latter directive came following testimony from several stakeholders regarding potential implementation difficulties and economic burden of adopting the more stringent criteria.[130]

In response to this direction, ODEQ not only revised the human health criteria but also developed several new and revised rules addressing the implementation of the revised criteria. Each revised implementation rule targeted specific situations raised as potential concerns by ODEQ staff and stakeholders. The adoption of a new site-specific background pollutant criterion provision and the revisions to the variance provision (discussed in previous section) were submitted to EPA for action under Section 303(c) of the CWA while other rules were adopted pursuant to state law and were not submitted to EPA. All revisions are addressed separately in this document.

Oregon developed an *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking*[131] that discusses how ODEQ will implement the revised criteria in NPDES permits. Section IV.3 of this paper speaks directly to the site-specific background pollutant criterion provision and provides greater detail on its purpose, development and content as well as providing some discussion of how the resultant

[128] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. page 7. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf
[129] Columbia River Inter-Tribal Fish Commission (CRITFC). October 1994. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin.* Technical Report 94.3. Available at: http://www.critfc.org/tech/94-3report.pdf
[130] Oregon Environmental Quality Commission (OEQC). October 23, 2008. *Oregon Environmental Quality Commission Minutes of the Three Hundred and Forty-sixth Meeting.* Available at: http://www.deq.state.or.us/about/eqc/minutes/2008/2008octEQCMinutes.htm
[131] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

criterion would be applied to NPDES permits.[132] Other issue papers were developed to address implementation of the criteria outside of the NPDES program including papers that address nonpoint sources, antidegradation and source control.[133]

One situation identified during the workgroup process as potentially problematic to dischargers as well as ODEQ when issuing NPDES permits as a result of the revised human health criteria is when a NPDES discharger takes in water from and discharges to the same waterbody, which contains pollutants from upstream sources over which the discharger has little to no control. ODEQ adopted an intake credit provision at OAR 340-045-0105 that does not hold facilities accountable for removing these upstream pollutants if the concentration of the pollutant does not exceed the water quality criteria, the facility does not chemically or physically modify the pollutant and several other conditions described in the rule are met.

However, facilities that concentrate pollutants in their discharge above the levels in the intake water are not eligible for the intake credit rule. For example, such an increase in concentration may occur when a facility's process involves evaporation (e.g. non-contact cooling water), and the facility recycles water, thus resulting in the same mass of the pollutant but a lower volume of water. If the upstream concentration of the pollutant in the waterbody exceeds the underlying criterion, a permit limit is established such that the criterion is met at the end of the discharge pipe and the facility would need to treat the water prior to discharge regardless of the upstream concentration.[134]

ODEQ discussed numerous options for addressing this type of situation with the objective for providing an approach that:

- protects human health;
- establishes reasonable implementation of the revised water quality standards for facilities in the situation described above;
- allocates limited State resources efficiently; and

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[132] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Section IV.3, pages 44-61. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[133] ODEQ. May 26, 2011. *Issue Paper: Revisions to the Water Quality Standards and TMDL Rules (Divisions 41 and 42), Clarifications on How Nonpoint Sources Meet Water Quality Standards, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/Div4142IssuePaper.pdf
ODEQ. December 29, 2010. *Issue Paper: Evaluating the Antidegradation Policy as a Means to Reduce Nonpoint Sources of Toxic Pollutants to Oregon Waters, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/AntidegIssuePaper.pdf
ODEQ. December 29, 2010. *Issue Paper: Source Control Small Group, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/SourceControlIssuePaper.pdf

[134] ODEQ. April 20, 2010. *Implementing Water Quality Standards for Toxic Pollutants in Clean Water Act Permits.* DRAFT. RWG April 27, 2010 Discussion. Oregon Department of Environmental Quality. page 6. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/BackgroundPollutantsIssuePaper20110427.pdf

- ensures that regulatory requirements and costs for a facility are commensurate with the environmental threat they pose.[135]

Oregon proposed a draft rule and accepted public comment on that rule during the public process described above for all other elements of this action submitted by Oregon on July 21, 2011. In EPA's public comments to ODEQ on March 21, 2011 regarding the previous version of the background pollutant criteria provision proposed for public comment, EPA stated that ODEQ could:

- Implement the criterion on a site specific basis and submit each application to EPA for evaluation on a case by case basis; or
- Revise the provision consistent with a performance-based approach as a viable alternative to submitting each revision to EPA on a site specific basis. If ODEQ were to choose this option, sufficiently detailed implementation procedures would need to be adopted directly into the WQS regulations which establish a framework that is binding, clear, predictable and transparent.

Following consideration of the comments received, ODEQ adopted a performance-based water quality standard that can be used to adopt site-specific criteria for human health carcinogens where all of the following conditions apply:

- The criterion at issue is a human health criterion, for a pollutant identified as a carcinogen.
- The discharge does not increase the mass load of the pollutant in the receiving water. The mass load of the pollutant discharged to a waterbody may not exceed the mass load of the pollutant taken in from the same waterbody or a hydrologically connected water.
- The pollutant concentration in the receiving water is not increased by more than 3% above the upstream ambient concentration.
- The water body concentration does not exceed a calculated value that represents the human health criterion calculated at a risk level of 10^{-4}.
- The discharger uses any feasible pollutant reduction measures known and available to minimize the pollutant concentration in their discharge.
- The criterion must be evaluated and revised, if appropriate, when the permit is reissued.
- No TMDL has been developed for the waterbody and pollutant at issue.[136]

The provision authorizes ODEQ to develop a site-specific criterion for the waterbody in the vicinity of a discharge and use that criterion to develop an effluent limit for the pollutant if all conditions of the rule are met. The criterion established would be based upon the most stringent of 1) the instream concentration following receipt of the current level of discharge from the

[135] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 45-46. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[136] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 44-45. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

facility, 2) a 3% increase in the ambient instream concentration of the pollutant, or 3) a concentration value that represents a 1×10^{-4} risk level. In addition, the criterion could not be established at a level that would allow the facility to increase the mass load of the pollutant from that in their intake water.[137]

A site-specific background pollutant criterion may only be developed under this provision if the waterbody serves as the receiving water for a NPDES discharge and the effluent discharged meets certain requirements. Oregon's rule limits the criteria developed under this rule by requiring the criteria be established at the most stringent of several options that are based on applying certain limitations on the effluent from the facility and on the resultant instream criteria. Therefore, the process outlined in Oregon's rule uses the same type of calculations made in establishing NPDES permit limits to calculate the resultant instream concentration at various effluent conditions. Once a site-specific criterion is adopted, it is to be used to develop permit effluent limits in the same manner as any other criteria.[138]

In order to provide further guidance to their permit writers ODEQ will be developing an Internal Management Directive (IMD) within 180 days of EPA's approval action.[139] This is one of several items identified by ODEQ as actions necessary to assist ODEQ staff and the public in implementing the provisions approved in this action.

B. *ODEQ'S JULY 21, 2011 SUBMITTAL*

ODEQ has added a new provision which establishes a site-specific background pollutant criteria at OAR 340-041-0033(6). This provision is a performance-based water quality standard that results in site-specific human health water quality criteria under the conditions and procedures specified within the rule. It addresses existing permitted discharges of a pollutant removed from the same body of water, as defined in the provision.

Below is Oregon's background pollutant criteria provision, found at OAR 340-041-0033(6).

340-041-0033(6)

Establishing Site-Specific Background Pollutant Criteria: This provision is a performance-based water quality standard that results in site-specific human health water quality criteria under the conditions and procedures specified in this rule section. It addresses existing permitted discharges of a pollutant

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[137] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[138] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[139] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. Supplemental Attachment 10, Timeline for Follow-Up Actions, WQS for Human Health Toxic Pollutants Rulemaking.

removed from the same body of water. For waterbodies where a discharge does not increase the pollutant's mass and does not increase the pollutant concentration by more than 3%, and where the water body meets a pollutant concentration associated with a risk level of $1x10^{-4}$, DEQ concludes that the pollutant concentration continues to protect human health.

(a) Definitions: For the purpose of this section [OAR 340-041-0033(6)]:

(A) "Background pollutant concentration" means the ambient water body concentration immediately upstream of the discharge, regardless of whether those pollutants are natural or result from upstream human activity.

(B) An "intake pollutant" is the amount of a pollutant that is present in public waters (including groundwater) as provided in subsection (C), below, at the time it is withdrawn from such waters by the discharger or other facility supplying the discharger with intake water.

(C) "Same body of water": An intake pollutant is considered to be from the "same body of water" as the discharge if the department finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

(i) The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

(ii) There is a direct hydrological connection between the intake and discharge points; and

(I) The department may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

(II) An intake pollutant from groundwater may be considered to be from the "same body of water" if the department determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to past or present human activity, such as industrial, commercial, or municipal operations, disposal actions, or treatment processes.

(iii) Water quality characteristics (e.g., temperature, pH, hardness) are similar in the intake and receiving waters.

(b) Applicability

(A) Site-specific criteria may be established under this rule section only for carcinogenic pollutants.

(B) Site-specific criteria established under this rule section apply in the vicinity of the discharge

for purposes of establishing permit limits for the specified permittee.
(C) The underlying waterbody criteria continue to apply for all other Clean Water Act programs.

(D) The site-specific background pollutant criterion will be effective upon department issuance of the permit for the specified permittee.

(E) Any site-specific criteria developed under this procedure will be re-evaluated upon permit renewal.

(c) A site-specific background pollutant criterion may be established where all of the following conditions are met:

(A) The discharger has a currently effective NPDES permit;

(B) The mass of the pollutant discharged to the receiving waterbody does not exceed the mass of the intake pollutant from the same body of water, as defined in section 6(a)(C) above, and, therefore, does not increase the total mass load of the pollutant in the receiving water body;

(C) The discharger has not been assigned a TMDL wasteload allocation for the pollutant in question;

(D) The permittee uses any feasible pollutant reduction measures available and known to minimize the pollutant concentration in their discharge;

(E) The pollutant discharge has not been chemically or physically altered in a manner that causes adverse water quality impacts that would not occur if the intake pollutants were left in-stream; and,

(F) The timing and location of the pollutant discharge would not cause adverse water quality impacts that would not occur if the intake pollutant were left in-stream.

(d) The site-specific background pollutant criterion must be the most conservative of the following four values. The procedures deriving these values are described in the sections (6)(e) of this rule.

(A) The projected in-stream pollutant concentration resulting from the current discharge concentration and any feasible pollutant reduction measures under (c)(D) above, after mixing with the receiving stream.

(B) The projected in-stream pollutant concentration resulting from the portion of the current discharge concentration associated with the intake pollutant mass after mixing with the receiving stream. This analysis ensures that there will be no increase in the mass of the intake pollutant in the receiving water body as required by condition (c)(B) above.

(C) The projected in-stream pollutant concentration associated with a 3% increase above the background pollutant concentration as calculated:

(i) For the mainstem Willamette and Columbia Rivers, using 25% of the harmonic mean flow of the waterbody.

(ii) For all other waters, using 100% of the harmonic mean flow or similar critical flow

value of the waterbody.

(D) A criterion concentration value representing a human health risk level of 1×10^{-4}. This value is calculated using EPA's human health criteria derivation equation for carcinogens (EPA 2000), a risk level of 1×10^{-4}, and the same values for the remaining calculation variables that were used to derive the underlying human health criterion.

(e) Procedure to derive a site-specific human health water quality criterion to address a background pollutant:

(A) The department will develop a flow-weighted characterization of the relevant flows and pollutant concentrations of the receiving waterbody, effluent and all facility intake pollutant sources to determine the fate and transport of the pollutant mass.

(i) The pollutant mass in the effluent discharged to a receiving waterbody may not exceed the mass of the intake pollutant from the same body of water.

(ii) Where a facility discharges intake pollutants from multiple sources that originate from the receiving waterbody and from other waterbodies, the department will calculate the flow-weighted amount of each source of the pollutant in the characterization.

(iii) Where intake water for a facility is provided by a municipal water supply system and the supplier provides treatment of the raw water that removes an intake water pollutant, the concentration and mass of the intake water pollutant shall be determined at the point where the water enters the water supplier's distribution system.

(B) Using the flow weighted characterization developed in Section (6)(e)(A), the department will calculate the in-stream pollutant concentration following mixing of the discharge into the receiving water. The resultant concentration will be used to determine the conditions in Section (6)(d)(A) and (B).

(C) Using the flow weighted characterization, the department will calculate the in-stream pollutant concentration based on an increase of 3% above background pollutant concentration. The resultant concentration will be used to determine the condition in Section (6)(d)(C).

(i) For the mainstem Willamette and Columbia Rivers, 25% of the harmonic mean flow of the waterbody will be used.

(ii) For all other waters, 100% of the harmonic mean flow or similar critical flow value of the waterbody will be used.

(D) The department will select the most conservative of the following values as the site-specific water quality criterion.

(i) The projected in-stream pollutant concentration described in Section 6(e)(B);

(ii) The in-stream pollutant concentration based on an increase of 3% above background described in Section 6(e)(C); or

(iii) A water quality criterion based on a risk level of 1×10^{-4}.

(f) Calculation of water quality based effluent limits based on a site-specific background pollutant criterion:

> *(A) For discharges to receiving waters with a site-specific background pollutant criterion, the department will use the site-specific criterion in the calculation of a numeric water quality based effluent limit.*
>
> *(B) The department will compare the calculated water quality based effluent limits to any applicable aquatic toxicity or technology based effluent limits and select the most conservative for inclusion in the permit conditions.*

(g) In addition to the water quality based effluent limits described in Section (6)(f), the department will calculate a mass-based limit where necessary to ensure that the condition described in Section (6)(c)(B) is met. Where mass-based limits are included, the permit shall specify how compliance with mass-based effluent limitations will be assessed.

(h) The permit shall include a provision requiring the department to consider the re-opening of the permit and reevaluation of the site-specific background pollutant criterion if new information shows the discharger no longer meets the conditions described in subsections (6)(c) and (e).

(i) Public Notification Requirements.

> *(A) If the department proposes to grant a site-specific background pollutant criterion, it must provide public notice of the proposal and hold a public hearing. The public notice may be included in the public notification of a draft NPDES permit or other draft regulatory decision that would rely on the criterion and will also be published on the water quality standards website;*
>
> *(B) The department will publish a list of all site-specific background pollutant criteria approved pursuant to this rule. A criterion will be added to this list within 30 days of its effective date. The list will identify: the permittee; the site-specific background pollutant criterion and the associated risk level; the waterbody to which the criterion applies; the allowable pollutant effluent limit; and how to obtain additional information about the criterion.*

C. *EPA ACTION ON ODEQ'S NEW BACKGROUND POLLUTANT CRITERIA PROVISION*

EPA Action

In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new background pollutant criteria provision at OAR 340-041-0033(6), as detailed below, because it is consistent with the Clean Water Act and the implementing Federal water quality standards regulations governing EPA's review and approval or disapproval of new or revised water quality standards as required in 40 C.F.R. part 131. In EPA's review of Oregon's background pollutant criteria provision, the Agency considered information submitted on July 21, 2011 including ODEQ's NPDES Implementation Issue Paper[140] and Response to

[140] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at:

Comments document.[141]

In its review and action on the background pollutant provision, EPA also considered the following three key elements:

- Whether the site-specific human health criteria to be generated under the provision are sufficient to protect Oregon's human health uses, as required under 40 CFR 131.6.
- Whether the site-specific human health criteria to be generated under the provision are consistent with EPA's regulatory specifications for criteria at 40 CFR 131.11.
- Whether this implementation procedure contains sufficient detail, and suitable safeguards, such that additional § 303(c) review of individual criteria generated under the provision would be redundant.

As described in further detail below, EPA has concluded that the site-specific background pollutant provision adequately addresses all three of these elements and thus is consistent with CWA § 303(c) and its implementing regulations.

EPA Rationale

The provision establishes site-specific human health criteria at a level to protect Oregon's human health uses

Oregon's site-specific background pollutant provision contains a binding restriction that any site-specific criterion to be generated under the provision must be established at the most conservative (stringent) of the conditions specified in OAR 340-041-033(6)(d) and reflect no net addition of the pollutant from the discharger to the waterbody segment. In no case may a criterion developed under this provision represent a carcinogenic human health risk level greater than 1.0 x10^{-4}, however, it may be more stringent. Since the least stringent scenario for a site-specific criterion generated under the provision (i.e., one generated based on a 10^{-4} risk level) is itself within EPA's recommended range of risk levels protective of human health designated uses, EPA concludes that a criterion developed using Oregon's site-specific background pollutant provision would be protective of Oregon's human health uses.

EPA's Human Health Methodology recognizes that States and Tribes have discretion in selecting appropriate risk ranges and recommends that states adopt criteria for carcinogens based on either a 1 x 10^{-6} or 1 x 10^{-5} risk level to protect the general population, as long as highly exposed populations do not exceed a 1 x 10^{-4} risk level.[142] Consistent with the flexibility accorded to States in developing risk ranges for carcinogenic pollutants, Oregon has chosen to exercise this discretion by allowing the risk level for carcinogens in waters in the vicinity of certain NPDES discharges not to exceed 10^{-4}. As discussed previously, Oregon used a fish consumption rate reflective of highly exposed consumers and a risk level of 1 x 10^{-6} for deriving their human

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http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[141] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[142] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

health criteria. In this case, the site specific criteria would continue to protect the highly exposed consumer but at a risk level between 1 x 10^{-6} and 1 x 10^{-4}. Thus, EPA concludes that any site-specific criterion calculated based on a 1 x 10^{-4} risk level would be consistent with EPA's guidance with respect to highly exposed populations, since the fish consumption rate already reflects highly exposed populations. EPA has recommended using a fish consumption rate for the general US population of 17.5 grams per day if no local or regional data is available. There is currently no available fish consumption data specific to the general population of Oregon. If one were to evaluate the protectiveness of a site-specific criterion developed under this provision at a 10^{-4} risk level but using EPA's default fish consumption rate of 17.5 grams per day, the result would protect at a carcinogenic risk level of 1 x 10^{-5}. This risk level is consistent with that recommended by EPA by EPA in the 2000 Human Health Methodology. Therefore, EPA finds that criteria established under this provision would be established at a level protective of both the general population and high fish consuming populations consistent with the levels recommended by EPA in the 2000 Human Health Methodology.

In response to several comments regarding the use of a 1 x 10^{-4} risk level, ODEQ affirmed that the criterion would be established at "the most protective of the following results: the current ambient pollutant concentration after discharge; the background concentration plus three percent; or the criteria value calculated at a 1 x 10^{-4} risk level" (emphasis added)).[143] In several other responses to comments as well as at several places in the Issue Paper, ODEQ has also stated that a 1 x 10^{-4} risk would be the greatest possible risk allowed under the criterion and that other conditions within the provision would often limit the criterion further.[144] ODEQ also specifies this fact in their July 21, 2011 letter to EPA requesting the review and approval of these rules.[145] In ODEQ's response to comments, they explained why they found this additional level of risk to be protective in this site-specific situation. They note that several restrictions have been included in the rule in order to limit any additional risk to the human health use.

- First, the rule requires that the pollutant be from the "same body of water" and that the mass of the pollutant associated with the facility may not be increased from its intake water to the effluent water. These requirements ensure that any discharge limits based on the site specific criterion would not add any additional mass to the waterbody, although the discharger may slightly increase the pollutant concentration relative to background (up to a maximum of three percent). In other words, the pollutant present in the

[143] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 54. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
[144] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. pages 49; 55-58. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 47; 49; 50; 58. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[145] ODEQ. July 21, 2011. Letter from Neil Mullane, Water Quality Division Administrator, to Michael Bussell, Office of Water and Watersheds, EPA Region 10. *Re: Oregon Submission of Revised State Water Quality Standards for Toxic Pollutants, Including a New Background Pollutant Provision and a Revised Variance Rule for EPA Review and Approval.*

waterbody segment to which the criteria will apply would have reached the vicinity of the outfall point had it not been intercepted by the discharger and there is no addition of pollutants by the facility.[146]

- Second, the application of the criterion is limited to the sole purpose of accommodating existing discharges from an existing NPDES discharger. In no case could a criterion decrease in stringency such that the current discharge concentration to a water body would be allowed to increase as a result of the revision.[147]
- Third, the underlying water quality criterion will remain in effect for all other CWA purposes including 303(d) listing and TMDL development. (as explained above)
- Finally, the rule requires that the criterion be re-evaluated upon permit renewal (OAR 340-041-0033(6)(b)(E)), thus making the criterion effective only for the duration of the permit and requiring that the site-specific criterion be reevaluated and revised, if appropriate, upon permit renewal using current ambient and effluent data in situations where all the prerequisite conditions continue to be present.[148] As noted above, if a TMDL was established prior to this renewal, a site-specific criterion could not be obtained under this rule and the facility's effluent limit must be consistent with the WLA in the TMDL.

ODEQ therefore determined that the relative increase in ambient concentration does not result in a significant change to human health risk[149] and that the criterion developed under this provision would be protective of the beneficial uses of that waterbody.[150]

Since this provision establishes a process for developing individual site-specific criteria, the exact location of each application cannot be specified in advance. However, the provision does specify criteria location relative to the pertinent discharger ("in the vicinity of the discharge for purposes of establishing permit limits for the specified permittee"). (OAR 340-041-0033(6)(b)). Thus, dischargers other than the specified permittee would not be able to use the site-specific criterion in permit calculations.[151] For the specified permitee, a site-specific criterion

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[146] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 51. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[147] OAR 340-041-0033(6)(d)(A) and (B)
ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[148] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[149] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[150] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 65. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[151] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water*

corresponding to a risk level of 1 x 10^{-4} or safer would be applicable to the water in the vicinity of the discharge.[152] Since the site-specific conditions are themselves predicated on the characteristics of the discharger, an appropriate matching of the criterion to discharger is an adequate specification of where the site-specific criteria will apply.

EPA notes that one commenter was concerned that the approach in the proposed rule introduced an inconsistency into Oregon's water quality criteria. The commenter questioned whether it was consistent with the Clean Water Act for Oregon to determine that a single risk target is both protective (where site-specific criteria apply) and non-protective (where site-specific criteria do not apply) of human health uses. ODEQ addressed this comment by adding additional detail in the final rule. In addition, EPA evaluated this concern relative to the final rule in light of the fact that Oregon already had the discretion, consistent with EPA's Human Health Methodology, to adopt criteria based on a risk range between 1 x 10^{-6} and 1 x 10^{-4} (in conjunction with a fish consumption rate that reflects high-consuming populations). If Oregon had adopted state-wide criteria reflecting a risk range less stringent than 1 x 10^{-6}, Oregon could have exercised its discretion, based on its own policy priorities and consistent with CWA § 510, to apply *more stringent* site-specific criteria where it deemed appropriate. Under these circumstances, a single risk target would be both protective (where site-specific criteria do not apply) and non-protective (where site-specific criteria apply). The only practical distinction between this scenario and the one raised in public comments is which risk level is treated as the normative baseline, and which is treated as site-specific departure from the baseline.

Since multiple risk levels for carcinogenic pollutants are within the range identified as acceptable in EPA's Human Health Methodology, and States/Tribes have the ability to define "local conditions" when establishing site specific criteria, EPA concludes that Oregon has discretion to apply both one risk level as a generally applicable value and other risk levels on a site-specific basis (i.e., as "site-specific conditions" under 40 CFR 131.11(b)). While the target risk level is combined with other values (based on a scientific rationale) to generate a criterion value for a carcinogenic pollutant, site-specific variation in the target risk level itself is based on Oregon's risk management judgment. In order for the overall site-specific criterion to be "based on sound scientific rationale," under 40 CFR 131.11(a)(1), it is sufficient that Oregon has clearly identified the rationale for the site-specific criteria as a policy decision within its discretion and consistent with EPA's Human Health Methodology.

EPA also notes that one commenter expressed concern about the interaction between the proposed background pollutant provision and Oregon's existing mixing zone policy. EPA acknowledges that, as with other Oregon criteria, the site specific criteria generated under the background pollutant provision would be used in developing water quality based effluent limits for the NPDES permit discharging to the waterbody. EPA also acknowledges that, in certain instances, Oregon's current mixing zone policy may be applied when developing such limits. In

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Quality Standards Implementation Policies. Oregon Department of Environmental Quality. page 56. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[152] As discussed below, Oregon's existing mixing zone policy would still affect the calculation of effluent limits based on the criterion. Nevertheless, the applicable criterion in the receiving water is constrained, by OAR 340-041-0033(6)(D), to be at least as stringent as the value calculated based on a risk level of 1x10^{-4}.

the Issue Paper ODEQ states that once the site-specific background pollutant criterion has been determined, the criterion will be used to establish a numeric permit effluent limit using the same procedures and guidance used for establishing permit limits for any human health criteria.[153] Furthermore, ODEQ's response to comments specifies that any mixing will be determined based on the guidance provided in [O]DEQ's Reasonable Potential Internal Management Directive (IMD) and that [O]DEQ's published guidelines (Regulated Mixing Zones IMD) would govern the siting and sizing of any zones of mixing.[154] Any mixing zone allowed would be required under the CWA to comply with the all requirements of the State's mixing zone provision prior to a mixing zone being authorized. In certain circumstances it is possible that a mixing zone for a site-specific criterion generated under this provision (or any other human health criterion for a carcinogen) may allow a limited area of the waterbody in which the cancer risk associated with the pollutant concentration would exceed 1×10^{-4}. However, EPA does not therefore conclude that the criterion is inconsistent with its Human Health Methodology. The potential for criteria to be implemented in concert with an EPA-approved state mixing zone policy is a background assumption of EPA's Human Health Methodology, not an additional factor that would weigh in favor of further limiting states' risk management discretion.

Furthermore, the language of OAR 340-041-0033(6)(d)(A) and (B) that speaks to the projected instream concentration "after mixing with the receiving stream" addresses the calculation of a projected instream value under specified effluent conditions. It does not establish a new mixing zone policy. EPA finds it appropriate that ODEQ utilize calculations similar to those used to develop permits when projecting this instream value as this allows the results of applying limitations to the effluent to be expressed as an insteam concentration and thus to be directly compared to the options limited by instream concentration. Furthermore, it provides that, for purposes of the stringency analysis, all options are expressed in the same units as the final criterion value. A similar practice is commonly used when EPA and States determine whether a discharge needs a water quality based effluent limit (see, e.g., 40 CFR 122.44(d)(1)(ii) "When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric water quality standard, the permitting authority shall use procedures which account for … where appropriate, the dilution of the effluent in the receiving water." (emphasis added)).

EPA considered whether implementation of the background pollutant provision is consistent

[153] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[154] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 55. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. August 2011. *Internal Management Directive: Reasonable Potential Analysis Process for Toxic Pollutants, Version 3.0. Oregon Department of Environmental Quality.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rpaIMD.pdf
ODEQ. December 2007. Oregon Department of Environmental Quality. *Regulatory Mixing Zone Internal Management Directive. Part 1: Allocating Regulatory Mixing Zones.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rmz/RMZIMDpart1.pdf and *Regulatory Mixing Zone Internal Management Directive. Part 2: Reviewing Mixing Zone Studies.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rmz/RMZIMDpart2.pdf

with the requirements of 40 CFR 131.10. For the following reasons, EPA concludes that it is. Oregon has expressly stated that a criterion based on a higher risk level, established pursuant to the provision, "continues to protect human health." OAR 340-041-0033(6). Thus, the background pollutant provision does not represent the revision of a human health use, but rather the articulation (within the range of the state's discretion) of the risk range the State considers protective of human health uses in this site-specific situation. The revision of criteria within the State's range of discretion for a designated use does not represent the removal or impairment of such a designated use. In conclusion, the provision contains a clear, predictable and transparent restriction that any site-specific criterion to be generated under the background pollutant provision must not correspond to a human health risk level of less stringent than 1×10^{-4}.[155] This minimum risk level is the most critical of the restrictions contained in the provision since it sets the least stringent criterion possible under the procedure. The least stringent criterion possible under the procedure is protective of Oregon's human health uses and is consistent with EPA's Human Health Methodology. Thus, EPA's approval of the provision may also serve as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision.

The provision generates site-specific human health criteria consistent with 40 CFR 131.11

EPA's regulations at 40 CFR 131.11 require States to adopt water quality criteria that protect the designated use and must be that are based on sound scientific rationale. It also allows States to modify criteria in order to reflect site-specific situations.[156] In OAR 340-041-0033(6) Oregon establishes a procedure to develop a site-specific human health criterion for carcinogens in a limited number of site-specific situations when developed consistent with the procedures specified in the rule.

Oregon has restricted the use of the site-specific background pollutant criteria provision to waterbodies where an existing NPDES discharger withdraws water from a waterbody and returns it to the same waterbody without adding any mass to the pollutant of concern. It is further limited to carcinogenic pollutants[157] and utilizes information about the discharge to limit the criterion. The rule provides a structured framework for developing a site-specific criterion which is limited by a number of factors, including a requirement that the criterion never exceed a criterion calculated at a 1×10^{-4} risk level. Further limitations are derived based on the pre-existing quantity and quality of the discharge into the receiving water, no greater than a three percent increase in instream concentration and no increase in mass load of the pollutant from the discharger. In no case will the criteria allow greater than a 10^{-4} carcinogenic risk level (as established using the same methodology used for all other human health criteria addressed in this action).

EPA has reviewed whether Oregon had supplied appropriate grounds to derive a site-specific human health criterion for carcinogens, consistent with 40 CFR 131.11. EPA's water quality standards regulations provide that water quality criteria "must be based on sound scientific

[155] OAR 340-041-0033(6)(d)
[156] 40 CFR 131.11 (A)(1); 40 CFR 131.11(b)(1)(ii)
[157] OAR 340-041-0033(6)(b)(A)

rationale,"[158] and contemplate that a State may adopt site-specific criteria, and provide that these site-specific criteria "should . . . reflect site-specific conditions."[159] EPA's Human Health Methodology further clarifies a State's flexibility to derive site-specific criteria for human health criteria. Human health criteria may be modified to reflect, in a justifiable manner, "local environmental conditions." Local conditions may be those which prevail over a particular river reach, an entire river, regionally, or Statewide.[160] In other guidance, EPA has acknowledged that *less stringent* site specific modifications to human health criteria may be appropriate (in that case, either based on local variation in fish consumption rates or applicable bioaccumulation factors).[161] Thus, EPA finds that the criteria are based on a sound scientific rationale, will reflect site-specific conditions and, as discussed above, are established at a level that will protect Oregon's human health uses.

The provision establishes site-specific human health criteria using the performance-based criterion approach

Finally, EPA reviewed whether the background pollutant provision contains sufficient detail, and suitable safeguards, that EPA's approval of the provision may also serve as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision**.**

EPA's water quality standard regulations at 40 CFR 131.21 provide that a state water quality standard adopted after May 30, 2000 is not applicable for Clean Water Act purposes until "EPA approves that water quality standard [under § 303(c)(3) of the CWA]." However, when EPA promulgated this regulation it made clear that states have the option to streamline this process by pursuing a "performance-based" approach whereby the state adopts a "process (i.e., a criterion derivation methodology) rather than a specific outcome (i.e., concentration limit for a pollutant) consistent with 40 CFR 131.11 and 131.13."[162] Under the performance-based approach, EPA conducts a CWA § 303(c)(3) review of the procedure and the criteria that would be generated under that procedure. EPA approval of the provision can encompass approval of the individual criteria to be generated under the provision where the procedure is "sufficiently detailed and has suitable safeguards to ensure predictable and repeatable outcomes." To this end, the procedure should establish a "structure or decision-making framework that is binding, clear, predictable, and transparent." [163] EPA further specified that the performance-based approach is particularly well suited to the derivation of site-specific numeric criteria where the proper construction and implementation of such an approach can result in defensible site-specific adjustments to numeric ambient water quality criteria.[164]

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[158] 40 CFR 131.11(a)
[159] 40 CFR 131.11(b)
[160] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. pages 2-13. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[161] 40 CFR 132 App. F., Proc. 1, A. 4
[162] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf
[163] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf
[164] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

Oregon's site-specific background pollutant criterion provision was adopted as a performance-based approach to develop site-specific human health criteria for carcinogens under the conditions and procedures specified in their rule.[165] Oregon's July 21, 2011 submission letter specifically states that the provision was "adopted [as] a new performance-based water quality standard" and that it "establishes the procedure by which a site-specific criterion may be developed for a limited portion of the waterbody".[166] ODEQ's staff report EQC at the time of rule adoption indicates a clear intent for the rule to be adopted as a procedure by which, when approved by EPA, could be used to develop site-specific criteria that will not need subsequent approval by EPA.[167]

A performance-based approach relies on the State to specify methodologies and decision thresholds in their water quality standards regulations so that a structure or decision-making framework that is binding, clear, predictable and transparent is established. As with all other modifications to state water quality standards, EPA requires that the state provide opportunity for the public to comment on this rule and that the regulation be adopted consistent with state law. Oregon's site-specific pollutant criterion provision has been promulgated in OAR 340-041-0033(6) of Oregon's Water Quality Standards, has undergone public review and hearing through the process used for all other revisions adopted by the State on June 16, 2011, and has been certified as having been adopted pursuant to State law.[168] Therefore, EPA finds that this provision provides a regulatory framework for decision-making (i.e. criteria development) that is binding, predictable and transparent and that the public has had the opportunity to provide comment on the proposed rule.

EPA's guidance further notes that a performance-based "approach is particularly useful for criteria which are heavily influenced by site-specific factors."[169] In this case, Oregon has restricted the use of this provision to waterbodies where a waterbody contains a pollutant upstream of a water supply source and a NPDES discharger withdraws water from the waterbody and returns it to the same waterbody without adding any mass to the pollutant of concern. Additionally, the background pollutant provision specifies that it only applies to carcinogenic pollutants, OAR 340-041-0033(6)(b)(A), and utilizes information about the discharge to limit the criterion. Thus, EPA believes it is appropriate that such criterion be developed on a site-specific basis.

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[165] OAR 340-041-0033(6)
[166] ODEQ. July 21, 2011. Letter from Neil Mullane, Water Quality Division Administrator, to Michael Bussell, Office of Water and Watersheds, EPA Region 10. *Re: Oregon Submission of Revised State Water Quality Standards for Toxic Pollutants, Including a New Background Pollutant Provision and a Revised Variance Rule for EPA Review and Approval.*
[167] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. page 11. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2011june/C-WQStdsStaffRpt.pdf
[168] Oregon Department of Justice. General Counsel Division. July 20, 2011. Letter from Larry Knudsen, Assistant Attorney General, Natural Resources Section, to Michael Bussell, EPA Region 10. *Re: Certification of Water Quality Standard Amendment (Fish Consumption Rate).*
[169] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

Finally, EPA's guidance specifies that such procedures "must include a public participation step to provide all stake-holders and the public an opportunity to review the data and calculations supporting the site-specific application of the implementation procedures." The State would also need to maintain a publically available, comprehensive list of all site-by-site decisions made

using the procedures.[170] Oregon's WQS regulation at OAR 340-041-0033(6)(i) establishes the public notification requirements for any criterion to be adopted under this provision. It specifically requires ODEQ to provide public notice of the proposal and hold a public hearing. In addition to other public notification procedures in place by the State, ODEQ will publish the proposal on their WQS website. Furthermore, the provision requires ODEQ to publish a list of all criteria approved pursuant to the rule within 30 days of its effective date and identifies the minimum elements to be contained in this list. EPA believes that the public process required by Oregon within OAR 340-041-0033(6)(i) is consistent with that described in EPA's guidance and required by 40 CFR 131.11.

In order to provide further guidance to ODEQ staff and to ensure consistent implementation of the provision, ODEQ will develop an Internal Management Directive (guidance document) within 180 days of EPA's action on this provision.[171] This document will be available on ODEQ's website and thus facilitate even greater clarity and transparency for the public.

In consideration of the above factors, EPA concludes that the provision contains a binding, clear, predictable, and transparent framework such that any site-specific criterion generated under the provision must not result in a human health risk level of greater than 1×10^{-4} and will protect the human health uses of Oregon's waters. Therefore, any additional oversight by EPA would be redundant. Thus, the provision contains sufficient detail, and suitable safeguards, that EPA's approval of the provision serves as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision. Since this procedure is adopted into State regulation and Oregon is bound by the decision-making framework contained therein, any criteria which are not derived in accordance with the approved procedures would need separate approval from EPA to be applicable under the CWA.

When EPA reviews the results of Oregon's triennial review, EPA expects to evaluate a representative subset of the site-specific decisions to ensure that Oregon is adhering to the EPA-approved procedure. Finally, EPA notes that if Oregon fails to follow these procedures and does not obtain separate CWA § 303(c)(3) approval for the site-specific criterion, this would provide EPA with a basis to object to an NPDES permit for not deriving from or complying with the applicable standards.[172]

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[170] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

[171] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. Supplemental Attachment 10, Timeline for Follow-Up Actions, WQS for Human Health Toxic Pollutants Rulemaking.

[172] 40 CFR 122.44(d)
April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

VII. VARIANCE PROVISION

A. *BACKGROUND*

EPA's regulations at 40 C.F.R. Part 131.13, provides that states may, at their discretion, include in state water quality standards policies generally affecting the application and implementation of water quality standards, such as general policies for variances. If a state chooses to adopt such a variance policy, the regulation specifies that such policies are required to be submitted to EPA for review and approval.

The objective of the Clean Water Act is to restore and maintain the chemical, physical and biological integrity of the Nation's waters. The CWA further specifies an interim goal that, "wherever attainable," water quality provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water.

40 C.F.R. Part 131.10(g) specifies the factors a state may use to determine that a designated use, which is not an existing use, is not ultimately attainable. These factors are:

1. Naturally occurring pollutant concentrations prevent the attainment of the use; or
2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges without violating state water conservation requirements to enable uses to be met; or
3. Human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place; or
4. Dams, diversions or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the use; or
5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses; or
6. Controls more stringent than those required by sections 301(b) and 306 of the Act would result in substantial and widespread economic and social impact.

In 1977, an Office of General Counsel legal opinion[173] considered the practice of temporarily downgrading the designated use and criteria, as it applies to a specific discharger rather than permanently[174] downgrading an entire water body or water body segment and determined that

[173] EPA. March 29, 1977. *Office of General Counsel on Matters of Law Pursuant to 40 CFR Section 125.36(m). No. 58.* U.S. Environmental Protection Agency. Washington, D.C. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/2008_08_04_standards_section40cfr3.pdf

[174] "Permanent" used in the context of a designated use is intended solely to differentiate from a time-limited variance. EPA's regulations at 131.20 require states to review uses that do not include those specified in CWA section 101(a)(2) and to revise standards accordingly if information becomes available to indicate such uses are attainable.

such a practice is acceptable as long as it is adopted consistent with the substantive requirements for permanently downgrading a designated use. EPA continued to articulate this position in its *Water Quality Standards Handbook* (Section 5.3) specifically stating:

> *Variance procedures involve the same substantive and procedural requirements as removing a designated use , but unlike use removal, variances are both discharger and pollutant specific, are time limited, and do not forego the currently designated use*.

Thus, the six 131.10(g) factors, which are used to justify a designated use change through a use attainability analysis, consistent with 131.10(g), are the same factors that must be evaluated when justifying a variance.

Variances allow for a more site-specific and time-limited consideration of attainability than a permanent designated use revision. They encourage states to maintain the underlying designated uses and criteria as goals instead of declaring them unattainable prematurely when they may be attainable in the long term. For example, technology improvements could lower treatment costs in the future such that attaining the designated use and criteria would no longer cause substantial and widespread economic and social impact. Variances are typically specific to a pollutant(s) and either apply to specific permittees or geographic areas. Variances only apply to the pollutants, permittees and geographic areas for which they were written; all other applicable standards remain in place.

Variances must be of a limited or temporary duration for a fixed term.[175] Variances are time-limited designated uses and associated criteria and are thus considered water quality standards. As such, any variances granted by the state must be submitted to EPA for review and approval or disapproval under CWA section 303(c). The preamble to EPA's 1983 regulation[176] states that EPA has approved state-adopted variances in the past and will continue to do so if each individual variance is adopted as a water quality standard and subject to the same public review as other changes in the water quality standards. EPA's *Water Quality Standards Handbook*[177] reiterates the 1983 Preamble as did EPA's Advanced Notice of Proposed Rulemaking (ANPRM), in 1998, seeking comments on possible revisions to the Water Quality Standards Regulation.[178]

EPA's *Water Quality Standards Handbook* also specifies that EPA has approved state-adopted variances in the past and will continue to do so if:

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[175] EPA. January 24, 1992. Office of General Counsel Memorandum *Re: Request for Views on Allowable Duration of Water Quality Standards Variances.* U.S. Environmental Protection Agency. Catherine A Winer, Attorney. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/1999_11_03_standards_variancememo.pdf

[176] November 8, 1983. *Federal Register*, Volume: 48, No.: 217, page 51403 (48 FR 51403). Available at: http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003ZVR.txt

[177] EPA. 1994. *Water Quality Standards (WQS) Handbook: Second Edition.* August 1994. United States Environmental Protection Agency, Office of Water. EPA-823-B-94-005a. page 5-12. Available at http://water.epa.gov/scitech/swguidance/standards/handbook/index.cfm

[178] July 7, 1998. *Federal Register*, Volume: 63, No.: 129, page: 36759 (63 FR 36759). Available at: http://water.epa.gov/scitech/swguidance/standards/handbook/upload/1998_07_07_1998_July_Day-07_w17513.pdf

- The State includes the individual variance as part of the water quality standard.
- The state demonstrates that meeting the standard is unattainable based on one or more of the factors in 131.10(g).
- The justification submitted includes documentation that treatment more advanced than that required by sections 301(b)(1)(b) and 306 of the Clean Water Act has been carefully considered and that alternative effluent control strategies have been evaluated.
- The more stringent State criterion is maintained and is binding upon all other dischargers on the stream or stream segment.
- The discharger who is given a variance for one particular constituent is required to meet the applicable criteria for other constituents.
- The variance was granted for a specific period of time.
- The discharger either must meet the standard upon the expiration of this time period or must make a new demonstration of "unattainability."
- Reasonable progress is being made toward meeting the water quality standards.
- The variance was subjected to public notice and opportunity for comment.

In summary, states have the discretion to include variance policies in their water quality standards regulation. Such policies are subject to EPA review and approval. In addition, if a state chooses to revise standards by granting a variance, states must adopt such variances pursuant to state law and each individual variance is subject to public review, consistent with EPA's regulations. Variances are not effective for Clean Water Act purposes until approved by EPA.

B. *ODEQ'S JULY 21, 2011 SUBMITTAL*

ODEQ has removed the variance language found at OAR 340-041-0061(2) and replaced it with new language at OAR 340-041-0059. Oregon's revised variance provision lays out the necessary process for obtaining a variance, the conditions under which a variance will be granted, and the requirements during a variance. DEQ's objective for these revisions is to ensure that variances and their accompanying pollutant reduction plans continue to ensure progress toward meeting standards, to streamline the administration process, to require pollutant reduction plans with specific milestones that will result in water quality improvement, and to add general clarification to the rule.[179]

Below is ODEQ's revised variance provision, found at OAR 340-041-0059.

OAR 340-041-0059
Variances

This rule (OAR 340-041-0059) does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality

[179] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

standards pursuant to 40 CFR 131.21 (4/27/2000).

(1) Applicability. Subject to the requirements and limitations set out in sections (2) through (7) below, a point source may request a water quality standards variance where it is demonstrated that the source cannot feasibly meet effluent limits sufficient to meet water quality standards. The director of the department will determine whether to issue a variance for a source covered by an existing NPDES permit. The commission will determine whether to issue a variance for a discharger that does not have a currently effective NPDES permit.

(a) The variance applies only to the specified point source permit and pollutant(s); the underlying water quality standard(s) otherwise remains in effect.

(b) The department or commission may not grant a variance if:

(A) The effluent limit sufficient to meet the underlying water quality standard can be attained by implementing technology-based effluent limits required under sections 301(b) and 306 of the federal Clean Water Act, and by implementing cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger; or

(B) The variance would likely jeopardize the continued existence of any threatened or endangered species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat; or

(C) The conditions allowed by the variance would result in an unreasonable risk to human health; or

(D) A point source does not have a currently effective NPDES permit, unless the variance is necessary to:

(i) Prevent or mitigate a threat to public health or welfare;

(ii) Allow a water quality or habitat restoration project that may cause short term water quality standards exceedances, but will result in long term water quality or habitat improvement that enhances the support of aquatic life uses;
(iii) Provide benefits that outweigh the environmental costs of lowering water quality. This analysis is comparable to that required under the antidegradation regulation contained in OAR-041-0004(6)(b); or

(E) The information and demonstration submitted in accordance with section (4) below does not allow the department or commission to conclude that a condition in section (2) has been met.

(2) Conditions to Grant a Variance. Before the commission or department may grant a variance, it must determine that:

(a) No existing use will be impaired or removed as a result of granting the variance and

(b) Attaining the water quality standard during the term of the variance is not feasible for one or

more of the following reasons:

(A) Naturally occurring pollutant concentrations prevent the attainment of the use;

(B) Natural, ephemeral, intermittent, or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges to enable uses to be met without violating state water conservation requirements;

(C) Human-caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place;

(D) Dams, diversions, or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way which would result in the attainment of the use;

(E) Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and unrelated to water quality preclude attainment of aquatic life protection uses; or

(F) Controls more stringent than those required by sections 301(b) and 306 of the federal Clean Water Act would result in substantial and widespread economic and social impact.

(3) Variance Duration.

(a) The duration of a variance must not exceed the term of the NPDES permit. If the permit is administratively extended, the permit effluent limits and any other requirements based on the variance and associated pollutant reduction plan will continue to be in effect during the period of the administrative extension. The department will give priority to NPDES permit renewals for permits containing variances and where a renewal application has been submitted to the director at least one hundred eighty days prior to the NPDES permit expiration date.

(b) When the duration of the variance is less than the term of a NPDES permit, the permittee must be in compliance with the specified effluent limitation sufficient to meet the underlying water quality standard upon the expiration of the variance.

(c) A variance is effective only after EPA approval. The effective date and duration of the variance will be specified in a NPDES permit or order of the commission or department.

(4) Variance Submittal Requirements. To request a variance, a permittee must submit the following information to the department:

(a) A demonstration that attaining the water quality standard for a specific pollutant is not feasible for the requested duration of the variance based on one or more of the conditions found in section (2)(b) of this rule;

(b) A description of treatment or alternative options considered to meet limits based on the applicable underlying water quality standard, and a description of why these options are not technically, economically, or otherwise feasible;

(c) Sufficient water quality data and analyses to characterize ambient and discharge water pollutant concentrations;

(d) Any cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger that addresses the pollutant the variance is based upon;

(e) A proposed pollutant reduction plan that includes any actions to be taken by the permittee that would result in reasonable progress toward meeting the underlying water quality standard. Such actions may include proposed pollutant offsets or trading or other proposed pollutant reduction activities, and associated milestones for implementing these measures. Pollutant reduction plans will be tailored to address the specific circumstances of each facility and to the extent pollutant reduction can be achieved; and

(f) If the discharger is a publicly owned treatment works, a demonstration of the jurisdiction's legal authority (such as a sewer use ordinance) to regulate the pollutant for which the variance is sought. The jurisdiction's legal authority must be sufficient to control potential sources of that pollutant that discharge into the jurisdiction's sewer collection system.

(5) Variance Permit Conditions. Effluent limits in the discharger's permit will be based on the variance and not the underlying water quality standard, so long as the variance remains effective. The department must establish and incorporate into the discharger's NPDES permit all conditions necessary to implement and enforce an approved variance and associated pollutant reduction plan. The permit must include, at a minimum, the following requirements:

(a) An interim concentration based permit limit or requirement representing the best achievable effluent quality based on discharge monitoring data and that is no less stringent than that achieved under the previous permit. For a new discharger, the permit limit will be calculated based on best achievable technology;

(b) A requirement to implement any pollutant reduction actions approved as part of a pollutant reduction plan submitted in accordance with section (4)(e) above and to make reasonable progress toward attaining the underlying water quality standard(s);

(c) Any studies, effluent monitoring, or other monitoring necessary to ensure compliance with the conditions of the variance; and

(d) An annual progress report to the department describing the results of any required studies or monitoring during the reporting year and identifying any impediments to reaching any specific milestones stated in the variance.

(6) Public Notification Requirements.

(a) If the department proposes to grant a variance, it must provide public notice of the proposal and hold a public hearing. The public notice may be included in the public notification of a draft NPDES permit or other draft regulatory decision that would rely on the variance;

(b) The department will publish a list of all variances approved pursuant to this rule. Newly approved variances will be added to this list within 30 days of their effective date. The list will identify: the discharger; the underlying water quality standard addressed by the variance; the waters of the state to which the variance applies; the effective date and duration of the variance;

the allowable pollutant effluent limit granted under the variance; and how to obtain additional information about the variance.

(7) Variance Renewals.

(a) A variance may be renewed if:

(A) The permittee makes a renewed demonstration pursuant to section (2) of this rule that attaining the water quality standard continues to be infeasible,

(B) The permittee submits any new or updated information pertaining to any of the requirements of section 4,

(C) The department determines that all conditions and requirements of the previous variance and actions contained in the pollutant reduction plan pursuant to section (5) have been met, unless reasons outside the control of the discharger prevented meeting any condition or requirement, and

(D) All other requirements of this rule have been met.

(b) A variance renewal must be approved by the department director and by EPA.

C. *EPA ACTION ON ODEQ'S REVISED VARIANCE PROVISION*

EPA Action

In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves certain sections of Oregon's revised variance provision at OAR 340-041-0059, as detailed below, because they are consistent with the Clean Water Act and the implementing Federal water quality standards regulations governing EPA's review and approval or disapproval of new or revised water quality standards as required in 40 C.F.R. part 131. These federal regulations as well as EPA's guidance, to date, on variances are detailed above. EPA outlines below the sections of the provision it is approving as water quality standards pursuant to CWA section 303(c) and the sections of the provision which are not water quality standards under CWA section 303(c) and therefore upon which EPA is taking no action. Oregon may use the full variance provision (both those sections approved as WQS and those identified as not being WQS) when developing and implementing any individual variance. Each individual variance the State adopts consistent with the regulations at OAR 340-041-0059, must be submitted to EPA for review and approval prior to its use in a NPDES permit or other CWA action. In EPA's review of Oregon's revised variance provision, the Agency considered information submitted on July 21, 2011 including ODEQ's NPDES Implementation Issue Paper[180] and Response to Comments document.[181]

[180] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[181] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

EPA Rationale
EPA has reviewed the provision at OAR 340-041-0059 in Oregon's water quality standards regulations, entitled, "Variances". EPA previously approved Oregon's existing variance provision at OAR 350-041-0061(2).

Oregon's revised variance provision adds more definition to what was required in OAR 350-041-0061(2) and requires the applicant to develop a schedule for improvements by implementing a pollution reduction plan. These revisions will assist in meeting the goal of facilitating water quality improvements and attaining the underlying criteria.

EPA is approving the specified sections of Oregon's variance regulation explained below as a "general policy" under §131.13. ODEQ is still required to submit each individual variance to EPA for review and action before it is effective for purposes of the CWA because the variances themselves are also water quality standards. Accordingly, each variance submitted for EPA's review must include the Attorney General's certification and be consistent with the CWA and EPA's implementing regulations, including all applicable public participation requirements. Thus, EPA's review of Oregon's variance authorizing provision need not evaluate each hypothetical variance the State may issue under OAR 340-041-0059 and consider whether such a variance would be consistent with the CWA and EPA's implementing regulation. EPA's approval of Oregon's variance provision at OAR 340-041-0059 is not an automatic approval of any future variance the State wishes to grant pursuant to these provisions.

Below, EPA outlines the sections it is approving as water quality standards pursuant to CWA section 303(c) and the sections upon which EPA is taking no action. EPA's approval reflects EPA's determination that the specific section adopted at OAR 340-041-0059 is consistent with the Clean Water Act and the implementing Federal water quality standards regulations in 40 C.F.R. part 131.

Introductory Language to OAR 340-041-0059
EPA is approving the introductory language which states, "This rule (OAR 340-041-0059) does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality standards pursuant to 40 CFR 131.21 (4/27/2000)."

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves this new language. This language describes when Oregon's revised variance provision becomes effective under state law and the Clean Water Act. The effective date of water quality standards provisions under the CWA is determined by the date of EPA approval. This language regarding timing is a water quality standard that provides for the sections of the revised variance provision to be immediately in effect at the time of EPA's approval action.

OAR 340-041-0059(1) "Applicability"
EPA is approving OAR 340-041-0059(1) "Applicability" and OAR 340-041-0059(1)(a) which reflects that the variance only applies to the specified point source and pollutant; the underlying water quality standards remain in effect. This scope of applicability is consistent with EPA interpretive Guidance and the 1977 Office of General Counsel legal opinion discussing

variances.

Moreover, EPA is approving OAR 340-041-0059(1)(b) and (1)(b)(A) as they are consistent with 131.10(h)(2) which prohibits a State's removal of a designated uses where "[s]uch uses will be attained…by implementing cost-effective and reasonable best management practices for nonpoint source control." EPA has concluded that Oregon's language at (1)(b)(A) that prohibits the State from issuing a variance where *"effluent limitations sufficient to meet the underlying water quality standards can be attained by…implementing cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger,"* is consistent with 131.10(h)(2) because Oregon's variance authorizing provision only allows the State to issue discharger-specific variances.[182] Given this scope of Oregon's variance authorizing provision, EPA believes it is reasonable for the State to limit the prohibition in (1)(b)(A) to those cost-effective and reasonable best management practices for nonpoint sources to those practices under the control of the discharger.[183]

EPA is approving OAR 340-041-0059(1)(b)(B)-(E) because these sections are not inconsistent with the CWA and EPA's implementing regulations. While OAR 340-041-0059(1)(b)(D) does not categorically prohibit the issuance of a variance to a new discharger, neither do the CWA or EPA's implementing regulations. While 40 CFR 122.4(i) limits discharges from "a new source or a new discharger" that "will cause or contribute to the violation of water quality standards," a variance is a revision to the water quality standard itself, and therefore 122.4(i) is not relevant. EPA notes, however, that the circumstances in which a new discharger will be able to meet the other requirements for a variance (e.g., a demonstration that [a]ttaining the water quality standard during the term of the variance is not feasible,") are likely to be significantly more limited for a new discharger than an existing discharger. EPA acknowledges that granting a variance to a new discharger may be appropriate under very specific and limited circumstances. It will review the appropriateness of particular circumstances on an individual variance basis.

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[182] OAR 340-041-0059(1)(a) provides that the "variance applies only to the specified point source permit and pollutant(s); the underlying water quality standard(s) otherwise remain in effect."

[183] EPA disagrees with the contrary contention, made in public comments, that the BMP requirements of 40 C.F.R. § 131.10(h)(2) must apply to "all nonpoint sources in the consideration of a variance application, not just those under the control of the applicant." Northwest Environmental Advocates (NWEA). March 17, 2011. Letter from Nina Bell, Executive Director, NWEA to Andrea Matzke, ODEQ, *Re: Proposed Revised Water Quality Standards for Human Health Toxic Pollutants and Revised Water Quality Standards Implementation Policies.* page 32. In support of this proposition, the commenter cites a 1994 EPA interpretive memorandum ("Tudor Davies memo") and a 1995 EPA economic guidance document. The Tudor Davies memo discusses how the requirements of 40 CFR 131.12(a)(2) apply to antidegradation policies, not the applicability of 40 CFR 131.10(h)(2) to variances. The citation to the 1995 Interim Economic Guidance for Water Quality Standards is similarly inapposite. This guidance addresses how an economic analysis under 131.10(g)(6) should be conducted to demonstrate that a variance is needed. Sections 40 C.F.R. 131.10(d) and (h)(2) are independent requirements from 131.10(g). EPA recognizes that the introduction section of the guidance document states that polluting entities can be point or nonpoint sources of pollution and that attainment of water quality standards is not limited to controls placed on point sources. However, this statement should be viewed in context of the stated scope of the guidance, which is to address economic factors considered under 131.10(g) and 131.12. Even if this statement could be read to apply to 131.10(d) and (h)(2), Oregon's provision at OAR 340-041-0059(1)(b)(A) is consistent with EPA's 1995 economic guidance document because the guidance contemplates that financial impacts are determined by the costs the entity itself would face by implementing the necessary pollution controls.

OAR 340-041-0059(2) "Conditions to Grant a Variance"

EPA is approving OAR 340-041-0059(2), (2)(a) and (2)(b) "Conditions to Grant a Variance" because it is consistent with the substantive requirements of permanently changing designated uses at §131.10, specifically §131.10(g).

OAR 340-041-0059(2)(a) requires the state to determine that "[n]o existing use will be impaired or removed as a result of granting the variance." One commenter argues that this section is inconsistent with EPA's regulations because it "does not explicitly require variances to meet the antidegradation policy[,]…falls short of full protection of existing uses[,]… [and] makes no reference to the water quality that is required to maintain and protect existing uses."[184] EPA disagrees that OAR 340-041-0059(2)(a) is inconsistent with EPA regulations. OAR 340-041-0059(2)(a) is consistent with 131.10(h)(1) and (g) which both prohibit a state from removing the protection for an existing use. While a state's adoption of new or revised water quality standards is not itself subject to antidegradation review, EPA notes that OAR 340-041-0059(2)(a) is also consistent with 131.12(a)(1): requiring the that "[e]xisting instream water uses and the level of water quality necessary to protect the existing uses shall be maintained and protected." EPA believes that prohibiting the impairment or removal of an existing use will achieve the goals of "maintain[ing] and protect[ing]" the "level of water quality necessary to protect the existing use."

Section OAR 340-041-0059(2)(b) is consistent with the substantive requirements at §131.10(g).

OAR 340-041-0059(3) "Variance Duration"

EPA is approving OAR 340-041-0059(3) and the first sentence of OAR 340-041-0059(3)(a) "Variance Duration" as a water quality standard that states "The duration of a variance must not exceed the term of the NPDES permit." EPA understands this section to mean that each variance will expire five years after the State adopts the variance, the maximum length of a NPDES permit consistent with federal regulations and OAR 340-045-0035(8), or the variance will specify a specific expiration date of less than five years after the variance was adopted into state regulation. As discussed earlier, the 1977 Office of General Counsel legal opinion explains that time-limited revisions to the designated use and criteria are environmentally preferable as compared with the permanent removal of a designated use because the more stringent standards apply to all other dischargers not covered by the variance. EPA is approving this sentence as it states the specific time limit for which the designated use and criteria have been determined to be "unattainable" consistent with §131.10(g).

EPA is taking no action on the last two sentences of OAR 340-041-0059(3)(a) "Variance Duration" that states "If the permit is administratively extended, the permit effluent limits and any other requirements based on the variance and associated pollutant reduction plan will continue to be in effect during the period of the administrative extension. The department will give priority to NPDES permit renewals for permits containing variances and where a renewal application has been submitted to the director at least one hundred eighty days prior to the

[184] Northwest Environmental Advocates (NWEA). March 17, 2011. Letter from Nina Bell, Executive Director, NWEA to Andrea Matzke, ODEQ, *Re: Proposed Revised Water Quality Standards for Human Health Toxic Pollutants and Revised Water Quality Standards Implementation Policies.* page 39.

NPDES permit expiration date." These sections are NPDES permitting requirements because they describe the permitting process for handling situations where there is a delay in reissuing a permit. Such language does not affect how long the variance applies as the approved water quality standard and the administrative extension of a permit is not subject to EPA WQS approval or disapproval.

EPA is also taking no action on OAR 340-041-0059(3)(b) "Variance Duration" because that section of the provision reiterates the permitting provisions at §122.44(d)(vii) requiring the NPDES permit limit to derive from and comply with the applicable water quality standards once the variance expires. Therefore, EPA does not consider this section to be a water quality standard.

EPA is approving OAR 340-041-0039(3)(c) "Variance Duration" as a water quality standard because it clearly states that the variance is not effective for CWA section 402 permitting purposes until EPA approves it, consistent with §131.21(c). EPA notes that once an individual variance has been approved, it is a water quality standard applicable for CWA section 402 permitting purposes (see 40 CFR 131.21) and thus becomes subject to the triennial review requirements at 40 C.F.R. 131.20.

OAR 340-041-0059(4) "Variance Submittal Requirements"
EPA is approving OAR 340-041-0059(4) "Variance Submittal Requirements" and OAR 340-041-0059(4)(a) consistent with §131.10(g) because it requires a demonstration that one of EPA's regulatory factors precludes attainment of the use. EPA is also approving OAR 340-041-0059(4)(b)-(f) because these sections provide substantive requirements for what the applicant must submit to the State to obtain a variance, and are not inconsistent with the requirements of the CWA and EPA's regulations.

OAR 340-041-0059(5) "Variance Permit Conditions"
EPA is approving OAR 340-041-0059(5), (5)(a) and (5)(b) "Variance Permit Conditions" because these sections establish the water quality requirements during a variance. While those requirements might typically be presented in the form of instream water quality criteria, EPA considers the requirement for a permit limit to include the best achievable effluent quality to be a surrogate for identifying the instream water quality criteria at the highest attainable condition. Thus, EPA is approving sections 5(a) and 5(b) because they describe the resulting instream concentration and together act as a surrogate for interim criterion applicable during a variance. Based on Oregon's regulatory language in this section, the best achievable effluent quality will be appropriately determined on a case-by-case basis.

EPA is not taking action on OAR 340-041-0059(5)(c) and (5)(d) because they are monitoring and reporting requirements applicable to a discharger's NPDES permit. These requirements are not considered WQS under CWA section 303(c) or addressed in EPA's water quality standards regulations because they are NPDES permitting requirements.

OAR 340-041-0059(6) "Public Notice Requirements"
EPA is approving OAR 340-041-0059(6) "Public Notice Requirements" and OAR 340-041-0059(6)(a) and 0059(6)(b) because they address the requirements for public notice of a variance

consistent with §131.20(b), and explain what information will be provided to the public. EPA notes that this section states that public notification for a variance can be included in the public notification of a draft NPDES permit or draft regulatory decision that would rely on the variance. In addition, EPA must approve the variance before it can be implemented and thus the State cannot finalize the NPDES permit with a limit that reflects a variance until EPA has approved the variance.

OAR 340-041-0059(7) "Variance Renewals"

EPA is approving OAR 340-041-0059(7) "Variance Renewals". EPA is approving OAR 340-041-0059(7)(a)(A) as consistent with 131.10(g) as it requires the permittee to demonstrate that attaining water quality standards during the term of the variance is still not feasible based on factors consistent with 131.10(g)(1)-(6). EPA is approving all other language in OAR 340-041-0059(7) because this regulatory language is not inconsistent with the CWA or EPA's implementing regulations. EPA notes that since variances are water quality standards, the state will need to include variances in the applicable water quality standards that the state reviews during its triennial review processes under §131.20(a). EPA understands that OAR 340-041-0059(7)(D) ("[a]ll other requirements of this rule have been met.") will require a new round of public notice, comporting with the requirements of OAR 340-041-0059(6), and all other requirements in OAR 340-041-0059 to be met when any variance is renewed.

VIII. BACTERIA

Oregon's revisions to its bacteria provision found at OAR 340-041-0009(10) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised text corrects a citation based on renumbering in OAR 340-041-0061.

(10) Water Quality Limited for Bacteria: In those water bodies, or segments of water bodies identified by the Department as exceeding the relevant numeric criteria for bacteria in the basin standards and designated as water-quality limited under section 303(d) of the Clean Water Act, the requirements specified in section 11 of this rule and in OAR 340-041-0061(11~~2~~) must apply.

EPA Action
In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves this minor editorial change as a non-substantive revision to water quality standards at OAR 340-041-0009.

EPA Rationale
The minor editorial change in this provision to correct the citation due to a renumbering revision in OAR 340-041-0061(12) does not alter the underlying provision that EPA previously approved and EPA is not acting on the underlying provision. EPA approves this non-substantive revision to Oregon's WQS under section 303(c) of the CWA and the implementing regulations at 40 CFR Part 131.

IX. REVISED RULES REGARDING IMPLEMENTAIN FOR NONPOINT SOURCES

A. *STATEWIDE NARRATIVE CRITERIA*

Oregon's revisions to OAR 340-041-0007(5) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised rule clarifies the state regulatory mechanisms for water quality control applicable to forest management activities.

(5) Logging and forest management activities must be conducted in accordance with the ~~Oregon~~ rules established by the Environmental Quality Commission and must not cause violation of water quality standards. Nonpoint sources of pollution from forest operations on state and private forest lands are subject to best management practices and other control measures established by the Oregon Board of Forestry as provided in ORS 527.765 and 527.770. Forest ~~Practices~~ operations conducted in good faith compliance with the best management practices and control measures established under the Forest Practices Act ~~to minimize adverse effects on water quality~~ are generally deemed not to cause violations of water quality standards as provided in ORS 527.770. Forest operations are subject to load allocations established under ORS 468B.110 and OAR Division 340-042 to the extent needed to implement the federal Clean Water Act.

Acknowledgement of OAR 340-041-0007(5)
EPA acknowledges the revised language contained in OAR 340-041-0007(5). ODEQ has revised their regulations to explain how the control measures applicable to forestry nonpoint sources under the Forest Practices Act are presumed to meet water quality standards and that forest operations are subject to load allocations in TMDLs.[185] Furthermore, the rule clarifies the water quality regulatory requirements for forest management activities in Oregon.

This rule states that certain activities related to logging and forest management are generally deemed not to cause violations of water quality standards if best management practices and control measures under the Forest Practices Act are followed. The CWA requires NPDES permits for discharges from point sources and compliance with that permit, but does not require that states develop enforceable regulatory programs for nonpoint sources. Whether a State chooses to make water quality standards directly enforceable for nonpoint sources is solely a matter of state law and the State has discretion as to how it enforces its laws. This provision is applicable only to nonpoint sources and their compliance with water quality standards and TMDL load allocations. As such EPA does not consider this provision to be a water quality standard under section 303(c) of the CWA. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)).

[185] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

In addition, this provision does not include language that has the effect of changing the level of protection provided by Oregon's water quality criteria and therefore does not constitute a new or revised water quality standard. The provision defines how logging and forest management nonpoint sources activities must control their discharges in order to comply with Oregon's water quality standards, but it does not establish or revise any of the components of the water quality standards themselves.

Therefore, this provision is not considered a water quality standard subject to EPA review and approval and EPA is taking no action to approve or disapprove this provision.

B. *OTHER IMPLEMENTATION OF WATER QUALITY*

Oregon's revisions to implementation provisions found at OAR 340-041-0061(9)(a)(E), (10), and (11) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised rule at (9)(a)(E) corrects an error to the cross-reference to the antidegradation policy. The revised rules in (10) and (11) explain how the mechanisms for forestry and agricultural nonpoint sources work to meet water quality standards and the total maximum daily load (TMDL) load allocations under the Forest Practices Act and Agriculture Water Quality Management Act.[186] Finally, the revised rule contains revised paragraph numbers for subsections (2) through (16) as the variance rule in section (2) was moved to OAR 340-041-0059.

(9)(a)(E) Mass loads assigned as described in paragraphs (B) and (C) of this subsection will not be subject to OAR 340-041-0004(~~9~~7);

Acknowledgement of OAR 340-041-0061(9)(a)(E)
EPA acknowledges the changed cross-reference located in OAR 340-041-0061(9)(a)(E) Other Implementation of Water Quality Criteria. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)). EPA has determined this provision is not a WQS. Instead, the provision at section (9)(a)(E) is a NPDES permitting implementation provision and corrects an error to a regulatory citation to the antidegradation policy.

*(10) Forestry on state and private lands. ~~For~~ Nonpoint sources of pollution from forest operations on state or private lands~~, water quality standards~~ are ~~intended to be attained and are implemented through~~ subject to best management practices and other control ~~mechanisms~~ measures established ~~under the Forest Practices Act (ORS 527.610 to 527.992) and rules thereunder, administered~~ by the Oregon Department of Forestry~~. Therefore,~~ under the Forest Practices Act, (ORS 527.610 to 527.992) Such forest operations ~~that are~~ when conducted in good faith compliance with the Forest Practices Act requirements are ~~(except for the limits set out in ORS 527.770) deemed in compliance with this division. DEQ will work with the Oregon~~

[186] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

~~*Department of Forestry to revise the Forest Practices program to attain water quality standards.*~~ *generally deemed not to cause violations of water quality standards as provided in ORS 527.770. Forest operations on state and private lands are subject to load allocations under ORS 468.110 and OAR 340, Division 42, to the extent necessary to implement the federal Clean Water Act.*

(11) ~~*Agricultural water quality management plans to reduce agricultural nonpoint source pollution are developed and implemented by the Oregon Department of Agriculture (ODA) through a cooperative agreement with the department to implement applicable provisions of ORS 568.900 to 568.933 and 561.191. If the department has reason to believe that agricultural discharges or activities are contributing to water quality problems resulting in water quality standards violations, the department may consult ODA. If water quality impacts are likely from agricultural sources and the department determines that a water quality management plan is necessary, the director may write a letter to the director of the ODA requesting that such a management plan be prepared and implemented to reduce pollutant loads and achieve the water quality criteria.*~~ *In areas subject to the Agricultural Water Quality Management Act, the Oregon Department of Agriculture (ODA) under ORS 568.900 to 568.933 and 561.191 develops and implements agricultural water quality management area plans and rules to prevent and control water pollution from agricultural activities and soil erosion on agricultural and rural lands. Area plans and rules must be designed to achieve and maintain water quality standards. If the department determines that the area plan and rules are not adequate to achieve and maintain water quality standards, the department will provide ODA with comments on what would be sufficient to meet WQS or TMDL load allocations. If a resolution cannot be agreed upon, the department will request the Environmental Quality Commission (EQC) to petition ODA for a review of part or all of water quality management area plan and rules. If a person subject to an ODA area plan and implementing rules causes or contributes to water quality standards violations, the department will refer the activity to ODA for further evaluation and potential requirements.*

Acknowledgement of OAR 340-041-0061(10) and (11)

EPA acknowledges the revised language in OAR 340-041-0061(10) and (11) Other Implementation of Water Quality Criteria. The revised rules in (10) and (11) explain how state rules for forestry and agricultural nonpoint sources are to be implemented consistent with water quality standards and the total maximum daily load (TMDL) load allocations.[187] These provisions set forth the extent to which Oregon requires nonpoint sources of pollution from forest operations under the Forest Practices Act and agricultural activities under the Agricultural Water Quality Management Act to control their discharges in order to protect water quality.

These rules state that forest operations and agricultural activities generally will not be deemed to cause violations of water quality standards if best management practices and control measures under the Forest Practices Act and water quality management area plans under the Agricultural Water Quality Management Act are followed and identify the process to be used when water quality concerns arise. Thus, the rule clarifies mechanisms for WQS implementation and

[187] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

compliance.

Whether a State chooses to make water quality standards directly enforceable for nonpoint sources is solely a matter of state law. The CWA requires NPDES permits for discharges from point sources and compliance with that permit, but does not require that states develop enforceable regulatory programs for nonpoint sources. These provisions are applicable only to nonpoint sources and how they comply with water quality standards and TMDL load allocations and as such are not water quality standards under section 303(c) of the CWA. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)).

In addition, these provisions do not include language that has the effect of changing the level of protection provided by Oregon's water quality criteria and therefore do not constitute new or revised water quality standards. The provisions define the extent to which forest operations and agricultural operations that result in nonpoint source discharges must control their discharges in order to comply with Oregon's water quality standards, but they do not establish or revise any of the components of the water quality standards themselves.

Therefore, these provisions are not considered water quality standards subject to EPA review and approval and EPA is taking no action to approve or disapprove the provisions.

Acknowledgment of Section Renumbering in OAR 340-041-0061(2)-(16)
The revised rule contains revised paragraph numbers for subsections OAR 340-041-0061(2) through (16) as the variance rule in section (2) was moved to OAR 340-041-0059. EPA acknowledges the renumbering for subsections that were previously approved by EPA under 303(c) of the CWA as a non-substantive formatting change which does not require EPA action.

RESPONSES TO PUBLIC COMMENTS RELATING TO MAINE'S JANUARY 14, 2013, SUBMISSION TO EPA FOR APPROVAL OF CERTAIN OF THE STATE'S NEW AND REVISED WATER QUALITY STANDARDS (WQS) THAT WOULD APPLY IN WATERS THROUGHOUT MAINE, INCLUDING WITHIN INDIAN TERRITORIES OR LANDS

January 30, 2015

INTRODUCTION

This document contains responses to the significant comments EPA received concerning Maine's January 14, 2013, submittal to EPA Region 1, in which Maine proposed certain revisions to its surface water quality standards (WQS or standards) pursuant to section 303(c) of the federal Clean Water Act (CWA). EPA Region 1 solicited comments from the public specifically relating to the aspect of Maine's request that EPA approve the State's WQS revisions to apply in waters within Indian territories or lands (hereinafter referred to as "Indian lands") located in Maine. It is important to note that, in the Agency's judgment, the public comments EPA received in relation to Maine's January 14, 2013, submission raised both significant legal and technical questions, which extend equally to the EPA's decisions addressed in its letter approving and disapproving certain of Maine's standards in waters within Indian lands. EPA's responses to the comments below will be presented in the context of Maine's January 14, 2013, submittal, but EPA applied the principles articulated in this document to our decision on all the WQS the State has asked the Agency to approve for waters in Indian lands.

Maine's 2013 submittal specifically included a request that EPA approve the WQS revisions as applying to all waters throughout the State of Maine, including to waters within Indian lands located within the State. Neither the CWA (and its implementing regulations), nor the federal Administrative Procedure Act (APA), specify any notice and comment requirements that EPA must satisfy before approving or disapproving a state's new or revised WQS submittal. EPA's longstanding position has been that it is sufficient for EPA to review the adequacy of a submitting state's public process for revisions to its WQS and to rely on that process if it adequately notified and involved the public. See 40 C.F.R. §§ 131.5(a)(3), 131.6(e), and 131.20(b) and 40 CFR part 25 for public participation requirements relevant to state adoption of WQS. The State of Maine's Department of Environmental Protection (ME DEP) provided public notice and an opportunity to comment (including a public hearing), at the state level, on the WQS revisions included in the State's January 14, 2013, submittal to EPA.

However, while ME DEP provided public notice of the substance of the WQS revisions as they would apply generally in the State, the State's notice may not have sufficiently informed the public that ME DEP intended to seek EPA's approval of these revisions to apply in waters within Indian lands. To ensure adequate public participation and development of a complete administrative record for EPA's subsequent decisions, EPA decided to seek further comment due to the possibility that the State's notice may not have been sufficiently clear to some members of the public about the State's intent to apply its WQS revisions to waters in

Indian lands. Accordingly, in August of 2013, EPA solicited additional comment on the approvability of these WQS for waters in Indian lands. In particular, EPA sought comments regarding the State's legal authority to establish WQS in waters in Indian lands under the Maine Implementing Act (MIA, 30 M.R.S.A § 6401, et seq.) as ratified by the Maine Indian Claims Settlement Act (MICSA, 25 U.S.C. § 1721, et seq.) and on whether these WQS revisions would adequately protect water quality in Indian lands.

This responses to comments (RTC) document contains EPA's responses to the significant comments EPA received. We reiterate that EPA lawfully used its discretion to seek additional public input to better inform its approval/disapproval decision and to ensure that any potential flaws in the State's public process are remedied. There is no legal prohibition in the CWA, the Administrative Procedure Act, or any other applicable legal requirement that precludes EPA from seeking such comment to better inform its decision when the administrative record before it is potentially incomplete. Adequate public participation in the context of a federal agency's decision-making process, where regulatory decisions are being made that potentially impact the public or where there is significant public interest, is a fundamental aspect of administrative law in our system of government. Furthermore, we emphasize that EPA's having sought public comment in this one instance, in addition to the State's public participation process, does not in any way set a legal or policy precedent that could in any way be used by any person in the future to require EPA to solicit public comment on any State's WQS submission for EPA review and approval or disapproval. As explained throughout EPA's RTC document and Decision Support Document related to EPA's decision on Maine's WQS submissions, the Agency has been presented with a unique set of circumstances due to the highly atypical legal framework that MIA and MICSA establish for Indian lands in Maine; circumstances which do not exist in other areas of the United States.

The WQS revisions in Maine's 2013 submittal include five new or revised WQS criteria, including three human health criteria (HHC) for the allowable levels or concentrations in surface waters for three toxic pollutants: arsenic, acrolein, and phenol. For arsenic, ME DEP changed the cancer risk level, fish consumption rate, and percentage of inorganic arsenic (relative to organic arsenic) used in calculating the criteria for *inorganic* arsenic, which is the form of arsenic that is harmful to human health. For acrolein and phenol, ME DEP updated its ambient water quality criteria consistent with updates EPA has made to its recommended criteria for those two pollutants based on newly published reference doses.

This RTC document is a source of information about EPA's decision on Maine's submissions, and should be read in conjunction with EPA's letter communicating its decision on these and other WQS to Maine DEP and with the accompanying Decision Support Document; the latter focusing specifically on, among other things, the question whether Maine has adequate legal authority to establish WQS in waters located in Indian lands and on whether Maine's standards meet the requirements of the CWA. This RTC document incorporates the terminology and reasoning presented in those other two documents, while expanding on it in certain respects to address the more specific individual comments EPA received. This responsiveness summary digests and organizes the significant comments received. Opposing comments concerning each issue were grouped together where EPA received comments on both sides of an issue. We received

comments from the State of Maine's Office of the Attorney General, the Commissioner of the ME DEP, and from three of the four federally recognized Indian Tribes in Maine – the Penobscot Nation, the Houlton Band of Maliseet Indians, and the Aroostook Band of Micmacs; no other parties provided comments to EPA.

The particular language used in the summary of each issue presented below may derive primarily from one set of comments. But this does not mean that EPA has not considered each of the comments received on the issue in question. EPA did not limit its analysis of the comments submitted to the digest presented below, and we have reviewed each comment in its entirety. This outline and its digest of the comments are simply designed to structure our responses and make them more accessible to the interested public, while addressing the substantive content of all of the significant comments received.

Comments and Responses to Comments on EPA's 2003 NPDES Program Approval

Some of the key issues relevant to Maine's WQS submission were also the subject of public comments EPA received in the context of EPA's 2003 action on Maine's National Pollution Discharge Elimination System (NPDES) program application. In fact, the Penobscot Nation and the Houlton Band of Maliseet Indians specifically incorporated by reference into their comments on Maine's WQS submission those Tribes' earlier comments on Maine's NPDES program application. Consequently, EPA's responses today to some of those same issues, or at least to certain aspects of those same issues, parallel EPA's earlier responses to comments received on Maine's NPDES program application. For completeness and efficiency, rather than repeat in this RTC document all of EPA's responses to the Tribes' comments on Maine's NPDES program, EPA hereby incorporates by reference its responses to public comments received on Maine's NPDES program application, but only to the extent those earlier responses are consistent with, and are not superseded by, the First Circuit's decision in *Maine v. Johnson*, 498 F.3d 37 (1st Cir. 2007), and the responses expressly articulated in this document and in EPA's accompanying Decision Support Document.

Federal Indian Common law cited by Maine Indian Tribes and Protecting the Tribes' Sustenance Fishing

As discussed in detail below in EPA's specific responses to specific public comments, many of the Maine Tribes' (primarily the Penobscot Nation's) legal arguments opposing Maine's jurisdiction to establish WQS in waters within Indian lands included citations to federal case law. EPA addresses that case law in more detail later in this RTC document. Many of the Tribes' comments rely heavily on the case law. It is therefore worth noting here in summary, for purposes of orienting the reader to what follows, that EPA found many of those cited cases compelling from the standpoint of supporting the proposition that the CWA requires protection of the quality of the water that supports the Maine Tribes' sustenance fishing practices, culture and lifestyle. The cases cited also represent a strong collection of federal Indian common law on subjects such as the federal government's trust responsibility to Indian tribes, the sovereign status of Indian tribes in

the United States, and the canons of statutory construction used by the federal courts to interpret treaties and statutes addressing the rights of Indian tribes.

With one very important and dispositive exception that arises due to the unique nature and jurisdictional provisions of the settlement acts[1], EPA does not disagree that the cases cited by the Maine Tribes articulate valid and accurate general principles of federal Indian common law. In EPA's view, however, none of these cases answers or is dispositive of the question whether Maine has legal jurisdiction to establish WQS in waters within Indian lands in Maine, but that is precisely the argument that the Maine Tribes frequently assert is supported by those cases. As EPA explains in this RTC document and in its Decision Support Document, the settlement acts clearly undermine the Maine Tribes' use of those cases to oppose Maine's assertion of jurisdiction. Moreover, EPA reads the vast majority of the Maine Tribes' comments as taking the position that protection of their sustenance fishing practices and a legal conclusion that Maine has jurisdiction to establish WQS in waters within Indian lands in Maine are mutually exclusive. The inaccuracy of that position is demonstrated by EPA's Decision Support Document. That is, EPA has determined that Maine has jurisdiction to establish WQS in waters within Indian lands in Maine and that EPA has no discretion to find otherwise given the settlement acts. At the same time, however, EPA has also disapproved certain of Maine's WQS as not being adequately protective of the applicable CWA designated uses, which encompass the Maine Tribes' sustenance fishing practices. Consequently, the jurisdictional scheme embodied in the settlement acts renders those cases inapposite to EPA's decision. In addition, to the extent that the Maine Tribes cite

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[1] Settlement Acts in Maine

MIA and MICSA

In 1980, Congress passed the Maine Indian Claims Settlement Act (MICSA), which resolved litigation in which the Southern Tribes asserted land claims to a large portion of the State of Maine. 25 U.S.C. §§ 1721, et seq. MICSA ratified a state statute passed in 1979, the Maine Implementing Act (MIA), which was designed to embody the agreement reached between the State and the Southern Tribes. 30 M.R.S. §§ 6201, et seq. In 1981, MIA was amended to include provisions for land to be taken into trust for the Houlton Band of Maliseet Indians, as provided for in MICSA. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Since it is Congress that has plenary authority as to federally recognized Indian Tribes, MIA's provisions concerning jurisdiction and the status of the Tribes are effective as a result of, and consistent with, the Congressional ratification in MICSA.

MSA and ABMSA

In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to the status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201, et seq. In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143. One principal purpose of both statutes was to give the Micmacs the same settlement that had been provided to the Maliseets in MICSA. See ABMSA § 2(a)(4) and (5). In 2007, the Federal Court of Appeals for the First Circuit confirmed that the Micmacs and Maliseets are subject to the same jurisdictional provisions in MICSA. Aroostook Band of Micmacs v. Ryan, 484 F.3d 41 (1st Cir. 2007).

Where appropriate, this document will refer to the combination of MICSA, MIA, ABMSA, and MSA as the "settlement acts."

to the First Circuit's opinions interpreting MIA and MICSA, EPA's RTC document explains why those cases also do not support the Tribes' assertion that Maine does not have jurisdiction.

Two examples illustrate this general point. While EPA agrees that *U.S. v. Adair*, 723 F. 2d 1394 (9th Cir. 1984); *Winters v. United States*, 207 U.S. 564 (1908); and *Washington v. Washington State Commercial Passenger Fishing Ass'n*, 443 U.S. 658 (1979), may be cited in support of arguments that address tribal sustenance fishing practices and the associated quantity and/or quality of the waters that support those fishing practices, nothing in those cases does or can supersede or affect the jurisdictional arrangement embodied in the settlement acts. Similarly, while *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *State of Washington, Dep't of Ecology v. U.S.E.P.A.* 725 F. 2d 1465 (9th Cir. 1985); *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130 (1982); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Oklahoma Tax Comm'n v Sac & Fox Nation*, 508 U.S. 114 (1993); and *Three Affiliated Tribes of Ft. Berthold v. Wold Eng'g*, 476 U.S. 877 (1986), may each stand for or support in some manner the proposition that states generally lack jurisdiction in Indian reservations absent express authorization by Congress, those cases cannot properly be cited to support an argument that Maine has no jurisdiction to apply state law in Indian lands in Maine, because Congress expressly granted Maine such authority in the settlement acts.

EPA's Specific Responses

I. Maine's legal authority or jurisdiction to establish WQS in Indian waters.

A central issue raised by Maine's WQS submission is whether Maine has the necessary legal authority, or jurisdiction, to establish WQS applicable to surface waters (both reservation and trust land waters) situated in Indian lands located within the exterior boundaries of the State of Maine. EPA received many comments about this legal issue from three of the Maine Indian Tribes and from the State of Maine.

EPA's Decision Support Document contains, among other things, a legal analysis of the specific statutory provisions of the settlement acts and their respective legislative histories. That analysis supports EPA's legal determination that Maine has the necessary legal authority to establish WQS in surface waters located in Indian lands in Maine. While the legal analysis constitutes EPA's reading of the language and legislative history of the statutes themselves, it does not always address directly the way in which the Maine Tribes' articulated their jurisdictional arguments opposing Maine's legal authority to establish WQS in waters in Indian lands in Maine.

The reason for that is that the Tribes' public comments on the jurisdictional question rely, to a great extent, on two concepts derived from principles of

federal Indian common law, i.e., the federal government's trust relationship to Indian tribes generally and the concept of inherent tribal sovereignty. It is for that reason that EPA's responses below to the Maine Tribes' public comments on the jurisdictional question principally are organized around the way in which the Tribes specifically crafted their jurisdictional arguments, i.e., primarily in terms of the federal trust responsibility and the concept of inherent tribal sovereignty. After addressing those comments from the Tribes, EPA's responses also address the State of Maine's comments on the federal trust responsibility and tribal sovereignty.

A. Does the federal trust responsibility affect or determine whether Maine has jurisdiction to establish WQS in waters within Indian lands?

Many of the Tribes' comments relating to whether Maine has jurisdiction focused on the federal trust responsibility to the Maine Indian Tribes. The Tribes asserted that the EPA's trust responsibility obligates EPA to conclude that Maine does not have jurisdiction. Examples of those comments are identified below first, followed by examples of the State of Maine's comments about the trust. EPA's responses to the comments are provided after the listed representative examples received from the parties who commented.

Representative examples of comments from Maine's Indian Tribes

1. EPA's federal trust responsibility and duties under the CWA preclude EPA from finding that Maine has jurisdiction to promulgate WQS applicable to waters in Indian lands.

2. EPA's Constitutionally-based trust responsibility and federal Indian common law require EPA to reject Maine's WQS application as to waters within Indian lands.

3. EPA's trust responsibility requires it to protect the Tribes' natural resources and sovereign authority against state encroachment.

4. Approval of Maine's WQS in waters within Indian lands would be an unlawful abdication of EPA's trust responsibility because it would empower Maine to control tribal resources when Maine does not even recognize the existence of the Penobscot Nation's sustenance fishery.

5. The authority to establish WQS under the CWA applicable to the Southern Tribes' sustenance fishery established under MIA and MICSA must reside with EPA in the first instance, as the Tribes' trustee, or, eventually with the Penobscot Nation.

6. Congress acquired the Houlton Band of Maliseet Indians' trust lands for the purpose of preserving the Tribe's riverine culture, including traditional fishing, hunting and gathering activities. EPA therefore has a trust responsibility to protect the quality of the waters in the Tribes' lands.

Representative examples of comments from the State of Maine

1. The concept of a federal "trust responsibility" to Indian tribes does not apply under the CWA because there are no substantive or procedural requirements written into the CWA that anyone may review to assess whether a particular action that EPA takes complies with a "trust responsibility." EPA cannot establish procedural or substantive requirements, pursuant to a trust responsibility, that are not already embodied in the CWA. The federal trust responsibility toward Indian tribes in Maine is fully and exclusively expressed through the substance of the statutes and regulations that an agency is charged with administering.

2. Even if the concept of a federal "trust responsibility" otherwise would apply toward the Maine Indian Tribes under the CWA, Title 25 U.S.C. section 1725(h) of MICSA makes clear that federal Indian law that would otherwise affect or preempt the jurisdiction of Maine relating to "environmental matters" has no effect in Maine.

3. Reservation lands in Maine are not held in trust by the federal government.

EPA's responses to comments concerning the general nature of the federal trust responsibility to the Maine Tribes in this case and the extent to which that trust responsibility is relevant or dispositive to the question whether Maine has adequate legal authority or jurisdiction to establish WQS for surface waters within Indian lands located in Maine

As EPA previously noted in its responses to public comments received on Maine's NPDES program application in 2003, the commenters' arguments (on both sides) regarding the federal government's trust responsibility to the Maine Indian Tribes do not accurately articulate the scope of the trust responsibility as relevant to EPA's decisions in this matter; and, more specifically, do not accurately articulate the scope of the trust responsibility to the Maine Indian Tribes as EPA exercises its authorities under the CWA.

First, it is important to note that the existence, operation and extent of the federal trust responsibility to the Maine Indian Tribes under the United States Constitution and

applicable federal statutory and common law cannot be determined in isolation from the allocation of legal jurisdiction among the tribal, State, and federal governments under the the settlement acts. For example, the jurisdictional framework set forth in the MIA was ratified by Congress in MICSA, and it is well-established law that Congress has plenary authority to legislate in the area of Indian affairs. EPA does not have the legal authority to alter the jurisdictional arrangement ratified by Congress in the settlement acts, either pursuant to the trust responsibility to the Maine Indian Tribes in relation to the CWA or pursuant to any other law.

At the same time, however, EPA still must consider the trust responsibility toward the Maine Indian Tribes when implementing the CWA, but must do so within the bounds of the jurisdictional scheme that Congress ratified in the settlement acts and the requirements of the CWA. It is for this reason that the federal trust cases cited by the Penobscot Nation in its comments are inapposite, i.e., none of these cases discusses the federal trust obligation against the backdrop of statutes such as the settlement acts, and they cannot properly be cited for the proposition that the trust obligation should or does override Congress' jurisdictional arrangement in those settlement acts such that Maine cannot establish WQS in waters in Indian lands in Maine. The cases cited by the Tribe include, e.g., *HRI, Inc. v. E.P.A.*, 198 F.3d 1224 (10th Cir. 2000); *Cherokee Nation v. State of Georgia*, 30 U.S. 1 (1831); *United States v. Mitchell (Mitchell II)*, 463 U.S. 206 (1983); *Seminole Nation v. United States*, 316 U.S. 286 (1942).

As EPA earlier explained in its responses to public comments on EPA's proposed approval of Maine's NPDES program, the trust responsibility towards the Maine Indian Tribes continues to operate in Maine in relation to the CWA, even under the settlement acts, but that the trust's reach and effect are more limited than might typically be the case in other states. In other words, the settlement acts significantly revise in Maine the jurisdictional arrangement that more typically exists elsewhere in the United States among Indian tribes, a state, and the federal government. EPA notes that the Penobscot Nation's comments cite to a number of federal court opinions that address the trust. See for example, *Worcester v. Georgia*, 31 U.S. 515 (1832); *Oneida County v. Oneida Indian Nation*, 470 U.S. 226 (1985); and *State of Washington, Dep't of Ecology v. U.S. E.P.A.*, 752 F.2d 1465 (9th Cir. 1985); *HRI, Inc. v. E.P.A.* 198 F.3d 1224 (10th Cir. 2000); *Cherokee Nation v. State of Georgia*, 30 U.S. 1 (1831); *United States v. Mitchell (Mitchell II)*, 463 U.S. 206 (1983); *Seminole Nation v. United States*, 316 U.S. 286 (1942). These cases and others of their kind, which may have addressed the federal trust, are not relevant to the analysis of whether Maine has jurisdiction to establish WQS in waters within Indian lands in Maine because the courts in those cases were not confronted with statutes like the settlement acts which, as EPA said above, alters the typical framework within which the trust operates.

The trust and federal Indian common law

As a threshold matter, when delving into the meaning of the settlement acts, EPA is employing, and always has employed, where appropriate, the interpretive canons of federal Indian common law that derive from the general trust responsibility. For

example, we agree that any ambiguity in the meaning of statutory provisions that attempt to limit tribal sovereignty must be narrowly construed and that such ambiguities must be resolved in favor of the tribes. EPA also agrees that the federal government's general trust responsibility charges the Agency with a responsibility to protect the tribes' inherent sovereignty from unwarranted state encroachment. Adhering to these basic common law elements of the trust doctrine does not run afoul of the settlement acts. They do not result in any alteration of the jurisdictional arrangement ratified in the settlement acts and simply require the Agency to consider the Maine Indian Tribes' interests and welfare consistent with Maine's authority, when EPA implements the CWA. In so doing, we are not thereby affecting or preempting Maine's jurisdiction, but merely applying the law which provides that jurisdiction to the State, and analyzing how that grant of authority from Congress affects EPA's CWA decisions in relation to the Maine Indian Tribes. We note that the First Circuit, without much comment, has invoked the general trust in support of the idea that ambiguities in MICSA should be interpreted in favor of the Tribes where possible. *Penobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999).

Consistent with the discussion above, the settlement acts do not create a complete barrier to the application of the federal common law concerning the federal government's trust responsibility in Maine. For one example, MICSA itself provides for certain lands and natural resources to be held in trust for the Penobscot Nation and the Passamaquoddy Tribe (hereinafter referred to for convenience as the "Southern Tribes") and the Houlton Band of Maliseet Indians. 25 U.S.C. § 1724. (Also for convenience, the Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs will hereinafter be referred to as the "Northern Tribes," where appropriate). So the mechanism of having the federal government serve as a trustee for tribal resources operates expressly under MICSA. The trust relationship is also evident elsewhere in the statute, albeit in a more inchoate form. MICSA clearly establishes that the Houlton Band of Maliseet Indians and the two Southern Tribes are federally recognized and it specifically charges them to document how their governments are structured. 25 U.S.C. §§ 1721(a) (3), (4), and (5), 1722(a), (h) and (k), and 1726. The Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 2(a)(1) and Sec. 3(1) and Sec. 7.[2] These various provisions are perfectly consistent with EPA's work with the Tribes on a government-to-government basis consistent with a trust relationship with the federal government. In addition, MICSA and MIA combine to explicitly reserve to the Southern Tribes the right to take fish for their individual sustenance within their reservations and to manage their lands and natural resources more generally. 30 M.R.S.A. § 6207(4); 25 U.S.C. § 1724(h); see also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. The Southern Tribes' statutorily reserved sustenance fishing right establishes an interest that the Southern Tribes have in the protection of specific natural resources, the fish that may

[2] In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201 et seq. In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143.

sustain them and the water quality on which the quality of that fishing right depends. In addition, as articulated in EPA's Decision Support Document, EPA has determined that Congress's intent in the settlement acts was to establish a land base for the four federally recognized Maine Tribes permitting them to sustain their unique culture and lifestyle practices. The legislative record regarding the trust land provisions in MIA, MICSA, MSA and ABMSA demonstrate Congress's intent to provide the Tribes with the opportunity to exercise their sustenance life ways, including sustenance fishing in waters of tribal trust lands. For additional discussion relevant to the Maine Tribes' sustenance fishing practices, see EPA's Decision Support Document and the Department of the Interior's (DOI) January 30, 2015 letter to EPA. In sum, it is relatively easy to conclude that all the elements of a trust relationship exist under the settlement acts for the four federally recognized Maine Tribes, consistent with the trust doctrine as it has been developed in the federal common law. The Tribes are federally recognized; the Tribes have an interest in specific natural resources which the CWA charges EPA to protect; and the federal government, including EPA, has a responsibility to consider the Tribes' interests, consistent with applicable law.

As stated earlier, however, the existence of this trust relationship does not and cannot legally alter the jurisdictional arrangement Congress ratified in the settlement acts. The trust by itself does not and cannot compel, or constitute an independent basis for, EPA to disapprove Maine's surface WQS as applied in waters within Indian lands in Maine on the grounds that the State does not have jurisdiction to do so where, in fact, the settlement acts and their jurisdictional provisions actually *do* provide Maine with the requisite legal authority. Accordingly, EPA disagrees with the Penobscot Nation's comments that cite to and characterize several of the First Circuit's legal opinions as providing a basis for applying the full suite of federal Indian common law principles and the trust *prior to* analyzing MIA and MICSA.. See Page 11 of the Penobscot Nation's comments, citing *Pènobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999) and *State of Rhode Island v. Narragansett Indian Tribe*, 19 F.3d 685 (1st. Cir. 1994).

Tribal comments that the trust obligates EPA to find that Maine does not have jurisdiction because the trust requires EPA to protect the Tribes from state encroachment

Outside Maine, EPA has typically excluded Indian country from EPA-approved state environmental programs based on the absence of state jurisdiction in Indian country. See, e.g., *HRI, Inc. v. EPA*, 198 F.3d 1224, 1247 (2000). By contrast, in Maine, the jurisdictional provisions of the settlement acts provide the State jurisdiction to administer WQS in waters in Indian lands. Moreover, MICSA's savings clauses (see more detailed discussion in EPA's Decision Support Document), in effect, prevent any federal law applicable to Indians from rewriting those jurisdictional provisions (*i.e.*, from preempting or affecting the application of Maine law) without explicit Congressional action made specifically applicable in Maine. Therefore, as discussed above in this RTC document, EPA has carefully considered how the trust operates consistent with MIA, MICSA and the CWA in the context of Maine's surface WQS submission. EPA is not relying on the trust to determine whether Maine has jurisdiction to establish water quality standards for waters in Indian lands. As discussed elsewhere in this RTC document, the jurisdictional

scheme established in the settlement acts bears on how the Agency implements our decision consistent with the trust responsibility.

However, notwithstanding that Maine does have jurisdiction to establish surface WQS that apply in waters within Indian lands in Maine, EPA's implementation role under the CWA and the trust responsibility to the Tribes nonetheless require EPA to consider the effects that Maine's WQS would have on the Maine Indian Tribes' interests and welfare as we exercise our existing CWA authority. This is not different in kind from the way in which the CWA generally obligates EPA to consider and comply with the requirements of the CWA in assessing impacts of state and EPA decisions on the interests and welfare (in this instance human health, specifically) of persons in light of the goals of the CWA. In other words, EPA must evaluate the adequacy of Maine's WQS as they apply to waters within Indian lands using a standard or methodology that is consistent with the requirements of the CWA. The trust responsibility to the Maine Indian Tribes together with the Agency's authorized means of implementing the CWA require EPA to consider impacts on the Tribes in relation to protections of tribal resources that are addressed by the settlement acts and the CWA. See e.g., the discussion in EPA's Decision Support Document regarding the "designated use" of sustenance fishing and its protection under the CWA.

In addition, as we will discuss further below, the CWA assigns EPA a very important role in overseeing state surface WQS programs. Therefore, EPA's decision finding that Maine has the authority to establish WQS for waters within Indian lands will not prevent EPA from continuing to work with the Tribes and will not prevent EPA from communicating with all interested parties to improve coordination in protecting water quality in the surface waters in question. In fact, EPA's decision letter to ME DEP is a concrete example and manifestation of how CWA requirements provide for EPA's protection of the Maine Indian Tribes' interests and welfare in a way that is consistent with the jurisdictional framework established by Congress in Maine through the settlement acts and with the trust responsibility to the Tribes.

Maine's comments about the trust

As EPA earlier articulated in its responses to comments on Maine's NPDES program application in 2003, EPA disagrees with Maine's assertion that the federal government has no trust relationship or responsibility with respect to the Southern Tribes' reservations. While it is true that Congress curtails the applicability of the Non-Intercourse Act to the Penobscot Nation and the Passamaquoddy Tribe in MICSA Section 1724(g)(1), Congress also created similar responsibilities in Sections 1724(g)(2) and (3) that apply post-MICSA. Section 1724(g)(3) requires the approval of the Secretary of the Interior for six specific types of land transfers within the Southern Tribes' "territories,"

which have been defined, in MIA,[1] to include the reservations.[2] See 25 U.S.C. §1724(g)(3). Section 1724(g)(2) states that "any transfer of land or natural resources within Passamaquoddy Indian Territory or Penobscot Indian Territory ... shall be void ab initio and without any validity in law or equity." 25 U.S.C. §1724(g)(2). This language is very similar to that of the Non-Intercourse Act which states that no transfer of land or title to land from any Indian nation or Tribe "shall be of any validity in law or equity, unless the same be made by treaty or convention entered into pursuant to the Constitution." 25 U.S.C. §177. More importantly, Congress intended for these MICSA sections to replace the Non-Intercourse Act as a source of federal trust responsibility. Both houses of Congress, in responding to concerns about federal protection of the Southern Tribes, acknowledged that "[o]ne of the most important federal protections is the restriction against alienation of Indian lands without federal consent. [The sections that eventually became Sections 1724(g)(2) and (3)] specifically provide] for such a restriction and, as was made clear during the hearings, this provision is comparable to the Indian Non-Intercourse Act, 25 U.S.C. §177." H.R. DOC. NO. 96-1653, at 15 (1980); S.R. DOC. NO. 96-957 at 15(1980). As Congress confirms, Sections 1724(g)(2) and (3) essentially replace the Non-Intercourse Act as a source of federal trust responsibility. Reading MICSA as Congress intended would mean that the reservations are subject to a federal trust responsibility by nature of their inclusion as delineated parts of Penobscot Indian Territory and Passamaquoddy Indian Territory. See 25 U.S.C. §§1724(g)(2) and (3); 30 M.R.S.A. §6205.

Additionally, there are other sources of the federal trust relationship with respect to the reservations, as well as to the Southern and Northern Tribes' trust lands. It is obvious that the reservation lands are central to federally protected rights reserved for the Penobscot Nation and the Passamaquoddy Tribe. MICSA federally recognizes the Passamaquoddy Tribe, the Penobscot Nation, and the Houlton Band of Maliseet Indians. 25 U.S.C. §1721. The Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains a similar provision at Sec. 2 (a)(1). In addition, MIA reserves, for the Southern Tribes, hunting and fishing rights within their reservations. 30 M.R.S.A. §6207(4). Both the House and Senate Committee reports relating to MICSA confirm that Congress intended for the Southern Tribes to have "the permanent right to control hunting and fishing ... within their reservations" according to the terms set out in MIA. H.R. DOC. NO. 96-1653, at 17 (1980); S.R. DOC. NO. 96-957 at 16 (1980). MICSA also reserves, for the Penobscot Nation and the Passamaquoddy Tribe, the right to manage their natural resources. 25 U.S.C. §1724(h). See also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. Therefore, it is reasonable to conclude that Congress reserved the trust lands in order to preserve the Maine Tribes' cultural activities, in

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[1]The Maine statute that is ratified by MICSA. See 30 M.R.S.A. §6205.

[2]The First Circuit has recognized that the necessity of the signature of the Secretary of the Interior implicates a federal trust responsibility. See Key Bank 112 F.3d. 538 at 553.

particular sustenance fishing, and intended that there be some federal responsibility to protect these activities consistent with the trust responsibility and the requirements of the CWA. For additional discussion relevant to the Maine Tribes' sustenance fishing practices, see EPA's Decision Support Document and DOI's January 30, 2015 letter to EPA.

Ultimately, the CWA provides the relevant authority for EPA to approve or disapprove Maine's surface WQS. 33 U.S.C. §1251 et. seq. As mentioned before, MIA, in 30 M.R.S.A. Section 6207(4), reserves for the Penobscot Nation and the Passamaquoddy Tribe, a sustenance fishing right within their reservations. MICSA, in 25 U.S.C. Section 1724(h), reserves for these Tribes, the right to manage their natural resources. See also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. Federal common law principles, and Congressional intent, support the position that the Tribes have the ability to practice sustenance fishing in their reservation and trust land waters. Section 303(c) of the CWA specifically gives EPA the authority to ensure that states adopt WQS that are protective of human health and the environment. 33 U.S.C. § 1313(c). EPA is the federal body charged with protecting the very resource that is reserved for Maine's federally recognized tribes, and the CWA gives EPA the authority to oversee state WQS. EPA should account for tribal resources, such as their fishing rights, in exercising that oversight authority, as required by the CWA and consistent with CWA authority and the trust relationship.

Moreover, it is clear that the State of Maine itself contemplated that sustenance fishing practices for the Maine Tribes would be part of the settlement embodied in MIA and subsequently ratified by Congress through MICSA. MIA section 6207(1) provides that "[i]n addition to the authority provided in this subsection, the Passamaquoddy Tribe and the Penobscot Nation, subject to the limitations of subsection 6, may exercise within their respective Indian territories all the rights incident to ownership of land under the laws of the State." The legislative history to MIA clearly indicates that both reservation lands and lands acquired pursuant to MIA after its enactment (trust lands) would enjoy riparian or littoral rights under state law and/or principles of common law.

> The boundaries of the Reservations are limited to those areas described in the bill, but include any riparian or littoral rights expressly reserved by the original treaties with Massachusetts or by operation of state law. Any lands acquired by purchase or trade may include riparian or littoral rights to the extent they are covered by the selling party or included by general principles of law. State of Maine, Maine Legislature, Joint Select Committee on the Indian Land Claims, Report of the Joint Select Committee on Indian Land Claims Relating to LD 2037 "AN ACT to provide for Implementation of the Settlement of Claims by Indians in the State of Maine and to Create the Passamaquoddy Indian Territory and Penobscot Indian Territory." Paragraph 14. 1980.

In support of the State's assertion that no trust relationship exists with respect to the reservations, Maine cites in its comments to a letter from DOI in which that Agency, according to Maine, stated that "fee title to the islands in the Penobscot River was held by Maine in trust for the benefit of the Penobscot Nation" and also cited to *Bangor Hydro-Electric Co.*, 83 FERC ¶ 61,037, 1998 WL292768 (F.E.R.C.). Bangor is a Federal Energy Regulatory Commission (FERC) case regarding the licensing of a hydro-electric project under the Federal Power Act (FPA). 16 U.S.C. §§797, 808. The Penobscot Nation and DOI intervened regarding parts of the Penobscot Nation's lands that were inundated when the project was originally built. Both Bangor and the case upon which it relies, *Federal Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99,115 (1960), recognized that the narrow definition of "reservations," which relies on a strictly property oriented understanding of the term, is confined to the FPA. Bangor at 10. Tuscarora plainly says that "the national 'paternal interest' in the welfare and protection of the Indians is not the 'interests in lands owned by the United States' required, as an element of 'reservations' by § 3(2) of the Federal Power Act." Tuscarora, at 115. FERC's assertion in Bangor that "no trust relationship exists" with respect to aboriginal lands, should therefore be understood in this limited capacity, that "no trust relationship exists" for the purposes of the FPA, which requires an interest in lands owned by the United States. Bangor is therefore irrelevant in determining whether there is a federal trust responsibility with respect to the reservations outside the context of the FPA, and therefore does not establish or constitute precedent for the trust responsibility in the context of EPA's implementation of under the CWA.

Tuscarora, however, highlights the difference between 1) a narrow trust responsibility relating to lands "held in trust" and 2) a more general interest in the welfare and protection of the Indians, which points to a general federal trust responsibility, a distinction which is important to this discussion. In federal Indian law, the federal government's general trust responsibility derives from the United States Constitution as further developed by the Supreme Court and other federal courts of the United States, and has become a key aspect of federal Indian common law. The general trust responsibility includes the notion that the federal government has a responsibility, as a general matter, to consider and protect Indian tribes' interests when implementing federal statutes or evaluating decisions that may affect tribes. The federal government's attention to the Indian law canons of statutory construction that have evolved in the common law is an element of this general trust responsibility. The general trust responsibility does not, however, create or establish substantive obligations on the part of the federal government.

The specific trust on the other hand derives from substantive rights established in statutes or regulations that are implemented by the federal government on behalf of Indian tribes. The specific trust is sometimes referred to as an obligation that entails fiduciary duties on the part of the federal government to protect specified tribal rights. As noted in Cohen's Handbook of Federal Indian Law, "[t]he concept of a federal trust responsibility to Indians evolved from early treaties with tribes; statutes, particularly the Trade and Intercourse Acts; and the opinions of the Supreme Court." Cohen explains that the Supreme Court played a major role in defining the relationship between the federal government and Indian tribes. The Court's cases established principles, among others,

such as tribes' right to own land and to set land use policies for those subject to tribal authority, as a federal duty to protect tribal rights including tribal property rights, and as a rationale for canons of construction of various legal documents in light of the federal government's obligation to protect tribal sovereignty and property. See generally section 5.04[3][a] of Cohen's Handbook. In this case, EPA has attended to the general trust responsibility to the Maine Tribes by consulting with them about and understanding their interests in the decisions we are making regarding Maine's WQS in tribal waters, and by implementing the requirements of the CWA that apply to the WQS program. The substance of EPA's review of those WQS is governed by the generally applicable requirements of the CWA that guide EPA's implementation, not by any authority that creates a specific fiduciary obligation to any particular tribe in Maine.

We note that Maine also argues that CWA Section 518, a provision that allows Indian tribes to apply for treatment in the same manner as a state ("treatment as a state" or "TAS") status for purposes of certain CWA programs, is not available to the Tribes in Maine. Accordingly, says Maine, that fact is another reason why EPA has no trust responsibility to the Maine Tribes. EPA responds that its decision on Maine's WQS submissions relates to *Maine's* submission regarding WQS for waters in Indian lands, which is governed by EPA's CWA authorities and responsibilities, and which is unaffected by the separate issue of potential tribal roles under Section 518.[3] Even assuming, only for purposes of responding to Maine's specific comment, that none of the Maine Tribes could qualify for TAS status under CWA Section 518, EPA strongly disagrees that such fact, even if true, would mean that no trust responsibility exists to the Maine Tribes. This RTC document and EPA's Decision Support Document each address and demonstrate EPA's exercise of its CWA authority consistent with the trust responsibility to the Maine Tribes notwithstanding EPA's determination that Maine has adequate legal authority to establish WQS for waters within Indian lands. Maine's comment about CWA section 518 is not relevant to the question of whether a federal trust responsibility exists in Maine under the settlement acts and the CWA.

From the perspective of EPA's earlier description of the general and specific trust responsibilities, and for all of the other reasons discussed above, a federal trust relationship clearly does exist with respect to the Penobscot Nation and Passamaquoddy Tribes' reservations as well as with respect to the Southern and Northern Tribes' trust lands. In summary, although MICSA Section 1724(g)(1) negates the application of the Non-Intercourse Act (a statute often identified as a source of the federal government's specific, as opposed to general, trust responsibility) to these Indians, Congress intentionally included modern non-intercourse provisions in MICSA Section 1724(g)(2) and (3), thereby continuing a federal trust responsibility to the Tribes, and more specifically to their reservations. In addition to these non-intercourse provisions and the common law sources of the federal government's general trust responsibility, the CWA

[3] EPA notes that on October 8, 2014, the Penobscot Nation submitted to EPA an application "to administer water quality standards program and for federal approval of the standards" covering the Maine Stem of the Penobscot River from Indian Island north to the confluence of the east and west branches of the river. Included in the Nation's submission was a TAS application. EPA has not commenced a formal review of the Nation's application, wanting first to address Maine's submissions.

gives EPA the authority to review the State's WQS for consistency with the statute and thereby to utilize its existing authority to protect the reservations and trust lands and the practices and rights associated with them. The relevant settlement acts established trust lands for the Northern and the Southern Maine Tribes, and specifically defined those holdings to include "land or natural resources," which in turn specifically includes "fishing and fishing rights." The settlement acts contain provisions about the potential disposition and management of those resources. The relevant statutory provisions have been cited earlier in this RTC document. So in utilizing our existing CWA authority to protect the Maine Tribes' interests and welfare in relation to the reservations and trust lands, EPA is acting consistently with the settlement acts in Maine and the trust responsibility.

The State also cites in its comments to the First Circuit's opinion in *Nulankeyutmonen Nkihttaqmikon v. Impson*, 503 F.3d 18, 31 (1st Cir. 2007) in support of its contention that EPA has no trust responsibility to the Maine Indians Tribes in making decisions under the CWA. Maine claims that the CWA contains no set of written standards that anyone may review to assess whether a particular implementation decision EPA may render complies with its trust obligation under the CWA. Thus, Maine asserts, an EPA decision that breathes substantive or procedural requirements into the CWA pursuant to its trust relationship, but independent of the CWA, would be arbitrary and capricious, citing to *Michigan v. EPA*, 268 F.3d 1075, 1085 (D.C. Circuit 2001).

EPA agrees with Maine's assertion that any specific requirements that flow from a specific trust relationship must derive their content from and are the product of applicable law, whether treaties, statutes, or regulations. See *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1482 (D.C. Cir. 1995); *State of California v. Watt*, 668 F.3d 1290, 1324 (D.C. Cir. 1981). However, EPA disagrees with Maine to the extent the State argues that EPA may not, in exercising our existing authority and discretion under the CWA, be informed by our consideration of tribal interests consistent with the general trust relationship. The CWA includes requirements for how EPA must review the adequacy of WQS, and EPA must apply those requirements to Maine's WQS in Indian waters. In considering the impacts of Maine's WQS on the water quality-related interests and welfare of the Indian Tribes in Maine, and most notably on the tribal sustenance fishing practices associated with Indian land waters, EPA is exercising its CWA authority consistent with the trust relationship, the requirements of the CWA, and the settlement acts. EPA's decision that Maine's human health criteria are not sufficiently protective of the CWA "designated uses" that apply to waters in Indian lands is directly tied to a fundamental requirement of the CWA, *i.e.* that WQS must protect designated uses. See EPA's Decision Support Document for a more detailed discussion. In this regard, EPA's decision to disapprove certain of Maine's WQS is entirely consistent with the holding in *Nulankeyutmonen Nkihttaqmikon v. Impson* in the sense that EPA's decision is derived from CWA requirements, provisions in the settlement acts, and Congress's intent to preserve the Tribes' sustenance fishing practices, culture, and lifestyle.

B. Many comments from the Maine Tribes relating to the question of Maine's jurisdiction focused on the concept of the Tribes' inherent sovereignty, and/or the concept of "internal tribal matters" as an explicit expression in MIA/MICSA of the Southern Tribes' retained inherent sovereign status. Maine submitted comments along the lines that MIA/MICSA provide the State with jurisdiction, at least implying that these concepts raised by the Tribes do not function to alter that outcome.

Examples of the Tribes' comments

1. Establishing an appropriate fish consumption rate (FCR) and cancer risk level (CRL) for use in establishing WQS under the CWA are each an "expressly retained sovereign activity."

2. Setting CRLs and FCRs amounts to regulation of the Tribes' sustenance fishing right, which the State is not authorized to do under MIA and MICSA.

3. Establishing WQS under the CWA is an inherent sovereign right and is an internal tribal matter.

4. If the Indian Tribes, as opposed to the State, were establishing WQS in Indian waters, the Tribes would not be regulating any non-tribal members.

5. An Indian Tribe's inherent authority or tribal sovereignty cannot be divested unless Congress expressly acts to do so.

6. Water quality in Indian waters is something that may directly threaten the "health or welfare of the tribe." Water rights and governmental jurisdiction are "critical elements necessary for tribal sovereignty."

7. Congress did not "unequivocally abrogate the Tribe's inherent authority to protect the sustenance fishery."

8. The legislative history to MICSA indicates that MICSA's sustenance fishing right is an example of an "expressly retained sovereign activity."

9. Inherent sovereignty applies in this context and allows Indian tribes to protect subsistence practices embodying cultural, spiritual, and physical elements.

10. Inherent sovereignty precludes Maine from regulating in this way. Sustenance fishing is an aboriginal right.

11. The notion that establishing WQS in Indian waters is an internal tribal matter is supported by federal and State governments' adoption of principles in the United Nations declaration on the Rights of Indigenous Peoples.

12. Determining a CRL that tribal members will be subjected to is an internal tribal matter. Maine is asking EPA to approve Maine's policy judgment about the level of risk the Tribes should face, which is inappropriate and inconsistent with the Tribes' inherent sovereignty.

13. Protection of tribal health and welfare is an internal tribal matter over which the State may not exercise jurisdiction, and includes environmental regulation.

Examples of the State's comments

1. The CWA and MIA/MICSA provide Maine with the authority to establish WQS in waters within Indian lands in Maine.

2. MICSA's savings clauses would preclude the Maine Indian Tribes from implementing a WQS program in Maine.

EPA's responses to comments concerning principles of inherent tribal sovereignty (and MIA's and MICSA's internal tribal matters provision) and its effect on Maine's legal authority to establish WQS for waters within Indian lands

Basic tenets or principles of federal Indian common law as they relate to tribal sovereignty

EPA agrees with the comments that set forth the basic tenets of federal Indian common law supporting the idea that Indian tribes have retained their inherent powers as sovereign entities (unless expressly abrogated by Congressional action), that such sovereign status has existed since long before contact with European nations, and that Indian tribes' sovereignty it is not something that was delegated or granted to the tribes by Congress. EPA has consistently sought to uphold the inherent sovereignty of Indian tribes wherever applicable. See, e.g., EPA's 1984 Indian Policy.

Many of the federal court opinions cited by the Penobscot Nation in its comments reflect or discuss certain aspects of these common law principles of federal Indian law. See, e.g., *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *State of Washington, Dep't of Ecology v. U.S.E.P.A.* 725 F. 2d 1465 (9th Cir. 1985); *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130 (1982); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Oklahoma Tax Comm'n v Sac & Fox Nation*, 508 U.S. 114 (1993); *Three Affiliated Tribes of Ft. Berthold v. Wold Eng'g*, 476 U.S. 877 (1986); *Kiowa Tribe of Oklahoma v. Mfg techs, Inc.* 523 U.S. 751 (1998); *Santa Clara Pueblo v. Martinez*, 436 U.S. 49 (1978); *Williams v. Lee*, 358 U.S. 217 (1959); *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005); *Montana v. United States*, 450 U.S. 544 (1981); *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996).

These general principles of Indian common law cited by the Penobscot Nation, however, are not dispositive of and do not directly answer the fundamental jurisdictional question before EPA in this matter: what effect do the settlement acts have on the jurisdictional relationship among the Southern and Northern Tribes, the State of Maine, and the federal government when implementing the CWA WQS program applicable to Indian waters within Indian lands in Maine? The cases cited by the Penobscot Nation were not decided against the backdrop of statutes like MIA and MICSA which, as EPA has explained throughout this RTC document, alter in certain important respects the Maine Indian Tribes' inherent sovereign status as compared to the more typical situation that exists in parts of the United States that do not have statutes like MIA and MICSA.[4]

EPA recognizes the fundamental principles of federal Indian law relating to inherent tribal sovereignty, and is aware that Congress has plenary power over Indian affairs as established in the Indian commerce clause of the Constitution. *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 56 (1978). As a result, only Congress may change the jurisdictional relationships in Indian country by expanding or contracting state, tribal and federal jurisdiction. If Congress takes any action to limit a tribe's sovereignty, it must do so expressly and any ambiguities must be resolved in the tribe's favor. Congress may provide for state law to apply in Indian country, but it must do so expressly. *See California v. Cabazon Band of Mission Indians*, 480 U.S. 202, 207 (1987).

In this matter, EPA is applying the Congressional grant of legal authority to Maine in the Southern and Northern Tribes' Indian lands which is adequate to support the State's assertion of legal authority to implement a CWA WQS program applicable to waters in Indian lands located in Maine. See EPA's Decision Support Document for a more detailed discussion and analysis. Both MIA and MICSA, as further elucidated in MIA's and MICSA's legislative histories, embody a jurisdictional framework that serves as a compromise in settlement of the land claims that gave rise to these statutes. The Senate Report accompanying MICSA specifically addressed concerns about the impact of these

[4] The Penobscot Nation also cites to *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005) as a First Circuit opinion that addresses tribal sovereignty "absent their divestment by the federal government." See Page 14 of the Penobscot Nation's comments. This case, however, like the others cited by the Tribe, does not stand for the proposition that MICSA did not give Maine the legal authority to establish WQS in waters within Indian lands.

two statutes on the Penobscot and Passamaquoddy Tribes' sovereign rights and jurisdiction. "While the settlement represents a compromise in which State authority is extended over Indian territory to the extent provided in the Maine Implementing Act, in keeping with [certain legal precedent] the settlement provides that henceforth the Tribes will be free from State interference in the exercise of their internal affairs. Thus, rather than destroying the sovereignty of the Tribes, by recognizing their power to control their internal affairs and by withdrawing the power which Maine previously claimed to interfere in such matters, the settlement strengthens the sovereignty of the Maine Tribes." Page 14, Special Issues. The Senate Report goes on to describe other ways in which the Tribes' sovereignty is protected, including, but not limited to, the hunting and sustenance fishing right provisions in the statutes and the provisions granting to the Southern Tribes state constitutional status of municipalities. However, the nature of this compromise in retaining certain aspects or elements of the Tribes' sovereignty does not override or conflict with the fact that Congress in MICSA ratified a jurisdictional relationship among the Tribes and the State that gave Maine the authority to apply state law to those matters not falling within either:1) the internal tribal matters provision in the statute; 2) the Southern Tribes' reservation hunting and fishing rights or 3) certain other matters specifically reserved by the statutes to the Tribes.[5] EPA's conclusion that Maine has the legal authority to establish WQS in waters within Indian lands is consistent with MIA and MICSA because, as discussed below in more detail, doing so is not an internal tribal matter and does not alter or regulate the Southern Tribes' right to take fish within their reservations for their individual sustenance. In fact, EPA's Decision Support Document explains that the Southern and Northern Tribes' fishing rights are being protected under the CWA notwithstanding Maine's authority to establish WQS in waters within Indian lands.

Consistent with the analysis above of the Maine Tribes' sovereign status, as expressed in MICSA, which ratifies MIA, the federal Indian common law cases cited by the Penobscot Nation are generally inapposite here. The vast majority of the cases did not address the scope of the sovereign status of an Indian tribe under statutes similar to MIA and MICSA. See e.g., *Kiowa Tribe of Oklahoma v. Mfg techs, Inc.* 523 U.S. 751 (1998); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Santa Clara Pueblo v. Martinez*, 436 U.S. 49 (1978); *Williams v. Lee*, 358 U.S. 217 (1959); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988); *Montana v. United States*, 450 U.S. 544 (1981); *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996). In addition, although the Penobscot Nation also cites to several First Circuit cases discussing some aspects of inherent tribal sovereignty generally, none of those cases held that Maine law did not generally apply to the Maine Indian Tribes under MIA section 6204 and MICSA sections 1725(a) and 1725(b)(1) on the basis of the Tribes' inherent sovereign status. See, e.g., *Akins v. Penobscot Nation*, 130 F. 3d 482 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F. 3d 706 (1st Cir. 1999); *Bottomly v. Passamaquoddy Tribe*, 599 F. 2d 1061 (1st Cir. 19179); and *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005).

[5] The other matters referenced here are not pertinent to EPAs decision.

The effect of the settlement acts on federal Indian common law as they relate to tribal sovereignty

The settlement acts clearly represent a substantial revision to the relationship between state and Indian jurisdiction that would apply in Maine absent the settlement acts. Virtually every court that has reviewed the statutes has emphasized that it is impossible in Maine to simply apply federal Indian common law without first starting with the settlement acts. See, e.g. *Akins v. Penobscot Nation*, 130 F.3d 482, 484 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F.3d 706, 708 (1st Cir. 1999), cert. denied 527 U.S. 1022 (1999); *Penobscot Nation v. Georgia-Pacific*, 254 F.3d 317, 320 (1st Cir. 2001), cert. denied 534 U.S. 1127 (2002); *Penobscot Nation v. Stilphen*, 461 A.2d 478, 482 (Me. 1983), app. dismissed 464 U.S. 923 (1983); *Great Northern Paper Inc. v. Penobscot Nation*, 770 A.2d 574, 580 (Me. 2001), cert. denied -- U.S. –, 122 S.Ct. 543 (2001); *Maine v. Johnson*, 498 F.3d 37, 42 (1st Cir. 2007). For example, the settlement acts create a status for the Northern and Southern Tribes (although there are statutory differences for each of the two groups) that is unique in the nation, and extends state authority over the Tribes to an unusual extent. Therefore, to say simply that federal Indian common law applies to the Maine Tribes (without any qualification) understates the critical role the settlement acts play in revising the customary formula for gauging Indian sovereignty.

On the other hand, it overstates the effect of the settlement acts to say that federal Indian law is irrelevant to interpreting how the settlement acts apply in Maine. As a threshold matter, for example, MICSA is a federal statute that modifies tribal jurisdiction, and therefore is subject to the interpretive doctrines in federal common law giving the tribes the benefit of the doubt where the statute is ambiguous. *Fellencer*, 164 F.3d at 709. Additionally, MICSA ratified the jurisdictional formulation in MIA for the Southern Tribes, and MIA specifically preserves "internal tribal matters" from state regulation. When analyzing the scope of "internal tribal matters," the First Circuit has twice referred to general principles of federal Indian law, both common law (*Akins*, 130 F.3d at 489-90) and statutory provisions (*Fellencer*, 164 F.3d at 711), to help understand the extent of that term. MICSA and its legislative history make it clear that "internal tribal matters" is not a reservation of the Southern Tribes' full inherent sovereignty that predated passage of MICSA. But the term nevertheless protects key elements of the Southern Tribes' inherent sovereignty from state regulation. Therefore, when confronted with MICSA, courts have looked to the body of federal Indian law to better understand how a tribe's inherent sovereignty works in the customary case. In EPA's decision on Maine's WQS submission, EPA has similarly filtered the body of general federal Indian common law through the lens of MICSA, recognizing its unique requirements, while understanding at the same time that the statute operates against the backdrop of federal Indian common law.

EPA would disagree with any assertion that the Southern or Northern Tribes are no longer sovereigns, notwithstanding that the Southern and Northern Tribes are treated differently by the settlement acts in certain respects. Congress specifically recognized the tribal governments of the Southern and Northern Tribes. 25 U.S.C. §§ 1721(a) (3),

(4), and (5), 1722(a), (h) and (k); Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, at Sec. 2 (a)(1) and Sec. 3(1). Congress charged the Tribes with developing written instruments to govern their affairs when acting in a governmental capacity. 25 U.S.C. § 1726 and Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, at Sec. 7. It is explicitly clear in MIA and MICSA that the Southern Tribes exercise sovereignty in the sense of having governmental authority over their internal affairs and may take fish for their individual sustenance within their reservations. Using the term sovereignty when referring to the activities of these tribal governments is completely consistent with, indeed is compelled by, the terms of MICSA and The Aroostook Band of Micmacs Settlement Act. But the focus of this matter is the extent of the State's authority in relation to that which may be reserved to the Southern and Northern Tribes, and simply embracing or banishing the term "sovereignty" (without any qualifications or more nuanced explanations) contributes little to answering that question.

Penobscot Nation's sovereignty argument in relation to MIA section 6204

The Penobscot Nation asserts that the Tribe's full aboriginal inherent sovereignty was intended by Congress to be retained in MICSA. The Penobscot Nation argues this is true notwithstanding the language in MIA section 6204 generally subjecting all Indian Tribes in Maine to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein. The Penobscot Nation argues that section 6204 "merely confirms that the Nation will adopt Maine law as its own, but it does not expressly impose any form of State regulatory authority upon the Tribe or its natural resources." The Tribe cited to *Wauneka v. Campbell*, 22 Ariz. App. 287, 526 P. 2d 1085 (C.A. 1974), a case included in one section of MICSA's legislative history.

Although the Tribe's comment doesn't refer to MIA section 6202, "Legislative findings and declaration of policy," EPA notes that this language may also be relevant to the Tribe's argument:

> The foregoing agreement between the Indian claimants and the State also represents a good faith effort by the Indian claimants and the State to achieve a just and fair resolution of their disagreement over jurisdiction on the present Passamaquoddy and Penobscot Indian reservations and in the claimed areas. To that end, the Passamaquoddy Tribe and the Penobscot Nation have agreed to adopt the laws of the State as their own to the extent provided in this Act. The Houlton Band of Maliseet Indians and its lands will be wholly subject to the laws of the State.

As part of this overall argument in support of the Tribe's assertion of full aboriginal inherent sovereignty, the Tribe also references certain passages from MICSA's legislative history and federal case law. For a number of reasons, EPA disagrees that this particular argument, either on its own, or in conjunction with the Tribe's other arguments about

inherent tribal sovereignty, results in a legal conclusion that Maine is precluded by MIA and MICSA from establishing WQS in waters within Indian lands in Maine.

First, as set forth in EPA's Decision Support Document, and as explained in various other portions of this RTC document, the statutory provisions of MIA and MICSA and those statutes' legislative histories, very clearly establish that state law applies to the Penobscot Nation and the Passamaquoddy Tribe (and the other Maine Tribes) in the context of environmental regulation. Moreover, as the First Circuit said in *Maine v. Johnson*:

> In our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies; and the scope of that exemption is determined by the character of the subject matter. Discharging pollutants into navigable waters is not of the same character as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property. [*Maine v. Johnson*, 498 F. 3d 37, 46.]
>
> In addition to Maine's explicit authority over tribal lands and natural resources, the Settlement Acts expressly divested the Maine Tribes of sovereign immunity, *25 U.S.C. § 1725(d)*, and with limited exceptions, made the Maine Tribes subject to the general criminal and civil law of Maine even with respect to activities carried out on tribal lands. *25 U.S.C. § 1725(a), (c)*; *30 M.R.S.A. § 6204*. [*Maine v. Johnson*, 498 F. 3d 37, 42-43.]
>
> [T]he question here is whether *Maine* has adequate authority to implement permitting as to the tribes' lands, and *section 6204* on its face is about as explicit in conferring such authority as is possible. [*Maine v. Johnson*, 498 F. 3d 37, 43.]

Each of these passages from *Maine v. Johnson* directly conflicts with the Tribe's argument that MIA and MICSA did not intend to provide Maine with the legal authority to regulate the Penobscot Nation under state law because the Settlement Acts intended to preserve the Maine Tribes' full aboriginal inherent sovereignty. Indeed, every time the U.S. Court of Appeals for the First Circuit has adjudicated the extent of Maine's jurisdiction in Indian territories, it is clear the court held that MICSA applies the laws of the State to the Southern Tribes.

Five different First Circuit cases adjudicating the application of state law in the Southern Tribes' territories have never hinted at the idea that state law applies to the Tribes as anything other than state law. *Passamaquoddy Tribe v. Maine*, 75 F.3d at 789, n. 1 (1st Cir. 1996) ("Among other things, the Gaming Act, if it applied, would preempt various provisions of Maine's criminal law, including 17–A Me. Rev. Stat. Ann. §§ 953–954."); *Akins v. Penobscot Nation*, 130 F.3d 482 (1st Cir. 1997) ("This case turns on whether the issuance of stumpage permits is an 'internal tribal matter.' If this is an internal tribal matter, then under both Settlement Act and the Implementing Act, Maine law does not apply and no claims arise under the Maine Constitution or under the Maine

Administrative Procedure Act. Thus no claim arises under state law warranting the exercise of diversity jurisdiction." 130 F.3d at 485); *Penobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999), cert. denied, 527 U.S. 1022, 119 S. Ct. 2367, 144 L. Ed. 2d 771 (1999) (Maine state law did not apply only because the decision whether to employ a tribal member or a non-tribal member as a community nurse fell within the "internal tribal matter" exception to the applicability of state law under MIA and MICSA); *Penobscot Nation v. Georgia Pacific Corporation*, 254 F. 3d 317 (1st Cir. 2001) (Company demanded documents from Maine Tribes based on Maine's Freedom of Access Act. "Under Maine law, the Tribes are regulated in certain respects as municipalities, and municipalities are covered by the Access Act." 254 F.3d at 318.); *Maine v. Johnson*, 498 F.3d 37, 43 (1st Cir. 2007) ("The Southern tribes say that state authority over land and water resources can coexist with tribal authority, pointing to certain provisions of the Settlement Acts that explicitly make state authority 'exclusive.' So, the tribes say, the existence of Maine's authority does not automatically negate concurrent tribal authority over the same subject matter. But the question here is whether Maine has adequate authority to implement permitting as to the tribes' lands, and section 6204 on its face is about as explicit in conferring such authority as is possible. What the tribes might do if Maine did not legislate is beside the point. The Southern tribes' concurrency argument would have bite only if their own 'concurrent' regulatory authority, if it existed, took priority over enacted Maine law. But this would turn on its head the explicit language of the Settlement Acts giving Maine authority over land and water resources in the tribes' territories. If there is 'concurrent' jurisdiction at all, it is subordinate to Maine's overriding authority to act within the scope of section 6204, which clearly includes Maine's power to regulate discharge permitting consistent with the Clean Water Act.") And none of these cases held that the reference to W*auneka v. Campbell*, 22 Ariz. App. 287, 526 P. 2d 1085 (C.A. 1974), in MICSA's legislative history, supports the proposition that Maine state law does not apply as state law to the Southern Tribes under MIA section 6204.

MIA's internal tribal matters provision

In this subsection of EPA's RTC document, EPA provides a legal analysis of the "internal tribal matters" provision in MIA, as ratified by MICSA, as well as a discussion of how the First Circuit has construed the provision in its decisions to date. As explained below, EPA concludes that establishing WQS in waters within Indian lands is not an internal tribal matter. That conclusion is well-supported by First Circuit precedent, which strongly suggested that the balancing factors from *Akins* and *Fellencer*, that should be used in circumstances that constitute close questions of the applicability of the internal tribal matters provision, would be *inappropriate* if applied to the question of Maine's authority to establish WQS in waters within Indian lands. *Maine v. Johnson,* at 46. Nevertheless, because of the prominence of the concept of internal tribal matters in the Penobscot Nation's comments, EPA analyzes the concept below in detail. EPA even analyzes the balancing factors from *Akins* and *Fellencer* as applied to the WQS question to demonstrate that, even if it were appropriate to apply the factors, the analysis shows that Maine has authority to establish WQS in waters in Indian lands and that such

authority is not inconsistent with and does not run afoul of the internal tribal matters provision in MIA.

EPA recognizes the importance of the "internal tribal matters" provisions in MIA section 6206(1), as ratified by MICSA section 1725(b)(1), which by its terms only applies to the two Southern Tribes. We agree that, to the extent a subject is an internal tribal matter, the State is precluded from regulating that subject and that it falls beyond the reach of the grant of state authority in MIA section 6204, as ratified by Congress. Therefore, the scope of the internal tribal matters concept essentially defines the boundary of the State's jurisdiction and the State's ability to regulate activities in the Southern Tribes' territories.[6]

The internal tribal matters provision in MIA and MICSA is a reservation of authority to the Southern Tribes based on their inherent sovereignty that predates MICSA. Congress did not intend, however, to reserve through MICSA the *full scope* of the Southern Tribes' inherent sovereignty which the federal courts had recently recognized prior to MICSA. *Bottomly v. Passamaquoddy Tribe*, 599 F.2d 1061, 1065-66 (1st Cir. 1979); *Joint Trib. Coun. of Passamaquoddy Tribe v. Morton*, 528 F.2d 370, 379 (1st Cir. 1975). That interpretation would cause the exception of internal tribal matters to swallow the rule Congress created, which is that state law generally applies to the Maine Tribes and their lands. But as we discuss further below, the common law generally interpreting Indian Tribes' inherent sovereignty is relevant to assessing the scope of internal tribal matters, at least as a threshold test. If a subject matter would be beyond the reach of any Indian Tribe's inherent sovereignty, it could not qualify as an internal tribal matter under MICSA. If a subject matter is generally within the inherent authority of a Tribe to govern (and one decides it is appropriate to undertake an internal tribal matters analysis), EPA concludes that the next step in the analysis consists of using the factors that the First Circuit has derived in analyzing the provisions of MIA and MICSA. In short, EPA has concluded that "internal tribal matters" under MICSA is a subset of the inherent authority Indian Tribes generally retain as reflected in the general principles of federal Indian common law.

In addition, we note that it would be difficult to reconcile the unique wording of MICSA section 1725(f) with the interpretation that internal tribal matters reserves the Southern Tribes' unimpaired inherent sovereignty. This section provides:

> The Passamaquoddy Tribe and the Penobscot Nation are hereby authorized to exercise jurisdiction, separate and distinct from the civil and criminal jurisdiction of the State of Maine, *to the extent authorized by the Maine Implementing Act, and any subsequent amendments thereto.*

25 U.S.C. § 1725(f) (emphasis added). These provisions of MICSA show that the jurisdictional arrangement Congress ratified in MICSA results in an atypical scope for the Southern Tribes' inherent authority. That is because an Indian Tribe's inherent

[6] MIA and MICSA also identify areas of jurisdiction specifically reserved to the Southern Tribes, but those provisions are not relevant to this WQS analysis under the CWA. See e.g. sections 6209-A and 6209-B.

sovereignty typically is not dependent on or subject to definition by state law in the United States, and it requires no affirmative grant of authority from Congress for a Tribe to assert its inherent sovereignty in relation to state law. See *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130, 148 n. 14 (1982) ("[N]either the Tribe's Constitution nor the Federal Constitution is the font of any sovereign power of the Indian tribes."], see also id. at 168 ("Tribal sovereignty is neither derived from nor protected by the Constitution. Indian tribes have, however, retained many of the powers of self-government that they possessed at the time of their incorporation into the United States." (Stevens, J. dissenting; footnote omitted)). But Congress has plenary authority to alter the scope of an Indian tribe's inherent sovereign authority.

Congress understood that MIA had essentially flipped the presumption against state law applying in Indian country, and the wording of section 1725(f) therefore makes sense. Faced with ratifying a state statute that included an aggressive extension of state authority over the Southern Tribes and their territories, using sweeping language creating a presumption that state law applies, Congress was being careful to point out that the Southern Tribes still exercised independent jurisdictional authority for certain purposes under the terms of the MIA. The wording of section 1725(f) is fully consistent when we conclude that internal tribal matters reserved some subset of the Southern Tribes' inherent sovereignty, and that Congress was expressly confirming that residual authority. MICSA, however, also ratifies a substantial grant of authority to the State, which includes adequate authority to establish WQS in waters in Indian lands. Normally, outside Maine, establishing WQS in Indian lands would fall outside state jurisdiction. Here, MIA and MICSA provide that authority to the State.

Consistent with the discussion above regarding the scope and limitations of the internal tribal matters provision, the portion of MICSA's legislative history which specifically speaks to the States' authority to regulate the *environment* in the Southern Tribes' territories is direct and compelling. Most notably, when discussing the specific section of MICSA that ratifies MIA's jurisdictional arrangement for the Southern Tribes, the Senate Report concludes:

> . . . State law, including but not limited to laws regulating land use or management, conservation and environmental protection, are fully applicable as provided in this Section and Section 6204 of the Maine Implementing Act. That the regulation of land or natural resources may diminish or restrict maximization of income or value is not considered a financial encumbrance and is not barred from application under this Act.

S. Rep. at 27(emphasis added).

The only other place in the Congressional Committee Reports that speaks directly to regulation by the State of environmental matters in Indian lands is the discussion of the first savings clause in MICSA, section 1725(h). This provision makes federal Indian law up to 1980 generally applicable in Maine, but only if that law does not affect or preempt state jurisdiction:

> Except as other wise [sic] provided in this subchapter, the laws and regulations of the United States which are generally applicable to Indians, Indian nations, or tribes or bands of Indians or to lands owned by or held in trust for [them] shall be applicable in the State of Maine, except that no law or regulation of the United States (1) which accords or relates to a special status or right of or to any Indian, Indian nation, tribe or band of Indians, Indian lands, Indian reservations, Indian country, Indian territory or land held in trust for Indians, and also (2) which affects or preempts the civil, criminal, or regulatory jurisdiction of the State of Maine, including, without limitation, laws of the State relating to land use or environmental matters, shall apply within the State.

25 U.S.C. § 1725(h)(emphasis added). This provision does not control what jurisdiction Maine received under MICSA; it simply protects the jurisdiction granted to the State elsewhere in MICSA from inadvertent intrusion by general federal Indian law. As a structural matter, however, it is notable that Congress specifically identified "environmental matters" as an area of state law to be protected, strongly supporting our conclusion that environmental regulation was included in the grant of authority to the State. The Senate Report confirms this conclusion:

> It is also the intent of this subsection, however, to provide that federal laws according special status or rights to Indian [sic] or Indian Tribes would not apply within Maine if they conflict with the general civil, criminal, or regulatory laws or regulations of the State. Thus, for example, although the federal Clean Air Act, 42 U.S.C. § 7474, accords special rights to Indian Tribes and Indian lands, such rights will not apply in Maine because otherwise they would interfere with State air quality laws which will be applicable to the lands held by or for the benefit of the Maine Tribes. This would also be true of police power laws on such matters as safety, public health, environmental regulations or land use.

S. Rep. at 31; see also H.R. Rep. at 29. This passage makes it very clear that Congress understood it was making state environmental law applicable to Indian lands.

As noted earlier, the First Circuit's precedent interpreting MIA and MICSA is consistent with Congress' intent to make Maine environmental law apply to Indian lands. And establishing WQS is, in character, much more akin to discharging pollutants into navigable waters than it is to such matters as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property.

First Circuit precedent interpreting MIA's and MICSA's internal tribal matters provision, including an analysis of the *Akins* and *Fellencer* factors

In its decision in *Maine* v. *Johnson*, the First Circuit squarely addressed the "internal tribal matters" provision in MIA, ratified by MICSA. In *Maine* v. *Johnson,* the Court noted that its decisions in *Akins* and *Fellencer* were the only two in which the Court had

directly construed the phrase "internal tribal matters" as applied to the Maine Tribes. The Court clearly distinguished both of those prior cases from the CWA NPDES program case before it, noting, among other things, that in each of *Akins* and *Fellencer*, the State disclaimed any interest in regulation or superintendence over the activities in question. The Court noted further that the Settlement Act's jurisdictional provisions clearly affirmed Maine's asserted power in the context of regulating discharges of pollutants into navigable waters, even for facilities located on tribal lands discharging into tribal waters. The Court stated that "[i]f the internal affairs exemption negated so specific a ground of state authority, it is hard to see what would be left of the compromise restoration of Maine's jurisdiction." *Maine* v. *Johnson,* at 45. The Court subsequently noted that "[i]n our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies," finding that discharging pollutants into navigable waters is not of the same character as the enumerated examples of internal tribal matters contained in the MIA. *Id.* At 46. The Court clearly rejected EPA's use of the "balancing test" that the Agency stated was consistent with the Court's analysis in *Akins* and *Fellencer*, noting that "discharging pollutants into navigable waters is not a borderline case in which balancing . . . or ambiguity canons . . . can alter the result." *Id.* At 46.

As noted above, in *Maine* v. *Johnson* the First Circuit suggested that EPA's application of the balancing factors and method of analysis derived from *Akins* and *Fellencer* was misplaced in an area of regulatory authority so clearly reserved to the State under MIA and MICSA. It therefore behooves EPA first to ask the question whether the facts and surrounding circumstances pertinent to Maine's WQS submissions are more akin to the circumstances present in *Maine v Johnson* or to those present in *Akins* and *Fellencer*. That is, is Maine's request to apply its WQS to waters within Indian lands clearly within its regulatory authority under MIA and MICSA in the way that the Court in *Maine v. Johnson* viewed regulating discharges of pollutants into navigable waters (where Maine expressed a strong interest in doing so)? Or does the WQS context before EPA now involve circumstances and relative tribal and state interests more akin to a dispute over whether non-tribal members have timber rights in Indian territory (where the State had disclaimed an interest in regulating the issue), or to a situation in which a tribe wanted the ability and right to determine who, as between a tribal member and non-tribal member, could work as a community nurse (and where the State disclaimed any interest in applying its anti-discrimination laws to that decision)?

Upon examination, the factual circumstances and relative tribal and state interests presented by Maine's establishment of WQS in tribal waters are clearly are more analogous and pertinent to those at issue in *Maine v. Johnson* than they are to those in *Akins* and *Fellencer*. Maine's WQS program falls within a broad area of environmental regulation; Maine has expressed a strong desire to exercise regulatory authority in this area; and there potentially would be non-trivial impacts on non-tribal members outside of tribal lands were EPA to find that MIA and MICSA preclude Maine from applying its WQS in waters in Indian land. Following the First Circuit's reasoning then, it would not even be appropriate for EPA to apply the balancing factors from *Akins* and *Fellencer* to determine whether Maine has jurisdiction to establish WQS for waters in Indian lands.

The Court found that the circumstances present in *Akins* and *Fellencer* were much closer legal questions as to whether the internal tribal matters provisions of MIA and MICSA applied, as compared to whether those provisions applied to the question whether Maine had authority to implement an NPDES program in Indian lands. Two critical factors that informed the Court's holding were the potential effects of a tribal NPDES program on non-members outside of Indian territories and the State's strongly expressed desire to implement such program itself throughout the State, including in waters within Indian lands. The Court's holding is consistent with the idea that the jurisdictional provisions of MICSA establish a presumption that Maine was provided with regulatory authority over a particular activity absent a finding that the internal tribal matter exception applied (and absent a showing that other explicitly reserved areas of tribal jurisdiction, clearly not relevant to the WQS context, applied).

Thus, the Penobscot Nation's use in its public comments of the *Akins* and *Fellencer* balancing factors as a basis of its jurisdictional analysis would be rejected by the First Circuit. Of central importance to the First Circuit's analysis of the internal tribal matters provision in MICSA is that its scope is *not* defined by the idea that the concept is intended to cover any and all matters that a sovereign government would typically have authority to regulate, but, rather, under MIA and MICSA the *character* of the activity at issue must be so internal to *tribal* government that it does not impact the State's authority in a way that affects non-tribal members or that is contrary to the State's interest in exercising its authority consistent with the atypical allocation of state jurisdiction under MIA and MICSA. At bottom, it is hard to discern how, given the potential effects of a tribal CWA WQS program on non-member upstream dischargers and on the application of State law, in an area of regulation where the State has expressed a strong desire that its standards apply throughout the State, that the First Circuit would decide that Maine did not have adequate jurisdiction to set WQS for waters in Indian lands. See EPA's Decision Support Document for additional discussion.

A direct comparison of the various factors, dynamics, and impacts described above in relation to a WQS program, with the factors considered by the First Circuit in its decision that Maine has jurisdiction under MIA and MICSA to issue NPDES permits to tribally-owned facilities located on tribal land and which discharge only to tribal waters, compels a legal conclusion that Maine has jurisdiction to establish WQS in waters within Indian lands. As discussed elsewhere in this document and in EPA's Decision Support Document, however, the State's authority and discretion to set such standards is not unbounded and must still comply with CWA requirements, including those that would protect the designated use of sustenance fishing in waters in Indian lands.

Nonetheless, EPA would like to respond fully and comprehensively to the Penobscot Nation's comments. Consequently, EPA provides below specific responses to the Penobscot Nation's internal tribal matters argument, even though the logic of the First Circuit's analysis in *Maine v. Johnson* suggests that these factors are not appropriately applied to the facts presented by Maine's WQS submission.

Before delving into the specifics of the Penobscot Nation's comments on this issue, we note that federal Indian common law plays a limited role in our interpretation of the internal tribal matters exception. The First Circuit has stated that:

> We stress that we do not read the reference by Congress to Santa Clara Pueblo in the legislative history of the Settlement Act as invoking all of prior Indian law . . . . But we also do not agree that reference to such law is never helpful in defining what is an internal tribal matter. Congress was explicitly aware of such law, and explicitly made existing general federal Indian law applicable to the Penobscot Nation in the Settlement Act. In other areas, courts have long presumed that Congress acts against the background of prior law.

Akins, at 489. Insofar as federal Indian common law provides insight into the sorts of activities that Congress and the courts considered to be matters of inherent tribal sovereignty, and thus what rights Congress may have reserved under the settlement acts, it is a useful aid for determining whether water quality regulation is an internal tribal matter. The First Circuit directs us to examine that common law. The court does say that federal Indian common law defines the scope of internal tribal matters. The internal tribal matter exception under MICSA is essentially a reservation of some elements of inherent tribal sovereignty. *Akins*, at 489. Therefore, in order to qualify as an internal tribal matter, an activity must, as a threshold matter, qualify as a matter of inherent tribal sovereignty. However, concluding that a matter would be treated as part of a tribe's inherent tribal sovereignty under federal Indian common law does not end the inquiry. The First Circuit then provides us a series of factors to determine whether the issue or activity is an internal tribal matter under MICSA.

EPA's responses to the Penobscot Nation's *Akins* and *Fellencer* factors analysis

Factors:

a. Does the activity regulate only tribal members?

Tribal comment: There would only be an indirect effect on non-tribal members. Non-tribal members are not being regulated directly.

EPA's response:

To the extent that the *Akins* and *Fellencer* balancing factors are analyzed, the degree to which an activity may affect non-tribal members has been a primary consideration for the First Circuit. A finding that Maine does not have authority to establish WQS for waters in Indian lands, and the corresponding finding that the Maine Indian Tribes do have that authority for those waters, could have a non-trivial effect on non-member facilities in Maine subject to effluent limitations in NPDES permits that must ensure compliance with WQS. *See*, e.g., *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996), *cert. denied*, 522 U.S. 965 (1997). In *City of Albuquerque v. Browner*, the City of Albuquerque challenged EPA's approval of the Isleta Pueblo's water quality standards on

a number of grounds, including that certain of the Tribe's standards were allegedly unattainable because they were too stringent, and would have an adverse effect on an upstream discharger located outside of Indian Country. The Tenth Circuit upheld the district court's opinion affirming EPA's approval of the Tribe's WQS. Under the First Circuit's analysis in *Akins* and *Fellencer*, the *potential* for impacts on non-members of a tribal CWA WQS program weighs heavily against finding that Maine does not have authority under MIA and MICSA to establish WQS in waters in Indian lands under the concept of internal tribal matters.

b. Does the activity relate to lands that define the Tribes' territories, particularly to the commercial use of tribal lands?

Tribal comment: The matter at hand concerns the harvesting or deriving of value from tribal resources.

The second factor in the *Akins* and *Fellencer* analysis concerns a tribe's ability to decide how to use its own resources to protect the interests of its members. The First Circuit found that the Tribe's decisions regarding commercial use of "the very land that defines the territory of the Nation" fell within the realm of internal tribal matters. Id. at 487, 488. This factor is not necessarily limited to commercial use of land, however. Rather, it has to do with resources within the tribe's territory that have a direct effect on tribal well-being. In *Fellencer*, the court analogized control of natural resources on tribal land to control of human resources on tribal land. *Fellencer*, 164 F.3d at 710. The particular "human resource" at issue was a community nurse who was not a tribal member, but who practiced on the Penobscot reservation serving tribal members, and whose practice had a direct effect on the health of tribal members. In this case, the court recognized that "Indian tribes may 'retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the ... health or welfare of the tribe.' " Id., quoting *Montana v. United States*, 450 U.S. at 566.

Fellencer confirms that in order to protect tribal health and welfare, tribes may control activities of non-members *within* Indian territory. However, tribes do not generally have authority to control such activities outside of Indian territory. *Montana v. United States*, 450 U.S. at 565-66. Here, many of the waters in question, *e.g.*, the Penobscot River, and the fish in those waters, are resources used by Maine, its citizens, and the Maine Tribes. The First Circuit's holdings in *Akins* and *Fellencer* do not provide EPA with any grounds to deny the state jurisdiction over setting WQS in any waters within Indian lands, and even more certainly not for waters and resources that are used by tribal and non-tribal members. Again, however, it is important to note that notwithstanding Maine's jurisdictional authority, EPA has the authority under the CWA to protect the Maine Tribes' sustenance fishing practices provided for under the settlement acts by ensuring that WQS applicable to waters in Indian lands protect the quality of water necessary to support those sustenance fishing practices.

c. Does the activity affect the Tribes' ability to regulate their natural resources?

Tribal comment: The matter concerns the regulation or conservation of tribal resources.

EPA's response

The First Circuit has held that an activity predominantly affecting a tribe's ability to control the use of its own resources is likely to be an internal tribal matter. *Akins* in particular examined an example of natural resource regulation, stumpage permits, which it determined was an internal tribal matter. However, the *Akins* holding is a narrow one. Under *Akins*, the test is not whether the assertion of state law interferes with the tribe's regulation of its natural resources, but whether the assertion of *tribal authority* over such resources interferes with *state* regulation. The court emphasized that "[b]y its own terms, the Implementing Act, § 6204, makes State laws regulating land use or management, conservation and environmental protection applicable to tribal lands. The absence of an assertion that any such [State] laws are involved here is telling." *Akins*, 130 F.3d at 488. The deciding element in the court's analysis of this factor seems to be that the stumpage permit system, "involving tribal lands, appears to have no significant impact on Maine's environmental or other interests." Id.

Also important in the First Circuit's consideration was the geographic component of inherent tribal sovereignty. Id. at 489. The court determined that timber permitting qualified as an internal tribal matter in part because "the policy concerns the harvesting of a natural resource from [land that defines Indian territory]." Id. at 487. The timber subject to the disputed permitting system was located entirely on the Penobscot Nation's territory. Because the resource was confined to Indian territory, the associated permitting system did not impair the State's ability to regulate its own natural resources.

The issue we face today is vastly more complicated than in *Akins* because many of the rivers and streams that are tribal waters flow through and touch both tribal and non-tribal lands. In addition, the WQS regulations at issue involve potential impacts to discharging facilities that operate inside and outside Indian territories. Following the First Circuit's analysis of MICSA, EPA begins with the assumption that the State's laws are generally applicable in all waters. See 25 U.S.C. § 1725(b)(1). Certain activities may be excluded from state regulation as internal tribal matters, but the general presumption is that state laws apply to all water bodies in Maine.

Based on this factor, the State has clear jurisdiction to establish WQS that may have the potential to affect the effluent limitations contained in NPDES permits issued to facilities that are largely located and operate outside of tribal territories and, under the reasoning in

Maine v. Johnson, even to sources that are on tribal lands and owned by tribal members and which have no measurable impact on non-members.[7]

d. Does the activity implicate or impair an interest of the State of Maine?

Tribal comment: The State's only interest in establishing WQS is in subverting sustenance fishing.

EPA response

Another important factor in the First Circuit's prior consideration of internal tribal matters was whether the State had asserted any interest in regulating the matter at issue. The *Akins* court noted at the outset that "[t]his is not a dispute between Maine and the Nation over the attempted enforcement of Maine's laws" and that the tribe's regulation of its own timber resources was "not of central concern to ... Maine." *Akins*, at 487, 488. In *Fellencer*, the court clarified that a general state interest in regulating a matter such as employment discrimination was not sufficient to remove the matter from the scope of internal tribal matters. But because the State expressly disavowed an interest in regulating *tribal* governmental employment decisions, the court found that tribal regulation of its own employees did not impair any *state* interest. *Fellencer*, at 710-11.

In its WQS submission, Maine has vigorously asserted its interest in regulating water quality throughout the State, including within waters located in Indian lands. That is a very different dynamic between the State and the Indian Tribes than the one that existed in the *Fellencer* and *Akins* disputes. Id., *Akins*, 130 F.3d at 488 ("This is ... a question of allocation of jurisdiction among different fora and allocation of substantive law to a dispute between tribal members where neither the Congress nor the Maine Legislature has expressed a particular interest."). In *Maine v. Johnson*, 498 F.3d 37, 45, the First Circuit stated:

> In both those cases, unlike this case, Maine disclaimed any interest in regulation or superintendence. *Akins*, 130 F.3d at 488; *Fellencer*, 164 F.3d at 710-11. By contrast, in the present case, Maine affirmatively asserts authority as to both tribal and non-tribal land to regulate discharges into navigable waters. The Settlement Act provisions just quoted affirm that power. If the internal affairs exemption negated so specific a ground of state authority, it is hard to see what would be left of the compromise restoration of Maine's jurisdiction.

[7] As discussed below, EPA is requiring the State to consider impacts on tribal resources and amend its WQS accordingly. However, the State is not required to cede regulatory authority simply because its activities have an impact on tribal resources.

e. Is defining the activity as an "internal tribal matter" consistent with prior legal understandings?

Tribal comment: Under federal Indian common law principles, the matter at hand involves the inherent authority of an Indian tribe, which must be free from undermining by a state.

EPA's response:

As explained earlier, Maine's jurisdiction to establish WQS in Indian lands is consistent with the First Circuit's analysis of MIA and MICSA and its holdings in *Maine v. Johnson, Akins* and *Fellencer* and, to the extent applicable given MIA and MICSA's unique jurisdictional arrangement, other federal Indian common law.

In order to understand the internal tribal matters exception, we must recognize that MICSA, while legislated against the backdrop of federal Indian common law, altered the operation of that common law in Maine. Under federal Indian common law, Indian tribes may have a paramount interest in regulating their own water quality that supersedes that of the state in which the tribes' territory is located. However, as discussed earlier and below, federal Indian common law may aid us in interpreting MICSA but cannot change the statute's general provision for state jurisdiction over natural resources. We must look carefully at what Congress and the courts have said regarding the extent of the internal tribal matters exception to state jurisdiction.

Following the First Circuit's example, we look first to the legislative history of MICSA, and then to federal Indian common law for prior legal understandings of internal tribal matters. As mentioned earlier, we rely largely on the Senate Report, which the House Report "accepts as its own" in part. H.R. Rep. at 20; *Garcia v. United States*, 469 U.S. 70, 76 (1984) (committee reports are an authoritative source for determining legislative consent), cited by *Akins*, at 489. The few references that the Senate Report makes to natural resource regulation are telling. In its discussion of the application of state environmental law under section 1725(b)(1), the provision of MICSA ratifying the MIA and its jurisdictional provisions, the Senate Report states:

> State law, including but not limited to laws regulating land use or management, conservation and environmental protection, are fully applicable as provided in this Section and Section 6204 of the Maine Implementing Act. That the regulation of land or natural resources may diminish or restrict maximization of income or value is not considered a financial encumbrance and is not barred from application under this Act.

S. Rep. at 27.

In addition, when explaining the operation of the savings clauses discussed earlier, the Senate Report provides a specific example of a federal environmental law that would be

excluded from operating in Maine Indian Country to avoid interfering with state environmental law. Although the example in this passage focuses on the provision in the Clean Air Act that allows Indian tribes to redesignate their lands to a new air quality classification under the prevention of significant deterioration (PSD) air permitting program, the passage ends by emphasizing that this exclusion would also operate more generally as to "police power laws on such matters as . . . environmental regulation."

> It is also the intent of this subsection, however, to provide that federal laws according special status or rights to Indian [sic] or Indian Tribes would not apply within Maine if they conflict with the general civil, criminal, or regulatory laws or regulations of the State. Thus, for example, although the federal Clean Air Act, 42 U.S.C. § 7474, accords special rights to Indian Tribes and Indian lands, such rights will not apply in Maine because otherwise they would interfere with State air quality laws which will be applicable to the lands held by or for the benefit of the Maine Tribes. This would also be true of police power laws on such matters as safety, public health, environmental regulations or land use.

S. Rep. at 31; see also H.R. Rep. at 29. In addition, this passage makes clear that Congress was not limiting the application of federal Indian law in Maine solely to avoid any interference with state environmental regulation as it applies to lands outside Indian territories. The report specifically discusses Congress's intent to protect the application of state air quality laws which will be applicable to land held "for the benefit of the Maine Tribes." Again, this discussion would be pointless if Congress did not specifically intend to make state environmental regulation applicable in the Southern Tribes' territory.

This passage in MICSA's legislative history is telling in the context of analyzing the State's authority to set WQS under the CWA. The Clean Air Act provision cited by the Senate report refers to the authority tribes have outside Maine to redesignate the air quality classification for their territory so that PSD permits for upwind facilities must include emission limits that protect the air quality consistent with the tribe's chosen classification of its territory. This example is strikingly similar to the function of the WQS program in the context of the CWA. Both programs involve the authority of non-federal sovereigns to determine the level of environmental quality that must be maintained within their territories, and that determination has the effect of controlling the content of permits issued to facilities that might impact those territories. Indeed, the "Area Redesignation" provisions in section 164 of the Clean Air Act are about as direct a cognate to the WQS program in the CWA as one could find in federal environmental law. It is reasonable then, for EPA to conclude, that Congress intended its grant of jurisdiction to the State to include a program like the CWA WQS.

Our inquiry does not end here. *Akins* opens the possibility that even in the area of natural resource regulation, activities may fit within the internal tribal matters exception and be free of state regulation. Here we turn to the federal Indian common law to help us define the contours of inherent tribal sovereignty, which in turn form the basis for internal tribal matters. The analysis of federal Indian common law in *Akins* draws a clear distinction

between inherent tribal authority over the activities of members and non-members. Tribes generally have authority over their own members. In some circumstances, federal Indian common law has found that tribal authority extends to non-member conduct on tribal territory, but not to non-member conduct outside of tribal territory. See *Akins*, at 490. MICSA constricted the common law understanding of inherent tribal sovereignty by establishing the general presumption that state law applies even within tribal territories. 33 U.S.C. § 1725(b)(1). Therefore, the fact that an activity takes place on or off reservation no longer answers the question. Instead, the relative involvement of tribal members and non-members becomes decisive.

Of course, *Akins* and *Fellencer* themselves form part of our prior legal understanding of internal tribal matters. However, these cases provide little more than an analytical framework for considering the issue. Neither case offers a definitive interpretation of the scope of internal tribal matters. To the contrary, the First Circuit emphasized that "[w]e tread cautiously and write narrowly, for the problems and conflicting interests presented by this case will not be the same as the problems and interests presented in the next case." *Akins*, 130 F.3d at 487. *Akins*, while recognizing one example of natural resource regulation as an internal tribal matter, was narrowly drawn to address only stumpage permits where state legal requirements were not at issue. Overall, *Fellencer* went somewhat further in addressing impacts on non-members, holding that a tribe could regulate the activities of a non-member who was acting on tribal territory, serving tribal members, and whose activities had a direct impact on tribal health and welfare. It is tempting to read these cases together to say that natural resource management decisions having a direct impact on tribal health and welfare are an internal tribal matter. But these holdings, as discussed earlier, are not so broad. *Akins* emphasized that tribal authority extended to activities of tribal members, and in some case non-members, *within* tribal territory. *Akins*, 130 F.3d at 489. *Fellencer* relied heavily on its understanding of employment discrimination law as a major source of support for its decision that tribal employment decisions are internal tribal matters. The law surrounding the employment issue indicated quite clearly that tribal governmental employment decisions were retained as an element of inherent tribal sovereignty under MICSA.

Although the situation outside Maine may be quite different, under MICSA EPA has concluded that establishing WQS in Indian water in Indian lands in Maine is not an internal tribal matter. Tribal comments have suggested that under *Fellencer*, tribes may regulate non-member activities that have a direct effect on tribal health and welfare. This reading, however, stretches the First Circuit's decision far past its boundaries. In finding that the Tribe could exercise authority over a non-member to protect tribal health and welfare, the *Fellencer* court emphasized the minimal effects on non-members versus the significant effect on tribal members, as well as the clear statutory basis for the Tribe's control over its governmental employment decision. Here, tribal WQS under the CWA potentially could impact non-tribal members. EPA cannot extend the results of these cases to such vastly different circumstances, particularly when the reasoning of the cases counsels us to do the opposite.

Tribal government as an element of internal tribal matters, including establishing cancer risk levels and fish consumption rates as a matter of tribal policy judgments.

The Tribes argue that establishing cancer risk levels and fish consumption rates are matters of tribal government policy that are part of a distinctly governmental function, that of establishing WQS under the CWA. The Tribes assert that this should lead EPA to conclude that as a legal matter Maine does not have jurisdictional authority to set such standards.

EPA's response

EPA agrees that Maine's fishing designated uses and the Northern and Southern Tribes' trust land and reservation land sustenance fishing practices require adequate protection under the CWA. However, that fact, as important as it is to the Tribes' physical, spiritual and cultural existence, does not alter the jurisdictional framework embodied in the settlement acts. Those vital interests and cultural practices of the Tribes, as critical elements of their survival and well-being may still be protected to the extent authorized under the CWA, and EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands demonstrates that very important point. As the First Circuit has stated, not every matter that might fall within the notion of a governmental function necessarily constitutes an internal tribal matter under MIA and MICSA. "That a tribe attempts to govern a matter does not render it an internal tribal matter." *Akins* at 486.

We agree with the comments from the Tribes' advocates that water quality regulation is of central importance to these Tribes and is a critical issue in maintaining their culture and way of life. We also understand the Tribes' desire to exercise as direct a control over that water quality as possible. Outside the context of the settlement acts, we agree with the Tribes that water quality management is a core governmental function, and therefore that it should generally be reserved to tribal governments. EPA cannot agree, however, that MIA's reference to "tribal government" as one of the examples of internal tribal matters sweeps into that concept all the attributes generally associated with Indian self-governance outside Maine.

C. Tribes commented that EPA will be unable to protect tribal resources if EPA determines Maine has authority to establish WQS in waters within Indian lands.

EPA's response

Certain comments from the Tribes generally raised concerns about the protection of tribal resources if EPA determines Maine has authority to establish WQS in waters within Indian lands. EPA recognizes that if Maine is the standard-setting authority, the State will have the first opportunity to make the judgment calls involved in implementing the WQS program. However, the State's WQS must still meet CWA requirements, which include establishing water quality criteria that assure uses are protected. As demonstrated

by EPA's decision to disapprove certain of Maine's WQS on the basis that they do not adequately protect tribal sustenance fishing practices, EPA's oversight of the State's program through authority established in the CWA plays an important role in protecting water quality in Indian lands notwithstanding the jurisdictional arrangement established by the settlement acts.

Notwithstanding the Tribes' concerns, the practical realities of how a state's WQS program operates do not suffice as a basis for ignoring the jurisdictional arrangement in the settlement acts. As discussed extensively above, Congress has revised that customary jurisdictional formula in Maine. So, pursuant to the settlement acts and the CWA, EPA must acknowledge that the State has the authority to establish WQS applicable to Indian lands, just as the First Circuit has already determined that Maine has the authority to issue federal NPDES permits in Indian lands.

EPA does not agree that finding Maine has authority to implement the WQS program in Indian lands constitutes some sort of delegation to the State of the trust responsibility. As already explained in this RTC document, EPA has discussed the proper interpretation of the trust responsibility to the Maine Tribes generally, and in this matter specifically. EPA has also explained its continuing role in CWA program oversight, in which the trust plays a role. The Agency's continuing role in program oversight does provide adequate tools under the CWA for protecting the Maine Tribes' interests. But before discussing those oversight mechanisms, it is important to understand the context within which EPA's oversight authority operates and how that relates to MICSA's provisions. There are various provisions in the CWA that assign EPA the task of reviewing a state's decisions in implementing the CWA. The Act expresses this authority in various ways, but essentially EPA is either charged with intervening or provided the opportunity to intervene when state decisions do not comply with the requirements of the CWA.[8]

Maine's comments suggest that MICSA's provisions, especially the savings clauses, prevent EPA from exercising its CWA oversight authorities on behalf of the Tribes consistent with the trust responsibility. In EPA's view, Maine inaccurately characterizes EPA's oversight in this matter as "apply[ing] heightened scrutiny to Maine's WQS before approving them as to Indian Territory." See page 10 of Maine's September 13, 2013 WQS comments. EPA is not applying heightened scrutiny to Maine's WQS, but rather is exercising its responsibility as required under the CWA, and consistent with the settlement acts, to protect the Maine Tribes' sustenance fishing practices. See EPA's Decision Support Document. In so doing, EPA is at the same time acting consistently with the trust responsibility to the Tribes. The implication embedded within Maine's comment is that such a decision by EPA would accord the Tribes a special status and that intervening in a state regulatory decision under the CWA would affect or preempt the

[8] See e.g., 33 U.S.C. § 1342(d)(2)(when objecting to a proposed State NPDES permit, EPA shall provide a State with "a statement of the reasons for such objection and the effluent limitations and conditions which such permit would include if it were issued by the Administrator") and 40 CFR 123.44(c), or 33 U.S.C. § 1313(c)(4)(B)(EPA shall promulgate a water quality standard "if a revised or new water quality standard submitted by such State . . . is determined by the Administrator not to be consistent with the applicable requirements of this chapter").

State's jurisdiction to make that decision, which would run afoul of MIA and MICSA. Ultimately, the CWA establishes EPA's relevant authority, which EPA is exercising consistent with the federal trust responsibility. 33 U.S.C. §1251 et. seq. As mentioned before, MIA, in 30 M.R.S.A. Section 6207(4), reserves for the Penobscot Nation and the Passamaquoddy Tribe a right to take fish for their individual sustenance within their reservations. MICSA, in 25 U.S.C. Section 1724(h), reserves for these Indians the right to manage their natural resources. The CWA specifically gives EPA the authority to administer the statute to protect surface waters. 33 U.S.C. § 1251 et. seq. More specifically, the CWA gives EPA certain authority to oversee state water quality standards to ensure that they adequately protect human health and the environment. 33 U.S.C. § 1313. And EPA is exercising that authority to protect the resource uses that are here of interest to the Tribes -- the sustenance fishing uses of those waters -- consistent with the trust relationship and the requirements of the CWA.

EPA does not agree with Maine's interpretation of the effect of MICSA's savings clauses on the trust, because the Agency's disapproval of Maine's HHC as they would apply to waters within Indian lands is grounded in the requirements of both the CWA and the settlement acts. No state in the nation has "jurisdiction" to establish WQS contrary to the requirements of the CWA, at least in the sense that states cannot do so without running the risk that EPA will disapprove them. Therefore, the savings clauses in MICSA do not shield Maine from EPA's oversight under the CWA when EPA bases its objections on CWA requirements, for such objections do not affect any authority or jurisdiction that Maine has.

D. EPA must protect a broad range of cultural, spiritual, and physical aspects of the Tribes' lifestyles and associated resources. Sustenance fishing touches on all of these aspects of the Tribes' existence and culture.

EPA's response

EPA fully recognizes, respects and appreciates the broad range of cultural, spiritual, and physical aspects of the Tribes' lifestyles and associated resources, and the ways in which a sustenance fishing lifestyle touches on all of these aspects of the Tribes' existence and culture. EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands reflects the extent to which, under the CWA, EPA has the authority to ensure that Maine's WQS adequately protect the Tribes' sustenance fishing practices in relation to the Tribes' fish consumption and therefore their health. EPA notes, however, that notwithstanding EPA's recognition of and respect for the multi-faceted nature of the Tribes' sustenance fishing lifestyle and the various ways in which the Tribes' existence and culture depends on that practice, the focus of EPA's decision to disapprove certain of Maine's WQS in Indian lands necessarily is specific to the physical health-related fish consumption practices of the Tribes. That focus is necessary pursuant to the authority

provided by Congress to EPA under the CWA and the WQS program when human health criteria are established.[9]

However, EPA recognizes that in so protecting the Maine Tribes' sustenance fishing practices, through a focus on human health impacts, other cultural and spiritual aspects of grave importance to the Tribes may also be protected. This does not mean that EPA is overreaching or extending its authority under the CWA; it simply means that there are collateral benefits that arise due to the fact that protecting the Tribes' health through protection of their sustenance fishing practices has implications for other important aspects of their lifestyle and culture.

E. Tribal comment: Maine's regulatory actions and expressed legal positions demonstrate that the Maine Tribes' subsistence practices will not be protected by Maine.

EPA's response

As explained earlier in this RTC document, the accuracy or inaccuracy of factual statements such as this one is not a factor that can affect the jurisdictional arrangement established by the settlement acts. EPA's earlier explanation in this document about its ability and obligation to ensure that the Maine Tribes' sustenance fishing practices are protected under Maine's WQS program shows how the Tribes' concerns about Maine's future intentions are being addressed by EPA in accordance with CWA requirements. See EPA's Decision Support Document for a more detailed discussion.

II. Tribal comment: Even if EPA approves Maine's WQS to apply in waters in Indian Territory, EPA should ensure that the Tribes have a "decisive role in decision-making that affects its waters."

EPA's response

Prior to EPA's decision today to approve and to disapprove certain of Maine's WQS, EPA complied with its obligations to consult with the Maine Indian Tribes about Maine's WQS submissions. EPA carefully considered the Tribes' views, interests, and policy and legal arguments, along with all other pertinent information, including public comments and other sources of information in the administrative record, in reaching its decision to approve and to disapprove certain of Maine's WQS for waters in Indian lands. EPA will continue to act within the confines of the CWA consistent with the trust responsibility in reviewing any future new or revised WQS by Maine that would affect tribal waters and

[9] Tribes have argued that in addition to fishing for their individual consumption, the definition of sustenance traditionally incorporated other components, including but not limited to barter and exchange. Commission Saltwater Fisheries Report, at p. 22-33. EPA is not deciding in its approval and disapproval of certain of Maine's new and revised WQS whether any of these other components, beyond the Tribes' individual consumption of fish, are properly part of the definition of the term "sustenance" as those other components are not, in any event, relevant to development of human heath criteria under the CWA.

uses. EPA will ensure that the Maine Tribes remain involved in any such matters through the government-to-government consultation process EPA is committed to follow.

III. Tribal comment: Even if EPA approves Maine's WQS to apply in waters in Indian Territory EPA should put written procedures in place to moderate between the State and Tribes.

EPA's response

See response to comment immediately above. In addition, EPA agrees that such written procedures would be very helpful, and EPA is prepared to facilitate discussions among the Maine Tribes and Maine. However, EPA notes that there is no legal basis for EPA to *demand* that such written procedures exist as a precondition to the State exercising its jurisdiction to establish WQS in waters in Indian lands.

IV. Tribal comment: EPA must ensure that "designated uses" are protected.

EPA's response

EPA's disapproval of certain of Maine's WQS demonstrates that EPA is fulfilling its CWA obligation to ensure that designated uses under the CWA are protected by water quality criteria. See EPA's Decision Support Document for a detailed discussion and explanation.

V. Tribal comment: A fundamental Congressional purpose in creating the Southern Tribes' reservations was to protect the sustenance fishery.

EPA's response

EPA agrees that a fundamental purpose behind creation of the Southern Tribes' reservations was to protect the sustenance fishery. As discussed earlier in this document, and in greater detail in EPA's Decision Support Document, this Congressional purpose supports EPA's decision to insist on criteria that protect the sustenance fishing rights associated with waters in the Southern Tribes' reservations in Maine. At the same time, however, this Congressional purpose does not function to alter the jurisdictional arrangement among the State, the federal government, and the Maine Tribes, established by Congress in MICSA.

VI. Tribal comment: MICSA sets forth a sustenance fishing right reserved to Southern Tribes (not abrogated by any provisions of MICSA).

EPA's response

EPA agrees that MICSA sets forth a sustenance fishing right reserved to Southern Tribes that has not been abrogated by any provisions of MICSA or any other federal law. As discussed earlier in this document, and in greater detail in EPA's Decision Support Document, this fact supports EPA's decision to insist on criteria that protect the sustenance fishing use associated with the Southern Tribes' reservations. At the same time, however, the sustenance fishing right reserved to the Southern Tribes does not function to alter the jurisdictional arrangement among the State, federal government, and the Maine Tribes, established by Congress in MICSA.

VII. Tribal comment: Maine fails to recognize the Maine Tribes as separate sovereigns, for purposes of downstream water quality protection.

EPA's response

EPA has addressed earlier in this RTC document the question of the sovereign status of the Maine Tribes and the extent to which that factor does or does not play a part in EPA's analysis of whether Maine has jurisdiction to establish WQS in Indian lands and how EPA views the general trust responsibility to the Maine Tribes.

Further, as noted earlier in relation to a similar comment about Maine's interactions with the Maine Tribes, the accuracy of factual statements such as this one is not a factor that can affect the jurisdictional arrangement established by MIA and MICSA. EPA's earlier explanation in this document about its ability and obligation to protect the Maine Tribes' fishing practices under the CWA, as demonstrated by EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands, shows how the Tribes' concerns about Maine's future intentions with regard to their sustenance fishing practices under the CWA are being addressed by EPA in compliance with CWA requirements.

Additionally, any NPDES permits issued by Maine must ensure adequate protection of WQS that may apply in tribal waters. Thus, if Maine or EPA were to promulgate more stringent WQS applicable to waters in Indian lands in Maine, in response to EPA's disapproval of Maine's HHC, any NPDES permits issued by Maine must ensure adequate protection of such WQS.

VIII. Maine's comments (not already responded to earlier in this RTC document).

1. **Maine's comment: Under the operative statutes Maine has authority and responsibility to establish WQS for all state waters, including waters near or within Indian territories.**

EPA's response

EPA's letter to Maine in response to its WQS submissions indicates that EPA agrees that Maine has adequate legal authority to establish WQS for all state waters, including waters in Indian lands. See EPA's Decision Support Document for a more detailed discussion.

2. **Maine's comment: The applicable statutes don't permit EPA or the Tribes to establish WQS in the State's stead.**

EPA's response

Today, EPA is affirming that Maine has the legal authority to set WQS for waters in Indian lands. Maine's assertion that the Tribes and EPA do not have the legal authority to establish such standards instead of Maine no longer is pertinent given EPA's determination that Maine has such authority. However, if Maine does not address in a timely manner under the CWA the WQS deficiencies EPA's decision letter has identified, the CWA *requires* EPA to promulgate such standards in the State's stead. Furthermore, as noted earlier in this RTC document in relation to Maine's assertion that the Maine Indian Tribes are not eligible for TAS status under CWA section 518, EPA's decision is not addressing whether the Tribes separately have such authority.

3. **Maine's comment: EPA must make a formal finding that the State lacks jurisdiction before it can assert federal jurisdiction, which EPA cannot do under MIA and MICSA and *Maine v. Johnson*.**

EPA's response

Today, EPA is affirming that Maine has such legal authority but has found that certain of Maine's WQS are not approvable under the CWA. In addition, Maine's assertion that EPA does not have the legal authority at this time to establish such standards is no longer pertinent given EPA's determination that Maine has such authority. However, if Maine does not address in a timely manner under the CWA the WQS deficiencies EPA's decision letter has identified, the CWA *requires* EPA to promulgate such standards in the State's stead.

4. **Maine's comment: EPA approved many WQS submissions, some including in the Penobscot River, without mentioning jurisdictional issues, and also approved designated uses that do not mention anything about tribal interests or sustenance fishing. EPA's NPDES record belies EPA's own legal position.**

EPA's response

See EPA's Decision Support Document for a partial response to and discussion of the issues raised by this comment.

In addition, as of 2004, EPA's letters to Maine responding to the State's proposed new and revised water quality standards expressly stated that EPA's decision to approve or disapprove did not apply to waters within Indian Country. Consequently, there would not have been a reason for EPA to address in those letters tribal interests in waters in Indian lands, including sustenance fishing. Moreover, the fact that ME DEP may have issued NPDES permits to facilities that discharged directly or indirectly into the Penobscot River, and that EPA may not have offered any comments about those permits, does not constitute an acknowledgment by EPA that Maine's WQS had been approved by EPA to apply in waters in Indian lands.

As to NPDES permits that EPA issued to the Penobscot Nation's POTW, EPA included language that indicated, not that Maine's WQS directly applied to such discharges as a legal matter, but that as a practical matter Maine's WQS provided some guidance as to how the NPDES permit's effluent limits for pollutants should be written or determined. When EPA recited that those permits met Maine WQS that applied "in the proximity" of the discharge, the Agency very consciously used a formulation that did not recite that Maine's WQS applied at the point of discharge. Basically, EPA looked to the nearest approved WQS as guidance for the discharge limits in those permits. The State's WQS approved outside Indian lands provided that guidance. In the absence of federal, state or Indian WQS applicable under the CWA at the point of discharge, this course of action makes abundant practical sense.

5. **Maine's comment: The State has asked EPA to explain its legal basis for not applying State WQS in Indian Territory and EPA has never responded.**

EPA's response

Whether or not the State's comment is accurate is no longer a relevant point because EPA's decision today has answered that question. In addition, EPA notes that a lack of a response before its decision today would, in any event, not be able to affect the outcome of a legal analysis dictated by the settlement acts and the CWA.

6. **Maine's comment: The "trust responsibility" only applies to trust lands, not reservation lands in Maine (which are not held in trust).**

EPA's response

See discussion above beginning at page 11.

7. **Maine's comment: MICSA's savings clauses render the "the trust obligation" inapplicable in Maine.**

EPA's response

See discussion above beginning at page 38.

8. **Maine's comment: Indian Tribes in Maine are not eligible for TAS status under CWA Section 518.**

EPA's response

See discussion above beginning at page 15.

9. **Maine's comment: Maine asserts that there is no basis for EPA to treat waters within Indian territories any differently than the waters in Maine outside of Indian territories.**

EPA's response

EPA's Decision Support Document demonstrates the inaccuracy of Maine's comment and discusses in detail the reasons why EPA has determined that there is a significant difference between such waters and their uses for purposes of the CWA.

10. **Maine's comment: EPA's current review is unlawful and unnecessary.**

    a. **Statute gives EPA 90 days to act and require changes to submitted WQS. EPA did not require changes within 90 days, so EPA cannot require changes now.**

EPA's response

EPA disagrees with Maine's reading of the CWA provisions at issue. As described by the United States Department of Justice in legal pleadings filed in Maine's case filed against EPA, State of Maine, et. al. v. McCarthy et. al., Civil Action No. 1:14cv264, (United States District Court for the District of Maine 2014), no provision of the CWA or its implementing regulations preclude EPA from disapproving a state's WQS on the basis that EPA did not inform such state within 90 days of its WQS submission to EPA that

changes to the state's proposed WQS are necessary. The following description of the relevant CWA authorities sets forth the correct sequence of events in relation to a state's WQS submission and EPA's review.

States must hold public hearings for the purpose of reviewing their WQS, and, as appropriate, modifying and adopting standards, at least once every three years beginning with October 18, 1972. 33 U.S.C. § 1313(c)(1). This review and revision process is commonly referred to as the triennial review process. Any new or revised WQS adopted by a state must be submitted to EPA for a determination of whether it meets the CWA's requirements. 33 U.S.C. § 1313(c)(1) and (3); 40 C.F.R. §§ 131.5, 131.6 and 131.20. EPA's review of such WQS involves the application of EPA's legal, scientific and policy expertise. *See* 40 C.F.R. § 131.5. If EPA determines that the new or revised WQS is consistent with the CWA, then EPA shall so notify the relevant state within 60 days from the date of submission. 33 U.S.C. § 1313(c)(3); 40 C.F.R. § 131.21(a)(1).

If EPA determines that the new or revised WQS is not consistent with the CWA, EPA shall notify the state within 90 days from the date the WQS is submitted that it is disapproved, and must specify necessary changes. 33 U.S.C. § 1313(c)(3); 40 C.F.R. § 131.21(a)(2). If the state then fails to adopt the specified changes within 90 days of EPA's notice, EPA must "promptly" propose a federal WQS for the waters involved. 33 U.S.C. § 1313(c)(4)(A); 40 C.F.R. § 131.22(a). Then, unless the state revises its WQS and EPA approves that revision, EPA must proceed to promulgate the WQS itself. 33 U.S.C. § 1313(c)(4)(A).

In the context of its CWA citizen suit claim, Maine asserted that EPA has waived its authority to disapprove Maine's outstanding WQS, that EPA is barred from disapproving such WQS, and that EPA is required to approve such WQS, apparently on the theory that EPA loses its authority to disapprove WQS when it misses the statutory deadline to do so. Congress provided EPA with authority to approve or disapprove new or revised WQS regardless of whether EPA has met the statutory deadline for doing so under CWA section 303(c)(3).
As discussed above, new and revised WQS must be submitted to EPA for review. 33 U.S.C. § 1313(c)(2)(A). *If* EPA determines that the new or revised WQS meets the requirements of the CWA, EPA shall approve the WQS within 60 days. *Id.* at § 1313(c)(3). *If* EPA determines that the new or revised WQS is not consistent with the requirements of the CWA, EPA shall within 90 days of submission disapprove the WQS and specify necessary changes. *Id.* "On its face, this language plainly supports . . . that Congress did not intend new or revised state standards to be effective until after EPA had reviewed and approved them." *Alaska Clean Water Alliance v. Clarke*, 1997 WL 446499 * 3 (W.D. Wash. July 8, 1997). Indeed, the CWA does not even remotely suggest that Congress intended for EPA to lose its authority to approve or disapprove a WQS, or that the WQS must automatically be deemed approved, if EPA fails to act by the 60 or 90-day statutory deadlines. *See* 33 U.S.C. § 1313(c)(2)(A); *United States v. James Daniel Good Real Property*, 510 U.S. 43, 63 (1993) ("[I]f a statute does not specify a consequence for noncompliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction.").

Moreover, to the extent the CWA is ambiguous on this point, EPA has explained in the context of a CWA rulemaking that "the concept of a default approval of state and tribal WQS submissions is not consistent with section 303 of the CWA [because] [s]ection 303(c)(3) requires EPA to make an affirmative finding that the standards revisions submitted to EPA are consistent with the CWA." 65 Fed. Reg. 24,641, 24,646 (Apr. 27, 2000). EPA's interpretation of CWA section 303(c) as not providing for automatic approvals or disapprovals of WQS if EPA does not act within the 60 or 90 day windows of that section is entitled to deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). In addition, Congress has expressly provided a remedy when EPA fails to timely respond to a WQS submission. The CWA citizen suit provision provides the district courts with jurisdiction to order EPA to perform its mandatory duty to approve or disapprove a new or revised WQS when EPA has failed to timely respond. 33 U.S.C. § 1365(a). As the Supreme Court has explained, "[w]hen, as here, there are less drastic remedies available for failure to meet a statutory deadline, courts should not assume that Congress intended the agency to lose its power to act." *Brock v. Pierce County*, 476 U.S. 253, 260 (1986).

b. Maine's comment: There is no basis for separate federal notice and comment.

EPA's response

See EPA's introduction to this RTC document for a response to this comment.

c. Maine's comment: The Maine Tribes were well aware and participated in the State's action.

EPA's response

EPA reviewed Maine's notice to the public and the public's comments on Maine's proposed WQS revisions. In the first instance, while the Tribes in Maine participated in the State's public process, their comments focused entirely on the adequacy of the state standards and whether they would protect sustenance fishing. The Tribes' comments did not focus on the State's authority to set standards for waters in the Tribes' lands. It is reasonable to assume that the Tribes were concerned about how Maine's WQS might impact sustenance fishing opportunities in waters outside Indian lands. It was not clear that Maine's notice alerted the public and the Tribes to the State's assertion of jurisdiction to set WQS for waters in the Tribes' lands.

Ultimately, EPA determined that, in light of the great deal of interest in the jurisdictional and technical issues involved in Maine's proposal, it would be prudent to err on the side of caution by taking additional steps to ensure that the Maine Tribes and other members of the public had clear notice of the implications of Maine's proposed WQS revisions.

EPA had never before approved or disapproved in Maine WQS revisions to be applied to waters within Indian lands. Moreover, EPA received additional comments from the Maine Tribes and from the ME DEP and the Maine Office of the Attorney General that were not part of Maine's administrative record for its WQS revisions at the state level; and to that extent the record before EPA is now more complete.

d. Maine's comment: Maine accuses EPA of bad faith, "creating" jurisdictional controversy where there is none.

EPA's response

As set forth in great detail in EPA's Decision Support Document, EPA's decision has two essential components, a legal jurisdictional component and a scientific/technical component. The latter required a complex assessment by EPA of the adequacy of Maine's criteria in relation to the designated uses of the waters in Indian lands, once EPA determined that Maine had jurisdiction. The complexity of the issues with which EPA was confronted, demonstrated by the content of its decision documents both as to the jurisdictional analysis and technical determinations, shows that EPA was not creating a jurisdictional controversy where there was none. In fact, it is a significant mischaracterization of the issues confronting EPA, and of EPA's deliberative process, to portray EPA's activities and process as nothing more than "creating" a jurisdictional controversy.

In the end, EPA concluded that there is no valid legal basis to distinguish or depart from the First Circuit's reasoning and decision in *Maine v. Johnson* that Maine has jurisdiction to implement the CWA NPDES program in Indian lands. A careful analysis was warranted, however, due to the arguable differences between the NPDES and WQS programs, and due to the copious substantive comments EPA received from the State and Maine Tribes on the jurisdictional question. For EPA not to have ensured that its decision had the benefit of the full explanation of the State's and the Tribes' views on this question could have led to a decision for which there was an incomplete and possibly flawed administrative record.

11. Maine's comment: Maine's submitted WQS are approvable and there is no basis upon which EPA may disapprove them.

EPA's response

EPA's Decision Support Document explains in detail the bases upon which EPA has decided to disapprove Maine's HHC for waters in Indian lands. EPA disagrees with Maine's assertion that "there is no basis upon which EPA may disapprove" any of Maine's WQS. In summary, EPA's disapproval of Maine's HHC for waters in Indian lands is based on the fact that Maine did not use a fish consumption rate that results in criteria that are sufficient to protect the designated use of sustenance fishing in those waters. EPA's Decision Support Document also contains an explanation of EPA's

identification of the sustenance fishing designated uses for waters in Indian lands that derives from Congress's purpose in confirming and establishing, through the settlement acts, sustenance fishing in the Southern Tribes' reservations and in the trust land waters of the Southern and Northern Tribes. We refer the reader to EPA's Decision Support Document for more detailed information relevant to Maine's comment.

12. Maine's comment: Maine's WQS protect sensitive subpopulations that engage in sustenance fishing.

EPA's response

EPA's Decision Support Document discusses EPA's determination, consistent with the requirements of the CWA, that Maine's HHC do not adequately protect the Maine Tribes' health given the Tribes' sustenance fishing practices and the designated use of sustenance fishing in waters in Indian lands. EPA also disagrees with Maine's characterization of the Maine Tribes as "sensitive subpopulations" of the State's general population. EPA's Decision Support Document explains that the Maine Tribes constitute their own *general* population in the geographic areas defined by their reservations and trust lands and that it would therefore be inappropriate to treat the Tribes merely as a "sensitive subpopulation" of Maine's general population in waters located within Indian lands. We refer the reader to EPA's Decision Support Document for more detailed information relevant to Maine's comment.

13. Maine's comment: Maine's WQS are based on technically sound and objective data and analysis regarding cancer risk, fish consumption rates and bioconcentration.

EPA's response

EPA has approved many of Maine's WQS as being technically sound regarding cancer risk, fish consumption rates and bioconcentration. However, for the reasons set forth in EPA's Decision Support Document, EPA does not agree that Maine's HHC meet CWA requirements as applied in waters within Indian lands in Maine, because the fish consumption rate on which they are based is not representative of the Tribes' sustenance fishing. See also EPA's responses to comments VIII. 10 and 11 above, regarding fish consumption rates used by Maine and the fact that it would not be consistent with the requirements of the CWA, as informed by the settlement acts, to treat the Maine Indian Tribes as a "sensitive subpopulation" of Maine's general population.

14. Maine's comment: EPA has used in the past some of this data (meaning the data used in establishing the WQS submitted to EPA in January 2013).

EPA's response

EPA has never "used" the data Maine refers to in its comment for purposes of determining whether Maine's WQS meet CWA requirements in waters within Indian lands in Maine. The fact that EPA may have considered this data in the past to approve Maine's HHC in waters outside Indian lands, including whether such criteria are protective of highly exposed subpopulations fishing in waters outside of Indian lands, is not relevant to the question whether Maine's WQS meet CWA requirements for the target population of tribal members engaged in sustenance fishing in waters located in Indian lands.

15. Maine's comment: Maine's human health criteria are grounded in the empirical, local population-specific data that EPA prefers.

EPA's response

EPA acknowledges that Maine's HHC are based in part on local, population-specific fish consumption data, and EPA has approved those criteria for waters outside of Indian lands. However, as discussed in EPA's Decision Support Document and summarized briefly in earlier responses above to some of Maine's other comments, EPA has determined that the localized data are not representative of unsuppressed tribal sustenance fish consumption in waters in Indian lands, and therefore the HHC that are based on the localized data are not adequate to protect the sustenance fishing use in those waters. Maine must use fish consumption data that are representative of unsuppressed tribal sustenance fish consumption in waters in Indian lands, such as the data from the Wabanaki Cultural Lifeways Exposure Scenario ("Wabanaki Study"), which was completed in 2009, rather than the 1990 study conducted by McLaren/Hart – ChemRisk, of Portland, Maine (the "ChemRisk Study"[10]) that was actually used by Maine. See also EPA's responses above relating to Maine's calculation of a fish consumption rate and the fact that the Maine Tribes are the general population to which HHC should be targeted for waters in Indian lands.

[10] ChemRisk, A Division of McLaren Hart, and HBRS, Inc., *Consumption of Freshwater Fish by Maine Anglers,* as revised, July 24, 1992. See also Ebert, E.S., N.W. Harrington, K.J. Boyle, J.W. Knight, R.E. Keenan, *Estimating Consumption of Freshwater Fish among Maine Anglers,* North American Journal of Fisheries Management, 13:4, 737-745 (1993); http://dx.doi.org/10.1577/1548-8675(1993)013<0737:ECOFFA>2.3.CO;2

IX. Maine Tribes' comments regarding the adequacy of Maine's WQS

1. **Tribal comment: Apart from the jurisdictional question, Maine's WQS for arsenic, phenol and acrolein are scientifically and legally flawed, and are arbitrary and capricious.**

EPA's response

EPA's Decision Support Document explains in detail the bases of EPA's decision to disapprove the three HHC identified in the comment, along with the rest of Maine's HHC, as applied to waters within Indian lands. We therefore refer the reader to that document. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

2. **Tribal comment: As to arsenic, EPA received comments from the Maine Tribes that Maine's arsenic standard failed to consider other exposure routes and synergistic effects; that the ChemRisk Study used by Maine to establish a fish consumption rate is flawed for a number of reasons; that unscientific manipulation of variables used by Maine to calculate in-stream criteria shouldn't be accepted by EPA; and that the fish consumption rate and cancer risk level used for arsenic by Maine are unacceptable.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's arsenic standard as it would apply to waters within Indian lands in Maine. While EPA's decision was not based on all of the objections raised by the Maine Tribes' comments, EPA agrees that Maine's arsenic criteria are not approvable under the CWA for waters in Indian lands. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

3. **Tribal comment: Using inconsistent fish consumption rates and cancer risk levels for different WQS is arbitrary and capricious.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. Because EPA is disapproving all of the HHC for waters in Indian lands due to an inadequate fish

consumption rate, it is not necessary at this time to consider the extent to which differing fish consumption rates or cancer risk levels for different criteria might be approvable for those waters.

4. **Tribal comment: The arsenic in-stream concentration is increasing as compared to Maine's prior in-stream concentration for arsenic, which imposes increased risks to tribal members.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC, including arsenic, as they would apply to waters within Indian lands in Maine. Because EPA is disapproving Maine's arsenic criteria as it would apply to waters in Indian lands, it is premature to address how Maine's arsenic HHC for waters in Indian lands will compare with the prior criterion.

5. **Tribal comment: The Penobscot Nation comments that the Wabanaki study contains "site specific" data, and that the CWA does not preclude the use of site-specific data from any particular time period in establishing WQS.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. EPA agrees with the Penobscot Nation that, based on the data and information available at this time, fish consumption data from the Wabanaki Study is the best available representative data and thus, barring any better data being collected, must be used in establishing HHC for waters in Indian lands in Maine. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

6. **Tribal comment: The Penobscot Nation comments that its sustenance fishing right is an "existing use" and a "designated use" as those terms are used in the CWA. The Tribe further comments that Maine's human health WQS submission shows that these uses will not be protected in waters within Indian lands.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. Included in the Decision Support Document is EPA's explanation of its identification of the designated use of sustenance fishing for waters within Indian lands and its relationship

both to CWA requirements and to Congress's purpose in establishing the Maine Tribes' reservations and trust lands under the settlement acts. EPA agrees that Maine's current HHC are not adequate to protect the designated use of sustenance fishing that applies to waters in Indian lands and therefore has disapproved those criteria. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

7. **Tribal comment: EPA has a duty to collect more accurate fish consumption rate data, and such data must account for suppression of fish consumption. Maine's WQS fail to consider and account for suppressed fish consumption.**

EPA's response

EPA does not agree that the CWA imposes a duty to collect more accurate fish consumption rate data. But states (or EPA, if EPA is developing the HHC) must use the best available fish consumption data or information to derive HHC that represent an unsuppressed fish consumption rate. EPA agrees that the fish consumption data used by Maine to establish its HHC is not representative of unsuppressed fish consumption associated with tribal sustenance fishing in waters in Indian lands. EPA's Decision Support Document explains the bases of the data derived from the Wabanaki Study and the ChemRisk Study Maine actually used. The Decision Support Document also explains EPA's basis for concluding that the Wabanaki Study provides the best available existing fish consumption data and information for deriving HHC based on an unsuppressed sustenance fish consumption rate for waters in Indian lands in Maine.

8. **Tribal comment: The situation at the Penobscot Nation is not dissimilar to that at other tribes, traditionally dependent upon a subsistence fishery. As EPA concluded in studying fish consumption rates at such tribes in the Northwest, there is "a simple relationship between tribal fish-consuming populations in the Pacific Northwest; people eat what's available to them, what's culturally preferred and at high consumption rates." EPA, TECHNICAL SUPPORT DOCUMENT FOR ACTION ON THE STATE OF OREGON'S NEW AND REVISED HUMAN HEALTH WATER QUALITY CRITERIA FOR TOXICS AND REVISIONS TO NARRATIVE TOXICS PROVISIONS SUBMITTED ON JULY 8, 2004 (June 1, 2010) at 47.**

EPA's response

See EPA's response to comment IX. 7., immediately above.

ATTACHMENT A

Analysis Supporting EPA's February 2, 2015 Decision to Approve, Disapprove, and Make No Decision on, Various Maine Water Quality Standards, Including Those Applied to Waters of Indian Lands in Maine

EXECUTIVE SUMMARY

Maine's Department of Environmental Protection (DEP) submitted numerous new or revised water quality standards (WQS) to EPA for review and approval under the Clean Water Act (CWA) between 2003 and 2014. In its decisions from 2004-2013 following review of such WQS, EPA limited its approvals of the new or revised WQS to state waters outside of Indian territories and lands in Maine ("Indian lands"), and explicitly refrained from taking any action on the WQS for waters in Indian lands. In its decision today, EPA is responding to the outstanding new and revised WQS from 2003-2014 as they relate to waters in Indian lands, and, in the case of some of the WQS, also as they relate to state waters outside of Indian lands.

As summarized below and explained in more detail in the body of this decision support document, Maine has the authority to establish WQS for waters in Indian lands, subject to EPA's authority under the CWA to review and approve or disapprove such standards. After evaluating the various new and revised WQS contained in DEP's submissions from 2003-2014, EPA is today approving all of the aquatic life criteria for toxic pollutants for waters in Indian lands except for ammonia, and all but one of the new aquatic life criteria submitted in 2013 for all waters, including in Indian lands.[1] EPA is also approving a number of other WQS provisions for waters in Indian lands, as well as Maine's classifications and designated uses for those waters. EPA is disapproving Maine's human health criteria as they apply to waters in Indian lands. Finally, EPA has identified a number of provisions on which it is taking no action because they are not WQS and therefore are not subject to EPA review.

The bases for two aspects of EPA's decision today are summarized below because of their complexity -- EPA's conclusion that Maine has the authority to establish WQS in waters in Indian lands, and EPA's conclusion that Maine's human health criteria do not protect the designated uses and therefore must be disapproved.

[1] EPA is taking no action on the ammonia criteria and certain provisions related to bacteria and pesticides, based on our understanding from discussions with DEP staff that DEP will be revising these criteria and provisions in light of recent EPA criteria recommendations and to ensure the protection of designated uses, nor is EPA taking action on the reclassification of a non-tribal water (Long Creek), pending further discussion with DEP. See section 4.8 below. EPA is also taking no action on one of the new phenol criteria for all waters pending DEP's correction of a mathematical error, which DEP has agreed to correct. See section 4.3 below. Finally, EPA is taking no action on the cancer risk level for arsenic in light of EPA's disapproval of the arsenic criteria for waters in Indian lands. See section 4.2.4 below.

The Issue: The State of Maine submitted numerous new and revised water quality standards (WQS) for EPA to approve under the Clean Water Act in the territories and lands of the federally recognized Indian Tribes in Maine – the Penobscot Nation, Passamaquoddy Tribes, Houlton Band of Maliseet Indians, and Aroostook Band of Micmacs. Under well-established principles of federal Indian law, states generally do not have authority to regulate the environment in Indian country. Maine asserts that in the Maine Indian Claims Settlement Act (MICSA) Congress granted the State jurisdiction to regulate the environment in the Tribes' lands, including the authority to set WQS. The Tribes contest that assertion, noting especially that state WQS have the potential to determine how much fish they may safely eat in waters where the Tribes fish for their sustenance. The Tribes assert the State has not adequately accounted for their sustenance fishing practices in setting the WQS submitted to EPA.

Jurisdiction to set WQS: EPA analyzed the jurisdictional provisions of MICSA extensively, including a careful review of comments from the Tribes and Maine on the jurisdictional provisions of the statute. EPA concludes that under the unique jurisdictional formula Congress established in Maine, the State has jurisdiction to set WQS in the waters on the Tribes' lands. See *Maine v. Johnson*, 498 F.3d 37 (1st Cir. 2007). But the Agency also finds that this authority is not unconstrained. EPA is required under the Clean Water Act to review state WQS, and will approve them when they comply with the Act. In these circumstances, where Maine is authorized to set WQS in tribal waters, EPA is informed by the operation of the Indian settlement acts in Maine and will require that WQS in tribal waters protect the Tribes' sustenance fishing use of those waters.

Sustenance Fishing Use in Tribal Waters: The first step in establishing and reviewing WQS is to determine the uses of the waters. In tribal waters, EPA must harmonize the CWA requirement that WQS must protect uses with the fundamental purpose for which land was set aside for the Tribes under the Indian settlement acts in Maine. Those settlement acts, which include MICSA and other state and federal statutes that resolved Indian land claims in the State, provide for land to be set aside as a permanent land base for the Indian Tribes in Maine. One clear purpose of that set aside is to provide a land base on which these Tribes could continue their unique cultures. A critical element of tribal cultural survival is the ability to exercise sustenance living practices, including sustenance fishing. There are multiple provisions in the Indian settlement acts that specifically codify the Tribes' sustenance practices. Maine general law regulating fish take accommodates sustenance fishing, and in several regards also specifically codifies the Tribes' ability to sustenance fish. The legislative record supporting the Indian settlement acts in Maine makes it clear that the statutes intend to create a land base on which the Tribes in Maine may fish for their sustenance. Therefore, EPA interprets the State's "fishing" designated use, as applied in tribal waters, to mean "sustenance" fishing; and EPA is approving a specific sustenance fishing right reserved in one of the settlement acts as a designated use for certain tribal reservation waters.

Protecting the Sustenance Fishing Use: To adequately protect that sustenance fishing use, the State must revisit two aspects of its analysis supporting the human health criteria that determine how clean the waters must be to allow the Tribes to safely consume fish for their sustenance. First, the analysis must treat the tribal population exercising the sustenance fishing use as the target general population, not as a high-consuming subpopulation of the State. EPA guidance

calls for WQS that provide a high level of protection for the general population, while recognizing that small subpopulations may face greater levels of risk. However, the Tribes are not a subpopulation using the waters on their own lands; they are the population for which that land base was established and set aside. Second, the data used to determine the fish consumption rate for tribal sustenance consumers must reasonably represent tribal consumers taking fish from tribal waters and fishing practices unsuppressed by concerns about the safety of the fish available to them to consume. The data on which the State relied to develop fish consumption rates for these WQS did not include information about the sustenance practices of tribal members fishing in their own waters, nor did they represent consumption levels that were unsuppressed by concerns about pollution. EPA concludes that the best available data that represent the unsuppressed sustenance fishing practices of tribal members fishing in tribal waters are contained in the Wabanaki Lifeways study, which looked at the historic sustenance practices of the Tribes in Maine.

EPA has received a written legal opinion dated January 30, 2015 from the Solicitor of the Department of the Interior (DOI) addressing several of the issues involved in EPA's decision. EPA sought DOI's advice because the Department is the federal government's expert agency on matters of Indian law and is charged with administering the settlement acts in Maine. *Passamaquoddy Tribe v. State of Maine*, 75 F.3d 784, 794 (1st Cir. 1996) (DOI is the department that administers MICSA). DOI has provided EPA important insight into how the Indian settlement acts in Maine address the Tribes' right to fish and the critical relationship between those rights and water quality. In making our decision on Maine's WQS, EPA has carefully considered and relied upon the DOI Solicitor's analysis, which is reflected in DOI's written opinion and is included in the administrative record for this decision.

The Remedy: EPA is disapproving Maine's human health criteria because they are not protective of human health for the target population. They are based on a fish consumption rate of 32.4 grams per day, with the exception of arsenic which is based on 138 grams per day. However, the Wabanaki study indicates that consumption values between 286 and 514 grams per day represent the sustenance fishing use in tribal waters. EPA is approving Maine's regulation requiring that human health criteria, except for arsenic, be based on a cancer risk level of no more than one in a million (10^{-6}) as applied to the Tribe's waters, because that is a reasonable level of risk for a general target population. EPA is approving nearly all the State's aquatic life criteria, because they are consistent with the Clean Water Act and unlike the human health criteria, they do not implicate the safety of fish for human consumption. The Clean Water Act gives the State 90 days to address the bases for EPA's disapproval of the human health criteria, after which time, if the State does not do so, EPA will propose and promulgate appropriate human health criteria for waters in Indian lands in Maine.

why?

1 Background

1.1 Overview

On January 14, 2013, the Maine Department of Environmental Protection (DEP) submitted a request to EPA to approve five new or revised water quality criteria (WQC) and specifically asked EPA to approve them in all waters located in the State of Maine, including waters in the territories and lands of the federally recognized Indian Tribes in Maine.

EPA's review of the State's submission determined that when the State provided public notice on its proposed WQS revisions, it was not clear on the record that the State had solicited comment on the question of the State's authority to set WQS in waters in the Tribes' territories and lands (as explained further below, hereinafter EPA will use the term Indian or tribal "lands" to refer to the entire tribal land base in Maine). Although EPA does not customarily provide public notice for state WQS submissions, the Agency exercised its discretion in the unique circumstances of this submittal to invite public comment on the issue of applying state WQS in waters in Indian lands in Maine. EPA identified two general areas for comment. First, has the State demonstrated adequate authority to set WQS in waters in Indian lands? Second, if so, are the WQC that the State submitted based on sound scientific rationale and adequate under the Clean Water Act (CWA) to protect uses in those waters?

This document contains the detailed explanation to accompany EPA's decision letter acting on the State's request that EPA approve these WQS for waters in Indian lands. In addition, from 2004 through 2010, in response to Maine's 2003 to 2009 submittals of new or revised WQS, EPA approved WQS for waters outside of Indian lands, but specifically stated that EPA was taking no action to approve or disapprove WQS within Indian lands. Today's decision addresses all of Maine's WQS submissions from 2003 through 2014 as they relate to waters in Indian lands, as well as certain submissions on which EPA has not yet acted for any waters in Maine.[2]

In summary, EPA finds that Maine has jurisdiction to set WQS for waters in Indian lands. Because EPA has not yet approved any of Maine's WQS for waters in Indian lands, EPA is first approving the State's classifications and associated designated uses for these waters. All of the relevant classifications include a designated use of "fishing," which the Agency interprets to include sustenance fishing consistent with these Tribes' sustenance practices in waters on their lands. EPA is also approving a specific sustenance fishing use for the inland waters of the reservations of the Penobscot Nation and Passamaquoddy Tribe. EPA is approving all but one of the State's aquatic life criteria. EPA has determined that Maine's human health criteria, however, do not adequately protect the designated use of sustenance fishing in the waters in tribal lands and, therefore, do not comply with the CWA's requirement that criteria protect the

[2] EPA is also approving today certain pre-2004 WQS for waters in Indian lands to the extent necessary to act on the submissions from 2003 through 2014. EPA intends to act on other pre-2004 WQS applicable to those waters as soon as possible. Before 2004, EPA's approvals or disapprovals of new or revised WQS in Maine did not address waters in Indian lands, or expressly consider the State's jurisdiction to establish WQS for such waters or the sufficiency of the State's WQS for such waters under the CWA. EPA thus takes the position that it has not previously approved any of the State's pre-2004 WQS for waters in Indian lands in Maine.

uses of the waters to which they apply. In a separate document EPA will respond to specific comments that interested parties submitted.

1.2 Indian Tribes in Maine

There are four federally recognized Indian Tribes in Maine represented by five governing bodies. The Penobscot Nation and the Passamaquoddy Tribe have reservations and trust land holdings in central and coastal Maine. The Passamaquoddy Tribe has two governing bodies, one on the Pleasant Point Reservation and another on the Indian Township Reservation. The Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs have trust lands further north in the State. To simplify the discussion of the legal framework that applies to each Tribe's territory, EPA will refer to the Penobscot Nation and the Passamaquoddy Tribe together as the "Southern Tribes" and the Houlton Band of Maliseet Indians and Aroostook Band of Micmacs as the "Northern Tribes." EPA acknowledges that these are collective appellations the Tribes themselves have not adopted, and the Agency uses them solely to simplify drafting this decision.

1.3 Settlement Acts in Maine

1.3.1 MIA and MICSA

In 1980, Congress passed the Maine Indian Claims Settlement Act (MICSA), which resolved litigation in which the Southern Tribes asserted land claims to a large portion of the State of Maine. 25 U.S.C. §§ 1721, *et seq.* MICSA ratified a state statute passed in 1979, the Maine Implementing Act (MIA), which was designed to embody the agreement reached between the State and the Southern Tribes. 30 M.R.S. §§ 6201, *et seq.* In 1981, MIA was amended to include provisions for land to be taken into trust for the Houlton Band of Maliseet Indians, as provided for in MICSA. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Since it is Congress that has plenary authority as to federally recognized Indian Tribes, MIA's provisions concerning jurisdiction and the status of the Tribes are effective as a result of, and consistent with, the Congressional ratification in MICSA.

1.3.2 MSA and ABMSA

In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to the status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201, *et seq.* In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143. One principal purpose of both statutes was to give the Micmacs the same settlement that had been provided to the Maliseets in MICSA. See ABMSA § 2(a)(4) and (5). In 2007, the Federal Court of Appeals for the First Circuit confirmed that the Micmacs and Maliseets are subject to the same jurisdictional provisions in MICSA. *Aroostook Band of Micmacs v. Ryan*, 484 F.3d 41 (1st Cir. 2007).

Where appropriate, this document will refer to the combination of MICSA, MIA, ABMSA, and MSA as the "settlement acts."

1.4 Indian Territories and Lands in Maine

MICSA, MIA, MSA and ABMSA establish a unique framework for confirming and enhancing the Tribes' land base in Maine. For the Southern Tribes, MIA uses the term "Indian territory" to describe the combination of the Southern Tribes' reservations, as described in treaties with the States of Maine and Massachusetts, plus 150,000 acres of land for each Tribe to be held in trust for the Tribes by the United States. 30 M.R.S. § 6205(1) and (2). As such, the Southern Tribes' land base is made up of both the reservations continuously occupied by the Tribes, and subsequently acquired trust lands.

The land base for the Northern Tribes is made up entirely of trust lands. MIA provides for the Houlton Band of Maliseet Indians to acquire trust land, and Congress provided $900,000 in MICSA to fund that acquisition. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Similarly, the MSA provides for the Aroostook Band of Micmacs to acquire trust land, and Congress again provided $900,000 in ABMSA to fund that acquisition. 30 M.R.S. § 7204, ABMSA §§ 4(a) and 5(a).

In this document, where appropriate depending on the context, EPA will refer to the tribal land base relevant to this decision as follows: "territories" for the Southern Tribes' land base, which as described above includes both reservations and trust lands; "trust lands" for the Northern Tribes' land base; and "Indian" or "tribal" lands for the entirety of all the Tribes' land base in Maine.[3]

1.4.1 Identification of waters covered by this decision

The Penobscot Indian Nation and Passamaquoddy Tribe have reservation lands as defined in MIA. 30 M.R.S. § 6203(5) (defining Passamaquoddy Indian Reservation); § 6203(8) (defining Penobscot Indian Reservation). The trust lands acquired for the Maine tribes are the product of modern conveyances. Generally, based on the default Maine property rule under which owners of riparian land also own out to the thread, or middle, of most streams, *Wilson & Son v. Harrisburg*, 107 Me. 207, 212-213 (1910), Indian waters include waters adjacent to land held in trust by the Secretary of the Interior and lands in the Tribes' reservations as defined in the Settlement Acts.[4] In addition, Maine common law provides that owners of shore land above the mean high water mark presumptively hold title in fee to intertidal land. *Bell v. Town of Wells*, 557 A.2d 168 (Supreme Judicial Court of Maine, 1989). In *Bell* (often referred to as the "Moody Beach case"), the court explained that such title is subject only to the public's right to fish, fowl, and navigate, and that the rule of law governing titles to intertidal land has its origin in the

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[3] In addition to their reservations and trust lands, the Tribes also hold certain lands in fee, which are not at issue in this matter. Any action EPA has taken to approve Maine WQS for waters outside Indian lands would apply to waters in these fee lands.

[4] See Report of the Joint Select Committee on Indian Land Claims, Maine Legislature (1980), par. 14. ("The boundaries of the Reservations are limited to those areas described in the bill, but include any riparian or littoral rights expressly reserved by the original treaties with Massachusetts or by operation of State law. Any lands acquired by purchase or trade may include riparian or littoral rights to the extent they are conveyed by the selling party or included by general principles of law. However, the Common Law of the State, including the Colonial Ordinances, shall apply to this ownership. The jurisdictional rights granted by this bill are coextensive and coterminous with land ownership.")

Colonial Ordinance of 1641-47 of the Massachusetts Bay Colony. As stated in an article written by the Marine Law Institute, University of Maine School of Law, "[t]he Moody Beach Case affirms that in Maine owners of beachfront property or property adjoining tidelands (also called littoral or riparian owners) have property rights to the low water mark or low tide area subject only to a public easement for fishing, fowling, and navigation." See Citizens' Guide to Ocean and Coastal Law, Public Shoreline Access and the Moody Beach Case, August, 1990. Therefore, the Passamaquoddy Tribe's reservation at Pleasant Point would include at least the waters present in the intertidal zone.

EPA acknowledges that there are remaining uncertainties over what waters are associated with Indian lands in Maine in a few locations. For instance, the boundaries of the Penobscot Nation's reservation are currently the subject of litigation in the United States District Court for the District of Maine. *Penobscot Nation v. Mills,* Case No. 1:12-cv-254-GZS. The United States has intervened in that case, and it is the Government's position that the reservation includes Penobscot River waters, while the State of Maine alleges it does not. Pending resolution of this dispute, EPA's decision to approve or disapprove Maine's WQS for Indian waters includes at least some portion of the Penobscot River in the main stem from Indian Island north surrounding the islands in the Nation's reservation.

In addition, this decision treats the Passamaquoddy Tribe's reservation as including the "15 islands in the St. Croix River in existence on September 19, 1794 and located between the head of the tide of that river and the falls below the forks of that river . . ." as specifically enumerated in MIA's definition of the reservation. 30 M.R.S. 6203(5).

It is not necessary or reasonable for EPA to suspend its decision on the State's WQS submissions to await an authoritative resolution of disputes over the boundaries of Indian waters. If any disputes over reservation boundaries result in an authoritative adjudication inconsistent with the assumptions made in this decision, EPA will revisit or clarify the scope of the Agency's determinations in this decision.

2 EPA's Determination that Maine has Authority to Set WQS in Indian Territories

EPA concludes that MICSA provides the State with jurisdiction to set WQS in the Northern Tribes' trust lands and that the federal statute ratifies provisions of MIA that provide the State with such authority in the Southern Tribes' territories. Although in both cases the settlement acts provide the State jurisdiction to establish WQS, EPA notes that MICSA provides a different jurisdictional framework for the Northern Tribes than that which applies to the Southern Tribes.

2.1 Northern Tribes

MICSA provides that the Northern Tribes are subject to state law:

> Except as provided in section 1727(e) and section 1724(d)(4) of this title, all Indians, Indian nations, or Tribes or bands of Indians in the State of Maine, other than the Passamaquoddy Tribe, the Penobscot Nation, and their members, and any lands or natural resources owned by any such Indian, Indian nation, Tribe or band of Indians and any

> lands or natural resources held in trust by the United States, or by any other person or entity, for any such Indian, Indian nation, Tribe, or band of Indians shall be subject to the civil and criminal jurisdiction of the State, the laws of the State, and the civil and criminal jurisdiction of the courts of the State, to the same extent as any other person or land therein.

25 U.S.C. 1725(a). In addition, MICSA ratified MIA, which also provides that all tribes in Maine, including the Northern Tribes are subject to state law:

> Except as otherwise provided in this Act, all Indians, Indian nations, and Tribes and bands of Indians in the State and any lands or other natural resources owned by them, held in trust for them by the United States or by any other person or entity shall be subject to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein.

30 M.R.S. § 6204. Both statutes make it clear that laws of the State include regulation and that lands and natural resources include water and water rights. 25 U.S.C. §§ 1722(b) and (d); 30 M.R.S. § 6203(3) and (4). The only exceptions to state jurisdiction provided in MIA apply to the Southern Tribes. There are no such exceptions for the Northern Tribes. Notably, the U.S. Court of Appeals for the First Circuit has expressly found that the State's jurisdictional reach in the Northern Tribes' lands is greater than in the Southern Tribes' territories. *Houlton Band of Maliseet Indians v. Ryan*, 484 F.3d 73, 74-75 (1st Cir. 2007). That same year the First Circuit ruled that, even as to the Southern Tribes, MICSA and MIA grant the State jurisdiction to regulate surface water discharge permitting. *Maine v. Johnson,* 498 F.3d 37 (1st Cir. 2007). As discussed below, EPA has concluded that the court's analysis controls our decision as to the State's authority to set WQS in the Southern Tribes' territories. Given that MICSA gives the State a broader scope of jurisdiction over the Northern Tribes than over the Southern Tribes, which are nevertheless subject to the State's authority to set WQS, it is clear that state law applies to the Northern Tribes, and the State has authority to set WQS for waters in these Tribes' trust lands.

The Aroostook Band of Micmacs has argued that the passage of ABMSA impliedly repealed the application of MICSA to the Tribe, and, therefore, that the Micmacs were not subject to the same jurisdictional framework as the Houlton Band of Maliseet Indians. The First Circuit, however, rejected that argument. *Aroostook Band of Micmacs v. Ryan*, 484 F.3d 41, 60-62 (1st Cir. 2007).

2.2 Southern Tribes

MICSA addresses the jurisdictional relationship between the Southern Tribes and the State by reference to MIA, which MICSA ratifies:

> The Passamaquoddy Tribe, the Penobscot Nation, and their members, and the land and natural resources owned by, or held in trust for the benefit of the Tribe, nation, or their members, shall be subject to the jurisdiction of the State of Maine to the extent and in the

> manner provided in the Maine Implementing Act and that Act is hereby approved, ratified, and confirmed.

25 U.S.C. § 1725(b)(1). As discussed above, MIA in turn provides generally that all Indian Tribes in the State are subject to state law:

> Except as otherwise provided in this Act, all Indians, Indian nations, and Tribes and bands of Indians in the State and any lands or other natural resources owned by them, held in trust for them by the United States or by any other person or entity shall be subject to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein.

30 M.R.S. § 6204. Importantly, MIA section 6204 refers to exceptions to the grant of state jurisdiction found elsewhere in the statute, and those exceptions are all applicable to the Southern Tribes. *See, e.g.*, §§ 6206 (internal tribal matters); 6207 (hunting and fishing in Indian territories); 6209-A & B (minor crimes, small claims, child custody, and domestic relations). EPA has carefully considered whether any of the exceptions provided in MIA operate to block the grant of jurisdiction to the State in the area of setting WQS in the Southern Tribes' waters. EPA concludes that they do not impede the State's jurisdiction to establish WQS under the CWA for the Southern Tribes' waters.

2.2.1 Maine v. Johnson Decision

The U.S. Court of Appeals for the First Circuit previously adjudicated the issue of Maine's authority to regulate water quality protection in the Southern Tribes' territories. In 2003, EPA approved the State to issue national pollutant discharge elimination system (NPDES) permits under the CWA generally in the Southern Tribes' territories, except for those dischargers where EPA concluded that permitting would qualify as an internal tribal matter. MIA section 6206 exempts the Southern Tribes' internal tribal matters from state regulation. EPA determined that two tribally owned and operated public treatment works, which served only tribal members on the Tribes' reservations and had minimal water quality impacts at the point of discharge, qualified as internal tribal matters, and thus excluded those two facilities from the State's approved permitting program. In *Maine v. Johnson,* 498 F.3d 37 (1st Cir. 2007), the First Circuit upheld EPA's approval of the State's program in the Southern Tribes' territories, but reversed EPA's decision to withhold approval of the State to issue the permits for the two tribal treatment works.

> In ordinary statutory construction, the [internal tribal matters] proviso thus reserves to the tribe matters pertaining to tribal membership and governance structure, expenditure of fund income and *other matters of the same kind . . .;* but it does not displace general Maine law on most substantive subjects, including environmental regulation. . . . [W]e readily uphold the position of the EPA and Maine that the nineteen non-Indian discharge sources draining into tribal waters can be regulated by the state. The only real question is the EPA's carve-out of the two source points that are on tribal lands and are owned by Tribe entities. . . .

> In our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies; and the scope of that exemption is determined by the character of the subject matter. Discharging pollutants into navigable waters is not of the same character as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property.

Id. at 44-46 (emphasis in original; citations omitted). EPA has concluded that the *Maine v. Johnson* decision makes it clear that the grant of jurisdiction to the State includes the area of environmental regulation, certainly as it applies to surface water discharge permitting. The Agency also finds no basis to distinguish the analysis in that case as applied to the State's authority to set WQS for surface waters in the Southern Tribes' territories.

2.2.2 Arguments Maine Tribes have Advanced for Exceptions to State Jurisdiction for Southern Tribes

EPA considered whether, given the jurisdictional provisions of the applicable statutes and the precedent set in *Maine v. Johnson*, there is any basis for concluding that the State's authority to administer the NPDES permitting program would not apply equally to the State's WQS program. EPA concludes there is no such basis.

2.2.2.1 Internal Tribal Matters

As a threshold matter, the court in *Maine v. Johnson* concluded that environmental regulation was part of the jurisdictional grant to the State in Indian lands:

> [T]he [internal tribal matters] proviso thus reserves to the tribe matters pertaining to tribal membership and governance structure, expenditure of fund income and *other matters of the same kind* . . .; but it does not displace general Maine law on most substantive subjects, including <u>environmental regulation</u>.

Id. at 45 (emphasis in original; underscore added). The WQS program is clearly a form of environmental regulation that would be covered by this characterization of the State's authority. Strictly speaking, the facts on which the court's holding rests only presented the question of the State's authority to issue waste water discharge permits. Nevertheless, the court's reasoning in that case makes it clear that this exception to State jurisdiction would not block the State from setting WQS.

When the Agency withheld approval from Maine to permit the two tribal treatment works, EPA conducted an analysis of the factors the First Circuit articulated in two prior cases examining whether a particular subject matter qualifies as an internal tribal matter not subject to state regulation. *Akins v. Penobscot Nation*, 130 F.3d 482, 486-490 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F.3d 706, 710-713 (1st Cir. 1999). In its review of EPA's decision, the *Johnson* court found it unnecessary to apply the factors developed in the *Akins* and *Fellencer* cases; rather it concluded that this multi-factor assessment is relevant only when an area of regulation is

"arguably close to the (perhaps blurred) statutory borderline" of what might qualify as an internal tribal matter. 498 F.3d at 46. The court concluded that "discharging pollutants into navigable waters is not a borderline case in which balancing . . . or ambiguity canons . . . alter the result." *Id.* (citations omitted).

EPA evaluated whether the authority to set WQS is any closer to the statutory borderline the First Circuit has outlined and, therefore, might properly be analyzed using the *Akins/Fellencer* factors rather than the more categorical analysis in the *Johnson* decision. The Penobscot Nation commented to EPA that setting WQS directly affects the quality of fish the Tribe is able to consume for its sustenance, an area of concern at the core of the Nation's existence. The Penobscot Nation's view is that this effect on the Tribe's ability to safely consume fish makes setting WQS an internal tribal matter. EPA does not agree. Indeed, the Agency concludes that setting WQS is an exercise of jurisdiction even further from the "borderline" between state jurisdiction and internal tribal matters that the *Johnson* court posited.

The decision EPA is making is approval of WQS that are an integral part of a larger legal framework provided for in the CWA. Within that framework, the CWA and EPA's regulations provide that NPDES permits for upstream dischargers must include limits that assure compliance with downstream WQS. 40 C.F.R. § 122.44(d)(4) and CWA § 401(a)(2). In reviewing Maine's NPDES program, EPA found that permitting the two tribal treatment works involved only tribal members and would have minimal effect on water quality outside the Tribes' territories. See 498 F.3d at 45 n. 8. EPA cannot make a corresponding finding here that setting a WQS would not have the potential for an effect on non-members or on water quality outside the Tribes' territories. When it established the multi-factor internal tribal matters analysis, the *Akins* court noted that "*First, and foremost*, the [stumpage policy at issue] purports to regulate only members of the Tribe . . .." 130 F.3d at 486 (emphasis added). On this "foremost" factor, EPA concludes that the WQS program can have regulatory effects beyond the Tribe. Generally, downstream WQS determine what limits upstream dischargers must meet to assure protection of those WQS, which is a legal effect that could reach beyond the membership of the Tribes and the boundaries of their territories. These effects put the setting of WQS even further from the "(perhaps blurred) statutory borderline" of what qualifies as an internal tribal matter under the MIA and MICSA.

In *Maine v. Johnson* the court was prepared to accept EPA's finding that permitting the two tribal treatment works would not have a substantial effect outside the Tribes' territories, and it still refused to treat the category of waste water discharge permitting as an internal tribal matter. Here, EPA cannot find that setting WQS will have no potential for a substantial effect outside the Tribes' territories. Therefore, under the principles announced in *Maine v. Johnson*, EPA concludes that setting WQS does not qualify as an internal tribal matter.

2.2.2.2 The Southern Tribes' Sustenance Fishing Right

EPA has also considered whether the reservation in MIA of the Southern Tribes' right to take fish for their individual sustenance within their reservations provides an exception to the State's jurisdiction. That right is reserved to the Southern Tribes "[n]otwithstanding . . . any other law of the State." 30 M.R.S. § 6207(4). Arguably, if a state law interfered with the Southern Tribes' right to take fish for their individual sustenance, this provision would block that law's

application in the Southern Tribes' reservations. However, EPA concludes that the State's administration of WQS, subject to CWA requirements and EPA's oversight, does not have the potential to interfere with the Southern Tribes' sustenance fishing right.

MIA is clear that the basic grant of jurisdiction to the State includes the authority to apply laws of the State, which include regulations, to the Tribes' natural resources, which include "water and water rights and hunting and fishing rights." 30 M.R.S. §§ 6204, 6203(3) and (4). To conclude that the reserved fishing right precludes the operation of all state laws affecting environmental regulation that might indirectly affect the fishing right, one would have to conclude that the State's regulation of water quality is inherently and necessarily inimical to the Tribes' ability to take fish for their individual sustenance. EPA cannot reach that conclusion.

First, there are many state WQS that are reasonably adequate to support a fishery that could provide for an individual tribal member's sustenance. Indeed, as discussed below, EPA is approving many state WQS provisions that EPA has determined are sufficient to protect aquatic life. In *Maine v. Johnson* the court made it clear that decisions about the scope of the State's jurisdiction in the Southern Tribes' territories should be made on the basis of the category of the subject matter at issue – the court specifically rejected EPA's attempt to find or reject state jurisdiction based on the facts of any particular application of state jurisdiction within a subject matter category. "So we accept the EPA's factual premise as to the [limited] impact of the discharges but not the EPA's legal characterization. . . . [T]he scope of [the internal tribal matters] exemption is determined by the character of the subject matter." 498 F.3d at 45-46. The subject category at issue in *Maine v. Johnson* was environmental regulation of pollutants in surface waters, the same category at issue here. The impact of a specific state WQS regulation on the Tribes' sustenance fishing rights might provide the basis for a challenge to that specific regulation, but the bare potential for such a specific challenge at some point provides no basis for precluding all state regulation of that subject area. It is possible for the State to exercise jurisdiction to set WQS without necessarily or inevitably interfering with the Tribes' fishing rights.

Second, if the State does submit a new or revised WQS that would interfere with the Tribes' reserved fishing right, EPA has authority under the CWA to ensure that the Tribes' fishing right is protected. As described further below, EPA is approving the reserved sustenance fishing right as a designated use for the tribal waters to which the right applies. Where the State adopts a new or revised WQS, EPA has the authority and the obligation under the CWA to review and determine whether such new or revised WQS is consistent with the CWA. If EPA disapproves, the CWA directs EPA to propose and promulgate a new or revised WQS unless the State adopts an adequate revision to protect the use. The CWA thus provides the mechanism to protect the sustenance fishing use and prevent interference with the Southern Tribes' reserved fishing right. EPA's oversight of Maine's WQS is adequate to protect the Tribes' right while maintaining the basic statutory grant of jurisdiction to Maine, including the authority to set WQS, as provided under MICSA in the first instance.

2.3 The Relationship Among MISCA, Jurisdiction, and the Trust Responsibility

Several Tribes in Maine commented that it would be inconsistent with the federal government's trust relationship with the Tribes for EPA to approve the State to set WQS for waters in the Tribes' lands. On the other hand, the State argues that the trust relationship does not apply in the State because of MICSA.

EPA has consistently maintained that there is a trust relationship between the federal government and the Tribes in Maine in the general sense that the Tribes are federally recognized, they have sovereign governments that EPA interacts with on a government-to-government basis, and EPA has a responsibility to consult with the Tribes to understand and consider their interests when EPA is making a decision that affects the Tribes. This general trust relationship, however, does not alter the jurisdictional framework Congress ratified in MICSA. MICSA impacts the jurisdictional relationship among the Tribes and the State, within which EPA works to address the Tribes' interests as appropriate. It is consistent with the trust relationship for EPA to approve the State's authority to set WQS for waters in the Tribes' lands, because MICSA has dramatically revised the jurisdictional framework within which the trust operates in Maine as compared to the customary jurisdictional framework that applies in Indian country outside Maine. EPA intends to continue to act consistently with the trust relationship, to consult with the Tribes, and to consider their interests as we oversee the State's WQS under the CWA.

2.4 The Penobscot Nation's Application for Treatment in the Same Manner as a State

On October 8, 2014, the Penobscot Nation submitted to EPA an application "to administer water quality standards program and for federal approval of the standards" covering the Main Stem of the Penobscot River from Indian Island north to the confluence of the east and west branches of the river. EPA is not acting today on the Nation's application. EPA is only deciding today that the State of Maine has authority to set WQS for waters in Indian lands, and then acting on the State's WQS as applied to those waters. The Nation's application raises complicated issues that EPA will address in a separate decision.

3 EPA's Determination to Approve Classifications and Designated Uses for Waters in Indian Lands

In Section 2, above, EPA focused on the settlement acts and judicial interpretation of those statutes to analyze Maine's assertion of jurisdiction to set WQS in the waters in Indian lands. Having concluded that the State has jurisdiction to set those standards, EPA must now analyze whether the State's WQS as applied to waters in Indian lands are approvable under the CWA. So the balance of this document will focus primarily on the requirements of the CWA, as applied to the unique circumstances EPA must address here where a state is setting WQS for waters in lands that Congress has set aside for federally recognized Indian tribes.

The first step in developing and reviewing WQS under the CWA is to determine the uses of the waters to which the WQS apply. Here the State is not writing on a blank slate in the selection of uses for tribal waters. As described in detail in this section 3, EPA has concluded that the settlement acts operate to require Maine and the Agency to focus on the sustenance fishing use that federal and state law provide for the Tribes in Maine in waters in Indian lands. In light of

the sustenance fishing use, the CWA requires the State's water quality criteria to protect that use as explained in section 4, below.

3.1 Status of Previous State WQS as Applied to Waters in Indian Lands

3.1.1 EPA's Prior Decisions on Maine WQS

Maine has periodically submitted new or revised WQS to EPA for review and approval or disapproval. Before 2004, EPA acted on those WQS without expressly considering or approving the State's jurisdiction to establish WQS for waters in Indian lands or the sufficiency of the State's WQS for such waters under the CWA. Since 2004, EPA has expressly stated, in all decisions that it made to approve or disapprove new or revised WQS, that its decisions applied only to Maine waters outside of Indian lands.

3.1.2 EPA's Approach to State Programs in Indian Country

The State has commented to EPA that, prior to 2004, EPA approved state WQS submissions without reference to or exclusion of waters in tribal lands. From this the State infers that EPA approved the State's WQS for waters in tribal lands prior to 2004. EPA disagrees with this inference.

First, Maine did not obtain authority to regulate in tribal lands until Congress passed MICSA in 1980. While the State asserted the authority to govern the Tribes prior to MICSA, the First Circuit's decision in *Joint Tribal Council of the Passamaquoddy Tribe v. Morton*, 528 F.2d 370 (1st Cir. 1975), cast considerable doubt on that proposition, and the decision in *Bottomly v. Passamaquoddy Tribe*, 599 F.2d 1061 (1st Cir. 1979), effectively foreclosed this argument. So any WQS that Maine submitted prior to MICSA's passage could have no legal effect in tribal lands. At that point the State had no clear authority to set WQS in those waters.

But even as to WQS that Maine submitted following the passage of MICSA in 1980, EPA's position is that none of the State's WQS, whether submitted prior to or following enactment of MICSA, were approved under the CWA for waters in Indian lands. Prior to the Agency's decision today, EPA has never made a formal determination on the record expressly addressing either the State's jurisdictional authority or the sufficiency under the CWA of the State's WQS as applied to waters in Indian lands.

Today's decision demonstrates that in acting on new or revised state WQS for waters in Indian lands, EPA must consider the adequacy of such WQS to protect the uses in those specific waters. Where, as here, waters in Indian lands have a different designated use (*i.e.*, sustenance fishing) than waters outside of Indian lands, the analysis of the adequacy of criteria will necessarily be different. It would be arbitrary for EPA to assume, without analysis, that if criteria are protective for waters outside of Indian lands, they are also protective for waters in Indian lands.

In addition, under basic principles of federal Indian law, states generally lack civil regulatory jurisdiction within Indian country as defined in 18 U.S.C. § 1151. *Alaska v. Native Vill. Of Venetie Tribal Gov't*, 522 U.S. 520, 527 n.1. (1998) ("[g]enerally speaking, primary jurisdiction

over land that is Indian country rests with the Federal Government and the Indian Tribe inhabiting it, and not with the States."). See also *Okla. Tax Comm'n v. Sac and Fox Nation*, 508 U.S. 114, 128 (1993) ("[a]bsent explicit congressional direction to the contrary, we presume against a State's having the jurisdiction to tax within Indian Country . . . ."). Thus, EPA cannot presume a state has authority to establish WQS or otherwise regulate in Indian country. Instead, a state must demonstrate its jurisdiction, and EPA must determine that the state has made the requisite demonstration and expressly determine that the state has authority, before a state can implement a program in Indian country.[5] Such a demonstration and approval of Maine's authority to administer WQS in waters of Indian lands has not occurred prior to the decision EPA is making today.[6]

Maine cites to several actions by EPA employees that, in the State's view, indicate EPA's recognition that state WQS approved before 2004 apply in at least some tribal waters. EPA notes that some of those actions applied to stretches of rivers that either included both tribal and state waters or that were then and continue to be the subject of disputes over whether they included both tribal and state waters. As a result, those actions were inherently ambiguous as to their relevance to the tribal portions of the waters. But the Agency concedes that in some instances the Agency appeared to assume, without any express consideration or decision regarding the jurisdictional or CWA issues, that state WQS applied in certain tribal waters. For example, there are instances when the Region asked Maine DEP to certify under section 401 of the CWA that NPDES permits for tribal facilities discharging into tribal waters complied with state WQS. Simply put, those prior actions were mistakes that do not affect this decision. At the time, EPA had made no finding that Maine had jurisdiction to adopt WQS for tribal waters and had not approved the State's WQS for such waters. EPA notes that unexplained mistakes by mid-level Agency officials cannot unilaterally revise a considered Agency-wide policy. *Puerto Rican Cement Co. v. EPA*, 889 F.2d 292, 299 (1st Cir. 1989).

3.2 EPA Approval of Water Classifications and Associated Designated Uses

Many of the WQS revisions under review for approval or disapproval for waters in Indian lands are water quality criteria, and the CWA requires that criteria be protective of designated uses. In order to evaluate whether the submitted criteria are protective of designated uses, EPA must first approve designated uses for these waters. Accordingly, EPA also reviewed and is approving

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[5] Consistent with EPA's responsibility to consult with Indian tribes about decisions affecting their interests, as embodied in the Agency's 1984 Indian Policy and EPA's more recent Tribal Consultation Policy, EPA would offer to consult with any Indian tribe in the context of an Agency determination that a state has authority to set standards in that tribe's territory. Notably, no such consultations occurred in the context of EPA's prior decisions on the State's WQS submissions, further evidencing that the Agency's prior approvals were not intended to extend to waters in Indian lands.

[6] Indeed, as described above in the Agency's analysis of the State's jurisdictional authority to set WQS in Indian waters, EPA's review and assessment of how Maine's WQS affect tribal uses in Indian waters is an essential step in the argument that it is possible to reconcile the State setting WQS in Indian waters with the fishing rights that MICSA reserves to Tribes in Maine. Ignoring or side-stepping EPA's role in overseeing Maine's WQS submissions as they apply to Indian waters risks creating an irreconcilable conflict between the jurisdictional grant to the State in MICSA and the provision for Tribes in Maine to sustain themselves on the land base that the Maine settlement acts established for the Tribes. Respecting EPA's oversight role effectively harmonizes those elements of the settlement acts in Maine.

Maine's surface water classifications and corresponding designated uses, adopted and submitted to EPA for review to date[7], for waters in Indian lands.[8]

The general classifications and their corresponding uses consist of the following:

- 38 M.R.S. § 465(1.A) Class AA freshwater uses: drinking water after disinfection, fishing, agriculture, recreation in and on the water, navigation, and as habitat for fish and other aquatic life. The habitat must be characterized as free-flowing and natural.
- 38 M.R.S. § 465(2.A) Class A freshwater uses: drinking water after disinfection; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as habitat for fish and other aquatic life. The habitat must be characterized as natural.
- 38 M.R.S. § 465(3.A) Class B freshwater uses: drinking water supply after treatment; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as habitat for fish and other aquatic life. The habitat must be characterized as unimpaired.
- 38 M.R.S. § 465(4.A) Class C freshwater uses: drinking water supply after treatment; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as a habitat for fish and other aquatic life.
- 38 M.R.S. § 465-A(1.A) Class GPA lake and pond uses: drinking water after disinfection, recreation in and on the water, fishing, agriculture, industrial process and cooling water supply, hydroelectric power generation, navigation, and as habitat for fish and other aquatic life. The habitat must be characterized as natural. This section applies to great ponds (as defined in 38 M.R.S. § 480-B (5)), natural lakes and ponds less than 10 acres in size, and impoundments of rivers that are defined as great ponds pursuant to 38 M.R.S. § 480-B (5).
- 38 M.R.S. § 465-B (1.A) Class SA estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and harvesting of shellfish, navigation, and as habitat for fish and other estuarine and marine life. The habitat must be characterized as free-flowing and natural.
- 38 M.R.S. § 465-B (2.A) Class SB estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and harvesting of shellfish, industrial process and cooling water supply, hydroelectric power generation, navigation, and as habitat for fish and other estuarine and marine life. The habitat must be characterized as unimpaired.
- 38 M.R.S. § 465-B (3.A) Class SC estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and restricted harvesting of shellfish,

[7] This includes the addition of "agriculture" as a designated use for freshwaters, submitted to EPA on August 26, 2003.

[8] There are other provisions of Maine's WQS that EPA is not approving or disapproving at this time because they are not directly related to the scope of this decision, which is responding to new and revised WQS submitted to EPA from 2003 to 2014. These remaining provisions include, for example, definitions, antidegradation policies, and WQS implementation policies in regulation and statute. EPA will review those elements in the coming months and make decisions accordingly.

industrial process and cooling water supply, hydroelectric power generation, navigation and as a habitat for fish and other estuarine and marine life.

Waters throughout Maine are identified by classification in 38 M.R.S. § 467 (classifications of major river basins), § 468 (classifications of minor drainages), and § 469 (classifications of estuarine and marine waters), which results in the assignment of designated uses for each waterbody.

Each of the classification categories identified above contains designated uses that are consistent with the requirements of Section 303(c)(2)(A) of the Clean Water Act and 40 C.F.R. § 131.6(a). In addition, EPA has concluded that the classifications as applied to specific waters in Indian lands are reasonable. Therefore, EPA is approving the general classifications and associated designated uses in 38 M.R.S. § 465(1.A), (2.A), (3.A), and (4.A); § 465-A(1.A) (and the definition of "great ponds" in 38 M.R.S. § 480-B (5)); and § 465-B(1.A), (2.A), and (3.A); as well as the classification of specific waters in 38 M.R.S. § 467, § 468, and § 468, as applied to waters in Indian lands, because they are consistent with Sections 101(a)(2) and 303(c)(2)(A) of the Clean Water Act and 40 C.F.R. §131.10(a). EPA is including in its approval of specific waterbody classifications the reclassifications, submitted to EPA on December 7, 2009, of Otter Creek, a tributary of Seboeis Stream, and Alder Stream from Class B to Class A; and of Grand Falls Flowage between Route 1(Princeton and Indian Township) and Black Cat Island from Class B to Class GPA.

3.3 EPA's Identification of the "Fishing" Designated Use as "Sustenance Fishing" in Waters in Indian Lands in Maine

3.3.1 The Purpose of the Tribal Land Base and Tribal Sustenance Fishing in Maine

The settlement acts in Maine include extensive provisions to confirm and expand the Tribes' land base, and the legislative record makes it clear that a key purpose behind that land base is to preserve the Tribes' culture and support their sustenance practices. MICSA section 1724 establishes a trust fund to allow the Southern Tribes and the Maliseets to acquire land to be put into trust. In addition, the Southern Tribes' reservations are confirmed as part of their land base. 30 M.R.S. § 6205(1)(A) and (2)(A). MICSA combines with MIA sections 6205 and 6205-A to establish a framework for taking land into trust for those three Tribes, and laying out clear ground rules governing any future alienation of that land and the Southern Tribes' reservations. Sections 4(a) and 5 of the ABMSA and 7204 of the state MSA accomplish essentially the same result for the Micmacs, consistent with the purpose of those statutes to put that Tribe in the same position as the Maliseets.

EPA has concluded that one of the over-arching purposes of the establishment of this land base for the Maine Tribes was to ensure their continued opportunity to engage in their unique cultural practices to maintain their existence as a traditional culture. An important part of the Maine Tribes' traditional culture is their sustenance life ways. The legislative history for MICSA makes it clear that one critical purpose for assembling the land base for the Tribes in Maine was to preserve their culture. The Historical Background in the Senate Report for MICSA opens with the observation that "All three Tribes [Penobscot, Passamaquoddy and Maliseet] are riverine in

their land-ownership orientation." Sen. Rep. No. 96-957, at 11. The Report's "Special Issues" section specifically refutes the concern that:

> *The Settlement will lead to acculturation of the Maine Indians.* – Nothing in the settlement provides for acculturation, nor is it the intent of Congress to disturb the cultural integrity of the Indian people of Maine. To the contrary, the Settlement offers protections against this result being imposed by outside entities by providing for tribal governments which are separate and apart from the towns and cities of the State of Maine and which control all such internal matters. The Settlement also clearly establishes that the Tribes in Maine will continue to be eligible for all federal Indian cultural programs.

Id. at 17. As the Tribes have extensively documented in their comments, their culture relies heavily on sustenance practices, including sustenance fishing. So if a purpose of MICSA is to avoid acculturation and protect the Tribes' continued political and cultural existence on their land base, then a key purpose of that land base is to support those sustenance practices.

As explained in more detail below, MICSA, MIA, ABMSA, and MSA include very different provisions governing sustenance practices, including fishing, depending on the type of Indian lands involved. But each set of provisions in its own way is designed to make a homeland for these Tribes where they may safely practice their sustenance life ways.

3.3.1.1 Southern Tribes' Sustenance Fishing Right Reserved in Their Reservations in MIA/MICSA

If there were any doubt that sustenance practices are central to tribal culture, MICSA ratifies the MIA's reservation of the Southern Tribes' right to take fish for their individual sustenance:

> SUSTENANCE FISHING WITHIN THE INDIAN RESERVATIONS. Notwithstanding any rule or regulation promulgated by the commission or any other law of the State, the members of the Passamaquoddy Tribe and the Penobscot Nation may take fish, within the boundaries of their respective Indian reservations, for their individual sustenance subject to the limitations of subsection 6.

30 M.R.S. § 6207(4). Under this section, "fish" is defined as "a cold blooded completely aquatic vertebrate animal having permanent fins, gills and an elongated streamlined body usually covered with scales and includes inland fish and anadromous and catadromous fish when in inland water." 30 M.R.S. § 6207(9).

The only limitation on the Southern Tribes' right to take fish for their individual sustenance on their reservations is the State's ability to limit the take based on a finding that the Tribes' fishing practices are threatening stocks outside the Tribes' reservations in a process in which the State carries the burden of proof. 30 M.R.S. § 6207(6). To date the State has made no such determination. So a plain language reading of this provision entitles the Southern Tribes to take as much fish as they deem necessary to sustain individual members.

The legislative history for MIA makes it clear that the Maine legislature intended to continue and ratify the State's practice of not regulating the Southern Tribes' sustenance fishing practices. See transcript of the public hearing held on March 28, 1980 by the Maine Legislature's Joint Select Committee on the Maine Indian Claims Settlement at 55-56. The special issues section of the Senate Report on MICSA confirms that the intent of this provision is to shield the Southern Tribes' right to take fish from the prospect that the State might someday interfere with it. By responding to a rhetorical assertion (in italics below), the report confirms that the Southern Tribes have a right to take fish that is subject to state regulation only under very limited circumstances:

> *Subsistence hunting and fishing rights will be lost since they will be controlled by the State of Maine under the Settlement.* – Prior to the settlement, Maine law recognized the Passamaquoddy Tribe's and Penobscot Nation's right to control Indian subsistence hunting and fishing within their reservations, but the State of Maine claimed the right to alter or terminate these rights at any time. Under Title 30, Sec. 6207 as established by the Maine Implementing Act, the Passamaquoddy Tribe and the Penobscot Nation have the permanent right to control hunting and fishing not only within their reservations, but insofar as hunting and fishing in certain ponds is concerned, in the newly-acquired Indian territory as well. The power of the State of Maine to alter such rights without the consent of the affected tribe or nation is ended by Sec. 6(e)(1) of S. 2829. The State has only a residual right to prevent the two tribes from exercising their hunting and fishing rights in a manner which has a substantially adverse effect on stocks in or on adjacent lands or waters. This residual power is not unlike that which other states have been found to have in connection with federal Indian treaty hunting and fishing rights. The Committee notes that because of the burden of proof and evidence requirements in Title 30, Sec. 6207(6) as established by the Maine Implementing Act, the State will only be able to make use of this residual power where it can be demonstrated by substantial [evidence] that the tribal hunting and fishing practices will or are likely to adversely affect wildlife stock outside tribal lands.

Sen. Rep. No. 96-957, pp. 16-17. Importantly, MIA section 6207 did not create a fishing right for the Southern Tribes. Rather it confirmed an aboriginal right the Tribes have continuously exercised, and shielded that right from state regulation absent a finding of depletion. DOI's legal opinion confirms that this statutorily reserved fishing right is rooted in treaty guarantees that were upheld through the settlement acts.

The Senate Committee's discussion of the similarity between MIA section 6207 and the structure of more traditional Indian treaty hunting and fishing rights is instructive. Essentially, the State of Maine has adopted into state law and Congress has ratified a reserved fishing right like the rights reserved to other Indian tribes by treaties, executive orders, or other statutes. It is axiomatic that the settlement acts in Maine significantly revised the customary formulae of federal Indian law that apply outside the State. *Akins*, 130 F.3d at 484. But it is equally important to recognize those elements of the settlement acts where both the state and federal governments made careful provision for tribal rights that mirror those more commonly seen elsewhere in Indian country. *See Washington v. Washington State Commercial Passenger Fishing Vessel Association*, 443 U.S. 658, 674 (1979) (Stevens Treaties explicitly reserved to the Pacific Northwest tribes "'[t]he

right of taking fish, at all usual and accustomed grounds and stations . . . in common with all citizens of the Territory'"). The Southern Tribes' reserved aboriginal right to take fish for their individual sustenance within their reservations is such a right.

3.3.1.2 Federal Law Framework for Sustenance Fishing in Trust Lands

Similarly, to understand how the Maine Tribes' sustenance fishing practices are provided for in their newly acquired trust lands, it is helpful to review the federal law background against which Congress and the State of Maine were legislating when they provided for land to be taken into trust for the benefit of the Maine Tribes. Courts have found that when Congress sets aside land for a fishing tribe, it implicitly grants to the tribe the right to carry out its traditional fishing practices on that land. See *Menominee v. U.S.*, 391 U.S. 404, 405-406 (1968) (holding that lands acquired for the Menominee Tribe included the implicit right to hunt and fish on those lands); *Parravano v. Babbitt*, 70 F.3d 539, 544 (9th Cir. 1995) (recognizing the doctrine "that the grant of hunting and fishing rights is implicit in the setting aside of a reservation 'for Indian purposes.'"); see also *Katie John v. U.S.*, 720 F.3d 1214, 1230 (9th Cir. 2013) (Reserved water rights "are created when the United States reserves land from the public domain for a particular purpose, and they exist to the extent that the waters are necessary to fulfill the primary purposes of the reservation.").

Courts have found an implicit fishing right based on legislative history indicating that, in setting aside land for a tribe, Congress intended to preserve a tribe's fishing culture/practices. See *Menominee*, 391 U.S. at 405 ("The essence of the Treaty of Wolf River was that the Indians were authorized to maintain on the new lands ceded to them as a reservation their way of life which included hunting and fishing."); *Parravano*, 70 F.3d at 542 (In enacting the Hoopa-Yurok Settlement Act, "[o]ne of the concerns of Congress at the time" was "to protect the Tribes' fisheries."); see also id. at 546 ("Although the 1988 Hoopa-Yurok Settlement Act did not explicitly set aside fishing rights, it did make clear that partitioning would not dispossess the Tribes of their assets. The legislative history of the 1988 Act indicates that Congress was aware that each Tribes' interests in their salmon fisheries was one of its principal assets."). As explained in greater detail below, there is such legislative history here.

There is an important distinction between the Southern Tribes' aboriginal fishing right, which Congress explicitly reserved on those Tribes' reservations, and tribal sustenance fishing on the trust lands, which Congress provided for based on its demonstrated intent to preserve the Tribes' riverine culture. EPA is not determining that the Tribes in Maine have an aboriginal fishing right in their trust lands. The Agency acknowledges there is dispute over the scope of the Tribes' aboriginal resource rights following enactment of MICSA. See 25 U.S.C. §§ 1722(b) and 1723(b) and Assessment of the Intergovernmental Saltwater Fisheries Conflict between Passamaquoddy and the State of Maine, Maine Indian Tribal-State Commission: Special Report 2014/1 (June 17, 2014) at 7.

But regardless of the status of aboriginal fishing rights outside the Southern Tribes' reservations, it is possible for Congress to make provision for tribal sustenance fishing on trust lands, not based on the reservation of aboriginal rights, but based on Congressional intent to establish a land base for a tribe in order to sustain its unique culture. As described in detail below, EPA has

determined that Congress did just that in the Maine settlement acts, and when Congress did so, it acted against the backdrop of the principles outlined in the cases above. The legislative record regarding the trust land provisions in MIA, MICSA, MSA and ABMSA demonstrate Congress's intent to provide the Tribes with the opportunity to exercise their traditional sustenance lifeways, including traditional sustenance fishing in waters of tribal trust lands.

3.3.1.2.1 Sustenance Fishing in the Trust Lands of the Southern Tribes

Both MICSA and MIA make it clear that the land acquisition fund for the benefit of the Passamaquoddy and Penobscot Tribes was established to ensure these Tribes not only had a land base to occupy, but also access to natural resources to sustain their continued existence as a unique culture, including their ability to exercise their fishing rights. "The Secretary is authorized and directed to expend . . . the land acquisition fund for the purpose of acquiring land or natural resources for the Passamaquoddy Tribe, [and] the Penobscot Nation . . . and for no other purpose." 25 U.S.C. § 1724(b) (emphasis added). "Land or natural resources" are defined to include "water and water rights, and hunting and fishing rights." 25 U.S.C. § 1722(b).[9]

As excerpted more fully above, MICSA's legislative history also makes it clear that the Southern Tribes would be engaged in sustenance fishing in the newly-acquired trust lands:

> Under Title 30, Sec. 6207 as established by the Maine Implementing Act, the Passamaquoddy Tribe and the Penobscot Nation have the permanent right to control hunting and fishing not only within their reservations, but insofar as hunting and fishing in certain ponds is concerned, in the newly-acquired Indian territory as well.

Sen. Rep. No. 96-957, pp. 16-17 (emphasis added). The legislative history of MIA also makes it clear that the Maine Legislature understood that MIA was designed to accommodate sustenance fishing practices in the Southern Tribes' trust lands. See transcript of the public hearing held on March 28, 1980 by the Maine Legislature's Joint Select Committee on the Maine Indian Claims Settlement at 151-152.[10] So it is clear that in creating the authority to take land into trust for the Southern Tribes, Congress understood that MIA made provision for the Tribes to engage in sustenance fishing in those trust lands and intended the trust lands to provide a base for the Tribes to engage in sustenance practices.

As recognized by Congress in MICSA's legislative history, the Southern Tribes' control of fishing in certain trust waters was specifically codified in MIA. Section 6207(1) provides that

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[9] Unlike MICSA, when MIA refers to Penobscot and Passamaquoddy trust lands, it uses the term "land acquired by the secretary [of Interior] for the benefit" of each tribe, without reference to natural resources. Compare 25 U.S.C. § 1724(d) with 30 M.R.S. § 6205(1)(B) and (2)(B). As explained in the section above, other provisions of MIA make it clear that the statute anticipated that those lands would include the attendant natural resources acquired with the land, especially fishing rights. Moreover, to the extent that this differing terminology suggests a conflict between MICSA and MIA in defining the scope of the tribes' interest in their trust lands and natural resources, the provisions of MICSA would control. 25 U.S.C.
§ 1735(a).

[10] "[The Tribes can adopt ordinances with respect to . . . fishing but only on ponds of less than ten acres in size. Those ordinances have to be equally applicable to Indians and non-Indians except that the Indians can make special provisions for sustenance hunting . . ." and fishing per MIA § 6207(1). Id. at 151.

the Southern Tribes have exclusive authority to enact ordinances regulating the taking of fish on ponds of less than ten acres in their trust lands. As with the Southern Tribes' fishing right in their reservations, this authority is subject only to the State's authority to limit the take after carrying the burden of proof that the Tribes are depleting fish stocks. MIA specifically anticipates that any tribal ordinances regulating fishing in these waters "may include special provisions for the sustenance of the individual members of the Passamaquoddy Tribe or the Penobscot Nation." *Id.*

As to greater ponds and rivers and streams in or along the Southern Tribes' trust lands, MIA also codifies the understanding that the Tribes would be engaged in sustenance fishing in those waters. MIA creates the Maine Indian Tribal-State Commission (defined as the "commission" 30 M.R.S. § 6203(1)), made up of representatives appointed by the State and the Southern Tribes. 30 M.R.S. § 6212. MIA provides that commission the exclusive authority to promulgate fishing rules in these waters. When it does so "the commission shall consider and balance" several factors, including "the needs or desires of the Tribes to establish fishery practices for the sustenance of the tribes or to contribute to the economic independence of the tribes, [and] the traditional fishing techniques employed by and ceremonial practices of Indians in Maine." 30 M.R.S. § 6207(3). Importantly, as analyzed in the record supporting this decision, none of the fishing regulations adopted by the commission would impinge on the ability of the Tribes to sustain themselves on fish taken from these waters.[11]

MICSA and MIA combine to authorize the establishment of trust lands for the Southern Tribes to provide a land base in which the Tribes can exercise their sustenance fishing practices. As compared with the sustenance fishing right reserved to the Southern Tribes within their reservations, MICSA and MIA allow for a greater, although still sharply limited, role for the State, through the commission, to participate in the development of fishing regulations on certain of the waters in the trust lands. But in exercising even that authority, the commission is charged with considering the Tribes' sustenance fishing practices. Therefore, it is clear that a critical purpose behind establishing the Southern Tribes' trust lands is to give the Tribes an opportunity to engage in sustenance fishing.

3.3.1.2.2 Sustenance Fishing in the Trust Lands of the Northern Tribes

Compared with the Southern Tribes' territories, the arrangement for the Northern Tribes' trust lands provides for more direct state regulation of fishing practices. Nevertheless, it appears Congress intended these trust lands to preserve the Northern Tribes' unique cultures as well. So the Northern Tribes' trust lands provide a land base in which the Tribes are able to exercise sustenance fishing practices to the extent consistent with the legal limits on their fishing. Again, similar to the situation for the Southern Tribes' trust lands, EPA is not concluding that there is an aboriginal fishing right reserved to the Northern Tribes on their trust lands. But the Agency does conclude that there is sufficient evidence in the legislative record to indicate that Congress intended the Northern Tribes to engage in sustenance practices on their trust lands to the extent they could.

[11] See memorandum from Ralph Abele to the file for this decision, regarding Effects of Maine Fishing Regulations on Sustenance Fishing by Maine Tribes, dated January 30, 2015.

Authority to establish the Northern Tribes' trust lands came in several rounds of legislation. The first involved the Maliseets, who came to the negotiations around MIA and MICSA late in the legislative process. In 1980, MICSA provided that "[t]he Secretary is authorized and directed to expend . . . the land acquisition fund for the purpose of acquiring land or natural resources for the . . . the Houlton Band of Maliseet Indians and for no other purpose." 25 U.S.C. § 1724(b) (emphasis added). "Land or natural resources" is defined to include "water and water rights, and hunting and fishing rights." 25 U.S.C. § 1722(b) (emphasis added).

At the time Congress authorized land to be taken into trust for the Maliseets, it specifically acknowledged that "[a]ll three tribes [Penobscot, Passamaquoddy and Maliseet] are riverine in their land-ownership orientation." Sen. Rep. No. 96-957, at 11. Congress also specifically noted that one purpose of MICSA was to avoid acculturation of the Maine Tribes:

> *The Settlement will lead to acculturation of the Maine Indians.* – Nothing in the settlement provides for acculturation, nor is it the intent of Congress to disturb the cultural integrity of the Indian people of Maine. To the contrary, the Settlement offers protections against this result being imposed by outside entities by providing for tribal governments which are separate and apart from the towns and cities of the State of Maine and which control all such internal matters. The Settlement also clearly establishes that the Tribes in Maine will continue to be eligible for all federal Indian cultural programs.

Id. at 17. Congress's purpose in providing for the establishment of the Maliseet trust lands was to provide a land base on which the Tribe could maintain its "cultural integrity." The Maliseets have submitted extensive comments documenting the sustenance fishing practices central to the Tribe's culture.

In 1981, the Maine Legislature added provisions to MIA to correspond to the action Congress took in MICSA to recognize the Maliseets and authorize trust lands to provide a resource base for the Tribe. In contrast to MIA's language describing the Southern Tribes' trust lands, the statute explicitly defines the Maliseet trust lands to include natural resources. 30 M.R.S.A §§ 6203(2-A) ("'Houlton Band Trust Land' means land or natural resources acquired by the secretary in trust for the Houlton Band of Maliseet Indians . . .."); see also § 6205-A ("Land or natural resources" may be taken into trust for the Maliseets). As in MICSA, MIA makes it clear that natural resources acquired for the Maliseets may include fishing rights. *Id.* at § 6203(3) ("'Land or other natural resources' means any real property or other natural resources . . . including, but without limitation, . . . water and water rights and hunting and fishing rights.")

It was not until 1989 that the Micmacs negotiated a settlement with Maine as codified in the MSA. Similar to the settlement with the Maliseets, MSA provides that the Micmacs' trust lands include natural resources. 30 M.R.S. § 7202(2) ("'Aroostook Band Trust Land' means land or natural resources acquired by the secretary in trust for the Aroostook Band of Micmacs . . .."). MSA further defines natural resources to include fishing rights. *Id.* at § 7202(3) ("'Land or other natural resources' means any real property or other natural resources . . . including, but without limitation . . . water and water rights and hunting and fishing rights.")

In 1991, Congress passed ABMSA, one key purpose of which was to ratify the MSA. ABMSA § 1(b)(4). Congress specifically found and declared that:

> It is now fair and just to afford the Aroostook Band of Micmacs the same settlement provided to the Houlton Band of Maliseet Indians for the settlement of that Band's claims, to the extent they would have benefited from inclusion in the Maine Indian Claims Settlement Act of 1980.

Id. at § 1(a)(5). To that end, Congress established the Aroostook Band of Micmacs Land Acquisition Fund, *id.* at § 4(a), and provided that:

> the Secretary is authorized and directed to expend, at the request of the Band, the principal of, and income accruing on, the Land Acquisition Fund for the purposes of acquiring land or natural resources for the Band and for no other purposes. Land or natural resources acquired within the State of Maine with funds expended under the authority of this subsection shall be held in trust by the United States for the benefit of the Band.

Id. at § 5(a). ABMSA defines "Band Trust Land" to mean "land or natural resources acquired by the Secretary of the Interior and held in trust by the United States for the benefit of the Band" and defines "land or natural resources" to mean "any real property or natural resources, or any interest in or right involving any real property or natural resources, including (but not limited to) . . . water and water rights, and hunting and fishing rights." *Id.* at § 3(3) and (4). As with the Maliseets, Congress clearly intended that the Micmacs' trust lands could encompass fishing rights.

The Senate conference report from the Select Committee on Indian Affairs on ABMSA indicates that Congress intended to remedy the plight of the Micmacs, who had been deprived of a land base on which to secure the Tribe's continuation as a unique culture. "As Maine's only Native American community without a tribal land base, the Aroostook Band of Micmacs faces major challenges in its quest for cultural survival." 102 S. Rpt 136 (1991). The report describes the cultural practices of the band, including its historic homeland range along the west bank of the St. John River. "The ancestors of the Aroostook Micmac made a living as migratory hunters, trappers, fishers and gatherers until the 19th century." It goes on to note that "[t]oday, without a tribal subsistence base of their own, most Micmacs in Northern Maine occupy a niche at the lowest level of the social order." The discussion of the Band's history ends by observing:

> It is remarkable that the Aroostook Band of Micmac Indians, as a long disenfranchised and landless native group, has not withered away over the centuries. To the contrary, this community in Northern Maine has demonstrated an undaunted collective will toward cultural survival.

As with the Maliseets, it is clear Congress intended to establish a land base for the Micmacs that would enable the Tribe to secure its "cultural survival" and avoid acculturation. Congress intended for the Northern Tribes' trust lands to provide a "subsistence base" on which the Tribes

could assure their continued existence as a unique culture. And Congress was aware that part of that subsistence base for the Northern Tribes was their sustenance fishing practices.

While Congress intended that the Indian lands in Maine provide a land base to support all the Tribes' sustenance practices, it ratified dramatically different regulatory frameworks within which the Southern and Northern Tribes could operate in exercising those practices. In their reservations and lesser ponds in their trust lands, the Southern Tribes are substantially free from state fishing regulations, and elsewhere in their trust lands any regulation of the Southern Tribes' fishing must consider their sustenance practices. As explained in the discussion of the State's jurisdictional authority above, the Northern Tribes and their trust lands are subject to the laws of the State, including the regulation of natural resources, which includes fishing rights. So unlike the Southern Tribes, the ability of the Northern Tribes to exercise their sustenance fishing practices is potentially subject to regulation directly under state law. As DOI's legal opinion explains, the Northern Tribes' trust lands include fishing rights appurtenant to those land acquisitions, which are subject to state regulation.

But this jurisdictional arrangement does not alter the fact that Congress established the Northern Tribes' trust lands for the purpose of providing these Tribes a land base on which to exercise their sustenance practices to the extent possible. Finding that state law applies to the Northern Tribes' fishing rights does not answer the question how those Tribes intend to use the waters on their trust lands consistent with the purpose of setting aside their land base. And the state law applicable to the Northern Tribes' fish take makes it clear that there are generous take limits that allow a catch sufficient to support sustenance fishing. As analyzed in the review of state fishing regulations supporting this decision, it appears state fishing regulations applicable to the Northern Tribes' trust lands do not impose limits that would prevent individual members of the Northern Tribes from taking fish sufficient to support a sustenance diet.[12] Further, under state law, the Department of Inland Fisheries and Wildlife has authority to set take limits on fisheries for the purposes of their preservation, protection, enhancement and use as well as the propagation of fish for the effective management of inland fisheries resources in public waters of the State. 12 M.R.S. § 10053.[13] While this regulatory process does not include the same kind of procedural and burden of proof protections MIA provides for the Southern Tribes' fishing rights, it still requires the State to have a legitimate, non-arbitrary reason for limiting the take in the Northern Tribes trust lands based on the need to preserve and protect state fisheries. So as provided under state law, there appears to be ample ability for the Northern Tribes to fish for their sustenance in tribal waters associated with their trust lands.

3.3.1.3 Passamaquoddy Marine Sustenance Fishing

The Passamaquoddy Tribe's Pleasant Point reservation is located on marine, not inland, waters. There is a dispute among the Tribe, the State, and the commission about whether the Tribe's aboriginal right to take fish in marine waters survived the passage of MICSA. See 25 U.S.C. §§ 1722(b) and 1723(b) and Assessment of the Intergovernmental Saltwater Fisheries Conflict between Passamaquoddy and the State of Maine, Maine Indian Tribal-State Commission: Special

[12] See memorandum from Ralph Abele to the file for this decision, regarding Effects of Maine Fishing Regulations on Sustenance Fishing by Maine Tribes, dated January 30, 2015.

[13] See memorandum from Greg Dain, re: Maine Fishing Regulation, December 23, 2014.

Report 2014/1 (June 17, 2014) at 7. EPA is taking no position at this time as to the Tribes' aboriginal rights to take fish in marine waters or the scope of the sustenance fishing right codified in MIA section 6207 in marine waters. Nonetheless, the marine waters that are part of the Pleasant Point reservation serve a function in supporting the sustenance of the Tribe identical to the inland waters in the Tribe's reservation and trust lands.

First, Congress understood that the Passamaquoddy Tribe exercised subsistence practices on its reservations, including the Pleasant Point Reservation. The Senate Report's discussion of Special Issues noted that "[p]rior to the settlement, Maine law recognized the Passamaquoddy Tribe's and Penobscot Nation's right to control Indian subsistence hunting and fishing within their reservations, but the State of Maine claimed the right to alter or terminate these rights at any time." As quoted more extensively above, the Senate Report then goes on to describe in detail MIA's provisions for the reserved sustenance fishing right of the Southern Tribes. Sen. Rep. No. 96-957 at 16-17. While some dispute whether the Southern Tribes' sustenance fishing extends into marine waters, at a minimum Congress understood that the Passamaquoddy Tribe fished for its sustenance on its reservation and that the State had accommodated that practice under state law.

Notably, Maine has continued its practice of recognizing and providing for the Passamaquoddy Tribe's sustenance marine fishing practices under state law. In 2013, the State codified a "tribal exemption" from otherwise applicable state fishing regulation of marine species for all four Indian Tribes in Maine to exercise a "sustenance use if the tribal member holds a valid sustenance fishing license issued by the tribe, nation or band . . .." That same subsection goes on to define "sustenance use" as:

> . . . all noncommercial consumption or noncommercial use by any person within Passamaquoddy Indian territory, as defined in Title 30, section 6205, subsection 1, Penobscot Indian territory, as defined in Title 30, section 6205, subsection 2, or Aroostook Band Trust Land, as defined in Title 30, section 7202, subsection 2, or Houlton Band Trust Land, as defined in Title 30, section 6203, subsection 2-A, or at any location within the State by a tribal member, by a tribal member's immediate family or within a tribal member's household.

12 M.S.A. § 6302-A(2)(emphasis added). This section imposes seasonal limits on the taking of sea urchins and limits on the number of lobster traps used to harvest lobsters for sustenance use. But it is a clear acknowledgement of and provision for the Passamaquoddy Tribe to take marine species for their sustenance "within Passamaquoddy Indian territory" as defined in MIA, which includes the Tribe's reservations.

Again, EPA acknowledges that there is a current dispute about the extent of the State's authority to regulate the Tribes' marine fishing practices. In citing section 6302-A, EPA does not take a position on the merits of that dispute. EPA is concluding, however, that even if EPA accepts the State's position on its ability to regulate the Passamaquoddy Tribe's marine fishing practices, state law makes ample provision for sustenance fishing on the Tribe's reservation. Therefore, as with the Northern Tribes' trust lands, even if the State has authority to regulate the Tribe's take of marine species, EPA concludes that one important purpose of the Tribe's reservation is to

serve as a land base for the Tribe's exercise of sustenance practices at least to the extent consistent with Maine law regulating the taking of fish. And consistent with that Maine law, the Tribe can consume sufficient marine species to sustain themselves under section 6302-A.

3.3.2 Purpose of MIA, MICSA, MSA, ABMSA and Water Quality

As explained above, all four settlement acts in Maine provide for the Tribes to exercise sustenance fishing practices on waters in Indian lands in Maine. The statutory mechanism supporting this conclusion is quite different depending on which element of Indian lands is involved. But the fundamental conclusion that Congress understood and intended that the Tribes be able to sustain their unique cultures and sustain themselves on Indian lands in Maine is clear.

EPA concludes that the purpose to which Congress dedicated these Indian lands has important implications for water quality regulation under the CWA. Some in Maine have argued that the fishing right reserved to the Southern Tribes in their reservations is simply an exception from otherwise applicable state creel limits, but has no bearing on whether the water supporting that fishing right must be clean enough to ensure that the fish that tribal members are consuming is safe to eat. EPA does not agree with this narrow approach to the relationship between the provisions for tribal sustenance practices on the one hand and water quality on the other. Fundamentally, the Tribes' ability to take fish for their sustenance under the Maine settlement acts would be rendered meaningless if it were not supported by water quality sufficient to ensure that tribal members can safely eat the fish for their own sustenance.

There are several examples of the courts finding that fishing rights for tribes encompass subsidiary rights that are not explicitly included in treaty or statutory language, but are nonetheless necessary to render those rights meaningful. One line of cases focuses on the tribes' ability to access fish. *See, e.g., United States v. Winans*, 198 U.S. 371, 384 (1905) (tribe must be allowed to cross private property to access traditional fishing ground); *Kittitas Reclamation District v. Sunnyside Valley Irrigation District*, 763 F.2d 1032, 1033-34 (9th Cir. 1985) (tribe's fishing right protected by enjoining water withdrawals that would destroy salmon eggs before they could hatch); *Grand Traverse Band of Ottawa and Chippewa Indians v. Director, Mich. Dept of Nat. Resources*, 141 F.3d 635 (6th Cir. 1989) (treaty right to fish commercially in the Great Lakes found to include a right to temporary mooring of treaty fishing vessels at municipal marinas because without such mooring the Indians could not fish commercially).

Another line of cases focuses on water quantity sufficient to support fish habitat. In *United States v. Adair*, the Ninth Circuit held that the tribe's fishing right implicitly reserved sufficient waters to "secure to the Tribe a continuation of its traditional . . . fishing lifestyle." 723 F .2d 1394, 1409-10 (9th Cir. 1983). *See also Colville Confederated Tribes v. Walton*, 647 F.2d 42, 47 -48 (9th Cir. 1981) (implying reservation of water to preserve tribe's replacement fishing grounds); *Winters v. United States*, 207 U.S. 564, 576 (1908) (express reservation of land for reservation impliedly reserved sufficient water from the river to fulfill the purposes of the reservation); *Arizona v. California*, 373 U.S. 546, 598-601 (1963) (creation of reservation implied intent to reserve sufficient water to satisfy present and future needs).

The preceding cases focus on fishing rights, and the attendant or implicit requirement that those fishing rights not be denied through collateral action impairing that right. Analogously, when diminished water quality has hindered tribal uses of water outside the fishing context, courts have held in favor of tribes and found that a right to put water to use for a particular purpose must include a subsidiary right to water quality sufficient to permit the protected water use to continue. This occurred in an Arizona case, *United States v. Gila Valley Irrigation District*, in which farmers whose properties were located upstream from an Indian reservation were required to take steps to decrease the salinity of the river reaching the tribe's reservation so that "the Tribe receives water sufficient for cultivating moderately salt-sensitive crops." 920 F. Supp. 1444, 1454-56 (D. Ariz. 1996), *aff'd*, 117 F. 3d 425 (9th Cir. 1997).

So there is precedent for the proposition that, when Congress identifies and provides for a particular purpose or use of specific Indian lands, an Agency should consider whether its actions have an impact on a tribe's exercise of that purpose or use and, to the extent possible, ensure that its actions protect that purpose or use. If a tribe could not survive on its land base without water, or water clean enough to farm, for example, courts have recognized that the purpose of that reservation or trust land would be entirely defeated. So too here, it would defeat the purpose of MIA, MICSA, MSA and ABMSA if the Maine Tribes cannot safely sustain themselves from the fish they can catch from their waters. DOI's legal opinion concludes that "fundamental, long-standing tenets of federal Indian law support the interpretation of tribal fishing rights to include the right to sufficient water quality to effectuate the fishing right." If EPA were to ignore the impact that water quality, and specifically water quality standards, could have on the Tribes' ability to safely engage in their sustenance fishing practices on their lands, the Agency would be contradicting the clear purpose for which Congress ratified the settlements in Maine and provided for the establishment of Indian lands in the State. Therefore, it is incumbent upon EPA when applying the requirements of the CWA to harmonize those requirements with this Congressional purpose.

3.3.3 Tribal Fishing Rights, the CWA, and the MICSA Savings Clauses

Accordingly, as explained in more detail below, EPA is identifying "sustenance fishing" to be a designated use in tribal waters, and is disapproving Maine's human health criteria because they are not stringent enough to protect the sustenance fishing use. EPA considered whether taking this action is prohibited by the so-called "savings clauses" in MICSA that are designed to block application of federal law in the State if it would both accord or relate to a special status or right for Indian tribes and affect or preempt the jurisdiction of the State. 25 U.S.C. §§ 1725(h) and 1735(b). EPA concludes that the savings clauses do not preclude EPA's actions under the CWA.

EPA is addressing the provisions of MICSA, which specifically provides for a land base for the Maine Tribes that is set aside for the purpose of preserving the Tribes' culture and sustenance practices, in the Agency's implementation of the CWA, which requires that water quality criteria protect designated uses and be based on sound scientific rationale. Unless EPA acts to ensure that the Tribes are able to safely exercise their sustenance practices, a key purpose behind the provisions in MICSA, MIA, ABMSA and MSA to assemble and preserve the Maine Tribes' land base and cultures would be largely defeated. When EPA identifies Maine's designated use of "fishing" to mean "sustenance fishing" in tribal waters, it is giving effect to MICSA within the

framework of Agency oversight of WQS provided for in the CWA. It certainly cannot be the case that the savings clauses in MICSA somehow operate to prevent the government from addressing MICSA itself.

In addition, the savings clauses cannot block operation of the CWA oversight authority EPA is exercising in this case. EPA's authority to review and approve or disapprove new or revised state WQS rests on the requirements of CWA section 303(c)(3), which provides general authority and a non-discretionary duty to review and approve or disapprove all new or revised WQS from states. Because this authority under the CWA neither "accords or relates to a special status or right of or to any Indian . . . tribe," nor "affects or preempts the ... regulatory jurisdiction of the State of Maine...," it is not blocked by the operation of the applicable MICSA savings clause. See 25 U.S.C. § 1725(h)(note that section 1735(b) would not apply to CWA section 303, because section 303 was enacted in 1972, and section 1735(b) applies only to laws enacted in and after 1980.). Nothing about EPA's oversight of Maine's WQS limits the State's jurisdiction to set WQS for waters in Indian lands. As to the adequacy of the WQS, no state has authority under the CWA to set standards that are "not consistent with the applicable requirements of this chapter [of the CWA]." 33 U.S.C. § 303(c)(3). In determining whether Maine's new or revised criteria are protective of the sustenance fishing designated use in Indian waters, EPA is simply exercising the same oversight authority it would exercise inside or outside Indian country anywhere in the nation. So this action does not accord the Indian Tribes in Maine a "special status or right."

EPA also considered whether, in looking to the federal common law of reserved tribal fishing rights when interpreting MICSA and implementing the CWA, EPA has somehow applied federal law to affect the application of state law. As a threshold matter, the MICSA savings clauses appear to be drafted entirely with Congressional statutory enactments in mind, and do not appear to address federal common law. For example, MICSA section 1725(h) provides that "no law or regulation of the United States" in existence at the time MICSA passed will apply in Maine if the conditions of that section are met. The formulation of "law or regulation" suggests Congress had in mind statutes that are routinely implemented by regulation. And the example provided in the Senate Committee Report of the operation of that section is a description of how section 164 of the Clean Air Act, a statutory law, would not apply in Maine. Sen. Rep. No. 96-957, p. 31.[14]

Finally, the operation and effect of these savings clauses is irrelevant to the use that EPA is making of federal common law in this case. The savings clauses are designed to prevent the federal government from unintentionally re-writing the jurisdictional deal embodied in MICSA. Only Congress has the authority to do that. In referencing certain principles of federal common

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[14] Section 1735(b) is the companion "savings" provision to section 1725(h), and it blocks the application of federal law enacted after 1980 if that law would benefit the Tribes and affect or preempt the application of state law. That section refers to "enacted Federal law" and includes the idea that a federal law may apply in Maine if it is made specifically applicable in Maine. This provision also appears aimed at statutes that Congress enacts where Congress has the opportunity to decide whether to call out Maine in particular. The Senate Report on MICSA confirms this reading: "*Subsection 16(b)* [codified as section 1735(b)] provides a rule of construction to govern interpretation of Federal *statutes* enacted after the date of enactment of this Act." Sen. Rep. No. 96-957, p. 35 (underscore added). Thus it appears that both of these savings provisions were designed to operate in combination to address congressional enactments and resulting regulations that might apply in Maine, not common law.

law noted above, EPA is merely acknowledging useful precedent that can inform how to interpret the purpose to which Congress dedicated the Tribes' lands under MICSA and the other settlement acts. Doing so does not revise MICSA or change its jurisdictional formula; rather EPA is ensuring that the tribal territories can continue to serve the purpose for which they were created under MICSA. This is precisely consistent with First Circuit precedent in which the court has looked to federal principles of Indian law to help interpret the meaning of MICSA. *Akins*, 130 F.3d at 489-490 and *Fellencer*, 164 F.3d at 711-712.

3.3.4 Designated Use of Sustenance Fishing

In section 3.2 above, EPA describes its approval of the designated uses contained in the various classifications of waters in Indian lands. Each classification includes the designated use of "fishing." As explained below, EPA is interpreting the designated fishing use for all waters in Indian lands to mean "sustenance fishing"; and for certain waters in the Southern Tribes reservations, EPA is also approving a sustenance fishing designated use specified in MIA.

3.3.4.1 EPA's Decision to Approve a Sustenance Fishing Use in the Southern Tribes' Inland Reservation Waters

As discussed above, MIA provides that: "Notwithstanding any rule or regulation promulgated by the commission or any other law of the State, the members of the Passamaquoddy Tribe and the Penobscot Nation may take fish, within the boundaries of their respective Indian reservations, for their individual sustenance subject to the limitations of subsection 6." 30 M.R.S. § 6207, sub-§ 4. "Fish" is defined to mean "a cold blooded completely aquatic vertebrate animal having permanent fins, gills and an elongated streamlined body usually covered with scales and includes inland fish and anadromous and catadromous fish when in inland water." 30 M.R.S. § 6207, sub-§ 9.

These provisions clearly codify a tribal right of sustenance fishing for inland, anadromous, and catadromous fish in the inland waters of the Penobscot Nation's and Passamaquoddy's reservations.[15] This right is subject only to 30 M.R.S. § 6207, sub-§ 6, which authorizes Maine's Commissioner of Inland Fisheries and Wildlife to, among other things, adopt remedial measures, including the rescission of any tribal ordinance or regulation by the Maine Indian Tribal-State Commission, to prevent substantial diminution of fish stocks in waters outside of the boundaries of lands or waters subject to regulation by the Passamaquoddy Tribe, the Penobscot Nation or the Commission.

EPA has evaluated whether 30 M.R.S. § 6207, sub-§§ 4 and 9, constitutes a new or revised water quality standard, in light of the Agency's recent guidance regarding how it determines what is or is not a new or revised WQS, summarized in EPA's 2012 Frequently Asked Questions (FAQ) publication on the subject.[16] As explained in the FAQ, EPA considers four questions in making this determination, and in this case, all four questions are answered in the affirmative. First,

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[15] EPA is taking no position here on whether this codified right includes or excludes fish in marine waters. See section 3.3.1.3, above. EPA is approving these provisions for inland waters where there is no ambiguity.

[16] EPA, What is a New or Revised Water Quality Standard Under CWA 303(c)(3)? Frequently Asked Questions, October 2012.

these provisions are legally binding and were established as a matter of state law. Second, they include and address one of the three core components of a water quality standard (i.e., a designated use), since they articulate a specific fishing use for the specified waters. Third, they express or establish the desired condition of the waters, or level of protection afforded the waters, by specifically providing for *sustenance* fishing. (As discussed above, to protect sustenance fishing, the water quality must be both adequate to support healthy fish populations at levels that provide a sufficient quantity of fish to be taken for sustenance purposes, and adequate to ensure that such fish may be safely consumed at sustenance rates by tribal members.[17]) Lastly, these provisions establish a new water quality standard since they have not previously been approved by EPA.

Based on this evaluation, EPA has determined that 30 M.R.S. § 6207, sub-§§ 4 and 9, constitutes a new or revised water quality standard, specifically a designated use, subject to EPA review and approval or disapproval under section 303(c) of the CWA.[18] EPA further finds that the sustenance fishing designated use established by 30 M.R.S. § 6207, sub-§§ 4 and 9, is consistent with the provisions of sections 101(a) and 303(c)(2) of the CWA, as well as EPA's implementing regulations. Accordingly, EPA is today approving the designated use of sustenance fishing for inland, anadromous, and catadromous fish, applicable to all inland waters of the Southern Tribes' reservations in which populations of fish are or may be found.[19]

3.3.4.2 EPA's Decision to Interpret the State's Designated Use of "Fishing" to Mean Sustenance Fishing for Waters in the Northern and Southern Tribes' Trust Lands

As explained above, EPA is approving the State's designated use of "fishing" as it applies to waters in Indian lands. In inland waters of the Southern Tribes' reservations EPA is also approving a specific additional designated use of sustenance fishing, as explained immediately above. In the trust lands for all the Tribes in Maine and the marine waters of the Passamaquoddy Tribe's reservation, EPA must determine how to interpret the fishing use that EPA is approving for those waters. EPA concludes that to protect the function of these waters to preserve the Tribes' unique culture and to provide for the safe exercise of their sustenance practices, EPA must interpret the fishing use to include sustenance fishing.[20]

In reviewing Maine's WQS as they apply to waters in Indian lands, EPA must reconcile two statutory frameworks. On the one hand, the CWA generally assigns to a state the responsibility of determining the designated uses in its waters (subject to certain restrictions at 40 C.F.R. § 131.10). 33 U.S.C. §§ 1251(a)(2), 1313(c)(2)(A). On the other hand, as explained above, the

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[17] As noted above, the sustenance fishing use is subject to the limitations of 30 M.R.S. § 6207, sub-§ 6, which authorizes Maine's Commissioner of Inland Fisheries and Wildlife to take steps to prevent substantial diminution of fish stocks. EPA considers this to be a fisheries management provision, and not a restriction on the *quality* of water needed to protect the sustenance fishing use.

[18] EPA's authority and duty to review and approve or disapprove new or revised WQS does not depend on whether such WQS have been submitted by the State to EPA for review, or on where in state law they are codified. *FAQ* at 2.

[19] EPA interprets this designated use of sustenance fishing as not applying to inland waters that are inherently incapable of sustaining fish populations, such as most ephemeral streams and vernal pools.

[20] EPA interprets the designated "fishing" use for the inland waters of the Southern Tribes' reservations in the same manner. However, because EPA is also approving a specific sustenance fishing use contained in 30 M.R.S. § 6207, sub-§§ 4 and 9 for those waters, the discussion in this section is focused on the waters in the Trust lands.

settlement acts in Maine recognize and create specific areas in the State to provide for the Tribes to use their waters in a way that is distinct from waters outside Indian lands. EPA is bound to attend to and comply with both statutory frameworks to the extent EPA is able to reconcile how they apply to the Agency's review of Maine's WQS in Indian waters.

It is possible to harmonize these two statutory frameworks by recognizing that the State's designated fishing use under the CWA must include the concept of sustenance fishing as provided for in the settlement acts. To do otherwise would run the risk that state WQS could be based on assumptions about fish consumption rates that could lead to criteria that fail to protect the Tribes' ability to safely consume fish for their sustenance. The settlement acts, adopted between 1980 and 1991, are designed to establish a land base on which the Tribes can sustain themselves as unique cultures going forward. Therefore, the Agency will interpret the designated fishing use to include the ability of tribal members to safely take fish for their individual sustenance.

The extent to which existing state law either codifies or at least accommodates tribal sustenance fishing supports this approach to harmonizing the settlement acts with the structure of the WQS program under the CWA. As described above, MIA codifies an express provision for sustenance fishing in the Southern Tribes' trust lands. The state fishing code as it applies to waters in the Northern Tribes' trust lands imposes take limits that appear to be consistent with those Tribes' ability to fish for their sustenance. And finally, in 2013, Maine explicitly provided for all the Tribes in Maine to take marine species for their sustenance. The role of tribal sustenance fishing is woven into the fabric of Maine law, so requiring that use to be protected in the State's WQS program as applied to tribal waters will not conflict with state law governing how the Tribes may use these waters.

As described above, EPA acknowledges that the Tribes' sustenance fishing practices are not free from state regulation. The State has varying degrees of authority to regulate the quantity of fish that can be taken depending on the type of Indian land involved. In the Southern Tribes' reservations, the State has very narrow authority to set limits in the reservations to prevent depletion of fish stock in waters outside the Southern Tribes' reservation waters. The commission can regulate fish take on certain waters on the Southern Tribes' trust lands based on factors enumerated in MIA. On the Northern Tribes' trust lands the State regulates take consistent with state law.[21] However, the State's authority to limit the taking of fish to manage fisheries for their protection and preservation is not inconsistent with the settlements acts' provision of sustenance fishing in tribal waters and EPA's identification of "sustenance fishing" as the designated use for these waters. Neither does the State's authority to limit take mean that state water quality criteria need not protect sustenance fishing in those waters. Water quality criteria must be sufficient to protect the designated uses, whether or not the uses are currently being achieved. CWA 303(c)(2)(A) and 40 C.F.R §§131.3(f) and 131.11.

[21] As noted earlier, EPA is not taking a position one way or the other on whether the State may regulate Passamaquoddy marine sustenance fishing where such fishing occurs within their reservation.

4 EPA's Decisions on Maine's New or Revised Water Quality Standards Submissions From 2003 through 2014

4.1 General Background

Section 303 of the CWA requires each state to adopt water quality standards to protect public health and welfare, enhance the quality of water, and otherwise serve the purposes of the CWA.[22] Any new or revised standard adopted by a state under section 303(c) must be submitted to EPA for review, to determine whether it meets the CWA's requirements, and approval or disapproval. 33 U.S.C. § 1313(c)(1) and (3); 40 C.F.R. §§ 131.5, 131.6 and 131.20.

WQS describe the desired condition of a waterbody and consist of three principle elements: (1) the "designated uses" of the state's waters, such as public water supply, recreation, propagation of fish, or navigation; (2) "criteria" specifying the amounts of various pollutants, in either numeric or narrative form, that may be present in those waters without impairing the designated uses; and (3) antidegradation requirements, providing for protection of existing water uses and limitations on degradation of high quality waters. EPA's regulations at 40 C.F.R. part 131describe the minimum requirements for each of these three elements of WQS.

In accordance with CWA § 303(c) and 40 C.F.R. §§ 131.5 and 131.11, EPA must ensure that new or revised criteria are based on sound scientific rationale and contain sufficient parameters or constituents to protect designated uses.

4.2 EPA's Decision to Disapprove Maine's Human Health Criteria for Waters in Indian Lands because They Do Not Protect the Designated Use of Sustenance Fishing in Waters in Indian Lands in Maine, and to Approve Maine's Cancer Risk Level of 10^{-6}

4.2.1 Maine's Human Health Criteria Submitted to EPA on May 14, 2004, January 11, 2006 and January 14, 2013

On May 14, 2004, DEP submitted revisions to the human health criteria for mercury at 38 M.R.S. § 420(1-B.A.(2)) to EPA for review and approval or disapproval. On January 11, 2006, Maine DEP submitted numeric Human Health Criteria ("HHC") for toxic pollutants, among other revisions, to EPA for review and approval or disapproval (the "2006 HHC").[23] These criteria replaced Maine's previous regulation that incorporated EPA's CWA § 304(a) recommended criteria by reference. The revisions reflected DEP's use of a statewide fish consumption rate ("FCR") of 32.4 g/day (an increase from the 6.5 g/day FCR on which EPA's

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[22] Section 303's requirements also apply to tribes that are authorized to implement a WQS program. Since EPA's decision today relates to a state's WQS program, the discussion of general statutory and regulatory requirements and guidance are framed in terms of state actions only.

[23] HHC are established to protect human health from exposure to pollutants that occur through the ingestion of water and/or contaminated fish and shellfish. Any human health criterion for a toxicant is based on at least three interrelated considerations: cancer potency or systemic toxicity, exposure (e.g., fish consumption rate), and risk characterization. http://water.epa.gov/scitech/swguidance/standards/handbook/chapter03.cfm#section13

then CWA § 304(a) recommended criteria were based).[24] The HHC revisions included a requirement that HHC for carcinogens be based on a cancer risk level (CRL) of $1x10^{-6}$. DEP Rule Chapter 584 § 4. Accordingly, all of the HHC for carcinogens submitted to EPA in 2006 were calculated using a 10^{-6} CRL. EPA approved the mercury criteria for waters outside of Indian lands on January 25, 2005, and approved the other criteria for waters outside of Indian lands on July 7, 2006 and September 18, 2006. EPA is today addressing these criteria for waters in Indian lands.

On January 13, 2014, DEP submitted new HHC for acrolein and phenol, and revised criteria for arsenic (discussed separately below), to EPA for review and approval. Similar to the 2006 HHC, the new HHC for acrolein and phenol were based on the statewide fish consumption rate of 32.4 g/day and a CRL of 10^{-6}. EPA is addressing these criteria in its decision today for all waters in the State, including in Indian lands.

In 2011, Maine's legislature enacted LD 515, which required DEP to revise Maine's HHC for arsenic by basing it on a CRL of 1 in 10,000 ($1x10^{-4}$) rather than the previous CRL of 1 in 1,000,000 ($1x10^{-6}$). DEP adopted the new criteria based on the 10^{-4} CRL and a revised FCR of 138 g/day, in order to protect highly exposed state subpopulations, and on January 14, 2013, submitted them to EPA for review and approval. EPA approved the revised arsenic criteria only for waters outside of Indian lands on May 16, 2013. EPA is addressing these criteria in its decision today for waters in Indian lands.

4.2.2 EPA's Analysis of the Adequacy of Maine's HHC for Waters in Indian Lands

4.2.2.1 EPA Guidance

As explained in EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (the "2000 Human Health Methodology" or "2000 Guidance"), EPA recommends that states provide adequate protection from adverse health effects to the general population, as well as to highly exposed populations, such as recreational and subsistence fishers, two distinct groups whose fish consumption rates may be greater than the general population.[25] EPA provides national default fish consumption rates ("FCR") of 17.5 grams per day ("g/day") for the general population and recreational anglers, and of 142.4 g/day for subsistence fishers.[26] However, because the level of fish consumption in highly exposed populations varies by geographic location, EPA strongly recommends that states use local or regional data over the default values. EPA has also recently explained that in order to provide for safe fish consumption, it is important that HHC avoid any suppression effects that may occur

[24] Although not explicitly stated in DEP Regulation Chapter 584, the mercury criteria in 38 M.R.S. § 420(1-B.A.(2)) were based on the Maine Bureau of Health Fish Tissue Action Level of 0.2 mg/Kg, which was derived using a fish consumption rate of 32.4 g/day. See *Development of Ambient Water Quality Criteria for Mercury, A Report to the Joint Standing Committee on Natural Resources,* by DEP, dated January 15, 2001.

[25] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004, p. 2-2. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[26] Id., pp. 1-12 and 1-13.

when a group's consumption rate is artificially diminished due to perceptions of pollutant contamination of the fish.[27]

4.2.2.2 Tribal Sustenance Fishers to be Protected as the Target Population in Tribal Waters

EPA concludes that when analyzing how the WQS program applies to the sustenance fishing use in the waters of Indian lands in Maine, the tribal population must be considered to be the "target population" for the purpose of determining whether the State's human health criteria are adequate to protect the tribes' health, including determining the appropriate fish consumption rate applicable in those waters and weighing the risk level to which tribal members should be exposed. Congress set aside Indian lands to provide a place for the Tribes to reside and to exercise their sustenance practices. Therefore, that tribal population and its sustenance fishing use must be the focus of the risk assessment supporting water quality criteria to adequately protect that use. To do otherwise risks undermining the purpose for which Congress established and confirmed the Tribes' land base.

EPA's 2000 Human Health Methodology provides that when developing in-stream water quality criteria to protect human health, states have some flexibility in determining which populations the state's criteria are designed to protect. Generally the guidance recommends that states consider how to protect both susceptible and highly exposed populations when setting criteria.

> When choosing exposure factor values [including fish consumption rates] to include in the derivation of a criterion for a given pollutant, EPA recommends considering values that are relevant to population(s) that is (are) most susceptible to that pollutant. In addition, highly exposed populations should be considered when setting criteria.[28]

EPA's approach in this guidance is to recommend protection of the general population based on fish consumption rates designed to represent "the general population of fish consumers," and then to recommend that states assess whether there might be more highly exposed subpopulations or "population groups" that require the use of a higher fish consumption rate to protect them as the "target population group(s)." *Id.* at 4-24 – 25. The guidance leaves states considerable discretion in determining which populations to target for protection using either statewide criteria or more geographically focused site-specific criteria.

The 2000 Guidance does not directly speak to the unique situation EPA confronts in this action, where 1) a state has authority to set human health criteria for waters in Indian lands, and 2) those lands have been set aside by Congress for, among other reasons, the preservation of tribal cultural practices, including sustenance fishing. Nevertheless, it is possible to apply the principles outlined in the 2000 Guidance to this situation, informed by the settlement acts. As discussed below, the settlement acts lead EPA to consider the Tribes to be the general target population in their waters, and the Guidance's recommendations on exposure and cancer risk for the general target population can be applied accordingly.

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[27] EPA 2013, Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions, page 2. Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf

[28] EPA 2000 Human Health Methodology at 4-17.

In Maine, the State has authority to set WQS for the waters in tribal lands where tribal members are the exclusive or predominant population. See 30 M.R.S. § 6206(1) (Penobscot Nation and Passamaquoddy Tribe control "the right to reside within the respective Indian territories" as an internal tribal matter.) Some of those lands and the waters in them are subject to a statutorily reserved tribal fishing right; some are set aside for the purpose of giving the resident tribe a land base on which to exercise traditional sustenance practices. What all the waters in these Indian lands have in common is, as explained above, that the fishing activity on them will involve tribal members, and may be predominated by tribal members, who have the right to, and desire to, fish for their sustenance. Also as explained above, consistent with the purpose of the settlement acts to preserve the Tribes' culture, these tribal members intend to fish for their sustenance. They are not a highly exposed or high-consuming subpopulation in their own lands; they are the general population for which the federal set-aside of these lands and their waters was designed.[29]

Therefore, as described above, EPA has identified and approved a designated sustenance fishing use applicable to waters in these Indian lands. That designated use requires the Agency to focus its analysis on sustenance fishers as the target general population. In effect, the settlement acts have determined how EPA and Maine must analyze the use of these waters and the population to be targeted for protection, because those acts established Indian lands in Maine for the clearly identifiable purpose of allowing the Tribes to sustain themselves on their own lands and waters.

A similar analysis applies to another critical factor in deriving human health criteria, the cancer risk level. For carcinogenic pollutants, EPA's 2000 Guidance recommends that states protect the general population to a level of risk no greater than one in one hundred thousand to one in one million (1×10^{-5} to 10^{-6}) of an additional cancer occurring in that population. Maine DEP has selected 10^{-6} as the level of risk that must be used to establish human health criteria for carcinogenic pollutants, with the exception of arsenic. Maine Rule Chapter 584 § 4. EPA's 2000 Guidance indicates that if there are highly exposed groups or subpopulations within that target general population, such as subsistence consumers, water quality standards should protect those consumers to a level of risk no greater than one in ten thousand (1×10^{-4}).[30] EPA and Maine relied on this aspect of the guidance in approving Maine's recently submitted revision to its human health criterion for arsenic as it applies to waters outside Indian lands. The Agency analyzed whether the State's revised arsenic criterion adequately protected subsistence consumers *outside* tribal waters as a *subpopulation* to a risk level of 10^{-4}.

Again, EPA concludes that it would be inconsistent with the intent of the settlement acts to treat the Tribes as a subpopulation of the State when developing HHC for waters in their own lands, and to expose them to levels of risk above what would be reasonable for the general population of the State. Therefore, the CWA requires that when establishing WQS for these waters, the tribal members must be considered to be the target general population for the purposes of setting

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[29] EPA recognizes that tribal members will not be the only population fishing from some of these waters. On major rivers such as the Penobscot River, for example, the general population has the right to pass through the waters in Indian lands. The presence of some nonmembers fishing on these waters, however, does not change the fact that the resident population in the Indian lands is made up of tribal members who expect to fish for their sustenance in the waters in Indian lands pursuant to the settlement acts.

[30] EPA 2000 Human Health Methodology at 2-6.

risk levels to protect the sustenance fishing use. In Maine, the State has codified a risk level of 10^{-6} for all but one carcinogen, and EPA is today approving that provision in Chapter 584 to apply to waters in Indian lands, as discussed further below.

4.2.2.3 Fish Consumption Rate

In evaluating the adequacy of Maine's HHC to protect the sustenance fishing designated use for waters in Indian lands, EPA reviewed the basis for the FCR used by Maine, and also considered whether other localized information exists that would be relevant and appropriate to consider in determining an adequate sustenance fishing consumption rate that is not artificially suppressed by pollution concerns.

4.2.2.3.1 ChemRisk Study

DEP derived the 32.4 g/day FCR, used for all of its HHC except arsenic, in part[31] from the results of a 1990 study conducted by McLaren/Hart – ChemRisk, of Portland, Maine (the "ChemRisk Study"[32]). While DEP considered several sources of information about fish consumption rates to develop the 2006 HHC, the ChemRisk Study contains the only localized data that DEP used. EPA reviewed the ChemRisk Study as well as additional information about the Study contained in comments from a primary author of the Study and responses to comments from DEP, contained in DEP's May 25, 2012 Response to Comments document submitted to EPA on January 14, 2013, to determine the Study's relevance to the target tribal populations' sustenance fish consumption rates in waters in Indian lands.

In 1990, to characterize the rates of freshwater fish consumption by Maine's resident anglers, ChemRisk conducted a statewide mail survey of Maine residents holding a valid Maine fishing license in 1989. The survey asked respondents to report the number of freshwater fish caught in Maine, their species, and the average length of each fish that was eventually consumed by them, including fish caught by other members of the respondent's household and by individuals outside the household. Along with other demographic information, respondents were asked to self-identify their ethnic background (white/non-Hispanic, Hispanic, Native American, Asian/Pacific Islander, Black, or other). Of the 2,500 surveys mailed, 1,612 were completed and returned. Of these, 1,053 anglers reported having consumed freshwater and anadromous fish obtained from Maine inland waters during the 1989-1990 ice fishing season or 1990 open water fishing season. The 95th percentile FCR (as calculated by rank without any assumption of statistical distribution) for the fish consuming anglers was 26 g/day.

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[31] Maine Bureau of Health, *Fish Tissue Action Levels,* February 20, 2001, published at https://www1.maine.gov/dhhs/mecdc/environmental-health/eohp/fish/documents/action-levels-writeup.pdf

[32] ChemRisk, A Division of McLaren Hart, and HBRS, Inc., *Consumption of Freshwater Fish by Maine Anglers,* as revised, July 24, 1992. See also Ebert, E.S., N.W. Harrington, K.J. Boyle, J.W. Knight, R.E. Keenan, *Estimating Consumption of Freshwater Fish among Maine Anglers*, North American Journal of Fisheries Management, 13:4, 737-745 (1993); http://dx.doi.org/10.1577/1548-8675(1993)013<0737:ECOFFA>2.3.CO;2

According to the Study, 148 Native Americans participated in the survey (11% of total participants), and 96 of those reported consuming freshwater fish that had been sport-caught.[33] The consumption rate for the Native American participants equaled or exceeded the rate of all other population groups at the 66th, 75th, and 90th percentiles[34], and the 95th percentile for Native Americans was nearly double the 95th percentile for the next highest population group.[35] However, the maximum rate reported by the Native Americans respondents (162 g/day) was lower than the maximum rate reported by the entire surveyed population (182 g/day).[36]

Ultimately, DEP used a statewide fish consumption rate of 32.4 g/day to establish its HHC, which is the equivalent of one 8-oz. fish meal per week, and, according to DEP, represents the 97th percentile FCR for Maine recreational anglers for all waters, and the 94th percentile for Native American anglers in Maine.[37] It was "designed to protect the subpopulation of recreational anglers that frequently consume sport-caught fish….."[38]

As explained above, in evaluating whether the sustenance fishing designated use for waters in Indian lands is protected by Maine's HHC, EPA considers the tribal sustenance fishers to be the "target" general population for such waters. This means that the FCR for the applicable HHC must reflect, as accurately as possible, the Tribes' sustenance level FCR, and the CRL must be protective of the sustenance fishers as a general population rather than as a highly exposed subpopulation.

Maine's FCR is based primarily on statewide data, which EPA's 2000 HH Methodology generally prefers over the use of national data. However, it is not based on localized data for the specific waters in Indian lands or the target tribal populations. The ChemRisk Study was not intended to be, nor was it, a survey of tribal sustenance fishers in tribal waters. The survey was sent to state-licensed recreational anglers, but tribal sustenance fishers are not required to have state licenses to fish in waters in Indian lands.[39] Therefore, EPA is unable to conclude that the Study results are representative of a fish consumption rate for tribal sustenance fishers in tribal waters.

In addition, the Study does not reflect unsuppressed fish consumption levels. At the time the ChemRisk survey was conducted, Maine had issued fish consumption advisories for the main stem of the Penobscot River, where the Penobscot Nation reservation is located, the Androscoggin River (1985), and the Kennebec River, (1987), and it issued advisories for the Presumpscot River and West Branch of the Sebasticook River in 1990.[40] DEP has acknowledged that "public awareness of historical pollution in industrialized rivers can be expected to have suppressed fish consumption on a local basis," and that the ChemRisk

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[33] ChemRisk Study, Tables 5 and 6a..
[34] Id., Table 6a.
[35] Id., as revised (see comment by Ellen Ebert in DEP's Response to Comments, May 25, 2012, page 16).
[36] Written comments from Ellen Ebert, primary author of the Chemrisk Study, to Maine DEP, as reported in DEP Response to Comments dated May 25, 2012 and submitted to EPA January 14, 2013.DEP, page 16.
[37] Maine RTC, May 25, 2012, page 20.
[38] Maine DEP testimony to the Maine Legislature, April 25, 2011, p. 3.
[39] Id., p. 19.
[40] Id., p. 20.

"estimates of fish consumption for rivers and streams as well as the inclusive 'all waters' category are likely to have been affected to some degree."[41]

Although the responses were not tallied and not analyzed in ChemRisk's report, the ChemRisk survey did include questions regarding the impact of fish consumption advisories. EPA analysis of the survey response data[42] indicates that 35% of respondents (556 individuals) were aware of the advisories during the time of the survey. Of the 160 respondents who reported that they ate fish from locations covered by fish consumption advisories, 82% (135) reported that the advisories affected whether they kept the fish caught at those locations.[43] It is not clear (because the question was not asked) whether anglers avoided certain waters in the 1989/1990 fishing season because of the fish advisories and whether that avoidance affected their total fish consumption. Nonetheless, it is clear that the existence of the advisories did result in some anglers reducing their take from those rivers.

EPA also reviewed the results of the Penobscot Nation's draft 1991 Penobscot River Users Survey.[44] While the survey was small (210 respondents) and the response rate was only 25%, and it was limited to Penobscot Nation members and their use of the Penobscot River, it does contain information that reinforces EPA's conclusion that the ChemRisk Study does not reflect unsuppressed sustenance fish consumption in tribal waters. For example, 72.9 % of the respondents stated they did not eat fish from the Penobscot River, and a majority (66.7%) stated that they had concerns about eating fish from the river.[45] The vast majority of those concerns were related to pollution.[46] In addition, of the 37.1% who reported not using the river at all, 16.3% identified the reason as concerns about pollution.[47]

4.2.2.3.2 Wabanaki Traditional Cultural Lifeways Exposure Scenario

In considering whether there are other sources of local data to inform EPA's determination of what FCR is representative of sustenance fishing in the waters in Indian lands, EPA reviewed the Wabanaki Cultural Lifeways Exposure Scenario ("Wabanaki Study"), which was completed in 2009. This peer reviewed Study was produced under a Direct Implementation Tribal Cooperative Agreement (DITCA) awarded by EPA to the Aroostook Band of Micmac Indians on behalf of all of the Maine Tribes. The purpose of the Study was to use available anthropological and ecological data to develop a description of Maine Tribes' traditional cultural uses of natural resources, and to present the information in a format that could be used by EPA to evaluate whether or not tribal uses are protected when EPA reviews or develops water quality standards in Indian lands in Maine.[48] It is relevant to contemporary water quality because another purpose of

[41] Id., pp. 20-21.
[42] Provided by the study author, Ellen Ebert, to EPA via email October 3, 2013.
[43] EPA, *Analysis of Suppression Questions from Chemrisk Study,* Memo to File, January 30, 2015.
[44] 1991 Penobscot River Users Survey conducted by the Penobscot Nation's Department of Natural Resources (draft).
[45] Id., Appendix A, §§ A.5 and A.6
[46] Id., Appendix A, § A.6
[47] Id., Appendix A, §A.1.a
[48] Harper, Barbara and Darren Ranco, *Wabanaki Traditional Cultural Lifeways Exposure Scenario*, prepared for EPA in collaboration with the Maine Tribes, p.7, July 9, 2009.

the Study "is to describe the lifestyle that was universal when resources were in better condition and that some tribal members practice today (and many more that are waiting to resume once restoration goals and protective standards are in place)."[49] It provides a numerical representation of the environmental contact, diet, and exposure pathways of the traditional tribal lifestyle, including the use of water resources for food, medicine, cultural and traditional practices, and recreation. The Study acknowledges that "the Wabanaki homelands extended further west and south into areas with different plants and climate and where farming was possible," but notes that "the scenario itself covers only areas most heavily used by Tribal members at present, and where farming is marginal due to climate."[50]

The report used anthropological and ecological data to identify major activities that contribute to environmental exposure and then to develop exposure factors related to traditional diet, drinking water, soil and sediment ingestion, inhalation rate and dermal exposure. Credible ethno historical, ecological, nutritional, archaeological, and biomedical literature was reviewed through the lens of natural resource use and activities necessary to survive in the Maine environment and support tribal traditions. Along with single, best-professional judgment estimates for direct exposures (inhalation, soil ingestion, water ingestion) as a reasonable representation (central tendency) of the traditional cultural lifeways, the Wabanaki Study provides an estimated range of diets that reflect three major habitat types.[51]

In developing the dietary component of the exposure scenario, the Wabanaki Study authors assembled information about general foraging, seasonal patterns, dietary breadth, abundance, and food storage. From these they evaluated the relative proportion of major food groups, including fish, as well as nutritional information, total calories and quantities of foods. This resulted in an estimate of a nutritionally complete diet for the area east of the Kennebec River, which is the area most heavily used by tribal members today and where farming is marginal due to climate.[52]

With regard to the consumption of fish, the Wabanaki Study identifies three traditional lifestyle models, each with its own diet:

1. Permanent inland residence on a river with anadromous fish runs ("inland anadromous"),
2. Permanent inland residence with resident fish only ("inland non-anadromous"), and
3. Permanent coastal residence ("coastal").

The study provides estimates of average consumption of aquatic resources, game, fowl, and plant based foods for each lifestyle model. Aquatic resources were divided into two categories: "resident fish and other resources" and "anadromous and marine fish and shellfish." Table 1 summarizes the consumption of aquatic resources for each lifestyle model.

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[49] Id., p. 9
[50] Id.
[51] Id., p. 16.
[52] Id., pages 8-9.

Table 1 – Consumption of Aquatic Resources by Lifestyle Model[53]

Lifestyle Model	Resident Fish & Other Aquatic Resources(g/day)	Anadromous & Marine Fish, Shellfish (g/day)[54]
Inland Anadromous	114	400
Inland Non-anadromous	286	0
Coastal	57	457

The Wabanaki Study provides a range of fish consumption rates specifically for Maine Indians using natural resources for subsistence living and reduces the uncertainties associated with a lack of knowledge about tribal exposure in Maine Indian waters. On their own, these fish consumption rates could form the basis for criteria protective of sustenance fishing. Alternatively, they could be the starting point that could be modified, based on additional information, to take into account present day circumstances related to the species composition of available fish. For example, in developing its 2014 tribal water quality criteria, the Penobscot Nation used a FCR of 286 g/day. The Nation explained that it chose the inland non-anadromous total FCR of 286 g/day because, although the Penobscot lands are in areas that would have historically supported an inland anadromous diet (with total FCR of 514 g/day), the contemporary populations of anadromous species in Penobscot waters are currently too low to be harvested in significant quantities. [55]

4.2.3 Disapproval of Maine's HHC Because They Are Based on FCRs that Fail to Protect Sustenance Fishing

EPA is today disapproving, for waters in Indian lands, the mercury human health criteria in 38 M.R.S. § 420(1-B.A.(2)) submitted to EPA on May 14, 2004; the fish consumption rate of 32.4 g/day specified in DEP Rule Chapter 584 § 5.C and all human health criteria in DEP Rule Chapter 584, Surface Water Quality Criteria for Toxic Pollutants, Appendix A, submitted to EPA on January 11, 2006; and the human health criteria revisions related to arsenic, acrolein, and phenol in DEP Rule Chapter 584, Surface Water Quality Criteria for Toxic Pollutants, Appendix A, as well as the last sentence in Ch. 584, § 5.C related to the fish consumption rate, submitted to EPA on January 14, 2013. The basis for the disapproval is that the HHC do not protect the sustenance fishing use in those waters. For the reasons discussed above, Maine's 32.4 g/day FCR is not representative of an unsuppressed sustenance fish consumption rate by tribal members in waters in Indian lands.

In the absence of a local survey of current fish consumption, adjusted to account for suppression, that documents fish consumption rates for sustenance fishing in the tribal waters, EPA finds that the Wabanaki Study contains the best currently available information for the purpose of deriving an FCR for HHC adequate to protect sustenance fishing for such waters. It is local, focused on the areas most heavily used by tribal members today. It identifies historic FCRs based on

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[53] Id., pp. 61-66.

[54] Includes marine mammals for coastal lifestyle model only.

[55] Penobscot Nation, Department of Natural Resources, *Response to Comments on Draft Water Quality Standards*, September 23, 2014, p. 9.

reasonable estimates for total calories and protein intake per day. Heritage rates provide reliable evidence of what unsuppressed rates would be for tribal populations.[56] The Study uses a sound methodology (peer reviewed, written by a range of experts in risk assessment and anthropology). It presents a range of FCRs from 286 g/day (freshwater fish only) to 514 g/day (combinations of freshwater, anadromous, and marine species), which can provide the basis for choosing an FCR that reflects traditional cultural practices in light of present day circumstances related to, for example, the species composition of available fish (as the Penobscot Nation recently did in adopting an FCR of 286 g/day).

Because the Wabanaki Study documents a substantially higher tribal sustenance fish consumption rate than the FCR on which Maine's HHC are based, EPA cannot conclude that the HHC are based on a sound scientific rationale consistent with 40 C.F.R. § 131.11(a) and protect the sustenance fishing use for the waters in Indian lands. EPA is therefore disapproving the HHC.

4.2.3.1 Remedy to Address EPA's Disapproval

Under CWA § 303(c)(3) and EPA's implementing regulations at 40 C.F.R. §§ 131.21 and 131.22, when the EPA disapproves a state's new or revised water quality standard, it must "specify the changes" necessary to meet the applicable requirements of the Act and EPA's regulations. The CWA requires that this disapproval of Maine's human health criteria for waters in Indian lands be addressed in a timely manner. In the first instance, the CWA and EPA's regulations provide the State up to 90 days to revise its WQS, and EPA prefers that Maine address this disapproval under its regulatory development process. However, if the State does not adopt necessary changes, EPA will propose and promulgate appropriate human health criteria for waters in Indian lands in Maine.

To address this disapproval action, Maine must develop new human health criteria for waters in Indian lands that protect tribal sustenance fishers as the target general population and are based on a fish consumption rate that represents unsuppressed sustenance fishing by tribal members.

Among the available existing information on fish consumption, the Wabanaki Study is most relevant for Maine to consider in revising human health criteria in Indian lands. As discussed in section 4.2.2.3, the Wabanaki study is directly applicable to the Maine Tribes fishing in waters on Indian lands. The fish consumption rates developed in the Wabanaki study are estimates of unsuppressed tribal fish consumption that could be used in the derivation of criteria protective of contemporary tribal sustenance fishing. In addressing the disapproval, Maine should use the fish consumption rates developed in the Wabanaki study either on their own or modified, based, for instance, on information that may be provided by the Maine Tribes, to take into account changes in species composition in tribal fisheries and contemporary tribal sustenance fishing goals.

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[56] National Environmental Justice Advisory Council, *Fish Consumption and Environmental Justice,* November 2002 (revised), page 49.

4.2.4 Approval of Maine's Cancer Risk Level of 10^{-6} and No Action on Maine's Arsenic CRL of 10^{-4}

Maine's water quality regulations specify that water quality criteria for carcinogens be based on a CRL of 10^{-6} for all pollutants except arsenic. DEP Rule Chapter 584 § 4. This CRL is consistent with the range of CRLs that EPA considers to be appropriate for the general population and is the risk level that EPA uses when publishing its CWA § 304(a) recommended criteria.[57] As explained above, EPA has determined that the Tribes are the target general population for waters in Indian lands. EPA is therefore today approving Maine's requirement to use 10^{-6} CRL for all carcinogens except arsenic (discussed further below) for the waters in Indian lands. Criteria based on this low level of cancer risk, along with other appropriate factors (including an appropriate FCR), will protect the sustenance fishing use for waters in Indian lands.

EPA recognizes that the Maine Legislature enacted a law that requires DEP to use a CRL of 10^{-4} when establishing arsenic criteria,[58] and that DEP Rule Chapter 584 was revised in 2012 to reflect this requirement. Since EPA is disapproving Maine's arsenic criteria along with all of the other HHC for waters in Indian lands due to an inadequate FCR, EPA is not acting on Maine's CRL for arsenic (i.e., the last sentence in Ch. 584, § 4, related to the cancer risk level to be used to calculate human health criteria for inorganic arsenic, and the first sentence of Footnote aME in Table I of Appendix A of Chapter 584). However, we note that when Maine revises its arsenic criteria, it must ensure that the criteria protect the Tribes as the general target population in these waters, not as a subpopulation. Based on the analysis above, the use of a sustenance level FCR developed for all of the HHC, in combination with a CRL of 10^{-4} for arsenic, would not protect the designated use of sustenance fishing.

4.3 EPA's Decision to Approve Maine's Human Health Criteria for Acrolein for the Consumption of Organisms Only and for the Consumption of Water and Organisms, and Phenol for the Consumption of Organisms Only, and to Take No Action on Phenol for the Consumption of Water and Organisms, in Waters Outside Waters in Indian Lands

For all waters in Maine *except* for waters in Indian lands, EPA approves the following water quality criteria contained in DEP Rule Chapter 584, Surface Water Quality Criteria for Toxic Pollutants, Appendix A, submitted to EPA on January 14, 2013:

- Human health criteria for the consumption of water plus organisms for acrolein; and
- Human health criteria for the consumption of organisms only for acrolein and phenol.

Maine's revised human health criteria for acrolein and phenol were derived using the same methodology and equations used to calculate EPA's current 304(a) recommended criteria for non-carcinogens. EPA updated recommended human health criteria for acrolein and phenol in 2009 based on new Integrated Risk Information System Reference Doses (RfDs) for the pollutants[59]. Consistent with EPA's criteria derivation, Maine has made no changes to the

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[57] *2000 Human Health Methodology*, p. 1-8.
[58] 38 M.R.S. § 420(1-B.J).
[59] Federal Register: June 10, 2009 (Volume 74, Number 110)

parameters incorporated into these criteria or to the equations used other than the new RfDs. The criteria calculations are summarized in attached Tables 1 and 2 below.

Table 1 – Calculation of Approved Acrolein Human Health Criteria

Parameter	2012 criteria
Reference Dose (RfD)	0.0005 mg/(kg-d)
Body Weight (BW)	70 kg
Water Consumption (DW)	2 L/day
Bioconcentration Factor (BCF)	215 L/kg
Fish Consumption Rate (FCR)	0.0324 kg/day
Criteria to protect human health for consuming fish and drinking water (water + organism) = $\frac{1{,}000\ \mu g/mg \times RfD \times BW}{DW + (BCF \times FCR)}$	3.9 µg/L
Criteria to protect human health for consuming fish only (organism only) = $\frac{1{,}000\ \mu g/mg \times RfD \times BW}{BCF \times FCR}$	5.0 µg/L

Table 2 – Calculation of Approved Phenol Human Health Criteria

Parameter	2012 criteria
RfD for Phenol	0.30 mg/(kg-d)
Body Weight (BW)	70 kg
Water Consumption (DW)	2 L/day
Bioconcentration Factor (BCF)	1.4 L/kg
Fish Consumption Rate (FCR)	0.0324 kg/day
Criteria to protect human health for consuming fish only (organism only) = $\frac{1{,}000\ \mu g/mg \times RF \times BW}{BCF \times FCR}$	462,963 µg/L

EPA's approval of Maine's revisions to its human health criteria for acrolein and to the human health criteria for phenol for the consumptions of organisms only is based on a review of whether the criteria protect the applicable designated uses, including consideration of EPA's National Recommended Water Quality Criteria published pursuant to Section 304(a) of the CWA. EPA finds that the revised criteria are scientifically defensible and are protective of designated uses for waters outside of Indian lands, for the reasons explained in the EPA criteria documents for each chemical constituent.

EPA understands that DEP will be revising the phenol criteria for the consumption of water and organisms to address a mathematical error made in the criteria derivation. Therefore, at this time EPA is not taking action on the human health criteria for phenol for the consumption of water and organisms, for waters outside of Indian lands, with the anticipation that the revised phenol criteria will be adopted and submitted to EPA for review and action within the coming months.

4.4 EPA's Decision to Approve Maine's Aquatic Life Criteria for Acrolein, Diazanon and Nonylphenol for waters throughout the State of Maine, including in Indian Lands

EPA's review of Maine's new aquatic life criteria for acrolein, diazanon and nonylphenol, submitted to EPA on January 14, 2013, is based on whether the criteria protect aquatic life uses, including consideration of EPA's National Recommended Water Quality Criteria published pursuant to Section 304(a) of the CWA. EPA finds that the revised criteria are scientifically defensible and are protective of designated uses for the reasons explained in the EPA criteria documents[60] for acrolein, diazanon and nonylphenol.

4.5 EPA's Decision to Approve Maine's Aquatic Life Criteria Tables I and II in DEP Rule Chapter 584, except for Ammonia, Approve Aquatic Life Criteria in 38 M.R.S. § 420(1-B.A.(1)), (1-B.C), (1-B.D), and (1-B.E), and Approve Biological Criteria in DEP Rule Chapter 579 for Waters in Indian lands

EPA's review of the aquatic life criteria, other than ammonia, in DEP Regulation Chapter 584 Tables I and II, submitted to EPA on January 11, 2006, and in 38 M.R.S. § 420(1-B.A.(1)), (1-B.C)[61],(1-B.D), and (1-B.E), submitted to EPA on May 14, 2004 (related to mercury and referenced in Table I of Chapter 584), for waters in Indian lands, is based on whether the criteria protect aquatic life uses, including consideration of EPA's National Recommended Water Quality Criteria published pursuant to Section 304(a) of the CWA. EPA finds that the revised criteria are scientifically defensible and are protective of designated uses for the reasons explained in the EPA criteria documents[62] for those pollutants. EPA approved these criteria for waters outside Indian lands on January 25, 2005 and July 7, 2006, and is now approving them for waters in Indian lands.

DEP Rule Chapter 579 provides numeric biological criteria that quantify aquatic life standards for Class AA, A, B and C waters. The rules use the benthic macroinvertebrate community as a surrogate to determine conformance with statutory aquatic life standards. EPA approves of these criteria because they are based on sound scientific rationale and are protective of designated aquatic life uses, as required by Section 303(c)(2)(B) of the CWA and 40 C.F.R. § 131.11. EPA approved this rule for waters outside Indian lands on January 25, 2005, and is now approving it for waters in Indian lands.

4.6 EPA's Decision to Approve Maine's Narrative Criteria for Toxic Pollutants and Implementation Policies Regarding the Development of Statewide Criteria and Site-Specific Criteria, except for Specified Fish Consumption Rates, in DEP Rule Chapter 584, for Waters in Indian Lands

EPA's review of Maine's narrative water quality criteria, as expressed in Chapter 584, §§ 1, 2, and 3.A(1), and submitted to EPA on January 11, 2006, is based on whether those provisions are protective of designated uses, as required in 40 C.F.R. § 131.11. Since the narrative criteria specifically call for waters to be free of pollutants in concentrations that cause waters to be

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[60] See http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm#altable for National Recommended Water Quality Criteria and access to criteria documents for each pollutant.

[61] Not including 38 M.R.S §420(1-B.C.(1)) and (1-B.C.(2)), which are not WQS requiring EPA review and approval – see section 4.9 below.

[62] See http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm#altable for National Recommended Water Quality Criteria and access to criteria documents for each pollutant.

unsuitable for the designated uses of the water body, EPA finds that they are consistent with the requirements. EPA approved these provisions for waters outside Indian lands on July 7, 2006, and is now approving them for waters in Indian lands.

EPA's review of Maine's implementation policies regarding the development of statewide criteria and site specific criteria in Chapter 584 §§ 3 and 5 (other than the fish consumption rates of 32.4 g/day and 138 g/day, which EPA is disapproving as discussed above) is based on whether the criteria developed from those policies would protect the applicable designated uses including a consideration of EPA's ambient water quality criteria guidance, published pursuant to Section 304(a) of the CWA. The implementation policies include requirements for developing scientific bases for new or revised criteria as well as assumptions regarding ambient waters characteristics (such as pH, temperature, and salinity), and human health (such as water consumption rate and average body weight). EPA approved these policies for waters outside Indian lands on July 7, 2006 and now approves the implementation policies in Chapter 584 §§ 3 and 5 (other than the fish consumption rates) for waters in Indian lands because they require criteria to protect designated uses, and since the procedures and numeric assumptions are consistent with currently published EPA guidance.

EPA is not taking action on the procedures described in Chapter 584 § 3 which describe how alternative statewide and site-specific criteria are to be initiated, reviewed and adopted under state law.[63] Such procedures are not WQS requiring review and approval by EPA. Any new or revised criteria developed under the procedures for statewide, alternative statewide, or site-specific criteria must be submitted to EPA for review and approved by EPA pursuant Section 303(c)(3) of the Clean Water Act and 40 C.F.R. part 131 in order to be effective for Clean Water Act purposes.

4.7 EPA's Decision to Approve Maine's Dissolved Oxygen (DO) Criteria for Class C waters, Requirements for Compliance with DO criteria in Riverine Impoundments, Requirements for Instream Design Flows, the Requirement to Hold a WQS Review Hearing Every Three Years and Provisions that Allow for Pesticide Discharges into Class B and SB Waters for Mosquito Control, for Waters in Indian Lands

EPA's review of the revision to the DO criteria for Class C waters in 38 M.R.S. §465(4.B), submitted to EPA on January 11, 2006, is based on whether the criteria protect aquatic life uses, particularly cold waters species. For the reasons provided in our July 7, 2006 approval of these criteria for waters that are not in Indian lands, EPA finds that the criteria are protective of aquatic life uses and approves them in Indian lands as well.

EPA's review of the revision to DO measurement requirements for riverine impoundments in 38 M.R.S. §464(13), submitted to EPA on August 26, 2003, is based on whether the criteria protect existing and designated uses for waters in Indian lands. As explained in our February 9, 2004

[63] Specifically, these provisions are: the requirement in Chapter 584 § 3(A.(2)) that "statewide criteria must be initiated in accordance with the petition for rulemaking provisions of the State Administrative Procedures Act, 5 M.R.S.A., Section 8055"; the provision in the first paragraph of Chapter 584 § 3(B) that site specific criteria "must only be adopted by the Board as part of a waste discharge license proceeding pursuant to 38 M.R.S.A. Sections 413, 414 and 414-A"; and the first two sentences of the second paragraph of Chapter 584 § 3(B).

approval of this revision for waters that are not in Indian lands, EPA finds that the narrative standard that accompanies the measurement requirements ("dissolved oxygen concentration in existing riverine impoundments must be sufficient to support existing and designated uses of these waters") ensures that, notwithstanding the measurement restrictions in this provision, the revision is consistent with the requirements of the Clean Water Act.

EPA's review of the revisions to DEP Rule Chapter 530 § 4(B), which contains instream design flows for the application of water quality criteria for aquatic life and human health, submitted to EPA on January 11, 2006, is based on whether the provision protect existing and designated uses for waters in Indian lands. The instream design flows (1Q10 low flow for acute aquatic life criteria, 7Q10 for chronic aquatic life criteria, and harmonic mean flow for human health criteria), are consistent with guidance intended to ensure protection of uses provided in Section 5.2 of EPA' Water Quality Standards Handbook[64]. EPA approved this provision for waters outside Indian lands on April 17, 2006, and is now approving it for waters in Indian lands.

EPA's review of the revision to provisions in 38 M.R.S. § 464(3.B), that ensure that a hearing will be held at least every three years for the purpose of reviewing Maine's WQS, and revising them, as appropriate, submitted to EPA on May 14, 2004, is based on whether the provision is consistent with federal WQS review requirements. This revision reversed a previous change to 38 M.R.S. § 464(3.B)[65] that specified hearings only every four years. Since CWA § 303(c)(1) and 40 C.F.R. § 131.20 require states to hold public hearings every three years, the revision is consistent with federal WQS requirements. EPA approved this provision for waters outside Indian lands on January 25, 2005, and is now approving it for waters in Indian lands.

Revisions submitted on April 8, 2008 included the addition of 38 M.R.S. § 465(3.C.(2)) and § 465-B(2.C) which allow the discharge to Class B and SB waters of aquatic pesticides approved by DEP for control of mosquito-borne diseases. EPA's review is based on whether the provision will protect existing and designated uses for waters in Indian lands and is consistent with the requirements of the Clean Water Act. Given the requirements that the methods and materials used be protective of non-target species, EPA anticipates that no degradation of water quality would occur due to the discharge of aquatic pesticides authorized under these revisions. EPA approved these provisions for waters outside Indian lands on August 19, 2009 and is now approving it for waters in Indian lands.

4.8 EPA's Decision to Take No Action on Maine's Ammonia and Recreational Bacteria Criteria for Waters in Indian lands; on the Reclassification of Long Creek; and on Certain Bacteria and Pesticide Provisions for Waters throughout Maine, Including Waters in Indian Lands

EPA understands that Maine will be conducting a comprehensive triennial review in the coming months and will be reviewing the ammonia criteria for protection of aquatic life and the bacteria

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[64] EPA-820-B-14-004, September 2014, provided on line at http://water.epa.gov/scitech/swguidance/standards/handbook/chapter05.cfm#section52.

[65] EPA did not act on the previous revision (calling for hearings every 4 years) which DEP submitted to EPA on August 26, 2003, since DEP agreed at that time to propose changing the requirement back to hearings every 3 years.

criteria for the protection of primary contact recreation, in light of EPA's recommendations[66] for these widespread pollutants, issued in 2013 and 2012, respectively. EPA expects that DEP will be revising these criteria for all waters in Maine, including waters in Indian lands, so that they are based on sound science and protective of the designated uses. For this reason, for waters in Indian lands, we are not taking action at this time on Maine's ammonia criteria for the protection of aquatic life in DEP regulation Chapter 584, Appendix A, and the numeric bacteria criteria for the protection of primary contact recreation for Class B and C waters in 38 M.R.S. §465(3.B) and (4.B), and the extension of the applicability of bacteria criteria for Class SB and SC waters to include bacteria of domestic animal origin in 38 M.R.S. § 465-B(2.B) and (3.B). For the same reason, we are not taking action for waters throughout the State, including waters in Indian lands, on the revisions to 38 M.R.S. §465(3.B) and (4.B) and 38 M.R.S. § 465-A(1.B), which extended the applicability of the bacteria criteria for Class B, C, and GPA waters to include bacteria of domestic animal origin. EPA would be happy to provide assistance to DEP as it develops the new criteria.

In addition, EPA is not taking action on the reclassification of a section of Long Creek (which is a water outside of Indian lands) from Class B to Class C. This downgrade in classification was adopted to achieve consistency in the Creek where the upstream and downstream reaches were already Class C waters. EPA agrees with DEP that it is unusual for a downstream section of a flowing water to be at a higher classification that the upstream section, However, EPA would like to discuss this reclassification further with DEP in the coming months to explore whether there are other means to remedy the inconsistency, such as reclassifying the upstream section to Class B if the restoration of Long Creek and Class B uses there are attainable.

EPA also reviewed the provisions related to certain pesticide discharges submitted to EPA in 2006, 2008 and 2014 and finds that many of these are not water quality criteria requiring review and approval by EPA (as discussed in the section that follows) and two are WQS that we have approved herein (as discussed in the preceding section). However, EPA finds that some of these revisions are WQS which EPA has not yet acted on for waters anywhere in Maine. The revisions related to pesticides that are WQS that we are continuing to take no action on are:

- The revisions made in L.D. 1304 at 38 M.R.S. § 464(4.A.(3)(a)), and § 465((3.C.(1)) and (4.C), related to certain pesticide discharges, submitted to EPA on January 11, 2006;
- The revision made in L.D. 1430 at 38 M.R.S. § 464(4.A.(3)(b)), related to certain pesticide discharges to tributaries of GPA waters, submitted to EPA on February 27, 2014.

The revisions made at 38 M.R.S. § 464(4.A.(3)(a) and (b)), would allow, in GPA waters and tributaries to GPA waters, the impairment of characteristics and designated uses and increase in trophic state due to discharges of aquatic pesticides or chemical discharges for the purpose of restoring biological communities affected by an invasive species or that are the unintended or incidental result of the spraying of pesticides. The revision made at 38 M.R.S. § 465((3.C.(1)) would allow, in Class B waters, impairment of the resident indigenous biological community due to discharges of aquatic pesticides or chemical discharges for the purpose of restoring biological

[66] See December 2, 2013 letter from EPA Region 1 Office of Ecosystem Protection Director, Ken Moraff to DEP Bureau of Land and Water Quality Director, Michael Kuhns.

communities affected by an invasive species. Similarly, the revision made at 38 M.R.S. § 465(4.C) would allow impairment of the function and structure of the indigenous biological community due to discharges of aquatic pesticides for the purpose of restoring biological communities affected by and invasive species. EPA understands from recent discussion with DEP, that Maine will be revising these provisions during the upcoming months to ensure that they are protective of designated uses. For this reason EPA is not taking action on these revisions at this time.

4.9 EPA's Determination That Various Provisions Submitted to EPA from 2004 through 2014 Are Not Water Quality Standards and Therefore EPA is Taking No Action on These Provisions

EPA has reviewed the following provisions and determined that they are not water quality standards and therefore EPA is taking no action on these provisions:

- Revisions made at 38 M.R.S. § 465(1.C.(2)) and (2.C.(2)), enacted as Chapter 574, L.D. 1833 "An Act to Amend Water Quality Laws to Aid in Wild Atlantic Salmon Restoration," submitted to EPA on May 14, 2004;
- Revisions made at 38 M.R.S. § 420(1-B.B) related to discharger compliance, submitted to EPA on May 14, 2004;
- Revisions made at in 38 M.R.S. § 420(1-B.C.(1)) and (1-B.C.(2)) that describe the state regulatory procedures for establishing site-specific bioaccumulation factors, submitted to EPA on May 14, 2004;
- Procedures in DEP Rule Chapter 584 that describe how alternative statewide and site-specific criteria are to be initiated, reviewed and adopted under state law, submitted to EPA on January 11, 2006;[67]
- Revisions made at 38 M.R.S. § 361-A(1-J) and (1-K), enacted as Chapter 330, L.D. 1588, Sections 7 and 8, which updated the definitions of "Code Of Federal Regulations" and "Federal Water Pollution Control Act" to include their amendments through January 1, 2005, submitted to EPA on January 11, 2006;
- Revisions made at 38 M.R.S. § 464(4.A.(1)(c) and (d)); § 465(1.C.(3)) and (2.C.(3)); and § 465-A(1.C), enacted as Chapter 182, L.D. 1304 "An Act Concerning Invasive Species and Water Quality Standards," submitted to EPA on January 11, 2006;
- Revisions made at 38 M.R.S. § 464(4.A.(1)(e)); § 465(1.C.(4)) and (2.C.(4)); § 465-A(1.C.(4)); and § 465-B(1.C.(2)), enacted as Chapter 291, L.D. 1274, "An Act to Allow the Discharge of Aquatic Pesticides Approved by the Department of Environmental Protection for the Control of Mosquito-borne Diseases in the Interest of Public Health and Safety," submitted to EPA on April 8, 2008;
- Revisions made at 38 M.R.S. § 420(1-B.F) and § 464(4.J) and (4.K), related to testing and licensing requirements for waste discharges that were included in LD 515, submitted to EPA on January 14, 2013; and

[67] Specifically, these provisions are: the requirement in Chapter 584 § 3(A.(2)) that "statewide criteria must be initiated in accordance with the petition for rulemaking provisions of the State Administrative Procedures Act, 5 M.R.S.A., Section 8055"; the provision in the first paragraph of Chapter 584 § 3(B) that site specific criteria "must only be adopted by the Board as part of a waste discharge license proceeding pursuant to 38 M.R.S.A. Sections 413, 414 and 414-A"; and the first two sentences of the second paragraph of Chapter 584 § 3(B).

- Revisions made at 38 M.R.S. § 464(4.A.(1)(f)); § 465(1.C.(5)) and (2.C.(5)); § 465-A (1.C.(5)); and § 465-B(1.C.(4)), enacted as Chapter 193, L.D. 1430, "An Act to Clarify the Permitted Use of Aquatic Pesticides," submitted to EPA on February 27, 2014.

Since many state and tribal laws that establish WQS include related provisions that are not themselves WQS, as defined by the Clean Water Act and EPA's regulations, EPA routinely reviews state submissions and identifies revisions that, while an important element of state law, are not WQS requiring EPA review and approval or disapproval pursuant to Section 303(c)(2) of the Clean Water Act and 40 C.F.R. part 131. EPA has in the past considered certain discharge prohibition exceptions, discharge licensing requirements, and alternative criteria adoption procedures in Maine to be WQS revisions and acted on them accordingly.[68] However, since the Region last considered such a revision in Maine, EPA has clarified how it determines what is or is not a new or revised WQS, as summarized in EPA's 2012 Frequently Asked Questions (FAQ) publication on the subject.[69] After careful review of Maine's submissions in light of this clarification, EPA finds that the provisions listed above are not WQS requiring EPA review and approval or disapproval.

As noted in the FAQ, one salient feature of a water quality standard is that it includes or addresses one of the three core components of WQS: designated uses, water quality criteria (narrative or numeric) to protect designated uses, and/or antidegradation requirements for waters of the United States. The provisions listed above, in contrast, do not establish, alter, or in any other way include or address designated uses, criteria or antidegradation requirements. Rather, most of the provisions allow the DEP to issue discharge licenses for certain previously prohibited discharges to occur in certain waters, and address compliance and testing requirements for certain discharges. In all cases, such discharges would still need to satisfy all applicable water quality standards. Therefore, the provisions are more accurately characterized as permit implementation provisions rather than water quality standards. The remaining provisions are purely procedural in nature, updating federal statutory and regulatory references, and establishing processes for adopting alternative criteria and establishing bioaccumulation factors, but they do not themselves alter uses, criteria, or antidegradation requirements, or mandate how they must be expressed or established in the future.

EPA has previously written approval letters for some of the above-listed provisions as applied in state waters, assuming that they were WQS (such as the discharge prohibition exceptions), or without calling out embedded non-WQS language in a longer narrative (such as the state adoption procedures in DEP rule Chapter 584). However, under CWA §303(c), EPA only has authority to approve or disapprove new or revised state WQS. Therefore, EPA's prior "approval" letters related to these provisions have no legal effect. EPA is hereby clarifying that

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[68] The latest example of EPA action on discharge prohibition exemptions in Maine as WQS was EPA's August 19, 2008 approval of discharge prohibition exemptions related to the discharge of aquatic pesticides for the control of mosquito-borne diseases in the interest of public health and safety using methods and materials that provide for the protection of non-target species.

[69] EPA, *What is a New or Revised Water Quality Standard Under CWA 303(c)(3)? Frequently Asked Questions*, October 2012.

in spite of letters that might indicate otherwise, the Agency has not taken action pursuant to CWA §303(c) on any of these provisions.

With respect to the new provisions enacted in L.D. 1304, submitted to EPA on January 11, 2006, and L.D. 1430, submitted to EPA on February 27, 2014 (both listed above), it is important to note that federal antidegradation regulations and Maine's WQS require that water quality in Outstanding National Resource Waters (ONRWs) be "maintained and protected" (*See* 40 C.F.R. § 131.12(a)(3) and Title 38 M.R.S. § 464(4)(F)(2)). EPA has interpreted that language to mean that states may only allow "some limited activity which may result in temporary and short-term changes in water quality" (*See* 48 FR 51402, November 8, 1983 preamble to changes in 40 C.F.R. part 131). The new provisions enacted in L.D. 1430 do not alter antidegradation requirements. Therefore, in any review of a request to apply pesticides to Class AA or other ONRWs, DEP must ensure that such application will result in no more than temporary and short term changes in water quality, as well as comply with all other CWA applicable WQS requirements.

4.10 List of Submissions from 2003 through 2014

DEP submissions from 2003-2014 to which EPA is responding in today's decision are:

- August 26, 2003 submission which included enacted legislative chapters from the 2002-2003 legislative session;
- May 14, 2004 submission which included statutory amendments and rulemakings from 2000 to 2004 that had not been previously submitted to EPA ;
- January 11, 2006 submission which included statutory amendments and rulemakings from 2004 and 2005;
- April 8, 2008 submission which included statutory amendments from the 2007 legislative session;
- December 7, 2009 submission which included statutory amendments from the 2009 legislative session;
- May 16, 2013 submission which included statutory amendments from the 2011-2012 legislative session and 2012 rulemaking; and
- February 27, 2014 submission which included statutory amendments from the 2013 legislative session.

Fish Consumption Rates Used in Human Health Criteria Calculations

*A Compilation of Fish Consumption Rates used by Assorted States and Tribes to Calculate Surface Water Quality Human Health Criteria**

** Data compiled from information provided to Ecology by the Environmental Protection Agency, Region 10, in January 2013.*

Entity	Entity Type	EPA Region	Fish Consumption Rate *	Additional Information
Alabama	State	4	30 grams/day	
Alaska	State	10	6.5 grams/day	Criteria in National Toxics Rule are also applicable.
Arizona	State	9	17.5 grams/day	
Arkansas	State	6	7.5 grams/day	
Bad River Band of Lake Superior Tribe of Chippewa Indians of the Bad River Reservation (WI)	Indian Tribe	5	142.4 grams/day	
California	State	9	6.5 grams/day	Mercury criterion uses 18.7 grams/day (fresh water, enclosed bays and estuaries) and 19.5 grams/day (ocean waters). More recent site-specific mercury criteria in CA apply the methymercury tissue criterion and a rate of 32 grams/day. Criteria in the National Toxics Rule and California Toxics Rule are also applicable.
Colorado	State	8	17.5 grams/day	
Confederated Salish and Kootenai Tribes of the Flathead Indian Reservation	Indian Tribe	8	17.5 grams/day	
Confederated Tribes of the Chehalis Reservation	Indian Tribe	10	6.5 grams/day	
Confederated Tribes of the Colville Reservation	Indian Tribe	10	narrative criteria	

02118

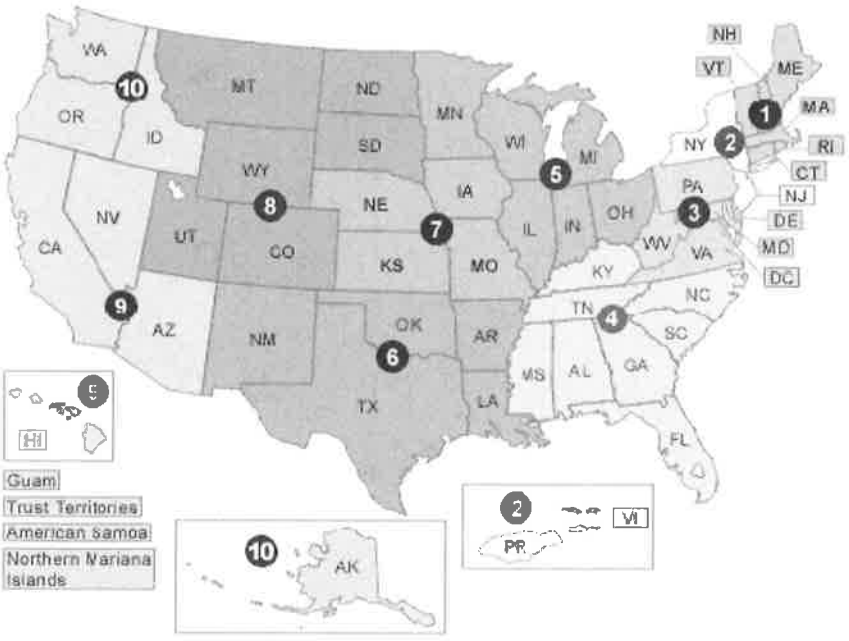
Entity	Entity Type	EPA Region	Fish Consumption Rate *	Additional Information
Confederated Tribes of the Umatilla Indian Reservation of Oregon	Indian Tribe	10	389 grams/day	
Confederated Tribes of the Warm Springs Indian Reservation of Oregon	Indian Tribe	10	170 grams/day	
Connecticut	State	1	17.5 grams/day or 6.5 grams/day	17.5 grams/day used for most parameters.
Coeur d'Alene Tribe	Indian Tribe	10	17.5 grams/day	Initial WQS submission - EPA has not acted on the submission.
Delaware	State	3	17.5 grams/day	
District of Columbia	State	3	17.5 grams/day	
Florida	State	4	6.5 grams/day	Florida is proposing to update criteria with an approach that calculates the criterion level necessary to achieve the minimum risk to Florida's population. This approach is currently being reviewed as part of the public comment process.
Georgia	State	4	17.5 grams/day	
Grand Portage Band of the Minnesota Chippewa Tribe	Indian Tribe	5	142.4 grams/day	
Hawaii	State	9	19.9 grams/day	
Idaho	State	10	6.5 grams/day	Idaho proposed a rate of 17.5 grams/day in 2006, which was disapproved by EPA in 2012.
Illinois	State	5	15 grams/day (Great Lakes Basin); 20 grams/day (outside Great Lakes Basin)	
Indiana	State	5	15 grams/day (Great Lakes Basin); 6.5 grams/day (outside Great Lakes Basin)	
Iowa	State	7	17.5 grams/day	
Kalispel Indian Community of the Kalispel Reservation	Indian Tribe	10	17.5 grams/day	Nickel, arsenic, and chloroform, use a FCR of 6.5g/day.

Entity	Entity Type	EPA Region	Fish Consumption Rate *	Additional Information
Kansas	State	7	6.5 grams/day or 17.5 grams/day	Criteria in National Toxics Rule are also applicable. Kansas is proposing to adopt updated criteria based on EPA's recommended §304(a) criteria in its current revision.
Kentucky	State	4	17.5 grams/day	
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation	Indian Tribe	5	32 grams/day	
Louisiana	State	6	20 grams/day	6.5 grams/day for Monte Sano Bayou.
Lummi Nation	Indian Tribe	10	142.4 grams/day	
Maine	State	1	32.2 grams/day	
Makah Tribe	Indian Tribe	10	142.4 grams/day	
Maryland	State	3	17.5 grams/day	
Massachusetts	State	1	17.5 grams/day or 6.5 grams/day	
Miccosukee Tribe Indians of Florida	Indian Tribe	4	17.5 grams/day	
Michigan	State	5	15 grams/day (Great Lakes Basin); 15 grams/day (outside Great Lakes Basin)	
Minnesota	State	5	30 grams/day (Great Lakes Basin); 30 grams/day (outside Great Lakes Basin)	
Mississippi	State	4	6.5 grams/day	Mississippi completed a WQS revision in June 2012, with criteria based on a consumption rate of 17.5 grams/day (will be submitted to EPA).
Missouri	State	7	6.5 grams/day	

Entity	Entity Type	EPA Region	Fish Consumption Rate *	Additional Information
Mole Lake Band of the Lake Superior Tribe of the Chippewa Indians, Sokaogon Chippewa Community	Indian Tribe	5	Superior Tribe of the Chippewa Indians, Sokaogon Chippewa Community 15 grams/day	
Montana	State	8	17.5 grams/day	
Nebraska	State	7	6.5 grams/day	Mercury criterion uses 32.4 grams/day
Nevada	State	9	6.5 grams/day	Mercury criterion uses 18.7 grams/day. Criteria in National Toxics Rule are also applicable.
New Hampshire	State	1	6.5 grams/day	
New Jersey	State	2	17.5 grams/day	
New Mexico	State	6	17.5 grams/day	
New York	State	2	33 grams/day	
North Carolina	State	4	17.5 grams/day	
North Dakota	State	8	17.5 grams/day	
Ohio	State	5	15 grams/day (Great Lakes Basin); 6.5 grams/day (outside Great Lakes Basin)	
Oklahoma	State	6	6.5 grams/day	Oklahoma intends to update criteria using 17.5 grams/day in next triennial revision.
Oregon	State	10	175 grams/day	
Pennsylvania	State	3	17.5 grams/day	
Port Gamble S'Klallam Tribe	Indian Tribe	10	142.4 grams/day	
Puyallup Tribe of Indians	Indian Tribe	10	6.5 grams/day	Puyallup Tribe has proposed rate of 142.4 grams/day, but has not submitted to EPA.
Rhode Island	State	1	17.5 grams/day	
Saint Regis Mohawk Tribe		2	33 grams/day	
South Carolina	State	4	17.5 grams/day	
South Dakota	State	8	17.5 grams/day	
Spokane Tribe of Indians	Indian Tribe	10	86.3 grams/day	Spokane Tribe submitted revised standards to EPA in 2010 using rate of 865 grams/day, but EPA has not acted on this submittal.
Tennessee	State	4	17.5 grams/day	

Entity	Entity Type	EPA Region	Fish Consumption Rate *	Additional Information
Texas	State	6	17.5 grams/day (carcinogens); 5.6 grams/day (noncarcinogens, childhood exposure factors)	Mercury criteria use 10 grams/day (fresh water) and 15 grams/day (salt water).
The Fond du Lac Band of the Minnesota Chippewa Tribe	Indian Tribe	5	60 grams/day	
Utah	State	8	17.5 grams/day	
Vermont	State	1	6.5 grams/day	
Virginia	State	3	17.5 grams/day	
Washington	State	10	6.5 grams/day	Applicable human health criteria are in the National Toxics Rule.
West Virginia	State	3	17.5 grams/day	
Wisconsin	State	5	20 grams/day (Great Lakes Basin); 20 grams/day (outside Great Lakes Basin)	
Wyoming	State	8	17.5 grams/day	

Environmental Protection Agency Regions



02122

United States Environmental Protection Agency

Response to Comments on the Draft NPDES Permits for the City of Coeur d'Alene, City of Post Falls and the Hayden Area Regional Sewer Board

September 2014

Contents

02125

Overview

On February 16, 2007, the EPA issued three draft reissued National Pollutant Discharge Elimination System (NPDES) permits for publicly owned treatment works (POTWs) operated by the City of Coeur d'Alene (Coeur d'Alene), City of Post Falls (Post Falls) and the Hayden Area Regional Sewer Board (HARSB) for public review and comment. The NPDES permit numbers for these permits are ID0022853, ID0025852, and ID0026590, respectively. These POTWs all discharge treated wastewater to the Spokane River, in Kootenai County, Idaho. The public comment period was scheduled to close on April 17, 2007, but was extended to May 17, 2007.

During the 2007 public comment period, the EPA received comments applicable to all three of the subject permits from the following parties:

- Bonnie Beavers
- Blue Water Technologies, Inc.
- Edward K. Bower
- The Center for Environmental Law and Policy (CELP)
- City of Coeur d'Alene (Coeur d'Alene)
- Center for Justice (CFJ)
- Scott Chaney
- Julie Dalgago
- Bart Haggin
- Hayden Area Regional Sewer Board (HARSB)
- Dennis Hinrichsen
- Jim Hollingsworth
- Gerry House
- JUB Engineers
- Kevin L. Lewis
- Jim Kimball
- Richard Moon
- John Osborn
- Public Employees for Environmental Responsibility (PEER)
- City of Post Falls (Post Falls)
- Zandra Saez
- Steve Shamion
- Clyde Sheppard
- W. Thomas Soeldner
- City of Spokane

On July 18, 2013, the EPA reopened the public comment period pursuant to 40 CFR 124.14. The EPA issued revised draft permits and revised fact sheets for all three dischargers for public review and

comment at that time. The public comment period was scheduled to close on September 3, 2013, but was extended until October 3, 2013.

During the 2013 public comment period, the EPA received comments applicable to all three of the subject permits from the following parties:

- Bob Bingham
- Coeur d'Alene
- HARSB
- Idaho Conservation League (ICL)
- Lisa Fitzner
- Post Falls
- City of Spokane
- Spokane Riverkeeper
- Spokane Tribe of Indians (Spokane Tribe)
- Washington State Department of Ecology (Ecology)

This document provides the EPA's response to the comments provided during both the 2007 and 2013 public comment periods which are germane to all three of the subject permits. The EPA has also prepared individual response to comments documents for comments that were specific to one of the subject permits. The comments are organized by the comment period during which they were received. Within each comment period, the comments are further organized by topic.

As a result of the comments received during the 2013 public comment period, the final permits include some changes relative to the 2013 draft permits. Changes made to the 2013 draft permits that were based upon comments received during the 2013 public comment period are identified in this document or in the individual response to comments documents, as appropriate.

Section 1: Comments Received during the 2013 Comment Period

Effluent Limits and Best Management Practices for Polychlorinated Biphenyls (PCBs)

Comment #1-1

The EPA received comments from several parties regarding whether or not the discharges from the POTWs operated by Coeur d'Alene, Post Falls and HARSB have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. Effluent limits are required for pollutants or pollutant parameters which "are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard…." (40 CFR 122.44(d)(1)(i)).

The Spokane Tribe stated that the EPA has sufficient data to perform a reasonable potential analysis for PCBs. Specifically, the Spokane Tribe referenced a decision by the Pollution Control Hearings Board

(PCHB) in Washington State, in the matter of the State of Washington's permit for the Spokane County Regional Water Reclamation Facility (WRF), in which the PCHB found that information such as the type of plant the applicant is operating, the available dilution, existing data, Washington State's 303d list and fish advisories were adequate to perform the reasonable potential analysis.

The Spokane Tribe stated that the PCHB also found that that there was a reasonable potential for the discharges of the Spokane County Regional WRF to cause or contribute to water quality violations. The Spokane Tribe also stated that the information available to Ecology for use in developing the Spokane County Regional WRF permit are also available to the EPA. Specifically, the Tribe referenced the Ecology's PCB Source Assessment and fish advisories issued by the Washington State Department of Health in the Spokane and Columbia rivers, and a statement by Ecology that "the Spokane River is one of the most studied rivers" in the State of Washington. The Spokane Tribe stated that "once EPA performs the reasonable potential analysis it will likely conclude that the potential for violations exists."

Coeur d'Alene, Post Falls and HARSB stated in their comments that there are insufficient data for PCBs in the publicly owned treatment works' (POTW) effluents and in the receiving water to perform a reasonable potential analysis and calculate effluent limits for PCBs.

Post Falls and HARSB stated that the PCHB's rationale for finding reasonable potential for the Spokane County WRF permit is not persuasive as applied to Post Falls and HARSB. Specifically, Post Falls and HARSB stated that the PCHB decision cited Section 3.2 of the EPA's *Technical Support Document for Water Quality-based Toxics Control* (TSD), which discusses factors other than effluent data that permitting authorities may consider as part of a reasonable potential analysis. Post Falls and HARSB stated that they have "few if any" industrial discharges that would be likely to contribute PCBs, and that they also have more dilution than the Spokane County WRF.

Post Falls and HARSB stated that the U.S. EPA NPDES Permit Writers' Manual (Permit Writers' Manual) expresses a strong preference for calculating water quality-based effluent limits (WQBELs) based on site specific monitoring data. Post Falls and HARSB note that the Permit Writers' Manual states that "EPA recommends that monitoring data be generated before effluent limitation development whenever possible," (Page 6-23), and that, when there are no site-specific data, "the permit writer must either postpone a quantitative analysis of the need for WQBELs and generate, or require the discharger to generate, effluent monitoring data, or base a determination for the need for WQBELs on other information, such as effluent characteristics of a similar discharge" (Page 6-15). Post Falls and HARSB stated that the EPA's proposal to require the POTWs to gather the missing data, which will be used to conduct a reasonable potential analysis in future permits, is fully consistent with the Permit Writers' Manual and the TSD.

Post Falls and HARSB also stated that the existing data does not support a finding of reasonable potential for PCBs. Specifically, Post Falls and HARSB stated that the EPA has no numeric PCB data for those utilities, that the PCB Source Assessment states that PCB sources to the Spokane River in Idaho are "negligible," that the Spokane River is not listed as water quality limited for PCBs in Idaho, and that there are no fish advisories in effect for PCBs in the Spokane River in Idaho. Post Falls and HARSB stated

that the concentration of PCBs in POTW effluents varies widely, and that Post Falls and HARSB are likely to be on the low end of the range. Post Falls and HARSB stated that the City of Medical Lake POTW, located southwest of Spokane, is similar to Post Falls and HARSB in that it is a primarily residential community without a large number of industrial users and that the Medical Lake POTW's effluent PCB concentration, as reported in the Fact Sheets for the Coeur d'Alene, Post Falls and HARSB permits, is 46.6 pg/L. Post Falls and HARSB also stated that none of the factors listed in on Page 6-30 of the Permit Writers' Manual, which may be used to determine reasonable potential without facility specific data, support numeric limits in their cases.

Post Falls and HARSB stated that the unique nature of PCB pollution supports the EPA's decision not to impose numeric effluent limits because PCBs have been banned since 1979 yet remain ubiquitous in the environment, and they are persistent and cannot be practically removed to low levels from municipal effluent. Post Falls and HARSB stated that "the dispersed nature of PCB pollution makes a point source treatment strategy singularly ineffective and impractical."

Post Falls and HARSB stated that, "in the Draft Fact Sheets, EPA notes that samples taken by the U.S. Geological Service ("USGS") in 1999 revealed fish-tissue concentrations of 270 µg/L, which arguably is above the fish-tissue concentrations that would be expected at the water-column criteria of 170 pg/L." Post Falls and HARSB stated that this information does not support numeric effluent limits for the following reasons: First, the relevant criterion is 170 pg/L in the water column; there is no criterion for fish-tissue concentration. Second, USGS study stated that "the brevity of sampling for this study did not allow adequate determination of the extent or permanence of contamination or impairment." Third, the study does not indicate the types of fish sampled, their probable origins or primary habitat, or other relevant information necessary to evaluate the study's accuracy. Finally, no data indicate the relationship between the subject discharges and fish-tissue concentrations.

Coeur d'Alene stated that the monitoring data for the Spokane River at the Idaho-Washington state line do not establish that Coeur d'Alene is a source of PCBs. Coeur d'Alene stated that the Fact Sheet describes a wide range of effluent data from other treatment plants in the Northwest and throughout the country. Coeur d'Alene stated that, while this information may support the imposition of best management practices under the authority of 40 CFR 122.44(k) to "carry out the purposes and intent of the Clean Water Act," EPA should acknowledge that it does not have sufficient information to conduct a qualitative reasonable potential analysis within the meaning of EPA's Permit Writer's Manual Section 6.3.3.

Response #1-1

Overview

The fact sheets (see, e.g., the Coeur d'Alene fact sheet at Page 16) state that:

> "currently, there are insufficient data to determine if the discharges from point sources to the Spokane River in Idaho have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs or dioxin in waters of the State of

> Washington or the Spokane Tribe of Indians. Therefore, no numeric water quality-based effluent limits are proposed for PCBs or dioxin in the draft permit."

Specifically, the EPA has no effluent PCB data for any of the three POTWs receiving reissued permits and no receiving water data for PCBs in the water column for the Spokane River in Idaho. Although the fact sheets (see, e.g., the Coeur d'Alene fact sheet at Pages 16 and 17) state that the USGS measured high concentrations of PCBs in fish tissue in the Spokane River in Idaho,, as noted by HARSB and Post Falls in their comments, the USGS stated that "the brevity of sampling for this study did not allow adequate determination of the extent or permanence of contamination or impairment" (USGS 2003). Without effluent data for the POTWs being permitted or data for PCBs in the water column in Lake Coeur d'Alene or in the Spokane River upstream of the subject discharges, the EPA cannot reasonably determine whether and to what extent any of the subject POTWs contribute to the measured PCB concentrations in the Spokane River at the Washington-Idaho state line, or to the measured PCB concentrations in fish tissue in Idaho.

As stated in the Permit Writers' Manual at Page 6-23, the "EPA recommends that monitoring data be generated before effluent limitation development whenever possible." Therefore, the EPA has required influent, effluent, and receiving water monitoring for PCBs. These data will be used to determine if the discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs when the permits are reissued.

The EPA may also modify permits for cause during their terms. One of the allowable causes for modification is the EPA's receipt of new information that was not available at the time of permit issuance and would have justified the application of different permit conditions at the time of issuance (40 CFR 122.62(a)(2)). If the effluent and receiving water monitoring data for PCBs demonstrates that one or more of the subject discharges has the reasonable potential to cause or contribute to excursions above water quality standards, the EPA may modify the appropriate permits to include effluent limits for PCBs, after preparing a draft permit and following other procedures for decisionmaking in 40 CFR Part 124 (see also 40 CFR 122.62). This is a discretionary action; the EPA may choose not to modify a permit during its term even if cause exists.

Reasonable Potential Analysis Without Effluent Data

Some commenters have correctly noted that the EPA may perform a reasonable potential analysis without facility-specific effluent data (see the TSD at Section 3.2 and the Permit Writers' Manual at Section 6.3.3). The TSD states that permit writers should consider the following factors when performing a reasonable potential analysis for a POTW without facility-specific effluent data:

- Dilution
- Type of industry or POTW
- Existing data on toxic pollutants
- History of compliance problems and toxic impact
- Type of receiving water and designated use

As explained below, the factors listed above do not support a finding of reasonable potential for the subject discharges to cause or contribute to PCB excursions in the absence of facility-specific effluent data.

Dilution

The Spokane River provides substantial dilution of the subject discharges, which suggests that the discharges may not have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs.

The combined design flow of the three subject POTWs is 13.4 million gallons per day (mgd), which is 20.7 cubic feet per second (CFS). Actual effluent flow rates are less than the design flows. For pollutants such as PCBs, for which the water quality criteria are based on cancer risk from lifetime exposure, the TSD recommends the long term harmonic mean stream flow for use in determining reasonable potential and calculating effluent limits (Page 88). The harmonic mean flow of the Spokane River is 2,050 CFS near Post Falls, Idaho (USGS station # 12419000), and 3,610 CFS at the Long Lake Dam in Washington (USGS station #12433000), which is near the upstream boundary of the Spokane Indian Reservation. Thus, the combined design flow of the three discharges is 1.01% of the harmonic mean flow of the Spokane River at Post Falls (99:1 dilution) and 0.57% of the harmonic mean flow of the Spokane River at the Long Lake Dam (174:1 dilution).

Type of POTW

The TSD states that POTWs with loadings from indirect dischargers (particularly primary industries) may be candidates for toxicity limits, but also states that household disposal of toxic pollutants may cause toxicity as well. The TSD states that permit writers should evaluate the types of industrial users, their product lines, and their control equipment.

HARSB has no significant industrial users. Post Falls has three significant industrial users, all of which are categorical industrial users: Two metal finishers and one pharmaceutical manufacturer. Coeur d'Alene has three significant industrial users, two of which are categorical industrial users. One of Coeur d'Alene's categorical industrial users is in the anodizing subcategory of the electroplating point source category, and the other is in the precious metals forming subcategory of the nonferrous metals forming and metal powders subcategory.

Among these, the only industrial category for which PCBs were sampled or otherwise mentioned as part of the development of categorical pretreatment standards is metal finishers. PCB Aroclors were known to be present in 1 – 6 cases (depending on the Aroclor) out of 1,048 data collection portfolios sent by the EPA to manufacturing facilities in the Metal Finishing Category (EPA 1983). Thus, PCBs were not known to be present in the wastewaters from the vast majority of metal finishers. PCBs were not specifically selected for regulation under effluent limit guidelines or categorical pretreatment standards for metal finishers. However, the categorical pretreatment standards for metal finishers include limits for total toxic organics (TTO), which includes PCBs (40 CFR 433.11(o), 433.15, 433.17). Buck Knives, which is one of the two metal finishers discharging wastewater to the Post Falls POTW, has tested its effluent for PCB aroclors using EPA method 608, with a practical quantification limit of 0.2 µg/L (200,000

pg/L) per aroclor. In semi-annual testing conducted between 2010 and 2013 (8 samples), no PCB aroclors were detected.

Thus, the EPA is not aware of any industrial users of any of the subject POTWs that would be likely to discharge measurable amounts of PCBs to the POTWs. However, the subject permits all require the permittees to address source control and elimination of PCBs from industrial and commercial sources in their toxics management plans.

Existing Data on Toxic Pollutants

There are a large number of pollutants that are toxic to humans, wildlife, livestock, and aquatic life, many of which are unrelated to PCBs in their chemical structures, chemical and physical properties, and sources. Data on toxic pollutants that are unrelated to PCBs are irrelevant to the question of whether or not the discharges cause or contribute to excursions above water quality standards for PCBs.

PCBs are classified as persistent organic pollutants (POPs). Other persistent organic pollutants include aldrin, chlordane, dichlorodiphenyl trichloroethane (DDT), dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, dioxins, and furans (EPA 2009). If other POPs had been measured in the effluents of any of these POTWs, this might suggest that the discharge has the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. Of these compounds, only hexachlorobenzene has been tested for in any of the three POTWs' effluents. Hexachlorobenzene was not detected in the Post Falls or HARSB effluents, using EPA Method 8270, at a detection limit of 1.0 µg/L. None of these compounds have been analyzed for the Coeur d'Alene effluent. Therefore, although the existing data on POPs are limited, they do not suggest that the discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs.

History of Compliance Problems and Toxic Impact

The TSD states that "regulatory authorities may consider particular dischargers that have had difficulty complying with limits on toxicants or that have a history of known toxicity impacts as probable priority candidates for effluent toxicity limits."

In general, the POTWs' compliance history for non-toxic pollutants unrelated to PCBs is irrelevant to a reasonable potential analysis for PCBs, except for the total suspended solids (TSS) removal performance discussed below. As discussed above, there are no quantitative data for any persistent organic pollutants, including PCBs, for these three POTWs.

Removal of PCBs from POTW influents is strongly correlated with TSS removal, with overall removal efficiencies for PCBs being slightly lower than the overall TSS removal efficiency of the POTW (EPA 1977). The average TSS removal rates for Coeur d'Alene, Post Falls, and HARSB during 2012 were 97.5%, 98.3%, and 98.0%, respectively, and the minimum TSS removal rates during 2012 were 96%, 97.2%, and 97%. These TSS removal efficiencies are consistently higher than the minimum permit requirement (85%) and are also higher than those for the POTWs evaluated in the EPA's *PCBs Removal in Publicly Owned Treatment Works*, for which TSS removal efficiencies ranged from 84 to 95%, and PCB removal efficiencies ranged from 82 to 89 % (id at 50). Thus, it is likely that the three POTWs remove most of any

PCBs that may be present in their influents. The permits include a condition requiring that a split of all influent and effluent samples analyzed for PCBs must be analyzed for TSS. This will facilitate a better understanding of the relationship between TSS and PCBs for the subject POTWs.

Furthermore, in order to comply with the new WQBEL for total phosphorus (TP), the subject POTWs will need to install filtration systems, which will further reduce effluent TSS concentrations. Because PCB removal is correlated with TSS removal, the filtration systems are likely to further improve PCB removal rates at the subject POTWs. For the purpose of a reasonable potential analysis without effluent data, these facilities do not have a history of compliance problems or toxic impact.

Type of Receiving Water and Designated Use

The TSD states that permitting authorities should compile water quality data for the discharges' receiving waters and "use this information as a means of identifying point sources that discharge to impaired waterbodies and that thus may be contributing to this impairment."

As stated in the fact sheets for these permits (see, e.g., the Coeur d'Alene fact sheet at Page 16) and by commenters, the Spokane River is listed in Washington's 2010 303(d)/305(b) integrated report as not attaining or not being expected to attain water quality standards for total polychlorinated biphenyls (PCBs), due to elevated concentrations in fish tissue. As also stated in the fact sheets, the Spokane Tribe has EPA-approved water quality standards for its waters, which are downstream of the Long Lake Dam, and data from lower Lake Spokane indicate that the Tribe's water quality criterion for PCBs (in the water column) is not being attained (Serdar et al. 2011). The EPA disagrees with Post Falls' and HARSB's characterization of the PCB load to the Spokane River at the Idaho-Washington border as "negligible." Although the State of Washington's *Spokane River PCB Source Assessment 2003 – 2007* (PCB Source Assessment) states that PCB sampling performed in 1994 "showed that sources upstream of the Idaho border were negligible," (id at 31), more recent sampling has shown that "PCB loading from Idaho at the state line represented 30% of the overall loading" (id at 9).

However, the fact that the Spokane River is currently impaired in Washington due to high concentrations of PCBs does not by itself justify a finding that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. The Spokane River is also impaired by temperature in Washington and cadmium in both Idaho and Washington, yet the EPA found that none of the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for cadmium or temperature. The mere fact that the waterbody is currently impaired does not necessarily require the conclusion that all dischargers to the waterbody are contributing to the impairment.

Although it has been suggested that loading at the Idaho-Washington border may account for 30 percent of the overall PCB loading to the Spokane River (Serdar et al. 2011 at 9), it is not known what fraction of the loading measured at the border, if any, is discharged by the subject POTWs. Available information suggests that PCB sources to the Spokane River watershed in Idaho other than the subject POTWs may be significant. Fish tissue sampling in Lake Coeur d'Alene near Blackwell Island (upstream from the three subject POTWs) showed PCB concentrations of 158 – 443 µg/kg in the tissue of largescale

and long-nose suckers (id at 86). Air deposition "holds the potential to deposit measurable quantities of PCBs in the mountains in the eastern portion of the Spokane River basin, eventually delivering PCBs to Lake Coeur D'Alene through the St. Joe, St. Maries, and Coeur D'Alene Rivers" (id at 91). City of Spokane stormwater contributes 44 percent of the overall PCB loading to the Spokane River (id at 9). Municipal stormwater PCB loads from Idaho are unquantified, but the large loading from City of Spokane stormwater suggests that Idaho municipal stormwater loads could be significant. Furthermore, the PCB concentration measured at the Washington-Idaho border is lower than that measured in the Little Spokane River (199 pg/L), a 35-mile-long tributary of the Spokane River that receives no permitted point source discharges.[1] Thus, the PCB loading to the Little Spokane River is entirely from non-point and legacy sources. Therefore, non-point, legacy, and stormwater sources to Lake Coeur d'Alene and its tributaries and to the main stem Spokane River in Idaho may account for the PCB loading measured in the Spokane River at the Idaho-Washington border.

Conclusion of Reasonable Potential Analysis Without Effluent Data

Although the EPA has no effluent PCB data for any of the three POTWs receiving reissued permits and no receiving water data for PCBs in the water column for the Spokane River in Idaho, the EPA has performed a reasonable potential analysis for PCBs in the subject discharges. As explained above, based on the available information, the EPA does not conclude at this time that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. The EPA reached this conclusion because the Spokane River affords the discharges substantial dilution, and because none of the existing data for other pollutants, nor the facilities' compliance history with existing permit requirements, nor information about the industrial users discharging to the POTWs suggest that the discharges have the reasonable potential to cause or contribute to PCBs, and, although it is known that the Spokane River transports a significant PCB load from Idaho into Washington, the origin of the Idaho PCB loading is currently unknown.

PCHB Decision

The fact that the PCHB held that the Spokane County WRF has the reasonable potential to cause or contribute to excursions above water quality standards for PCBs does not mean that the subject permits have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. As explained above, the EPA has performed a reasonable potential analysis for the subject POTWs using available information and considering the specific factors identified in the TSD. The EPA does not conclude at this time that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs.

Summary

In summary, the EPA does not have the necessary data to perform a reasonable potential analysis using facility-specific effluent data, as described in Section 3.3 of the TSD. Therefore, EPA performed a reasonable potential analysis conducted without facility-specific effluent data, as described in Section

[1] The Little Spokane River had one source that was covered under Washington's construction stormwater general permit (permit #WAR011881) but that coverage is now inactive. Information about permitted point sources to the Little Spokane River was obtained from the State of Washington's Water Quality Permitting and Reporting Information System (PARIS) on December 20, 2013.

3.2 of the TSD. The EPA's conclusion is that there is insufficient information to justify a finding of reasonable potential for PCBs. Therefore, the EPA has not established effluent limits for PCBs in the subject permits.

As the EPA stated in the fact sheets for these permits:

> "(T)he EPA believes that, similar to POTWs in the State of Washington and elsewhere, the Idaho POTWs may be discharging PCBs and dioxin, and that best management practices (BMP) requirements to control or abate the discharge of PCBs and dioxin are reasonably necessary to carry out the purposes and intent of the Clean Water Act. Due to the lack of data, it is infeasible to calculate numeric water quality-based effluent limits for PCBs and dioxin at this time. Therefore, the draft permit includes BMP requirements for PCBs and dioxin, consistent with 40 CFR 122.44(k)(3) and (4)."

It is not necessary for the EPA to find that the discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs in order to require BMPs.

Comment #1-2

The Spokane Tribe stated that the PCHB found that the conditions in the Spokane County WRF permit do not constitute a narrative limit. Specifically, the Tribe stated that a requirement in the Spokane County WRF permit to develop a toxics management plan with a goal of reducing PCB discharges to the "maximum extent practicable" does not meet the requirements of the Clean Water Act (CWA).

The Spokane Tribe requested that the EPA revise the permits "to include numeric or narrative standards that will ensure that the discharges from these three facilities do not cause or contribute to the violation of water quality standards, including the Tribe's."

Post Falls and HARSB stated that the NPDES permitting rules do not refer to narrative effluent limitations in the context of point source discharge permits. Rather, the regulations and guidance uniformly refer to BMPs as the proper type of condition to impose when data is sparse or when it is infeasible to impose numeric limits, e.g., 40 CFR 122.44(k).

Post Falls and HARSB stated that the Spokane County PCHB Ruling insists that the conditions "must require defined steps toward compliance with standards" (Spokane County PCHB Ruling at 24), and that the conditions must specify "the expected reductions in toxicant loadings, the schedule for initiating such reductions, and at a minimum, offer greater definition and timelines for/of this expected outcome." Id. at 25. Post Falls and HARSB stated that, while we all hope the PCB BMPs will improve water quality, nothing in the CWA requires the performance-based approach to the BMPs mandated by the PCHB. Rather, BMPs "are inherently pollution prevention practices." Guidance Manual for Developing Best Management Practices, EPA 833-B-93-004) (October 1993) at 1-4. As the name implies, BMPs are practices the permittee undertakes to minimize the pollutants discharged from a facility. If the permittee implements the practices, it complies with the conditions.

Post Falls and HARSB stated that "numeric reduction targets should be left for when there is sufficient data and a need to impose a numeric effluent limitation."

Response #1-2

The BMP requirements for PCBs in the draft permit need not be revised.

As explained in the response to comment #1-1, currently available information does not support a finding that the subject POTWs have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs, so the permits do not include effluent limits.

Having determined that it is neither necessary nor feasible to include effluent limits for PCBs in the permits at this time, the EPA instead has chosen to require BMPs to reduce or eliminate the three subject POTWs' discharge of PCBs (if any). BMPs are defined as "schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of 'waters of the United States.' BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage" (40 CFR 122.2). The EPA Permit Writers' Manual elaborates on this definition, stating that "BMPs are, by their nature, pollution prevention practices." One way of requiring BMPs in an NPDES permit is to require the permittee to develop a BMP plan, and this approach is preferable when the specific practices that the permittee should use to prevent pollution are not known at the time of permit issuance (see the EPA Permit Writers' Manual at Section 9.1.2.2). In general, the BMP requirements in the subject permits are required by way of a toxics management plan, although the permits do require the toxics management plan to address source control and elimination of PCBs in certain specific ways.

Effluent limitations, on the other hand, are defined as "any restriction imposed by the Director on quantities, discharge rates, and concentrations of 'pollutants' which are 'discharged' from 'point sources' into 'waters of the United States,' the waters of the 'contiguous zone,' or the ocean (40 CFR 122.2). Because they restrict "quantities, discharge rates and concentrations," effluent limitations are inherently quantitative.

Thus, there is an important distinction between effluent limitations and BMPs. Effluent limitations restrict the "quantities, discharge rates and concentrations" of pollutants, and generally leave the decision of how to achieve compliance with these restrictions up to the permittee. BMP requirements, in a sense, do the reverse; i.e., they specify the practices that the permittee must use in order to reduce their discharges of pollution, with the expectation that, when properly implemented, these practices will reduce the discharge of pollutants, although they do not explicitly restrict the quantity of pollutants discharged.

Since the EPA has appropriately required BMPs in the subject permits instead of effluent limitations for PCBs, it is not necessary for the permits to specify the expected reductions in toxicant loadings.

Comment #1-3

Post Falls and HARSB stated that the Spokane County PCHB Ruling exceeds the reopener requirements of the CWA by requiring "the use of ongoing monitoring data to set a numeric effluent limitation at the earliest possible time, including during the term of the current permit, in order to be in compliance with water quality standards." Spokane County PCHB Ruling at 26. Post Falls and HARSB stated that the EPA should not adopt this approach. Rather, the agency should retain its discretion as to the timing of permit modification and /or reissuance, and include only a standard reopener clause in the permit.

Response #1-3

As provided for in 40 CFR 122.62, the EPA may modify a permit during its term for cause. This is a discretionary action; the EPA may choose not to modify a permit during its term even if cause exists.

One of the allowable causes for modification is the EPA's receipt of new information that was not available at the time of permit issuance and would have justified the application of different permit conditions at the time of issuance (40 CFR 122.62(a)(2)). If the effluent and receiving water monitoring data for PCBs demonstrates that one or more of the subject discharges has the reasonable potential to cause or contribute to excursions above water quality standards, the EPA may modify the appropriate permits to include effluent limits for PCBs, after preparing a draft permit and following other procedures for decisionmaking in 40 CFR Part 124 (see also 40 CFR 122.62). Since this authority is provided by the NPDES regulations, it is not necessary to include a reopener clause in the permit for this purpose.

Comment #1-4

The City of Spokane stated that the EPA should consider how the PCHB's decision in the matter of the NPDES permit issued to the Spokane County WRF might affect permits issued to Idaho dischargers.

Spokane Riverkeeper stated that the PCHB found that the NPDES permit needs to specify that measures to achieve PCB reductions must be clarified regardless of the work of the Spokane River Regional Toxics Task Force.

Response #1-4

As described in the responses to comments 1-1, 1-2, and 1-3, the EPA has reviewed the PCHB decision in the matter of the Spokane County WRF. The EPA has determined that no changes are necessary to the subject draft permits' requirements as a result of the PCHB decision in the matter of the Spokane County WRF.

Comment #1-5

Coeur d'Alene requests that the EPA remove the requirement for a new local pre-treatment standard for PCBs at 3 µg/L. The City has reviewed its industrial and commercial customers and cannot identify any customer with effluent that might be a particular source of PCB loading. Coeur d'Alene should be allowed to identify any potential PCB problems in its effluent before engaging in source control through its pre-treatment program. The City ordinance and EPA regulations regulating pre-treatment do not require monitoring for PCBs, so setting any pretreatment limit now would be meaningless and unnecessary.

Response #1-5

Coeur d'Alene is referring to Part II.I.1.b.ii of their draft permit; this requirement is identical in the other two subject permits. This requirement is included in the permits because federal regulations already prohibit discharges of water containing PCBs in concentrations greater than or equal to 3 µg/L by any person to any treatment works, including POTWs (40 CFR 761.50(a)(3), see also 40 CFR 503.9(aa)).

This requirement is not a "local pre-treatment standard" since it applies to all treatment works in the United States and it also applies to any person, not just to industrial users of the POTW. This requirement therefore requires the permittee to enforce an existing requirement of federal law, which restricts discharges of PCBs to treatment works. Consistent with 40 CFR 761.50(a)(3), the permits do not prevent the permittees from establishing local pretreatment limits more stringent than 3 µg/L.

Since this requirement applies to any person, the EPA has moved this requirement so that it is not subordinate to the requirement to address source control and elimination of PCBs from industrial and commercial sources.

Spokane River Regional Toxics Task Force (SRRTTF or Task Force)

Comment #1-6

The Spokane Tribe expressed concern about the EPA's reliance on the Task Force as a means to achieve applicable water quality standards on numerous occasions. The Spokane River PCB TMDL Stormwater Loading Analysis Final Technical Report identifies a total PCB load reduction of 95% from Idaho as necessary to meet the Tribe's water quality standards for PCBs. First, the EPA has clearly stated that it does not believe that it has the authority to force Idaho dischargers to participate in the Task Force and can only require participation in the permits by the voluntary agreement of the dischargers. (Attachment E). Second, the PCHB identified the Task Force as a good idea but far too vague to have much effect, and the Tribe agrees with this assessment. (Order at 26). Third and finally, the EPA has presented the Task Force as a way to eventually meet the Tribe's water quality standards. The Tribe fundamentally believes that the decision to attempt to use the Task Force as a means to meet water quality standards is not supportable in law or fact because the Task Force and all of its goals are unenforceable, there is no required funding mechanism, and there are no deadlines to meet any of the amorphous goals. Simply put, the EPA cannot reasonably expect 95- to 99-percent reductions in PCBs through voluntary means alone.

The EPA has the authority to develop a multi-jurisdiction PCB TMDL and this approach could utilize the efforts of the Task Force, but in the end have an enforceable plan to meet water quality standards. Given the complexity of the watershed, it will only delay the goals of the CWA by imposing the Task Force on the Idaho Dischargers without the EPA simultaneously leading a multi-jurisdictional PCB TMDL. EPA is the only entity that can prepare such a PCB TMDL given that the State of Idaho, the Coeur d'Alene Tribe, the State of Washington, the Spokane Tribe, and the Colville Confederated Tribe all assert some jurisdiction over the waters impacted by these discharges of PCBs.

In the end, these permits contemplate 10-year compliance schedules, a multi-jurisdictional PCB TMDL would give the Idaho dischargers regulatory certainty in understanding what the various technologies they are implementing will need to accomplish for PCB removal.

The Tribe requests that the EPA reassess its decision to utilize the Task Force and instead begin the process of preparing a multi-jurisdictional PCB TMDL.

Response #1-6

The issue of a PCB TMDL for the Spokane River is beyond the scope of these permitting actions. Nothing in the CWA or NPDES regulations requires that a TMDL be developed to address water quality impairments in the permittee's receiving water prior to the issuance of an NPDES permit. Indeed, the Spokane River is on the 303(d) list for pollutants other than PCBs and for which there are no valid TMDLs, including cadmium, lead, zinc, and total phosphorus in Idaho and temperature in Washington. The EPA addressed PCBs in the same way as it addressed these other pollutants; i.e., it performed a reasonable potential analysis to determine if the discharges cause or contribute to excursions above water quality standards for those pollutants. If the EPA found that the discharges had the reasonable potential to cause or contribute to such excursions, the EPA included effluent limits for those pollutants in the permits. As explained in the response to comment #1-1, based on the available information, the EPA did not find that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs.

If, in the future, a TMDL for PCBs which includes wasteload allocations for the subject discharges is approved or prepared by the EPA, then the EPA will reissue or modify the subject permits to include effluent limits for PCBs that are consistent with the wasteload allocations, as required by 40 CFR 122.44(d)(1)(vii)(B).

It is correct that the EPA has stated that it does not have the authority to require the subject permittees to participate in the SRRTTF. The draft permits contain a requirement to participate in the task force because the permittees mutually agreed with Spokane Riverkeeper, the Lands Council, and Kootenai Environmental Alliance that the permits should include language requiring such participation.

The EPA supports the goal of the SRRTTF to make measurable progress toward bringing the Spokane River into compliance with applicable water quality standards for PCBs. The EPA believes the SRRTTF should be given an adequate opportunity to achieve its goal, and participation in the SRRTTF is the preferred option at this time for achieving toxics loading reductions in the Spokane River. Numeric toxics control remains an option once more effluent and receiving water data and an appropriate approved test method approved for use in NPDES permits are available, and in the event that the SRRTTF fails to achieve measurable reductions in PCB loads.

Comment #1-7

Coeur d'Alene stated that the EPA should affirm that it will become a signatory to the Task Force agreement and that it will seek funding to support the Task Force.

Spokane Riverkeeper stated that success of the SRRTTF depends upon consistent participation of the EPA (and Idaho Department of Environmental Quality (IDEQ)) in the process, in order to track the effectiveness of Idaho permittees in the process and assess measureable progress. Spokane Riverkeeper requests that the EPA dedicate staff to participate in a meaningful way in the SRRTTF, and that the EPA's and IDEQ's participation in the SRRTTF is built into work plans and budgets to ensure that there is consistent participation as the process proceeds.

Response #1-7

The EPA intends to sign the SRRTTF memorandum of agreement (MOA) once the subject NPDES permits are finalized.

The SRRTTF is eligible to compete for EPA grants, and the EPA can work to ensure that the SRRTTF is aware of related grant competitions. If the SRRTTF is amenable to this option, the EPA could pursue contract funding in an existing EPA contract to support SRRTTF work efforts. In that case, the EPA would have to manage that work in partnership with the SRRTTF.

As stated in a letter to Spokane Riverkeeper on September 20, 2013, Tom Eaton, the Director of the EPA's Washington Operations Office, is the EPA's primary representative on the SRRTTF.

Comment #1-8

Spokane Riverkeeper requests that the requirements for "measurable progress" contained in the Washington NPDES permits be included in the EPA-issued permits. The Washington permits state:

> If Ecology determines the Regional Toxics Task Force is failing to make measurable progress toward meeting applicable water quality criteria for PCBs, Ecology would be obligated to proceed with development of a TMDL in the Spokane River for PCBs or determine an alternative to ensure water quality standards are met.

Spokane Riverkeeper views "measurable progress" as concrete, on-the-ground efforts toward reduction of PCBs, including, but not limited to, source control, implementation of best management practices, institutional practices (e.g., eliminating the purchase of products with PCBs), local ordinances, and site cleanup. If measurable progress is not achieved, the EPA must take appropriate action to require end-of-the-pipe cleanup to ensure compliance with water quality standards.

Response #1-8

The EPA does not agree with Spokane Riverkeeper that the permits must include a clause requiring "measurable progress" toward meeting water quality standards for PCBs. The permits do include requirements for some of the actions that Spokane Riverkeeper views as "measurable progress," including preferentially using PCB-free products, source control, and including industrial and commercial users of the POTWs' collection systems and sources within the direct control of the permittee. As explained in the responses to comments 1-1 and 1-2, the BMP requirements in the draft permit are appropriate and authorized by NPDES regulations (40 CFR 122.44(k)).

Effluent Limits for Nutrients and Oxygen-Demanding Pollutants

Comment #1-9

Post Falls and HARSB stated that the infrastructure improvements required in the Idaho NPDES permits completely address the water quality impacts to the Spokane River coming from the State of Idaho point sources and provide substantial assimilative capacity to their downstream neighbors. Any further efforts to meet Washington regulations should therefore be led and implemented solely by and within the State of Washington.

Response #1-9

The issue raised by this comment is whether the subject permittees will be required to implement "further" (presumably meaning more stringent) efforts to meet Washington's water quality standards for dissolved oxygen (DO), beyond those required in the subject permits. The issue raised by this comment is therefore beyond the scope of the subject permit actions. The EPA will not speculate as to what specific requirements may be necessary in reissued or modified permits for the subject POTWs in the future.

If, at the time that the permits are reissued, new information demonstrates that more stringent effluent limits for nutrients and/or oxygen demand are necessary for any or all of the subject permits in order to meet Washington's water quality standards for DO, the EPA will include such limits in the permits.

Any reissued or substantively modified permits will be made available for public review and comment prior to issuance and subject to appeal, as required by 40 CFR 122.62 and Part 124.

Comment #1-10

The Idaho Conservation League (ICL) stated that the draft permits call for Phosphorus Management Plans in lieu of phosphorus limits in the winter months, and that while the plans contain laudable practices, a management plan is not an effluent limit and should not take the place of one. Instead, the new seasonal limits for phosphorus should be applied throughout the year. When phosphorus enters the watershed, whether in the winter or the summer, some of it will remain in the watershed. As the draft permit acknowledges, the effects of nutrient loading are not immediate. Some of the phosphorus discharged in the winter months will settle in the sediments downstream in Long Lake and could be released due to negative retention in the sediments during the summer months.[2] This release could contribute to plant growth in the summer, and cause a decrease in DO. Therefore, these limits should be applied throughout the year, not just during the warmer months.

Response #1-10

The subject permits include seasonal average effluent limits for total phosphorus (TP), which apply from February 1st to October 31st, or nine months of the year. During November, December, and January, there are no effluent limits for TP in any of the permits.

[2] Martin Sondergaard, Jens Peder Jensen, Erik Jeppesen, "Role of sediment and internal loading of phosphorus in shallow lakes," Hydrobiologia 506-509, (2003), 235-145.

The EPA does not dispute the commenter's statement that the effects of nutrient loading are not immediate. Indeed, modeling has shown that discharges of phosphorus as early as January can affect DO concentrations in Lake Spokane during the following summer. Therefore, the modeling that supports the limits in the draft permits assumes that, because there are no effluent limits in effect, the discharge concentrations of phosphorus in January will be unchanged from typical current discharges. The modeling shows that water quality standards for DO will be attained in Lake Spokane on a cumulative basis despite the impact of these relatively high TP discharges in January.

Currently, the CE-QUAL-W2 model used to develop the State of Washington's DO TMDL and the subject permits cannot simulate the effects of pollutants discharged late in one calendar year (e.g., November and December) upon DO concentrations in Lake Spokane during the following year. Therefore, it is infeasible for the EPA to calculate effluent limits for TP for November and December at this time. Federal regulations allow the EPA to establish BMP requirements in lieu of effluent limits when numeric effluent limits are infeasible (40 CFR 122.44(k)(4)), and, as the commenter notes, the permits require BMPs for phosphorus through the phosphorus management plans. The EPA has used the best available information and tools to establish protective WQBELs for nutrients in the subject permits. The EPA has addressed the model's inability to simulate the effects of pollutants discharged late in one calendar year upon DO concentrations in Lake Spokane during the following year by requiring year-round BMPs.

Comment #1-11

ICL stated that, although phosphorus is greatly reduced, they are concerned that the combined reductions of phosphorus, carbonaceous biochemical oxygen demand (CBOD), and ammonia are not sufficient to achieve the Washington State DO criteria. Of the three pollutants, ammonia discharges remain relatively high in the draft permits, and it appears that the seasonal amount that would be allowed under Post Falls' permit would actually increase from the existing permit's average monthly limit. According to the Spokane DO TMDL, Ecology developed assumptions about "the anticipated permit-driven reductions of anthropogenic loading of phosphorous, CBOD and ammonia from wastewater treatment plants and stormwater in Idaho. These assumptions are based on point sources discharging equivalent pollutant concentrations at wastewater treatment plants in both states and have been incorporated into the model scenarios supporting this TMDL." (p. 35, Spokane DO TMDL). The sum total of the seasonal averages for TP, CBOD, and ammonia in the draft permits for the three Idaho dischargers is significantly more than the total assumed anthropogenic loading of the three pollutants as listed in the Washington TMDL. For example, the presumed load from ammonia was 94.4 lb/day, while the actual loading under the draft permits is 604.4 lb/day. Therefore, the overall reduction in the oxygen-consuming pollutants does not appear to be sufficient to meet the downstream State's needs. Given the state of DO downstream, it would make all the more sense to attempt to decrease ammonia from Post Falls, rather than allow an increase in discharge. It's difficult to see how the state of Washington is going to achieve its goals downstream in the Spokane River TMDL if the Idaho dischargers are allowed to exceed the suggested wasteload allocation assigned to Idaho in the TMDL. We recommend the EPA revisit the CBOD and ammonia levels in an effort to be consistent with the downstream TMDL.

Response #1-11

As explained in Appendix B to all three fact sheets, the seasonal average ammonia limits in the draft permits, in combination with the TP and CBOD limits, the load and wasteload allocations for Washington pollution sources in the Spokane DO TMDL, and Avista Corporation's DO responsibility, will ensure compliance with Washington's water quality standards for DO on a cumulative basis.

As explained in Appendix B to all three fact sheets, the modeling assumptions that Ecology made when developing the TMDL are not binding on the EPA when it drafts the Idaho permits. The EPA is free to establish any limits in the Idaho permits for CBOD5, ammonia, and TP so long as those limits ensure compliance with both Idaho and Washington WQS, when considered cumulatively with other sources of pollution (40 CFR 122.4(d), 122.44(d)(4)).

The subject dischargers may have higher ammonia limits than assumed in the TMDL modeling because, in other respects, their limits for nutrients and oxygen-demanding pollutants are lower than assumed in the TMDL modeling. For example, the TMDL modeling assumed that stringent limits for TP, ammonia, and CBOD would begin on March 1st, but the subject permits generally have seasonal average limits for those pollutants that become effective on February 1st, with the sole exception being that Coeur d'Alene's ammonia limits do not take effect until March 1st.

Comment #1-12

Mr. Bob Bingham of the North West Property Owners Association (NWPOA) asked the EPA to please describe the current percent permit removal or achievement for nitrogen and phosphorus and the proposed change.

Response #1-12

None of the subject permits include effluent limits for any form of nitrogen other than ammonia. All of the subject permits include effluent limits for TP; the phosphorus limits are stated in terms of mass as opposed to percent removal.

Tables 1-3, below, provide a comparison of the ammonia and phosphorus effluent limits in the 1999 permits and the corresponding limits in the reissued permits.

Table 1: Comparison of Ammonia and Phosphorus Effluent Limits in the 1999 and 2013 Permits for Coeur d'Alene

Ammonia						
Month	**1999 Permit**			**2013 Permit**		
	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit
January	None	None	None	None	None	None
February						
March				272 lb/day	649 lb/day	1,547 lb/day
April						
May						
June						
July		350-370 lb/day	1,000 – 1,100 lb/day		330 lb/day	786 lb/day
August						
September						

October		None	None		None	None
November				None		
December						
Phosphorus						
Month	**1999 Permit**			**2013 Permit**		
	Seasonal Average Limit		Average Monthly Limit	Seasonal Average Limit	Average Monthly Limit	
January	None		None	None	None	
February						
March			85% removal or 1,000 µg/L	3.17 lb/day		
April						
May						
June						
July						
August						
September						
October						
November			None	None		
December						

Table 2: Comparison of Ammonia and Phosphorus Effluent Limits in the 1999 and 2013 Permits for HARSB						
Ammonia						
Month	**1999 Permit**			**2013 Permit**		
	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit
January	None	985 lb/day	985 lb/day	None	1,575 lb/day	5,004 lb/day
February				77.4 lb/day	None	
March						
April						
May						
June	No Discharge when river flow is ≤ 2,000 CFS					
July						
August						
September						
October	None	985 lb/day	985 lb/day	None	1,575 lb/day	5,004 lb/day
November						
December						
Phosphorus						
Month	**1999 Permit**			**2013 Permit**		
	Seasonal Average Limit		Average Monthly Limit	Seasonal Average Limit	Average Monthly Limit	
January	None			None	None	
February				1.33 lb/day		
March						
April						
May						
June	No Discharge when river flow is ≤ 2,000 CFS					
July						
August						
September						
October	None					

November December		None	

Table 3: Comparison of Ammonia and Phosphorus Effluent Limits in the 1999 and 2013 Permits for Post Falls

Ammonia

Month	**1999 Permit**			**2013 Permit**		
	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit	Seasonal Average Limit	Average Monthly Limit	Maximum Daily Limit
January	None	737 lb/day	2,661 lb/day	None	1,059 lb/day	3,824 lb/day
February				255 lb/day		
March						
April						
May						
June						
July		238 lb/day	856 lb/day		342 lb/day	1,230 lb/day
August						
September						
October		737 lb/day	2,661 lb/day	None	1,059 lb/day	3,824 lb/day
November						
December						

Phosphorus

Month	**1999 Permit**		**2013 Permit**	
	Seasonal Average Limit	Average Monthly Limit	Seasonal Average Limit	Average Monthly Limit
January	None	None	None	None
February			3.19 lb/day	
March		70% removal		
April				
May				
June				
July				
August				
September				
October				
November		None	None	
December				

Comment #1-13

Mr. Bob Bingham of the NWPOA asked, if these permits are instituted, please provide the projected net gains (whatever they may be) to river quality and the methods used to predict/forecast such gains.

Response #1-13

The goal of the WQBELs for TP, ammonia, and CBOD in the subject permits is to meet water quality standards for DO in Lake Spokane. Because Lake Spokane is more sensitive to loading of nutrients and oxygen-demanding pollution than the relatively free-flowing upstream reaches of the Spokane River, the limits will ensure compliance with water quality standards for DO in the Spokane River, as well.

Improving DO levels in Lake Spokane will provide better habitat for fish and other aquatic life. The reductions in TP discharges will also reduce the occurrence of algae blooms in Lake Spokane, including blooms of blue-green algae or cyanobacteria, which can be toxic to humans, livestock, and wildlife. The

reductions in TP discharges will also prevent periphyton (i.e. attached algae) densities in the Spokane River from reaching nuisance levels.

As explained in the 2013 Fact Sheets to the subject permits at Appendix B, the EPA used the CE-QUAL-W2 model to predict the impact of the subject discharges as well as other point and non-point sources of nutrients and oxygen-demanding pollution in both Idaho and Washington upon water quality in Lake Spokane. The same model was used by the State of Washington to develop the Spokane DO TMDL.

Effluent Limits for Metals

Comment #1-14

Coeur d'Alene previously submitted comments on the cadmium and lead effluent limits proposed in the Idaho's Revised Draft 401 Water Quality Certification for its draft permit. Those comments are attached and incorporated herein. We request that the cadmium and lead limits be adjusted in the permit to the extent IDEQ modifies the proposed limits in its final 401 Certification. We also request that the permits allow for modification of the limits following any review of the state 401 Certification.

Response #1-14

Although this comment was submitted by Coeur d'Alene, all three of the subject draft permits contained cadmium and/or lead limits that are specified in the Idaho's draft CWA Section 401 certifications, thus, the comment could be applicable to any of the subject permits.

As stated in the fact sheets (e.g., the Coeur d'Alene Fact Sheet at Page 13), the State of Idaho specified effluent limits for cadmium (and, for Coeur d'Alene, lead) in its draft CWA Section 401 certifications. The draft certifications stated that these limits were necessary to ensure compliance with IDAPA 58.01.02.055.04. The draft permits included these effluent limits in order to incorporate the requirements specified in the draft CWA Section 401 certifications (40 CFR 124.53(e), 124.55(a)(2)).

The final CWA Section 401 certifications do not specify any cadmium or lead limits. On June 4, 2014, a rule became effective under Idaho state law (Docket No. 58-0102-1301), which repealed the language in IDAPA 58.01.02.055.04 that had stated that the loading of pollutants causing water quality impairments in high-priority water-quality-limited waters must remain constant or decrease within the watershed. As stated in Appendix D to each of the subject fact sheets, none of the subject POTWs have the reasonable potential to cause or contribute to excursions above water quality criteria for cadmium. In addition, Coeur d'Alene does not have the reasonable potential to cause or contribute to excursions above water quality criteria for lead (see the Coeur d'Alene fact sheet at Table 2 in Appendix D).

Thus, there is no basis to include effluent limits for cadmium in any of the subject final permits, and there is no basis to include effluent limits for lead in the Coeur d'Alene final permit. The final permits do not include such limits.

Comment #1-15

Several parties submitted comments comparing the effluent limits for cadmium, lead, and/or zinc to those in the State of Washington's permits for POTWs discharging to the Spokane River in Washington.

Ecology stated in its comments on the subject draft permits that the Spokane River Dissolved Metals TMDL for cadmium, lead, and zinc requires waste load allocations for Washington dischargers as the more stringent of either end-of-pipe limits based on discharge hardness or performance-based limits for each facility. In its comments on the subject draft permits, Ecology recommended that the EPA use the same method of calculation for the Idaho dischargers.

The City of Spokane stated that they reviewed the effluent limits for metals such as zinc. In order to protect water quality, Spokane (53.8 µg/L monthly average) is required to achieve effluent limits for zinc that are twice as stringent as the EPA's proposed effluent limits for Idaho dischargers (135 µg/L monthly average). The City of Spokane stated that it is not clear from the Fact Sheets why municipal discharges in Idaho are not being held to the same standard as Spokane.

Riverkeeper stated that the proposed effluent limits for the Idaho dischargers for metals do not appear to be protective of water quality in Washington. For example, the effluent limit for zinc is twice the limit of the dischargers in Washington (53.8 v. 135 µg/L monthly average), the average monthly limit for lead is 2.5 v. 0.772 µg/L, and the average monthly limit for cadmium is 0.149 v. 0.076 µg/L. It is unclear why these limits are significantly higher than the limits set for Washington dischargers.

Response #1-15

The bases for the cadmium, lead, and zinc effluent limits in the draft permits are explained in Appendix C to the subject fact sheets.

As explained in the response to comment #1-14, above, the effluent limits for cadmium (and, for Coeur d'Alene, lead) in the draft permits were removed from the final permits because they were removed from the final CWA Section 401 certifications, following changes to Idaho's water quality rules at IDAPA 58.01.055.04.

The effluent limits for lead and zinc in the subject final permits have two possible bases, as summarized in Table 4, below. Some of the limits are based on meeting Idaho water quality criteria at the end-of-pipe (i.e., with no mixing zone), using discharge hardness. Other limits are based on ensuring compliance with the anti-backsliding requirements of the CWA. The limits that appear in the permits are the more stringent limits resulting from these possible bases.

Table 4: Bases for Cadmium, Lead, and Zinc Effluent Limits

Metal	Average Monthly Limit	Maximum Daily Limit
City of Coeur d'Alene		
Zinc	Idaho water quality criteria	Idaho water quality criteria
City of Post Falls		
Lead	Anti-backsliding[1]	Anti-backsliding[1]
Zinc	Anti-backsliding[1]	Anti-backsliding[1]
Hayden Area Regional Sewer Board		
Lead	Concentration: Idaho water quality criteria[2] Mass: Anti-backsliding[1]	Anti-backsliding[1]
Zinc	Anti-backsliding[1]	Anti-backsliding[1]

Notes:
1. Concentration limits were identical to the limits in the 1999 permits, but mass limits were increased because of the increased design flows of the Post Falls and HARSB POTWs.
2. Because the shape of the lead criteria curves, when plotted against hardness, are "concave up," (i.e., the second derivative is always positive), calculating criteria end-of-pipe water quality-based effluent limits for lead, using the hardness of the effluent, can contribute to excursions above water quality criteria as the discharge mixes with a receiving water that is softer than the effluent. This was addressed in this case by calculating a tangent line to the water quality criteria at the State of Idaho's hardness "floor" of 25 mg/L as CaCO3 and calculating water quality-based effluent limits based on the tangent line.

As stated by Ecology in its comments, some of the wasteload allocations (WLAs) for cadmium, lead, and zinc in the State of Washington's Spokane River Dissolved Metals TMDL are based on the dischargers' performance. States have the discretion to set any WLA for a discharger in a TMDL, including WLAs based on performance, as long as the TMDL complies with the EPA's regulations in 40 CFR 130.7. However, there is no provision in the CWA or the NPDES regulations that allows the EPA to independently set effluent limits based on performance.

Effluent limits in an NPDES permit are either technology-based (TBEL) or water quality-based (WQBEL). Effluent limits based on WLAs in a TMDL are a type of WQBEL. When a state specifies additional or more stringent requirements in a CWA Section 401 certification, these requirements are also based on the state's water quality standards or other provisions of state law.

The applicable technology-based limits for POTWs are the secondary treatment standards in 40 CFR Part 133. The secondary treatment standards do not address cadmium, lead, or zinc. Therefore, unless more stringent effluent limits are necessary to ensure compliance with the anti-backsliding provisions of the CWA or to ensure consistency with a state certification, the effluent limits for cadmium, lead, and zinc in the permits are WQBELs. WQBELs apply Idaho water quality criteria at the end-of-pipe, using discharge hardness. Some of WLAs in the Spokane River Dissolved Metals TMDL are calculated similarly, using Washington's water quality criteria.

As stated in the fact sheets (e.g., the Coeur d'Alene fact sheet at Page 15), the EPA has determined that the subject discharges do not have the reasonable potential to cause or contribute to excursions above Washington's water quality standards for cadmium, lead, or zinc. Idaho and Washington have identical water quality criteria for lead. Because the effluent limits for lead ensure compliance with Idaho's water quality criteria, they will also ensure compliance with Washington's water quality criteria. Idaho's water quality criteria for cadmium are more stringent than Washington's. Because none of the subject POTWs have the reasonable potential to cause or contribute to excursions above Idaho's water quality criteria for cadmium, none of the subject POTWs have the reasonable potential to cause or contribute to excursions above Washington's water quality criteria for cadmium.

Regarding zinc, the increase in zinc concentration attributable to the Idaho dischargers at the state line is less than the increase in water quality criteria (and, in turn, loading capacity) caused by the hardness of the effluents. Therefore, although Idaho's water quality criteria for zinc are marginally less stringent than Washington's criteria, the EPA has determined that the subject discharges do not have the reasonable potential to cause or contribute to excursions above Washington's water quality criteria for zinc.

Therefore, the effluent limits for lead and zinc in the subject permits are as stringent as necessary to ensure compliance with the water quality standards of both Idaho and Washington, as well as the anti-backsliding provisions of the CWA. Washington dischargers may have more stringent effluent limits where the Spokane River Dissolved TMDL specified more stringent WLAs for Washington dischargers. For example, the Washington WLAs and limits may be more stringent if they were performance-based. Or, since the water quality criteria are based on discharge hardness, and water quality criteria for cadmium, lead, and zinc increase with increasing hardness, the effluent limits for a particular Washington discharger may be more stringent than the Idaho dischargers' effluents if the effluent of a particular Washington discharger was softer than the Idaho dischargers' effluents.

Influent and Effluent Monitoring and Reporting Requirements

Comment #1-16

Coeur d'Alene requests clarification as to how the EPA will use data collected using the unapproved test method 1668. The fact sheet states that the EPA will be using the data to perform a reasonable potential analysis and derive numeric limits but acknowledges that compliance with such limits cannot be enforced using an unapproved test method. Is it correct to assume that this statement in the Fact Sheet regarding the use of method 1668 is a statement of current intentions and not a permit decision? That is, is it correct to assume that the reasonableness and legality of the potential future use of 1668 data to set permit limits will be fully considered in future permits and is not being determined in this permit cycle? This is an important issue given the expense, variability, and uncertainty regarding the reliability of the data that will be collected using an unapproved test method.

Response #1-16

The EPA believes, barring unforeseen data quality issues, that the data collected using EPA Method 1668 (or Method 8082) will be useful in performing a reasonable potential analysis for PCBs in the future.

Nothing in the CWA or regulations prevents the EPA from using data produced using an analytical method that is not approved under 40 CFR Part 136 in a reasonable potential analysis. Indeed, as discussed in the response to comment #1-1, reasonable potential analyses may be conducted without *any* facility-specific effluent data (see also the TSD at Section 3.2). Although the EPA chose to defer approval of Method 1668C while it considers the large number of comments received on the proposed approval, the EPA has stated that "this decision does not negate the merits of this method for the determination of PCB congeners in regulatory programs or for other purposes when analyses are performed by an experienced laboratory" (77 FR 29763). The EPA also requires permittees to submit data for any parameter upon request, regardless of the test methods used (see the permits at Part III.D.).

As stated in the fact sheets, (e.g. the Coeur d'Alene Fact Sheet at Page 27), the EPA may require the use of methods 1668 or 8082 in this case because the permit requires analysis of PCB congeners, and the methods approved under 40 CFR 136 are not capable of analysis for individual PCB congeners. For pollutants for which there are no approved methods under 40 CFR Part 136 (such as PCB congeners),

monitoring must be conducted according to a test procedure specified in the permit (40 CFR 122.44(i)(1)(iv); see also the EPA Permit Writers' Manual at Section 8.3).

In addition to their inability to differentiate PCB congeners, the PCB analytical methods that are approved under 40 CFR Part 136 have high detection limits that render them useless for effluent characterization for the purpose of a reasonable potential analysis. The lowest published method detection limit for the approved PCB methods is 0.065 µg/L, which is 65 ng/L or 65,000 pg/L, for PCB-1242, in Method 608. This is 383 times the Washington water quality criterion for PCBs (170 pg/L), 1,016 times the Idaho water quality criterion for PCBs (64 pg/L) and 50,000 times the Spokane Tribe's water quality criterion for PCBs (1.3 pg/L).

EPA Method 1668 is the only analytical method for PCBs with detection limits comparable to the water quality criteria for the States of Washington and Idaho (i.e. 64 – 170 pg/L). The EPA is not aware of any analytical methods that can detect PCBs in whole water samples at the Spokane Tribe's water quality criterion.

Comment #1-17

Post Falls and HARSB stated that the draft permits require PCB monitoring of the influent at the frequency of once every two months but quarterly for the final effluent. Since HARSB's and Post Falls' collection and treatment system was constructed after 1978 when PCB production and use was banned and it has no Significant Industrial Users that predate the ban, it is not reasonable to expect significant fluctuations in influent concentrations of PCB. In addition, it would be beneficial to conduct influent PCB sampling contemporaneously with effluent PCB sampling in order to calculate removal rates. The influent and effluent PCB sampling will be further coordinated with the required Toxics Management Plan, with the Regional Toxics Task Force, and with surface water quality monitoring. Therefore, we request the Draft Permit be revised with the influent PCB monitoring to match the quarterly effluent monitoring for this permit cycle.

Coeur d'Alene stated that the monitoring frequency in Table 1 for influent and effluent samples for PCBs should be equivalent.

Response #1-17

The EPA does not agree that the influent PCB sampling frequency should be reduced. As explained below, the EPA believes the proposed influent sampling frequency of once every two months is reasonable.

As stated in the fact sheets (e.g. the Coeur d'Alene Fact Sheet at Page 26), the proposed influent and effluent monitoring frequencies for PCBs are the same as those in the State of Washington's permit for the Liberty Lake Sewer and Water District, which operates the smallest of the three POTWs that discharge to the Spokane River in Washington and, like the subject dischargers, serves a primarily residential community.

As explained in the response to comment #1-1, POTWs that comply with removal requirements for TSS are likely to remove a large percentage of the PCBs in their influents. Thus, some PCB congeners that

are present at detectable concentrations in the influent may not be detectable in the effluent. Since the specific PCB congeners detected can aid in source identification, influent sampling will be more useful for source identification than effluent sampling. Since source identification aids in source control, it is reasonable to require PCB sampling of the influents to the POTWs somewhat more frequently than the effluents.

Furthermore, the fact that the required influent sampling frequency is different from the required effluent sampling frequency does not preclude contemporaneous influent and effluent sampling, because sampling once every two months will result in at least one influent sample every quarter. For example, influent sampling during the odd-numbered months would result in two samples during the first quarter (January – March) and the third quarter (July – September) and one sample during the second quarter (April – June) and the fourth quarter (October – December). Conversely, influent sampling during the even-numbered months would result in one sample during the first and third quarters and two samples during the second and fourth quarters. The quarterly effluent sample could be taken at the same time as one of the influent samples for a given quarter, thus allowing the calculation of a PCB removal rate.

Comment #1-18

Ecology stated that, currently, DO monitoring is required only once per month. Ecology would like the EPA to consider increasing the DO monitoring to five times per week for a more representative monitoring event. The facilities will be required to monitor pH five times per week and we feel that including the additional parameter will not be burdensome on the facilities. Also, since the permits were written with the intention of protecting DO levels in Lake Spokane, the increased DO monitoring will help in the validation that our state water quality standards will be met.

Response #1-18

The EPA agrees that, since pH must already be monitored at least 5 times per week with a grab sample, it would not be a significant burden for the permittees to test for DO 5 times per week as well. The EPA agrees that, since many of the subject permits' conditions are intended to ensure compliance with water quality standards for DO, it is reasonable to better characterize the discharges' effluent DO concentrations. Therefore, the EPA has changed the required effluent monitoring frequency for DO from once per month in the draft permits to five times per week in the final permits.

Comment #1-19

Ecology stated that they would like to be allowed access to review monthly DMRs from each of the three dischargers.

Response #1-19

Effluent data, as reported on DMRs, for all NPDES discharges in Idaho, including the subject POTWs, will be entered into the EPA's Integrated Compliance Information System (ICIS) database. The EPA will assist in granting access to the ICIS database to appropriate Ecology staff so that Ecology staff may review the DMR data. Also, to address this comment, the subject POTWs will be required to submit their DMR data electronically using NetDMR within 6 – 12 months and, thereafter, will not submit paper DMRs to the EPA. This is consistent with EPA Region 10's current reporting policy for major dischargers.

The public can access the information in ICIS on the internet by using Enforcement and Compliance History Online[3] (ECHO), Envirofacts[4], or the DMR Pollutant Loading Tool[5].

Comment #1-20

ICL stated that the PCB monitoring should be more frequent to ensure a robust database for determining the sources of contamination and the ability of the treatment plants to capture the PCBs. A monitoring regimen that compares influent to effluent should be added.

Response #1-20

The EPA believes the influent and effluent PCB monitoring requirements in the draft permits are adequate to characterize the utilities' discharges of PCBs (if any). The influent and effluent monitoring frequencies for PCBs are identical to those in the NPDES permit for the Liberty Lake Sewer and Water District, which discharges to the Spokane River in Washington and is of comparable size to the subject POTWs.

The following relative errors were calculated using the procedures described in Appendix N to the EPA's Local Limits Development Guidance (EPA 2004).

Assuming a coefficient of variation of 0.6, which is recommended by EPA permitting guidance in cases where the actual effluent variability is unknown (see TSD at Pages 53 and E-3), the 20 effluent samples that will be collected over the permit term (i.e., quarterly sampling for five years) will quantify the average effluent concentration with a 22.5% relative error, at a confidence level of 90%. For the influent (30 samples) the relative error will be 18.3%, at a confidence level of 90%.

Analysis of PCBs using EPA Method 1668 is expensive, costing about $1,000 per sample. The EPA has attempted to balance the cost of the monitoring with the need to adequately characterize the utilities' discharges of PCBs (if any).

Comment #1-21

Coeur d'Alene requests that the permit clarify that any test results below the detection limit of the test method be treated as zero for calculating monthly mass discharge levels.

Response #1-21

The draft permits state, in relevant part, "For purposes of calculating seasonal, monthly and weekly averages, except for E. coli, zero may be assigned for values less than the method detection limit (MDL)…." This language is applicable to the reporting of averages for both concentration and mass. In the final permits, this sentence has been edited to read, "For purposes of calculating seasonal, monthly and weekly average mass loadings and concentrations, except for E. coli, zero may be assigned for values less than the MDL…."

[3] echo.epa.gov
[4] www.epa.gov/enviro/index.html
[5] cfpub.epa.gov/dmr

Comment #1-22

Coeur d'Alene requests that the text in Part I.B.3 be revised to state, "Effluent loading of zinc and silver (October-June) and concentrations of cadmium, copper, lead, silver and zinc must be reported as total recoverable metal." The language in the draft permit suggests that loading must be reported for all parameters where zinc and silver (October-June) are the only metal parameters with mass loading limits.

Response #1-22

The EPA agrees that the language suggested by Coeur d'Alene is clearer than the language of the draft permit. The EPA has made the suggested change to the Coeur d'Alene permit and has made similar changes to the Post Falls and HARSB permits.

Comment #1-23

Coeur d'Alene requests that the reporting deadline for seasonal average TP, $CBOD_5$ and ammonia loads be revised from the October DMR to the November DMR to allow sufficient time for analysis and reporting.

Response #1-23

The EPA has addressed this comment by changing the DMR due date from the 10th day of the month following the monitoring month to the 20th day of the month following the monitoring month, for all three of the subject permits. The seasonal average TP, ammonia, and $CBOD_5$ loads are still required to be reported on the October DMR, but the October DMR is now due on November 20th instead of November 10th.

The EPA does not agree that more time is necessary for analysis and reporting of a seasonal average limit than for an average monthly limit. A seasonal average discharge is calculated in much the same way as a monthly average discharge (i.e., it is the arithmetic average of daily discharges measured during a defined time frame).

Comment #1-24

Mr. Bob Bingham of the NWPOA asked the EPA to please provide a summary of the methods used for collection, handling and analyzing of samples including standardization of equipment.

Response #1-24

In general, the required methods used for collection, handling, and analysis of samples are specified in 40 CFR Part 136. The one exception is the influent, effluent, and receiving water sampling and analysis of PCB congeners. The EPA specified the methods to be used for analysis of PCB congeners, because there is no approved method for PCB congeners in 40 CFR part 136.

Specific information about analytical methods can be found online at the National Environmental Methods Index at www.nemi.gov and at the EPA's website at water.epa.gov/scitech/methods/cwa/methods_index.cfm.

Comment #1-25

Coeur d'Alene stated that, Table 2, in Part I.B.6; some of the maximum Minimum Levels (MLs) for reporting are not consistent with approved EPA Methods. Coeur d'Alene stated that the permit writer seems to have picked the lowest value for any EPA approved or non-approved method regardless of its applicability.

For example, most laboratories utilize EPA Method 351.2 for total Kjeldahl nitrogen (TKN). This method has a working range according to the method of 100 ug/L to 20 mg/L. The approved EPA Method 351.1 has a working range of 50 ug/L to 2 mg/L, but it is only applicable to surface or saline waters, and not to domestic or industrial wastewaters. Thus, the ML for TKN in Table 2 should be set at 100 ug/L in this case to match EPA Method 351.2.

Response #1-25

The EPA agrees that the ML for total Kjeldahl nitrogen (TKN) for effluent monitoring (Table 2) should be changed to 100 µg/L, consistent with the minimum of the working range of EPA Method 351.2 (O'Dell 1993).

Surface Water Monitoring and Reporting Requirements

Comment #1-26

The Spokane Tribe stated that the monitoring should require that the dischargers utilize high volume sampling such as the CLAM methodology when collecting surface water samples for PCBs to increase sensitivity.

Response #1-26

The permits require the use of EPA Method 1668 for receiving water sampling of PCBs. Method 1668 is the most sensitive method available for analysis of whole-water samples for PCBs. According to the May 1, 2014, draft Quality Assurance Project Plan prepared for the Spokane River Regional Toxics Task Force, the Task Force's analyses for PCBs will use EPA Method 1668C (LimnoTech 2014). Method 1668 is not necessarily a high-volume method. Method 1668C does not specify a sample volume for aqueous samples, but rather states "collect one liter (or a larger or smaller volume) of sample sufficient to meet project needs."

Comment #1-27

Coeur d'Alene stated that Part I.F.1 requires monitoring stations upstream and downstream from the Coeur d'Alene outfall. The locations have to be approved by IDEQ. Coeur d'Alene requests guidance as to where the monitoring stations should be located.

Response #1-27

The permittees should work with IDEQ to establish monitoring locations that fit the descriptions in Part I.F of the final permits. The EPA has chosen to leave the required monitoring locations somewhat general, so that representative, safe, and accessible monitoring locations may be chosen based on site-specific conditions.

Comment#1-28

Ecology stated that the permits specify that analysis for PCB congeners must use EPA Method 1668, with target MDLs no greater than 10 picograms per liter per congener. You should note that EPA Method 1668C includes MDLs for individual congeners, many of which exceed the 10 pg/L target value. Ecology wants to ensure that the permit language will not exclude EPA Method 1668C as a preferred monitoring method. In addition, Ecology would like to ensure that the discharger's involvement in the Spokane River Toxics Task Force (SRRTTF) requires each facility to follow their recommended Quality Assurance Plan for toxics monitoring in the receiving water.

Response #1-28

In the final permits, the EPA has changed the language in Part I.B.11.e to require the permittees to target the MDLs listed in Table 2 of EPA Method 1668 Revision C for analyses of PCBs using Method 1668. The EPA referenced the MDLs from Method 1668C because the earlier revisions of Method 1668 listed *estimated* MDLs (EMDLs). This will provide clarity as to the acceptable MDLs for each congener. The reference to the MDLs published in Method 1668 Revision C does not require the use of Revision C.

Comment #1-29

Coeur d'Alene stated that Parts I.B.11 (PCB Congeners) and I.B.12 (2,3,7,8 TCDD) of the draft permit incorporate the word "target" for MDLs and MLs. Coeur d'Alene asked how "targeting" is accomplished and explained to EPA inspectors during audits. Coeur d'Alene stated that none of the three permittees have or will have the capability to analyze for PCBs or TCDD onsite, and contract laboratories do not provide target MDLs or MLs, only sample results and the associated reporting/quantitation limits (i.e. minimum level of detection (ML). Coeur d'Alene asked if an MDL above the target MDL is a permit violation.

Response #1-29

The word "target" is intended to recognize the fact that, even if a sensitive method is used and appropriate quality assurance and quality control (QA/QC) procedures are followed, the actual MDL or ML achieved in a particular analysis is dependent upon the sample matrix and may be higher than the MDLs or MLs published in the method. If the permittee can demonstrate that it has strived to meet the "target" MDLs and MLs in the draft permit, then, an actual MDL or ML higher than the targets would not be considered a permit violation.

Comment #1-30

Coeur d'Alene stated that total phosphorus has an ML of 10 µg/L in Table 2, which is consistent with the working ranges of approved EPA Methods 365.1, 365.3, 365.4, but Section I.F. Table 4 for "Surface Water Monitoring Requirements" indicates an ML of 5 µg/L for Total Phosphorus and Orthophosphate which is not consistent with any approved EPA method. Total Phosphorus and Orthophosphate target MLs should be consistent with ML requirements listed in Table 2 at 10 µg/L. Coeur d'Alene stated that all current approved EPA TP methods list a working range minimum of 10 µg/L.

Coeur d'Alene stated that all other MLs should be reviewed for consistency with approved EPA Methods and applicability to domestic wastewater and or surface/receiving water.

Response #1-30

The EPA does not agree that the required MLs for total phosphorus and orthophosphate in Table 4 should be changed to 10 µg/L. There are EPA-approved methods for surface water that can achieve a ML no greater than 5 µg/L, for example, Standard Method 4500-P F, which has an applicable concentration range of 1 µg/L to 10 mg/L.

The EPA has reviewed all of the other MLs and MDLs in the permits. The EPA has changed the ML for total Kjeldahl nitrogen, for effluent monitoring, from 50 µg/L to 100 µg/L consistent with the minimum of the working range of EPA Method 351.2 (O'Dell 1993). Otherwise, the EPA has not found any other MLs or MDLs that cannot be achieved.

Phosphorus Management Plan

Comment #1-31

Coeur d'Alene, HARSB and Post Falls requested that the EPA delete the phosphorus management plan requirements from the permits.

Coeur d'Alene stated that a ban on the retail or wholesale sale of phosphorus-containing laundry cleaning products in Coeur d'Alene has been in place since 1990 (Coeur d'Alene Municipal Code Chapter 13.28) and that the state of Washington's ban on dishwashing detergent containing phosphorus applies to Northern Idaho as well since distributors carry only Washington compliant products in the Coeur d'Alene market.

Coeur d'Alene requests that the EPA remove the requirement in Part II.B.2 to evaluate the WWTP TP reduction potential because the City has already engaged in an extensive evaluation of multiple treatment trains for TP removal. Based on this information, the City has updated its facility plan and secured financing and increased utility rates to construct facilities that are tailored to unique needs of Coeur d'Alene. No further evaluation of TP removal should be required until the current facility plan needs to be updated.

Coeur d'Alene requests that the EPA remove the requirement in Part II.B.3 to identify "total phosphorus reduction goals" and any reference to "goals" in Parts II.B.4, 5 and 7 to the extent such goals are anything other than the final effluent limits in the permit. Coeur d'Alene also objects to the potentially vague and burdensome obligation to meet some "typical value" outside its permit limits. The treatment system to be developed by the City was the result of a multi-year evaluation of several different treatment systems. The resulting design is unique to Coeur d'Alene and should not at any time be compared to other facilities. Simply stated, the TP reduction goal for Coeur d'Alene is to achieve compliance with its final effluent limits through optimal operation of its existing, and to be improved, treatment plant.

Coeur d'Alene requests that the EPA remove Part II.B.7 regarding revision of a phosphorus management plan. The performance of the WWTP and applicable TP limits, which should be the only "goals" that are legally required, should be addressed in the ordinary course of the permit cycle. TP removal planning should be addressed in the Facility Plan. It is improper and unlawful for the EPA to impose a de facto

permit limit through the proposed phosphorus removal planning and deadlines of 180 days as proposed in this permit condition. The City cannot manage its utility, its utility rate base, or public financing obligations when subject to an unpredictable extra-permit process. EPA should explain in response to these comments how the 180-day deadline in this section can be consistent with the ten-year compliance schedule to meet the final TP limits.

Coeur d'Alene requests that the EPA remove the annual reporting requirements for a phosphorus management plan in Part II.B.8. An annual report in the next permit cycle is redundant and unnecessary. The City will be filing monthly DMRs. Under Section I.D Coeur d'Alene must file annual progress reports on meeting the final phosphorus limits and reports on interim milestones of the compliance schedule. It is unlikely during the compliance schedule that the City will have anything else to report in terms of phosphorus management. Even if the City engaged in the "planning" required under Part II.B, it is more likely than not that the City would ultimately rely on Part II.B.6.g "total phosphorus removal at the WWTP" and Part II.B.6.h "ongoing monitoring" as its specific actions under the plan throughout the compliance period. EPA does not need a separate report under Part II.B.8 to determine the status of the implementation and optimization of the WWTP upgrades.

Post Falls and HARSB stated that the Draft Permit requires preparation of a Phosphorus Management Plan, ostensibly to reduce influent TP to the treatment plant so as to reduce resulting loading to the Spokane River. This requirement serves no purpose for HARSB and Post Falls for two reasons. First, HARSB has no significant industrial or commercial entities that would discharge inordinate quantities of TP to the treatment plant (i.e. dairies, food processors, metal finishers, etc.).

Post Falls stated that they have utilized a year-round biological TP removal process since the late 1990's which requires the influent TP in order to maintain adequate populations of phosphorus accumulating organisms. Reducing influent TP will reduce the population of those organisms but will have virtually no impact, or perhaps a slightly negative impact, on effluent TP concentrations. Therefore, we request that the requirements for a Phosphorus Management Plan be removed from this permit.

Coeur d'Alene, Post Falls and HARSB stated that the current influent concentrations and loadings of TP are typical for domestic wastewater. Thus, it would be elusive to reduce the influent loading.

Response #1-31

The phosphorus management plan requirements in the draft permits are not unduly burdensome. The requirements are modeled after the Phosphorus Management Plan Guide developed by the Minnesota Pollution Control Agency (MPCA) and the Minnesota Technical Assistance Program at the University of Minnesota. The Phosphorus Management Plan Guide is a 14-page template, available as a Microsoft Word document from the MPCA website[6], which allows utilities to complete a phosphorus management plan by printing the document and filling it in by hand, or by entering information electronically into the document using Microsoft Word and/or Excel. The goal of the phosphorus management plan is to help

[6] www.pca.state.mn.us/index.php?option=com_k2&view=item&id=722

the utilities achieve the lowest possible effluent TP concentrations, in part through strategies to reduce influent TP concentrations.

The EPA recognizes that, in this case, the final water quality-based effluent limits for TP can only be achieved through upgrades to the treatment facilities. Because the final water quality-based effluent limits will require roughly 99% removal of TP from the influent wastewater, the EPA agrees that, once the TP removal upgrades are completed, strategies to reduce influent TP concentrations, even if successful, are unlikely to result in substantial further reductions in effluent TP loads from February to October, when the TP effluent limits apply. Such strategies would be more likely to reduce effluent TP loads at treatment plants that are not designed for TP removal, or that use chemical addition as their only means of TP removal. Therefore, the EPA has deleted those portions of the phosphorus management plan requirements that are intended to reduce influent TP concentrations.

However, the EPA believes those portions of the phosphorus management plan requirements that are concerned with improving the TP removal performance of the treatment plants themselves are useful and are authorized by federal regulations, which allow permitting authorities to include BMP requirements in permits when "(t)he practices are reasonably necessary to achieve effluent limitations and standards or to carry out the purposes and intent of the CWA" (40 CFR 122.44(k)(3)).

Even after the necessary upgrades are completed, the achievement of the subject permits' stringent TP effluent limits will require a high level of skill and attention by the POTW operators. The EPA believes it will be beneficial for the utilities to develop a plan for achieving the high level of performance necessary to achieve the effluent limitations. Careful attention to maintenance, operational parameters such as chemical dosing and in-plant DO concentrations, and up-to-date knowledge of performance achieved by other POTWs using similar treatment technology has the potential to save the utilities money on energy and chemicals.

Couer d'Alene asked the EPA to explain how the 180-day deadline in Part II.B.7 of the draft permit (which appears as Part II.B.5 in the final permits) for revising the phosphorus management plan under certain circumstances is consistent with the ten year compliance schedule to meet the final water quality-based TP limits. The 180-day deadline for revision of the phosphorus management plan is independent of the compliance deadline for the final TP limits, because the phosphorus management plan requirements apply during the term of the compliance schedule. Part II.B.3.a of the final permits states that "effluent total phosphorus reduction goals must be consistent with interim or final total phosphorus effluent limits, as appropriate, or with typical values for the type of treatment process employed by the wastewater treatment plant…." Thus, it is not necessary for the final effluent TP limits to have become effective in order for the utilities to develop phosphorus reduction goals. The EPA believes that implementation of the phosphorus management plans prior to completion of phosphorus removal upgrades and imposition of the final TP limits may result in reductions in TP loadings during the terms of the compliance schedules, which is also consistent with the purposes and intent of the CWA.

The EPA understands that the phosphorus management plan will have some overlap or redundancy with other efforts, such as the utilities' facility plans and operation and maintenance plans. However, since

the TP limits present unique challenges, and because it will take several years to complete the upgrades necessary to comply with those limits, the EPA believes it is nonetheless useful and authorized by 40 CFR 122.44(k)(4) to have a plan specifically for TP removal.

Furthermore, as explained in the response to comment #1-10, modeling predicts that discharges of TP during the month of January can influence DO concentrations in Lake Spokane during the following summer. Therefore, even though there are no numeric effluent limits in effect from November to January, it is reasonably necessary to carry out the purposes and intent of the CWA (e.g., to achieve water quality standards) for the EPA to require the phosphorus management plan to include a phosphorus reduction goal for November to January. This requirement is not intended to significantly increase operating costs above those necessary to meet the February to October TP limits. That is to say, the phosphorus reduction goal for November to January should reflect the level of TP control that the permittee can achieve without incurring significant additional operating costs (e.g., for chemicals and energy) beyond those necessary to comply with permit requirements other than TP limits.

The permits require the utilities to "compare … effluent total phosphorus concentrations against typical values for wastewater treatment plants utilizing similar treatment technology," and further requires that "if the effluent total phosphorus concentrations are higher than typical levels, the permittee must investigate the cause of the high total phosphorus concentrations and take steps to reduce total phosphorus concentrations." The EPA disagrees with Coeur d'Alene that there are no "typical" values for its facility. This requirement does not require a comparison with treatment plants using identical technology, merely "similar" technology. For example, Coeur d'Alene could compare its performance against other treatment plants that use trickling filters for biological treatment and chemical addition for TP removal, Post Falls could compare its performance against other treatment plants using oxidation ditches with biological phosphorus removal, and HARSB could compare its performance against oxidation ditches without biological phosphorus removal. Once upgrades are completed, there are likely to be other treatment plants using similar tertiary processes for TP removal against which the treatment plants' performance could be compared.

Therefore, those portions of the phosphorus management plan requirements that are concerned with improving the TP removal performance of the treatment plants themselves, as well as the associated reporting requirements, have been retained in the final permits.

Tribal Trust Responsibility

Comment #1-32

The Spokane Tribe stated that it has specific water rights and fishing rights in the Spokane and Columbia River that are negatively impacted by upstream pollution and that the federal government is the trustee of the Spokane Tribe's rights, including its fishing rights

The Tribe further stated that if the EPA proceeds to issue these permits substantially unchanged and also fails to initiate a multi-jurisdictional PCB TMDL, it will be in violation of its fiduciary duties.

The Tribe requests that the EPA review these draft permits for compliance with its statutory duties under the Clean Water Act in light of its trust responsibility to the Spokane Tribe of Indians. Further, the EPA should articulate how it is meeting its separate federal common law trust responsibility that is owed to the Spokane Tribe.

Response #1-32

The EPA has reviewed the draft permits for compliance with the CWA and applicable federal regulations. As explained in the response to comment #1-1, the EPA did not conclude, based on the available information, that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs, and therefore has not included effluent limits for PCBs, consistent with 40 CFR 122.44(d). As explained in the response to comment #1-2, the EPA has also reviewed the BMP requirements for PCBs in the draft permits and has determined that these requirements are consistent with 40 CFR 122.44(k) and thus do not need to be changed, even though the PCHB held that similar requirements in the Spokane County WRF permit needed to be changed. As explained in the response to comment #1-5, the issue of a PCB TMDL for the Spokane River is beyond the scope of these permitting actions. The EPA need not delay issuance of these permits until a PCB TMDL is in place.

Because the permits comply with the CWA and applicable federal regulations, the EPA has met its trust responsibility to the Spokane Tribe.

Schedules of Compliance

Comment #1-33

The City of Spokane stated that each Idaho discharger will receive a compliance schedule to meet final effluent limits in 2023. Spokane noted that each discharger has interim milestones for engineering (1 yr), pilot testing (3 yrs), system design (5 yrs), and construction completion (8 yrs). Spokane is encouraged by these milestones, and by the fact that each Idaho discharger will have a period of time (2 to 3 years) to work with their new system and then comply with final limits in 2023. It is concerned that Ecology is scheduled to complete its initial ten-year review of the success of the DO TMDL in 2020. The concept was for Ecology to look at water quality in the Spokane River after all municipal entities had installed the next level of treatment and operated these new systems for a period of 2 to 3 years. EPA and Ecology should consider how a useful ten-year review can be conducted in 2020 if the Idaho dischargers do not upgrade their wastewater facilities until 2023.

Response #1-33

The regulatory requirement for the length of a compliance schedule in a permit is that the schedule "shall require compliance as soon as possible" (40 CFR 122.47(a)(1)). As explained in Appendix G to each of the fact sheets, the EPA has determined that the schedules of compliance proposed in the draft permits require compliance with the final water quality-based effluent limits as soon as possible. Therefore, the EPA has no basis to require compliance sooner than proposed in the draft permits.

The EPA believes that, even if some Spokane River dischargers have not achieved compliance with their final water quality-based effluent limits at the time of the ten-year assessment for the State of

Washington's DO TMDL, there nonetheless will be substantial reductions made in discharges of nutrients and oxygen-demanding pollution to the Spokane River, relative to pre-TMDL conditions, as well as additional water quality data, that can be used to update the CE-QUAL-W2 model used to develop the TMDL and the permits.

Comment #1-34

Mr. Bob Bingham NWPOA stated that the EPA should amend the permits to extend the compliance date (of 10 years) to a point when at least 50% to 70% of all the Washington State municipal NPDES point discharge entities also meet these same stringent standards along the river system to the west coast and/or extend the compliance deadline to 15 to 18 years to allow each of the permittees to gradually begin to raise sewer rates and to gradually accumulate the required funds instead of having to force citizens to experience doubling and perhaps tripling of their sewer rates.

Response #1-34

Federal regulations state that schedules of compliance in NPDES permits must require compliance with effluent limits as soon as possible (40 CFR 122.47(a)(1)). As explained in Appendix G to the fact sheets for all three permits, the ten-year schedules of compliance in the permits require compliance as soon as possible. If the schedules of compliance were extended beyond ten years, they would not comply with 40 CFR 122.47.

Furthermore, it would not be consistent with federal regulations nor would it be practical or reasonable to link the schedules of compliance for new water quality-based effluent limits in the subject permits to schedules for permits in Washington. Federal regulations state that compliance schedules must require compliance as soon as possible. Some permittees will be able to achieve compliance with new water quality-based effluent limits sooner than others, so the meaning of "as soon as possible" will be different for each permit. Furthermore, different permits are reissued on different schedules. Therefore, it would be unreasonable and would violate federal regulations if schedules of compliance were somehow linked to the achievement of similar effluent limits by municipalities in Washington.

Finally, it should be noted that the schedules of compliance for TP and CBOD effluent limits in the NPDES permits for existing POTWs in the State of Washington that discharge to the Spokane River above Lake Spokane (i.e. the City of Spokane and the Liberty Lake Sewer and Water District) do, in fact, require compliance with their new water quality-based effluent limits no later than March 1, 2021, which is sooner than the subject POTWs must achieve compliance with such limits. The Spokane County WRF permit does not include any schedules of compliance because it is a new discharger, and schedules of compliance are generally prohibited for new dischargers (40 CFR 122.47(a)(2)).

Timing of Permit Issuance

Comment #1-35

The City of Spokane stated that the EPA's decision approving the Spokane River DO TMDL was appealed to the U.S. District Court in Idaho by dischargers in Idaho. The City of Spokane filed a motion to intervene in the litigation in order to preserve the progress achieved through the TMDL process, and to protect Spokane's investment in new wastewater treatment systems. The appeal is pending but we

understand it will be dismissed with prejudice after the Idaho dischargers receive final NPDES Permits. We urge EPA to move quickly so that the uncertainty created by the litigation is alleviated and the Idaho dischargers can join Spokane and others in implementing new technologies and programs that will continue to improve water quality in the Spokane River.

Response #1-35

The EPA has issued the subject permits as expeditiously as possible.

Effluent Limit Structure

Comment #1-36

ICL stated that the permits do not list any average weekly limits for E. coli, total residual chlorine, total ammonia, or metals (except for cadmium). Weekly average limits should be established for these pollutants. Those pollutants with only monthly average limits and daily maximum limits risk exceeding the monthly limit if the daily maximum is reached multiple times over a period of several days. Therefore, average weekly limits for E. coli, total residual chlorine, total ammonia, and metals should be included.

Response #1-36

There is no basis to include average weekly limits for any of the pollutants mentioned, to the extent that such limits were not already included in the draft permits.

Federal regulations state that effluent limits for POTWs that discharge continuously shall be stated as average monthly and average weekly discharge limitations "unless impracticable" (40 CFR 122.45(d)(2). The HARSB permit does, in fact, include average weekly limits for total residual chlorine, from October to May. Otherwise, the effluent limits in the permits for the pollutants mentioned by ICL in its comments are stated as average monthly and maximum daily limits, because it is impracticable for the EPA to state the limits as average weekly limits.

Specifically, for E. coli, as explained in Appendix C to the 2013 fact sheets, it is impracticable to properly implement a 30-day geometric mean criterion in a permit using monthly and weekly arithmetic average limits. Therefore, the permit limits for E. coli are stated as a monthly geometric mean concentration, which is identical to the water quality standard in both its magnitude and its averaging. Because a single sample value exceeding 406 organisms per 100 ml indicates a likely exceedance of the geometric mean criterion, the EPA has imposed an instantaneous (single grab sample) maximum effluent limit for E. coli of 406 organisms per 100 ml, in addition to a monthly geometric mean limit.

For ammonia, chlorine, and metals, structuring the limits as average monthly and maximum daily limits is consistent with the recommendations of the TSD. The TSD recommends using maximum daily limits in lieu of the generally required average weekly limits for POTWs, because an average weekly limit has an averaging period that is too long to prevent acute toxicity to aquatic life (Section 5.2.3). The October to May limits for chlorine for HARSB are an exception because they are technology-based effluent limits, which are based upon standard operating practices rather than toxicity.

Availability of Information

Comment #1-37

Ecology respectfully requests a courtesy review of the required toxics monitoring quality assurance plans to confirm the monitoring protocols meet the same requirements as Washington dischargers.

Response #1-37

To address this comment, the EPA has required Post Falls and Coeur d'Alene to submit their quality assurance plans (QAPs) to the EPA as an electronic attachment to their DMRs. Thus, the QAPs will thus be available in the ICIS database. As explained in the response to comment #1-19, the EPA will assist in providing ICIS access to the appropriate Ecology staff. This will allow Ecology staff to obtain and review the QAPs.

In its final permit, HARSB is not required to begin submitting monitoring data using NetDMR by the time they must submit their QAP to the EPA. Thus, HARSB's QAP may not be submitted as an electronic attachment to a DMR. The EPA will work with Ecology staff to obtain a copy of the HARSB QAP for review by Ecology.

Other Comments

Comment #1-38

Mr. Bob Bingham of the NWPOA asked how many municipal wastewater NPDES permits are there in the EPA database that the EPA oversees, and how many municipal wastewater NPDES permits are there in State run programs database that the EPA requires, but allows the respective state to assume oversight and jurisdiction? Mr. Bingham also asked what percentage of those permits are as strict as the proposals being put forth upon Post Falls, Coeur d'Alene, and HARSB. Mr. Bingham also asked the EPA to please quantify the number of total other municipal permits being required to attain these same reduction goals.

Response #1-38

The database that is used to track NPDES permits is the Integrated Compliance Information System (ICIS). The public can access the information in ICIS on the internet by using Enforcement and Compliance History Online[7] (ECHO), Envirofacts[8], or the DMR Pollutant Loading Tool[9]. The EPA performed queries of the ICIS database in order to answer the questions posed in this comment.

According to the ICIS database, there are 22,369 NPDES permits for facilities with a standard industrial classification (SIC) code of 4952, which is the code for sewerage systems. This includes individual NPDES permits and coverages under general NPDES permits. Of these, 20,779 (93%) were issued by State and Territorial agencies, and 1,590 (7%) were issued by the EPA.

[7] echo.epa.gov
[8] www.epa.gov/enviro/index.html
[9] cfpub.epa.gov/dmr

It is not clear what the commenter meant by permits that are "as strict as" the subject permits. The subject permits have water quality-based effluent limits for a number of pollutants. However, the phosphorus limits in the subject permits are the limits that present the greatest technical challenge and that require the most extensive upgrades to meet. Thus, for the purpose of this comment, the EPA has searched for permits with phosphorus effluent limits that are comparable to or more stringent than the phosphorus limits in the subject permits.

The phosphorus limits in the subject permits are expressed as seasonal average limits for mass. Effluent limits for phosphorus may be expressed in terms of mass, concentration, removal rate, or a combination of these. The effective stringency of a mass limit depends on the facility's flow rate and, in turn, the effluent concentration that a POTW must achieve in order to achieve the mass limit. As explained in the fact sheets (see Table 4 in Appendix B), the phosphorus mass effluent limits in the draft permits are equivalent to a discharge of 0.05 mg/L (50 µg/L) TP at projected future flow rates. The ICIS database does not include flow projections, but it does include facilities' current design flow rates as reported on their most recent permit applications. At the POTWs' current design flow rates, the phosphorus mass limits in the subject draft permits are equivalent to 63 µg/L, 66 µg/L, and 76.5 µg/L for Coeur d'Alene, HARSB and Post Falls, respectively.

Effluent limits may also be expressed using a variety of different averaging periods. Because effluent discharges are variable, meeting an effluent limit of a given magnitude requires the POTW to achieve lower long-term average concentration or loading if the averaging period for the limit is relatively short. Thus, it is important to consider the differences in averaging periods when comparing the stringency of effluent limits. Regarding effluent variability, for the purpose of reasonable potential and effluent limit calculations, the TSD recommends making the assumption that the coefficient of variation (CV) is equal to 0.6, if there are not enough effluent data available to calculate a CV (Pages 53 and E-3). Assuming a sampling frequency of four samples per month, a CV of 0.6, and using the 99th percentile probability basis for both the average monthly and maximum daily limits, the ratio between an average monthly and an average weekly limit is 1.64:1 (see TSD at Table 5-3). Thus, a maximum daily limit of 126 µg/L is roughly equally as stringent as an average monthly limit of 76.5 µg/L (76.5 µg/L × 1.64 = 126 µg/L).

Thus, to address this question, the EPA searched for facilities with phosphorus limits that met at least one of the following criteria:

- For concentration limits:
    - Limits with an averaging period of monthly or longer with a magnitude of 76.5 µg/L or lower. As explained above, Post Falls' proposed seasonal average TP limit is equivalent to a concentration of 76.5 µg/L at the facility's current design flow rate. Or,
    - Limits with an averaging period shorter than monthly (e.g., average weekly limits or maximum daily limits) with a magnitude of 126 µg/L or lower.
- For mass limits:
    - Effluent limits that meet the above criteria for concentration limits, when the mass limits are converted to equivalent concentrations using the design flow of the facility. Facilities without a design flow value in ICIS were not considered.

- For percent removal:
    - A minimum percent removal requirement of at least 98%.

The database queries located 52 NPDES permits for POTWs in 11 States and in the Virgin Islands that have limits that meet the above criteria. The TP limits in the permits for the three POTWs discharging to the Spokane River in Washington were not in the ICIS database; these three POTWs also have TP limits that meet the above criteria. The final water quality-based TP effluent limits for the City of Boise, Idaho's two POTW treatment plants were not in the ICIS database, and would have also met these criteria. The phosphorus limits in the Boise, City of Spokane, Spokane County and Liberty Lake permits are shown in Table 5, below.

Thus, there are at least five permits (the two City of Boise permits and the three Washington permits for discharge to the Spokane River) that have limits at least as strict as those in the subject permits that were not found by the ICIS search, resulting in a total of 57 permits in 12 States and in the Virgin Islands. There may be other permits with similar limits which are not in the database. Of these 57 permits, 8 (14%) were issued by the EPA and the remaining 49 (86%) were issued by State or territorial permitting authorities.

Comment #1-39

Please list all municipal permits that have equal to or stricter limits and their permit limits along the entire river path to the Pacific Ocean.

Response #1-39

It is not clear what the commenter meant by "the entire river path to the Pacific Ocean." The subject POTWs discharge to the Spokane River, which is a tributary to the Columbia River, which flows to the Pacific Ocean. For the purposes of responding to this comment, the EPA will list permits with phosphorus limits at least as stringent as those in the subject permits, which are in the Columbia River watershed. Those permits are listed in Table 5, below. The permits listed may have other phosphorus limits in addition to those listed in the table. If the permit had phosphorus limits with multiple averaging periods (e.g. average monthly and average weekly limits), then the limits listed in the table are those with the longest averaging period. If the permit had phosphorus limits for both mass and concentration, only the concentration limits are listed.

Table 5: Permits with Low Phosphorus Limits in the Columbia River Watershed

NPDES ID	Permit Effective Date	Permit Name	City	State	Issuing Agency Type	TP Limit	Limit Unit	Statistical Base	Design Flow (mgd)	Equiv. Conc. Limit (mg/L)
ID0020036	10/1/2005	Grangeville, City of	Grangeville	ID	U.S. EPA	67	µg/L	Monthly Average	0.88	
ID0020443	8/1/2012	Boise, City of (Lander St.)	Boise	ID	U.S. EPA	70	µg/L	Monthly Average	15	
ID0021016	10/1/2013	Notus, City of	Notus	ID	U.S. EPA	70	µg/L	Monthly Average	0.2	
ID0022781	7/1/2012	Plummer, City of	Plummer	ID	U.S. EPA	50	µg/L	Monthly Average	0.32	

Table 5: Permits with Low Phosphorus Limits in the Columbia River Watershed										
NPDES ID	**Permit Effective Date**	**Permit Name**	**City**	**State**	**Issuing Agency Type**	**TP Limit**	**Limit Unit**	**Statistical Base**	**Design Flow (mgd)**	**Equiv. Conc. Limit (mg/L)**
ID0023159	8/1/2013	New Meadows, City of	New Meadows	ID	U.S. EPA	6.6	lb per month	Monthly Total	0.36	0.0733
ID0023981	8/1/2012	Boise, City of (West Boise)	Boise	ID	U.S. EPA	70	µg/L	Monthly Average	24	
ID0028304	1/1/2013	Greenleaf, City of	Greenleaf	ID	U.S. EPA	70	µg/L	Monthly Average	0.24	
ID0028355	6/1/2009	Kuna, City of	Kuna	ID	U.S. EPA	70	µg/L	Monthly Average	3.5	
OR0034002	4/1/2004	Mcminnville, City of	Mcminnville	OR	State	70	µg/L	Monthly Median	5.6	
WA0024473	7/1/2011	Spokane AWWTP	Spokane	WA	State	17.8	lb/day	Seasonal Average	55.9	0.038
WA0045144	7/1/2011	Liberty Lake Sewer and Water Dist.	Liberty Lake	WA	State	0.45	lb/day	Seasonal Average	2	0.027
WA0093317	12/1/2011	Spokane County Regional WRF	Spokane	WA	State	2.8	lb/day	Seasonal Average	8	0.042

Comment #1-40

Mr. Bob Bingham of the NWPOA asked how many municipal wastewater NPDES permits are there in Region 10 along the waterway system that these three utilities discharge into. Mr. Bingham asked the EPA to provide a map showing the locations of each and their respective permit limits (nitrogen and phosphorus/phosphate) and respective permit renewal dates.

Response #1-40

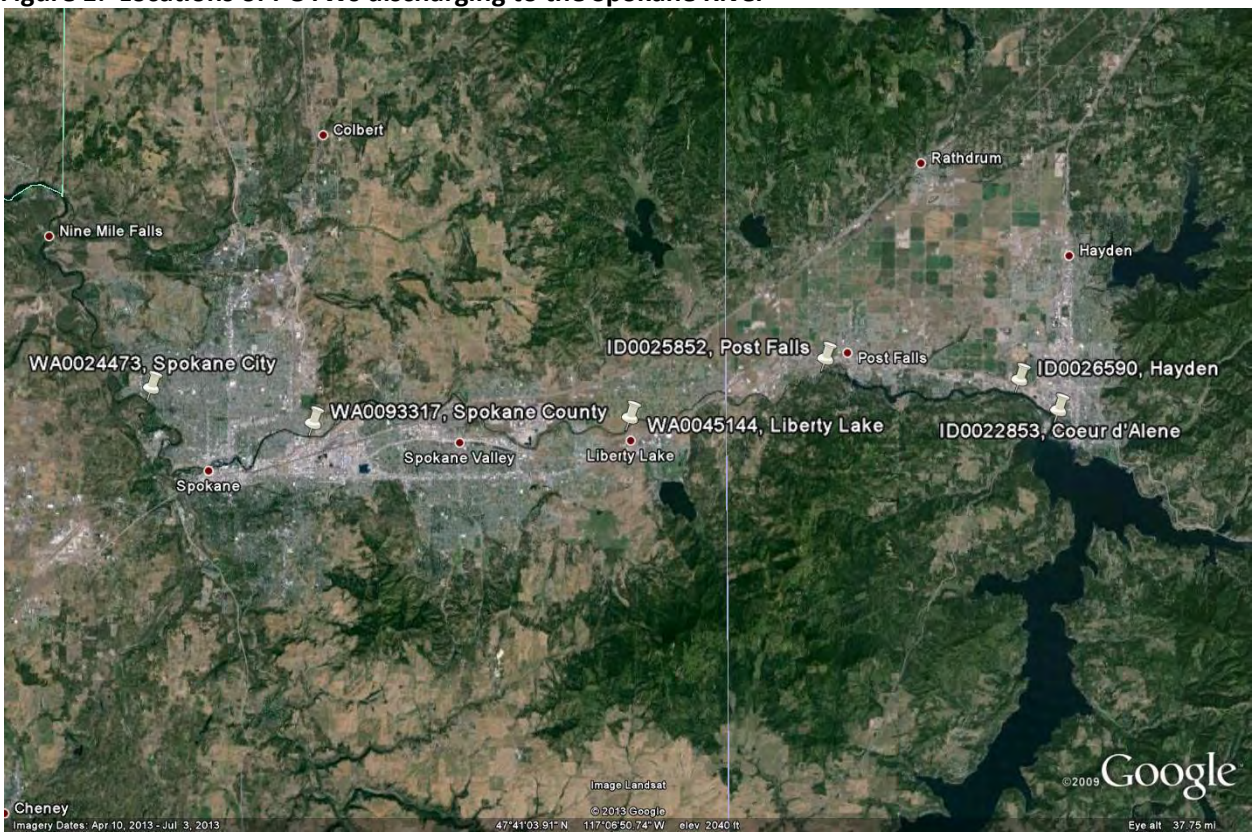
It is not clear what the commenter meant by "the waterway system that these three utilities discharge into." For the purposes of responding to this comment, the EPA will assume that the commenter was referring to the Spokane River, which flows about 111 miles from Lake Coeur d'Alene in Idaho to the Columbia River (Lake Roosevelt) in Washington.

The three subject permits (Coeur d'Alene, HARSB and Post Falls) are the only three NPDES permits for discharges of municipal wastewater to the Spokane River in Idaho. In the State of Washington, there are three additional NPDES permits for discharges of municipal wastewater to the Spokane River. These permits are issued to the Liberty Lake Sewer and Water District, the Spokane Advanced Wastewater Treatment Plant, which is operated by the City of Spokane, and the Spokane County Regional Water Reclamation Facility. Table 6, below, shows the effective dates and the TP and ammonia limits for all six of these permits (none of the permits include effluent limits for any form of nitrogen other than ammonia). As shown in the table, all six of these permits have stringent water quality-based effluent limits for phosphorus and ammonia, which are necessary to meet water quality standards for DO in Lake Spokane.

A map showing the outfall locations of these six POTWs is shown in Figure 1, below.

Table 6: NPDES Permits for Discharge of Municipal Wastewater to the Spokane River					
Name	**Permit #**	**Design Flow**	**Effective Date**	**TP Limit**	**NH3 Limit**
Liberty Lake Sewer and Water District	WA0045144	2 mgd	7/1/2011	0.45 lb/day	2.27 – 8.94 lb/day
Spokane County Regional Water Reclamation Facility	WA0093317	8 mgd	12/1/2011	2.8 lb/day	14.0 – 55.4 lb/day
Spokane Advanced Wastewater Treatment Plant	WA0024473	55.9 mgd	7/1/2011	17.8 lb/day	89 – 351 lb/day
City of Coeur d'Alene	ID0022853	6 mgd	12/1/2014	3.17 lb/day	272 lb/day
City of Post Falls	ID0025852	5 mgd	12/1/2014	3.19 lb/day	255 lb/day
Hayden Area Regional Sewer Board	ID0026590	2.4 mgd	12/1/2014	1.33 lb/day	77.4 lb/day

Figure 1: Locations of POTWs discharging to the Spokane River



Comment #1-41

Mr. Bob Bingham of the NWPOA asked the EPA to please discuss the known effects of farming and ranching along the path 50 miles upstream and 250 miles downstream of these 3 cities.

Response #1-41

The water quality-based effluent limits in the subject permits are based on the effects of the discharges upon water quality in the Spokane River and Lake Spokane. In developing the draft permits, the EPA did not evaluate the effects of the subject discharges at points downstream from the Long Lake Dam, which forms Lake Spokane and is located at river mile 33.9 on the Spokane River. The farthest upstream of the subject discharges is the City of Coeur d'Alene, which is located at river mile 110.2. Thus, the EPA evaluated the effects of the subject discharges only as far as 76.3 miles downstream from any of the subject POTWs. Because the effluent limits in the permits ensure compliance with water quality standards either at the point of discharge, at the edges of small mixing zones near the outfalls, or, for nutrients and oxygen demand, in Lake Spokane, and the discharges will experience additional dilution and attenuation of discharged phosphorus, the discharges will have a negligible effect upon water quality at points downstream from the Long Lake Dam. Therefore, the effects of farming and ranching upon the Spokane and Columbia Rivers at points downstream from Long Lake Dam (i.e., more than 76.3 miles downstream of the subject POTWs) are irrelevant to the subject permits.

The Spokane DO TMDL addresses non-point source loading to the Spokane River, including loading from farming and ranching, in Figure 4, on Page 32, and on Pages 36 – 40. The Spokane DO TMDL was based on 2001 river flow conditions (see the Spokane DO TMDL at Page 20) and the CE-QUAL-W2 model was calibrated to the conditions observed in 2001. As shown in Figure 4, in 2001, from March to October, most of the anthropogenic phosphorus loading to Lake Spokane was discharged by point sources. Non-point source loadings from Hangman Creek, the Little Spokane River, groundwater inflow, and the Lake Spokane watershed can be significant at times. Loading from Coulee Creek, stormwater discharges, and combined sewer overflows are less significant. The Spokane DO TMDL calls for reductions from current levels of non-point source loading as shown in Table 6.

Comment #1-42

Mr. Bob Bingham of the NWPOA asked the EPA to please provide the last 10 yrs of annual historical records for nitrogen and phosphorus/phosphate sampling along the path 50 miles upstream and 250 miles downstream of these 3 discharge source points.

Response #1-42

The subject POTWs discharge to the Spokane River, which is 111 miles long and flows from Lake Coeur d'Alene in Idaho to Lake Roosevelt in Washington, and the length of the Spokane River within Idaho is only about 15 miles. Therefore, to provide data for nitrogen and phosphorus "50 miles upstream" and "250 miles downstream" requires including data from the Columbia River downstream from the Spokane River and from the Lake Coeur d'Alene watershed, upstream from the Spokane River.

To respond to this comment, the EPA used the EPA's Nitrogen and Phosphorus Data Access Tool[10] to download nitrogen and phosphorus data for the watershed that receives the discharges (Upper Spokane, HUC 17010305), as well as the Coeur d'Alene Lake watershed, which is upstream from the discharges (HUC 17010303) and the Lower Spokane (HUC 17010307), Franklin D. Roosevelt Lake (HUC

[10] gispub2.epa.gov/npdat

17020001), and Chief Joseph (HUC 17020005) watersheds, downstream from the discharges. The EPA also downloaded data from the Washington Department of Ecology's river and stream water quality monitoring website[11], for water resource inventory areas (WRIAs) 57 (Middle Spokane), 54 (Lower Spokane), 53 (Lower Lake Roosevelt), 50 (Foster), 47 (Chelan) and 44 (Moses Coulee).

The Nitrogen and Phosphorus Data Access Tool includes data from 1995 to the present, which is sourced from the USGS National Water Information System (NWIS) and from the EPA's Storage and Retrieval (STORET) database. No data from the Nitrogen and Phosphorus Data Access Tool was excluded from the summary provided below because it was older than the ten-year time frame requested by the commenter. To ensure consistency with the NWIS and STORET retrievals, data from prior to 1995 was excluded from the summary statistics provided below, for the Washington Department of Ecology data. There were no post-1995 water quality data from Ecology for the Columbia River in WRIAs 50 or 47.

For the Upper Spokane watershed and all watersheds and WRIAs downstream of the subject POTWs, only data from the main stem Spokane and Columbia rivers are summarized below. Data were available for multiple species of phosphorus and nitrogen. Data are summarized below for TP, and, if available, total nitrogen. If total nitrogen data were not available, data are summarized below for nitrate+nitrite and for ammonia. The downstream watersheds and WRIAs encompass the Columbia River as far downstream as Wenatchee, Washington. The data are summarized in the tables below. All concentrations are reported in mg/L unless otherwise noted.

Table 7: Lake Coeur d'Alene Watershed (HUC 17010303) Total Phosphorus Data from USGS NWIS

Monitoring Location	Min of Results	Average of Results	Max of Results	Std. Dev. of Results	Count of Results	Date of Earliest Sample	Date of Latest Sample
USGS 12413500 Coeur D'Alene River Near Cataldo, ID	0.007	0.031	0.152	0.035	25	2/10/1996	10/22/2013
USGS 12413810 Coeur D'Alene River At Rose Lake, ID	0.050	0.050	0.050	N/A	1	2/10/1996	2/10/1996
USGS 12413858 Coeur D'Alene River Below Blue Lake Near Harrison ID	0.012	0.013	0.013	0.001	2	3/9/1999	3/9/1999
USGS 12413860 Coeur D Alene River Near Harrison, ID	0.002	0.027	0.356	0.049	109	2/10/1996	12/3/2013
USGS 12417610 Spokane River Near Coeur D'Alene Lake Outlet at Coeur d'Alene ID	0.004	0.007	0.016	0.003	35	5/22/2006	10/24/2013
USGS 472500116450000 Coeur D'Alene Lake NE of Blue Pt Near Harrison, ID	0.005	0.014	0.038	0.009	76	6/2/1999	8/22/2006
USGS 472730116475900 Coeur D'Alene Lake at Mouth Of Cd'A River At Harrison, ID	0.010	0.010	0.010	N/A	1	6/2/1999	6/2/1999
USGS 473054116500600 Coeur D'Alene Lake 1.7 Mi NE of Univ. Pt Near Harrison, ID	0.003	0.011	0.049	0.010	128	6/2/1999	8/23/2006

[11] www.ecy.wa.gov/programs/eap/fw_riv/rv_main.html

Table 7: Lake Coeur d'Alene Watershed (HUC 17010303) Total Phosphorus Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 473500116482000 Coeur D Alene Lk 0.8 Mi SW Of Driftwood Pt Near Coeur d'Alene, ID	0.002	0.007	0.027	0.004	88	6/3/1999	8/21/2006
USGS 473555116474300 Coeur D'Alene Lake Near Driftwood Pt Near Coeur d'Alene, ID	0.002	0.006	0.040	0.008	21	12/3/2003	5/24/2005
USGS 473900116453000 Coeur D Alene Lk 1.3 Mi SE of Tubbs Hill Near Coeur d'Alene, ID	0.002	0.007	0.076	0.009	98	6/3/1999	8/24/2006
USGS 474030116480600 Coeur D Alene Lake @ Outlet of Spokane R At Coeur d'Alene, ID	0.008	0.008	0.008	N/A	1	6/3/1999	6/3/1999

Table 8: Lake Coeur d'Alene Watershed (HUC 17010303) Total Nitrogen Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 12413500 Coeur d'Alene River Near Cataldo, ID	0.44	0.44	0.44	N/A	1	2/10/1996	4/15/2002
USGS 12413858 Coeur d'Alene River Below Blue Lake Near Harrison, ID	0.17	0.18	0.18	0.01	2	3/9/1999	3/9/1999
USGS 12413860 Coeur d'Alene River Near Harrison, ID	0.07	0.19	0.71	0.13	28	2/10/1996	8/21/2003
USGS 472500116450000 Coeur D'Alene Lake Ne Of Blue Pt Near Harrison, ID	0.12	0.20	0.42	0.11	6	6/2/1999	10/19/1999
USGS 472730116475900 Coeur d'Alene Lake at Mouth Of Cd'A R at Harrison, ID	0.16	0.16	0.16	N/A	1	6/2/1999	6/2/1999
USGS 473054116500600 Coeur d'Alene Lake 1.7 Mi NE of Univ. Pt Near Harrison, ID	0.07	0.16	0.30	0.06	12	6/2/1999	10/19/1999
USGS 473500116482000 Coeur d'Alene Lake 0.8 MI SW of Driftwood Pt Near Coeur d'Alene, ID	0.13	0.20	0.42	0.08	13	6/3/1999	10/19/1999
USGS 473900116453000 Coeur d'Alene Lake 1.3 MI SE of Tubbs Hill Near Coeur d'Alene, ID	0.16	0.21	0.25	0.06	2	6/3/1999	6/3/1999
USGS 474030116480600 Coeur d'Alene Lake @ Outlet of Spokane R at Coeur d'Alene, ID	0.16	0.16	0.16	N/A	1	6/3/1999	6/3/1999

Table 9: Lake Coeur d'Alene Watershed (HUC 17010303) Total Phosphorus Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
BUNKER_USGS-LC-50 (USGS Cataldo)	0.007	0.025	0.062	0.023	7	3/30/2010	7/13/2011
BUNKER_USGS-LC-60 (USGS Harrison)	0.007	0.054	0.356	0.091	16	1/10/2009	7/19/2011
IDEQ_CDAOFFICE_WQX-C1-TUBBS (USGS - 1.3 miles southeast of Tubbs Hill) (µg/L)	3.00	6.19	16.0	2.59	47	7/24/2007	10/9/2009
IDEQ_CDAOFFICE_WQX-C4-UNIV (USGS - 1.7 miles northeast of University Point) (µg/L)	3.00	9.11	25.0	5.03	46	7/24/2007	10/8/2009
R10BUNKER-LC-4000 (Latitude 47.6499059, Longitude -116.7593534, NAD 83)	0.002	0.006	0.028	0.004	40	6/3/1999	10/20/2004
R10BUNKER-LC-4001 (Latitude 47.5832386, Longitude -116.8065743, NAD 83)	0.002	0.006	0.040	0.007	26	6/3/1999	10/20/2004
R10BUNKER-LC-4002 (Latitude 47.5986111, Longitude -116.7952778, NAD83)	0.002	0.004	0.010	0.002	16	12/3/2003	8/25/2004
R10BUNKER-LC-4003 (Latitude 47.5149051, Longitude -116.8360166, NAD83)	0.003	0.023	0.310	0.060	51	6/2/1999	10/20/2004
R10BUNKER-LC-4004 (Latitude 47.4165724, Longitude -116.7510095, NAD83)	0.005	0.012	0.031	0.006	28	6/2/1999	10/19/2004
R10BUNKER-LC-4006 (Latitude 47.4133333, Longitude -116.7402778, NAD 83)	0.009	0.013	0.018	0.004	4	10/22/2003	8/25/2004
R10BUNKER-LC-4007 (Latitude 47.4558333, Longitude -116.7916667, NAD83)	0.005	0.008	0.015	0.005	4	10/22/2003	8/26/2004
R10BUNKER-LC-4008 (Latitude 47.4638889, Longitude -116.9330556, NAD83)	0.005	0.007	0.012	0.003	4	10/22/2003	8/25/2004
R10BUNKER-LC-4009 (Latitude 47.505, Longitude -116.9005556, NAD83)	0.005	0.007	0.012	0.003	4	10/22/2003	8/25/2004
R10BUNKER-LC-4010 (Latitude 47.4955556, Longitude -116.8208333, NAD83)	0.004	0.008	0.016	0.006	4	10/21/2003	8/25/2004
R10BUNKER-LC-4011 (Latitude 47.5366667, Longitude -116.7777778, NAD83)	0.004	0.008	0.023	0.008	5	10/21/2003	8/26/2004
R10BUNKER-LC-4012 (Latitude 47.5572222, Longitude -116.8255556, NAD83)	0.004	0.008	0.013	0.004	4	11/4/2003	8/26/2004
R10BUNKER-LC-4013 (Latitude 47.5983333, Longitude -116.8530556, NAD83)	0.005	0.007	0.014	0.005	4	11/4/2003	8/26/2004

Table 9: Lake Coeur d'Alene Watershed (HUC 17010303) Total Phosphorus Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
R10BUNKER-LC-4014 (Latitude 47.6075, Longitude -116.7688889, NAD83)	0.004	0.008	0.014	0.005	4	11/4/2003	8/26/2004
R10BUNKER-LC-4015 (Latitude 47.6458333, Longitude -116.8, NAD83)	0.004	0.007	0.014	0.004	5	11/5/2003	8/27/2004
R10BUNKER-LC-4016 (Latitude 47.6730556, Longitude -116.8122222, NAD83)	0.004	0.009	0.015	0.005	4	11/5/2003	8/27/2004
R10BUNKER-LC-4017 (Latitude 47.6147222, Longitude -116.6880556, NAD83)	0.004	0.006	0.008	0.002	4	11/5/2003	8/27/2004
R10BUNKER-LC-50 (USGS Cataldo)	0.008	0.044	0.152	0.051	9	4/15/2002	9/15/2008
R10BUNKER-LC-60 (USGS Harrison)	0.004	0.021	0.230	0.035	92	10/23/1998	1/10/2009
R10BUNKER-SR-1 (Spokane River At Lake Outlet at Coeur d'Alene, ID)	0.002	0.008	0.015	0.003	50	11/7/2002	1/12/2009

Table 10: Lake Coeur d'Alene Watershed (HUC 17010303) Total Nitrogen Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
BUNKER_USGS-LC-50 (USGS Cataldo)	0.05	0.14	0.26	0.09	7	3/30/2010	7/13/2011
BUNKER_USGS-LC-60 (USGS Harrison)	0.05	0.18	0.53	0.15	16	1/10/2009	7/19/2011
IDEQ_CDAOFFICE_WQX-C1-TUBBS (USGS - 1.3 miles southeast of Tubbs Hill) (µg/L)	65	144	281	47	40	7/24/2007	10/9/2009
IDEQ_CDAOFFICE_WQX-C4-UNIV (USGS - 1.7 miles northeast of University Point) (µg/L)	54	161	269	62	41	7/24/2007	10/8/2009
NARS_WQX-NLA06608-1985 (Latitude 47.4486876, Longitude -116.7986927, WGS84) (µg/L)	27	27	27	N/A	1	7/21/2007	7/21/2007
R10BUNKER-LC-4000 (Latitude 47.6499059, Longitude -116.7593534, NAD 83)	0.03	0.13	0.28	0.05	38	10/22/2003	10/20/2004
R10BUNKER-LC-4001 (Latitude 47.5832386, Longitude -116.8065743, NAD 83)	0.05	0.15	0.32	0.06	21	10/22/2003	10/20/2004
R10BUNKER-LC-4002 (Latitude 47.5986111, Longitude -116.7952778, NAD83)	0.06	0.14	0.20	0.04	16	12/3/2003	8/25/2004
R10BUNKER-LC-4003 (Latitude 47.5149051, Longitude -116.8360166, NAD83)	0.06	0.20	1.23	0.22	45	10/21/2003	10/20/2004

Table 10: Lake Coeur d'Alene Watershed (HUC 17010303) Total Nitrogen Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
R10BUNKER-LC-4004 (Latitude 47.4165724, Longitude -116.7510095, NAD83)	0.07	0.16	0.30	0.07	23	10/23/2003	10/19/2004
R10BUNKER-LC-4006 (Latitude 47.4133333, Longitude -116.7402778, NAD 83)	0.07	0.15	0.28	0.09	4	10/22/2003	8/25/2004
R10BUNKER-LC-4007 (Latitude 47.4558333, Longitude -116.7916667, NAD83)	0.07	0.11	0.16	0.04	4	10/22/2003	8/26/2004
R10BUNKER-LC-4008 (Latitude 47.4638889, Longitude -116.9330556, NAD83)	0.06	0.12	0.20	0.06	4	10/22/2003	8/25/2004
R10BUNKER-LC-4009 (Latitude 47.505, Longitude -116.9005556, NAD83)	0.09	0.12	0.21	0.06	4	10/22/2003	8/25/2004
R10BUNKER-LC-4010 (Latitude 47.4955556, Longitude -116.8208333, NAD83)	0.04	0.11	0.16	0.05	4	10/21/2003	8/25/2004
R10BUNKER-LC-4011 (Latitude 47.5366667, Longitude -116.7777778, NAD83)	0.03	0.13	0.20	0.07	5	10/21/2003	8/26/2004
R10BUNKER-LC-4012 (Latitude 47.5572222, Longitude -116.8255556, NAD83)	0.10	0.16	0.27	0.08	4	11/4/2003	8/26/2004
R10BUNKER-LC-4013 (Latitude 47.5983333, Longitude -116.8530556, NAD83)	0.09	0.11	0.15	0.03	4	11/4/2003	8/26/2004
R10BUNKER-LC-4014 (Latitude 47.6075, Longitude -116.7688889, NAD83)	0.06	0.10	0.15	0.04	4	11/4/2003	8/26/2004
R10BUNKER-LC-4015 (Latitude 47.6458333, Longitude -116.8, NAD83)	0.07	0.11	0.22	0.06	5	11/5/2003	8/27/2004
R10BUNKER-LC-4016 (Latitude 47.6730556, Longitude -116.8122222, NAD83)	0.09	0.13	0.20	0.05	4	11/5/2003	8/27/2004
R10BUNKER-LC-4017 (Latitude 47.6147222, Longitude -116.6880556, NAD83)	0.05	0.12	0.21	0.07	4	11/5/2003	8/27/2004
R10BUNKER-LC-50 (USGS Cataldo)	0.08	0.18	0.32	0.10	8	10/17/2007	9/15/2008
R10BUNKER-LC-60 (USGS Harrison)	0.03	0.14	0.32	0.09	18	10/9/2003	1/10/2009
R10BUNKER-SR-1 (Spokane River At Lake Outlet At Coeur d'Alene, ID)	0.04	0.11	0.20	0.05	20	10/14/2003	1/12/2009

Table 11: Upper Spokane Watershed (HUC 17010305) Total Phosphorus Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 12417598 Spokane River At Lake Outlet At Coeur d'Alene ID	0.002	0.008	0.015	0.004	27	11/7/2002	4/8/2006
USGS 12419000 Spokane River Near Post Falls, ID	0.004	0.013	0.057	0.009	99	1/11/1995	10/25/2013
USGS 12419495 Spokane River At Stateline Bridge Near Greenacres, WA	0.006	0.009	0.017	0.003	11	5/14/2003	4/26/2010
USGS 12419500 Spokane River Above Liberty Bridge Near Otis Orchard, WA	0.005	0.011	0.020	0.004	10	4/15/1999	4/5/2000
USGS 12420500 Spokane River At Greenacres, WA	0.005	0.013	0.024	0.005	10	4/15/1999	4/5/2000
USGS 12420800 Spokane River At Sullivan Road Bridge Near Trentwood, WA	0.006	0.013	0.020	0.004	10	4/15/1999	4/5/2000
USGS 12422000 Spokane River Below Green St At Spokane, WA	0.004	0.010	0.016	0.004	10	4/16/1999	4/5/2000
USGS 12422500 Spokane River At Spokane, WA	0.005	0.011	0.024	0.004	16	10/19/1998	4/3/2000

Table 12: Upper Spokane Watershed (HUC 17010305) Total Nitrogen Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 12417598 Spokane River At Lake Outlet At Coeur d'Alene, ID	0.11	0.20	0.40	0.14	4	11/7/2002	8/19/2003
USGS 12419000 Spokane River Near Post Falls, ID	0.09	0.22	0.68	0.10	81	1/11/1995	9/11/2007
USGS 12419495 Spokane River At Stateline Bridge Near Greenacres, WA	0.12	0.21	0.40	0.13	4	5/14/2003	8/19/2003
USGS 12419500 Spokane River Above Liberty Bridge Near Otis Orchard, WA	0.11	0.19	0.31	0.06	10	4/15/1999	4/5/2000
USGS 12420500 Spokane River At Greenacres, WA	0.13	0.20	0.29	0.05	10	4/15/1999	4/5/2000
USGS 12420800 Spokane River At Sullivan Road Bridge Near Trentwood, WA	0.11	0.30	0.87	0.23	10	4/15/1999	4/5/2000
USGS 12422000 Spokane River Below Green St At Spokane, WA	0.20	0.42	1.10	0.28	9	4/16/1999	4/5/2000
USGS 12422500 Spokane River At Spokane, WA	0.19	0.40	1.10	0.26	12	10/19/1998	4/3/2000

Table 13: Upper Spokane Watershed (HUC 17010305) Total Phosphorus Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
BUNKER_USGS-SR-5 (Latitude 47.6819444, Longitude -116.7975, NAD83)	0.004	0.007	0.016	0.003	16	1/12/2009	7/20/2011
BUNKER_USGS-SR-50 (USGS Near POST FALLS, Latitude 47.7030556, Longitude -116.9777778, NAD83)	0.008	0.010	0.012	0.002	5	7/12/2010	7/20/2011
BUNKER_USGS-SR-55 (USGS Spokane River at Stateline Br, Latitude 47.6986, Longitude -117.0431, NAD83)	0.006	0.007	0.007	0.001	2	4/6/2010	4/26/2010
R10BUNKER-SR-50 (USGS Near Post Falls, Latitude 47.7030556, Longitude -116.9777778, NAD83)	0.001	0.012	0.057	0.008	103	4/23/1996	9/3/2003
R10BUNKER-SR-55 (USGS Spokane River At Stateline Bridge, Latitude 47.6986, Longitude -117.0431, NAD83)	0.005	0.010	0.027	0.005	19	4/15/1999	9/17/2008
R10BUNKER-SR-65 (USGS Near Trentwood, WA, Latitude 47.6762, Longitude -117.3522, NAD83)	0.006	0.011	0.020	0.005	7	4/15/1999	9/9/1999
R10BUNKER-SR-70 (USGS At Spokane, Latitude 47.6617, Longitude -117.4255, NAD83)	0.004	0.008	0.016	0.004	7	4/16/1999	9/9/1999
R10BUNKER-SR-75 (USGS At Spokane, Latitude 47.6594, Longitude -117.4481, NAD83)	0.005	0.011	0.024	0.005	13	10/19/1998	9/8/1999

Table 14: Upper Spokane Watershed (HUC 17010305) Total Nitrogen Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
BUNKER_USGS-SR-5 (Latitude 47.6819444, Longitude -116.7975, NAD83)	0.05	0.09	0.16	0.03	16	1/12/2009	7/20/2011
BUNKER_USGS-SR-50 (USGS Near POST FALLS, Latitude 47.7030556, Longitude -116.9777778, NAD83)	0.05	0.13	0.20	0.06	5	7/12/2010	7/20/2011
BUNKER_USGS-SR-55 (USGS Spokane River At Stateline Bridge, Latitude 47.6986, Longitude -117.0431, NAD83)	0.14	0.15	0.15	0.01	2	4/6/2010	4/26/2010
NARSTEST-FW08ID019 (Latitude 47.6961111, Longitude -116.9155556, WGS84) (µg/L)	86	86	86	N/A	1	8/12/2009	8/12/2009

Table 14: Upper Spokane Watershed (HUC 17010305) Total Nitrogen Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
NARSTEST-FW08WA040 (Latitude 47.679816, Longitude -117.217191, WGS84)	441	441	441	N/A	1	9/9/2008	9/9/2008
R10BUNKER-SR-55 (USGS Spokane River At Stateline Bridge, Latitude 47.6986, Longitude -117.0431, NAD83)	0.13	0.18	0.23	0.04	8	10/2/2007	9/17/2008

Table 15: Lower Spokane Watershed (HUC 17010307) Total Phosphorus Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 12433000 Spokane River At Long Lake, WA	0.007	0.031	0.087	0.021	29	10/20/1998	9/10/2003

Table 16: Lower Spokane Watershed (HUC 17010307) Total Phosphorus Data from USGS NWIS							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
USGS 12433000 Spokane River At Long Lake, WA	0.29	0.86	1.80	0.34	27	10/20/1998	9/10/2003

Table 17: Lower Spokane Watershed (HUC 17010307) Total Phosphorus Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
MIDNITE_2-LR-01 (Spokane Arm - upstream of confluence with Blue Creek, Latitude 47.8774, Longitude -118.1392, NAD83)	0.01	0.02	0.07	0.02	45	3/29/2011	2/14/2012
MIDNITE_2-LR-02 (Spokane Arm - adjacent to confluence with Blue Creek, Latitude 47.887, Longitude -118.1491, NAD83)	0.01	0.03	0.07	0.02	38	3/29/2011	2/14/2012
MIDNITE_2-LR-03 (Spokane Arm - downstream of confluence with Blue Creek, Latitude 47.886, Longitude -118.1556, NAD83)	0.01	0.03	0.07	0.02	36	3/30/2011	2/15/2012
R10BUNKER-SR-85 (USGS AT LONG LAKE, Latitude 47.8364, Longitude -117.8395, NAD83)	0.007	0.030	0.087	0.021	42	10/20/1998	9/10/2003

Table 18: Franklin. D. Roosevelt Lake Watershed (HUC 17020001) Total Phosphorus Data from EPA STORET							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
1119USBR_WQX-FDR006 (FDR at Lincoln City Boat Ramp, Latitude 47.8315833, Longitude -118.40345)	0.016	0.021	0.026	0.007	2	6/19/2008	6/19/2012
1119USBR_WQX-FDR008 (FDR at Keller Ferry Area, Latitude 47.91215, Longitude -118.713)	0.010	0.014	0.023	0.006	4	6/18/2008	6/19/2012
1119USBR_WQX-FDR010 (FDR at log boom upstream of FDRW water quality site, Latitude 47.9519333, Longitude -118.97535)	0.010	0.014	0.022	0.004	19	6/18/2008	5/22/2013
1119USBR-FDR008 (FDR at Keller Ferry Area, Latitude 47.91215, Longitude -118.713)	0.000	0.006	0.018	0.008	12	6/18/2008	6/18/2008

Table 19: WRIA 57 (Middle Spokane) Total Phosphorus Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
57A123 Spokane R @ Sandifer Bridge	0.0050	0.0089	0.0145	0.0025	30	4/14/2008	9/20/2010
57A125 Spokane R blw Monroe Street	0.0034	0.0054	0.0070	0.0012	12	5/9/2007	3/10/2008
57A140 Spokane R @ Plante's Ferry Park	0.0036	0.0085	0.0146	0.0025	37	10/2/2007	9/20/2010
57A146 Spokane R @ Sullivan Rd	0.0074	0.0106	0.0174	0.0026	24	10/14/2008	9/20/2010
57A148 Spokane R @ Barker Rd	0.0044	0.0075	0.0142	0.0026	16	5/9/2007	7/15/2008
57A150 Spokane R @ Stateline Br	0.0031	0.0137	0.1260	0.0117	210	1/9/1995	9/24/2012
57A190 Spokane R nr Post Falls	0.0046	0.0051	0.0057	0.0005	5	5/9/2007	9/12/2007
57A240 Spokane R @ Lake Coeur d'Alene	0.0013	0.0061	0.0135	0.0023	42	5/9/2007	9/20/2010

Table 20: WRIA 57 (Middle Spokane) NO2+NO3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
57A123 Spokane R @ Sandifer Bridge	0.064	0.371	0.952	0.236	30	4/14/2008	9/20/2010
57A125 Spokane R blw Monroe Street	0.099	0.466	0.928	0.278	11	5/9/2007	3/10/2008
57A140 Spokane R @ Plante's Ferry Park	0.042	0.281	0.752	0.190	36	10/2/2007	9/20/2010
57A146 Spokane R @ Sullivan Rd	0.017	0.125	0.324	0.088	24	10/14/2008	9/20/2010
57A148 Spokane R @ Barker Rd	0.010	0.075	0.173	0.045	15	5/9/2007	7/15/2008
57A150 Spokane R @ Stateline Br	0.010	0.066	0.264	0.047	209	1/9/1995	9/24/2012
57A190 Spokane R nr Post Falls	0.015	0.079	0.199	0.076	5	5/9/2007	9/12/2007
57A240 Spokane R @ Lake Coeur d'Alene	0.010	0.021	0.074	0.016	41	5/9/2007	9/20/2010

Table 21: WRIA 57 (Middle Spokane) NH3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
57A123 Spokane R @ Sandifer Bridge	0.010	0.010	0.020	0.002	30	4/14/2008	9/20/2010
57A125 Spokane R blw Monroe Street	0.010	0.010	0.010	0.000	11	5/9/2007	3/10/2008
57A140 Spokane R @ Plante's Ferry Park	0.010	0.011	0.028	0.004	36	10/2/2007	9/20/2010
57A146 Spokane R @ Sullivan Rd	0.010	0.012	0.029	0.004	24	10/14/2008	9/20/2010
57A148 Spokane R @ Barker Rd	0.010	0.011	0.017	0.002	15	5/9/2007	7/15/2008
57A150 Spokane R @ Stateline Br	0.010	0.015	0.137	0.012	209	1/9/1995	9/24/2012
57A190 Spokane R nr Post Falls	0.010	0.011	0.013	0.001	5	5/9/2007	9/12/2007
57A240 Spokane R @ Lake Coeur d'Alene	0.010	0.010	0.015	0.001	41	5/9/2007	9/20/2010

Table 22: WRIA 54 (Lower Spokane) Total Phosphorus Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
54A070 Spokane R @ Long Lake	0.0051	0.0256	0.0816	0.0185	38	5/9/2007	8/16/2010
54A090 Spokane R @ Ninemile Br	0.0081	0.0330	0.1720	0.0294	46	6/11/2000	9/20/2010
54A120 Spokane R @ Riverside State Pk	0.0052	0.0413	0.6930	0.0578	212	1/9/1995	9/24/2012
54A130 Spokane R @ Fort Wright Br	0.0052	0.0116	0.0385	0.0075	18	4/14/2009	9/20/2010

Table 23: WRIA 54 (Lower Spokane) NO2+NO3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
54A070 Spokane R @ Long Lake	0.139	0.814	1.600	0.393	37	5/9/2007	8/16/2010
54A090 Spokane R @ Ninemile Br	0.147	1.039	2.830	0.663	45	6/11/2000	9/20/2010
54A120 Spokane R @ Riverside State Pk	0.080	0.825	3.300	0.600	212	1/9/1995	9/24/2012
54A130 Spokane R @ Fort Wright Br	0.106	0.492	1.220	0.313	18	4/14/2009	9/20/2010

Table 24: WRIA 54 (Lower Spokane) NH3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
54A070 Spokane R @ Long Lake	0.010	0.016	0.033	0.007	37	5/9/2007	8/16/2010
54A090 Spokane R @ Ninemile Br	0.010	0.012	0.051	0.007	45	6/11/2000	9/20/2010
54A120 Spokane R @ Riverside State Pk	0.010	0.016	0.203	0.018	212	1/9/1995	9/24/2012
54A130 Spokane R @ Fort Wright Br	0.010	0.010	0.010	0.000	18	4/14/2009	9/20/2010

Table 25: WRIA 53 (Lower Lake Roosevelt) Total Phosphorus Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
53A070 Columbia R @ Grand Coulee	0.0023	0.0158	0.8610	0.0606	209	1/11/1995	9/24/2012

Table 26: WRIA 53 (Lower Lake Roosevelt) NH3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
53A070 Columbia R @ Grand Coulee	0.010	0.013	0.074	0.008	209	1/11/1995	9/24/2012

Table 27: WRIA 44 (Moses Coulee) Total Phosphorus Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
44A190 Columbia R @ Hwy 2 Bridge	0.0045	0.0058	0.0077	0.0010	11	10/3/2005	9/11/2006

Table 28: WRIA 44 (Moses Coulee) NO2+NO3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
44A190 Columbia R @ Hwy 2 Bridge	0.045	0.104	0.234	0.061	11	10/3/2005	9/11/2006

Table 29: WRIA 44 (Moses Coulee) NH3 Data							
Monitoring Location	**Min of Results**	**Average of Results**	**Max of Results**	**Std. Dev. of Results**	**Count of Results**	**Date of Earliest Sample**	**Date of Latest Sample**
44A190 Columbia R @ Hwy 2 Bridge	0.010	0.010	0.010	0.000	11	10/3/2005	9/11/2006

Comment #1-43

Mr. Bob Bingham of the NWPOA asked why not all permits are being forced to the same standards for phosphorus removal.

Response #1-43

As explained in Appendix C to the subject fact sheets, there are two kinds of effluent limits that may appear in an NPDES permit: technology-based effluent limits and water quality-based effluent limits.

For POTWs, the EPA has promulgated technology-based effluent limits (40 CFR Part 133, see also CWA §301(b)(1)(B)). The technology-based effluent limits for POTWs define the minimum level of effluent quality that can be achieved through application of secondary treatment in terms of BOD_5 or $CBOD_5$, TSS, and pH. The secondary treatment rule, which requires all POTWs to meet certain minimum standards, does not include technology-based effluent limits for any other parameters, including phosphorus.

The phosphorus effluent limits in the subject permits are water quality-based effluent limits. Water quality-based effluent limits are based on the water quality standards for a specific facility's receiving water and the receiving water's capacity to assimilate pollutant loading while still meeting the water quality standards. NPDES permits include conditions that meet the water quality requirements of all States that are affected by the discharge, not just the State in which the discharge originates.

Permits would only need to include stringent effluent limits for phosphorus if facility's discharge of phosphorus had the reasonable potential to cause or contribute to excursions above water quality standards (e.g., for DO, pH, or nuisance algae growth), and the loading capacity of the receiving water for phosphorus was small.

In this case, the State of Washington's DO water quality criterion for lakes and reservoirs is stringent, allowing only a small (0.2 mg/L) decrease in DO concentrations from natural conditions (WAC 173-201A-200(1)(d)(ii)). In the summer, Lake Spokane has a long residence time (greater than 50 days overall and as much as 150 days for the hypolimnion) due to reduced flows in the Spokane River, and it thermally stratifies, both of which make it sensitive to nutrient loading (Moore and Ross 2010). Furthermore, the Spokane River flows through a densely populated area, which includes Spokane, which is the second most-populous city in the State of Washington (pop. 208,916), Spokane Valley (89,755), Coeur d'Alene (44,125), Post Falls (27,574), and Liberty Lake (7,591). Thus, there are numerous other point and non-point sources of nutrients and oxygen-demanding pollution to the Spokane River in addition to the subject permits. The combined effects of all of these factors result in a need to establish stringent phosphorus limits in the subject permits.

Other POTWs that discharge to waters with less stringent water quality standards, fewer sources of nutrients, and/or with characteristics that allow them to assimilate greater loadings of nutrients (e.g. higher flow rates, lower temperatures, shorter residence times) than the Spokane River and Lake Spokane may not need effluent limits for phosphorus as stringent as those that are necessary here.

Comment #1-44

Mr. Bob Bingham of the NWPOA asked the EPA to please comment on the BPA government program that is adding both phosphate and nitrogen to improve fisheries in a NW river.

Response #1-44

It is not clear which nutrient supplementation project the commenter was referring to, so the EPA cannot comment on any specific nutrient supplementation project.

In general, in some waterbodies, human actions such as dam construction and operation can cause a phenomenon called cultural oligotrophication, resulting in waters with nutrient (i.e., phosphorus and/or nitrogen) concentrations that are too low to support a healthy fishery (Anders and Ashley 2007). Nutrient supplementation can increase fish populations in such waters. This is not the case in the Spokane River and in Lake Spokane, which suffer from cultural eutrophication, in which anthropogenic nutrients from numerous municipal and industrial wastewater, stormwater, and non-point sources have over-enriched the waters to such an extent that they do not meet applicable water quality standards for DO and aesthetics.

Comment #1-45

Ms. Lisa Fitzner commented "Great job getting Coeur d'Alene, etc. to clean up the Spokane River. Just wish it could happen sooner."

Response #1-45

Comment noted. The EPA has issued the subject permits as expeditiously as possible. As explained in Appendix G to the three subject fact sheets, the compliance schedules in the permits require compliance with new water quality-based effluent limits as soon as possible.

Section 2: Comments Received during the 2007 Public Comment Period

Effluent Limits for Nutrients and Oxygen-Demanding Pollutants

Comment #2-1

A number of commenters, including the Center for Justice (submitting comments on behalf of the Sierra Club, Upper Columbia River Group) (CFJ), the Lands Council, the Center for Environmental Law and Policy (CELP), Public Employees for Environmental Responsibility (PEER), and several individuals, stated that the proposed effluent limits for TP, ammonia, and CBOD in the 2007 draft permits were not stringent enough and will contribute to violations of Washington's water quality standards for DO in Lake Spokane. The central issue raised by these commenters is that the effluent limits must be based on a cumulative analysis of all sources of human-caused pollution to the watershed, including those in the State of Washington. The commenters assert that it is not enough for the EPA to ensure that the Idaho permits will ensure the Idaho sources do not *cause* an exceedance of Washington's DO criterion for Lake Spokane. Rather, the commenters' position is that the EPA must ensure that the effluent limits for the three Idaho municipalities will ensure that the resulting discharges will not *contribute* to an exceedance of the DO standard by taking into account the contributions from all other sources in the watershed when deriving the effluent limits for the three Idaho municipalities.

Response #2-1

These comments have been addressed by changes made in the revised draft permits issued for public comment in 2013. As explained in the fact sheets to all three permits, the EPA has recalculated the water quality-based effluent limitations for TP, ammonia, and $CBOD_5$ in the 2013 draft permits. These effluent limits ensure that the level of water quality to be achieved by limits on point sources is derived from and complies with all applicable water quality standards (40 CFR 122.44(d)(1)(vii)(A)) and are based on the cumulative impact of all human actions that affect DO concentrations in Lake Spokane, including the load and wasteload allocations and Avista Corporation's DO responsibility in the State of Washington's Spokane DO TMDL. See the 2013 fact sheets at Appendix B.

Comment #2-2

CFJ stated that the EPA assumed there was more dilution than is truly available when setting water quality-based effluent limits for oxygen-demanding pollutants, when developing the 2007 draft permits.

Response #2-2

In the context of water quality, "dilution" means a reduction in pollutant concentration caused by mixing with water with a lower concentration of the pollutant. Wastewater effluents discharged to flowing waters are diluted by mixing with the flow of the receiving water. When the receiving water flow is lower, there is less dilution available.

The modeling performed in support of the effluent limits in the 2007 and 2013 draft Idaho permits (and the draft TMDLs prepared by the State of Washington) used river flow rates that were very conservative. The flows used were the actual flows observed in calendar year 2001. The calendar year mean flow rate of the Spokane River at Long Lake (USGS station #12433000) during calendar year 2001 was 4,000 CFS, which was the third lowest annual mean flow rate measured between 1940 and 2011, which is the period of record for which full calendar years of data are available. The calendar year mean flow rate of the Spokane River at Long Lake was lower than it was in 2001 only in 1944 (3,576 CFS) and 1994 (3,939 CFS). By using the 2001 actual flows in the modeling, the EPA was assuming less dilution than will normally be the case.

Comment #2-3

CFJ stated that the proposed permits "leave Washington sources no allowable loading" for nutrients and oxygen-demanding pollution. CFJ stated that, if the State of Washington were to "(consider) the Idaho discharges as boundary or background conditions at the State line" for the purposes of completing a DO TMDL, it would violate its own standards and the Clean Water Act. CFJ stated that "the combined effect of the EPA proposed permit limitations…as incorporated into the Washington TMDL is to…(support) an additional 0.2 mg/L degradation." The commenters conclude that the total DO decrease will be 0.4 mg/L below natural conditions. As such, the commenters request that the EPA recalculate the effluent limits considering the presence of Washington loading and request that the EPA require Washington's TMDL to do the same.

CFJ further stated that the State of Washington has a duty to object to the issuance of these permits under Section 401(a) of the Act. Moreover, CFJ stated that the absence of an objection from the State of Washington does not relieve the EPA of its independent duty to "condition these permits such that they do not cause or contribute to nonattainment" of Washington water quality standards pursuant to Clean Water Act Section 301(b)(1)(C).

CFJ cited to a 2005 e-mail from Mark Hicks of Ecology. In this email, Mr. Hicks appears to question EPA's approach for permitting the Idaho dischargers. Specifically, Mr. Hicks stated that "EPA appears poised to grant a 0.2 mg/L depression from naturally low DO levels to the point sources in Idaho, and then grant another 0.2 mg/l depression for the Washington dischargers."

Response #2-3

This comment was addressed by the revised draft permits issued for public review and comment in 2013. Both the Spokane DO TMDL and the subject NPDES permits for discharge to the Spokane River in Idaho have been revised such that compliance with the State of Washington's water quality standards for DO are achieved on a cumulative basis in Lake Spokane. See also the response to comment #2-1 and the 2013 fact sheets at Appendix B.

Comment #2-4

CFJ recommends that the EPA allocate 0.1 mg/L DO decrease for the Idaho permits (one half of the 0.2 mg/L decrease allowed under the Washington standards), or apportion loading according to flow. CFJ

states that by accepting their recommendation, Ecology's TMDL would be more defensible and the EPA could then state that the Idaho permits conformed with the Washington TMDL.

Response #2-4

This comment was addressed by the revised draft permits issued for public review and comment in 2013. The Spokane DO TMDL and the NPDES permits for discharge to the Spokane River in Idaho have been revised such that compliance with the State of Washington's water quality standards for dissolved are achieved on a cumulative basis in Lake Spokane. See also the response to comment #2-1 and the 2013 fact sheets at Appendix B.

Comment #2-5

CFJ stated that effluent limits for TP, ammonia, and CBOD should be expressed in concentration and mass.

Response #2-5

The federal regulation at 40 CFR 122.45(f) requires NPDES permits to contain mass limitations except (1) for pH, temperature, radiation, or other pollutants that cannot be expressed as mass, (2) when applicable standards are expressed in terms of other measurements, or (3) if in establishing permit limits pursuant to 40 CFR 125.3, (i.e. technology-based effluent limits), mass limitations are infeasible. In all cases, effluent limits for TP, ammonia, and CBOD have been, at a minimum, expressed in terms of mass. See the 2013 fact sheets at Page B-13.

Effluent limits expressed in terms of mass may also be expressed in terms of other units of measurement (40 CFR 122.45(f)(2)). Whenever there was a basis to include concentration limits for TP, ammonia, and CBOD in addition to mass limits, the concentration limits were included in the permits. See the 2013 fact sheets at Page B-14.

In general, effluent limits for CBOD are expressed in terms of mass, concentration, and removal rate. The concentration and removal rate limits are the applicable technology-based limits (40 CFR 133.102(a)(4)), and the mass limits are water quality-based effluent limits.

In general, the water quality-based effluent limits for ammonia are expressed in terms of mass. However, concentration limits have also been established where necessary to ensure compliance with the anti-backsliding provisions of the Clean Water Act or to prevent direct toxicity to aquatic life.

With respect to TP, as stated on Page B-13 of the 2013 fact sheets:

> "Effluent limits for TP are expressed exclusively in terms of mass because there are no applicable technology-based standards or numeric in-stream water quality standards for TP, the effluent limitations for TP are intended to meet Washington water quality standards, which apply several miles downstream from the discharges after complete mixing has occurred, and phosphate phosphorus is neither directly toxic to aquatic life nor directly hazardous to human health. Therefore, there is no basis to express the water quality-based TP limits in units other than mass."

Comment #2-6

CFJ stated that effluent limits for CBOD, TSS, and phosphorus should include maximum daily limits. They cite the fact that DO criteria are expressed as daily minima, and the *Friends of the Earth* v. *EPA* decision regarding "daily loads" in TMDLs.

Response #2-6

The averaging periods for effluent limits in NPDES permits for POTWs are governed by 40 CFR 122.45(d)(2), which states that, "(f)or continuous discharges all permit effluent limitations, standards, and prohibitions, including those necessary to achieve water quality standards, shall unless impracticable be stated as…(a)verage weekly and average monthly discharge limitations for POTWs."

The effluent limits for TSS and the November to January effluent limits for $CBOD_5$ in the subject permits are technology-based effluent limits, which are stated as maximum allowable 30-day and 7-day averages (40 CFR 133.102). The EPA has determined that the technology-based effluent limits for TSS and for $CBOD_5$ from November to January are adequately stringent to ensure compliance with water quality standards. There is no basis to express the effluent limits for TSS or November to January $CBOD_5$ as maximum daily limits.

As explained on Pages B-9 – B-12 of the 2013 fact sheets, the EPA has determined that it is impracticable to state the water quality-based effluent limits for phosphorus and $CBOD_5$, which apply from February 1st through October 31st, as average monthly and average weekly limits, and that those limits should be expressed as seasonal average limits. As explained on Page B-10, modeling shows that controlling the average loading of oxygen-demanding pollution to the Spokane River will ensure compliance with water quality standards for DO in Lake Spokane. It is not necessary to control short-term (e.g. daily or weekly) maximum concentrations or loadings of phosphorus or CBOD in order to ensure such compliance.

Friends of the Earth v. EPA, 446 F.3d 140 (DC Cir. 2006), is inapplicable to these discharges because *Friends of the Earth* is a decision that is relevant only to TMDLs, not effluent limits in NPDES permits. None of the effluent limits in the subject permits are based on a wasteload allocation in an approved TMDL.

Comment #2-7

CFJ is concerned about the ammonia limits in the 2007 draft permits, which CFJ stated are much higher than the waste load allocations (WLAs) in Washington's draft Spokane DO TMDL. CFJ believes that 0.1 mg/L ammonia is achievable.

Response #2-7

Although CFJ was comparing the ammonia limits in the subject permits to the ammonia WLAs in a draft of the State of Washington's TMDL for DO in the Spokane River and Lake Spokane, for the purposes of this response, the EPA will compare the ammonia limits in the subject permits to the final, EPA-approved TMDL.

This comment was addressed to some extent by changes made in the revised draft permits issued for public comment in 2013. As shown in Figures 2 and 5, the seasonal average ammonia effluent limits in

the permits for Coeur d'Alene and HARSB require lower effluent ammonia loads than the monthly average ammonia limits in the 2007 draft permits at all times from February to October. The seasonal average ammonia limits for Post Falls are 7% higher than the monthly average ammonia limits in the 2007 draft permit from March to October (255 lb/day instead of 238 lb/day), but are 65% lower during February (255 lb/day instead of 726 lb/day). The seasonal average ammonia effluent limits for the subject discharges are expressed in terms of mass, but are equivalent to concentrations of 3.9 – 6.1 mg/L at the facilities' design flow rates.

The WLAs for ammonia for point sources discharging to the Spokane River in the State of Washington's TMDL for DO in Lake Spokane and the Spokane River, are, in fact, more stringent than the ammonia limits in the subject permits. The ammonia WLAs for Washington POTWs range from 0.18 – 0.83 mg/L (see Moore and Ross 2010 at Table 5).

However, there is no basis to include more stringent ammonia limits than proposed in the drafts in any of the subject permits. The EPA has determined that the proposed seasonal average ammonia limits ensure compliance in Lake Spokane with the State of Washington's water quality criteria for DO as well as Washington's water quality criteria for ammonia (see the 2013 fact sheets at Appendix B). Post Falls and HARSB do not have the reasonable potential to cause or contribute to excursions above Idaho's water quality standards for ammonia near their respective outfalls; therefore, it is not necessary to include ammonia limits in addition to the seasonal average limits, which are based on Washington's water quality standards for DO, in the Post Falls or HARSB permits in order to ensure compliance with Idaho's water quality criteria for ammonia[12].

Coeur d'Alene does have the reasonable potential to cause or contribute to excursions above Idaho's water quality criteria for ammonia near its outfall from March to September. Therefore, in addition to the seasonal average effluent limit for ammonia, the Coeur d'Alene permit includes average monthly and maximum daily effluent limits which are derived from and ensure compliance with Idaho's water quality criteria for ammonia.

The EPA's permits are designed to ensure compliance with Washington's and Idaho's water quality standards. The practicability of achieving 0.1 mg/L ammonia is consequently not relevant.

Comment #2-8

Blue Water Technologies, Inc. states that sediments in the river and particularly behind dams will use up DO in the water. These sediment beds are loading year round. According to the commenter, phosphorus laden sediments deposited in the winter when there is no phosphorus control required on the Spokane River will become stirred up and/or released during turbulent activity in the spring.

Response #2-8

As stated in the response to comment #1-10, modeling predicts that Idaho discharges of TP during the month of January can influence DO concentrations in Lake Spokane during the following summer. Due

[12] The July – September average monthly and maximum daily ammonia limits in the City of Post Falls permit are included to ensure compliance with the anti-backsliding provisions of the Clean Water Act.

to limitations of the model, the EPA cannot determine at this time if Idaho discharges of TP during November or December influence DO concentrations in Lake Spokane during the following year.

The modeling scenario that supports the TP, CBOD, and ammonia limits in the permits assumes that discharges of high concentrations of TP will continue from January 1st until the TP effluent limits become effective on February 1st. Therefore, the modeling demonstrates that the proposed effluent limits will ensure compliance with water quality standards, even though no TP effluent limits are proposed for the winter. Furthermore, the phosphorus management plan requirements apply throughout the year.

Comment #2-9

Post Falls and HARSB commented that the State of Washington adopted water quality standards for Lake Spokane (formerly Long Lake) classifying it as a "lake" with no allowable measurable decrease in DO from "natural conditions". Post Falls and HARSB feel that this is a factual contradiction because the reservoir is a man-made impoundment, not a lake that ever existed in an actual natural condition. Moreover, Post Falls and HARSB state that the free-flowing reaches of the Spokane River continue to demonstrate very few water quality impairments, as demonstrated by the EPA and Washington in the recent modeling efforts for this permit. Therefore, although the EPA has attempted to balance this inherent unfairness through the permit process, Idaho dischargers are still being required to help pay for solving a problem that was only created by a for-profit corporation's construction of an impoundment.

Response #2-9

As recognized by the commenters, the Washington water quality standards do not distinguish between natural and man-made lakes (WAC 173-201A-200(1)(d)(ii)). Washington's water quality standards have been approved by the EPA. Federal regulations state that the EPA must establish conditions in the subject permits that ensure compliance with the applicable water quality requirements of the State of Washington, including its water quality standards, even though Washington's water quality standards do not apply to waters of the State of Idaho.

Water quality standards are set at a level which protects the designated and existing uses of surface waters, without regard to the cost of attaining those standards. Likewise, water quality-based effluent limits are set without regard to the cost of attaining such limits. Regardless of the origins of Lake Spokane, it has designated and existing uses which must be protected through the application of the Washington water quality standards. Although the EPA recognizes that the commenters find this unfair, the permits must still be written to ensure compliance with downstream water quality standards.

Comment #2-10

Post Falls and HARSB commented that, based on the EPA and Washington computer model of the river, even if all the point dischargers were removed along with a substantial loading from the non-point dischargers, the Long Lake reservoir would still not meet the Washington 8.0 mg/L DO water quality standard. The commenters point out that a Use Attainability Analysis (UAA) was completed by the Spokane River dischargers to address this issue, but this UAA was apparently rejected by Ecology. Post Falls believes it is necessary to maintain its right to enter into a UAA process should that be necessary in the future.

Response #2-10

The Washington DO water quality criterion for Lake Spokane (Long Lake) is not 8.0 mg/L. The commenters may have confused Washington's water quality criterion for DO in lakes with that for flowing fresh waters supporting the uses of salmonid spawning, rearing, and migration (WAC 173-201A, Table 200(1)(d)). The DO criterion for lakes (WAC 173-201A-200(1)(d)(ii)) is "human actions considered cumulatively may not decrease the dissolved oxygen concentration more than 0.2 mg/L below natural conditions" The natural condition of Lake Spokane varies with space and time, so the numeric value of the DO criterion may be greater than, less than, or equal to 8.0 mg/L depending on the place and time of interest.

The fact that an applicable water quality standard may be difficult to attain does not relieve the EPA of its duty to establish water quality-based effluent limits necessary to meet that standard (CWA Section 301(b)(1)(C), 40 CFR 122.4(d), 40 CFR 122.44(d)).

Ecology did not act on the Use Attainability Analysis (UAA) petition referenced by the commenters. The petition was withdrawn by the dischargers in favor of a collaborative approach to TMDL implementation.[13] The commenters (Post Falls and HARSB) were both members of the Spokane River TMDL Collaboration which took place following withdrawal of the UAA petition.[14] The EPA's issuance of NPDES permits to the Idaho dischargers to the Spokane River in no way prevents a future UAA for Lake Spokane.

Comment #2-11

CFJ stated that the EPA's permitting approach for the 2007 draft permits is being used to support a pollution trading strategy in Washington that is not scientifically defensible. CFJ noted the large percent reductions in non-point source pollution that the 2004 draft DO TMDL stated were necessary to meet the DO criterion in Lake Spokane, and noted that under the revised draft TMDL, the tributaries are now able to contain much more loading of phosphorus, ammonia, and CBOD, according to a technical memorandum from Portland State University regarding pending revisions to the TMDL. The commenters stated that the non-point source load allocations in the pending revised DO TMDL were manipulated. The commenters state that, because it is difficult to reduce non-point source pollutant loading, it is unlikely that there could be a viable trading program.

Response #2-11

Washington's TMDL and the issuance of the Idaho permits are independent actions. Comments on the Washington TMDL for DO and its implementation are beyond the scope of the NPDES permitting actions proposed.

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[13] http://www.ecy.wa.gov/programs/wq/tmdl/spokaneriver/dissolved_oxygen/docs/spokaneriver_tmdl_exchange_of_ltrs_0205.pdf. Accessed September 29, 2014.

[14] http://www.ecy.wa.gov/programs/wq/tmdl/spokaneriver/dissolved_oxygen/historicalinfo-ross/historical_info-fullgroup.html. Accessed September 29, 2014.

In general, the EPA supports water quality trading as a means to achieve water quality standards, where appropriate.

Comment #2-12

CFJ stated that the EPA's permitting approach is inconsistent with the EPA's policy for watershed-based approaches, which includes permitting actions. The EPA's policy acknowledges that watersheds transcend political boundaries; therefore, CFJ stated that the EPA must examine the long-term consequences of the current permitting actions and, pursuant to the EPA's policy, reintegrate the Washington and Idaho permitting actions.

Response #2-12

The Policy Statement and the Watershed Permitting Guidance clearly state that the statements in the documents are not binding and that the permitting authority can consider other approaches consistent with the Clean Water Act and its implementing regulations. See Policy Statement at p. 3; Watershed Permitting Guidance introduction. Thus, even if the permits were inconsistent with the EPA's watershed-based permitting guidance, that would not necessarily mean that they are not in compliance with the Clean Water Act and its implementing regulations.

However, the EPA has made changes in the revised draft permits issued for public comment in 2013. The revised permits are consistent with the *Watershed-Based National Pollutant Discharge Elimination System (NPDES) Permitting Implementation Guidance* (Watershed Permitting Guidance) and *Watershed-Based NPDES Permitting Policy Statement*, from G. Tracy Mehan III, dated January 7, 2003 (Policy Statement).

The watershed-based permitting documents encourage the permitting authority to focus on watershed goals and to consider multiple pollutant sources and stressors, including where watersheds transcend political boundaries. As explained Appendix B in the 2013 fact sheets to all three permits, the EPA has recalculated the water quality-based effluent limitations for TP, ammonia, and $CBOD_5$. The effluent limits in the final permits ensure that the level of water quality to be achieved by limits on point sources is derived from and complies with all applicable water quality standards (40 CFR 122.44(d)(1)(vii)(A)). The current limits are based on the cumulative impact of all human actions that affect DO concentrations in Lake Spokane, including the load and wasteload allocations and Avista Corporation's DO responsibility in the State of Washington's Spokane River DO TMDL. The Watershed Permitting Guidance also discusses the benefits of synchronizing the issuance of permits in a given basin. Here, the EPA has chosen to issue the three permits for discharge to the Spokane River in Idaho on the same schedule.

Comment #2-13

The Spokane River Property Owners Association stated that, based on the current Coeur d' Alene Lake Management Plan (1996) (LMP) it is clearly evident by subtracting the acceptable phosphate content in Lake Coeur d'Alene (i.e., 9 parts per billion) from the median phosphate level of the lake (i.e., 6 parts per billion), Coeur d'Alene's wastewater treatment facility is adding a maximum of approximately 3 parts per billion phosphate to the Spokane River. Therefore, the commenter states that Coeur d'Alene should

not have to expend a large amount of money to upgrade its facility and believes that the money is more well spent on addressing non-point source pollution.

Response #2-13

The Clean Water Act (section 301(b)(1)(C)) requires the establishment of effluent limitations in NPDES permits necessary to meet water quality standards. The EPA has determined that the discharges of phosphorus from the subject point sources have the reasonable potential to cause or contribute to nonattainment of water quality standards in the State of Washington. Therefore, the permits contain water quality-based effluent limits for phosphorus, consistent with federal regulations (40 CFR 122.4(d), 40 CFR 122.44(d)(1)). See the 2013 fact sheets at Appendix B.

Comment #2-14

Ms. Julie Dalgago noted that, in the 2007 draft permits, the strictest phosphorus effluent limits are applied for Idaho during a four-month period, meaning June, July, August, and September, and requested that the EPA evaluate the need to expand the period of time during in which these phosphorus limits apply.

Response #2-14

This comment was addressed by changes made in the revised draft permits issued for public comment in 2013. The phosphorus limits in the revised permits are seasonal average limits that apply for nine months out of the year, from February 1st through October 31st.

Comment #2-15

Mr. Jim Hollingsworth stated that EPA should not rely only on computer models. Instead, EPA should rely on actual observations. If EPA is unable to document any actual health impacts, then EPA should wait until it is certain that the discharges impact human health.

Response #2-15

The only effluent limits in the subject permits that are based on computer modeling are the seasonal average effluent limits for phosphorus, ammonia, and CBOD that are based on Washington's water quality standards for DO.

As explained in the 2013 fact sheets at Appendix B, the effluent limits for phosphorus, ammonia, and CBOD are intended to meet Washington's water quality standards for DO. DO criteria are necessary to provide suitable habitat for fish and other aquatic life, as opposed to protecting human health. The Clean Water Act protects aquatic life, as well as human health. The absence of a human health hazard is not a basis to fail to implement water quality criteria. Furthermore, as discussed in the response to comment #1-13, human health could be at risk from blue-green algae blooms in Lake Spokane, which are caused by excess nutrients.

The water quality problems caused by excess nutrients have been extensively documented by the Department of Ecology in its *Spokane River and Lake Spokane (Long Lake) Pollutant Loading Assessment for Protecting Dissolved Oxygen* (Cusimano 2004). This document references earlier studies of nutrient-related water quality problems in Lake Spokane by Cunningham and Pine (1969), Patmont, et. al. (1985,

1987), Soltero, et. al., (1973-1976, 1978-1985, and 1992), and URS Corporation (1981). The fact that excess nutrient loading to the Spokane River from human sources causes eutrophication, toxic algae blooms, and low DO in Lake Spokane is well-documented and has been studied for decades.

Washington's water quality standard for DO in lakes and reservoirs is expressed in terms of natural conditions. "Natural conditions" are defined in Washington's water quality standards as "surface water quality that was present before any human-caused pollution" (WAC 173-201A-020).

In this case, actual measurements cannot provide EPA with the required information to establish water quality-based effluent limits for nutrients and oxygen-demanding pollutants, because measurements can only quantify the current condition of the watershed, at the current levels of discharge. As shown by numerous studies dating back as far as 1969, the current condition of the watershed in terms of nutrient enrichment and DO is poor, does not meet applicable water quality, and is far removed from the natural condition. Computer modeling is necessary to ascertain the natural condition of the watershed and to derive effluent limitations that comply with water quality standards, which are linked to natural conditions.

Comment #2-16

Mr. Jim Hollingsworth stated that EPA has accepted the standards set by the State of Washington without question and that this does not seem fair.

Response #2-16

The only effluent limits in the subject permits that are based on Washington's water quality standards are the seasonal average effluent limits for phosphorus, ammonia, and CBOD.

The Washington water quality standards have been reviewed and approved by EPA pursuant to Section 303(c) of the Clean Water Act. See the letter dated February 11, 2008, from Michael F. Gearheard, EPA Region 10, to Dave Peeler, Washington State Department of Ecology. The process by which standards are approved is the same for Washington and Idaho. Once state water quality standards are approved, the permitting authority (in Idaho's case, EPA is the permitting authority) is required to include effluent limits in NPDES permits that are necessary to meet those standards pursuant to Section 301(b)(1)(C) of the Act. Pursuant to 40 CFR 122.4(d), the permitting authority must impose conditions in NPDES permits that ensure compliance with the water quality standards of all affected States, including, in this case, the State of Washington.

Comment #2-17

Mr. Jim Hollingsworth comments that, although the public has been told that the problem is phosphorus, phosphorus is not really a pollutant unless it reaches toxic levels. The commenter further states that phosphorus in the water is actually a benefit to the plants that live in the water. Moreover, the commenter believes that there are cheaper ways to deal with the phosphorus problem, such as introducing fish into Lake Spokane which eat the excess algae, or introducing zinc or copper into the lake to inhibit algae growth.

Response #2-17

Pollutants, as defined by the Clean Water Act and its regulations, include sewage and municipal waste that is discharged into waters of the United States. See Section 502 of the CWA and 40 CFR 122.2. As explained in the fact sheets, EPA has established conditions and limits, including the limits on phosphorus, in accordance with the Clean Water Act and its implementing regulations.

It is true that dissolved zinc and copper are toxic to, and therefore inhibit the growth of, algae. Metal salts (e.g., copper sulfate) can be added to constructed impoundments, which are not waters of the United States (e.g., wastewater stabilization ponds or lagoons) in order to control the growth of algae. It is also true that nutrients such as phosphorus and nitrogen are beneficial to water quality in small amounts. However, excess nutrients can cause violations of water quality standards for DO, pH, and can cause nuisance algae growth including toxic blue-green algae blooms.

One reason it is necessary to reduce excess algae growth is to increase DO concentrations in order to ensure that the Spokane River and Lake Spokane provide suitable habitat for fish and other aquatic life. Zinc and copper are both toxic to fish and other aquatic life at very low concentrations, and in fact the Spokane River already contains concentrations of zinc that are above the levels necessary to protect aquatic life from its toxic effects. The State of Washington has developed a TMDL to reduce discharges of zinc (as well as cadmium and lead) to the Spokane River, with the goal of meeting water quality standards. Because zinc and copper are both toxic to fish at very low concentrations, it would be counterproductive and may cause or exacerbate violations of water quality standards and/or the CWA to add zinc or copper to Lake Spokane for the purpose of inhibiting algae growth or improving DO concentrations.

The EPA is not aware of any fish species that could be introduced into Lake Spokane that would consume the excess algae. In any event, the introduction of nonnative species could potentially displace native fish species, which would be counter to the Clean Water Act goal of protecting native fish through improved water quality.

Comment #2-18

Mr. Jim Hollingsworth asked in his comments why DO is only a problem in the lower end of Lake Spokane.

Response #2-18

Low DO is not a problem exclusively in the lower end of Lake Spokane. However, the CE-QUAL-W2 model predicts that the nutrients and biochemical oxygen demand discharged by the sources upstream from Lake Spokane exert their greatest impact upon DO in the lower end of Lake Spokane. This is because the lower end of Lake Spokane is the deepest part of the lake, and since the lake thermally stratifies in the summer, the deeper water is isolated from, and therefore cannot be oxygenated by, the atmosphere.

Comment #2-19

Mr. Jim Hollingsworth asked in his comments about the quality of the water that leaves the State of Washington.

Response #2-19

The quality of waters outside the watersheds affected by the subject permits is irrelevant to the subject permit actions. The EPA has provided a summary of water quality data for phosphorus and nitrogen in the Spokane and Columbia rivers as far downstream as Wenatchee, Washington in the response to comment #1-39.

Additional water quality data for waters of the State of Washington can be found at the State of Washington Department of Ecology's environmental assessment program website at www.ecy.wa.gov/programs/eap/index.html, on the EPA's STOrage and RETreival (STORET) website at www.epa.gov/storet, or at the USGS National Water Information System (NWIS) website at waterdata.usgs.gov/wa/nwis/qw.

Comment#2-20

Mr. Jim Hollingsworth states that the State of Washington can make demands, but it would be far better if (Idaho and Washington) could work together as neighbors to implement a plan that would be mutually acceptable.

Response #2-20

Because waters of the State of Washington are affected by the subject discharges, the EPA is required to establish water quality-based effluent limits that meet Washington's water quality standards. This is not a "demand" made by the State of Washington; it is a requirement of federal law (40 CFR 122.4(d)).

The State of Idaho has had extensive involvement in the development of the subject permits as well as the Spokane DO TMDL developed by the State of Washington.

Comment #2-21

Coeur d'Alene made several comments about how EPA evaluated the impact of the Idaho dischargers upon waters of the State of Washington, including the following:

- EPA should explain in more detail how the assumptions made for determining the appropriate loads for DO parameters and associated permit limits for ammonia, $CBOD_5$ and phosphorous will not cause or contribute to downstream water quality standards non-attainment in Washington State portions of the Spokane River and Lake Spokane.
- EPA should explain if its model assumptions are the same as the assumptions in the Washington DO TMDL model for upstream waste load allocations.
- EPA should more fully explain how the limits in the draft permit ensure compliance with the applicable water quality requirements of all affected states as required in 40 CFR 122.4(d).
- EPA should provide a better explanation of its rationale for ensuring that the draft permit limits will not cause nonattainment of Washington DO standards and any other State of Washington standards applicable to the permit limits.
- EPA should also explain whether a revision to TMDL model assumptions used by Ecology would impact EPA's derivation of the limits in the draft permit.
- EPA should disclose whether Ecology concurs with EPA's determination and whether there is any documentation of such concurrence.

Response #2-21

In general, this comment has been addressed by changes made in the revised draft permits issued for public comment in 2013.

Appendix B to the 2013 fact sheets explains in detail how the effluent limits for TP, ammonia, and $CBOD_5$ ensure compliance with water quality standards in the Spokane River and Lake Spokane in the State of Washington, and, in turn, with 40 CFR 122.4(d). As stated in Appendix B, the effluent limits for the subject dischargers are somewhat different than those assumed in the modeling supporting the State of Washington's Spokane DO TMDL, but they have an impact to DO in Lake Spokane that is no greater than the discharges assumed in the modeling supporting the TMDL.

Regarding whether revisions to the TMDL model assumptions used by Ecology would impact the EPA's derivation of limits, as stated in the permits at Part I.G:

> "In the future, the State of Washington may modify the Spokane River TMDL and/or the effluent limits in NPDES permits for point sources discharging to the Spokane River within the State of Washington. Such modifications may allow for less-stringent effluent limits for total phosphorus, ammonia and/or $CBOD_5$ in this permit, while nonetheless ensuring that the cumulative effect of all such revised effluent limitations will ensure the attainment of water quality standards for DO in the State of Washington. In that case, EPA could revise the water quality-based effluent limits for total phosphorus, ammonia and/or $CBOD_5$…."

Regarding Ecology's concurrence with the EPA's determination, the EPA shared preliminary drafts of the subject permits with Ecology prior to the public comment period, and the EPA made changes to the draft permits in order to address concerns raised by Ecology. Although Ecology submitted comments on the draft permits during the public comment period, none of those comments concerned the effluent limits for TP, ammonia, or CBOD. Ecology stated in its comment letter that, "We feel that the draft permits are protective of downstream water quality and meet the intent of Washington State water quality rules for the Spokane River and Lake Spokane. Comments for the draft permits are relatively minor…."

After receiving final CWA section 401 certifications from the State of Idaho and before issuing the final permits, the EPA notified the State of Washington that it had received the certifications and that the discharges may affect the quality of waters of the State of Washington, consistent with Section 401(a)(2) of the CWA. Also, pursuant to Section 401(a)(2) of the CWA, the State of Washington was allowed 60 days to notify the EPA of any objection to the issuance of the permits, and the State of Washington did not object within the 60-day period.

Comment #2-22

BlueWater Technologies, Inc. (BlueWater) stated that it believes that the "waste load computation" that EPA conducted is faulty. According to BlueWater, if a discharger with a 10 µg/L phosphorus limit increases their flow, then their phosphorus limit will become more stringent. This would mean that a growing city such as Post Falls would have a very stringent limit that would rob the ecosystem of an

important and essential nutrient. BlueWater concludes that "[t]o require a standard less than 10 µg/L when that is considered natural background is mathematically incongruent."

Response #2-22

This comment was addressed by changes made in the 2013 draft permits. None of the 2013 draft permits nor the final permits have an effluent limit for TP equal to 10 µg/L, nor do they have a mass limit equivalent to 10 µg/L at the POTWs' design flow rates or at the POTWs' projected future flow rates. Rather, the effluent limits for TP are equivalent to a discharge of TP at a concentration of 50 µg/L at projected future flow rates. The background concentrations of nutrients in the Spokane River are less than 50 µg/L, therefore, the permits will not result in a shortage of phosphorus in the river ecosystem.

The mass effluent limits in the final permits require the permittees to achieve lower concentrations of phosphorus (and other pollutants) if and when their effluent flows increase above the projected future flow rates used in modeling and effluent calculations, in order to maintain compliance with effluent limits expressed in terms of mass. These limits will ensure that the permits remain protective of water quality even if flow rates increase above the current design flows of the treatment plants.

The commenter expressed its comments as if the effluent limitations were expressed as concentrations. Federal regulations require that effluent limitations in NPDES permits be expressed in terms of mass, with certain exceptions, none of which are applicable to effluent limits for phosphorus (40 CFR 122.45(f)).

Comment #2-23

Mr. Jim Kimball, representing Post Falls and the Hayden Area Regional Sewer Board, stated that the 2004 draft TMDL prepared by Ecology would have allocated 0.1 lb/day of phosphorus to the City of Post Falls. Mr. Kimball states that, at the design flow of the Post Falls treatment plant, this would be equivalent to a concentration of 4 µg/L in the effluent, which "would cause a severe economic impact on Idaho." Mr. Kimball notes that this contrasted with a loading of 2.9 lb/day for the City of Spokane and Spokane County.

Response #2-23

Mr. Kimball was referring to Figure 10 of Ecology's October 2004 draft TMDL for DO in Lake Spokane (Merrill and Cusimano 2004). Although Mr. Kimball's statement was specific to the City of Post Falls, EPA notes that this figure also included loading figures for the City of Coeur d'Alene and HARSB. EPA will therefore consider this comment to be applicable to all three dischargers.

This comment was addressed by the revised draft permits issued for public review and comment in 2013. The water quality-based effluent limit for TP in the City of Post Falls' final permit is 3.19 lb/day, which is equivalent to 76.5 µg/L at the City's current design flow of 5.0 mgd. The final water quality-based TP effluent limits for Coeur d'Alene and HARSB are equivalent to 63 µg/L and 66 µg/L, respectively, at the facilities' current design flows.

The State of Washington can neither regulate discharges of pollution nor set water quality standards for waters of the State of Idaho or any other jurisdiction outside of Washington. The figures referenced by

Mr. Kimball came from a draft TMDL that was neither finalized by the State of Washington nor approved by EPA.

Comment #2-24

Ms. Julie Dalgago states that if the EPA were to "apply the (strictest) standards to the people that are upriver…that will affect the outcome at the end of the river and Lake Roosevelt."

Response #2-24

It is not clear what Ms. Dalgago meant by the phrase "the people that are upriver." The EPA believes it is reasonable to assume she was referring to the subject POTWs, since Ms. Dalgago was commenting on the subject permits, and the Spokane River originates in Idaho, at Lake Coeur d'Alene. Thus, it appears that Ms. Dalgago is stating that the effluent limits in permits for discharge to the Spokane River in Idaho should be "the strictest," meaning they should be more stringent than those in permits issued by Ecology, to dischargers in the State of Washington.

As explained in detail in Appendix B to the 2013 fact sheets, the permits contain effluent limits for phosphorus, ammonia, and CBOD that ensure compliance with Washington's water quality standards for DO in Lake Spokane and the Spokane River on a cumulative basis. In developing these permits, the EPA did not evaluate the effects of the discharges at points downstream of the Long Lake Dam, including Lake Roosevelt. Due to additional dilution, continued decay of the effluent CBOD, and continued attenuation of the effluent phosphorus (e.g., accumulation in sediment behind dams), the discharges' effect on water quality in Lake Roosevelt is likely to be too small to measure.

Comment #2-25

Ms. Julie Dalgago states that "discharge limits must be (the) more stringent of both the technology and water quality-based limits." Ms. Dalgago stated that she was concerned that the "stringent standards" in the permits were based on "economic feasibility."

Response #2-25

The Clean Water Act requires that all NPDES permits contain technology-based effluent limits (CWA Sections 301(b)(1)(B), 304(d)(1), 40 CFR Parts 125.3, 133), and more stringent effluent limitations if necessary to ensure that water quality standards are met(CWA Section 301(b)(1)(C), 40 CFR 122.4(d), 40 CFR 122.44(d)). As stated in the fact sheets and in this response to comments, EPA has established water quality-based effluent limits that are more stringent than technology-based effluent limits, whenever those limits were necessary for pollutants discharged by the subject permittees. Whenever a technology-based effluent limit was imposed in lieu of a water quality-based effluent limit, EPA made a finding in the fact sheet that the technology-based effluent limit was adequately stringent to protect water quality. Water quality-based effluent limits are based solely on the water quality standards; they are not based on economic feasibility.

Comment #2-26

The City of Spokane stated that the interim and final effluent limits for phosphorus and other nutrients in the proposed permits are too generous. By imposing these effluent limits, the City of Spokane is

concerned that other downstream discharges, such as the City of Spokane, will be unable to meet the phosphorus goals and targets set forth in the Foundational Concepts.

Response #2-26

In this comment, the City of Spokane was referring to the *Foundational Concepts for the Spokane River TMDL Managed Implementation Plan*, dated June 30 2006.[15] This comment was addressed by the revised draft permits issued for public review and comment in 2013. The final water quality-based effluent limits for TP, ammonia, and CBOD in the subject permits ensure compliance with water quality standards for DO in Lake Spokane on a cumulative basis.

Like all point sources discharging to the Spokane River in Washington, the City of Spokane's obligations with respect to phosphorus are stated in its NPDES permit, which is based on the City's phosphorus wasteload allocation in the Spokane DO TMDL. Even if the allocations in the Spokane DO TMDL and the limits in the NPDES permits for discharges to the Spokane River should fail to ensure compliance with water quality standards, the limits in the City of Spokane's permit could not be changed without following the requirements in 40 CFR Part 124, including preparation of a draft permit, a public comment period of no less than 30 days, and the opportunity for a public hearing. Nothing in the subject permits will affect the City of Spokane's ability to meet its phosphorus effluent limit or wasteload allocation.

Comment #2-27

The City of Spokane stated that "it is critical that both the EPA and the State interpret and apply the State of Washington standards for dissolved oxygen consistently." The City of Spokane cited numerous examples where it believed that EPA has not consistently interpreted Washington's DO water quality standards. For example, the City of Spokane believed that EPA had concluded that the Washington standards allow each Idaho discharger to reduce DO by up to 0.2 mg/L in Long Lake, while the State of Washington appeared to look at all human-caused sources combined when determining compliance with this standard. The City of Spokane compared the 2007 Coeur d' Alene Fact Sheet, p. C-10, with the 2004 Draft TMDL (Merrill and Cusimano 2004), pp. 5 and 21. In addition, the City of Spokane stated that Washington used 0.005 to 0.006 mg/L for the "natural background" phosphorous concentration whereas the EPA appeared to have used 0.14 mg/L.

Response #2-27

This comment was addressed by the revised draft permits issued for public review and comment in 2013. The final water quality-based effluent limits for TP, ammonia, and CBOD in the subject permits ensure compliance with water quality standards for DO in Lake Spokane on a cumulative basis, considering all human actions that affect DO in Lake Spokane, which is consistent with the plain language of the standard (WAC 173-201A-200(1)(d)(ii)).

The EPA did not state in the 2007 HARSB fact sheet that the natural background phosphorus concentration in the Spokane River was 0.14 mg/L. It appears that the commenter is referring to the proposed average monthly phosphorus loading limit of 0.14 *lb/day*. This loading of phosphorus is

[15] http://www.ecy.wa.gov/programs/wq/tmdl/spokaneriver/dissolved_oxygen/foundational_concepts-v21.pdf

equivalent to a concentration of 10 µg/L (0.010 mg/L) at the HARSB facility's design flow rate (at the time the 2007 draft permit was issued for public review and comment) of 1.65 mgd. When EPA stated on Page C-7 of the 2007 HARSB fact sheet that this level of phosphorus was "comparable to natural background," EPA was referring to an effluent concentration of 10 µg/L (0.010 mg/L), which is equivalent to the proposed phosphorus loading limit of 0.14 lb/day in the 2007 draft HARSB permit.

Comment #2-28

The City of Spokane stated in comments on the 2007 draft permits that, in establishing the effluent limits in the permits, it appeared that EPA had assumed that the Washington dischargers would control nonpoint sources. The City of Spokane believed that EPA should require the Idaho dischargers to work on nonpoint source control so that the burden is not just placed on the downstream Washington dischargers.

Response #2-28

The effluent limits for TP, ammonia, and CBOD in the 2013 draft permits and the final permits are based on the assumption that the load allocations for non-point sources, the wasteload allocations for point sources, and Avista Corporation's DO responsibility in the Spokane DO TMDL will be attained. The EPA did not assume that the Washington dischargers would be involved in controlling non-point sources so that the non-point source load allocations in the TMDL would be attained.

The modeling supporting the Spokane DO TMDL and the subject permits also considered the estimated loading from municipal stormwater in Idaho. Non-point source loading to the Spokane River in Idaho from tributaries is unquantified, but is believed to be negligible (Annear, Wells and Berger 2005).

Comment #2-29

HARSB and Post Falls stated that EPA appeared to have resolved an issue by providing a "dynamic" permit. These commenters provided an Exhibit 4 that was obtained from Ecology's files. The exhibit shows that a substantially higher loading in April, May, June, and October (the shoulder season) can be discharged to the river. HARSB and Post Falls both included diversion from the river to reuse (e.g., for irrigation) during the July, August, and September critical period. HARSB and Post Falls commended EPA for providing a defendable dynamic permit that would possibly reduce some of the required technology for phosphorus removal in the shoulder season so that entities like the City can invest in land application reuse during the critical months.

Response #2-29

The phosphorus limits in the 2013 draft permits and the final permits are not "dynamic" in the same way as those in the 2007 draft permit. The 2007 draft permits had phosphorus limits from March to October, but there were different limits within that time frame. For example, the average monthly loading limits in the 2007 draft permit for the City of Post Falls were 29 lb/day in March, 7.26 lb/day in April and May, 1.45 lb/day from June to September, and 29 lb/day in October. The final Post Falls permit has a seasonal average limit of 3.19 lb/day, which applies from February to October. See Figures 1 – 9 in Appendix B to the 2013 fact sheets for comparisons of the TP, ammonia, and CBOD limits in the 2007 draft permits to those in the 2013 draft permits (which are identical to those in the final permits).

However, because the phosphorus limits in the final permits are stated in terms of mass and as seasonal averages, the limits afford the dischargers flexibility similar to the "dynamic" limits in the 2007 draft permits. For example, if a utility employs partial re-use to reduce its effluent flow rate, it could discharge a somewhat higher concentration of TP in its effluent and still comply with its seasonal average loading limit. Also, if a utility ceases its discharge to the river through 100% re-use, the permittee may report a loading of zero pounds per day for the period of time when there is no discharge. This will reduce the seasonal average loading that the utility must report, thus allowing the utility to discharge somewhat more loading during the time when it is discharging to the river and still comply with the seasonal average loading limit.

The effluent limits nonetheless restrict the total amount of TP, ammonia, and CBOD that the utilities may discharge to the Spokane River from February through October to amounts which have been shown through modeling to ensure compliance with Washington's water quality standards for DO. The flexibility described above will therefore not result in violations of water quality standards.

Comment #2-30

Post Falls and HARSB stated that, at the 2007 public hearing on the three Idaho NPDES permits, there were numerous pleas for a basin approach and that EPA should not have interceded in providing separate analyses for the Idaho dischargers. Post Falls and HARSB provided a loading reduction table obtained from Ecology's files, which shows that the ultimate loading from the point source dischargers in both Idaho and Washington should be reduced to 4.6 pounds of phosphorus per day. In the table referenced by the commenters, only 0.2 pounds (4 percent) was allocated to the Idaho dischargers. According to Post Falls and HARSB, this restriction would cause severe limitations on the Idaho dischargers because the loading set forth in the permits are less than one half the 0.44 pounds that should have been allocated. The Idaho dischargers were not given a realistic and equitable portion of the loading in the Spokane River. Post Falls and HARSB stated that they believe the 2007 draft permits equitably allocate loading to the Spokane River.

Response #2-30

As explained in Appendix B to the 2013 fact sheets, the EPA determined to use a "basin approach," in which the effluent limits for nutrients and oxygen-demanding pollution are calculated such that they ensure compliance with Washington's water quality criteria for DO in Lake Spokane on a cumulative basis.

The sum of the final water quality-based TP effluent limits for the subject Idaho POTWs is 7.69 lb/day. The sum of the TP wasteload allocations for Washington's point sources (except for stormwater and combined sewer overflows) in the Spokane DO TMDL is 25.5 lb/day. Thus, the Idaho dischargers have been allocated 23% of the total non-stormwater point source load.

Effluent Limits for Metals

Comment #2-31

CFJ stated that the EPA incorrectly calculated the reasonable potential for lead, cadmium, and zinc. CFJ notes that the EPA used effluent hardness for cadmium, lead, and zinc, and stated that this approach "is

appropriate if no dilution factor (mixing zone) is included in the reasonable potential calculations." The commenters believed that, since the EPA calculated and presented dilution factors in Appendix E of the fact sheets, the EPA used these dilution factors in reasonable potential calculations for cadmium, lead, and zinc. The commenters concluded that the EPA should have used the hardness at the edge of the mixing zone.

Response #2-31

The toxicity of metals to aquatic life, and, in turn, the water quality criteria, varies depending on the hardness of the water. As stated in the fact sheets, the EPA did not use dilution factors in reasonable potential and effluent limit calculations for cadmium, lead, or zinc. See the 2007 fact sheets at Appendices E and F, the 2013 fact sheets at appendices D and E, and the discussion under the heading of "Water Quality Limited Segment" in the bodies of the 2013 and 2007 fact sheets. Reasonable potential and effluent limit calculations for cadmium, lead, and zinc applied water quality criteria at the end-of-pipe, using effluent hardness.

For metals other than cadmium, lead, and zinc, dilution was considered (because the ambient water meets criteria). For those metals, the EPA used the hardness at the edge of the mixing zone to calculate the values of the metals criteria.

EPA has used the 5th percentile hardness for both the effluent and the receiving water in calculating effluent limits for metals. This is a reasonable "worst case" effluent hardness, thus, it is not necessary to place an additional limit on effluent hardness.

Comment #2-32

CFJ stated that the EPA cannot assume that the effluent limits for cadmium, lead, and zinc will not contribute to WQS violations in Washington simply because Idaho's criteria are as stringent as or more stringent than Washington's. CFJ concluded that the EPA must "condition these permits such that they do not cause or contribute to water quality violations downstream." CFJ stated that the EPA did not calculate the cumulative impact of all existing and identified sources downstream and did not include a "margin of safety."

Response #2-32

NPDES regulations require the EPA to identify pollutants that are or may be discharged at a level which has the reasonable potential to cause or contribute to excursions above WQS and then establish limits on those pollutants that are derived from and comply with the applicable water quality criteria (40 CFR 122.44(d)(1). There is no requirement for a margin of safety when establishing NPDES permit conditions. It is, however, appropriate to use conservative assumptions when deriving water quality-based effluent limits, and the EPA has done so here.

The EPA established criteria end-of-pipe effluent limits for cadmium, lead, and zinc, expressed in terms of concentration, where reasonable potential existed, and where it was necessary to continue forward effluent limits from the 1999 permit in order to ensure compliance with the anti-backsliding provisions of the Clean Water Act. These limits are derived from and comply with Idaho WQS. Idaho's cadmium and lead criteria are at least as stringent as those in Washington. The Idaho dischargers either do not

have the reasonable potential to cause or contribute to excursions above the Idaho criteria (at the end-of-pipe) or are required to meet water quality-based effluent limits that apply the Idaho criteria concentrations at the end-of-pipe. Discharges of pollutants at concentrations at or below the applicable water quality criteria do not contribute to excursions above those criteria. Therefore, the water quality-based effluent limits for lead comply with the water quality standards of both States, and the reasonable potential analyses for lead and cadmium, including the finding that the dischargers do not have the reasonable potential to cause or contribute to excursions above water quality standards for cadmium, are valid for both States, in compliance with 40 CFR 122.4(d).

The Idaho zinc criteria are marginally less stringent than those in Washington, but the EPA has demonstrated that the Idaho dischargers do not have the reasonable potential to cause or contribute to excursions above Washington's zinc criterion. See, e.g. the 2007 Coeur d'Alene fact sheet at Page 14. Therefore, the effluent limits for zinc in the subject permits comply with 40 CFR 122.4(d).

Comment #2-33

CELP stated that the EPA has abandoned adopting a TMDL for metals in Idaho and is therefore obligated to condition wastewater discharge permits with water quality-based toxics control for metal discharges causing or contributing to water quality violations in Idaho and Washington. Washington's ambient monitoring show repeated violations for metals lead, zinc, and cadmium when river hardness is low. The EPA protocols for these limits should be followed using the appropriate in-stream criterion and actual river critical conditions.

Response #2-33

A TMDL for metals encompassing the Spokane River in Idaho was completed jointly by the Idaho Department of Environmental Quality and the EPA and was approved by the EPA in August of 2000. The TMDL was vacated by the Idaho Supreme Court in 2003. In the absence of a TMDL, the EPA is required by Section 301(b)(1)(C) of the Act and 40 CFR 122.44(d)(1) to include water quality-based effluent limits for metals where the discharge has the reasonable potential to cause or contribute to excursions above water quality standards. In any case where the subject dischargers had the reasonable potential to cause or contribute to excursions above water quality standards for any metal or any other pollutant, a water quality-based effluent limit has been imposed, with water quality criteria applied at the end-of-pipe. Because these limits apply at the end-of-pipe, the discharge will comply with water quality criteria under all likely hardness scenarios. The imposition of such effluent limits wherever reasonable potential exists satisfies the EPA's obligations under Section 301(b)(1)(C) of the CWA and its implementing regulations, for the pollutants in question.

Comment #2-34

CELP stated that there is inadequate information presented in the Fact Sheets to determine if appropriate water quality criteria were applied during critical conditions. A general reference to the old NPDES permits as justification for lead and zinc limits in the new permits is not adequate, particularly given that the old permit limits were likely inappropriately derived. Since the Spokane River already exceeds metals criteria for lead, zinc, and cadmium, the discharges must meet end-of-pipe limits.

CELP stated that end-of-pipe toxicity-based limits must be derived from criteria for critical conditions in the river where aquatic organisms live.

Response #2-34

In neither the 2007 nor the 2013 draft permits did the EPA did "reference" or continue any previously-established effluent limits under the anti-backsliding provisions of the CWA in the reissued permits without verifying that these effluent limits remain protective of water quality.

Water quality criteria for metals were applied under critical conditions. However, the appropriate critical condition for hardness depends on whether the metals criteria are applied at the end-of-pipe or at the edge of a mixing zone. For cadmium, lead, and zinc, water quality criteria qre applied at the end-of-pipe (no mixing zone). Thus, the receiving water flow rate and receiving water hardness are irrelevant because mixing with the receiving water is not a factor in determining whether the discharge has the reasonable potential to cause or contribute to excursions above water quality standards. The appropriate hardness to use in determining reasonable potential or calculating effluent limits is the hardness expected at the point where criteria are applied (either at the end-of-pipe or the edge of the mixing zone). Therefore, in these permits, the appropriate hardness to use in determining reasonable potential and in calculating effluent limits for cadmium, lead, and zinc is the effluent hardness.

The Spokane River does not consistently meet criteria for these metals. However, any point source discharge of these metals when the criteria are met at the end-of-pipe, with effluent hardness, will not contribute to excursions above criteria in-stream, even though the effluent concentration of the metals may be relatively high. This is because the hardness of the effluents reduces the toxicity of the discharged metals and raises the numeric value of the water quality criteria accordingly, wherever the hardness and the metal concentration is influenced by the discharge. This phenomenon is explained in detail in the Washington State Department of Ecology's total maximum daily load for metals in the Spokane River (Butkus and Merrill 1999).

Due to the "concave up" curvature (positive second derivative) of the water quality criterion for lead, this is not always the case for lead. However, in establishing water quality-based effluent limits for lead, the EPA has corrected for this, by establishing effluent limits for lead based on the tangent line to the lead water quality criteria curve at a hardness of 25 mg/L.

For other metals (e.g. copper), the hardness used in reasonable potential and effluent limits calculations is the hardness at the edge of the mixing zone (a mixture of ambient and effluent hardness in the proper proportions). Where a mixing zone is allowed, the critical river flow rates used in calculating dilution factors are the 7-day, 10-year low flow (7Q10) for chronic water quality criteria and the 1-day, 10-year low flow for acute water quality criteria (1Q10) for acute criteria. These are the flows recommended for use in steady-state modeling in the TSD (see Appendix D). The critical river flow rates used in calculating dilution factors are the design flow rates of the treatment works. The dilution factors are provided in Appendix D to each of the 2013 fact sheets.

The specific hardness values used to calculate the values of the water quality criteria for metals are shown in Table 30, below.

Table 30: Hardness Values Used to Calculate Metal Criteria (mg/L as $CaCO_3$)			
Parameter	Coeur d'Alene	HARSB	Post Falls
Cadmium, lead and zinc	132	95.3	97.6
Others	25	25	25

Comment #2-35

Mr. Jim Hollingsworth recommends that the EPA reevaluate the level at which dissolved metals are beneficial and/or harmful to human health.

Response #2-35

Water quality standards and the effluent limits based upon those standards must protect all existing and designated uses of the subject waters, including, in this case, cold water aquatic life (CWA §301(b)(1)(C), 40 CFR 131.11, 131.12, IDAPA 58.01.02.051.01, 58.01.02.110.12). Human health is only one of several concerns that must be considered when establishing water quality criteria and effluent limits based upon those criteria. The effluent limits in the subject permits are set to ensure that both human health and aquatic life are protected.

In general, human beings can tolerate much higher concentrations of metals in drinking water than fish can tolerate in their habitat. For example, the State of Idaho's water quality criteria for zinc, for human health protection, are 7,400 µg/L for consumption of water and organisms and 26,000 µg/L for the consumption of organisms only. In contrast, the acute and chronic water quality criteria for protection of aquatic life are both 120 µg/L, at a hardness of 100 mg/L as $CaCO_3$.

Temperature

Comment #2-36

CFJ stated that the EPA failed to consider the cumulative temperature impact of these discharges on waters of the State of Washington. Specifically, CFJ recommended that the EPA consider whether the total cumulative impact is greater than 0.3 °C downstream of the border (assuming non-point sources are not an issue during the critical period) as specified in 40 CFR 122.44(d).

Response #2-36

As explained on pages B-22 to B-23 of the 2013 fact sheets, the EPA has considered the cumulative temperature impact of the subject discharges on waters of the State of Washington and has determined that the dischargers do not have the reasonable potential to cause or contribute to excursions above Washington's water quality standards for temperature. Specifically, the maximum temperature increase attributable to the Idaho dischargers, at any time, is 0.27 °C, which is much less than the allowable increase (0.96 °C).[16] At times when the predicted temperature, with no discharge from Idaho point

[16] Washington's site-specific temperature criterion for the Spokane River from Nine Mile Bridge to the Idaho border reads as follows: "Temperature shall not exceed a 1-DMax of 20.0 ºC due to human activities. When natural conditions exceed a 1-DMax of 20.0 ºC, no temperature increase will be allowed which will raise the receiving water temperature by greater than 0.3 ºC; nor shall such temperature increases, at any time, exceed t = 34/(T + 9)." (WAC 173-201A-602). The capital "T" represents the background temperature as measured at a point or points unaffected by the discharge and representative of the highest ambient water temperature in the vicinity

sources, is greater than or equal to 20 °C, the maximum temperature increase attributable to the Idaho point sources is 0.13 °C, which is less than half the increase allowed by the criterion (0.3 °C) (WAC 173-201A-602).

Monitoring Requirements

Comment #2-37

Mr. Jim Hollingsworth objected to requiring the dischargers to incur significant costs in conducting their own monitoring, and expressed concern that there is no incentive for the permittees to actually perform the monitoring, and to accurately and truthfully report the results of the monitoring. The commenter recommends that the EPA conduct the monitoring.

Response #2-37

The NPDES permitting program is a self-monitoring program. 40 CFR 122.44(i) requires all NPDES permits to impose monitoring requirements on permittees that will "assure compliance with permit limitations." In addition, 40 CFR 122.41(j) requires that records of monitoring information include the results of the sampling analysis.

Monitoring, recording, and reporting requirements are enforceable provisions of NPDES permits. If the permittees choose not to perform the required monitoring, or not to report the results of such monitoring, or to make false statements in such reporting, they will be subject to civil or criminal enforcement action at the EPA's discretion. Possible penalties for violations of permit conditions are listed in Part IV.B of the permits.

Comment #2-38

Post Falls stated that paragraph F.1 on Page 12 of the 2007 Post Falls draft permit unreasonably requires surface water sampling at multiple locations that are outside the influence or control of the City and its wastewater discharge. Post Falls stated that only the water quality immediately above and below the City's outfall is pertinent to this permit and the sampling points should be changed to reflect such an approach. Post Falls stated that it will cooperate with the IDEQ to select appropriate sampling locations at or near the Post Falls Dam and at or near the old Pleasant View Bridge in the River.

Post Falls also stated that Paragraph F.1 on Page 12 and Fact Sheet Page C-2 list Skalan Creek as a sampling point but maintained that Skalan Creek is unaffected by the City's discharge and rarely flows with water. Sampling requirements for Skalan Creek also require access to private property that cannot reasonably be assured by the City. Skalan Creek should be removed from this permit as a sampling point.

Response #2-38

The surface water monitoring requirements in all three of the 2007 draft permits were very similar. Therefore, EPA will consider this comment to be applicable to all three of the 2007 draft permits.

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of the discharge (WAC 173-201A-200(1)(c)(ii)(A)). The maximum "no source" temperature is 26.4 ºC; the value of 34/(T + 9) therefore equals 0.96 ºC.

This comment has been addressed by changes proposed in the 2013 draft permits and retained in the final permits. Specifically, the permits no longer require receiving water monitoring in Skalan Creek, and the sampling locations within the Spokane River have been changed such that sampling is required in the Spokane River upstream and downstream from each facility's outfall.

Comment #2-39

CFJ stated that there is no evidence that the required monitoring is adequate to populate the Spokane CE-QUAL-W2 model to verify and/or determine water quality trends as restoration activities are implemented, or to provide statistically significant information on PCBs. CFJ recommended that EPA consult with EPA staff working on the PCB TMDL to ensure that the sampling is adequate and further suggested a minimum sampling frequency of once per month for total PCBs with a quarterly congener specific analysis, as well as quarterly measuring of dissolved and particulate PCBs attached to sediment.

Response #2-39

The monitoring for PCBs required by the final permits will result in statistically robust data sets. The TSD states that the uncertainty is too large to calculate a standard deviation or mean with sufficient confidence for data sets with less than 10 results (Page 53). Over the five-year term of the permits, the required monitoring for PCBs will result in 30 influent samples, 20 effluent samples, 10 upstream receiving waters samples, and 10 downstream receiving water samples. Therefore, the PCB monitoring requirements will produce a data set that meets the TSD's recommendation of at least 10 samples at each of the required monitoring locations.

The following relative errors were calculated using the procedures described in Appendix N to the EPA's Local Limits Development Guidance (EPA 2004).

Assuming a coefficient of variation of 0.6, which is recommended by EPA permitting guidance in cases where the actual effluent variability is unknown (see TSD at Pages 53 and E-3), the 20 effluent samples that will be collected over the permit term (i.e., quarterly sampling for five years) will quantify the average effluent concentration with a 22.5% relative error, at a confidence level of 90%. For the influent (30 samples) the relative error will be 18.3%, at a confidence level of 90%.

The receiving water monitoring requirements for parameters that would be useful for CE-QUAL-W2 modeling to refine permit requirements for nutrients and oxygen demand (i.e., CBOD5, ammonia, pH, nitrate + nitrite, TP, orthophosphate, DO, and chlorophyll a), require 8 samples per year both upstream and downstream of the outfalls, resulting in 40 upstream samples and 40 downstream samples for each permit. Assuming a coefficient of variation of 0.6, 40 samples will quantify the average concentrations of these constituents with a relative error of 15.7%, at a confidence level of 90%.

Phosphorus Management Plan

Comment #2-40

CFJ stated that the phosphorus management plans required in the permits provide no regulatory mechanism to track performance. CFJ recommended that the EPA include requirements for regular

reporting requirements on phosphorus reductions achieved through the phosphorus management plans. Moreover, CFJ stated that there should be an opportunity for public "review and comment."

Response #2-40

This comment has been addressed by changes made to the revised draft permits issued for public review and comment in 2013. The revised draft permits were changed to require annual reporting of reductions achieved through the phosphorus management plans, and to require that the plans themselves be submitted to the EPA. These requirements have been retained in the final permits.

The annual reports and the phosphorus management plans themselves are a matter of public record. As such, the general public will be able to request them from the EPA pursuant to the Freedom of Information Act.

Polychlorinated Biphenyls

Comment #2-41

CELP stated that PCBs are present in municipal effluent. The commenter cited to Ecology's latest PCB studies to explain that extremely low levels of PCBs will need to be achieved to protect water quality. Therefore, the commenter recommended that EPA include permit limits for PCBs that are derived from existing data obtained in these Spokane River studies performed by Ecology. Monthly samples of effluent PCB in the first year are needed to fully and adequately characterize each discharge.

Response #2-41

As explained in the response to comment #1-1, based on the available information, the EPA has not concluded at this time that the subject discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs. Therefore, the permits do not contain effluent limits for PCBs. The permits include monitoring requirements for PCBs in the influent, effluent, and receiving water. The data obtained from this monitoring will be used to determine if the discharges have the reasonable potential to cause or contribute to excursions above water quality standards for PCBs in the future. The permits also include BMP requirements to control or abate the discharge of PCBs (if any) from the subject POTWs.

Pretreatment

Comment #2-42

CELP stated that the pretreatment program requirements need to specifically require industrial dischargers of phosphorus to be classified as SIUs and to require phosphorus removal down to 5 mg/L before discharge to the treatment plants. This requirement should include sludge discharges, for example from water treatment system maintenance.

Response #2-42

The term "significant industrial user" (SIU) is defined in 40 CFR 404.3(v) as an industrial user that is subject to categorical pretreatment standards, and any other industrial user that discharges an average of 25,000 gallons per day or more of process wastewater to the POTW (excluding sanitary, non-contact

cooling and boiler blowdown wastewater); contributes a process wastestream which makes up five percent or more of the average dry weather hydraulic or organic capacity of the POTW treatment plant, or is designated as such by the "control authority" on the basis that the industrial user has a reasonable potential to adversely affect the POTW's operation or to violate any pretreatment standard or requirement. The control authority is the POTW in cases where the POTW has an approved pretreatment program. Otherwise, it is the approval authority (which, for the State of Idaho, is the EPA). The City of Coeur d'Alene has an approved pretreatment program. The City of Post Falls and the Hayden Area Regional Sewer Board do not. However, the City of Post Falls is required to develop a pretreatment program for EPA approval as a condition of its reissued permit.

In general, the determination of whether an industrial user is an SIU is independent of whether that discharger discharges phosphorus. The only time in which a discharge of phosphorus would be relevant to this determination would be when the discharge of phosphorus "has a reasonable potential for adversely affecting the POTW's operation or for violating any Pretreatment Standard or requirement."

The decision to label an industrial user (which does not otherwise fit the definition of an SIU) as an SIU on the basis that the user has the reasonable potential for adversely affecting the POTW's operation or for violating any pretreatment standard or requirement would be made by the control authority. Therefore, the EPA, as the control authority for HARSB and (for the time being) Post Falls, would be required to demonstrate that a particular industrial user's discharge of phosphorus to the POTW has the reasonable potential to adversely affect the POTW's operation or to violate any pretreatment standard or requirement, in order to label this user as an SIU (if the user did not otherwise fit the definition of an SIU). At this time, the EPA has no information demonstrating this reasonable potential and the commenter submitted none with this comment. Typical untreated domestic sewage contains 4 to 15 mg/L of total phosphorus. Therefore, most of the phosphorus loading to a POTW treatment plant is from domestic sources, and pretreatment program requirements are inapplicable to such sources (40 CFR 403.1). Additional phosphorus from non-domestic sources would be unlikely to adversely affect the POTW's operation, because POTWs are designed to operate properly in spite of the relatively high concentrations of total phosphorus in untreated domestic wastewater. Therefore, the EPA cannot label an industrial user as an SIU simply because it discharges phosphorus.

Capacity Expansions

Comment #2-43

CFJ stated that the EPA did not discuss the planned POTW capacity expansions in the 2007 Fact Sheets.

Response #2-43

In compliance with 40 CFR 122.45(b)(1), all of the effluent limits in the 2007 fact sheets were calculated based on the existing design flows of the treatment plants as reported on the most recent applications available at the time the draft permits were issued for public review and comment.

The City of Post Falls and the Hayden Area Regional Sewer Board submitted updated applications in 2010, reflecting the facility expansions that had taken place at that time. In compliance with 40 CFR

122.45(b)(1), the effluent limits in revised permits are calculated based on the expanded design flows of the treatment plants.

Whole Effluent Toxicity

Comment #2-44

CELP stated that reasonable potential determinations and permit limits to prevent effluent toxicity need to consider additive or synergistic toxicity affects when multiple heavy metal pollutants consistently occur together in relatively high concentrations.

Response #2-44

Effluent limits for individual chemical constituents intended to prevent direct toxicity to aquatic life are derived from and comply with numeric water quality criteria that have been shown to be protective of aquatic life. However, the EPA recognizes that mixtures of chemicals in a point source discharge can be more toxic than the individual chemical constituents within that discharge. Since the toxicity of mixtures of chemicals cannot be generalized or predicted with any certainty, the permits require quarterly chronic whole effluent toxicity (WET) testing. This is consistent with the *Regions 9 and 10 Guidance for Implementing Whole Effluent Toxicity Programs* (EPA 1996).

The EPA has determined, based on existing WET data, that none of the three discharges have the reasonable potential to cause or contribute to excursions above water quality standards for toxicity (see the 2013 fact sheets at Appendix D).

The 2007 draft permits did omit some WET permit conditions that are recommended in EPA guidance. The EPA has incorporated these permit conditions in the 2013 draft permits, and these requirements have been retained in the final permits. These conditions include accelerated testing when toxicity is detected above the toxicity triggers for each facility, and a requirement that the facility re-test its effluent if a test does not meet test acceptability criteria. In the final permits, the EPA added language to Part I.E.2.b to clarify how the most sensitive species is to be determined. The WET results will be used to determine if the discharges have the reasonable potential to cause or contribute to excursions above Idaho's narrative criterion for toxicity in the next permit reissuance.

Compliance Schedules and Interim Limits

Comment #2-45

CFJ states that Section 301(b)(1)(C) of the Clean Water Act establishes a firm deadline of July 1st, 1977, for complying with water quality-based effluent limits, beyond which no extensions can be granted by a state. CFJ points out that, under Section 301(i) of the Act, compliance schedules could be granted for POTWs in certain circumstances if construction could not be completed by the July 1st, 1977, deadline, but that such schedules are not allowed to extend past July 1st, 1988. CFJ references 40 CFR 122.47, which states that compliance schedules cannot extend past "the applicable statutory deadline under the CWA." Therefore, CFJ concludes that the statutory deadline for compliance has expired and any attempt to extend compliance with such limitations after those dates violates the statutory compliance deadline in the Clean Water Act.

Response #2-45

The issue raised by this comment is whether Sections 301(b)(1)(C) and 301(i) of the Act and 40 CFR 122.47 prohibit schedules of compliance in permits after July 1, 1977, or July 1, 1988, respectively.

Section 301(i) of the Act is irrelevant to the subject permits. In order to invoke Section 301(i), the owner or operator of a POTW would have needed to request the EPA to issue an NPDES permit within 180 days after February 4, 1987 (August 4, 1987). This could not have happened for the permit reissuances in question.

In *In The Matter of Star-Kist Caribe, Inc.*, 3 E.A.D. 172 (1990), EPA's Administrator interpreted Section 301(b)(1)(C) of the Act to mean that NPDES permits must require immediate compliance with effluent limitations based on water quality standards adopted before July 1, 1977. Thus, the subject permits may not contain compliance schedules for effluent limits that are based on pre-1977 water quality standards. However, for new or revised water quality standards adopted after July 1, 1977, NPDES permits may contain compliance schedules as long as the state has clearly indicated in its water quality standards or implementing regulations that it intends to allow them. See StarKist at 176-177; see also the Permit Writers' Manual at Section 9.1.3. Therefore, if a state adopts a new or revised water quality standard after July 1, 1977, the state may authorize the permitting authority to include a compliance schedule in the NPDES permit to allow time for the permittee to meet the new water quality-based effluent limit in the permit.

Compliance schedules are authorized under the water quality regulations in both Idaho and Washington. See IDAPA 58.01.02.400.03 and WAC 173-201A-510. Since the discharges authorized in the subject permits occur in Idaho, it is Idaho's regulation that is applicable to these permits.

Since the water quality standards of both affected states allow schedules of compliance, the next issue is whether the relevant water quality standard was in effect prior to July 1, 1977. The Washington water quality standard upon which the effluent limits for phosphorus, CBOD, and ammonia are based is the DO criterion for lakes and reservoirs, applied in Lake Spokane (WAC 173-201A-200(1)(d)(ii)). The currently effective version of that standard appears in the 2003 revision of Chapter 173-201A WAC and became effective for Clean Water Act purposes when it was approved by EPA on February 11, 2008. This standard reads, "For lakes, human actions considered cumulatively may not decrease the dissolved oxygen concentration more than 0.2 mg/L below natural conditions." Prior to 2003, the State of Washington's DO standard for lakes and reservoirs read "no measurable decrease from natural conditions." The Washington water quality criterion for DO in lakes and reservoirs has therefore been revised after 1977. Since the relevant water quality standard has been revised after 1977, and because the applicable state law allows for compliance schedules, a compliance schedule may be authorized.

Comment #2-46

CFJ stated that, by extending beyond the term of the permit, the compliance schedules violate the CWA's mandate that NPDES permits be established for a fixed term not to exceed five years. CFJ stated that the compliance schedules "are not for a fixed term." CFJ referenced a 9th Circuit Court of Appeals decision in *Citizens for a Better Environment* v. *Union Oil Company of California* (*CBE* v. *UNOCAL*) and

quotes the following language from the opinion: "there is a five year duration on the life of an NPDES permit that the 'effective modification' here would violate." CFJ argued that the proposed compliance schedules extend the substantive requirements of a permit beyond the five-year limit established by the Act. CFJ referenced the City of Moscow NPDES permit appeal before the Environmental Appeals Board (EAB) and stated that the EPA argued in that case that to extend the compliance schedule beyond the term of that permit would be illogical as there was no guarantee that the permit would be administratively extended or renewed.

Response #2-46

The EPA does not agree with the commenters that a compliance schedule longer than five years violates the Clean Water Act's mandate that NPDES permits be established for a fixed term not to exceed five years. The five-year maximum permit term required by Section 402(b)(1)(B) of the Act does not establish a deadline for meeting a water quality-based effluent limitation; it simply requires the permitting authority to re-evaluate NPDES permits every five years (see letter dated 11/29/06 from Alexis Strauss, EPA Region 9 to Tom Howard, California State Water Resources Control Board at Page 6, and the enclosure to that letter at Page 6).

The *CBE* v. *UNOCAL* case referenced by the Center for Justice (CFJ) is irrelevant to the issue of how long a compliance schedule in a permit may be. In *CBE* v. *UNOCAL,* the Ninth Circuit addressed two issues: 1) whether the cease and desist order (CDO) barred a citizen suit under Clean Water Act Section 309(g)(6)(A), and 2) whether the CDO effectively deferred the compliance date for a selenium effluent limit such that UNOCAL was not in violation of that effluent limit. The Court concluded that the CDO neither barred a citizen suit nor effectively deferred the compliance date for the selenium effluent limit.

The Court determined that the CDO did not defer the compliance date for the selenium effluent limit for the following reasons: 1) the CDO was an exercise of prosecutorial discretion and did not purport to modify the permit, 2) the federal and state regulations (e.g. 40 CFR 122.62) that govern the modification of permits were not followed, and, 3) even if the CDO were considered a modification of the permit, that modification may have violated the Clean Water Act's anti-backsliding provisions.

The language from the opinion that CFJ quoted in its comments on these permits was an observation made by the *CBE* Court that one of the requirements of the NPDES permitting program that was not followed by the CDO was the requirement that permits be limited to a fixed term not to exceed five years. However, the question of whether a compliance schedule could extend beyond the term of an NPDES permit was not before the Ninth Circuit in *CBE* v. *UNOCAL* and was not addressed by the Court.

CFJ also references the City of Moscow, Idaho NPDES permit appeal, 10 EAD 135 (EAB 2001). That case does not stand for the proposition that compliance schedules as a general matter are limited to five years under the CWA. Furthermore, that case is not applicable to the current situation. In City of Moscow, the EAB upheld EPA's authority to impose compliance schedules shorter than those set forth in the state's 401 certification where the State of Idaho's compliance schedule authorizing provision at the time the City of Moscow permit was issued allowed compliance schedules only for "five years or the life of the permit."

Following that decision, the State of Idaho revised its compliance schedule regulations to allow schedules with no specific time limitation. The State of Idaho's current compliance schedule regulation states, in full: "Discharge permits for point sources may incorporate compliance schedules which allow a discharger to phase in, over time, compliance with water quality-based effluent limitations when new limitations are in the permit for the first time." See IDAPA 58.01.02.400.03. The State of Idaho can now determine, on a case-by case basis, what an appropriate schedule of compliance is for a particular effluent limitation and discharger. The schedules of compliance in these permits were determined by the State of Idaho in its 401 certification for these permits.

The commenters also point out that there is no guarantee that the subject permits will be administratively extended or reissued, so that each point source will hold an effective NPDES permit at the time that compliance with the final water quality-based effluent limits is ultimately required by the compliance schedule certified by the State of Idaho. This is largely irrelevant to the subject permits. It is unlikely that any of the subject permittees will implement an alternative method of disposing of their wastewater and cease their discharges within the five-year terms of these permits. Therefore, the permits are likely to be administratively continued or reissued. In the unlikely scenario that a permit for any of the subject POTWs is neither administratively continued nor reissued, the discharger would have no authorization to discharge at all upon expiration of the permit, so the compliance schedule would be irrelevant.

If the permits were administratively extended, the final compliance deadline, as well as any interim deadlines, would be in effect and enforceable.

If the permits were reissued before the compliance deadline, then, as with all of the permit conditions, the permitting authority would be required to re-evaluate the compliance schedule at the time of reissuance. Depending on the particular facts, the permitting authority may conclude that the compliance schedule in the initial permit need not be altered, or the permitting authority may find that the schedule should be shortened, extended, or deleted.

The status of the permit is not a concern as long as the initial permit contains the entire compliance schedule and final effluent limits that must be met. See further discussion below in 2-48 as to the enforceability of these terms in an NPDES permit.

Comment #2-47

CFJ stated that a compliance schedule beyond the term of a permit is unenforceable and is inconsistent with EPA's definition of a compliance schedule (CWA Section 502(17) and 40 CFR 122.2). CFJ stated that the permits' attempts to issue schedules that extend the deadline for compliance for nine years are unenforceable schedules.

Response #2-47

The term "schedule of compliance" is defined in federal statute (Clean Water Act Section 502(17)), federal regulations (40 CFR 122.2), and in State of Idaho regulations (IDAPA 58.01.02.010.15). None of the definitions of "schedule of compliance," nor the provision allowing schedules of compliance in the Idaho Water Quality Standards, limit the term of a schedule of compliance to the term of an NPDES

permit or any other specific length of time. This gives the State of Idaho and the EPA the discretion to make case-by-case determinations as to the appropriate length of the compliance schedules.

The schedules of compliance for the Idaho permits are established under Idaho state law. The permits therefore comply with the Clean Water Act's requirement that permits be conditioned to comply with "schedules of compliance established pursuant to any State law or regulations" (Section 301(b)(1)(C), see also the enclosure to letter dated 11/29/06 from Alexis Strauss, EPA Region 9, to Tom Howard, California State Water Resources Control Board at pages 8-9). The fact that compliance schedules established under state law are to be included in a permit issued for a term not to exceed five years does not mean that the length of the compliance schedule must be limited to five years.

In Idaho, the length of a compliance schedule is limited only by the federal regulatory requirement of 40 CFR 122.47(a)(1) that compliance be achieved "as soon as possible." The State of Idaho determined that the appropriate length of the schedules of compliance for new water quality-based effluent limits for TP, $CBOD_5$, and for Coeur d'Alene, ammonia, is ten years. To ensure compliance with Section 301(b)(1)(C) of the Act, the schedules, including the final effluent limits and any interim requirements with compliance deadlines beyond the term of the permit, have been included in the permit.

EPA agrees with the commenter that schedules of compliance in NPDES permits must be enforceable. Every condition in an NPDES permit, including those that are part of a compliance schedule, are enforceable conditions (see Locust Lane v. Swarta Township Authority, 636 F. Supp. 534, 539 (M.D. Pa. 1986)). Therefore, a compliance schedule that includes interim milestones leading to compliance with a final effluent limitation at a date later than the expiration date of the initial permit is enforceable, as long as all the requirements of the compliance schedule, including those that extend beyond five years or begin after the fifth year, are included as permit terms (See enclosure to letter dated 11/29/06 from Alexis Strauss, EPA Region 9, to Tom Howard, California State Water Resources Control Board at Page 9). The requirements of the compliance schedules have been included as permit terms in the subject permits and are therefore enforceable.

The schedules in the final permits were included as conditions in Idaho's Clean Water Act Section 401 certifications, which defer the deadline for compliance with water quality-based effluent limits for a fixed amount of time, unless the schedules are modified at some future date. The compliance schedules in the final permits represent IDEQ's judgment as to the amount of time that the subject dischargers require to achieve compliance with new WQBELs in the final permits, based on the record before IDEQ at the time. The EPA concurs with IDEQ's findings regarding the compliance schedules, based on the record before the EPA at this time, as discussed in the 2013 fact sheets at Appendix G, and has included the schedules in the permits.

The reissuance of the permits will provide EPA and IDEQ an opportunity to re-evaluate the compliance schedules (along with the other permit conditions) to determine if the schedules remain appropriate (40 CFR 122.47(a)(1)) in light of any new information obtained during the term of the permit. In addition, the State of Idaho reserves the right to modify its Clean Water Act Section 401 certifications, and EPA may modify the compliance schedules (or other permit conditions) in compliance with 40 CFR 122.62

and 122.63. The fact that the compliance schedules (like any other permit conditions) may be modified in the future does not mean that they are not enforceable.

Comment #2-48

CFJ stated that a compliance schedule longer than five years undermines the public's right to comment on future NPDES permits.

Response #2-48

The public has had an opportunity to comment on the compliance schedule. Indeed, the EPA has received comments on the compliance schedules and has responded to them in this response to comments. When the subject permits are reissued, the EPA and IDEQ will re-evaluate the compliance schedules. The public will be able to submit comments on any condition in the reissued permits, including any compliance schedules. If the compliance schedules are modified during the terms of the permits, the public will have an opportunity to comment on the modifications at that time, since permit modifications must follow the public review and comment procedures of 40 CFR Part 124 (see also 40 CFR 122.62).

The only change that may be made to a compliance schedule without public review and comment is to change an *interim* compliance date in a schedule of compliance, provided the new date is not more than 120 days after the date specified in the existing permit and does not interfere with attainment of the final compliance date requirement (40 CFR 122.63(c)).

The fact that the compliance schedules extend beyond the terms of the permits in no way denies the public the right to comment on the compliance schedules nor does it deny the public the right to comment on any other aspect of a future permit.

Comment #2-49

CFJ stated that the interim phosphorus limits for Post Falls and HARSB are inconsistent with the 1989 Phosphorus Management Plan, which required 85% phosphorus removal, seasonally. CFJ believed that the interim limits should be at least this stringent.

Response #2-49

The interim phosphorus limits in the subject permits are discussed in the 2013 fact sheets (see the 2013 Post Falls fact sheet at Pages 20-21, the 2013 HARSB fact sheet at Pages 20-22, and both fact sheets at Appendix G). The interim limits ensure compliance with 40 CFR 122.44(l)(1), which generally requires that interim effluent limits be at least as stringent as the final limits in the previous permit. The interim phosphorus limits also comply with 40 CFR 122.45(f), which generally requires effluent limits to be expressed in terms of mass. The interim mass limits for phosphorus were calculated based on the design flows of the POTWs at the time the prior permits were issued (in 1999), which ensures that they are "as stringent" as any phosphorus limits in the 1999 permits.

The Spokane River Phosphorus Management Plan would not independently require 85% phosphorus removal for Post Falls or HARSB. This plan is not a legally binding or enforceable document.

Furthermore, the plan has been superseded by the Spokane River DO TMDL. Nonetheless, we discuss below the substantive content of the plan as well.

The management plan was signed in 1989 and was intended to implement the 25 µg/L euphotic zone site-specific phosphorus criterion for Lake Spokane. The management plan stated that the City of Spokane had been removing phosphorus at its wastewater treatment plant "for many years, and will continue to operate with a discharge permit that requires at least 85% (phosphorus) removal." See Spokane River Phosphorus Management Plan at Page 2. The City of Spokane had begun phosphorus removal in late 1977 (Cusimano 2004).

As for the other municipal dischargers, including Post Falls and HARSB, the management plan stated that "as the need for further phosphorus reduction is identified, the other municipalities will sequentially implement phosphorus removal, at rates of at least 85%, and that "the discharger with the greatest daily total phosphorus load is required to treat first." The management plan anticipated that the sequence for additional phosphorus removal to be Coeur d'Alene, followed by Post Falls, followed by Liberty Lake, followed by HARSB. The City of Coeur d'Alene is already required to remove 85% of influent phosphorus and has done so since the early 1990s.

The management plan stated that the next phosphorus removal action would be triggered when existing phosphorus controls no longer achieved a loading of 259 kg/day or less to Lake Spokane (Long Lake). This trigger loading has not yet been reached. Although more recent studies show that phosphorus loading to Lake Spokane must be reduced below 259 kg/day in order to meet Washington's water quality criterion for DO, the 1989 phosphorus management plan has not been updated. Because the trigger loading of 259 kg/day has not yet been reached, the phosphorus management plan does not independently require interim phosphorus limits of 85% phosphorus removal.

Comment #2-50

CELP and CFJ stated that interim limits that apply during the terms of compliance schedules in the permits should be based on performance.

The Center for Environmental Law and Policy stated that, because in-stream water quality violations for DO currently exist, the permits must be conditioned so that the ultimate BOD loading does not increase during the interim compliance schedule. This will require controls on both CBOD and NBOD (nitrogenous biochemical oxygen demand). CELP stated that it is not appropriate to use technology-based CBOD limits without also controlling ammonia to appropriate levels.

The Center for Environmental Law and Policy recommended that the EPA include an evaluation of performance as part of determining interim ammonia limits so that ammonia loadings are not allowed to increase where they contribute to water quality standards violations.

CFJ also stated that "no increases in pollutant loading through growth should be allowed during the interim period while treatment facilities are being upgraded." CFJ stated that EPA must "ensure no increases in pollutant loading while these facilities are being upgraded" in order to "avoid backsliding."

Response #2-50

In the final permits, schedules of compliance have been established for new water quality-based effluent limits for TP, CBOD, and, for Coeur d'Alene, ammonia. The limits that apply during the compliance schedules in the permit are the interim limits.

Interim limits are discussed in the fact sheets at Appendix G and also in the bodies of the fact sheets (see the Coeur d'Alene fact sheet at pages 20-21, the Post Falls fact sheet at pages 20-21, and the HARSB fact sheet at pages 20-22). Nothing in the CWA or NPDES regulations requires the EPA to establish interim effluent limits based on performance so that the actual pollutant loading does not increase during the compliance schedules. Federal regulations require only that, in general, the interim limits are at least as stringent as the limits in the previous permit (40 CFR 122.44(l)(1)). That is to say, the regulations generally prohibit increases to *authorized* loading (i.e., the loading authorized by the effluent limits) during the term of a compliance schedule, but do not necessarily prohibit increases to actual loading as long as the actual loading is in compliance with effluent limits.

In all cases, the interim effluent limits are at least as stringent as the final limits in the previous permit. The interim phosphorus limits in the subject permits are discussed in the 2013 fact sheets (see the 2013 Post Falls fact sheet at Pages 20-21, the 2013 HARSB fact sheet at Pages 20-22, and both fact sheets at Appendix G). The interim limits ensure compliance with 40 CFR 122.44(l)(1), which generally requires that interim effluent limits be at least as stringent as the final limits in the previous permit. The interim phosphorus limits also comply with 40 CFR 122.45(f), which generally requires effluent limits to be expressed in terms of mass. Interim mass limits for phosphorus were calculated based on the design flows of the POTWs at the time the prior permits were issued (in 1999).

The interim $CBOD_5$ limits in the Coeur d'Alene permit are identical to the limits in the previous permit. As explained in the HARSB and Post Falls fact sheets at Appendix G, the interim limits for $CBOD_5$ for those facilities are as stringent as the previous permits' limits for BOD_5. The technology-based average monthly concentration limit for $CBOD_5$ is numerically 17% less than that for BOD_5 (i.e., 25 mg/L instead of 30 mg/L), in recognition that some fraction of the total BOD discharged by a facility is nitrogenous. The interim loading limits for $CBOD_5$ are calculated from the technology-based concentration limits using the design flows of the POTWs as of 1999, when the prior permits were issued. The BOD_5 limits in the previous (1999) permits were calculated from the technology-based BOD_5 limits using those same flows.

With respect to ammonia, for HARSB and Post Falls, this comment was addressed by changes made in the revised draft permits issued for public comment in 2013. Neither the revised draft permits nor the final permits for HARSB or Post Falls include schedules of compliance for ammonia limits; the final water quality-based ammonia limits in those permits must be met immediately upon the effective dates of the final permits. The final ammonia limits, in combination with the effluent limits on phosphorus and CBOD, ensure compliance with Washington's water quality standards for DO, on a cumulative basis.

Coeur d'Alene has a compliance schedule for ammonia, which includes interim effluent limits. Coeur d'Alene's interim ammonia limits are identical to the ammonia limits in the previous permit, in compliance with 40 CFR 122.44(l)(1).

Comment #2-51

The City of Spokane stated that the compliance schedules in the proposed permits are too generous. The City of Spokane was concerned that the although the Idaho dischargers do not need to improve their effluent until at least mid-2016, the downstream Washington dischargers will be required to upgrade their facilities sooner (i.e., by 2011 and 2012). The City of Spokane concluded that any data collected after 2011 and 2012 would be of little use unless the Idaho dischargers are required to upgrade by 2011 and 2012.

Response #2-51

The Idaho regulation allowing the State of Idaho to authorize compliance schedules (IDAPA 58.01.02.400.03) does not contain a specific limitation on the duration of a compliance schedule. Federal regulations, however, require that compliance is achieved as soon as possible (40 CFR 122.47(a)(1)). As explained in Appendix G to each of the three fact sheets, the compliance schedules in the subject permits do, in fact, require compliance with water quality-based effluent limits as soon as possible.

Comment #2-52

CFJ stated that the proposed compliance schedules do not comply with 40 CFR 122.47, which requires that compliance with final effluent limits be achieved "as soon as possible."

Moreover, CFJ did not believe that the 401 certifications or the fact sheets explained the need for a nine-year schedule of compliance and did not make an adequate showing that the nine-year compliance schedule satisfied the "as soon as possible" test. CFJ attached and referenceds a report from a third-party engineering firm that concludeds that 56 to 58 months is a reasonable time frame to achieve the proposed limits. CFJ further referenced cost estimates by BlueWater Technologies showing the cost of upgrading a plant to meet 50 ppb TP in the effluent would be roughly $1 million per MGD of capacity. CFJ referred to an e-mail from Dave Ragsdale of EPA Region 10 in which he noted that compliance schedules to complete new secondary treatment plants are generally 5 years or less. The commenters stated that EPA and DEQ should require permittees to better justify the need for a compliance schedule of a certain duration.

Response #2-52

As explained in Appendix G to each of the 2013 fact sheets, the schedules of compliance in each of the permits require compliance with new water quality-based effluent limits as soon as possible, in compliance with 40 CFR 122.47(a)(1).

Comment #2-53

CFJ stated that EPA has an independent duty to incorporate more stringent permit conditions than those in Idaho's certifications if necessary to achieve WQS pursuant to CWA Section 301(b)(1)(C). CFJ did not believe that the compliance schedules set forth in Idaho's 401 certifications were protective of

downstream water quality standards and illegally deferred compliance with the final effluent limits in violation of 40 CFR 122.47(a)(1).

Response #2-53

As explained in the 2013 fact sheets at Appendix G, the schedules of compliance in each of the permits require compliance with new water quality-based effluent limits as soon as possible, in compliance with 40 CFR 122.47(a)(1).

State Certification

Comment #2-54

Mr. Jim Hollingsworth asked the EPA to explain the purpose of the Section 401 certification that is issued by IDEQ.

Response #2-54

Section 401(a)(1) of the Clean Water Act requires IDEQ to either grant or waive Section 401 certification before EPA issues a NPDES permit. In issuing the 401 certification, IDEQ is essentially stating that they have reviewed the subject NPDES permit and certifying that the permit meets state water quality requirements.

States may respond to requests for certification of EPA-issued NPDES permits in one of three ways. First, the state may certify the permit, with or without specifying additional or more stringent conditions in the certification that the State deems necessary to comply with the CWA and state law. Second, the state may waive certification, which allows the permit to be issued. Third, the state may deny certification, which prevents a final permit from being issued.

The State may not condition or deny a certification on the grounds that state law allows a less stringent permit condition (40 CFR 124.55(c)). Therefore, EPA's effluent limits, which are based on Washington's water quality standards in compliance with 40 CFR 122.4(d), may be more stringent than necessary to meet Idaho's water quality standards, but that is not a basis for the State of Idaho to deny or condition their certifications.

Comment #2-55

CFJ stated that Section 401(a)(1) of the Act requires that the State of Idaho certify that the conditions in all three permits comply with Sections 301, 302, 303, 306, and 307 of the Act and that Section 301 requires compliance with Sections 302, 306, 307, 308, 402, and 404.

CFJ stated that neither the interim nor the final limits are protective of Washington's water quality standards, in violation of Section 301 of the Clean Water Act, and that the permits were not in compliance with Section 301's effluent limitations and timelines. The Center for Justice also stated that the permits were not in compliance with Section 302's requirement that effluent limitations be established that will ensure attainment or maintenance of water quality, Section 308's requirement to monitor at such intervals and in such manner as to track river restoration and PCB pollution, and Section

402's requirement that permits be conditioned to protect the water quality of all affected States, that permits be limited to five years, and that the permits not allow backsliding.

CFJ stated that, for these reasons, the State of Idaho should not issue 401 certifications, and final permits should therefore not be issued, unless EPA includes more stringent conditions in the permits.

Response #2-55

The issuance or denial of a 401 certification for any of the three subject permits is an action to be taken by the State of Idaho. Moreover, the legality of a state's CWA 401 certification, or its conditions, is not to be determined by EPA, the permit issuing agency. The 401 certification and its conditions must be challenged in State court. *American Rivers v. FERC*, 129 F. 3d. 99, 102 (2d Cir. 1999). However, having reviewed the commenter's concerns with the certification in light of the 2013 draft permits, EPA believes the final permits comply with sections 301, 302, 308, and 402 of the Clean Water Act, as explained below. EPA believes that the State of Idaho can appropriately issue 401 certifications for the subject permits.

Section 301

There are two main requirements in Section 301 of the. First, the permits must comply with Section 301(b)(1)(B), which requires that NPDES permits for POTWs require compliance with effluent limitations based on secondary treatment. As explained in the fact sheets, the effluent limits in the permits are at all times at least as stringent as the secondary treatment requirements of 40 CFR Part 133, which implements Section 301(b)(1)(B) of the Act. Second, Section 301(b)(1)(C) requires that NPDES permits contain effluent limits that are more stringent than technology-based effluent limits (such as secondary treatment) when those limits are necessary to meet water quality standards or other requirements of state or federal laws and regulations. The final permits contain water quality-based effluent limits whenever necessary, i.e., whenever the discharges had the reasonable potential to cause or contribute to excursions above water quality standards (40 CFR 122.44(d)(1)(i)), as explained in the fact sheets. The permits are also in compliance with Section 301(b)(1)(C)'s "timelines" (i.e., compliance schedules) as explained in Appendix G to each of the three 2013 fact sheets.

Section 302

Section 302 authorizes the EPA to promulgate water quality-based effluent limits when discharges from a point source will interfere with the attainment of WQS after the application of technology-based limits based on the "best available technology economically achievable" (BAT). Section 302 is not applicable to the subject permits for a number of reasons.

BAT limits are applicable to point sources other than POTWs. The subject permits are for POTWs, so Section 302 is not applicable to these permits. Furthermore, any effluent limits that would apply under Section 302 would be arguably less stringent than the effluent limits included in the final permits (which are based on Section 301(b)(1)(C) of the Act) because Section 302 requires a cost-benefit analysis and Section 301(b)(1)(C) does not. Finally, even though Section 302 is not applicable, the Section 301(b)(1)(C) water quality-based limits can nonetheless "reasonably be expected to contribute to the attainment or maintenance of…water quality," which is what would be required under Section 302.

Section 308

Section 308 of the Act concerns monitoring and reporting requirements, inspections, and entry. The subject permits contain monitoring, reporting, and recordkeeping requirements, including receiving water monitoring requirements, which ensure that the permits comply with Section 308 of the Act. The permits also contain conditions requiring that EPA, Idaho DEQ, and authorized representatives may enter and inspect the facilities, perform sampling, and access and copy records, in compliance with Section 308 of the Act.

Section 402

Section 402 of the Clean Water Act creates the National Pollutant Discharge Elimination System (NPDES). NPDES permits represent one of the exceptions to the general prohibition on discharges of pollutants in Section 301(a) of the act. The subject permits comply with all applicable requirements of Section 402 of the Act.

As stated in the 2013 fact sheets, the subject permits are conditioned to ensure compliance with the water quality standards of all affected states, as required by Section 402 of the Act and 40 CFR 122.4(d). Section 402(b)(1)(B) states that permits shall be issued for a fixed term not to exceed five years. The subject permits comply with this requirement, which is not violated by the fact that the permits implement compliance schedules that extend beyond the durations of the permits. See the response to comment 2-51 and the letter dated 11/29/06 from Alexis Strauss, EPA Region 9, to Tom Howard, California State Water Resources Control Board, and its enclosure.

Section 402(o) of the Act concerns backsliding, or the establishment of less-stringent effluent limitations in a reissued permit than the corresponding limits in the previous permit. There are exceptions provided in Sections 402(o)(2) and 303(d)(4) of the Act. Whenever an effluent limit in the subject draft permits was less stringent than that in the expired permits, this was explained in the fact sheets, and was done in compliance with Section 402(o) of the Act. This was the case for Post Falls' and HARSB's mass limits for TSS and November to January $CBOD_5$ and ammonia, Post Falls' limits for copper mass and chlorine, and HARSB's discharge authorization for June to September when river flows are less than or equal to 2,000 CFS.

Ammonia Toxicity

Comment #2-56

The Center for Environmental Law and Policy stated that since the upper pH limit is 9.0, EPA should use this value to model pH at the edge of the mixing zone and subsequent ammonia criteria instead of actual performance. Moreover, the commenter recommended that if performance limits for pH are used to calculate effluent limits for ammonia, they should also be placed in the permit to regulate pH.

Response #2-56

The EPA has used appropriately conservative pH assumptions to evaluate water quality criteria for ammonia, and to determine reasonable potential, and to calculate effluent limits based on Idaho's water quality standards for ammonia toxicity. Therefore, it is not necessary for the EPA to establish

more stringent "performance-based" effluent limits for pH in the permits in order to ensure compliance with water quality criteria.

Specifically, the EPA has used the 95th percentile pH observed at all the available USGS stations in the Spokane River in Idaho. There were a total of 349 pH results, and the 95th percentile pH was 7.9 standard units. Chronic water quality criteria for ammonia are influenced by both pH and temperature, and the EPA has also used the 95th percentile temperature of the Spokane River for each season to calculate the values of the ammonia criteria. By using an upper percentile for both pH and temperature, the EPA has ensured that there is a low probability that the ammonia criteria will be more stringent than the values used to determine reasonable potential and calculate effluent limits.

In addition to using conservative assumptions for pH and temperature when calculating the values of the ammonia criteria, the EPA has also used critical conditions for the receiving water flow rate when calculating the available dilution, specifically the 30Q10 for use with chronic ammonia criterion and the 1Q10 for use with the acute criterion, or, if it was greater than the critical low flows calculated from historic data, the minimum flow rate of 500 CFS mandated by the Federal Energy Regulatory Commission (FERC) License for the Spokane River Hydroelectric Project (FERC 2009 at page 17).

The cumulative effects of the conservative assumptions used to calculate the value of the ammonia criteria, to determine reasonable potential to cause or contribute to excursions above those criteria, and, if necessary, to calculate effluent limits ensures that the discharges are very unlikely to cause or contribute to excursions above water quality criteria for ammonia because of pH.

Elimination of Surface Water Discharges

Comment #2-57

Mr. Gerry House, chairman of the Hayden Lake Recreational Water and Sewer District, stated that utilities and regulatory agencies should be "looking at ways to not discharge into the [Spokane] river at all."

Mr. Bart Haggin of the Lands Council stated that "the small amounts of discharges from these three discharge(s)…can easily be taken care of without putting any water in the [Spokane] river."

Response #2-57

Coeur d'Alene, Post Falls, and the Hayden Area Regional Sewer Board currently have administratively extended NPDES permits and have applied for new NPDES permits, which authorize the cities to discharge treated wastewater to the Spokane River subject to the conditions set forth in those permits, for five years. The permits contain conditions that, among other things, ensure compliance with all affected states' water quality standards.

Pursuant to 40 CFR 122.64, EPA has the authority to deny NPDES permit applications, which would effectively force the applicants to cease discharging pollutants, but only when at least one of the listed causes are met. In this situation, EPA has concluded that it does not have an allowable cause to deny the subject applications under 40 CFR 122.64.

Wastewater re-use is a method by which the dischargers can reduce the amounts of pollutants they discharge to the Spokane River, in an effort to achieve the stringent water quality-based effluent limits set forth in the final permits. For example, HARSB currently re-uses (or land applies) 100% of its wastewater during the summer months. All three permits require the dischargers to consider wastewater re-use as a means to reduce phosphorus discharges as part of their phosphorus management plans. The phosphorus management plan requirements in the permits are authorized by federal regulations (40 CFR 122.44(k)).

Anti-backsliding and Antidegradation

Comment #2-58

CFJ stated that the permits violate federal and state antidegradation and anti-backsliding requirements because EPA did not limit phosphorus, CBOD5, and ammonia to prior performance.

The commenter noted that, in general, effluent limitations for POTWs are based on design flow, and that Washington's permit writers' manual requires no additional loading of the pollutants of concern. The commenter pointed out that EPA did not calculate current mass loadings of pollutants from the Idaho dischargers. The commenter back-calculated the flow rates used to calculate effluent limits in the permits, and noted that the City of Coeur d'Alene's average flow rate over the previous five years was 3.2 mgd and the maximum daily flow rate was 4.62 mgd, both of which are well below the design flow rate of 6.0 mgd. The commenter therefore argued that "the proposed mass limits will exceed the loadings discharge during the last five years…(causing) further degradation for another nine years."

The commenter argued that Section 303(d)(4)(a) "governs backsliding into impaired waterways for which there is a TMDL or other wasteload allocation." Although the commenter disagreed with how EPA calculated wasteload allocations and effluent limits for the Idaho permits, the commenter argued that these are nonetheless wasteload allocations and that therefore EPA "may not allow increased loading into Lake Spokane."

The commenter argued that EPA "must conduct an antidegradation analysis to calculate permissible loading limits in compliance with federal and state antidegradation policies to restrict loading to prior performance and to ensure that any expansion does not further degrade the waters."

Response #2-58

Anti-backsliding

The anti-backsliding restrictions in Sections 402(o) and 303(d)(4) of the Clean Water Act and 40 CFR 122.44(l) limit the circumstances under which effluent limits and other permit conditions may be made less stringent than those in previous permits. The anti-backsliding restrictions would only be violated if the conditions in the reissued permits were made less stringent than the effluent limits in the previous NPDES permit without meeting one of the exceptions in the CWA or the regulations.

The EPA Permit Writers Manual discusses anti-backsliding requirements in Section 7.2. In general, the Permit Writers' Manual recommends that the permit writer follow the statutory provisions for effluent

limits based on state standards (including water quality-based effluent limits), and that the permit writer apply the statutory anti-backsliding provisions. For other limitations, standards, or conditions, the permit writer should apply the regulatory provisions in 40 CFR 122.44(l)(1). The anti-backliding requirements do not apply to actual historic discharge levels, but rather they apply to current permit effluent limits as compared to previous NPDES permit limits. Current permitted limits may only be less stringent than previous limits if there is an applicable exception to the general prohibitions on backsliding in the CWA or federal regulations.

From February to October, all of the interim and final effluent limits for TP, ammonia, and CBOD in all of the subject permits are at least as stringent as the final effluent limits in the previous permits. This is true for the $CBOD_5$ limits in the reissued permits for Post Falls and HARSB even though the prior permits had BOD_5 limits in lieu of $CBOD_5$ (see the 2013 Post Falls and HARSB fact sheets at Appendix G). Therefore, none of those limits violate the anti-backsliding provisions of the CWA or federal regulations.

From November to January, for Post Falls and HARSB, the loading limits for CBOD have been increased due to the increased design flows of the treatment plants. As explained in the 2013 fact sheets for these facilities, the increased loading limits comply with the anti-backsliding provisions of 40 CFR 122.44(l) because the physical expansions of the subject POTWs are material and substantial alterations to the permitted facilities that justify different permit conditions. See the 2013 Post Falls fact sheet at Page 22 and the 2013 HARSB fact sheet at Pages 22 – 23).

Antidegradation

Neither Idaho's nor Washington's antidegradation policies require the EPA to limit phosphorus, ammonia, or $CBOD_5$ to prior performance.

Idaho

As stated in the 2013 fact sheets, the antidegradation reviews were conducted as part of the State of Idaho's CWA section 401 certifications. The draft certifications, including the antidegradation reviews, were appended to the 2013 fact sheets as Appendix H. The State of Idaho determined that the permits are consistent with Idaho's antidegradation policy and implementation methods.

IDEQ properly provided Tier 1 antidegradation protection to the Spokane River for aquatic life uses and both Tier 1 and Tier 2 protection for recreation uses. Ammonia and CBOD discharges would not affect the recreation use, so only a Tier 1 analysis was performed for ammonia and CBOD. IDEQ determined that, because the ammonia and CBOD limits in the permits are set at levels that ensure compliance with the narrative and numeric criteria in the Idaho WQS the permits will protect and maintain existing and designated beneficial uses in the Spokane River, thus ensuring compliance with Tier I antidegradation requirements. IDEQ found that the phosphorus limits in the permits meet the Tier 2 requirements under the antidegradation policy because there will be no degradation in water quality, but rather an improvement in TP levels.

The EPA has reviewed Idaho's antidegradation reviews for the subject permit and finds that they are consistent with the state's 401 certification requirements and the state's antidegradation implementation procedures.

Washington

The subject permits can affect water quality in the State of Washington, therefore Washington's antidegradation policy is potentially applicable to the subject permits pursuant to 40 CFR 122.4(d). As explained in Appendix B to each of the 2013 fact sheets, the subject permits are consistent with the Washington's antidegradation policy. With respect to the phosphorus, CBOD, and ammonia limits, the Spokane River and Lake Spokane are 303(d)-listed for DO in the State of Washington. Washington's antidegradation policy states that "for waters that do not meet assigned criteria, or protect existing or designated uses, the department will take appropriate and definitive steps to bring the water quality back into compliance with the water quality standards." As explained in Appendix B to the fact sheets, the subject permits' final effluent limits for TP, $CBOD_5$, and ammonia ensure compliance with Washington's water quality criteria for DO on a cumulative basis.

Other Comments

Comment #2-59

Mr. Dennis Hinrichsen stated that he is troubled that "only cities are being required to meet these standards," and asked why there is "no mandate for near lake developments like Arrow Point who allegedly spilled 20,000 gallons of untreated sewage."

Response #2-59

Alleged previous noncompliance with the Clean Water Act or similar state laws by entities other than those receiving permits cannot affect the permits in question.

Arrow Point Resort (on the east side of Lake Coeur d'Alene) is now connected to the Gozzer Ranch Development/Golf Course's wastewater treatment and disposal system. Arrow Point was formerly on a community drain field. The new system utilizes a membrane bioreactor (MBR) to produce high-quality (Class A) effluent that is seasonally stored in golf course ponds and then used to irrigate the golf course during the growing season.

Comment #2-60

Mr. Gerry House stated that "the water quality in Hayden Lake continues to deteriorate because elected officials and agencies are unable to enforce storm water, site disturbance ordinances….Yet, we seem to focus most of our interest on sewer and sewage treatment plants."

Response #2-60

The subject permits authorize POTWs to discharge treated wastewater to the Spokane River. The Spokane River does not drain to Hayden Lake, and the subject discharges do not affect water quality in Hayden Lake. Water quality problems in Hayden Lake are not relevant to the subject permits.

Comment #2-61

Mr. Clyde Sheppard of the Spokane River Property Owners' Association stated that "we believe the current monitoring by DEQ of all the waste water treatment facilities of one visit per year is not satisfactory."

Response #2-61

The commenter was referring to inspections conducted by Idaho DEQ. The NPDES program is a self-monitoring program. The permits require the dischargers to conduct routine self-monitoring of the discharges and to report the results of this monitoring on a monthly basis to allow EPA and citizens to determine whether the effluent limits and other conditions in the permits are being met. The permits also require the permittees to report all instances of noncompliance with the permits. Inspections may reveal some violations that would not be detected in monitoring reports, but discharges causing water quality violations will show up in the monitoring. The frequency with which a facility is inspected by DEQ or EPA is a separate issue from the reissuance of the permits.

Comment #2-62

Mr. Jim Hollingsworth stated that, although the fact sheets state that the permits protect human health, there is nothing in the draft permits that indicate that human health is at risk and that the only thing that may be affected by the discharge are fish at the lower end of Lake Spokane.

Response #2-62

NPDES permits must contain effluent limits necessary to meet water quality standards. Water quality standards are established in part to protect human health, but also to protect other beneficial uses of the waters such as the growth and propagation of fish, aquatic life and wildlife, aesthetics, and water supply for industry or agriculture. Waters are generally protected for multiple beneficial uses, each of which has water quality criteria that are necessary to support those uses.

For some pollutants, the criteria necessary to support aquatic life uses are more stringent than those necessary to protect human health, e.g., DO, temperature, and certain metals. For other pollutants, the human health criteria are more stringent. For example, the effluent limits for *E. coli* bacteria are based on water quality criteria that protect swimmers from illness, and the monitoring and best management practices for PCBs are intended to reduce the concentration of PCBs in fish tissue, which will minimize the risk of cancer for people who eat fish caught from the Spokane River.

The CWA and NPDES regulations require the TP limits in the subject permits in order to achieve water quality criteria to protect fish and other aquatic life. But human health may also be at risk because of the excess nutrient loading to Lake Spokane. The excess nutrient loading to Lake Spokane has resulted in blue-green algae blooms in the lake (Cusimano 2004). Blue-green algae can be highly toxic to humans, wildlife, and livestock. The toxins in certain kinds of blue-green algae can attack the liver or the nervous system and can cause death in as little as 30 minutes. Blue-green algae are unsightly, so adults are unlikely to drink water contaminated with blue-green algae, but wildlife, livestock, and children may drink not reject contaminated water and could therefore suffer illness or death as a result of the contamination. The toxins in blue-green algae are not removed by boiling the water. Swimming in water contaminated with blue-green algae (even without ingesting any of the water) can cause skin and eye irritation (British Columbia Ministry of Health 2012). Reducing levels of nutrients to the level necessary to meet DO criteria (for aquatic life) will also address the risks to humans, livestock, and wildlife from the algae problem.

Comment #2-63

CFJ stated that the Spokane Tribe of Indians is an "affected State," thus, EPA is required to evaluate the impacts of the Idaho dischargers upon waters of the Spokane Tribe of Indians.

Response #2-63

In developing the draft permits, the EPA did not specifically evaluate the effects of the subject permits upon waters of the Spokane Tribe of Indians. The EPA evaluated the effects of the subject permits as far downstream as the Long Lake Dam, which is at river mile 33.9 on the Spokane River. The permits include conditions that ensure compliance with the water quality standards of the states of Idaho and Washington in Lake Spokane and in the Spokane River upstream from Lake Spokane. Due to additional dilution and continued decay of non-conservative pollutants at points downstream of the Long Lake Dam, the subject discharges will have a lesser impact upon water quality in waters of the Spokane Tribe of Indians than in Lake Spokane and in the Spokane River upstream from Lake Spokane.

The following toxic pollutants have been detected in the effluents of at least one of the subject POTWs:

- Ammonia
- Butylbenzyl Phthalate
- Cadmium
- Chlorine
- Chloroform
- Copper
- Diethyl Phthalate
- Di-N-Butyl Phthalate
- Lead
- Nitrate + Nitrite
- Phenol
- Silver
- Zinc

Idaho's water quality criteria for ammonia, cadmium, chlorine, lead, nitrate + nitrite[17], and silver are at least as stringent as the Spokane Tribe's water quality criteria for these pollutants. Since the permits are conditioned to ensure compliance with Idaho's water quality criteria for these pollutants, they will also ensure compliance with the Spokane Tribe's water quality criteria for these pollutants.

The Spokane Tribe's aquatic life criteria for zinc are more stringent than Idaho's water quality criteria, but are identical to Washington's aquatic life criteria for zinc. As explained in the 2007 fact sheets, the subject POTWs do not have the reasonable potential to cause or contribute to excursions above Washington's water quality criteria for zinc. Thus, the subject POTWs do not have the reasonable

[17] Idaho does not have numeric criteria for nitrate + nitrite, but for the purpose of developing the subject draft permits, the EPA interpreted Idaho's narrative criterion for toxic pollutants using the EPA's recommended criterion of 10 mg/L, which is identical to the Tribe's criterion for primary contact ceremonial and spiritual uses.

potential to cause or contribute to excursions above the Spokane Tribe's aquatic life water quality criteria for zinc. The Spokane Tribe also has human health water quality criteria for zinc that are more stringent than those of Idaho or Washington. However, in all cases, the effluent limits for zinc in the subject permits require lower effluent concentrations of zinc than the Tribe's human health zinc criterion for consumption of water and organisms (470 µg/L).

Butylbenzyl phthalate, diethyl phthalate, di-n-butyl phthalate (or dibutyl phthalate), and phenol were detected in the effluent from Post Falls but not Coeur d'Alene or HARSB. Table 31, below, shows the maximum projected receiving water concentrations of these pollutants from Table 2 on Page D-6 of the 2013 Post Falls fact sheet, as well as the most stringent criterion for these pollutants in the Spokane Tribe's water quality standards. The maximum projected receiving water concentrations are calculated based on the mixing zones authorized by Idaho under critical conditions for river flow, effluent flow, and effluent concentration. These pollutants will be further diluted by the time the Spokane River reaches waters of the Spokane Tribe. In all cases, the maximum projected receiving water concentrations are less than the Spokane Tribe's water quality criteria. Therefore, the Post Falls discharge does not have the reasonable potential to cause or contribute to excursions above the Spokane Tribe's water quality criterion for butylbenzyl phthalate, diethyl phthalate, di-n-butyl phthalate (or dibutyl phthalate), or phenol, even though the Spokane Tribe's criteria for these pollutants are more stringent than Idaho's criteria.

Table 31: Comparison of Maximum Projected Receiving Water Concentrations in Post Falls Reasonable Potential Analysis to Spokane Tribe WQS for Phthalates and Phenol

Pollutant	Maximum Projected Receiving Water Concentration in RPA (µg/L)	Most Stringent Spokane Tribe Criterion (µg/L)
Butylbenzyl phthalate	1.08	38.7
Diethyl phalate	1.08	834
Di-n-butyl phthalate	1.23	86.4
Phenol	6.92	8,060

Chloroform was detected in the effluent from HARSB, but not Coeur d'Alene or Post Falls. In the reasonable potential analysis for HARSB, the maximum projected receiving water concentration of chloroform was 0.22 µg/L (see the 2013 HARSB fact sheet at Page D-5). This is less than the Spokane Tribe's criterion of 1.58 µg/L. Therefore, the HARSB discharge does not have the reasonable potential to cause or contribute to excursions above the Spokane Tribe's water quality criterion for chloroform, even though the Spokane Tribe's criterion is more stringent than Idaho's criterion.

The Spokane Tribe's water quality criteria for copper are more stringent than Idaho's criteria. However, in all cases, the maximum projected receiving water concentrations of copper in the reasonable potential analyses are less than the Tribe's chronic water quality criterion for copper for protection of aquatic life, which is the most stringent copper criterion in the Spokane Tribe's water quality standards. The maximum projected receiving water concentrations are calculated based on the mixing zones authorized by Idaho, under critical conditions for river flow, effluent flow, and effluent concentration. The copper in the subject effluents will be further diluted by the time the Spokane River reaches waters of the Spokane Tribe.

Table 32: Comparison of Maximum Projected Receiving Water Concentrations in Reasonable Potential Analyses to Spokane Tribe WQS for Copper		
POTW	Maximum Projected Receiving Water Concentration in RPA (µg/L)	Spokane Tribe Chronic aquatic life criterion (µg/L)[1]
Coeur d'Alene	0.96	3.05
Post Falls	1.55	
HARSB	0.86	

Notes:
1. The Spokane Tribe's aquatic life water quality criteria for copper are based on the hardness of the receiving water. The chronic criterion listed was calculated at a hardness of 28.4 µg/L, which is the 5th percentile hardness measured at USGS station number 12433000 (Spokane River at Long Lake, WA) from 1998 to 2003. These were the most recent hardness data available at this station.

With respect to nutrients and oxygen-demanding pollution, the effects of upstream nutrients and oxygen-demanding pollution upon the Spokane Arm of Lake Roosevelt are discussed in the *Lake Roosevelt/Spokane River Arm Modeling Project* (Cadmus Group and Scott Wells and Associates 2009). Two of the modeling scenarios described in this report are relevant to the question of whether the subject dischargers significantly impact DO in waters of the Spokane Tribe: scenario 1, which used the draft Spokane River TMDL's modeling predictions as upstream boundary conditions, and set DO concentrations in the Long Lake Dam outflow to 8 mg/L, which is the Spokane Tribe's water quality criterion for the Spokane River, if they were below 8 mg/L, and scenario 3, which used "no source" (i.e. natural conditions) modeling predictions as upstream boundary conditions, and set DO concentrations in the Long Lake Dam outflow to 8 mg/L if they were below 8 mg/L. Thus, the difference between scenarios 1 and 3 represents the effect of anthropogenic sources of nutrients and oxygen-demanding pollution as allocated in the draft TMDL. As explained in Appendix B, the TP, ammonia, and CBOD limits in the subject permits are somewhat different from those assumed in the TMDL modeling, but they have an equivalent impact upon DO in Lake Spokane. As shown in Tables 30 and 31, of the *Lake Roosevelt/Spokane River Arm Modeling Project*, the difference between the average DO concentrations from Scenarios 1 and 3 is 0.13 mg/L for January 1st through October 29th and 0.2 mg/L for July 1st through September 30th. The difference between the average TP concentration between Scenarios 1 and 3 is 3 µg/L for both January 1st through October 29th and July 1st through September 30th. A change of 0.2 mg/L is within the monitoring measurement error for recording instruments typically used to monitor DO (see the enclosure to the letter dated February 11, 2008 approving Washington's water quality standards, from Michael F. Gearheard, EPA Region 10, to Dave Peeler, Washington State Department of Ecology). The subject dischargers represent a small fraction of the total anthropogenic loading of nutrients and oxygen-demanding pollution to Lake Spokane. The DO and TP impacts of the subject POTWs upon waters of the Spokane Tribe, which are just downstream from Lake Spokane and thus subject to additional dilution and continued decay of non-conservative pollutants, will be negligible.

With respect to PCBs, as explained in the response to comment #1-1, the EPA does not have the necessary data to perform a reasonable potential analysis using facility-specific effluent data, as described in Section 3.3 of the TSD. Therefore, a reasonable potential analysis was conducted without facility specific effluent data, as described in Section 3.2 of the TSD. That analysis did not result in a

finding of reasonable potential for PCBs. Therefore, the EPA has not established effluent limits for PCBs in the subject permits.

Comment #2-64

CFJ states that EPA needs to better explain which water quality based effluent limits are based on mixing zones, and the EPA should describe the size of the mixing zones.

Response #2-64

A mixing zone is "an area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where water quality criteria can be exceeded as long as acutely toxic conditions are prevented" (EPA 2010 at page A-10).

This comment was addressed by the revised fact sheets that were issued with the revised draft permits in 2013. Idaho's draft CWA Section 401 certifications, dated June 25, 2013, which were included in the 2013 fact sheets as Appendix H, identified the pollutants for which mixing zones are authorized and the sizes of the mixing zones in terms of the percentages of the critical low flow volumes allowed for mixing. In Table D-1, in Appendix D to the 2013 fact sheets, the EPA listed the dilution factors afforded by the authorized mixing zones. The mixing zone sizes and dilution factors are also listed in the reasonable potential and effluent limit calculation tables in Appendices D and E of the fact sheets.

In some cases, effluent limits based on the anti-backsliding provisions of the Clean Water Act or upon Washington water quality standards were more stringent than the limits that would have resulted from the application of Idaho water quality criteria at the edge of the authorized mixing zones. In those cases, in Appendix C to the 2013 fact sheet, the EPA identified anti-backsliding or the requirement to meet the water quality requirements of all affected States (40 CFR 122.4(d)) as the bases for the limits. In those cases, as a practical matter, less dilution than authorized by Idaho in its draft CWA Section 401 certification is necessary to meet Idaho's water quality criteria.

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From: Chung, Angela [mailto:Chung.Angela@epa.gov]
Sent: Thursday, June 19, 2014 3:55 PM
To: Johnson, Ken
Subject: RE: Environmental Justice

Hi Ken,

Sorry for the delay in responding, its been a busy week. Here are my responses to your questions. Let me know if you'd like to discuss further. Thanks.

1) does EPA read into 40 CFR 131.11 and .21 that there must be a stand-alone EJ review, or does it implicitly occur in the judgment on whether criteria will allow designated uses to be protected?

EPA must ensure that the human health water quality criteria that Washington adopts are protective of applicable designated uses and based on a sound scientific rationale, consistent with 40 CFR § 131.11(a) and .21. EPA does not read these requirements to necessitate the development of a stand-alone EJ analysis in the context of reviewing water quality standards and taking approval or disapproval actions under the Clean Water Act. Consistent with Executive Order 12898, EPA incorporates environmental justice considerations into its decision-making, and has the discretion to complete a stand-alone EJ review for an Agency action.

2) which of the documents listed below offer the current/relevant EPA thinking on how to make whatever EJ assessment is needed?

I recommend that you review the Executive Order 12898 (http://www.epa.gov/environmentaljustice/resources/policy/exec_order_12898.pdf); and EPA's December 2011 EJ Legal Tools document (http://www.epa.gov/compliance/ej/plan-ej/law.html). Section 4-4 of Executive Order 12898 addresses fish consumption and states that the federal agency shall: 1) collect, maintain, and analyze information on subsistence consumption and communicate information to the public; and 2) publish guidance on human health risks related to consumption of pollutant bearing fish and consider the guidance in developing policies and rules. The December 2011 EJ Legal Tools document has a discussion on water quality criteria guidance and water quality standards on pages 24-29.

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HON. ROBERT S. LASNIK

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SIERRA CLUB; and CENTER FOR ENVIRONMENTAL LAW AND POLICY, Plaintiffs, and THE SPOKANE TRIBE OF INDIANS, Plaintiff-Intervenor v. DENNIS McLERRAN; GINA MCCARTHY and U.S. ENVIRONMENTAL PROTECTION AGENCY, Defendants. and SPOKANE COUNTY; KAISER ALUMINUM OF WASHINGTON LLC; and STATE OF WASHINGTON DEPARTMENT OF ECOLOGY, Defendant-Intervenors.	No. 2:11-cv-01759-RSL EPA'S CONSOLIDATED BRIEF (A) IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AND (B) IN OPPOSITION TO PLAINTIFFS' AND INTERVENOR-PLAINTIFF TRIBE OF SPOKANE INDIANS' RESPECTIVE MOTIONS FOR SUMMARY JUDGMENT Filed pursuant to order on briefing schedule Oral Argument Requested

TABLE OF CONTENTS

INTRODUCTION AND SUMMARY

Defendants United States Environmental Protection Agency, et al., (collectively "EPA"), oppose Plaintiffs' and Intervenor Spokane Tribe of Indians' motions for summary judgment and cross-move for summary judgment in EPA's favor.

The Washington State Department of Ecology ("Ecology") has a robust program establishing total maximum daily loads ("TMDLs") throughout Washington State. Over the past fifteen years, Ecology has established hundreds of TMDLs, and it is continuing to develop others for waterbody segments that do not meet water quality standards, including many within the Spokane River Basin. Notwithstanding such ongoing TMDL work, because many TMDLs remain to be completed, Ecology has had to make necessarily difficult choices regarding the priority and timing of which TMDLs will be developed before others, how to allocate limited resources among competing environmental demands, and the establishment of interim, supplemental steps to reduce pollution until required TMDLs are completed. Among its many prioritization decisions, Ecology determined that a TMDL for polychlorinated biphenyls ("PCBs") for the Spokane River should be a lower priority, primarily due to the lack of critical information and analysis, and that Ecology will devote its efforts and resources in the interim to reduce PCBs in the River through a Task Force created for this purpose comprised of State and local agencies, dischargers of pollutants, and environmental groups created for this purpose. If these or other supplemental measures are not enough for the Spokane River to attain applicable PCB standards, Ecology has committed to develop a Spokane River PCB TMDL. Based upon EPA's review of Ecology's plans and the rest of the record in this case, EPA reasonably concluded that Ecology has not renounced its obligation to develop and establish a Spokane River PCB TMDL and that the absence of such a State-submitted TMDL at this time does not constitute Ecology having constructively submitted "no" PCB TMDL (i.e., a State determination that none will be needed). Accordingly, the Clean Water Act ("CWA") does not require that EPA approve or disapprove such a constructive submission.

Plaintiffs and the Spokane Tribe invoke the constructive submission theory in an effort to

circumvent and undermine this and other ongoing State decisions as to how best to protect the environment. By demanding a PCB TMDL for the Spokane River, which Plaintiffs and the Tribe believe should be prioritized before all other TMDLs and other State efforts to reduce pollution, and by seeking a court order that EPA establish that particular TMDL, Plaintiffs and the Tribe ask the Court to usurp Ecology's role and substitute their own priorities for the State's reasonable pollution prevention and remediation plans. Plaintiffs and Intervenor are understandably focused on concerns posed by PCBs in the Spokane River. There are, however, other, ongoing efforts to reduce PCBs and other pollutants in the Spokane River and in numerous other impaired water-bodies throughout the State that also require the attention of limited State and federal resources.

Section I.A below demonstrates that as a matter of law the constructive submission theory is not applicable where, as here, parties seek to compel the establishment of one particular TMDL above all others, and that such claims must therefore be dismissed and summary judgment entered for EPA. Section I.B explains that Plaintiffs have waived their right to challenge EPA's administrative finding that there has been no constructive submission, because they elected not to brief that Administrative Procedure Act challenge in their summary judgment motion. Section I.C demonstrates that EPA reasonably concluded that Ecology has not disavowed establishing a PCB TMDL for the Spokane River, that Ecology has a reasonable plan for reducing PCBs in the Spokane River and obtaining needed information, and that Ecology remains committed to developing a TMDL if necessary. Ecology, therefore, has not made a constructive submission, and thus EPA has no duty to approve or disapprove such a submission. Section II responds to the arguments proffered by Intervenor Spokane Tribe. Finally, Section III demonstrates that even if there is a constructive submission, Plaintiffs and the Tribe are not entitled to the relief they seek.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

The Clean Water Act establishes a comprehensive program "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters" through the reduction and eventual elimination of the discharge of pollutants into those waters. 33 U.S.C. § 1251(a). States

are primarily responsible for achieving these goals. *Id.* § 1251(b); *Chevron U.S.A. v. Hammond*, 726 F.2d 483, 489 (9th Cir. 1984) ("[T]he states maintain primary responsibility for abating pollution in their jurisdictions."); *District of Columbia v. Schramm*, 631 F.2d 854, 860 (D.C. Cir. 1980) (the CWA "scheme . . . impose[s] major responsibility for control of pollution on the states"). State lists of water quality limited segments ("WQLS") within their boundaries ("Section 303(d) lists") and Total Maximum Daily Loads ("TMDLs") are but one part of the complex water pollution control regime created by the CWA.

A. The NPDES Permit Program

The CWA's central regulatory features are established by the National Pollutant Discharge Elimination System ("NPDES") permit program. 33 U.S.C. § 1342(a)(1); 40 C.F.R. §122.44(a), (d)(1). Pollutant discharges from point sources[1]/ into waters of the United States are prohibited unless in compliance with specified sections of the CWA. 33 U.S.C. § 1311(a). If the conditions of a permit are violated, they may be enforced by the United States, or any interested person, including a State. *Id.* § 1319. Forty-six States, including Washington, are authorized to administer NPDES permit programs under their State laws and regulations, though EPA retains an oversight role. *Id.* § 1342(b). In the remaining States, EPA issues the permits. *Id.* § 1342(a). EPA first approved Washington's NPDES permitting program in 1973. 54 Fed. Reg. 40517 (Oct. 2, 1989).

NPDES permits control water pollution from point sources by means of two different overarching strategies. The first approach, the "technology-based" approach, reduces pollution by requiring dischargers to achieve specified restrictions on the quantities, rates, and concentrations (known as "effluent limitations") based on specific process-based controls. 33 U.S.C. §§ 1311, 1314, 1316-17, 1363(11). The CWA requires EPA to develop and promulgate national technology-based regulations establishing minimum levels of wastewater treatment for categories of industrial sources. *Rybachek v. EPA*, 904 F.2d 1276, 1283 (9th Cir. 1990). During the 1970s

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[1]/ A "point source" is defined as "any discernible, confined and discrete conveyance ... from which pollutants are or may be discharged." *Id.* § 1362(14) (*e.g.*, industrial, commercial and municipal discharges). This statutory definition excludes "agricultural stormwater discharges and return flows from irrigated agriculture." *Id.* § 1362(14). The term "nonpoint source" commonly refers to any source of water pollution that is not a point source and is typically associated with diffuse sources and rural areas.

and 1980s, EPA gave priority to developing the new technology-based regulations, which EPA and the states implemented through the new NPDES permit program. Because of the magnitude and scope of the national water pollution control task, and consistent with stated Congressional intent, EPA and the States dedicated implementation resources to developing these technology-based controls and basic programs, deferring action on the next level of controls based on water quality standards. *See* 1A *Leg. History of the Water Pollution Control Act Amendments of 1972* (Comm. Print 1973), at 171. Accordingly, EPA has issued technology-based regulations for more than 50 major categories of industrial dischargers. 40 C.F.R. Pts. 405-471. After establishment of NPDES permitting programs, including technology-based controls, regulatory efforts focused on the difficult task of determining the desired water quality for each waterbody and establishing effluent limits based upon such standards.

B. Water-Quality-Based Controls

The CWA is designed to ensure that water quality standards would be attained even if technology-based controls were insufficient to do so. CWA § 303 directs the States, with federal approval and oversight, to adopt water quality standards for each particular waterbody or waterbody segment within their boundaries. 33 U.S.C. § 1313(a), (b) & (c)(1). Water quality standards identify (1) the "designated uses" for each waterbody (e.g., public water supply, propagation of fish, and/or recreational uses) and (2) the "water quality criteria" expressed as levels (e.g., concentrations and/or conditions) that must not be exceeded in order for the waterbody to support those uses (e.g., oxygen concentrations necessary for healthy fish). *Id.* § 1313(c)(2). EPA either approves a State's proposed water quality standards or, if it disapproves, proposes and promulgates standards for the State. *Id.* § 1313(c)(3).

After adoption and approval of water quality standards, CWA section 303(d) directs the States to identify and prioritize the impaired or threatened waters within their borders, known as water-quality-limited segments ("WQLSs"). *Id.* § 1313(d)(1)(A) & (B); 40 C.F.R. § 130.7(b)(1). States are then to develop plans, known as total maximum daily loads ("TMDLs") for pollutants in those WQLSs. 33 U.S.C. § 1313(d).

CWA § 303(d)(2) requires that each State submit "from time to time" its list of WQLSs. *Id.* § 1313(d)(2). EPA's regulations specify that the States submit their lists of WQLSs (the "Section 303(d) list") to EPA on a biennial basis. 40 C.F.R. § 130.7(d). EPA must approve or disapprove Section 303(d) lists within 30 days after submission. 33 U.S.C. § 1313(d)(2). If EPA disapproves, it must identify the WQLSs to be added within 30 days from the date of disapproval. *Id*. Although States submit their priority rankings of WQLSs for TMDL development with their Section 303(d) lists, EPA does not approve or disapprove the substance of these rankings. *Id.* Moreover, if a WQLS on a 303(d) list subsequently achieves the water quality standard for which it is impaired, it may be removed from the next Section 303(d) list and thus a TMDL is no longer required. 40 C.F.R. §§ 131.7(b)(1) & 130.2(j).

States are required to establish a priority ranking for TMDL development for WQLSs included on the Section 303(d) list. 33 U.S.C. § 1313(d)(1)(A). In establishing priority ranking, States must consider the severity of the pollution and the uses of the listed waterbody. *Id.* § 1313(d)(1)(A). Beyond these two statutory factors, States retain considerable discretion and may consider other factors, including: vulnerability of particular waters; recreational, economic, and aesthetic importance of particular waters; restoration potential; degree of public interest and support; State or national policies and priorities; technical considerations, such as the complexity of the impairment; availability of adequate data and models; and implementation of watershed-based permitting programs or basin planning cycles. *See* V.1, T.47 at 971-72; V.1, T.19 at 242.[2]/

States identify those WQLSs targeted for TMDL development in the next two years. 40 C.F.R § 130.7(b)(4) & (d)(1). States have discretion in selecting higher and lower ranked waters for TMDL development based on the numerous factors described above.

TMDL development requires States to identify the maximum amount of pollutant

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[2]/ The administrative record for judicial review in this case was filed on April 22, 2013, in paper form, in five binders (or volumes), as well on a compact disc. Dkt. No. 60. References in this brief to that record are to the volume and document number (or tab), cited as "V._, T._, at __." Page numbers are to the bate-stamped number, except as indicated. Documents supplementing the Court's review were filed September 17, 2013, Dkt. 79, and are bate-stamped beginning with "Supp." Some exhibits to Plaintiffs' brief attach only selected pages from the record, with Plaintiffs' underlining that is not in the record.

"loading", *i.e.*, quantity of a particular pollutant that the WQLS can receive from all combined sources and still meet the relevant water quality standard for a pollutant. 33 U.S.C. § 1313(d)(1)(C); 40 C.F.R. § 130.2(e). Each TMDL must, among other things: (1) be designed to meet water quality standards; (2) include, as appropriate, both wasteload allocations from point sources and load allocations from non-point sources; (3) consider the impacts of background pollutant contributions; (4) consider seasonal variations; (5) include a margin of safety; and (6) be subject to public participation. *Id.* §§ 130.7, 130.7(c)(1), 130.2(g)-(i). Developing a TMDL often requires a significant amount of work, and may take years once initiated depending, among other things, upon the information and studies required. Once a State submits a TMDL to EPA, the CWA requires that EPA approve or disapprove that TMDL within 30 days of its submittal by the State, and if EPA disapproves a particular TMDL, EPA must establish a federal TMDL for the WQLS within 30 days of the Agency's disapproval. 33 U.S.C. § 1313(d)(2).

The CWA does not requires States to develop and submit TMDLs to EPA on any particular schedule, requiring instead that States submit TMDLs to EPA "from time to time." *Id.* § 1313(d)(2). In 1997 Guidance, EPA recommended that States normally plan to establish TMDLs for all WQLSs on their 1998 Section 303(d) lists and subsequent lists within eight to thirteen years of initial listing, but recognized that shorter or longer times may be needed depending on State-specific factors.[3]/ These factors may include: number of impaired segments; length of river miles, lakes or other bodies for which TMDLs are needed; proximity of list waters to each other within a watershed; number and relative complexity of TMDLs; number and similarities or differences among the source categories to be allocated; availability of monitoring data or models; and relative significance of the environmental harm or threat. *Id*.

Importantly, TMDLs function primarily as planning devices and are not self-executing. *Pronsolino v. Nastri*, 291 F.3d 1123, 1129 (9th Cir. 2002). A TMDL does not, by itself, prohibit any conduct or require any actions. Instead, each TMDL represents a goal that may be

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[3]/ *See* http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/upload/2003_10_21_tmdl_ratepace 1997guid.pdf (at p.3). Though not part of the administrative record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

implemented by adjusting pollutant discharge requirements in individual NPDES permits and/or by establishing nonpoint source controls. *Sierra Club v. Meiburg*, 296 F.3d 1021, 1025 (11th Cir. 2002). Thus, TMDLs form the basis for further State actions that may require or prohibit conduct with respect to particularized pollutant discharges. Regardless of whether a TMDL has been established, States must include effluent limits as stringent as necessary to meet water quality standards in NPDES permits. 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A).

Where a TMDL has been established for a WQLS, the TMDL may provide allocation information for individual NPDES permits for point sources and/or establish goals for non-point source controls. The absence of TMDLs does not prevent NPDES permitting authorities from otherwise assuring that point source discharges do not cause or contribute to exceedances of water quality standards. *See* 43 Fed. Reg. 60,662, 60,665 (Dec. 28, 1978). EPA guidance to permitting agencies explains how to derive water-quality-based permit limits, both prior to establishment of a TMDL and consistent with any applicable TMDL once established.[4/] Where a TMDL has not been established, EPA's guidance recommends that the permit writer establish as part of the process to develop a specific NPDES permit, a facility-specific allocation, sometimes referred to in this context as a discharge-specific concentration allowance. Manual at 6-31--6-35. In this process, the more current and reliable the underlying information, the more effective and defensible the allocation. *See id.* at 6-30--6-31. Where numeric effluent limitations are infeasible to calculate, NPDES permits may include best management practices. 40 C.F.R. § 122.44(k)(3).

C. The Constructive Submission Theory

The CWA requires that EPA approve or disapprove a TMDL within 30 days of its submittal by the State, and if EPA disapproves, EPA must establish a federal TMDL for the WQLS at issue within 30 days of disapproval. 33 U.S.C. § 1313(d)(2). On its face, however, the CWA imposes no duty for EPA to establish TMDLs if a State fails to establish and submit them to

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[4/] [NPDES] Permit Writers' Manual, EPA-833-K-10-001 (2010) ("Manual"), Ch. 6, 6-30–6-35 (available at: http://cfpub.epa.gov/npdes/writermanual.cfm?program_id=45). Though not part of the administrative record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

EPA. In the past, many States were not able to develop any TMDLs while implementing technology-based approaches to address water pollution. Because a State's refusal to submit any TMDLs over a prolonged period of time could frustrate the TMDL program, some courts adopted what came to be known as the "constructive submission" theory. The theory holds that the prolonged failure by a State to submit *any* TMDLs may constitute the "constructive" submission of no TMDLs (*i.e.*, that none are necessary), which submission EPA must approve or disapprove. *San Francisco Baykeeper v. Whitman*, 297 F.3d 877, 881 (9th Cir. 2002). If EPA disapproves such a constructive submission, this triggers the requirement that EPA establish TMDLs for the State.

D. Judicial Review Under the Clean Water Act

The CWA jurisdictional scheme restricts the types of claims that can be brought against EPA. The citizen suit provision allows suits to be brought in district court against the "the Administrator [of EPA] where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator." 33 U.S.C. § 1365(a)(2). Such citizen suit claims are available only where Congress has imposed a clear-cut, mandatory duty for EPA to act in the statute. *Infra* at 26, n.12. The reasonableness of the content of EPA's action or prospective action, however, cannot be dictated or reviewed by the Court under the citizen suit provision. *Scott v. City of Hammond, Ind.*, 741 F.2d 992, 995 (7th Cir. 1984).

In contrast, content-based review of certain EPA final actions, not at issue here, is available under the CWA exclusively in the U.S. Courts of Appeal. 33 U.S.C. § 1259(b)(1). Review of other "final agency actions" not covered by that Section is based upon the Administrative Procedure Act, in federal district court, under the APA's arbitrary, capricious or not in accordance with law standard of review. 5 U.S.C. § 706(2)(A).

NPDES permit decisions by Ecology are reviewed in the appropriate State tribunals.

II. FACTUAL BACKGROUND

A. The Development of Washington's Section 303(d) Program

Ecology's first Section 303(d) list was prepared in 1992. The 1996 Section 303(d) list had

666 WQLS listed. Ecology subsequently submitted, and EPA approved, 303(d) lists in 1998, 2004, 2008, and 2010. See V.1, T.16 & 21; V.2, D.40. As Ecology has continued to monitor the numerous waterbody segments throughout Washington, it has added additional WQLS to its 303(d) lists. Ecology's 2010 303(d) list, which EPA approved on December 21 2012, contains 4009 WQLSs for TMDL development. V.2, D.40 at 672..

In 1998, after two environmental groups filed a lawsuit in this Court, EPA entered into an out-of-court settlement agreement by which Ecology would complete a large number of TMDLs by December 31, 2013. The agreement provides that EPA would complete the TMDLs, if Ecology failed to do so. V.1, D.32 at 446-447. Ecology has since devoted significant resources to TMDL development. Since 1999, Ecology has completed 1372 TMDLs. V.1, T.A, at 1 n.1; V.1, D.16 at 220. Ecology is currently working on the development of TMDLs in 23 sub-watersheds throughout the State for numerous pollutants, including temperature, dissolved oxygen, bacteria, and pH. The Administrative Record in this case amply documents Ecology's TMDL output and its continued commitment to develop TMDLs. *E.g.*, V.1, T.A, 3, 5, 6, 8-14, 16-17 & 19-29.

Four segments of the Spokane River and one tributary (called the Little Spokane River) were first listed for PCBs on its 1996 Section 303(d) list. Dkt. 79, at Supp. 2710 & 2732. Over the years, as Ecology continued to gather information, the numbers of segments and parameters for the Spokane watershed continued to increase. There are currently 15 waterbody segments of the Spokane exceeding standards for PCBs. V.1, D.15 at 80. Ecology spent over 12 years completing work on dissolved oxygen TMDLs that addressed elevated levels of phosphorus, ammonia and CBOD (carbonaceous biochemical oxygen demand) in the Spokane River. V.1, D.4 at 503. EPA approved these nine Spokane River and Lake Spokane Dissolved Oxygen TMDLs in May 2010. V.1, D.17 at 000224. Ecology also developed 23 TMDLs for waters impaired by temperature, bacteria and turbidity in a major tributary to the Spokane River, Hangman (Latah) Creek. EPA approved these TMDLs in September 2009. *Id.* at 222-23. Ecology also developed 36 TMDLs for waters impaired by temperature, bacteria and turbidity in the Little Spokane River. EPA approved

these TMDLs in April, 2012.[5]/ In 1999, Ecology developed, and EPA approved, five TMDLs for cadmium, lead, and zinc in the Spokane watershed. *See* V.1, T.15 at 82. Ecology is currently working on an additional TMDL to address the dissolved oxygen and pH impairments on the Little Spokane River. Even with these TMDLs, the Spokane watershed remains impaired for temperature, fecal coliform, and dioxin, as well as PCBs.

B. Ecology's Preliminary Work on a PCB TMDL for the Spokane River

1. The Nature of PCB Pollution

PCBs were first produced for commercial use in 1929 and have been used for hundreds of purposes. Production continued until a 1979 ban on all PCB manufacturing, processing, and distribution due to evidence that PCBs build up in the environment and concerns about possible human carcinogenicity. V.1, T.15 at 91. PCBs are released into the environment through improper disposal or leakage. *Id.* Even after their release, PCBs do not break down readily in the environment and can bioaccumulate. *Id.* at 92. Many of the same properties that made PCBs commercially desirable - their stability and resistance to degradation - make them extremely persistent in the environment. *Id.* at 92. Thus, in important respects, PCBs are a legacy pollutant.

Washington State's water quality standards include a human health criterion for PCBs at 170 picograms per liter ("pg/l"). V.1, T.15 at 83-84. When this lawsuit was filed, the Spokane Tribe water quality standard included a PCB human health criterion set at 3.37 pg/l. *Id.* at 83.[6]/ Based on elevated levels of PCBs and other pollutants in Spokane River fish, the Washington Department of Health and the Spokane Regional Health District issued an advisory in 2003, updated in 2008, to avoid or limit consumption of fish in parts of the Spokane River. *Id.* at 97.

Though PCBs can pose significant environmental concerns, they are one of many pollutants that demand attention within Washington's waterways. As discussed above, numerous

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[5]/ *See* http://www.ecy.wa.gov/programs/wq/tmdl/littlespokane/ (EPA's April 2012 approval is available by clicking the link in next to last paragraph of this page). Though not part of the record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

[6]/ EPA recently approved, on December 19, 2013, a revised Tribal criterion set at 1.3 pg/l.

WQLSs continue to require attention, and Ecology continues to prioritize this task consistent with its assessment of the environmental benefits that would be realized and the resources available.

2. Ecology's Efforts to Obtain Information Necessary for a Spokane River PCB TMDL

While devoting significant resources to investigations supporting TMDL development for numerous WQLSs on its 303(d) lists, Ecology also conducted preliminary investigations into PCBs and the Spokane River. For example, Ecology's environmental assessment program identified numerous ongoing projects to which it intended to commit resources in Fiscal Year 2003, including TMDL development. V.5, T.105. Among many TMDL projects, Ecology explained that it was initiating certain preliminary work for potential use in developing a PCB TMDL in the Spokane River, pertaining to the "numerous variables [that] present sampling and analytical difficulties in developing predictive models of PCB behavior in the environment." *Id.* at 002426. This would "develop a sampling and monitoring strategy for gathering information to understand PCB dynamics in wastewaters, sediment, surface waters, and fish tissue from the Spokane River." *Id.*

By June of 2006, Ecology had prepared a document titled "Spokane River PCBs Total Maximum Daily Load[:] Water Quality Improvement Plan." V.3, T.90, at 1319-1645. This document includes the header "Draft – 6-19-06 – Do not cite or quote," *id.* at 1319, and was submitted for inclusion in the administrative record in this case by Plaintiffs. *See* V.1, T.B & C. Although this draft document focused on portions of the Spokane River administered by Washington, Ecology used the more stringent PCB water quality standard adopted by the Spokane Tribe as the basis for any such potential TMDL. V.3, D.90 at 1331. Although this document included, in preliminary draft form, some elements of a proposed TMDL, it failed to include critical information in numerous areas, primarily because more investigation remained necessary. For example, in a section titled "What Needs to be Done?," *id.* at 1419, the draft document explains that "PCB Source Identification" must occur in numerous significant areas. *Id.* The draft document states that stormwater discharges contribute significantly to PCBs in the Spokane River

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(55 percent of known source categories). The draft explained, however, that particular sources of PCBs in stormwater are not generally known and thus could not be targeted for reduction, *id.* at 1419-21, and that the stormwater data available was not reliable.[7]/ The draft document stated that "more thorough sampling needs to be conducted in this first step in this process," *id.* at 1419, explaining that "PCB source identification begins with determining how the PCBs have entered the storm drains and if ongoing sources exist." *Id.* at 1420. The draft explained the similar need to identify PCB sources within the sanitary sewer system. *Id.* at 1421.

Another example of critical, missing information involves the fact that "[t]he Spokane River at Stateline [the Idaho/Washington border] contributes about 25 percent of the PCB load to the system." *Id.* The draft document explains that "data needs to be gathered on the potential sources of PCBs (e.g, point sources, stormwater, contaminated and/or potential contaminated sites) in the Idaho portion of the Spokane River." *Id.* A similar need exists to identify PCB sources from watersheds draining to the Little Spokane River, which enters the Spokane River. *Id.*

Finally, the 2006 draft document identified the total daily loading of PCBs into the relevant reach of the Spokane River (3,664 mg/d), V.3, D.90 at 1401, but failed to identify PCB sources or otherwise account for nearly half (46.3%) of that daily loading. *Id.*[8]/ Thus the 2006 draft document does not account for 46.3% of the PCB loading, in addition to the lack of information described above regarding PCB loading from the Spokane stormwater, the Spokane sanitary sewer, the Stateline border, and the Little Spokane River source categories. Because of the limited information available and inability to assign reductions to unknown sources, the draft document suggested that for the known categories of PCB sources very aggressive reductions could be necessary for the known catagories of PCB sources, in some cases exceeding 99%. *Id.* at 1402-03.

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[7]/ *See id.; also id.* at 1413 (*"*Stormwater from Spokane has the potential to deliver large PCB loads to the river (1,100 mg/d) and may account for a significant portion of loading from exogenous sources. However, stormwater sampling was limited and since data had not been previously collected from this source in the Spokane River basin, the representativeness of those data is uncertain.")

[8]/ The chart at 1401 (V.3, T.90) shows a total daily PCB load of 3,664 mg/d, but identifies sources totaling only 1968.9 mg/d, which includes the loading of 477 mg/d at the Idaho border. Thus the 2006 draft document fails to identify sources or categories of sources or otherwise account for 46.3% of the PCB loading.

The draft document contemplated that some of the missing information and analysis may be included in a separate, future document to be developed by Ecology that would be called a "Water Quality Implementation Plan." *Id.* at 1417-21. The draft did not suggest a strategy to identify the sources or otherwise account for the very high percentage of unidentified PCB loading to the River.

Ultimately, given the significant information gaps about PCB occurrences and sources in the Spokane River, Ecology recognized that considerable new studies and analyses would be necessary before a PCB TMDL for the Spokane River could be completed. *See, e.g.*, V.1, T.14A at 503; *infra* at 16-17 (Ecology's decision not to prioritize the completion of the PCB TMDL). Thus the State did not issue the 2006 draft document for the public notice and comment that would be required for any proposed TMDL prior to deeming it complete for submission to EPA.[9]/ Rather, Ecology initiated additional investigations regarding PCBs in the Spokane River. For example, to better understand the role of stormwater and obtain more reliable data, the State conducted a study "to refine PCB loading estimates to the Spokane River from the City of Spokane's stormwater drainage system" and, as "[a] secondary goal . . . to begin PCB source identification for future mitigation efforts," and issued a report in 2007 based on its findings.[10]/

Thereafter, the State further sought to identify other information gaps and the means to close those gaps. One 2009 draft document, entitled "Draft Spokane River PCBs TMDL: Volume 1. Water Quality Study Findings," which also includes the header "DRAFT – 7-09 – Do not cite or quote," V.3, T.69 at 1102, was submitted to EPA by Plaintiffs for inclusion in the administrative record in this case. V.1, T.B &C. This draft document is not a draft TMDL – it does not, for

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[9]/ Although some Ecology reports suggest that Ecology submitted a proposed Spokane River PCB TMDL for the public notice and comment required before it could be finalized, V.2, T.42 at 705; V.1, T.14 at 503, EPA believes that this statement is in error. The administrative record in this case does not contain any such proposal, public notice, public comments nor Ecology responses to comments from such a process, and EPA has no record that it ever occurred.

[10]/ *See* Spokane River PCB TMDL Stormwater Loading Analysis Final Technical Report, at v. (abstract) (December 2007). Although not included in the administrative record in this case, this report is available on the State's web site, https://fortress.wa.gov/ecy/publications/publications/0703055.pdf, and the Court may take judicial notice of it for the purpose for which it is introduced.

example, contain proposed load allocations for sources. Rather, as its subtitle indicates, it is a draft technical study that could be used in developing a future draft TMDL V.2, T.68 at 1217 ("This project constitutes a technical water quality study to support TMDL development for PCB contaminants in the Spokane River."); *also id.* at 1121-21.

In part to better reflect this draft document's contents, and the fact that it was not itself a draft TMDL, in 2011 Ecology issued this report, in modified and final form, titled "Spokane River PCB Source Assessment 2003-2007." V.1, T.15 at 63-216. Although this 2011 report indicates progress in addressing some information gaps and data reliability issues in some areas, *see* V.5, T132 at 2675, it did not, among other things, identify or otherwise account for the large unknown sources of PCB loadings into the relevant reach of the Spokane River. For example, of the total daily PCB loading of 3,664 mg into the River, only a total loading of 1571 mg/day from seven categories of sources were identified, including 477 mg/day at the Stateline. V.1, T.15 at 163. Based upon its updated data, this 2011 report could not account for 57% of the PCB loading in the relevant reach of the River. The 2009 precursor draft also lacks this information. V.3, T.69 at 1205.

C. Ongoing State Efforts to Reduce PCBs and Other Toxics in the Spokane River

Ecology has worked to reduce PCBs in the Spokane River while investigating PCBs and their sources for a potential PCB TMDL. Ecology has utilized available information and taken significant steps to reduce and cleanup toxics in or that may enter the River, including PCBs. For example, as detailed in Ecology's 2012 Spokane River Toxics Reduction Strategy, V.2, T.42, Ecology in 2007 provided oversight as contractors removed PCB-contaminated soil from Donkey Island in the Spokane River. *Id.* at 701. Prior to that, Ecology directed contractors in 2006 to cap over PCB-contaminated sediments on the river bottom near the Upriver Dam. *Id.* PCBs at several other sites have either been cleaned up or are undergoing required investigation of appropriate remedial options pursuant to the State's cleanup laws to address past pollution. *Id.* at 701-2; V.2, T.68, at 1091-93. In addition to these cleanup efforts focused on PCBs, the 2012 Spokane River Toxics Reduction Strategy details the State's ongoing efforts to reduce other toxics in the Spokane

River, such as dioxins and furans, metals such as arsenic, cadmium, lead and zinc, and pharmaceuticals and personal care products. *Id.* at 692-95 & 697-712.

Ecology has also worked closely with the City of Spokane, which in 2011 entered into a settlement agreement with the Spokane Riverkeeper to develop an adaptive management plan for reducing PCB discharges from Spokane's stormwater as much as possible, by:

> 1. Analyzing, organizing, and interpreting existing PCB sampling data as it relates to the City's stormwater NPDES permit.
> 2. Identifying likely sources of PCBs and prioritizing appropriate remedial actions to be accomplished and best management practices to be followed.
> 3. Developing and designing an adaptive approach for additional data collection and additional remedial actions that further reduce PCBs within the City and in the Spokane River for the long term.

Id. at 707-708.

In addition, in 2011, the Department of Ecology, together with PCB dischargers in the Spokane River Basin, conservation and environmental groups, local and regional government agencies, EPA, and other interested parties created the Spokane River Regional Toxics Task Force ("Task Force"). V.1, T.4, at 14. The final January 23, 2012, Memorandum of Agreement establishing the Task Force explains that its "goal . . . will be to develop a comprehensive plan to bring the Spokane River into compliance with applicable quality standards for PCBs." *Id.* This includes the more stringent PCB water quality standard adopted by the Spokane Tribe. *Id.* at 15. To accomplish that goal, the Task Force's functions include:

> – Identify data gaps and collect necessary data on PCBs and other toxics . . . for the Spokane River
>
> – Further analyze the existing and future data to better characterize the amounts, sources and locations of PCBs and other toxics as defined above entering the Spokane River.
>
> – Prepare recommendations for controlling and reducing the sources of listed toxics in the Spokane River.
>
> – Review Toxic Management Plans, Source Management Plans, and BMPs [Best Management Practices].
>
> – Monitor and assess the effectiveness of toxic reduction measures. . . .

Id. at 14.

Members of the Task Force include the Washington Departments of Ecology and Health, the City of Spokane, Spokane County, and the Spokane Regional Health District, the Lake Spokane Association, the Spokane Riverkeeper, the Lands Council, Kaiser Aluminum Washington, LLC, and the Inland Empire Paper Co. *Id.* at 30-40. EPA has also committed its support for and participation in the Task Force. V.1, T.7. All holders of Washington NPDES permits that may discharge PCBs into the Spokane River are required, as a condition of their permit, to participate in the Task Force. *See, e.g.*, V.2, T.45, at 845. The Spokane Tribe was invited to join the Task Force. Although it initially supported the Task Force and its efforts, V.3, T.89 at 1317, it ultimately elected not to participate in it. Plaintiffs in this case also elected not to participate in the Task Force.

The first draft work plan of the Task Force, adopted October 24, 2012, explains in detail specific work plan elements for the years 2012 through 2016, which include "Work Plan Element 1 – Data review, data gap evaluation, analysis, and implementation plan," V.2, T.41 at 679-81 (emphasis in orig.), and "Work Plan Element 5 – Develop strategy for reduction of point sources and non-point sources of PCBs," *id.* at 683-84 (emphasis in org.). The Task Force's documents its monthly activities and other information regarding its operation on its web site (www.srrttf.org). Thus, the Task Force works to identify PCB sources and to develop strategies for reducing PCBs.

Current PCB concentrations in fish tissue are lower than they have been historically. Between 1996 and 2005 there has been a significant decrease in the PCB levels in Mountain Whitefish and Rainbow Trout in the Spokane River. V.1, D.15 at 152-53.

D. Ecology's Decision to Defer Continued Development of a Spokane River PCB TMDL for Submission to EPA at This Time

Ecology has determined not to continue to devote its limited resources for the development and completion of a PCB TMDL for the Spokane River at this time. Ecology's reasons for deferring completion of the TMDL are documented in the administrative record in this case. As an initial matter, Ecology has a robust TMDL program, and Ecology is continuing to devote its limited resources to the development of other TMDLs, both within the Spokane Basin Watershed

and in other water-quality-limited segments throughout the State. *See supra* at 9-10. Against this backdrop, Ecology explained several specific reasons for deferring a PCB TMDL at this time. First, there are significant data gaps that precluded it from completing a TMDL at this time, with much work remaining. *See, e.g.*, V.1, T.A at pp 3-4; V.2, T.42 at 705; V.1, T.15 at 173 & V.1, T.35 at 481-83 (data to be obtained). In this regard, Ecology employee Jim Bellatty, testifying on behalf of Ecology in 2013 before the Washington State Pollution Control Hearings Board, explained that Ecology's draft PCB TMDL could not be finalized because sources for 57% of the PCB loading in the relevant reach of the Spokane River have not been identified. V.5, T.132, at 2671-72 & 2683. In light of key gaps in information, Ecology is concerned that any TMDL at this time would be highly uncertain, inequitable, and impracticable. *Id.* at 7671 & 2683. In addition, Ecology had recently devoted a great deal of its resources, spanning 12-years, in a difficult process to complete in 2010 a dissolved oxygen TMDL for the Spokane River. V.1, D.4 at 503; V.5, T132 at 2671-72. In light of that experience, Ecology was concerned that, given the significant information gaps for PCBs, and absent a cooperative approach, the continued development to finalization of a PCB TMDL at this time would suffer lengthy delays and expend considerable resources, without resulting in timely environmental benefits. *Id.; also* V.1, T.A at p.4. At the same time, Ecology was aware that community support exists for it to make as much direct progress as possible to reduce PCBs through its Task Force (described *supra*), rather than to delay such potential progress until after a TMDL is completed. V.2, T.42 at 706; V.1, T.1.

Ecology has also made clear that the Task Force's work is not in lieu of development of a Spokane River PCB TMDL. V.1, T.1, at 2. The Task Force serves as a measure designed to obtain critical information about PCBs and their sources in the Spokane River and to implement strategies that can obtain near-term PCB reductions where possible. *Supra* at 15-16; V.1, T.35. Ecology expressly recognized that it would still be obliged to complete a PCB TMDL for the Spokane River if the Task Force or other measures fail to achieve applicable water quality standards. V.2, T.44 at 706 ("a PCB TMDL still remains a tool and will be necessary if ongoing toxics reduction strategies do not result in compliance with water quality standards.").

E. EPA's April 12, 2013, Letter Determining That Ecology Has Not Renounced Establishing a Spokane River PCB TMDL If One Is Required and That EPA Is Therefore Not Required to Establish Such a TMDL Under Plaintiffs' Constructive Submission Theory

Plaintiffs' original, one-count Complaint in this action (Dkt. No. 1, ¶¶ 23-26) alleged that Ecology's failure to finalize a PCB TMDL for the Spokane River constitutes its intent to never complete such a TMDL and thus the constructive submission of no PCB TMDL, the disapproval of which by EPA would create a mandatory duty under the CWA citizen suit provision for EPA to establish a PCB TMDL for the Spokane River. On November 6, 2012, this Court held that review in this case is limited to the administrative record. Dkt. No. 49. Thereafter, in December 2012, Plaintiffs submitted two letters to EPA, attaching numerous documents not in EPA's administrative record, for EPA to review administratively. V.1, T.B & C. These documents included several internal Ecology draft documents, many of which are described above. Based on these documents, Plaintiffs contend that Ecology has disavowed submitting an actual PCB TMDL for the Spokane River, thereby constructively submitting no TMDL; Plaintiffs thus requested that EPA approve or disapprove that constructive submission, and if disapproved, to establish a PCB TMDL. *Id.*

EPA reviewed the full administrative record in this case, including the new documents submitted by Plaintiffs, and on April 12, 2013, issued its administrative determination, concluding that "Ecology's decision to delay completion of a PCB TMDL for the Spokane River is within the discretion of the State of Washington" and that "Ecology has not renounced completion of a PCB TMDL for the Spokane River if one is required." V.1, T.A, at 1 (internal citation). EPA thus concluded that there has not been a constructive submission by Ecology of a PCB TMDL and that EPA is not "required to issue such a TMDL in lieu of Ecology." EPA also detailed the bases for its findings. EPA first noted that Ecology has "demonstrated its commitment to develop and implement" a robust TMDL program under Section 303(d) of the Act over the past fifteen years, and that "Ecology is continuing to establish large numbers of TMDLs each year in accordance with its judgment of how best to protect the environment and allocate its limited resources." *Id.*

Ecology established and EPA approved 1372 TMDLs since 1999 using EPA's national counting system. *Id. & n.1*. EPA further explained Ecology's priority-setting process, and noted that in December 2012 EPA approved Ecology's 303(d) list and found "that the state's process for targeting waters for TMDL development in this period is appropriate." *Id.* at 2 (internal citation).

In its administrative determination, EPA expressed support for Ecology's use of interim, supplemental approaches to achieve water quality standards, especially for those WQLSs for which a TMDL will not be issued in the near term, in an effort to reduce pollution and achieve water quality standards. This approach is reasonable because "[i]f water quality standards are attained through implementation of such interim, supplemental approaches, development of a TMDL [for that WQLS] would not be necessary." *Id.* EPA explained that Ecology's use of the Task Force to make progress achieving the applicable PCB standards represents such a measure, and that EPA supports the Task Force's work. *Id.* at 3.

EPA also explained its support for the Task Force's reasonable goal of completing the work outlined in its work plan by 2016 to reduce PCBs, *id.*, Ecology's commitment in its May 2012 letter (V.1, T.1 at 1-2) that it will in five years "evaluate progress in reducing PCB contamination in the Spokane River," and Ecology's acknowledgment that "[i]f Ecology determines that the [Task Force] is failing to make measurable progress toward meeting applicable water quality criteria for PCBs, Ecology . . . will proceed with development of a TMDL in the Spokane River for PCBs if necessary." V.1, T.A at 3. EPA further reviewed Ecology's acknowledged commitment to proceed with development of a TMDL for PCBs in the Spokane River if necessary, and explained that this "leads EPA to conclude that Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed." *Id.* at 4.

EPA noted that a "straight to implementation" ("STI") project is a type of interim approach used by Ecology, *id.* at 2-3 (describing such approaches), and that Ecology may have once intended to develop an STI project for the Spokane River, but that as Ecology further developed its STI program, it appeared that the Task Force was not an STI. *Id.* at 2-3. EPA noted, however, that the name given to a particular project or project type is not important, so long as it remains

"an interim, supplemental tool that does not displace ultimate TMDL development if needed." *Id.* at 3 n.10.

EPA also reviewed Ecology's decision to defer the continued development and completion of a PCB TMDL for the Spokane River at this time, and found them reasonable. In particular, EPA highlighted the significant information gaps that led Ecology not to finalize its draft PCB TMDL, and Ecology's experience of lengthy delays and large resource expenditures establishing the dissolved oxygen TMDL for the Spokane River. *Id.* at 4. "These factors support Ecology's decision not to finalize a PCB TMDL for the Spokane River prematurely, e.g., before adequate information and resources are available." *Id.* Further, the Task Force has "the potential to fill the existing data gaps and to achieve PCB reductions until such time that a needed PCB TMDL is issued." *Id.*

Finally, EPA explained that Ecology's approach reflects its priorities to "balance[] its available resources for issuing TMDLs with other effective tools to reduce pollution within its borders where TMDLs have not yet been issued." *Id.* at 4. EPA thus concluded that it would not be appropriate "in these circumstances for it to usurp Ecology's authority by issuing a PCB TMDL for the Spokane River at this time." *Id.* EPA therefore concluded that "Ecology has not constructively submitted to EPA a PCB TMDL for the Spokane River, and to the extent that such a constructive submission could be considered to have occurred, EPA declines to disapprove such a constructive submission." *Id.* EPA explained that it will monitor Ecology's efforts to reduce PCB pollution in the Spokane River, including "its ongoing progress in issuing TMDLs for other water bodies," and that it "may reconsider this decision if significant relevant circumstances change." *Id.*

After EPA issued this determination, Plaintiffs filed an amended complaint on April 22, 2013, which retained Plaintiffs' original constructive submission claim under the Clean Water Act citizen suit provision, Dkt. No. 61 ¶¶ 36-39, and added a new, second claim challenging EPA's April 12, 2012, determination under the Administrative Procedure Act. *Id.* ¶¶ 41-42.

F. The Pollution Control Hearing Board's July 2013 Decision

In 2011, Ecology issued the Spokane County Regional Water Reclamation Facility an NPDES permit for discharges into a water-body segment that is not listed as impaired for PCBs under Washington's 303(d) lists. Plaintiffs in this case challenged that permit before the Washington Pollution Control Hearing Board (the "Board"), alleging that it unlawfully authorized PCB discharges. Board Decision pg.1 (attached hereto as Exhibit A). The Board agreed with Ecology that the available data was not adequate for preparation of a numeric effluent limit for PCBs in the permit, *id.* pg.22, that the permit therefore required best management practices, or narrative effluent limits, *id.*, and that any narrative limits used in such a circumstance must "require defined steps towards compliance with standards." *Id.* at p.24. Therefore, the Board remanded the matter to Ecology with instructions, among other things, that Ecology (a) include deadlines and mandatory requirements for identification and implementation of measures to reduce PCBs coming into the treatment facility, (b) identify the expected reductions in toxicant loadings and the schedule for initiating such reductions; and (c) requiring the use of ongoing monitoring data to set a numeric effluent limitation at the earliest possible time. *Id. at* p.27. In so ruling, the Board reviewed the important role of the Task Force and stated that it "finds that the creation of the Task Force is a positive step toward bringing the Spokane River into compliance with water quality standards for PCBs" and that "the actions undertaken by the Task Force are necessary to address the water quality problems in the Spokane River . . . ." *Id.*

STANDARD OF REVIEW

I. EPA'S DECISION MUST BE UPHELD UNLESS PLAINTIFFS ESTABLISH THAT EPA'S ACTION WAS ARBITRARY AND CAPRICIOUS.

Under the Administrative Procedure Act, EPA's final agency actions under the Clean Water Act must be upheld unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The scope of review under this standard is narrow, and a court may not substitute its judgment for that of the agency. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983); *Citizens to Preserve*

Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Rather, "Congress has assigned the courts perform 'only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes,' and whether the agency has committed 'a clear error of judgment.'" *Maryland Dep't of Human Resources v. U.S. Dep't of Agric.*, 976 F.2d 1462, 1475 (4th Cir. 1992) (quoting *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97 (1983), and *Overton Park*, 401 U.S. at 416).

The party asserting an APA challenge bears the burden of demonstrating that the agency's actions were arbitrary or capricious. *Nw. Ecosystem Alliance v. U.S. Fish & Wildlife Serv.*, 475 F.3d 1136, 1140 (9th Cir. 2007). This standard is a "highly deferential, presuming the agency action to be valid." *Id.* "The court may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action." *Friends of the Earth v. Hintz*, 800 F.2d 823, 831 (9th Cir. 1986).

Under this deferential standard the agency's factual determinations are entitled to substantial deference. *Arkansas v. Oklahoma*, 503 U.S. 91, 112 (1992); *Central Arizona Water Cons. Dist. v. EPA*, 990 F.2d 1531, 1539-40 (9th Cir. 1993). As long as the agency's factual determinations are supported by the administrative record they should be upheld, even if there are alternative findings that could also be supported by the record. *Arkansas*, 503 U.S. at 112. Even an agency decision "of less than ideal clarity" may be upheld by the court "if the agency's path may reasonably be discerned." *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1525 (9th Cir. 1995) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Ins.*, 463 U.S. 29, 43 (1983)). Further, when examining agency scientific findings made within an area of an agency's technical expertise, a reviewing court must generally be at its most deferential. *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 376-77 (1989).

II. JUDICIAL REVIEW IS LIMITED TO THE ADMINISTRATIVE RECORD AND IS CONDUCTED THROUGH A SUMMARY JUDGMENT PROCEEDING.

In a case such as this, judicial review is limited to the administrative record prepared by the agency for its decision. *Overton Park*, 401 U.S. at 419-20; *Vermont Yankee Nuclear Power Corp.*

v. NRDC, 435 U.S. 519, 549 (1978). This rule implements the well-settled principle that judicial review of agency action is confined to review of the record that was before the agency when it made its decision, and not extra-record material that was not considered by the agency at the time that it took final action. *Federal Power Comm'n v. Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). Extra-record declarations, however, may be submitted by the Agency to clarify or explain information contained in the record. *See Camp v. Pitts*, 411 U.S. 138, 142-43 (1973). This Court has held that review in this case is limited to the administrative record. Dkt. No. 49.

Finally, because review is limited to the administrative record, resolution of this case is proper through summary judgment. *Adams v. United States*, 318 F.2d 861, 865 (9th Cir. 1963). In such a proceeding, the district court "is not required to resolve any facts in a review of an administrative proceeding. Certainly, there may be issues of fact before the administrative agency. However, the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985). The Parties to this matter have stipulated that all claims for relief in this case will be resolved through the instant summary judgment proceedings. *Infra* at 30 n.15.

ARGUMENT

I. ECOLOGY HAS NOT MADE A CONSTRUCTIVE SUBMISSION FOR A SPOKANE RIVER PCB TMDL, AND THEREFORE PLAINTIFFS' COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE AND SUMMARY JUDGMENT ENTERED FOR EPA.

A. The Constructive Submission Theory May Not, As a Matter of Law, Apply Where, As Here, the State Has a Robust Program for Establishing TMDLs.

Plaintiffs invoke the nondiscretionary duty prong of the CWA citizen suit provision, 33 U.S.C. § 1365(a)(2), alleging that Ecology has constructively submitted no PCB TMDL for the Spokane River, and that this triggers EPA's nondiscretionary duty under CWA § 303(d)(2), *id.* § 1313(d)(2), to approve or disapprove that submission. Plaintiffs and the Spokane Tribe thus invoke the constructive submission doctrine in an effort to circumvent and undermine Ecology's

decisions as to how best to protect the environment, by targeting a particular TMDL that they believe should be established before all others. As discussed below, the constructive submission theory is inapplicable where, as here, the State has a robust program for establishing TMDLs.

1. The Constructive Submission Caselaw Supports EPA's Interpretation.

Plaintiffs' claim depends on a novel, and untenable, reading of the CWA and the applicable caselaw that would expand the constructive submission theory well beyond the limited circumstances in which it applies. The Ninth Circuit explained in San Francisco Baykeeper v. Whitman, 297 F.3d 877, 881 (9th Cir. 2002), that the doctrine was created by the courts to address the narrow situation in which a State has submitted no TMDLs at all for a prolonged period of time, *id.* at 881 (i.e.,"a complete failure by a state to submit TMDLs"), and this State inaction is "construed as a constructive submission of no TMDLs, which in turn triggers the EPA's nondiscretionary duty to act." *Id.* If EPA disapproves the constructive submission of no TMDLs, EPA then becomes obliged to establish the TMDLs pursuant to section 303(d)(2). If EPA approves the constructive submission of no TMDLs, that decision is reviewable under the Administrative Procedure Act. *Hayes v. Whitman*, 264 F.3d 1017, 1023 (10th Cir. 2001) (citing *Scott*, 741 F.2d at 995 & 997). In *Baykeeper*, the Ninth Circuit concluded that California's actions, having submitted at least eighteen TMDLs, "preclude any finding that the state has 'clearly and unambiguously' decided not to submit any TMDLs." *Id.* at 883 (citing *Hayes*, 264 F.3d at 1024).

In its decision adopting the constructive submission theory, the Ninth Circuit carefully reviewed the caselaw, and explained that since its first formulation in *Scott v. City of Hammond*, 741 F.2d 992 (7th Cir. 1984), the theory has been narrowly interpreted and applied "only when 'the state fails to submit any TMDLs and has no plans to remedy this situation.'" *Baykeeper*, 297 F.3d at 882 (explaining and quoting the district court's interpretation of *Scott*); *id.* (concluding that "the district court's ruling is consistent with how other circuits have interpreted and applied *Scott*"). Thus the Ninth Circuit concluded that the doctrine may apply only where no TMDLs have been submitted by the State over a prolonged period of time and the State has no plan to remedy this situation. *Baykeeper*, 297 F.3d at 881-883.

In this case, there is no dispute that Ecology has an ongoing, robust program for establishing TMDLs, having submitted 1372 TMDLS to EPA since 1999. *Supra* at 9-10. Even where States have submitted far fewer TMDLs, the courts have declined to find a constructive submission. *See Baykeeper*, 297 F.3d at 882-83) (citing cases). Moreover, where the doctrine has been found to apply, the State has submitted no, or only very few, TMDLs over a prolonged period of time and had no intention of remedying that situation.[11]/

The theory is not available here, as a means to alter Ecology's priorities regarding the order or timing in which particular TMDLs should be established or how limited State resources should be allocated. Although Plaintiffs prefer that Ecology establish a PCB TMDL for the Spokane River immediately, a claim for such relief is simply not available. The Tenth Circuit stated in *Hayes,* 264 F.3d at 1024, the "constructive-submission theory is not designed to challenge the timeliness or adequacy of the state's TMDL submissions . . . ." *See also Sierra Club v. Browner,* 843 F.Supp. 1304, 1314 (D.Minn.,1993) ("the Act does not set deadlines for the development of a certain number of TMDLs."). And in the Ninth Circuit the law is clear that the theory may apply only where the State has submitted no TMDLs. *Baykeeper*, 297 F.3d at 882.

Plaintiffs' contend that the *Baykeeper* case is inapposite, because it involved what Plaintiffs call a "programmatic" challenge where the "plaintiffs complained of a state's overall failure to submit any or an adequate number of TMDL," Pl Br. at 24-25, whereas Plaintiffs here are concerned with one particular TMDL. Such a distinction cannot evade the rule in *Baykeeper.* A necessary corollary to the *Baykeeper* holding, *i.e.*, that an ongoing State TMDL program that has already established 18 TMDLs precludes finding a constructive submission, is the Ninth Circuit's acknowledgment that there are many more TMDLs in that State (California) to be established. For these remaining TMDLs, whether taken as a group or individually, the constructive submission doctrine cannot be used to upset the State's priorities and resource allocations. As explained in

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[11]/ *E.g., Kingman Park Civic Ass'n v. EPA*, 84 F. Supp. 2d 1, 6 (D.D.C. 1999) ("An eighteen-year failure to calculate and submit any TMDLs constitutes constructive – if not outright – determination that no TMDLs are necessary."); *Alaska Center for the Environment v. Reilly,* 762 F. Supp. 1422, 1426-27 (W.D. Wa. 1991) (holding that failure by state to submit to EPA any TMDL for over ten years was constructive submission).

section B below, the reason for so limiting the theory is clear. Courts quite properly are not willing to invoke the constructive submission theory, and the necessarily narrow nondiscretionary duty prong of the CWA citizen suit provision,[12]/ in order to second-guess and supersede discretionary policy choices Congress reserved to States to prioritize waters under their 303(d) programs and to allocate limited State resources as the State believes appropriate to protect the environment. That is why *Hayes* concluded that a constructive submission theory cannot challenge "the timeliness" of a State's TMDL submissions or their content, and the Ninth Circuit concluded that the doctrine may apply only where no TMDLs have been submitted.

Plaintiffs' reliance (at 25) on three other cases for their overly expansive view of the constructive submission theory is unavailing. Although the claim in *Scott* concerned TMDLs for only Lake Michigan, it arose in a context in which the State had submitted no TMDLs at all over a prolonged period, 741 F.2d at 996-97, and it is that circumstance that the Court explained that the theory may apply. *Id.* Here, Ecology has already submitted and EPA has approved 1372 TMDLs statewide and, for the Spokane River watershed alone, Ecology has already submitted and EPA has approved 73 TMDLS. *Supra* at 9-10. Moreover, as explained in *Baykeeper*, 297 F.3d at 882, the *Scott* court remanded the case to the district court instructing it "to proceed as if the states had submitted proposals of no TMDL's" and still left open the possibility that a constructive submission may not be found. *Scott*, 741 F.2d at 997 n.11.

Plaintiffs' reliance on *Hayes* is also misplaced. While the Court in one part of its opinion describes the constructive submission theory in the singular, referring to the clear intent to submit no TMDL for a particular waterbody, in others places it speaks in the plural, referring to the submission of no TMDLs needed to trigger the theory. 264 F.3d at 1023 (the theory applies "[o]nly upon this determination that the states' inaction was so clear as to constitute a 'constructive submission' of no TMDLs"). Moreover, as the Ninth Circuit in *Baykeeper*

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[12]/ Claims against EPA under citizen suit provisions are limited to "'clear-cut' nondicretionary dut[ies]." *Farmers Union Cent. Exchange, Inc. v. Thomas*, 881 F.2d 757, 760 (9th Cir. 1989) (reviewing the similar citizen suit provision under the Clean Air Act). Thus, the CWA citizen suit provision "cannot be employed to challenge the substance or content of an agency action." *Scott*, 741 F.2d at 996; *see also Sierra Club v. Thomas*, 828 F.2d 783, 791 (D.C. Cir. 1987).

explained, the key fact in *Hayes* for why no constructive submission was found was not the focus on a particular TMDL, but the fact that Oklahoma had submitted between three and twenty-nine TMDLs with a commitment for more. *Baykeeper*, 297 F.3d at 882. Accordingly, the Ninth Circuit explained that *Hayes* should be construed to mean the constructive submission theory may apply only when no TMDLs are submitted. *Id.* Finally, in *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005), also relied upon by Plaintiffs, the court described the constructive submission theory using the singular, but it did so only in passing, in a background section, and the holding of the case did not involve application of the theory at all. This passing reference carries no weight whatsoever. In sum, Plaintiffs have not cited a single case in which the constructive submission theory has been applied to compel establishment of a single, particular TMDL from among the many that may ultimately be required, and EPA is not aware of such a case.

2. EPA's Reasonable Interpretation is Fully Supported by the CWA

EPA's interpretation is also fully supported by the CWA § 303(d) provisions regarding State TMDL prioritization and the cases interpreting it. The CWA vests States with authority to exercise their own judgment as to when particular TMDLs should be established and how their limited resources should be allocated, without the threat of judicial intervention requiring that EPA usurp that State discretion and decisionmaking. For example, while the CWA requires that States establish a priority ranking for TMDLs, EPA is not required to pass judgment on that prioritization or approve or disapprove the State's order. Although CWA § 303(d)(1)(A) requires that "[e]ach State shall identify those waters within its boundaries . . . * * * [and] establish a priority ranking for such waters," 33 U.S.C. § 1313(d)(1)(A), the CWA only requires each State "from time to time" to submit to EPA for approval "the waters identified and the loads established." *Id.* § 1313(d)(2) (emphasis added). Thus, the CWA is specific and clear: EPA must review only the 303(d) list (the "waters identified") and the TMDLs (the "loads") once they are submitted to EPA. Conspicuously absent from Section 303(d)(2) is any mention of EPA approval of priority rankings set by the States under Section 303(d)(1)(A). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally-presumed

that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. U.S.*, 464 U.S. 16, 23 (1983).

Accordingly, the courts that have reviewed this question have agreed that EPA is not required to review and approve the particular priority ranking States establish for TMDL development. The Court in *Potomac Riverkeeper, Inc. v. EPA*, 2006 WL 890755, at 10 (D. Md. 2006), explained as follows:

> While a state's § 303(d) list must list waters 'targeted' for TMDL development within the next two years, this requirement is a form of goal setting. This requirement does not, however, require EPA, prior to approval, to ascertain, based on the state's historic average number of impairments resolved per year, whether the state can actually complete the 'targeted' TMDLs in the next two years. In addition, there is no provision that requires EPA to approve or disapprove a state's priority rankings.

Id. at 10 (footnote omitted).[13]/

Plaintiffs' theory in this lawsuit, therefore, contradicts the CWA's clear text and structure and is not supported by applicable caselaw. The constructive submission theory may not, as a matter of law, be used, as Plaintiffs' intend here, to supersede and reorder the State's priorities and decisions.

This limitation on the constructive submission theory is a corollary to the prohibition on its use to challenge the timing or content of State TMDLs, *Scott*, 741 F.3d at 995, and the Ninth Circuit's holding that the theory may apply only if no TMDLs have been submitted and the State

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[13]/ EPA also notes that, in *Sierra Club, Inc. v. Leavitt*, 393 F.Supp.2d 1263, 1273 (N.D. Fla. 2005) (N. D. Fla. 2005), *aff'd and rev'd in part; judgment vacated in relevant part*, 488 F.3d 904 (11th Cir. 2007), the district court declined to second-guess the State's particular priority ranking for completing TMDLs in a case challenging EPA's approval of a 303(d) list, explaining:

> No requirement is present that EPA approve the [States'] rankings. Importantly, in its Decision Document, while the EPA specifically approves or disapproves [the State's] decision to list, not list, or delist waters, the section discussing prioritization does not "approve" or "disapprove" [the State's] ranking; it merely concludes that Florida did, in fact, rank its waters and set a TMDL schedule accordingly. Because there is no requirement that the EPA actually approve or disapprove of a state's priority rankings, . . . summary judgment is granted in favor Defendants

On appeal, the Eleventh Circuit concluded that plaintiffs did not actually challenge the particular ranking of listed waters, and thus it did not address that issue and vacated district court's summary judgment on that claim and remanded. 488 F.3d at 917-918. Nevertheless, the district court properly addressed this issue.

has no plan to remedy that situation. *Baykeeper*, 297 F.3d at 882. This limitation also follows from the discretion CWA § 303(d) preserves for the States. A contrary ruling would open the floodgates to numerous lawsuits against EPA by groups dissatisfied with how limited State or federal resources were allocated, in an effort to redirect development to their preferred TMDL in lieu of other environmental projects or TMDLs in other communities. Such "special pleading" lawsuits on behalf of those groups' narrow priorities would ensnare the courts in disputes they are ill-suited and not authorized by statute to resolve, *i.e.*, second-guessing the States' judgments about how to best protect the environment in the face of limited resources. These are precisely the types of claims the CWA and caselaw foreclose.[14]/

EPA's interpretation is fully consistent with the plain meaning of Section 303(d) and the applicable caselaw. However, even were the statute ambiguous, EPA's construction is reasonable, and should be upheld. Accordingly, EPA has not failed to perform a nondiscretionary duty under the CWA citizen suit provision, and thus Plaintiffs' and the Tribe's complaints should be dismissed and summary judgment entered for EPA.

B. Plaintiffs Have Waived Their Right to Challenge EPA's Determinations That Ecology Has Not Renounced Establishing a PCB TMDL for the Spokane River If Necessary and That Ecology Has Thus Not Constructively Submitted Such a TMDL.

Even assuming, arguendo, that a constructive submission claim could be used to compel EPA to establish a particular TMDL, Plaintiffs have waived their right to raise such a claim here. As discussed *supra* at 18-20, on April 12, 2012, EPA reached its administrative determination that Ecology has not disavowed establishing a Spokane River PCB TMDL if needed and that Ecology has not therefore constructively submitted such a TMDL. In their amended complaint, Plaintiffs include an additional claim (claim two) against EPA under the Administrative Procedure Act challenging EPA's April 12, 2012, determination, alleging that EPA's "determination that Ecology has not submitted a Spokane River PCB TMDL is arbitrary, capricious, an abuse of discretion, and

[14]/ EPA does not here opine on what recourse Plaintiffs may have on claims in State court directly against Ecology regarding its priorities under State law or regulations. That matter is not before the Court.

not in accordance with law, and their refusal to approve or disapprove the TMDL, and, if disapprove, to establish a TMDL as required by 33 U.S.C. § 1313(d)(2) constitutes agency action unlawfully withheld or unreasonably delayed." Dkt. No. 61¶ 41. Because Plaintiffs have elected not to argue their second claim to challenge EPA's determination in their motion for summary judgment, that claim is waived in accordance with the caselaw and the parties' stipulated agreement and the Court's Scheduling Orders that all claims in this case will be resolved by these summary judgment proceedings.[15]/

The rule in this Court is clear that such claims must be dismissed with prejudice. *See, e.g.,Wild Bainbridge v. Mainlander Services Corp.* 544 F. Supp. 2d 1159, 1167 (W.D. Wash. 2008) ("Pursuant to the parties' agreement that all claims against the federal defendants will be resolved by summary judgment, all claims not raised in Wild Bainbridge's summary judgment motion are dismissed as to the Corps."); *Thunderbird Trading v. U.S. Bureau of Alcohol, Tobacco and Firearms*, No. C92-5181, 2007 WL 1128810, at *10 (W.D. Wash. Ap. 16, 2007) (where all parties agreed that all issues are to be decided on summary judgment, on those issues in the Plaintiff's complaint not raised in the Plaintiff's brief "the Court presumes that Plaintiff has abandoned them. Therefore, to the extent that Plaintiff makes claims, if any, regarding these issues, Plaintiff's claims should be dismissed with prejudice and summary judgment for the Defendants should be granted.").[16]/

Accordingly, because Plaintiffs elected not to pursue its challenge to EPA's April 12, 2012, determination, the determination necessarily stands intact.

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[15]/ Order, dated April 8, 2013 (Dkt. No. 58) (entering the parties Stipulation and Proposed Order to Modify Scheduling Order at 2 & 4 ¶ 7); Order, dated September 12, 2013 (Dkt. No. 78) (entering the parties' Stipulation and [Proposed] Briefing Schedule, at 4 ¶ 5); *see also* Order, dated December 23, 2013 (Dkt. No. 88) (entering the parties Stipulation and [Proposed] Modified Briefing Schedule).

[16]/ *Also Mountain States Legal Found. v. Espy*, 833 F. Supp. 808, 813 nn.4-6 (D. Id. 1993) (where the plaintiff agreed that all claims in its complaint would be resolved through summary judgment, claims not raised in its summary judgment motion were waived and dismissed with prejudice); *City of Santa Clarita v. Dep't of Interior*, No. 02-00697, 2006 WL 4743970 at *11 (C.D. Cal. Jan. 30 2006) (same), *aff'd*, 249 Fed. Appx. 748 (9th Cir. 2007).

C. The Court Should Uphold EPA's Reasonable Determined That Ecology Has Not Renounced Submitting a PCB TMDL for the Spokane River if Needed and That Such a TMDL Has Not Been Constructively Submitted to EPA.

1. The Administrative Record Supports EPA's Finding That There Has Not Been a Constructive Submission.

Assuming, arguendo, that Plaintiffs can overcome the legal bars discussed above to either of their claims, the Court should uphold EPA's reasonable determination and reject those claims. As explained in detail, *supra* at 18-20, EPA in its April 12, 2013, determination concluded that "Ecology's decision to delay completion of a PCB TMDL for the Spokane River is within the discretion of the State of Washington" and that "Ecology has not renounced completion of a PCB TMDL for the Spokane River if one is required." V.1, T.A, at 1. EPA thus determined that there has not been a constructive submission by Ecology of a PCB TMDL. These determinations are amply supported by the record.

As detailed above, Ecology has a robust, ongoing TMDL program, having issued 1372 TMDLs since 1999, including 73 TMDLs in the Spokane River watershed, and Ecology is committed to continuing this progress. *Supra* at 9-10. Although Ecology initiated the process to develop a PCB TMDL for the Spokane River, those efforts disclosed significant information gaps and the need for additional study and analysis, which prevented Ecology from completing that TMDL. *Supra* at 11-14; V.1, T.A at p.4; V.5, D.132 at 2671, 2675, 2683. Ecology also recently completed a lengthy, technically complex and contentious twelve-year process to establish a dissolved oxygen TMDL for the Spokane River, V.1, T.A at p.4, V.1, D.4 at 503; V.5, T.132 at 2671-72, and based upon lessons it learned there, Ecology was concerned that pressing forward on a PCB TMDL for that same water-body, especially given the significant gaps in information and the importance of a cooperative approach, would result in further, lengthy delays in establishing such a TMDL. *Id.; supra* at 16-17. Ecology thus determined to devote its limited resources to other TMDLs at this time, and to supplemental measures, including the Task Force, to fill data gaps and to achieve near-term PCB reductions. *Id.* EPA supports the work of the Task Force and other interim measures until such time that a PCB TMDL can be completed if necessary. V.1, T.A

at pp.2-3. Moreover, even if the Task Force or other measures fail to adequately reduce PCBs, the information gained by the Task Force would assist in the development of a TMDL. *Supra* at 15-16.

EPA also found reasonable Ecology's commitment to review the Task Force's progress in five years. V.1, T.A at 3. Ecology further committed to establish a PCB TMDL if the Task Force or other measures it may adopt fail to achieve applicable PCB water quality standards. V.2, T.44 at 706 ("a PCB TMDL still remains a tool and will be necessary if ongoing toxics reduction strategies do not result in compliance with water quality standards."); *also* V.1, T.1 at 2. If the applicable PCB water quality standards are met through supplemental measures, no TMDL would be required. EPA explained that this "leads EPA to conclude that Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed." Id. at 4. EPA concluded that Ecology must retain discretion to manage and establish priorities for TMDL development, including how limited resources should be expended to reduce pollution where TMDLs have not yet been completed. *Id.*

In their effort to discredit Ecology's reasons for deferring a PCB TMDL, Plaintiffs argue that Ecology shared with EPA a "complete draft TMDL" to review, that this draft TMDL included all elements required in a TMDL for approval by EPA, and that Ecology's draft TMDL went through the public notice process required for TMDL development. This is incorrect. As an initial matter, the documents Plaintiffs contend are technically complete TMDLs are each marked "Draft . . . Do not cite or quote," V.3, T.90, at 1319; V.3, T.69 at 1102, which demonstrates that Ecology never believed them complete. Ecology also has not conducted the notice and comment proceedings required before a TMDL can be submitted to EPA. *Supra* at 13 n.9. Moreover, Ecology itself explained that significant gaps in information and need for additional new information prevented these preliminary drafts from being finalized. The background section of this brief details important areas where these draft documents are incomplete. *Supra* at 11-14, 17.

For example, the draft document that Plaintiffs and the Tribe contend is a complete and approvable PCB TMDL for the Spokane River could not identify the sources or categories of sources or otherwise account for 57% of the PCB loading in the relevant reach of the River. V.1, T.15 at 163 (figure 19); *supra* at 14. Further, in uncontested testimony in a proceeding before the

Pollution Control Hearing Board involving the same plaintiffs in this case, a spokesperson for Ecology explained as follows:

> Q And I believe you testified earlier that this draft TMDL failed to account or was unable to discover roughly 57 percent of the sources of PCB loading to the river?
> A Correct.
> Q Would Ecology develop a total maximum daily load for a pollutant if it didn't even know where 57 percent of the sources of that pollutant came from?
> A No.
> Q Why not?
> A It would leave too much uncertainty and I think it would require the dischargers to pay an inequitable amount of their resources to solve the rest of the PCB problem.

V.5, D.132 at 2683 (questions by counsel for Ecology; answers by Ecology employee Jim Bellatty); *id.* at 2671 (this large information gap "leaves a lot of unanswered questions and uncertainty with our ability to be able to do a TMDL"). This and the other record information readily rebuts Plaintiffs' conclusory assertions that political pressure prevented Ecology from finalizing the TMDL.

In sum, EPA fully explained the bases for its April 12, 2013, determination and the record amply supports EPA's findings. Plaintiffs' burden to demonstrate otherwise is particularly high in this case, where inherent in the State's decisions are judgments about how best to allocate limited resources to protect the environment.

2. Plaintiffs' Arguments Challenging EPA's Decision Are Without Merit.

Plaintiffs contend that a Memorandum of Agreement between EPA and Ecology in 1997 regarding Ecology's commitment to establish TMDLs, as well as Ecology's 303(d) lists from 1996 through 2010, required that Ecology have developed a PCB TMDL for the Spokane River by 2013. Pl. Br. at 26-27 & 34. This argument is flawed on several counts. First, neither that Memorandum of Agreement, V.1, T.34, nor the out-of-court settlement agreement that EPA entered in 1998 with two environmental groups regarding TMDL development, V.1, T.32, required Ecology to have established and submitted a Spokane River PCB TMDL to EPA by this time. Consistent with the CWA, those documents necessarily preserve Ecology's discretion to

select which particular TMDLs to develop and when to do so. For example, Attachment A to the Memorandum of Agreement and settlement agreement describes Ecology's 303(d) prioritization process for initiating development of TMDLs in different management area watersheds throughout the State over five-year cycles, V.1, T.33, including the Spokane area. It does not require that the TMDL on which Ecology initiates development in the Spokane area be for PCBs. *Id.* at 457. Similarly, the settlement agreement preserves Ecology's discretion to substitute between TMDLs it intends to develop from the State's different 303(d) lists. V.1, T.32 at 47-48 (¶ 7).

Nor is there anything to Plaintiffs' claim that Ecology has departed from its prioritization process and ignored the Spokane River and its tributaries. As explained above, since 1999, Ecology submitted and EPA has approved 1372 TMDLs, many of which were for WQLSs in the Spokane River and its tributaries. Further, on April 12, 2012, EPA approved an additional 57 TMDLs submitted by Ecology for the Little Spokane River watershed, for fecal coliform bacteria, temperature and turbidity. [Is the 57 Included in the total?] Thus, Ecology has not, as Plaintiffs' claim, departed from its prioritization process and ignored the Spokane River. Rather, Ecology has exercised its discretion by prioritizing and completing the particular TMDLs that in its judgment will best protect water quality most efficiently with the State's finite resources.

Plaintiffs further argue that because Ecology initiated development of a PCB TMDL for the Spokane River, Ecology was required to have already completed and submitted that TMDL to EPA. However, as explained above, Ecology has adapted its priorities based upon the circumstances, deciding to defer establishing a PCB TMDL for the Spokane River and to establish other TMDLs at this time, and to adopt interim, supplemental measures to reduce PCBs in the Spokane River. Nothing in the CWA or EPA's regulations precludes Ecology from altering course in this manner. Moreover, while EPA's regulations direct States to submit 303(d) lists every two years, and to include a priority ranking of waters "targeted for TMDL development within the next two years," 40 C.F.R. § 130.7(d)(1), this language plainly does not require completion of such TMDLs within that two-year period. Nor could it, since, as discussed above, the CWA preserves the State's discretion in this regard, requiring only that States submit TMDLs to EPA "from time

to time," 33 U.S.C. § 1331(d)(2). Rather than require TMDLs be submitted in two years, this language expressly preserves State discretion to determine when such TMDLs should be developed and submitted to EPA. Similar "time to time" language under a different Section 303 provision are construed precisely in this manner. *American Canoe*, 30 F. Supp. 2d at 923. Indeed, "courts have generally held that the use of the phrase 'time to time' does not create a nondiscretionary administrative duty." *Id.* [17]/

Plaintiffs argue that Ecology has decided to utilize a "straight-to-implementation project" ("STI") for reducing PCBs in the Spokane River, that STI projects necessarily preclude TMDLs, and that this demonstrates that Ecology has decided no PCB TMDL for the Spokane River will ever be established. Pl. Br. at 28. EPA reasonably addressed this in its April 2012 determination, explaining that STIs are a type of interim approach to identify PCB sources and practices to prevent contamination reaching the water body, and that Ecology's "definition and use of this term [i.e., STI] are changing over time." V.1, T.A at pp. 2-3. Further, while Ecology once appeared to refer to the Task Force or other measures to reduce PCBs in the Spokane as an STI, it no longer does so. *Id.* at p.3 n.10. The key point here, however, is that Ecology has committed to establish a PCB TMDL if it is ultimately needed, and that it therefore does not matter whether the Task Force, or any other interim, supplemental measures Ecology may adopt, may have once been or are called STIs. *Id.* Moreover, if Plaintiffs here intend to challenge STIs generally or in other contexts, that issue is not before the Court; neither the issues nor administrative record in this case provide the Court with the opportunity or ability to resolve whether STIs generally or in other contexts preclude TMDLs. And then, Plaintiffs depiction of STIs is incorrect, because an Ecology presentation in the record from 2011 states that an STI "does not preclude further TMDL

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[17]/ *See, e.g., NRDC v. Thomas*, 885 F.2d 1067, 1075 (2nd Cir. 1989) (Clean Air Act provision requiring revision of a list of air pollutants "from time to time" does not impose a nondiscretionary duty); *Oljato Chapter of the Navajo Tribe v. Train*, 515 F.2d 654, 661 (D.C. Cir. 1975) (Clean Air Act provision imposing a duty in which EPA may from "time to time" revise certain standards does not impose a nondiscretionary duty). Rather, a nondiscretionary duty is typically one in which the statute requires performance by a date certain. *Sierra Club*, 828 at 791 (absent a readily-ascertainable deadline, "it will be almost impossible to conclude that Congress accords a particular agency action such high priority as to impose upon the agency a 'categorical[] mandat[e]' that deprives it of all discretion over the timing of its work.").

pathway." V.3, T.86 at 1307.

Eventually, Plaintiffs frankly concede in their brief, as they must, that Ecology has not renounced its obligation to establish a PCB TMDL if one is ultimately necessary, but they then argue that Ecology has not adequately identified what "measurable progress," "activities," or "metrics" would make the TMDL "unnecessary." Pl. Br. at 28-29. Plaintiffs confuse the issue and distort Ecology's position; it is undisputed that the TMDL will ultimately not be needed if and when the Spokane River meets the applicable PCB water quality standards. *See supra* at 5. Moreover, Ecology's point is that, for now, it has chosen to pursue various interim measures, such as the Task Force, to reduce PCBs in the Spokane River, while development of the PCB TMDL is deferred for the reasons discussed above. At the same time, Ecology has clearly committed that it will evaluate the Task Force's progress in five years, V.1, T.1 at 1-2, and if "measurable progress" is not being made and other measures are not available, "Ecology would be obligated to proceed with development of a [Spokane River PCB] TMDL . . . ." *Id.* at 2. Thus Ecology explained that "it is committed to proceed with a TMDL should it be necessary." *Id.* Further, if such a TMDL is needed, Ecology will have the benefit of the additional needed information gathered (based on the work of the Task Force) for developing the TMDL. *Supra* at 15-16; V.1, T.35 at 481-84 (data to be gathered). Based upon this, EPA reasonably concluded that "Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed," *V.1 T.A*, at 4.

Plaintiffs next complain that the Task Force is not adequate, alleging that it is "controlled by the NPDES dischargers." Pl. Br. at 29. Such an attack, however, is incorrect, given that several governmental entities and other environmental groups are members of the Task Force. *Supra* at 15. Indeed, Plaintiffs as well as the Spokane Tribe were invited to participate in the Task Force, but declined. Although Plaintiffs doubt that the Task Force will achieve its goal, this is no reason to fault Ecology for pursuing interim measures to reduce PCB pollution, much less to equate Plaintiffs' projections of the Task Force's failure to Ecology constructively renouncing ever establishing a TMDL. Nor is it a proper criticism that the Task Force did not, up-front, identify measures it will adopt to reduce PCB pollution, given that it was only recently established and part

of its mission is to identify those measures. *Supra* at 15-16. Moreover, Plaintiffs inaccurately suggest that the Pollution Control Hearing Board was critical of the Task Force. To the contrary, while the Board merely concluded that participation in the Task Force is not a defense to NPDES permit compliance, Board Decision at p.27, a matter not at issue here, the Board stated that it "finds that the creation of the Task Force is a positive step toward bringing the Spokane River into compliance with water quality standards for PCBs" and that "the actions undertaken by the Task Force are necessary to address the water quality problems in the Spokane River . . . ." *Id.* at p.26.

Finally, Plaintiffs allege that absent a PCB TMDL for the Spokane River, NPDES permits issued by Ecology for PCB discharges into the Spokane River will be inadequate. Pl. Br. at 33. This argument is flawed for several reasons, and we address it in detail *infra* at 42-43 & 45. EPA highlights here that if Plaintiffs believe those State-issued permits are inadequate, the remedy is to challenge them through the State administrative process and court system, rather than improperly attempt to adjudicate their adequacy in this case. Plaintiffs' unsupported claims that NPDES permits will be inadequate thus provide no support for the claims in this case. Moreover, as explained *supra* at 7, even where a TMDL has not yet been established, States still must include effluent limits in NPDES permits as stringent as necessary to meet water quality standards, 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A). Indeed, as explained below, the presence of a PCB TMDL may not result in any change in the stringency of NPDES permits.

In sum, Plaintiffs have not met the high burden to upset EPA's April 12, 2013, determination nad have not established that a constructive submission has occurred.

II. THE INTERVENOR SPOKANE TRIBE'S CLAIMS SHOULD BE REJECTED.

The Tribe in its second amended complaint asserts two claims for relief. In its first claim, under the CWA citizen suit provision, the Tribe incorporates portions of Plaintiffs' claim and alleges that "EPA breached its trust responsibility and fiduciary duty to the Tribe by failing to perform its nondiscretionary duties under 33 U.S.C. § 1313(d)(2)," Dkt. No. 74, Attach. 1 ¶ 22. The Tribe's second claim, after incorporating Plaintiffs' description, alleges that "EPA Defendants' April 12, 2013 determination failed to protect the interests of the Spokane Tribe, and

EPA Defendants have breached and will continue to breach their trust responsibility and minimum fiduciary duty owed to the Spokane Tribe because the April 12, 2013 determination is not in accordance with 33 U.S.C. § 1313(d)(2) and federal common law, and is in violation of 5 U.S.C. § 706(2)(A)&(D) [*i.e.*, APA standards of review]." *Id.* ¶ 24. This language explicitly limits the claims in this case to arguments that EPA's alleged failure to comply with the CWA, the APA, and any applicable common law, also constitutes a breach of EPA's alleged trust responsibility and fiduciary duty owed the Tribe.

In its brief, the Tribe argues that, for the downstream PCB-impaired water-body segment it administers within its jurisdiction, the Tribe has established PCB water quality standards that are more stringent than those adopted by Ecology for the upstream segments Ecology administers, to account for risks posed by the greater fish consumption assumed for Tribal members. The Tribe argues that unless PCBs upstream are adequately reduced, the Tribe's more stringent water quality standard in the downstream segment within its jurisdiction cannot be met. According to the Tribe, only an EPA-established TMDL for the upstream segment administered by Ecology will ensure NPDES limits within that segment that can accomplish PCB reductions downstream on the reservation, and that the general fiduciary duty weighs in favor of finding a constructive submission under the CWA citizen suit (claim one). In the alternative, the Tribe contends that EPA's determinations that Ecology has not renounced its obligation to establish a TMDL and that no constructive submission has occurred should be set aside under the Administrative Procedure Act (claim two). The Tribe's arguments miscast the nature of EPA's general trust responsibility and provide no basis to find a constructive submission or upset EPA's determination. As discussed below, there is no specific fiduciary duty owed the Tribe in this case. Moreover, nothing in EPA's decision undermines the Tribe's ability to enforce its tribal PCB standard.

A. EPA's Compliance with the CWA and its Regulations Satisfies its General Trust Responsibility.

Although the relationship between the United States and Indian tribes has been described as a trust, the scope of the federal trust responsibility is not defined by common law fiduciary

duties or those imposed on a private trustee. *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2323 (2011). Rather, tribes must point to specific statues and regulations that "establish [the] fiduciary relationship and define the contours of the United States' fiduciary responsibilities." *Id.* at 2325 (citation omitted). Thus the only cognizable breach of trust claim is one founded upon a definite and express fiduciary duty imposed on the federal government by administrative regulation or Act of Congress. *United States v. Navajo Nation*, 537 U.S. 488, 511 (2003); *United States v. White Mountain Apache Tribe*, 537 U.S. 465, 477 (2003). Accordingly, the federal common law trust duties applicable to private beneficiaries, which the Tribe seeks to impute to the federal government, *see* Tribe Br. at 15, do not provide independent bases for the claims asserted by the Tribe. *See Pacific Coast Fed'n of Fisherman's Ass'ns v. United States BLM,* 2005 U.S. Dist. *LEXIS* 36035, *34 (N.D. Cal. Mar 8, 2005).

There is a "distinctive obligation of trust incumbent upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801, 810 (9th Cir. 2006) (quoting *United States v. Mitchell*, 463 U.S. 206, 225 (1983)). However, "[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one only." *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995). While that general trust relationship allows the federal government to consider and act in the tribes' interests in taking discretionary actions, it does not impose a duty on the federal government to take action beyond complying with generally applicable statutes and regulations. *Jicarilla,* 131 S. Ct. at 2325. Accordingly, in the absence of a specific duty that has been placed on the government with respect to the Tribe, the United States' general trust responsibility "is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. F.A.A.*, 161 F.3d 569, 574 (9th Cir. 1998); *Okanogan Highlands Alliance v. Williams*, 236 F.3d 468, 479 (9th Cir. 2000) (Bureau of Land Management's approval of gold mine satisfied trust obligations by the agency's compliance with NEPA); *Gros Ventre*, 469 F.3d at 814.

Here, the Tribe alleges in its CWA citizen suit claim that EPA breached fiduciary duties owed in the CWA by not establishing a TMDL. Second Amended Complaint ¶ 24 (Dkt. No. 73, Attach. 1). The Tribe does not identify where the CWA establishes a fiduciary duty mandating that EPA establish a PCB TMDL for the Spokane River, much less that a mandatory duty requires EPA do so at this time. Instead, the Tribe duplicates the arguments of Plaintiffs (which we refute above) based upon the government's general statutory and regulatory obligations under the CWA. Accordingly, EPA satisfied its general trust responsibility by its compliance with the CWA.

B. The Indian Law Canon of Construction Raise by the Tribe Does Not Apply, and Even if It Did, It Would Not Result in a Finding of a Constructive Submission.

The Tribe contends that an Indian law canon of construction requires that any statutory ambiguity be interpreted to benefit the Tribe, and that this canon is triggered in this matter because under CWA section 518(e), 33 U.S.C. § 1377(e), the Tribe has been granted the right "to be treated as a state," *id.*, for purposes of issuing water quality standards. Tribe Br. at 5-6. Even assuming arguendo this were accurate, this canon is inapplicable because, as demonstrated in Section 1.A above, the provision of the CWA at issue in this case is not ambiguous: the constructive submission theory does not, as a matter of law, apply in this case. And beyond that, the CWA calls for EPA to approve or disapprove TMDLs arises only if TMDL submissions (actual or constructive) have occurred, and there is no ambiguity in that statutory proposition. The canon of construction raised by the Tribe does not apply when the statue is clear. Thus the Court need not decide whether the canon cited by the Tribe applies here.

Even were the applicable law ambiguous, the referenced canon would not apply in this circumstance. This canon applies only to "'statutes passed for the benefit of dependant Indian tribes.'" *Hoonah Indian Ass'n v. Morrison*, 170 F.3d 1223. 1228 (9th Cir. 1999) (quoting *Bryan v. Itasca County, 426 U.S. 373, 392 (1976)).* Regardless of whether this canon may apply to ambiguous interpretations of the Tribe's authority under 33 U.S.C. § 1377(e), or the Tribe's administration of its own program, it certainly would not extend here to the Section 303(d) TMDL program administered by Ecology, *id.* § 1313(d), EPA's obligation to approve or disapprove a

TMDL once submitted, *id.* § 1313(d)(2), or the CWA provisions governing the Tribe's assertion that the Court must order EPA to establish a PCB TMDL and thereby usurp Ecology's role and substitute the Tribe's priorities for the State's reasonable pollution prevention and remediation plans. The latter generally applicable provisions of the CWA just discussed are the only provisions at issue in this case, and thus the referenced canon would not apply.

The Tribe also appears to rely upon the canon when recounting selected documents and information in the administrative record, which it construes in its favor, in an effort to establish that Ecology has renounced its obligation to issue a TMDL that may be necessary, and thus has constructively submitted a PCB TMDL to EPA. However, even if the canon somehow applied to the interpretation of the CWA, it does not apply to the judicial review of record information. Rather, the applicable arbitrary and capricious standard of the Administrative Procedure Act applies. The Tribe has not met its burden to demonstrate that EPA's determinations are arbitrary and capricious or contrary to law.

C. The Tribe's Arguments Based Upon Alleged Impacts to Its Fishing Rights Are Not Properly Before the Court, and Provide No Basis to Reject EPA's Determination.

In the context of its APA claim, the Tribe contends that EPA's April 12, 2013, decision is arbitrary, capricious or contrary to law because it "fails to preserve and protect the Tribe's fishing rights." Tribe Br. at 16. The Tribe appears to base its argument on its assertion that it has "a right to water quality that can sustain fish and other aquatic life." Tribe Br. at 6 (citing *United States v. Anderson*, 591 F. Supp. 1, 5 (E.D. Wash. 1982), *aff'd in part and rev'd in part*, 736 F.2d 1358 (9th Cir. 1984)). That case, however, involved an adjudication of the Tribe's water rights in the Chamokane Stream, and the Court addressed only "[t]he quantity of water needed to carry out the reserved fishing purposes" as it relates to "flow" and "water temperature." Moreover, this is far different than the circumstance here, where the issue is PCB contamination and the State's decision of how best to expend resources to reduce that pollutant. *See Hopi Tribe v. United States*, 113 Fed. Cl. 43, 49 (2013) (reserved water rights do not impose mandatory fiduciary duties on the United States to build drinking water infrastructure). This issue, however, is not properly before

the Court, regardless of what the scope of the Tribe's fishing rights may be, and should be dismissed. Plaintiffs' second amended complaint does not include a claim based upon alleged violation of fishing rights. Stipulations entered by the Parties and filed in Court further demonstrate that the Intervenor Tribe's complaint was not to so expand the claims in this case.[18]/

Even if this issue were properly before the Court, the Tribe has not made the necessary showing to support its assertion that the lack of an EPA-issued TMDL adversely impacts the Tribe's fishing rights. TMDLs are not self-executing and thus do not themselves reduce pollution.

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[18]/ After this Court ruled that review in this case is limited to the administrative record, Dkt. No. 49, Plaintiffs requested that EPA review documents and approve or disapprove a constructive submission, V.1, T.B & C, which resulted in EPA's April 12, 2012, determination that no constructive submission had occurred, V.1, T.A, and the inclusion of additional documents in the record for judicial review. Dkt. No. 58 at 2, 4-5 (¶ 8) (Order dated April 8, 2013). Counsel for the Tribe did not, as part of that process, request that EPA consider or determine impacts to its fishing rights. *See id.* Moreover, Plaintiffs, and the Tribe, were to add an additional cause of action in their amended complaints only to secure their challenge to EPA's April 12, 2013, determination. That process, however, was not to enlarge the basic issues originally in this case. After the Tribe filed its First Amended Complaint, Dkt. No. 64, counsel for EPA contacted counsel for the Tribe and objected because the Tribe's new second and third causes of action added the claims that EPA failed to comply with certain specific alleged fiduciary duties, including primarily an alleged failure to consult with the Tribe as part of that process. *Id.* ¶¶ 19-23. Ultimately, to ensure no misunderstanding, through an exchange of emails and calls, the Parties' all agreed to the following:

> The Parties agree that in the Tribe's Second Amended Complaint, the Tribe is not raising a breach of trust/fiduciary duty claim based upon EPA's alleged failure to consult with the Tribe upon considering the additional documents and in issuing its April 12 letter. Thus, the Tribe, in the second claim of its second amended Complaint, may only challenge as a breach of trust/fiduciary duty the merits of EPA's decision that there has been no constructive submission.

Emails dated September 6 and 9, 2013, Attachment A hereto. Based on this agreement, the Parties' filed a joint stipulation, Dkt. No. 73, which the Court entered on September 12, 2013, Dkt. No. 74, thereby authorizing the filing of the Tribe's Second Amended Complaint, to ensure that the claims in this action were not expanded. The stipulation filed by the Parties explained as follows:

> To resolve disagreements regarding the scope of the amended complaint filed by the Tribe, the Parties hereby stipulate to the Intervenor-Plaintiff Spokane Tribe of Indians filing a second amended complaint, which is attached (Attachment 1). This proposed second amended complaint is narrower than the Complaint previously filed by Intervenor-Plaintiff Spokane Tribe, and thus its filing will neither expand the claims in this lawsuit nor delay their resolution, while also resolving disputes the Parties had regarding the scope of the first amended complaint previously filed by the Spokane Tribe of Indians.

Doc. Nos. 73 & 74, ¶ 3 (emphasis added). Accordingly, the Tribe's arguments in its motion for summary judgment alleging fishing rights have been violated are not properly before the Court and must be dismissed.

Even if EPA were required to establish a PCB TMDL, it may not result in any reduction in PCBs in the River or in fish located within the Tribe's fishing grounds. The Tribe contends that the lack of an EPA-issued PCB TMDL has resulted or will result in State-issued NPDES permits that lack adequate PCB limits or will not make adequate progress reducing PCBs in the Spokane River. They offer, however, only speculative and conclusory assertions in this regard, and neither the issues nor administrative record in this case provide the Court with the authority, or basis, to assess the adequacy of such future permits. As explained *supra* at 7, the lack of a TMDL does not preclude the inclusion of appropriate effluent limits in NPDES permits. Regardless of whether a TMDL has been established, NPDES permits still must include effluent limits as stringent as necessary to meet water quality standards. 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A). A PCB TMDL, therefore, would not necessarily make NPDES permits any more stringent. Moreover, the Tribe's theory of how of its fishing rights are impacted inappropriately assumes the Task Force will fail to reduce PCBs. Ecology, however, reasonably reached the contrary conclusion, and the Pollution Control Hearing Board concurred that the work of the Task Force is necessary to reducing PCBs and meeting water quality standards. *Supra* at 37.

The Tribe's argument also fails because the issuance of NPDES permits will also take into account the Tribe's PCB water quality standard. The Tribe's recourse for inadequate NPDES permits is to appeal them. Thus, the Tribe has not demonstrated that an EPA-issued TMDL is required to protect the Tribe's fishing rights.

The Tribe also appears to argue that EPA was under a mandatory fiduciary duty to take into consideration impacts to the Tribe's fishing rights in deciding that Ecology has not constructively submitted a Spokane River PCB TMDL. Tribe Br. at 15-16. As noted *supra* at 42 n.18, as part of EPA's consideration of Plaintiffs' administrative request, the Tribe did not request that EPA determine or consider any potential impact to its fishing rights, and that issue is not properly raised in this case. In any event, the Tribe does not point to a source of law containing a specific mandatory fiduciary duty that would require that EPA disrupt Ecology's priorities and efforts to reduce PCBs and establish a federal PCB TMDL for the Spokane River at this time.

In sum, the Tribe's fishing rights claim is not properly before the Court. Even if it were, the Tribe has not shown that its fishing rights have been adversely affected by EPA's determination that there has not been a constructive submission, or that there is a mandatory fiduciary duty for EPA to establish a PCB TMDL for the Spokane River.

III. PLAINTIFFS ARE NOT ENTITLED TO THE REMEDY SOUGHT.

Plaintiffs request that the Court order EPA to establish a Spokane River PCB TMDL "within 90 days." Pl. Br. at 32. Plaintiffs' requested relief is unfounded and impracticable. Thus, even assuming that Plaintiffs were entitled to some relief, the requested relief should be denied.

Injunctive relief may not be granted as a matter of course. *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982); *Amoco Prod. v. Gambell*, 480 U.S. 531, 546 n.12 (1982). The Supreme Court explained in a citizen suit case that "the court [must] 'balance[] the conveniences of the parties and possible injuries to them according[ly] as they may be affected by the granting or withholding of the injunction." *Weinberger*, 456 U.S. at 312; *Amoco*, 480 U.S. at 542. In formulating a remedy, "the court must be careful not to intrude upon the agency's realm of discretionary decision making." *Idaho Sportsmen v. Browner*, 951 F. Supp. 962, 968 (W.D. Wash. 1996).

To the extent that the Court determines that some injunctive relief is appropriate here, the CWA citizen suit provision provides that the remedy is limited to "order[ing] the Administrator to perform [the nondiscretionary] act or duty" 33 U.S.C. § 1365(a) (i.e., a remand to EPA to approve or disapprove the constructive submission). A constructive submission triggers a mandatory duty on the part of the EPA Administrator to either approve or disapprove the constructive submission. *Hayes*, 264 F.3d at 1023. Only if the Administrator disapproves the constructive submission is the EPA Administrator under a duty to establish a TMDL. *Id.; also Scott*, 741 F.2d 997. Accordingly, imposing a schedule on EPA to establish a PCB TMDL is not an appropriate remedy. *See also American Canoe Ass'n v. EPA*, 30 F. Supp.2d 908, 922 & n.17 (E.D. Va. 1998) ("the appropriate remedy for the plaintiffs' TMDL [complaint] would appear to be an order directing EPA to approve or disapprove Virginia's constructive submission within 30 days . . . .").

Furthermore, EPA's determination on remand could be challenged by Plaintiffs as final agency action; the Court's role would then be limited to reviewing EPA's approval or disapproval determination. *Hayes*, 264 F.3d at 1023; *American Canoe*, 30 F. Supp. 2d at 923 n.17 ("[i]f the EPA approved the [constructive] submission, this would appear to be a final agency action which could be challenged for abuse of discretion under the Administrative Procedure Act").

Even assuming the Court's authority extends to ordering EPA to establish a Spokane River PCB TMDL, Plaintiffs' have not shown that the injury to them if the relief is not granted outweighs the damage to EPA and the public interest if it is. For example, Plaintiffs contend that the lack of a PCB TMDL has resulted or will result in State-issued NPDES permits that lack PCB limits necessary to reduce PCB discharges and achieve water quality standards. As explained *supra* at 7, 37, 42-43, such assertions lack any foundation. As explained, NPDES permits must require effluent limits that ensure water quality standards will be met, regardless of whether a relevant TMDL has been established, 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A), and Plaintiffs' recourse if they believe State-issued permits are inadequate is to appeal such permits in the appropriate State administrative or judicial tribunal. Nor have Plaintiffs demonstrated that the Task Force will fail to reduce PCBs or that the relief they seek would result in any, let alone quicker, PCB reductions.

Plaintiffs also make no showing that the public interest will not be harmed by the Order they seek, due to the diversion of resources from equally or even more important State or federal TMDL development effort or other environmental projects. In this regard, it should be recognized that the entire docket of EPA involves issues affecting health and welfare. An increase in resources devoted to the PCB TMDL sought by Plaintiffs and Intervenor would result in a concomitant re-direction of resources devoted to other EPA programs designed to protect health and welfare.

If the Court were to conclude that an order requiring EPA to establish a PCB TMDL is appropriate, EPA should not be ordered to comply with Plaintiffs' proposed schedule to establish a PCB TMDL within 90 days. While Plaintiffs argue that this is reasonable "because the work has

already been done to prepare a technically sound TMDL," Pl. Br. at 32, this is clearly not the case. As discussed above, there are significant gaps in the draft TMDL Ecology prepared that would require an extended period of time to address. In considering the time necessary for EPA to complete such a complex regulatory action, the Agency must have the time it reasonably determines necessary to investigate and develop the necessary information. Even once a complete proposal is prepared, for complex regulatory actions EPA must have the time to consider the "complex scientific, technological, and policy questions" raised, reach "considered results," and establish a defensible action that will protect the environment. *Sierra Club v. Thomas*, 828 F.2d at 798. "[B]y decreasing the risk of later judicial invalidation and remand to the agency, additional time spent reviewing a rulemaking proposal before it is adopted may well ensure earlier, not later, implementation of any eventual regulatory scheme." *Id*. at 798-99. Finally, EPA's consideration of what schedule might be possible would require the consideration of additional information well beyond that contained in the administrative record in this case.

In short, even if Plaintiffs prevailed under a constructive submission theory, they would not be entitled to any of the injunctive relief they seek.

CONCLUSION

For the reasons stated above, the Court should grant EPA's cross-motion for summary judgment and deny Plaintiffs' and Intervenor's motions for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing filing was electronically filed with the Clerk of the Court on January 29, 2014, PST, using the Court's electronic filing system, which will send notification of said filing to the attorneys of record that have, as required, registered with the Court's system.

/S/ David Kaplan

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SIERRA CLUB; and CENTER FOR ENVIRONMENTAL LAW AND POLICY,

Plaintiffs,

and

THE SPOKANE TRIBE OF INDIANS,

Plaintiff-Intervenor,

v.

DENNIS MCLERRAN; GINA MCCARTHY; and UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Defendants,

and

SPOKANE COUNTY; KAISER ALUMINUM OF WASHINGTON LLC; and STATE OF WASHINGTON DEPARTMENT OF ECOLOGY,

Defendant-Intervenors.

Case No. 11-CV-1759-BJR

MEMORANDUM ORDER REMANDING MATTER FOR FURTHER CONSIDERATION

This matter is before the Court on cross motions for summary judgment by Plaintiffs, Plaintiff-Intervenor, Defendants, and Defendant Intervenors. Plaintiffs Sierra Club and Center for Environmental Law and Policy (hereinafter "Plaintiffs") claim that Defendant EPA failed to perform a nondiscretionary duty under the Clean Water Act ("CWA"). Plaintiffs raise claims

under the citizen-suit provisions of the CWA, 33 U.S.C. § 1365(a)(2), and the Administrative Procedures Act ("APA"), 5 U.S.C. § 706. Plaintiff-Intervenor Spokane Tribe of Indians ("Spokane Tribe") incorporates Sierra Club's claims and asserts additional claims under the CWA, APA, and federal trust responsibility. Having reviewed the parties' briefs together with all relevant materials, the Court grants partial summary judgment for Defendant EPA and Defendant-Intervenors (collectively, "Defendants") and grants partial summary judgment for Plaintiffs and the Spokane Tribe. The Court's reasoning follows:

I. BACKGROUND

A. The CWA Statutory Framework

Congress passed the CWA to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251. In order to achieve that objective, Congress declared as a "national goal" that the "discharge of pollutants into the navigable waters be eliminated by 1985." 33 U.S.C. § 101(a)(1).[1]

The CWA's regulatory program focuses on two potential sources of pollution: "point" sources and "nonpoint" sources. A "point" source is any "discernible, confined and discrete conveyance" from which pollutants are or may be discharged. *See id.* § 1362(14). A "nonpoint" source is any non-discrete source, such as runoff from stormwater or irrigation agriculture. *Id.* The CWA regulates point source pollution through the National Pollution Discharge Elimination System ("NPDES") permit process.[2] NPDES permits limit the discharge of pollutants through quantitative limits on the amount of pollutants released from each point source. *See id.* § 1342.

[1] Needless to say, this goal has proven optimistic.

[2] Most states, including Washington, are authorized to administer the NPDES permit program.

As part of its regulatory program, Section 303(d) of the CWA imposes duties on the states and the EPA. States are required, subject to federal oversight, to adopt water quality standards for each waterbody or waterbody segment within the state's boundaries. 33 U.S.C. § 1313. If a waterbody does not meet these standards or is not expected to meet them, the state must then designate that body as a "water quality limited segment." *Id.* § 1313(d)(1)(A); *see* 40 C.F.R. § 130.2. The list of "water quality limited segments" is known as the "303(d) list." After creating the 303(d) list, states must prioritize the water quality segments based on the severity of their pollution and their beneficial uses. *See* 33 U.S.C. § 1313(d)(1)(A). States are required to develop a "total maximum daily loads" (TMDL) for each pollutant impairing each water segment on the 303(d) list in accordance with these priorities. 40 CFR § 130.2 (f). A TMDL establishes the maximum amount of pollutants a water quality limited segment can receive daily without violating the state's water quality standards. TMDLs are supposed to be developed in accordance with their priority ranking on the 303(d) list. *See* 33 U.S.C. § 1313(d)(1)(C).

States must submit the ranked list of water quality limited segments and TMDLs to the EPA "from time to time." *Id.* § 1313(d)(2). The first such submission was due on June 26, 1979, just 180 days after the CWA was enacted. Once a submission is made, certain mandatory EPA duties are triggered. First, within 30 days of submission, the EPA must approve or disapprove of the water quality limited segments and the corresponding TMDLs. *Id.* If the EPA approves a submission, the submission is incorporated by the state into its continuing planning process and NPDES permitting. *Id*. at §303 (e) (3). If the EPA disapproves, the EPA must, within 30 days of the disapproval, make its own identification of appropriate water quality limited segments or establish its own TMDLs. *Id.* The CWA is silent as to the nature of the

EPA's obligations if a state fails to make any submissions or fails to make a particular submission.

B. History of Spokane River TMDL for PCBs

In the State of Washington, the 303(d) list and TMDLs are prepared by Intervenor Washington State Department of Ecology (hereinafter "Ecology"). This case concerns the regulation of polychlorinated biphenyls (PCBs) in the Spokane River.[3] It is undisputed that PCBs are industrial chemicals that are "persistent, bioaccumulative, and toxic." AR 14A at 487. The Spokane River has the worst PCB contamination in the state and has been subject to a Spokane County and Washington Department of Health fish consumption advisory since 1994 and 2003, respectively. AR 15 at 97; AR Supp. 5, 7. The 303(d) list Ecology submitted in 1996 identified five segments of the Spokane River that exceeded water quality standards for PCBs. AR 2710. The most current 303(d) lists, for 2008 and 2010, identify fifteen segments of the Spokane River that exceed water quality standards for PCBs. AR 80.[4] Ecology had also identified segments that exceed water quality standards for other pollutants in the Spokane River, and has developed TMDLs for other pollutants in the Spokane River and tributaries. AR 222-23. Of particular note was a recent group of nine TMDLs for dissolved oxygen in the Spokane River. AR 503. Ecology prepared this group of nine TMDLs over the course of 12 years; EPA approved them in 2010. AR 224.

[3] For convenience, the Court uses "Spokane River" to refer to the Spokane River itself, the lake into which it flows (Spokane Lake, also known as Long Lake), and the Little Spokane River. The parties generally group these waterbodies together and this action appears to target regulation of all three.

[4] Upon Sierra Club's request, and with no opposition by Defendants, the Court takes judicial notice of the 2010 303(d) list, and the EPA approval of that list, which occurred in 2012. Neither documents are part of the administrative record in this case. *Available at* http://www.ecy.wa.gov/programs/wq/303d/currentassessmt.html; http://yosemite.epa.gov/r10/water.nsf/tmdls/WA-303d-2010-approval.

No TMDLs for PCB have been submitted to EPA to date. Ecology conducted a TMDL assessment for PCBs in the Spokane River during 2003 and 2004. AR 1331. In 2006, Ecology produced a document entitled "Spokane River PCBs Total Maximum Daily Load [:] Water Quality Improvement Plan." AR 1319. The document was labeled "Draft – 6-19-06 – Do not cite or quote." *Id.* In the document, Ecology cited the statutory requirement that "[w]aters placed on the 303(d) list require preparation of [TMDLs]." AR 1333. Recognizing that fifteen segments of the Spokane River were on the 303(d) list for PCB pollutants, Ecology explained that "[a] TMLD has been determined to be the action needed to address these listings." *Id.*

There are several water quality criteria applicable to the Spokane River, including levels promulgated by the federal government, by Washington State, and by the Spokane Tribe. AR 1348. Ecology selected the most stringent water quality standard, the Spokane Tribe's, as the "the basis for calculating necessary load reductions and load allocations" for the draft. AR 1402. The parties agree that adopting the Spokane Tribe's water criterion would likely mean PCB load reductions of 95-99 percent. AR 1409. The draft document set load reductions for various dischargers on the Spokane River, with reductions of over 99 percent for some of the dischargers. AR 1409. In 2006, Ecology shared a draft TMDL with the EPA, the tribe, the state of Idaho, the dischargers, and interested members of the public.

The parties dispute whether this draft document contained sufficient information from which a final PCB TMDL could have been produced. Emails from Ecology staff members indicate that Ecology originally contemplated finalizing the TMDL at some point in 2007, and by mid-2008 was projecting a completion date of June 2009. AR 1062. Throughout this period, Ecology continued to collect data. Delays in the preparation of the dissolved oxygen TMDL caused some uncertainty as to when the PCB TMDL would be completed. AR 1071.

Eventually, Ecology issued a finalized version of the 2006 draft document, but with several significant revisions. The document title did not include any reference to Total Maximum Daily Load. Instead the document, released in April 2011, was retitled "Spokane River PCB Source Assessment 2003-2007." AR 63. Some introductory material explaining TMDLs was also excised. AR 63. Though the document still identified the target water quality level for PCBs and explained the overall loading reductions that would be needed to comply with that standard, it did not include permissible wasteload amounts for individual Spokane River dischargers.

The following month, Ecology released a second document, the "Spokane River Toxics Reduction Strategy," which set forth the agency's "strategy or 'road map' for reducing and removing toxic contamination in water, water sediments and soil in the Spokane River watershed." AR 485. That document contained the following explanation of Ecology's change in course:

> A draft Spokane River PCB TMDL was issued for public comment in June 2006 but was not completed because of the need for more data, including more accurate stormwater data, updated fish tissue sampling results, and the addition of new Spokane Tribe water quality standards for PCBs based on updated fish consumption rates. The draft TMDL was revised with this updated information in 2009 and issued as the Spokane River Source Assessment Report in 2011.
>
> ***
>
> Ecology is not currently planning to develop a PCB TMDL with wasteload allocations, but this is still a potential tool for the future. Setting wasteload allocations through a TMDL would set a target well below the 'background' PCB concentrations observed in remote bodies of water with no obvious source of contamination other than aerial deposition.
>
> In part because it would establish an impossible near-term target, and based on its experience with the Spokane River Dissolved Oxygen TMDL, which took 12 years to complete, Ecology is opting to proceed directly to implementing measures to reduce all toxics to the Spokane River. Those measures are described in this strategy. Such a *straight-to-implementation* plan is a recent strategy being

> adopted by the EPA and Ecology to address the many bodies of water that are on the list of polluted waters [called the 303(d) list] through tools other than TMDLs. Ecology plans to develop a straight-to-implementation plan for Spokane River toxics in 2012.

AR. 503 (emphasis in original). After 2010, Ecology renewed the permits of several Spokane River dischargers, and issued a new permit to Spokane County. None of these permits reflected the load reductions anticipated by the draft TMDL. However, Ecology did condition permits on permittee monitoring and permittee participation in a "Regional Toxics Task Force."

Sierra Club brought this action in October 2011. On May 25, 2012, Ecology submitted a letter to the EPA, stating:

> If Ecology determines that the Task Force is failing to make measurable progress toward meeting applicable water quality criteria for PCBs, Ecology would be obligated to proceed with development of a TMDL in the Spokane River for PCBs or determine an alternative to ensure water quality standards are met. Ecology remains committed to proceeding with a TMDL should it be necessary.

AR 1 at 2. In December 2012, Sierra Club submitted documents to the EPA for inclusion in the administrative record, and requested a determination from the EPA regarding whether Ecology had, through its conduct, made a "constructive submission" of the PCB TMDL, i.e. abandoned the TMDL, thereby triggering the EPA's duty to prepare a TMDL. AR B and C. The EPA responded on April 12, 2012, finding no constructive submission. AR A. The EPA determined that "Ecology's decision to delay completion of a PCB TMDL for the Spokane River is within the discretion of the State of Washington," and that "Ecology has not renounced completion of a PCB TMDL for the Spokane River if one is required." *Id.* In reaching this decision, the EPA noted that Ecology had submitted 1372 TMDLs since 1999. *Id.* The EPA cited the gaps in

information concerning PCBs, the lengthy delays associated with preparing a TMDL, and the scarcity of resources supporting Ecology's decision to defer the TMDL. *Id.* The EPA also observed that interim measures to achieve water quality standards are an acceptable alternative to a TMDL. *Id.* The EPA pledged to monitor the situation, along with Ecology's progress in issuing other TMDLs, and indicated that it "may reconsider this decision if significant relevant circumstances change." *Id.* Sierra Club then amended its complaint to include two APA claims challenging the April 2013 letter, in addition to its preexisting CWA citizen-suit claim.

II. DISCUSSION

A. CWA – Claim Based Upon Section 505(a)(2)

§505(a)(2) of the CWA authorizes citizens to institute actions in federal court against the EPA for failure to perform any act or duty under the CWA that is not discretionary with the EPA. 33 U.S.C. § 1365(a)(2). Plaintiffs contend that the EPA is subject to §505(a) liability because it breached a mandatory duty under § 303(d) of the CWA. According to Plaintiffs, the EPA's non-discretionary duty to either approve or disapprove a TMDL was triggered when Ecology "clearly and unambiguously" indicated that it will not be preparing a TMDL for PCBs in the Spokane River.

1. EPA Has a Non-Discretionary Duty to Act When a State Clearly and Unambiguously Abandons a Particular TMDL

Defendants argue that, as a matter of law, the EPA does not have a statutory duty to approve or disapprove a state's failure to submit a particular TMDL. In determining the scope of the EPA's mandatory duty under Section 303(d), the court is guided by the fundamental principles of statutory construction. "Proper statutory construction requires

more than linguistic examination and review of the rules of statutory construction. The interpretation should be reasonable, and where the result of one interpretation is unreasonable, while the result of another interpretation logical, the latter should prevail." *Sierra Club v. Train*, 557 F.2d 485 (5th Cir. 1977). A court must construe a statute's language so as to give effect to the intent of Congress. *Id*.

The mandatory TMDL process requires that states identify water segments that are below the state's relevant water quality limits; establish a priority ranking for those waters; and establish TMDLs in accordance with the priority ranking. The relevant text of the CWA is as follows:

> (2) Each state shall submit to the Administrator from time to time, with the first such submission not later than 180 days after the date of publication of the first identification of pollutants under §1314(a)(2)(D) of this title, for his approval, the waters identified and the loads established. . . . The Administrator shall either approve or disapprove of such identification and load not later than 30 days after the date of submission. If the Administrator approves such identification and load, such State shall incorporate them into its current plan . . . If the Administrator disapproves such identification and load, he shall not later than 30 days after the date of such disapproval identify such waters in such State and establish such loads for such waters as he determines necessary to implement the water quality standards applicable to such waters and . . . shall incorporate them into its current plan . . .

The statute clearly contemplates (somewhat naively as time has shown) that states will promptly submit TMDLs for their listed waterways and that the EPA's duty to prepare a TMDL would be triggered when it disapproved of a state's submitted TMDL. The problem with the statute has not arisen in the context of disapproved submitted TMDLs but in a state's failure to submit TMDLs. Notably, the CWA is silent as to the EPA's responsibilities when a state abdicates its responsibility to submit TMDLs. *See Alaska Ctr. for the Env't v. Reilly*, 762 F. Supp. 1422, 1425 (W.D. Wash. 1991). The

Seventh Circuit was the first Circuit to address the nature of the EPA's obligations in light of this silence. In *Scott v. City of Hammond, Indiana*, the Seventh Circuit held that, even in the absence of express language in the statute, the EPA has a duty to develop TMDLs for a particular waterbody when a state fails to comply with the CWA's submission requirements. 741 F.2d 992 (7th Cir. 1984). The *Scott* case involved a citizen suit against the EPA for failure to prescribe TMDLs for pollutants discharged into Lake Michigan after Illinois and Indiana failed to submit any draft TMDLs for Lake Michigan over the course of several years. *Id.* Finding it "unlikely that an important aspect of the federal scheme of water pollution could be frustrated by the refusal of states to act," the court rejected the EPA's argument that Congress did not intend to establish a statutory duty for the EPA in the case of state inaction. *Id*. Instead, the *Scott* court held "if a state fails over a long period of time to submit proposed TMDLs, this prolonged failure may amount to the constructive submission by that state of no TMDLs," thereby triggering the EPA's mandatory duty. *Id.* Since Indiana and Illinois had produced no TMDLs for the Lake Michigan waterbody, the court remanded the matter to the district court with instructions "to proceed as if the states had submitted proposals of no TMDLs unless [there is] evidence indicating that the states are, or will soon be, in the process of submitting TMDL proposals or some factor beyond the scope of the complaint has made TMDL submission impracticable." *Id*. at 997, n. 11.

In 2002, the Ninth Circuit expressly adopted the constructive submission doctrine in *San Francisco BayKeeper v. Whitman*. 297 F.3d 877, 883 (9th Cir. 2002). *BayKeeper* concerned a citizen suit alleging that California's failure to submit any TMDLs for any water bodies in California constituted a "constructive submission" of no TMDLs for the

entire state, thereby triggering the EPA's non-discretionary duty to prepare TMDLs for the entire state. *Id.* Citing *Scott*, the Ninth Circuit held that state inaction can amount to a constructive submission if a state "clearly and unambiguously" indicates that it will not submit any TMDLs. *Id.* However, in applying this standard, the court held that California had not clearly and unambiguously abandoned its TMDL program for the state. *Id.* This holding was premised on a finding that, since 1994, California submitted "at least eighteen TMDLs and . . . established a schedule for completing its remaining TMDLs." *See id.* at 883-84.[5]

Defendants assert that a constructive submission occurs only when a state produces few or no TMDLs for the whole state over a substantial period of time: If a state has a robust TMDL program, its decision to abandon a particular TMDL does not trigger the EPA's non-discretionary duty. Doc. No. 91 at 27. The Court questions this narrow interpretation of the doctrine for the reasons set forth below.

In making this argument, Defendants rely on *BayKeeper's* holding and language, which focused on the state-wide TMDL program. This reliance is misplaced. The issue in *BayKeeper* was whether California's failure to produce a significant number of TMDLs constituted a *programmatic* failure for the *entire* state. *Id.* at 880-82. Clearly, California's producing several TMDLs and committing to more demonstrates that California had not abandoned its TMDL program. *See id.* However, the question here is whether Washington has abandoned a specific component of its CWA obligations—a question that was not before the *BayKeeper* court and one not resolved by looking to a

[5] The *BayKeeper* court expressed no opinion on California's failure to submit TMDLs prior to 1994 and eschewed any "broad, generic determination of the point in time at which a state's inaction may be deemed a constructive submission." *Id.*

state's general compliance. Accordingly, the Court finds it insignificant that the Ninth Circuit did not address an issue not raised by the facts of the case. Moreover, far from foreclosing the application of the constructive submission doctrine to a particular pollutant or waterbody segment, the *BayKeeper* court cited with approval to *Scott*, which applied the constructive submission doctrine to TMDLs for a particular waterbody segment, Lake Michigan. *See BayKeeper*, 297 F.3d at 882 (characterizing ruling as "consistent" with *Scott*).

Defendants also argue that applying the "constructive submission" doctrine to a particular TMDL interferes with the state's discretion to prioritize its TMDLs. Unquestionably, state discretion is an important component of the CWA. Resource constraints compel difficult choices as to which TMDLs should be performed before others—a choice that states are often better situated to make. Perhaps in recognition of these constraints, the CWA provides no specific mechanism for reviewing this prioritization. *See* § 303(d)(1)(A). However, the state discretion argument is a red herring in this context for several reasons.

Applying the constructive submission doctrine to individual TMDLs does not invade state prioritization. A constructive submission occurs only when a state has clearly and unambiguously *abandoned* its obligation to produce a TMDL or TMDLs. *See, e.g., San Francisco BayKeeper*, 297 F.3d at 883; *see also Alaska Ctr. for the Env't*, 762 F. Supp. at 1427(constructive submission when Alaska clearly and unambiguously abandoned its TMDL obligation). It does not occur merely because a state has prioritized one TMDL over another. *See Hayes*, 264 F.3d at 1024.

Relatedly, applying the constructive submission in this instance does not encroach upon Washington's ability to prioritize its TMDLs. Ecology has not identified a specific TMDL which it is prioritizing over the TMDL at issue.[6] In fact, Ecology has treated the Spokane River as a priority and kept it as such for a prolonged period of time, producing at least 78 TMDLs for this very water segment. Ecology has already engaged in a significant amount of work with regard to this specific TMDL by compiling scientific data, preparing at least a preliminary TMDL draft, discussing its contents with the EPA, submitting it to other parties for some form of comment, and creating the Task Force for PCBs.

More importantly, while a state's failure to produce any TMDLs is perhaps the clearest indication that it has abandoned its statutory obligations, the Court finds nothing in the text of the CWA or its purpose to support Defendants' contention that a state's abandonment of a specific statutory obligation should be treated differently from a state's wholesale failure. To the contrary, a state's discretion to prioritize TMDLs over other TMDLs does not remove its ultimate obligation to produce a TMDL for each water pollutant of concern in every 303(d) water segment. *See* 33 U.S.C. § 1313(d) (2). In light of this statutory obligation, it would be absurd for the Court to hold that a state could perpetually avoid this requirement under the guise of prioritization; such an administrative purgatory clearly contravenes the goal and purpose of the CWA. 33 U.S.C.A. § 1251 (a)(1) ("it is the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985"). Accordingly, the Court rejects Defendants

[6] Defendants assert that Ecology is currently producing other TMDLs; however, Defendants do not demonstrate that pursuing these other TMDLs precludes Ecology from pursing the PCB TMDL as well. *See* Doc. No. 91 at 12.

contention that the constructive submission doctrine cannot apply when a state abandons its obligations under the CWA by clearly and unambiguously indicating that it will not produce a particular TMDL.

2. No Constructive Submission Has Yet Occurred

In examining whether Ecology "clearly and unambiguously" decided not to submit a TMDL for PCBs in the Spokane River, the Court is confronted with an issue that has not been directly addressed by any other court: at what point does a state's failure to prepare a particular TMDL ripen into a constructive submission?

According to the EPA, Ecology's failure to submit the PCB TMDL is not a constructive submission because Washington has a robust TMDL program, which has produced 1,372 TMDLs statewide since 1999. While a healthy TMDL program is required to show that a state is prioritizing other TMDLs over the TMDL in question, it is not, on its own, sufficient. *See supra* II A 1. Naturally, a state that has publicly indicated, as Plaintiffs claim Ecology has, that it will not produce a specific TMDL has violated its statutory obligations with respect to that TMDL, no matter how robust its program otherwise is. *See* 40 CFR § 130.2 (f) (states shall produce a TMDL for each water segment on the 303(d) list regarding each pollutant of concern). Accordingly, the Court finds consideration of Washington's general TMDL program relevant but not dispositive in a case concerning failure to submit a particular TMDL.

Plaintiffs present Ecology's actions as an exceptional case, in which an agency essentially completed a TMDL and then abandoned the TMDL for an alternate course, actions which, according to Plaintiffs, unambiguously indicate Ecology will never comply with its statutory obligations, thus requiring the EPA to prepare the TMDL. Doc.

No. 101 at 9. The EPA and Ecology counter that information gaps, scarce resources, and lengthy administrative processes led Ecology to adopt an alternative approach, for the time being, without ruling out a TMDL in the future. Doc. No. 91 at 15-17. If, as Plaintiffs contend, the PCB TMDL was essentially complete and ready for submission, a last-minute pivot to an illusory alternative may indicate a decision to abandon the TMDL. By contrast, if information gaps persisted such that Ecology determined that it could not confidently issue a TMDL at any point in the near future, adopting an alternative may, under some circumstances, represent a reasonable interim measure rather than an abandonment of any future plans to prepare a TMDL.

The Court need not define the precise contours of this doctrine at this time. The facts in the record readily demonstrate that Ecology had sufficient reasons for not completing the TMLD: The Court finds that Ecology lacked sufficient scientific data and had not satisfied certain pre-submission requirements, i.e. public notice and consultation.

i. Scientific Data

Defendants assert that, far from being essentially complete, substantial work remained to be done before Ecology could submit the TMDL. First, Defendants argue that Ecology lacked sufficient scientific data to produce a complete TMDL. According to the EPA, Ecology did and still does not know the source of 57% of PCB loading in certain parts of the Spokane River. V. 1, T. 15 at 163. Similar information gaps existed in other segments. V.3, T.69 at 1205; V. 5, D. 132 at 2683. In light of this uncertainty, the EPA contends it would be unfair and unproductive to impose severe restrictions on only a fraction of identifiable polluters. Plaintiffs counter that scientific uncertainty regarding pollution sources is not a sufficient justification for delay because it is inherent

in the TMDL process. Plaintiffs' argument relies on language in the CWA stating that TMDLs should include "margins of safety." The Court rejects this argument. The "margins of safety" in the CWA are designed to take "into account any lack of knowledge concerning the *relationship between effluent limitations and water quality*." 33 U.S.C. §1313(d)(1)(C)(emphasis added). In other words, "margins of safety" address uncertainty over the effect pollutants at certain levels will have on water quality; they do not address a lack of knowledge regarding the *source* of the pollutants. *See Natural Resources Defense Council, Inc. v. Muszynski*, 268 F.3d 91, 101-02 (2d Cir. 2001). While there may be a point at which a state possesses enough scientific data that failing to submit the TMDL demonstrates intent to abandon that TMDL, the EPA did not err in finding that the uncertainty here does not rise to that level.[7]

ii. Procedural Gap

Defendants point out that Ecology also needed to perform certain procedural steps before submitting the PCB TMDL. An important preparatory step in the submission process is the public notice and consultation period. According to Plaintiffs, Ecology satisfied these requirements when it sent the draft to the following stakeholders for comment: Plaintiffs; Defendant-Intervenors; and certain EPA and Idaho state officials. Plaintiffs assert that Ecology admitted that the draft "was issued for public comment in June 2006" in its "Spokane River Toxics Reduction Strategy." AR 485, 503.[8]

[7] Plaintiffs assert that the CWA specifically contemplates that the states will, at least occasionally, submit incomplete TMDLs because it gives the EPA the authority to disapprove of TMDLs. The Court rejects this argument. While the CWA contains a mechanism for rejecting an incomplete TMDL, the mere existence of this mechanism is not a sufficient reason to compel submission when a significant amount of data is missing.

[8] Plaintiffs also cite an email exchange between members of the EPA and Ecology in which EPA provided Ecology with various feedback over technical and practical issues associated with the PCB TMDL. However, Plaintiffs do not demonstrate how these comments amount to a formal step in the process that would amount to proper notice.

Defendants counter that the draft TMDL was still in the preparatory stages and such informal comments and requests for feedback do not satisfy the formal notice requirements. According to Defendants, the draft TMDL was specifically designated as incomplete and preliminary; it was marked "Draft – 6-19-06 – Do not cite or quote." *See* AR 1331. Defendants further assert that Ecology contemplated several additional steps before formal public disclosure, including additional studies of stormwater runoff and drainage. *See* Spokane River PCB TMDL Stormwater Loading Analysis Final Technical Report, at v (Dec. 2007). Plaintiffs have not shown these additional studies were unnecessary. Accordingly, Ecology did not, as Plaintiffs contend, essentially complete the TMDL and withhold it without sufficient reason.[9] Therefore, Ecology's failure to submit the PCB TMDL did not clearly and unambiguously indicate its intent to abandon the PCB TMDL.

B. Violation of Section 706(1) of the APA

Plaintiffs' APA claim under Section 706(1) relies on the same operative facts asserted in the CWA claim. Plaintiffs allege that the EPA's failure to disapprove Ecology's constructive submission constitutes "agency action unlawfully withheld or unreasonably delayed." a violation Section 706(1) of the APA. This claim fails because it is premised on an assumption that Ecology's inaction amounted to a constructive submission. As set forth above, no constructive submission has occurred.

[9] Scientific uncertainty and procedural gaps indicate that Ecology has not clearly and unambiguously abandoned its TMDL obligations in this specific context because Ecology has engaged in significant work toward completing the TMDL. The Court need not decide whether these factors would be relevant in other scenarios, i.e. if Ecology had engaged in no (or very little) work on the PCB TMDL or if Ecology fails to make any scientific progress in the coming years.

C. Violation of Section 706(2)(A) of the APA

a. The EPA Abused its Discretion

Under the APA, final agency actions must be upheld unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. §706(2)(A). The scope of the court's review under the APA is narrow, and a court may not substitute its own judgment for that of the agency. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). The agency's factual determinations are entitled to substantial deference and should be upheld if they are supported by the administrative record. *Arkansas v. Oklahoma*, 503 U.S. 91, 112 (1992). When reviewing an examining agency's scientific findings made within the area of an agency's technical expertise, the court must be at its most deferential. *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 376-77 (1989). The party asserting the APA challenge bears the burden of demonstrating that the agency's actions were arbitrary or capricious. *Nw. Ecosystem Alliance v. U.S. Fish & Wildlife Serv.*, 475 F.3d 1136, 1140 (9th Cir. 2007).

Plaintiffs allege that the EPA's finding no constructive submission is arbitrary and capricious. As discussed *supra*, the Court found that the EPA did not err in finding no constructive submission has yet occurred on the grounds that significant scientific information and procedural gaps remained.

Plaintiffs further allege that the EPA acted contrary to law and abused its discretion in approving the Task Force as an alternative to the TMDL. Doc. No. 84 at 16. The Court agrees with Plaintiffs; the EPA does not have the statutory authority to

approve a Task Force in lieu of a TMDL. States may pursue reasonable courses to reducing pollution in addition to establishing TMDLs. *See, e.g., City of Arcadia v. U.S. EPA*, 411 F.3d 1103, 1106 (9th Cir. 2005) ("states remain at the front line of combatting pollution"). However, nothing in the CWA provides that states may pursue these courses in place of, or as a means of indefinitely delaying, a TMLD. To the contrary, the CWA expressly requires states to produce a TMDL for each pollutant of concern in each 303(d) water segment. *See* U.S.C. § 1313(d)(1)(A); 40 CFR § 130.2 (f); *see also Alaska Ctr. for the Env't v. Reilly*, 762 F. Supp. 1422, 1425 (W.D. Wash. 1991) (states must submit TMDLs). Similarly, the CWA does not give the EPA authority to approve an indefinite delay; the CWA commands the EPA to ensure prompt compliance with the CWA. *See Scott v. City of Hammond*, 741 F.2d 992, 998 (Congress intended TMDLs be established "promptly"); *Idaho Sportsmen's Coalition*, 951 F. Supp. at 967 ("Congress prescribed early deadlines for the TMDL process;" those deadlines could be interpreted to mean "months and a few years, not decades."). Therefore, the EPA may not approve a task force as an alternative to a TMDL, i.e. a task force not designed to complete or assist in completing a TMDL. *See Alaska Ctr. for the Env't*, 796 F. Supp. at 1379 ("The responsibility of the court is to ensure prompt and attentive adherence to the mandate of the CWA."). The Task Force as presently proposed provides no way of determining if the Task Force has been effective in furthering the preparation of a TMDL.

In its letters, Ecology indicated that it is pursuing a Task Force in place of a TMLD because the TMDL would establish "an impossible near-term target." *See* AR 14A at 503. Ecology further stated that it views a TMDL as a "potential" "alternative" to be re-visited only if the Task Force fails to make "measurable progress." *See* AR 14A at

503 (Ecology is not "currently planning to develop a PCB TMDL"). Ecology did not, however, define what constitutes measurable progress, nor did it clearly illustrate how the Task Force would produce or assist in preparing a TMDL. Even more troubling, Ecology provides no firm deadline for when the Task Force will end and Ecology will submit a TMDL. Rather, Ecology states only that it would "monitor and assess the effectiveness of toxic reduction measures" in 2017. V. 1, T. 4, at 14; V. 1, T.A. at 3. Thus, there is no metric to measure success, no clear trigger after which Ecology would produce a TMDL, and no specific date on which such a TMDL would be submitted to the EPA. Compounding this uncertainty is the worrying lack of progress made with respect to the scientific data in recent years. The EPA found that scientific uncertainty prevents the submission of a TMDL, yet it is unclear how or whether the Task Force will resolve that problem.[10] The record indicates that the Spokane River has been on the 303(d) list since 1996 and after nearly 20 years still contains the worst PCB pollution in the state. Despite this known problem and Ecology's prioritization of the Spokane River PCBs, a substantial percentage of the pollution sources remain unknown. The failure to submit a TMDL also affects the ability of the Washington State Pollution Control Hearing Board to effectively limit pollutants and monitor water quality. Had a TMDL been established, any issuance of permits would have been tied to the wasteload allocations specified in the TMDL. 40 C.F.R. §122.44(d)(1)(vii)(B). Meanwhile, it is significant that no effective limitations have been put in place by the Board and the only significant condition imposed by the Board has been that point polluters participate in the Task Force.

[10] During oral argument, counsel for the EPA was unable to articulate precisely how the Task Force would resolve the scientific uncertainty.

There comes a point at which continual delay of a prioritized TMDL and detours to illusory alternatives ripen into a constructive submission that no action will be taken. With the Task Force as presently proposed, Ecology is coming dangerously close to such a point, and with EPA's support. Accordingly, the Court finds that the EPA acted contrary to law in finding the Task Force, as it is currently comprised and described, a suitable "alternative" to the TMDL. For the reasons set forth below, the Court remands the matter to the EPA for further consideration and consultation with Ecology. *See e.g., Idaho Sportsmen's Coal.*, 951 F. Supp. at 969 (finding EPA abused its discretion in approving insufficient TMDL schedule, even though no constructive submission occurred).

b. The Issue Is Remanded to the EPA

When an agency "does not reasonably accommodate the policies of a statute or it reaches a decision that is 'not one that Congress would have sanctioned,' . . . a reviewing court must intervene to enforce the policy decisions made by Congress." *Environmental Defense Fund v. EPA*, 852 F.2d 1316, 1326 (D.C. Cir. 1988) (citations omitted). An EPA regulation requires that "[s]chedules for submission of TMDLs shall be determined by the Regional Administrator and the State." 40 C.F.R. §130.7(d)(1). This regulation derives from Congress's direction that states submit TMDLs "from time to time" under 33 U.S.C. §1313 (d). Thus, the EPA has authority to set, with a state, a schedule to complete the TMDL process. *See Idaho Sportsmen's Coal. v. Browner*, 951 F. Supp. 962, 968 (W.D. Wash. 1996); *see also Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1527-28 (9th Cir. 1995). A firm schedule and concrete goals are important in this

case, especially since the state is pursuing an alternative route that may delay an already delayed TMDL. *See* AR 90 at 1334; AR 132 at 2675-76.

Accordingly, the Court sets aside the EPA's decision and remands this issue to the EPA for additional consideration consistent with this order. Specifically, the EPA shall work with Ecology to create a definite schedule with concrete goals, including: clear statements on how the Task Force will assist in creating a PCB TMDL in the Spokane River by reducing scientific uncertainty; quantifiable metrics to measure progress toward that goal; regular checkpoints at which Ecology and the EPA will evaluate progress; a reasonable end date, at which time Ecology will finalize and submit the TMDL for the EPA's approval or disapproval; and firm commitments to reducing PCB production from known sources in the interim.

D. Spokane Tribe's Claims

The Spokane Tribe asserts that the EPA, in addition to its obligations under the CWA and APA, owed a trust responsibility to the Spokane Tribe. The EPA counters that it owes only a general trust obligation in this instance, which, according to the EPA, it discharged by complying with generally applicable law. There is a "distinctive obligation of trust upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801, 812 (9th Cir. 2006). This obligation alone, however, "does not impose a duty on the government to take action beyond complying with generally applicable statutes and regulations." *Id*. at 810; *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995) ("[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one"). Unless a specific duty exists, an agency's compliance with general regulations and statutes discharges

the agency's general trust responsibility to Indian tribes. *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569, 574 (9th Cir. 1998). In order to create a specific duty, the statutory language must "go[] beyond a bare trust and permit[] a fair inference that the Government is subject to duties as a trustee and liable in damages for breach." *United States v. White Mountain Apache Tribe*, 537 U.S. 465, 474 (2003). This analysis involves an examination of whether specific rights are created by the statute—either creating a duty or imposing statutory or regulatory "prescriptions." *United States v. Navajo Nation*, 537 U.S. 488, 506 (2003).

In Count I, the Spokane Tribe asserts that the EPA breached its trust responsibility by failing to disapprove a "constructive submission" and not producing a TMDL. Doc. No. 64. The EPA counters that it discharged its trust responsibility by complying with generally applicable law, namely the CWA. The Court agrees with the EPA; the Spokane Tribe has not identified a specific duty in this context. The Spokane Tribe contends its status as a state for the purposes of the CWA and the EPA's approval of the Spokane Tribe's water quality standards imposed a heightened trust obligation on the EPA. AR Supp. 10 at paras 8-9. However, the Spokane Tribe cites to nothing that grants any specific rights to the Indian tribes. In the absence of a specific right or obligation, the EPA's responsibilities amount to no more than a bare trust obligation, which can be discharged by complying with generally applicable law. *See Gros Ventre Tribe*, 469 F.3d at 812 (observing that no breach exists where statutes and treaties only recognize a general or limited trust obligation to protect tribes on Reservation lands). The Court has already found that the EPA has not violated the CWA by failing to find a constructive submission. Accordingly, the EPA has not breached a trust obligation with respect to the CWA.

The Spokane Tribe further argues that the EPA owed the Spokane Tribe a trust duty regarding its April 12, 2013 approval of the Task Force as an alternative to the TMDL. Doc. No.

64. In addition to the APA obligations discussed *supra,* the Spokane Tribe asserts that the EPA had to consider the Spokane Tribe's fishing rights. Doc. No. 64. The EPA counters that "the [Spokane] Tribe's theory on how its fishing rights are impacted [by this decision] inappropriately assumes the Task Force will fail to reduce PBCs." Doc. No. 102 at 12. Since the Court has already found that the EPA violated generally applicable law with respect to its April 12, 2013 determination and will remand the matter to the EPA, the Court need not consider whether the EPA has any specific trust obligations at this time.

III. CONCLUSION

While the Court does not find that on the record before it there has been a constructive submission, the Court does find that EPA's approval of the Task Force without adequate assurances that it will result in a TMDL within a reasonable time is in violation of EPA's statutory duties and, therefore, contrary to law and arbitrary and capricious.

NOW THEREFORE, IT IS ORDERED AS FOLLOWS:

1. Plaintiffs and the Spokane Tribe's Motions for Summary Judgment are GRANTED with respect to their claims pursuant to § 706(2)(A) of the APA. EPA's approval of the Task Force as an alternative to the TMDL development, to extend over an indefinite period of time without adequate assurances that a TMDL will result, is held to be arbitrary and capricious, an abuse of discretion, and contrary to law;
2. This matter is remanded to the EPA with directions to consult with Ecology and file herein, within 120 days of the date of this order, a complete and duly adopted reasonable schedule for the measuring and completion of the work of the Task Force, including quantifiable benchmarks, plans for acquiring missing scientific

information, deadlines for completed scientific studies, concrete permitting recommendations for the interim, specific standards upon which to judge the Task Force's effectiveness, and a definite endpoint at which time Ecology must pursue and finalize its TMDL;

3. EPA's Motion for Summary Judgment is GRANTED, with respect to Plaintiffs' CWA claims and the Spokane Tribe's claims under the CWA and related claims under the federal trust doctrine;

4. Plaintiffs and Spokane Tribe's claims under the CWA and the Spokane Tribe's claim for EPA's breach of its federal trust responsibility are DISMISSED WITHOUT PREJUDICE;

5. The Court retains jurisdiction pending compliance with this order.

Barbara J. Rothstein

BARBARA J. ROTHSTEIN
UNITED STATES DISTRICT JUDGE

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9 January 2013

Mary Lou Soscia
Columbia River Coordinator
US EPA
805 S.W. Broadway, Suite 500
Portland, OR 97205

Sent by email to: Soscia.Marylou@epamail.epa.gov

RE: Concerns with Idaho's Water Quality Standards Revision Process

Dear Mary Lou:

I am writing to clarify why the Kalispel Tribe does not currently support the process that Idaho has charted, and EPA apparently does not oppose, for revising the State's fish consumption rate ("FCR") and water quality standards. I want to emphasize at the outset that the Tribe has no interest in receiving any portion of the IGAP funds that EPA may be using to finance a fish consumption survey among the five tribes with reservations in Idaho. Our interest in this matter is to ensure that Idaho's revised water quality standards protect Kalispel people who eat fish that are harvested in Idaho or that are exposed to water pollution originating within Idaho. This is a very real concern to our members who harvest fish within the Tribe's aboriginal territory in Idaho, on lands owned by the Tribe in Idaho, or in Kalispel waters located downstream of Idaho. It is also a very real concern to our members who would harvest fish in these locales if it were safe to do so. The fact is that the FCR used to derive water quality standards in both Washington and Idaho has been outdated for more than a decade, resulting in elevated health risks for Kalispel people who eat more than 6.5 g/day of local fish or dietary avoidance of local fish. As both of these consequences are unacceptable to the Tribe, we cannot support further delay in adopting a more protective fish consumption rate.

The potential consequences of additional delay should not be underestimated. The process that Idaho has outlined will take at least three years from the date of EPA's disapproval of Idaho's water quality standards, which date was more than five years after the State submitted its water quality standards to EPA. Under the best case scenario, fifteen years will have passed from the date EPA published its 2000 Methodology requiring states to adopt an FCR of at least 17.5 g/day to the date that EPA approves an FCR in Idaho of at least 17.5 g/day. The cumulative delay of Idaho's proposed process accordingly amounts to an entire childhood, not a few years. To be clear, we are confronting a generational problem in terms of both unacceptable health risks for people who continue to eat fish and cultural destruction for those who do not.

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If EPA and the Idaho tribes believe that a new survey will be useful in helping Idaho develop more protective water quality standards, then we support that effort. We do not, however, think that the availability of funds and opportunity to develop new data should supplant the adoption of more protective state water quality standards right now. Idaho could defensibly adopt an FCR of at least 175 g/day tomorrow based on data supportive of the EPA-approved FCR in Oregon and more recent fish consumption surveys conducted by Washington tribes. The real issue at hand is not the absence of relevant fish consumption data, but how to manage the regulated community's effort to preserve its entitlement to pollute in a manner that is unsafe for people. That concern has no place in describing how much fish people eat or would like to eat, and should be addressed instead by developing an implementation schedule that protects human health and is reasonably fair to those who are regulated.

If EPA believes that it needs data from a new survey to be able to defend an FCR that is sufficiently protective of Indian people, we need to know that. And even if this belief turns out to be well founded, it does not justify leaving Indian people underprotected while these studies are designed and conducted. EPA guidance sets forth a national default FCR for subsistence fishers of 142.4 g/day that may be adopted without any new studies whatsoever. To demonstrate to the tribes that the goal of conducting a new tribal fish consumption survey in Idaho is to actually protect Indian people, EPA should insist that Idaho take a step in that direction by adopting an FCR of 142.4 g/day. The new survey will take at least three years to complete, so this FCR could be revised appropriately during the next triennial review.

The Tribe is also concerned that EPA has not developed parameters to ensure that the information derived from the IGAP survey will be used to protect Indian people. For instance, tribes need to know in advance that EPA will require Idaho to protect Indian people to a risk threshold that tribes support before the new survey is conducted. If EPA is not willing to provide this guarantee, then the regulated community may be able to manipulate data in a way that understates actual human health impacts to tribal members and other people who eat a large amount of fish. This effort is already underway in IDEQ's Negotiated Rulemaking Process. It is no defense that tribes will be able to adopt FCRs of their own because the bulk of toxic pollution originates from outside reservation boundaries.

During a December 11th phone call with EPA and the Idaho tribes, we specifically asked whether EPA would require subsistence fishers to be protected to the same extent as the general population. Christine Psyk responded that EPA would not because that requirement does not appear in EPA regulations or guidance. With all due respect, this response did nothing but reinforce our concern. EPA's 2000 Methodology states that it is acceptable for subsistence fishers to be protected at a 10^{-4} risk level as long as the general population is protected at a 10^{-6} risk level. If Idaho really has two orders of magnitude worth of wiggle room with which to "protect" subsistence fishers, we do not understand why EPA disapproved Idaho's standards in the first place, much less why it makes sense to spend $2 million on a tribal fish consumption survey. It is even more confounding to understand why people who eat the most fish are seen as dispensable in a risk assessment designed to protect the beneficial use of fishing. Frequent flyers certainly would not stand for this approach where airline safety is concerned, nor would there be many frequent flyers if 1 in 10,000 of them were involved in a plane crash.

EPA has curried some degree of regional support among tribes for its proposed use of the IGAP funds by saying that the IGAP survey will provide data that can be used by other tribes throughout the region. This is a spurious rationale, as EPA's actions in Idaho have demonstrated its unwillingness to require states to use relevant regional data. Instead, EPA is devoting millions to a new survey among Idaho tribes and supporting the State's decision to begin a new survey from scratch. The 2000 Methodology certainly does not require states or tribes to finance new surveys in the absence of available local or regional information, so Region 10 is effectively amending national policy to create a tremendous financial onus on any state or tribe wishing to adopt an FCR greater than the national default rate. The sounder policy choice here is to interpret EPA's permissive policy allowing states and tribes to set FCRs based on available local and regional informational as a mandatory requirement when such information demonstrates that vulnerable populations are underprotected. EPA arguably already made this policy decision in Oregon, and the result of that decision was an FCR of 175 g/day. If Idaho prefers devoting its scarce resources to financing a new survey rather than relying on regional data, it should adopt a rate of 142.4 g/day as suggested above during the pendency of the survey. EPA's disapproval letter did not clearly specify what was required of Idaho, so a clarifying letter would be helpful in outlining Idaho's range of options.

I would appreciate the opportunity to discuss these concerns with you in more detail in the near future.

Regards,

Deane Osterman
Executive Director, Kalispel Natural Resources Department

Cc: Dan Opalski, Director, EPA Region 10 Office of Water & Watersheds
Scott Aikin, Deputy Regional Director, Indian Services

CALIFORNIA TOXICS RULE
RESPONSE TO COMMENTS REPORT

VOLUME I

December 1999

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TABLE OF CONTENTS

VOLUME I

Subject Matter Codes

E-01b Cost Triggers
E-01b01 Regulatory Relief Above Threshold
E-01c Executive Order 12866
E-01c01 $100M Threshold
E-01c02 Benefits do not Balance Cost
E-01d Direct Dischargers
E-01d01 Cost Estimate by Commenter
E-01e Indirect Dischargers
E-01e01 Sunnyvale/San Jose
E-01e02 No Costs for Non-SIUs
E-01e03 No Savings from Poll. Red

VOLUME II

Subject Matter Codes
E-01g Sample Facilities
E-01g01 Low or Zero Dilution
E-01g02 Another EA for Sample Facilities
E-01g03 Cost Effectiveness Ratio
E-01g04 AMLs vs. MDLs
E-01g05 Effluent Data
E-01g06 Reasonable Potential
E-01g08 Discharger Representation
E-01g09 Affected Facilities
E-01g10 Toxic Pound Equivalents
E-01h Treatment Assumptions
E-01h01 25% Reduction Assumption
E-01h02 Unit Cost Assumptions
E-01i Alternative Cost Analysis
E-01j
E-01l UMRA - Economic Comments
E-01m Regulatory Relief
E-01m02 Success in Regulatory Relief
E-01m03 Cost of Water Effect Ratios
E-01n Detection Limits
E-01n01 Non-Detects, No Cost
E-01o Background Levels
E-01p Risk Level Costs
E-01q Source Reduction
E-01q01 25% Assumption
E-01q03 Unit Cost Assumption
E-01r Economic Variances
E-01s Secondary, Indirect Cost Impact
E-01u Economic Considerations Task Force
E-01v Discharge Over Time
E-01w Cost per Facility
E-01y Cost of Efforts to Date
E-02 Benefits Analysis
E-02c Overstated Benefits
E-02d Passive Use Value
E-02e Include Omitted Benefits
E-02f Use More Recent Data
E-02g Benefits & Pollution Reduction
E-02h Un-Enclose, Enclose Bay Data
E-02i Impaired Waters Assumptions

Subject Matter Code	Comment ID
A Anti-degradation	CTR-002-010a
A Anti-degradation	CTR-026-001a
A Anti-degradation	CTR-029-001
A Anti-degradation	CTR-029-002c
A Anti-degradation	CTR-039-002
A Anti-degradation	CTR-039-003b
A Anti-degradation	CTR-065-002a
A Anti-degradation	CTRH-001-015
B Comment Period	CTR-002-001
B Comment Period	CTR-004-005
B Comment Period	CTR-005-002
B Comment Period	CTR-007-005
B Comment Period	CTR-021-001
B Comment Period	CTR-025-006a
B Comment Period	CTR-031-008a
B Comment Period	CTR-034-001
B Comment Period	CTR-035-001
B Comment Period	CTR-052-001
B Comment Period	CTR-052-013
B Comment Period	CTR-054-001
B Comment Period	CTR-056-001
B Comment Period	CTR-057-002
B Comment Period	CTR-001-001
B Comment Period	CTR-038-001
B Comment Period	CTR-041-001
B Comment Period	CTR-037-004
B Comment Period	CTR-044-001
B Comment Period	CTR-044-002
B Comment Period	CTR-045-001
B Comment Period	CTR-049-001
B Comment Period	CTR-058-002
B Comment Period	CTR-059-003
B Comment Period	CTR-067-001
B Comment Period	CTR-068-001
B Comment Period	CTR-069-001
B Comment Period	CTR-070-001
B Comment Period	CTR-081-001
B Comment Period	CTR-082-001
B Comment Period	CTR-083-001
B Comment Period	CTR-085-001
B Comment Period	CTR-085-002
B Comment Period	CTR-089-002
B Comment Period	CTR-090-001
B Comment Period	CTR-061-004
B Comment Period	CTR-065-001
B Comment Period	CTR-066-001
B Comment Period	CTR-043-001
B Comment Period	CTR-094-001
B Comment Period	CTR-096-005
B Comment Period	CTRE-001-001a
B Comment Period	CTRE-001-002
B Comment Period	CTRE-002-001
B Comment Period	CTRE-002-005
B Comment Period	CTRE-003-001a
B Comment Period	CTRE-003-001b
B Comment Period	CTRE-004-001a
B Comment Period	CTRE-005-001
B Comment Period	CTRE-006-001
B Comment Period	CTRE-007-001
B Comment Period	CTRE-008-001
B Comment Period	CTRE-009-001
B Comment Period	CTRE-010-001
B Comment Period	CTRE-011-001
B Comment Period	CTRE-012-001
B Comment Period	CTRE-013-001
B Comment Period	CTRE-014-001
B Comment Period	CTRE-015-001
B Comment Period	CTRE-016-001
B Comment Period	CTRE-017-001
B Comment Period	CTRE-018-001
B Comment Period	CTRE-019-001
B Comment Period	CTRE-020-001
B Comment Period	CTRE-021-001
B Comment Period	CTRE-022-001
B Comment Period	CTRE-023-001a
B Comment Period	CTRE-024-001
B Comment Period	CTRE-025-001
B Comment Period	CTRH-001-002
B Comment Period	CTRH-001-019a
B Comment Period	CTRH-001-0211a
B Comment Period	CTRH-001-0211b
B Comment Period	CTRH-001-035
B Comment Period	CTRH-001-036
B Comment Period	CTRH-001-043
B Comment Period	CTRH-001-045a
B Comment Period	CTRH-001-060a
B Comment Period	CTRH-002-007
B Comment Period	CTRH-002-010
B Comment Period	CTRH-002-021a
B Comment Period	CTRH-002-027
C-01 Mercury	CTR-002-007a
C-01 Mercury	CTR-002-007b
C-01 Mercury	CTR-003-009
C-01 Mercury	CTR-005-003c
C-01 Mercury	CTR-006-001a
C-01 Mercury	CTR-006-001b
C-01 Mercury	CTR-006-002a

Subject Matter Code	Comment ID
C-01 Mercury	CTR-006-003
C-01 Mercury	CTR-016-007
C-01 Mercury	CTR-020-004a
C-01 Mercury	CTR-020-004b
C-01 Mercury	CTR-027-012c
C-01 Mercury	CTR-030-006
C-01 Mercury	CTR-030-007
C-01 Mercury	CTR-032-006a
C-01 Mercury	CTR-035-002b
C-01 Mercury	CTR-035-026
C-01 Mercury	CTR-038-002c
C-01 Mercury	CTR-039-005
C-01 Mercury	CTR-040-002b
C-01 Mercury	CTR-041-004
C-01 Mercury	CTR-041-007a
C-01 Mercury	CTR-043-002c
C-01 Mercury	CTR-044-003c
C-01 Mercury	CTR-045-006
C-01 Mercury	CTR-051-003a
C-01 Mercury	CTR-051-003b
C-01 Mercury	CTR-052-002b
C-01 Mercury	CTR-053-003a
C-01 Mercury	CTR-054-003
C-01 Mercury	CTR-056-003
C-01 Mercury	CTR-058-010
C-01 Mercury	CTR-059-009
C-01 Mercury	CTR-060-008
C-01 Mercury	CTR-061-012
C-01 Mercury	CTR-066-008
C-01 Mercury	CTR-081-002f
C-01 Mercury	CTR-085-009
C-01 Mercury	CTR-086-002
C-01 Mercury	CTR-089-001b
C-01 Mercury	CTR-091-001a
C-01 Mercury	CTR-091-001b
C-01 Mercury	CTR-095-002a
C-01 Mercury	CTR-095-002b
C-01 Mercury	CTR-104-002a
C-01 Mercury	CTR-106-002a
C-01 Mercury	CTR-109-002a
C-01 Mercury	CTRH-001-003c
C-01 Mercury	CTRH-001-013
C-01 Mercury	CTRH-001-018a
C-01 Mercury	CTRH-001-018b
C-01 Mercury	CTRH-001-050a
C-01 Mercury	CTRH-001-062
C-01 Mercury	CTRH-001-063
C-02b Copper Aquatic Life	CTR-002-008
C-02b Copper Aquatic Life	CTR-020-011
C-02b Copper Aquatic Life	CTR-020-012
C-02b Copper Aquatic Life	CTR-025-004a
C-02b Copper Aquatic Life	CTR-033-001
C-02b Copper Aquatic Life	CTR-053-003b
C-02b Copper Aquatic Life	CTR-054-008a
C-02b Copper Aquatic Life	CTR-060-013
C-02b Copper Aquatic Life	CTR-064-001
C-02b Copper Aquatic Life	CTR-065-007
C-02b Copper Aquatic Life	CTR-092-013b
C-02b Copper Aquatic Life	CTRH-001-014
C-03b Nickel Aquatic Life	CTR-063-001
C-03b Nickel Aquatic Life	CTR-092-012a
C-04b Selenium Aquatic Life	CTR-008-001
C-04b Selenium Aquatic Life	CTR-009-005
C-04b Selenium Aquatic Life	CTR-016-005
C-04b Selenium Aquatic Life	CTR-030-005
C-04b Selenium Aquatic Life	CTR-030-011
C-04b Selenium Aquatic Life	CTR-030-012
C-04b Selenium Aquatic Life	CTR-030-013
C-04b Selenium Aquatic Life	CTR-030-014
C-04b Selenium Aquatic Life	CTR-030-015
C-04b Selenium Aquatic Life	CTR-030-016
C-04b Selenium Aquatic Life	CTR-060-007
C-04b Selenium Aquatic Life	CTR-051-002
C-04b Selenium Aquatic Life	CTR-058-005
C-04b Selenium Aquatic Life	CTR-058-006
C-04b Selenium Aquatic Life	CTR-103-001
C-05b Lead Aquatic Life	CTR-020-013
C-06b Chromium Aquatic Life	CTR-061-013
C-07b Cyanide Aquatic Life	CTR-058-013
C-07b Cyanide Aquatic Life	CTR-092-012b
C-08a Arsenic Human Health	CTR-020-007
C-08a Arsenic Human Health	CTR-030-003
C-08a Arsenic Human Health	CTR-035-002c
C-08a Arsenic Human Health	CTR-035-025
C-08a Arsenic Human Health	CTR-056-004
C-08a Arsenic Human Health	CTR-060-004
C-08a Arsenic Human Health	CTR-041-005
C-08a Arsenic Human Health	CTR-045-007
C-08a Arsenic Human Health	CTR-059-007
C-08a Arsenic Human Health	CTR-081-002g
C-08a Arsenic Human Health	CTR-085-010
C-08a Arsenic Human Health	CTR-089-001c
C-08a Arsenic Human Health	CTR-066-009
C-09a Dioxin Human Health	CTR-002-006
C-09a Dioxin Human Health	CTR-016-008
C-09a Dioxin Human Health	CTR-035-024

Subject Matter Code	Comment ID
C-09a Dioxin Human Health	CTR-053-003c
C-09a Dioxin Human Health	CTR-039-006
C-09a Dioxin Human Health	CTR-058-012
C-09a Dioxin Human Health	CTR-095-003
C-09a Dioxin Human Health	CTR-097-003
C-09a Dioxin Human Health	CTR-104-004a
C-09a Dioxin Human Health	CTR-106-004a
C-09a Dioxin Human Health	CTR-109-003
C-09a Dioxin Human Health	CTR-110-002
C-09a Dioxin Human Health	CTRH-001-012
C-09a Dioxin Human Health	CTRH-001-051
C-10b PCBs Aquatic Life	CTR-037-010
C-11b PAHs Aquatic Life	CTR-060-014
C-12a THMs Human Health	CTR-020-018
C-12a THMs Human Health	CTR-025-003c
C-12a THMs Human Health	CTR-059-008
C-12a THMs Human Health	CTR-089-004
C-12a THMs Human Health	CTR-090-022
C-13 Risk Level	CTR-003-003
C-13 Risk Level	CTR-005-007
C-13 Risk Level	CTR-011-001a
C-13 Risk Level	CTR-015-002
C-13 Risk Level	CTR-021-005a
C-13 Risk Level	CTR-035-004
C-13 Risk Level	CTR-035-021
C-13 Risk Level	CTR-035-027
C-13 Risk Level	CTR-052-003a
C-13 Risk Level	CTR-054-007
C-13 Risk Level	CTR-055-001
C-13 Risk Level	CTR-056-012
C-13 Risk Level	CTR-057-005
C-13 Risk Level	CTR-060-016
C-13 Risk Level	CTR-040-015b
C-13 Risk Level	CTR-044-007a
C-13 Risk Level	CTR-049-003
C-13 Risk Level	CTR-050-006
C-13 Risk Level	CTR-058-001
C-13 Risk Level	CTR-081-003
C-13 Risk Level	CTR-082-004
C-13 Risk Level	CTR-085-013
C-13 Risk Level	CTR-090-013
C-13 Risk Level	CTR-066-011
C-13 Risk Level	CTR-043-006b
C-13 Risk Level	CTR-096-008
C-13 Risk Level	CTR-092-015
C-13 Risk Level	CTRH-001-026
C-13 Risk Level	CTRH-001-046
C-13 Risk Level	CTRH-002-013
C-13 Risk Level	CTRH-002-023
C-14 Fish or Water Consumption	CTR-002-002a
C-14 Fish or Water Consumption	CTR-002-005a
C-14 Fish or Water Consumption	CTR-006-002b
C-14 Fish or Water Consumption	CTR-010-002
C-14 Fish or Water Consumption	CTR-015-001
C-14 Fish or Water Consumption	CTR-026-007a
C-14 Fish or Water Consumption	CTR-029-003
C-14 Fish or Water Consumption	CTR-035-022
C-14 Fish or Water Consumption	CTR-060-015
C-14 Fish or Water Consumption	CTR-039-004
C-14 Fish or Water Consumption	CTR-065-003a
C-14 Fish or Water Consumption	CTR-095-001d
C-14 Fish or Water Consumption	CTR-097-001b
C-14 Fish or Water Consumption	CTR-098-001
C-14 Fish or Water Consumption	CTR-099-002
C-14 Fish or Water Consumption	CTR-101-001a
C-14 Fish or Water Consumption	CTR-102-002
C-14 Fish or Water Consumption	CTR-104-001
C-14 Fish or Water Consumption	CTR-104-002b
C-14 Fish or Water Consumption	CTR-105-001b
C-14 Fish or Water Consumption	CTR-106-001
C-14 Fish or Water Consumption	CTR-106-002b
C-14 Fish or Water Consumption	CTR-109-001a
C-14 Fish or Water Consumption	CTR-109-002b
C-14 Fish or Water Consumption	CTRH-001-050b
C-14 Fish or Water Consumption	CTRH-001-053
C-15 Salinity	CTR-016-004
C-15 Salinity	CTR-035-030
C-15 Salinity	CTR-054-011
C-15 Salinity	CTR-038-011
C-15 Salinity	CTR-058-004
C-15 Salinity	CTR-059-011
C-16 SDWA	CTR-025-001a
C-16 SDWA	CTR-025-002b
C-16 SDWA	CTR-025-003b
C-16 SDWA	CTR-025-004b
C-16 SDWA	CTR-025-006b
C-17 Methodologies	CTR-061-005b
C-17 Methodologies	CTR-061-008
C-17 Methodologies	CTR-061-009
C-17 Methodologies	CTR-061-010
C-17 Methodologies	CTR-061-011
C-17 Methodologies	CTR-096-001b
C-17a Methodologies Human Health	CTR-002-002b
C-17a Methodologies Human Health	CTR-002-004a
C-17a Methodologies Human Health	CTR-025-002a
C-17a Methodologies Human Health	CTR-025-003a

Subject Matter Code	Comment ID
C-17a Methodologies Human Health	CTR-026-003b
C-17a Methodologies Human Health	CTR-026-007b
C-17a Methodologies Human Health	CTR-029-002a
C-17a Methodologies Human Health	CTR-031-002b
C-17a Methodologies Human Health	CTR-031-004a
C-17a Methodologies Human Health	CTR-057-007
C-17a Methodologies Human Health	CTR-037-003b
C-17a Methodologies Human Health	CTR-090-002a
C-17a Methodologies Human Health	CTR-090-019
C-17a Methodologies Human Health	CTR-065-002b
C-17a Methodologies Human Health	CTR-095-001b
C-17a Methodologies Human Health	CTR-097-001a
C-17a Methodologies Human Health	CTR-099-001a
C-17a Methodologies Human Health	CTR-102-001a
C-17a Methodologies Human Health	CTR-104-004b
C-17a Methodologies Human Health	CTR-105-002a
C-17a Methodologies Human Health	CTR-106-004b
C-17a Methodologies Human Health	CTR-110-001
C-17a Methodologies Human Health	CTRH-001-024e
C-17b Methodologies Aquatic Life	CTR-002-004b
C-17b Methodologies Aquatic Life	CTR-026-002a
C-17b Methodologies Aquatic Life	CTR-026-003a
C-17b Methodologies Aquatic Life	CTR-029-002b
C-17b Methodologies Aquatic Life	CTR-031-002c
C-17b Methodologies Aquatic Life	CTR-031-004b
C-17b Methodologies Aquatic Life	CTR-037-002
C-17b Methodologies Aquatic Life	CTR-037-003a
C-17b Methodologies Aquatic Life	CTR-065-002c
C-17b Methodologies Aquatic Life	CTR-065-004
C-17b Methodologies Aquatic Life	CTR-099-001b
C-17b Methodologies Aquatic Life	CTR-102-001b
C-17c Meth.New Human Health Meth.	CTR-035-023
C-18 Conversion Factors	CTR-035-017
C-19 FDA Action Levels	CTR-016-006
C-20 Scope Prty Toxic Poll. List	CTR-025-001b
C-20 Scope Prty Toxic Poll. List	CTR-026-008
C-20 Scope Prty Toxic Poll. List	CTR-058-009
C-20 Scope Prty Toxic Poll. List	CTR-090-005
C-20 Scope Prty Toxic Poll. List	CTR-090-016
C-20 Scope Prty Toxic Poll. List	CTR-090-017
C-20 Scope Prty Toxic Poll. List	CTR-061-006
C-20 Scope Prty Toxic Poll. List	CTR-065-006b
C-20 Scope Prty Toxic Poll. List	CTR-095-001a
C-20 Scope Prty Toxic Poll. List	CTR-100-001
C-20 Scope Prty Toxic Poll. List	CTR-101-001b
C-20 Scope Prty Toxic Poll. List	CTR-105-001a
C-20 Scope Prty Toxic Poll. List	CTR-109-001b
C-20 Scope Prty Toxic Poll. List	CTRH-001-016
C-21 Legal Concerns	CTR-002-005b
C-21 Legal Concerns	CTR-002-009
C-21 Legal Concerns	CTR-005-006a
C-21 Legal Concerns	CTR-005-008b
C-21 Legal Concerns	CTR-007-004
C-21 Legal Concerns	CTR-010-003
C-21 Legal Concerns	CTR-020-002
C-21 Legal Concerns	CTR-031-003a
C-21 Legal Concerns	CTR-034-010b
C-21 Legal Concerns	CTR-035-012a
C-21 Legal Concerns	CTR-052-021a
C-21 Legal Concerns	CTR-054-014
C-21 Legal Concerns	CTR-055-002a
C-21 Legal Concerns	CTR-038-006a
C-21 Legal Concerns	CTR-040-011
C-21 Legal Concerns	CTR-040-016b
C-21 Legal Concerns	CTR-042-007a
C-21 Legal Concerns	CTR-036-005
C-21 Legal Concerns	CTR-044-006a
C-21 Legal Concerns	CTR-050-001
C-21 Legal Concerns	CTR-050-002
C-21 Legal Concerns	CTR-050-003
C-21 Legal Concerns	CTR-050-004
C-21 Legal Concerns	CTR-050-007a
C-21 Legal Concerns	CTR-065-003b
C-21 Legal Concerns	CTR-043-005a
C-21 Legal Concerns	CTR-041-014
C-21 Legal Concerns	CTR-095-001c
C-21 Legal Concerns	CTR-099-004
C-21 Legal Concerns	CTR-105-002b
C-21 Legal Concerns	CTR-044-044
C-21 Legal Concerns	CTR-054-048
C-21 Legal Concerns	CTRH-001-010
C-21 Legal Concerns	CTRH-001-017
C-22 Dissolved v. Ttl Recoverable	CTR-004-004c
C-22 Dissolved v. Ttl Recoverable	CTR-005-003a
C-22 Dissolved v. Ttl Recoverable	CTR-007-001
C-22 Dissolved v. Ttl Recoverable	CTR-017-002a
C-22 Dissolved v. Ttl Recoverable	CTR-021-002c
C-22 Dissolved v. Ttl Recoverable	CTR-026-004
C-22 Dissolved v. Ttl Recoverable	CTR-027-012a
C-22 Dissolved v. Ttl Recoverable	CTR-029-002d
C-22 Dissolved v. Ttl Recoverable	CTR-032-002b
C-22 Dissolved v. Ttl Recoverable	CTR-034-008
C-22 Dissolved v. Ttl Recoverable	CTR-035-002a
C-22 Dissolved v. Ttl Recoverable	CTR-035-016
C-22 Dissolved v. Ttl Recoverable	CTR-052-002a

Subject Matter Code	Comment ID
C-22 Dissolved v. Ttl Recoverable	CTR-054-002a
C-22 Dissolved v. Ttl Recoverable	CTR-056-005
C-22 Dissolved v. Ttl Recoverable	CTR-057-006
C-22 Dissolved v. Ttl Recoverable	CTR-038-002a
C-22 Dissolved v. Ttl Recoverable	CTR-039-003a
C-22 Dissolved v. Ttl Recoverable	CTR-041-002
C-22 Dissolved v. Ttl Recoverable	CTR-041-007b
C-22 Dissolved v. Ttl Recoverable	CTR-042-006
C-22 Dissolved v. Ttl Recoverable	CTR-044-003a
C-22 Dissolved v. Ttl Recoverable	CTR-045-004
C-22 Dissolved v. Ttl Recoverable	CTR-058-003
C-22 Dissolved v. Ttl Recoverable	CTR-067-002
C-22 Dissolved v. Ttl Recoverable	CTR-077-003
C-22 Dissolved v. Ttl Recoverable	CTR-081-002d
C-22 Dissolved v. Ttl Recoverable	CTR-082-003
C-22 Dissolved v. Ttl Recoverable	CTR-085-006
C-22 Dissolved v. Ttl Recoverable	CTR-086-004b
C-22 Dissolved v. Ttl Recoverable	CTR-089-001a
C-22 Dissolved v. Ttl Recoverable	CTR-090-002c
C-22 Dissolved v. Ttl Recoverable	CTR-065-005
C-22 Dissolved v. Ttl Recoverable	CTR-066-005
C-22 Dissolved v. Ttl Recoverable	CTR-066-019
C-22 Dissolved v. Ttl Recoverable	CTR-043-002a
C-22 Dissolved v. Ttl Recoverable	CTR-092-002
C-22 Dissolved v. Ttl Recoverable	CTRH-001-003a
C-22 Dissolved v. Ttl Recoverable	CTRH-001-024c
C-22 Dissolved v. Ttl Recoverable	CTRH-001-032b
C-22 Dissolved v. Ttl Recoverable	CTRH-001-048
C-22 Dissolved v. Ttl Recoverable	CTRH-001-057f
C-22 Dissolved v. Ttl Recoverable	CTRH-002-011c
C-23 Sediments/Dredged Materials	CTR-007-002
C-23 Sediments/Dredged Materials	CTR-077-001
C-23 Sediments/Dredged Materials	CTRH-001-021
C-23 Sediments/Dredged Materials	CTRH-001-059
C-24 Site Specific Criteria	CTR-002-003
C-24 Site Specific Criteria	CTR-003-006
C-24 Site Specific Criteria	CTR-004-008
C-24 Site Specific Criteria	CTR-005-008a
C-24 Site Specific Criteria	CTR-008-002
C-24 Site Specific Criteria	CTR-009-003
C-24 Site Specific Criteria	CTR-009-006a
C-24 Site Specific Criteria	CTR-010-001
C-24 Site Specific Criteria	CTR-011-001b
C-24 Site Specific Criteria	CTR-016-001
C-24 Site Specific Criteria	CTR-016-002
C-24 Site Specific Criteria	CTR-017-001
C-24 Site Specific Criteria	CTR-020-003
C-24 Site Specific Criteria	CTR-021-007
C-24 Site Specific Criteria	CTR-026-006
C-24 Site Specific Criteria	CTR-032-006b
C-24 Site Specific Criteria	CTR-035-014
C-24 Site Specific Criteria	CTR-052-008
C-24 Site Specific Criteria	CTR-052-017
C-24 Site Specific Criteria	CTR-053-006
C-24 Site Specific Criteria	CTR-054-008b
C-24 Site Specific Criteria	CTR-056-015b
C-24 Site Specific Criteria	CTR-057-010c
C-24 Site Specific Criteria	CTR-057-011
C-24 Site Specific Criteria	CTR-060-006
C-24 Site Specific Criteria	CTR-038-007
C-24 Site Specific Criteria	CTR-038-008a
C-24 Site Specific Criteria	CTR-039-001
C-24 Site Specific Criteria	CTR-039-009
C-24 Site Specific Criteria	CTR-040-050
C-24 Site Specific Criteria	CTR-037-001a
C-24 Site Specific Criteria	CTR-044-007b
C-24 Site Specific Criteria	CTR-050-005a
C-24 Site Specific Criteria	CTR-051-001
C-24 Site Specific Criteria	CTR-086-004e
C-24 Site Specific Criteria	CTR-090-018
C-24 Site Specific Criteria	CTR-043-006a
C-24 Site Specific Criteria	CTR-041-046
C-24 Site Specific Criteria	CTR-092-010
C-24 Site Specific Criteria	CTR-032-002e
C-24 Site Specific Criteria	CTR-044-041
C-24 Site Specific Criteria	CTR-054-045
C-24 Site Specific Criteria	CTRH-001-047
C-24a SSC Water Effect Ratios	CTR-003-001
C-24a SSC Water Effect Ratios	CTR-004-004b
C-24a SSC Water Effect Ratios	CTR-005-003b
C-24a SSC Water Effect Ratios	CTR-017-002b
C-24a SSC Water Effect Ratios	CTR-020-005
C-24a SSC Water Effect Ratios	CTR-020-006
C-24a SSC Water Effect Ratios	CTR-021-002b
C-24a SSC Water Effect Ratios	CTR-027-012b
C-24a SSC Water Effect Ratios	CTR-034-009
C-24a SSC Water Effect Ratios	CTR-035-002h
C-24a SSC Water Effect Ratios	CTR-035-019
C-24a SSC Water Effect Ratios	CTR-054-002b
C-24a SSC Water Effect Ratios	CTR-056-006
C-24a SSC Water Effect Ratios	CTR-056-009
C-24a SSC Water Effect Ratios	CTR-038-002b
C-24a SSC Water Effect Ratios	CTR-040-002a
C-24a SSC Water Effect Ratios	CTR-041-003b
C-24a SSC Water Effect Ratios	CTR-044-003b
C-24a SSC Water Effect Ratios	CTR-045-005

Subject Matter Code	Comment ID
C-24a SSC Water Effect Ratios	CTR-049-002
C-24a SSC Water Effect Ratios	CTR-081-002b
C-24a SSC Water Effect Ratios	CTR-085-004
C-24a SSC Water Effect Ratios	CTR-085-008
C-24a SSC Water Effect Ratios	CTR-086-004d
C-24a SSC Water Effect Ratios	CTR-090-002b
C-24a SSC Water Effect Ratios	CTR-061-014
C-24a SSC Water Effect Ratios	CTR-066-003
C-24a SSC Water Effect Ratios	CTR-066-007
C-24a SSC Water Effect Ratios	CTR-043-002b
C-24a SSC Water Effect Ratios	CTR-092-004
C-24a SSC Water Effect Ratios	CTR-092-013a
C-24a SSC Water Effect Ratios	CTR-032-002d
C-24a SSC Water Effect Ratios	CTRH-001-003b
C-24a SSC Water Effect Ratios	CTRH-001-024d
C-24a SSC Water Effect Ratios	CTRH-001-032a
C-24a SSC Water Effect Ratios	CTRH-001-039a
C-24a SSC Water Effect Ratios	CTRH-001-057b
C-24b SSC Recalculation Procedure	CTR-009-004
C-24b SSC Recalculation Procedure	CTR-025-005
C-24b SSC Recalculation Procedure	CTR-082-005
C-24c SSC Santa Ana River	CTR-033-002
C-24d SSC Effluent Dependent Wtr	CTR-034-007
C-24d SSC Effluent Dependent Wtr	CTR-035-006
C-24d SSC Effluent Dependent Wtr	CTR-056-011
C-24d SSC Effluent Dependent Wtr	CTR-057-003
C-24d SSC Effluent Dependent Wtr	CTR-040-016a
C-24d SSC Effluent Dependent Wtr	CTR-042-005
C-24d SSC Effluent Dependent Wtr	CTR-036-009
C-24d SSC Effluent Dependent Wtr	CTR-044-008
C-24d SSC Effluent Dependent Wtr	CTR-049-004
C-24d SSC Effluent Dependent Wtr	CTR-059-010
C-24d SSC Effluent Dependent Wtr	CTR-081-004a
C-24d SSC Effluent Dependent Wtr	CTR-085-014
C-24d SSC Effluent Dependent Wtr	CTR-089-006
C-24d SSC Effluent Dependent Wtr	CTR-043-007
C-24d SSC Effluent Dependent Wtr	CTR-096-006
C-24d SSC Effluent Dependent Wtr	CTRH-002-012
C-24d SSC Effluent Dependent Wtr	CTRH-002-020
C-24e SSC Desgntd/Beneficial Uses	CTR-013-006b
C-24e SSC Desgntd/Beneficial Uses	CTR-020-017
C-24e SSC Desgntd/Beneficial Uses	CTR-026-001b
C-24e SSC Desgntd/Beneficial Uses	CTR-027-007b
C-24e SSC Desgntd/Beneficial Uses	CTR-035-007
C-24e SSC Desgntd/Beneficial Uses	CTR-035-038
C-24e SSC Desgntd/Beneficial Uses	CTR-056-013
C-24e SSC Desgntd/Beneficial Uses	CTR-040-018d
C-24e SSC Desgntd/Beneficial Uses	CTR-049-005
C-24e SSC Desgntd/Beneficial Uses	CTR-081-004b
C-24e SSC Desgntd/Beneficial Uses	CTR-082-006
C-24e SSC Desgntd/Beneficial Uses	CTR-085-015
C-24e SSC Desgntd/Beneficial Uses	CTR-066-012
C-24e SSC Desgntd/Beneficial Uses	CTR-096-007
C-25 Hardness	CTR-026-005
C-26 Avrging pds&Exceedence Freq.	CTR-003-002
C-26 Avrging pds&Exceedence Freq.	CTR-009-007
C-26 Avrging pds&Exceedence Freq.	CTR-020-008
C-26 Avrging pds&Exceedence Freq.	CTR-020-009
C-26 Avrging pds&Exceedence Freq.	CTR-020-010
C-26 Avrging pds&Exceedence Freq.	CTR-020-014
C-26 Avrging pds&Exceedence Freq.	CTR-020-015
C-26 Avrging pds&Exceedence Freq.	CTR-035-020
C-26 Avrging pds&Exceedence Freq.	CTR-035-028
C-26 Avrging pds&Exceedence Freq.	CTR-035-031
C-26 Avrging pds&Exceedence Freq.	CTR-060-012
C-26 Avrging pds&Exceedence Freq.	CTR-040-018a
C-26 Avrging pds&Exceedence Freq.	CTR-036-007a
C-26 Avrging pds&Exceedence Freq.	CTR-037-007
C-26 Avrging pds&Exceedence Freq.	CTR-037-009
C-27 Additive/Synergistic Effects	CTR-026-002b
C-27 Additive/Synergistic Effects	CTR-029-002e
C-28 Detection Limits	CTR-005-009
C-28 Detection Limits	CTR-011-002
C-28 Detection Limits	CTR-013-004
C-28 Detection Limits	CTR-020-020
C-28 Detection Limits	CTR-021-005b
C-28 Detection Limits	CTR-027-004
C-28 Detection Limits	CTR-030-009
C-28 Detection Limits	CTR-033-003a
C-28 Detection Limits	CTR-034-010a
C-28 Detection Limits	CTR-035-005
C-28 Detection Limits	CTR-035-012b
C-28 Detection Limits	CTR-052-018
C-28 Detection Limits	CTR-054-009
C-28 Detection Limits	CTR-056-014
C-28 Detection Limits	CTR-057-004
C-28 Detection Limits	CTR-060-010
C-28 Detection Limits	CTR-038-009a
C-28 Detection Limits	CTR-041-008a
C-28 Detection Limits	CTR-040-017
C-28 Detection Limits	CTR-042-003
C-28 Detection Limits	CTR-036-006
C-28 Detection Limits	CTR-037-006
C-28 Detection Limits	CTR-044-009a
C-28 Detection Limits	CTR-059-006a
C-28 Detection Limits	CTR-067-003

Subject Matter Code	Comment ID
C-28 Detection Limits	CTR-082-009b
C-28 Detection Limits	CTR-085-018b
C-28 Detection Limits	CTR-089-003
C-28 Detection Limits	CTR-090-006
C-28 Detection Limits	CTR-090-011
C-28 Detection Limits	CTR-066-015b
C-28 Detection Limits	CTR-043-008
C-28 Detection Limits	CTRH-001-020
C-28 Detection Limits	CTRH-001-028
C-28 Detection Limits	CTRH-001-038
C-28 Detection Limits	CTRH-002-003
C-29 Bioaccumulation	CTR-026-002c
C-29 Bioaccumulation	CTR-029-002f
C-29 Bioaccumulation	CTR-097-002
C-29 Bioaccumulation	CTR-099-003
C-30 Narrative Criteria	CTR-053-002
C-30 Narrative Criteria	CTR-054-010
C-30 Narrative Criteria	CTR-038-010
C-30 Narrative Criteria	CTR-041-011
C-30 Narrative Criteria	CTR-040-018c
C-30 Narrative Criteria	CTR-044-010
C-30 Narrative Criteria	CTR-061-007
C-30 Narrative Criteria	CTR-043-009
D Preamble Editorial Comments	CTR-022-001
D Preamble Editorial Comments	CTR-022-002
D Preamble Editorial Comments	CTR-022-004
D Preamble Editorial Comments	CTR-035-013
D Preamble Editorial Comments	CTR-035-015
D Preamble Editorial Comments	CTR-052-004
D Preamble Editorial Comments	CTR-036-012
D Preamble Editorial Comments	CTR-061-015
E-01 Cost Analysis	CTR-052-003b
E-01 Cost Analysis	CTR-040-020
E-01 Cost Analysis	CTR-040-022
E-01 Cost Analysis	CTR-040-023
E-01 Cost Analysis	CTR-047-001
E-01 Cost Analysis	CTR-059-026
E-01 Cost Analysis	CTR-041-018
E-01 Cost Analysis	CTR-041-019
E-01 Cost Analysis	CTR-091-002a
E-01 Cost Analysis	CTR-107-001
E-01 Cost Analysis	CTR-107-002a
E-01 Cost Analysis	CTR-044-013
E-01 Cost Analysis	CTR-044-014
E-01 Cost Analysis	CTR-054-017
E-01 Cost Analysis	CTR-054-018
E-01a Baselines	CTR-040-035
E-01a Baselines	CTR-041-031
E-01a Baselines	CTR-092-017
E-01a Baselines	CTR-044-026
E-01a Baselines	CTR-054-030
E-01a02 Cost Diff. for Eff. Limit	CTR-035-058
E-01a02 Cost Diff. for Eff. Limit	CTR-060-018
E-01a03 Model 1 Weaknesses	CTR-035-045
E-01a03 Model 1 Weaknesses	CTR-035-057
E-01a03 Model 1 Weaknesses	CTR-040-026
E-01a03 Model 1 Weaknesses	CTR-041-022
E-01a03 Model 1 Weaknesses	CTR-044-017
E-01a03 Model 1 Weaknesses	CTR-054-021
E-01b Cost Triggers	CTR-021-017
E-01b Cost Triggers	CTR-034-014b
E-01b Cost Triggers	CTR-035-047a
E-01b Cost Triggers	CTR-056-018
E-01b Cost Triggers	CTR-056-019
E-01b Cost Triggers	CTR-040-033
E-01b Cost Triggers	CTR-040-040
E-01b Cost Triggers	CTR-059-019
E-01b Cost Triggers	CTR-082-007b
E-01b Cost Triggers	CTR-041-029
E-01b Cost Triggers	CTR-041-036
E-01b Cost Triggers	CTR-044-024
E-01b Cost Triggers	CTR-044-031
E-01b Cost Triggers	CTR-054-028
E-01b Cost Triggers	CTR-054-035
E-01b01 RegRelief Above Threshold	CTR-085-016b
E-01b01 RegRelief Above Threshold	CTR-066-013b
E-01b01 RegRelief Above Threshold	CTR-092-022b
E-01c Executive Order 12866	CTR-021-005c
E-01c Executive Order 12866	CTR-021-006b
E-01c Executive Order 12866	CTR-031-006c
E-01c Executive Order 12866	CTR-035-008f
E-01c Executive Order 12866	CTR-035-010
E-01c Executive Order 12866	CTR-035-039
E-01c Executive Order 12866	CTR-052-021b
E-01c Executive Order 12866	CTR-054-008c
E-01c Executive Order 12866	CTR-055-003
E-01c Executive Order 12866	CTR-038-005a
E-01c Executive Order 12866	CTR-038-006b
E-01c Executive Order 12866	CTR-038-008b
E-01c Executive Order 12866	CTR-041-013a
E-01c Executive Order 12866	CTR-040-009c
E-01c Executive Order 12866	CTR-040-012a
E-01c Executive Order 12866	CTR-042-007b
E-01c Executive Order 12866	CTR-036-002b
E-01c Executive Order 12866	CTR-044-006b
E-01c Executive Order 12866	CTR-044-009b

Subject Matter Code	Comment ID
E-01c Executive Order 12866	CTR-045-012b
E-01c Executive Order 12866	CTR-050-007b
E-01c Executive Order 12866	CTR-059-002a
E-01c Executive Order 12866	CTR-059-004a
E-01c Executive Order 12866	CTR-059-006b
E-01c Executive Order 12866	CTR-059-015a
E-01c Executive Order 12866	CTR-090-012a
E-01c Executive Order 12866	CTR-043-005b
E-01c Executive Order 12866	CTR-041-015
E-01c Executive Order 12866	CTR-092-016a
E-01c Executive Order 12866	CTR-092-022a
E-01c Executive Order 12866	CTR-044-045
E-01c Executive Order 12866	CTR-054-049
E-01c01 $100M Threshold	CTR-034-003
E-01c01 $100M Threshold	CTR-035-044a
E-01c01 $100M Threshold	CTR-035-056b
E-01c01 $100M Threshold	CTR-045-013
E-01c01 $100M Threshold	CTR-082-011
E-01c01 $100M Threshold	CTR-084-002a
E-01c01 $100M Threshold	CTR-066-017
E-01c01 $100M Threshold	CTR-096-003a
E-01c02 Bnfts do not Balance Cost	CTR-005-005
E-01c02 Bnfts do not Balance Cost	CTR-029-004a
E-01c02 Bnfts do not Balance Cost	CTR-032-008b
E-01c02 Bnfts do not Balance Cost	CTR-035-043
E-01c02 Bnfts do not Balance Cost	CTR-035-056a
E-01c02 Bnfts do not Balance Cost	CTR-035-064
E-01c02 Bnfts do not Balance Cost	CTR-038-004d
E-01c02 Bnfts do not Balance Cost	CTR-040-008a
E-01c02 Bnfts do not Balance Cost	CTR-040-042
E-01c02 Bnfts do not Balance Cost	CTR-044-005e
E-01c02 Bnfts do not Balance Cost	CTR-043-004e
E-01c02 Bnfts do not Balance Cost	CTR-041-038
E-01c02 Bnfts do not Balance Cost	CTR-044-033
E-01c02 Bnfts do not Balance Cost	CTR-054-037
E-01c02 Bnfts do not Balance Cost	CTRH-001-037a
E-01c02 Bnfts do not Balance Cost	CTRH-002-016a
E-01d Direct Dischargers	CTR-011-001c
E-01d Direct Dischargers	CTR-035-008c
E-01d Direct Dischargers	CTR-035-061
E-01d Direct Dischargers	CTR-052-006
E-01d Direct Dischargers	CTR-052-011
E-01d Direct Dischargers	CTR-045-012a
E-01d Direct Dischargers	CTR-081-005b
E-01d Direct Dischargers	CTR-082-010
E-01d Direct Dischargers	CTR-085-019
E-01d Direct Dischargers	CTR-089-005
E-01d Direct Dischargers	CTR-066-016
E-01d Direct Dischargers	CTRH-001-027
E-01d01 Cost Estmte by Commenter	CTR-005-004
E-01d01 Cost Estmte by Commenter	CTR-035-044b
E-01d01 Cost Estmte by Commenter	CTR-052-005b
E-01d01 Cost Estmte by Commenter	CTR-052-010
E-01d01 Cost Estmte by Commenter	CTR-054-005
E-01d01 Cost Estmte by Commenter	CTR-056-020
E-01d01 Cost Estmte by Commenter	CTR-038-003
E-01d01 Cost Estmte by Commenter	CTR-041-009
E-01d01 Cost Estmte by Commenter	CTR-044-004
E-01d01 Cost Estmte by Commenter	CTR-059-001
E-01d01 Cost Estmte by Commenter	CTR-067-006b
E-01d01 Cost Estmte by Commenter	CTR-070-002b
E-01d01 Cost Estmte by Commenter	CTR-111-001
E-01d01 Cost Estmte by Commenter	CTRH-001-044
E-01e Indirect Dischargers	CTR-021-011
E-01e Indirect Dischargers	CTR-034-014c
E-01e Indirect Dischargers	CTR-035-008b
E-01e Indirect Dischargers	CTR-035-049
E-01e Indirect Dischargers	CTR-056-022a
E-01e Indirect Dischargers	CTR-041-010c
E-01e Indirect Dischargers	CTR-092-020
E-01e01 Sunnyvale/San Jose	CTR-059-020
E-01e01 Sunnyvale/San Jose	CTR-092-018
E-01e02 No Costs for Non-SIUs	CTR-040-037
E-01e02 No Costs for Non-SIUs	CTR-043-003
E-01e02 No Costs for Non-SIUs	CTR-041-033
E-01e02 No Costs for Non-SIUs	CTR-044-028
E-01e02 No Costs for Non-SIUs	CTR-054-032
E-01e03 No Savings from Poll. Red	CTR-092-019
E-01g Sample Facilities	CTR-021-008
E-01g Sample Facilities	CTR-021-014
E-01g Sample Facilities	CTR-035-059
E-01g Sample Facilities	CTR-041-010d
E-01g Sample Facilities	CTR-043-004a
E-01g Sample Facilities	CTR-092-014
E-01g01 Low or Zero Dilution	CTR-108-001
E-01g02 Another EA for Sample Fac	CTR-052-014
E-01g02 Another EA for Sample Fac	CTR-057-001
E-01g03 Cost Effectiveness Ratio	CTR-054-013a
E-01g03 Cost Effectiveness Ratio	CTR-056-016
E-01g03 Cost Effectiveness Ratio	CTR-056-017
E-01g03 Cost Effectiveness Ratio	CTR-040-039
E-01g03 Cost Effectiveness Ratio	CTR-041-035
E-01g03 Cost Effectiveness Ratio	CTR-044-030
E-01g03 Cost Effectiveness Ratio	CTR-054-034
E-01g04 AMLs vs. MDLs	CTR-021-010
E-01g05 Effluent Data	CTR-040-027

Subject Matter Code	Comment ID
E-01g05 Effluent Data	CTR-041-023
E-01g05 Effluent Data	CTR-093-001
E-01g05 Effluent Data	CTR-044-018
E-01g05 Effluent Data	CTR-054-022
E-01g06 Reasonable Potential	CTR-021-016
E-01g08 Discharger Representation	CTR-034-014a
E-01g08 Discharger Representation	CTR-035-008a
E-01g08 Discharger Representation	CTR-035-046a
E-01g08 Discharger Representation	CTR-035-063
E-01g08 Discharger Representation	CTR-060-017
E-01g08 Discharger Representation	CTR-038-004a
E-01g08 Discharger Representation	CTR-040-024
E-01g08 Discharger Representation	CTR-044-005a
E-01g08 Discharger Representation	CTR-045-009a
E-01g08 Discharger Representation	CTR-049-006a
E-01g08 Discharger Representation	CTR-059-018
E-01g08 Discharger Representation	CTR-059-023a
E-01g08 Discharger Representation	CTR-082-007a
E-01g08 Discharger Representation	CTR-085-016a
E-01g08 Discharger Representation	CTR-066-013a
E-01g08 Discharger Representation	CTR-041-020
E-01g08 Discharger Representation	CTR-044-015
E-01g08 Discharger Representation	CTR-054-019
E-01g08 Discharger Representation	CTRH-001-058
E-01g09 Affected Facilities	CTR-021-004
E-01g09 Affected Facilities	CTR-035-046b
E-01g09 Affected Facilities	CTR-035-048
E-01g10 Toxic Pound Equivalents	CTR-052-012
E-01h Treatment Assumptions	CTR-003-011
E-01h Treatment Assumptions	CTR-003-013
E-01h Treatment Assumptions	CTR-021-009
E-01h Treatment Assumptions	CTR-035-008e
E-01h Treatment Assumptions	CTR-038-004b
E-01h Treatment Assumptions	CTR-040-032
E-01h Treatment Assumptions	CTR-040-038
E-01h Treatment Assumptions	CTR-045-009b
E-01h Treatment Assumptions	CTR-049-006b
E-01h Treatment Assumptions	CTR-086-003
E-01h Treatment Assumptions	CTR-043-004b
E-01h Treatment Assumptions	CTR-041-028
E-01h Treatment Assumptions	CTR-041-034
E-01h Treatment Assumptions	CTR-044-023
E-01h Treatment Assumptions	CTR-044-029
E-01h Treatment Assumptions	CTR-054-027
E-01h Treatment Assumptions	CTR-054-033
E-01h Treatment Assumptions	CTRH-002-016b
E-01h01 25% Reduction Assumption	CTR-040-029b
E-01h01 25% Reduction Assumption	CTR-044-005b
E-01h01 25% Reduction Assumption	CTR-041-025b
E-01h01 25% Reduction Assumption	CTR-044-020b
E-01h01 25% Reduction Assumption	CTR-054-024b
E-01h02 Unit Cost Assumptions	CTRH-001-037c
E-01i Alternative Cost Analysis	CTR-003-012
E-01i Alternative Cost Analysis	CTR-021-015
E-01i Alternative Cost Analysis	CTR-052-005a
E-01i Alternative Cost Analysis	CTR-052-009
E-01i Alternative Cost Analysis	CTR-059-027
E-01i Alternative Cost Analysis	CTR-092-021
E-01j	CTR-069-002b
E-01l UMRA - Economic Comments	CTR-059-024
E-01m Regulatory Relief	CTR-003-007
E-01m Regulatory Relief	CTR-032-004
E-01m Regulatory Relief	CTR-035-008d
E-01m Regulatory Relief	CTR-035-047b
E-01m Regulatory Relief	CTR-054-013c
E-01m Regulatory Relief	CTR-038-004c
E-01m Regulatory Relief	CTR-040-008b
E-01m Regulatory Relief	CTR-041-010b
E-01m Regulatory Relief	CTR-040-031
E-01m Regulatory Relief	CTR-040-036
E-01m Regulatory Relief	CTR-040-041
E-01m Regulatory Relief	CTR-044-005c
E-01m Regulatory Relief	CTR-045-009c
E-01m Regulatory Relief	CTR-049-006c
E-01m Regulatory Relief	CTR-086-006
E-01m Regulatory Relief	CTR-043-004c
E-01m Regulatory Relief	CTR-041-027
E-01m Regulatory Relief	CTR-041-032
E-01m Regulatory Relief	CTR-041-037
E-01m Regulatory Relief	CTR-032-001
E-01m Regulatory Relief	CTR-044-022
E-01m Regulatory Relief	CTR-044-027
E-01m Regulatory Relief	CTR-044-032
E-01m Regulatory Relief	CTR-054-026
E-01m Regulatory Relief	CTR-054-031
E-01m Regulatory Relief	CTR-054-036
E-01m02 Success in Reg. Relief	CTR-090-003
E-01m03 Cost of WERs	CTR-060-019
E-01n Detection Limits	CTR-003-008
E-01n Detection Limits	CTR-004-002
E-01n Detection Limits	CTR-021-013
E-01n Detection Limits	CTR-033-003b
E-01n Detection Limits	CTR-038-009b
E-01n Detection Limits	CTR-041-008b
E-01n Detection Limits	CTR-041-010a
E-01n Detection Limits	CTR-045-011

Subject Matter Code	Comment ID
E-01n Detection Limits	CTR-067-004a
E-01n Detection Limits	CTR-070-003
E-01n Detection Limits	CTR-082-009a
E-01n Detection Limits	CTR-085-018a
E-01n Detection Limits	CTR-066-015a
E-01n Detection Limits	CTR-107-002c
E-01n Detection Limits	CTRH-002-019
E-01n Detection Limits	CTRH-002-022
E-01n01 Non-Detects, No Cost	CTR-040-028
E-01n01 Non-Detects, No Cost	CTR-041-024
E-01n01 Non-Detects, No Cost	CTR-044-019
E-01n01 Non-Detects, No Cost	CTR-054-023
E-01o Background Levels	CTR-003-010
E-01p Risk Level Costs	CTR-035-050
E-01p Risk Level Costs	CTR-035-056c
E-01p Risk Level Costs	CTR-052-016
E-01q Source Reduction	CTR-004-003
E-01q Source Reduction	CTR-021-012
E-01q Source Reduction	CTR-035-062
E-01q Source Reduction	CTR-040-030
E-01q Source Reduction	CTR-041-026
E-01q Source Reduction	CTR-044-021
E-01q Source Reduction	CTR-054-025
E-01q01 25% Assumption	CTR-054-013b
E-01q01 25% Assumption	CTR-040-029a
E-01q01 25% Assumption	CTR-041-025a
E-01q01 25% Assumption	CTR-044-020a
E-01q01 25% Assumption	CTR-054-024a
E-01q03 Unit Cost Assumption	CTRH-001-037b
E-01r Economic Variances	CTR-035-060
E-01s 2ndary,Indirect Cost Impact	CTR-009-008a
E-01s 2ndary,Indirect Cost Impact	CTRH-001-023
E-01u Economic Consid. Task Force	CTR-032-008a
E-01u Economic Consid. Task Force	CTR-034-016
E-01u Economic Consid. Task Force	CTR-035-011a
E-01u Economic Consid. Task Force	CTR-056-023
E-01u Economic Consid. Task Force	CTR-045-014
E-01u Economic Consid. Task Force	CTR-049-007
E-01u Economic Consid. Task Force	CTR-082-012
E-01u Economic Consid. Task Force	CTR-066-018
E-01u Economic Consid. Task Force	CTR-096-009
E-01v Discharge Over Time	CTR-034-014d
E-01v Discharge Over Time	CTR-059-021
E-01w Cost per Facility	CTR-005-001
E-01w Cost per Facility	CTR-059-022
E-01w Cost per Facility	CTR-070-002a
E-01w Cost per Facility	CTR-081-005a
E-01y Cost of Efforts to Date	CTR-092-022c
E-01y Cost of Efforts to Date	CTRH-002-018
E-02 Benefits Analysis	CTR-034-015
E-02 Benefits Analysis	CTR-035-071
E-02 Benefits Analysis	CTR-035-072
E-02 Benefits Analysis	CTR-052-003c
E-02 Benefits Analysis	CTR-052-007
E-02 Benefits Analysis	CTR-040-052
E-02 Benefits Analysis	CTR-090-008
E-02 Benefits Analysis	CTR-041-048
E-02 Benefits Analysis	CTR-091-002b
E-02 Benefits Analysis	CTR-044-043
E-02 Benefits Analysis	CTR-054-047
E-02c Overstated Benefits	CTR-009-008b
E-02c Overstated Benefits	CTR-035-009b
E-02c Overstated Benefits	CTR-035-065b
E-02c Overstated Benefits	CTR-035-068
E-02c Overstated Benefits	CTR-040-008c
E-02c Overstated Benefits	CTR-040-043
E-02c Overstated Benefits	CTR-044-005d
E-02c Overstated Benefits	CTR-061-018
E-02c Overstated Benefits	CTR-043-004d
E-02c Overstated Benefits	CTR-041-039
E-02c Overstated Benefits	CTR-044-034
E-02c Overstated Benefits	CTR-054-038
E-02d Passive Use Value	CTR-026-009
E-02d Passive Use Value	CTR-035-055
E-02d Passive Use Value	CTR-040-047
E-02d Passive Use Value	CTR-041-043
E-02d Passive Use Value	CTR-044-038
E-02d Passive Use Value	CTR-054-042
E-02e Include Omitted Benefits	CTR-029-004b
E-02e Include Omitted Benefits	CTR-092-023a
E-02f Use More Recent Data	CTR-035-009a
E-02f Use More Recent Data	CTR-035-051b
E-02f Use More Recent Data	CTR-056-021
E-02f Use More Recent Data	CTR-045-010
E-02f Use More Recent Data	CTR-082-008
E-02f Use More Recent Data	CTR-085-017
E-02f Use More Recent Data	CTR-066-014
E-02g Benefits & Poll. Reduction	CTR-035-051a
E-02g Benefits & Poll. Reduction	CTR-035-066
E-02g Benefits & Poll. Reduction	CTR-040-044
E-02g Benefits & Poll. Reduction	CTR-041-040
E-02g Benefits & Poll. Reduction	CTR-044-035
E-02g Benefits & Poll. Reduction	CTR-054-039
E-02h Un-Enclose,Enclose Bay Data	CTR-035-053
E-02h Un-Enclose,Enclose Bay Data	CTR-035-070
E-02i Impaired Waters Assumptions	CTR-035-054

Subject Matter Code	Comment ID
E-02i Impaired Waters Assumptions	CTR-040-046
E-02i Impaired Waters Assumptions	CTR-041-042
E-02i Impaired Waters Assumptions	CTR-044-037
E-02i Impaired Waters Assumptions	CTR-054-041
E-02k Long-Term Contamination	CTR-035-051c
E-02k Long-Term Contamination	CTR-035-065a
E-02l Marginal Impacts/Benefits	CTR-035-052
E-02l Marginal Impacts/Benefits	CTR-035-067
E-02l Marginal Impacts/Benefits	CTR-054-006
E-02l Marginal Impacts/Benefits	CTR-054-013d
E-02l Marginal Impacts/Benefits	CTR-092-023b
E-02m Few Pollutant Mask Analysis	CTR-035-069
E-02m Few Pollutant Mask Analysis	CTR-059-025
E-02o Analysis from Wisconsin	CTR-009-008c
E-02o Analysis from Wisconsin	CTR-040-045
E-02o Analysis from Wisconsin	CTR-041-041
E-02o Analysis from Wisconsin	CTR-044-036
E-02o Analysis from Wisconsin	CTR-054-040
E-02o01 No Peer Review Reference	CTR-090-004
E-02q Benefits to Public at Large	CTR-092-023c
F Endangered Species Act	CTR-012-001
F Endangered Species Act	CTR-031-002a
F Endangered Species Act	CTR-031-007a
F Endangered Species Act	CTR-034-006
F Endangered Species Act	CTR-035-042
F Endangered Species Act	CTR-001-009a
F Endangered Species Act	CTR-059-017
F Endangered Species Act	CTRH-001-009b
G-01 Reasonable Potential	CTR-032-002a
G-01 Reasonable Potential	CTR-037-001b
G-01 Reasonable Potential	CTR-086-004a
G-01 Reasonable Potential	CTR-090-010a
G-02 Compliance Schedules	CTR-002-010b
G-02 Compliance Schedules	CTR-009-002
G-02 Compliance Schedules	CTR-009-006b
G-02 Compliance Schedules	CTR-013-007b
G-02 Compliance Schedules	CTR-015-006
G-02 Compliance Schedules	CTR-016-003
G-02 Compliance Schedules	CTR-020-021
G-02 Compliance Schedules	CTR-021-002f
G-02 Compliance Schedules	CTR-022-003
G-02 Compliance Schedules	CTR-027-008b
G-02 Compliance Schedules	CTR-030-004a
G-02 Compliance Schedules	CTR-031-005a
G-02 Compliance Schedules	CTR-032-002i
G-02 Compliance Schedules	CTR-034-013
G-02 Compliance Schedules	CTR-035-037
G-02 Compliance Schedules	CTR-052-020
G-02 Compliance Schedules	CTR-053-004
G-02 Compliance Schedules	CTR-054-012
G-02 Compliance Schedules	CTR-056-010
G-02 Compliance Schedules	CTR-060-005
G-02 Compliance Schedules	CTR-038-012
G-02 Compliance Schedules	CTR-039-007
G-02 Compliance Schedules	CTR-041-012
G-02 Compliance Schedules	CTR-040-019
G-02 Compliance Schedules	CTR-036-010a
G-02 Compliance Schedules	CTR-044-011
G-02 Compliance Schedules	CTR-045-003
G-02 Compliance Schedules	CTR-058-007
G-02 Compliance Schedules	CTR-059-013
G-02 Compliance Schedules	CTR-067-005
G-02 Compliance Schedules	CTR-081-002c
G-02 Compliance Schedules	CTR-082-002
G-02 Compliance Schedules	CTR-085-005
G-02 Compliance Schedules	CTR-086-004i
G-02 Compliance Schedules	CTR-089-001f
G-02 Compliance Schedules	CTR-090-002e
G-02 Compliance Schedules	CTR-090-024
G-02 Compliance Schedules	CTR-066-004
G-02 Compliance Schedules	CTR-043-010
G-02 Compliance Schedules	CTR-092-009
G-02 Compliance Schedules	CTR-095-004
G-02 Compliance Schedules	CTR-104-003
G-02 Compliance Schedules	CTR-106-003
G-02 Compliance Schedules	CTR-107-002b
G-02 Compliance Schedules	CTR-109-004
G-02 Compliance Schedules	CTR-110-003
G-02 Compliance Schedules	CTRH-001-011
G-02 Compliance Schedules	CTRH-001-024a
G-02 Compliance Schedules	CTRH-001-039c
G-02 Compliance Schedules	CTRH-001-052
G-02 Compliance Schedules	CTRH-002-011a
G-02 Compliance Schedules	CTRH-002-014
G-03 Design/Minimum Flows	CTR-003-004
G-03 Design/Minimum Flows	CTR-020-016
G-03 Design/Minimum Flows	CTR-027-005a
G-03 Design/Minimum Flows	CTR-035-029
G-03 Design/Minimum Flows	CTR-040-018b
G-03 Design/Minimum Flows	CTR-036-007b
G-03 Design/Minimum Flows	CTR-037-005
G-03 Design/Minimum Flows	CTRH-001-034c
G-04 Interim Limits	CTR-003-005
G-04 Interim Limits	CTR-005-003f
G-04 Interim Limits	CTR-021-002a
G-04 Interim Limits	CTR-030-001

Subject Matter Code	Comment ID
G-04 Interim Limits	CTR-030-004b
G-04 Interim Limits	CTR-032-002g
G-04 Interim Limits	CTR-034-012a
G-04 Interim Limits	CTR-035-002e
G-04 Interim Limits	CTR-035-033
G-04 Interim Limits	CTR-052-002e
G-04 Interim Limits	CTR-054-004c
G-04 Interim Limits	CTR-056-002
G-04 Interim Limits	CTR-060-001
G-04 Interim Limits	CTR-038-002d
G-04 Interim Limits	CTR-039-008
G-04 Interim Limits	CTR-041-006a
G-04 Interim Limits	CTR-044-003f
G-04 Interim Limits	CTR-045-002
G-04 Interim Limits	CTR-059-012
G-04 Interim Limits	CTR-081-002a
G-04 Interim Limits	CTR-085-003
G-04 Interim Limits	CTR-085-012
G-04 Interim Limits	CTR-086-004g
G-04 Interim Limits	CTR-090-002f
G-04 Interim Limits	CTR-066-002
G-04 Interim Limits	CTR-043-002d
G-04 Interim Limits	CTR-092-006
G-04 Interim Limits	CTRH-001-039b
G-04 Interim Limits	CTRH-001-057c
G-04 Interim Limits	CTRH-002-011b
G-05 Mixing Zones&Dilution Credit	CTR-004-004a
G-05 Mixing Zones&Dilution Credit	CTR-004-009
G-05 Mixing Zones&Dilution Credit	CTR-005-003e
G-05 Mixing Zones&Dilution Credit	CTR-015-004
G-05 Mixing Zones&Dilution Credit	CTR-020-019
G-05 Mixing Zones&Dilution Credit	CTR-021-002e
G-05 Mixing Zones&Dilution Credit	CTR-027-012e
G-05 Mixing Zones&Dilution Credit	CTR-032-002h
G-05 Mixing Zones&Dilution Credit	CTR-035-002d
G-05 Mixing Zones&Dilution Credit	CTR-035-034
G-05 Mixing Zones&Dilution Credit	CTR-052-002d
G-05 Mixing Zones&Dilution Credit	CTR-052-019
G-05 Mixing Zones&Dilution Credit	CTR-054-004b
G-05 Mixing Zones&Dilution Credit	CTR-056-007
G-05 Mixing Zones&Dilution Credit	CTR-060-002
G-05 Mixing Zones&Dilution Credit	CTR-038-002e
G-05 Mixing Zones&Dilution Credit	CTR-040-002d
G-05 Mixing Zones&Dilution Credit	CTR-041-006b
G-05 Mixing Zones&Dilution Credit	CTR-040-051
G-05 Mixing Zones&Dilution Credit	CTR-044-003e
G-05 Mixing Zones&Dilution Credit	CTR-045-008
G-05 Mixing Zones&Dilution Credit	CTR-058-008
G-05 Mixing Zones&Dilution Credit	CTR-077-002
G-05 Mixing Zones&Dilution Credit	CTR-081-002h
G-05 Mixing Zones&Dilution Credit	CTR-085-011
G-05 Mixing Zones&Dilution Credit	CTR-086-004h
G-05 Mixing Zones&Dilution Credit	CTR-089-001d
G-05 Mixing Zones&Dilution Credit	CTR-090-002d
G-05 Mixing Zones&Dilution Credit	CTR-066-010
G-05 Mixing Zones&Dilution Credit	CTR-043-002e
G-05 Mixing Zones&Dilution Credit	CTR-041-047
G-05 Mixing Zones&Dilution Credit	CTR-092-007
G-05 Mixing Zones&Dilution Credit	CTR-044-042
G-05 Mixing Zones&Dilution Credit	CTR-054-046
G-05 Mixing Zones&Dilution Credit	CTRH-001-022b
G-05 Mixing Zones&Dilution Credit	CTRH-001-024b
G-05 Mixing Zones&Dilution Credit	CTRH-001-032c
G-05 Mixing Zones&Dilution Credit	CTRH-001-057g
G-06 NWQI	CTR-061-020
G-07 Variances	CTR-004-007
G-07 Variances	CTR-015-005
G-07 Variances	CTR-035-035
G-07 Variances	CTR-057-010b
G-07 Variances	CTR-040-049
G-07 Variances	CTR-050-005b
G-07 Variances	CTR-090-020
G-07 Variances	CTR-041-045
G-07 Variances	CTR-092-008
G-07 Variances	CTR-044-040
G-07 Variances	CTR-054-044
G-07 Variances	CTRH-001-022a
G-07 Variances	CTRH-001-057d
G-08 State Policy	CTRE-004-001b
G-09 Translators	CTR-004-004d
G-09 Translators	CTR-005-003d
G-09 Translators	CTR-027-012d
G-09 Translators	CTR-030-008
G-09 Translators	CTR-032-002c
G-09 Translators	CTR-035-002f
G-09 Translators	CTR-035-018
G-09 Translators	CTR-052-002c
G-09 Translators	CTR-054-004a
G-09 Translators	CTR-056-008
G-09 Translators	CTR-060-009
G-09 Translators	CTR-038-002f
G-09 Translators	CTR-040-002c
G-09 Translators	CTR-041-003a
G-09 Translators	CTR-044-003d
G-09 Translators	CTR-081-002e
G-09 Translators	CTR-085-007

Subject Matter Code	Comment ID
G-09 Translators	CTR-086-004c
G-09 Translators	CTR-089-001g
G-09 Translators	CTR-066-006
G-09 Translators	CTR-043-002f
G-09 Translators	CTR-092-003
G-09 Translators	CTRH-001-045b
G-09 Translators	CTRH-001-049
G-09 Translators	CTRH-001-057e
G-10 Pretreatment	CTR-096-004a
G-11 Intake Credits	CTR-084-001
H Paperwork Reduction Act	CTR-019-004b
I Stormwater/Wet Weather Flows	CTR-019-004a
I Stormwater/Wet Weather Flows	CTR-030-004c
I Stormwater/Wet Weather Flows	CTR-031-004c
I Stormwater/Wet Weather Flows	CTR-031-005b
I Stormwater/Wet Weather Flows	CTR-042-004
I Stormwater/Wet Weather Flows	CTR-036-008
I Stormwater/Wet Weather Flows	CTR-036-010b
I Stormwater/Wet Weather Flows	CTRH-002-006a
I-01 Application Sec 301 vs. MEP	CTR-013-001
I-01 Application Sec 301 vs. MEP	CTR-014-001
I-01 Application Sec 301 vs. MEP	CTR-019-001a
I-01 Application Sec 301 vs. MEP	CTR-021-006e
I-01 Application Sec 301 vs. MEP	CTR-024-001
I-01 Application Sec 301 vs. MEP	CTR-027-001
I-01 Application Sec 301 vs. MEP	CTR-030-010
I-01 Application Sec 301 vs. MEP	CTR-031-001a
I-01 Application Sec 301 vs. MEP	CTR-035-036
I-01 Application Sec 301 vs. MEP	CTR-056-015a
I-01 Application Sec 301 vs. MEP	CTR-060-011
I-01 Application Sec 301 vs. MEP	CTR-001-003
I-01 Application Sec 301 vs. MEP	CTR-001-005
I-01 Application Sec 301 vs. MEP	CTR-001-011
I-01 Application Sec 301 vs. MEP	CTR-040-003
I-01 Application Sec 301 vs. MEP	CTR-042-001
I-01 Application Sec 301 vs. MEP	CTR-036-001
I-01 Application Sec 301 vs. MEP	CTR-071-001
I-01 Application Sec 301 vs. MEP	CTR-072-001
I-01 Application Sec 301 vs. MEP	CTR-073-001
I-01 Application Sec 301 vs. MEP	CTR-074-001
I-01 Application Sec 301 vs. MEP	CTR-075-001
I-01 Application Sec 301 vs. MEP	CTR-076-001
I-01 Application Sec 301 vs. MEP	CTR-078-001
I-01 Application Sec 301 vs. MEP	CTR-079-001
I-01 Application Sec 301 vs. MEP	CTR-087-001
I-01 Application Sec 301 vs. MEP	CTR-090-014
I-01 Application Sec 301 vs. MEP	CTR-062-001
I-01 Application Sec 301 vs. MEP	CTR-092-011
I-01 Application Sec 301 vs. MEP	CTRE-002-002
I-01 Application Sec 301 vs. MEP	CTRH-001-001a
I-01 Application Sec 301 vs. MEP	CTRH-001-004
I-01 Application Sec 301 vs. MEP	CTRH-001-006
I-01 Application Sec 301 vs. MEP	CTRH-001-031
I-01 Application Sec 301 vs. MEP	CTRH-001-040
I-01 Application Sec 301 vs. MEP	CTRH-002-001
I-01 Application Sec 301 vs. MEP	CTRH-002-008
I-02 Elliott Memorandum	CTR-031-001b
I-02 Elliott Memorandum	CTR-001-006
I-02 Elliott Memorandum	CTR-040-014a
I-02a Applying WQBELs, Stormwater	CTR-020-001
I-02a Applying WQBELs, Stormwater	CTR-020-022
I-02a Applying WQBELs, Stormwater	CTR-001-002
I-02a Applying WQBELs, Stormwater	CTR-001-004
I-02a Applying WQBELs, Stormwater	CTR-087-002
I-03 Applicability of Criteria	CTR-007-003
I-03 Applicability of Criteria	CTR-013-005
I-03 Applicability of Criteria	CTR-027-006
I-03 Applicability of Criteria	CTR-031-003b
I-03 Applicability of Criteria	CTR-037-008
I-03 Applicability of Criteria	CTR-061-005a
I-03 Applicability of Criteria	CTR-096-001a
I-03 Applicability of Criteria	CTRE-002-004
I-03 Applicability of Criteria	CTRH-001-007
I-03 Applicability of Criteria	CTRH-001-061
I-03 Applicability of Criteria	CTRH-002-024
I-04 Site-Specific Criteria	CTR-013-006a
I-04 Site-Specific Criteria	CTR-027-007a
I-04 Site-Specific Criteria	CTRH-002-025
I-05 Compliance Schedules	CTR-013-007a
I-05 Compliance Schedules	CTR-027-008a
I-05 Compliance Schedules	CTRH-001-034b
I-05 Compliance Schedules	CTRH-002-026
I-07 Attainability of Criteria	CTR-040-005
I-07 Attainability of Criteria	CTR-096-002
I-08 SWRCB Flexibility&Authority	CTR-001-010
I-08 SWRCB Flexibility&Authority	CTRH-001-034a
I-09 Pesticides in Runoff	CTR-061-001
I-10 CSO Policy	CTR-090-021
J Storm Water Economics	CTR-013-003
J Storm Water Economics	CTR-013-008b
J Storm Water Economics	CTR-014-003

Subject Matter Code	Comment ID
J Storm Water Economics	CTR-014-004b
J Storm Water Economics	CTR-018-001
J Storm Water Economics	CTR-019-001b
J Storm Water Economics	CTR-019-002a
J Storm Water Economics	CTR-019-003a
J Storm Water Economics	CTR-021-006a
J Storm Water Economics	CTR-024-003
J Storm Water Economics	CTR-024-004b
J Storm Water Economics	CTR-027-003
J Storm Water Economics	CTR-027-009b
J Storm Water Economics	CTR-027-010
J Storm Water Economics	CTR-028-001b
J Storm Water Economics	CTR-031-002d
J Storm Water Economics	CTR-031-006a
J Storm Water Economics	CTR-034-014e
J Storm Water Economics	CTR-035-044c
J Storm Water Economics	CTR-001-007
J Storm Water Economics	CTR-040-004
J Storm Water Economics	CTR-040-006
J Storm Water Economics	CTR-040-007
J Storm Water Economics	CTR-040-010a
J Storm Water Economics	CTR-040-014b
J Storm Water Economics	CTR-036-002a
J Storm Water Economics	CTR-036-003b
J Storm Water Economics	CTR-036-004a
J Storm Water Economics	CTR-047-003
J Storm Water Economics	CTR-047-004a
J Storm Water Economics	CTR-059-023b
J Storm Water Economics	CTR-071-003
J Storm Water Economics	CTR-071-004a
J Storm Water Economics	CTR-072-003
J Storm Water Economics	CTR-072-004a
J Storm Water Economics	CTR-073-003
J Storm Water Economics	CTR-073-004a
J Storm Water Economics	CTR-074-003
J Storm Water Economics	CTR-074-004a
J Storm Water Economics	CTR-075-003
J Storm Water Economics	CTR-075-004a
J Storm Water Economics	CTR-076-003
J Storm Water Economics	CTR-076-004a
J Storm Water Economics	CTR-078-003
J Storm Water Economics	CTR-078-004a
J Storm Water Economics	CTR-079-003
J Storm Water Economics	CTR-079-004a
J Storm Water Economics	CTR-080-001
J Storm Water Economics	CTR-061-002
J Storm Water Economics	CTR-061-003
J Storm Water Economics	CTR-061-017
J Storm Water Economics	CTR-061-019
J Storm Water Economics	CTR-062-003
J Storm Water Economics	CTR-062-004a
J Storm Water Economics	CTRE-002-003
J Storm Water Economics	CTRH-001-001b
J Storm Water Economics	CTRH-001-029
J Storm Water Economics	CTRH-001-033
J Storm Water Economics	CTRH-001-054
J Storm Water Economics	CTRH-002-005
J Storm Water Economics	CTRH-002-006b
J Storm Water Economics	CTRH-002-009
J Storm Water Economics	CTRH-002-017
J-01 MS4s/CSOs/Industries Costs	CTR-013-002
J-01 MS4s/CSOs/Industries Costs	CTR-014-002
J-01 MS4s/CSOs/Industries Costs	CTR-024-002
J-01 MS4s/CSOs/Industries Costs	CTR-027-002
J-01 MS4s/CSOs/Industries Costs	CTR-040-034
J-01 MS4s/CSOs/Industries Costs	CTR-073-002
J-01 MS4s/CSOs/Industries Costs	CTR-074-002
J-01 MS4s/CSOs/Industries Costs	CTR-071-002
J-01 MS4s/CSOs/Industries Costs	CTR-072-002
J-01 MS4s/CSOs/Industries Costs	CTR-075-002
J-01 MS4s/CSOs/Industries Costs	CTR-076-002
J-01 MS4s/CSOs/Industries Costs	CTR-078-002
J-01 MS4s/CSOs/Industries Costs	CTR-079-002
J-01 MS4s/CSOs/Industries Costs	CTR-087-003
J-01 MS4s/CSOs/Industries Costs	CTR-062-002
J-01 MS4s/CSOs/Industries Costs	CTR-041-030
J-01 MS4s/CSOs/Industries Costs	CTR-069-002a
J-01 MS4s/CSOs/Industries Costs	CTR-044-025
J-01 MS4s/CSOs/Industries Costs	CTR-054-029
J-02 RFA - Small Entity Cost	CTR-001-008a
J-02 RFA - Small Entity Cost	CTRH-001-005a
J-02 RFA - Small Entity Cost	CTRH-001-008b
J-02 RFA - Small Entity Cost	CTRH-002-004
J-04 End-of-Pipe Treatment v. BMP	CTR-031-007b
J-04 End-of-Pipe Treatment v. BMP	CTR-042-002
J-04 End-of-Pipe Treatment v. BMP	CTR-047-002
J-04 End-of-Pipe Treatment v. BMP	CTR-080-002
J-04 End-of-Pipe Treatment v. BMP	CTRH-001-042
J-04 End-of-Pipe Treatment v. BMP	CTRH-001-060b
J-04 End-of-Pipe Treatment v. BMP	CTRH-002-002
J-05 BMPs Inability to Comply	CTR-040-025
J-05 BMPs Inability to Comply	CTR-041-021
J-05 BMPs Inability to Comply	CTR-096-003b
J-05 BMPs Inability to Comply	CTR-044-016
J-05 BMPs Inability to Comply	CTR-054-020
J-06 NEPA	CTR-001-009b

Subject Matter Code	Comment ID
J-06 NEPA	CTRH-001-009a
K Water Shed Approach	CTR-021-003
K Water Shed Approach	CTR-032-002f
K Water Shed Approach	CTR-032-007
K Water Shed Approach	CTR-034-011
K Water Shed Approach	CTR-035-003
K Water Shed Approach	CTR-036-011
K Water Shed Approach	CTR-059-014
K Water Shed Approach	CTR-067-004b
K Water Shed Approach	CTR-083-002
K Water Shed Approach	CTRH-002-015
K-01 TMDLs	CTR-004-006
K-01 TMDLs	CTR-021-002d
K-01 TMDLs	CTR-034-012b
K-01 TMDLs	CTR-035-002g
K-01 TMDLs	CTR-035-032a
K-01 TMDLs	CTR-057-010a
K-01 TMDLs	CTR-040-048
K-01 TMDLs	CTR-058-011
K-01 TMDLs	CTR-086-001b
K-01 TMDLs	CTR-089-001e
K-01 TMDLs	CTR-090-010b
K-01 TMDLs	CTR-041-044
K-01 TMDLs	CTR-092-005
K-01 TMDLs	CTR-044-039
K-01 TMDLs	CTR-054-043
K-01 TMDLs	CTRH-002-011d
K-02 Watershed Permitting	CTR-090-023a
K-03 Watershed/Effluent Trading	CTR-035-032b
K-03 Watershed/Effluent Trading	CTR-086-004f
K-03 Watershed/Effluent Trading	CTR-061-016
K-03 Watershed/Effluent Trading	CTRH-001-057a
L Anti-Backsliding	CTR-030-002
L Anti-Backsliding	CTR-060-003
M Re-Open Comment Period	CTR-005-010
M Re-Open Comment Period	CTR-013-009
M Re-Open Comment Period	CTR-027-013a
M Re-Open Comment Period	CTR-031-010
M Re-Open Comment Period	CTR-034-017
M Re-Open Comment Period	CTR-035-011b
M Re-Open Comment Period	CTR-052-022
M Re-Open Comment Period	CTR-053-001
M Re-Open Comment Period	CTR-054-016
M Re-Open Comment Period	CTR-038-013
M Re-Open Comment Period	CTR-044-012
M Re-Open Comment Period	CTR-059-005
M Re-Open Comment Period	CTR-059-004b
M Re-Open Comment Period	CTR-067-007
M Re-Open Comment Period	CTR-043-011
O Offer of Assistance/Review	CTR-027-013b
O Offer of Assistance/Review	CTR-040-001
O Offer of Assistance/Review	CTR-040-021
P Whole Effluent Toxicity	CTR-057-008
P Whole Effluent Toxicity	CTR-065-006a
Q Nonpoint Sources	CTR-086-001a
Q Nonpoint Sources	CTR-090-007
Q Nonpoint Sources	CTR-090-015
Q Nonpoint Sources	CTR-090-023b
R RFA/SBREFA	CTR-005-006c
R RFA/SBREFA	CTR-013-008a
R RFA/SBREFA	CTR-014-004a
R RFA/SBREFA	CTR-019-003b
R RFA/SBREFA	CTR-021-005d
R RFA/SBREFA	CTR-021-006c
R RFA/SBREFA	CTR-023-001
R RFA/SBREFA	CTR-024-004a
R RFA/SBREFA	CTR-027-009a
R RFA/SBREFA	CTR-027-011
R RFA/SBREFA	CTR-028-001a
R RFA/SBREFA	CTR-031-006b
R RFA/SBREFA	CTR-031-009
R RFA/SBREFA	CTR-034-005
R RFA/SBREFA	CTR-035-041
R RFA/SBREFA	CTR-052-021c
R RFA/SBREFA	CTR-054-008d
R RFA/SBREFA	CTR-001-008b
R RFA/SBREFA	CTR-038-005b
R RFA/SBREFA	CTR-038-006c
R RFA/SBREFA	CTR-038-008c
R RFA/SBREFA	CTR-038-009c
R RFA/SBREFA	CTR-041-013b
R RFA/SBREFA	CTR-040-009a
R RFA/SBREFA	CTR-040-010b
R RFA/SBREFA	CTR-040-013
R RFA/SBREFA	CTR-036-004b
R RFA/SBREFA	CTR-044-005f
R RFA/SBREFA	CTR-044-006c
R RFA/SBREFA	CTR-044-009c
R RFA/SBREFA	CTR-047-004b
R RFA/SBREFA	CTR-050-007c
R RFA/SBREFA	CTR-059-002b
R RFA/SBREFA	CTR-059-016
R RFA/SBREFA	CTR-067-006a
R RFA/SBREFA	CTR-071-004b
R RFA/SBREFA	CTR-072-004b
R RFA/SBREFA	CTR-073-004b

Subject Matter Code	Comment ID
R RFA/SBREFA	CTR-074-004b
R RFA/SBREFA	CTR-075-004b
R RFA/SBREFA	CTR-076-004b
R RFA/SBREFA	CTR-078-004b
R RFA/SBREFA	CTR-079-004b
R RFA/SBREFA	CTR-062-004b
R RFA/SBREFA	CTR-043-005c
R RFA/SBREFA	CTR-041-017
R RFA/SBREFA	CTR-092-016b
R RFA/SBREFA	CTR-096-004b
R RFA/SBREFA	CTR-044-047
R RFA/SBREFA	CTR-054-051
R RFA/SBREFA	CTRE-003-001c
R RFA/SBREFA	CTRH-001-005b
R RFA/SBREFA	CTRH-001-008a
R RFA/SBREFA	CTR-040-056
R RFA/SBREFA	CTR-040-056
S UMRA	CTR-005-006b
S UMRA	CTR-019-002b
S UMRA	CTR-021-005e
S UMRA	CTR-021-006d
S UMRA	CTR-034-004
S UMRA	CTR-035-040
S UMRA	CTR-052-021d
S UMRA	CTR-054-008e
S UMRA	CTR-056-022b
S UMRA	CTR-038-005c
S UMRA	CTR-038-006d
S UMRA	CTR-038-008d
S UMRA	CTR-038-009d
S UMRA	CTR-041-013c
S UMRA	CTR-040-009b
S UMRA	CTR-040-012b
S UMRA	CTR-040-015a
S UMRA	CTR-042-007c
S UMRA	CTR-036-003a
S UMRA	CTR-044-005g
S UMRA	CTR-044-006d
S UMRA	CTR-044-009d
S UMRA	CTR-050-007d
S UMRA	CTR-059-002c
S UMRA	CTR-059-006c
S UMRA	CTR-059-015b
S UMRA	CTR-084-002b
S UMRA	CTR-090-012b
S UMRA	CTR-043-005d
S UMRA	CTR-041-016
S UMRA	CTR-092-016c
S UMRA	CTR-044-046
S UMRA	CTR-054-050
S UMRA	CTR-040-055
T State Implementation Policy	CTR-004-001
T State Implementation Policy	CTR-007-006
T State Implementation Policy	CTR-009-001
T State Implementation Policy	CTR-015-003
T State Implementation Policy	CTR-027-005b
T State Implementation Policy	CTR-032-003
T State Implementation Policy	CTR-032-005b
T State Implementation Policy	CTR-052-015
T State Implementation Policy	CTR-053-005
T State Implementation Policy	CTR-055-002b
T State Implementation Policy	CTR-057-009
T State Implementation Policy	CTR-038-008e
T State Implementation Policy	CTR-086-005
T State Implementation Policy	CTR-086-007
T State Implementation Policy	CTR-090-009
T State Implementation Policy	CTR-092-001
T State Implementation Policy	CTRH-001-055
V Collaborative Approach	CTR-031-002e
V Collaborative Approach	CTR-031-008b
V Collaborative Approach	CTR-054-015
V Collaborative Approach	CTR-032-005a
V Collaborative Approach	CTR-034-002
V Collaborative Approach	CTRE-001-001b
V Collaborative Approach	CTRE-023-001b
V Collaborative Approach	CTRH-001-019b
V Collaborative Approach	CTRH-001-025
V Collaborative Approach	CTRH-001-030
V Collaborative Approach	CTRH-001-056
V Collaborative Approach	CTRH-002-021b

Comment ID	Subject Matter Code
CTR-001-001	B Comment Period
CTR-001-002	I-02a Applying WQBELs, Stormwater
CTR-001-003	I-01 Application Sec 301 vs. MEP
CTR-001-004	I-02a Applying WQBELs, Stormwater
CTR-001-005	I-01 Application Sec 301 vs. MEP
CTR-001-006	I-02 Elliott Memorandum
CTR-001-007	J Storm Water Economics
CTR-001-008a	J-02 RFA - Small Entity Cost
CTR-001-008b	R RFA/SBREFA
CTR-001-009a	F Endangered Species Act
CTR-001-009b	J-06 NEPA
CTR-001-010	I-08 SWRCB Flexibility&Authority
CTR-001-011	I-01 Application Sec 301 vs. MEP
CTR-002-001	B Comment Period
CTR-002-002a	C-14 Fish or Water Consumption
CTR-002-002b	C-17a Methodologies Human Health
CTR-002-003	C-24 Site Specific Criteria
CTR-002-004a	C-17a Methodologies Human Health
CTR-002-004b	C-17b Methodologies Aquatic Life
CTR-002-005a	C-14 Fish or Water Consumption
CTR-002-005b	C-21 Legal Concerns
CTR-002-006	C-09a Dioxin Human Health
CTR-002-007a	C-01 Mercury
CTR-002-007b	C-01 Mercury
CTR-002-008	C-02b Copper Aquatic Life
CTR-002-009	C-21 Legal Concerns
CTR-002-010a	A Anti-degradation
CTR-002-010b	G-02 Compliance Schedules
CTR-003-001	C-24a SSC Water Effect Ratios
CTR-003-002	C-26 Avrging pds&Exceedence Freq.
CTR-003-003	C-13 Risk Level
CTR-003-004	G-03 Design/Minimum Flows
CTR-003-005	G-04 Interim Limits
CTR-003-006	C-24 Site Specific Criteria
CTR-003-007	E-01m Regulatory Relief
CTR-003-008	E-01n Detection Limits
CTR-003-009	C-01 Mercury
CTR-003-010	E-01o Background Levels
CTR-003-011	E-01h Treatment Assumptions
CTR-003-012	E-01i Alternative Cost Analysis
CTR-003-013	E-01h Treatment Assumptions
CTR-004-001	T State Implementation Policy
CTR-004-002	E-01n Detection Limits
CTR-004-003	E-01q Source Reduction
CTR-004-004a	G-05 Mixing Zones&Dilution Credit
CTR-004-004b	C-24a SSC Water Effect Ratios
CTR-004-004c	C-22 Dissolved v. Ttl Recoverable
CTR-004-004d	G-09 Translators
CTR-004-005	B Comment Period
CTR-004-006	K-01 TMDLs
CTR-004-007	G-07 Variances
CTR-004-008	C-24 Site Specific Criteria
CTR-004-009	G-05 Mixing Zones&Dilution Credit
CTR-005-001	E-01w Cost per Facility
CTR-005-002	B Comment Period
CTR-005-003a	C-22 Dissolved v. Ttl Recoverable
CTR-005-003b	C-24a SSC Water Effect Ratios
CTR-005-003c	C-01 Mercury
CTR-005-003d	G-09 Translators
CTR-005-003e	G-05 Mixing Zones&Dilution Credit
CTR-005-003f	G-04 Interim Limits
CTR-005-004	E-01d01 Cost Estmte by Commenter
CTR-005-005	E-01c02 Bnfts do not Balance Cost
CTR-005-006a	C-21 Legal Concerns
CTR-005-006b	S UMRA
CTR-005-006c	R RFA/SBREFA
CTR-005-007	C-13 Risk Level
CTR-005-008a	C-24 Site Specific Criteria
CTR-005-008b	C-21 Legal Concerns
CTR-005-009	C-28 Detection Limits
CTR-005-010	M Re-Open Comment Period
CTR-006-001a	C-01 Mercury
CTR-006-001b	C-01 Mercury
CTR-006-002a	C-01 Mercury
CTR-006-002b	C-14 Fish or Water Consumption
CTR-006-003	C-01 Mercury
CTR-007-001	C-22 Dissolved v. Ttl Recoverable
CTR-007-002	C-23 Sediments/Dredged Materials
CTR-007-003	I-03 Applicability of Criteria
CTR-007-004	C-21 Legal Concerns
CTR-007-005	B Comment Period
CTR-007-006	T State Implementation Policy
CTR-008-001	C-04b Selenium Aquatic Life
CTR-008-002	C-24 Site Specific Criteria
CTR-009-001	T State Implementation Policy
CTR-009-002	G-02 Compliance Schedules
CTR-009-003	C-24 Site Specific Criteria
CTR-009-004	C-24b SSC Recalculation Procedure
CTR-009-005	C-04b Selenium Aquatic Life
CTR-009-006a	C-24 Site Specific Criteria
CTR-009-006b	G-02 Compliance Schedules
CTR-009-007	C-26 Avrging pds&Exceedence Freq.
CTR-009-008a	E-01s 2ndary,Indirect Cost Impact
CTR-009-008b	E-02c Overstated Benefits
CTR-009-008c	E-02o Analysis from Wisconsin
CTR-010-001	C-24 Site Specific Criteria
CTR-010-002	C-14 Fish or Water Consumption

Comment ID	Subject Matter Code
CTR-010-003	C-21 Legal Concerns
CTR-011-001a	C-13 Risk Level
CTR-011-001b	C-24 Site Specific Criteria
CTR-011-001c	E-01d Direct Dischargers
CTR-011-002	C-28 Detection Limits
CTR-012-001	F Endangered Species Act
CTR-013-001	I-01 Application Sec 301 vs. MEP
CTR-013-002	J-01 MS4s/CSOs/Industries Costs
CTR-013-003	J Storm Water Economics
CTR-013-004	C-28 Detection Limits
CTR-013-005	I-03 Applicability of Criteria
CTR-013-006a	I-04 Site-Specific Criteria
CTR-013-006b	C-24e SSC Desgntd/Beneficial Uses
CTR-013-007a	I-05 Compliance Schedules
CTR-013-007b	G-02 Compliance Schedules
CTR-013-008a	R RFA/SBREFA
CTR-013-008b	J Storm Water Economics
CTR-013-009	M Re-Open Comment Period
CTR-014-001	I-01 Application Sec 301 vs. MEP
CTR-014-002	J-01 MS4s/CSOs/Industries Costs
CTR-014-003	J Storm Water Economics
CTR-014-004a	R RFA/SBREFA
CTR-014-004b	J Storm Water Economics
CTR-015-001	C-14 Fish or Water Consumption
CTR-015-002	C-13 Risk Level
CTR-015-003	T State Implementation Policy
CTR-015-004	G-05 Mixing Zones&Dilution Credit
CTR-015-005	G-07 Variances
CTR-015-006	G-02 Compliance Schedules
CTR-016-001	C-24 Site Specific Criteria
CTR-016-002	C-24 Site Specific Criteria
CTR-016-003	G-02 Compliance Schedules
CTR-016-004	C-15 Salinity
CTR-016-005	C-04b Selenium Aquatic Life
CTR-016-006	C-19 FDA Action Levels
CTR-016-007	C-01 Mercury
CTR-016-008	C-09a Dioxin Human Health
CTR-017-001	C-24 Site Specific Criteria
CTR-017-002a	C-22 Dissolved v. Ttl Recoverable
CTR-017-002b	C-24a SSC Water Effect Ratios
CTR-018-001	J Storm Water Economics
CTR-019-001a	I-01 Application Sec 301 vs. MEP
CTR-019-001b	J Storm Water Economics
CTR-019-002a	J Storm Water Economics
CTR-019-002b	S UMRA
CTR-019-003a	J Storm Water Economics
CTR-019-003b	R RFA/SBREFA
CTR-019-004a	I Stormwater/Wet Weather Flows
CTR-019-004b	H Paperwork Reduction Act
CTR-020-001	I-02a Applying WQBELs, Stormwater
CTR-020-002	C-21 Legal Concerns
CTR-020-003	C-24 Site Specific Criteria
CTR-020-004a	C-01 Mercury
CTR-020-004b	C-01 Mercury
CTR-020-005	C-24a SSC Water Effect Ratios
CTR-020-006	C-24a SSC Water Effect Ratios
CTR-020-007	C-08a Arsenic Human Health
CTR-020-008	C-26 Avrging pds&Exceedence Freq.
CTR-020-009	C-26 Avrging pds&Exceedence Freq.
CTR-020-010	C-26 Avrging pds&Exceedence Freq.
CTR-020-011	C-02b Copper Aquatic Life
CTR-020-012	C-02b Copper Aquatic Life
CTR-020-013	C-05b Lead Aquatic Life
CTR-020-014	C-26 Avrging pds&Exceedence Freq.
CTR-020-015	C-26 Avrging pds&Exceedence Freq.
CTR-020-016	G-03 Design/Minimum Flows
CTR-020-017	C-24e SSC Desgntd/Beneficial Uses
CTR-020-018	C-12a THMs Human Health
CTR-020-019	G-05 Mixing Zones&Dilution Credit
CTR-020-020	C-28 Detection Limits
CTR-020-021	G-02 Compliance Schedules
CTR-020-022	I-02a Applying WQBELs, Stormwater
CTR-021-001	B Comment Period
CTR-021-002a	G-04 Interim Limits
CTR-021-002b	C-24a SSC Water Effect Ratios
CTR-021-002c	C-22 Dissolved v. Ttl Recoverable
CTR-021-002d	K-01 TMDLs
CTR-021-002e	G-05 Mixing Zones&Dilution Credit
CTR-021-002f	G-02 Compliance Schedules
CTR-021-003	K Water Shed Approach
CTR-021-004	E-01g09 Affected Facilities
CTR-021-005a	C-13 Risk Level
CTR-021-005b	C-28 Detection Limits
CTR-021-005c	E-01c Executive Order 12866
CTR-021-005d	R RFA/SBREFA
CTR-021-005e	S UMRA
CTR-021-006a	J Storm Water Economics
CTR-021-006b	E-01c Executive Order 12866
CTR-021-006c	R RFA/SBREFA
CTR-021-006d	S UMRA
CTR-021-006e	I-01 Application Sec 301 vs. MEP
CTR-021-007	C-24 Site Specific Criteria
CTR-021-008	E-01g Sample Facilities
CTR-021-009	E-01h Treatment Assumptions
CTR-021-010	E-01g04 AMLs vs. MDLs
CTR-021-011	E-01e Indirect Dischargers

Comment ID	Subject Matter Code
CTR-021-012	E-01q Source Reduction
CTR-021-013	E-01n Detection Limits
CTR-021-014	E-01g Sample Facilities
CTR-021-015	E-01i Alternative Cost Analysis
CTR-021-016	E-01g06 Reasonable Potential
CTR-021-017	E-01b Cost Triggers
CTR-022-001	D Preamble Editorial Comments
CTR-022-002	D Preamble Editorial Comments
CTR-022-003	G-02 Compliance Schedules
CTR-022-004	D Preamble Editorial Comments
CTR-023-001	R RFA/SBREFA
CTR-024-001	I-01 Application Sec 301 vs. MEP
CTR-024-002	J-01 MS4s/CSOs/Industries Costs
CTR-024-003	J Storm Water Economics
CTR-024-004a	R RFA/SBREFA
CTR-024-004b	J Storm Water Economics
CTR-025-001a	C-16 SDWA
CTR-025-001b	C-20 Scope Prty Toxic Poll. List
CTR-025-002a	C-17a Methodologies Human Health
CTR-025-002b	C-16 SDWA
CTR-025-003a	C-17a Methodologies Human Health
CTR-025-003b	C-16 SDWA
CTR-025-003c	C-12a THMs Human Health
CTR-025-004a	C-02b Copper Aquatic Life
CTR-025-004b	C-16 SDWA
CTR-025-005	C-24b SSC Recalculation Procedure
CTR-025-006a	B Comment Period
CTR-025-006b	C-16 SDWA
CTR-026-001a	A Anti-degradation
CTR-026-001b	C-24e SSC Desgntd/Beneficial Uses
CTR-026-002a	C-17b Methodologies Aquatic Life
CTR-026-002b	C-27 Additive/Synergistic Effects
CTR-026-002c	C-29 Bioaccumulation
CTR-026-003a	C-17b Methodologies Aquatic Life
CTR-026-003b	C-17a Methodologies Human Health
CTR-026-004	C-22 Dissolved v. Ttl Recoverable
CTR-026-005	C-25 Hardness
CTR-026-006	C-24 Site Specific Criteria
CTR-026-007a	C-14 Fish or Water Consumption
CTR-026-007b	C-17a Methodologies Human Health
CTR-026-008	C-20 Scope Prty Toxic Poll. List
CTR-026-009	E-02d Passive Use Value
CTR-027-001	I-01 Application Sec 301 vs. MEP
CTR-027-002	J-01 MS4s/CSOs/Industries Costs
CTR-027-003	J Storm Water Economics
CTR-027-004	C-28 Detection Limits
CTR-027-005a	G-03 Design/Minimum Flows
CTR-027-005b	T State Implementation Policy
CTR-027-006	I-03 Applicability of Criteria
CTR-027-007a	I-04 Site-Specific Criteria
CTR-027-007b	C-24e SSC Desgntd/Beneficial Uses
CTR-027-008a	I-05 Compliance Schedules
CTR-027-008b	G-02 Compliance Schedules
CTR-027-009a	R RFA/SBREFA
CTR-027-009b	J Storm Water Economics
CTR-027-010	J Storm Water Economics
CTR-027-011	R RFA/SBREFA
CTR-027-012a	C-22 Dissolved v. Ttl Recoverable
CTR-027-012b	C-24a SSC Water Effect Ratios
CTR-027-012c	C-01 Mercury
CTR-027-012d	G-09 Translators
CTR-027-012e	G-05 Mixing Zones&Dilution Credit
CTR-027-013a	M Re-Open Comment Period
CTR-027-013b	O Offer of Assistance/Review
CTR-028-001a	R RFA/SBREFA
CTR-028-001b	J Storm Water Economics
CTR-029-001	A Anti-degradation
CTR-029-002a	C-17a Methodologies Human Health
CTR-029-002b	C-17b Methodologies Aquatic Life
CTR-029-002c	A Anti-degradation
CTR-029-002d	C-22 Dissolved v. Ttl Recoverable
CTR-029-002e	C-27 Additive/Synergistic Effects
CTR-029-002f	C-29 Bioaccumulation
CTR-029-003	C-14 Fish or Water Consumption
CTR-029-004a	E-01c02 Bnfts do not Balance Cost
CTR-029-004b	E-02e Include Omitted Benefits
CTR-030-001	G-04 Interim Limits
CTR-030-002	L Anti-Backsliding
CTR-030-003	C-08a Arsenic Human Health
CTR-030-004a	G-02 Compliance Schedules
CTR-030-004b	G-04 Interim Limits
CTR-030-004c	I Stormwater/Wet Weather Flows
CTR-030-005	C-04b Selenium Aquatic Life
CTR-030-006	C-01 Mercury
CTR-030-007	C-01 Mercury
CTR-030-008	G-09 Translators
CTR-030-009	C-28 Detection Limits
CTR-030-010	I-01 Application Sec 301 vs. MEP
CTR-030-011	C-04b Selenium Aquatic Life
CTR-030-012	C-04b Selenium Aquatic Life
CTR-030-013	C-04b Selenium Aquatic Life
CTR-030-014	C-04b Selenium Aquatic Life
CTR-030-015	C-04b Selenium Aquatic Life
CTR-030-016	C-04b Selenium Aquatic Life
CTR-031-001a	I-01 Application Sec 301 vs. MEP
CTR-031-001b	I-02 Elliott Memorandum

Comment ID	Subject Matter Code
CTR-031-002a	F Endangered Species Act
CTR-031-002b	C-17a Methodologies Human Health
CTR-031-002c	C-17b Methodologies Aquatic Life
CTR-031-002d	J Storm Water Economics
CTR-031-002e	V Collaborative Approach
CTR-031-003a	C-21 Legal Concerns
CTR-031-003b	I-03 Applicability of Criteria
CTR-031-004a	C-17a Methodologies Human Health
CTR-031-004b	C-17b Methodologies Aquatic Life
CTR-031-004c	I Stormwater/Wet Weather Flows
CTR-031-005a	G-02 Compliance Schedules
CTR-031-005b	I Stormwater/Wet Weather Flows
CTR-031-006a	J Storm Water Economics
CTR-031-006b	R RFA/SBREFA
CTR-031-006c	E-01c Executive Order 12866
CTR-031-007a	F Endangered Species Act
CTR-031-007b	J-04 End-of-Pipe Treatment v. BMP
CTR-031-008a	B Comment Period
CTR-031-008b	V Collaborative Approach
CTR-031-009	R RFA/SBREFA
CTR-031-010	M Re-Open Comment Period
CTR-032-001	E-01m Regulatory Relief
CTR-032-002a	G-01 Reasonable Potential
CTR-032-002b	C-22 Dissolved v. Ttl Recoverable
CTR-032-002c	G-09 Translators
CTR-032-002d	C-24a SSC Water Effect Ratios
CTR-032-002e	C-24 Site Specific Criteria
CTR-032-002f	K Water Shed Approach
CTR-032-002g	G-04 Interim Limits
CTR-032-002h	G-05 Mixing Zones&Dilution Credit
CTR-032-002i	G-02 Compliance Schedules
CTR-032-003	T State Implementation Policy
CTR-032-004	E-01m Regulatory Relief
CTR-032-005a	V Collaborative Approach
CTR-032-005b	T State Implementation Policy
CTR-032-006a	C-01 Mercury
CTR-032-006b	C-24 Site Specific Criteria
CTR-032-007	K Water Shed Approach
CTR-032-008a	E-01u Economic Consid. Task Force
CTR-032-008b	E-01c02 Bnfts do not Balance Cost
CTR-033-001	C-02b Copper Aquatic Life
CTR-033-002	C-24c SSC Santa Ana River
CTR-033-003a	C-28 Detection Limits
CTR-033-003b	E-01n Detection Limits
CTR-034-001	B Comment Period
CTR-034-002	V Collaborative Approach
CTR-034-003	E-01c01 $100M Threshold
CTR-034-004	S UMRA
CTR-034-005	R RFA/SBREFA
CTR-034-006	F Endangered Species Act
CTR-034-007	C-24d SSC Effluent Dependent Wtr
CTR-034-008	C-22 Dissolved v. Ttl Recoverable
CTR-034-009	C-24a SSC Water Effect Ratios
CTR-034-010a	C-28 Detection Limits
CTR-034-010b	C-21 Legal Concerns
CTR-034-011	K Water Shed Approach
CTR-034-012a	G-04 Interim Limits
CTR-034-012b	K-01 TMDLs
CTR-034-013	G-02 Compliance Schedules
CTR-034-014a	E-01g08 Discharger Representation
CTR-034-014b	E-01b Cost Triggers
CTR-034-014c	E-01e Indirect Dischargers
CTR-034-014d	E-01v Discharge Over Time
CTR-034-014e	J Storm Water Economics
CTR-034-015	E-02 Benefits Analysis
CTR-034-016	E-01u Economic Consid. Task Force
CTR-034-017	M Re-Open Comment Period
CTR-035-001	B Comment Period
CTR-035-002a	C-22 Dissolved v. Ttl Recoverable
CTR-035-002b	C-01 Mercury
CTR-035-002c	C-08a Arsenic Human Health
CTR-035-002d	G-05 Mixing Zones&Dilution Credit
CTR-035-002e	G-04 Interim Limits
CTR-035-002f	G-09 Translators
CTR-035-002g	K-01 TMDLs
CTR-035-002h	C-24a SSC Water Effect Ratios
CTR-035-003	K Water Shed Approach
CTR-035-004	C-13 Risk Level
CTR-035-005	C-28 Detection Limits
CTR-035-006	C-24d SSC Effluent Dependent Wtr
CTR-035-007	C-24e SSC Desgntd/Beneficial Uses
CTR-035-008a	E-01g08 Discharger Representation
CTR-035-008b	E-01e Indirect Dischargers
CTR-035-008c	E-01d Direct Dischargers
CTR-035-008d	E-01m Regulatory Relief
CTR-035-008e	E-01h Treatment Assumptions
CTR-035-008f	E-01c Executive Order 12866
CTR-035-009a	E-02f Use More Recent Data
CTR-035-009b	E-02c Overstated Benefits
CTR-035-010	E-01c Executive Order 12866
CTR-035-011a	E-01u Economic Consid. Task Force
CTR-035-011b	M Re-Open Comment Period
CTR-035-012a	C-21 Legal Concerns
CTR-035-012b	C-28 Detection Limits
CTR-035-013	D Preamble Editorial Comments
CTR-035-014	C-24 Site Specific Criteria

Comment ID	Subject Matter Code
CTR-035-015	D Preamble Editorial Comments
CTR-035-016	C-22 Dissolved v. Ttl Recoverable
CTR-035-017	C-18 Conversion Factors
CTR-035-018	G-09 Translators
CTR-035-019	C-24a SSC Water Effect Ratios
CTR-035-020	C-26 Avrging pds&Exceedence Freq.
CTR-035-021	C-13 Risk Level
CTR-035-022	C-14 Fish or Water Consumption
CTR-035-023	C-17c Meth.New Human Health Meth.
CTR-035-024	C-09a Dioxin Human Health
CTR-035-025	C-08a Arsenic Human Health
CTR-035-026	C-01 Mercury
CTR-035-027	C-13 Risk Level
CTR-035-028	C-26 Avrging pds&Exceedence Freq.
CTR-035-029	G-03 Design/Minimum Flows
CTR-035-030	C-15 Salinity
CTR-035-031	C-26 Avrging pds&Exceedence Freq.
CTR-035-032a	K-01 TMDLs
CTR-035-032b	K-03 Watershed/Effluent Trading
CTR-035-033	G-04 Interim Limits
CTR-035-034	G-05 Mixing Zones&Dilution Credit
CTR-035-035	G-07 Variances
CTR-035-036	I-01 Application Sec 301 vs. MEP
CTR-035-037	G-02 Compliance Schedules
CTR-035-038	C-24e SSC Desgntd/Beneficial Uses
CTR-035-039	E-01c Executive Order 12866
CTR-035-040	S UMRA
CTR-035-041	R RFA/SBREFA
CTR-035-042	F Endangered Species Act
CTR-035-043	E-01c02 Bnfts do not Balance Cost
CTR-035-044a	E-01c01 $100M Threshold
CTR-035-044b	E-01d01 Cost Estmte by Commenter
CTR-035-044c	J Storm Water Economics
CTR-035-045	E-01a03 Model 1 Weaknesses
CTR-035-046a	E-01g08 Discharger Representation
CTR-035-046b	E-01g09 Affected Facilities
CTR-035-047a	E-01b Cost Triggers
CTR-035-047b	E-01m Regulatory Relief
CTR-035-048	E-01g09 Affected Facilities
CTR-035-049	E-01e Indirect Dischargers
CTR-035-050	E-01p Risk Level Costs
CTR-035-051a	E-02g Benefits & Poll. Reduction
CTR-035-051b	E-02f Use More Recent Data
CTR-035-051c	E-02k Long-Term Contamination
CTR-035-052	E-02l Marginal Impacts/Benefits
CTR-035-053	E-02h Un-Enclose,Enclose Bay Data
CTR-035-054	E-02i Impaired Waters Assumptions
CTR-035-055	E-02d Passive Use Value
CTR-035-056a	E-01c02 Bnfts do not Balance Cost
CTR-035-056b	E-01c01 $100M Threshold
CTR-035-056c	E-01p Risk Level Costs
CTR-035-057	E-01a03 Model 1 Weaknesses
CTR-035-058	E-01a02 Cost Diff. for Eff. Limit
CTR-035-059	E-01g Sample Facilities
CTR-035-060	E-01r Economic Variances
CTR-035-061	E-01d Direct Dischargers
CTR-035-062	E-01q Source Reduction
CTR-035-063	E-01g08 Discharger Representation
CTR-035-064	E-01c02 Bnfts do not Balance Cost
CTR-035-065a	E-02k Long-Term Contamination
CTR-035-065b	E-02c Overstated Benefits
CTR-035-066	E-02g Benefits & Poll. Reduction
CTR-035-067	E-02l Marginal Impacts/Benefits
CTR-035-068	E-02c Overstated Benefits
CTR-035-069	E-02m Few Pollutant Mask Analysis
CTR-035-070	E-02h Un-Enclose,Enclose Bay Data
CTR-035-071	E-02 Benefits Analysis
CTR-035-072	E-02 Benefits Analysis
CTR-036-001	I-01 Application Sec 301 vs. MEP
CTR-036-002a	J Storm Water Economics
CTR-036-002b	E-01c Executive Order 12866
CTR-036-003a	S UMRA
CTR-036-003b	J Storm Water Economics
CTR-036-004a	J Storm Water Economics
CTR-036-004b	R RFA/SBREFA
CTR-036-005	C-21 Legal Concerns
CTR-036-006	C-28 Detection Limits
CTR-036-007a	C-26 Avrging pds&Exceedence Freq.
CTR-036-007b	G-03 Design/Minimum Flows
CTR-036-008	I Stormwater/Wet Weather Flows
CTR-036-009	C-24d SSC Effluent Dependent Wtr
CTR-036-010a	G-02 Compliance Schedules
CTR-036-010b	I Stormwater/Wet Weather Flows
CTR-036-011	K Water Shed Approach
CTR-036-012	D Preamble Editorial Comments
CTR-037-001a	C-24 Site Specific Criteria
CTR-037-001b	G-01 Reasonable Potential
CTR-037-002	C-17b Methodologies Aquatic Life
CTR-037-003a	C-17b Methodologies Aquatic Life
CTR-037-003b	C-17a Methodologies Human Health
CTR-037-004	B Comment Period
CTR-037-005	G-03 Design/Minimum Flows
CTR-037-006	C-28 Detection Limits
CTR-037-007	C-26 Avrging pds&Exceedence Freq.
CTR-037-008	I-03 Applicability of Criteria
CTR-037-009	C-26 Avrging pds&Exceedence Freq.

Comment ID	Subject Matter Code
CTR-037-010	C-10b PCBs Aquatic Life
CTR-038-001	B Comment Period
CTR-038-002a	C-22 Dissolved v. Ttl Recoverable
CTR-038-002b	C-24a SSC Water Effect Ratios
CTR-038-002c	C-01 Mercury
CTR-038-002d	G-04 Interim Limits
CTR-038-002e	G-05 Mixing Zones&Dilution Credit
CTR-038-002f	G-09 Translators
CTR-038-003	E-01d01 Cost Estmte by Commenter
CTR-038-004a	E-01g08 Discharger Representation
CTR-038-004b	E-01h Treatment Assumptions
CTR-038-004c	E-01m Regulatory Relief
CTR-038-004d	E-01c02 Bnfts do not Balance Cost
CTR-038-005a	E-01c Executive Order 12866
CTR-038-005b	R RFA/SBREFA
CTR-038-005c	S UMRA
CTR-038-006a	C-21 Legal Concerns
CTR-038-006b	E-01c Executive Order 12866
CTR-038-006c	R RFA/SBREFA
CTR-038-006d	S UMRA
CTR-038-007	C-24 Site Specific Criteria
CTR-038-008a	C-24 Site Specific Criteria
CTR-038-008b	E-01c Executive Order 12866
CTR-038-008c	R RFA/SBREFA
CTR-038-008d	S UMRA
CTR-038-008e	T State Implementation Policy
CTR-038-009a	C-28 Detection Limits
CTR-038-009b	E-01n Detection Limits
CTR-038-009c	R RFA/SBREFA
CTR-038-009d	S UMRA
CTR-038-010	C-30 Narrative Criteria
CTR-038-011	C-15 Salinity
CTR-038-012	G-02 Compliance Schedules
CTR-038-013	M Re-Open Comment Period
CTR-039-001	C-24 Site Specific Criteria
CTR-039-002	A Anti-degradation
CTR-039-003a	C-22 Dissolved v. Ttl Recoverable
CTR-039-003b	A Anti-degradation
CTR-039-004	C-14 Fish or Water Consumption
CTR-039-005	C-01 Mercury
CTR-039-006	C-09a Dioxin Human Health
CTR-039-007	G-02 Compliance Schedules
CTR-039-008	G-04 Interim Limits
CTR-039-009	C-24 Site Specific Criteria
CTR-040-001	O Offer of Assistance/Review
CTR-040-002a	C-24a SSC Water Effect Ratios
CTR-040-002b	C-01 Mercury
CTR-040-002c	G-09 Translators
CTR-040-002d	G-05 Mixing Zones&Dilution Credit
CTR-040-003	I-01 Application Sec 301 vs. MEP
CTR-040-004	J Storm Water Economics
CTR-040-005	I-07 Attainability of Criteria
CTR-040-006	J Storm Water Economics
CTR-040-007	J Storm Water Economics
CTR-040-008a	E-01c02 Bnfts do not Balance Cost
CTR-040-008b	E-01m Regulatory Relief
CTR-040-008c	E-02c Overstated Benefits
CTR-040-009a	R RFA/SBREFA
CTR-040-009b	S UMRA
CTR-040-009c	E-01c Executive Order 12866
CTR-040-010a	J Storm Water Economics
CTR-040-010b	R RFA/SBREFA
CTR-040-011	C-21 Legal Concerns
CTR-040-012a	E-01c Executive Order 12866
CTR-040-012b	S UMRA
CTR-040-013	R RFA/SBREFA
CTR-040-014a	I-02 Elliott Memorandum
CTR-040-014b	J Storm Water Economics
CTR-040-015a	S UMRA
CTR-040-015b	C-13 Risk Level
CTR-040-016a	C-24d SSC Effluent Dependent Wtr
CTR-040-016b	C-21 Legal Concerns
CTR-040-017	C-28 Detection Limits
CTR-040-018a	C-26 Avrging pds&Exceedence Freq.
CTR-040-018b	G-03 Design/Minimum Flows
CTR-040-018c	C-30 Narrative Criteria
CTR-040-018d	C-24e SSC Desgntd/Beneficial Uses
CTR-040-019	G-02 Compliance Schedules
CTR-040-020	E-01 Cost Analysis
CTR-040-021	O Offer of Assistance/Review
CTR-040-022	E-01 Cost Analysis
CTR-040-023	E-01 Cost Analysis
CTR-040-024	E-01g08 Discharger Representation
CTR-040-025	J-05 BMPs Inability to Comply
CTR-040-026	E-01a03 Model 1 Weaknesses
CTR-040-027	E-01g05 Effluent Data
CTR-040-028	E-01n01 Non-Detects, No Cost
CTR-040-029a	E-01q01 25% Assumption
CTR-040-029b	E-01h01 25% Reduction Assumption
CTR-040-030	E-01q Source Reduction
CTR-040-031	E-01m Regulatory Relief
CTR-040-032	E-01h Treatment Assumptions
CTR-040-033	E-01b Cost Triggers
CTR-040-034	J-01 MS4s/CSOs/Industries Costs
CTR-040-035	E-01a Baselines
CTR-040-036	E-01m Regulatory Relief

Comment ID	Subject Matter Code
CTR-040-037	E-01e02 No Costs for Non-SIUs
CTR-040-038	E-01h Treatment Assumptions
CTR-040-039	E-01g03 Cost Effectiveness Ratio
CTR-040-040	E-01b Cost Triggers
CTR-040-041	E-01m Regulatory Relief
CTR-040-042	E-01c02 Bnfts do not Balance Cost
CTR-040-043	E-02c Overstated Benefits
CTR-040-044	E-02g Benefits & Poll. Reduction
CTR-040-045	E-02o Analysis from Wisconsin
CTR-040-046	E-02i Impaired Waters Assumptions
CTR-040-047	E-02d Passive Use Value
CTR-040-048	K-01 TMDLs
CTR-040-049	G-07 Variances
CTR-040-050	C-24 Site Specific Criteria
CTR-040-051	G-05 Mixing Zones&Dilution Credit
CTR-040-052	E-02 Benefits Analysis
CTR-040-055	S UMRA
CTR-040-056	R RFA/SBREFA
CTR-040-056	R RFA/SBREFA
CTR-041-001	B Comment Period
CTR-041-002	C-22 Dissolved v. Ttl Recoverable
CTR-041-003a	G-09 Translators
CTR-041-003b	C-24a SSC Water Effect Ratios
CTR-041-004	C-01 Mercury
CTR-041-005	C-08a Arsenic Human Health
CTR-041-006a	G-04 Interim Limits
CTR-041-006b	G-05 Mixing Zones&Dilution Credit
CTR-041-007a	C-01 Mercury
CTR-041-007b	C-22 Dissolved v. Ttl Recoverable
CTR-041-008a	C-28 Detection Limits
CTR-041-008b	E-01n Detection Limits
CTR-041-009	E-01d01 Cost Estmte by Commenter
CTR-041-010a	E-01n Detection Limits
CTR-041-010b	E-01m Regulatory Relief
CTR-041-010c	E-01e Indirect Dischargers
CTR-041-010d	E-01g Sample Facilities
CTR-041-011	C-30 Narrative Criteria
CTR-041-012	G-02 Compliance Schedules
CTR-041-013a	E-01c Executive Order 12866
CTR-041-013b	R RFA/SBREFA
CTR-041-013c	S UMRA
CTR-041-014	C-21 Legal Concerns
CTR-041-015	E-01c Executive Order 12866
CTR-041-016	S UMRA
CTR-041-017	R RFA/SBREFA
CTR-041-018	E-01 Cost Analysis
CTR-041-019	E-01 Cost Analysis
CTR-041-020	E-01g08 Discharger Representation
CTR-041-021	J-05 BMPs Inability to Comply
CTR-041-022	E-01a03 Model 1 Weaknesses
CTR-041-023	E-01g05 Effluent Data
CTR-041-024	E-01n01 Non-Detects, No Cost
CTR-041-025a	E-01q01 25% Assumption
CTR-041-025b	E-01h01 25% Reduction Assumption
CTR-041-026	E-01q Source Reduction
CTR-041-027	E-01m Regulatory Relief
CTR-041-028	E-01h Treatment Assumptions
CTR-041-029	E-01b Cost Triggers
CTR-041-030	J-01 MS4s/CSOs/Industries Costs
CTR-041-031	E-01a Baselines
CTR-041-032	E-01m Regulatory Relief
CTR-041-033	E-01e02 No Costs for Non-SIUs
CTR-041-034	E-01h Treatment Assumptions
CTR-041-035	E-01g03 Cost Effectiveness Ratio
CTR-041-036	E-01b Cost Triggers
CTR-041-037	E-01m Regulatory Relief
CTR-041-038	E-01c02 Bnfts do not Balance Cost
CTR-041-039	E-02c Overstated Benefits
CTR-041-040	E-02g Benefits & Poll. Reduction
CTR-041-041	E-02o Analysis from Wisconsin
CTR-041-042	E-02i Impaired Waters Assumptions
CTR-041-043	E-02d Passive Use Value
CTR-041-044	K-01 TMDLs
CTR-041-045	G-07 Variances
CTR-041-046	C-24 Site Specific Criteria
CTR-041-047	G-05 Mixing Zones&Dilution Credit
CTR-041-048	E-02 Benefits Analysis
CTR-042-001	I-01 Application Sec 301 vs. MEP
CTR-042-002	J-04 End-of-Pipe Treatment v. BMP
CTR-042-003	C-28 Detection Limits
CTR-042-004	I Stormwater/Wet Weather Flows
CTR-042-005	C-24d SSC Effluent Dependent Wtr
CTR-042-006	C-22 Dissolved v. Ttl Recoverable
CTR-042-007a	C-21 Legal Concerns
CTR-042-007b	E-01c Executive Order 12866
CTR-042-007c	S UMRA
CTR-043-001	B Comment Period
CTR-043-002a	C-22 Dissolved v. Ttl Recoverable
CTR-043-002b	C-24a SSC Water Effect Ratios
CTR-043-002c	C-01 Mercury
CTR-043-002d	G-04 Interim Limits
CTR-043-002e	G-05 Mixing Zones&Dilution Credit
CTR-043-002f	G-09 Translators
CTR-043-003	E-01e02 No Costs for Non-SIUs
CTR-043-004a	E-01g Sample Facilities
CTR-043-004b	E-01h Treatment Assumptions

Comment ID	Subject Matter Code
CTR-043-004c	E-01m Regulatory Relief
CTR-043-004d	E-02c Overstated Benefits
CTR-043-004e	E-01c02 Bnfts do not Balance Cost
CTR-043-005a	C-21 Legal Concerns
CTR-043-005b	E-01c Executive Order 12866
CTR-043-005c	R RFA/SBREFA
CTR-043-005d	S UMRA
CTR-043-006a	C-24 Site Specific Criteria
CTR-043-006b	C-13 Risk Level
CTR-043-007	C-24d SSC Effluent Dependent Wtr
CTR-043-008	C-28 Detection Limits
CTR-043-009	C-30 Narrative Criteria
CTR-043-010	G-02 Compliance Schedules
CTR-043-011	M Re-Open Comment Period
CTR-044-001	B Comment Period
CTR-044-002	B Comment Period
CTR-044-003a	C-22 Dissolved v. Ttl Recoverable
CTR-044-003b	C-24a SSC Water Effect Ratios
CTR-044-003c	C-01 Mercury
CTR-044-003d	G-09 Translators
CTR-044-003e	G-05 Mixing Zones&Dilution Credit
CTR-044-003f	G-04 Interim Limits
CTR-044-004	E-01d01 Cost Estmte by Commenter
CTR-044-005a	E-01g08 Discharger Representation
CTR-044-005b	E-01h01 25% Reduction Assumption
CTR-044-005c	E-01m Regulatory Relief
CTR-044-005d	E-02c Overstated Benefits
CTR-044-005e	E-01c02 Bnfts do not Balance Cost
CTR-044-005f	R RFA/SBREFA
CTR-044-005g	S UMRA
CTR-044-006a	C-21 Legal Concerns
CTR-044-006b	E-01c Executive Order 12866
CTR-044-006c	R RFA/SBREFA
CTR-044-006d	S UMRA
CTR-044-007a	C-13 Risk Level
CTR-044-007b	C-24 Site Specific Criteria
CTR-044-008	C-24d SSC Effluent Dependent Wtr
CTR-044-009a	C-28 Detection Limits
CTR-044-009b	E-01c Executive Order 12866
CTR-044-009c	R RFA/SBREFA
CTR-044-009d	S UMRA
CTR-044-010	C-30 Narrative Criteria
CTR-044-011	G-02 Compliance Schedules
CTR-044-012	M Re-Open Comment Period
CTR-044-013	E-01 Cost Analysis
CTR-044-014	E-01 Cost Analysis
CTR-044-015	E-01g08 Discharger Representation
CTR-044-016	J-05 BMPs Inability to Comply
CTR-044-017	E-01a03 Model 1 Weaknesses
CTR-044-018	E-01g05 Effluent Data
CTR-044-019	E-01n01 Non-Detects, No Cost
CTR-044-020a	E-01q01 25% Assumption
CTR-044-020b	E-01h01 25% Reduction Assumption
CTR-044-021	E-01q Source Reduction
CTR-044-022	E-01m Regulatory Relief
CTR-044-023	E-01h Treatment Assumptions
CTR-044-024	E-01b Cost Triggers
CTR-044-025	J-01 MS4s/CSOs/Industries Costs
CTR-044-026	E-01a Baselines
CTR-044-027	E-01m Regulatory Relief
CTR-044-028	E-01e02 No Costs for Non-SIUs
CTR-044-029	E-01h Treatment Assumptions
CTR-044-030	E-01g03 Cost Effectiveness Ratio
CTR-044-031	E-01b Cost Triggers
CTR-044-032	E-01m Regulatory Relief
CTR-044-033	E-01c02 Bnfts do not Balance Cost
CTR-044-034	E-02c Overstated Benefits
CTR-044-035	E-02g Benefits & Poll. Reduction
CTR-044-036	E-02o Analysis from Wisconsin
CTR-044-037	E-02i Impaired Waters Assumptions
CTR-044-038	E-02d Passive Use Value
CTR-044-039	K-01 TMDLs
CTR-044-040	G-07 Variances
CTR-044-041	C-24 Site Specific Criteria
CTR-044-042	G-05 Mixing Zones&Dilution Credit
CTR-044-043	E-02 Benefits Analysis
CTR-044-044	C-21 Legal Concerns
CTR-044-045	E-01c Executive Order 12866
CTR-044-046	S UMRA
CTR-044-047	R RFA/SBREFA
CTR-045-001	B Comment Period
CTR-045-002	G-04 Interim Limits
CTR-045-003	G-02 Compliance Schedules
CTR-045-004	C-22 Dissolved v. Ttl Recoverable
CTR-045-005	C-24a SSC Water Effect Ratios
CTR-045-006	C-01 Mercury
CTR-045-007	C-08a Arsenic Human Health
CTR-045-008	G-05 Mixing Zones&Dilution Credit
CTR-045-009a	E-01g08 Discharger Representation
CTR-045-009b	E-01h Treatment Assumptions
CTR-045-009c	E-01m Regulatory Relief
CTR-045-010	E-02f Use More Recent Data
CTR-045-011	E-01n Detection Limits
CTR-045-012a	E-01d Direct Dischargers
CTR-045-012b	E-01c Executive Order 12866
CTR-045-013	E-01c01 $100M Threshold

Comment ID	Subject Matter Code
CTR-045-014	E-01u Economic Consid. Task Force
CTR-047-001	E-01 Cost Analysis
CTR-047-002	J-04 End-of-Pipe Treatment v. BMP
CTR-047-003	J Storm Water Economics
CTR-047-004a	J Storm Water Economics
CTR-047-004b	R RFA/SBREFA
CTR-049-001	B Comment Period
CTR-049-002	C-24a SSC Water Effect Ratios
CTR-049-003	C-13 Risk Level
CTR-049-004	C-24d SSC Effluent Dependent Wtr
CTR-049-005	C-24e SSC Desgntd/Beneficial Uses
CTR-049-006a	E-01g08 Discharger Representation
CTR-049-006b	E-01h Treatment Assumptions
CTR-049-006c	E-01m Regulatory Relief
CTR-049-007	E-01u Economic Consid. Task Force
CTR-050-001	C-21 Legal Concerns
CTR-050-002	C-21 Legal Concerns
CTR-050-003	C-21 Legal Concerns
CTR-050-004	C-21 Legal Concerns
CTR-050-005a	C-24 Site Specific Criteria
CTR-050-005b	G-07 Variances
CTR-050-006	C-13 Risk Level
CTR-050-007a	C-21 Legal Concerns
CTR-050-007b	E-01c Executive Order 12866
CTR-050-007c	R RFA/SBREFA
CTR-050-007d	S UMRA
CTR-051-001	C-24 Site Specific Criteria
CTR-051-002	C-04b Selenium Aquatic Life
CTR-051-003a	C-01 Mercury
CTR-051-003b	C-01 Mercury
CTR-052-001	B Comment Period
CTR-052-002a	C-22 Dissolved v. Ttl Recoverable
CTR-052-002b	C-01 Mercury
CTR-052-002c	G-09 Translators
CTR-052-002d	G-05 Mixing Zones&Dilution Credit
CTR-052-002e	G-04 Interim Limits
CTR-052-003a	C-13 Risk Level
CTR-052-003b	E-01 Cost Analysis
CTR-052-003c	E-02 Benefits Analysis
CTR-052-004	D Preamble Editorial Comments
CTR-052-005a	E-01i Alternative Cost Analysis
CTR-052-005b	E-01d01 Cost Estmte by Commenter
CTR-052-006	E-01d Direct Dischargers
CTR-052-007	E-02 Benefits Analysis
CTR-052-008	C-24 Site Specific Criteria
CTR-052-009	E-01i Alternative Cost Analysis
CTR-052-010	E-01d01 Cost Estmte by Commenter
CTR-052-011	E-01d Direct Dischargers
CTR-052-012	E-01g10 Toxic Pound Equivalents
CTR-052-013	B Comment Period
CTR-052-014	E-01g02 Another EA for Sample Fac
CTR-052-015	T State Implementation Policy
CTR-052-016	E-01p Risk Level Costs
CTR-052-017	C-24 Site Specific Criteria
CTR-052-018	C-28 Detection Limits
CTR-052-019	G-05 Mixing Zones&Dilution Credit
CTR-052-020	G-02 Compliance Schedules
CTR-052-021a	C-21 Legal Concerns
CTR-052-021b	E-01c Executive Order 12866
CTR-052-021c	R RFA/SBREFA
CTR-052-021d	S UMRA
CTR-052-022	M Re-Open Comment Period
CTR-053-001	M Re-Open Comment Period
CTR-053-002	C-30 Narrative Criteria
CTR-053-003a	C-01 Mercury
CTR-053-003b	C-02b Copper Aquatic Life
CTR-053-003c	C-09a Dioxin Human Health
CTR-053-004	G-02 Compliance Schedules
CTR-053-005	T State Implementation Policy
CTR-053-006	C-24 Site Specific Criteria
CTR-054-001	B Comment Period
CTR-054-002a	C-22 Dissolved v. Ttl Recoverable
CTR-054-002b	C-24a SSC Water Effect Ratios
CTR-054-003	C-01 Mercury
CTR-054-004a	G-09 Translators
CTR-054-004b	G-05 Mixing Zones&Dilution Credit
CTR-054-004c	G-04 Interim Limits
CTR-054-005	E-01d01 Cost Estmte by Commenter
CTR-054-006	E-02l Marginal Impacts/Benefits
CTR-054-007	C-13 Risk Level
CTR-054-008a	C-02b Copper Aquatic Life
CTR-054-008b	C-24 Site Specific Criteria
CTR-054-008c	E-01c Executive Order 12866
CTR-054-008d	R RFA/SBREFA
CTR-054-008e	S UMRA
CTR-054-009	C-28 Detection Limits
CTR-054-010	C-30 Narrative Criteria
CTR-054-011	C-15 Salinity
CTR-054-012	G-02 Compliance Schedules
CTR-054-013a	E-01g03 Cost Effectiveness Ratio
CTR-054-013b	E-01q01 25% Assumption
CTR-054-013c	E-01m Regulatory Relief
CTR-054-013d	E-02l Marginal Impacts/Benefits
CTR-054-014	C-21 Legal Concerns
CTR-054-015	V Collaborative Approach
CTR-054-016	M Re-Open Comment Period

Comment ID	Subject Matter Code
CTR-054-017	E-01 Cost Analysis
CTR-054-018	E-01 Cost Analysis
CTR-054-019	E-01g08 Discharger Representation
CTR-054-020	J-05 BMPs Inability to Comply
CTR-054-021	E-01a03 Model 1 Weaknesses
CTR-054-022	E-01g05 Effluent Data
CTR-054-023	E-01n01 Non-Detects, No Cost
CTR-054-024a	E-01q01 25% Assumption
CTR-054-024b	E-01h01 25% Reduction Assumption
CTR-054-025	E-01q Source Reduction
CTR-054-026	E-01m Regulatory Relief
CTR-054-027	E-01h Treatment Assumptions
CTR-054-028	E-01b Cost Triggers
CTR-054-029	J-01 MS4s/CSOs/Industries Costs
CTR-054-030	E-01a Baselines
CTR-054-031	E-01m Regulatory Relief
CTR-054-032	E-01e02 No Costs for Non-SIUs
CTR-054-033	E-01h Treatment Assumptions
CTR-054-034	E-01g03 Cost Effectiveness Ratio
CTR-054-035	E-01b Cost Triggers
CTR-054-036	E-01m Regulatory Relief
CTR-054-037	E-01c02 Bnfts do not Balance Cost
CTR-054-038	E-02c Overstated Benefits
CTR-054-039	E-02g Benefits & Poll. Reduction
CTR-054-040	E-02o Analysis from Wisconsin
CTR-054-041	E-02i Impaired Waters Assumptions
CTR-054-042	E-02d Passive Use Value
CTR-054-043	K-01 TMDLs
CTR-054-044	G-07 Variances
CTR-054-045	C-24 Site Specific Criteria
CTR-054-046	G-05 Mixing Zones&Dilution Credit
CTR-054-047	E-02 Benefits Analysis
CTR-054-048	C-21 Legal Concerns
CTR-054-049	E-01c Executive Order 12866
CTR-054-050	S UMRA
CTR-054-051	R RFA/SBREFA
CTR-055-001	C-13 Risk Level
CTR-055-002a	C-21 Legal Concerns
CTR-055-002b	T State Implementation Policy
CTR-055-003	E-01c Executive Order 12866
CTR-056-001	B Comment Period
CTR-056-002	G-04 Interim Limits
CTR-056-003	C-01 Mercury
CTR-056-004	C-08a Arsenic Human Health
CTR-056-005	C-22 Dissolved v. Ttl Recoverable
CTR-056-006	C-24a SSC Water Effect Ratios
CTR-056-007	G-05 Mixing Zones&Dilution Credit
CTR-056-008	G-09 Translators
CTR-056-009	C-24a SSC Water Effect Ratios
CTR-056-010	G-02 Compliance Schedules
CTR-056-011	C-24d SSC Effluent Dependent Wtr
CTR-056-012	C-13 Risk Level
CTR-056-013	C-24e SSC Desgntd/Beneficial Uses
CTR-056-014	C-28 Detection Limits
CTR-056-015a	I-01 Application Sec 301 vs. MEP
CTR-056-015b	C-24 Site Specific Criteria
CTR-056-016	E-01g03 Cost Effectiveness Ratio
CTR-056-017	E-01g03 Cost Effectiveness Ratio
CTR-056-018	E-01b Cost Triggers
CTR-056-019	E-01b Cost Triggers
CTR-056-020	E-01d01 Cost Estmte by Commenter
CTR-056-021	E-02f Use More Recent Data
CTR-056-022a	E-01e Indirect Dischargers
CTR-056-022b	S UMRA
CTR-056-023	E-01u Economic Consid. Task Force
CTR-057-001	E-01g02 Another EA for Sample Fac
CTR-057-002	B Comment Period
CTR-057-003	C-24d SSC Effluent Dependent Wtr
CTR-057-004	C-28 Detection Limits
CTR-057-005	C-13 Risk Level
CTR-057-006	C-22 Dissolved v. Ttl Recoverable
CTR-057-007	C-17a Methodologies Human Health
CTR-057-008	P Whole Effluent Toxicity
CTR-057-009	T State Implementation Policy
CTR-057-010a	K-01 TMDLs
CTR-057-010b	G-07 Variances
CTR-057-010c	C-24 Site Specific Criteria
CTR-057-011	C-24 Site Specific Criteria
CTR-058-001	C-13 Risk Level
CTR-058-002	B Comment Period
CTR-058-003	C-22 Dissolved v. Ttl Recoverable
CTR-058-004	C-15 Salinity
CTR-058-005	C-04b Selenium Aquatic Life
CTR-058-006	C-04b Selenium Aquatic Life
CTR-058-007	G-02 Compliance Schedules
CTR-058-008	G-05 Mixing Zones&Dilution Credit
CTR-058-009	C-20 Scope Prty Toxic Poll. List
CTR-058-010	C-01 Mercury
CTR-058-011	K-01 TMDLs
CTR-058-012	C-09a Dioxin Human Health
CTR-058-013	C-07b Cyanide Aquatic Life
CTR-059-001	E-01d01 Cost Estmte by Commenter
CTR-059-002a	E-01c Executive Order 12866
CTR-059-002b	R RFA/SBREFA
CTR-059-002c	S UMRA
CTR-059-003	B Comment Period

Comment ID	Subject Matter Code
CTR-059-004a	E-01c Executive Order 12866
CTR-059-004b	M Re-Open Comment Period
CTR-059-005	M Re-Open Comment Period
CTR-059-006a	C-28 Detection Limits
CTR-059-006b	E-01c Executive Order 12866
CTR-059-006c	S UMRA
CTR-059-007	C-08a Arsenic Human Health
CTR-059-008	C-12a THMs Human Health
CTR-059-009	C-01 Mercury
CTR-059-010	C-24d SSC Effluent Dependent Wtr
CTR-059-011	C-15 Salinity
CTR-059-012	G-04 Interim Limits
CTR-059-013	G-02 Compliance Schedules
CTR-059-014	K Water Shed Approach
CTR-059-015a	E-01c Executive Order 12866
CTR-059-015b	S UMRA
CTR-059-016	R RFA/SBREFA
CTR-059-017	F Endangered Species Act
CTR-059-018	E-01g08 Discharger Representation
CTR-059-019	E-01b Cost Triggers
CTR-059-020	E-01e01 Sunnyvale/San Jose
CTR-059-021	E-01v Discharge Over Time
CTR-059-022	E-01w Cost per Facility
CTR-059-023a	E-01g08 Discharger Representation
CTR-059-023b	J Storm Water Economics
CTR-059-024	E-01l UMRA - Economic Comments
CTR-059-025	E-02m Few Pollutant Mask Analysis
CTR-059-026	E-01 Cost Analysis
CTR-059-027	E-01i Alternative Cost Analysis
CTR-060-001	G-04 Interim Limits
CTR-060-002	G-05 Mixing Zones&Dilution Credit
CTR-060-003	L Anti-Backsliding
CTR-060-004	C-08a Arsenic Human Health
CTR-060-005	G-02 Compliance Schedules
CTR-060-006	C-24 Site Specific Criteria
CTR-060-007	C-04b Selenium Aquatic Life
CTR-060-008	C-01 Mercury
CTR-060-009	G-09 Translators
CTR-060-010	C-28 Detection Limits
CTR-060-011	I-01 Application Sec 301 vs. MEP
CTR-060-012	C-26 Avrging pds&Exceedence Freq.
CTR-060-013	C-02b Copper Aquatic Life
CTR-060-014	C-11b PAHs Aquatic Life
CTR-060-015	C-14 Fish or Water Consumption
CTR-060-016	C-13 Risk Level
CTR-060-017	E-01g08 Discharger Representation
CTR-060-018	E-01a02 Cost Diff. for Eff. Limit
CTR-060-019	E-01m03 Cost of WERs
CTR-061-001	I-09 Pesticides in Runoff
CTR-061-002	J Storm Water Economics
CTR-061-003	J Storm Water Economics
CTR-061-004	B Comment Period
CTR-061-005a	I-03 Applicability of Criteria
CTR-061-005b	C-17 Methodologies
CTR-061-006	C-20 Scope Prty Toxic Poll. List
CTR-061-007	C-30 Narrative Criteria
CTR-061-008	C-17 Methodologies
CTR-061-009	C-17 Methodologies
CTR-061-010	C-17 Methodologies
CTR-061-011	C-17 Methodologies
CTR-061-012	C-01 Mercury
CTR-061-013	C-06b Chromium Aquatic Life
CTR-061-014	C-24a SSC Water Effect Ratios
CTR-061-015	D Preamble Editorial Comments
CTR-061-016	K-03 Watershed/Effluent Trading
CTR-061-017	J Storm Water Economics
CTR-061-018	E-02c Overstated Benefits
CTR-061-019	J Storm Water Economics
CTR-061-020	G-06 NWQI
CTR-062-001	I-01 Application Sec 301 vs. MEP
CTR-062-002	J-01 MS4s/CSOs/Industries Costs
CTR-062-003	J Storm Water Economics
CTR-062-004a	J Storm Water Economics
CTR-062-004b	R RFA/SBREFA
CTR-063-001	C-03b Nickel Aquatic Life
CTR-064-001	C-02b Copper Aquatic Life
CTR-065-001	B Comment Period
CTR-065-002a	A Anti-degradation
CTR-065-002b	C-17a Methodologies Human Health
CTR-065-002c	C-17b Methodologies Aquatic Life
CTR-065-003a	C-14 Fish or Water Consumption
CTR-065-003b	C-21 Legal Concerns
CTR-065-004	C-17b Methodologies Aquatic Life
CTR-065-005	C-22 Dissolved v. Ttl Recoverable
CTR-065-006a	P Whole Effluent Toxicity
CTR-065-006b	C-20 Scope Prty Toxic Poll. List
CTR-065-007	C-02b Copper Aquatic Life
CTR-066-001	B Comment Period
CTR-066-002	G-04 Interim Limits
CTR-066-003	C-24a SSC Water Effect Ratios
CTR-066-004	G-02 Compliance Schedules
CTR-066-005	C-22 Dissolved v. Ttl Recoverable
CTR-066-006	G-09 Translators
CTR-066-007	C-24a SSC Water Effect Ratios
CTR-066-008	C-01 Mercury
CTR-066-009	C-08a Arsenic Human Health

Comment ID	Subject Matter Code
CTR-066-010	G-05 Mixing Zones&Dilution Credit
CTR-066-011	C-13 Risk Level
CTR-066-012	C-24e SSC Desgntd/Beneficial Uses
CTR-066-013a	E-01g08 Discharger Representation
CTR-066-013b	E-01b01 RegRelief Above Threshold
CTR-066-014	E-02f Use More Recent Data
CTR-066-015a	E-01n Detection Limits
CTR-066-015b	C-28 Detection Limits
CTR-066-016	E-01d Direct Dischargers
CTR-066-017	E-01c01 $100M Threshold
CTR-066-018	E-01u Economic Consid. Task Force
CTR-066-019	C-22 Dissolved v. Ttl Recoverable
CTR-067-001	B Comment Period
CTR-067-002	C-22 Dissolved v. Ttl Recoverable
CTR-067-003	C-28 Detection Limits
CTR-067-004a	E-01n Detection Limits
CTR-067-004b	K Water Shed Approach
CTR-067-005	G-02 Compliance Schedules
CTR-067-006a	R RFA/SBREFA
CTR-067-006b	E-01d01 Cost Estmte by Commenter
CTR-067-007	M Re-Open Comment Period
CTR-068-001	B Comment Period
CTR-069-001	B Comment Period
CTR-069-002a	J-01 MS4s/CSOs/Industries Costs
CTR-069-002b	E-01j
CTR-070-001	B Comment Period
CTR-070-002a	E-01w Cost per Facility
CTR-070-002b	E-01d01 Cost Estmte by Commenter
CTR-070-003	E-01n Detection Limits
CTR-071-001	I-01 Application Sec 301 vs. MEP
CTR-071-002	J-01 MS4s/CSOs/Industries Costs
CTR-071-003	J Storm Water Economics
CTR-071-004a	J Storm Water Economics
CTR-071-004b	R RFA/SBREFA
CTR-072-001	I-01 Application Sec 301 vs. MEP
CTR-072-002	J-01 MS4s/CSOs/Industries Costs
CTR-072-003	J Storm Water Economics
CTR-072-004a	J Storm Water Economics
CTR-072-004b	R RFA/SBREFA
CTR-073-001	I-01 Application Sec 301 vs. MEP
CTR-073-002	J-01 MS4s/CSOs/Industries Costs
CTR-073-003	J Storm Water Economics
CTR-073-004a	J Storm Water Economics
CTR-073-004b	R RFA/SBREFA
CTR-074-001	I-01 Application Sec 301 vs. MEP
CTR-074-002	J-01 MS4s/CSOs/Industries Costs
CTR-074-003	J Storm Water Economics
CTR-074-004a	J Storm Water Economics
CTR-074-004b	R RFA/SBREFA
CTR-075-001	I-01 Application Sec 301 vs. MEP
CTR-075-002	J-01 MS4s/CSOs/Industries Costs
CTR-075-003	J Storm Water Economics
CTR-075-004a	J Storm Water Economics
CTR-075-004b	R RFA/SBREFA
CTR-076-001	I-01 Application Sec 301 vs. MEP
CTR-076-002	J-01 MS4s/CSOs/Industries Costs
CTR-076-003	J Storm Water Economics
CTR-076-004a	J Storm Water Economics
CTR-076-004b	R RFA/SBREFA
CTR-077-001	C-23 Sediments/Dredged Materials
CTR-077-002	G-05 Mixing Zones&Dilution Credit
CTR-077-003	C-22 Dissolved v. Ttl Recoverable
CTR-078-001	I-01 Application Sec 301 vs. MEP
CTR-078-002	J-01 MS4s/CSOs/Industries Costs
CTR-078-003	J Storm Water Economics
CTR-078-004a	J Storm Water Economics
CTR-078-004b	R RFA/SBREFA
CTR-079-001	I-01 Application Sec 301 vs. MEP
CTR-079-002	J-01 MS4s/CSOs/Industries Costs
CTR-079-003	J Storm Water Economics
CTR-079-004a	J Storm Water Economics
CTR-079-004b	R RFA/SBREFA
CTR-080-001	J Storm Water Economics
CTR-080-002	J-04 End-of-Pipe Treatment v. BMP
CTR-081-001	B Comment Period
CTR-081-002a	G-04 Interim Limits
CTR-081-002b	C-24a SSC Water Effect Ratios
CTR-081-002c	G-02 Compliance Schedules
CTR-081-002d	C-22 Dissolved v. Ttl Recoverable
CTR-081-002e	G-09 Translators
CTR-081-002f	C-01 Mercury
CTR-081-002g	C-08a Arsenic Human Health
CTR-081-002h	G-05 Mixing Zones&Dilution Credit
CTR-081-003	C-13 Risk Level
CTR-081-004a	C-24d SSC Effluent Dependent Wtr
CTR-081-004b	C-24e SSC Desgntd/Beneficial Uses
CTR-081-005a	E-01w Cost per Facility
CTR-081-005b	E-01d Direct Dischargers
CTR-082-001	B Comment Period
CTR-082-002	G-02 Compliance Schedules
CTR-082-003	C-22 Dissolved v. Ttl Recoverable
CTR-082-004	C-13 Risk Level
CTR-082-005	C-24b SSC Recalculation Procedure
CTR-082-006	C-24e SSC Desgntd/Beneficial Uses
CTR-082-007a	E-01g08 Discharger Representation
CTR-082-007b	E-01b Cost Triggers

Comment ID	Subject Matter Code
CTR-082-008	E-02f Use More Recent Data
CTR-082-009a	E-01n Detection Limits
CTR-082-009b	C-28 Detection Limits
CTR-082-010	E-01d Direct Dischargers
CTR-082-011	E-01c01 $100M Threshold
CTR-082-012	E-01u Economic Consid. Task Force
CTR-083-001	B Comment Period
CTR-083-002	K Water Shed Approach
CTR-084-001	G-11 Intake Credits
CTR-084-002a	E-01c01 $100M Threshold
CTR-084-002b	S UMRA
CTR-085-001	B Comment Period
CTR-085-002	B Comment Period
CTR-085-003	G-04 Interim Limits
CTR-085-004	C-24a SSC Water Effect Ratios
CTR-085-005	G-02 Compliance Schedules
CTR-085-006	C-22 Dissolved v. Ttl Recoverable
CTR-085-007	G-09 Translators
CTR-085-008	C-24a SSC Water Effect Ratios
CTR-085-009	C-01 Mercury
CTR-085-010	C-08a Arsenic Human Health
CTR-085-011	G-05 Mixing Zones&Dilution Credit
CTR-085-012	G-04 Interim Limits
CTR-085-013	C-13 Risk Level
CTR-085-014	C-24d SSC Effluent Dependent Wtr
CTR-085-015	C-24e SSC Desgntd/Beneficial Uses
CTR-085-016a	E-01g08 Discharger Representation
CTR-085-016b	E-01b01 RegRelief Above Threshold
CTR-085-017	E-02f Use More Recent Data
CTR-085-018a	E-01n Detection Limits
CTR-085-018b	C-28 Detection Limits
CTR-085-019	E-01d Direct Dischargers
CTR-086-001a	Q Nonpoint Sources
CTR-086-001b	K-01 TMDLs
CTR-086-002	C-01 Mercury
CTR-086-003	E-01h Treatment Assumptions
CTR-086-004a	G-01 Reasonable Potential
CTR-086-004b	C-22 Dissolved v. Ttl Recoverable
CTR-086-004c	G-09 Translators
CTR-086-004d	C-24a SSC Water Effect Ratios
CTR-086-004e	C-24 Site Specific Criteria
CTR-086-004f	K-03 Watershed/Effluent Trading
CTR-086-004g	G-04 Interim Limits
CTR-086-004h	G-05 Mixing Zones&Dilution Credit
CTR-086-004i	G-02 Compliance Schedules
CTR-086-005	T State Implementation Policy
CTR-086-006	E-01m Regulatory Relief
CTR-086-007	T State Implementation Policy
CTR-087-001	I-01 Application Sec 301 vs. MEP
CTR-087-002	I-02a Applying WQBELs, Stormwater
CTR-087-003	J-01 MS4s/CSOs/Industries Costs
CTR-089-001a	C-22 Dissolved v. Ttl Recoverable
CTR-089-001b	C-01 Mercury
CTR-089-001c	C-08a Arsenic Human Health
CTR-089-001d	G-05 Mixing Zones&Dilution Credit
CTR-089-001e	K-01 TMDLs
CTR-089-001f	G-02 Compliance Schedules
CTR-089-001g	G-09 Translators
CTR-089-002	B Comment Period
CTR-089-003	C-28 Detection Limits
CTR-089-004	C-12a THMs Human Health
CTR-089-005	E-01d Direct Dischargers
CTR-089-006	C-24d SSC Effluent Dependent Wtr
CTR-090-001	B Comment Period
CTR-090-002a	C-17a Methodologies Human Health
CTR-090-002b	C-24a SSC Water Effect Ratios
CTR-090-002c	C-22 Dissolved v. Ttl Recoverable
CTR-090-002d	G-05 Mixing Zones&Dilution Credit
CTR-090-002e	G-02 Compliance Schedules
CTR-090-002f	G-04 Interim Limits
CTR-090-003	E-01m02 Success in Reg. Relief
CTR-090-004	E-02o01 No Peer Review Reference
CTR-090-005	C-20 Scope Prty Toxic Poll. List
CTR-090-006	C-28 Detection Limits
CTR-090-007	Q Nonpoint Sources
CTR-090-008	E-02 Benefits Analysis
CTR-090-009	T State Implementation Policy
CTR-090-010a	G-01 Reasonable Potential
CTR-090-010b	K-01 TMDLs
CTR-090-011	C-28 Detection Limits
CTR-090-012a	E-01c Executive Order 12866
CTR-090-012b	S UMRA
CTR-090-013	C-13 Risk Level
CTR-090-014	I-01 Application Sec 301 vs. MEP
CTR-090-015	Q Nonpoint Sources
CTR-090-016	C-20 Scope Prty Toxic Poll. List
CTR-090-017	C-20 Scope Prty Toxic Poll. List
CTR-090-018	C-24 Site Specific Criteria
CTR-090-019	C-17a Methodologies Human Health
CTR-090-020	G-07 Variances
CTR-090-021	I-10 CSO Policy
CTR-090-022	C-12a THMs Human Health
CTR-090-023a	K-02 Watershed Permitting
CTR-090-023b	Q Nonpoint Sources
CTR-090-024	G-02 Compliance Schedules
CTR-091-001a	C-01 Mercury

Comment ID	Subject Matter Code
CTR-091-001b	C-01 Mercury
CTR-091-002a	E-01 Cost Analysis
CTR-091-002b	E-02 Benefits Analysis
CTR-092-001	T State Implementation Policy
CTR-092-002	C-22 Dissolved v. Ttl Recoverable
CTR-092-003	G-09 Translators
CTR-092-004	C-24a SSC Water Effect Ratios
CTR-092-005	K-01 TMDLs
CTR-092-006	G-04 Interim Limits
CTR-092-007	G-05 Mixing Zones&Dilution Credit
CTR-092-008	G-07 Variances
CTR-092-009	G-02 Compliance Schedules
CTR-092-010	C-24 Site Specific Criteria
CTR-092-011	I-01 Application Sec 301 vs. MEP
CTR-092-012a	C-03b Nickel Aquatic Life
CTR-092-012b	C-07b Cyanide Aquatic Life
CTR-092-013a	C-24a SSC Water Effect Ratios
CTR-092-013b	C-02b Copper Aquatic Life
CTR-092-014	E-01g Sample Facilities
CTR-092-015	C-13 Risk Level
CTR-092-016a	E-01c Executive Order 12866
CTR-092-016b	R RFA/SBREFA
CTR-092-016c	S UMRA
CTR-092-017	E-01a Baselines
CTR-092-018	E-01e01 Sunnyvale/San Jose
CTR-092-019	E-01e03 No Savings from Poll. Red
CTR-092-020	E-01e Indirect Dischargers
CTR-092-021	E-01i Alternative Cost Analysis
CTR-092-022a	E-01c Executive Order 12866
CTR-092-022b	E-01b01 RegRelief Above Threshold
CTR-092-022c	E-01y Cost of Efforts to Date
CTR-092-023a	E-02e Include Omitted Benefits
CTR-092-023b	E-02l Marginal Impacts/Benefits
CTR-092-023c	E-02q Benefits to Public at Large
CTR-093-001	E-01g05 Effluent Data
CTR-094-001	B Comment Period
CTR-095-001a	C-20 Scope Prty Toxic Poll. List
CTR-095-001b	C-17a Methodologies Human Health
CTR-095-001c	C-21 Legal Concerns
CTR-095-001d	C-14 Fish or Water Consumption
CTR-095-002a	C-01 Mercury
CTR-095-002b	C-01 Mercury
CTR-095-003	C-09a Dioxin Human Health
CTR-095-004	G-02 Compliance Schedules
CTR-096-001a	I-03 Applicability of Criteria
CTR-096-001b	C-17 Methodologies
CTR-096-002	I-07 Attainability of Criteria
CTR-096-003a	E-01c01 $100M Threshold
CTR-096-003b	J-05 BMPs Inability to Comply
CTR-096-004a	G-10 Pretreatment
CTR-096-004b	R RFA/SBREFA
CTR-096-005	B Comment Period
CTR-096-006	C-24d SSC Effluent Dependent Wtr
CTR-096-007	C-24e SSC Desgntd/Beneficial Uses
CTR-096-008	C-13 Risk Level
CTR-096-009	E-01u Economic Consid. Task Force
CTR-097-001a	C-17a Methodologies Human Health
CTR-097-001b	C-14 Fish or Water Consumption
CTR-097-002	C-29 Bioaccumulation
CTR-097-003	C-09a Dioxin Human Health
CTR-098-001	C-14 Fish or Water Consumption
CTR-099-001a	C-17a Methodologies Human Health
CTR-099-001b	C-17b Methodologies Aquatic Life
CTR-099-002	C-14 Fish or Water Consumption
CTR-099-003	C-29 Bioaccumulation
CTR-099-004	C-21 Legal Concerns
CTR-100-001	C-20 Scope Prty Toxic Poll. List
CTR-101-001a	C-14 Fish or Water Consumption
CTR-101-001b	C-20 Scope Prty Toxic Poll. List
CTR-102-001a	C-17a Methodologies Human Health
CTR-102-001b	C-17b Methodologies Aquatic Life
CTR-102-002	C-14 Fish or Water Consumption
CTR-103-001	C-04b Selenium Aquatic Life
CTR-104-001	C-14 Fish or Water Consumption
CTR-104-002a	C-01 Mercury
CTR-104-002b	C-14 Fish or Water Consumption
CTR-104-003	G-02 Compliance Schedules
CTR-104-004a	C-09a Dioxin Human Health
CTR-104-004b	C-17a Methodologies Human Health
CTR-105-001a	C-20 Scope Prty Toxic Poll. List
CTR-105-001b	C-14 Fish or Water Consumption
CTR-105-002a	C-17a Methodologies Human Health
CTR-105-002b	C-21 Legal Concerns
CTR-106-001	C-14 Fish or Water Consumption
CTR-106-002a	C-01 Mercury
CTR-106-002b	C-14 Fish or Water Consumption
CTR-106-003	G-02 Compliance Schedules
CTR-106-004a	C-09a Dioxin Human Health
CTR-106-004b	C-17a Methodologies Human Health
CTR-107-001	E-01 Cost Analysis
CTR-107-002a	E-01 Cost Analysis
CTR-107-002b	G-02 Compliance Schedules
CTR-107-002c	E-01n Detection Limits
CTR-108-001	E-01g01 Low or Zero Dilution
CTR-109-001a	C-14 Fish or Water Consumption
CTR-109-001b	C-20 Scope Prty Toxic Poll. List

Comment ID	Subject Matter Code
CTR-109-002a	C-01 Mercury
CTR-109-002b	C-14 Fish or Water Consumption
CTR-109-003	C-09a Dioxin Human Health
CTR-109-004	G-02 Compliance Schedules
CTR-110-001	C-17a Methodologies Human Health
CTR-110-002	C-09a Dioxin Human Health
CTR-110-003	G-02 Compliance Schedules
CTR-111-001	E-01d01 Cost Estmte by Commenter
CTRE-001-001a	B Comment Period
CTRE-001-001b	V Collaborative Approach
CTRE-001-002	B Comment Period
CTRE-002-001	B Comment Period
CTRE-002-002	I-01 Application Sec 301 vs. MEP
CTRE-002-003	J Storm Water Economics
CTRE-002-004	I-03 Applicability of Criteria
CTRE-002-005	B Comment Period
CTRE-003-001a	B Comment Period
CTRE-003-001b	B Comment Period
CTRE-003-001c	R RFA/SBREFA
CTRE-004-001a	B Comment Period
CTRE-004-001b	G-08 State Policy
CTRE-005-001	B Comment Period
CTRE-006-001	B Comment Period
CTRE-007-001	B Comment Period
CTRE-008-001	B Comment Period
CTRE-009-001	B Comment Period
CTRE-010-001	B Comment Period
CTRE-011-001	B Comment Period
CTRE-012-001	B Comment Period
CTRE-013-001	B Comment Period
CTRE-014-001	B Comment Period
CTRE-015-001	B Comment Period
CTRE-016-001	B Comment Period
CTRE-017-001	B Comment Period
CTRE-018-001	B Comment Period
CTRE-019-001	B Comment Period
CTRE-020-001	B Comment Period
CTRE-021-001	B Comment Period
CTRE-022-001	B Comment Period
CTRE-023-001a	B Comment Period
CTRE-023-001b	V Collaborative Approach
CTRE-024-001	B Comment Period
CTRE-025-001	B Comment Period
CTRH-001-001a	I-01 Application Sec 301 vs. MEP
CTRH-001-001b	J Storm Water Economics
CTRH-001-002	B Comment Period
CTRH-001-003a	C-22 Dissolved v. Ttl Recoverable
CTRH-001-003b	C-24a SSC Water Effect Ratios
CTRH-001-003c	C-01 Mercury
CTRH-001-004	I-01 Application Sec 301 vs. MEP
CTRH-001-005a	J-02 RFA - Small Entity Cost
CTRH-001-005b	R RFA/SBREFA
CTRH-001-006	I-01 Application Sec 301 vs. MEP
CTRH-001-007	I-03 Applicability of Criteria
CTRH-001-008a	R RFA/SBREFA
CTRH-001-008b	J-02 RFA - Small Entity Cost
CTRH-001-009a	J-06 NEPA
CTRH-001-009b	F Endangered Species Act
CTRH-001-010	C-21 Legal Concerns
CTRH-001-011	G-02 Compliance Schedules
CTRH-001-012	C-09a Dioxin Human Health
CTRH-001-013	C-01 Mercury
CTRH-001-014	C-02b Copper Aquatic Life
CTRH-001-015	A Anti-degradation
CTRH-001-016	C-20 Scope Prty Toxic Poll. List
CTRH-001-017	C-21 Legal Concerns
CTRH-001-018a	C-01 Mercury
CTRH-001-018b	C-01 Mercury
CTRH-001-019a	B Comment Period
CTRH-001-019b	V Collaborative Approach
CTRH-001-020	C-28 Detection Limits
CTRH-001-021	C-23 Sediments/Dredged Materials
CTRH-001-0211a	B Comment Period
CTRH-001-0211b	B Comment Period
CTRH-001-022a	G-07 Variances
CTRH-001-022b	G-05 Mixing Zones&Dilution Credit
CTRH-001-023	E-01s 2ndary,Indirect Cost Impact
CTRH-001-024a	G-02 Compliance Schedules
CTRH-001-024b	G-05 Mixing Zones&Dilution Credit
CTRH-001-024c	C-22 Dissolved v. Ttl Recoverable
CTRH-001-024d	C-24a SSC Water Effect Ratios
CTRH-001-024e	C-17a Methodologies Human Health
CTRH-001-025	V Collaborative Approach
CTRH-001-026	C-13 Risk Level
CTRH-001-027	E-01d Direct Dischargers
CTRH-001-028	C-28 Detection Limits
CTRH-001-029	J Storm Water Economics
CTRH-001-030	V Collaborative Approach
CTRH-001-031	I-01 Application Sec 301 vs. MEP
CTRH-001-032a	C-24a SSC Water Effect Ratios
CTRH-001-032b	C-22 Dissolved v. Ttl Recoverable
CTRH-001-032c	G-05 Mixing Zones&Dilution Credit
CTRH-001-033	J Storm Water Economics
CTRH-001-034a	I-08 SWRCB Flexibility&Authority

Comment ID	Subject Matter Code
CTRH-001-034b	I-05 Compliance Schedules
CTRH-001-034c	G-03 Design/Minimum Flows
CTRH-001-035	B Comment Period
CTRH-001-036	B Comment Period
CTRH-001-037a	E-01c02 Bnfts do not Balance Cost
CTRH-001-037b	E-01q03 Unit Cost Assumption
CTRH-001-037c	E-01h02 Unit Cost Assumptions
CTRH-001-038	C-28 Detection Limits
CTRH-001-039a	C-24a SSC Water Effect Ratios
CTRH-001-039b	G-04 Interim Limits
CTRH-001-039c	G-02 Compliance Schedules
CTRH-001-040	I-01 Application Sec 301 vs. MEP
CTRH-001-042	J-04 End-of-Pipe Treatment v. BMP
CTRH-001-043	B Comment Period
CTRH-001-044	E-01d01 Cost Estmte by Commenter
CTRH-001-045a	B Comment Period
CTRH-001-045b	G-09 Translators
CTRH-001-046	C-13 Risk Level
CTRH-001-047	C-24 Site Specific Criteria
CTRH-001-048	C-22 Dissolved v. Ttl Recoverable
CTRH-001-049	G-09 Translators
CTRH-001-050a	C-01 Mercury
CTRH-001-050b	C-14 Fish or Water Consumption
CTRH-001-051	C-09a Dioxin Human Health
CTRH-001-052	G-02 Compliance Schedules
CTRH-001-053	C-14 Fish or Water Consumption
CTRH-001-054	J Storm Water Economics
CTRH-001-055	T State Implementation Policy
CTRH-001-056	V Collaborative Approach
CTRH-001-057a	K-03 Watershed/Effluent Trading
CTRH-001-057b	C-24a SSC Water Effect Ratios
CTRH-001-057c	G-04 Interim Limits
CTRH-001-057d	G-07 Variances
CTRH-001-057e	G-09 Translators
CTRH-001-057f	C-22 Dissolved v. Ttl Recoverable
CTRH-001-057g	G-05 Mixing Zones&Dilution Credit
CTRH-001-058	E-01g08 Discharger Representation
CTRH-001-059	C-23 Sediments/Dredged Materials
CTRH-001-060a	B Comment Period
CTRH-001-060b	J-04 End-of-Pipe Treatment v. BMP
CTRH-001-061	I-03 Applicability of Criteria
CTRH-001-062	C-01 Mercury
CTRH-001-063	C-01 Mercury
CTRH-002-001	I-01 Application Sec 301 vs. MEP
CTRH-002-002	J-04 End-of-Pipe Treatment v. BMP
CTRH-002-003	C-28 Detection Limits
CTRH-002-004	J-02 RFA - Small Entity Cost
CTRH-002-005	J Storm Water Economics
CTRH-002-006a	I Stormwater/Wet Weather Flows
CTRH-002-006b	J Storm Water Economics
CTRH-002-007	B Comment Period
CTRH-002-008	I-01 Application Sec 301 vs. MEP
CTRH-002-009	J Storm Water Economics
CTRH-002-010	B Comment Period
CTRH-002-011a	G-02 Compliance Schedules
CTRH-002-011b	G-04 Interim Limits
CTRH-002-011c	C-22 Dissolved v. Ttl Recoverable
CTRH-002-011d	K-01 TMDLs
CTRH-002-012	C-24d SSC Effluent Dependent Wtr
CTRH-002-013	C-13 Risk Level
CTRH-002-014	G-02 Compliance Schedules
CTRH-002-015	K Water Shed Approach
CTRH-002-016a	E-01c02 Bnfts do not Balance Cost
CTRH-002-016b	E-01h Treatment Assumptions
CTRH-002-017	J Storm Water Economics
CTRH-002-018	E-01y Cost of Efforts to Date
CTRH-002-019	E-01n Detection Limits
CTRH-002-020	C-24d SSC Effluent Dependent Wtr
CTRH-002-021a	B Comment Period
CTRH-002-021b	V Collaborative Approach
CTRH-002-022	E-01n Detection Limits
CTRH-002-023	C-13 Risk Level
CTRH-002-024	I-03 Applicability of Criteria
CTRH-002-025	I-04 Site-Specific Criteria
CTRH-002-026	I-05 Compliance Schedules
CTRH-002-027	B Comment Period

Subject Matter Code: A Anti-degradation

Comment ID: CTR-002-010a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: A Anti-degradation
References:
Attachments? Y
CROSS REFERENCES G-02

Comment: The proposed implementation plan allowing compliance schedules for effluent limits to attain the criteria to be placed in permits may not pass the antidegradation test either. CBE believes EPA recognizes that permit schedules which allow continued impairment of fishing and aquatic life uses are improper (See e.g., section 1311(b)(1)(C), section 1314(l)(1)(D), section 1342(o)(1) and (3) and section 1313(d)(4)(A) of the Clean Water Act). In the alternative case, however, a schedule allowing discharge of these persistent pollutants to waters attaining the criteria will result in the accumulation of pollutants and will degrade water quality. This degradation is unnecessary as the state has accommodated important economic and social development for years while placing compliance schedules in administrative enforcement orders, and is thus impermissible under 40 CFR section 131.12(a)(2). Indeed, existing California dischargers have been made aware of the need to meet similar or more restrictive criteria since at least 1991, and further extension of time for more pollution should be done through schedules in enforcement orders. Any desire to avoid the administrative effort of continuing to prepare these enforcement orders is easily outweighed by the public interests in clean water and public participation afforded.

In sum, EPA's weaker criteria shown in Table 2 do not protect designated uses of water based on sound scientific rationale, and even if this were true for some toxics in some areas of the Bay, the weaker criteria are not necessary to allow important economic or social development. Therefore, revision of water quality standards by adopting these criteria would not meet the tests set forth by 40 CFR section 131.11(a)(1) and section 131.12 and the Clean Water Act provisions these regulations implement, Further, incorporating schedules allowing polluters to harm fishing and aquatic life in water quality standards and effluent limits is improper, and there is no legitimate need for schedules allowing degradation of water quality and restricting public participation to be in permits instead of putting them in administrative enforcement orders as is done today. Thus EPA's proposal may, by failing to provide equal protection for people of color who fish for food and unfairly restricting public participation, also conflict with the Executive Order on environmental justice and civil rights law.

Response to: CTR-002-010a

See legal response to CTR-002-009. EPA disagrees that compliance schedules will prevent antidegradation requirements from being met. First, the antidegradation policy at 40 CFR 131. 12 requires, as an absolute minimum, that existing uses (those uses established on or after November 28, 1975) must be fully protected in all waters. Secondly, the antidegradation policy allows some degradation in high quality waters (i.e., those waters whose quality exceeds levels necessary to support fishable/swimmable uses) provided that any such degradation would not reduce water quality to such levels below that needed to maintain the fishable/swimmable uses. Before allowing any degradation in

high quality waters, the State must ensure that all statutory and regulatory requirements for point sources and all cost-effective and reasonable best management practices are achieved. Furthermore, in allowing degradation to high quality waters the State must provide for public participation and intergovernmental coordination in demonstrating that the lowering of water quality is necessary for important economic and social advancements in the area that the discharge is located. Thirdly, no degradation (other than short term or temporary lowering of water quality) is allowed in waters classified as Outstanding National Resource Waters (ONRWs). ONRWs include the highest quality waters in the U. S. Additionally, the ONRW classification offers special protection for waters of "exceptional ecological significance, " i.e., those waters that are important, unique, or of ecological importance, but whose water quality, as determined by traditional parameters such as dissolved oxygen or pH, may not be particularly high.

Thus, although EPA notes that there is some degradation allowed to certain waters under the antidegradation policy, EPA believes that a compliance schedule can be complementary to the antidegradation provisions. The Agency has supported reasonable compliance schedules based on new or reviewed water quality standards adopted after July 1, 1977. A compliance schedule will accommodate the practical real world problems in meeting a new effluent limit where it is adequately justified. The whole basis for a compliance schedule is when a facility needs to invest in capitol improvements to install the additional treatment technologies necessary to meet more stringent effluent limitations. Furthermore, EPA is not aware of any specific instances where the State has either allowed any unnecessary degradation or allowed degradation to occur to a degree that is inconsistent with 40 CFR 131.12. Moreover, the commenter did not provide any analysis to demonstrate that antidegradation provisions are not being met or not being appropriately implemented in the State of California. Furthermore, although the antidegradation provisions are essential in maintaining and protecting water quality, those provisions are outside of the scope of today's rule.

Comment ID: CTR-026-001a
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES C-24e

Comment: 1 . DESIGNATED USES AND ANTIDEGRADATION POLICY

The DFG is concerned with the issues of "designated uses" and an "antidegradation policy" as they apply to the formation of water quality standards. It is our understanding that water quality standards are comprised of, or defined by, three components: 1) designated uses, 2) numeric water quality criteria, and 3) an antidegradation policy. The CTR is not clear on which designated uses are being identified and when they were established. The rule needs to identify what designated uses are being assigned and when these uses were or should be attained. At issue is which uses should be maintained and protected, and what the baseline should be for designating the various beneficial or designated uses for inland freshwater and bay and estuarine waters of the state. We believe that any baseline for applying the antidegradation policy should establish what the quality of the water would have been historically in the absence of human impacts. Under the Porter Cologne Act, the State's primary water quality statute, the

discharge of waste into state waters is not a right but a privilege. Since the discharge of waste is not considered a beneficial use, it should not be permitted in public waters unless it is determined that all beneficial uses, especially publicly entrusted fish and wildlife resources, are fully protected. This is especially true for wetlands throughout the State. The proposed rule is not clear as to when the baseline starts (i.e., historical vs. statutory). The DFG believes that, to the extent practicable, designated uses should be reflective of what has been realized in the past. If the CTR is utilizing a statutory date for which baseline designated uses were identified, then the CTR needs to include a justification for such a date.

With respect to antidegradation, it is not clear whether or not the proposed rule is subject to these requirements. It is our understanding that when a proposed action would allow less stringent criteria than previously proposed or adopted, and if that action would result in more loading of a particular constituent into waters of the State, then an appropriate antidegradation analysis shall be required. It is not clear what process EPA has undertaken to adequately address antidegradation issues related to the proposed new criteria. It may be that the applicability of the antidegradation policies are more pertinent with respect to site-specific criteria that may be included in the final rule. We recommend that the CTR adequately address this issue and apply the antidegradation policy where necessary.

Response to: CTR-026-001a

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance and where those pollutants could reasonably be expected to interfere with the designated uses of state waters. In today's action, EPA is relying on the use designations developed by the State of California, the State's existing antidegradation policy, and the criteria promulgated in this action to ensure that adequate water quality standards are in place to protect the waterbodies identified in the State's Regional Basin Plans. The adoption of criteria sufficient to protect designated uses is not an action which in and of itself results in any change in water quality. Thus, antidegradation implementation and baselines for applying the antidegradation policy are outside of the scope of today's rule.

Comment ID: CTR-029-001
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act section 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is

of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water quality throughout the state. These three points are reviewed below.

Use of the Majority of the State's Waters Is Threatened or Impaired by Pollution

Increasing pollution seriously jeopardizes the health of the state's waters. The most recently available data shows that pollution threatens or impairs the use of 98% of California's tidal wetlands, 93% of its bays and harbors, 90% of its estuaries, 88% of its freshwater wetlands, 79% of its lakes and reservoirs, and 74% of its rivers and streams.(*1)

Where specific toxics data are available, they demonstrate that these contaminants are particularly significant threat to the health of the state's waters. For example, use of 98% of the state's tidal wetlands, 85% of its estuaries, 72% of its freshwater wetlands, 72% of its groundwater, 68% of its bays and harbors, and 52% of its rivers and streams are threatened or impaired by toxic pollutants.(*2)

Significantly, these figures represent only water bodies whose water quality has been measured. The health of many waters in the state is unknown. For example, the water quality of only 9% of the state's rivers and streams has been assessed.(*3) Moreover, even when a water body is reported as being "monitored," it may only be tracked for one or a handful of contaminants, leaving its overall health unclear. In other words, the number of water bodies known to be contaminated is only the minimum; actual pollution problems may be far greater.

In light of these statistics, it is imperative that the state move forward swiftly in implementing strong numeric controls on the discharge of toxics into our waterways. It is unacceptable California is the only state in the nation in substantial noncompliance with Clean Water Act section 303(c)(2)(B), and CMC welcomes EPA's extensive efforts in helping California work towards compliance.

These statistics, however, also call for the strongest criteria supportable by science. The significant threats demonstrated by the statistics show that the proposed rule's move backwards from published criteria documents should be viewed with an extremely critical eye.

(*1) State Water Resources Control Board, California 305(b) Report on Water Quality, pp. 43-47 (Aug. 1996).

(*2) Id. at p. 80.

(*3) Id. at p. 2.

Response to: CTR-029-001

EPA acknowledges that the criteria in the proposed CTR appeared in some instances to be inconsistent with EPA's published criteria recommendations. EPA explained in the preamble to the proposed CTR that EPA's policy has always been to utilize the latest toxicity information in IRIS when evaluating criteria. In this regard, EPA disagrees with the commentor that the criteria in the CTR are inconsistent with published EPA guidance. Since the proposed CTR, EPA has updated its National 304(a) published criteria to include the latest IRIS toxicity values (see 63 FR 68353 published on 12/10/98 and 64 FR 19781 published on 4/22/99). The values in the final CTR are now consistent with EPA's published criteria recommendations.

Comment ID: CTR-029-002c
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES C-17a
C-17b
C-22
C-27
C-29

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the published guidance documents is "insignificant"(*4); however, in light of the current contamination

problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be under protective because additive and synergistic effects were not considered; and because the effects on wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).

(*5) Id. at 42168.

(*6) Id. at 42172.

Response to: CTR-029-002c

See response to CTR-029-001.

Comment ID: CTR-039-002
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES

Comment: EPA should defer to the State's prior technical decisions to establish metals criteria based on total recoverable metals. EPA should defer to the State's prior determinations on dioxin and mercury as well as fish consumption rates. In establishing water quality standards under the federal Clean Water Act, neither EPA nor the States can factor in the anticipated economic burden which may result from implementation of the standards. The standards must be based solely on science and the needs of the beneficial uses established for the particular waters. The only reason that the State's promulgation of many of the requisite criteria in 1991 was overturned in state court was because of a flawed economic analysis pursuant to provisions unique to state law. EPA had approved many of those final criteria as technically sound and within the State's delegated discretion. EPA should not backslide on that prior

determination at this late date but instead should be attempting to close the gap in criteria by deferring to its previous approval.

Response to: CTR-039-002

EPA believes that in promulgating the criteria in today's rule, the Agency is not backsliding on criteria that were previously approved in California. Rather, in taking this action, the Agency intends to establish numeric criteria for priority toxic pollutants as required by CWA Section 303(c)(2)(B) until such time that California can adopt such criteria sufficient to protect the designated uses of the waters that are subject to this rule. The criteria included in today's rule are largely the same criteria that were adopted by the State. However, there are some differences. For example, because the criteria included in today's rule have been updated by EPA to reflect the Agency's latest scientific recommendation, the criteria values may be different from those adopted by State in the Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan. EPA notes that the State, in the future, is not precluded from adopting criteria for total recoverable metals (instead of dissolved), adopting human health criteria that are based on higher fish consumption rates, or from adopting criteria for dioxin that are based on toxicity equivalents since these provisions are viewed as risk management decisions. The basis for EPA's use of metals criteria based on dissolved rather than total recoverable is discussed in the responses CTR-026-004, CTR-039-003a, and CTR-065-005, a record document entitled "Discussion of Use of Dissolved Metals in the CTR," and elsewhere in the record for the rule.

Comment ID: CTR-039-003b
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES C-22

Comment: I . APPLYING DISSOLVED METALS CRITERIA AS PROPOSED VIOLATES THE ANTIDEGRADATION POLICY FOR SAN FRANCISCO BAY AND OTHER WATERS OF THE STATE

The practical effect of EPA's decision to rely on dissolved metals criteria is to allow higher levels of total recoverable metals to be discharged from point sources into San Francisco Bay as well as other waters of the State. Since 1991, many permits in the Bay area and else where have been issued applying the State Water Resources Control Board's technically-based and EPA approved numeric criteria for numerous toxic pollutants. For at least three years, permits throughout the State were required to be issued using the duly-promulgated criteria established by the State Water Resources Control Board ("SWRCB"). After the Sacramento court vacated the criteria on economic grounds, numerous permitting decisions were made by local regional boards and their staffs applying the previously applicable standards using their best professional judgement ("BPJ") in order to assure the protection of beneficial uses. Each of the permitting decisions based directly or deferentially on the SWRCB's criteria would be more stringent than permits for the same parameters authorized by EPA's proposed rule where a discharger opts to follow the Water Effects Ratio protocol for translating the criteria into a permit limit. BayKeeper would

not anticipate that many, if any, dischargers will opt for the default WER of 1.0 Thus, for many regulated dischargers, EPA's proposal will lead to major increases in the total metals they are allowed to discharge into the Bay and other waters of the State. This massive increase in the total pollution proposed to be allowed to be discharged into the Bay and other State waters is completely inconsistent with the State's and EPA's antidegradation policies mandating that existing water quality be maintained and protected. As the State's policy sets forth:

Whenever the existing quality of water is better than the quality established in policies as of the date on which such policies become effective, such existing high quality will be maintained until it has been demonstrated to the State that any change will be consistent with maximum benefit to the people of the State, will not unreasonably affect present and anticipated beneficial use of such water and will not result in water quality less than that prescribed in the policies.

SWRCB Resolution No. 68-16. Under the federal version of the policy:

[w]here the quality of the waters exceed levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water, that quality shall be maintained and protected unless the State finds, after full satisfaction of the intergovernmental coordination and public participation provisions of the State's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development.

40 C.F.R. 131.12(a)(2). The antidegradation policies apply both to permit decisions as well as decisions establishing water quality standards. See, e.g., In The Matter of the Petition of Remmon C. Fay , SWRCB Order No. WQ 86-17 (Nov. 20, 1986). In the case of EPA's proposed rule, throughout California the rule, if adopted, will allow more pollution to be discharged than is currently allowed by permits validly issued to numerous dischargers throughout the State without any consideration of the policies, including the intergovernmental coordination and public participation requirements, required by the antidegradation policies.

Of course, in addition to that procedural problem, BayKeeper is opposed to the proposed reliance on dissolved numbers, especially in the Bay area, because it will in fact allow more pollution to be discharged into the State's waters than is currently allowed today and likely will prove detrimental to beneficial uses. See Comments of Communities For A Better Environment. BayKeeper also is very concerned about the burdens and uncertainty placed on the public by the need for translators in order to apply the dissolved criteria in permit limits that must be based on total recoverable numbers. As noted above, BayKeeper does not anticipate that many dischargers will opt for EPA's proposed WER default of 1.0 BayKeeper views this proposal as an invitation for dischargers to prepare site-specific limitations based on their own studies which will frustrate the public' s ability to participate effectively in the formulation of effluent limits. Further, the proposal will present a moving target for the public to understand and will burden the resources of regional board staff to a degree that may undermine the quality of those site by site determinations.

Response to: CTR-039-003b

See response to CTR-026-004. First, EPA disagrees with the contention that the CTR will result in massive increases in the total pollution allowed in the San Francisco Bay. See response to CTR-002-003 for a detailed response to this same comment.

EPA disagrees that the dissolved criteria will violate California's or EPA's antidegradation provisions contained in 40 CFR 131.12. The use of dissolved criteria in establishing aquatic life criteria for metals

is based on EPA's determination (with widespread support and input from experts in the scientific community) that dissolved metals more accurately approximates the portion of the metals in water that is biologically available to cause toxicity to aquatic organisms.

The antidegradation policy at 40 CFR 131.12 and the State's antidegradation policy ensures full protection of existing uses (those uses established on or after November 28, 1975) and provides a means to assess the impacts of discharges to high quality waters. There is some degradation allowed to high quality waters (see response to CTR-002-010a), provided certain procedures are implemented and certain provisions are met. However, EPA does not support the notion that dissolved metals will violate the antidegradation policy. EPA contends that the use of dissolved metals will provide a greater degree of accuracy in protecting aquatic ecosystems.

Furthermore, the adoption of criteria sufficient to protect designated uses is not an action which in and of itself results in any change in water quality. The implementation of such criteria may raise antidegradation issues in specific instances in the future, but this rule does not.

Comment ID: CTR-065-002a
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES C-17a
C-17b

Comment: PROPOSED RULE ALLOWS SIGNIFICANT AND UNACCEPTABLE INCREASES IN TOXIC POLLUTANT CONCENTRATIONS IN BAYS AND ESTUARIES

Our initial review indicates that the proposed criteria for a number of toxic constituents are unacceptably high and will allow more pollution of bays and estuaries by several orders of magnitude. If adopted as proposed, the CTR will allow a 900% increase of dioxin, 140% increase of PCBs, 325% increase of mercury, 2760% increase of zinc, 23,000% increase of lead, and a stunning 430 million % increase for total PAH, some of the most problematic pollutants in San Diego Bay. The CTR only improves (i.e. strengthens) criteria for only 3 of 64 pollutants. This does not square with new studies that show reasons for concern about the synergistic and long-term effects of exposures to these toxic pollutants. In sum, the CTR proposes weaker criteria for 58% of the pollutants and no change for 37% of the criteria. This kind of action will not bring us closer to our goal of cleaner water containing healthier organisms in the future.

Response to: CTR-065-002a

See comment response CTR-065-002b.

Comment ID: CTRH-001-015
Comment Author: Greg Karras

Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: A Anti-degradation
References:
Attachments? N
CROSS REFERENCES

Comment: Now, I won't go through each of the pollutants one by one here. I want to give some other speakers some time.

But to summarize on the criteria point, EPA's proposal criteria ranges from slightly less to more than a thousand percent weaker than the state's previous proposal for 37 of the 64 pollutants of concern identified by the San Francisco Estuary Project -- that's according to our preliminary analysis -- or 58 percent of these pollutants, as compared with previous EPA-approved state standards.

Time and again, when environmental standards required action to prevent pollution, and this was done right, this resulted in long-term economic benefits rather than costs.

And I have an antidegradation question here: Will EPA allow these pollutants to degrade water quality when your own economic analysis shows no evidence of widespread economic concern?

And our data show that in fact doing it right and preventing pollution could save jobs and provide long-term economic benefits, as well as environmental health benefits.

Response to: CTRH-001-015

See response to CTR-002-010a, CTR-039-003b, and CTR-002-003.

Subject Matter Code: B Comment Period

Comment ID: CTR-001-001
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: B Comment Period
References:
Attachments?
CROSS REFERENCES

Comment: (*1) As you know, several storm water systems have requested additional time to comment on the proposed rule, a request in which the ACCWP has joined. Additional time is particularly important given the interdependence between the CTR and the recently proposed "Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California," ("State Implementation Policy" or "SIP") released by the SWRCB on September 12, 1997, just two weeks before the comment deadline an the CTR. The way in which the CTR is implemented is central to its effects on storm water dischargers, as discussed below. Unfortunately, the State Implementation Policy does not fully correct or moderate the critical problems created by the proposed CTR.

Response to: CTR-001-001

EPA acknowledges that many dischargers have requested a longer comment period than was provided for the proposed CTR. The proposed CTR was published in the Federal Register on August 5, 1997 and the public comment period ended on September 26, 1997. This gave the public an opportunity of 52 days (over 7 weeks) within which to review and draft comments. The document was available through the Internet at EPA's website. EPA believes that this was a reasonable and sufficient time within which to complete a thorough review and to draft and submit comments to the Agency. The proposed CTR was not substantially different from California's prior law or the National Toxics Rule; it proposed to establish water quality criteria for priority toxic pollutants in the State of California and a compliance schedule provision for permits based on the proposed criteria. These provisions were not extensive or new; similar provisions have been in existence for the State of California and elsewhere in the country for many years.

The comment period is intended to provide commenters with a chance to substantively review the merits of the proposed action. For the proposed CTR, EPA expected and received comments on the scientific sufficiency of the criteria values and their underlying derivations, and on the compliance schedule provision. Comments concerning the implementation of the criteria should have been, and were, directed to the State of California. The State had proposed an implementation plan on September 12, 1997, during the public comment period of the proposed CTR. The comment period for the proposed implementation plan ended in December of 1997. The State's plan was also available to the public through the Internet.

Many commenters requested a longer comment period for the proposed CTR, to extend the time within which to review both the proposed CTR and the State's proposed implementation plan. The comment period for the proposed CTR overlapped with the first two weeks of the comment period for the State's

proposed implementation plan. EPA believes this was a reasonable and sufficient time within which to determine and comment on any issues concerning the proposed CTR criteria and compliance schedule provision due to the State's action. Commenters had several additional weeks to thoroughly review and comment on the State's specific implementation provisions in light of the proposed CTR criteria values. Although the CTR criteria and the State's implementation plan are related, the issues for comment are distinctly different and should have been directed to the respective appropriate entity. The CTR proposed water quality criteria which are scientifically-based and do not take economics into account; implementation procedures are not necessary in order to comment on the scientific underpinnings of the proposed water quality criteria.

The CTR and the State's implementation plan were not proposed together; they are separate phases of a comprehensive water quality control plan for the State of California and as such, can be commented on in phases. Both the EPA and the State published economic analyses which looked at the economic impacts of implementation of the respective proposed regulations. EPA's analysis for the proposed rule looked at the potential economic impacts of implementation of the proposed criteria using current State implementation procedures. The State's economic analysis for its proposed plan looked at the economic impacts of specific proposed implementation procedures.

Comment ID: CTR-002-001
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Ms. Frankel, Regional Administrator Marcus and Administrator Browner:

CBE believes that adoption of EPA's "California Toxics Rule" as proposed might represent the biggest step backward in toxics policy for San Francisco Bay in the twenty-five year history of the Clean Water Act.

The Rule would allow far more pollution than state water quality standards criteria EPA is trying to replace for most of the toxic pollutants of concern in the Bay. It would allow levels of dioxin compounds, mercury, polycyclic aromatic hydrocarbons, and toxic metals that already harm the fishing public and aquatic life to increase. Despite EPA's admission of soaring cancer risk and other toxic threats to Bay anglers, it would fail to protect people who fish for food unless they eat only starvation rations of one-seventieth of a pound of fish per day. Its dioxin criteria deregulate sixteen of the seventeen most toxic compounds known to science. It ignores proof of mercury bioaccumulation and evidence that its weaker copper criteria allow pollution levels that wiped out aquatic populations. It then proposes a system of "permits to pollute" above even-these inadequate standards for up to ten years. Many of these problems extend state-wide beyond the Bay.

EPA's analysis in the proposed Rule ignores protection of fishing people of color who are disproportionately imperiled by toxic pollution it would allow, and evidence EPA asked us for showing

that stronger rules than EPA'S drive pollution prevention which results in economic benefits to the manufacturing base. The proposed Rule does not appear to comply with federal laws which require protection of public health, fishing and aquatic life and equal protection under the law.

The massive scope of this policy change suggests the need for maximum public involvement. Unfortunately, EPA staff report receiving only one "public" comment to date. We believe that this critically important environmental health decision is not receiving adequate public scrutiny.

Accordingly, we request that EPA extend the comment period for the Rule beyond the present September 26, 1997 deadline, revise the toxics criteria to address the concerns detailed in our enclosed comments, and require present state implementation procedures instead of allowing permit schedules which could grant "permits to pollute."

We have begun to discuss these concerns with EPA staff, and hope to continue this process with you, Regional Administrator Marcus, and Administration environment officials, in order to seek ways in which we can move forward together to solve the serious toxic pollution problems affecting people and aquatic life in San Francisco Bay and throughout California. We propose a meeting at your offices at 2 p.m. or later on Wednesday, October 1, 1997 as a next step in these discussions.

Response to: CTR-002-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment requesting present state implementation procedures instead of allowing permit schedules as proposed in the CTR, the State's implementation procedures were overturned by a State Courtruling in 1994. Thus, the State does not have a comprehensive set of implementation procedures. Each of the Regional Water Quality Control Boards implements water quality-based effluent limitations based on varying procedures, some of which have been formally adopted and others which have not. The Regional Boards may always implement any State adopted, federally approved water quality criteria through a State adopted, federally approved compliance schedule provision.

Comment ID: CTR-004-005
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: As stated above, most of the SBSA's concerns with the CTR, relate to the uncertainty of how the objectives will be implemented in permits. The CTR comment period should be extended to 90 days to allow sufficient time to review the draft implementation policy recently released by the state.

SBSA appreciates the opportunity to comment on the proposed rule. Please call me at (650) 594-8411 ext. 124 if you have any questions regarding the SBSA comments or need any additional information.

Sincerely,

James B. Bewley Manager

Response to: CTR-004-005

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-005-002
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: 1. The deadline for submission of comments should be extended at least 60 days. This is necessary to allow a more detailed review of the rule and its impacts on the District, especially in light of the recent release of the Draft State Policy for Implementation of Toxics Standards.

Response to: CTR-005-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-007-005
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: 4. It is the District's understanding that the State Water Resources Control Board's ("SWRCB") implementation policy for the CTR will include a policy determination on which criteria will be used in mixing zones i.e. fresh or salt water. If this is indeed the case (which the District does not know because it has not yet received its copy of the implementation policy) then the District requests that the comment period be extended in order to evaluate the CTR with the SWRCB's implementation policy.

Response to: CTR-007-005

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-021-001
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: In particular, Sunnyvale supports CASA/Tri-TAC's request for additional time in which to evaluate the potential impacts of the CTR in conjunction with the implementation plan being proposed by the State of California (the "State Proposal"). Sunnyvale obtained the State Proposal from the Internet as soon as it became available, yet Sunnyvale has had little time to digest the massive proposal and analyze its potential impacts on the implementation of the CTR. We suggest that most other California dischargers are in the same position and we strongly urge the Agency to reconsider its unfair and probably illegal decision to provide only a few days to assess and comment on what amounts to a joint promulgation by EPA and the State.

Response to: CTR-021-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-025-006a
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES C-16

Comment: Some of the concerns noted above could be addressed through the implementation provisions of the CTR. As you know, the State Water Resources Control Board has just made available for public review the Proposed Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Proposed ISWP/EBEP Policy), the implementing document for the CTR. Because of the length of the document (several hundred pages) and the fact that it has only

recently become available, there has been insufficient time for thorough review. Yet, this document is crucial to understanding the practical impact of the CTR.

Metropolitan strongly requests that U.S. EPA extend the comment period on the CTR to December 10, 1997, the end of the comment period for the Proposed ISWP/EBEP Policy. This would allow drinking water suppliers and others affected by the CTR to evaluate the CTR in the context of its implementation. Without workable implementation provisions, the operational and economic impacts on drinking water suppliers could be significant and may need to be taken into account in the CTR. If the comment period is not extended, we ask that U.S. EPA fully consider the impacts of the freshwater aquatic life criteria on the operation and maintenance activities of drinking water suppliers and the effect on water reclamation activities and to modify the CTR, as necessary, so that these activities can continue to be undertaken in an economically feasible manner.

The CTR forms the backbone of the water quality regulatory process and Metropolitan urges U.S. EPA to review the proposed criteria in light of regulatory requirements of the California/Federal SDWA and the operating and maintenance requirements of drinking water suppliers. If you have any questions regarding Metropolitan's comments, please feel free to call Marcia Torobin of my staff at (213) 217-7830.

Response to: CTR-025-006a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning the CTR's impact on drinking water suppliers, EPA notes that the criteria in the CTR do not impose any cost on anybody or entity. It is only when they are implemented through the State's process that economic impacts may be felt. The CTR's criteria legally apply only to water quality-based effluent limits in NPDES permits. The State on its own accord may apply the water quality criteria in other contexts and/or in other programs, and those applications may cause economic impacts.

Comment ID: CTR-031-008a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES V

Comment: d. The proposed CTR and the recently released proposed State Implementation Plan must be fully integrated, internally consistent, and their combined effect thoroughly assessed. However, EPA has allowed only one week of overlap between the proposals for stakeholder review.

The EPA concedes within the proposed CTR that the criteria themselves lack substance without the corresponding implementation measures. EPA also acknowledges that the economic impact of the CTR can not be fully evaluated without consideration of the ISWP. However, the EPA can not simply abdicate its responsibility to assess the impact of its proposal, nor can it expect stakeholders to accept the

proposed CTR without full understanding of its implementation.

All stakeholders require the opportunity to evaluate the proposed CTR and Implementation Plan together as a comprehensive, cohesive body of regulation.

Response to: CTR-031-008a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-034-001
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: The Southern California Alliance of Publicly Owned Treatment Works, or SCAP, is pleased to submit comments to the Environmental Protection Agency (EPA) regarding the Proposed Rule Regarding Water Quality Criteria for Toxic Pollutants for California (known as the California Toxics Rule, or CTR) SCAP's members include 47 public agencies that provide wastewater treatment services in Southern California.(*1) Collectively, our member agencies serve over 16 million residents of Southern California. Our member agencies range in size from very small to very large, and include wastewater treatment facilities that discharge to inland surface waters, bays and estuaries, and the ocean. Most of our members are also involved in water reclamation activities. We appreciate the opportunity to comment on the proposed California Toxics Rule.

As noted in SCAP's testimony at EPA's public hearing held on September 18, 1997 in Los Angeles, we would like to request that EPA re-open the comment period on the CTR. We would, like the opportunity to more fully review the proposed rule and supporting documentation, and believe that the extra time would afford us the opportunity to develop additional meaningful comments on the proposed regulation and its potential impacts on the POTW community in southern California.

(*1) SCAP's members are located in the following counties: Santa Barbara, Ventura, Los Angeles, San Bernardino, Riverside, Orange, and San Diego

Response to: CTR-034-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-035-001

Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: We are writing on behalf of Tri-TAC and the California Association of Sanitation Agencies (CASA), which are California-based organizations comprised of members from public agencies responsible for wastewater treatment. Tri-TAC is an advisory group which includes representatives from CASA, the California Water Environment Association, and the League of California Cities. CASA is comprised of over 80 agencies responsible for the operation of publicly owned treatment works (POTWs). The constituency base for Tri-TAC and CASA encompasses most of the sewered population of California.

We have reviewed the draft rule containing proposed water quality criteria for toxic pollutants for California ("California Toxics Rule" or "CTR") that was published in the Federal Register on August 5, 1997. We have numerous specific comments on the proposed rule. Our specific comments are contained in two attachments. Attachment 1 contains our comments on specific sections of the draft regulation and the Economic Analysis. Attachment 2 is a critique of the Economic Analysis prepared by M.Cubed, a resource economics consultant to Tri-TAC, CASA, the Southern California Alliance of POTWs (SCAP), and the Bay Area Dischargers Association (BADA). We would like to highlight several priority concerns below.

First, we would like to reiterate our previous requests (see letters of July, 21, 1997 and August 12, 1997) that EPA reopen the comment period for the proposed rule in order to facilitate a more complete review by the public, and in particular, by those in the POTW community. EPA's own analysis shows that POTWs are the sector most affected by the rule (according to the Preamble. POTWs will incur 67 percent or 96 percent of costs under the low and high cost scenarios, respectively) (62 Fed. Reg. 42189). We believe that it is common practice for the Agency to provide 90 days -- or even longer -- for comment periods on proposed rules, particularly if there is no court order dictating a promulgation schedule (and we are not aware of any court decision requiring a specific schedule for promulgation of the CTR). It is our understanding, for instance, that EPA provided a 150-day comment period for the Great Lakes Initiative in 1993.

In addition, as we noted in our previous letters, we understand that EPA and the State Water Resources Control Board (SWRCB) are promulgating the criteria and Statewide Implementation Policies in a collaborative manner. We respectfully request that you provide an extension in order to facilitate a more complete review of the SWRCB's Draft Implementation Policy, which was released on September 12. Because of the impending deadline for comment on the CTR, we have not had time to conduct more than a cursory review of the SWRCB's proposal. Therefore our comments by and large do not take into account the draft Implementation Policy of the SWRCB, which may after our interpretation of some aspects of the CTR.

Further, we believe that EPA has an obligation under Section 6(a) of Executive Order 12866, which requires all federal agencies, including EPA, to provide a "meaningful opportunity to comment on any

proposed regulation, which in most cases should include a comment period of not less than 60 days." (emphasis added). While we believe that the CTR is a "significant regulatory action," the comment period requirement applies even if EPA does not agree. The Agency is also required under the Unfunded Mandates Reform Act of 1995 (2 U.S.C.A. 1511 et. seq.) to provide "meaningful and timely review" by small governments. Aside from the fact that EPA has not provided the minimum of 60 days on the proposed CTR itself, the State Water Resource Control Board did not make its proposed implementation plan (the "State Proposal") available until September 12 (with effective distribution delayed for several days), which means that the public will have a period of less than two weeks to review the State Proposal, relate its provisions to the proposed CTR and formulate comments. This is obviously an inadequate time period in which to review a package of approximately 200 pages, which contains many proposals on a variety of complex matters which could substantially alter the potential impacts of the CTR.

We believe that the State Proposal is an integral part of the CTR; this belief is supported by the dozens of references to the future exercise of regulatory authority by the State of California scattered throughout the Preamble to the CTR (see, for instance, pp. 42173, 42174, and 42185, as well as numerous references in the Economic Analysis). The EPA even concedes (at p. 42188): "A more precise measure of costs and benefits may not be known until the State adopts its implementation provisions." In short, the CTR may have many significant impacts on the regulated community, the nature of which are dependent upon the contents of the State Proposal, and yet EPA is not willing to give the affected community the time to analyze and comment meaningfully upon the EPA rule, as proposed to be implemented by the State. This is, we believe, a violation of the Executive Order and the Unfunded Mandates Reform Act. We do not believe that EPA can justify its comment deadline by the requirement of Section 303(c)(4) to promulgate the final rule within 90 days after the proposal, since EPA has already signaled its Intention to take longer than 90 days to finalize the rule. EPA thus has no obvious reason to object to allowing additional time for review of the CTR nor has EPA offered any reasonable explanation for its lack of compliance with Executive Order 12866 and the Unfunded Mandates Reform Act.

Response to: CTR-035-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning the Great Lakes Initiative (GLI), the GLI was a much more complex rulemaking than the CTR. The GLI applied to eight states and promulgated water quality criteria and many implementation procedures. In contrast, the proposed CTR promulgated criteria for only one state and had only one implementation procedure - a compliance schedule provision. The proposed CTR was not substantially different from California's prior law or the National Toxics Rule. Although the GLI comment period may have been substantially longer, the complexity of the rule was much greater, warranting the longer time frame. EPA's usual comment period is 45 days; EPA extended this to over 50 days for the proposed CTR to ensure that a reasonable overlap of time existed with the comment period for the State's proposed implementation plan.

In response to the comment concerning Executive Order (E.O.) 12866 and the Unfunded Mandates Reform Act, each of which discusses comment periods for proposed rulemaking activities, see the preamble to the final rule. EPA believes that over 7 weeks to review and comment on this proposed straightforward and basic water quality rule was adequate, especially because this rule was not substantially different from California's prior law or the National Toxics Rule. Although E.O. 12866 states that in most cases, agencies should afford a comment period of not less than 60 days, in this case, EPA provided 52 days because it thought this period adequate (for reasons stated above) and because EPA had a statutory deadline to promulgate 90 days after proposal.

Comment ID: CTR-037-004
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: 4. EPA has not provided sufficient time to review and comment on all of the changes that it is making in various water quality criteria. Only 7 weeks were provided to comment on over 20 different criteria, when EPA is providing almost 9 weeks to comment on one criterion (TBT, Aug. 7 - Oct. 6, 1997). This magnitude of change requires at least a 180 day comment period. Therefore the comment period should be extended, at a minimum, to February 1, 1998.

Response to: CTR-037-004

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-038-001
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: 1. The deadline for submission of comments should be extended at least 60 days. This is necessary to allow a more detailed review of the rule and its impacts on the District, especially in light of the recent release of the Draft State Policy for Implementation of Toxics Standards.

Response to: CTR-038-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-041-001
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Sacramento Regional County Sanitation District (District) appreciates the opportunity to submit these comments on the proposed California Toxics Rule (CTR). The District provides wastewater treatment service to approximately one million people in the Sacramento metropolitan area. The Sacramento Regional Wastewater Treatment Plant (SRWTP) discharges approximately 160 million gallons per day of treated wastewater to the Sacramento River.

Our response has been limited due to the limited comment period. We are also concerned about not having time to analyze the CTR with the State Water Resources Control Board's draft policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California which was released on September 12. It is essential that sufficient time is provided to conduct a detailed review of the CTR and to assess its impact on the draft implementation policy by the State. As we have previously requested, the comment period should be extended.

Response to: CTR-041-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-043-001
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: Our comments on the proposed CTR are as follows:

1. The deadline for submission of comments should be extended at least 60 days. This is necessary to allow a more detailed review of the rule and its impacts on the City, especially in light of the recent release of the Draft State Policy for Implementation of Toxics Standards.

Response to: CTR-043-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-044-001
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: The City of Woodland appreciates the opportunity to submit these comments on the proposed California Toxics Rule (CTR). We would appreciate the opportunity to provide additional comments based on the draft implementation policy recently released by the State. This letter summarizes the comments based on our review to date.

Response to: CTR-044-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-044-002
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: We have reviewed the proposed CTR and offer the following comments:

1. The deadline for submission of comments should be extended at least 60 days. This is necessary to allow a more detailed review of the rule and its impacts on the City, especially in light of the recent release of the Draft State Policy for Implementation of Toxics Standards.

Response to: CTR-044-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-045-001
Comment Author: Sausalito-Marin Sanitary Dist.

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: It is requested that the comment period for the California Toxics Rule (CTR) be reopened. An additional sixty days would allow for a more complete review of the impacts on the District as well as facilitating a more complete review by the public. An extension would also enable a more complete review of the State Water Resources Control Board's Draft Implementation Policy, which is not taken into account in the following comments:

Response to: CTR-045-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-049-001
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: WateReuse believes that the designation of the relatively short comment period proposed of fifty days does not afford a comprehensive and complete public review of the rule. It is our opinion that should a decision be made to reopen and/or extend the public comment period on this subject, USEPA and the rulemaking process will benefit from the additional input of appropriate and valuable information. This would allow for, and include, a more thorough review and coordination of public comment with the lengthy Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California just released by the State Water Resources Control Board (SWRCB) on September 12, 1997. We therefore would request that the comment period for the draft CTR be reopened and/or extended to reflect the weight of this proposed rule, the impact it will have on all statewide stakeholders, and the need for better coordination of comments with the just released draft state plan.

Response to: CTR-049-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-052-001
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: The Authority acknowledges the importance of the CTR and the efforts that went into its creation. EPA has taken several years to prepare the CTR, yet has given the public only a 45 day period in which to develop comments. In addition, the State Water Resources Control Board issued its Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Implementation Plan) on September 12, 1997. The Authority received its copy on September 16, 1997. Thus there has been less than two weeks to review both documents to determine the potential impact on the Authority, its member agencies, and the public which they serve. On July 17, 1997, requested an extension of the public comment period, and that request was denied.

In the short time available to review the CTR and the EA, it has been determined that the CTR, as currently proposed, will have tremendous economic impacts on our ratepayers. In addition, it appears that the EA is so seriously flawed from both a cost and benefit perspective, that EPA's justification for promulgating the CTR is seriouslyquestioned. The CTR and the EA briefly discuss "relief options" for dischargers that will be available through the State. We have been so preoccupied with reviewing the CTR that there has been no opportunity to properly review the Implementation Plan. In view of the cost implications, more time is needed to provide adequate review time for the Implementation Plan as it relates to the CTR and the EA. Therefore, I again repeat my request for EPA to reopen the public comment period. It should be reopened through December 10, 1997 to coincide with the comment period for the Implementation Plan.

Response to: CTR-052-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-052-013
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Reopen the public comment period to coincide with the comment period for the State Implementation Plan, through at least December 10, 1997.

Response to: CTR-052-013

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-054-001
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: The comment period should be extended to 90 days. The rule is critical to California and it is essential that all parties have ample time to review it in detail and to assess its impact based on the draft implementation policy recently released by the State. There is no reason to rush the final version of the rule.

Response to: CTR-054-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-056-001
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: B Comment Period
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: First, like many other agencies submitting public comment, EBMUD requests that EPA give serious consideration to reopening the comment period for the CTR to provide affected dischargers sufficient time to conduct a thorough review of the proposed rule. This is especially of concern to the EBMUD in the context of having to also review the recently published, "Policy for Implementation of

Toxics Standards for Inland Surface Waters and Enclosed Bays, and Estuaries of California" and "Functional Equivalent Document" [September 11, 1997]. For POTWs, the only way to completely evaluate the regulatory and economic impacts of the CTR is to review both documents together. Because of the limited time in which to conduct such a review, and in recognition that EPA has provided extensions for past rulemaking (e.g. a 150-day comment period for the Great Lakes Initiative in 1993), this request is reasonable and will result in a more complete review by the public.

Response to: CTR-056-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035-001.

Comment ID: CTR-057-002
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: We also wish to emphasize the need for additional time to review the proposed Rule in light of the State Water Resources Control Board's (SWRCB) Draft Implementation Policy for Toxics Standards, which was released for general distribution less than two weeks ago. Because these proposed plans involve complicated issues that may significantly increase our treatment costs, and because we have not had sufficient time to review the State's draft document, we may submit additional comments based on further analysis of the CTR as it relates to the SWRCB's September 12, 1997 draft document.

Response to: CTR-057-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-058-002
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: We are also deeply concerned that EPA has given a relatively short comment period on this very lengthy and complex rulemaking. EPA has taken years to develop these rules. We see no reason for EPA's failure to grant an additional 30 days for comments on this important rule since the promulgation and implementation of this proposal is many months away, and considering that stakeholders have had only a few days to obtain and consider the state's implementation policy which is a parallel rulemaking.

Response to: CTR-058-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-059-003
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The Sanitation Districts would greatly appreciate additional time to review the proposed rule. As discussed above, the rule will clearly have significant impacts on our facilities and on the residents and businesses in our service area, as well as on numerous other POTWs and local governments in California. While EPA has minimized the significance of the rule in its analysis, the bottom line is that the rule will promulgate some 190 water quality criteria for California for about 70 different pollutants. While a few of these criteria have previously been promulgated by EPA through the 1992 National Toxics Rule (NTR), approximately 70 of them have been recalculated, modified, or added by EPA since the 1992 NTR, To adequately review these changes requires a great deal of time and effort, especially since only a few of the changes are discussed in the Preamble and many of the supporting documents cannot be readily accessed outside of EPA. Therefore, the Sanitation Districts respectfully request that EPA provide at least 30 additional days for public review and comment.

Response to: CTR-059-003

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning records, a complete record of supporting documents is available at the U.S. EPA Region 9 office in San Francisco, and many of the important documents are available at the U.S. EPA Headquarters Office in Washington, D.C. The availability of these documents was published on the first page of the preamble to the proposed CTR.

Comment ID: CTR-061-004
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: While I do not know how long it would take the US EPA to conduct the required analyses of the urban stormwater runoff costs and real water quality benefits, it would seem appropriate that taking a few months to accomplish this could, in the long term, represent a time and resource savings in terms of ultimately correcting the significant technical problems that exist today in regulating urban stormwater runoff. I recommend the following:

Urban stormwater dischargers as well as other interested parties should be provided a several-month period during which a preliminary assessment of the potential costs and water quality benefits associated with having to meet CTR criteria as standards in the receiving waters for stormwater runoff of concern to the discharger, is conducted and reported to US EPA Region 9.

The US EPA should take several months to develop an amended draft CTR that provides a reliable economic analysis of costs and potential benefits covering the current regulatory approach for regulating chemical constituents urban stormwater runoff which involves a ratcheting down of BMPS to achieve the ultimate goal of only one exceedance of a water quality standard every three years in the receiving waters for stormwater runoff.

The public should be given a two-month period during which to review and comment on the adequacy of the US EPA's economic analysis of costs and benefits of achieving the currently mandated goal of using CTR criteria as standards for receiving waters for regulated urban stormwater runoff.

Adoption of this approach will send a clear signal to the public that the US EPA is finally willing to meaningfully address the heart of the urban wet-weather runoff water quality management problem. With the Agency's, for the first time, reliably developing information on costs and true water quality benefits, the public, Congress, regulators and the regulated will begin to understand the need to change how urban and highway stormwater runoff is regulated to protect the designated beneficial uses of waterbodies without significant unnecessary expenditures for chemical constituent control.

Response to: CTR-061-004

See response to CTR-013-003.

Comment ID: CTR-065-001
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Environmental Health Coalition (EHC) has not yet fully reviewed the proposed California Toxics Rule (CTR). We were unable to successfully download the document and therefore have not been able to conduct a full- review on the proposed rule in time to meet the comment period deadline. We request additional time to-comment but will make our comments based on limited review today.

Response to: CTR-065-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-066-001
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The District has done its best to stay up-to-date on happenings surrounding the CTR and have attempted to complete our review of the proposed rulemaking. However, given the nature of this rulemaking and the companion pieces currently being pursued by the State Water Resources Control Board, it is practically impossible for us to give you anything more than preliminary comments on the CTR. Extensive work has been done by your agency to fill the void left by the litigation that overturned the State Board's rulemaking, and that has resulted in a significant period of time for both your staff and others to complete this rulemaking. It is our belief that you should allow adequate time for medium-sized agencies such as ours to be able to hire consultants or other technical professionals to assist us in this very important rulemaking. In addition, the information related to the economic analysis associated with this is difficult at best and we have not been able to hire anyone to assist us in completing our evaluation. Consequently, we would request a significant extension of either 90 or 150 days to allow us to complete our analysis. We will also be preparing our NPDES permit renewal request in the next six months and expect that many of the issues that will come out of our review of the CTR will relate directly to our activities on the permit. As a consequence, we would request that this extension in time be allowed for all agencies in the state.

The District fully supports EPA and the State Water Resources Control Board (SWRCB) program to promulgate both the criteria and statewide Implementation Policies in the collaborative manner currently being approached. However, because of the late release of the Implementation Policy by the state, we are not able to have reviewed both that policy and the CTR for conformance and detail. We have only had a short 14 days to complete this analysis and that just has not been adequate to complete the response. We believe that the state's comment period lasting until December, 1997, is far more equitable and reasonable given the substantial nature of the criteria being established. We would further request that EPA and SWRCB give serious consideration to establishing a blue ribbon technical committee to assist with this collaborative effort so that concerns and needs of the regulated community can be thoroughly considered so that there will be broad public acceptance of the results of this most important work.

Response to: CTR-066-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning the blue ribbon technical committee, the State, during its redrafting process of the implementation plan, convened numerous task force groups with a number of different stakeholder representatives on each task force, to solicit comments and ideas concerning the issues. EPA was fully represented on each task force, and listened to all comments concerning the State's water quality control plans. EPA hopes the commenter had the opportunity to participate in these task force groups.

Comment ID: CTR-067-001
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Having just completed such a costly time consuming project, OVSD requests that EPA extend the comment period on the CTR. Allowing an extended comment period would provide for a more thorough review of the proposed rule and supporting documentation, and allow OVSD .adequate time to develop specific comments on the rule relative to its impact on our new treatment plant and our residents. In addition, an extended comment period would allow EPA the opportunity to work more closely with the State Water Resources Control Board (SWRCB) in developing simultaneous comment periods and joint final promulgation, since EPA acknowledges that the impacts of the CTR criteria depend greatly on the State's approach to implementation. This would provide the added benefit that a more streamlined and effective CTR and Statewide Implementation Policy be developed, potentially reducing the resistance by dischargers upon promulgation and implementation. Thus, OVSD asks that EPA extend the comment period until December 10, 1997, the SWRCB's public comment deadline, or at a minimum, for 30 (thirty) days.

Response to: CTR-067-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-068-001
Comment Author: California Chamber of Commerce
Document Type: Industry Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:

Attachments? N
CROSS REFERENCES

Comment: We find ourselves in a quandary over the timeline for commenting on this proposed rulemaking package. The Environmental Protection Agency is allowing only 50 days for public comment on a proposal whose complexity really warrants more time. A public comment period spanning the summer months further exacerbates the situation by ensuring that only a minimal staff would be available to review the proposal.

We are further concerned that our members have had virtually no time to obtain the state's proposed implementation policy, which is parallel rulemaking to this one, as it has just been released for public review. Given the potential enormous impacts of this rulemaking, it is not unreasonable to suggest extending the deadline for comments.

The California Chamber of Commerce, on behalf of its members, requests that you consider extending the deadline for comments for at least another 30 days and preferably 60 days to accommodate the business community's concerns on this important package.

Response to: CTR-068-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment that since the comment period spanned the summer months which exacerbated the situation since minimal staff were available, EPA had no intention of proposing during aninconvenient time period. This was the time period after which the Agency obtained it internal administrative and OMB approval to propose the rule. EPA notes that the comment period ran through September 26, 1997, a month in which most people have returned from summer vacations.

Comment ID: CTR-069-001
Comment Author: CA Bus Prop Ass & Bldg Ind Ass
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: In light of the recent release of the State Water Resources Control Board Proposed Policy for Implementation of Toxic Standards for Inland Surface Waters, Fnclosed Bays, and Estuaries of California, CBIA and CBPA request that EPA extend the comment period on its proposed rule for at least an additional 30 days in order for CBIA and CBPA to analyze the proposed rule in relation to the state's proposed implementation policy. Of primary concern to CBIA and CBPA is how the proposed rule in concert with the state's proposed implementation policy will affect the construction stormwater permit process.

Response to: CTR-069-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-070-001
Comment Author: Sewerage Agency of Sthrn Marin
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: B Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: Request to extend comment period Initial review indicates that the proposed rule will have a significant impact on SASM. An additional 60 days is requested to allow for a complete review. Extension of the comment period will also help to facilitate a more complete review of the companion State Water Resources Control Board's Draft implementation Policy.

Response to: CTR-070-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-081-001
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: * The WCA strongly requests that the comment period be extended or reopened. This is appropriate to facilitate a more complete review by the public, particularly other POTWs. In addition, our agency needs additional time to review SWRCB's State Implementation Policy before the full impact of the CTR can be estimated. It is our understanding that a 90-day comment period is common. We recommend the comment period be extended to 90 days.

Response to: CTR-081-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-082-001
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Even though the EPA is not obligated to provide more than 30 days for public comment, it has been common practice for the agency to provide comment periods of 90 days or longer for significant rules. As an example, your agency provided a 150 day comment period for Great Lakes Initiative in 1993.

* The request for extension of the comment period for this rule is really necessary and justified to facilitate a complete review of the State Water Resources Control Board's (SWRCB's) Draft Implementation Policy which was released on September 12, 1997. As the USEPA and STWRCB are simultaneously promulgating the CTR and Criteria and Statewide Implementation Policy, the POTW's did not have adequate time to review the CTR, State Implementation Policy and supporting discussion which are quite lengthy and voluminous. As a result any comments we have, by and large don't take into account the draft implementation policy.

Response to: CTR-082-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035-001.

Comment ID: CTR-083-001
Comment Author: Fairfield-Suisun Sewer Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References: Letter CTR-083 incorporates by reference letters CTR-035 and CTR-054
Attachments? N
CROSS REFERENCES

Comment: The District believes that Region IX has been remiss in its failure to allow sufficient time to comment on this complex regulation. By adhering to minimum legal requirements and denying

additional time for review and comment, Region IX will not benefit from a comprehensive review by affected parties that could lead to a more effective regulation.

Response to: CTR-083-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-085-001
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The District is an active member of both the California Association of Sanitation Agencies (CASA) and the Southern California Alliance of Publicly Operated Treatment Works (SCAP) and vAH be reiterating several of the comments of these organizations on the California Toxics Rule, which the District fully supports:

The District requests that the EPA reopen the comment period for the proposed California Toxics Rule in order to facilitate a more complete review by the public and in particular, by those in the Publicly Operated Treatment Works (POTW) community. While the District realizes that the EPA is not obligated to provide more than 30-days for public comments, the Agency has provided comment periods of 90 days or longer for significant rules. For example, the EPA provided a 150-day comment period for the Great Lakes Initiative in 1993.

Response to: CTR-085-001

In response to the first comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035-001.

Comment ID: CTR-085-002
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The District is an active member of both the California Association of Sanitation Agencies (CASA) and the Southern California Alliance of Publicly Operated Treatment Works (SCAP) and vAH be reiterating several of the comments of these organizations on the California Toxics Rule, which the District fully supports:

The District also believes that an extension of the comment period is justified to facilitate a more complete review of the State Water Resources Control Board's (SWRCB) Draft Implementation Policy, which was released on September 12, 1997. It is the District's understanding that the EPA and the SWRCB are promulgating the criteria and statewide implementation policies in a collaborative manner and the extension would allow for more complete review of and comments on the California Toxics Rule, the Implementation Policy and supporting documents.

Response to: CTR-085-002

In response to the second comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-089-002
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Adequacy of the 30-Day Public Comment Period

The CTR is a major revision of the regulations governing the discharge of toxic pollutants throughout the state. While not required by law, we respectfully request that the USEPA extend the draftt CTR public comment period to at least 90 days. We believe this is justified and necessary given the scope, length, and technical content of the proposed regulations. In particular, due to the limited time to review these regulations, we were unable to closely examine the proposed State Implementation Policy (SIP), which provides detailed guidance to the state's Regional Water Quality Control Boards, which must enforce these new regulations.

SUMMARY

We hope these comments will help to make the final CTR a better document and a better law. Overall, the draft CTR reflects substantial thought and effort on how best to implement the Clean Water Act's mandate of reducing pollutant discharges to the nation's receiving waters. The draft CTR clearly advances this goal, but our hope is that those agencies and parties most-directly affected by it will be

allowed additional time to review it to their satisfaction. We strongly encourage a more detailed assessment of the actual economic impacts that could result from these new regulations. The ability of public utilities to fund new projects has never been louver, and every rate increase requires sound and well-founded justification. No ratepayer should be asked to shoulder the cost of new regulations without a clear and detailed explanation of what it is going to cost, and what benefits will result. State mandated costs require state funding.

We appreciate this opportunity to comment on the draft California Toxics Rule. Please do not hesitate call myself or Dr. Randal Orton in our Resource Conservation and Public Outreach Department to tell us how we can help you further.

Response to: CTR-089-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-090-001
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: The proposed rule and the accompanying economic analysis contain a significant amount of highly technical and complex information. We appreciate the time and effort that went into this proposal. However, we are extremely disappointed that EPA is unwilling to allow a longer review time, especially considering the delay in releasing the State Implementation Policy. We join other who have already requested an extension of the comment period.

Response to: CTR-090-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035 -001.

Comment ID: CTR-094-001
Comment Author: SAIC
Document Type: Engineering Firm
State of Origin: CA
Represented Org:
Document Date: 09/30/97
Subject Matter Code: B Comment Period
References:
Attachments? N

CROSS REFERENCES

Comment: SAIC has reviewed the draft rule proposing water quality criteria for toxic pollutants for California (California Toxics Rule) that was published in the Federal Register on August 5, 1997 and believe that the breadth and complexity of the draft CFR and the accompanying economic impact analysis warrant an extension of the comment period for an additional 30 days.

SAIC is a diversified, scientific, engineering, research, and development company that provides technical and management services and products to private industry and the Federal government. SAIC was organized in 1969 to apply the techniques successfully employed in high technology areas to major national and international programs. Over the past 28 years, SAIC's team of professionals has grown from a handful to more than 22,000 employees throughout 250 locations in the United States and abroad.

SAIC is making this request to ensure that sufficient time is available to the public to coordinate the review of the CFR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by the US EPA and partially developed by the State in 303 (c)(2)(b) of the Clean Water Act.

If you have any questions, please call me at 650-604-0924. Thank you for your consideration of our request.

Response to: CTR-094-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTR-096-005
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

5. Additional time is needed to assess the specific impacts that the proposed Rule will have on the City of Modesto system.

Specifically, the City submits the following comments:

H. Although Modesto's wastewater treatment system and storm water disposal system is not entirely

unique to most Central Valley communities, it is one of the more complex systems in the state. It is among the top 20 in size in a state with nearly 500 POTWs. In order to best evaluate the effect of The California Toxics Rule on Modesto, additional comment time is needed. Also, more time is needed to facilitate a more complete review of the State Water Resources Control Board's (SWRCB) draft implementation policy, which was released September 12, 1997. By and large, these comments do not take into account the draft implementation policy of the SWRCB.

Response to: CTR-096-005

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-001-001a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 07/21/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES V

Comment: We are writing to you on behalf of Tri-TAC and the California Association of Sanitation Agencies regarding the forthcoming publication of the proposed Water Quality Standards for Toxic Pollutants for California ("California Toxics Rule") and release of draft state implementation policies and functional equivalent document. As you are aware, Tri-TAC and CASA have supported the decisions of the U.S. Environmental Protection Agency (EPA) and the State Water Resources Control Board (SWRCB) to eliminate duplication in state and federal water quality rulemaking activities through the pursuit of a collaborative approach. Our understanding is that, through this approach, EPA will adopt water quality criteria for toxic pollutants that will apply in California and the SWRCB will adopt implementation policies that will guide the Regional Water Quality Control Boards in the implementation of those criteria. In a later phase, the SWRCB intends to adopt state criteria that will replace the federal criteria.

We have been informed recently by EPA staff that publication of the draft California Toxics Rule is imminent and is expected to take place by the end of July. According to staff, a 50-day public comment period will be provided. We have heard from SWRCB staff that they plan to release the proposed state implementation policies and FED on September 12. We have asked each agency to provide an overlapping comment period for these draft regulations, and have been informed that the current schedule will provide about one week of overlap, assuming that both agencies release their drafts on schedule. We are quite concerned about this situation in several respects. First, we believe that a one-week overlap does not provide sufficient time for a meaningful review and comparison of the regulations (and comparative analysis of the economic impact analyses, which depend heavily on the implementation policies). We believe that a minimum of 30 days is necessary for the overlap review period, and that the slight delay that this would create for EPA is warranted and would have a negligible impact on the timing of the overall rule promulgation process. Second, we are very concerned about whether the SWRCB will meet its projected release schedule. While we believe that sufficient time has been available to prepare

the draft policies and FED, it is imperative that the SWRCB do everything possible to meet its commitment to move forward in a timely manner, and that any extension of EPA's comment period not be used to adjust the state's schedule. Third, we understand that both EPA and the SWRCB plan to hold public hearings regarding their respective proposals this fall. We believe that it is important that representatives of both agencies attend and participate in the hearings that each agency holds, and that an explanation be provided regarding both the CTR and the implementation policy.

In short, we request that EPA and the SWRCB carefully review their efforts to coordinate both the development and release of the California Toxics Rule and State implementation Policies, and specifically, we request that EPA provide a comment period sufficient to ensure that a 30-day overlap will occur with the SWRCB's release of the FED for the State Implementation Policies. More generally, we hope that both agencies will offer flexibility in the promulgation process so that the various scheduling and review needs can be met. We hope that your respective agencies will continue to move forward with a collaborative rulemaking process, and are concerned that cooperation not break down due to institutional barriers at this point in the process.

Thank you for your consideration of our comments. We would be happy to discuss these issues further at your convenience.

Response to: CTRE-001-001a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning the coordination of public hearings, the State was invited to speak about its proposed implementation plan at EPA's public hearings on the CTR. Although they did not make any formal presentation, they were available to answer questions and in fact did answer questions posed to them concerning the implementation policy.

Comment ID: CTRE-001-002
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 07/21/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing on behalf of Tri-TAC and the California Association of Sanitation Auencies (CASA), which are California-based organizations comprised of members from public agencies responsible for wastewater treatment. Tri-TAC is an advisory group which includes representatives from CASA, the California Water Environment Association, and the League of California Cities. CASA is comprised of over 85 agencies responsible for the operation of publicly owned treatment works (POTWs). The constituency base for Tri-TAC and CASA encompasses most of the sewered population of California. Representatives of CASA and Tri-TAC have met with EPA staff over the past several years to discuss the development of the proposed rule, and appreciate the Agency's efforts to inform the regulated community about the pending regulation.

We have reviewed the draft rule proposing water quality criteria for toxic pollutants for California ("California Toxics Rule" or "CTR") that was published in the Federal Register on August 5, 1997 and believe that the breadth and complexity of the draft CTR and the accompanying economic impact analysis warrant an extension of the comment period for an additional 30 days. In particular, we are making this request to ensure that sufficient time is available to the public to coordinate the review of the CTR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria which is scheduled to be released September 12, 1997. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by EPA and partially developed by the State in order to achieve full compliance with Section 303(c)(2)(b) of the Clean Water Act.

I would appreciate it if you would notify me at the above address of your decision. Thank you very much for your consideration of our request.

Response to: CTRE-001-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-002-001
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I wish to follow up on yesterday afternoon's US EPA Region 9 hearing on the draft California Toxics Rule (CTR) criteria to reinforce the comments made by a number of urban stormwater dischargers about the need to extend the deadline for receipt of written comments. I have been involved in water quality criteria development and implementation since the mid-1960s where I have worked with federal, state and local governmental agencies and/or the regulated community. I find that it would be a serious error on the part of US EPA Region 9 and US EPA headquarters to proceed with the September 26, 1997 deadline for receipt of written comments on the CTR. There are many reasons for providing at least a 30- to 45-day extension of the date by which the written comments should be received. These include the fact that it took the USEPA Region 9 several years to develop the Califoniia Toxics Rule criteria beyond when they were due. To now not grant politically important entities, such as the major urban stormwater dischargers, adequate time to develop the information that needs to be developed and that should have been developed by the US EPA Region 9 as part of promulgating the draft California Toxics Rule would, in my opinion, be viewed as extremely short-sighted on the part of US EPA Region 9 and US EPA headquarters.

Response to: CTRE-002-001

In response to the comment requesting an extension of the comment period, please refer to response to

CTR-001-001.

Comment ID: CTRE-002-005
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: As I testified at yesterday's hearing, the issue of urban stormwater runoff water quality management is in chaos. This situation has been well understood for at least five years. While attempts are being made to address these issues through the US EPA headquarters' various wet weather committees, thus far the fudainental issue that was raised yesterday at the hearing by urban stormwater discharger after discharger has not been adequately addressed, i.e. ultimately having to achieve water quality standards based on CTR criteria in the receiving waters for the discharge through ever-increasingly more stringent BMPS. While the proposed CTR does not specify a time period over which the BMP ratcheting-down process will occur, there can be no doubt that this time period will be set by the courts through litigation brought by envirorunental groups who will assert that an NPDES-permitted stormwater discharger is not making adequate progress toward achieving the ultimate goal of only one violation of a water quality standard every three years for regulated constituents. Because of the uncertainty of how the courts will handle this matter, stormwater dischargers could be faced with having to achieve water quality standards in the discharge waters within five to ten years. Clearly there is need to understand the cost and benefits associated with achieving these standards as part of adopting the CTR as it is applied in regulating urban stormwater runoff water quality.

As part of my comments on the significant technical deficiencies in the CTR as drafted, I will be providing a discussion of technical back-up to these issues from the published literature. Many of my papers and reports on this topic are available from my web site (http://members.aol.com/ gfredlee/gfl.htm).

It is my recommendation that US EPA Region 9 and US EPA headquarters should postpone any adoption of the California Toxics Rule until the US EPA properly presents and discusses the potential costs and the potential benefits in terms ofreal improvements in designated beneficial uses of receiving waters that will likely accrue as the result of regulated urban stormwater discharges ultimately having to comply with water quality standards based on CTR criteria. The US EPA Region 9 should allow the starmwater dischargers tlte opportunity to provide information on the cost and benefits arising from applying these criteria to stormwater discharges as required by the Clean Water Act when it becomes clear that BMPs of the type that are readily available today win not eliminate the administrative exceedances ofwater quality standards numerically equal to the aquatic life criteria set forth in the. CTR. After allowing the urban stormwater dischargers to provide this information, the US EPA then, in turn, should develop an economic analysis that rcliably presents and discusses these issues. As I testified, this process is the necessary first step to correcting the significant chaos that now exists in the urban stormwater runoff water quality management field.

While I do not know how long it would take the US EPA to conduct the required analyses of the urban stormwater runoff costs and real water quality benefits, it would seem appropriate that taking a few months to accomplish this could in the long term represent a time and resource saving in terms of ultimately correcting the sigiifflcant technical problems that exist today in regulating urban stomlwater runoff.

I recommend the Following:

* Urban stormwater dischargers as well as other interested parties should be provided a several-month period during which preliminary assessment of the potential costs and water quality benefits associated with having to meet CTR criteria as standards in the receiving waters for stormwater runoff of concern to the discharger is conducted and reported to US EPA Region 9.

* The US EPA should take several months to develop an amended draft CTR that provides a reliable economic analysis and the potential benefits covering the current regulatory approach for regulating chemical constituents in urban stormwater runoff which involves a ratcheting down of BMPs to achieve the ultimate goal of only one exceedance of a water quality standard every three years in the receiving waters for stormwater runoff.

* The public sould be given a two-month period upon which to review and comment on the adequacy ofthe US EPA's economic analysis of costs and benefits of achieving the currently mandated goal of using CTR criteria as standards for receiving waters for regulated urban stormwater runoff.

Adoption of this approach will send a clear signal to the public that the US EPA is finally willing to meaningful address the heart of the urban wet weather problem. With the Agency for the first time reliably developing information on costs and true water quality benefits, the public, Congress, regulators and the regulated will begin to understand the need to change how urban and highway stormwater runoff is regulated to protect the designated beneficial uses of waterbodies without significant unnecessary expenditures for chemical constituent control.

If you have questions on these conunents, please contact me. I hope that those who control US EPA Region 9 activities associated with CTR development will address the highly significant deficiencies that exist now in how US EPA Region 9 and US EPA headquarters developed the draft CTR relative to urban stormwater runoff water quality issues. If I can be of assistance in this matter, please contact me.

Response to: CTRE-002-005

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous

discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-040-004.

For analysis of the final CTR, EPA updated its Economic Analysis to reflect the most recent data and information for each sample facility and also increased the sample size for minor facilities. Based on this revised analysis, EPA estimated that minor POTWs will incur costs of approximately $5,000 per facility per year under the low cost scenario and $7,800 per facility per year under the high cost scenario. See also response to CTR-058-018.

Comment ID: CTRE-003-001a
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/09/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES J
R

Comment: The Bay Planning Coalition represents approximately 200 maritime industry, shoreline businesses, local governments and Bay users along the S.F. Bay shoreline and is most significantly affected by the proposed California Toxics Rule. One of our primary interests is the economic analysis which under the EPA's model estimates a range of annual costs of $14.9 to $86.6 million.

We believe the annual costs for implementation of the Rule statewide exceed the EPA estimate range. We are particularly concerned because it appears that the economic impact analysis did not include the costs of compliance for the NPDES stormwater permit applicants. In order for us to provide EPA with sufficient detail on our economic analysis and cost projection as well as the impact of the Rule on small business under the Regtory Flexibility Act, we request an extension of time to respond. A 30-day extension from September 26 to October 27, 1997 would be acceptable. Thank you so much for your consideration.

Response to: CTRE-003-001a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment concerning the Regulatory Flexibility Act, the proposed CTR did not itself establish any requirements that were applicable to small entities, and thus, the EPA Administrator certified that the proposed rule would not have a significant economic impact on a substantial number of small entities. The final CTR likewise did not establish any requirements that were applicable to small entities and thus, the EPA Administrator certified that the regulation would not have a significant economic impact on a substantial number of small entities. Thus, no initial regulatory flexibility analysis was conducted.

Comment ID: CTRE-003-001b
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/09/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES B
R

Comment: The Bay Planning Coalition represents approximately 200 maritime industry, shoreline businesses, local governments and Bay users along the S.F. Bay shoreline and is most significantly affected by the proposed California Toxics Rule. One of our primary interests is the economic analysis which under the EPA's model estimates a range of annual costs of $14.9 to $86.6 million.

We believe the annual costs for implementation of the Rule statewide exceed the EPA estimate range. We are particularly concerned because it appears that the economic impact analysis did not include the costs of compliance for the NPDES stormwater permit applicants. In order for us to provide EPA with sufficient detail on our economic analysis and cost projection as well as the impact of the Rule on small business under the Regtory Flexibility Act, we request an extension of time to respond. A 30-day extension from September 26 to October 27, 1997 would be acceptable. Thank you so much for your consideration.

Response to: CTRE-003-001b

EPA's EA, which uses many conservative costing assumptions, indicates that the cost of the State implementing water quality standards based on the proposed criteria in the CTR is likely to be below $100 million per year. Benefits are also estimated to be below $100 million per year. These estimates indicate that the action is not "significant" under E.O. 12866, under the provision concerning annual effects on the economy.

Criteria, by themselves, do not directly impose economic impacts. Criteria are one of three parts of a water quality standard. A water quality standard is comprised of: a criterion, a designated use, and an antidegradation requirement. The CTR promulgates criteria for priority toxic pollutants. When these criteria are combined with State adopted designated uses and antidegradation requirements, water quality standards will be created. When the State implements these water quality standards, costs may be imposed. However, in the spirit of the intent of E.O. 12866, EPA prepared the EA which looks at the costs and benefits of the State's implementation of the resulting water quality standards based on the CTR criteria into the NPDES permit program.

The Unfunded Mandates Reform Act of 1995 (UMRA) in general requires federal agencies to assess the effects of their regulatory actions on State and local governments, and on the private sector. The agency must prepare a written statement including a cost-benefit analysis for actions with a "federal mandate" that may result in expenditures to State and local governments, in the aggregate, or to the private sector of $100 million or more in any one year. The CTR does not contain any federal mandate that may result in expenditures by State and local governments, or the private sector, of $100 million or more in any one

year. The CTR imposes no direct enforceable duties on the State, local or private sector; rather the rule promulgates water quality criteria which, when combined with State-adopted designated uses and antidegradation requirements, will create water quality standards. The CTR does not directly regulate or affect any entity and therefore is not subject to the requirements of UMRA.

The Regulatory Flexibility Act in general requires federal agencies to describe the impact of their regulatory actions on small entities as part of the rulemaking. If the Administrator certifies that the action will not have a significant economic impact on a substantial number small entities, the agency is not required to prepare the analysis. The Administrator certified in the proposed rule, and is certifying again today that the rule will not have a significant economic impact on a substantial number of small entities. EPA's promulgation of water quality criteria will assist the State in establishing water quality standards. The State will, in turn, implement the resulting water quality standards in its water quality regulatory programs such as the NPDES permit program. The State has discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet those standards. While the State's implementation of water quality standards based on federally-promulgated criteria may result in new or revised discharge limits being placed on small entities, the criteria or standards themselves to not apply to any discharger, including small entities. Thus, EPA's action today does not impose any of these as yet unknown requirements on small entities.

See also response to CTR-044-045.

Comment ID: CTRE-004-001a
Comment Author: Victor Valley Wastewater Auth.
Document Type:
State of Origin: CA
Represented Org:
Document Date: 09/11/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES G-08

Comment: The Victor Valley Wastewater Reclamation Authority (VVWRA) respectfully requests that the comment period deadline be extended for the California Toxics Rule (CTR). The current comment period deadline is September 26, 1997. We request that the latter deadline be extended for at least 60 days so that we can fully evaluate the potential impact on VVWRA

The reasons for our request are as follows:

1. VVWRA discharges to the Mojave River, which is considered by the Lahontan RWQCB as an impaired waterway. Although portions of the Mojave exhibit year-round surface flow, the River directly above VVWRA does not exhibit consistent surface flow. However, the Lahontan RWQCB considers the Mojave an underflow stream, which is often considered as surface flow. Whether an underflow stream would be considered under the CTR for receiving stream dilution has yet to be determined;

2. It is difficult if not impossible to evaluate the impacts of a proposed regulation without considering the mechanism by which it will be implemented. The SWRCB is not expected to release the

implementation plan until September 12, 1997. Therefore, VVWRA takes exception to the imposition of a regulation with an undefined implementation plan;

3. Because of the latter unknowns and the complexity of the regulation V has not had sufficient time to evaluate the potential economic impacts, if any, of the proposed regulation.

Response to: CTRE-004-001a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-005-001
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/10/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Western States Petroleum Association (WSPA) is a trade association, which represents a majority of the petroleum-related interests in the western United States. These interests include production, transportation, refining, and marketing of petroleum and petroleum based products. WSPA appreciates to opportunity to provide comments on the proposed rule regarding "Water Quality Criteria For Toxic Pollutants For California." Upon review, it has become clear that the limited time available for preparing meaningful comments is too short. This is a significant and complex rule development, which will impact our operations. We therefore, would like to request an additional 30 days to review the proposal and provide written comments. These concerns over timing are worsened by the anticipated September 12, 1997, release of the State of California's proposed implementation policies for the criteria. Due to their inter-relationship, it is important that interested parties be given the opportunity to review both of these proposals together.

Response to: CTRE-005-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-006-001
Comment Author: County of Los Angeles
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/19/97
Subject Matter Code: B Comment Period
References:

Attachments? N
CROSS REFERENCES

Comment: I am writing on behalf of the Sanitation Districts of Los Angeles County regarding the public comment period for the Proposed Rule Regarding Water Quality Criteria for Toxic Pollutants for California, which was published in the Federal Register on August 5, 1997. As noted in the Federal Register notice, the public comment period is scheduled to close on September 26, 1997. The Sanitation Districts requests that EPA extend the comment period for 30 days from that date.

We have reviewed the draft rule, and believe that its importance and complexity warrant an in-depth review, including an assessment of the rule's impacts on the seven water reclamation plants owned and operated by the Districts that will be affected by the rule. In addition, we believe that an extra 30 days is necessary to enable us to review the State of California's anticipated proposal of implementation policies for the criteria, which is not expected to be released until mid-September. As has been discussed with your staff and State Water Resources Control Board staff, we believe that a sufficient overlapping review period is necessary to fiilly implement the collaborative process embarked upon by EPA and the SWRCB last year.

Response to: CTRE-006-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-007-001
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 08/11/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing on behalf of the Souther California Alliance of Publically Owned Treatment Works (SCAP) to request an extension of the comment period for the proposed rule regarding water quality criteria for toxic pollutants for California (the California Toxics Rule) for 30 days. SCAP is a non-profit organization formed in 1992 to provide a common voice for the Southern California community of municipal nwastewater treatment agencies in expressing our interest in promotng reasonable regulations that are in the public's best interest. We have forty-six member agencias serving a combined population of over 10 million people.

CAP has reviewed the draft rule and believes that an extension of the comment period for an additional 30 days is warranted to ensure that sufficient time is available to review the changes made in the water quality criteria in the CTR from the National Toxics Rule, which was promulgated several years ago. In addition, the extension is necessary to provide sufficient overlap for a meaningful review and comparison of the proposed regulations and the State Water Resources Control Board's draft policies regarding the implementation of the CTR. We understand that the State plans to release proposed policies and draft

Functional Equivalent Document on September 12, 1997. We believe that our comments on the CTR will be more informed if there is an adequate opportunity to review the State's proposal before the close of the federal comment period. Therefore, we request that the comment period be extended until at least October 27, 1997.

Response to: CTRE-007-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the comment that additional time was necessary to review the changes in criteria values from the National Toxics Rule (NTR), EPA provided a table in the preamble to the proposed CTR which outlined all the changes in aquatic life numbers from the NTR. The text that followed explained the changes in detail. EPA believes that the comment period was sufficient time within which to review and comment on these changes from the NTR.

Comment ID: CTRE-008-001
Comment Author: Cupertino Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Cupertino Sanitary District is a wastewater collection agency which transports approximately 4.5 MGD of wastewater to the San Jose/Santa Clara Water Pollution Control Plant. The San Jose/Santa Clara Water Pollution Control Plant is a regional treatment facility capable of treating 167 MGD. The staff at the plant have begun a review of the draft rule for toxic pollutants for California, as published August 5, 1997, in the Federal Register. The complexity of the document, however, and the need to compare our plant's assessment with other wastewater agencies, leads me to ask for a 30-day extension of the comment period. This additional time will allow for a concurrent evaluation of the state's implementation policies for the numeric criteria.

Thank you very much for considering this request.

Response to: CTRE-008-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-009-001
Comment Author: Dublin San Ramon Services Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/15/97

Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Dublin San Ramon Services District treats wastewater from a population of 100,000 residents of the East San Francisco Bay area. We have begun our review of the draft rule for toxic pollutants for California as published August 5, 1997, in the Federal Register. The complexity of the document, its importance to our future operation and our need to compare our assessment with other wastewater agencies leads me to ask for an extension of the comment period through say October 26, 1997, a 30 day extension. This would allow us to concurrently evaluate the state's implementation policies for the numeric criteria.

Thank you for considering this request.

Response to: CTRE-009-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-010-001
Comment Author: Moulton Niguel Water District
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 08/15/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Moulton Niguel Water District is aware that the California Toxics Rule (CTR) has been published in the Federal Register and the comment period for it is scheduled to close on September 26, 1997. Public hearings have also been scheduled for September 17 and 18 in San Francisco and Los Angeles.

We are concerned with the time allowed to review this complex issue and are requesting your office to extend the review period by 30 days. We are aware that a similar request has been made by the California Association of Sanitation Agencies (CASA) and Tri-TAC and we also support their position.

Response to: CTRE-010-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035-001.

Comment ID: CTRE-011-001

Comment Author: County of Orange
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/15/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The County Sanitation Districts of Orange County, California (Districts) operates the third largest wastewater agency west of the Mississippi River, having the responsibility for collecting and safely treating wastewater for 2.1 million residents and businesses in metropolitan Orange County. We are members of the California Association of Sanitation Agencies (CASA) and Tri-TAC (an advisory group for CASA, California Water Environment Association, and the League of California Cities), and through these groups we have met with EPA staff to discuss the development of the proposed rule.

We appreciate the Agency's efforts to inform the regulated community about the pending regulation, however, we believe the complexity of the draft "California Toxics Rule" that was published in the Federal Register on August 5,1997 and the accompanying economic impact analysis warrant an extension of the comment period for an additional 30 days. We are making this request to ensure that sufficient time is available to the public to coordinate the review of the "California Toxics Rule" with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. This overlapping comment period will provide the interested parties the opportunity to understand the contents and implications of the regulations, which are being partially adopted by EPA and partially developed by the State in order to achieve full compliance with Section 303(c)(2)(b) of the Clean Water Act.

Should you have any questions regarding this request for extension, please call Nancy J. Wheatley, Director of Technical Services, or me at (714) 962-2411.

Response to: CTRE-011-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-012-001
Comment Author: CA Council Env & Econ Balance
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/09/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The California Council for Environmental and Economic Balance (CCEEB) has been advised

that the State Water Resources Control Board (SWRCB) staff is planning to release the proposed State Implementation Policies on September 12, 1997. Since the release of these policies may indeed have an effect on the proposed California Toxics Rule, the Council is concerned that there may not be sufficient time provided for comment prior to the release of these policies.

At this time, we would like to request that EPA provide a comment period of the draft California Toxics Rule sufficient to ensure that adequate time is given prior to release of the State Implementation Policies.

Furthermore, we trust that EPA and SWRCB will be flexible in the promulgation process in order that everyone's scheduling and review needs can be met.

Response to: CTRE-012-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-013-001
Comment Author: Calaveras County Water Dist.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 08/15/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Concern has been raised by various agencies in California (i.e., Tri-TAC and CASA) about the above-referenced proposed Rule which could have a sizable monetary impact on California agencies involved with wastewater treatment. Considerable more time is required to thoroughly study the proposed Rule and its economic impacts on California agencies.

As an agency involved with wastewater treatment, I hereby request that at least a 30 day extension of time be allowed for further review and comment.

Response to: CTRE-013-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-014-001
Comment Author: City of Riverside
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/03/97

Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The City of Riverside is requesting a 30 day extension in the comment period for the proposed California Toxics Rule. As the City was used as a case study for the economic analysis we feel that it is our responsibility to review these documents in some detail. Further, revelations regarding the status of the Santa Ana River Use Attainability Analysis and the site specific objectives that came out of that study, require considerable evaluation and consensus building within the watershed prior to comment.

Thank you for your consideration of this matter. Should you agree with our request, we would appreciate a notice of your decision.

Response to: CTRE-014-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-015-001
Comment Author: Oro Loma Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/30/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Oro Loma Sanitary District is a P.O.T.W. located in Alameda County between San Leandro and Hayward. We are also a member of the California Association of Sanitation Agencies (CASA) which actively monitors legislation and regulatory rule making.

We have reviewed the draft rule proposing water quality criteria for toxic pollutants for California ("California Toxics Rule" or "CTR") that was published in the Federal Register on August 5, 1997 and believe that the breadth and complexity of the draft CTR and the accompanying economic impact analysis warrant an extension of the comment period for an additional 30 days.

We are making this request to ensure that sufficient time is available to the public to coordinate the review of the CTR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. Thank you for your consideration.

Response to: CTRE-015-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-016-001
Comment Author: League of California Cities
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/03/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the League of California Cities, I am writing to respectfully request a 30 day extension to the comment period on the draft rule proposing water criteria for toxic pollutants for California ("California Toxics Rule" or "CTR"). That rule was published in the Federal Register on August 5 1997.

The League agrees with others who have requested an extension of the comment period that the complexity and breadth of the draft CTR, and the accompanying economic impact analysis, warrant additional time for comment. In addition, it is necessary to ensure that sufficient time is available to the public to coordinate the review of the CTR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. We believe that the quality of the public comment submitted will benefit by providing an overlapping time period in which interested parties can evaluate both sets of proposals.

For these reasons, the League of California Cities respectfully requests an extension of the public comment period for the draft CTR. Thank you for your careful consideration of our request.

Response to: CTRE-016-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-017-001
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/28/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: We have reviewed the draft rule proposing water quality criteria for toxic pollutants for California ("California Toxics Rule" or "CTR") that was published in the Federal Register on August 5, 1997 and believe that the breadth and complexity of the draft CTR and the accompanying economic

impact analysis warrant an extension of the comment period for an additional 30 days. In particular, we are making this request to ensure that sufficient time is available to the public to coordinate the review of the CTR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by the EPA and partially developed by the State in order to achieve full compliance with Section 303(c)(2)(b) of the Clean Water Act.

I would appreciate if you would notify me at the above address of your decision. Thank you very much for your consideration of our request.

Response to: CTRE-017-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-018-001
Comment Author: BASMAA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/03/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the Bay Area Stormwater Management Agencies Association (BASMAA), I am writing to respectfully request an extension of the comment period for the California Toxics Rule for an additional 30 days.

The Bay Area Stormwater Management Agencies Association is a consortium of the seven municipal storm water programs in the San Francisco Bay Area representing 89 agencies, including 78 cities and 5 counties. BASMAA is focused on regional challenges and opportunities to improving the quality of urban runoff to the San Francisco Bay and Delta.

BASMAA is working with its member agencies and the California Stormwater Quality Task Force to expedite its review of the proposed CTR. However, the completion of our review is complicated by the planned release on September 12 of the State Board's draft policy for implementing the numeric criteria included in the CTR. Providing more overlapping conunent periods for the CTR and the implementation policy will facilitate more coordination between storm water programs on their review and comments, likely saving a significant amount of time for both USEPA and State Board staff in the long run.

Thank you for consideration of our request, and for notifying us of your decision.

Response to: CTRE-018-001

In response to the comment requesting an extension of the comment period, please refer to response to

CTR-001-001.

Comment ID: CTRE-019-001
Comment Author: Crockett-Valona Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/27/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing in support of Tri-TAC and the California Association of Sanitation Agencies (CASA), which are California-based organizations comprised of members from public agencies responsible for wastewater treatment.

The Crockett-Valona sanitary Distrilct is attempting to obtain a copy of the California Toxics Rule so that we may properly review and comment on this important regulatory document. To do so, and with the belief that the breadth and complexity of the draft CTR and the accompanying economic impact analysis alone warrant an extension of the comment period, we request an extension of 30 days.

In particular, we are making this request to ensure that sufficient time is available to CASA and Tri-TAC to coordinate the review of the CTR with an evaluation of the State of Californials anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by EPA and partially developed by the State in order to achieve full compliance with Section 303(c)(2)(b) of the Clean Water Act.

Response to: CTRE-019-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-020-001
Comment Author: Mt. View Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/02/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing on behalf of the Mt. View Sanitary District, a publicly owned treatment works

located in Martinez, California. We have reviewed the draft rule proposing water quality criteria for toxic pollutants for California("California Toxics Rule" or "CTR") that was published in the Federal Register on August 5, 1997, and believe that the breadth and complexity of the draft CTR and the accompanying economic impact analysis warrant and extension of the comment period for an additional 30 days. In particular, we are making this request to ensure that sufficient time is available to the public to coordinate the review of the CTR with an evaluation of the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by EPA and partially developed by the State in order to achieve full compliance with Section 303(c)(2)(b) of the Clean Water Act.

I would appreciate it if you would notify me at the address on this letterhead of your decision. Thank you very much for your consideration of our request.

Response to: CTRE-020-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-021-001
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Novato Sanitary District (District) has reviewed the draft rule proposing water quality criteria for toxic pollutants for California ("California Toxics Rule" or'CTR") that was published in the Federal Register on August 5, 1997. The District believes that the breadth and complexity of the draft CTR and the accompanying economic impact analysis warrant an extension of the comment period for an additional 30 days. In particular, we are making this request to ensure that sufficient time is available for the public to coordinate the review of the CTR with the State of California's anticipated proposal of implementation policies for the criteria, which is scheduled to be released September 12, 1997. Providing overlapping comment periods will allow interested parties to understand the full contents and implications of the regulations, which are being partially adopted by EPA and partially developed by the State in order to achieve full comoliance with Section 303(c)(2)(b) of the Clean Water Act.

Thank you very much for your consideration of our request.

Response to: CTRE-021-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-022-001
Comment Author: West County Wastewater Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 08/20/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the Board of Directors of the West County Wastewater District, a public agency, it is requested that the public comment period for the draft California Toxics Rule (CTR) be extended for an additional 30 days. This request is made in order to allow for a meaningful review by California Association of Sanitation Agencies and Tri-TAC, our public agencies' representatives.

Thank you for considering our request.

Response to: CTRE-022-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001 and CTR-035-001.

Comment ID: CTRE-023-001a
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 07/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES V

Comment: The Bay Area Dischargers Association (BADA) is comprised of 10 POTWs in the San Francisco Bay Area. Our five largest charter members include the Central Contra Costa Sanitary District, City and County of San Francisco, City of San Jose, East Bay Dischargers Authority, and East Bay Municipal Utility District. Together BADA agencies provide wastewater service to most of the Bay Area.

BADA requests that the U.S. EPA allow at least 90 days for public review of the proposed California Toxics Rule (CTR). We understand the proposed rule will be published in the Federal Register toward the end of this month. The reasons for our request are as follows:

1. The CTR could have a significant economic impact on California municipalities and businesses. In

order to properly assess the impacts of the proposed CTR standards, it is necessary to know how the standards are to be implemented. Yet, the proposed implementation provisions being developed by the State Water Resources Control Board will not be available until September 12, 1997. The several days of overlap are insufficient for California municipalities and businesses to assess the economic and environmental impacts of the proposed standards. At least 45 days of overlap is needed.

2. The U.S. EPA has spent more than three years developing the proposed CTR, in part because of its importance. It is therefore, reasonable to provide at least 90 days for the public to review and comment on the rule, especially considering its potential economic impact on the State and the unavailability of the implementation provisions

3. It is recommended that the EPA work closely with the SWRCB during the review period to define the implementation policy and procedures that the EPA would be likely to approve.

For these reasons, BADA urges you to issue a notice extending the review period from 45 days to 90 days.

Response to: CTRE-023-001a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-024-001
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 07/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The Sacramento Regional County Sanitation District (District) understands that the proposed California Toxics Rule (CTR) will be published in the Federal Register at the end of this month. The District also understands that there will be a 45-day period set for public review and comment on this document. The District strongly requests that the period for review and comment be extended to a minimum of 90 days. The reasons for our request are as follows:

1. Previous studies have shown that the specific numeric values set for water quality criteria on metals such as mercury could have a major economic impact on the District. The key conclusion of these studies is that removal of mercury from the District's effluent could cost, more than $1 billion, but would only result in removing a very small percentage of the mercury being discharged to the Sacramento River from unregulated nonpoint sources in the watershed.

2. In addition, the CTR could have a significant economic impact on many California municipalities and businesses without providing any measurable water quality benefits. This statement is based on in-state studies of the attainability of the U.S. EPA recommended water quality criteria that will be incorporated

into the CTR.

3. The District believes it is necessary to know how the standards are to be implemented, in order to properly assess the impacts of the proposed CTR standards. However, the proposed implementation provisions being developed try the State Water Resources Control Board (SWRCB) will not be available until mid-September, 1997. The few days of possible overlap with a 45-day comment period are insufficient for California municipalities and businesses to assess the economic and environmental impacts of the proposed standards. In our opinion, at least 45 days of overlap are needed.

4. The U.S. EPA has spent more than three years developing the proposed CTR, in part because of its importance. The District believes it is unreasonable to provide only 45 day for the public review and comment on such an important rule, especially in light of both its significant potential economic impacts on the entire State and the unavailability of the SWRCB implementation provisions.

For these reasons, the District urges you to issue a notice extending the review period from 45 days to 90 days.

Response to: CTRE-024-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRE-025-001
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 07/16/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: The East Bay Dischargers Authority is a joint powers public agency providing wastewater treatment and disposal services for approximately 600,000 people in southern and eastern Almeda County, California. The Authority's members include City of San Leandro, City of Hayward, Oro Loma Sanitary District, Castro Valley Sanitary District, and Union Sanitary District.

The Authority and its member agencies have been following the process of U.S. EPA's development of the California Toxics Rule (CTR) and the State Water Resources Control Board's effort to develop implementation provisions for the CTR. We have been informed that the CTR will be published in the Federal Register late this month, and we are very dismayed by reports that there will only be a 45 day comment period. In addition, the comment period may not overlap with the release of the State Board's implementation provisions.

The Authority and its member agencies request that U.S. EPA allow at least 90 days, and preferably 120 days, for public review of the CTR. The reasons for our request include the following:

1. U.S. EPA has taken more than three years to develop the proposed CTR. It is unreasonable to provide only 45 days for the public to review and comment on the rule, especially considering the fact that the rule and its implementation could have significant economic consequences on the Authority and its member agencies.

2. In order to properly analyze the impacts of the CTR, it is imperative that the State Board's implementation provisions be examined concurrently. Yet the proposed release date of the implementation provisions is September 12, 1997. With a 45 day comment period, there is essentially no overlap, which is unacceptable from a public policy perspective.

3. An economic analysis of the CTR and the implementation provisions must be conducted concurrently. Such an analysis, by the parties most effected, must be allowed adequate time to be both accurate and meaningful. You will recall that the State Plans were invalidated in part because of a poor economic analysis by the State Board. We are skeptical that U.S. EPA and the State Board will have performed the necessary economic analyses and require adequate time to perform them ourselves.

The Authority and its member agencies believe that it is in the best interests of U.S. EPA, the State Board, the regulated community, and the public that the comment period for the CTR be extended to at least 90 days. Your consideration of this request is appreciated. Please feel free to contact me if you have any questions or need additional information.

Response to: CTRE-025-001

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-002
Comment Author: Robert Hale
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: That gets me to my next point. We got this thing about two weeks ago here. The task force is struggling on this. Our key people have been working on it around the clock for the last week. I'm looking at Mac Walker; he's been doing that. We really are very pressed by the shortage of the time we've got here. And other people have been asking for this, too.

I think it's only reasonable that we would get more time to look at this, time to perform economic analysis of the impact of this, and have a chance to do a little noodling. Forty-five days would be an absolute minimum extension on this thing.

We've waited a long time to get this. It wouldn't hurt us to extend it just that much longer to be able to look at the issues of this thing, rather than getting the numbers off the back of somebody's envelope.

That's really the last point.

Response to: CTRH-001-002

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-019a
Comment Author: Phil Bobel
Document Type: Public Hearing
State of Origin: CA
Represented Org: Tri-TAC
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES V

Comment: MR. BOBEL: Thank you, Steve.

I'm Phil Bobel. I represent Tri-TAC, an organization of sewage treatment plants, the POTWs as we call them, made up of three groups: CASA, the California Association of Sanitation Agencies; the League of Cities; and the California Water Environment Association.

And later this afternoon you're going to hear from Bob Reid who represents CASA. And our comments are essentially the same, so I'm going to not repeat and just summarize a couple things.

I was even going to say you guys had done a really good job. But in light of all the previous speakers, I deleted that part of my testimony.

I will try to be positive and constructive. I promised to do that. In describing the nature of my comments on your little form, I put that I would be constructive. So I will do that.

The first point I'd like to make is positive. I think that the coordination you're doing with the state is great. The fact that we're going to have coordination with the feds focusing on the numeric criteria, the state focus on the implementation policy, working to come up with a system that will serve us all, is a good way to use resources of both organizations.

I applaud you for that and hope you will be able to pull that off. This is different than what we've tried to do before, and it will require some creativity.

One specific thing that I think would help if we did, is to allow all of us to see both what the state is proposing and what the feds are proposing, so we need a little more time in this comment period.

We've appealed before and been told no, but I still put that on the table as a good idea for the ultimate goal of a coordinated, consolidated, as much as possible, federal and EPA approach to this thing.

If you don't do that, or even if you do do that, I think it's going to require some other kinds of creativity as

we move out of -- away from your hearing and toward a final rule.

And in that period of time, I would ask you and the state to sit down together and see what kind of a process you can use to take the comments that you'll hear from your federal regs and the comments you hear on the state plan, and put those together, hear more back from folks that are interested and come up with a package that makes sense.

You're going to need some way of going back to interested parties over a longer period of time -- communicating, coordinating -- and I would refer you to the process that the state used on their task force approach and suggest that we need something like that as we move to the future. Creativity is going to be needed.

Response to: CTRH-001-019a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-0211a
Comment Author: Julio Guerra
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Merced
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES E-01d

Comment: MR. GUERRA: My name is Julio Guerra with the City of Merced. And in my capacity with the City of Merced, I function as NPDES compliance coordinator and have to directly deal with these issues .

I did serve on the Inland Surface Waters Task force as a POTW representative to the agricultural waters subgroup, and so I am somewhat familiar with the issues at hand.

The first thing I would like to say is that the high-end cost estimated in the economic analysis done in the case study that was part of the California Toxics Rule background work was $4 million a year, $13 million capital expense. Characterized in the toxics rule is that the plants, of which Merced was one, was deemed to be representative of the proportionate facilities located within the different California regional water control boards.

Now, if we are representative, then you could assume that a plant such as Merced without a heavy industrial base would be typical of a lot of plants in the state, which would lead to the conclusion that perhaps the $87 million per year figure was a projection that did not match what could actually happen.

The city of Merced discharges to an ephemeral stream. The effluent is dominated at certain times of year by agricultural waste water, and stormwater-dominated at other times of the year. We provide the only treated water to that stream.

The ephemeral stream is dammed about a half mile further down by a farmer who uses all of the -- as much of the water as he can. He has water rights to about 15 million gallons a day. We can only discharge between 4 and 5 million gallons a day to that stream.

Our operating budget is between 2 and $3 million a year. If the assumptions were all correct, and we had to -- had to expend an additional $4 million a year to meet these standards, we would be spending an awful lot of money to take care of our neighbor.

The other side of that issue is that my cursory review of the economic impact work there leads me to observe that certain interpretations of our -- the data were not properly applied. And I would be most willing to work to get a more accurate picture of it to the EPA people.

And it would really take longer than the remaining comment period to do that, and so I would also add my voice to those asking for extension of the comment period.

Response to: CTRH-001-0211a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-0211b
Comment Author: Julio Guerra
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Merced
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES B

Comment: MR. GUERRA: My name is Julio Guerra with the City of Merced. And in my capacity with the City of Merced, I function as NPDES compliance coordinator and have to directly deal with these issues .

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The first thing I would like to say is that the high-end cost estimated in the economic analysis done in the case study that was part of the California Toxics Rule background work was $4 million a year, $13 million capital expense. Characterized in the toxics rule is that the plants, of which Merced was one, was deemed to be representative of the proportionate facilities located within the different California regional water control boards.

Now, if we are representative, then you could assume that a plant such as Merced without a heavy industrial base would be typical of a lot of plants in the state, which would lead to the conclusion that perhaps the $87 million per year figure was a projection that did not match what could actually happen.

The city of Merced discharges to an ephemeral stream. The effluent is dominated at certain times of year by agricultural waste water, and stormwater-dominated at other times of the year. We provide the only treated water to that stream.

The ephemeral stream is dammed about a half mile further down by a farmer who uses all of the -- as much of the water as he can. He has water rights to about 15 million gallons a day. We can only discharge between 4 and 5 million gallons a day to that stream.

Our operating budget is between 2 and $3 million a year. If the assumptions were all correct, and we had to -- had to expend an additional $4 million a year to meet these standards, we would be spending an awful lot of money to take care of our neighbor.

The other side of that issue is that my cursory review of the economic impact work there leads me to observe that certain interpretations of our -- the data were not properly applied. And I would be most willing to work to get a more accurate picture of it to the EPA people.

And it would really take longer than the remaining comment period to do that, and so I would also add my voice to those asking for extension of the comment period.

Response to: CTRH-001-0211b

See response to CTR-021-008.

EPA acknowledges that evaluating the impact of each individual direct discharger to inland waters, enclosed bays, and estuaries within the State of California would be the most accurate method to determine impacts of the CTR. However, the resources that would be required to perform such an analysis for each of the over 1,241 direct dischargers are beyond the resources typically available for development of environmental regulations.

In developing the methodology for estimating the compliance costs for the proposed CTR, time and budget constraints limited EPA's costing review to a subset of the regulated community. However, EPA believes that the sample selected adequately represents the various types of direct dischargers in the State.

EPA acknowledges that minor dischargers were under sampled as compared to the major dischargers. However, by definition, under the NPDES permit program, facilities classified as minor would not be expected to discharge toxic pollutants in toxic amounts. Since the CTR addresses only toxic pollutants, EPA would not expect significant, if any, impact to minor dischargers.

In analyses of the final CTR, EPA increased the sample of minors by five randomly selected facilities to bolster its analysis. EPA estimated costs of $872 per minor facility under the low scenario, and $2,682 per minor facility under the high scenario due to the CTR.

EPA also replaced Silvergate with South Bay in the sample in order to improve the estimate of the impacts of the CTR on the electric utility industry. The draft CTR cost analysis included costs for Silvergate, but the facility had closed and the data available was over five years old. The addition of South Bay, an electric utility facility with no costs, to the sample results in a more realistic, lower overall cost estimate for the electric utility industry.

Comment ID: CTRH-001-035
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: And finally, you've heard it brought up before, but I'd like to request an extension of an additional 90 days to provide comments so that we can compare this rule with the state implementing rules which are the Inland Surface waters Plan and the Enclosed Bays and Estuaries state water plan.

Thank you.

Response to: CTRH-001-035

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-036
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: I'm Robert Reid, manager of the Sanitation District of Santa Clara County. I'm here today representing CASA and to present CASA's comments.

CASA is the California Association of Sanitation Agencies and represents more than 80 publicly owned treatment works in the State of California, I'll keep my comments brief as CASA will be submitting detailed written comments prior to the close of the public comment period.

We have four main issues to which we would like to draw your attention today.

First, as has been said many times over today, because the state's Draft implementation Policy was issued only last Friday, the comment period for this proposed rule should be extended by 45 days, or at least 30 days, to allow adequate time for analysis of the proposed rule as it will be implemented by the state.

Our comments are going to focus on the contents of the CTR only and its potential impacts, without consideration for the state's implementation policy and how those may change those impacts, because we have not yet had time to really evaluate the draft implementation policy.

Response to: CTRH-001-036

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-043
Comment Author: Charles Batts
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: MR. BATTS: Thank you.

I'm Charles Batts. I am Plant Operations Department Manager at the Central Contra Costa Sanitary District, a publicly owned treatment works, and I'm here today as chairman for the Bay Area Dischargers Association, a group of the five largest municipal dischargers to the San Francisco Bay, serving approximately three and a half million people. Our goal is only to protect the environment and to provide cost-effective service for our rate payers.

We are very appreciative of the work done by EPA on the California Toxics Rule. I hope my comments today will be of help in developing regulations that will continue to protect the waters of the state, and that everyone can live with.

First, I think I need to get in line and ask as everyone else has and as I asked earlier by letter, for the period of comment to be extended to 90 days.

There is no reason to rush the final version of these rules. The impact of state plans which are already out will not be greatly impacted beyond the extent they already have been. This will allow the state plan to reflect the changes and comments or modifications that may come out of your toxics rule.

Response to: CTRH-001-043

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-001-045a
Comment Author: Charles Batts
Document Type: Public Hearing

State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES G-09

Comment: We would ask the EPA to extend the comment period to encourage further comments.

We would encourage you to look at actual agencies' calculations, that all translators be reviewed to ensure accuracy, even if special studies are required by individual dischargers.

Response to: CTRH-001-045a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the request that we look at actual translators to ensure accuracy in our economic analysis, the economic analysis for the proposed rule and for the final CTR is a broad-brushed analysis. EPA neither had the time nor resources to look at individual translators for individual pollutants for each of the sample facilities used in its analysis. However, where information was available on a particular pollutant and its translator, EPA reviewed the information and considered its application where appropriate.

Comment ID: CTRH-001-060a
Comment Author: Ellen Johnck
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Planning Coalition
Document Date: 09/17/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES J-04

Comment: Secondarily and thirdly -- these two are tied together, the whole -- all our members that comply and have to secure the stormwater permits, we have been looking at how much it would cost us to build facilities to do some kind of end-of-pipe treatment to actually meet some of these numeric criteria for stormwater.

We don't think the economic evaluation that EPA has done is valid. Basically, there are a lot of shortcomings to it, and you have already heard today some of the numbers. The actual amount of money needed to build new facilities is way beyond the $86 million estimate that you have indicated in your analysis.

And based on this very serious economic evaluation shortcoming, I am recommending that at least a 30-day time limit be provided so that you can hear from the permit applicants regarding the statement to show you what the costs really are, and we'd like some more time to do that.

Those are essentially the substance of my comments today. Thank you.

Response to: CTRH-001-060a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-002-007
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: Conclusion:

In conclusion, we believe that there are significant and fundamental issues associated with the proposed rule that require serious consideration.

We recommend an extension of the public review period for the proposed rule is requested to allow EPA, municipalities, industry, and others to further evaluate the wet weather discharge requirements of the rule and the resulting legal and economic impacts in light of the recently released Inland Surface Waters and Enclosed Bays and Estuaries plans.

Response to: CTRH-002-007

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001. In response to the issue concerning wet weather discharge requirements, the preamble to the proposed CTR had a detailed discussion concerning application of the proposed criteria to wet weather discharges. See the discussion at 62 FR 42186. See also the discussion on wet weather flows in the preamble to the final rule. A complete discussion of wet weather flows and potential economic impacts is also included in this Response to Comments document after the specific comments concerning potential economic impacts from wet weather flows.

Comment ID: CTRH-002-010
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: B Comment Period
References:

Attachments? N
CROSS REFERENCES

Comment: MS. ONLUND: I'm Lisa Ohlund. I'm an associate with the Southern California Alliance, a Publicly Owned Treatment Works. My business address is 30290 Rancho Viejo Road, San Juan Capistrano, 92675. I am here today representing SCAP. SCAP is comprised of 47 public agencies that provide wastewater treatment services in Southern California. Collectively, our member agencies serve over 16 million residents of Southern California. We appreciate the opportunity to testify on the proposed California Toxics Rule.

Before I make any substantive comments, I would like to reiterate the request that EPA extend or reopen the comment period on this CTR for an additional 30 days. We are still reviewing the proposed rule and its potential impacts on Southern Californials POTWs, and I believe that the number of changes proposed to the national water quality criteria and the extensive documentation that accompanies and explains the rule warrants the extension of the comment period.

In addition, as we noted in our letter requesting an extension, we would also appreciate the opportunity to review the CTR in the context of the State Water Resources Board's draft Implementation Policy which was just released last Friday, which I happen to have a copy here.

We're asking for an extension until at least October 27.

Response to: CTRH-002-010

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-002-021a
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES V

Comment: As you are aware, the California Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California, the proposed policy, was issued a few days ago. EPA and State essentially had the same objective to establish water quality criteria that are implementable for the water of California. Therefore, it is necessary for regulators and dischargers alike to fully comprehend the consequences of these rules on similar issues but from perhaps a different perspective.

Consequently, we strongly urge EPA to allow for additional 30 days for you and for us to fully review both documents together. We also urge EPA and State to coordinate these two rule-making process to minimize inconsistencies that might otherwise occur, EPA is the final focal point of this concern because

the process of State's obtaining EPA approval of ISWP and EBEP will be greatly enhanced if EPA and State can work together; and without EPA's approval, State's plan will be no good. So I think it will be ideal if CTR and the State's proposed policy can be promulgated simultaneously.

Thank you again for the opportunity to address you.

Response to: CTRH-002-021a

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Comment ID: CTRH-002-027
Comment Author: Fred Jacobsen
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Diego Gas & Electric
Document Date: 09/19/97
Subject Matter Code: B Comment Period
References:
Attachments? N
CROSS REFERENCES

Comment: MR. JACOBSEN: Hi, Fred Jacobsen. I'm here representing San Diego Gas & Electric. My comments, just purely process. Then I would just request that due to the volume of information that relates to the propsed rule and the fact that the State Water Board implementation policy was just released that the comment period be extended on the comment on the CTR rule for at least a minimum of 30 days. Thank you.

Response to: CTRH-002-027

In response to the comment requesting an extension of the comment period, please refer to response to CTR-001-001.

Subject Matter Code: C-01 Mercury

Comment ID: CTR-002-007a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Proposed mercury criteria ignore the concentration of mercury in the food chain and site specific field data in a scientifically insupportable manner. One reason EPA's criterion allows mercury to harm Bay fishing, as shown above, is that EPA's proposed "bioconcentration factor" predicts that I part per trillion (ppt) of mercury in water results in 7,374 ppt in fish eaten by the public. EPA rejected "bioaccumulation factors" from the Great Lakes which-predict that the same I ppt in water results in 27,900 to 140,000 ppt mercury in fish eaten by the public. This decision weakens the criterion drastically by ignoring mercury's most dangerous aquatic property.

EPA's rejection of data on mercury concentration in the aquatic food chain is scientifically insupportable. The fact that mercury concentrates strongly in aquatic food chains is beyond dispute. However, EPA's bioconcentration factor includes data on the "uptake and retention of a substance. from water only." EPA'S criterion thus fails to protect against human exposure to all mercury that gets into fish from the food the fish eat, which comprises most of this human mercury exposure. (The statement that EPA's "PBCFs take into account uptake from food as well as water" appears to mean food and water consumption by humans, and should not be read to obfuscate this problem.)

EPA's rationale for rejecting mercury bioaccumulation data for protection of San Francisco Bay is incorrect. The proposal states that. "Lacking the data, it is difficult to determine if the [bioaccumulation factors] used in the [Great Lakes Initiative] represent the potential for mercury bioaccumulation in surface waters in California." However, numerous high quality field measurements of San Francisco Bay water and fish eaten by the public demonstrate mercury bioaccumulation comparable with Great Lakes estimates and far greater than EPA'S "bioconcentration factor.(*3) (*16) These data are summarized in Table 7. It is unscientific to ignore high quality, consistent field data showing mercury concentration in aquatic food webs while proposing a criterion which allows harm to fishing.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH concentrations in San Francisco Bay waters.

(*16) California Regional Water Quality Control Board, San Francisco Bay Region, 1995. Contaminant levels in fish tissue from San Francisco Bay. Final draft report. Excerpt including data from toxic pollutant analyses of fish tissue samples from S.F. Bay. December, 1994.

Response to: CTR-002-007a

See response to CTR-002-007b on this issue.

Comment ID: CTR-002-007b
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Proposed mercury criteria ignore the concentration of mercury in the food chain and site specific field data in a scientifically insupportable manner. One reason EPA's criterion allows mercury to harm Bay fishing, as shown above, is that EPA's proposed "bioconcentration factor" predicts that I part per trillion (ppt) of mercury in water results in 7,374 ppt in fish eaten by the public. EPA rejected "bioaccumulation factors" from the Great Lakes which-predict that the same I ppt in water results in 27,900 to 140,000 ppt mercury in fish eaten by the public. This decision weakens the criterion drastically by ignoring mercury's most dangerous aquatic property.

EPA's rejection of data on mercury concentration in the aquatic food chain is scientifically insupportable. The fact that mercury concentrates strongly in aquatic food chains is beyond dispute. However, EPA's bioconcentration factor includes data on the "uptake and retention of a substance. from water only." EPA'S criterion thus fails to protect against human exposure to all mercury that gets into fish from the food the fish eat, which comprises most of this human mercury exposure. (The statement that EPA's "PBCFs take into account uptake from food as well as water" appears to mean food and water consumption by humans, and should not be read to obfuscate this problem.)

EPA's rationale for rejecting mercury bioaccumulation data for protection of San Francisco Bay is incorrect. The proposal states that. "Lacking the data, it is difficult to determine if the [bioaccumulation factors] used in the [Great Lakes Initiative] represent the potential for mercury bioaccumulation in surface waters in California." However, numerous high quality field measurements of San Francisco Bay water and fish eaten by the public demonstrate mercury bioaccumulation comparable with Great Lakes estimates and far greater than EPA's "bioconcentration factor.(*3) (*16) These data are summarized in Table 7. It is unscientific to ignore high quality, consistent field data showing mercury concentration in aquatic food webs while proposing a criterion which allows harm to fishing.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH concentrations in San Francisco Bay waters.

(*16) California Regional Water Quality Control Board, San Francisco Bay Region, 1995. Contaminant levels in fish tissue from San Francisco Bay. Final draft report. Excerpt including data from toxic pollutant analyses of fish tissue samples from S.F. Bay. December, 1994.

Response to: CTR-002-007b

EPA acknowledges concerns expressed by the commentors about mercury bioaccumulation and the protectiveness of the mercury human health in the final rule. EPA is well aware of the adverse human health and environmental effects associated with mercury exposure and the role that bioaccumulation plays. Several reports have been published recently documenting EPA's concern for, and guidance on, protection from mercury exposure. These documents include: Mercury Study Report to Congress, (EPA-452/R-97-008); The National Survey of Mercury Contamination in Fish. Database Summary 1990-1995. September 29, 1997; 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water, (EPA-820-B-96-001); and Final Water Quality Guidance for the Great Lakes System: Final Rule. Fed Register, 60(56):15366-15425 (March 23, 1995). As noted in these documents and many other publications, mercury bioaccumulation is a very complex process that is not fully understood. Methylmercury is the most toxic and readily bioaccumulated form, but mercury methylation and bioaccumulation varies from location to location due to biological, physical, and chemical factors that are not completely understood. Much additional research is need to characterize these factors so that accurate predictions of methylmercury bioaccumulation can be made. EPA is working to improve the body of knowledge on mercury bioaccumulation, toxicity, and risk management, which will lead to improved protective mercury criteria. For example, EPA's Office of Research and Development is sponsoring a multi-year, several million dollar, Science to Achieve Results (STAR) research grant program to specifically investigate the fate and transport of mercury in the aquatic environment. Grants and funding will be awarded to successful applicants beginning in 1999.

In addition to these research activities, EPA is reviewing the basis for the human health mercury criterion and is conducting a comprehensive review of its overall human health criteria methodology. In 1998, Congress directed the National Academy of Sciences (NAS) to review the toxicological basis for EPA's reference dose (RfD) for mercury. NAS will review toxicological data generated from studies conducted in the Faroe and Seychelles Islands and assess its appropriateness for use in the RfD derivation. This review is scheduled to begin in mid-1999 and be completed in July, 2000. EPA plans to update the National 304(a) criteria once the review is complete, and then subsequently update criteria for California.

EPA believes the 304(a) mercury criteria will also be improved once the recently proposed revisions to the Ambient Water Quality Criteria Derivation Methodology Human Health (EPA-822-B-98-005) are final and ready for use in deriving National recommended criteria. Proposed changes to the human health methodology affect both the reference dose derivation and exposure assessment applicable to mercury. As recommended by a number of commentors, the proposed revisions to the human health methodology would use bioaccumulation factors (BAFs) rather than bioconcentration factors (BCFs) or practical bioconcentration factors (PBCFs), to derive water quality criteria in the future. EPA has received public comment on the proposed revisions to the health methodology and held an external peer review workshop in May,1999. EPA believes that such peer review is essential to maintaining the scientific defensibility of its water quality criteria. Once the methodology is finalized based on reviewers' comments, new National recommended mercury criteria for human health and aquatic life can be derived, and then subsequently criteria for California can be updated.

Any revision to either a National or California mercury criterion will include an evaluation of all relevant bioaccumulation data. The data in the GLWQI is specific to the Great Lakes region and its applicability to California waters has not been finally determined. The GLWQI BAFs alone cannot be directly applied

to California because the biological, chemical, and physical factors that influence mercury bioaccumulation will be different in California when compared to the Great Lakes region. Examples of these factors include: foodchain interactions, physicochemical parameters (e.g. pH, temperature, dissolved and particulate organic matter), and size and type of watershed. Additionally, the GLWQI BAFs were developed for lakes only, whereas the waters affected by mercury in California include rivers and estuaries, for which very little data on the bioaccumulation potential of mercury is available. Virtually nothing is known about the applicability to rivers or estuaries of BAFs which are based on lake ecosystems. However, EPA is currently gathering bioaccumulation data on lentic (lakes), lotic (streams, rivers) and estuarine environments in order to assess the nature and extent of bioaccumulation in different water bodies and the application of BAFs across ecosystems. Although the bioaccumulation data cited by the commentors for San Francisco Bay and Clear Lake appear to be quality data, the development of any California-specific BAFs would require more than these few limited studies.

In summary, EPA agrees that mercury in the environment is a problem and has clearly documented its adverse effects to humans and ecological receptors. Regulatory controls are need to protect humans, wildlife, and aquatic life from exposure to mercury. However, there are a number of issues that must be considered and resolved before EPA can conduct a revision of the National 304 (a) mercury criteria and promulgate revised values for California. The dominant issues are:1) finalize the overall Ambient Water Quality Criteria Derivation Methodology for Human Health, 2) within the human health methodology, finalize the approach for deriving bioaccumulation factors, and 3) wait completion of the NAS review and subsequently revise the National human health criteria for mercury. For these reasons EPA is at this time promulgating mercury criteria of 0.05 ug/L (consumption of water and organisms) and 0.051 ug/L (consumption of organisms only) as proposed in the CTR, rather than promulgating revised criteria based on partially peer reviewed methodologies, evolving science, and incomplete understandings of the factors that affect mercury bioaccumulation. Once this comprehensive review is complete, the mercury criteria will be revised as appropriate, supported by scientifically defensible and peer reviewed methodologies and data.

Comment ID: CTR-003-009
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: 9) The use of a $200 and $500 per toxic pounds-equivalent as a upper end cost basis seems arbitrary. From our perspective, there is no reason to assume that an alternative regulatory approach to toxics compliance will or, where uses may have been previously obtained, can be made available to the City at no cost. Although we disagree with EPA guidance, it clearly states that a minimum of 1-2% of median household income must be spent prior to relief based on economics. Relief may be available for expenses above that level. Assuming a median disposable household income of $30,000 the ceiling would be $300 - $600 per year. Since households are now spending $156.60 a year, that means that costs could go up $143.40 - $443.40 per household before the EPA would consider it an economic hardship. For 110,000 households, that is an increase of $15,774,000 - $48,774,000 per year for the City of

Riverside alone. When performing an economic analysis the EPA should be consistent with its own guidance.

Response to: CTR-003-009

See response to CTR-032-004 and CTR-060-019 (Category E-01m; Regulatory Relief)

Comment ID: CTR-005-003c
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-09
G-05
G-04

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003c

EPA agrees with the comment.

Comment ID: CTR-006-001a
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: The Natural Resources Defense Council strongly opposes the Region 9 EPA proposal to raise the allowable mercury criterion for continuous concentration in water from 0.012 parts per billion (ppb) to 0.770 ppb for aquatic life. This proposal is difficult to justify from the point of view of science and of public health. On behalf of our over 350,000 members nationwide and our over 55,000 California

members, we are writing to register our opposition to the EPA proposed rule.

Mercury is a highly poisonous metal which results in toxicity to the brain and nervous system and toxicity to human reproduction. In addition, in sediments, mercury is bio-transformed into the even more toxic form, methyl mercury, which has resulted in some of the largest epidemics of neuro-developmental poisoning known to mankind. Methyl mercury bioaccumulates in the food chain and thereby results in greatly concentrated exposures to humans, because we eat off the top of the food chain. Underestimates of the toxicity and bioaccumulation of mercury have led to major mistakes in the past. The Minamata Bay disaster in Japan was caused by a failure to predict the potency of mercury and the extent of human exposure through fish. U.S. EPA's Draft Mercury Study Report to Congress documents that children of high-end fish consumers in the U.S. may be exposed to enough mercury to cause adverse neuro-developmental effects.

In this setting it is anomalous to relax the standards for mercury contamination in California water. Furthermore, the scientific reasoning behind the Region 9 EPA decision to relax the mercury standard 60-fold is fraught with errors. NRDC's major concerns with this approach are summarized below.

*Extrapolation for the Reference Dose (RfD) should start at a NOAEL, not at a level of 10% increased risk. *An additional 10-fold safety factor should be added in deriving the RfD to account for the vulnerability of fetuses, infants, and children. *The body weight in the calculation should be for a child, not an adult male. *The Fish consumption rates for those who do eat fish should be used instead of rates for the entire population including those who do not eat fish. *Average fish consumption quantities greatly understate the risk to those who eat a lot of fish. Instead, fish consumption for the top 5% of the population should be used.' *Bioaccumulation is known to be 10 to 100 fold greater than the estimate used by EPA. *California's waters are already too polluted with mercury.

Insufficiently Protective Reference Dose

The risk assessment used the-current reference dose (RfD) from U.S. EPA's Integrated Risk Information System (IRIS) which contains several problems that make it likely to be too high to be health protective. The starting point for the extrapolation was the dose which conferred a I 0% increased risk to exposed humans. This is certainly not a No Observable Adverse Effects Level (NOAEL), and in fact, a 10% increase in risk is quite significant in scientific and public health terms. Despite the fact that the NOAEL was not used as a starting point for derivation of the RfD, only a 10-fold uncertainty factor was added to derive the RfD. This was presumably a half-log of 10 for within human variability and a half-log of 10 for lack of a two generation reproductive study. A half-log of 10 is clearly insufficient to account for the wide range of human variability. In fact, the effects of mercury on the developing nervous system and the appearance of clinical mercury toxicity at much lower doses in children make it highly likely that fetuses, infants, and children are far more than an order of magnitude more susceptible to the effects of mercury intoxication than are adults. Thus an additional factor of at least 10 should be added to account for the disproportionate susceptibility of children.

Incorrect Choice of Body Weight

The body weight used in the equation for the mercury criterion is 70 kg. This is an average adult male body weight. Average female body weight is around 60 kg and a child would weigh less than 10 kg (7.5 kg is a common choice in risk assessment). It is extremely odd to use an adult male body weight in the risk calculation when the populations of interest are pregnant women and children. It is a fact that adult males are simply at much less risk for the adverse health effects of mercury. Choice of an excessively large body weight leads to a larger predicted tolerable dose. Such a large dose might well be tolerable to

an adult male, but in the case of mercury, we are concerned with a different population at risk. Therefore the calculation should use the body weight of the lightest member of the population at risk, ie. the weight of a child, in the equation if there is any hope that the result of the calculation will provide any health protection for a child.

NRDC strongly urges Region 9 EPA to reassess the proposed standard for mercury. Recalculation of the reference dose to accommodate the known disproportionate impact of mercury on fetuses, infants, and children will require addition of at least another 10-fold safety factor. The starting point for RfD calculation should be a true NOAEL. The body weight calculation should use an average weight for a child. Fish consumption data should reflect the "high-end" consumer. Finally, the outdated and unsupportable bioaccumulation factor of 7300 should be discarded in favor of a BAF which is supported by the current science in California.

Response to: CTR-006-001a

Regarding the choice of body weight, EPA disagrees that the use of a 70 Kg body weight is inappropriate for the calculation of the mercury criterion. Although the use of a 70 kg assumption results in a slightly less stringent value, the Agency disagrees that this represents an excessively large body weight. The comment author is also incorrect in the statement that the 70 kg assumption only represents adult males. The 70 kg assumption is, in fact, based on the combined average body weights of adult males and females according to data from the Second National Health and Nutrition Examination Survey (NHANES II). These data indicate that the average body weight for adult females of childbearing age is 65 kg. EPA does not believe that an adjustment of 5 kg would result in a significant change in the mercury criterion. However, EPA is developing a revised methodology for deriving water quality criteria to protect human health and is considering different default body weight recommendations for women of childbearing age and children (see draft revisions published August 14, 1998, Federal Register, Vol. 63, No. 157). EPA is currently reviewing public comments and is awaiting the results of a peer review on the draft methodology revisions. As part of this effort, EPA also intends to consider the more recently published NHANES III data for the same gender and age categories. Until these reviews are complete, it would be inappropriate to change the 70 kg assumption used to calculate the human health criteria for mercury.

EPA disagrees that the body weight of a child should be used for the calculation of the mercury criterion. The effect of concern is a developmental effect which is caused by exposure of the female to mercury and the transmigration of the mercury into the developing fetus to cause the developmental neurotoxic effect. Thus, if the exposure to the pregnant female is reduced to a level which is not toxic to the fetus, then the fetus is protected. This is achieved by calculating a maternal exposure level that corresponds to a NOAEL for developmental effects in the fetus, and in doing so, the weight of the pregnant female is the appropriate number on which to base the calculation.

For issues concerning the derivation of the Reference Dose and safety factors, see the response to CTR-006-002a. Regarding the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding the bioaccumulation issue, see the response in CTR-002-007b.

Comment ID: CTR-006-001b
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA

Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Ms. Frankel,

The Natural Resources Defense Council strongly opposes the Region 9 EPA proposal to raise the allowable mercury criterion for continuous concentration in water from 0.012 parts per billion (ppb) to 0.770 ppb for aquatic life. This proposal is difficult to justify from the point of view of science and of public health. On behalf of our over 350,000 members nationwide and our over 55,000 California members, we are writing to register our opposition to the EPA proposed rule.

Mercury is a highly poisonous metal which results in toxicity to the brain and nervous system and toxicity to human reproduction. In addition, in sediments, mercury is bio-transformed into the even more toxic form, methyl mercury, which has resulted in some of the largest epidemics of neuro-developmental poisoning known to mankind. Methyl mercury bioaccumulates in the food chain and thereby results in greatly concentrated exposures to humans, because we eat off the top of the food chain. Underestimates of the toxicity and bioaccumulation of mercury have led to major mistakes in the past. The Minamata Bay disaster in Japan was caused by a failure to predict the potency of mercury and the extent of human exposure through fish. U.S. EPA's Draft Mercury Study Report to Congress documents that children of high-end fish consumers in the U.S. may be exposed to enough mercury to cause adverse neuro-developmental effects.

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Response to: CTR-006-001b

With respect to the bioaccumulation factors see response to CTR-002-007b. With respect to the mercury aquatic life criteria, EPA is not promulgating these criteria in today's rule (see the preamble of today's rule for further explanation). For an explanation why EPA does not believe today's rule will worsen water quality see response to CTR-002-003.

With respect to EPA's risk assessment procedures see responses to CTR-006-001a and CTR-006-002a.

Comment ID: CTR-006-002a
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES C-14

Comment: Dear Ms. Frankel,

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Use of Average Fish Consumption is not Health Protective

The assumption used by Region 9 EPA for fish consumption relies on the average fish and shellfish consumption in the entire general population, along with the average intake from each body of water. It is quite clear that fish consumption follows a highly skewed, or Poisson distribution in the population (see attachment from the U.S. EPA Draft Mercury Study Report to Congress, Appendix H, p. 20). Many people eat little or no fish, but a smaller, yet highly significant segment of the population eats a very large amount of fish. Surely EPA should strive just as hard to protect the health of those who eat fish frequently as it does to protect the health of those who do not eat fish.

In fact, this analysis adequately protects only those who eat little or no fish. The average which was used in the Region 9 EPA analysis appears to derive from the "per capita" data from the USDA Continuing Surveys of Food Intake by Individuals (CSF 11) from 1989-91 for males ages 15-44 years. (See attached tables from U.S. EPA Mercury, Report, Appendix H, pp. 8 & I 1). In fact, this average is highly influenced by those individuals who consume little or no fish. Non-fish-consumers, however, are not the population of interest for purposes of this analysis. Instead, if an average is to be used, it should be the average fish consumption rate for those people who do eat fish. This is substantially higher, at 53.7 g/day for males ages 15-44 years, and 41.4 g/day for females in the same age range. Furthermore, the average fish consumption will likely underestimate the fish consumption rate for the "high end" fish

consumer by many orders of magnitude. For example, in the case of females ages 15-44 years, average fish consumption (among those who do eat fish) is 41.4 g/day, while fish consumption by the top 5% of the population of these women of childbearing age is about 112 g/day, or more than double the average consumption rate.

The implications of not adequately protecting the high fish consumer are not trivial. The population of California is nearly 30 million, of whom overall 31% would be expected to be fish consumers according to the CSF II survey. This represents over 9 million people who would be at disproportionate risk. The top 5% of that population consists of nearly half a million people in California who would be expected to eat fish at nearly 10-times greater quantity than the EPA calculations would predict. 10 times greater consumption would translate into roughly 10-times greater risk from the mercury in the fish. EPA is not adequately protecting this substantial portion of the California population from mercury hazards.

NRDC strongly urges Region 9 EPA to reassess the proposed standard for mercury. Recalculation of the reference dose to accommodate the known disproportionate impact of mercury on fetuses, infants, and children will require addition of at least another 10-fold safety factor. The starting point for RfD calculation should be a true NOAEL. The body weight calculation should use an average weight for a child. Fish consumption data should reflect the "high-end" consumer. Finally, the outdated and unsupportable bioaccumulation factor of 7300 should be discarded in favor of a BAF which is supported by the current science in California.

Response to: CTR-006-002a

The commenter criticizes the current RfD on IRIS in several respects. While EPA intends to develop a revised IRIS value, once it receives recommendations from the National Academy of Sciences (see discussion in response to CTR-030-007 and CTR-002-007b), EPA strongly believes that some level of protection needs to be in place for mercury because of its toxicity to humans and aquatic life (see response to CTR-002-007b). Therefore, EPA thinks it is reasonable to keep in place the human health value based on the current RfD, which it believes is scientifically defensible based on the state of the science at the time it was derived.

The EPA disagrees with the comment that an RfD should be calculated by selecting the NOAEL and applying the appropriate safety factor in the case of mercury due to the nature of the data. The data base for mercury allow for the use of continuous human data (i.e., there are no dose groups and no NOAEL as it is defined for a controlled animal study) on the most sensitive subpopulation which is the fetus.

In regard to the methodology used to calculate the Reference Dose (RfD), the following discussion is intended to clarify why the Benchmark Dose (BMD) approach is the most appropriate method to use for the mercury data. Traditionally, when assessing the human health hazard and dose response relationship for a toxicant which produces a non-cancer effect in humans or animals following exposure, a No Observed Adverse Effect Level (NOAEL) and the Lowest Observed Adverse Effect Level (LOAEL) is selected for the critical effect from among all the available data, and a series of uncertainty factors are applied as appropriate to determine the Reference Dose. This methodology is widely used by regulatory agencies as the first step in assessing potential human health risk from exposure to the substance in question. As more refined mathematical models are developed and better scientific data on toxicants are generated, there is the opportunity to calculate a BMD which more closely approaches the true NOAEL because more of the data and the characteristics of the data are utilized in the analysis. When the data base is robust and such refinements are possible, it is incumbent upon the risk assessors to generate these more realistic estimates of human health hazard for the reasons listed below.

People often misinterpret the NOAEL that is selected from a critical study as the actual level of exposure at which no adverse effects are observed, but actually, it is only the highest level at which no adverse effects are observed in that particular study or in a group of studies. The NOAEL is a function of study design, (i.e., the number of animals tested, the number of doses, the spacing between doses, the duration of exposure, and the route of administration). If the study design has adhered to the toxicity testing guidelines and Good Laboratory Practice (GLP) requirements, the NOAEL actually represents an effect level because of the number of animals used. As the number of test animals increases and more dose levels are tested, the power of the study and its ability to detect a toxic effect increases; the data generated are more robust and the NOAEL decreases as it approaches the real value. Studies with higher power result in lower NOAELs, smaller RfDs and a greater confidence in the level of safety. Also, NOAELs are often controversial since scientific judgment is applied to reach the conclusion that what is observed at the LOAEL is really adverse in nature; and the selection of one number for the NOAEL disregards valuable information gained
from looking at the whole study and the slope of the dose response curve (There is a higher level of concern when the slope is steep because a small change in dose/exposure produces significant changes in the effects noted. Shallow slopes indicate that exposures can be increased over a broader range and the increase in the number or severity of the effects will be less dramatic). Consequently, there are many disadvantages to this methodology, but it is nevertheless frequently used due to the lack of better and more data on the toxicant under review.

However, some toxicants have presented a high level of interest to the scientific community and the regulatory programs and there exists an abundance of toxicology data (often times human data) from which to calculate risk. In these situations, it is preferable to use as much of the data as possible and to select an appropriate model for the data which allows the analyst to determine a Benchmark Dose (BMD). To do this, EPA chooses among a series of appropriate mathematical models. EPA fits each of these to the data. EPA then uses a statistical procedure to select the model that gives the best fit to the data. A BMD is a statistical lower confidence limit on the dose that produces a selected level of change in response rate in comparison to untreated control animals (e.g., 5% or 10% change in response when compared to the background response) (EPA 1995). In other words, the BMD approach selects a data point (point of departure at which there is a certain response level, in this case a 10% response level) and selects the appropriate mathematical model for the data which takes into account the slope of the dose response curve and the variability of the data. For mercury, the BMD thus represents the lower confidence limit for the dose that is estimated to produce the 10% level of change in response in the study population. The BMD thus represents the probability that 95% of the time, the dose producing the given level of response will be higher than the BMD. This approach is well suited to the data base for mercury since the human
data are continuous, i.e., there is a response associated with all exposure levels and there is no non-exposed group. The BMD approach is a newer and more robust analysis which utilizes all the data and the special characteristics of these data, and the Agency would be errant in its mission if it did not utilize state of the art methods in risk assessment to achieve its goals of public health protection. Using this methodology improves the resulting non cancer risk assessment because it uses the dose response data to select an appropriate model which does not extrapolate to doses below the experimental range. The BMD can either be less than or greater than the corresponding NOAEL, it is not restricted to one of the experimental dose levels, and it accounts more appropriately for sample size and dose-response characteristics (Crump 1984, Dourson et al. 1985, Kimmel and Gaylor 1988). In deriving an RfD using this method, the BMD is then divided by the appropriate uncertainty factors. Where the data are appropriate and lend themselves well to the use of a BMD as in the case of the type and quantity of data on mercury, the Agency would be errant in its mission of public health protection if it assessed the hazard of mercury by using the simplistic NOAEL/LOAEL approach.

In the EPA RfD calculation for mercury, an estimate of a NOAEL was used; namely the lower 95% confidence limit on a dose corresponding to a 10% effect level for all reported neurodevelopmental effects reported in a population of 81 Iraqi children reported in Marsh et al. 1987. The 10% effect level refers to the dose which produces the defined effect in 10% of the study population. A Weibull model was fit to the data as recent research suggests that it may be the best model for developmental toxicity data (Faustman et al. 1994). Other research indicates that the lower confidence limit on the dose which produces a 10% response level (i.e., the BMD) is the appropriate choice when correlated with the NOAEL for developmental effects in controlled animal studies (Allen et al. 1994a, b). In the case of the mercury RfD, the 10% effect level was determined to be the most appropriate regarding the aforementioned discussion on compariosn to background response (i.e., statistical significance) and when correlated to the NOAEL. It should be noted that the data on developmental effects in the Iraqi children are continuous with respect to dose. That is, there are no dose groups and no NOAEL as it is defined for a controlled animal study. The benchmark dose modeling procedure provides a reasonable approach to determining the exposure at which effects are observable above background.

EPA also disagrees with the comment that the adult males are at much less risk for the adverse health effects of mercury, and that the RfD should be recalculated with the addition of at least another 10 fold safety factor to accommodate the known disproportionate impact of mercury on fetuses, infants and children. In regard to the sensitivity of adult males vs fetuses, infants and children, the original RfD of 0.3 @g/kg/day was based on paresthesia in Iraqi adults exposed to methylmercury in grain. This is within a factor of three of the current RfD (0.1 @g/kg/day based on developmental neurotoxicity in the same population. According to EPA, an RfD is defined as "an estimate (with uncertainty spanning perhaps an order of magnitude)"of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effect during a lifetime. Thus, by this "order of magnitude" standard, the RfD based on adult effects overlaps that based on developmental endpoints. In the most recent publications on the poisonings in Minamata, exacerbation or onset of neurological symptoms have been noted as the population has aged.

In regard to the addition of another safety factor for fetuses, infants and children, the scientific community agrees that when deriving an RfD for methylmercury using sensitive developmental neurotoxic endpoints that the data represent the effects in children and fetuses. Thus, an additional 10 fold factor would be redundant. In calculation of the RfD, a composite uncertainty factor of 10 was used to account for a number of uncertainties related to the data. First, this uncertainty factor was applied for variability in the human population, in particular, the wide variation in biological half-life of methylmercury and the variation that occurs in the hair to blood ratio for mercury. In addition, the factor accounts for lack of a two-generation reproductive study and lack of data for possible chronic manifestations of the adult effects (e.g., paresthesia that was observed during gestation). EPA also considers whether to incorporate a modifying factor to address limitations on the data used (e.g., number of animals, sex of animals). The default value of one was used for the modifying factor. Additional discussion regarding the uncertainty factor based on the Marsh et
al 1987, is excerpted from the Mercury Study Report to Congress, 1997, see "Addendum" for this information.

The fish intake rate of 6.5 gm/day is from a national, 30-day survey (the National Purchase Diary), based on an empirical distribution, where 6.5 gm/day represents the average value for the general population. Regarding the fish consumption analysis, the commenter is incorrect on several points.
First, although EPA agrees that fish consumption distributions do tend to be skewed, the Agency disagrees that they follow a Poisson distribution. Nor has the commenter demonstrated that fish consumption follows a Poisson distribution. On the contrary, numerous studies have shown that average fish consumption rates are generally approximated by log-normal distributions. This is specifically true

for the CSFII survey data that the commenter references. The commenter is also incorrect that "many people eat little or no fish." According to the National Purchase Diary (NPD), the basis of the 6.5 gm/day intake rate, 94 percent of the survey respondents stated that they eat some fish. It is not EPA's intention to specifically protect non-consumers of fish. However, survey designs generally, and the referenced CSFII survey in particular, do not allow segregating the data to isolate consumers from non-consumers. The only determination that can be made from the CSFII data is whether a respondent did or did not eat fish during the three consecutive survey days. Therefore, the extrapolation made by the commenter that only 31 percent of the population are fish consumers is incorrect. The commenter is also incorrect that the basis of the chosen intake rate is for males ages 15-44 years. The 6.5 gm/day is based on all respondents from the NPD and, therefore, is representative of males and females in the general population. Further, the "per capita" data submitted by the commenter (from the 1996 draft version of the Mercury Study Report to Congress) are based on rates that include marine species (not used in the water quality criteria derivations), in additon to the estuarine/freshwater species that do comprise the value used in deriving water quality criteria. For additonal discussion regarding the basis of the fish consumption rate, including the exclusion of marine species, see the response to this issue in CTR-002-002a.

Regarding the choice of body weight, see response to CTR-006-001a. Regarding the issues on bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-006-003
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Ms. Frankel,

The Natural Resources Defense Council strongly opposes the Region 9 EPA proposal to raise the allowable mercury criterion for continuous concentration in water from 0.012 parts per billion (ppb) to 0.770 ppb for aquatic life. This proposal is difficult to justify from the point of view of science and of public health. On behalf of our over 350,000 members nationwide and our over 55,000 California members, we are writing to register our opposition to the EPA proposed rule.

Mercury is a highly poisonous metal which results in toxicity to the brain and nervous system and toxicity to human reproduction. In addition, in sediments, mercury is bio-transformed into the even more toxic form, methyl mercury, which has resulted in some of the largest epidemics of neuro-developmental poisoning known to mankind. Methyl mercury bioaccumulates in the food chain and thereby results in greatly concentrated exposures to humans, because we eat off the top of the food chain. Underestimates of the toxicity and bioaccumulation of mercury have led to major mistakes in the past. The Minamata Bay disaster in Japan was caused by a failure to predict the potency of mercury and the extent of human exposure through fish. U.S. EPA's Draft Mercury Study Report to Congress documents that children of high-end fish consumers in the U.S. may be exposed to enough mercury to cause adverse

neuro-developmental effects.

In this setting it is anomalous to relax the standards for mercury contamination in California water. Furthermore, the scientific reasoning behind the Region 9 EPA decision to relax the mercury standard 60-fold is fraught with errors. NRDC's major concerns with this approach are summarized below.

*Extrapolation for the Reference Dose (RfD) should start at a NOAEL, not at a level of 10% increased risk. *An additional 10-fold safety factor should be added in deriving the RfD to account for the vulnerability of fetuses, infants, and children. *The body weight in the calculation should be for a child, not an adult male. *The Fish consumption rates for those who do eat fish should be used instead of rates for the entire population including those who do not eat fish. *Average fish consumption quantities greatly understate the risk to those who eat a lot of fish. Instead, fish consumption for the top 5% of the population should be used. *Bioaccumulation is known to be 10 to 100 fold greater than the estimate used by EPA. *California's waters are already too polluted with mercury.

The Bioconcentration Factor is Incorrect

The proposed EPA rule calculates a bioconcentration factor (BCF) in fish of 7300. Available data from the state of California indicates that this factor is wrong by between IO and I 00-fold. In the Great Lakes, mercury has been shown to accumulate with bioaccumulation factors (BAF) of 27,900 for trophic level 3 fish and 140,000 for trophic level 4 fish. Despite this evidence, EPA rejects these data for use in California and calculates a BCF more than 10-fold lower based on a model created 27 years ago. In fact, current data are available on bioaccumulation in California fish.

The San Francisco Bay Regional Monitoring Program has found BAFs of 60,000 to 200,000 in bivalves and research in California lakes has found a calculated BAF of over 500,000 fold. These data have been presented elsewhere in the rulemaking record by researchers from the University of California at Santa Cruz. Underestimating by one to two orders of magnitude the amount of bioaccumulation that will occur in the environment is a major error with potentially devastating public health implications. The potential result is that water will contain "permissible" concentrations of mercury while fish will be contaminated at levels too high for safe human consumption.

California is already Suffering from Mercury Pollution

Numerous water bodies in the state of California are already under fish advisory for mercury. These include Clear Lake, Lake Berryessa, the San Francisco Bay and Delta, Lake Herinan, Guadalupe Reservoir, Calero Reservoir, Almaden Reservoir, Guadalupe River, Guadalupe Creek, and Lake Nacimiento. In the face of this widespread environmental pollution with mercury, all incentives should be driving toward further reduction of mercury emissions and releases to water sources. By relaxing the mercury standards for water, U.S. EPA is heading in absolutely the wrong direction. Increases in allowable levels of mercury in the environment can only lead to more contaminated fish, more fish advisories, more pregnant women and children potentially exposed to this toxic metal, and more risks to public health.

NRDC strongly urges Region 9 EPA to reassess the proposed standard for mercury. Recalculation of the reference dose to accommodate the known disproportionate impact of mercury on fetuses, infants, and children will require addition of at least another 10-fold safety factor. The starting point for RfD calculation should be a true NOAEL. The body weight calculation should use an average weight for a child. Fish consumption data should reflect the "high-end" consumer. Finally, the outdated and unsupportable bioaccumulation factor of 7300 should be discarded in favor of a BAF which is supported

by the current science in California.

Response to: CTR-006-003

Regarding the commenter's statements on the Reference Dose (RfD), refer to the responses on this same issue in CTR-006-001a and CTR-006-002a. Regarding the bioaccumulation issue, see response to CTR-002-007b.

Comment ID: CTR-016-007
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Comments on the Proposed Mercury Criteria

The Regional Board supports the use of the current Reference Dose from IRIS in deriving the proposed mercury criteria, but we do not agree that the proposed weighted practical average BCF is appropriate for several reasons.

First, is has been our experience that accurate models of bioaccumulative metal uptake require detailed understandings and representations of biogeochemical cycling in aquatic environments. In the absence of a much more detailed, criteria derivation method that accounts for differences between aquatic environments, the Board agrees with current EPA policy that the BAF model used in the Great Lakes Initiative is a more technically sound approach for addressing bioaccumulative substances than approaches using BCFs.

Second, we disagree with EPA's conclusion that data are lacking to determine if the Great Lakes' BAFs are appropriate for use in California. There are ample data sets for derivation of BAFs for coastal waters and the major estuary in the State, as well as detailed water column, invertebrate, and fish tissue data available for mercury in the Sacramento River watershed and reservoir systems affected and unaffected by mercury.(*1) The Board encourages EPA to conduct the same level of analysis for the State of California as it did for the Great Lakes Region using existing data. Towards that end, we have calculated BAFs for two trophic levels for the San Francisco Bay Estuary using data from the San Francisco Buy Regional Monitoring Program according to the methodology outlined in the Great Lakes Initiative. For bivalves (trophic level 3), the field-measured BAF is 23,435; for trophic level 4 fish species typically caught by local fishermen, the field-measured BAF is 144,335.(*2)

The next set of comments relates specifically to the proposed "weighted average practical BCF" method. As written, we believe this method would be appropriate if the goal were to calculate the maximum marginal increase in mercury dose that a population could receive without exceeding the RfD. In other words, this approach allows the weighted dietary average to "dilute" the effects of high levels of mercury in individual water bodies. We do not believe that such an approach is appropriate for the derivation of

criteria that will be used to determine whether mercury levels are affecting uses of individual water bodies in California. Instead, consideration should be given to protecting established beneficial uses that rely on water quality in one stream segment. Our second comment is that it is not clear why EPA is including data for open ocean levels of mercury in the derivation of criteria for inland and estuarine waters. Third, it is also not clear whether the referenced BCFs pertain to the dissolved mercury fraction, or total recoverable and if the latter, why the proposed criteria are in terms of the dissolved fraction. Nor is it clear that the data used to derive the early BCFs were obtained using the ultra clean sampling techniques necessary to obtain true water column concentrations. Improper sampling and analytical techniques would yield higher water column values and lower BCFs than the true measurements.

In summary, the Regional Board requests that EPA calculate an appropriate set of BAFs for mercury applicable to the State of California and not adopt the criteria derived using the proposed method. The proposed mercury criteria are under protective of California waters by several orders of magnitude, and the implicit public concern being protected (average diet of the state's population) is inappropriate. For example, San Francisco Bay is currently listed as a water quality limited segment due to high levels of mercury in fish tissue. The mean dissolved mercury concentration in San Francisco Bay is 0.0019 ug/I and no samples have ever exceeded EPA's proposed standard of 0.05 ug/l.

(*1) It is our understanding that extensive data sets exist for at least Clear Lake, Lake Nacimiento, Cache Creek, Walker Creek, Marsh Creek, the Sacramento River, and the New Almaden mining area. These water bodies encompass most of the types of aquatic systems where mercury levels pose water quality threats in the State.

(*2) Both of these calculations are based on high quality data sets and report wet weight tissue concentrations and dissolved mercury concentrations. Because of the time constraints for comments, they are, however, first-cut estimates using mean reported values. The derivation of a BAF for San Francisco Bay can be made much more precise by separating out location, time, specific species, deployment variables (such as size, growth, and post-deployment bioaccumulation), and available TOC using this data base.

Response to: CTR-016-007

EPA acknowledges the San Francisco Bay Regional Water Quality Board's agreement with EPA's position that a BAF model better represents bioaccumulation potential than a BCF. As noted by the commentor, the issue of mercury bioaccumulation is very complex. EPA is working to improve the knowledge base on mercury bioaccumulation and is in the process of updating its overall method for assessing bioaccumulation and deriving BAFs. EPA's National human health water quality criteria are based on national averages of fish consumption from all relevant sources, which is why the PBCF is based on a weighted average that includes open ocean data. The mercury PBCFs and criteria for human health protection are based on total mercury, not the dissolved total form. Only the freshwater and saltwater CMC and CCC are based on the dissolved inorganic form (Hg-II). For further response to the bioaccumulation issue, refer to response to CTR-002-007b.

Comment ID: CTR-020-004a
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:

Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

A. Criteria that Fail to Reflect Updated Scientific Information

1. Mercury

Mercury criteria were significantly corrected, and the City supports this action. The acute criteria were changed to the dissolved form, the misclassified chronic criteria were changed from 0.012 ppb to 770 ppb, and the human health fish tissue-based criteria were raised from 12 parts per trillion ("ppt") to 50 ppt and now apply at harmonic mean flows. These corrections appear to reflect the latest available scientific information. EPA indicated that the human health criteria were based upon fish tissue contaminant levels. Because the underlying basis for the criteria is an assumed fish tissue contamination level, the human health criteria should either (1) allow for adjustment of the criteria where it is apparent that fish tissue levels are acceptable but the criteria may be exceeded or (2) specify that information on fish tissue contamination may be used as a screening tool to determine if the discharge has a reasonable potential to cause exceedance of the criteria. If the fish tissue data indicate that the existing discharge is acceptable, no limitation should be included in the permit.

Response to: CTR-020-004a

EPA acknowledges the commenter's support for the criteria reflecting the latest scientific information, notwithstanding the fact that the commenter has incorrectly referred to the previous aquatic life criterion of 12 ppt as the previous human health value. Regarding the two options that the commenter presents for human health criteria when the underlying basis is a fish tissue concentration, EPA disagrees that the first option is a plausible scenario, given the BCF-based calculation. EPA believes the reverse scenario is far more likely (i.e., when the fish tissue levels are not acceptable but the water column value is not exceeded). For the second option, EPA agrees that the use of fish tissue is more acceptable for back-calculating from fish tissue concentrations to ambient concentrations in order to determine remaining assimilative capacity.

Comment ID: CTR-020-004b
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:

Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

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Response to: CTR-020-004b

See response to CTR-020-004a.

Comment ID: CTR-027-012c
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-22
C-24
G-09
G-05

Comment: PROVISIONS OF THE PROPOSED RULE WE SUPPORT

Not withstanding the above comments, we believe there are certain elements of the proposed rule with respect to establishing water quality standards that we can support:

* Metal criteria expressed in the dissolved fraction rather than expressed in the total recoverable fraction.

* Metal criteria that are developed as a function of the water-effect-ratio (WER).

* The current proposed human health criterion for mercury.

* The current preamble language regarding metal translators and mixing zones.

We believe the above provisions provide a more acceptable, scientific approach to the water quality-based pollution control approach. We recommend these provisions of the current rule remain as proposed.

Response to: CTR-027-012c

EPA acknowledges the commenter's support of the rule.

Comment ID: CTR-030-006
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: B. The Proposed Mercury Human Health Criterion is Technically Deficient

EPA proposes a human health criterion for mercury of 50 nanograms per liter for California. 62 Fed. Reg. at 42,194. This criterion, while substantially less stringent than that applied in the Great Lakes Water Quality Rule, is technically deficient because assumptions used in developing the criterion are not scientifically defensible. For example, the Bioconcentration Factor (BCF) used in the criterion equation assumes a "steady state" relationship between mercury levels in the water column and mercury levels in fish. In fact, the California proposal's preamble states "the BCF is defined as the ratio of chemical concentration in the organism to that in the surrounding water." 62 Fed. Reg. at 42,179, col. 3. The preamble also references EPA's water quality criteria document for mercury, which stipulates that "These [BCF] calculations depend upon a number of assumptions. The basic assumption is that, on the average, the concentration of methylmercury in fish muscle is related to the concentration of total mercury in water. This might be true if (1) methylmercury on the average is a constant fraction of total mercury in water . . . " Ambient Water Quality Criteria for Mercury, EPA 440/5-80-058 (October 1980) (Mercury Criteria Document) at C-25 to C-28. However, the ratio of mercury in the water column to mercury

levels in fish is not a "steady state" but can vary by as much as a factor of 100, particularly in streams and littoral areas of larger bodies of water. This variability is described at length in the Proceedings of the Third International Conference on Mercury as a Global Pollutant, reprinted in Water, Air and Soil Pollution Journal 80 (1-4) 1995 (Proceedings of Third International Conference). The preamble to the California proposal does not address the variability of totalmercury concentrations in the water column, but acknowledges the variability in the ratio of methylmercury to total mercury concentrations in the water column, stating:

To a considerable degree the magnitude of the BAF for mercury in a given system depends on how much of the total mercury in that system is present in the methylated form. Methylation rates vary widely from one aquatic system to another for reasons that are not fully understood.

62 Fed. Reg. at 42,180, cols. 1-2. Having acknowledged that methylation rates vary widely, EPA should not employ a model which is preconditioned on the existence of constant methylation rates.

UWAG also notes the following additional questionable assumptions of the proposed criterion.

* The criterion does not adequately acknowledge fate and transport processes such as evasion and deep sediment burial, which in many aquatic systems can remove 90 percent or more of the available mercury. Although the California proposal incorporates the concept of mixing zones, mixing zones only provide for partial consideration of the fate and transport mechanisms which reduce water column concentrations of mercury. Fate and transport processes - particularly evasion - take place over several days whereas mixing is a more instantaneous process. Since fish bioaccumulate mercury over their lifespan, it is the range of mercury concentrations that fish experience over their entire life (and not the concentration at the edge of a mixing zone) which is of concern. A subcommittee of EPA's Science Advisory Board (SAB) has criticized EPA's fate and transport models for ignoring evasion. In its recent report, the Subcommittee states: "It is unfortunate that soil and water loss degradation constants were not incorporated in the model. Several recent studies have shown that (elemental) Hg production and evasion are common processes in soils and surface waters." SAB, Report of the Mercury Review Subcommittee, Executive Committee Review Draft, dated June 30, 1997, p. 30.

* The RfD is inappropriate because it is based on a chronic exposure study done in Iraq under poor field conditions. Newer and much better data are available from a number of studies, including those conducted in the Seychelles Islands. (See 11 papers presented in Neurotoxicology Vol. 16, no. 4 (1995)). These data should be evaluated and should result in a larger RfD.

* The California proposal's BCFs (*2) are not valid because they use erroneous water column concentrations and arbitrary fish concentrations. The open ocean mercury concentration of 15 ng/l apparently was taken from an outdated 1979 report by Fitzgerald. In more recent peer-reviewed literature, Fitzgerald identifies the open ocean mercury concentration as more than ten fold less than the cited values (see Proceedings of Third International Conference, particularly "Methylation and Elemental Mercury Cycling in Surface and Deep Ocean Water of the North Atlantic" by Mason, Rolfus and Fitzgerald). The 17 ng/l estuarine and 40 ng/l fresh water values are similarly off by a factor of ten.(See Proceedings of Third International Conference, particularly "Mercury Speciation in the Scheldt Estuary" by Leermakers et al., and "Mercury Concentrations in Two Great Waters" by Cleckner et al.) Moreover, the range of concentrations between water bodies is great and prompted the SAB Subcommittee to conclude that BAFs (and, presumably, BCFS) can only be derived and used on a site-specific basis. The Subcommittee similarly concluded that fish mercury concentrations between various species in a given body of water vary dramatically.

* Furthermore, the BCFs are not valid for use in the California proposal because they were developed primarily on the basis of species from the Eastern half of the United States and the Atlantic Ocean (e.g., sardines). See Mercury Criteria Document.

For all of these reasons, UWAG believes the proposed human health mercury criterion is fundamentally flawed and should be subject to rigorous reevaluation by the Agency.

(*2) The term BCF is used inconsistently in the California proposal's preamble and in the Mercury Criteria Document. In the preamble, BCF is defined as fish uptake of mercury by respiration alone and specifically excludes mercury uptake through ingestion of food. The preamble goes to considerable length to explain that uptake by both respriation and ingestion is a different process defined as bioaccumulation. The preamble explains that a criterion based on bioaccumulation is not being considered at this time but may be incorporated into future rulemakings. The preamble then explains how its bioconcentration values were taken from the Mercury Criteria Document. That document, however, uses the term "bioconcentration" in a completely different sense. Bioconcentration, as used in the Mercury Criteria Document, is actually bioaccumulation as defined in the 1997 preamble. The Mercury Criteria Document derives its bioconcentration values from actual fish levels measured in ocean and lake fish caught for commercial purposes. Consequently, those fish were exposed to mercury both from the water column and from their food sources. Bioconcentration factors (as the term is defined in the 1997 preamble) can only be obtained from fish reared in carefully constructed laboratory experiments where the diet is purposefully devoid of the naturally occurring mercury commonly found in natural forage.

Response to: CTR-030-006

EPA agrees with the commenter that considerable variability can exist in both total and methymercury concentrations in the water column. However, predicting the amount of methylmercury present for a given concentration of total mercury is very difficult. The amount of methylmercury formed is affected by numerous chemical, physical, and biological factors which are not well understood. Examples of these include: foodchain interactions; physicochemical parameters (e.g., pH, temperature, dissolved and particulate organic matter); and size and type of watershed. It is readily acknowledged that mercury is toxic, causing a variety of adverse effects to both humans, fish, and wildlife. Thus, methods are need to assess mercury exposure and effects, and to control its release to the environment. These issues are discussed in the Mercury Study Report to Congress, (EPA-452/R-97-008); The National Survey of Mercury Contamination in Fish. Database Summary 1990-1995. September 29, 1997; 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water, (EPA-820-B-96-001); and Final Water Quality Guidance for the Great Lakes System: Final Rule. Fed Register, 60(56):15366-15425 (March 23, 1995). EPA is not aware of any method to accurately predict concentrations of methylmercury in the water column and subsequent bioaccumulation in aquatic biota, nor does the commenter suggest any method. Although there are a few fate/transport models that could be used to assess the fate of mercury in the environment, these models are still in developmental stages, have only been applied under a narrow range of environmental and biological conditions, and will require validation before they are ready for use on a broad scale. Therefore, EPA believes that the use of BCFs represents the most appropriate method at this time for use in the CTR. Furthermore, as suggested by the commenter, EPA is currently undergoing a comprehensive review of the human health mercury criteria, in addition to the overall hman health criteria derivation methodology. Once this review is complete, EPA intends to revise its National human health mercury criteria, and subsequently update California's mercury criteria. For further response to the bioaccumulation issue, refer to response to comment for

CTR-002-007b.

Regarding comments on the Reference Dose (RfD), EPA has on two occasions published RfDs for methyl mercury which have represented the Agency consensus for that time. These are described in the sections below. The original RfD of 0.3 @g/kg/day was determined in 1985. The current RfD of 0.1 @g/kg/day was established as Agency consensus in 1995, based on the study by Marsh et al. 1987. The Agency is aware of all the additional data that have become available since the calculation of the current RfD. At the time of the generation of the Mercury Study Report to Congress, it became apparent that considerable new data on the health effects of methyl mercury in humans were emerging. Among these are large studies of fish, or fish and marine mammal, consuming populations in the Seychelles and Faroes Islands. Smaller scale studies are in progress which describe effects in populations around the Great Lakes.

However, as much of this new data have either not yet been published or have not yet been subject to rigorous peer review, it was decided that it was premature for EPA to make a change in the 1995 methyl mercury RfD at this time. This decision was approved by the Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the EPA. The SAB is structured to provide balanced, expert assessment of scientific matters relating to problems facing the Agency. Their report makes the following statement.

"In general, from the standpoint of looking at human health effects and the uncertainties, the draft report is a very good document and an important step forward in terms of bringing the relevant information together into one place for the first time. The current RfD, based on the Iraqi and New Zealand data, should be retained at least until the on-going Faroes and Seychelles Islands studies have progressed much further and been subjected to the same scrutiny as has the Iraqi data."

The SAB report continues:

"Investigators conducting two new major prospective longitudinal studies--one in the Seychelles Islands the other in the Faroe Islands--have recently begun to publish findings in the literature and are expected to continue releasing their findings during the next 2-3 years. These studies have advantages over those cited in the previous paragraph in that they have much larger samples sizes, a larger number of developmental endpoints, potentially more sensitive developmental endpoints, and control a more extensive set of potential confounding influences. On the other hand, the studies have some limitations in terms of low exposures (to PCBs in the Faroes) and ethnically homogenous societies. Since only a small portion of these new data sets have been published to date and because questions have been raised about the sensitivity and appropriateness of the several statistical procedures used in the analyses, the Subcommittee concluded that it would be premature to include any data from these studies in this report until they are subjected to appropriate peer review. Because these data are so much more comprehensive and relevant to contemporary regulatory issues than the data heretofore available, once there has been adequate opportunity for peer review and debate within the scientific community, the RfD may need to be reassessed in terms of the most sensitive endpoints from these new studies."

An inter-agency process, with external involvement, will be undertaken for the purpose of reviewing these new data, their evaluations, and the evaluations of existing data. An outcome of this process will be an assessment by EPA of its RfD for methyl mercury to determine if a change is warranted.

Comment ID: CTR-030-007

Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: C. EPA Should Delay Promulgation of a Mercury Human Health Criterion Until SAB Subcommittee Comments

In forming a SAB subcommittee to comment on its draft Mercury Report to Congress, EPA has engaged a group of very knowledgeable scientists to assist it in understanding the fate and transport of mercury. That subcommittee has prepared draft comments and will finalize those comments within the next few months. EPA should review and evaluate the Subcommittee's final comments before promulgating mercury criteria for California.

Response to: CTR-030-007

EPA has reviewed and incorporated all of the SAB subcommittee's final comments that are possible to incorporate at this time. However, there are further analyses on mercury that are in progress. EPA has entered into an 18-month agreement with the National Academy of Sciences (NAS) to resolve outstanding issues with the mercury risk assessment. Additionally, EPA is in the process of developing methods to more accurately measure bioaccumulation, as part of the revisions to the human health methodology for deriving water quality criteria. After finalization of the methodology and completion of the NAS agreement, EPA intends to update its criterion for mercury. Until that time, EPA believes that the proposed CTR criteria value for mercury is appropriate and reflects the best available scientific information.

Comment ID: CTR-032-006a
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-24

Comment: Mercury Criteria

The District supports the proposed revised human health criteria for mercury based on updated IRIS information. The District also supports EPA's decision (CTR P. 42180) not to apply the bioaccumulation factor (BAF) developed for the Great Lakes Initiative to the CTR mercury criteria. We agree that mercury methylation rates vary widely and are not well understood, particularly for amalgam related

mercury. We believe that adoption of a national BAF under consideration as part of the "Mercury Study Report to Congress: SAB Review Draft" is inappropriate for California, particularly for the complex San Francisco Bay system. CDA recommends that EPA direct the State to develop a site specific objective (SSO) for mercury for San Francisco Bay based on a site specific BAF and data on natural cleanup processes and methylation processes. The proposed CTR criteria should serve as interim criteria until the SSO is developed and adopted.

Response to: CTR-032-006a

EPA acknowledges the commenter's support of the rule. Regarding the recommendation for a "site-specific objective" for mercury in San Francisco Bay, EPA always advocates that states develop site-specific criteria when local data are available. However, EPA also believes that protective defaults are appropriate.

Comment ID: CTR-035-002b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-22
C-08a
G-05
G-04
G-09
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002b

EPA acknowledges the commenter's support of the rule.

Comment ID: CTR-035-026
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42179-42180 -- Mercury Criteria We support EPA's promulgation of revised human health criteria for mercury based on updated IRIS information We also support EPA's decision not to apply the bioaccumulation factor (BAF) developed for the Great Lakes in the Great Lakes Initiative to the CTR mercury criteria. We agree that there is insufficient evidence at this time to substantiate whether this is an appropriate BAF for California. Further, we question whether a single BAF should be developed in the future for California, given the varied nature of the water bodies in the State -- ranging from the Bay-Delta in northern California to concrete-lined effluent-dominated streams and the saline, agricultural drainage-dominated Salton Sea in southern California -- as well as the variation in methylation rates and the amount of methylated mercury in these varied ecosystems. For these reasons, we also doubt that it is possible to derive a valid national BAF for mercury.

Response to: CTR-035-026

EPA acknowledges the comment on the Agency's choice not to use a BAF for the mercury criterion. EPA believes that the use of a BCF is most appropriate at this time for the CTR. EPA further understands the complexity surrounding the issue of bioaccumulation and is currently working on improving its methodology, including evaluating the impact that the type of water body has on bioaccumulation.

Comment ID: CTR-038-002c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002c

EPA acknowledges the provisions of the rule supported by the commenter.

Comment ID: CTR-039-005
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: III. EPA'S PROPOSED MERCURY NUMBER IS FLAWED BECAUSE IT IGNORES RELEVANT DATA REGARDING ITS POTENTIAL TO BIOACCUMULATE

EPA's proposed mercury number, in addition to using an inappropriate fish and shellfish consumption rate, also fails to factor in bioaccumulation of mercury into fish tissue. Assuming EPA is accurate in that it does not know the specific potential for mercury to bioaccumulate in waters of the State of California, it is certain that some rate of bioaccumulation is occurring. Unfortunately, EPA only applies a bioconcentration factor, ignoring the mercury that is entering fish through their own food consumption. In fact, in at least one region of the State -- the San Francisco Bay area -- there is ample data from which an accurate bioaccumulation factor can be determined. See Comments of Communities For A Better Environment. That factor is comparable to the rate of bioaccumulation observed in Great Lakes fish, which is from four times to 20 times greater than EPA's proposed bioconcentration factor.

Response to: CTR-039-005

EPA acknowledges the comments made on the use of BCFs. EPA believes that this represents the most appropriate method at this time for use in the CTR. EPA further understands the complexity surrounding the issue of bioaccumulation and is currently working on improving its methodology. Regarding the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding bioaccumulation and available data from the San Francisco Bay area, see response to CTR-002-007b.

Comment ID: CTR-040-002b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: C-01 Mercury
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-24a
G-09
G-05

Comment: PROVISIONS SUPPORTED

We support a number of provisions of the Rule, including: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury- and (4) the Preamble discussions regarding metals translators and mixing zones. These provisions provide a firmer scientific base for the water quality-based approach to pollution control and are a marked improvement over the old Inland Surface Waters Plan. We would urge EPA to retain these provisions in the final Rule.

Response to: CTR-040-002b

EPA acknowledges the provisions of the rule supported by the commenter.

Comment ID: CTR-041-004
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: Third, the District strongly supports the revised human health criteria for mercury, and EPA's recognition that bioaccumulation factors (BAF) from the Great Lakes are highly unlikely to be applicable in the diverse California environment. Consequently, the District does not believe that the proposal to develop a national BAF for mercury is scientifically sound. The use of most recently available and applicable data from EPA's resources to revise the human health criteria is the type of sound scientific procedure that should be used. Similarly, EPA's recognition that mercury methylation, the key to the magnitude of the BAF for a given system, is widely variable and not understood is also welcomed and supported. Given these statements in the proposal, however, EPA's subsequent proposal to develop a national BAF has little merit and is not supported by the District.

Response to: CTR-041-004

EPA disagrees that its effort to derive national default bioaccumulation factors for mercury are inappropriate. EPA acknowledges the complexity of mercury biogeochemical cycling and bioaccumulation in aquatic ecosystems, but believes that need to control mercury risks to humans

warrants the development of national, default human health criteria that reflect the latest science on mercury toxicity and bioaccumulation. EPA is aware of only one comprehensive model on mercury cycling and bioaccumulation that has been developed (the Mercury Cycling Model) and believes, at this time, that the model cannot be extrapolated with sufficient certainty to ecosystems that differ substantially upon which it was based (i.e., northern oligotrophic lakes). This model was specifically developed with northern oligotrophic lakes and reservoirs in mind, and EPA believes at this time it can not be extrapolated with sufficient certainty to ecosystems that differ substantially from this (e.g., streams, rivers, estuaries), and for which mercury bioaccumulation is also an important issue. This uncertainty exists partly because the model represents ecosystem dynamics rather simplistically, though more because of limitations in the science than by preference. Mercury bioaccumulation to higher order trophic levels influenced heavily by the type of food chain (i.e. benthic or pelagic based) and complexity of food chain interactions. The model must make assumptions about food chain interactions that limit the models predictive capability. Uptake and depuration of mercury in natural systems is also difficult to measure and predict, the model must make assumptions about these processes that limit its predictive capability. In order to minimize the effect that model assumptions have on predicting mercury uptake for a given application, it is necessary to have some local hydrological, physical, and biological data to calibrate the model. In most cases, such data is not available. Such limitations are common for most predictive models. Terefore, given the state of the science for the few available models, and because EPA must address mercury bioaccumulation for a broad range of aquatic ecosystems (e.g. lakes, streams, estuaries), EPA believes at this time it is most appropriate to derive BAFs for mercury. EPA is currently collecting data on bioaccumulation for all aquatic ecosystems, however, it is unclear whether BAFs will be developed separately for each type of aquatic system or if one value will be derived for application to all aquatic systems. Therefore, EPA anticipates the need to develop BAFs for mercury which have applicability to a broad range of aquatic ecosystems (rivers, lakes, estuaries). At this time, it is unclear whether BAFs will be developed separately for each type of waterbody because EPA is currently collecting and evaluating mercury bioaccumulation data.

Comment ID: CTR-041-007a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-22

Comment: 2. Additional Strong Reasons to Maintain use of Dissolved Metals and Mercury Criteria

The District also has significant economic reasons to support the use of dissolved metals and the updated mercury criteria. Previous District studies have shown that adoption of metal criterion as total recoverable would cost the District more than $50 million a year while reducing metal loads in the Sacramento River by several percent. Likewise, if old mercury criteria were adopted it would cost the District over $100 million a year while reducing mercury loads in the Sacramento River by several percent.

Response to: CTR-041-007a

EPA acknowledges the commenter's support, however the commenter did not provide enough information for EPA to comment on its cost estimate related to total recoverable criteria and the old mercury criteria.

Comment ID: CTR-043-002c
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002c

EPA acknowledges the provisions of the rule supported by the commenter.

Comment ID: CTR-044-003c
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-09
G-05
G-04

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003c

EPA acknowledges the provisions of the rule supported by the commenter.

Comment ID: CTR-045-006
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

The revised human health criterion for mercury.

Response to: CTR-045-006

EPA acknowledges the commenter's support of the mercury criterion.

Comment ID: CTR-051-003a
Comment Author: Cal. RWQCB Central Valley Reg.
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:

Attachments? N
CROSS REFERENCES

Comment: Mercury

The proposed mercury criteria are not appropriate for California waters and could seriously undermine ongoing regulatory and watershed efforts to address regionwide mercury concerns. In the Central Valley Region, existing ambient concentrations of dissolved mercury are two orders of magnitude lower than the proposed criteria, yet there are widespread beneficial use impairments that result form elevated mercury levels in fish. There are consumer advisories in effect in the Delta, Clear Lake and Lake Berryessa because of elevated fish tissue levels of mercury. There is widespread concern about mercury bioaccumulation in fish and wildlife. Mercury cycling and transfer through the ecosystem is very complicated. More research is needed to determine which sources and forms of mercury, in California, are important in controlling how much mercury is concentrated in aquatic systems. Also, use of national orstatewide fish consumption values are inappropriate. Subsistence fishing is practiced by many of California's subpopulations. Protection of these subpopulations necessitates establishing site specific consumption estimates upon which to base a criterion. For the reasons stated above, the proposed criteria for mercury should not be adopted.

Please call me at (916)255-3087 or Jerry Bruns at (916)255-3093 if you have any questions regarding these comment.

Response to: CTR-051-003a

EPA disagrees that its program to derive national default criteria is inappropriate. EPA understands that conditions vary from state to state and can vary among different site-specific locations within a given state. However, under Section 304(a) of the Clean Water Act, EPA is required to develop, and from time to time revise, such default criteria to help protect human health and designated uses of the nation's water bodies. As such, EPA believes that the criteria program is necessary and appropriate. The State will be translating the state's narrative criteria, site-specifically, to better account for exposure to mercury. The State will also develop regulatory controls that will protect designated uses. If there is widespread beneficial use impairment, then these waterbodies will appear on EPA's 303 list for TMDL development and protective target goals for the waterbodies will be addressed as part of that process. In addition, EPA will be updating its human health water quality criteria methodology to better reflect exposures through the food chain.

Regarding the fish consumption values chosen, see response to CTR-002-002a.

Comment ID: CTR-051-003b
Comment Author: Cal. RWQCB Central Valley Reg.
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N

CROSS REFERENCES

Comment: Mercury

The proposed mercury criteria are not appropriate for California waters and could seriously undermine ongoing regulatory and watershed efforts to address regionwide mercury concerns. In the Central Valley Region, existing ambient concentrations of dissolved mercury are two orders of magnitude lower than the proposed criteria, yet there are widespread beneficial use impairments that result form elevated mercury levels in fish. There are consumer advisories in effect in the Delta, Clear Lake and Lake Berryessa because of elevated fish tissue levels of mercury. There is widespread concern about mercury bioaccumulation in fish and wildlife. Mercury cycling and transfer through the ecosystem is very complicated. More research is needed to determine which sources and forms of mercury, in California, are important in controlling how much mercury is concentrated in aquatic systems. Also, use of national orstatewide fish consumption values are inappropriate. Subsistence fishing is practiced by many of California's subpopulations. Protection of these subpopulations necessitates establishing site specific consumption estimates upon which to base a criterion. For the reasons stated above, the proposed criteria for mercury should not be adopted.

Please call me at (916)255-3087 or Jerry Bruns at (916)255-3093 if you have any questions regarding these comment.

Response to: CTR-051-003b

See responses to CTR-002-007b and CTR-051-003a.

Comment ID: CTR-052-002b
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-22
G-09
G-05
G-04

Comment: EPA will recall the State Water Quality Plans Task Forces that included all stakeholders, including EPA. The Authority appreciates the incorporation of many of the consensus recommendations from the Task Forces into the CTR, including:

* Adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio

* Adoption of the proposed new human health criterion for mercury

* Preamble discussions regarding metals translators, mixing zones, and interim permit limits

Response to: CTR-052-002b

EPA acknowledges the commenter's support of the consensus recommendations.

Comment ID: CTR-053-003a
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES C-02b
C-09a

Comment: In spite of our lack of detailed comments for specific criteria, we have concerns regarding any weakening of California's previously developed standards, particularly those for mercury and copper. Also, we question the absence of criteria for dioxin and dioxin-like compounds. In order to ensure these issues are considered in future improvements of the Rule, we incorporate by reference the comments of the Natural Resources Defense Council regarding mercury, and the comments of Communities for a Better Environment ("CBE") regarding dioxin compounds and copper.

Response to: CTR-053-003a

With respect to the comment on mercury see responses to CTR-002-007b and 006-001b. With respect to the comments on copper and dioxin see response to CTR-002-003.

Comment ID: CTR-054-003
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: BADA supports the adoption of the proposed new human health criterion for mercury. Several of the BADA agencies would have serious attainability problems with the old EPA human health criteria for mercury, whereas none have a problem with the criteria proposed in the CTR. Although we concur with environmental groups testifying at the September 17 hearing that mercury is a major

problem, there is little to be gained through more stringent regulation of point sources. Mercury levels of concern in water and tissue are largely the result of unregulated nonpoint sources, namely abandoned mines and downstream sediments. The way to address mercury is through the watershed management approach and control of nonpoint sources. BADA's support for the new mercury criteria is not meant to imply that BADA agencies are unwilling to implement reasonable source controls aimed at reducing mercury levels in our discharges or to participate in watershed management studies aimed at reducing nonpoint sources of mercury. On the contrary our agencies support and are committed to such activities.

Response to: CTR-054-003

EPA acknowledges the commenter's support of the rule and proposed mercury criterion.

Comment ID: CTR-056-003
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* The revised human health criterion for mercury based on data from more current research than for the National Toxics Rule criteria,

Response to: CTR-056-003

EPA acknowledges the commenter's support of the proposed mercury criterion.

Comment ID: CTR-058-010
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Mercury. WSPA concurs with EPA that mercury BAFs for a particular water body is highly dependent on the amount of organic mercury in that system. At this time WSPA supports the use of the BCFs until a more representative estimate of BASFs in pertanent water bodies in California can be

established.

Response to: CTR-058-010

EPA agrees with these comments supporting a five year compliance schedule.

Comment ID: CTR-059-009
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Mercury Human Health Criteria

EPA has proposed human health criteria for mercury for consumption of water and organisms (0.05 ug/L) and for consumption of organisms only (0.051 ug/L). We have a number of concerns about these criteria and recommend that EPA defer adoption or revise them for the final rule.

First, we can find no basis for the range of Bioconcentration Factors (BCFs) listed in the CTR Administrative Record Matrix (ARM). The ARM lists BCFs for mercury ranging from 3,765 to 9,000. No specific references are provided in the 1986 criteria document (the "Gold Book") for mercury for the derivation of the BCFs. EPA should provide information on the scientific basis for the derivation of the BCFs used to derive the mercury criteria. The discussion in the Preamble (p. 42179) indicates that there are three different BCFs for fresh water, estuarine waters, and the open ocean. This indicates that it would be most appropriate to calculate separate criteria for each type of water (i.e. fresh, estuarine, and ocean). More to the point, the Preamble also indicates that methylation rates vary widely from one aquatic system to another, thus making it difficult to know the actual potential for bioaccumulation in surface waters in California (p. 42180). Therefore, we believe that for mercury it is necessary for EPA to derive California-specific BCFs for different types of water bodies before adopting human health criteria for mercury in the CTR. At a minimum, separate freshwater and estuarine criteria should be developed. Alternatively, EPA could defer to the State for adoption of appropriate regional or site-specific mercury criteria by RWQCBs using local fish tissue concentration data.

Response to: CTR-059-009

The scientific basis for the range of BCFs is stated in the 1980 ambient water quality criteria document for mercury (Report No. EPA 440/5-80-058), which was part of the CTR Administrative Record Matrix. EPA acknowledges the comment on the differences between types of water bodies (i.e., fresh, estuarine, and ocean) and the Agency is currently evaluating the need to develop separate BAFs for such different water body types. For further response to the bioaccumulation issue, refer to response to CTR-002-007b.

Comment ID: CTR-060-008
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Mercury human health criteria is technically deficient

The mercury human health criterion has used unrealistic assumptions in developing the criterion, including: * the Bioconcentration Factor (BCF) used in calculating the criterion assumes a steady state condition between the mercury concentrations in the water column and fish. The preamble itself acknowledges that there is significant variability in the ratio of water column to fish concentrations (see 62 Fed. Reg. at 42,180, Cols. 1-2). Consequently, EPA should not endorse the use of a single BCF for all California waters. * the BCFs were developed primarily on the basis of species from the Eastern half of the United States and the Atlantic Ocean (e.g., sardines) (See Ambient Water Quality Criteria for Mercury, EPA 440/5-80-058, October 1980) and are not valid for use in the California proposal.

EPA should delay promulgation of a mercury human health criterion until the Science Advisory Board (SAB) Subcommittee comments on EPA's report to congress on mercury

EPA has formed a SAB Subcommittee to comment on its draft Mercury Report to Congress. This Subcommittee is reviewing the fate and transport of mercury which are important factors in developing the mercury human health criterion. EPA should postpone the adoption of the proposed CTR criterion until the final report from this committee is available so that the SAB's findings can be reviewed and incorporated into the CTR criterion.

Response to: CTR-060-008

EPA acknowledges the complexity of issues associated with steady state assumptions when calculating criteria. EPA also believes that it has used appropriate assumptions based on the best methodologies currently in-place. EPA is currently working to enhance its methodology to address these complex issues. Further, once EPA develops the BAF-based human health water quality criteria, EPA will work with the State of California to adopt either that recommended value or a value that is consistent with the final methodology. For additional discussion, refer to responses on CTR-002-007b, CTR-030-007, and CTR-041-004.

Comment ID: CTR-061-012
Comment Author: G. Fred Lee & Associates

Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42168, third column, first paragraph, states, "The mercury criteria also differ in this proposal due to the Agency's movement away from aquatic life criteria based on the Final Residue Value (FRV) procedure of the 1985 Guidance." It has been learned that the proposed CTR's apparent raising of the Hg criterion for protection from excessive bioaccumulation from the current 12 ng/L to 50 ng/L total mercury is only temporary. The regulation of Hg is under review at the national level. The Agency should have indicated to the regulated community in the proposed CTR that the total Hg criterion for prevention of bioaccumulation will likely decrease from the current 12 ng/L set forth in the "Gold Book" to about 5 ng/L. This revised Hg criterion will cause most domestic wastewater discharges to be in violation of this criterion.

Rather than trying to regulate Hg in wastewater effluents and other sources based on the exceedance of the total Hg criterion to prevent excessive Hg bioaccumulation in edible fish tissue, Hg should be regulated based on excessive Hg concentrations in fish tissue. It is technically invalid to assume, as the US EPA has been assuming and proposes to continue to assume, that there is a constant bioconcentration factor that relates the total concentration of Hg in water to excessive Hg concentrations in fish tissue. The actual bioconcentration of total Hg is highly site-specific. To require that all POTWs and other dischargers or sources of Hg have no more than 5 ng/L in the discharge will grossly over-regulate Hg from many sources.

Response to: CTR-061-012

EPA notes that this response addresses what the commenter believes will be the national criteria recommendations for mercury and human health. EPA disagrees that the proposed criterion for mercury is inappropriate. The Mercury Study Report To Congress has been published and an Agency Mercury Action Plan is being developed. EPA has also begun work to develop a new criterion for mercury that will be based on the Mercury Study Report To Congress and upcoming proposed revisions to the human health methodology. In addition, EPA is evaluating the complexity of determining the BAF and how best to express its value for criteria-setting purposes.

Comment ID: CTR-066-008
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The revised human health criterion for mercury.

Response to: CTR-066-008

EPA acknowledges the commenter's support of the proposed mercury criterion.

Comment ID: CTR-081-002f
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
G-02
C-22
G-09
C-08a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are perfomed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002f

EPA acknowledges the commenter's support of the proposed rule.

Comment ID: CTR-085-009
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The revised human health criterion for mercury.

Response to: CTR-085-009

EPA acknowledges the commenter's support of the proposed mercury criterion.

Comment ID: CTR-086-002
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: C-01 Mercury
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: CDA is a strong supporter of water quality and human health protection. CDA's primary goals in commenting on the draft CTR are to request that mercury criteria be based on sound science and that mercury regulation be implemented via a watershed management, phased TNML-type approach.

CDA is particularly concerned that the CTR does not adequately assess the economic impacts on indirect dischargers nor the extent to which there will be measurable water quality benefits solely from adoption of the proposed mercury criteria for point sources.

Mercury Criteria

CDA supports the proposed revised human health criteria for mercury based on updated IRIS information. CDA also supports EPA's decision (p. 42180) not to apply the bioaccumulation factor (BAF) developed for the Great Lakes Initiative to the CTR mercury criteria. We agree that mercury methylation rates vary widely and are not well understood, particularly for amalgamrelated mercury. We believe that adoption of a national BAF under consideration as part of the "Mercury Study Report to Congress: SAB Review Draft" is inappropriate for California, particularly for the complex San Francisco Bay system. CDA recommends that EPA direct the State to develop a site specific objective (SSO) for mercury for San Francisco Bay based on a site specific BAF and data on natural cleanup processes and methylation processes. The proposed CTR criteria should serve as interim criteria until the SSO is developed and adopted.

Response to: CTR-086-002

EPA agrees with the commenter's support of the proposed mercury criterion. EPA encourages the State or Tribe to utilize site-specific information on bioaccumulation when available to calculate criteria. For additional discussion on the complexity of BAF use in the mercury criterion, refer to response on this issue in CTR-041-004.

Comment ID: CTR-089-001b
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-22
C-08a
G-05
K-01
G-02
G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001b

EPA acknowledges the commenter's support of the proposed rule.

Comment ID: CTR-091-001a
Comment Author: Abu-Saba, Ganguli, Flegal
Document Type: Environmental Group
State of Origin: CA
Represented Org: Coastal Advocates
Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: This comment addresses the mercury criteria for continuous concentration (CCC) proposed in

40 CFR, part 13 1(*1). The proposed aquatic health and human health criteria do not protect aquatic life or humans from mercury contamination. This is demonstrated by the scientific data presented herein. That information includes published and unpublished results from scientists with established reputations in environmental research.

The aquatic life mercury CCC is proposed to be raised sixty-fold, from the National Toxics Rule standard of 0.012 micrograms per liter (ppb) to 0.770 ppb. The human health criteria is proposed to be raised four-fold, from 0.0 12 ppb to 0.050 ppb. These proposed changes have potentially devastating economic and environmental costs that must be included in the EPA's cost-benefit analysis. Water treatment costs for the metals mercury, silver, and chromium account for 30% of costs projected in the, California Toxics Rule (CTR) economic analysis.(*2) However, the long term environmental and economic cost of mercury contamination may far exceed the short term economic savings resulting from an increase in the mercury CCC. This is especially true in California, a mining state that has devoted hundreds of millions of dollars to restoration and enhancement of commercial and sport fisheries by enactment of Proposition 204.

Four specific points are substantiated by data and-literature: (1) California should maintain the National Toxics Rule standard of 0.012 ppb for protection of both aquatic life and human health; (2) The proposed increase in CCC standards do not protect against uncontrolled point-source releases; (3) The proposed criteria of 0.77 ppb (aquatic life) and 0.050 ppb (human health) were derived using assumptions about mercury bioconcentration that are not scientifically justified ; and (4) Wetlands may require even more protective measures than open waterways.

The proposed aquatic life CCC offers no protection from mercury point sources, such as the acid mine drainage shown in Figure 1. The data from San Carlos Creek, above and below the New Idria mercury mine in San Benito County, California, indicate that this mine, which was at one time the second largest producer of mercury in North America(*3), represents an uncontrolled point source mercury release(*4). Acidic water from the abandoned mine mixes with the waters of San Carlos Creek, leading to elevated mercury concentrations below the mine opening.

Figure 2 shows dissolved mercury concentrations upstream and downstream of the mine opening. The existing standard, 0.012 parts per billion (shown by the heavy, black horizontal line), distinguishes between background mercury concentrations (upstream) and point source mercury contamination (downstream). The low concentrations from the two upstream stations reflect natural ambient dissolved mercury concentrations resulting from water drainage through mercury ore deposits in that region(*5). The elevated concentrations downstream of the mine opening clearly exceed the National Toxics Rule mercury criteria. The proposed 0.77 ppb criteria, shown in Figure 3, would not distinguish between natural ambient upstream water and the contaminated water downstream from the mine.

The aquatic life CCC is more than two times greater than concentrations toxic to aquatic life. A water concentration as low as 0.3 ppb inhibits invertebrate reproduction and egg hatching success, and impairs fish physiology(*6). Although the lower human health criteria of 0.05 ppb would apply to essentially all California surface waters(*7), establishment of an aquatic life criteria above toxic effect levels sets a poor precedent for environmental protection.

The New Idria mine is but one example of mercury point source contamination within the State of California; there are many others. Mercury contamination is part of this state's mining legacy(*8). Historically, cinnabar (mercury, sulfide) was mined in California from New ldria, New Almaden, and other mines, and purified to elemental mercury (quicksilver). Thousands of tons of quicksilver were used to amalgamate gold and silver during the late 1800's. It is estimated that 0.3 to 3 kg of mercury was lost,

via volatilization and spillage, for every ton of gold recovered during this period.(*8)

Recent measurements(*9) from California lakes, including Clear Lake, Davis Creek Reservoir, and Lake Nacimiento indicate that dissolved mercury concentrations were twenty to fifty times lower than the proposed human health criteria of 0.05 ppb. However, in each lake largemouth bass contained part per million tissue mercury concentrations which exceeded the National Academy of Sciences guideline for acceptable mercury concentrations in fish.

Part per trillion mercury concentrations in water may be magnified a million-fold, to health-threatening, part per million mercury concentrations in fish. The form of mercury which is most readily bioaccumulated is methylmercury, a form of organic mercury which is produced by bacterial metabolism. Organomercury compounds are highly toxic. Karen Wetterhahn, the prominent Dartmouth researcher who was recently studying mercury toxicity, spilled two drops of dimethylmercury on her hand. Three months later she died from neuralgic damage resulting from acute mercury poisoning(*10) (Figure 5). The disaster in Minimata Bay, Japan, resulted from bacterial conversion of inorganic mercury to methylmercury, and its subsequent bioconcentration.(*11) Birth defects and infant mortality were directly linked to consumption of contaminated fish which had accumulated organomercury.

Methylmercury accumulates in proteins and lipids(*12). So at each subsequent trophic level in a food web, the tissue concentration of mercury increase(*13) . Figure 4 illustrates mercury bioconcentration in a very simple, three-tiered food chain. Methylmercury in water is bioconcentrated by plankton, at the base of the food chain.(*14) Subsequent bioconcentration occurs as plankton are consumed by filter feeders, and again as the filter feeders are consumed by higher level predators. This is a simple food chain example; bioconcentration increases with increasing food web complexity and increasing numbers of trophic levels.

Figure 4 also highlights the importance of mercury in sediments. Sediment-bound mercury can serve as an additional source to filter feeders, as these zones represent the primary location of microbially mediated mercury-methylation in aquatic systems(*15). Wetlands and marshes may be particularly susceptible to mercury pollution. These areas typically have shallow water columns and a large inputs of organic matter to the sediment, which leads to enhanced bacterial activity and subsequently greater mercury-methylation rates(*15). Further, wetlands and marshes provide breeding habitat for diverse populations of fish, birds, and reptiles, and hence, are composed of tightly knit, complex food webs. The susceptibility of these types of environments to mercury pollution has been demonstrated in the Florida Everglades, where low dissolved mercury concentrations result in high concentrations in top level predators, including panthers and sport fish(*16,17,18).

The ratio of the mercury concentration in an organism to the mercury concentration in the organism's ambient water is defined as the bioconcentration factor(*19). Assumptions about the bioconcentration factor are critical to the way the currently proposed human health criteria were derived, because the principle dose of mercury to humans is attributed to contaminated fish. So the appropriate criteria depend on the accepted value of the mercury bioconcentration factor.

Table I compares the bioconcentration factors used in the currently proposed criteria to bioconcentration factors derived from recent research. The practical bioconcentration factor of 7342.6 used in the proposed water quality standards was derived from research that is now almost two decades old. Most mercury data, particularly aqueous dissolved mercury measurements, generated prior to 1988 are suspect. Technological advances in mercury quantification and the establishment of trace metal clean sampling procedures made it possible to accurately measure environmentally relevant mercury concentrations in water(*20,21). The EPA has recently recognized the need for adequate analytical methods and trace

metal clean techniques(*22,23,24). The 1980 bioconcentration factors were derived before trace metal clean techniques for mercury analysis were established. If the dissolved mercury concentration is overestimated due to contamination, the bioconcentration factor will be underestimated.

In the Federal Register discussion of bioconcentration factors, values derived from the Great Lakes Initiative are dismissed, "because it is uncertain whether the bioaccumulation factors of 27,900 and 140,000 are appropriate for use in California at this time..."(*1). However, California field data support bioconcentration factors equal to or greater than those of the Great Lakes Initiative. In 1995, the San Francisco Bay Regional Monitoring program reported tissue concentrations in bivalves that averaged 0.2 ppm. At the same time, aqueous dissolved mercury values ranged from 0.001-0.003 ppb(*25), resulting in a bioconcentration factor between 60,000 and 200,000. In the Gill and Bruland study of mercury in California lakes(*9), tissue and dissolved mercury concentrations lead to a bioconcentration factor between 300,000 and 800,000. Clearly, the bioconcentration factor of 7342.6 used to derive the proposed mercury standard is not appropriate to California.

To summarize, the proposed human health mercury CCC (0.05 ppb) does not sufficiently safeguard human health from mercury contamination. and the proposed aquatic life mercury CCC (0.77 ppb) offers no protection to aquatic life. The aquatic life CCC does not distinguish between contaminated and uncontaminated waters, and is two times higher than published toxic effect levels for mercury(*6). Even though the human health criteria will apply in California(*1,7), the 0.77 ppb criteria for protection of aquatic life sets a dangerous national precedent. In California, mercury concentrations twenty to fifty times lower than the proposed human health criteria lead to elevated concentrations in sport-fish. The aquatic life and human health criteria are based on faulty assumptions about mercury bioconcentration factors in the environment. Using bioconcentration factors appropriate to California would result in much lower mercury water quality criteria.

We ask that Region Nine of the Environmental Protection Agency maintain the established National Toxics Rule standard of 0.012 ppb. Furthermore, we strongly suggest that adequate regulation of mercury consider microbial mercury-methylation potentials and evaluate food web complexity to develop site-specific criteria.

(*1) Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule. U.S. Environmental Protection Agency, Region Nine; U.S. Government Printing Office: Washington D.C., 1997; Federal Register, 62, 42159-42207.

(*2) Mitchel, M. United States Environmental Protection Agency, 1997. Economic analysis presented at hearing for public comment on proposed California Toxics Rule, September 17, 1997, EPA Region Nine offices, San Francisco, California.

(*3) Eckel, E.B.; Myers, W.B. In Report XLII of State Mineralogist; United States Department of the Interior, Geological Survey, 1946. Chapter 2, Quicksilver Deposits of the New ldria District San Benito and Fresno Counties, California.

(*4) Ganguli, P.M.; Abu-Saba, K.E.; Mason, R.P.; Flegal, A.R. 1997. Mercury speciation in San Carlos Creek, San Benito California. Manuscript in preparation.

(*5) Rytuba, J. Environmental geochemistry of mercury in the Coast Range mercury belt, California. Abstract in 1997 International Society of Environmental Geochemistry meeting, Oct. 5-10, Vale CO.

(*6) Eisler, R. 1987. Mercury hazards to fish, wildlife and invertebrates: a synoptic review. U.S. Fish and Wildlife Service, Research and Development Biological report 85- 1.10.

(*7) Wood, P. United States Environmental Protection Agency. Personal communication at hearing for public comment on proposed California Toxics Rule, September 17, 1997, EPA Region Nine offices, San Francisco, California.

(*8) Nriagu. J.O.; Wong, H.K.T. In Mercury and its Effects on Environment and biology; Sigel, A. ; Sigel H. Eds.; Metal Ions in Biological Systems. Vol. 34; Dekker: New York, 1997. Chapter 5, Gold Rushes and Mercury Pollution.

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(*10) Time, 149, June 23, 1997, p. 29

(*11) Harada, M. 1995. Minimata disease: methylmercury poisoning in Japan caused by environmental pollution. Critical Reviews in Toxicology, 1997, 25, 1-24.

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(*14) Mason, R.P.; Reinfelder, J.R.; Morel, F.M.M.. Uptake, toxicity, and trophic transfer of mercury in a coastal diatom. Environ. Sci. TechnoL 1996, 30, 1835.

(*15) Baldi F. In Mercury and its Effects on Environment and Biology; Sigel, A. ; Sigel H. Eds.; Metal Ions in Biological Systems. Vol. 34; Dekker: New York, 1997. Chapter 8, Bacterial Transformation of Mercury Species and Their Importance in the Biogeochemical Cycle of Mercury.

(*16) Ware F.; Royals H.; Lange T. Mercury contamination in Florida Largemouth Bass.Proc. Amer. Conf. Southeast Assoc. Fish Wildl. Agen. 1990, 44, 5-12.

(*17) Roelke M.; Schultz D.; Facemire C.; Sundlof S.; Royals H. Mercury contamination in Florida panthers. Gainsville, FL, Florida Game and Freshwater Fish Commission report, 1991.

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(*19) Meili M. In Mercury and its Effects on Environment and Biology; Sigel, A. ; Sigel H. Eds.; Metal Ions in Biological Systems. Vol. 34; Dekker: New York, 1997. Chapter 2, Mercury in Lakes and Rivers.

(*20) Bloom N.S.; Fitzgerald W.F., Determination of volatile mercury species at the picogram level by low temperature gas chromatography with cold-vapor fluorescence detection. Analytica Chimica Acta. 1988, 208, 151-161.

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(*22) Guidance on the Documentation and Evaluation of Trace Metals Data Collected for Clean Water Act Compliance Monitoring. U. S. Environmental Protection Agency, Office of Water, Engineering and Analysis Division; U.S. Government Printing Office: Washington, D.C., 1995; EPA-821-B-95-002.

(*23) Method 1631: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry. U.S. Environmental Protection Agency, Office of Water; U.S. Government Printing Office: Washington, D.C., 1995; EPA-821-R-95-027.

(*24) Method 1669: Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels. U.S. Environmental Protection Agency, Office of Water; U. S. Government Printing Office: Washington, D.C., 1995; EPA-821-R-95-034.

(*25) Regional Monitoring Program 1995 Annual Report; San Francisco Estuary Institute: Richmond, California.

Response to: CTR-091-001a

Regarding the protectiveness of the mercury criteria, refer to responses in CTR-029-002b, CTR-030-007 and CTR-051-003a. EPA recognizes the significance of the accumulation of toxic chemicals, particularly bioaccumulatives, in our nation's sediments. For this reason, EPA is in the process of developing "Equilibrium Partitioning Sediment Guidelines" for use in identifying contaminated sediments which are potentially toxic to benthic organisms. These chemical guidelines are calculated based on the organic carbon content of the sediment for nonionic organic chemicals and acid volatile sulfide content for divalent cationic metals. At this time, EPA has developed guidance for the calculation of bioaccumulation factors (BAFs) for a variety of chemicals. The BAFs are used to ensure that protective levels of water column contaminants are established. BAFs are based on the freely dissolved concentration of the bioaccumulative chemical, such as mercury. The use of BAFs, particularly those calculated based on field data, will provide a mechanism to address the accumulation of chemicals in organisms at higher trophic levels in the food web. For further discussion, refer to the response to CTR-002-007b.

EPA is also currently working to enhance its methodology to address the complex BAF issues. Further, once EPA develops the BAF-based human health water quality criteria, EPA will work with the State of California to adopt either that recommended value or a value that is consistent with the final methodology. By 2003, EPA will promulgate revised criteria for California for mercury based on a BAF for the protection of human health. As part of this process, EPA will evaluate all available published information, including data originating in California.

Comment ID: CTR-091-001b
Comment Author: Abu-Saba, Ganguli, Flegal
Document Type: Environmental Group
State of Origin: CA
Represented Org: Coastal Advocates

Document Date: 09/25/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: This comment addresses the mercury criteria for continuous concentration (CCC) proposed in 40 CFR, part 13 1(*1). The proposed aquatic health and human health criteria do not protect aquatic life or humans from mercury contamination. This is demonstrated by the scientific data presented herein. That information includes published and unpublished results from scientists with established reputations in environmental research.

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To summarize, the proposed human health mercury CCC (0.05 ppb) does not sufficiently safeguard human health from mercury contamination. and the proposed aquatic life mercury CCC (0.77 ppb) offers no protection to aquatic life. The aquatic life CCC does not distinguish between contaminated and uncontaminated waters, and is two times higher than published toxic effect levels for mercury(*6). Even though the human health criteria will apply in California(*1,7), the 0.77 ppb criteria for protection of aquatic life sets a dangerous national precedent. In California, mercury concentrations twenty to fifty times lower than the proposed human health criteria lead to elevated concentrations in sport-fish. The aquatic life and human health criteria are based on faulty assumptions about mercury bioconcentration factors in the environment. Using bioconcentration factors appropriate to California would result in much lower mercury water quality criteria.

We ask that Region Nine of the Environmental Protection Agency maintain the established National Toxics Rule standard of 0.012 ppb. Furthermore, we strongly suggest that adequate regulation of mercury consider microbial mercury-methylation potentials and evaluate food web complexity to develop site-specific criteria.

(*1) Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule. U.S. Environmental Protection Agency, Region Nine; U.S. Government Printing Office: Washington D.C., 1997; Federal Register, 62, 42159-42207.

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(*10) Time, 149, June 23, 1997, p. 29

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(*22) Guidance on the Documentation and Evaluation of Trace Metals Data Collected for Clean Water Act Compliance Monitoring. U. S. Environmental Protection Agency, Office of Water, Engineering and Analysis Division; U.S. Government Printing Office: Washington, D.C., 1995; EPA-821-B-95-002.

(*23) Method 1631: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry. U.S. Environmental Protection Agency, Office of Water; U.S. Government Printing Office: Washington, D.C., 1995; EPA-821-R-95-027.

(*24) Method 1669: Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels. U.S. Environmental Protection Agency, Office of Water; U. S. Government Printing Office: Washington, D.C., 1995; EPA-821-R-95-034.

(*25) Regional Monitoring Program 1995 Annual Report; San Francisco Estuary Institute: Richmond, California.

Response to: CTR-091-001b

EPA will address this concern as part of its mercury re-assessment -- as it relates to bioaccumulation. See responses to CTR-002-007b and CTR-091-001a.

Comment ID: CTR-095-002a
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: Also, the rules pertaining to mercury, fail to take into account the bioaccumulation of mercury in fish tissue. Studies done in the Gr. Lakes show that bioaccumulation is 4 to 20 times greater than what the EPA estimates for California.

Response to: CTR-095-002a

Regarding the issue on mercury bioaccumulation, refer to the response to CTR-002-007b.

Comment ID: CTR-095-002b
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

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Response to: CTR-095-002b

See response to CTR-002-007b.

Comment ID: CTR-104-002a
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-14

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-104-002a

Regarding the issue on mercury bioaccumulation, refer to the response to CTR-002-007b.

Comment ID: CTR-106-002a
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA

Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-14

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-106-002a

Regarding the issue on mercury bioaccumulation, refer to the response to CTR-002-007b.

Comment ID: CTR-109-002a
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-14

Comment: Second, the proposed mercury standards fall to account for the bioaccumulation of mercury in fish tissue. The proposed standard ignores mercury that enters fish through their own consumption of food.

Response to: CTR-109-002a

Regarding the issue on mercury bioaccumulation, refer to the response to CTR-002-007b.

Comment ID: CTRH-001-003c
Comment Author: Robert Hale
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-22
C-24a

Comment: In summing up -- not summing up, just as a parting shot -- I do appreciate the fact that in

working up the toxics rule here that EPA has done certain things which in fact we see as improvements in actually making the standards fit with what we think -- have come to see as perhaps the actual impacts of the stormwater part of this. And by that, I'm referring to the dissolved metals criteria and the water effect ratio in there, and the human health criteria revisions for mercury and the other -- the other items.

I appreciate some of the stuff in there, and -- with the exception of the preamble language. And you really need to get that out of there. We're going to pursue this as far as we have to.

I appreciate your hearing me.

Response to: CTRH-001-003c

EPA acknowledges the comments made and their support of the rule.

Comment ID: CTRH-001-013
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: Issues on mercury:

Bay fisherpeople report eating more mercury-tainted fish than the state says is safe for developmental neurotoxicity. EPA proposes a weaker standard that allows these mercury pollution levels in the vast majority of the bay rather than reducing this harm.

EPA says it has itself weakened the standard because EPA doesn't know whether mercury bioaccumulates here as much as it bioaccumulates in the Great Lakes. San Francisco Bay data show that it does. Will EPA use these data?

Response to: CTRH-001-013

The commenter is incorrect regarding the proposed standard for the San Francisco Bay. The previous standard of 0.025 ug/L will remain in effect for the San Francisco Bay. The commenter is also incorrect about EPA's position regarding bioaccumulation. EPA did not suggest that it did not know if mercury bioaccumulated as much in the Bay as in the Great Lakes. Rather, EPA stated that the Great Lakes data were not appropriate for use in the Bay. EPA is evaluating available bioaccumulation data to determine its appropriateness for use in California. EPA is also currently working to enhance its methodology to address these complex issues. Further, once EPA develops the BAF-based human health water quality criteria, EPA will work with the State of California to adopt either that recommended value or a value that is consistent with the final methodology. Within the next several years, EPA or the State will promulgate revised criteria for California for mercury based on a BAF for the protection of human health. For additional discussion on mercury bioaccumulation, refer to the response to CTR-002-007b.

Comment ID: CTRH-001-018a
Comment Author: Khalil Abu-Saba
Document Type: Public Hearing
State of Origin: CA
Represented Org: UCSC
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: MR. ABU-SABA: Good afternoon. My name is Khalil Abu-Saba. I'm a graduate student in chemistry at the University of California, Santa Cruz. I want to thank Kathleen Van Velsor of Coastal Advocates for having me here to speak today.

Today we'd like to address mercury criteria for continuous concentration as proposed in the California Toxics Rule. The facts I'll be presenting today come from the interpretations of a number of scientists of established reputation in environmental research. In the written transcript of this speech, there are 20 references giving the names of those authors, who reviewed this presentation before I submitted it.

The mercury criteria for continuous concentration is proposed to be raised from the National Toxics Rule standard of 0.012 parts per billion up to 0.770 parts per billion. That is a 60-fold increase in the mercury criteria. We will present the facts showing that allowing that level of mercury in fresh water has potentially devastating economic and environmental consequences.

We will show why mercury regulation should consider particulate as well as dissolved concentrations and why wetlands may require even more protective measures than open waterways.

Finally, we will demonstrate how the proposed standard was derived using assumptions about mercury bioconcentration that are scientifically unsound.

First, let's compare the current National Toxics Rule standard to mercury concentrations downstream from a point source. The preliminary measurements for this stream were provided by Priya Ganguli and Russ Flegal of University of California Santa Cruz and Rob Mason of the Chesapeake Bay Laboratory of the University of Maryland.

The data come from San Carlos Creek, above and below the New Idria mercury mine in San Benito County. This mine, which was at one time the second largest producer of mercury in North America, represents an uncontrolled point source mercury release.

Acidic water from the abandoned mine mixes with the waters of San Carlos Creek, leading to elevated mercury concentrations below the mine opening. The brown water you see in this slide is from metals precipitated after the acid mine drainage mixes with the clear water of San Carlos Creek.

The next graph we'll be showing you will be the part-per-billion concentrations of filtered mercury above and below the mine opening. These are filtered mercury concentrations consistent with the promulgated standard.

The point of this graph is that the existing standard, 0.012 parts per billion, shown by the heavy, black horizontal line, distinguishes between background regional processes and point source contamination. The two lowest mercury concentrations on the left are from water samples upstream of the mine opening in clear water; those concentrations represent mercury concentrations in water which could result naturally from drainage of mercury ore deposits in that region.

The concentrations downstream of the mine opening, in the brown water you just saw, clearly exceed the current National Toxics Rule standard of .012 parts per billion. In contrast, if we were to put the proposed continuous criteria concentration standard on the same scale with this graph, that standard would be two stories above our heads right now.

The next graph shows the same mercury concentrations from New ldria on scale with the proposed criteria of 0.77 parts per billion. Clearly, the proposed criteria does not distinguish between background processes and point source contamination. Mercury levels in the clear water and in the brown water are equal in the eyes of the proposed criteria.

That is the economic benefit that will be derived from raising limits on mercury in water. The citizens of California will be asked to ignore point source contamination of mercury. This is one example from within the State of California; there are many others.

Mercury contamination is part of our mining legacy in this state, we ignore it at our peril. In a 1990 publication in Environmental Science and Technology, Gary Gill and Ken Bruland show that Clear Lake, Davis Creek Reservoir, and Lake Nacimiento all had filtered mercury concentrations that were several hundred times lower than the 0.77 parts per billion proposed standard. Those lakes also had largemouth bass with part-per-million tissue mercury concentrations exceeding the National Academy of Sciences guideline for acceptable mercury concentrations in fish.

How are subpart-per-billion mercury concentrations in water magnified a million-fold to health-threatening part-per-million mercury concentrations in fish? To understand this, we have to recognize that not all mercury is created equal.

This is cinnabar or mercury sulfide. This is an example of inorganic mercury. This type of ore was mined in California at the New Idria and New Almaden mines, and roasted to make elemental mercury or quicksilver, which we're familiar with in the tip of a common thermometer.

Thousands of tons of elemental mercury were used to extract gold during the Gold Rush, distributing mercury throughout California. In the environment, bacterial action can convert inorganic mercury into organic mercury compounds, including methylmercury. The toxicity of mercury depends on its chemical form.

I didn't bring any organic mercury in today; it is too toxic to safely handle in public. I did bring in the obituary of Karen Wetterhahn. As most of you know, she was a prominent Dartmouth researcher who was studying mercury toxicity. This year, she spilled two drops of dimethylmercury on her hand. Three months later, she was dead from neurological damage resulting from acute mercury poisoning.

The disaster in Minimata Bay, Japan, resulted from bacterial conversion of inorganic mercury to methylmercury, and its subsequent bioconcentration.

Methylmercury accumulates in proteins, so at each level in a complex food web the tissue concentration

of mercury increases. This graph shows an example of mercury bioconcentration in a very simple, three-tiered food chain.

Methylmercury in water is bioconcentrated by plankton at the base of the food chain. Subsequent bioconcentration occurs as plankton are consumed by filter feeders, and again as the filter feeders are consumed by higher level predators. This is a simple food chain example; bioconcentration increases with increasing food web complexity.

This figure also highlights the importance of mercury in sediments. Sediment-bound mercury can serve as an additional source to filter feeders. Moreover, conversion of inorganic mercury to methylmercury is regulated by bacteria.

Extensive bacterial methylation occurs in sediments, which host bacterial communities. Wetlands and marshes are much more sensitive areas because intense bacterial activity leads to greater methylation rates, and because they have complex food webs.

This has already been demonstrated in the Florida Everglades, where relatively low dissolved mercury concentrations result in high concentrations in top-level predators, including panthers and sport fish.

Deriving a criteria for dissolved mercury alone and ignoring particulate mercury concentrations, bacterial metabolism, and ecosystem structure is inadequate to protecting the health of California citizens.

The magnification of mercury in water to tissue mercury can be qualified by a value referred to as bioconcentration factor. Assumptions about the bioconcentration factor are critical to the way the proposed criteria was derived because the primary source of mercury to humans is attributed to contaminated fish. So the appropriate criteria, depends on what we accept as a reasonable value for the mercury bioconcentration factor.

The bioconcentration factor of mercury is simply defined as the ratio of the mercury concentration in an organism to the mercury concentration in the organism's surrounding waters, just tissue mercury over water mercury.

In the justification of the proposed criteria, this table compares the bioconcentration factors used in the proposed criteria to bioconcentration factors developed from more recent research. The bioconcentration factor of 7,300 as used in the proposed criteria was derived from research now almost two decades old.

All mercury data and in particular water measurements generated prior to 1988 are suspect. The methods published in 1988 by Bloom and Fitzgerald, and the establishment of trace metal clean sampling procedures to avoid contamination made it possible to measure environmentally relevant concentrations of mercury in water.

The EPA has recognized in their own publications the need for adequate analytical methods and trace metal clean techniques. This is EPA method 1631, mercury in water by cold vapor atomic fluorescence spectrometry, April 1995. This is EPA method 1669, sampling ambient water for EPA water criteria levels. This method 1669 describes how to avoid contamination in trace metal analysis.

The 1980 bioconcentration factors used to derive the proposed criteria come from data generated before trace metal clean techniques were established. If you overestimate the water mercury concentration due to contamination, you will underestimate the bioconcentration factor, because the dissolved concentration appears here in the denominator.

In the Federal Register discussion of the bioconcentration factors, values derived from the Great Lakes initiative are dismissed, "because it is uncertain whether the bioaccumulation factors of 28,000 and 140,000 are appropriate for use in California at this time." That's a quote from the Federal Register.

We can compare the relevance of these bioconcentration factors by examining field data from California, as Greg Karras suggested. In 1995, the San Francisco Bay regional monitoring program reported tissue concentrations in bivalves that averaged 0.2 parts per million.

At the same time, quantifiable dissolved mercury values ranged from 0.001 to 0.003 parts per billion. If you just plug those numbers into the formula for bioconcentration factor, you get a bioconcentration factor between 60,000 and 200,000.

In the Gill and Bruland study of mercury in California lakes, tissue and dissolved mercury concentrations lead to a bioaccumulation factor between 300,000 and 800,000. Clearly, the bioconcentration factor of 7,300 used to derive the proposed standard is not appropriate to California.

To summarize, the proposed mercury standard of 0.77 parts per billion does not distinguish between contaminated and uncontaminated waters. The proposed standard is based on faulty assumptions about mercury bioconcentration in the environment.

The potential economic costs of this legislation far exceed any perceived benefits from ignoring mercury contamination. For example, one of the goals of Proposition 204 is the protection and enhancement of commercial and sport fishing in the State of California. To that end, hundreds of millions of dollars have been committed to water quality improvement and habitat restoration. A 60-fold increase in the permissible mercury limits can only hinder these goals.

We ask that Region 9 of the Environmental Protection Agency promulgating the California Toxics Rule maintain the established National Toxics Rule standard of 0.012 parts per billion. Furthermore, we strongly suggest that adequate regulation of mercury should incorporate particulate mercury concentrations and should consider the potential for bacterial activity and evaluate ecosystem complexity to develop site-specific criteria.

Response to: CTRH-001-018a

See response to CTR-002-007b.

Comment ID: CTRH-001-018b
Comment Author: Khalil Abu-Saba
Document Type: Public Hearing
State of Origin: CA
Represented Org: UCSC
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
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We ask that Region 9 of the Environmental Protection Agency promulgating the California Toxics Rule maintain the established National Toxics Rule standard of 0.012 parts per billion. Furthermore, we strongly suggest that adequate regulation of mercury should incorporate particulate mercury concentrations and should consider the potential for bacterial activity and evaluate ecosystem complexity to develop site-specific criteria.

Response to: CTRH-001-018b

See response to CTR-002-007b.

Comment ID: CTRH-001-050a
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES C-14

Comment: For mercury, certainly I would concur with the previous comments, that the number should be -- that is appropriate is accumulation factors.

Now the bioconcentration factor, in deference to this state's consumption rates that have been determined are appropriate for California, I think using the average consumption rate for everyone in the country, by definition, lops off about half of the population. It seems to me that it doesn't account for those users of the bay who are the high consumption -- high fish-consumption users, which obviously there's a number of them, and that's not reflected in that average at all.

So I think that those bioaccumulation factors are important to the mercury number base data that we have for the bay for all the reasons stated earlier, and similarly for dioxin. It seems as if EPA would like to back away on that, the criteria that is listed.

Response to: CTRH-001-050a

Regarding the comments on mercury human health toxicity, see responses to CTR-006-002a and CTR-030-007. Regarding mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTRH-001-062
Comment Author: Fred Lee
Document Type: Public Hearing
State of Origin: CA
Represented Org:
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: The other point I want to make, we had a discussion about mercury today and that discussion doesn't address the issues properly. That discussion focused on the number -- I think it was .77 parts per billion, and that's not a human health criteria. That is the toxicity part. That's a dissolved mercury. As related to aquatic life, that number's about right.

Response to: CTRH-001-062

EPA acknowledges the comment.

Comment ID: CTRH-001-063
Comment Author: Fred Lee
Document Type: Public Hearing
State of Origin: CA
Represented Org:
Document Date: 09/17/97
Subject Matter Code: C-01 Mercury
References:
Attachments? N
CROSS REFERENCES

Comment: In another part of the Federal Register promulgating the rule, there is a statement about -- for human health, the number is proposed to be 50 nanograms per liter -- going from 12 nanograms per liter, now the current gold book number, to 50 under these criteria. But if you go further and you ask what does that mean really? Do I think mercury is less toxic? No way.

What it's headed for is that within two to six months to a year, as state and federal rules on mercury are developed through the Science Advisory Board review, so forth, it's a pretty good chance that's going to drop, 3 to 5.

You should understand we're headed for 3 to 5 nanograms per liter for total mercury as a number to protect from excessive bioaccumulation. That's where we're headed.

I'll stop at this point.

Response to: CTRH-001-063

Regarding the comments on mercury human health toxicity, see responses to CTR-006-002a and CTR-030-007. Regarding mercury bioaccumulation, see response to CTR-002-007b.

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Subject Matter Code: C-02b Copper Aquatic Life

Comment ID: CTR-002-008
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Proposed copper criteria ignore San Francisco Bay data that show damage to sensitive populations at lower dissolved copper concentrations and led the state to reject criteria that deregulate total copper in its water quality criteria. The proposed rule states that: "New data including data collected from studies for the New York/New Jersey Harbor and the San Francisco Bay indicated a need to revise the copper criteria documents to reflect a change in the saltwater" criteria. In contrast to this statement, many scientists involved in review of the San Francisco Bay study reached a very different conclusion.

Many scientists commented during the state's review that the data did not necessarily support a revised copper criterion. EPA scientists raised many questions regarding: inadequate seasonal sampling; departure from standard testing recommendations; interpretation of toxicity test endpoints and precision; interpretation of widely varying responses; failure to measure dissolved copper in key bioassays and sites; overestimation of the amount of copper producing an effect; significant problems with algal test interpretation; confusion of acute versus chronic exposure; unmeasured effects of filtration; joint toxicity of copper with other metals; multiple stresses; bioaccumulation; and, generally, how lab results will "mimic environmental reality."(*17)

Other scientists stated similar and stronger concerns, Dr. Michael Perrone commented that "there isn't a positive demonstration that dissolved copper is a good predictor" of environmental ion.(*18) The state's Department of Fish and Game also stated that "[t]otal copper can become protect unbound and available for uptake by organisms" in comments voicing many of the concerns listed above, and recommended: "Retain the existing criteria of 2.9 ug/L as total copper."(*19)

The weight of scientific opinion raised sufficient questions about how these laboratory studies "mimic environmental reality" to warrant analysis of field data. This showed species had responded to changes in Bay copper, and those bivalve shellfish and phytoplankton which are most vulnerable to copper toxicity were severely reduced in abundance although they once thrived here, and thrive in similar estuaries at dissolved copper levels of about I ug/L or less.(*1) Comparison of high quality data between estuaries further demonstrated S.F. Bay copper pollution similar to other polluted estuaries, and dissolved copper levels below 1 ug/L in unpolluted or less polluted estuaries where these copper-sensitive species thrive.(*2) There is a "reasonable probability" that copper levels in waters of the southern reach affect the ecosystem, and cutting copper pollution will likely benefit aquatic life.(*1)

Therefore, the state's review of all of this evidence led to a decision to adopt a criterion for total copper that would require reduced copper concentrations. The fundamental rationale for this was that cutting copper pollution was necessary in order to ensure the protection of aquatic life. In contrast, EPA's

proposed 3.1 ug/L dissolved copper criterion, which would not require less copper in most Bay waters as shown in Table 4, and which allows dissolved copper three times levels at which sensitive estuarine species are known to thrive, cannot ensure the protection of Bay aquatic life based on sound scientific rationale.

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.

(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten other estuaries. Communities for a Better Environment (CBE). July, 1992.

(*17) USEPA, 1992. Comments on the data presented in the Hansen Report. Includes cover letter from Maria Rea, Chief, Water Quality Standards Section, to Steven R. Ritchie, Executive Officer, Regional Water Quality Control Board, San Francisco Bay Region. July 15, 1992.

(*18) California State Water Resources Control Board, 1992. Memorandum from Michael Perrone, Ph. D., to Lynn Suer, Ph.D., Regional Water Quality Control Board, re: Review of draft final report entitled "Development of site specific criteria for copper for San Francisco Bay." June 29, 1992.

(*19) California Department of Fish and Game, 1992. Conunents on the Draft Final Report Entitled "Development of site-specific criteria for copper for San Francisco Bay." Letter from John Turner, DFG, to Steven R. Ritchie, RWQCB. July 14,1992.

Response to: CTR-002-008

EPA does not agree with the commenter's comment concerning a copper criterion of 1 ug/L. This issue was raised in 1992 when the San Francisco Bay Regional Water Quality Control Board (SF RWQCB) published its site-specific copper value (based on total copper). EPA agrees with the SF RWQCB's position, which it articulated in its October 21, 1992, "Responses to Comments - Site-specific Copper Objective" for the September 25, 1992, report titled "Revised Report on Proposed Amendment to Establish a Site-Specific Objective for Copper in San Francisco Bay". The SF RWQCB noted that the ambient concentrations in South San Francisco Bay were well above the 1 ug/L in Tomales Bay and then stated that, "the observation that some organisms are more abundant in Tomales Bay where concentrations are less than 1 ug/L does not mean that 1 ug/L is needed to insure protection of these organisms in San Francisco Bay." This would be setting a criterion "based on correlation rather than controlled experimentation, and does not account for the many other factors that can affect the distribution and abundance of organisms."

EPA believes that the weight of sound scientific evidence fully supports the protectiveness of its copper criterion. EPA does not consider the commenter's interpretation of reference 17 (1992 EPA comments on the site-specific modifications of the copper criterion for San Francisco Bay) relevant to the CTR copper criterion. The subject of reference 17 was not the CTR criterion, and the information available to EPA when it formulated its 1992 comments (the commenter's reference 17) was less than the information available to EPA in formulating the criterion in this rule. In its 1995 "Ambient Water Quality Criteria - Saltwater Copper Addendum", EPA examined the data available from the San Francisco Bay studies and utilized only the data with suitable quality into its revised national criterion (which was used in the CTR).

Concerning the comment about whether dissolved copper is a good predictor of environmental ion

(reference 18), EPA does not agree that such prediction is cogent. The intent of the copper criterion in the rule is to prevent copper toxicity, not to achieve any fixed concentration of free ionic copper.

Concerning the comment that "total copper can become unbound and available", EPA notes that unbound and available copper is covered by the criterion incorporated in the rule. Thus, EPA does not believe that this a concern. See also the response to CTR-026-004 concerning dissolved v. total recoverable metals criteria.

Comment ID: CTR-020-011
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

B. Outdated Science

1. Copper

The proposed copper criteria do not reflect the expected toxicity of this pollutant in the environment and will result in unnecessarily restrictive requirements throughout the state. Although required by the National Guidelines, the copper criteria fail to include an adjustment to account for binding with organic material such as that expected to occur in storm waters and in treatment plant effluents that renders this pollutant non-toxic (see enclosed article, Exhibit 5). Application of the criteria as a dissolved standard will likely result in many facilities being identified as in violation of the criteria. Few storm waters are expected to meet the acute criteria due to low hardness of such waters. The City's storm water monitoring has indicated that such waters exceed the proposed acute criteria. The typical Total Organic Copper ("TOC") level present in storm waters (8-20 mg/l) is well above the 3 mg/l value specified in EPA's Copper Criteria Document as indicative of significant organic complexing and the need to modify the criteria. Consistent with the available technical data and criteria development guidelines, the copper criteria must be modified to address organic binding as part of the criteria to avoid classifying many dischargers as toxic threats when no such threat actually exists. The following identifies the scope of concerns regarding proper application of copper criteria and the technical information that demonstrates EPA's copper criteria routinely overestimate actual aquatic life threats.

(a) Introduction

No single issue in the development and application of water quality criteria for metals is of greater importance to NPDES permittees than the accurate assessment of aquatic toxicity of copper. The infrastructure of the nation's drinking water supply depends on copper and copper alloy pipes. Along with drinking water conveyance, copper chemicals are widely used for algae control in drinking water supplies and reservoirs. Because of the intimate association between copper and the nation's water supply, it is inevitable that some form of copper will be discharged in wastewater and present in storm waters.

EPA's current approach to copper regulation assumes that the toxic form of the metal exists in biologically treated effluents and storm waters even when all scientific information confirms that it does not. This assumption causes permittees to conduct expensive studies to correct the standard to reflect the lack of environmental threat present. This approach (1) is wasteful of local resources, constituting an unauthorized, unfunded mandate; (2) penalizes small communities which have both limited budgets and access to updated scientific approaches; (3) is inconsistent with EPA's statutory mandates and guidance; and (4) violates regulatory principles outlined in the President's "Reinventing Environmental Regulation" initiative. Because EPA's approach does not reflect reality and easily implemented, less costly approaches exist to properly regulate copper discharges, this criteria should be withdrawn or, at a minimum, narrowed in its application. The following summarizes the scientific and regulatory bases for withdrawal and reconsideration of laboratory-derived numerical water quality criteria for copper to biologically treated effluents.

First, existing copper criteria are not appropriate for biologically treated effluents or situations where elevated TOC levels are known to exist (the typical case where the criteria are applied) because the database used to derive this criterion did not consider the dramatic detoxification of copper by constituents commonly present in biological waste treatment systems. Second, laboratory studies, field surveys, and water effects ratios conducted by regulatory authorities and independent researchers all confirm that copper rapidly binds ("complexes") with organic and inorganic matter (e.g., phosphates) during biological waste treatment, thus rendering copper non-bioavailable and hence non-toxic to aquatic life. Third, all field studies conducted by EPA and state agencies confirm that copper in biologically treated effluents is not toxic to sensitive species which were used to establish the federal copper criteria. This demonstrates that biologically treated effluents eliminate copper toxicity and should pose no threat to resident species instream after mixing.

Briefly, the current body of laboratory research on the detoxifying effects of organic and inorganic matter on copper, including total organic carbon, particulate matter, humic and fulvic and amino acids, explains why scientific field studies consistently show that copper in biologically treated effluents, and by extension storm waters, is not expected to be toxic to aquatic life. Current copper criteria application to treated effluents and storm waters is not appropriate or necessary to protect aquatic life. Use of acute daphnid whole effluent toxicity tests would be sufficient to regulate copper at a level of protection equivalent to the national criteria for copper and eliminate the need for expensive WER analyses.

(b) EPA Must Follow Its Guidance

EPA's national guidance for Clean Water Act Section 304(a) criteria development requires all relevant factors regarding toxicity of a pollutant to be considered in establishing water quality criteria for that pollutant.(*16) Because the current copper criteria are based on assessments of dissolved metal salts in laboratory water with little or no ability to complex copper, the commonly encountered dramatic detoxifying effect of treated effluent and other naturally existing substances present in storm waters were

not considered.

EPA guidance on implementing metals criteria expressly states that it is only the biologically available fraction of the metal that is intended to be regulated.(*17) Although recent guidance from EPA specifying that metals criteria assessed as "dissolved" may be a better approximation of the toxic fraction under some circumstances, measurements of filterable "dissolved" copper in biologically treated effluents or in storm water samples with high (greater than 5 mg/l) TOC levels are, to a certainty, not relevant to assessing the toxic fraction of copper. Such measurements erroneously assesses non-toxic filterable organo-copper complexes as "dissolved" which is the form in which the metal will be discharged from these facilities or will preferentially exist in the environment. Because the vast majority of facilities that discharge copper utilize biological treatment, it is apparent that widespread misapplication of the copper criteria may result from use of a dissolved metals approach. Similarly, storin waters typically contain TOC levels equivalent to well treated municipal effluent (5-20 mg/l TOC).

(*16) Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses, USEPA (1985) (emphasis supplied).

(*17) Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, USEPA (May 28,1992) ("Interim Guidance").

Response to: CTR-020-011

See response to CTR-020-012.

Comment ID: CTR-020-012
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

(e) Copper Criteria Development and Application

(1) Criteria Based on the Dissolved Metal Fraction Overestimate Bioavailable Copper

In 1992, the Pellston Conference of the Society for Environmental Toxicology and Chemistry recommended that water quality standards be established on the basis of bio-availability.(*18) On May 28, 1992, EPA released the Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals ("Interim Guidance"), a final policy which modified all prior Section 304(a) criteria documents for metals and implemented this recommendation. In issuing its Interim Guidance, EPA acknowledged that only the biologically available fraction of metals is responsible for aquatic toxicity, and therefore is the proper focus of permit limit derivation:

The principal issue is the correlation between metals that are measured and metals that are biologically available.(*19)

In the Interim Guidance and contemporaneous correspondence, EPA acknowledged that expressing water quality criteria for metals as dissolved measurements is a conservative approach and that a state should consider further reductions in toxicity from complexing:

Alternatively, we are allowing States to apply criteria to dissolved metals only. However, we suspect that this may be a somewhat less accurate method of excluding "nontoxic" metal from regulation, because some dissolved metal exists in forms that have little toxicity (particularly copper, a pollutant of great concern to municipal dischargers)...(*20)

Following the January 1993 Annapolis Conference on the development and implementation of metals criteria, EPA modified its criteria implementation guidance to use dissolved metal (i.e., filterable through a 0.45 u membrane) concentrations in setting water quality standards "because dissolved metal more closely approximates the bioavailable fraction of metal in the water column than does total recoverable metal.(*21) Scientists at the Annapolis Conference emphasized that under certain circumstances, dissolved metal standards are conservative and may overstate the toxic fraction: "In some cases, even the dissolved concentration may overestimate the bioavailable fraction for metals that strongly complex to either inorganic or organic ligands (e.g., filterable carbon containing particles).(*22) Because the dissolved approach erroneously equates all "filterable" dissolved copper to bioavailable copper, dissolved metals measurements overstate the toxic metal fraction in biologically treated effluents.

(2) All Laboratory Studies Confirm Copper is Detoxified by Organic Substances in Sewage

The detoxifying influence of organic and inorganic complexation on copper was reported in EPA's 1984 Copper Criteria Document.(*23) Among the heavy metals, copper is particularly amenable to complexation with organic and inorganic matter to render this metal non-bioavailable and hence non-toxic to aquatic life. Aquatic organisms respond to free ionic metal and monohydroxy complexes as bioavailable forms.(*24) Rapid detoxification of copper in the presence of inorganic and organic substances occurs due to the high reactivity of this metal:

[t]he cupric ion is highly reactive and forms moderate to strong complexes with many inorganic and organic constituents of natural waters (e.g., carbonate, phosphate, amino acids and humates), and is readily sorbed onto surfaces of suspended solids.(*25)

EPA's 1984 criteria application guidance provided a criteria adjustment for hardness -- one of the many substances present in biologically treated effluents -- but omitted similar consideration of organic ligands, even though EPA recognized their greater importance in detoxifying copper:

Lind, et al., (Manuscript) measured the toxicity of copper to Daphnia pulicaria in a variety of surface

waters and found that total organic carbon (TOC) is a more important variable than hardness, with acute values varying approximately 30-fold over the range of TOC covered. Similar results were obtained with the fathead minnow. This indicates that the criteria should be adjusted upward for surface waters with TOC significantly above the 2 to 3 mg/L usually found in waters used for toxicity tests.(*26)

The scientific literature is replete with peer reviewed studies confirming that organic ligands similar to those in municipal effluents dramatically mitigate copper toxicity.(*27) Callahan, et al., concluded that most cupric salts are not readily water soluble and reported that inorganic and organic complexation and adsorption of copper reduce the level of soluble copper to very low values, even in the presence of total copper.(*28) The linear relationship between reduction in toxicity of total copper to rainbow trout with increasing concentrations of suspended organic solids was reported by Brown.(*29) This work reported that doubling the concentration of organic ligand from 4 mg/l to 8 mg/l approximately doubled the 96-hour LC50 for copper. Brown concluded:

toxicity to rainbow trout of a given total concentration of copper was quantitatively reduced in the presence of a good quality sewage effluent, of an amino acid, of humicsubstances, and of suspended organic solids.(*30)

Similar results were obtained by Sunda and Lewis, who reported complexation of 61 to 99 percent of free copper by river water containing natural organic matter at 22 mg/l.(*31) Erickson, et al., reported that copper complexed with organic ligands appears to be one-fifth as toxic as free ionic copper, and that addition of organic matter (humic substances) increased the LC50 of copper by 2.7. Morrison and Florence reported that copper toxicity to algae and Daphnia magna was decreased by sixty (60) percent in the presence of 5 mg/l fulvic acids and eliminated in the presence of 1.3 to 8 mg/l humic acid colloids.(*32) As noted previously, storm waters typically contain TOC levels in excess of these values.

The above laboratory studies conducted under conditions with relatively low levels of binding agents confirm that even when relatively high "dissolved" copper concentrations were measured, the toxicity of copper to sensitive species was greatly reduced or eliminated in the presence of organic and inorganic compounds. The amount of copper complexed in the presence of high concentrations of organic ligands in biological waste treatment systems or urban storm waters would, of course, be much greater. As the amount of ligands and other binding agents is, stoichiometrically, greatly in excess of the ionic copper for typical municipal and storm water conditions, no copper will be present in a toxic form. This fact was demonstrated by Allen and Hansen.(*33)

On the basis of over twenty years of observations and research on metal speciation chemistry and fate of metals in receiving waters and in treatment facilities, Dr. Allen concluded that virtually all copper in biologically treated effluent is non-toxic:

Following biological treatment, virtually all the copper present in a municipal treatment plant effluent would be in the form of soluble copper complexes or it would be sorbed to particulate material not removed from the effluent stream in the final clarifier. Certainly, as in any chemical equilibrium situation, there will be a finite concentration of free, ionic copper present in the effluent. However, this concentration will be very low and will not pose a toxicity risk. This is borne out by a lack of metal toxicity in treatment plant effluents when effluent monitoring studies have been conducted. As far as I know, such studies have not demonstrated that there is toxicity from metals in effluents.(*34)

Field studies of WERs have repeatedly confirmed laboratory observations and validate the total detoxification of copper by biologically treated effluents. DiToro, et al., performed WERs on the site-specific detoxification of copper in the Naugatuck River.(*35)

Very little difference in toxicity was observed between laboratory water with minimal complexing ability and river water from pristine segments. However, where river water contained treated municipal effluents, up to a twelve-fold reduction in copper toxicity was recorded, and it was concluded that the copper present in the municipal effluent was non-toxic. A 1992 summary of WERs for heavy metals compiled by Brungs showed that copper is up to 26 times less toxic in water influenced by municipal effluent.(*36) It should be noted that to have a WER significantly above one (1), the existing metal in the discharge must be complexed. The WERactually represents the excess binding capacity of the effluent.

The dramatic detoxification of copper in the presence of municipal effluent was also reported in a field study on Shayler Run by Geckler, et al.

It was suspected that the Shayler Run sewage treatment plant was discharging materials that were detoxifying copper in Shayler Run water. Bioassays, using diluent water from above and below the entrance of the effluent, indicated that copper was much less toxic in Shayler Run water below the plant. Additional toxicity tests, in which Shayler Run water was diluted with a reconstituted water similar in hardness and alkalinity, indicated that the reduction in toxicity was not due to hardness or alkalinity, but to some other detoxifying agent or agents being diluted.(*37)

The North Carolina Department of Environment, Health, and Natural Resources documented 78 cases in which total recoverable copper in effluents and in receiving waters was measured in excess of water quality criteria without observed chronic toxicity. Instream total copper ranged up to 378 ug/l. Bioassay testing was conducted using Daphnia magna, one of the most sensitive species to copper (see Exhibit 7). The Massachusetts Department of Environmental Protection confirmed the same results in their survey of 35 facilities. These documents have previously been provided to EPA as part of the public comments on the May 1995 National Toxics Rule revision. No public response to those comments was ever published. As a result of the extensive NWR analysis performed by the Connecticut Department of Envirom-nental Protection, it was demonstrated that water upstream from municipal dischargers exhibit a typical WER of three (3) while those downstream of publicly owned treatment works ("POTWs") exhibit WERs ranging from 8 to 25 (Exhibit 8). As expected, the higher WERs are associated with increased levels of municipal effluent and organic material.

The above field studies confirm the observations made by laboratory research and validate the rapid detoxification of copper in the presence of treated effluents and elevated TOC levels. Stockton is not aware of any reported instances that contraindicate copper in biologically treated effluent is non-toxic to sensitive species. Thus, it is apparent that there is no technical or environmental basis for concern regarding copper levels typically discharged by biologically treated facilities (copper ranging from 20 to 200 ppb). Nor is there any rational basis to be concerned with low level dissolved copper measurements in storm waters where TOC levels are capable of fully binding the available copper. The continued application of a dissolved criteria approach which would classify these effluents as problematic when they clearly are not is arbitrary and capricious and wastes local resources on problems that do not exist.

(3) Water Quality Criteria Must be Based on the Latest Scientific Information and the Proper Application of Science

The fundamental oversight in translating dissolved copper criteria into permit conditions is the failure to regulate only bioavailable metal. The laboratory conditions of the EPA criteria development experiments accurately reflect the maximum toxic impacts to highly sensitive species when exposed to a highly toxic dissolved, ionic form of copper in pure water having little or no complexing ability. Such conditions are

plainly unrelated to copper discharged from biological waste treatment systems. Because of the greater abundance of complexing agents present in biological treatment process, all copper in a discharge will be in a complexed and therefore non-bioavailable form. This is particularly true for effluent dominated, low dilution streams and storm waters where proper criteria application is most critical.

EPA must apply copper water quality criteria in the same manner in which they were developed. The National Guidelines prohibit application of the criteria in a manner not contemplated by that document:

Criteria must be used in a manner that is consistent with the way in which they were derived if the intended level of protection is to be provided in the real world... Concentrations, durations and frequencies specified in criteria are based on biological, ecological and toxicological data, and are designed to protect aquatic organisms and their uses from unacceptable effects.(*38)

Application of water quality standards for copper must reflect the pollutant form assessed in the criteria. The National Guidelines require revision of criteria whenever it is demonstrated that the national criteria "would probably be substantially over or under protective."(*39) As the dissolved approach has been demonstrated to be overprotective in all cases involving biologically treated effluents and elevated TOC, this procedure requires revision.

By allowing scientifically defensible biomonitoring/bioassay methods as an alternative method of developing water quality criteria and water quality-based effluent limitations, EPA would assure adequate protection of only the toxic or bioavailable fraction of copper. This approach is outlined in the most recent SETAC Conference report on proper application of metals criteria. Unlike standards expressed in terms of analytical measurements (e.g., "total recoverable" or "dissolved"), use of bioassay tests to directly evaluate the bioavailable fraction of copper is rationally related to the actual potential for aquatic life impacts to the species that drove the national criteria (ie., daphnids).

The language of EPA regulations makes it clear that the Agency's authority to develop criteria rests on the scientific accuracy by which those criteria relate to aquatic impacts:

Section 304(a) criteria are developed by EPA under authority of Section 304(a) of the Act based on the latest scientific information on the relationship that the effect of a constituent concentration has on a particular aquatic species and/or human health. 40 C.F.R. 131.3(c) (emphasis supplied).

Therefore, Agency endorsement of test methods that are known to exhibit little relationship to aquatic life protection needs exceeds the scope of the Agency's authority to develop and implement criteria.

(4) EPA Is Bound to Adhere to Published Guidance

Both the Clean Water Act and EPA's National Guidelines establish the underlying mechanism for establishing Section 304(a) criteria for metals. As previously discussed, the National Guidelines describe the various methods of justifying numerical criteria values that are protective of aquatic life uses and specify that all factors that significantly influence the toxicity of a pollutant must be taken into account. EPA's National Metals Policies all state that only the biologically available fraction is intended to be regulated. Unfortunately, a dissolved approach to copper does not meet that objective.

EPA is not free to wander from its published guidance and regulations when the result of such deviation adversely affects the substantive rights of an individual who relied on the Agency's published representations.(*40) In Massachusetts Fair Share v. Law Enforcement Assistance, 758 F.2d 708, 711-712 (D.C. Cir. 1985), the court reinforced the philosophy established in Morton v. Ruiz:

It has long been settled that a federal agency must adhere firmly to self-adopted rules by which the interests of others are regulated. This precept is rooted in the concept of fair play and in abhorrence of unjust discrimination, and its ambit is not limited to rules attaining the status of formal regulations. The Supreme Court has declared that'[w]here the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures, even though the procedural requirement there spoken of had not been published in the Federal Register, and other courts have concluded similarly.

Both the CWA and EPA's published regulations require that criteria accurately reflect the latest scientific knowledge on aquatic life protection needs. See, 33 U.S.C. section 304(a). EPA's current criteria do not reflect the latest information on copper detoxification by treated effluents or in the presence of elevated TOC levels, the most common cases for applying the criteria. The continued application of current numerical copper criteria to such situations is inappropriate and unnecessary

(5) Conclusion

For all the foregoing reasons, EPA should ensure that the criteria-based water quality standard for copper is applied to the same pollutant form assessed in the Copper Criteria Document "bioavailable" or, in this case, ionic copper). Laboratory and field studies overwhelmingly support the conclusion that copper in storm waters and biologically treated effluents exists in organo-complexes and is not bioavailable. There is no information to the contrary. Current approaches to criteria development erroneously equate filterable copper to dissolved bioavailablemetal, and overstate the toxic fraction in treated effluents, wasting local and state resources on time consuming, administratively complex and expensive WER tests. Consistent with the National Guidelines and the "Reinventing Government" initiative, a less costly, more environmentally appropriate approach is required.

It is clear from the preceding discussion that the existing copper criteria requires amendment because the criteria, as implemented, are not limited to the toxic form of the metal. Since there are no approved analytical techniques to allow measurement of the toxic form of copper in state waters, EPA needs to establish a procedure to better define the toxic fraction and defer implementation of copper water quality criteria for any discharge that has demonstrated no acute toxicity to copper sensitive organisms. This approach is used by the State of North Carolina and is conceptually the same as the simplified water effect ratio approach EPA is developing. This methodology will provide significant benefit to EPA and better focus environmental resources. By establishing an objective basis to evaluate actual copper toxicity, EPA and the regulated community will better be able to define where real copper toxicity problems exist.

(*18) Benson, W.H., Alberts, J., Allen, H.E., Hunt, C.D., and Newman, M.C. "Bioavailability of Inorganic Elements." In A Mechanistic Understanding of Bioavailability: Physical Chemical Interactions, ed. J.K. Hamelink, W.H. Benson, H.L. Bergman, and P.F. Landnim. Chelsea, MI: Lewis Publishers, 1993.

(*19) Interim Guidance at 1.

(*20) Letter from LaJuana S. Wilcher, USEPA, to Congressman Hammerschmidt, dated March 13, 1992 (emphasis supplied).

(*21) Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Critera, USEPA (October 1, 1993) at 2.

(*22) Implementation of Metals Criteria," USEPA Memorandum (April 1, 1993).

(*23) Ambient Water Qualiiy Criteria for Copper - 1984, USEPA/440/5-84-031 (January 1985).

(*24) Allen, Herbert E. and Bo Shi. Copper Speciation and Bioavailability: Critical Evaluation for POTW Effluent Discharges. Proceedings of the Water Environment Federation Conference on Toxic Substances in Water Environments (May, 1995) pp. 5-11

(*25) Copper Criteria Document at 2.

(*26) Copper Criteria Document at 7.

(*27) Boggs, S., D.G. Livermore, and M.G. Seitz. "Humic Macromolecules in Natural Waters." Reviews in Macromolecular Chemistry and Physics, C25, 599-657 (1985); Sposito, G. "Sorption of Trace Metals by Humic Materials in Soils and Natural Waters." CRC Critical Reviews in Environmental Control (I 6):193-299 (1986); Buffle, J.Complexation Reactions in Aquatic Systems: An Analytcal Approach. Ellis-Horwood, London(1988).

(*28) Callahan, M.A., M.W. Slimak, N.W. Gabel, I.P. May, C.F. Fowler, J.R. Freed, P. Jennings, R.L. Durfee, F.C. Whitmore, B. Maestri, W.R. Mabey, B.R. Holt and C. Gould. Water-Related Environmental Fate of 129 Priority Pollutants. USEPA 440/4-79-029a (1979).

(*29) Brown, V.M., T.L. Shaw, and D.G. Shurben. "Aspects of Water Quality and the Toxicity of Copper to Rainbow Trout." Water Research 8:797-803 (1974).

(*30) Id. at 801.

(*31) Sunda, W.G. and J.M. Lewis. "Effect of Complexation by Natural Organic Ligands on the Toxicity of Copper to a Unicellular Algae, Monochrysis lutheri." Limnology od Oceanography 23:870-876 (1978).

(*32) Morrison, G.M.P. and T.M. Florence. "Comparisons of Physiochemical Speciation Procedures with Metal Toxicity to Chlorella pyrenoidosa." Analytica Chimica Acta 209:97-109 (1988).

(*33) Allen, H.E., and Hansen, D.J. "Importance of Trace Metal Speciation to Water Quality Criteria." Draft manuscript dated January 7, 1994 (attached hereto as Exhibit 2).

(*34) Letter from Dr. Herbert E. Allen to J.C. Hall regarding speciation and bioavallability of metals, dated October 15, 1993 (attached hereto as Exhibit 6).

(*35) DiToro, D.M., J.A. Hallden, and J.L. Plafkin. "Modeling Ceriodaphnia Toxicity in the Naugatuck River: II. Copper, Hardness and Effluent Interactions." Environmental Toxicology and Chemistry 10:261-174 (1991).

(*36) Brungs, W.A. "Synopsis of Water-Effect Ratios for Heavy Metals as Derived for Site Specific Water Quality Criteria." USEPA Contract No. 68-CO-0070 (1992).

(*37) Geckler, J.R., W.B. Homing, T.M. Neiheisel, Q.H. Pickering, E.L. Robinson and C.E. Stephan. "Validity of Laboratory Tests for Predicting Copper Toxicity in Streams." USEPA 600/3-76-116 (1976)

at pp. 168-169.

(*38) National Guidelines at 14 (emphasis supplied).

(*39) National Guidelines at 18.

(*40) See Morton v. Ruiz, 415 U.S. 199, 235. In a dispute between an American Indian and the Department of Interior's Bureau of Indian Affairs ("BIA"), the Supreme Court held that where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required.

Response to: CTR-020-012

EPA agrees that the factors discussed in the comment strongly affect the toxicity of copper, but does not agree that the criteria formulas specified in the rule do not account for these factors. The freshwater copper criterion is expressed as formula having two parameters, hardness and the water-effect ratio. The saltwater copper criterion is expressed as a formula having one parameter, the water-effect ratio.

The water-effect ratio (WER) is a generalized parameter that accounts for the difference in biological activity or toxicity of the copper in the site water versus in laboratory water. EPA agrees that the WERs typically observed in waters carrying substantial amounts of municipal effluent are generally large enough that no copper toxicity is manifested in such waters. EPA also agrees that the organic carbon content of such waters plays a key role in rendering copper nontoxic. However, EPA does not believe that the facts set forth in the comment indicate that the WER concept incorporated into the rule is incapable of satisfactorily accounting for the effects that organic carbon and other site water factors have on copper toxicity.

The rule has cited EPA's current guidance on determining water-effect ratios. However, the rule does not require that WER determinations follow only this guidance. Rather, it allows "other scientifically defensible methods adopted by the state...and approved by EPA." EPA understands the concerns raised in the comment about the resources needed to complete a WER determination pursuant to its guidance. EPA is working with states and dischargers in developing more streamlined approaches for determining WERs using fewer toxicity tests. EPA has also been funding development of a biotic ligand modeling approach, which will predict a site WER for copper using chemical measurements of hardness, alkalinity, dissolved organic carbon, and pH, thereby eliminating the need for the side-by-side site water and lab water toxicity testing of the traditional WER determination. EPA also supports conventional regression techniques for developing a relationship between site chemical parameters, such as DOC, and the WER. EPA's approval of such alternative procedures will be based on their scientific merit. With the anticipated improvements in techniques for predicting the WER from chemical measurements, EPA believes that in many cases it may be simpler to implement than the whole effluent toxicity approach advocated in the comment.

Comment ID: CTR-025-004a
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES C-16

Comment: The proposed CTR freshwater aquatic life criteria for copper are also problematical for many drinking water suppliers. Copper algaecides are a necessary element of algal control strategies for drinking water reservoirs and conveyances. Even with a comprehensive reservoir management program based on limnological principles, copper algaecides need to be part of the algal control arsenal. Algal growth, if uncontrolled, can lead to unacceptable levels of trihalomethanes (THMS) in treated water supplies, among other impacts.

The CTR proposes freshwater aquatic life criteria for copper which could severely hamper the ability of drinking water suppliers to use copper algaecides. The dosage of these algaecides which is effective for controlling algal growth could lead to periodic exceedances of the copper freshwater criteria. Yet, use of copper algaecides is sometimes necessary to protect drinking water beneficial uses, and there is currently no economically feasible alternative available. Drinking water suppliers have the difficult task of meeting conflicting requirements to protect drinking water beneficial uses while ensuring that aquatic life criteria for copper are met.

Response to: CTR-025-004a

EPA acknowledges the comment, but notes that tradeoffs between drinking water benefits and aquatic life benefits were not considered.

Comment ID: CTR-033-001
Comment Author: San Bernardino Muncpl Wtr Dept
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-02b Copper Aquatic Life
References: Letter CTR-033 incorporates by reference letter CTR-020
Attachments? Y
CROSS REFERENCES

Comment: The application of the proposed copper criteria to municipal effluent is overly restrictive. Copper in municipal effluents have been demonstrated not to be toxic at higher levels than proposed due to the nature of the constituents in the effluent. Attached is a recent article that appeared in the Water Environment Federation Journal that highlights the rational for high copper limits in municipal effluent.

Response to: CTR-033-001

See response to CTR-020-012.

Comment ID: CTR-053-003b

Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-02b Copper Aquatic Life
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES C-01b
C-09a

Comment: In spite of our lack of detailed comments for specific criteria, we have concerns regarding any weakening of California's previously developed standards, particularly those for mercury and copper. Also, we question the absence of criteria for dioxin and dioxin-like compounds. In order to ensure these issues are considered in future improvements of the Rule, we incorporate by reference the comments of the Natural Resources Defense Council regarding mercury, and the comments of Communities for a Better Environment ("CBE") regarding dioxin compounds and copper.

Response to: CTR-053-003b

See response to CTR-002-004b.

Comment ID: CTR-054-008a
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES C-24
E-01c
R
S

Comment: Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Francisco Bay, or alternatively EPA should specify in the Preamble implementation policies for copper that will result in reasonable control measures actions. To comply with the Clean Water Act and EPA regulations, EPA is required to consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act, EPA is required to evaluate regulatory alternatives based on an analysis of costs and benefits. Based on BADA's analysis of costs and benefits, EPA should either adopt copper criteria that are reasonably achievable or alternatively specify implementation policies that will avoid costly end-of-pipe controls. Potential implementation measures that could be specified include use of the following in calculating effluent limitations: actual dilution based on modeling studies; copper translators; probability of compliance less than 99.9%; and water-effect ratios determined for different

segments of the Bay. Unless EPA specifies these or similar implementation policies in the rule, it is possible that the CTR could result in significant costs ($12 million per year to $78 million per year) while resulting in minor environmental benefit (a 1% reduction in copper loading to the Bay). In that case, the CTR would violate the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. (see the discussion under Item 11 below.)

Response to: CTR-054-008a

See response to CTR-092-013a.

Comment ID: CTR-060-013
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Copper criteria

The metal criteria, including copper, are based on toxicity tests run in relatively pure water. Naturally occurring elevated ambient concentrations of suspended organic matter in bays and estuaries can significantly reduce the bioavailable portion of the metal. Since the criteria do not account for the presence of organic matter, the proposed criteria for metals, including copper, will be unnecessarily over-protective. As provided, water effects ratios (WERs) can be developed to account for this effect. However, WER studies can be very costly (see comments below regarding the economic analysis).

EPA appears to have deviated from its standard protocol in developing the copper criteria. Normally, a criteria is based upon toxicity tests of multiple species. However, the proposed criteria appear to be based upon the single species (i.e., the blue mussel) with the lowest toxicity concentration. This has resulted in a somewhat lower criteria than would have otherwise been derived. The criteria should be recalculated to be based upon the results of multiple species.

Response to: CTR-060-013

Concerning the comment on water-effect ratios, see response to CTR-020-012. EPA does not agree that it has departed from its standard protocol in deriving the saltwater copper criterion. The criteria Guidelines provide that the criterion derived to protect the fifth percentile genus is to be lowered, if necessary, to protect recreationally or commercially important species. This has been done for the saltwater copper criterion.

Comment ID: CTR-064-001
Comment Author: El Dorado Irrigation District
Document Type: Irrigation District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: The CTR proposes to establish a dissolved approach for copper with typical limits for a low flow stream ranging from 8 to 15 parts per billion (ppb). The preamble to the CTR recognizes that copper rapidly binds with organic materials and may not be toxic in municipal effluents. In fact, EPA has acknowledged in a number of forums that copper is not expected to be toxic in municipal effluents; nonetheless, the proposed CTR does not reflect this reality.

As explained by EPA criteria derivation guidelines, water quality criteria are required to reflect expected environmental impacts and are to be revised if they are determined to be significantly over or under-protective. EPA has in its possession an extensive amount of research data and field study results which demonstrate that copper is never toxic in municipal effluents. If copper is discharged to low flow streams, there is no influence of upstream water quality -and therefore, the toxicity of the copper will not be altered. The copper level in EID's discharge typically ranges from 20 to 40 ppb and has been found to be non-toxic to copper-sensitive organisms (i.e., daphnids).

The proposed copper criteria do not reflect the expected toxicity of this pollutant in the environment and will result in unnecessarily restrictive requirements throughout the state. Although required by the National Guidelines, the copper criteria fall to include an adjustment to account for binding with organic material such as that expected to occur in treatment planteffluents that renders this pollutant non-toxic (see enclosure).

Application of the criteria as a dissolved standard will likely result in many facilities being identified as in violation of the criteria. This proposed approach wastes scarce local resources, imposes an unauthorized, unfunded mandate on municipalities, penalizes small communities which have both limited budgets and access to updated scientific approaches, and is inconsistent with EPA's statutory mandates and guidance.

EPA should take one of two actions: (1) withdraw application of the copper criteria to municipalities, or (2) establish a screening level procedure which will only apply the criteria where copper-sensitive organisms indicate that copper is toxic.

We thank you for the opportunity to comment on this proposed rulemaking and look forward to EPA's reevaluation of the copper criteria as applied to municipalities.

Response to: CTR-064-001

See response to CTR-020-012.

Comment ID: CTR-065-007
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: PROPOSED COPPER CRITERION WILL CONTRIBUTE TO DEGRADATION OF SAN DIEGO BAY

EPA's proposed 3.1 ug/L dissolved copper criterion will allow copper three times the levels at which sensitive species are known to be impacted in an areas such as San Francisco Bay. San Diego Bay is already listed as impaired for copper. This criterion is too high and will allow more degradation of our water resources.

Response to: CTR-065-007

See response to CTR-002-008.

Comment ID: CTR-092-013b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-02b Copper Aquatic Life
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-24a

Comment: Validity Of The Proposed Copper Criteria For South San Francisco Bay

Attachment 3 to this letter is a technical report entitled "Development of a Site-Specific Water-Effect Ratio for Copper in South San Francisco Bay", dated September 1997 and prepared by the City of San Jose Environmental Services Department.

This attachment is also incorporated as part of our comments and is being submitted for inclusion in the record for this rulemaking. Because EPA is proposing to promulgate water quality criteria for all waterbodies in the State of California, we believe that it is required toconsider site-specific data to the extent that it is available, especially, where, as in the case of the submitted data, it appears that there is a less costly/appropriately protective alternative to the proposed criteria.

Response to: CTR-092-013b

See response to CTR-092-013a.

Comment ID: CTRH-001-014
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-02b Copper Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: On copper, EPA says it has weakened the copper standards to allow copper levels which, again, now violate the state standard of 4.99 in most of the bay. And EPA says this is too tight because the new data shows the quantity standard for total copper is overprotective.

But the highest dissolved copper level found in the estuaries with less copper pollution, where species that are apparently decimated by copper pollution in parts of San Francisco Bay still thrive, is three times smaller than EPA's proposal.

Our question here is, will EPA prove that its proposal will protect these species in the bay before adopting it?

Response to: CTRH-001-014

See response to CTR-002-008.

Subject Matter Code: C-03b Nickel Aquatic Life

Comment ID: CTR-063-001
Comment Author: Wilner, Cutler & Pickering
Document Type: Specific Industry
State of Origin: CA
Represented Org: Ni DI, Ni PERA, Inco U.S.
Document Date: 09/22/97
Subject Matter Code: C-03b Nickel Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: In this rulemaking, EPA proposes to set the freshwater acute aquatic life water quality criterion for nickel (the so-called "Criterion Maximum Concentration" or "CMC") at a level of 470 ug Ni/L, while the freshwater chronic aquatic life water quality criterion (the so-called "Criterion Continuous Concentration" or "CCC") would be set at a level of 52 ug Ni/L -in both cases expressed as the dissolved fraction of nickel in the water column corresponding to a water hardness of 106 mg/L as CaCO3- See 62 Fed. Reg. at 42169 (Table), 42194, These values are less than one-third of the CMC and CCC values that EPA has adopted for nickel in its National Toxics Rule, See 62 Fed. Reg. at 42169.

As explained in the rulemaking notice, the reason why the freshwater nickel aquatic life criteria proposed for California are so much lower than the values set forth in the National Toxics Rule is that the California values were "calculated using data published subsequent to the issuance of [the Clean Water Act section] 304(a) criteria document [for nickel]." Id. at 42168/3. In particular, eight sets of acute toxicity (LC50/EC50) data were added to the database for nickel. Seven of these eight LC50/EC50 values (adjusted to a water hardness of 50 mg/L CaCO3) ranged from 66,100 ug/L to 160,521 ug/L(*1). The eighth value, an LC50, for the snail species Physa gyrina, was 416 ug/L, more than two orders of magnitude lower than the values in the other seven studies.(*2) This value also was far below any other acute aquatic toxicity value for nickel that had been reported previously.(*3)

Since EPA calculates the CMC acute toxicity value by using the lowest four Genus Mean Acute Values for the chemical(*4), the LC50 of 416 mg/L reported for Physa gyrina replaced a Genus Mean Acute Value of 6,707 ug/L for the fathead minnow in the calculation of the CMC for nickel.(*5) This substitution of LC50 values caused the proposed California CMC for nickel to be 470 ug/L at a water hardness of 100 mg/L CaCO3, while the National Toxics Rule CMC for nickel corresponding to that water hardness is 1400 ug/L. See 62 Fed. Reg. at 42169. It also caused the proposed California CCC for nickel to be 52 ug/L at a water hardness of 100 mg/L CaCO3, compared to a National Toxics Rule CCC of 160 ug/L at that water hardness. See id. (The chronic toxicity CCC was affected by the change in acute toxicity data because, in the absence of sufficient chronic toxicity data for nickel, the CCC was derived by applying an acute to-chronic ratio to the acute toxicity data. See Nickel Criteria Document at K-1.)

The LC50 of 415 ug/L for Physa gyrina that is driving the reduction in the acute and chronic aquatic toxicity values for nickel in the California proposal is derived from a study by A.V. Nebeker, et al., "Effects of Copper, Nickel and Zinc on Three Species of Oregon Freshwater Snails, " Environmental Toxicology and Chemistry 5:807-811 (1986). For the reasons discussed below, we do not believe that data from this study (which was conducted in part to develop new test methods) should be used to calculate CMC and CCC values for nickel.

Under the methodology used by EPA to derive CMC values, "results of acute tests during which the test organisms were fed shall not be used, unless data indicate that the food did not affect the toxicity of the test material(*6). The article by Nebeker, et al. does not mention whether or not the snails were fed during testing. When a NiPERA scientist contacted the study's lead investigator in August 1993, she was informed that the investigator believed the snails had been fed. A subsequent check of the original data book for the 96-hour and 30-day Physa gyrina zinc test conducted as part of the same study disclosed that food had indeed been placed in each test container.(*7) The data book for the Physa gyrina nickel test could not be found (apparently some archived material was lost when the EPA laboratory was closed in 1985). In the absence of the data book, the study's author explained that while animals normally are not fed during acute (96-hour) tests, they may have been fed in this instance because the investigators "were developing new test methods, as well as obtaining criteria data.(*8) The authors of the study simply "have no way to verify" whether or not the snails were fed in the Physa gyrina nickel test.(*9)

In these circumstances, data from the Physa gyrina nickel test should not be used to set water quality criteria, particularly since the authors' data book clearly shows that the snails were fed in the 96-hour zinc test performed by the same investigators, in the same series of tests, in the same lab.(*10) Another reason why data from the Physa gyrina nickel study should not be used is that the loss of the primary data notebook makes it impossible to verify the experimental conditions and results of the study.

Apart from the possibility that the snails were fed, data from the test by Nebeker, et al. should be interpreted cautiously because these particular snails are very sensitive to heavy metals, especially copper.(*11) In one of the snail species tested by Nebeker (Lithoglyphus virens), the 30-day LC50 for copper was found to be <0.004 mg/L, while in a second test of the same species, 50% of the snails died at a copper concentration of 0.008 mg/L (the lowest level tested) at 96 hours.(*12) Overall, Nebeker et al. noted that the effect levels they observed were "in the lower range of those that have been reported," a result they attributed in part to the extreme softness of their test water (approximately 20 mg/L) and the resulting "higher percentage of biologically active metal species (e.g., more Cu++ in solution).(*13) It may be that exposure to low ambient levels of copper and other metals in this extremely soft test water had compromised the overall health of the snails and made them more sensitive to nickel.(*14) In the absence of positive control data (which are not reported in the article and which are not otherwise available given the loss of the primary data notebooks), one cannot determine whether the snails' health was compromised.(*15)

In sum, substantial questions exist as to whether the study by Nebeker et al. -which was conducted in part to develop new test methods -- satisfies EPA's methodological criteria for developing acute aquatic toxicity values. The possibility (indeed, likelihood) that the snails were fed during the 96-hour test, the apparent heightened sensitivity of the organisms resulting from exposure to low levels of copper in the soft water while the snails were held in culture prior to testing, and the absence of a data notebook that would make it possible to verify the experimental conditions and results all suggest that data from this study should not be used to set freshwater aquatic toxicity criteria for nickel. This is particularly true in light of the fact that the LC50 value for the only other snail species for which acute nickel toxicity data are reported (Amnicola sp.) was 12,770 ug/L (adjusted to a hardness of 50 mg/L), a value that is 30 times higher than the LC50 reported by Nebeker et al. for Physa gyrina.(*16) This striking disparity between the LC50 values for the two snail species is an additional reason for excluding the data from the Nebeker et al. study of Physa gyrina in calculating the acute water quality criterion for nickel.(*17) With those data excluded, the freshwater CMC for nickel would be 1400 ug/L (adjusted to a hardness of 100 mg/L as CaCO3), and the freshwater CCC would be 160 ug/L (adjusted to a hardness of 100 mg/L as CaCO3). Those values (and the corresponding water hardness equation from which they are calculated) should be adopted as the numeric freshwater aquatic life criteria for nickel in the State of California.

(*1) See 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water - 1995 Update: Freshwater Aquatic Life Criterion for Nickel, September 1996 (hereinafter "Nickel Criteria Document") at K-3, Table KI.
(*2) See id.
(*3) See id., Table K2.
(*4) See id. at K-1.
(*5) See id. at K-5, Table K2.
(*6) See 58 Fed. Reg. 20802, 21017/2 (April 16, 1993).
(*7) Personal communication from Alan V. Nebeker to Barbara Andon, August 27, 1993 (submitted herewith as Attachment 1).
(*8) id.
(*9) Id.
(*10) There is, of course, no data to indicate whether any feeding that might have occurred affected the toxicity of the test material.
(*11) See Nebeker, et al., supra, at 807.
(*12) See id. at 808 Table 1, 809.
(*13) Id. at 810.
(*14) See id. at 81 1 ("The prior acclimation of the test species to very low copper concentrations (less than 0,003 mg/L) also may affect their sensitivity.")- cf 58 Fed. Reg. at 21016 (stating that data must be rejected if the organisms "were previously exposed to substantial concentrations of the test material or other contaminants").
(*15) Cf 58 Fed. Reg. at 21016 (stating that data must be rejected "if they are from tests that did not contain a control treatment"). Similarly, since the study was not repeated, possible anomalies in the study (such as possible miscalculations in the dosing concentrations) cannot be ruled out.
(*16) See Nickel Criteria Document at K-4, Table K2; R.L. Rehwoldt, et al., The Acute Toxicity of Some Heavy Metal Ions Toward Benthic Organisms," Bull. Environ. Contain. Toxicol. 10:291-294 (1973) (static test procedure).
(*17) Cf 58 Fed. Reg. at 21017/3 ("Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is probably appropriate.").

Response to: CTR-063-001

EPA does not agree that the Nebeker et al. test results should be rejected. EPA does not believe that the question of whether the snails were or were not fed is of overriding importance. Feeding of organisms is not desirable in acute tests because the material in the food may reduce the biological availability of the toxicant, thus reducing its toxicity and raising its LC50, and because feeding is generally not necessary in a short test. Feeding of organisms is necessary in chronic tests, because of their longer duration. EPA does not believe that the feeding of organisms in a either an acute or chronic test has any effect on increasing the sensitivity of organisms to the toxicant, and likewise does not believe that feeding of organisms in the Nebeker et al. test, if it had been done (which is not known), would explain the results.

EPA does not expect lab books to be retained for perpetuity and does not consider loss of the original lab books to be grounds for discarding the data.

EPA agrees that Physa gyrina appears to be significantly more sensitive than other species. EPA recognizes that in general the chemical characteristics of the lab water affect the toxicity of metals in

ways not taken into account by the hardness normalization. However, EPA does not have information indicating that the characteristics of the (very soft) lab water used in the Nebeker et al. test are so unusual as to be unrepresentative of California waters.

EPA has considered whether the organisms may have been stressed by the chemical characteristics of the lab water. However, subsequent communications with Nebeker revealed that the organisms have been successfully reproducing for years in ponds feed by the same wells that provided the lab water (Alan Nebeker memorandum to Charles Stephan, January 6, 1995). EPA can thus find no reason to believe that the control organisms were stressed.

Consequently, although Physa gyrina, as tested by Nebeker et al., is substantially more sensitive than other tested organisms, EPA has not found a good reason to reject the data. The freshwater nickel criterion in the rule is therefore unchanged for the final rule.

Comment ID: CTR-092-012a
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-03b Nickel Aquatic Life
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-07b

Comment: Validity Of Proposed Nickel And Cyanide Criteria On A Statewide Basis

Attachment 1 to this letter is a technical report entitled "Task Report 1: Update and Recalculation of the Freshwater and Saltwater Cyanide Criteria", dated November 5, 1996 and prepared by Tetra Tech, Inc. for the City of San Jose. Attachment 2 to this letter is a technical report entitled "Final Report Recalculation of the Nickel Criteria for South San Francisco Bay", dated November 1, 1995 and prepared by Tetra Tech, Inc. for the City of San Jose. All of the attachments to this letter are incorporated as part of our comments and are being submitted for inclusion in the record for this rulemaking.

EPA has an obligation to consider the most current, scientifically defensible data in this rulemaking. EPA's obligations in this regard are particularly significant in light of its obligations under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C.A. 601 et seq.) to consider a full range of cost effective alternatives to promulgation of the proposed Rule.

Although the title of Attachments 1 and 2 suggest that the data submitted relates only to San Francisco Bay, the data in fact relates to the entire state of California, and indicates that lessstringent cyanide and nickel criteria than are proposed by the Rule would adequately protect water quality in California. Under the Executive Order 12866 and the Regulatory Flexibility Act, EPA should include consideration of the these less stringent criteria in its Economic Analysis.

Response to: CTR-092-012a

See response to CTR-092-012b.

Subject Matter Code: C-04b Selenium Aquatic Life

Comment ID: CTR-008-001
Comment Author: San Luis&Delta-Mendota
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/15/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: Dear Ms. Frankel:

The San Luis & Delta-Mendota Water Authority objects to the freshwater selenium criteria set forth in Environmental Protection Agency's ("EPA") proposed "Water Quality Standards: Establishment of Numeric Criteria for Priority Toxic Pollutants in the State of California" (Federal Register Vol. 62, #150, pages 42160-42208, Tuesday, August 5, 1997) on the following grounds:

1. The criteria are based on data assembled before 1987 (as reported in EPA 440/5-87-003 "Ambient Water Quality Criteria for Selenium - 1987"). Therefore, the criteria do not take account of more recent data on selenium toxicity.

2. In particular, the freshwater selenium criteria are scientifically inadequate because they fail to take account of the known interference between selenate and sulfate uptake in high sulfate waters like those in the San Joaquin Valley {see, e.g., Ogle and Knight, Arch, Environ. Contam. Toxical, 30, 274-279 (1996); Williams et al., Arch. Environ. Contam. Toxicol. 27,449-453 (1994); Hansen et al., Arch. Environ. Contam. Toxicol. 25, 72-78 (1993)]. This interference means that criteria based largely on effects observed in the low sulfate waters of Belews Lake, North Carolina, are probably overprotective for the high sulfate waters of the San Joaquin Valley. EPA itself (Federal Register Vol. 62, #150, page 42168, Tuesday, August 5, 1997) explicitly recognizes this inadequacy by stating "Chemical toxicity is often related to certain receiving water characteristics (pH, hardness, etc.) of a water body. Adoption of some criteria without consideration of these parameters could result in the criteria being overprotective."

The proposed California Toxics Rule should not be adopted without adequately addressing the difference for high-sulfate waters. The Rule should also not be adopted if it undercuts EPA's commitment to the cooperative review of appropriate long-term standards in the San Joaquin River Basin.

Response to: CTR-008-001

EPA agrees with the comment that the proposed acute freshwater criteria equation for selenium should not be promulgated, and has decided not to promulgate the proposed freshwater acute criterion, however, not for all of the reasons specified by the commenter. EPA's proposed acute criterion for the California Toxics Rule was revised in 1996 to reflect newer data supporting the additive toxicity of two predominant selenium forms (selenite and selenate) and is expressed as an equation. The acute criterion equation is designed to account for the additive toxicity of selenite and selenate in freshwater ecosystems and relies on assumptions of the relative toxicity and additivity of other forms of selenium since the

separate and combined toxicity of these other forms present in natural aquatic systems is not well defined. In 1996, the revised acute criterion underwent external peer review and was proposed for adoption under the Great Lakes Water Quality Initiative (GLI) (61 FR 58444-58449, November 14, 1996). This proposal has not yet been finalized because EPA is currently responding to public comments, which have called to attention a significant source of uncertainty in the expression of the relative toxicity of selenite and selenate in EPA's proposed acute criteria equation. Specifically, EPA is responding to the comment that the relative acute toxicity of selenite and selenate as expressed by the proposed individual CMCs (185.9 ug/L and 12.8 ug/L, respectively) is not consistent with the weight of toxicological data suggesting the opposite relative toxicity relationship and is an artifact of nuances in the selenate data set (i.e., its relatively small size combined with one extremely sensitive toxicity test result for the amphipod, Gammarus pseudolimnaeus).

EPA is currently responding to this comment by conducting additional toxicity tests on the relative toxicity of selenite and selenate to G. pseudolimnaeus and other acutely sensitive species. EPA is also updating its acute toxicity database with newer information, including newer data on the potential sulfate dependency of acute selenium toxicity. Therefore, because additional toxicity tests may result in substantial changes in the relative acute toxicity relationship of selenite and selenate that was proposed in the GLI and subsequently in the California Toxics Rule, EPA has chosen defer promulgation of acute, freshwater criteria for selenium until after the new toxicity data have been fully evaluated and incorporated. Further, EPA will consider in its forthcoming update of selenium freshwater acute criteria newer information since 1987 on the importance of sulfate and other factors on selenium freshwater acute toxicity.

EPA disagrees with the commenter that the chronic freshwater selenium criterion of 5 ug/L should not be promulgated as proposed. First, EPA believes that its chronic criterion is scientifically defensible, because having been based on field data, it incorporates principles and effects of bioaccumulation of selenium in aquatic ecosystems which are critical for estimating a long-term (chronic) toxicological threshold for selenium. Second, EPA does acknowledge that since 1987 (the latest revision of the selenium freshwater CCC), additional data are available that might be germane to the freshwater CCC for selenium. However, unlike the acute criterion, where the new data have been collected and almost certainly will change the criterion, EPA can not predict at this time the impact of any new data on freshwater CCC. Currently, EPA is in the early stages of reviewing this data and is addressing technical issues whose impact on the CCC is not easily predicted (e.g., the impact of basing chronic toxicity thresholds on tissue residue concentrations vs. water column concentrations). To facilitate this review of the freshwater CCC, and to address many of the technical issues associated with selenium bioaccumulation and toxicity, EPA conducted a peer consultation workshop in May 1998 with selenium experts external to the Agency to ascertain the degree of scientific basis and consensus on these issues (EPA-822-R98-007).

Regarding the comment that EPA should not promulgate the CCC of 5 ug/L total recoverable selenium because it does not account for sulfate dependency, EPA disagrees. EPA disagrees with this comment because at this time, EPA believes that insufficient data exist to quantify the effect of sulfate on the chronic toxicity of selenium to aquatic life. Specifically, none of the data referenced by the commenter quantify the effect of sulfate dependency on the chronic toxicity of selenium forms to aquatic animals. Rather, they apply to the effect sulfate on selenium acute toxicity and bioaccumulation in aquatic animals, and its toxicity to algae. EPA's assertion of insufficient data on sulfate dependency of chronic toxicity is supported by the opinion of experts at EPA's 1998 peer consultation workshop who concluded: "...insufficient information exists to correlate water quality characteristics (such as sulfate, pH and TOC)" (p. 9 in EPA-822-R-98-007). Furthermore, EPA considers application of sulfate-toxicity relationships based on acute toxicity or bioaccumulation to chronic toxicity to be highly uncertain and

unreliable. This conclusion is also supported by expert option, who concluded that toxicity relationships derived from acute toxicity studies cannot be reliably extrapolated to chronic toxicity, owing to the important influence of dietary exposure on selenium chronic toxicity (p. 9 in EPA-822-R-98-007). After EPA's review of the available information and expert opinions, EPA believes that it would be premature to withdraw its proposed CCC of 5 ug/L because it does not address possible effects of sulfate on selenium chronic toxicity.

Comment ID: CTR-009-005
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: At Federal Register page 42170, EPA begins its discussion about the derivation of its proposed Selenium criterion. This criterion is essentially based on a very few site specific field situations, and is applied, generally, to all situations regardless of how dissimilar they may be to the criterion spawning field incidents. The Kesterson Slough/Belews Lake type of problems and aquatic toxicity have not been found in other waters where Selenium is present in elevated concentrations, but that lack the sediment/food-chain conditions of these particular water bodies. Recent investigators found that Selenium water column concentrations were poor predictors of aquatic toxicity, and instead, posit a rationale for sediment-based toxicity criteria that EPA should consider as part of this rulemaking. (Selenium Sediment Toxicity Thresholds and Derivation of Water Quality Criteria for Freshwater Biota of Western Streams, Van Derveer and Canton, Environmental Technology and Chemistry and Selenium Toxicity to Aquatic Life: An Argument for Sediment-Based Water Quality Criteria, Canton and Van Derveer, Environmental Toxicology and Chemistry. Copies enclosed)

Response to: CTR-009-005

EPA derived its CCC for selenium using the Belews lake data in combination with laboratory data because laboratory toxicity data have been shown to consistently underestimate selenium effect levels compared to field situations. This underestimation of adverse effect levels by laboratory toxicity data is believed to be due to the bioaccumulation of selenium in aquatic food webs and subsequent exposure in top predator fish; a phenomenon which occurs in the field but not in routine laboratory tests. EPA acknowledges the conditions at Belews Lake that may differ from those at sites to which the CCC of 5 ug/L is applied. However, as discussed in EPA's response to CTR-058-006, EPA believes that the Belews lake data are reasonably consistent with adverse effect levels observed in other types of ecosystems and are scientifically defensible. For example, Hermanutz et al. (1992) and Schultz and Hermanutz (1990) studied the effects of chronic selenium exposure in large outdoor experimental streams in Minnesota on bluegill and fathead minnow, respectively. Despite the potential effect that the different hydrology of Belews lake and the Minnesota streams might have on selenium effect levels, the two stream studies showed adverse effects at levels similar to those observed in Belews lake (i.e., 10 ug/L). Furthermore, Lemly (1993) exposed bluegill in the laboratory to combined dietary (5.1 ug/g dry weight) and waterborne (4.8 ug/L) selenium and adverse effects including significant mortality in 60

days compared to fish in equivalent warm water exposures. Thus, EPA believes that the similarity between the adverse effect levels associated with Belews lake and the stream and laboratory studies supports the notion that EPA's CCC for selenium can be reasonably applied to other aquatic ecosystems.

Regarding sediment-based criteria, EPA believes that basing the CCC on concentrations of selenium in sediments is premature at this time because of the lack of scientific consensus on this issue and because of the preliminary nature and limited scope of the studies cited by the commenter. This assertion is generally supported by the opinions of experts at EPA's May 1998 peer consultation workshop on selenium who characterize the selenium/sediment toxicity database as sparse and largely limited to observations in western streams (p. 37-38 in EPA-822-R-98-007).

Comment ID: CTR-016-005
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Comments on the Proposed Selenium Freshwater Acute Criteria

The Regional Board supports EPA's efforts to develop an acute criterion for selenium that takes into account the presence of several oxidation states in natural waters, and the different and additive nature of toxicity associated with these different forms. The Board also supports EPA's determination that the existing chronic aquatic life criterion should not be modified to include consideration of different chemical species and that selenium interconverts from one chemical species to another in ambient waters. There are several practical consequences associated with the proposed additive toxicity approach that we would like to address from the perspective of our experience with selenium-related environmental problems in the San Francisco Bay Region.

The first comment is that the bioaccumulative potential of different chemical forms of selenium appears to be precisely the reverse of the toxicity potentials. For example, selenite is much more easily taken up into the food chain (preliminary estimates derived here in the Region are that selenite is about 10 times more bioavailable than selenate) but the proposed toxicity-based calculation method indicates precisely the opposite--that about ten times more selenite than selenate can be in the water column without causing unacceptable effects. The proposed model may work in systems that quickly flush out selenium such as stream segments, but do not accurately reflect conditions where selenium concentrations are elevated and occasionally spike upwards towards levels where acute toxic effects may occur-in the latter, bioaccumulative problems are likely more sensitive environmental endpoints. Thus, as a practical matter, the side-by-side application of the proposed acute and existing chronic criterion could have the unanticipated effect of over regulating selenate- and underregulating selenite-related bioaccumulation problems. For this reason, we recommend not using the proposed toxicity-based approach for a new acute criterion without additional considerations.

Additional considerations that EPA could make before changing the acute criterion to address this

practical problem include (a) reviewing the chronic criterion with the intent of including information to distinguish the bioaccumulative potential (and interconversion) of different chemical forms of selenium; (b) developing an alternative method for the acute criterion that takes into account the effect of short-term increases in selenium in aquatic systems on sensitive ecological indicators such as bird reproductive effects; or (c) developing more detailed guidance on the application of the acute and chronic criteria that would distinguish between aquatic systems potentially stressed with elevated levels of selenium in the food chain and those where such stresses are not a concern and the acute criteria are appropriate indicators of short-term problems.

Response to: CTR-016-005

EPA agrees with the commenter that it would be premature to promulgate the proposed freshwater acute criteria for selenium, and has chosen to defer promulgation of freshwater acute criteria for selenium until such time EPA has completed its evaluation of additional data and response to earlier comments on the proposed CMC equation in (61 FR58444, November 14, 1996. For additional detail on why EPA has chosen to defer promulgation of the freshwater CMC equation, see EPA's response to CTR-008-001.

Comment ID: CTR-030-005
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: II. ISSUES NEEDING CLARIFICATION OR MAJOR SUBSTANTIVE CHANGES

A. EPA's Proposed Selenium Acute Criterion is Technically Deficient

EPA's consideration of the toxicity of selenium has rapidly evolved over the last several years. In the Great Lakes Water Quality Rule (60 Fed. Reg. 15,366 (Mar. 23, 1995)), EPA proposed a selenium acute criterion that failed to consider the differing toxicities of two prevailing types of selenium, selenite and selenate. UWAG and other industry groups challenged the selenium acute criterion, and EPA eventually agreed to a remand of the criterion. The Court, however, ordered that the criterion be vacated and remanded. Following the vacatur, in November 1996 EPA proposed a new Great Lakes selenium acute criterion, adjusted to account for the selenite/selenate differences. UWAG submitted comments on the proposal, which are attached and incorporated into this comment document. (Attachment A). In the California proposal, EPA proposes to apply a selenium acute criterion that is identical to that proposed for the Great Lakes. EPA is still considering the comments it received in response to its revised acute selenium criterion for the Great Lakes - it has not taken final action on the proposal. UWAG therefore believes it would be inappropriate to promulgate the selenium acute criterion for California until the Agency has thoroughly assessed the record for the Great Lakes selenium acute criterion, and has determined appropriate final action on the Great Lakes criterion.

In commenting on the Great Lakes selenium acute criterion, UWAG raised the following points:

(1) EPA should reexamine and expand the LC50 database underlying the criteria maximum concentration (CMC) for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic water under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

All of these arguments apply with equal force to the proposed acute selenium criterion for California. For further elaboration of each of these points, see Attachment A.

Response to: CTR-030-005

EPA agrees with the commenter that it would be premature to promulgate the proposed freshwater acute criteria for selenium, and has chosen to defer promulgation of freshwater acute criteria for selenium until such time EPA has completed its evaluation of additional data and response to earlier comments on the proposed CMC equation in (61 FR58444, November 14, 1996. For additional detail on why EPA has chosen to defer promulgation of the freshwater CMC equation, see EPA's response to CTR-008-001.

Comment ID: CTR-030-011
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's

decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50 database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

1. THE CALCULATED CMC FOR SELENATE IS INCONSISTENT WITH THE VAST MAJORITY OF THE SCIENTIFIC DATA. THUS, EPA SHOULD REEXAMINE AND EXPAND THE DATABASE UNDERLYING THE CMC FOR SELENATE BEFORE GOING FORWARD.

EPA's proposed equation for calculating a CMC for total selenium relies on CMCs for selenite and scienate that the Agency calculated in the "Ambient Water Quality Criteria for Selenium -- 1987" (EPA 440/5-87-008) (the "1987 Criteria Document") and in the "Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water (EPA-8200-B-95-004) (the " 1995 Criteria Document"). See 61 Fed. Reg. 58,447. The CMC for selenate, which is fourteen times lower than the CMC for selenite(*3), is particularly troublesome, given that the overwhelming weight of the toxicological evidence indicates that selenate is less toxic than selenite. See Attachment A to these comments. This is apparent both from the data cited in EPA's 1987 Criteria Document and from numerous published papers in which a given researcher compared selenate and selenite toxicity in paired tests. Looking at the entire EPA database for selenate and selenite for all species where there are LC, values for both oxidation states, Gammarus pseiidolimnaeus is the only genus with a selenite LC50, to selenate LC50, ratio of less than one (1). While the ratio for Gammarus is 0.024, the range of ratios for all other genera range from 1.46 (for Daphnia) to 5.53 (for A. hypnorum (snail)).

A review of the CMC for selenate indicates that this anomalous result is caused by a combination of three factors: (1) the inclusion in the LC50, database for selenate of a Genus Mean Acute Value ("GMAV") of 0.065 mg/l for Gammarus pseudolimnaeus; (2) the fact that the database for selenate is relatively sparse (consisting of only eight GMAVS); and (3) the application of EPA's standard statistical technique for calculating CMCS, which produces results that are highly conservative in situations where

data are sparse and there is a substantial gap between the most sensitive species and the next most sensitive species.

UWAG believes that this combination of factors has lead EPA to derive a CMC for selenate that is inconsistent with the vast majority of comparative toxicity data. As two of the peer reviewers who commented on the July 1996, Draft Addendum to the 1987 Water Quality Criteria Document for Selenium (the "Draft Addendum") noted, this result appears questionable at best. See Adams, W.J., "Review of Selenium Water Quality Criteria: Revised" at p. 9 (undated) ("Adams Comments") (Attachment B to these comments); and DeGraeve, G.M., and McIntyre, D.O., "Review of The 'Freshwater CMC for Selenium: Addendum to Ambient Water Quality Criteria for Selenite -- 1987'" at p. 2 (Aug. 16, 1996) (Attachment C to these comments).

For example, Dr. Adams noted that another freshwater amphipod, Hyalella azteca, followed the expected pattern of toxicity and was more sensitive to seleaite than selenate. Adams Comments at 9. As Dr. Adams notes, one would expect selenate to be less toxic than selenite, because selenate is more chemically stable and less likely to be metabolized as organo-selenium. Id.

Several technical concerns with the two studies of Gammarus pseudolimnaeus by Brooke, et al., on which the GMAV is based, could have affected the accuracy of the results. First, Brooke et al. did not report the background concentrations of likely contaminants in the City of Superior water used in the tests. Thus, it is not possible to assess whether such contaminants may have affected the test results.

Second, the researchers do not report the actual concentration of selenate (or selenite) during or after the test. Instead, they appear to have made the assumption that no conversion occurred. Such assumptions are inappropriate, as evidenced by EPA's protocol for the Water Effects Ratio procedure, which requires that both the total recoverable and dissolved forms of the metal be measured at the start and end of any static exposure test. U.S. EPA, 1994 Interim Guidance on Determination and Use of Water Effect Ratios for Metals, EPA-823-B-94-001, pp. 55-56.

Third, UWAG questions the propriety of the researchers' decision to prepare their own reference standard solution, which they apparently used both to calibrate their measurement instruments and to prepare the test dilutions. Such a procedure is not standard, and could lead to biased results.

In sum, EPA should not blindly use the Brooke, et al., data for Gammarus without further verification, nor should it apply the standard criteria derivation procedure to the available data without first considering the suitability of that procedure in light of the inconsistency between the result obtained and the overwhelming weight of the available evidence. UWAG understands that EPA has commissioned additional acute toxicity tests of three species -- Gammarus pseudolittviaeus, Daphnia magna, and Ceriodaphnia dubia -- with both selenate and selenite. UWAG applauds this effort. We urge the Agency to forego taking any final action on issuance of a selenium CMC for the Great Lakes until those tests are complete and have been subject to review and comment.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

(*3) EPA appears to have reversed the CMCs for selenate and selenite in the discussion at 61 Fed. Reg. 58,446, col. 2 (Section B. 1.3.a. and b. of the proposal). In other places in the notice (e.g., 61 Fed. Reg. 58,445, col. 2), EPA correctly states that the calculated CMC for selenite is 185.9 ug/l and the CMC for scienate is 12.82 ug/l.

Response to: CTR-030-011

For reasons specified in the response to CTR-008-001, EPA agrees with the comment that the acute toxicity database for selenate should be reexamined prior to promulgating the proposed acute criterion for selenium. As described in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criterion for selenium and is conducting additional acute toxicity tests on Gammarus pseudolimnaeus and two species of daphnids to confirm the relative toxicity of selenite and selenate.

Comment ID: CTR-030-012
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50, database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and

organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

II. EPA SHOULD ACKNOWLEDGE AND PROVIDE GUIDANCE ON TAKING INTO ACCOUNT THE MODERATING EFFECTS OF SULFATE LEVELS ON SELENIUM TOXICITY.

The available evidence suggests that the toxicity of selenium to certain taxa decreases as sulfate concentrations increase. This relationship may be expected, because sulfur and selenium are chemically similar and follow many of the same physical, chemical, and biological pathways. Stadtman, T.C., 1974. Selenium Biochemistry. Scietice. 183:915-922. Thus, sulfur seems to directly compete with selenium at the molecular level.

For example, the relationship between sulfate concentrations and selenate toxicity was examined in a paper by Ogle and Knight (1996). The authors compiled all of the published data from acute toxicity tests on Daphnia magna in which sulfate was measured. They found a highly significant correlation (r-square value = 0.84) using untransformed data.(*4) This strong correlation clearly indicates that the toxicity of selenate decreases as the concentration of sulfur increases.

In its proposed addenda to the 1987 Criteria Document, EPA acknowledges that sulfate may decrease the toxicity of selenate and selenite.(*5) But UWAG believes that this issue specifically warrants more prominent discussion in the preamble to any final rule published by EPA. UWAG urges EPA to advise states, as part of this rulemaking, to consider the potential mitigating effects of sulfate on selenium toxicity, and to take those effects into account when establishing their own criteria.

In both the Draft Addendum and the September 1996 Addendum,(*6) EPA also says that the Water Effects Ratio ("WER") procedure for deriving site-specific criteria can be used to derive appropriate criteria in situations where sulfate levels affect selenium toxicity. While UWAG agrees that such a procedure could be an appropriate mechanism for taking into account the moderating effects of sulfate, it is not clear how EPA anticipates the WER procedure would be applied.

For example, would it be applied to develop site-specific CMCs for selenate and selenite respectively, which could then be used in EPA's equation? Or does EPA expect that the WER procedures would somehow be applied to examine the effect of sulfate on the toxicity of the mixture of several selenium forms? If the latter, it is not clear how the procedure would work, since application of the WER typically involves comparison of the toxicity of a given pollutant in source waters with toxicity exhibited in the laboratory tests on which the generic criterion is based. Because EPA's proposed selenium CMC is based not on toxicity tests of mixtures, but instead on an equation that relies on calculated CMCs based on laboratory tests of two distinct selenium oxidation states, EPA should explain how the WER should be applied in this situation.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

(*4) An even higher correlation would be expected if the data were log-transformed (the procedure EPA uses when examining the relationship between metal hardness and acute toxicity).

(*5) Draft Addendum at p. 3-6; U.S. EPA, "The Freshwater CMC for Selenate: Addendum to Ambient Water Quality Criteria for Selenium -- 1987" (Sept. 30, 1996) ("September 1996 Addendum") at p. 6.

(*6) See July 1996 Draft Addendum at p. 3-6; September 1996 Draft Addendum at p.6.

Response to: CTR-030-012

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium. EPA is currently generating and evaluating additional toxicity data (including those that evaluate sulfate dependency of acute toxicity) to facilitate its review of the acute criterion for selenium.

Comment ID: CTR-030-013
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50 database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

III. EPA SHOULD ACKNOWLEDGE AND PROVIDE GUIDANCE FOR DEALING WITH SITUATIONS WHERE SIMPLE ADDITIVITY DOES NOT OCCUR

EPA has not provided any guidance to the states on how to determine whether something less (or greater) than simple additivity might be occurring. While EPA notes in the September 1996 Addendum at p. 6 that the WER procedure might be used to account for "possible deviations from additivity," it does not explain how the WER could be used to accomplish this. For the reasons discussed above, it is not clear how the WER would be adapted for use in this context, where effects of a mixture under actual instream conditions are being compared to effects of separate metal oxidation states in laboratory tests.

UWAG believes that EPA has an obligation both to provide a more reasoned basis for its assumption that simple additivity occurs, and to explain what and how available procedures may be used to develop defensible criteria in situations where such additivity may not be occurring.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

Response to: CTR-030-013

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium.

Comment ID: CTR-030-014
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:

Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50 database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

IV. EPA SHOULD ACKNOWLEDGE AND PROVIDE GUIDANCE FOR DISTINGUISHING BETWEEN ORGANIC FORMS OF SELENIUM AND ELEMENTAL SELENIUM.

EPA proposes to employ an equation for calculating a CMC for total selenium, in part to address the potential toxicity of certain organo-selenium forms, which EPA says may be more toxic than selenate or selenite. EPA proposes to "assume that half of the measured or derived concentration of 'other' selenium forms is as toxic as selenate and half is as toxic as selenite." 61 Fed. Reg. 58,446. This proposal is troubling because it suggests that EPA may intend to allow states to "derive" organo-selenium concentrations by (1) measuring total selenium, selenate, and selenite; (2) subtracting the amount of selenite and selenate from the amount of total selenium; and (3) assuming that the difference is all organo-selenium, which EPA assumes is always at least as toxic as selenite or selenate.

Yet recent reviews of selenium cycling data show that some of that "other" selenium is likely to be elemental selenium, especially in anaerobic waters under reducing conditions. Maier, K.J. and A.W.

Knight. 1994: Ecotoxicity of selenium in freshwater systems. Reviews of Environmental Contamination and Toxicology. 134:31-48. Because of its insolubility and affinity for anoxic sediments, elemental selenium is far less bioavailable and, hence, less toxic than other selenium forms.

EPA's assumptions regarding the toxicity of organo-selenium forms clearly are based on a very limited amount of data on certain organic selenium forms. EPA has no data showing that either elemental selenium, or organic forms of selenium other than those for which data are provided in the proposal, are as or more toxic than selenite or selenate. Thus, EPA should specify that only measured amounts of the organic selenium forms for which it has sufficient toxicity data are to be included in the calculation. Equally important, EPA should specify that elemental selenium should be excluded from the calculation.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

Response to: CTR-030-014

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium.

Comment ID: CTR-030-015
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50 database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

V. EPA SHOULD CLARIFY THAT THE PROPORTION OF SELENITE, SELENATE, AND ORGANO-SELENIUM FORMS ARE TO BE DETERMINED INSTREAM, UNDER FULLY MIXED CONDITIONS.

EPA's proposal does not specifically discuss where in the waterbody the determination should be made as to the relative amounts of selenite, selenate, and organo-selenium present. Because water quality criteria are designed to protect aquatic organisms from plausible exposures instream,(*7) it seems logical that states would make this determination under fully mixed instream conditions(*8).

While the proposal does not discuss this point, on p. 58,448 it refers to deriving the acute criteria for selenium "depending on the relative proportions of the various forms of selenium in a facility's discharge." EPA has provided no explanation or support for making the determination on a discharge-by-discharge basis, nor would such an approach be consistent with the purpose of EPA's water quality criteria. Moreover, such an approach appears inconsistent with EPA's statements about the potential for chemical conversion of different selenium forms in ambient waters and the effects of water chemistry on various selenium forms. See 61 Fed. Reg. 58,446. Thus, an approach which requires determination of relative proportions instream, under the exposure conditions that are likely to occur, would seem the more technically sound and logically consistent approach in most cases.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

(*7) See, e.g., U.S. EPA, Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (1985).

(*8) UWAG recognizes that, in some cases, the concentrations of various selenium forms instream may

be so low as to make accurate analysis infeasible. In such cases, it may be more appropriate to allow for testing of the different selenium forms at the discharge point, as long as factors that are likely to affect selenium chemistry instream are taken into account.

Response to: CTR-030-015

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium. When EPA finalizes its freshwater acute criterion for selenium, EPA will consider providing additional guidance on the determination of the fractions of total selenium that exist in various forms.

Comment ID: CTR-030-016
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Mr. Morris:

On behalf of the Utility Water Act Group ("UWAG")(*1), we are writing to comment on EPA's "Proposed Selenium Criterion Maximum Concentration for the Water Quality Guidance for the Great Lakes System," published at 61 Fed. Reg. 58,444 (Nov. 14, 1996). UWAG appreciates the Agency's decision to extend the comment period(*2) for the selenium criterion maximum concentration ("CMC"), in light of the important technical issues raised by this proposed rule.

After reviewing the proposal, UWAG has the following recommendations:

(1) EPA should re-examine and expand the LC50 database underlying the criteria maximum concentration ("CMC") for selenate, which as currently derived is inconsistent with the vast majority of the available toxicity data for selenate and selenite;

(2) EPA should acknowledge and provide guidance for taking into account the effect of varying sulfate levels on selenium toxicity;

(3) EPA should acknowledge and provide guidance for dealing with situations where simple additivity does not occur;

(4) EPA should acknowledge and provide guidance for distinguishing between organic forms of selenium and elemental selenium, which may be found in anaerobic waters under reducing conditions;

(5) EPA should provide guidance on where in the waterbody the proportions of selenate, selenite, and organo-selenium will be determined; and

(6) EPA should avoid making unfounded assumptions about the effect of potential selenium bioaccumulation on the CMC, and should delete from its final guidance or rule any discussion of unproven methodologies taking such bioaccumulation into account.

Each of these recommendations is discussed in greater detail below.

VI. EPA'S ASSUMPTIONS REGARDING THE POTENTIAL EFFECTS OF SELENIUM "BODY BURDENS" ON THE ACUTE TOXICITY OF SELENIUM ARE NOT SUPPORTED BY SOUND SCIENCE, AND SHOULD BE DELETED FROM ANY FINAL RULE OR ADDENDUM EPA ULTIMATELY ISSUES.

In its proposal, EPA says that it is not proposing to amend the 304(a) criteria document for acute or chronic selenium embodied in the EPA document entitled "Ambient Water Quality Criteria for Selenium -- 1987" (EPA 440/5-87-0008). 61 Fed. Reg. 58,445, col. 1. Thus, EPA says, it does not intend to respond to any comments on that document. Yet on the same page, EPA also says that it is proposing to incorporate into the 1987 Criteria Document an addendum(*9) reflecting its new proposed approach for calculating a selenium CMC. 61 Fed. Reg. 58,445, col. 3. UWAG believes that EPA should clarify whether or not it intends by this rulemaking to affect the national criteria guidance document. If so, EPA should provide potentially interested persons appropriate notice and an opportunity to conunent on the implications of applying this approach beyond the Great Lakes.

UWAG agrees with EPA's decision not to go forward with any proposal based on the theory, set forth in the Draft Addendum and the September 1996 Addendum, that fish exposed to organic selenium may carry a "body burden" that makes them more sensitive to acute selenium exposure. We agree that there are no hard data Co support this theory and, thus, reliance on it would be indefensible. Although elevated bioaccumulation of selenium occurring as a result of long-term exposure has been associated with reproductive impairment and mortality in some environments, EPA has provided no technical support for the notion that a certain level of selenium "body burden" predisposes an aquatic organism to greater, or lesser, sensitivity to acute exposures.

Furthermore, even if there were some theoretical or experimental basis for the hypothesis that a "body burden" of selenium increases an organism's sensitivity to acute effects, there is no rational basis for its application to a Great Lake. Great Lakes waters typically contain undetectable concentrations of selenium. Low background concentrations, combined with the enormous size of the Great Lakes and the migratory nature of Great Lakes fish, do no provide the same opportunity for bioaccumulation which might theoretically exist in small, well-mixed water bodies. This premise is confirmed by actual selenium levels in Great Lakes fish, which do not contain elevated concentrations of selenium (Schmitt and Brumbaugh, 1990).(*10) A "body burden" model is therefore particularly inappropriate for the Great Lakes.

In the same vein, we agree with EPA's decision not to propose Guidance implementing an unsupported theory that pollutants should be placed in one of three categories, based on their potential to bioconcentrate and bioaccumulate, and that this potential be taken into account in deriving criteria. The theories contained in this section of the Addendum amount to pure speculation, supported by little or no empirical data. The relationship between body burdens and toxic effects is very controversial, and there is no scientific consensus that bioaccumulation per se results in adverse effects (e.g., Chapman, 1996).(*11) For example, Reash et al. (1996)(*12) showed that bluegills exposed to water selenium concentration, much higher than EPA's criterion continuous concentration ("CCC") of 5 ILglf resulted in elevated bioaccumulation of seleaium but these "body burdens" did not cause mortality or reproductive impairment in the population. Moreover, the presence of additional pollutants which contribute to the

entire "body burden" of pollutants in an organism makes the relationship between tissue levels of one pollutant and adverse effects quite unclear. Heinz (1996) sununarized these concerns when discussing the significance of selenium residues in birds:

Selenium's ability to interact with other enviroru-nental contaminants, especially other elements, also sometimes complicates an interpretation of toxic thresholds in tissues of birds . . . the reader needs to be aware that such interactions exist."

In summary, EPA's theory that a "body burden" of selenium could increase an organism's sensitivity to acute selenium exposure is interesting scientifically, but EPA currently has no mechanism to link the two processes. Furthermore, this concept makes little sense froi-ii an exposure viewpoint. Bioaccumulation occurs over a much longer period in an organism's life cycle relative to acute effects. Hence, UWAG strongly recommends that EPA keep the distinctions between acute and chronic exposure/effect unambiguous. Therefore, UWAG urges EPA to delete this discussion from any guidance or Addendum it issues for any selenium CMC.

(*1) UWAG is a voluntary, ad hoc, non-profit, unincorporated group of seventy-three electric utility systems, which own and operate over fifty percent of the nation's total generating capacity. The Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association also are UWAG members.

(*2) 61 Fed. Reg. 66,007 (Dec. 16, 1996).

(*9) It is not clear whether the September 1996 Addendum to which EPA refers is a draft or final document. If it is not a draft, then EPA's use of that document in its current form would appear to run contrary to the Agency's statements that the sections of the Addendum dealing with "body burden" and BAF/BCF issues are not being proposed for comment and will not be included in either the Great Lakes Guidance or the addendum to the criteria document. See 61 Fed. Reg. 58445, cot. 1, 58446, col. 2. For the sake of clarity, EPA should provide the public with the specific version of any addendum that itproposes to apply in any context.

(*10) Schmitt, C.J., and W.G. Brumbaugh. 1990. National contaminant biomonitoring program: concentrations of arsenic, cadmium, copper, lead, mercury, selenium, and zinc in U.S. freshwater fish. Archives of Environmental Contamination and Toxicology 19:731-747.

(*11) Chapman, P.M. 1996. Is bioaccumulation useful for predicting impacts? Paper presented at 1996 meeting of the Society of Environmental Toxicology and Chemistry, Washington, D. C.

(*12) Reash, R.J., T. Lohner, K.V. Wood, and R. Leville. 1996, Selenium in fish inhabiting a fly asli receiving stream: implications for national water quality criteria, Paper presented at 1996 meeting of the Society of Environmental Toxicology and Chemistry, Washington, D. C.

(*13) Heinz, G. H. 1996. Selenium in birds. pp. 447-458 in W.N. Beyer, G. H. Heinz, and A.W. Redmond -- Norwood (eds), Environmental Contaminants in Wildlife: Interpreting Tissue Concentrations. SETAC Special Publication Series. Lewis Publishers, New York. 494 pp.

Response to: CTR-030-016

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed

freshwater acute criteria for selenium.

Comment ID: CTR-051-002
Comment Author: Cal. RWQCB Central Valley Reg.
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: Selenium

In 1996, the Regional Board amended the Water Quality Control Plan for the Sacramento River and San Joaquin River Basins, updating the selenium control program in the San Joaquin River watershed. The amendment contains water quality objectives and an implementation timetable for the San Joaquin River and numerous water bodies in the Grassland area. It was finalized earlier this year and has been forwarded to US EPA for approval. If approval of the 1996 amendments is not obtained before promulgation of the final Toxics Rule, the current federally recognized objectives will remain in place indefinitely. This will unnecessarily complicate a control program that is already complex in nature. Therefore, US EPA is urged to approve the 1996 amendment and recognize it as the appropriate selenium control effort for the affected water bodies.

Response to: CTR-051-002

The commenter expressed concerns that the selenium control program and implementation timetable contained in the 1996 amendments to the Water Quality Control Plan for the Sacramento River and San Joaquin River Basins (Basin Plan) would be overriden by the CTR. The commenter also expressed concerns regarding the selenium criteria contained in the CTR and the potential for complications that could result from having state and federal criteria for the same waterbodies. EPA disagrees with these concerns.

First, it should be noted that already there are federal selenium criteria in place for parts of San Joaquin River, Salt Slough, Mud Slough (north), etc. These criteria were promulgated as part of the NTR on December 22, 1992. (57 Fed.Reg. 60848,60921, December 22, 1992.) The current CTR action does not change the NTR standards for those waters.

For the other named waterbodies subject to the 1996 Basin Plan amendments (Appendix 40), EPA is promulgating selenium criteria as part of the CTR. EPA has not yet approved the 1996 amendments, and in the absence of EPA-approved, site-specific criteria, EPA must promulgate criteria for toxic pollutants, including selenium, to meet the requirements of CWA section 303(c)(2)(B).

As with other site-specific criteria, if EPA approves the State's site-specific criteria for selenium for San Joaquin River, Salt Slough, Mud Slough (north), etc., EPA can undertake rulemaking to stay the the applicable selenium criteria in the CTR as well as the NTR. In the meantime, where site-specific criteria have already been adopted by the State in accordance with State law, but not yet acted upon by EPA,

such State-adopted criteria are in effect under State law. If those criteria are more stringent than applicable federal (CTR or NTR) criteria, those would be the controlling criteria for CWA purposes even without a stay of the applicable CTR (federal) criteria and would thus be implementable by the State. (This would not be affected by the so-called "Alaska Rule" which EPA proposed July 9, 1999, 64 Fed.Reg. 37072. See p. 37076.) This is the case with the site-specific criteria for selenium adopted by the State for the San Joaquin River, Salt Slough, Mud Slough (north), etc. Since the State must use the most stringent criteria in effect for its water quality programs, the 1996 Basin Plan site-specific selenium criteria remain in effect notwithstanding the CTR and NTR fresh water aquatic life criteria for selenium. Moreover, the selenium control program and implementation timetable will continue to apply to the State's site-specific criteria.

Comment ID: CTR-058-005
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: 4. Acute Selenium Criteria. EPA's assumption that the toxicities of all forms of selenium are additive is not adequately supported.

In the Great Lakes Initiative rulemaking, at pp 61 FR 58444 and 58446, EPA states that new data indicate that all forms of selenium are additive, and therefore takes that conclusion into account in setting the CMC for selenium without any further discussion.

The basis provided by EPA to support this conclusion consists of studies reported by Hamilton and Buhl (1990) and Maier et al. (1993) [at p. 61 FR 58446]. Interestingly, these reports more accurately suggest that mixtures of different selenium forms may not always reflect "additive" effects in the classic sense where the effect of two chemicals is equal to the sum of the effects of the individual chemicals applied alone. Instead, these two studies suggest that the combined effect can be substantially less than or somewhat greater than the "simple additivity" which EPA assumes and on which it bases its proposed equation. Moreover, the 1987 criteria document data do not support the additivity assumption made by EPA.

EPA should either abandon its stated assumption or provide a scientifically defensible explanation for basing its assumption upon the two studies cited as authority.

Response to: CTR-058-005

For the reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium. Therefore, this comment is no longer applicable to the final rule. During its review of the acute criterion, EPA will be generating additional data on the additive toxicity of different selenium forms to sensitive aquatic organisms.

Comment ID: CTR-058-006
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: 5. Chronic Selenium Criterion, SF Bay. WSPA does not support the choice of a freshwater criterion for SF Bay, Suisun Bay, San Pablo Bay and adjacent waters.

The proposed rule makes no attempt to defend the choice of a 5 ug/L freshwater criterion for selenium in these marine waters. This approach is arguably arbitrary and capricious. EPA says, more or less, we set this site-specific criterion in these waters in a previous rulemaking and we won't change. EPA should defend the choice of a criterion based on freshwater data for these waters, and stakeholders should be allowed to comment on the basis for this approach once they can see and evaluate EPA's attempt to justify it.

Furthermore, we dispute the 5 ug/L freshwater chronic criterion, which we understand to be based on the anomalous data of the Belews Lake, North Carolina study. We know of no other study where such a low threshold of concern was supported and challenge the Agency to cite any. Belews Lake is a lake with a very little flushing which arguably will not model many or most of the reaches of water in California to which EPA wants this criterion to apply (specifically, river reaches as well as the San Francisco/San Pablo/Suisun Bay system). We do not know what sort of mechanisms may occur in Belews Lake to convert selenium from one form to a more toxic form. We do not know if this transformation takes several steps. Additionally, we do not know whether these mechanisms would occur in the more common well-flushed reaches to which EPA seeks to apply the criterion here in California. EPA should justify both the value of 5 ug/L and the use of a freshwater criterion in marine waters.

Response to: CTR-058-006

EPA promulgated the freshwater CCC of 5 ug/l for San Francisco Bay, Suisun Bay, San Pablo Bay, and adjacent waters as part of the National Toxics Rule [NTR](57 FR 60848-60921, December 22, 1992). EPA disagrees that this approach is arbitrary and capricious. EPA explained its rationale for this decision in response to comments for the NTR (57 FR 60898, December 22, 1992). The purpose of today's rule is to promulgate criteria that fill the gap created when previous State criteria were invalidated as a result of State litigation. The rule is not intended to change or supersede any criteria previously promulgated for California in the NTR, as amended (Administrative Stay of Federal Water Quality Criteria for Metals and Interim Final Rule, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance-Revision of Metals Criteria, 60 FR 22228, May 4, 1995). The freshwater CCC for selenium is re-printed in the text of the CTR for the convenience of the user.

EPA disagrees with the commenter that the Belews Lake data are "anomalous" and are therefore not appropriate for application to California waters. The selenium effects data of Belews lake are supported

by other more recent data indicating adverse effects on aquatic organisms at comparable levels. For example, in a year-long study of selenium effects on aquatic life in outdoor experimental streams, Hermanutz et al. (1992) report statistically significant reductions in adult bluegill survival during the final 98-d exposure period to 10 ug/L selenium (introduced as sodium selenite) and complete mortality at 30 ug/L during the same exposure period. Hermanutz et al. (1992) also report statistically significant reductions in embryo hatch and higher incidence of developmental abnormalities at 10 ug/L and 30 ug/L compared to controls. This level (10 ug/L) is the same as that associated with unacceptable effects in the Belews lake study upon which the freshwater CCC is based. A chronic test conducted by Schultz and Hermanutz (1990) on the effect of selenium on fathead minnow in the same outdoor experimental streams is also consistent with results from the Belews Lake data. Specifically, Schultz and Hermanutz (1990) report statistically significant differences in the incidence of developmental abnormalities (lordosis and edema) in larvae from fish exposed in 10 ug/L streams compared to controls. In a laboratory study, Lemly (1993) exposed bluegill exposed to combined dietary (5.1 ug/g dry weight) and 4.8 ug/L waterborne selenium and reported that a combination of elevated selenium and low temperature resulted in reduced feeding, depletion of body lipids and significant mortality in 60 days (termed winter stress syndrome) compared to fish in equivalent warm water exposures.

The Belews lake data and supporting studies used to derive the freshwater CCC for selenium indicate that adverse effects on bluegill occurred at about 10 ug/L (as was also observed in experimental streams by Hermanutz et al., 1992) and that bluegill were unaffected at concentrations of 5 ug/L or below. Therefore, EPA believes that the similarity between the adverse effect levels associated with Belews lake and those of Hermanutz et al. (1992), Schultz and Hermanutz (1990), and Lemly (1993), which involved very different exposure systems, demonstrates that the Belews lake data are not "anomalous" as the commenter stated and can be reasonably extrapolated to other types of waterbodies. Finally, EPA notes that because these and other new data have become available since EPA's publication of the aquatic life criteria for selenium in 1987, EPA is currently reviewing this new data for potentially revising as appropriate its 304(a) criteria for selenium.

References:

Lemly, A.D. 1993. Metabolic stress during winter increases the toxicity of selenium to fish. Aquatic Toxicology, 27:133-158.

Hermanutz, R.O., K.N. Allen, T.H. Roush and S.F. Hedtke. 1992. Effects of elevated selenium concentrations on bluegills, Lepomus macrochirus, in outdoor experimental streams. Environ. Toxicol. Chem. 11(2):217-224.

Schultz, R. and R. Hermanutz. 1990. Transfer of toxic concentrations of selenium from parent to progeny in the fathead minnow (Pimephales promelas). Bull. Environ. Contam. Toxicol. 45:568-573.

Comment ID: CTR-060-007
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? N

CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Selenium acute criteria is technically deficient

This rule proposes to adopt the proposed revised Great Lakes acute selenium criterion. EPA has yet to respond to comments submitted on this criterion during a previous comment period. Until such time as EPA reviews and responds to the comments submitted previously on this proposed criterion, it would be premature for EPA to adopt the criterion as proposed in the CTR.

Response to: CTR-060-007

EPA agrees with the comment that it should not promulgate its proposed acute freshwater criterion for selenium until after it completes its response to comments on a previous proposal that relies on the same criterion. For additional reasons specified in the response to CTR-008-001, EPA is not promulgating its proposed freshwater acute criteria for selenium.

Comment ID: CTR-103-001
Comment Author: Fish and Wildlife Service
Document Type: Federal Government
State of Origin: CA
Represented Org:
Document Date: 10/10/97
Subject Matter Code: C-04b Selenium Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: The U.S. Environmental Protection Agency (EPA.) recently received a letter, directed to your attention, from Daniel G.Nelson (Executive Director of the San Luis & Delta-Mendota Water Authority) dated September 15, 1997. Mr. Nelson's letter presented an objection to proposed freshwater selenium criteria recently announced by EPA (California Toxics Rule; Federal Register Vol. 62 (150):42160-42208, August 5, 1997). Mr. Nelson asserts in his letter that the proposed "... freshwater selenium criteria are scientifically inadequate because they fail to take account of the known interference between selenate and sulfate uptake in high sulfate waters like those in the San Joaquin Valley...." Mr. Nelson then requests that EPA delay adoption of proposed water-quality criteria for selenium, pending review of the sulfate-interference issue.

The U.S. Fish and Wildlife Service (Service) recently reviewed our copy of Mr. Nelson's letter and does not see a scientifically substantive basis for justifying the delay and further review that Mr. Nelson requests. Sulfate-interference does not appreciably affect selenium bioaccumulation in real-world enviroruments and that has been known for at least 60 years.

Dr. Joseph Skorupa, of my environmental contaminants staff, has recently reviewed the issue of sulfate-interference and its relevance to establishment of freshwater selenium criteria and has concluded

that fish and wildlife toxicity thresholds for waterborne selenium are not sulfate dependent (Skorupa, in press). Mr. Nelson supports his view that sulfate-interactions should be an important regulatory consideration by citing recent laboratory bench studies (Hansen et al. 1993; Williams et al. 1994; Ogle and Knight 1996). Such studies often suffer from the so-called lab-to-field-dilemma (Landis and Yu 1995:28) because they are very simplified and environmentally unrealistic and cannot be extrapolated to the real world. The authors of the studies that Mr. Nelson cites are clearly aware of this important dilemma.

For example, Hansen et al. (1993:77) wrote:

"Thus, at this time, it does not appear that we have sufficient evidence to justify the consideration of sulfate as a factor in the regulation of Se in aquatic environments.

Williams et al. (1994:452) wrote:

"At present, there is little information available that allows us to assess how relevant this study's conclusions will be in natural waters containing a complex assemblage of selenium species.

Ogle and Knight (1996:278) reported that in the region of 5 ug/L waterborne selenium (the critical threshold region recognized in the California Toxics Rule):

"...the differences [in selenium bioaccumulation and toxicity] between extremely different sulfate concentrations are not significant.....

There is a clear record of highly relevant field data supporting Hansen et al.'s and Williams et al.'s cautions against extrapolation of their lab results. Field data show that simplistic selenate-sulfate lab bench results do not extrapolate well to real environments (Skorupa, in press). Realworld data unanimously support the conclusion that toxicity thresholds for seleniun are notsulfate dependent. In the absence of any new field data to the contrary, the objection raised in Mr. Nelson's letter must be viewed as inapplicable..

The findings of Dr. Skorupa's review can be summarized as follows:

As early as the 1930's (e.g., Hurd-Karrer 1937, 1938) competitive uptake interactions between selenate and sulfate had already been confirmed experimentally. In the same era it had also already been demonstrated that sulfate-interference did not apply to any form of environmental selenium other than selenate, and that the field significance of sulfate-interference was negligible. Sixty years ago, Beath (1937) concluded that the "...sulfur-selenium antagonism theory has not been found generally applicable tofarm and range practices [for ameliorating selenium toxicity to range animals] of the Rocky Mountain region." Thus, although recent experiments cited by Mr. Nelson (Hansen et al. 1993; Williams et al. 1994; Ogle and Knight 1996) provide useful information corroborating earlier work, it is inaccurate for Mr. Nelson to suggest that recent studies provide any fundamentally new conceptual insights not already known by 1987 when EPA derived the 5 ug/L chronic criterion for selenium.

Twenty years ago, Birkner (1978) came to essentially the same conclusion for aquatic habitats that Beath (1937) had reported for open range habitats. Birkner surveyed 30 freshwater sites in Colorado and Wyoming for waterborne, sediment, and foodchain selenium content. The sites that Birkner surveyed included levels of dissolved sulfate that ranged from 5-9,611 mg/L. Statistical analyses of his data led Birkner to conclude that levels of dissolved sulfate did not influence the level to which selenium is bioaccumulated by aquatic organisms.

The lack of sulfate dependency for selenium bioaccumulation in the real world was affirmed once again in the late 1980's and early 1990's. This time the Service collected eggs of waterbirds from agricultural evaporation ponds in California that varied in dissolved sulfate concentrations from 2,000-100,000 mg/L. Selenium concentrations in the bird eggs, which are directly related to the contamination of aquatic foodchains at each sampling site, were strongly predictable from waterborne concentrations of selenium regardless of variable sulfate concentrations that spanned three orders of maagnitude (Skorupa, in press). The Service's failure to find a sulfate-interference effect for bioaccumulation of selenium in bird eggs, was corroborated by studies of aquatic invertebrates (the food supply for birds) at the same sites by the California Department of Water Resources (John Shelton, unpubl. data). Combining Birkner's (1978) results with,the results from California evaporation ponds, no sulfate-interference effect could be detected in the real world for dissolved sulfate concentrations spanning from 5-100,000mg/L! Furthermore,the field-verified toxic threshold point of 3-4 ug/L waterborne selenium for birds at the high-sulfate ponds in California showed excellent correspondence with the field-verified toxic threshold point of 2-5 ug/L for fish residing in the low-sulfate waters of Belews Lake, North Carolina (Skorupa, in press).

Finally, a comprehensive review of the best documented case studies of selenium poisoning in nature revealed that 7 of 12 real-world toxic episodes occurred at sites with high-sulfate waters (Skorupa, in press). This rich body of real-world data on selenium toxicity to fish and wildlife affirmatively, and unequivocally, supported the conclusion that toxic thresholds for selenium arenot sulfate dependent.

Why are simple laboratory bench studies contradicted by field data? Bench studies confirm that high-sulfate waters can reduce bioaccumulation of selenate, but not eliminate it. Thus, even in the face of high concentrations of dissolved sulfate, over time, functionally significant amounts of waterborne selenate are nonetheless taken up by biota and transformed to other forms of environmental selenium that are not subject to sulfate-interference. Those other forms of selenium are far more bioaccumulative than selenate, are free of any interference from sulfate and, over time, come to dominate the bioaccumulation process (e.g., Besser et al. 1989). Recent 48-hr-96-hr lab bench experiments are simply too short in duration and too simple in design to mimic this progression from selenate-dominated water to a complex mixture of multiple chemical species of selenium that characterizes the ecotoxicology of selenium in the real world.

For example, drainage water in the San Joaquin Valley of California was found to contain selenium as selenate, selenite, and selenomethionine (Se-Meth) in a ratio of approximately 18:3:1 (Besser et al. 1989). Bioconcentration factors for periphyton, however, showed a reverse ratio of about 1:6:120 (Besser et al. 1989). Thus, the approximate ratio of selenium uptake from selenate, selenite, and Se-Meth would be 18:18:120. Therefore, only about 11 percent (18/156) of bioaccumulated selenium in the periphyton would be taken up directly from the inventory of dissolved selenate. Under these circumstances, even if a sulfate-interference effect as high as 50 percent were occurring it would have only about a 5 percent (0.5 x 0. 11) inhibitory impact on overall bioaccumulation of selenium. At toxic threshold exposures in the region of 2-5 ug/L waterborne selenium, a 5 percent effect would be very negligible in absolute terms. Even this example probably overestimates the contribution of selenate to bioaccumulation of selenium because it does not account for the cumulative loading of predominantly non-selenate species of selenium into aquatic sediments, which is another major bioaccumulation pathway that further devalues the relative importance of dissolved selenate selenimn. It is quite plausible that in real aquatic environments even where concentrations of dissolved sulfate are low, only a minute proportion of selenium bioaccumulation is due to direct uptake of selenate selenium.

Much of the technical information presented in this letter was also presented to the scientific consultants

retained b the San Luis & Delta-Mendota Water Authority during a meeting with Dr. Skorupa on July 19, 1995. If Mr. Nelson possesses fundamentally new data that are unequivocally relevant to the real-world, by all means the data should be evaluated by EPA. The studies that Mr. Nelson cites in his letter do not, however, constitute such data.

Questions regarding this letter may be directed to Drs. Joseph Skorupa or Steven Schwarzbach by contacting them at (916)-979-2110.

Response to: CTR-103-001

EPA agrees with the commenter that by itself, the current state of the science on the sulfate dependent toxicity of various selenium forms is not adequate justification to delay promulgation of freshwater selenium criteria in the CTR. However, EPA has chosen not to promulgate acute freshwater criteria for selenium for the reasons stated in EPA's response to CTR-008-001. EPA has chosen to proceed with promulgation of the freshwater CCC for selenium for the reasons stated in EPA's response to CTR-008-001. EPA will consider additional data on sulfate dependency of selenium toxicity, including those cited by the commenter, during its review of freshwater selenium aquatic life criteria.

Subject Matter Code: C-05b Lead Aquatic Life

Comment ID: CTR-020-013
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-05b Lead Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

2. Lead

The 1984 lead criteria establishes very stringent chronic criteria due to an artifact of EPA's criteria calculation procedure - where inadequate data are available, a lower criteria is calculated. Thus, even where it is apparent that less restrictive criteria should be developed, the calculation procedures produce a lower criteria. This anomaly of criteria calculation could have been rectified by updating the criteria to add additional organisms that were tested since the 1984 Lead Criteria Document was published. Unfortunately, EPA failed to update the lead chronic water quality criteria which would have increased the chronic value from about 1.5 ppb to 15 ppb. This update has been acknowledged by EPA Duluth representatives in a number of public forums as acceptable, and it was approved for the Delaware River Basin Commission, a quasi-federal entity in 1996 (Exhibit 9). EPA's failure to update the lead database for the CTR is arbitrary and capricious and needs to be corrected

(a) The Technical Basis for EPA's Lead Criteria is Flawed

EPA criteria for lead were first published in 1980 and revised in 1984. The database from which the criteria were derived is very limited. EPA assessed only ten freshwater species and eleven saltwater species. Consequently, the data used to develop the lead criteria do not meet the minimum data requirements set forth in EPA's guidelines. (*41) In addition, the analytical methodology (acid soluble metal) used to assess lead concentration in the toxicity tests used to develop the criteria was a rigorous digestion that measured non-toxic, as well as toxic, forms of the metal.

Because the tests used to develop the lead criteria measured non-toxic forms of metal, and lead salts tend to form carbonates and precipitate readily from solution, the criteria overestimated the toxic fraction of lead. Thus, the lead criteria are very conservative. In addition, statistical deficiencies in the underlying data base render the lead criteria significantly more uncertain thanother criteria derived using the requisite data. As a result, some states have deferred adoption of EPA's lead criteria; others have adopted

more appropriate lead standards that are scientifically supported. North Carolina, for example, adopted a 25 ug/l lead standard (as total recoverable) because:

We believe that a standard based on an acid-soluble equivalent value of 1.3 ug/l Pb is extremely and unnecessarily overly protective, especially when considering the vast differences in Pb concentration that can be measured from the same sample, as shown by EPA's data. Since these values can vary as much as 50-75 fold for Pb according to EPA's data, implementing a standard of 25 ug/l measured as total recoverable metal which is less than 20 times higher than the acid-soluble criterion of 1.3 ug/l) is sufficiently conservative and technically sound... (*42)

The geometric mean for water effect ratios reported for lead using C. dubia and fathead minnows are consistently greater than five (5), which confirms a reduction in lead toxicity in natural waters by a factor of five relative to laboratory water of minimal complexing ability. (*43) This is not surprising since lead is readily complexed by inorganic and organic ligands in natural waters. (*44) Pagenkopf reported that relatively low concentrations of humic acids readily detoxify lead:

If there is 1 mg/liter humic acid (HA) in the water with an effective gram formula weight of 1000, a sizable amount of lead could be complexed. With these conditions the HA concentration would be 10E-6M, and if the 108 stability constant were applicable, essentially all of the humic acid would complex PbE+2. This would raise the total nontoxic species concentration and in fact could cause a shift from apparent toxicity to nontoxicity. (*45)

Given the abundance of complexing agents in biologically treated effluents and storm waters, a dissolved lead standard based on EPA's criteria is overly conservative.

(b) Conclusions With Respect to Lead

EPA should withdraw the proposed lead standard as unnecessarily restrictive and recalculate the criteria to reflect the additional studies conducted since the criteria were issued. Given the prevalence of lead in virtually all municipal effluents and storm waters, a minor change in the lead criteria will significantly affect treatment requirements. EPA should not apply the lead chronic criteria to storm waters where elevated TOC levels are prevalent and will detoxify the metal present.

(*41) See National Guidelines.

(*42) Letter from North Carolina DEHNR to EPA Region IV (January 23, 1990) (Exhibit 7).

(*43) See, Hall, Scott, et al. "The Use of Stream Side Macrocosms in the Evaluation of Copper, Lead and Zinc Effects on Acidic Stream Biota in Support of Deriving Site-Specific Water Quality Criteria." See also, Brungs, W. A. et al. "Synopsis of Water-Effects Ratios for Heavy Metals as Derived for Site-Specific Water Quality Criteria" (March 1992).

(*44) EPA Lead Criteria Document at 3.

(*45) Pagenkopf, Gordon K. "Metal Ion Speciation and Toxicity in Aquatic Systems, in Concepts in Metal Ion Toxicity." G.K Pagenkopf, H. Sigel, eds., at 113.

Response to: CTR-020-013

Although EPA agrees that the freshwater lead data set is less diverse by one taxon than the Aquatic Guidelines call for, EPA is retaining the criteria in the rule. EPA does not believe that the decreased taxonomic diversity in the data set is by itself a substantial shortcoming that would invalidate the criterion.

The comment about statistical deficiencies is not sufficiently specific for EPA to be able to identify to what the comment refers.

EPA is addressing the issue on bioavailability of different forms of lead (that is, the presence of "non-toxic" forms of lead) through expressing the criterion as dissolved lead and as function of a site-specific Water-Effect Ratio.

Subject Matter Code: C-06b Chromium Aquatic Life

Comment ID: CTR-061-013
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-06b Chromium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42168, third column, near the bottom, states, "However, EPA believes that it is appropriate to propose criteria in this rule based on the most recent data." Following that statement is a table (located on the bottom of page 42168 and top of 42169) in which the proposed freshwater criteria (CMC) for Cr VI is 16 ug/L. That table also lists the CCC for Cr VI as 11 ug/L. I have reviewed the literature on Cr VI toxicity (see attached "Chromium Speciation: Key to Reliable Control of Chromium Toxicity to Aquatic Life ") and find that 11 ug/L will not protect zooplankton from toxicity. There is substantial reliable data in the literature which show that Cr VI is toxic to zooplankton at 0.5 ug/L. This situation should have been discussed in the proposed CTR so regulatory agencies, the regulated community and the public learn that an 11 ug/L Cr VI criterion will not prevent zooplankton toxicity and could thereby violate the narrative toxicity standard of no discharge of toxic chemicals in toxic amounts. The CTR should also discuss the fact that in many ambient water systems Cr III (which is allowed to be discharged at 50 ug/L) can convert to Cr VI resulting in concentrations of Cr VI above those that are known to be toxic to zooplankton.

Response to: CTR-061-013

EPA does not agree that the 11 ug/L criterion will not protect zooplankton from toxicity. EPA believes its criterion for chromium is adequately protective. EPA has examined the quotation appearing in the submitted document "Chromium Speciation: Key to Reliable Control of Chromium Toxicity to Aquatic Life". EPA believes that the comment's Elnabarawy et al. (1986) citation refers to those authors' data published in Environmental Toxicology and Chemistry (Vol 5, pp. 393-398), and has examined that reference.

This material dealt with additional toxicity testing data rather than the data EPA used to derive the criterion. The material does not have data on previously untested species. Consequently, even if EPA were to include the Elnabarawy et al. (1986) data, then the results would be averaged with other study results for the same species, in order to obtain new Genus Mean Acute Values and Acute-Chronic Ratios, and recalculate the CMC and CCC.

Furthermore, even if the Elnabarawy et al. (1986) data were acceptable and included in a new criteria derivation, under no circumstances would EPA's criteria derivation procedure allow setting the criterion to the lowest test result (0.5 ug/L) among replicate tests. The averaging of test results prevents the criteria from being unnecessarily influenced by experimental errors. Consequently, even if EPA were to update the criterion for this rule, it cannot be predicted whether the entire body of new data (as opposed to the lowest test results therein) would cause the criterion to go up or down, or leave it essentially unchanged.

An additional problem is that there is doubt as to whether EPA could judge the Elnabarawy (1986) data to be acceptable. Although all or nearly all treatment concentrations for Ceriodaphnia reticulata and Daphnia magna had reproductive success that was statistically significantly lower than the control response, essentially all treatments had the same response, only slightly lower than the control, despite 100 fold differences in concentration.

Data from Elnabarawy et al. (1986)

	Average number of young per adult			Adult survival percentage		
Cr (VI) ug/L	D.magna	D.pulex	C.reticulata	D.magna	D.pulex	C.reticulata
Control	85	53	23	100	100	100
0.5	76	44	16*	100	100	100
1.5	69*	44	16*	100	80	100
5.0	71*	45	16*	100	80	100
15.0	71*	45	14*	60	80	100
50.0	47*	42	14*	0*	50	100

* Significantly different from control, p less than or equal to 0.05.

The expected behavior for this experiment would be a sigmoidal concentration-response curve (in this case a backwards "S" shape) with the low concentrations displaying similar responses to the control, and the higher concentrations with more or less progressively lower reproductive or survival success. The character of Elnabarawy et al. (1986) data suggest that the somewhat depressed reproductive success for D. magna between 0.5 and 15.0 ug/L and for C. reticulata between 0.5 and 50.0 ug/L may not due to chromium.

Consequently, EPA cannot accept the comment's contention that new evidence has demonstrated that the CCC specified in the rule, 11 ug/L, would not adequately protect aquatic life uses.

With regard to the conversion of chromium (III) to chromium (VI), EPA does not agree that the rule, in setting forth criteria concentrations, needs any provision for interconversion of oxidation states. EPA believes that site-specific fate considerations are best handled during the waste load allocation or permitting processes, not during the state-wide standards setting process.

Finally it should be noted that in analyzing the toxicity tests underlying the CMC and CCC for chromium (III), EPA assumed that none of the chromium (III) was converted to chromium (VI). To the degree (if any) that chromium (III) was oxidizing to chromium (VI) in the underlying toxicity tests, the chromium (III) criterion would already account for that degree of conversion.

Subject Matter Code: C-07b Cyanide Aquatic Life

Comment ID: CTR-058-013
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-07b Cyanide Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Marine Cyanide Criteria. In 1996 WSPA submitted to the Washington Department of Ecology three reports in support of developing site-specific water quality criteria for cyanide. These reports were:

* Acute Toxicity of Cyanide to Two Species of West Coast Crabs, Cancer productus and Cancer gracilis;

* Literature Review of Cyanide Toxicity Data * Range and Distribution of Cancer branneri

These studies support an acute criterion of 9.4 ug/L and a chronic criterion of 1.5 ug/L using the EPA calculation procedures with data for C. irroratus being replaced by the Genus Mean Acute Value for four West Coast Cancer species. An acute to chronic ratio of 6.458 was used based on a recommendation by Mark Hicks of the Department of Ecology.

WSPA incorporates these studies into the record by reference (we will transmit the studies under separate cover) and urges EPA to review these data and support site specific marine cyanide criteria of 9.4 ug/L and 1.5 ug/L for California as well.

Response to: CTR-058-013

EPA agrees with incorporating the data generated for Cancer magister, C. oregonensis, C. productus, and C. gracilis into the data set underlying the cyanide saltwater criterion. The data for all tested species in genus Cancer are then as follows:

C. magister: LC50s 51.24 & 91.5 ug/L; SMAV 68.47 ug/L
C. oregonensis: LC50s 111.3 & 154.1 ug/L; SMAV 131.0 ug/L
C. productus: LC50 219 ug/L; SMAV 219 ug/L
C. gracilis: LC50 153 & 135 ug/L; SMAV 143.7 ug/L
C. irroratus: LC50s 4.2 & 5.7 ug/L; SMAV 4.893 ug/L

Within a genus, such as Cancer, in situations where toxicity data are available for some of the species, but not all of the species found in a state, data on tested resident species and data on tested non-resident species are both used to represent the untested species, when calculating site- or state-specific standards.

In contrast, for the State of Washington, where all resident Cancer species were tested (that is, C. magister, C. oregonensis, C. productus, and C. gracilis), EPA agreed that the GMAV for Cancer could be

recalculated after excluding C. irroratus, because (a) C. irroratus did not occur in Washington, and (b) it could not represent any untested Cancer species in that state since all resident Cancer species had been tested.

However, EPA has no data on the occurrence of Cancer species in California. Nor did the commenter submit any such data. As a result, EPA is unable to make the determination that C. irroratus could not represent any untested Cancer species occurring in California. That is, with the information available, EPA is not able to determine whether some Cancer species other than the above five occurs in California. If such Cancer untested species did occur in California, then C. irroratus would be considered as likely as any of the others above to represent the sensitivity of the untested Cancer species, and would thus not be deleted from the data set. Consequently, for this rule, the cyanide criterion was determined by considering all five of the above species.

The SMAV for C. irroratus is more than an order of magnitude less that the LC50 for any other species in the genus Cancer. The tests on C. irroratus were flow-through, measured tests at 20 degrees C. The tests on the other Cancer species were renewal, measured tests at 10 degrees C. EPA has not found any persuasive reason to believe the C. irroratus data to be in error. The observed difference between C. irroratus and the other Cancer species may be due to (a) genuine biological differences among species (although such large differences within a genus are not common), (b) reproducible differences stemming from different experimental conditions (flow-through test at 20degrees C versus renewal test at 10 degrees C), or (c) non-reproducible experimental variation.

The Aquatic Life Guidelines (the procedures EPA uses to derive criteria) discuss the situation where there are large differences among species in a genus. The Guidelines caution against taking a geometric mean of SMAVs when the values differ by more than a factor of 10, but do not precisely indicate what should be done in such cases. Generally, for other criteria included in the rule, when the SMAVs differed by more than a factor of 5, the GMAV was set equal to the lowest SMAV. When that is done for Cancer, the GMAV remains at 4.893 ug/L. The CMC and CCC thus remain unchanged from the proposed rule, both having the value of 1.0 ug/L.

Comment ID: CTR-092-012b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-07b Cyanide Aquatic Life
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-03b

Comment: Validity Of Proposed Nickel And Cyanide Criteria On A Statewide Basis

Attachment 1 to this letter is a technical report entitled "Task Report 1: Update and Recalculation of the Freshwater and Saltwater Cyanide Criteria", dated November 5, 1996 and prepared by Tetra Tech, Inc. for the City of San Jose. Attachment 2 to this letter is a technical report entitled "Final Report Recalculation of the Nickel Criteria for South San Francisco Bay", dated November 1, 1995 and prepared

by Tetra Tech, Inc. for the City of San Jose. All of the attachments to this letter are incorporated as part of our comments and are being submitted for inclusion in the record for this rulemaking.

EPA has an obligation to consider the most current, scientifically defensible data in this rulemaking. EPA's obligations in this regard are particularly significant in light of its obligations under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C.A. 601 et seq.) to consider a full range of cost effective alternatives to promulgation of the proposed Rule.

Although the title of Attachments 1 and 2 suggest that the data submitted relates only to San Francisco Bay, the data in fact relates to the entire state of California, and indicates that lessstringent cyanide and nickel criteria than are proposed by the Rule would adequately protect water quality in California. Under the Executive Order 12866 and the Regulatory Flexibility Act, EPA should include consideration of the these less stringent criteria in its Economic Analysis.

Response to: CTR-092-012b

EPA does not agree that the nickel and cyanide site-specific criteria developed for South San Francisco Bay necessarily apply to the entire State of California. EPA has examined the two reports ("Final Report: Recalculation of the Nickel Criteria for South San Francisco Bay" and "Update and Recalculation of the Freshwater and Saltwater Cyanide Criteria") referenced in the comment, and could not find evidence that the analysis contained therein applies to or was intended to apply to the entire state. EPA is not claiming that it has evidence that the San Francisco Bay analysis is not valid in other parts of the state. However, because the comment provided no information to support its assertion that the cited data relate to the entire state, and because EPA has no information of its own to determine the occurrence of species in the state, EPA is not able to conclude that the South Bay analysis applies state wide. To adjust the nickel and cyanide criteria statewide, EPA would need a statewide analysis of the type done for South San Francisco Bay. These site-specific studies must first be reviewed and approved by State authorities; they may then come to approval. If approved, EPA would rescind the criteria for nickel and/or cyanide in the CTR for the South San Francisco Bay.

With respect to the commenter's suggestion that these studies should be considered in any costing analysis for the CTR under Executive Order (E.O.)12866 and the Regulatory Flexibility Act, EPA does not agree. EPA has made clear elsewhere in the record of the rule that these criteria are health-based and are not based on cost-benefit balancing. The E.O. 12866 is supplemental information that shows the indirect costs and benefits of CTR criteria; it is an indication of the magnitude of the costs and benefits of the resulting water quality standards implemented through the NPDES permit program. With respect to the RFA, EPA addresses this issue in the preamble to the final rule and elsewhere in the final record for the final rule.

[The remaining parts of the response were written by Region 9 and are not shown here because I do not have an electronic version of them. All issues with that portion of the response deal with regional matters outside the purview of the national program.]

Subject Matter Code: C-08a Arsenic Human Health

Comment ID: CTR-020-007
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

3. Arsenic

Arsenic human health criteria have been deleted as not being based on reliable scientific information. (This action followed a petition for rulemaking to amend the NTR for Alaska.) In the preamble, EPA tries to promote use of a 5 ppb human health criteria which was never adopted by the state. The number routinely approved by the Agency for other states is 50 ppb. Based upon the Agency's recent discussion of the current scientific information regarding arsenic addressed in the modification of the National Toxics Rule for Alaska (62 Fed. Reg. 27707-27710), EPA should clarify that the 50 ppb drinking water objective is acceptable to meet all Clean Water Act requirements.

Response to: CTR-020-007

In the final rule, EPA is not promulgating human health criteria for arsenic. As stated in the preamble, EPA made the decision not to promulgate human health criteria in light of number of issues and uncertainties that have arisen concerning the effects of arsenic on human health. A discussion of these issues are contained in a document entitled "Issues Related to Health Risk of Arsenic" that is contained in the administrative record for this rule. EPA is currently completing a review of the risk assessment for arsenic in an effort to resolve these concerns.

Although the State did not adopt a human health criterion for arsenic, California has previously expressed its scientific and policy position by recommending the use of 5 ppb in providing human health protection. This value has been utilized by the State in implementing its narrative criteria. EPA expects that the State will continue to implement its narrative criteria to ensure that protections are in place for arsenic.

As the commenter noted, many states have adopted human health criteria for arsenic based on the maximum contaminant levels (MCL) under the Safe Drinking Water Act. In addition, many States have arsenic criteria in place that are based on EPA's existing Section 304(a) criteria guidance. As stated in EPA's December 12, 1988 guidance to states on complying with CWA Section 303(c)(2)(B) and in the Agency's policy on the use of Section 304(a) criteria and MCLs (published at 45 FR 79320, November

28, 1980), EPA encourages the use of MCLs for the protection of public water supplies. However, where fish consumption is an important activity in a waterbody, EPA recommends the use of the Section 304(a) criteria. EPA does not believe that any further clarification is needed.

Comment ID: CTR-030-003
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: C. EPA is Correct to Delay Promulgation of Human Health Criteria for Arsenic

Given the numerous uncertainties involved in developing scientifically defensible human health criteria for arsenic, UWAG supports EPA's decision to delay promulgation of such criteria in theCalifornia water quality standards. As noted in the preamble, those uncertainties include: (1) arsenic exposure evaluations, (2) metabolism and detoxification processes, (3) analytical methods, and (4) effects at low doses. 62 Fed.Reg. at 42,179, col. 1. EPA has prudently decided to await resolution of these uncertainties before promulgating additional arsenic human health criteria.

Response to: CTR-030-003

EPA acknowledges the numerous comments that support the Agency's decision not to promulgate human health criteria for arsenic in today's rule.

Comment ID: CTR-035-002c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
G-05
G-04
G-09
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible

regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002c

See response to CTR-030-003.

Comment ID: CTR-035-025
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42179 - Arsenic Human Health Criteria We support EPA's decision not to promulgate human health criteria for arsenic at this time. However, in light of the scientific uncertainties identified by EPA, we strongly recommend that EPA remove from the Preamble the recommendation that State permitting authorities use 5 ug/l in evaluating and interpreting the narrative water quality criteria, since EPA's own scientific judgment is that there is an insufficient basis for setting valid human health criteria at this time. Instead, as an interim measure, EPA should recommend that the maximum contaminant level (MCL) for arsenic of 50 ug/l be used by permit writers, as has been approved as the human health criterion for the State of Alaska.

Response to: CTR-035-025

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-041-005
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Fourth, for arsenic, the District strongly supports EPA's recognition that human health criteria should not be proposed at this time. The District is aware of the confusion in issues and the uncertainties that have developed concerning the measurement of the health effects of arsenic, and consequently the District supports the Agency's review of risk assessments for arsenic before promulgating criteria in any more states. In light of this reasoning, the District recommends that EPA withdraw its final sentence in this discussion recommending that permitting authorities in California refer to the State's criterion level of 5 ug/l in interpreting and evaluating narrative water quality criteria.

Response to: CTR-041-005

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-045-007
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

EPA's decision not to promulgate human health criteria at this time in light of the issues surrounding human health criteria for arsenic.

Response to: CTR-045-007

See response to CTR-030-003.

Comment ID: CTR-056-004
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-08a Arsenic Human Health
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N

CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* The decision NOT to promulgate human health criteria at this time for arsenic in light of uncertainty surrounding the human health effects of this element,

Response to: CTR-056-004

See response to CTR-030-003.

Comment ID: CTR-059-007
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Arsenic Human Health Criteria

We support EPA's decision not to promulgate human health criteria for arsenic at this time in light of the scientific uncertainties regarding the risks posed by arsenic in water. EPA currently has two different human health values for arsenic in water: 0.018 ug/L for the ambient water criterion and 5 0 ug/L for the drinking water maximum contaminant level (MCL). In its own decision document for arsenic(*2), EPA states that "Having two very different criteria for arsenic (0.018 ug/L ambient water v 50 ug/L in drinking water) to protect human health drinking water exposures is very confusing to the public. These different values have been difficult to explain, defend, and implement in EPA and State Programs." Based on this discussion, we strongly recommend that EPA remove from the Preamble the recommendation that State permitting authorities use 5 ug/l in evaluating and interpreting the narrative water quality criteria. Instead, as an interim measure, EPA should recommend that the MCL for arsenic of 50 ug/l be used by permit writers, as has been approved by EPA as the human health criterion for the State of Alaska.(*3)

(*2) U.S. Environmental Protection Agency, Decision Document for Arsenic. I.A.9.c Issues Related to Health Risk of Arsenic (no date).

(*3) 62 Federal Register 27707-27710 (May 21, 1997).

Response to: CTR-059-007

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-060-004
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E SUPPORTS

EPA has included in the proposed CTR provisions which are reasonable and with which SDG&E supports. These include:

Delay of arsenic human health criteria

The preamble states that EPA has decided to not propose human health criteria for arsenic in this rule due to a number of issues and uncertainties concerning the health effects of arsenic (see 62 Fed. Reg. at 42179, Col. 1). SDG&E supports this decision because it is important to base criteria upon sound science. Adoption of the criteria should be delayed until the referenced issues and uncertainties are resolved.

Response to: CTR-060-004

See response to CTR-030-003.

Comment ID: CTR-066-009
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The decision not to promulgate human health criteria at this time in light of the issues surrounding the human health criteria for arsenic.

Response to: CTR-066-009

See response to CTR-030-003.

Comment ID: CTR-081-002g
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
G-02
C-22
G-09
C-01a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are perfomed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002g

See cross references in categories C-24a, G-02, C-22, G-09, C-01a, G-05.

See response to CTR-030-003.

Comment ID: CTR-085-010
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's decision not to promulgate human health criteria at this time in light of the issues surrounding the human health criteria for arsenic.

Response to: CTR-085-010

See response to CTR-030-003.

Comment ID: CTR-089-001c
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
G-05
K-01
G-02
G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001c

See cross references in categories C-01a, G-05, K-01.

See response to CTR-030-003.

Subject Matter Code: C-09a Dioxin Human Health

Comment ID: CTR-002-006
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA unscientifically rejects criteria for 16 dioxin-like chemicals that impair San Francisco Bay. The 16 dioxin compounds that are not controlled by EPA's proposed criteria cause 80% of dioxin-like toxicity in San Francisco Bay fish tests supporting the human health advisory noted above.(*20) Subtracting all 2,3,7,8-TCDD toxicity does not change these dioxin-like toxicity estimates enough to reverse the conclusions which support this advisory.(*20) (*16) Thus, these 16 compounds impair fishing uses in San Francisco Bay. A criterion which includes the 16 dioxins developed by the state was approved in EPA's prior technical review, and the discussion in EPA's proposal shows that EPA still believes this criterion is scientifically defensible. Therefore, EPA's rejection of a criterion it believes is scientifically sound renders EPA's refusal to include criteria needed to protect San Francisco Bay fishing from these 16 dioxin-like chemicals without any valid scientific support.

(*16) California Regional Water Quality Control Board, San Francisco Bay Region, 1995. Contaminant levels in fish tissue from San Francisco Bay. Final draft report. Excerpt including data from toxic pollutant analyses of fish tissue samples from S.F. Bay. December, 1994.

(*20) Comparison of dioxin-like toxicity equivalents in San Francisco Bay fish tissue: 2,3,7,8-TCDD v. seventeen 2,3,7,8-substituted dioxins and furans. Table using data from Attachment 16, and analysis by CBE.

Response to: CTR-002-006

A commenter suggests that the Agency not include dioxin (2,3,7,8-TCDD) in this rule, pending completion of its ongoing reassessment of risks associated with exposure to dioxin and related compounds. In a contrary view, other commenters suggest that the Agency promulgate criteria not only for dioxin, but for related compounds--to include toxicity equivalent factors (TEFs) for– polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans and co-planar polychlorinated biphenyls (PCBs). TEFs evaluate these related compounds as equivalent concentrations of 2,3,7,8-TCDD and are used as a method for capturing the total dose associated with environmental exposure to mixtures of dioxin and dioxin-like compounds.

In response to the first comment, EPA disagrees. EPA still views dioxin as an extremely serious health threat and, therefore, does not wish to delay further establishment of an ambient water quality criterion for California subject to this rule.

In order to base its regulatory decisions on the best available science, EPA periodically updates its

scientific assessment of the risk associated with exposure to environmental toxicants. In September of 1991 EPA's Office of Research and Development (ORD) began such a reassessment on the toxicology and exposure science of dioxin and related compounds. The scope of this reassessment effort has been much broader than previous dioxin assessments. Included in the dioxin reassessment effort are the identification and characterization of: dioxin sources; dioxin environmental fate and transport; pathways of human exposure; levels of and trends in human exposure; full assessment of cancer, and non-cancer toxic effects; development of quantitative dose response relationships for all the effects; and the characterization of risks posed by dioxin exposure. Once completed after a final, upcoming peer review, the reassessment will serve as the principal scientific and technical basis for EPA's future dioxin risk management policies and programs.

When the reassessment began, the Administrator of EPA directed that Agency actions move forward without change in substance or timing until the reassessment is completed (Memorandum of William K. Reilly, September 11, 1991 "Dioxin Regulatory Program"). This direction has not changed. EPA continues to rely upon its 1985 assessment and the cancer slope factor it describes as the technical basis for policy and regulation; this is the assessment of dioxin in place as of September 11, 1991.

Consistent with this direction, EPA knows of no compelling reason not to include dioxin in the rule at this time. Instead, EPA believes it is an appropriate public health step to apply the current dioxin criteria in this rule and consider the merits of revising the criterion applicable in this rule (and to all other states covered by the National Toxic Rule) once the entire dioxin reassessment is complete and EPA revises its dioxin criteria. In the National Toxics Rule, EPA noted that a number of factors (as discussed below) may change but that the resulting criterion might remain the same. These concerns were reflected in EPA's response to comments in the National Toxics Rule. "It is too early in the process of scientific reassessment to support major changes in either the substance or timing of regulatory decisions related to dioxin." 57 Fed. Reg. 60884. EPA notes further that this approach, with respect to the National Toxics Rule, was upheld by the U.S. District Court for the District of Columbia in American Forest & Paper Assn, Inc. v. U.S. Environmental Protection Agency, No. 93-cv-0694 slip op. at 14-16 (D. D.C. 1996); 1996 U.S. Dist. LEXIS 13230. Based on information currently available to the Agency, the dioxin limit promulgated today for 2,3,7,8- tetraclorodibenzo[p]dioxin remains in the range of scientific defensibility.

EPA has provided a leadership role in the adoption and application of TEFs and is generally supportive of their use for risk assessment and risk management. However, the expansion of water quality criteria to include the full range of dioxin-like compounds is only one of many issues that needs to be addressed in revising water quality criteria. From an EPA perspective, the public is best served by having all these factors considered simultaneously. For this full review of the dioxin Water Quality Criteria to be well founded in science, it needs the benefit of a completed, peer reviewed, reassessment. Reexamining the cancer slope factor for 2,3,7,8- tetraclorodibenzo[p]dioxin and TEFs are among many issues important to future water quality criteria, but are not the only issues. The reassessment also includes coverage of reproductive, developmental, neurotoxic and other effects as well as fundamental questions as to the mode of action by which dioxin causes all of its effects. These will be considered in a thorough revision of water quality criteria. Interim adjustments based on only some parts of the toxicology or quantitative assessment would not support coherence in the scientific work or policy development that underlie Agency action. There are a number of outstanding issues that could result in modification of the water quality criteria, including: expanding the criteria to all dioxin-like compounds; adopting a new cancer slope factor; considering non-cancer effects as well as cancer effects; taking into account background levels and exposure; adjusting fish consumption patterns; adjusting bioconcentration and bioavailability factors; and adopting new TEF values. Some of these factors could lead to strengthening the water quality criteria while others might support relaxation. It is presently unknown what the net effect of all these factors may have on revised dioxin criteria. EPA continues to believe that waiting for the final

peer review reassessment to be completed so that all of these issues can be addressed simultaneously, is preferable to a sequence of incremental revision to the criteria based on only a few of these concerns. Thus, until EPA completes this reassessment, when EPA promulgates water quality criteria for a State, EPA will not use this approach.

For the reasons discussed above, the Agency is promulgating an ambient water quality standard only for 2,3,7,8-TCDD. This action is consistent with Section 303(c)(2)(B) and the National Toxics Rule (57 Federal Register 60863-60864, December 22, 1992) based on EPA's 1984 Ambient Water Quality Criteria Document for Dioxin. California, however, may adopt criteria for other related compounds.

See also response to CTR-002-003 (Category C-24; Site-Specific Criteria).

Comment ID: CTR-016-008
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: Comments on the Proposed Dioxin Criteria

In the preamble, EPA states its support for California's use of Toxicity Equivalents (TEQ) in setting NPDES permit limits, yet proposes standards for only one type of dioxin. We have found that appropriate water quality protection requires consideration of all congeners because it is only through congener "fingerprints" that distinctions can be made between atmospheric deposition and wastewater sources. Most dioxins and furans are released to the environment through air emissions. In addition, EPA should also provide guidance for determining permit compliance for discharges dominated by higher chlorinated congeners given the slim data base that established the equivalent factors for these higher chlorinated congeners. Below are the reasons for these recommendations.

EPA is proposing standards for 2,3,7,8-tetrachlorinated dibenzo-p-dioxin (TCDD) that are consistent with the NTR and that are based on the 1984 criteria. The TEQ concept uses toxicity equivalency factors (TEF) to convert mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) to equivalent concentrations of 2,3,7,8-TCDD.

EPA states in the preamble:

"...The concept of TEQ and the use of the I-TEFs/89, as outlined in EPA's 1989 Interim Procedures, provided valuable guidance in using the 2,3,7,8-TCDD water quality criteria in setting National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits that are protective of human health for dioxin and dioxin-like compounds."

Discharge data from our region, which we have shared with EPA, show that applying this statement strictly would raise significant permit compliance issues for many wastewater point sources. Guidance

on an implementation strategy for dioxin is needed. We believe it is appropriate for EPA to provide this guidance because they have a broad multimedia understanding of the current state of knowledge about the major sources and fate of PCDD/PCDF.

Based on an extensive review of local and international scientific data, we have found that the major sources of dioxins to the environment are from emissions to air. However, the ultimate sink for PCDD/PCDF is the aquatic sediment. As a result, aquatic indicators such as fish tissue may show a problem regardless of the significance or insignificance of current wastewater point sources in that area.

In the San Francisco Bay area, we find that most of the PCDD/PCDF enters surface waters from storm water runoff. Another significant portion may come from direct deposition of PCDD/PCDF onto the bay surface from the ambient air. The sources to storm water are most likely from emissions to air and reservoir sources.

Considering this, control of the air emissions sources rather than controls through the NPDES permit program would appear to us to have the most impact on water quality. Of course, in certain areas where there is a significant point source such as paper and pulp mills, it may be prudent to control that source because of potential impacts on the local area.

In any case, because of the significance of air emission sources, EPA should provide an implementation strategy for regulating PCDD/PCDF using the TEQ approach.

On the issue of uncertainty of TEFs, we believe that, as part of the California Toxic Rule, EPA should provide guidance for determining permit compliance on samples dominated by hepta- and octa-CDDs and CDFs. We believe this is necessary because of the uncertainty of the TEF values for these congeners, and because of the dominance of these congeners in many of the discharge samples in our region.

According to EPA's 1989 Interim Procedures document, the data base for the TEFs for hepta- and octa-CDDs and CDFs are very slim. For octa-CDD and CDF specifically, EPA acknowledged in the document that the TEFs reflect the results of a single experiment. Permit violations triggered by TEFs that are based on a very slim data base concerns us. This concern is compounded by the fact that discharge and storm water sample data from our region show hepta- and octa-CDDs and CDFs account for 20 to 100% of the total TEQ of the samples.

Response to: CTR-016-008

See response to CTR-002-006.

Comment ID: CTR-035-024
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N

CROSS REFERENCES

Comment: p. 42178 -- 2,3,7,8-TCDD (Dioxin) Criteria We recommend that EPA not adopt criteria for dioxin at this time for the following reasons. First, we recommend that EPA is still completing the dioxin reassessment, and, similar to EPA's decision regarding the human health criteria for arsenic, we believe that EPA should defer adoption of the criteria at this time. Second, as pointed out elsewhere in these comments, we believe that there are fundamental problems in EPA's adopting criteria that are below detection limits and for which compliance costs cannot be properly determined. Third, use of dioxin has been banned, and therefore traditional control methods are unlikely to succeed in achieving meaningful reductions in dioxin levels in the ambient environment. Therefore, we urge EPA and the State to instead focus watershed management efforts on developing strategies for addressing dioxin issues (where dioxin is demonstrated to be causing water quality use impairment).

Response to: CTR-035-024

See response to CTR-002-006.

Comment ID: CTR-039-006
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: IV. EPA MUST LOWER THE PROPOSED 2,3,7,8 TCDD DIOXIN NUMBER IN ORDER TO ACCOUNT FOR THE ADDITIVE TOXICITY OF 16 OTHER DIOXIN CONGENERS

BayKeeper believes that the only appropriate water quality standard for dioxin is zero. That being said, the State of California's 1991 criteria for dioxin included all 17 dioxin compounds. EPA's rule purposes to establish a criteria for only one of those congeners - 2,3,7,8-TCDD. The State's 1991 rule applied toxicity equivalency factors ("TEFs") promoted but not promulgated by EPA in the proposed rule. The toxicity equivalency concept takes into account the additive toxicity of the congeners on each other and, as EPA appears to acknowledge, more likely protects human health for dioxin and dioxin-like compounds. Unfortunately, EPA once again defers to a non-existent state process to fill in the regulatory gap for the other 16 dioxin compounds. As is clear from the State of California's recently proposed implementation plan for EPA's proposed criteria, the State is not proposing to take EPA up on its offer to make the dioxin criteria truly protective by applying TEFs after the fact. Assuming that EPA insists on attempting to protect people from dioxin by only regulating one of the congeners, at a minimum, in order to account for the toxicity of 2,3,1,8-TCDD where a mixture of dioxins is present, EPA should reduce the proposed criteria of .014 pg/L to .0014 pg/L to account for additional toxicity resulting from the presence of other dioxins and consistent with the State's prior technical decision on dioxin.

Response to: CTR-039-006

See response to CTR-002-006.

Comment ID: CTR-053-003c
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-09a Dioxin Human Health
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES C-01b
C-02b

Comment: In spite of our lack of detailed comments for specific criteria, we have concerns regarding any weakening of California's previously developed standards, particularly those for mercury and copper. Also, we question the absence of criteria for dioxin and dioxin-like compounds. In order to ensure these issues are considered in future improvements of the Rule, we incorporate by reference the comments of the Natural Resources Defense Council regarding mercury, and the comments of Communities for a Better Environment ("CBE") regarding dioxin compounds and copper.

Response to: CTR-053-003c

See response to CTR-002-006.

Comment ID: CTR-058-012
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: 2,3,7,8-TCDD ("dioxin"). EPA has proposed a criterion for 2,3,7,8-TCDD ("dioxin') and is encouraging the state to implement the TEQ approach in implementing this criterion. WSPA does not agree with the TEQ approach entirely and strongly urges EPA and the state to wait until EPA and EPA's Science Advisory Board complete the re-evaluation of the health risk assessment of dioxin and its congeners. EPA may find that some congeners, especially the more highly substituted congeners which seem to be ubiquitous in the environment, are not as toxic as originally perceived. Until EPA's studies are complete, EPA and the state should regulate 2,3,7,8-TCDD based on the criteria set by EPA for this compound in the proposed rule.

Response to: CTR-058-012

See response to CTR-002-006.

Comment ID: CTR-095-003
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Dioxin is only regulated in one compound. Ca. used to have standards for all 17 dioxin compounds. The proposed new standard for only one Dioxin compounded is .014 parts per billion. It should be at least .0014 ppb; OR BETTER: ZERO!

Response to: CTR-095-003

See response to CTR-002-006.

Comment ID: CTR-097-003
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: In addition the proposed standards apply to only one dioxin compound, and that proposed standard is O.014 parts per billion. A more appropriate standard for dioxin - ALL dioxin compounds- is zero parts per billion.

Response to: CTR-097-003

See response to CTR-002-006.

Comment ID: CTR-104-004a
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA

Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-104-004a

See response to CTR-002-006.

Comment ID: CTR-106-004a
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-106-004a

See response to CTR-002-006.

Comment ID: CTR-109-003
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-09a Dioxin Human Health
References:

Attachments? N
CROSS REFERENCES

Comment: Third, California used to have standards for all 17 dioxin compounds. The proposed new standard applies only to one, and that proposed standard is severely inadequate.

Response to: CTR-109-003

See response to CTR-002-006.

Comment ID: CTR-110-002
Comment Author: Judith A. Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/02/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Please consider standards for all seventeen dioxin compounds, not just one.

Response to: CTR-110-002

See response to CTR-002-006.

Comment ID: CTRH-001-012
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: On dioxin, despite proof that there are 17 dioxin compounds which harm the fishing public, EPA proposes a standard for only one of these compounds. EPA then says that it encourages the state to use the states previous scientifically correct standards for all 17 dioxins, instead of using the one EPA proposes, which deregulates 16 of the 17 most toxic chemicals known to science.

Our question here is, why does EPA think the state will have the courage to do the right thing about dioxin if EPA doesn't?

Response to: CTRH-001-012

See response to CTR-002-006.

Comment ID: CTRH-001-051
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: The toxicity equivalents notion is sort of held up as a good idea, and all states should go about doing that. It seems to me a simple step to say that the state has to do it. Just make those other 16 congeners --

And, of course, Baykeeper has signed on and there are a number of groups in the Bay Area that have signed on to the statewide notion of a zero dioxin standard anywhere possible. And I think that would be certainly the most practical place to put a zero discharge standard, would be in the standards themselves.

And to the extent there's other issues related to the particular permits, then we would obviously raise those at the time the permits came up. So we would propose a zero number for dioxin and all the congeners at this point.

Response to: CTRH-001-051

See response to CTR-002-006.

Subject Matter Code: C-10b PCBs Aquatic Life

Comment ID: CTR-037-010
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-10b PCBs Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: 10. EPA has modified the PCB criteria from an approach where each aroclor has its own criteria to one where a single criterion applies to the sum of all aroclors. However, the new criterion does not represent the sum of the criteria for the aroclors. This, in effect, results in a much more stringent PCB criterion because an effluent previously could discharge several aroclors at concentrations which were not detrimental to biota but now those same concentrations add up to a sum which is greater than the new criterion. The 1995 Update document does not address why this change is made, and justification could not be located in the proposed rule. Such changes must be technically and scientifically defensible and necessary to protect and support designated uses. EPA should provide data and logic supporting the new approach and illustrate why it is now necessary to protect aquatic organisms.

Response to: CTR-037-010

The Agency agrees that the presentation of the aquatic life criteria for polychlorinated biphenyls (PCB) in the criteria matrix for this proposal differ from that in the NTR as amended; for this final rule, aquatic life criteria are expressed as the sum of aroclors (1242, 1254, 1221, 1232, 1248, 1260 and 1016, CAS numbers 53469219, 11097691, 11104282, 11141165, 12672296, 11096825 and 12674112, respectively) while for the NTR, as amended, the criteria limits are expressed for each of seven different aroclors. The Agency agrees that a criterion based on the sum of several aroclors may be more stringent than a criterion where each of several individual aroclors has a concentration limit. For example, a criterion of 0.014 ug/L applying to the sum of seven aroclors is more stringent than each of seven aroclors having a concentration limit of 0.014 ug/L.

The Agency does not agree that justification for a criterion based on the sum of aroclors could not be located in the proposed rule. Page 42168 of the Preamble states: "The presentation of the polychlorinated biphenyls (PCB) criteria in the criteria matrix for this proposal differ from that in the NTR, as amended: for this proposal, the criteria are expressed as a total of all aroclors, while for the NTR, as amended, the criteria are expressed for each aroclor." The aquatic life criteria proposed in the CTR were based on the criteria contained in the 1980 criteria document entitled, Ambient Water Quality Criteria for Polychlorinated Biphenyls, (EPA 440/5-80-068, October 1980) which was included in the Record for the proposed rule. This criteria document explains the derivation of aquatic life criteria based on total PCBs. Therefore, a criteria based on the sum of aroclors is comparable with the aquatic life criteria presented in the 1980 criteria document.

Subject Matter Code: C-11b PAHs Aquatic Life

Comment ID: CTR-060-014
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
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Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

PAHs criteria

EPA's proposed criteria for high molecular weight (HMW) carcinogenic PAHs (e.g., Benzo (a) Anthracene, Benzo (a) Pyrene, Benzo (b) Fluoranthene, Benzo (k) Fluoranthene, Chrysene, Dibenzo (a,h) Anthracene, Indeno (1,2,3-cd) Pyrene) used a number of assumptions which have made the resulting criteria overly conservative. Following is a discussion of these factors.

* PAHs are highly hydrophobic molecules and consequently bind to available suspended organic matter. Currently accepted methods for measuring concentrations of PAHs in water neglect the binding of such hydrophobic compounds to suspended organic matter(*1). The dissolved fraction (DOM) of this suspended material passes through a 0.45um filter and the organic extraction required for analysis of PAHs insures that both DOM-bound and free PAH will be reported. Since only the free PAH is bioavailable, this results in the proposed criteria being unnecessarily overprotective. The PAH criteria should account for the bio-availability of PAHs, as they do for the bio-availability of metals (e.g., dissolved criteria vs. total recoverable, translators, WERs).

* The simple use of octanol-water partition coefficients or fugacity modeling show that these HMW PAHs are only vanishingly soluble in seawater and to reach the proposed criteria values would have to originate from a large well-mixed source. For instance, assuming the HMW PAHs has a log octanol/carbon partition coefficient (log Koc) of 5.0, the sediment source would have to be 4.9 ppm in order to be the source for the proposed water quality criterion of 0.049 ppb. While there may be sites where this level has been reported for total PAHs, the highest values for a single HMW PAH reported at a very contaminated site was 2.3 ppb of benzo(a)pyrene(*2). Since the source of HMW PAHs in fish is unlikely to be the water column, the back-calculation of human health standards to water standards makes little sense.

* The fish consumption rate of 6.5 g/day used is not representative of fish consumption within the State of California, and overestimates exposure. This value is reported by the EPA to represent an estimate of average consumption of fish and shellfish from estuarine and fresh waters by the U.S. population(*3) . The draft EPA Exposure Factors Handbook (*4)(EFH) summarizes studies on the intake of fish and shellfish, and includes study results for Northern and Southern California from the National Marine Fisheries Service. While this data is compiled for fish from marine habitats, other data summarized in

Table 10-8 of the draft EFH suggests that the percentage of the population consuming and the mean daily fish intakes are higher for fish from marine habitats than for freshwater/estuarine habitats. The mean daily intake of marine finfish for anglers was 2.0 g/day for both Northern and Southern California, and the intake was 0.2 or 0.3 g/day on a per capita basis in the coastal population. The value of 2.0 g/day would be a more reasonable consumption rate and should be sufficiently health-protective of the more highly exposed sub-population of the state, because this intake is restricted to the angler population, which may reasonably be expected to consume their own catch and to represent a greater exposed population than the entire population of the state. The intake rate from this database is more up-to-date and is geographically representative. The criteria should be recalculated using the California fish intake rate.

* The use of a single, deterministic value of the BCF for each chemical is a gross oversimplification, and is likely to overestimate exposure. Some of the issues that should be considered in the selection of BCF values to use in the analysis are listed below:

* Most BCFs are reported for whole body samples, whereas the edible portion of the fish is typically only a fillet (muscle, skin, and adipose tissue). For example, in a study of the uptake and distribution benzo(a)pyrene in Northern Pike, less than 3% of the total accumulation of benzo(a)pyrene was located in the edible portion of the fish. The use of whole body BCFs in general overestimates the concentration of the chemical in the edible portion of the fish.(*5)

* BCFs have been shown to vary widely depending upon the fish species. Fish species with a higher content of lipids tend to bioconcentrate lipophilic substances to a greater degree than less oily, leaner fish from the same environment. In addition, fish species which lack or have a reduced capacity for metabolic elimination of a chemical tend to bioconcentrate chemicals to a greater degree. For example, the BCF for benzo(a)pyrene in snails is 82,000, while the BCF for benzo(a)pyrene in bluegill is 2,600.(*6) Creel studies should be utilized to select fish species caught and consumed by recreational fishers in California, and the appropriate BCFs selected to represent the regional fish populations ingested.

* Because of their low solubility and high affinity for organic carbon, PAHs in aquatic systems are primarily found sorbed to particles that are either settled to the bottom or are suspended in the water column.(*7) The sediments can be major sinks for PAHS. The concept of estimating concentrations in fish from water concentrations and BCF factors neglects the potentially very significant contribution of uptake from sediments into benthic organisms and subsequent ingestion by higher trophic levels.

* The presence of particulate organic material (POM) and dissolved organic material (DOM) may exhibit a significant effect on the BCF measured. For example, the BCF for benzo(a)pyrene in bluegills decreases from 2,600 to 220 in the presence of 20 mg/L DOM.(*8) Because the amount of organic materials in the waterbody may vary depending upon the freshwater or estuarine habitat, the BCFs should reflect the organic material in the freshwater and estuarine water bodies in California.

* Several studies by NOAA and others have shown that HMW PAHs do not bioaccumulate in fish tissue even under very polluted environmental conditions.(*9) This is because they either pass through the gut unchanged,(*10) or are extensively metabolized(*11) and excreted.(*12) Metabolism occurs in several tissues, but primarily in the liver and gut. Metabolism that occurs in the gut reduces the amount of PAH that is available for distribution within the fish flesh.

* There is a wide range of published BCFs for HMW PAHs. This is because a number of different methods and assumptions were used to deduce these values. Most laboratory studies derived BCFs

during short-term exposures to environmentally irrelevant high concentrations of PAHs, while field studies assumed that the only source of PAHs was the water column. In short-term high level exposures, the fish does not reach equilibrium and metabolic capacities are overwhelmed. The inability of fish to clear these PAHs results in apparently high BCFS. However, as discussed above, high levels of HMW PAHs do not occur even at very polluted sites.

* The use of BAF values in future evaluations is suggested in the proposed Water Quality Standards document. With regard to carcinogenic PAHs, extensive metabolism of the compounds by high-trophic-level consumers such as predatory fish has been demonstrated, therefore food chain biomagnification of these compounds does not appear to be significant, and the use of a BAF does not result in the conservatism that a BCF does.

* The EPA uses the oral slope factor for benzo(a)pyrene as the toxicity criteria for the other carcinogenic PAHs. While it is our understanding that the EPA does not have a national standard for assigning cancer potencies to different PAHs, both the EPA Region IX(*13) and the California EPA(*14) have policies which result in the assignment of toxicity equivalence factors to the carcinogenic PAHs. In general, the other carcinogenic PAHs are less potent than benzo(a)pyrene (i.e. the toxicity equivalence factors are less than one). Because the proposed Water Quality Standards are specific to California, the toxicity criteria used in the derivation should at a minimum reflect either current California EPA or EPA Region IX policies.

* The EPA should consider the use of probabilistic approaches to determine numeric water quality standards related to fish ingestion. The wide variability and relatively high uncertainty in the essential exposure parameters related to the intake rates, species of fish consumed, bioconcentration factors, and human sub-populations are ideally suited to a non-deterministic approach, and the expansion of studies which report distributional data should make a probabilistic approach feasible.

(*1) Readman, J.W., et al. 1982. Aquatic distribution and heterotrothic degradation of polycyclic aromatic hydrocarbons (PAH) in the Tamar Estuary. Estuar. Coast. Shelf Sci. 14: 369-389.

(*2) Krahn, M..M. et al. 1986. Associations between metabolites of aromatic compounds in bile and the occurrence of hepatic lesions in English sole (Parophys vetulus) from Puget Sound, Washington. Arch. Env. Contam. Toxicol. 15: 6167.

(*3) U.S. EPA, 1989. Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish. Office of Water Regulations and Standards. EPA-503/8-89-002.

(*4) U.S. EPA, 1996. Exposure Factors Handbook. EPA/600/P-95/002Ba. Office of Research and Development.

(*5) Balk, L.; Meijer, J.; DePierre, J.W.; Appelgren, L.E. 1984. Toxicology and Applied Pharmacology, 74, 430-449.

(*6) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*7) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*8) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*9) Krahn, M.M. et al. 1986. Associations between metabolites of aromatic compounds in bile and the occurrence of hepatic lesions in English sole (Parophys vetulus) from Puget Sound, Washington. Arch. Env. Contam. Toxicol. 15: 6167.

(*10) Niimi, A.J. and G.P Doorkhran. 1989. Dietary absorption efficiencies and elimination rates of polycyclic aromatic hydrocarbons (PAHS) in rainbow trout (Salmo gairdneri). Env. Toxicol. Chem. 8: 719-722.

(*11) VanVeld,P.A.etal. 1988. Induction of monooxygenase activity in the intestine of spot (Leiostomusxanthurus), a marine teleost, by dietary aromatic hydrocarbons. Drug Metab. Disposition l6: 659-65; and Stegeman, J.J. 1978.

(*12) Krahn, M.M. et al. 1992. Mass spectrometric analysis for aromatic compounds in bile of fish sampled after the Exxon Valdez oil spill. Env. Sci. Technol. 26: 116-126.

(*13) U.S. EPA Region IX, 1993. Memo from Gerald Hiatt, Senior Risk Assessment Advisor at USEPA Region IX, to Richard Becker, Chief of Human and Ecological Risk at California EPA. Subject: EPA national and regional policies on assessment of cancer risks from exposure to mixtures of PAHs. May 25, 1993.

(*14) Califomia EPA, 1994. California Environmental Protection Agency Criteha for Carcinogens. November 1, 1994.

Response to: CTR-060-014

1. In response to the comment that EPA's proposed criteria for PAHs are overly conservative because they are not based on the freely dissolved fraction in water, EPA disagrees. While EPA agrees that the freely dissolved fraction of PAHs is the most bioavailable fraction for uptake by aquatic organisms, EPA believes that it would be premature to place in the final rule a criterion that is based on bioaccumulation factors normalized to the freely dissolved fraction because EPA has not yet completed peer review of its proposed national methodology for taking this approach. Until EPA completes the peer review of its national methodology for development of bioaccumulation factors, EPA believes it is most appropriate to base the criterion on the BCF, as is consistent with the NTR and EPA's current national recommended section 304(a) criteria. With respect to PAHs, EPA disagrees that its BCF of 30 necessarily results in an overly conservative criterion. Specifically, this BCF was derived from a study by Lu et al. (1977) and was measured in a model aquatic ecosystem environment containing multiple species at different trophic levels (e.g., algae, zooplankton, mosquito larvae, fish). Therefore, it is likely that some organic carbon was present in the study and that some sorption of the PAH compound (benzo-alpha-pyrene) onto dissolved and particulate carbon occurred thereby reducing the bioavailability of some portion of the PAH compound present. Further, since sufficient information is not presented in the Lu et al. study to estimate the freely dissolved fraction of the PAH compound, there is no basis for assuming that the bioavailability in the Lu et al. study was greater than waters in California generally.

EPA acknowledges that its revised national human health methodology would seek to develop water quality criteria for PAHs that are based on BAFs that consider the freely dissolved fraction in water (see 63 Fed. Reg. 43,756-43828; August 14, 1998, specifically pp. 43806-43823). However, this methodology has not been finalized and is currently undergoing external scientific peer review. EPA believes that

scientific peer review is essential to maintaining the scientific defensibility of its water quality criteria. In the aforementioned notice, EPA described its proposed methodology for appropriately determining bioaccumulation factors that are used to derive a criterion. As proposed, this would entail a two-step process: (1) calculation of a baseline BAF for organisms at each relevant trophic level from available field, laboratory, or model-derived bioaccumulation data, and (2) conversion of the trophic level-specific baseline BAFs to AWQC BAFs that reflect factors affecting bioavailability at the sites to which the AWQC is being applied. These factors include lipid content of consumed aquatic organisms and the organic carbon content (i.e., dissolved and particulate organic carbon) of waters applicable to the AWQC. In addition, EPA's proposed methodology includes guidance on selection of octanol-water partition coefficients (Kow), which are integral to several aspects of the methodology.

Although strong similarities exist between EPA's proposed national human health methodology (which includes the bioaccumulation methodology) and the 1995 methodology established under the Great Lakes Water Quality Initiative, all of the elements of EPA's proposed national bioaccumulation methodology require scientific peer review since it would be applied in a much broader scope than the GLWQI methodology (i.e., the national methodology applies to estuaries, lakes, streams, rivers throughout the United States whereas the GLWQI methodology applies just to waters of the Great Lakes region). In addition, the proposed national bioaccumulation methodology contains substantive changes since the 1995 publication of the GLWQI methodology (e.g., new guidance on selecting Kow values, revised estimates of food chain multipliers, additional guidance for the use of field data, revised default assumptions on lipid content of consumed aquatic organisms and particulate and dissolved organic carbon).

At the time of this rulemaking, EPA did not have sufficient time to adapt the GLWQI methodology in order to develop National or California-specific BAF estimates for the 304(a) criteria being promulgated, and also have these modifications peer reviewed. After the peer review process on the revised national methodology is complete, EPA plans to update its National 304(a) criteria on a periodic basis. As National 304(a) criteria are updated, EPA will evaluate the need to promulgate revisions to criteria in the CTR. Given that California is the only state with no numeric human health criterion in place for PAHs, and given that EPA has not completed a national methodology for developing BAFs on a freely dissolved basis, EPA believes it is most appropriate to promulgate the PAH criterion using the BCF that is consistent with the NTR and its most current national 304(a) recommendations.

2. In response to the comment that back calculation of human health criteria makes little sense because the source of PAHs in fish is not likely to be the water column, EPA disagrees that expressing human health criteria in the form of ambient water column concentrations is inappropriate for hydrophobic chemicals such as PAHs. For highly hydrophobic chemicals (i.e., log Kow > 6), EPA agrees that it is often the case that the concentrations in the water column are much lower than those in other environmental compartments such as sediment or food. EPA also acknowledges that the contribution of chemicals in food and sediment-based organisms to overall chemical uptake in higher trophic level organisms such as fish can be substantial, compared to the water column. However, EPA believes that expressing human health criteria in terms of concentrations in the water column concentrations is valid because environmental compartments in aquatic ecosystems (water, organisms, sediments) are all interconnected and therefore, concentrations of contaminants within these compartments are continuously being exchanged as a result of ongoing and competing chemical and biological partitioning processes. At equilibrium, contaminant concentrations within these environmental compartments are expected to be closely correlated, which is consistent with chemical equilibrium partitioning theory (i.e., higher water column concentrations would be correlated with higher sediment and prey concentrations). Thus, valid expressions of human health criteria can in theory be made for various environmental compartments (water, organisms, sediments). The Agency's choice of the water column for expressing

human health criteria largely reflects the need to use chemical criteria for determining acceptable chemical loadings to the water column and because more advanced implementation procedures are available for relating water column concentrations to chemical loadings, as compared to other compartments such as sediments and fish tissue.

3. In response to the comment concerning fish consumption, EPA disagrees with the comment regarding the consumption rate. For additional discussion of this issue, refer to the response to CTR-002-002a concerning fish consumption.

4. EPA disagrees with the comment that because lipid content in finfish is generally higher on a whole body basis compared to edible portions (e.g., fillet), the use of whole-body BCFs to calculate EPA's ambient water quality criteria significantly overestimates the concentration of the chemical in the edible portion of the fish and by implication is overly conservative. EPA disagrees with this comment because for lipophilic compounds such as PAHs, each BCF used in calculation of a human health ambient water quality criterion is first normalized to the lipid content of the tissue in which the residue was measured (45 FR 79346-79348). For example, BCFs determined from whole body residues are adjusted for the lipid content measured in the whole body, and BCFs determined from fish fillet residues are adjusted for the lipid content measured in the fish fillet. EPA performs this lipid normalization because it is widely recognized that accumulation of lipophilic chemicals is generally proportional to lipid content (Mackay 1982; Connolly and Pederson, 1988; Thomann, 1989) and this adjustment makes BCFs determined for different tissues and species comparable. Because of this proportionality with lipid content, steady-state BCFs for lipophilic compounds can be extrapolated from one tissue to another so long as they are expressed on a percent lipid basis. Once the average of the individual lipid normalized, BCFs are determined, this average, lipid normalized BCF is then adjusted to reflect the lipid content in the edible portions of aquatic organisms consumed by humans, which is 3.0% based on the EPA's 1980 Human Health Water Quality Criteria Methodology (45 FR 79318). In this way, the final BCF used to determine the human health water quality criterion reflects the chemical accumulation expected in the edible portions of consumed aquatic organisms. EPA further notes that for non-lipophilic compounds such as metals where lipid normalization does not apply, BCFs determined from only the edible portions are used in criteria calculations, per EPA's 1980 methodology.

References:

Connolly, J. and C. Pedersen. 1988. A Thermodynamic-based Evaluation of Organic Chemical Accumulation in Aquatic Organisms. Environ. Sci. Technol. 22: 99-103.

Mackay, D. 1982. Correlation of Bioconcentration Factors. Environ. Sci. Technol. 16: 274-278.

Thomann, R.V. 1989. Bioaccumulation Model of Organic Chemical Distribution in Aquatic Food Chains. Environ. Sci. Technol. 23: 699-707.

5. In response to the comment that EPA's BCFs for PAHs are oversimplified and overly conservative because BCFs have been shown to vary widely depending on fish species and therefore, BCFs should only be used from organisms consumed by recreational fishers in California, EPA disagrees. EPA agrees that BCFs from specific organisms caught and consumed in California, if available and appropriately weighted by consumption data, would allow for derivation of BCFs that would be most tailored to the California situation. However, EPA believes that the use of BCFs in its 304(a) criteria are still appropriate to California because they were selected and derived to reflect accumulation in aquatic organisms consumed throughout the United States, including those consumed in California. While EPA agrees that BCFs can vary depending on the species due to a variety of factors (e.g., lipid content of the

organism, differences in chemical metabolism, bioavailability differences, duration of exposure), EPA has taken a number of steps in its determination of BCFs for its 304(a) criteria to limit this variability. For example, EPA in its 1980 criteria guidance recommends that individual BCFs be adjusted for lipid content and be based on steady-state conditions (typically > 28 days) in order to reduce variability in BCF estimates. Furthermore, in its calculation of human health criteria, the final BCF used is adjusted for the consumption-weighted lipid content based on the variety of aquatic organisms consumed throughout the United States. In its more recent Great Lakes Water Quality Initiative guidance (60 FR 15366) and in its proposed national human health criteria guidance (63 FR 43,756), EPA also recommends BAFs and BCFs also be adjusted based on the freely dissolved fraction of the contaminant in water and be determined separately for organisms of different trophic levels as further means for reducing variability. However, until EPA's national methodology for deriving human health water quality has undergone scientific peer review and is made final, the human health criteria for PAHs in the final CTR represent the most recent 304(a) criteria available and are based on the most current national human health criteria methodology. With respect to BCFs for PAHs, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977) which was measured from a 33-day exposure in a model aquatic ecosystem environment. EPA believes that this value is appropriate because it is believed to more closely approximate steady-state conditions compared to other, more variable BCF values which were based on much shorter exposure periods (e.g., 3-days) and because it accounts for the effects of metabolism which is known to be important for PAHs.

6. In response to the comment that the BCF neglects potential uptake from sediments for PAHs into benthic organisms and subsequent ingestion by higher organisms, EPA agrees that in general, standard laboratory-based BCFs involving water-only exposures ignore the potential uptake of contaminants from sediment-dwelling organisms (and other prey species). For some chemicals (e.g., high log Kow chemicals that are not readily metabolized), omission of exposure via the aquatic food web can underestimate exposure and bioaccumulation. For this and other reasons, EPA relies on bioaccumulation factors (BAFs), which incorporate multiple routes of exposure, for determining human health water quality criteria under the Great Lakes Water Quality Initiative Guidance (60 FR 15366). EPA is also in the process of adopting this general BAF approach in its proposed revisions to its 1980 National guidance for determining human health water quality criteria (63 FR 43,756). However, because the Great Lakes BAFs rely on a number of considerations and assumptions that are specific to the Great Lakes (i.e., lipid content of aquatic species consumed in the Great Lakes region, freely dissolved fraction in the Great Lakes, food chain multipliers specific to the Great Lakes ecosystem), they cannot be directly applied to national 304(a) criteria or other areas without adjustment and significant additional analyses to develop appropriate BAFs. As stated earlier, EPA is in the process of updating its national methodology which is undergoing scientific peer review and is developing national, default BAFs. Until such time as EPA revises its national methodology, the human health criteria for PAHs in the CTR represent the most recent 304(a) criteria available and are based on the most current national methodology.

With respect to EPA's PAH criteria, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977). This BCF was measured from a 33-day exposure period in a model aquatic ecosystem environment using a model food chain that included benthic organisms. Therefore, while the model ecosystem used by Lu et al (1977) may not completely replicate the exposure conditions of typical field situations, EPA believes that it does not ignore potential exposure via benthic organisms and disagrees with the comment.

7. In response to the comment that DOM (dissolved organic matter) may exhibit a significant effect on the BCF for PAHs, EPA agrees with the commenter that DOM (what EPA calls dissolved organic carbon or DOC) can influence the freely dissolved fraction of PAHs and other nonpolar organic chemicals. As stated above, EPA agrees that the freely dissolved fraction of PAHs is the most bioavailable fraction for

uptake by aquatic organisms. However, EPA believes that it would be premature to place in the final rule a criterion that is based on bioaccumulation factors normalized to the freely dissolved fraction in water because EPA has not yet completed peer review of its proposed national methodology for taking this approach. Until EPA completes the peer review of its national methodology for development of bioaccumulation factors, EPA believes it is most appropriate to base the criterion on the BCF, as is consistent with the NTR and EPA's current national recommended section 304(a) criteria.

Although EPA based its bioaccumulation factors (BAFs) on the freely dissolved fraction for the Great Lakes Water Quality Initiative (GLWQI) rulemaking, EPA did not have sufficient time to adapt the GLWQI methodology in order to develop National or California-specific BAF estimates for the human health criteria being promulgated, and also have these modifications peer reviewed. After the peer review process on the revised national methodology is complete, EPA plans to update its National 304(a) criteria on a periodic basis. As National 304(a) criteria are updated, EPA will evaluate the need to promulgate revisions to the CTR. Thus, given that California is the only state with no numeric human health criterion in place for PAHs, and given that EPA has not completed a national methodology for developing BAFs on a freely dissolved basis, EPA believes it is most appropriate to promulgate the PAH criterion using the BCF that is consistent with the NTR and its most current national 304(a) recommendations.

With respect to the BCF used to derive the PAH criteria, EPA's BCF was derived from a study by Lu et al. (1977) which was measured in a model aquatic ecosystem environment containing multiple species at different trophic levels (e.g., algae, zooplankton, mosquito larvae, fish). Therefore, it is likely that some organic carbon was present in the study and that some sorption of the PAH compound (benzo-alpha-pyrene) onto dissolved and particulate carbon occurred thereby reducing the bioavailability of some portion of the PAH compound present. Further, since sufficient information is not presented in the Lu et al. study to estimate the freely dissolved fraction of the PAH compound, EPA cannot determine the extent to which the freely dissolved fraction associated with the Lu et al. (1977) study would be systematically higher or lower than sites in California to which the criteria would apply.

8. In response to the comment EPA's PAH criteria are overly simplified and overestimates exposure because metabolism of PAHs and other factors indicate that some PAHs do not bioaccumulate extensively in fish, EPA disagrees. EPA agrees that some PAHs are known to metabolize rapidly in fish which results in much lower residues than would be predicted by the octanol-water coefficient (Kow). For this very reason, EPA chose not to rely on Kow-based estimates of bioconcentration for deriving the proposed human health water quality criteria for PAHs. Instead, EPA based the proposed criterion for PAHs on a bioconcentration factor of 30 determined for mosquito fish from Lu et al. (1977). This BCF was measured from a 33-day exposure in a model aquatic ecosystem environment and incorporates the effects of metabolism by organisms at various trophic levels. Thus, EPA believes that its BCF is appropriate for PAHs and is not overly conservative because it takes into account the effects of metabolism.

9. Another comment was made that EPA's BCF for PAH is oversimplified and overestimates exposure because: (1) a wide range of BCFs exists for high molecular weight PAHs, (2) different methods are used to determine BCFs, (3) BCFs are used from exposure durations that are too short, (4) use of field BCF studies only assumes that water is the exposure source, (5) BCF studies involve high exposure concentrations. While EPA agrees that BCFs can vary depending on the species due to a variety of factors (e.g., lipid content of organism, differences in chemical metabolism, bioavailability differences, duration of exposure), EPA has taken a number of steps in its determination of BCFs for its 304(a) criteria to limit this variability and disagrees with this comment. For example, EPA in its 1980 criteria guidance recommends that individual BCFs be adjusted for lipid content and be based on steady-state

conditions (typically > 28 days) in order to reduce variability in BCF estimates. Furthermore, in its calculation of human health criteria, the final BCF used is adjusted for the consumption-weighted lipid content based on the variety of aquatic organisms consumed throughout the United States. EPA also recommends that exposure concentrations be below levels that are cause overt toxicity to the test organisms. In its more recent Great Lakes Water Quality Initiative guidance (60 FR 15366) and in its proposed national human health criteria guidance (63 FR 43,756), EPA also recommends BCFs and bioaccumulation factors (BAFs) also be adjusted based on the freely dissolved fraction of the contaminant in water and be determined separately for organisms of different trophic levels as further means for reducing variability. However, until EPA's national methodology for deriving human health water quality has undergone scientific peer review and is made final, the human health criteria for PAHs in the CTR represent the most recent 304(a) criteria available and are based on the most current national human health criteria methodology. Therefore, EPA believes BCFs derived using its existing 1980 national methodology and BAFs resulting from its forthcoming revised national methodology are not oversimplified and do not result in overly conservative estimates of chemical accumulation.

With respect to BCFs for PAHs, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977) which was measured from a 33-day exposure period in a model aquatic ecosystem environment. This value was chosen for the BCF because it is believed to more closely approximate steady-state conditions compared to other, more variable BCF values which were based on much shorter exposure periods (e.g., 3-days) and accounts for the effects of metabolism which is known to be important for PAHs. Therefore, EPA disagrees that this BCF is oversimplified or results in an overestimation of PAH accumulation.

EPA disagrees that BCFs based on field data are inappropriate because they assume that chemical exposure result from only from water. On the contrary, such field-measured BCFs (now called BAFs) reflect uptake from multiple exposure routes (water, diet, sediment) but merely reference the accumulation to the water concentration. EPA believes that expressing human health criteria in terms of concentrations in the water column concentrations is valid because environmental compartments in aquatic ecosystems (water, organisms, sediments) are all interconnected and therefore, concentrations of contaminants within these compartments are continuously being exchanged as a result of ongoing and competing chemical and biological partitioning processes. At equilibrium, contaminant concentrations within these environmental compartments are expected to be closely correlated, which is consistent with chemical equilibrium partitioning theory (i.e., higher water column concentrations would be correlated with higher sediment and prey concentrations). Thus, valid expressions of human health criteria can in theory be made for various environmental compartments (water, organisms, sediments). The Agency's choice of the water column for expressing human health criteria largely reflects the need to use chemical criteria for determining acceptable chemical loadings to the water column and because more advanced implementation procedures are available for relating water column concentrations to chemical loadings, as compared to other compartments such as sediments and fish tissue.

10. Regarding the comment that BAFs should be used for further bioaccumulation evaluations in water quality criteria documents with particular reference to PAHs, EPA agrees. As discussed previously, EPA is in the process of revising its national human health methodology and has proposed a methodology that would develop water quality criteria for PAHs that are based on BAFs (see 63 Fed. Reg. 43,756-43828; August 14, 1998, specifically pp. 43806-43823). However, this methodology has not been finalized and is currently undergoing external scientific peer review. EPA believes that scientific peer review is essential to maintaining the scientific defensibility of its water quality criteria. When this methodology is made final, EPA will develop revised 304(a) criteria for chemicals, including PAHs, that are based on BAFs rather than BCFs. EPA notes that with respect to the BCF used in deriving the proposed PAH criteria, this BCF was similar to a BAF because it was measured in a model aquatic ecosystem

environment that contained organisms at different trophic levels.

11. The proposed PAH water quality standards for California are part of a Clean Water Act (CWA) Section 303promulgation that EPA has undertaken. For this promulgation, EPA utilizes published IRIS cancer slope factors and utilizes published guidance documents and adopted Agency policies. As such, the commenter is correct that EPA does not have an established policy on assigning cancer potencies based on TEFs to the various PAH chemicals. However, the State of California can endeavor to establish subsequent standards based on their own current policy. EPA would most likely approve such a decision during the Agency's triennial review of State standards, as long as the standard was scientifically defensible and was consistent with CWA requirements.

12. EPA agrees with the commenter that probabilistic approaches can be a viable option for addressing uncertainty and variability in the development of ambient human health water quality criteria, provided sufficient data are available from which to estimate statistical properties of input distributions (e.g., mean, standard deviation, type of distribution) and the methods are scientifically defensible. However, in many situations, insufficient data are available to estimate the necessary statistical properties of input distributions with sufficient confidence to provide meaningful results. Furthermore, it is highly unlikely that scientifically defensible input distributions could be used for all input parameters for all criteria in the CTR. It should be noted that EPA's criteria methodology does not preclude States and Tribes from using probabilistic approaches for criteria determinations, provided such approaches produce criteria which are scientifically defensible and achieve an appropriate level of protection. However, EPA does not consider the use of probabilistic modeling approach to be a prerequisite for deriving scientifically defensible criteria. EPA has demonstrated and continues to believe that scientifically defensible water quality criteria can be produced based on point estimates of toxicity and exposure parameters provided the estimates are based on reasonable and appropriate assumptions (i.e., worst case assumptions for all input parameters would probably not be reasonable because they would probably correspond to a highly unlikely or nonexistent risk scenario). EPA's criteria are not based on worst case assumptions but rather are based on assumptions that reflect different levels of conservatism depending on the input parameter. Together, these input parameters result in criteria that the Agency believes achieves an appropriate level of protection for its national 304(a) criteria and are appropriate for promulgation in California.

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Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

7. Adoption of More Stringent Requirements for Maximum Containment Levels ("MCLs") is Inappropriate

A number of the water quality-based criteria establish water ingestion-related requirements more stringent than tap water criteria. This leads to the anomalous result that ingestion of effluent is regulated more stringently than ingestion of tap water. An example of this problem is bromodichloromethane ("BDCM") and dibromochloromethane ("DBCM") which are two types of halomethanes formed by chlorination of effluents. EPA studies recognize that tap water contains higher levels of these constituents, but their presence is tolerated due to the beneficial effects of chlorine on killing bacteria. The CTR would regulate these pollutants in surface waters at one-tenth the level present in tap water.

EPA policies recognize that this is not a reasonable result and that application of the MCL should be considered protective in such instances (see, 62 Fed. Reg. 27709). Consistent with recent EPA action to delete the arsenic criteria from the CTR the Agency should delete the water ingestion-related requirements for BDCM and DBCM. Such action is even more appropriate for these pollutants as they are volatile and very shortlived in the environment. Thus, the discharge of these pollutants by publicly owned treatment works presents no actual threat of drinking water contamination.

Response to: CTR-020-018

EPA disagrees with commenter. EPA believes that discharges can meet both the requirements of the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA) after the CTR is promulgated. EPA believes that any final limits for THMs would be feasible to meet because it is unlikely that a discharger would receive criteria end-of-pipe limits due to the dilution in the receiving stream, as well as other factors taken into account, when translating a criterion into a water quality criteria-based effluent limit. EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and

CTR-025-003a). Under the CWA, water quality criteria are required to protect the designated use, without respect to economic factors. Under the SDWA, EPA may take into account cost or availability of treatment technology in setting an MCL. As expressed by the commenter, the presence of the two trihalomethanes mentioned is a matter of balancing the potential for chemical risk associated with the formation of these chlorine byproducts and the beneficial effects of chlorine reducing microbial risk. Although EPA has stated that MCLs may be considered protective in the absence of water quality criteria, the Agency recommends the development of water quality criteria since the methodology specifically accounts for fish ingestion route exposure. Because water quality criteria take into account exposure to fish as well as water, they may be more stringent. Other factors that may also account for stringency differences are discussed in the response to CTR-025-002a. Concerning volatility, EPA does not disregard chemicals simply because they are volatile. Many chemicals may be somewhat volatile or short-lived, but may present health risks due to the frequency of discharge, biomagnification, or other factors.

Comment ID: CTR-025-003c
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-12a THMs Human Health
References:
Attachments? Y
CROSS REFERENCES C-17a
C-16

Comment: Human health water quality criteria for a number of other priority pollutants are at levels significantly below the corresponding California SDWA MCL. While Metropolitan favors a margin of safety between human health-water quality criteria and the SDWA MCL, significant differences between these two regulatory requirements can create problems in the course of maintenance of drinking water facilities.

For example, water utilities need to periodically "de-water" their lines as part of routine maintenance. The de-watering of distribution lines transporting treating drinking water results in discharges containing trihalomethanes (THMs). The CTR proposes human health criteria for each of the four compounds comprising the THM classification. The total limit under the CTR for THMs as a group is 11 ug/L, sigficantly below the California SDWA MCL of 100 ug/L as well as the proposed level of 80 ug/L for Stage 1 of the Disinfection/Disinfectant By-Products Rule. Thus, the discharge of water that meets California SDWA standards could potentially violate CTR human health criteria if that water is discharged to a source of drinking water supply. Metropolitan requests that EPA establish CTR human health criteria for THMs consistent with the California SDWA MCLs for THMS.

Response to: CTR-025-003c

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a).

Comment ID: CTR-059-008
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-12a THMs Human Health
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we reconunend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attaimnent of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of water body.

Trihalomethanes Human Health Criteria

EPA has proposed human health criteria for consumption of water and organisms for four of the Trihalomethanes (THMs): bromofom (4.3 ug/L), Chlorodibromomethane (0.41 ug/L), Chloroform (5.7 ug/L), and Dichlorobromomethane (0.56 ug/L). We have a number of concerns about these criteria and recommend that EPA defer the adoption of these criteria or consider utilizing either the current or proposed drinking water standards in lieu of the proposed criteria.

First we can find no basis for the Bioconcentration Factor (BCF) fisted in the CTR Administrative Record Matrix (ARM), or in any of EPA's supporting documentation for the CTF, The ARM lists the BCF for chloroform as 3.75; the other three compounds have been assigned the sarne BCF "based on chloroform." We have been unable to determine the origins of the 3.75 BCF. The Administrative Record Matrix refers back to the 1980 Water Quality Criteria Document (WQCD).(*4) On page C-39 of the WQCD, EPA notes that

"Approximately 1 percent of the chloroform exposure results from the consumption of aquatic organisms which exhibit an average bioconcentration potential of 3.75-fold. The remaining 99 percent of chloroform exposure results from drinking water."

No further reference is provided for the derivation of the 3.75 bioconcentration factor.

Second, we do not believe that the four THMs bioaccumulate in fish tissue, EPA has established a policy for setting hunan health criteria in the Great Lakes Initiative whereby chemicals with half-lives less than eight weeks in water columns, sediments or biota are not bioaccumulative chemicals of concern (BCCs). Literature on chloroform indicates that it is non-persistent in water, with a half-life of less than two

days.(*5) Based on this finding, chloroform should not be considered as a BCC. This conclusion is supported by other information in the literature which shows that the THMs do not bioaccumulate in fish.(*6)(*7)(*8) Thus, the BCF of 3.75 used by EPA in calculating criteria for these four THMs is not a documented nor reasonable assumption for calculating human health criteria.

Third, similar to the situation with arsenic, EPA has different human health values for drinking water and for ambient water. The current drinking water MCL for the THMs is 100 ug/L with a proposed MCL of 80 ug/L. The proposed MCL was recently endorsed by EPA's Microbial/Disinfection By-Products Federal Advisory Committee as part of an Agreement in Principle, and will form the basis for the 1998 Enhanced Surface Water Treatment Rule. We believe that the application of the CTR criteria is inappropriate and potentially wasteful of the status resources if it causes POTWs to invest in treatment merely for treatment's sake. Thus, we recommend that EPA defer the adoption of these criteria or consider utilizing either the existing or proposed MCL in setting the human health criteria for the THMs in the CTR.

(*4) U.S. Environmental Protection Agency, Ambient Water Quality Criteria for Chloroform (EPA 440/5-80-033, October 1980).

(*5) Information obtained from University of Virginia, Office of Recycling and Environmental Information.

(*6) Oliver, B.G. and A.J. Niimi. "Bioconcentration Factors of Some Halogenated Organics for Rainbow Trout: Limitations in Their Use for Prediction of Environmental Residues." Environ. Sci Technol. 1985, 19,842-849.

(*7) Young, D.R., R.W. Gossett, R.B. Baird, D.A. Brown, P.A. Taylor and M.J. Miille. "Wastewater Inputs and Marine Bioaccumulation of Priority Pollutant Organics Off Southern California." Chapter 60 In Water Chlorination Environmental Impact and Health Effects. Ann Arbor Science Publishers, Inc., Ann Arbor Michigan, 1983.

(*8) Scott, G.I. "Physiological Effects of Chlorine-Produced Oxidants, Dechlorinated Effluents and Trihalomethanes on Marine Invertebrates." Chapter 57 In Water Chlorination Environmental Impact and Health Effects. Ann Arbor Science Publishers, Inc., Ann Arbor Michigan, 1983.

Response to: CTR-059-008

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to responses on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018. Regarding detection limit issues, refer to the response on effluent-dependent waters in CTR-034-007 and CTR 036-009.

The commenter is incorrect regarding the lack of documentation on the BCF for chloroform. The basis of the value of 3.75 is explained in the very document that the commenter claims it is lacking from. Using a documented BCF of 6 and an average lipid content of 4.8 percent from bluegills, EPA used a lipid adjustment factor based on the weighted average lipid percentage of 3 for the same freshwater and estuarine species that represent the fish consumption rate of 6.5 gm/day. Refer to text in EPA 440/5-80-033, October 1980, pp. C-3 and C-4).

However, EPA has decided to reserve the numeric criteria for chloroform in the final rule. EPA is

revisiting the cancer risk assessment for chloroform (see section G.6. of the preamble).

Comment ID: CTR-089-004
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-12a THMs Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Disinfection By-Products

Sanitation utilities may not be able to meet the proposed criteria for trihalomethanes (chloroform, dichlorobromomethane, chlorodibromomethane), which appear to be more stringent than those adopted for drinking water standards. Some consideration should be given to dischargers who must, by law, disinfect their effluent discharges, as the most widely-used disinfection method (oxidation by chlorine) unavoidably produces trihalomethanes. In addition, chlorine is an integral treatment process additive for control of filamentous algae in our activated sludge process and for operational control of our tertiary filtration process -- we simply must use this chemical to optimize process performance.

The proposed criteria imply a potentially enormous investment in alternative disinfection methods, or equally-expensive post-disinfection removal using carbon adsorption or air-stripping towers. Our preliminary estimate is that compliance with the proposed criteria for trihalomethanes would cost our served communities over $650,000 per year. Furthermore, the benefits of these expenditures are unclear, since neither drinking water supplies nor consumptive uses such as fishing are important uses of the receiving,waters.

Response to: CTR-089-004

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018.

Comment ID: CTR-090-022
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-12a THMs Human Health

References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Trihalomethanes (THM) - The current California Department of Health services criterion for Total THMs, is 100ug/L to be reduced to 80 ug/L in 1998. Chloroform is the dominant THM in drinking water and is a disinfection byproduct and is typically found in drinking water in the range of 34-45 ug/l. The proposed value under the CTR is 5.7 ug/L, which is two orders of magnitude below the chronic toxicity criterion and one order of magnitude below the California DHS standard for drinking water promulgated under the auspices of the Safe Drinking Water Act. Such a restrictive criterion will inhibit municipal water supply agencies in operation and maintenance of their water supply system. EPA needs to explain the rationale for such a restrictive criterion for THM.

Response to: CTR-090-022

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018. However, EPA has decided to reserve the numeric criteria for chloroform in the final rule. EPA is revisiting the cancer risk assessment for chloroform (see section G.6. of the preamble).

Subject Matter Code: C-13 Risk Level

Comment ID: CTR-003-003
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: 3) We do not agree with the use of the 10'-6 risk level proposed here. As is noted in the proposed rule, a significant uncertainty factor ranging from 10 to 10,000 is used to set human health criteria. We can understand the use of these factors but the public should understand that they may be paying to protect to the 10'-10 or one in ten billion risk level. We suggest that the risk level used be tied to the certainty of risk. For example, where uncertainty factors range from 1 - 10, use 10E-6; 11 - 100, 10E-5 101 - 10,000, 10E-4 risk level. Another option would be to promulgate a range from which the permit writer may choose depending on the site specific nature of the waters and the needs of the effected individuals. At a minimum the EPA should promulgate at a factor of 10E-5 and allow the regional boards to set more stringent criteria if warranted. We all need to keep in mind that lower limits mean higher costs and higher costs here mean fewer resources available elsewhere. Even with the best of intentions, we may be sacrificing hundreds in an attempt to save one. For example, an increase in sewer rates reduces the discretionary money normally used for the purchase of food and medical services with potentially significant impacts on the poor.

Response to: CTR-003-003

See also response to Comment CTR-058-001.

The comment author suggests that the rule provide variable risk levels dependent on the uncertainty factor used in calculating national criteria guidance. It is suggested that higher risk levels be allowed for parameters having criteria based on a higher uncertainty factor. This suggestion runs counter to EPA policy that greater protection be provided when uncertainty concerning the adequacy of protection is greatest.

This author also suggests giving individual permit writers the authority/responsibility to choose the risk level on a site specific basis for each permit. This approach, along with the above suggestion, would result in risk levels that vary both on a parameter specific basis and a site specific basis. This approach may result in selective inadequate protection for highly exposed populations and even for the general population. EPA would support, in this case, an approach that includes scientifically valid site-specific criteria.

If the State has a scientific basis, and wants to adopt more or less protective site-specific criteria, it is within the State's discretion to do so (See response to CTR-058-001), but this rule is a reasonable attempt to protect all of California's waters.

EPA cannot respond specifically to the author's assertion of higher costs for sewer ratepayers because it

is provided without supporting evidence. EPA's Economic Analysis indicates that a change in the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs for the State as a whole based on a sample of California facilities (Economic Analysis of the California Toxics Rule, P. A-2). Due to limited resources, EPA was not able to estimate potential costs for every facility in the State. In any case, water quality criteria must be based on that which is necessary to protect human health and the environment and must be scientifically based. Under, the Clean Water Act, this requirement overrides consideration of economic impacts.

Comment ID: CTR-005-007
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: 6. Human health criteria for carcinogens should be adopted at a 10E-5 risk level. Based on the analyses performed by other Bay Area POT\ft, the District is concerned that organics monitoring of its effluent will identify human health criteria that cannot be achieved without dilution well beyond 1 0: 1 (e.g., aldrin, PAHS, heptachlor). At a 10E-6 risk level, the District would be forced to add activated carbon at a significant cost or possibly go to land disposal at an enormous cost. The benefits would be nil because the District is such a small contributor to the Bay and generally, according to the results of the Regional Monitoring Program, these criteria are not exceeded in the Bay.

Response to: CTR-005-007

EPA disagrees with this comment.

The comment author suggests that the rule should provide for a higher allowable risk level because monitoring indicates that current effluent concentration for certain pollutants exceed the levels provided at a risk level of 10-6 leading to enormous treatment/disposal costs. In the first place, the comment author has not provided specific data or evidence that shows any additional treatment will be needed. Secondly, EPA cannot justify reducingprotection to California's population across the State based on an assertion of a need for additional treatment and consequent added costs. Other federal and State processes such as site-specific criteria that lessen the need for pollutant removal and TMDLs that shift the need for pollutant load removal to other sources of that pollutant may be scientifically justified and could facilitate moving toward less costly treatment alternatives, should additional treatment be indicated; however, it is essential that beneficial uses remain fully protected.

In addition, the commentor notes that the criteria are not exceeded in the Bay. The State permit authority must show that the discharge of organics have reasonable potential to cause or contribute to an exceedence of water quality criteria in order to establish effluent limits. If no reasonable potential is established, the facility will not incur any costs for the control of organics.

Comment ID: CTR-011-001a
Comment Author: City of Simi Valley
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-011 incorporates by reference letters CTR-027 and CTR-034
Attachments? Y
CROSS REFERENCES C-24
E-01d

Comment: The City of Simi Valley discharges approximately 10 million gallons per day (mgd) of tertiarytreated wastewater (as well as municipal storm water) to the Arroyo Simi, an effluent dependent water body. Through much of the year, Arroyo Simi is dry several miles downstream from the City. The Arroyo Simi Characterization Report, completed by the City in 1995, concluded that the arroyo does not support a significant fishery, and observed only arroyo chub, mosquito fish and blunt-nosed minnow in the stream. Although designated as a potential municipal water supply in the Basin Plan, the arroyo waters are not used for municipal purposes. Effluent monitoring are limited, but available data indicate that the City's discharge may have a reasonable potential to exceed the proposed aquatic life criteria for several metals and the proposed human health criteria for several carcinogens.

Since Simi Valley is largely a residential community with supporting commercial development and little industry, and since the City already has an effective pretreatment program, it is unlikely that pollution prevention efforts would effectively reduce the problematic constituents. More likely, the City would be faced with end-of-pipe treatment controls such as lime precipitation and carbon adsorption to achieve the proposed criteria. The costs would undoubtedly be significant and the benefits relatively minor.

Under these circumstances, it appears reasonable to adopt criteria for Arroyo Simi, and similar effluent dependent waters, that are reasonably achievable without costly end-of-pipe controls and that reflect the actual use of the water (i.e., generally such waters are used for fishing or drinking). One way to address this issue, consistent with the requirements of the Clean Water Act, would be to adopt specific human health criteria for Arroyo Simi and other effluent dependent streams based on a cancer risk coefficient of 10E-5 or in some cases 10E-4. Based on the limited data collected by the City, risk levels of 10E-4 would have to be adopted for dioxins, aldrin, alpha-BHC and 4,4,-DDD (see Table 1). Risk levels of 10E-5 would be sufficient for chloroform and endoslfan 11 (Id.).

Response to: CTR-011-001a

EPA disagrees with this comment.

See also responses to CTR-058-001 and CTR-005-007.

When EPA promulgates a rule, it follows national policy and what it understands to be the policy of the state in selecting a risk level for the general population. (See response to comment CTR-058-001) EPA would not use a higher general risk level for specific pollutants unless it had data showing that consumption of those pollutants is less than the general consumption levels EPA uses along with the general risk level of 10-6.

The commenter suggests determining criteria by assessing what the condition of the effluent is, without assuming application of what it deems as costly controls, by applying a different risk level for various pollutants for the same waterbody. In other words, the commenter proposed that site specific human health criteria be adopted for their receiving water based on individual pollutant effluent data. Site specific criteria are the prerogative of the State and are generically recognized in this rule; however, effluent data cannot serve as sufficient justification for criteria.

The State could remove a use designation pursuant to its own regulations as long as it is not an existing use. Justification for the use removal or replacement would need to be developed as provided for in 40 CFR Part 131. This action would require a Use Attainability Analysis and would need to assure that full protection of existing uses and other designated beneficial uses of the waterbody is provided.

EPA cannot respond specifically to the commentor's assertion that it would incur costs for end-of-pipe costs for sewer ratepayers because it is provided without supporting data. EPA's Economic Analysis indicates that a change in the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs for the State as a whole based on a sampling of facilities (Economic Analysis of the California Toxics Rule, P. A-2). Due to limited resources, EPA was not able to estimate potential costs for every facility in the State. In any case, water quality criteria must be based on that which is necessary to protect human health and the environment and must be scientifically based. Under, the Clean Water Act, this requirement overrides consideration of economic impacts.

Comment ID: CTR-015-002
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Cancer Risk Level (FR p.42181, Preamble section E.3.f.)

The Agency requests comment on the adoption of a 10E-5 risk level for carcinogenic pollutants rather than a 10E-6 risk level. The Agency should be aware of an analysis conducted by the State Water Resources Control Board ("State Board") as part of the Functional Equivalent Document, or environmental impact review, for the Inland Surface Waters Plan in March, 1992. The analysis compared inland discharger's ability to attain objectives at both risk levels. Effluent data from 23 inland dischargers for the period of 1989 to 1991 were used. Thirty-nine constituents (mostly organic compounds) were examined. Although the State Board selected the 10E-6 level, differences in attainability were shown and described.

In the Agency's Economic Analysis of July, 1997 for this Rule, there was a comparison of costs between the two risk levels in Section 4. It is stated on p. 4-17 that there was a lack of data for organic pollutants and, for those facilities with data, most of these pollutants were found below detection limits. It is not certain, then, how many constituents were examined for the risk level economic analysis. Also, fewer dischargers were examined by the Agency than by the State Board in its previous studies. However, in

Section 10 (p. 10-2), it was concluded by the Agency that there were minimal cost differences between the two risk levels.

Obviously, the 10E-5 risk level would be more attainable and less costly than the 10E-6 risk level. It is probable, from our review so far, that the Agency has underestimated the cost differences. A more thorough cost/benefit analysis, i.e., a comparison done at a greater level of detail such as the State Board had done for attainability, is needed for the Agency's Rule before a risk level is suggested or adopted.

Response to: CTR-015-002

EPA disagrees with this comment.

See response to CTR-058-001.

In regard to the comment about the results of the economic analysis which compared the potential costs of a 10-5 and 10-6 risk level, EPA believes that its methodology is sound. EPA examined recent monitoring data for eachsample facility. The fact that some facilities have a lack of data or that many of the organic pollutants that were monitored were measured below the detection limit does not necessarily mean that these facilities would not be able to comply with WQBELs based on a 10-6 risk level Even if facilities expand monitoring efforts or if detection limits are improved, the commenter has provided no evidence that compliance costs would significantly increase. EPA included as many sample facilities it could to project statewide costs taking into account time and resource constraints.

Comment ID: CTR-021-005a
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-28
E-01c
R
S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments ont eh CTR and teh EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the

human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's inovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe that EPA has needlessly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005a

EPA disagrees with this comment.

See response to Comment CTR-058-001 and CTR-011-001a.

In regard to the comment about the results of the economic analysis which compared the potential costs of a 10-5 and 10-6 risk level, EPA believes that its methodology is sound. The fact that many of the organic pollutants that were monitored were measured below the detection limit does not necessarily mean that these facilities would not be able to comply with WQBELs based on a 10-6 risk level. Even if detection limits are improved, compliance could not be determined until the results of using the new monitoring method was completed.

Comment ID: CTR-035-004
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: [INDENT]- EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. This approach would be consistent with other EPA regulatory actions such as the Great Lakes Initiative for which EPA used the 10E-5 risk level in setting the criteria, or the national drinking water program where maximum contaminant levels are commonly developed with a risk level of 10E-4 to 10E-5. Moreover, EPA should acknowledge that there is considerable uncertainty and variability in the risk assessment process. The criteria are calculated using a model that assumes low dose linearity. When using this kind of model, the calculation of risk to several significant figures at any given low dose gives the illusion of knowledge and precision that are not really there. Thus, the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6, yet the socioeconomic impacts associated with complying with criteria promulgated using the 10E-6 risk level can be significant. Thus, EPA should reconsider the risk level used in calculating criteria in the CTR and should select a lower risk level.

Response to: CTR-035-004

EPA disagrees with this comment.

See response to CTR-058-001.

The fact that maximum contaminant levels in the drinking water program are sometimes developed with a risk level in the range of 10-4 to 10-5 is not a factor in setting ambient water quality criteria. Under the Safe Drinking Water Act, MCLs are set taking best available technology into account, while under the Clean Water Act, water quality criteria are set solely based on human health or aquatic protection.

Comment ID: CTR-035-021
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42175-42176 -- Reference Doses (RfDs) For non-carcinogenic human health criteria, EPA divides a "no observed effect" dose in animal studies by an uncertainty factor, which ranges from 10 to 10,000 based on various factors such as whether the data are being extrapolated from animals to humans. In addition, a modifying factor greater than 0 and less than 1O is applied to reflect the professional judgment of toxicologists. The use of such large uncertainty factors indicates that there is a large margin

of safety in the criteria, and some flexibility in the application of these factors. We recommend that EPA consider using this flexibility, for instance, to develop criteria appropriate to effluent dependent waters. In many cases, little or no fish consumption occurs and no direct use of the water for drinking water supplies may occur in effluent dependent waters; therefore the risk of human exposure is small, and it would be appropriate to use lower uncertainty and modifying factors in promulgating criteria for these water bodies.

Response to: CTR-035-021

EPA disagrees with this comment.

See response to CTR-058-001.

The comment author recommends that EPA develop criteria appropriate to effluent dependent waters. In the CTR, EPA has applied criteria on the basis of State adopted beneficial uses. As the State has not used a beneficial use category that distinguishes effluent dependent waters, there are no waters to assign a separate set of criteria. The CTR does not preclude the State from developing a special beneficial use category for effluent dependent waters should it choose that course of action. (See EPA Region 9's Interim Final "Guidance for Modifying Water Quality Standards and Protecting Effluent-Dependent Ecosystems", June 17, 1992, for guidance.)

Comment ID: CTR-035-027
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42181 -- Risk Factors for Carcinogens EPA has calculated the human health criteria for carcinogens in the proposed CTR using a 10E-6 risk level, but invites comment on whether the criteria for carcinogens should instead be calculated using a risk level of 10E-5. We recommend that EPA consider a range of risk levels between 10E-4 and 10E-6, which we understand to be consistent with EPA's policy of allowing States to use risk levels in the range of 10E-4 to 10E-6 when adopting criteria for carcinogenic priority pollutants in water quality standards (U.S., EPA, 1994b). We do not agree with EPA's proposition to adopt a 10E-6 risk level based upon previous regulatory decisions by the State. Any new determination by the State will be subject to the legal requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. Moreover, EPA should acknowledge that there is considerable uncertainty and variability in the risk assessment process. The criteria are calculated using a model that assumes low dose linearity. When using this kind of model, the calculation of risk to several significant figures at any given low dose gives the illusion of knowledge and precision that are not really there. Thus, the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6, yet the socioeconomic impacts associated with complying with criteria promulgated using the 10E-6 risk level can be significant. EPA

should therefore revise its alternative analysis for the 10E-5 risk level evaluated for the cost analysis, and reassess its conclusions. We believe this re-analysis to be necessary for EPA to adequately comply with the requirements of Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule.

Response to: CTR-035-027

EPA disagrees with this comment.

See response to CTR-058-001. In that response EPA explained that protection of the general population at the 10-6 risk level was necessary to assure that those segments of the California population that are more highly exposed are protected at a 10-4 risk level.

EPA is unable to respond to the generic comment that "...the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6,..." when using a linear cancer risk model. The commenter has provided no supporting evidence for this assertion.

Comment ID: CTR-040-015b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES S

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

II. Recommendation: Adopt human health criteria for PAHs at a 10 (-4) risk level and human health criteria for other carcinogens at risk levels that are generally achieved by municipal wastewater and stormwater dischargers.

* As previously stated, the Sacramento Stormwater Management Program would have to expend on the order of $260 million per year to treat stormwater, and this may not achieve the proposed criteria for PAHS, which is based on a 10 (-6) cancer risk level.

* Under the Unfunded Mandates Reform Act, EPA must adopt the least cost alternative for complying with the CWA, unless the Administrator explains in the final rule why the least cost alternative is not adopted. As indicated in the Preamble, risk levels of 10 (-5) and 10 (-4) are acceptable under the CWA.

* Therefore, pursuant to the spirit of the Unfunded Mandates Reform Act, EPA should adopt the PAH criteria at a 10 (-4) risk level. The same should be true for other carcinogens that present attainability problems for dischargers. Most carcinogenic constituents are not readily controllable through source control or BMPs and would generally require end-of-pipe controls to achieve significant reduction. The benefits associated with additional reduction of carcinogenic constituents are not expected to be measurable since, as acknowledged in the economic analysis,point sources are relatively minor sources of these constituents.

Response to: CTR-040-015b

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-043-006b
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: 6. EPA should adopt separate, site-specific human health criteria for Old Alamo Creek based on a 10 (-4) risk level. As previously indicated the City would have to construct costly end-of-pipe controls to comply with the human health criteria for several carcinogens. The subject criteria are based on a cancer risk level of 10 (-6). These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria. The City does not believe Old Alamo Creek is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that none of these carcinogens were identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-043-006b

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-044-007a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: We have reviewed the proposed CTR and offer the following comments:

6. EPA should adopt separate, site-specific human health criteria for Tule Canal based on a 10 (-4) risk level. Based on effluent sampling, the City would have to construct costly end-of-pipe controls to comply with criteria for aldrin (and perhaps other carcinogens) based on a 10 (-6) risk level. These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria in Tule Canal. The City does not believe Tule Canal is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that aldrin was not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-044-007a

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers

are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-049-003
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

1 . Adopt human health criteria for carcinogens which are based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. (Based on all the conservative assumptions included in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. This draft CTR should factor in this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria);

Response to: CTR-049-003

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-050-006
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: III. The Acceptable Risk Level Should be greater than 10E-6.

EPA has proposed that the criteria for carcinogens should be based on an acceptable risk level of 10E-6.

However, the Agency has also, at the request of the State of California, requested comment on an alternative risk level of 1OE-5. (62 Fed. Reg. at 42181). The 10E-5 figure is recognized and utilized by EPA in various Clean Water Act guidance documents as well as in other Agency programs: Moreover, in the most comprehensive development and implementation of water quality standards that the Agency has ever conducted - the Great Lakes Initiative (GLI) -EPA used this risk level in setting the criteria. Also, every State in Region 5 has followed the EPA policy and used 10E-5 as the acceptable risk level in setting water quality standards as part of their GLI rules. EPA should continue that policy in this rulemaking.

Response to: CTR-050-006

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-052-003a
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01
E-02

Comment: However, the Authority is greatly disappointed that EPA chose not to follow the consensus recommendations for many of the most significant issues, including the methodology used for the EA and the choice of using the most conservative carcinogenicity factor for organic pollutants.

Response to: CTR-052-003a

EPA disagrees with this comment.

See response to CTR-058-001.

The risk level chosen for the CTR is not "the most conservative carcinogenicity factor for organic pollutants."

Comment ID: CTR-054-007
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level

References:
Attachments? Y
CROSS REFERENCES

Comment: Human health criteria for carcinogens should be adopted at a 10 (-5) risk level at least for San Francisco Bay waters. BADA's attainability analyses shows that adoption of criteria for carcinogens based on a 10 (-6) risk level would result in significant costs without improving the present level of compliance in Bay waters. At a 10 (-6) risk level, two BADA agencies could be faced with adding carbon adsorption facilities at a total annual costs of $56 million per year (to achieve effluent limitations for aldrin, heptachlor and several PAHS). At a 10 (-5) risk level, carbon adsorption facilities would be unnecessary at these BADA agency plants. The cost savings would be significant, and the present high level of compliance would remain unchanged.

Response to: CTR-054-007

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-055-001
Comment Author: USS-POSCO Industries
Document Type: Specific Industry
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: UPI requests the EPA use a Cancer Risk Level at 10E-5 (1 in 100,000) in the subject regulation.

The U.S. Environmental Protection Agency (EPA) and the State of California (State) have requested comment on the adoption of a 1OE-5 carcinogenic risk factor (page 42181) in lieu of the proposed 10E-6 factor. The EPA criteria documents for priority toxic pollutants do not recommend a specific carcinogenic risk factor, but rather a range of risk factors is recommended. The EPA is proposing a California rule that meets Clean Water Act (CWA) section 304(a) minimum. Since a 10E-5 carcinogenic risk factor meets CWA criteria as determined by the EPA, a 10E-5 carcinogenic risk factor is appropriate for the subject Section 131.38. The State should have the authority to use a 10E-5 carcinogenic level. The State needs the option of developing regulatory standards to protect the people and the environment in California in a manner which considers local conditions within the state.

For the above reasons, UPI requests the EPA promulgate a 10E-5 carcinogenic risk factor (1 in 100,000) in the subject regulation.

Response to: CTR-055-001

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-056-012
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Select human health criteria for carcinogens based on the 10E-5 or more appropriate risk level instead of the 10E-6 level being proposed. Based upon the conservative risk assumptions included in the calculation of criteria, there is sufficient uncertainty in the numbers to permit the use of a less restrictive value than 10E-6. EBMUD believes that by using the "one in a million" risk assumption an undue attainability burden is being placed on dischargers to meet ultra-low water quality criteria for very little gain in risk reduction. EPA should factor the uncertainty of the numbers into the risk assessment along with the population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-056-012

EPA disagrees with this comment.

See response to CTR-058-001. For an additional response, see also the response to CTR-003-003.

Comment ID: CTR-057-005
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Risk Level

The EPA is strongly encouraged to consider the use of the 10E-5 carcinogenic human health risk

criterion as a baseline for all priority-pollutant criteria that can be adjusted as appropriate when conditions merit a change. The 10E-6 criterion, which itself already appears to serve as such a baseline, is too problematic for this purpose in view of the number of priority constituents which represent immediate compliance problems under the proposed Rule. The attached tables compare our chances for compliance with the proposed Rule under the two factors for our three facilities. We believe that the problems associated with the 10E-6 factor primarily reflect a difficulty with criteria compliance rather than an indication of environmental impact.

In addition, we believe that cost-benefit ratios of mitigation efforts based on a 10E-5 risk factor are considerably more justifiable than 10E-6 in view of the diminishing returns most POTWs would experience in terms of net environmental cost-benefit. For example, years of toxicity testing of Tillman effluent has not established any relationship between effluent lindane and/or DDT levels and aquatic survivability, yet further reduction of these pollutants below currently-observed levels does not justify the enormous required treatment costs. By comparison, the cost effectiveness of best-management practices for non-point sources is attractive, but the trade-off in terms of immediate benefit is a significant limitation- These observations imply that the 10E-5 risk factor should also be applicable on a constituent-specific basis, and we urge the EPA to consider this application as well.

Another factor to consider in setting the risk criterion involves pollutant source-controllability. For example, DDT is a banned pesticide that is ubiquitous in the environment and also a pass-through pollutant in conventional treatment processes what purpose does a 10E-6 factor serve when it cannot be controlled by either point or non-point sources? If treated, where and how are the wastes disposed? The provenance and ultimate fate of such pollutants should be considered as part of a more holistic approach to their control, and the establishment of overly-stringent risk criteria does not accomplish that.

Response to: CTR-057-005

EPA disagrees with this comment.

See response to CTR-058-001.

The comment author cites "years of toxicity testing of Tillman effluent" as evidence that effluent levels of lindane and/or DDT do not need to be further reduced . However, this comment overlooks the fact that these two pollutants are highly bioaccumulative, and standard toxicity tests, because of their short duration, do not account for most bioaccumulation. Thus, if anything, a 10-6 risk level is particularly appropriate for bioaccumulative pollutants.

EPA disagrees that a factor to consider in setting of risk criterion should involve pollutant source controllability. First, the commenter has provided no evidence supporting the assertion that either point or nonpoint sources cannot be controlled. EPA also disagrees that it should set criteria for pollutants that are difficult to control (which have been banned but remain persistent in the environment) at a higher risk level than other pollutants. The Clean Water Act requires that criteria be protective of designated uses. While EPA has discretion in setting risk levels appropriate to protect uses, EPA believes that it is appropriate to base the risk level on nationally appropriate risk levels and the risk level established by the State for the general population. (See the response to Comment CTR-058-001.) By doing so, EPA will be providing an acceptable measure of protection to all exposed subpopulations. If it is not feasible to attain a designated use due to human caused conditions or if sources of pollution prevent the attainment of the use and cannot be remedied, EPA regulations allow the State to remove the designated use if it is not an existing use. This approach allows for regulatory relief where attainment is infeasible while avoiding the lowering of water quality protection to people who live in areas where it may be feasible to

attain the criteria at a risk level of 10-6.

Comment ID: CTR-058-001
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: We appreciate the care that EPA has given to this proposal and especially the attempt to base the proposal on good science. Although there are significant improvements in the proposal, there are several issues of concern to WSPA. We are especially concerned that EPA has chosen to base the proposal on a human health risk level of 1x10E-6 while other environmental management programs administered by EPA or by California regulatory agencies have based decisions on risk levels of 1x10E-5 and above. EPA has not justified this overly cautious and potentially expensive approach. Our comments are included in the attachment to this letter.

1. Acceptable Risk Levels. WSPA opposes use of a 1x10E-6 risk level as a trigger level for regulatory action.

EPA has historically considered health risks above 1x10E-6 to be adequately protective of human health (see, e.g., 40 CFR 42176 in this rulemaking and review articles by Travis et al., Environ. Science Tech. 21(5): 415-420, 1987 and Rodricks et al., Toxicol. Pharmacol. 7: 307-320, 1987). Yet, "EPA is proposing criteria that protect at an incremental cancer risk level of one in a million (1x10E-6) for all priority toxic pollutants regulated as carcinogens" [62 FR 42181, subpart f]. EPA apparently bases this decision on what it believes to be the state's historical policy, although adequate justification for the target risk level selected is not provided.

EPA is overlooking an overwhelming consensus of state and national-level policy which indicates that, in reality a target risk level of 1x10E-6 is not commonly applied in developing regulatory levels. For example, in the most comprehensive rulemaking on development and implementation of water quality standards that EPA has ever conducted -- the Great Lakes Initiative -- EPA used a target risk level of 1x10E-5 in setting the criteria. Also, every state in Region V has followed EPA policy and used 1x10E-5 as the acceptable risk level in setting water quality standards as part of their GLI rules.

EPA's National Contingency Plan codifies 1x10E-4 to 1x10E-6 as the target acceptable risk range for evaluating hazardous waste sites under CERCLA. EPA has selected and promulgated a single risk level of 1x10E-5 in the Hazardous Waste Management System Toxicity Characteristics Revisions [55FR 11798-11863]. In so doing, EPA notes that "The chosen risk level of 10E-5 is at the midpoint of the reference risk range for carcinogens (10E-4 to 10E-6) generally used to evaluate CERCLA actions.". EPNs benzene waste NESHAPs used 10E-5 and drinking water MCLs are commonly associated with acceptable risk levels that exceed 1x10E-6. OSHA's recently proposed procedures for developing risk-based Permissible Exposure Limits (PELs) are based on acceptable risk levels of 1x10E-3 to 1x10E-4.

In California, state agencies commonly rely on target risk levels above 1x10E-6 for setting regulatory action levels. Cal-EPA, including the DTSC, the SWRCB and the RWQCBs routinely set cleanup levels for remediation projects based on a target risk of 1x10E-5 The air quality management districts charged with administering the California Air Toxics "Hot Spots" Program under AB2588 commonly rely on a 1x10E-5 target risk level for risk management purposes. California's proposed revision to the hazardous waste classification system is also similarly based on a 1x10E-5 risk level. California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) established a no significant risk level of 1x10E-5 for evaluating potential exposures of the general population to carcinogenic chemicals.

Reliance on a single target risk level of 1x10E-6 for setting water quality criteria is now mostly an historical artifact. In reality, even when the Food and Drug Administration originally proposed that a 1x10E-6 target risk level be used to set safety standards in the 1970s, this level was clearly meant to be a de minimis level representing risks that are so small as to be of negligible concern. In the interest of responsible public policy, EPA's target risk level should reflect an enlightened understanding of the uncertainty and variability inherent in the risk assessment process gained since that time. In addition, given that the background cancer risk in the U.S. is now about 30%, EPA should recognize that a risk level of 0.30001, or for that matter 0.3001, is virtually indistinguishable from a risk level of 0.300001. By contrast, the socioeconomic impacts associated with the overly conservative reliance on a 1x10E-6 risk level could be staggering.

Response to: CTR-058-001

EPA disagrees with this comment.

EPA's section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer per 100,000 people (10-5), per 1,000,000 people (10-6), and per 10,000,000 people (10-7). However, the criteria documents do not recommend a particular risk level as EPA policy. EPA uses a 10-6 risk level in establishing human health criteria guidance because it believes that a 10-6 risk level is an appropriate level of risk for the general population. This risk level is used by a majority of states and Tribes.

Subpopulations within a state may exist, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the assumed 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2.0 liters per day of drinking water with pollutant levels meeting the water quality criteria.

When EPA promulgates criteria as regulations, EPA generally follows the policies of the affected state. In this case, California has articulated a policy choice of 10-6 for the general population. By establishing rules at the 10-6 risk level, EPA applies a risk management policy which ensures protection for all exposed population groups (Draft Water Quality Criteria Methodology: Human Health, EPA 822-Z-98-001,August 1998, Appendix II, page 72). EPA acknowledges that at any given risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10-6, individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10-5 risk level. Similarly individuals consuming 100 times the general population rate would be protected at a 10-4 risk level. EPA therefore believes that protection at the 10-6 risk level is a reasonable risk management decision protective of designated uses under the CWA. While outside the scope of this rule, EPA notes that states and Tribes, however, have the discretion to adopt water quality criteria that result in a higher risk level (e.g., 10-5). EPA expects to approve such criteria if the state or

Tribe has identified the most highly exposed subpopulation within the state or Tribe, demonstrates the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation.

This demonstration has not happened in California. Further, the information that is available on highly exposed subpopulations in California supports the need to protect the general population at the 10-6 level. California has cited the Santa Monica Bay Seafood Consumption Study as providing the best available dataset for estimating consumption of sport fish and shellfish in California for either marine or freshwater sources (Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States, Final Draft Report, July 1997). Consumption rates of 21g/day, 50 g/day,107 g/day, and 161 g/day for the median, mean, 90th, and 95th percentile rates, respectively, were determined from this study. Additional consumption of commercial species in the range of approximately 8 to 42 g/day would further increase those values. Clearly the consumption rates for the most highly exposed subpopulation within the State exceeds 10 times the 6.5 g/day rates used in the CTR. Therefore, use of a risk level of 10-5 to protect the general population would not be sufficient to protect the most highly exposed population in California at a 10-4 risk level. On the other hand, even the most highly exposed subpopulations cited in the California study do not have consumption rates approaching 100 times the 6.5 g/day rate used in the CTR. The use of the 10-6 risk level to protect median level consumers does not subject these subpopulations to risk levels as high as 10-4.

EPA believes it would be reasonable to conclude that carcinogens that bioaccumulate, particularly given the exposure of fishermen to such carcinogens, may justify site-specific criteria that result in more protective risk level than 10-6 for the average fish consumer. EPA has generally supported such decisions when adequate data are available. In this rulemaking, EPA has adopted a reasonable risk level to protect all of California's inland waters and enclosed bays and estuaries for consumption of fish and drinking water.

EPA believes its decision to establish a 10-6 risk level for the CTR is also consistent with EPA's policy in the NTR and GLI to select the risk level that reflect the policies or preferences of Clean Water Act programs in the affected states. CA adopted standards for priority toxic pollutants for its ocean waters in 1990 using a 10-6 risk level to protect human health (California Ocean Plan, 1990). In April 1991, and again in November 1992, CA adopted standards for its inland waters and enclosed bays and estuaries in its ISWP and EBEP using a 1x10-6 risk level. To be consistent with CA's WQS, EPA used a 10-6 risk level for CA in the NTR at 57 FR 60867/3. CA has continued using a 10-6 risk level to protect human health for its standards that were not withdrawn with the ISWP and EBEP. The most recent expression of risk level preference is contained in the Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan for Ocean Waters of California, October 1998, where staff recommended maintaining a consistent risk level of 10-6 for the human health standards that they were proposing to revise. See also the discussion in responses to CTR-002-002a and CTR-002-005a.

The citation of programs that occasionally allow a risk level as high as 10-4 under specific circumstances does not prove to be inconsistent with protection of the general population at the 10-6 level recognizing that more highly exposed sub-populations such as ethnic or economically disadvantaged populations may face an excess risk level approaching 10-4.

There are several differences between the guidelines for the derivation of human health criteria contained in the Great Lakes Water Quality Guidance (the Guidance) and the California Toxics Rule (CTR) that make a 10-5 risk factor appropriate for the Guidance, but not for the CTR. These differences result in criteria developed using the 10-5 risk factor in the Guidance being at least as stringent as criteria derived under the CTR using a 10-6 risk factor. The relevant aspects of the Guidance include:

* targeting of sensitive subgroups of the population, such as people who routinely eat fish caught in the Great Lakes, in assessing risk (the CTR targets the population in general)

* use of fish consumption rates that are considerably higher (because of the targeted subgroup) than fish consumption rates for the CTR

* use of bioaccumulation factors rather than bioconcentration factors in estimating exposure, considerably increasing the dose of carcinogens to sensitive subgroups

* use of additivity of effects of mixtures of both carcinogenic and noncarcinogenic pollutants.

This combination of factors increase the calculated carcinogenic risk substantially under the Guidance (the combination would generally be more than one order of magnitude), making a lower overall risk factor acceptable. The Guidance risk factor provides, in fact, criteria with at least the same level of protection against carcinogens as criteria derived with a higher risk factor using the CTR. A lower risk factor for the CTR would not be appropriate absent concomitant changes in the derivation procedures that provide equivalent risk protection.

Remediation efforts and OSHA PELs were cited by the comment author as activities allowing risk levels higher than 10-6. These activities are site-specific and have far less impact beyond a very local area as contrasted to WQS which, in combination with existing California WQS providing protection of the general population at the 10-6 level, will provide consistent protection to the statewide population. [See the reference to HHM Notice above].

EPA disagrees that reliance on a 10-6 target risk level for setting water quality criteria is now mostly a historical artifact. The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act to prohibit EPA from issuing tolerances for pesticide residues in or on food unless the agency determined that there is "reasonable certainty" that the residues will result in "no harm." The legislative history of FQPA indicated Congressional support for EPA's view that reasonable certainty of no harm would be met when a non-threshold risk is below a 10-6 level.

EPA believes that comparing the "background cancer risk in the U.S." (an aggregate risk combining the effect of all causes of cancer) with the excess cancer risk from a single toxic pollutant in water is not appropriate because they are not comparable measures. The comment author's argument does not lend support for raising the risk level specified in this rulemaking. The purpose of the CWA is to protect waters (in this case for the various human uses) irrespective of the cancer risk derived from other sources.

Finally, EPA is unable to respond to the author's assertion of "staggering" socioeconomic impacts because it is provided without supporting evidence (see response to CTR-005-007). EPA's Economic Analysis indicates that lowering the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs (Economic Analysis of the California Toxics Rule, p. A-2). In any case, under the Clean Water Act, EPA must establish scientifically based criteria that protect designated uses. This requirement overrides any consideration of socioeconomic impacts. The Clean Water Act does allow consideration of socioeconomic impacts in decisions to remove a designated use which is not an existing use.

Comment ID: CTR-060-016
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

* Health risk factor - The preamble to the rule (see 62 Fed. Reg. at 42,181, Col. 3) states that the cancer risk level used to calculate the criteria is 1 excess cancer case per 1,000,000 people. The State of California voters approved an initiative in 1986 "The Safe Drinking Water andToxic Enforcement Act of 1986" ("Prop. 65") to address concerns over exposures to toxic chemicals. Prop. 65 defines the "no significant risk" level as follows:

"For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question,...".(*15)

The criteria proposed in the rule should be recalculated to reflect a one excess case of cancer in an exposed population of 100,000 risk factor, which would be consistent with an existing risk factor which is acceptable to the voters in the State of California.

(*15) Subsection 12703 (b) at CCR Title 22, Division 2, Part 2, Subdivision 1, Chapter 3, Article 7.

Response to: CTR-060-016

EPA disagrees with these comments.

See response to CTR-058-001.

Comment ID: CTR-066-011
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* With respect to the criteria proposed for adoption in the draft CTR, we believe EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. Based on all the conservative assumptions embedded in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-066-011

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-081-003
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: * EPA should select human health criteria on levels other than the 10E-6 level, based on the conservative assumptions included in the calculation of the criteria.

Response to: CTR-081-003

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-082-004
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Recommend USEPA use human health criteria for carcinogens based on the 10(*-5) or 10(*-4) instead of the 10(*-6) level. It is important to note that all conservative assumptions included in the calculation of the EPA proposed criteria there is a significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor in this uncertainty into the risk amount along with population exposure when calculating risk and appropriate human factor.

Response to: CTR-082-004

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-085-013
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* With respect to the criteria proposed for adoption in the draft California Toxics Rule, the EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk level instead of the 10E-6 level. Based on all the conservative assumptions included in the calculations of the criteria, there is significant uncertainty in the number, witch may translate to negligible risk in using the lower risk levels. The EPA should factor this uncertainty into the risk assessment, along with population exposure, when calculating risk and appropriate human health criteria.

Response to: CTR-085-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-090-013

Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: 2. The Cancer Potency Risk Factor Should Be 10E-5 EPA should not assume that 10E-6 is California's preferred risk level for estuarine and inland surface waters. The action adopting that risk level was invalidated by the courts specifically on the grounds that the SWRCB did not follow the required procedures of the Water Code section 13241. In fact, the State of California and the voters of California have made a clear policy statement about cancer risk factors when they enacted in 1986, the Safe Drinking Water and Toxic Enforcement Act, known as Proposition 65. This Proposition established significant restrictions on the use of toxicants based on a cancer risk level of 10E-5. This voter approved cancer risk is far more valid and should be the guide to the EPA for the criteria.

The use of the 10E-6 as a risk level for human health will cause some constituents to be to considered problem pollutants when in fact no problem exists based on site specific data and bioaccumulation data. This high level of risk compounds the very conservative assumptions and other safety factors already within the formula for the criteria.

We urge the EPA to revise the cancer risk level to 10-5. Until such time that a source of problem toxicants are better identified, interim CRFs of less than 10E-5 would be appropriate for some carcinogens (more discussion in the detailed comments)

Response to: CTR-090-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-092-015
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: We want to highlight our technical concern with one aspect of the Economic analysis in the text of this letter - EPA's proposal to protect at an incremental cancer risk level of one in one million (10E-6) for all priority toxic pollutants regulated as carcinogens. The CTR states that "EPA recommends

that states consider minimum risk levels in the range of 10E-4 to 10E-6 for carcinogenic priority pollutants to protect public health and welfare." The City supports EPA's policy of allowing States the flexibility to use a range of cancer risk levels in their derivation ofcriteria for carcinogenic priority pollutants, however the City believes that the EPA has the same obligation in promulgating the CTR. The City recommends that risk levels be determined dependent upon the degree of scientific uncertainty inherent with the appropriate criterion. Stringency of risk levels should be established based upon the degree of significance, that assumptions and uncertainties drive the criterion derivation process.

Response to: CTR-092-015

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-096-008
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

Specifically, the City submits he following comments:

G. Further, with respect to the criteria proposed in the draft CTR, EPA should select human health criteria for carcinogens based on 10E-5 or 10E-4 risk levels instead of the 10E-6 level. Based on all the conservative assumptions included in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-096-008

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-001-026
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA

Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: In your proposed rule you said that 10 to the minus 6 is the appropriate cancer risk factor, but you're asking for comments on the 10 to the minus -- to the -- 10 to the minus 5. And I would like to point out that although the state originally in their guidelines for effluents had 10 to the minus 6, that was one of the grounds for the court case which overthrew that, those plans, in that they did not do a thorough analysis. The 10 to the minus 6, we will be giving you more information in written comments why we believe that 10 to the minus 5 is an appropriate risk level.

Response to: CTRH-001-026

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-001-046
Comment Author: Charles Batts
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: We would ask you to review scientific carcinogenic criteria with concern for special pathways that disclose how carcinogenics in aquatic runoff and wastewater interact with human health.

Presently the risk factor of 10 to the minus 6 is heaped on an already overly conservative criteria. The use of 10 to the minus 4 or 10 to the minus 5 have been incorporated by EPA in many other risk analysis plans that they've done, including the Safe Drinking Water Act and the Great Lakes Initiative,

Also in this area, greater study should be done to look at individual organic compounds to see what the cost/benefit ratio is and see if there is a way for removal of these specific organic compounds by source control or pollution prevention techniques.

Response to: CTRH-001-046

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-002-013
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: We'd like to see the EPA reexamine risk level for carcinogens in the human health criteria, taking into consideration the actual change in risk to the exposed population for each constituent and balancing that with the potential cost of compliance.

Response to: CTRH-002-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-002-023
Comment Author: John Behjan
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Simi Valley
Document Date: 09/19/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: MR. BEHJAN: Good afternoon. My name is John Behjan, B-e-h-j-a-n. My business address is 500 West Los Angeles Avenue, Simi Valley, California 93065.

Basically, I want to go over the CTR's proposed numerical objective for human health risk -- human health criteria which is based on human health risk assessment of 10(-6). That is basically for the cases that are consumable water for fish.

The previous speaker mentioned about waterways and this is where I'm coming from. We recommend EPA's consideration of another factor than the 10(-6). EPA does provide that, the flexibility. And this is a very appropriate application, perhaps in for -- because that would reduce the objectives more -- make them more difficult than for a lot of fish in Southern California who are discharging it into water.

Thank you.

Response to: CTRH-002-023

EPA disagrees with this comment.

See response to CTR-058-001.

Subject Matter Code: C-14 Fish or Water Consumption

Comment ID: CTR-002-002a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES C-17a

Comment: I. TOXIC POLLUTANTS THREATEN PUBLIC HEALTH AND SAN FRANCISCO BAY.

Toxic pollution causes harm in San Francisco Bay. Species of bivalve shellfish, plankton and phytoplankton that are especially vulnerable to toxic trace elements such as copper are decimated in its southern reach though they thrive in comparable estuaries with less metals pollution.(*1) (*2) Mounting evidence suggests its sediment is toxic to some aquatic life.(*3) Extensive research strongly suggests that PCBs and PAHs released to the Bay negatively effect reproduction in starry flounder. (*4) Reproductive effects are also correlated with PCBs in Bay cormorant eggs, Bay harbor seals have PCBs levels twice those associated with immunotoxicity and a disease epidemic that decimated a European population of this species.(*5) Health advisories are in effect because dioxin, PCBS, mercury, chlordane, DDT, dieldrin, and selenium contaminate Bay food resources eaten by the public.(*6) (*7)

Public health threats from toxics in the food chain are of particular concern. A recent count found approximately 270,000 fishing licenses were issued to Bay Area residents. Surveys by CBESAFER!, the Save San Francisco Bay Association, and the Asian Pacific Environmental Network show that many people fish the Bay regularly to supplement their families' diet, that some people eat up to a maximum of a pound of fish per day, and that the majority of those who eat their catch regularly are people of color. [See attachment (*8)] A pound of fish per day is about 480 oz./month, sixty times the 8 oz./month "safety" cutoff for cancer and slow learning in the state's advisory.(*6)

In addition to these severe environmental health and justice problems, pollutant monitoring of the Bay is far from comprehensive, and undetected problems are likely. Indeed, EPA acknowledged that designated uses of the Bay are threatened or impaired by toxic pollutants when it named the Bay as a "toxic hot spot" under Section 304(l) of the Clean Water Act.(*9)

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.

(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten other estuaries. Communities for a Better Environment (CBE). July, 1992.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control

value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH concentrations in San Francisco Bay waters.

(*4) Spies et al., (2 papers), 1988: Effects of organic contaminants on reproduction of the starry flounder Platichthys stellatus in San Francisco Bay, I., Hepatic contamination and mixed-function oxidase (MFO) activity during the reproductive season. Marine Biology 98: 181-189; and II. Reproductive success of fish captured in San Francisco Bay and spawned in the laboratory. Marine Biology 98: 191-200. Excerpt including abstracts.

(*5) Kopec and Harvey, 1995, Toxic pollutants, health indices, and population dynamics of harbor seals in San Francisco Bay, 1989-1992. Moss Landing Marine Laboratories Technical Publication 96-4. ISSN 1088-2413. October, 1995. Excerpt regarding PCBs levels as compared to European seals in which a disease epidemic and population crash was observed.

(*6) Cal. EPA, 1994. Health advisory on catching and eating fish, interim sport fish advisory for San Francisco Bay. December, 1994.

(*7) California Department of Health Services, 1994. Health Warnings, Contained in the 1994 California Hunting Regulations for Resident and Migratory Game Birds issues by the state's Fish and Game Conunission, Sacramento, Calif. Excerpt including health warning for selenium.

(*8) Previously unpublished data froma 1993-4 survey of 500 anglers using South and Central San Francisco Bay by conununities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994.(excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence..

(*9) EPA, 1990. Decision of the United States Environmental Protection Agency on listing under section 304(l) of the Clean Water Act regarding the state of California. Excerpt including pages listing San Francisco Bay waters as a "toxic hot spot."

Response to: CTR-002-002a

See response to CTR-001-002.

EPA acknowledges the impacts of pollution in the San Francisco Bay. EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. The fish intake rate of 6.5 gm/day is from a national, 30-day survey - the National Purchase Diary (NPD), based on an empirical distribution, where 6.5 gm/day represents the average value for the general population. According to the NPD, which was based on over 25,000 individual respondents, 94 percent of the survey respondents reported that they ate fish. Therefore, EPA believes that 6.5 gm/day is an appropriate basis for characterizing the general population. EPA understands that fish intake patterns vary and that there are population groups that consume significantly greater amounts than the overall population.

For this regulation, the promulgated criteria were derived using a 10-6 risk level, which the Agency believes reflects an appropriate risk for the general population and ensures protection for all exposed population groups. EPA also considers that the goal is satisfied if the general population will be adequately protected by human health criteria when the criteria are met in ambient water. EPA acknowledges that at any given risk level for the general population, those segments of the population

that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10-6, individuals consuming up to 10 times the assumed fish consumption rate would be protected at a 10-5 risk level. Similarly, individuals consuming up to 100 times the assumed rate would still be protected at a 10-4 risk level. Consistent with this, a criterion based on 6.5 gm/day at a risk level of 10-6 would protect those who consumed 650 gm/day at a 10-4 risk level.

EPA has advocated State and Tribal flexibility to develop criteria, on a site-specific basis, that provides additional protection appropriate for highly exposed populations. EPA has not found that such a demonstration has been made for specific waterbodies covered by the CTR that warrants a change or re-proposal of the CTR criteria at this time. EPA understands that highly exposed populations may be widely distributed geographically throughout a given State and Tribal area. Thus, if the State or Tribe determines that a highly exposed population would not be adequately protected by criteria based on the general population, EPA recommends that the State/Tribe adopt more stringent criteria. Furthermore, EPA recommends that States and Tribes ensure that the most highly exposed populations not exceed a risk level of 10-4.

It should also be understood when comparing the fish intake assumption of 6.5 grams/day used to develop these criteria with other studies, including the studies referenced by the commenter (such as the surveys by "CBESAFER!", the Save San Francisco Bay Association, etc.), that the 6.5 gm/day value reflects consumption of fresh/estuarine species only and does not include marine species. It is the fresh/estuarine species that apply to the development of water quality criteria for the waters covered under this rule. Specifically, the CTR's ambient water quality criteria are applicable to inland waters and estuaries. The CTR does not apply to ocean waters that are covered by California's Ocean Plan. The commenter needs to separate out marine species before any comparisons between studies can be appropriately made. EPA's water quality criteria program policy has historically been to evaluate fish intake from fresh and estuarine species only, based on knowledge of life-cycles of the species including relevant information from the National Marine Fisheries Service. The purpose is to include those species that are anticipated to be potentially exposed to pollutants in fresh and estuarine waterbodies, based on this life-cycle information [for further discussion on this policy, see the Ambient Water Quality Criteria Derivation Methodology Human Health Technical Support Document, Final Draft (EPA-822-B-98-005)].

EPA is developing a revised methodology for deriving water quality criteria to protect human health and is updating its recommendations for estimating fish consumption, including evaluating the most recent survey data (see draft revisions published August 14, 1998, Federal Register, Vol. 63, No. 157). EPA is currently reviewing public comments and is awaiting the results of a peer review on the draft methodology revisions. However, until the methodology is finalized, EPA believes that the current methodology is scientifically defensible.

Comment ID: CTR-002-005a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y

Comment: C. Criteria for the pollutants of most concern do not provide equal protection for people of color and are not supportable by science.

EPA cannot show that its weaker proposed criteria will protect fishing and aquatic life from dioxin-like compounds, mercury, and copper. Further, EPA's proposal to allow greater health risks for subsistence fishers fails to provide equal protection under the law and is contrary to the President's Executive Order on Environmental Justice.

The proposed criteria provide unequal protection for people of color who fish for food. EPA admits in the proposal that: "There may be subpopulations within a state, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish.. ." Indeed, ample data show that some people exercise their fishing rights to "use" Bay waters by eating up to a pound (450 grams) per day of fish from San Francisco Bay, and most of them are people of color.(*8) EPA's discussion then goes on to admit that it is proposing to provide less protection for these subsistence anglers: "[I]ndividuals that ingest ten times more of a carcinogenic pollutant than is assumed in derivation of the criteria at a [one excess cancer in a million] risk level will be protected to a [one in 100,000] level, which EPA has historically considered to be adequately protective." However, people who eat a pound per day eat seventy times more, and pages 8- 11 and 8-12 of EPA's economic analysis admit people eat 16 times more, than the 6.5 grams (1/70th of a pound) of Bay fish per day assumed in EPA's criteria. EPA's own calculations show present cancer threats of nearly 1 in 1,000 for some Bay anglers at these higher consumption levels. Thus, EPA itself predicts that its proposal will result in lesser, inadequate protection for people of color who rely on Bay-caught fish for food.

(*8) Previously unpublished data from a 1993-4 survey of 500 anglers using South and Central San Francisco Bay by Conununities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994. (excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence.

Response to: CTR-002-005a

EPA believes that this rule is consistent with the terms of the Executive Order (E.O.) on Environmental Justice. EPA rejects the notion that the rule is, in any respect, discriminatory against persons or populations because of their race, color, or national origin. The final rule establishes criteria that are designed to ensure protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA believes that these groups will nonetheless receive a level of public health protection within the range that EPA has long considered to be appropriate in its environmental programs (e.g., 10-4 to 10-6 incremental cancer risk). Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increase cancer risks greater than the risk range that the EPA has long considered protective. EPA disagrees that individuals who consume up to a pound of fish per day would face a 10-3 cancer risk. Given that the basis of the criteria

are a 6.5 gm/day assumption at a 10-6 risk level, individuals who consume a pound of fish per day would be protected within the established acceptable range of 10-4 to 10-6, consistent throughout current EPA program office guidance and regulatory actions. See also the discussion in response to CTR-002-002a.

Comment ID: CTR-006-002b
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES C-01a

Comment: Dear Ms. Frankel,

The Natural Resources Defense Council strongly opposes the Region 9 EPA proposal to raise the allowable mercury criterion for continuous concentration in water from 0.012 parts per billion (ppb) to 0.770 ppb for aquatic life. This proposal is difficult to justify from the point of view of science and of public health. On behalf of our over 350,000 members nationwide and our over 55,000 California members, we are writing to register our opposition to the EPA proposed rule.

Mercury is a highly poisonous metal which results in toxicity to the brain and nervous system and toxicity to human reproduction. In addition, in sediments, mercury is bio-transformed into the even more toxic form, methyl mercury, which has resulted in some of the largest epidemics of neuro-developmental poisoning known to mankind. Methyl mercury bioaccumulates in the food chain and thereby results in greatly concentrated exposures to humans, because we eat off the top of the food chain. Underestimates of the toxicity and bioaccumulation of mercury have led to major mistakes in the past. The Minamata Bay disaster in Japan was caused by a failure to predict the potency of mercury and the extent of human exposure through fish. U.S. EPA's Draft Mercury Study Report to Congress documents that children of high-end fish consumers in the U.S. may be exposed to enough mercury to cause adverse neuro-developmental effects.

In this setting it is anomalous to relax the standards for mercury contamination in California water. Furthermore, the scientific reasoning behind the Region 9 EPA decision to relax the mercury standard 60-fold is fraught with errors. NRDC's major concerns with this approach are summarized below.

*Extrapolation for the Reference Dose (RfD) should start at a NOAEL, not at a level of 10% increased risk. *An additional 10-fold safety factor should be added in deriving the RfD to account for the vulnerability of fetuses, infants, and children. *The body weight in the calculation should be for a child, not an adult male. *The Fish consumption rates for those who do eat fish should be used instead of rates for the entire population including those who do not eat fish. *Average fish consumption quantities greatly understate the risk to those who eat a lot of fish. Instead, fish consumption for the top 5% of the population should be used. *Bioaccumulation is known to be 10 to 100 fold greater than the estimate used by EPA. *California's waters are already too polluted with mercury.

Use of Average Fish Consumption is not Health Protective

The assumption used by Region 9 EPA for fish consumption relies on the average fish and shellfish consumption in the entire general population, along with the average intake from each body of water. It is quite clear that fish consumption follows a highly skewed, or Poisson distribution in the population (see attachment from the U.S. EPA Draft Mercury Study Report to Congress, Appendix H, p. 20). Many people eat little or no fish, but a smaller, yet highly significant segment of the population eats a very large amount of fish. Surely EPA should strive just as hard to protect the health of those who eat fish frequently as it does to protect the health of those who do not eat fish.

In fact, this analysis adequately protects only those who eat little or no fish. The average whichwas used in the Region 9 EPA analysis appears to derive from the "per capita" data from the USDA Continuing Surveys of Food Intake by Individuals (CSF 11) from 1989-91 for males ages 15-44 years. (See attached tables from U.S. EPA Mercury, Report, Appendix H, pp. 8 & I 1). In fact, this average is highly influenced by those individuals who consume little or no fish. Non-fish-consumers, however, are not the population of interest for purposes of this analysis. Instead, if an average is to be used, it should be the average fish consumption rate for those people who do eat fish. This is substantially higher, at 53.7 g/day for males ages 15-44 years, and 41.4 g/day for females in the same age range. Furthermore, the average fish consumption will likely underestimate the fish consumption rate for the "high end" fish consumer by many orders of magnitude. For example, in the case of females ages 15-44 years, average fish consumption (among those who do eat fish) is 41.4 g/day, while fish consumption by the top 5% of the population of these women of childbearing age is about 112 g/day, or more than double the average consumption rate.

The implications of not adequately protecting the high fish consumer are not trivial. The population of California is nearly 30 million, of whom overall 31% would be expected to be fish consumers according to the CSF II survey. This represents over 9 million people who would be at disproportionate risk. The top 5% of that population consists of nearly half a million people in California who would be expected to eat fish at nearly 10-times greater quantity than the EPA calculations would predict. 10 times greater consumption would translate into roughly 10-times greater risk from the mercury in the fish. EPA is not adequately protecting this substantial portion of the California population from mercury hazards.

NRDC strongly urges Region 9 EPA to reassess the proposed standard for mercury. Recalculation of the reference dose to accommodate the known disproportionate impact of mercury on fetuses, infants, and children will require addition of at least another 10-fold safety factor. The starting point for RfD calculation should be a true NOAEL. The body weight calculation should use an average weight for a child. Fish consumption data should reflect the "high-end" consumer. Finally, the outdated and unsupportable bioaccumulation factor of 7300 should be discarded in favor of a BAF which is supported by the current science in California.

Response to: CTR-006-002b

Regarding the issues on mercury health effects, derivation of the RfD, and basis of the fish intake assumption (including discussion of the CSFII survey), see response to CTR-006-002a. For additonal discussion regarding the basis of the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding the choice of body weight, see response to CTR-006-001a. Regarding the issues on bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-010-002

Comment Author: Save San Francisco Bay Assoc.
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES

Comment: The Bay is already highly polluted, as is evidenced by the adverse impacts on beneficial uses, particularly fish consumption. The State's Bay Protection and Toxic Cleanup Program has identified numerous probable toxic hot spot locations in the San Francisco and Santa Monica Bays, and confirmed hot spots in San Diego Bay. As bad as San Francisco Bay water quality already is, EPA's Toxics Rule proposal will make current conditions seem pristine compared to what lays ahead if this proposal is enacted.

Response to: CTR-010-002

Regarding the site-specific contamination issues, see response to CTR-002-003.

Comment ID: CTR-015-001
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: Dear Ms. Frankel:

Eastern Municipal Water District ("District") provides potable and reclaimed water and sewer service to an area of 555 square miles in western Riverside County in Southern California. The District has five regional water reclamation facilities in Moreno Valley, Hemet/San Jacinto, Perris Valley, Temecula Valley and Sun City with a total available capacity of 49 million gallons per day. There are 77,000 fresh water customers and 122,000 sewer connections. The District has a National Pollutant Discharge Elimination System ("NPDES") permit to discharge effluent, which could be combined from all five facilities, to Temescal Creek in the Santa Ana River Basin.

Submitted herewith are comments from the District on the Proposed Rule referenced above, appearing in the August 5 Federal Register, also called the California Toxics Rule ("Rule") . Several District staff have participated in the State Water Quality Planning Process since 1990. It has been complicated and frustrating, especially in light of attempting to obtain NPDES permits while the state was developing plans. Generally, the District is pleased that your agency ("Agency") is bringing some closure to the

issue by promulgating criteria. We do have some recommendations and concerns, however, which we present for your consideration.

Human Health Criteria (FR p. 42178, Preamble section E.3.)

Regarding fish and shellfish consumption rates, which are an important factor in calculating these water quality criteria, the District supports the Agency's use of 6.5 grams/day. What is of concern is the Agency's statement, "EPA supports the State's use of any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans." The discussion centers on the adopted California Ocean Plan's use of 23 grams/day, which was based on a California Department of Health Services memorandum of 1989. It is important to note that this exposure value was based on ocean fish consumption, whereas the Agency's value is based on non-marine fish consumption.

If a high consumption rate is used, the water quality criterion is lower or more stringent. This would become an additional burden for inland dischargers such as our District. For inland waters, and for any developed inland surface water quality criteria, we would like the Agency to recognize that lower consumption rates could also be used. The following shows the mean consumption rates of fish which are representative of California freshwater fisheries. These rates were taken from the Agency's Exposure Factors Handbook of 1989.

Bluegills --O.089 grams/day Carp --O.016 grams/day Catfish --O.292 grams/day
Perch --O.062 grams/day Sunfish --O.020 grams/day Trout --O.294 grams/day

Generally, the District hopes that appropriate consumption rates are used and desires that site-specific studies be conducted before different rates are selected. We would like to summarize the Agency's own procedures for developing data upon which to base alternative consumption rates, from the Exposure Factors Handbook, 1989, p. 2-39:

1. Interview local recreational fishermen in the affected area and obtain actual consumption rates. Local surveys can provide the most accurate data for exposure assessment purposes.

2. Obtain productivity data for the area and divide total catch data by the number of recreational fishermen in the area.

3. Estimate what portion of fish consumed in the local area is caught in the local area. Apply the diet fraction to the 50th and 90th percentile consumption rates.

4. Develop exposure scenarios assuming a number of fish meals eaten in the area per year, applying a meal size in the range of 100 to 200 grams/meal.

The Agency should encourage the state to conduct, at a minimum, studies in the manner described above for the following situations: lakes and reservoirs, inland surface streams, effluent-dominated streams, and ephemeral and-intermittent streams.

Response to: CTR-015-001

EPA acknowledges the commenters support of the 6.5 gm/day fish intake assumption. EPA also generally agrees that the rate should be indicative of consumption of freshwater and estuarine species only (see additional discussion on the fish intake rate assumptions in response to CTR-002-002a). However, the commenter has expressed concern over the use of California's Ocean Plan fish consumption

rate as a potential "additional burden" for inland dischargers. The commenter appears to support this concern by providing six species-specific intake rates "representative of California freshwater fisheries." EPA believes that this comparison is not appropriate. First, the State of California has both an Inland Surface Waters Plan and an Enclosed Bays and Estuaries Plan that would be more relevant to inland dischargers. Second, the commenter has chosen only several species of fish from a much larger tabulated list in the original 1989 Exposure Factors Handbook (revised in 1995). The table presents consumption data from a study conducted approximately 20 years ago for fish consumers in the United States. EPA believes that this is not necessarily representative of California-specific consumption patterns. EPA has long supported the States' use of local site- or State-specific data over EPA's default values to better reflect the variability of local or regional consumption patterns, when adequate data are available. EPA has published guidance on how to conduct such surveys. The Agency's most recent document is Guidance for Conducting Fish and Wildlife Consumption Surveys (EPA-823-B-98-007).

Comment ID: CTR-026-007a
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: 7. HUMAN HEALTH CRITERIA

As you are aware the Department of Fish and Game is the trustee for the natural resources of the State and, as such we are not in an appropriate position to address human health issues. However, we would like to take this opportunity to make EPA aware of our concerns in two areas. The first issue deals with one component of the formula that was used to derive the human health criteria. Obviously, the human health criteria takes into account fish consumption rates, as well as what portion of the fish is consumed. The CTR indicates that the consumption rate utilized was 6.5 grams per day of fish tissue. This consumption rate, at least for the portion of the population that are subsistence fishermen, appears to be very low. If the human health criteria is to be adequately protective, this consumption rate should be revisited and a new rate developed to better protect these fishermen. Our second comment deals with the proposal to base criteria on fish tissue as opposed to water concentration. The DFG does not have a position with respect to this approach except to point out that compliance monitoring for fish tissue criteria may impact resources. This approach would mean an increased number of fish being collected for monitoring purposes which may impact fish resources. It may also impact the DFG's fiscal resources since we regulate scientific collection activity under which fish monitoring would fall.

Response to: CTR-026-007a

Regarding the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding the comments on collecting fish for compliance monitoring and its impact on the Department of Fish and Game's (DFG) resources, the commenter has misunderstood EPA's reference to elevated fish tissue levels. The CTR criteria values are for ambient water quality criteria - that is, the numerical values represent water concentrations. EPA does not intend to add, through the CTR, the collection of fish for

monitoring purposes. Therefore, the DFG should not expect to have any additional workload for collecting or analyzing fish, nor should the DFG anticipate any loss to fisheries resources as a result of the CTR.

Comment ID: CTR-029-003
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

Fish Consumption Figures Should Be Recalculated to Protect Exposed Subpopulations Adequately

For purposes of establishing human health criteria, the proposed rule assumes the consumption of 6.5 grams of fish and shellfish per day by an average adult with a body weight of 70 kilograms.(*7) These two figures should be adjusted to better protect subpopulations exposed to contaminated fish and shellfish, particularly mercury contaminated fish and shellfish.

First, the 6.5 grams per day figure simply averages fish consumption over all of the population without accounting for the fact that much of the population either does not eat fish at all or relies on fish for much of their daily diet. A simple average thus underprotects much of the more significantly exposed population. Moreover, this figure is inconsistent with the Ocean Plan's estimate of 23 grams of fish and shellfish ingested per day. At a minimum, the analysis should be revised to use this more conservative figure.

Second, the use of a 70-kilogram man significantly underprotects children and pregnant women, who are most at risk from eating fish and shellfish contaminated with toxics. The proposed rule justifies this figure by claiming that "[p]ersons of smaller body weight are expected to ingest less ... so the dose per kilogram of body weight is generally expected to be roughly comparable." In fact, growing children and pregnant women often eat as much or more than many 70-kilogram adults, and so the calculated "safe" dose will be far too high for their body size. We urge EPA to base the human health criteria on a child 's weight in order to better protect this most vulnerable group of people.

(*7) Id. at 42176.

Response to: CTR-029-003

Regarding the protectiveness of the proposed criteria, see response to CTR-029-002a. With respect to EPA's estimation of costs and benefits, see response to CTR-029-004a.

EPA disagrees with the commenter that the fish consumption rate is based on "the fact that much of the population does not eat fish" - the opposite is true (see discussion on this same issue in the response to CTR-002-002a). Also, the commenter has advocated the use of 23 gm/day from the State of California's Ocean Plan estimate. This Plan, which is the State's undertaking, and the fish intake estimate is based on consumption relevant to marine species of fish and is, therefore, not an appropriate comparison to the estimate of 6.5 gm/day, which is based on fresh/estuarine species only. EPA acknowledges that there are population groups who consume greater amounts of fish than the overall population. However, EPA believes that its assumption of 6.5 gm/day is adequately protective. These issues are discussed in the response to CTR-002-002a. Regarding the body weight assumption, EPA believes that 70 kg is an appropriate body weight because it represents a reasonable measurement for adults and most of the criteria are based on chronic health effects [i.e., Reference Doses (RfDs) based on exposure over the course of a lifetime] for which the adult population is most appropriate. EPA acknowledges that where the RfD is based on health effects in children, the exposure parameters, including the body weight assumption, should be adjusted for a child. Such assumptions may be used on a chemical-by-chemical basis in calculating criteria. However, for this rule EPA believes it has made appropriate assumptions with the chemicals being regulated. For a specific discussion on this issue related to the mercury criterion, see the response to CTR-006-001a.

Comment ID: CTR-035-022
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42176 & 42178 - Fish Consumption Rates In general, we support EPA's use of a fish consumption rate of 6.5 g/day in the CTR criteria. However, it may be more accurate to develop rates based on freshwater fish/shellfish consumption and marine/estuarine fish/shellfish consumption. While

EPA says on p. 42176 that the State may want to develop site-specific criteria where warranted, the Preamble also states on p. 42178 that EPA "supports the State's use of any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans." (emphasis added) We believe that the latter statement should be consistent with the previous statement, and that site-specific criteria should be developed using local fish and shellfish consumption rates where warranted, regardless of whether they are higher or lower than the national average consumption rate. For instance, in recalculating human health criteria for effluent dependent waters where fish consumption is a designated use, EPA or the State should consider using 1.72 g/day (see 62 Fed. Reg. 42179). We believe that this freshwater consumption rate may even be high, based on the following mean consumption rates of fish that are representative of California's freshwater fisheries (U.S. EPA, 1990b):

Bluegills 0.089 grams/day Carp 0.016 grams/day Catfish 0.292 grams/day Perch 0.062 grams/day Sunfish 0.020 grams/day Trout 0.294 grams/day

Response to: CTR-035-022

EPA disagrees that the two referenced statements regarding criteria development and fish intake rates are inconsistent. If a State determined, based on adequate data, that its population did in fact consume less fish than EPA's default value, EPA would support the State's use of that value. However, the commenter has presented values from only several species of fish from a much larger tabulated list in the original 1989 Exposure Factors Handbook (revised in 1995) and suggested that they are appropriate for a site-specific criterion. EPA disagrees with this rationale. The table actually presents consumption data from a study conducted for fish consumers in the United States. EPA believes that this is not necessarily representative of California-specific consumption patterns. The point of allowing such flexibility with site-specific criteria is that data are available for that particular site, which the commenter has not demonstrated. Further, EPA disagrees that the use of 1.72 gm/day would protect the general population of California. See additional discussion on protecting the general population in response to CTR-002-002a.

Comment ID: CTR-039-004
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of San Francisco BayKeeper, its Stockton-based DeltaKeeper project, San Diego BayKeeper and Santa Monica BayKeeper (hereinafter "BayKeepeer"), I am submitting these comments for consideration in finalizing EPA's proposed rule establishing water quality criteria for priority toxic pollutants for the waters of the State of California. The need for numeric criteria for priority toxic pollutants was identified by Congress ten years ago when, in October, 1987, it enacted amendments to the Clean Water Act mandating that States issue such criteria by not later than October 18, 1990. The State of California adopted a portion of the mandated criteria in April, 1991, which, in large part, EPA approved. However, even that partial compliance was thwarted by the Sacramento Superior Court's

overly broad decision vacating the State's decision based solely on a flawed economic analysis purportedly required by State law.

Now, seven years later, although appreciative of the complexity of the task required by Congress, BayKeeper is deeply concerned that EPA's proposed rule to cure the State's violation will undermine permit limits promulgated throughout the Bay area and other regions, allowing more pollution to be discharged to San Francisco Bay and other state waters in violation of the State and EPA's antidegradation policies. BayKeeper also is very concerned that EPA is promulgating criteria for mercury, dioxin and 13 other pollutants which are based on drastic underestimates of the quantity of fish consumed by recreational and subsistence anglers throughout the State of California. BayKeeper also believes that at this late date, the proposal to allow compliance schedules which could delay for up to ten years compliance with permit effluent limitations based upon the proposed criteria is inappropriate given the already seven year delay suffered by California's aquatic ecosystems and the people who depend upon the health of those systems for food and recreation.

II. MANY RECREATIONAL AND SUBSISTENCE ANGLERS EAT MORE THAN 6.5 GRAMS OF FISH PER DAY.

According to EPA's "Economic Analysis of the Proposed California Water Quality Toxics Rule," (July 1997), anglers throughout the State who eat on average 107.1 grams/day of fish from California's waters (about 10% of the people fishing), after the proposed rule is enacted, will still be confronted with a lifetime cancer risk of from 6.65 x 10E-4 to 9.26 x 10E-4. Economic Analysis at 8-15. That correlates

roughly to a 1000 times greater chance of those anglers getting cancer than the 1 x E10-6 risk established by the State or an increased cancer risk of approximately I cancer death per 1,000 people. 107 grams is about a quarter of a pound. Surveys in the San Francisco Bay area have found that many anglers eat up to a pound (450 grams) per day of fish, increasing the risk even beyond that documented in the Economic Analysis. There is no reason to assume that subsistence anglers throughout the State are not consuming fish at a similar rate. In calculating criteria for mercury, dioxin, PCBs and other contaminants, EPA "assumes" a consumption rate of 6.5 grams per day. That number purports to be "equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish and shellfish for the U.S. population." 62 Fed. Reg. at 42176. Congress' directive that the "solution to pollution is not dilution" should apply even more forcefully to human health impacts. EPA should not be allowed to dilute the health effects of fish consumption in California by averaging it into the fish consumption rates of the entire country nor should EPA dilute the effects of contaminated fish on those people who choose or need to use the Nation's waters more than others -- recreational and subsistence anglers -- by lumping their consumption rates in with the general populations.

Despite the fact that EPA has acknowledged in its Economic Analysis that it is well-documented that a significant subpopulation of people eat considerable amounts of fish, the proposed rule chooses to ignore this fact, couching it as a mere possibility which the State should address if it chooses to. See 62 Fed. Reg. 42176 ("[t]here may ... be circumstances where site specific numeric criteria are more stringent than the statewide criteria are necessary to adequately protect highly exposed subpopulations [like subsistence anglers'). Of course, the whole rationale for EPA to be issuing the proposed rule is inaction by the State of California. The notion that certain critical determinations involving direct human health impacts should be left to a crippled process is arbitrary and does not accomplish what Congress set out to do in establishing Section 303(c)(2)(B) back in 1987.

Perhaps the greatest irony of EPA's methodology in selecting a consumption rate is apparent if one considers that, as our waters become more and more deteriorated from toxic contaminants and people become more and more aware of that contamination, they are likely to eat less and less fish, driving down the national fish consumption average and, under EPA's way of calculating, allowing more pollution to be discharged. EPA must set a consumption level that protects the most sensitive users and renders California's waters truly "fishable" not "fishable if you want torisk getting cancer."

Response to: CTR-039-004

EPA believes its estimate of consumption level for the general population is reasonable and its selection of risk level for the general population affords adequate protection for all populations. For water quality criteria established in the CTR, individuals consuming 107.1 gm/day would be protected at approximately a 10^{-5} risk level and that individuals consuming up to a pound a day would still be protected at a 10^{-4} level. For a more detailed discussion on this same issue see the response to CTR-002-002a.

EPA acknowledges that the commenter drew its lifetime cancer risk estimates for people who eat an average of 107.1 gm/day of fish of 6.7×10^{-4} to 9.3×10^{-4} from the benefits portion of EPA's Economic Analysis (EA). However, the post rule cancer risk estimates in EPA's EA were calculated conservatively and are likely overstated for two reasons.

First, the benefits portion of the EA only accounts for risk reduction that occurs from reducing point source discharges. Thus, the post rule risk estimate in the EA is only a partial accounting of the potential reductions in fish contamination that will eventually result from implementation of the CTR. The reason for this is that EPA only accounted for costs of the rule to NPDES dischargers. In order to fairly compare costs with benefits, the benefits only included estimates of risk reductions that would take place due to increased controls on NPDES dischargers. However, in actuality, the standards established in the CTR apply to the waterbodies (i.e., inland

surface waters and enclosed bays and estuaries). As controls on other sources are implemented, perhaps as a matter of state law, (*e.g.*, remediation of contaminated sediments; best management practices to control non point sources and runoff from agricultural land), EPA expects that in the future the CTR criteria will be attained in the waterbodies and concentrations of pollutants in fish tissue will decline further.

Second, the baseline and post-regulatory risk estimate in the benefits portion of the EA was calculated by adding together all of the individual excess lifetime cancer risks for all of the chemicals identified in fish tissue data collected throughout the State. This assumes that an individual is eating fish contaminated with all of the chemicals identified in the study. To the extent that not all fish contain all contaminants at the assumed concentrations, both baseline and post-regulatory cancer risk estimates in the EA may be overstated. While this approach is appropriate for analytical purposes in the economic analysis' benefits assessment, agency scientists who establish ambient water quality criteria do not believe that the science demonstrates that individual risks can simply be added together for purposes of criteria development.

The commenter, in its discussion, also states that the consumption rate accounts for both contaminated and non-contaminated fresh/estuarine fish and shellfish. Although there are many circumstances relevant to fish consumption and contamination patterns, in an effort to be protective of populations that do consume most or all of their fish from a given water body, the equation to derive criteria does not subtract any of the consumption rate - that is, there is no discounting for non-contamination. This assumption helps to ensure that people can safely consume fish from waters designated for fishing and to derive allowable levels of toxics that are adequately protective of human health under the Clean Water Act.

EPA believes that its criteria are adequately protective. States have the flexibility to be more protective if they believe it is appropriate. However, with this rule, EPA is only promulgating criteria. That is, antidegradation policies are not affected by this action. Regulated entities must still comply with existing State antidegradation policies and procedures. Also, compliance schedules are a fact-specific, facility-specific determination. All stakeholders will have an opportunity to review the facts and comment on the appropriateness of a compliance schedule for any given situation as part of the public noticing of the draft NPDES permit. With respect to the comments regarding the length of the compliance schedule, see response to comment CTR-002-010b.

Comment ID: CTR-060-015
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

* The fish consumption rate of 6.5 g/day used is not representative of fish consumption within the State of California, and overestimates exposure. This value is reported by the EPA to represent an estimate of average consumption of fish and shellfish from estuarine and fresh waters by the U.S. population(*3) . The draft EPA

Exposure Factors Handbook (*4)(EFH) summarizes studies on the intake of fish and shellfish, and includes study results for Northern and Southern California from the National Marine Fisheries Service. While this data is compiled for fish from marine habitats, other data summarized in Table 10-8 of the draft EFH suggests that the percentage of the population consuming and the mean daily fish intakes are higher for fish from marine habitats than for freshwater/estuarine habitats. The mean daily intake of marine finfish for anglers was 2.0 g/day for both Northern and Southern California, and the intake was 0.2 or 0.3 g/day on a per capita basis in the coastal population. The value of 2.0 g/day would be a more reasonable consumption rate and should be sufficiently health-protective of the more highly exposed sub-population of the state, because this intake is restricted to the angler population, which may reasonably be expected to consume their own catch and to represent a greater exposed population than the entire population of the state. The intake rate from this database is more up-to-date and is geographically representative. The criteria should be recalculated using the California fish intake rate.

General human health criteria issues

* Fish consumption rate - See the above discussion for PAHs regarding the over estimation of fish consumption rates used in the human health criteria.

(*3) U.S. EPA, 1989. Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish. Office of Water Regulations and Standards. EPA-503/8-89-002.

(*4)U.S. EPA, 1996. Exposure Factors Handbook. EPA/600/P-95/002Ba. Office of Research and Development.

Response to: CTR-060-015

EPA disagrees with the commenter. EPA believes that the 6.5 grams/day fish intake estimate is adequately protective of the general population of fish consumers over the course of a lifetime and is appropriate for this rule. The commenter suggests that EPA use an intake value based on marine finfish consumption of 2.0 gm/day. However, it is the fresh/estuarine species of finfish and shellfish that apply to the development of water quality criteria for the waters covered under this rule. Specifically, EPA's ambient water quality criteria are applicable to inland waters and estuaries. Further, EPA is aware of other studies that indicate higher consumption rates than suggested by the commenter. For further discussion on the basis of EPA's estimate, refer to the response for CTR-002-002a.

Comment ID: CTR-065-003a
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-21

Comment: HUMAN HEALTH CRITERIA

EHC is very concerned about the use of 6.5 grams per day of fish tissue as a basis upon which to derive human health criteria. This is not adequate to protect the many thousands of subsistence fishers of California coastal waters. We trust EPA is not in the business of protecting "most of the people, most of the time" as is the indicated goal for marine organisms elsewhere in the CTR (see comments below).

We refer you to a study conducted by the Save San Francisco Bay Association that concluded that fishers of San Francisco Bay consumed 81grams per day in the week prior to the survey with consumption rates as high as 450 grams/day... This element of the CTR must be recalculated at a higher rate of consumption and with a healthy safety margin to accommodate for synergistic and cumulative effects. Further, the Save San Francisco study showed that heads and skin were frequently consumed, the health criteria must reflect these actual eating patterns and practices as well and reflect the cultural diversity of users of the Bays. Since many subsistence fishers are people of color, adoption of this rule could violate the President's Order on Environmental Justice b exposing these populations to increased and undue environmental health risks.

Response to: CTR-065-003a

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. EPA has reviewed the materials submitted by the commenter from the Save San Francisco Bay Association and, as is discussed in CTR-002-002a, the commenter needs to separate out those species defined as marine from the referenced tables (e.g., shark, ray, cod, halibut, mackerel, marine salmon) in order to appropriately compare fish intake rates that are relevant to the development of the CTR criteria. Other issues on the fish consumption rate are also discussed in the response to CTR-002-002a. Regarding the comment on the President's Executive Order on Environmental Justice, see the response to CTR-002-005a.

Comment ID: CTR-095-001d
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20
C-17a
C-21

Comment: In regard to the numeric water quality standards criteria for California surface water, they have been revealed by environmental groups to be insufficiently protective and environmentally unjust. The proposed new rules assume fish ingestion of 6.5 grams per day. In reality, consumption of fish in some communities can be as high as 1 pound per day. This level of consumption is especially likely among subsistence fishers.

Please prevent toxic pollution in California's bays by making more protective standards that consider all toxic pollutants and consider the fish consumption habits of subsistence anglers.

Response to: CTR-095-001d

See responses to CTR-002-002a, CTR-002-005a and the response to CTR-058-001 (Subject Matter Code C-13, Risk Level).

Comment ID: CTR-097-001b
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: I am writing to urge you to more stringent - and more protective - water quality standards for California surface water. The proposed standards are too weak and discriminatory in their effects.

Lastly, the proposed standards are discriminatory in their effects in that they assume consumption of only 6.5 grams of fish per day per person. Many poorer communties catch and eat fish for subsistence - as much as a pound per day per person (more than sixty what the EPA estimates!) placing them at greater risk. The standards should be set to protect everybody, including those who happen to be poor and/or eat a significant amount of fish.

Please set the standards to protect us all and move us closer to the goals of the Clean Water Act, that our waters be safely fishable and swimmable.

Response to: CTR-097-001b

See responses to CTR-002-002a, CTR-002-005a and the response for Subject Matter Code C-13, Risk Level.

Comment ID: CTR-098-001
Comment Author: Elena Goldstein
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing to urge you to work towards the prevention of toxic pollution in the bavs of California. It is evident that more protectiive standards are needed to protect those who fish and those who consume the

fish. Not to do so would be completely irresponsible. Turning a deaf ear to the situation or bending to pressure from business interests would, I suggest, also be immoral.

Response to: CTR-098-001

See responses to CTR-002-002a and CTR-002-005a.

Comment ID: CTR-099-002
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: First, the 6.5 grams per day must be out in left field. Your staff must have divided the total consumption by the population. It ignored that some people do not eat fish, some eat very little and others eat fish regularly. Subsistence fishers are the obvious case in point, but what about so many of us who have eschewed red meat for a contemporary healthy diet of fish and fowl. We eat about I/3 LB three times a week. This comes to about 61 grams a day, almost an order of magnitude larger than you baseline case.

Response to: CTR-099-002

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. For a more detailed discussion on this issue, see response to CTR-002-002a.

Comment ID: CTR-101-001a
Comment Author: Cheesemans' Ecology/Brd Safari
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 10/06/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: We would like to thank the EPA for accepting comments on its proposed numeric water quality standards criteria for California surface water. We urge the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-101-001a

Regarding fish consumption, refer to the response to CTR-002-002a.

Comment ID: CTR-102-002
Comment Author: Bryan Gordon
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/10/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: California EPA should not be satisfied that our state's water quality standards are adequate if they only protect the segment of the population that does not have regular or frequent contact with the water or aquatic organisms. Water quality standards should ensure that the state's waterways are pure enough to protect that segment of the population that includes subsistence fish consumers.

Since the Clean Water Act has the goal of making our Nation's waterways "fishable and "swimable", any water quality standards that do not protect the health of that segment of the population that consumes more fish than the prescribed 6.5 grams per day is simply flawed.

Response to: CTR-102-002

See response to CTR-002-002a.

Comment ID: CTR-104-001
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: It has been proven that unacceptable amounts of such toxins as mercury, cioxin and 13 other pollutants are in our state's surface waters. In establishing standards for these toxins, proposed new rules assume fish consumption at 6.5 grams per day. But in certain communities where subsistence anglers eat fish more often, it can amount to one pound daily. Even at 1/4 pound daily, the proposed standards would mean a cancer risk 1000 times higher than current state law states as "acceptable".

We should address the consumption habits of subsistence fishers, as well as the average fish consumer from the general public.

Thank you for your immediate attention to the above.

Response to: CTR-104-001

EPA disagrees with the commenter that persons consuming a quarter pound of fish per day would experience a cancer risk 1,000 times higher than the basis of the CTR. EPA believes that individuals consuming this amount would be protected at approximately a 10-5 risk level and that idividuals consuming up to a pound a day would still be protected at a 10-4 risk level. For a more detailed discussion on this issue, see response to CTR-002-002a.

Comment ID: CTR-104-002b
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-104-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-105-001b
Comment Author: Heather Catherine Park Tausig
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/13/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: I understand that the EPA is currently accepting comments on its proposed numeric water quality standards criteria for California surface water. I am writing to urge the EPA support the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-105-001b

Regarding the fish consumption issue, refer to response to CTR-002-002a.

Comment ID: CTR-106-001
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: It has been proven that unacceptable amounts of such toxins as mercury, cioxin and 13 other pollutants are in our state's surface waters. In establishing standards for these toxins, proposed new rules assume fish consumption at 6.5 grams per day. But in certain communities where subsistence anglers eat fish more often, it can amount to one pound daily. Even at 1/4 pound daily, the proposed standards would mean a cancer risk 1000 times higher than current state law states as "acceptable".

We should address the consumption habits of subsistence fishers, as well as the average fish consumer from the general public.

Thank you for your immediate attention to the above.

Response to: CTR-106-001

See response to CTR-104-001.

Comment ID: CTR-106-002b
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-106-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-109-001a
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: The new water quality standards the EPA is proposing for California surface waters disturbs me greatly. There are several problems with the proposed rules. First in establishing standards for mercury, dioxin, PCBs, and other contaminants, the proposed new rules assume fish consumption at 6.5 grams per day yet consumption of fish in certain communities can be as high as one pound per day, over 60 times more than estimated by the EPA. Please don't underestimate fish consumption by people of different races and cultures.

Please prevent the toxic pollution of California waters by creating more protective standards that consider all toxic pollutants and all consumers of fish. Thank you.

Response to: CTR-109-001a

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. For a more detailed discussion on this issue, see responses to CTR-002-002a and CTR-002-005a.

Comment ID: CTR-109-002b
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Second, the proposed mercury standards fall to account for the bioaccumulation of mercury in fish tissue. The proposed standard ignores mercury that enters fish through their own consumption of food.

Response to: CTR-109-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTRH-001-050b
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-1a

Comment: For mercury, certainly I would concur with the previous comments, that the number should be -- that is appropriate is accumulation factors.

Now the bioconcentration factor, in deference to this state's consumption rates that have been determined are appropriate for California, I think using the average consumption rate for everyone in the country, by definition, lops off about half of the population. It seems to me that it doesn't account for those users of the bay who are the high consumption -- high fish-consumption users, which obviously there's a number of them, and that's not reflected in that average at all.

So I think that those bioaccumulation factors are important to the mercury number base data that we have for the bay for all the reasons stated earlier, and similarly for dioxin. It seems as if EPA would like to back away on that, the criteria that is listed.

Response to: CTRH-001-050b

Regarding the issue on the fish consumption rate, see response to CTR-002-002a. Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTRH-001-053
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: I already mentioned average consumption rate, but 6.5 grams is just not realistic. I have people out fishing every day at -- my office is on the end of a pier in San Francisco, and every day there are at least five or six people fishing off that pier, the same people every day, and some of them are great at it. They throw that line in and get six or seven fish every day, and I'm sure they're eating them.

I can't actually communicate with them very well -- one of them, I can. And people who eat a lot of fish, consuming fish regularly from the bay, 6.5 is really not a realistic number to protect the most sensitive part of the population.

And EPA is doing air rules related to asthma, geared for the most sensitive part of the population, but you get to the water rules and we're looking at very little -- the average for the whole country, even including Montana or Idaho, where -- I don't even know whether fish consumption goes down in the middle of the country, but I have to imagine that in the coastal states it's much higher.

So the average has nothing to do with the most sensitive population. so that should be taken into account. That would adjust some numbers pretty drastically.

Response to: CTRH-001-053

See responses to CTR-002-002a and CTR-002-005a.

Subject Matter Code: C-15 Salinity

Comment ID: CTR-016-004
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-15 Salinity
References:
Attachments? Y
CROSS REFERENCES

Comment: Proposed Application of Saltwater and Freshwater Criteria

In the proposed California Toxics Rule, EPA is proposing to use the definitions in 40 CFR 131.38(c)(3) to determine when saltwater and freshwater criteria should apply to water bodies. The proposal is to use the lower of the freshwater and saltwater criteria when salinities are between less than 1 ppt 95% of the time and greater than 10 ppt 95% of the time. In the 1995 Basin Plan amendments, the Regional Board included a different application procedure. Like EPA, the Regional Board uses the lower of the freshwater and saltwater objectives for estuarine waters, but defines estuarine water as having salinities between less than 5 ppt 75% of the time and greater than 5 ppt 75% of the time, or "tidally influenced fresh waters that support estuarine beneficial uses." The Regional Board elected to use a combination of biological indicators (estuarine beneficial uses) and salinity measurements to define estuarine areas because of the difficulty of accurately depicting estuarine zones using salinity measurements without extensive data spanning channel depth and width, and variability with tides, seasons, and riverine flows.

The Regional Board's definition of how salt and freshwater objectives/ standards will be applied in estuarine waters was part of the 1995 Basin Plan amendments (p. 4-13, first column--attached). Those amendments have been formally approved by all of the appropriate state agencies and have been submitted to EPA for final approval.

We recommend that EPA add a provision to the proposed rulemaking that indicates the primary decision for whether waters are classified as estuarine should be based on the presence of estuarine organisms for any significant period of time and the secondary decision based on salinity measurements. In addition, we request that EPA specifically exclude the proposed federal definition of estuarine waters for implementation of federally promulgated standards within the San Francisco Bay Region (or formally approve the 1995 Basin Plan amendments and indicate that Basin Plan provisions take precedence over provisions in this proposed rule).

Response to: CTR-016-004

Comment ID: CTR-035-030
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: C-15 Salinity
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42183-42184 -- Applicability of Freshwater or Saltwater Aquatic Life Criteria in Estuarine Environments The proposed regulation includes a provision for estuarine waters where the salinity is between 1 and 10 parts per thousand, whereby the more stringent of the freshwater and saltwater criteria would apply unless EPA approves the application of the freshwater or saltwater criteria based on a biological assessment. We challenge the basis for the following rationale put forth in the Preamble: "In the brackish water transition zones of estuaries, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply." We find this conclusion to be questionable; it is equally possible that the saltwater or freshwater species that occur in brackish environments may be more tolerant rather than more sensitive. We recommend that EPA include these procedures for determining appropriate criteria for those instances where salinity is between 1 and 1O parts per thousand as guidance in the Preamble, rather than placing them in the rule itself.

Response to: CTR-035-030

Comment ID: CTR-038-011
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-15 Salinity
References:
Attachments? Y
CROSS REFERENCES

Comment: 10. EPA should allow permit authorities flexibility in establishing saltwater criteria where the salinity is between 1 and 10 parts per thousand. The proposed rule states that for these salinities the more restrictive of the salt and freshwater criteria should apply. This is unnecessary and has the effect of preempting the permit authority's flexibility to apply the most appropriate criteria in any given circumstance. In preempting the permit authority's flexibility, it conflicts with numerous statements in the Preamble and the economic analysis, which point to the considerable flexibility the State has in implementing the criteria.

Response to: CTR-038-011

Comment ID: CTR-054-011
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: C-15 Salinity
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should allow permit authorities flexibility in establishing saltwater criteria where the salinity is between 1 and 10 parts per thousand. The rule states that for these salinities the more restrictive of the salt and freshwater criteria should apply. This is unnecessary and has the effect of preempting the permit authority's flexibility to apply the most appropriate criteria in any given circumstance. In preempting the permit authority's flexibility, it conflicts with numerous statements in the Preamble and the economic analysis, which point to the considerable flexibility the State has in implementing the criteria.

Response to: CTR-054-011

Comment ID: CTR-058-004
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-15 Salinity
References:
Attachments? Y
CROSS REFERENCES

Comment: 3. Freshwater/saltwater. WSPA supports giving permit writers and other regulators flexibility when selecting the appropriate criteria when waters may not be clearly salty or clearly fresh.

EPA proposes to require using the more stringent of freshwater or saltwater criteria when the receiving water is neither >10 ppt salinity 95% of the time (i.e., clearly salty) nor <1 ppt salinity 95% of the time (i.e., clearly fresh). This approach is needlessly inflexible. Permit writers and others should be allowed to judge which criterion is appropriate.

For example, there may be many cases when the freshwater criterion is lower, but the receiving water is salty enough that no freshwater aquatic life could survive. Thus, a freshwater criterion to protect species that are not there is invalid, inappropriate, and potentially wasteful of the state's resources if it causes point sources to invest in treatment merely for treatment's sake. Conversely, a saltwater criterion might be the lower value in a receiving water which is never salty enough to support marine life. A similar argument applies.

Lastly, it will probably be common to find receiving waters which may support both marine and freshwater organisms and in such cases the permit writer would use the more restrictive criterion. Each receiving water should be evaluated based on the facts and the permit writer should be allowed to exercise their professional judgment.

EPA trusts permit writers to select different criteria based on seasonal concerns. There is no reason not

to allow them to select the appropriate criteria I in the'case of ambiguous salinity as well.

Response to: CTR-058-004

Comment ID: CTR-059-011
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-15 Salinity
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Applicability of Freshwater/Saltwater Criteria in Estuarine Environments

We disagree with EPA's proposal in the Preamble to apply the more stringent of the freshwater and saltwater criteria when waters are in an intermediate salinity range or when salinity fluctuates diurnally due to tidal action. We believe a more valid approach is for the State to approve the choice of criteria based on a biological assessment. There may be many cases when the freshwater criterion is lower, but the receiving water is salty enough so that no freshwater aquatic life could survive there. Under this scenario, the application of a freshwater criterion to protect species that are not present is inappropriate and a waste of resources should it trigger the need for additional control efforts. A similar argument applies in cases where a saltwater criterion is used for a receiving water which is never salty enough to support marine life. Each receiving water should be evaluated based on the facts and the permit writer should be allowed to exercise his professional judgment in selecting the appropriate criteria and establishing water quality-based effluent limits. We recommend that EPA delete this provision from the Preamble, and if necessary develop guidance on determining appropriate criteria for those instances where salinity is between 1 and 10 parts per thousand.

Response to: CTR-059-011

Subject Matter Code: C-16 SDWA

Comment ID: CTR-025-001a
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-16 SDWA
References:
Attachments? Y
CROSS REFERENCES C-20

Comment: Proposed California Toxic Rule

The Metropolitan Water District of Southern California (Metropolitan) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (U.S.EPA) proposed California Toxics Rule(CTR). Metropolitan, through its 27 member agencies, supplies nearly 60% of the drinking water used by approximately 16 million people living in the six-county region of Southern California. Our sources of supply are surface waters from Northern California and the Colorado River.

The water quality criteria proposed in the CTR are of critical importance to Metropolitan and other drinking water suppliers. These criteria create the basis for source water protection activities which are the first line of defense for ensuring a safe drinking water supply. Further, the criteria help protect aquatic species, including the unique aquatic resources of the Bay-Delta. The health of the Bay-Delta ecosystem and waters tributary to the Delta is linked to the amount of water available for export and thus directly affects water supply reliability of the exporting water agencies such as Metropolitan. Lastly, the CTR criteria affect the ability of water suppliers to operate and maintain their facilities.

Metropolitan recognizes that the CTR is only required to address the Clean Water Act's "priority pollutants". We note, however, that many of the drinking water contaminants regulated under the Federal and/or California Safe Drinking Water Acts (SDWA) are not among the priority pollutants. Table I lists the drinking water chemical constituents regulated under the California SDWA which are not priority pollutants. (The California SDWA regulates a broader set of contaminants than the Federal SDWA and provides the appropriate regulatory comparison since the CTR pertains solely to California.) Drinking water beneficial, uses cannot be fully protected without water quality criteria for all California SDWA regulated contaminants. Metropolitan requests that U.S. EPA consider including human health criteria for the contaminants listed in Table I as part of the CTR.

Response to: CTR-025-001a

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance the discharge or presence of which could reasonably be expected to interfere with the designated uses of state waters. The promulgation of pollutants that are not identified as priority toxic pollutants (i.e, those pollutants that are not contained in the CWA Section 307(a) list) are outside of the scope of today's rule.

While EPA agrees that there may be other pollutants that adversely impact environmental protection,

EPA notes that states do have the authority to develop and adopt criteria for pollutants that are not contained on the 307(a) list in order to protect the designated uses of their waters. The Water Quality Standards Regulation (see 40 CFR 131) requires all states, including California, to adopt criteria that provide sufficient coverage to protect the designated uses of their waters. Furthermore, where a state has not adopted sufficient coverage of numeric criteria to protect the designated uses, the state may utilize its narrative criteria to derive criteria for pollutants to supplement the numeric criteria.

Comment ID: CTR-025-002b
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-16 SDWA
References:
Attachments? Y
CROSS REFERENCES C-17a

Comment: For California SDWA regulated contaminants which are also priority pollutants, the human health water quality criteria proposed under the CTR and existing California SDWA primary Maximum Contaminant Levels (MCLs) are not always consistent. While CTR criteria apply to source waters and drinking water MCLs apply to finished drinking water, Metropolitan urges that U.S. EPA ensure greater consistency between these regulatory levels.

Table 2 identifies the priority pollutants which have California SDWA primary MCLs and for which the CTR either does not establish any human health criteria or the CTR human health criteria exceed the California SDWA primary MCL. Metropolitan requests that U.S. EPA set the CTR human health criteria for the contaminants in Table 2 at levels not to exceed the California SDWA MCL.

Response to: CTR-025-002b

When multiple criteria apply to a waterbody, the most stringent criterion governs. For instances where California has adopted an MCL as a water quality standard that is more stringent than criteria contained in the final CTR, the MCL would provide the basis for protecting the drinking water use.

Comment ID: CTR-025-003b
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-16 SDWA
References:
Attachments? Y
CROSS REFERENCES C-17a
C-12a

Comment: Human health water quality criteria for a number of other priority pollutants are at levels significantly below the corresponding California SDWA MCL. While Metropolitan favors a margin of safety between human health-water quality criteria and the SDWA MCL, significant differences between these two regulatory requirements can create problems in the course of maintenance of drinking water facilities.

For example, water utilities need to periodically "de-water" their lines as part of routine maintenance. The de-watering of distribution lines transporting treating drinking water results in discharges containing trihalomethanes (THMs). The CTR proposes human health criteria for each of the four compounds comprising the THM classification. The total limit under the CTR for THMs as a group is 11 ug/L, significantly below the California SDWA MCL of 100 ug/L as well as the proposed level of 80 ug/L for Stage 1 of the Disinfection/Disinfectant By-Products Rule. Thus, the discharge of water that meets California SDWA standards could potentially violate CTR human health criteria if that water is discharged to a source of drinking water supply. Metropolitan requests that EPA establish CTR human health criteria for THMs consistent with the California SDWA MCLs for THMS.

Response to: CTR-025-003b

See response to CTR-025-003b.

Comment ID: CTR-025-004b
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-16 SDWA
References:
Attachments? Y
CROSS REFERENCES C-02b

Comment: The proposed CTR freshwater aquatic life criteria for copper are also problematical for many drinking water suppliers. Copper algaecides are a necessary element of algal control strategies for drinking water reservoirs and conveyances. Even with a comprehensive reservoir management program based on immunological principles, copper algaecides need to be part of the algal control arsenal. Algal growth, if uncontrolled, can lead to unacceptable levels of trihalomethanes (THMS) in treated water supplies, among other impacts.

The CTR proposes freshwater aquatic life criteria for copper which could severely hamper the ability of drinking water suppliers to use copper algaecides. The dosage of these algaecides which is effective for controlling algal growth could lead to periodic exceedances of the copper freshwater criteria. Yet, use of copper algaecides is sometimes necessary to protect drinking water beneficial uses, and there is currently no economically feasible alternative available. Drinking water suppliers have the difficult task of meeting conflicting requirements to protect drinking water beneficial uses while ensuring that aquatic life criteria for copper are met.

Response to: CTR-025-004b

See responses to CTR-020-018 and CTR-025-002a.

EPA believes that discharges can meet both the requirements of the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA) after the CTR is promulgated. EPA believes that any final limits for copper would be feasible to meet because it is unlikely that a discharger would receive criteria end-of-pipe limits due to the dilution available in the receiving stream, as well as other factors taken into account, when translating a criterion into a water quality criteria-based effluent limit. EPA acknowledges that controlling trihalomethanes is important, but does not believe it is incompatible with protecting aquatic life in the stream. EPA is including the freshwater copper criteria in today's rule to ensure adequate protection of aquatic organisms in California. EPA also notes that there are some flexibilities and regulatory relief mechanisms that California may exercise to assist dischargers in meeting their permit limits for the criteria included in today's rule. (See preamble discussion on E.O. 12866).

Comment ID: CTR-025-006b
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-16 SDWA
References:
Attachments? Y
CROSS REFERENCES B

Comment: Some of the concerns noted above could be addressed through the implementation provisions of the CTR. As you know, the State Water Resources Control Board has just made available for public review the Proposed Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Proposed ISWP/EBEP Policy), the implementing document for the CTR. Because of the length of the document (several hundred pages) and the fact that it has only recently become available, there has been insufficient time for thorough review. Yet, this document is crucial to understanding the practical impact of the CTR.

Metropolitan strongly requests that U.S. EPA extend the comment period on the CTR to December 10, 1997, the end of the comment period for the Proposed ISWP/EBEP Policy. This would allow drinking water suppliers and others affected by the CTR to evaluate the CTR in the context of its implementation. Without workable implementation provisions, the operational and economic impacts on drinking water suppliers could be significant and may need to be taken into account in the CTR. If the comment period is not extended, we ask that U.S. EPA fully consider the impacts of the freshwater aquatic life criteria on the operation and maintenance activities of drinking water suppliers and the effect on water reclamation activities and to modify the CTR, as necessary, so that these activities can continue to be undertaken in an economically feasible manner.

The CTR forms the backbone of the water quality regulatory process and Metropolitan urges U.S. EPA to review the proposed criteria in light of regulatory requirements of the California/Federal SDWA and the operating and maintenance requirements of drinking water suppliers. If you have any questions regarding Metropolitan's comments, please feel free to call Marcia Torobin of my staff at (213) 217-7830.

Response to: CTR-025-006b

See responses to CTR-025-002b, CTR-025-004b.

Subject Matter Code: C-17 Methodologies

Comment ID: CTR-061-005b
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? Y
CROSS REFERENCES I-03

Comment: Additional Comments

Presented below are some specific comments on statements made in the proposed CTR Federal Register.

Page 42160, third column, near the bottom, municipal stormwater dischargers should be added to the list of NPDES dischargers who have an interest in this rule. If anything, they probably will be affected more than any other entity.

Page 42161, third column, first paragraph, states,

"Numeric criteria for toxic pollutants allow the State and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Numeric criteria also provide a more precise basis for deriving water quality-based effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits to control toxic pollutant discharges."

That statement is somewhat unreliable and misleading.

While it is bureaucratically simpler for regulatory agencies to numerically compare concentrations found in an effluent or in ambient waters with a chemical concentration-based water quality criterion, the claim made in the quoted statement is not necessarily true. In fact, rarely is the exceedance of numeric criteria a reliable basis for assessing the impacts of constituents on human health or the environment. While it may be more precise, it can be highly inaccurate. This is one of the areas that needs to be corrected by the US EPA where biological effects-based approaches are used, rather than chemical-based approaches for regulating such impacts as aquatic life toxicity for potentially toxic constituents.

Response to: CTR-061-005b

EPA agrees that storm water dischargers may be affected by this rule. EPA does not agree that application of numeric criteria, after adjustment by the site-specific water-effect ratio provided by the rule, would rarely be reliable. Also see response to CTR-020-006.

In addition, EPA believes that for the regulated community, the chemical-specific approach offers the advantage of allowing the permittee to focus immediately on a single contaminant for the purposes of designing effluent treatment. In contrast, whole effluent toxicity often leads to a facility conducting fairly extensive investigations to identify the cause of adverse effects on the tested organisms and to

develop an effective approach to reducing the effects.

Comment ID: CTR-061-008
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42162, third column, last paragraph, states,

"The forward to that guidance noted EPA's two-fold water quality based approach to controlling toxic pollutants: chemical specific numeric criteria and biological testing in whole effluent or ambient waters to comply with narrative 'no toxics in toxic amounts' standards. "

That statement was published in 1983 in the US EPA Water Quality Standards Handbook. While the significant technical deficiencies of this two-fold approach have been known now for over 15 years, the Agency has still not addressed the over-regulation that occurs from trying to use chemical concentration-based criteria to regulate biological impacts associated with aquatic life toxicity and excessive bioaccumulation of hazardous chemicals in aquatic life tissue.

Response to: CTR-061-008

EPA does not agree. EPA believes that the rule's provision for site-specific adjustments to criteria addresses the problem of unnecessarily stringent chemical criteria. See response to CTR-061-005b. With respect to bioaccumulative chemical risks, EPA believes that the best way to monitor bioaccumulative chemicals is to measure the concentration in the portions or tissues of aquatic biota that are consumed by humans and wildlife.

Comment ID: CTR-061-009
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42163, first column, last paragraph, states,

"Congress was frustrated that states were not using the numerous CWA section 304(a) criteria guidance that EPA had and was continuing to develop, to assist states in controlling the discharge of priority toxic pollutants. "

The reason the states were not adopting those criteria was that the criteria as implemented tend to over-regulate. The criteria do not properly consider how chemical constituents impact beneficial uses. The US EPA's adjustments of the criteria do not properly incorporate the aqueous environmental chemistry of the constituents in developing site-specific criteria. Basically, there is still a significant problem with how the US EPA developed criteria relative to how they are implemented at the state and local level. I was involved as a US EPA invited peer-reviewer of the criteria development approach, as well as several criterion documents that became part of the "Gold Book" criteria. I am, therefore, familiar with this topic area and know that it was never the intent of those who helped develop those criteria to have them mechanically implemented, as is being done today, into discharge limits. This leads to significant over-regulation and significant waste of public and private funds in construction of unnecessary treatment works beyond those that would be needed to protect the designated beneficial uses of a waterbody.

One of the fundamental problems that exist today is the US EPA's Independent Applicability Policy. That Policy was adopted without public review in the early 1990s. It establishes that chemical-specific criteria must be met, even if appropriately conducted biological assessments of toxicity, bioaccumulation, etc. show that the chemical-specific criteria are technically invalid for the particular situation of concern. This is a fundamentally flawed approach that should be terminated. This issue has been discussed in a paper, "Independent Applicability of Chemical and Biological Criteria/standards and Effluent Toxicity Testing" (Lee and Jones-Lee, 1995). While the US EPA criteria and standards group in Washington, D.C. has indicated that it is proposing to change the Independent Applicability Policy, the proposed changes as discussed thus far are not adequate to eliminate the fundamentally technically flawed aspects. The purpose of water quality criteria and standards is to protect designated beneficial uses, which for aquatic life means to prevent toxicity as might be measured by the kinds of tests that were used to establish the criteria. It is inappropriate to require achieving chemical-specific criteria as they currently exist, in waters in which there is no toxicity; that Independent Applicability Policy is obviously fundamentally flawed and should not be perpetuated.

Response to: CTR-061-009

EPA does not agree that the criteria, when adjusted for site-specific factors as provided by the rule, do not properly consider how chemical constituents impact beneficial uses. In setting criteria, EPA considers the scientific evidence of the toxicity of a pollutant. EPA stands behind the judgements made in its derivation of the criteria, and believes these judgements are reasonable.

The independent application policy is outside the scope of this rule. Nevertheless, independent application means that in stream biological monitoring and ambient or effluent toxicity testing can be used in a scientifically sound procedure for site-specific modification of the chemical criteria, but may not be used as a rationale simply to suspend implementation of the criteria.

Comment ID: CTR-061-010
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42168, first column, first paragraph, states,

"EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time, but not necessarily all of the species all of the time (1985 Guidelines, page 1). EPA 's 1985 Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of substantial overprotection or underprotection. "

While the statement is appropriate for under-protection for the regulated chemicals, it is inappropriate for over-protection. Many of the water quality criteria tend to grossly over-protect based on the way they are implemented. This applies even to metals implemented as salt species.

Response to: CTR-061-010

EPA does not believe that the rule's provisions tend to grossly over-protect. The rule includes some provisions to modify criteria concentrations, averaging periods, and allowable exceedance frequencies to avoid either over- or under-protection.

Comment ID: CTR-061-011
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42168, first column, first paragraph, the statement, "The approach EPA is using is believed to be as well balanced as possible, given the state of the science." is inappropriate. The US EPA has still not graduated to the level of science that was present as part of the National Academies of Science and Engineering "Blue Book" "Water Quality Criteria" which focused on directly measuring toxicity of chemicals rather than trying to estimate toxicity through chemical-specific criteria.

Response to: CTR-061-011

EPA stands behind its technical assumptions made in the derivation of its criteria, and believes the resulting criteria are reasonable. EPA believes the calculation of water quality criteria for aquatic life based on toxicity data for aquatic species is appropriate. Congress further endorsed this approach in the 1987 amendments that added section 303(c)(2)(B) to the CWA.

EPA does not believe that chemical-specific criteria are inconsistent with the 1972 Blue Book approach. The Blue Book recommended numerous chemical-specific criteria, where available toxicity data were sufficient to support them.

Comment ID: CTR-096-001b
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17 Methodologies
References:
Attachments? N
CROSS REFERENCES I-03

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

1. The numerical standards are ambiguous or incomplete to address the variety of operating conditions under which discharges to waters of the United State occur.

Specifically, the City submits the following comments:

A. California's receiving waters have a very wide diversity of hydraulic and environmental conditions. The numerical standards do not take into account the wide range of rainfall patterns, storm durations, irrigation flows and power generation flows that are the current aquatic habitat. California's rivers are highly regulated, highly managed. The proposed regulations neither address this variety, nor provide a means by which numerical standards can be readily developed to address such variety.

B. The California Toxic Rule presents new water quality standards for the State of California. This rule presents water quality standards for all water bodies within the state. Water quality standards as presented in this rule would apply to all environmental conditions (dry and wet weather). During wet weather, conditions in the receiving streams can be extremely variable due to the quality and quantity of stormwater. Treatment plants generally have hydraulic capacity to process twice the average dry weather flow received. Water quality standards were developed based on dry weather conditions. Therefore, numerical water quality standards should not need to be achieved during storm events. If water quality standards need to be achieved during storm conditions, it is suggested that new standards be developed to account for the changes in environmental conditions.

Response to: CTR-096-001b

The criteria specified in the rule are adequate across California because they are designed to apply under all environmental conditions. EPA does not agree that its criteria concentrations were based on dry-weather conditions. Most of concentrations are based on laboratory toxicity tests. EPA agrees that its numerical exceedance frequency and design flow specifications are based on dry-weather conditions. Nevertheless, the rule provides for alternative development of averaging periods and exceedance frequencies, thereby allowing the extension of their applicability to wet-weather conditions. In addition, the Rule provides for site-specific modifications of criteria concentrations, to account for a site's water

quality characteristics.

The criteria specified in the rule are adequate across California because they are designed to apply under all environmental conditions. EPA does not agree that its criteria concentrations were based on dry-weather conditions. Most of concentrations are based on laboratory toxicity tests. EPA agrees that its numerical exceedance frequency and design flow specifications are based on dry-weather conditions. Nevertheless, the rule provides for alternative development of averaging periods and exceedance frequencies, thereby allowing the extension of their applicability to wet-weather conditions. In addition, the Rule provides for site-specific modifications of criteria concentrations, to account for a site's water quality
characteristics.

Subject Matter Code: C-17a Methodologies Human Health

Comment ID: CTR-002-002b
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? Y
CROSS REFERENCES C-14

Comment: I. TOXIC POLLUTANTS THREATEN PUBLIC HEALTH AND SAN FRANCISCO BAY.

Toxic pollution causes harm in San Francisco Bay. Species of bivalve shellfish, plankton and phytoplankton that are especially vulnerable to toxic trace elements such as copper are decimated in its southern reach though they thrive in comparable estuaries with less metals pollution. (*1) (*2) Mounting evidence suggests its sediment is toxic to some aquatic life.(*3) Extensive research strongly suggests that PCBs and PAHs released to the Bay negatively effect reproduction in starry flounder. (*4) Reproductive effects are also correlated with PCBs in Bay cormorant eggs, Bay harbor seals have PCBs levels twice those associated with immunotoxicity and a disease epidemic that decimated a European population of this species.(*5) Health advisories are in effect because dioxin, PCBS, mercury, chlordane, DDT, dieldrin, and selenium contaminate Bay food resources eaten by the public (*6) (*7)

Public health threats from toxics in the food chain are of particular concern. A recent count found approximately 270,000 fishing licenses were issued to Bay Area residents. Surveys by CBESAFER!, the Save San Francisco Bay Association, and the Asian Pacific Environmental Network show that many people fish the Bay regularly to supplement their families' diet, that some people eat up to a maximum of a pound of fish per day, and that the majority of those who eat their catch regularly are people of color. [See attachment (*8)] A pound of fish per day is about 480 oz./month, sixty times the 8 oz./month "safety" cutoff for cancer and slow learning in the state's advisory.(*6)

In addition to these severe environmental health and justice problems, pollutant monitoring of the Bay is far from comprehensive, and undetected problems are likely. Indeed, EPA acknowledged that designated uses of the Bay are threatened or impaired by toxic pollutants when it named the Bay as a "toxic hot spot" under Section 304(l) of the Clean Water Act.(*9)

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.

(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten other estuaries. Communities for a Better Environment (CBE). July, 1992.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control

value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH concentrations in San Francisco Bay waters.

(*4) Spies et al., (2 papers), 1988: Effects of organic contaminants on reproduction of the starry flounder Platichthys stellatus in San Francisco Bay, I., Hepatic contamination and mixed-function oxidase (MFO) activity during the reproductive season. Marine Biology 98: 181-189; and II. Reproductive success of fish captured in San Francisco Bay and spawned in the laboratory. Marine Biology 98: 191-200. Excerpt including abstracts.

(*5) Kopec and Harvey, 1995, Toxic pollutants, health indices, and population dynamics of harbor seals in San Francisco Bay, 1989-1992. Moss Landing Marine Laboratories Technical Publication 96-4. ISSN 1088-2413. October, 1995. Excerpt regarding PCBs levels as compared to European seals in which a disease epidemic and population crash was observed.

(*6) Cal. EPA, 1994. Health advisory on catching and eating fish, interim sport fish advisory for San Francisco Bay. December, 1994.

(*7) California Department of Health Services, 1994. Health Warnings, Contained in the 1994 California Hunting Regulations for Resident and Migratory Game Birds issues by the state's Fish and Game Commission, Sacramento, Calif. Excerpt including health warning for selenium.

(*8) Previously unpublished data from a 1993-4 survey of 500 anglers using South and Central San Francisco Bay by Communities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994.(excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence..

(*9) EPA, 1990. Decision of the United States Environmental Protection Agency on listing under section 304(l) of the Clean Water Act regarding the state of California. Excerpt including pages listing San Francisco Bay waters as a "toxic hot spot."

Response to: CTR-002-002b

EPA acknowledges the impacts of pollution in the San Francisco Bay. Regarding the issue of fish consumption, refer to response to CTR-002-002a on this same issue.

Comment ID: CTR-002-004a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? Y
CROSS REFERENCES C-17b

Comment: B. The criteria do not control pollution that harms fishing, and aquatic life.

Adoption of EPA's proposed criteria values will result in less control of toxic pollutants that exceed state criteria values in large parts of San Francisco Bay. Examples of this problem are shown in tables 3 through 6 for mercury, copper, nickel and PAH measured in 1995 at monitoring stations shown on a map of San Francisco Bay (Figure 1). The EPA-proposed criteria would allow:

- mercury violations triggered by state criteria values through much of the northern reach of the Bay. EPA-proposed criteria trigger violations only at the Petaluma river mouth and in South Bay. Bay-wide, 8 of 15 state criteria-triggered violations (53%) are allowed by EPA criteria.

- copper violations triggered by state criteria (4.9 ug/L total) throughout the northern reach of the Bay. EPA'S 3.1 ug/L dissolved value triggers violations only in the Petaluma river and in' South Bay. Bay-wide, 15 of 25 state-triggered violations (60%) are allowed by EPA criteria,

- nickel violations triggered by state criteria throughout most of the northern and southern reaches of the Bay. EPA's 8.2 ug/L dissolved value triggers violations at the Petaluma river mouth and one South Bay slough. Bay-wide, 20 of the 22 water quality standards violations (91 %) triggered by the 7.1 ug/L criterion are allowed by EPA criteria.

- PAH violations triggered by state criteria at Coyote Creek and the Petaluma River mouth, EPA-proposed criteria trigger 4 violations for benzo(a)pyrene and indeno(1,2,3-cd)pyrene while state criteria trigger 40 violations for these compounds and 6 other PAHS.

Though EPA criteria do not control mercury except at the Petaluma River and in South Bay, a state human health advisory cites mercury contamination,(*6) and demonstrates that mercury restricts fishing uses Bay-wide. A severe threat and possible harm to aquatic life of the Bay's entire southern reach is evidenced by reduced abundance of all species known to be most vulnerable to copper toxicity, while these same species thrive in otherwise similar estuaries with less copper and nickel pollution.(*1) (*2) EPA criteria do not control copper and nickel in most of this area. Nor do EPA criteria control PAHs which -- with PCBs -- cause toxic effects in starry flounder in Central Bay.(*4)

Further, EPA'S proposed criteria include no criteria for 16 dioxin compounds that are included in the state dioxin criterion for TCDD equivalents.(*10) (*21) These 16 compounds are 6 dibenzo-paradioxins chlorinated in the 2,3,7, and 8 positions (except for 2,3,7,8-TCDD which is included in the EPA criterion), and 10 dibenzofurans chlorinated in the 2,3,7 and 8 positions. Under the state criteria, these 16 compounds and 2,3,7,8-TCDD are assigned toxicity equivalence factors as discussed in the proposed rule. Under the state criterion all these compounds are limited: if only 2,3,7,8-TCDD is present it cannot exceed 0.014 pg/L; if only OCDD is present it cannot exceed 14 pg/L; and if a mixture of dioxins is present the sum of their toxicities cannot exceed 0.014 pg/L. By failing to use toxicity equivalents and then failing to propose separate criteria for these 16 compounds, EPA is essentially deregulating 16 of the most toxic chemicals known to science even though these dioxins harm fishing uses, as shown by the health advisory discussed above. (*6)

The EPA criteria do not control toxics that threaten and harm the Bay, fishing and public health.

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.

(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten

other estuaries. Communities for a Better Environment (CBE). July, 1992.

(*4) Spies et al., (2 papers), 1988: Effects of organic contaminants on reproduction of the starry flounder Platichthys stellatus in San Francisco Bay, I., Hepatic contamination and mixed-function oxidase (MFO) activity during the reproductive season. Marine Biology 98: 181-189; and II. Reproductive success of fish captured in San Francisco Bay and spawned in the laboratory. Marine Biology 98: 191-200. Excerpt including abstracts.

(*6) Cal. EPA, 1994. Health advisory on catching and eating fish, interim sport fish advisory for San Francisco Bay. December, 1994.

(*10) California State Water Resources Control Board, 1991. California Enclosed Bays and Estuaries Plan; water quality control plan for enclosed bays and estuaries in California. 91-13WQ. April, 1991. Excerpt including adopted water quality criteria and definition of terms.

(*21) California State Water Resources Control Board, 1997. Staff technical report, Division of Water Quality, Petitions of CBE, San Francisco BayKeeper, and Tosco Corporation for review of Order No. 95-138 of the San Francisco Bay Regional Water Quality Control Board. Office of Chief Counsel [OCC File Nos. A-983 and A-983(A)].

Response to: CTR-002-004a

See response to CTR-002-004b.

Comment ID: CTR-025-002a
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? Y
CROSS REFERENCES C-16

Comment: For California SDWA regulated contaminants which are also priority pollutants, the human health water quality criteria proposed under the CTR and existing California SDWA primary Maximum Contaminant Levels (MCLs) are not always consistent. While CTR criteria apply to source waters and drinking water MCLs apply to finished drinking water, Metropolitan urges that U.S. EPA ensure greater consistency between these regulatory levels.

Table 2 identifies the priority pollutants which have California SDWA primary MCLs and for which the CTR either does not establish any human health criteria or the CTR human health criteria exceed the California SDWA primary MCL. Metropolitan requests that U.S. EPA set the CTR human health criteria for the contaminants in Table 2 at levels not to exceed the California SDWA MCL.

Response to: CTR-025-002a

With respect to the issue of pollutants where the MCL is more stringent than the CTR criterion, EPA has determined that the CTR criteria are appropriate. As background, the Agency agrees with the commenter that the SDWA Maximum Contaminant Levels (MCLs) and the ambient water quality criteria are not always consistent. There are several reasons why this may be the case. First, while water quality criteria are health-based values only, MCLs take into account availability of treatment technologies and associated costs, and the availability of analytical methods. Second, the methodologies between the two programs differ in numerous ways, including the way that carcinogens are handled, the selection of the risk level, the approach to accounting for exposure, and the fact that water quality criteria specifically account for fish exposure. Third, there are differences associated with the fact that the information that each criterion is based on at the time of development also varies. That is, criteria developed at different times for the same chemical may be based on different exposure data and/or toxicity studies. The MCLs also apply to the chemical concentration in public water supply distributed tap water, whereas water quality criteria are used to develop State standards which are then used with water transport models to derive permit limits for point source discharges. For a more detailed discussion on the reasons for differences between these two methodologies, refer to the Notice of Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (Federal Register, Vol. 63, No. 157, August 14, 1998). See also 63 FR 36742, 36775-36777 (July 7, 1998).

The Agency believes that for a given pollutant, the drinking water component of a water quality criterion should be consistent with the Maximum Contaminant Level Goal (MCLG) and is working to foster greater consistency between these two programs. Specifically, the Agency is currently revising the water quality criteria human health methodology, referenced above. Once finalized, EPA will revisit the methodology for deriving MCLGs, again, with a focus toward greater consistency.

The following policy is that recommended in the draft EPA methodology revisions when either water quality criteria have not been established or when the water quality criteria exceed MCL values. Although the use of MCLs is acceptable in the absence of 304(a) criteria, EPA is recommending that MCLs only be used when they are numerically the same as the MCLG and only when the sole concern is the protection of public water supply sources and not the protection of the CWA section 101(a) goal regarding fish consumption (e.g., where the chemically toxic form in water is not the form found in fish tissue and, therefore, fish ingestion exposure is not an issue of concern). Where consideration of available treatment technology, costs, or availability of analytical methodologies has resulted in MCLs that are less protective than MCLGs or water quality criteria, States and Tribes should consider using MCLGs and/or the health-based water quality criteria to protect water uses. Where fish consumption is an existing or potential activity, States and Tribes should ensure that their adopted human health criteria adequately address this exposure route. When fish consumption is a use, EPA recommends development of water quality criteria due to the fact that fish consumption and bioaccumulation are explicitly addressed. In all cases, water quality criteria should be set to ensure that all routes of exposure have been considered. EPA believes if water monitored at existing drinking water intakes has concentrations at or below MCLGs, then the water could be considered to meet a designated use under the CWA as a drinking water supply. In situations where a 304(a)criterion was less protective than an MCL, it is permissible to use the MCL as the criterion for segments designated as drinking water supplies. For carcinogens where the MCLG is equal to zero, States are encouraged to base water quality criteria at the drinking water intake on an acceptable cancer risk level (i.e., a level within the range of 10-4 to 10-6), to promote pollution prevention and anti-degradation.

The commenter has provided a short list indicating where some of the proposed CTR human health criteria are less stringent than the California MCLs. In some cases, the listed MCL has been developed by the State of California only - that is, there is no EPA national SDWA MCL (e.g., 1,3-dichloropropene, nickel). In some cases, California's MCL is more stringent than EPA's national SDWA MCL (e.g.,

benzene, vinyl chloride). However, where MCLs are more stringent than the CTR criteria, EPA has chosen not to revise the CTR number to make it the same as the MCL because the CTR criteria are adequate to protect the designated use.

As stated above, EPA is in the process of revising its water quality criteria human health methodology. EPA is currently reviewing public comments and is awaiting the results of a peer review on the published draft revisions. Again, as part of this effort, EPA intends to foster greater consistency between its drinking water and surface water programs, where appropriate.

Comment ID: CTR-025-003a
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? Y
CROSS REFERENCES C-16
C-12a

Comment: Human health water quality criteria for a number of other priority pollutants are at levels significantly below the corresponding California SDWA MCL. While Metropolitan favors a margin of safety between human health-water quality criteria and the SDWA MCL, significant differences between these two regulatory requirements can create problems in the course of maintenance of drinking water facilities.

For example, water utilities need to periodically "de-water" their lines as part of routine maintenance. The de-watering of distribution lines transporting treating drinking water results in discharges containing trihalomethanes (THMs). The CTR proposes human health criteria for each of the four compounds comprising the THM classification. The total limit under the CTR for THMs as a group is 11 ug/L, significantly below the California SDWA MCL of 100 ug/L as well as the proposed level of 80 ug/L for Stage 1 of the Disinfection/Disinfectant By-Products Rule. Thus, the discharge of water that meets California SDWA standards could potentially violate CTR human health criteria if that water is discharged to a source of drinking water supply. Metropolitan requests that EPA establish CTR human health criteria for THMs consistent with the California SDWA MCLs for THMS.

Response to: CTR-025-003a

In general, EPA believes it is appropriate that water quality criteria are at levels below MCLs in consideration of the Agency's goals of pollution prevention. That is, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment. However, there are numerous reasons why a water quality criterion may not be the same as an MCL. This is discussed in the response to CTR-025-002a.

Regarding the issue of the proposed human health criteria for trihalomethanes (THMs), the commenter has made an inappropriate comparison between the values in the CTR and the Stage I

Disinfection/Disinfectant By-Product (DDBP) Rule. The commenter has attempted to add the separate values proposed in the CTR for each individual THM and compare that total to the DDBP value, which represents total THMs. These values cannot be compared directly because the basis for their derivation is significantly different. The THM values in the CTR are based on four separate cancer potency factor values (i.e., q1* values) and a chosen acceptable cancer risk level (specifically, a 10-6 risk level), which were then both used in the water quality criteria equation (which includes factors for body weight, water ingestion, fish consumption, and bioconcentration) to derive the individual criteria values. The DDBP Rule that determined the MCL for total THMs - a composite value for all four THMs combined - was based on a weight-of-evidence approach that considered the available toxicological data, known epidemiological information on the incidence of disease associated with chlorinated drinking water (i.e., morbidity rates), information on the relative proportions and uncertainties in the composition of total THMs (including regional and seasonal variation, as well as other variables and their uncertainties) and technological feasibility. The MCLs were the output of an extensive "regulatory negotiation" between EPA and stakeholders. The approach used in the DDBP Rule is vastly different from the ambient water quality criteria calculations used for the CTR. Additionally, the water quality criteria derivations are health-based values only, whereas the MCLs include consideration of economic and feasibility issues, as was the case with the DDBP regulatory negotiation.

Regarding the commenter's concern for the periodic "dewatering" of utility lines, refer to the response to CTR-020-018.

Comment ID: CTR-026-003b
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-17b

Comment: 3 . TOXICITY DATABASE USED TO DEVELOP CRITERIA

The CTR indicates that the criteria being proposed are based upon a review of the most recent literature and toxicity data bases. The DFG is concerned that the databases utilized by EPA may not be as comprehensive as they could be with respect to inclusion of toxicity studies on a wide variety indigenous species found in State waters. Furthermore, data included in such databases such as EPA's AQUIRE have been found, in some instances, to be less than acceptable. Obviously we would like to see the criteria based on the most recent and scientifically sound toxicity data available. The DFG believes that it would be beneficial to describe in more detail the literature and databases utilized by EPA in development of the proposed criteria.

Also a discussion on appropriate and acceptable methodologies for data collection needs to be provided. It is not only important that the databases utilized by EPA be as comprehensive as possible, with respect to the inclusion of toxicity studies on a wide variety of indigenous species found in State waters. It is also important to know how the data was developed so that it won't be misinterpreted. For example, DFG would prefer using data that was derived from sampling whole organisms rather than edible filets if

we were looking at bioaccumulation, biomagnification, or other types of food chain issues. Most predators don't limit their diet to only the edible portions of a prey organism. Sampling only the edible portions of an organism could lead to faulty conclusions.

Finally, with regards to the development of chronic toxicity standards or criteria based on a straight percentage of the determined acute toxicity level, we would like to participate in any process that attempts to establish chronic levels in that manner.

Response to: CTR-026-003b

Regarding the comment on comprehensive evaluation of toxicity data, refer to the response to CTR-026-003a. Regarding the comment on sampling, edible portions are relevant when deriving human health criteria. Therefore, the practice of sampling edible filets is appropriate. The commenter's statement on the use of whole organisms because "most predators don't limit their diet to only the edible portions of a prey organism" is not relevant because the aquatic life criteria derivation process does not rely on the use of BCFs.

Comment ID: CTR-026-007b
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-14

Comment: 7. HUMAN HEALTH CRITERIA

As you are aware the Department of Fish and Game is the trustee for the natural resources of the State and, as such we are not in an appropriate position to address human health issues. However, we would like to take this opportunity to make EPA aware of our concerns in two areas. The first issue deals with one component of the formula that was used to derive the human health criteria. Obviously, the human health criteria takes into account fish consumption rates, as well as what portion of the fish is consumed. The CTR indicates that the consumption rate utilized was 6.5 grams per day of fish tissue. This consumption rate, at least for the portion of the population that are subsistence fishermen, appears to be very low. If the human health criteria is to be adequately protective, this consumption rate should be revisited and a new rate developed to better protect these fishermen. Our second comment deals with the proposal to base criteria on fish tissue as opposed to water concentration. The DFG does not have a position with respect to this approach except to point out that compliance monitoring for fish tissue criteria may impact resources. This approach would mean an increased number of fish being collected for monitoring purposes which may impact fish resources. It may also impact the DFG's fiscal resources since we regulate scientific collection activity under which fish monitoring would fall.

Response to: CTR-026-007b

Regarding the issue of fish consumption, refer to the response to CTR-002-002a on this same issue.

Regarding the issue of basing the criteria on fish tissue versus water column concentrations, refer to the response to CTR-020-004b on this same issue.

Comment ID: CTR-029-002a
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-17b
A
C-22
C-27
C-29

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the published guidance documents is "insignificant"(*4); however, in light of the current contamination problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be under protective because additive and synergistic effects were not considered; and because the effects on

wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest. criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).

(*5) Id. at 42168.

(*6) Id. at 42172.

Response to: CTR-029-002a

Regarding the evaluation and protectiveness of the proposed criteria, the commenter states that many of the criteria in the proposed rule "are weaker than those contained in published guidance." However, EPA has updated its national criteria guidance from that previously published. The values proposed in the CTR are a part of that update and, therefore, there is now consistency with all criteria values [see 63 FR 68353-68364 (December 10, 1998)]. Regarding the issue of fish consumption, refer to the response to CTR-002-002a on this same issue.

Comment ID: CTR-031-002b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES F
C-17b
J
V

Comment: 2. Since the preamble implies that CTR criteria may be applied in NPDES permits for municipal storm water dischargers as numeric effluent limitations, the proposed rule is flawed with regard to: a) setting attainable, scientifically valid criteria in a manner consistent with state and federal regulatory approaches; b) assessing the potential economic impact on the public served by municipal storm water dischargers; c) assessing environmental impacts pursuant to the National Environmental Policy Act and the Endangered Species Act; and d) providing for the coordinated review and evaluation of the proposed CTR in conjunction with the proposed State Implementation Plan. y

Response to: CTR-031-002b

With respect to comments about municipal stormwater discharges see response to CTR-013-003 (Category J; Stormwater Economics).

With respect to comments about the Endangered Species Act see response to CTR-031-002e (Category V; Collaborative Approach).

With respect to the comment about coordination with the State Implementation Plan see response to CTR-031-008b (Category V; Collaborative Approach).

Comment ID: CTR-031-004a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES C-17b
I

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

ii. Scientific Defensibility of Standards

Municipal storm water discharges require a uniquely different scientific as well as regulatory approach. The episodic nature of storm flow events; the huge variances in flow volume, rate, timing, concentrations, and loads; the variability in receiving waters; and organism tolerance for and recovery f rom episodic exposure need to be taken into account in developing standards.

In a July 1992 memorandum addressing a Combined Sewer Overflow/Wet Weather workshop, Tudor Davies, Director of EPA's Office of Science and Technology wrote: "Changes being considered in the aquatic criteria development methodology to enhance the scientific defensibility of the criteria would be applicable to both constant and to wet weather discharges. One such change undergoing consideration is a change in the duration and frequency of exposure assumptions to make criterion more toxicologically realistic.

EPA has begun this work and is apparently nearing completion. With EPA's own Science and Technology office recognizing the inadequacy of the current approach to setting criteria relative to wet weather discharges, it must be concluded any attempt to apply the CTR criteria to municipal stormwater system discharges is ill-founded and likely inconsistent with the CWA.

Response to: CTR-031-004a

See response to CTR-031-004c.

Comment ID: CTR-037-003b
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-17b

Comment: 3. EPA has deleted data from several databases without indicating the reason for the deletions. This introduces the same problem as that described in #2 above, and results in variability in how water quality criteria are developed. Additionally, stakeholders need to know why data is deleted so that these decision criteria can be used in the development of defensible site-specific criteria. EPA should provide their reasoning for deleting data that was once believed acceptable so that this same reasoning can be used to update current criteria and to develop new sound criteria.

Response to: CTR-037-003b

See response to CTR-037-003a (Category C-17b; Methodologies Aquatic Life).

Comment ID: CTR-057-007
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Organics

In proposing criteria for toxic organic compounds, we urge the EPA to include considerations of net environmental benefit. We see a potential for stringent pollutant limits as a means of influencing

replacements in the service area by other, equally toxic constituents. We have seen this occur to varying extent for chromium, selenium, zinc and molybdenum, and feel that similar instances involving trace organics can occur as well. We support the EPA's intention to evaluate receiving-water background concentrations and provide credit as appropriate.

Response to: CTR-057-007

"Net environmental benefit" is not an appropriate concept for establishing ambient water quality criteria. Ambient water quality criteria, as articulated in CWA Section 304, are supposed to characterize "all identifiable effects" from individual pollutants. See response to CTR-042-007a (Category C-21; Legal Issues). Ambient water quality criteria define the maximum pollutant concentrations allowable in order to maintain a specific designated use. The concept of "net environmental benefit" can be incorporated into other aspects of water quality standards if a State or Tribe so chooses. Designated uses, variances, and antidegradation all allow for the balancing of water quality goals with community priorities. For example, a community may choose to downgrade the designated use for a waterbody to address exceedances of specific chemical criteria because remediation of contaminated sediments (in this case, the source of loading to the water column) through dredging would cause more harm to the biological community through habitat destruction although the chemical concentrations for individual pollutants would decrease as a result. The CTR does not affect California's flexibility with respect to designated uses, variances, and antidegradation.

Comment ID: CTR-065-002b
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES A
C-17b

Comment: PROPOSED RULE ALLOWS SIGNIFICANT AND UNACCEPTABLE INCREASES IN TOXIC POLLUTANT CONCENTRATIONS IN BAYS AND ESTUARIES

Our initial review indicates that the proposed criteria for a number of toxic constituents are unacceptably high and will allow more pollution of bays and estuaries by several orders of magnitude. If adopted as proposed, the CTR will allow a 900% increase of dioxin, 140% increase of PCBS, 325% increase of mercury, 2760% increase of zinc, 23,000% increase of lead, and a stunning 430 million % increase for total PAH, some of the most problematic pollutants in San Diego Bay. The CTR only improves (i.e. strengthens) criteria for only 3 of 64 pollutants. This does not square with new studies that show reasons for concern about the synergistic and long-term effects of exposures to these toxic pollutants. In sum, the CTR proposes weaker criteria for 58% of the pollutants and no change for 37% of the criteria. This kind of action will not bring us closer to our goal of cleaner water containing healthier organisms in the future.

Response to: CTR-065-002b

See response to CTR-002-003 (Category C-24; Site-Specific Criteria).

Comment ID: CTR-090-002a
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-24a
C-22
G-05
G-02
G-04

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002a

EPA agrees with the comment and its endorsement of the rule.

Comment ID: CTR-090-019
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17a Methodologies Human Health
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Human health criteria - p 42175 - Human Health Criteria - These criteria are based on a hypothetical series of events. Each link in the series must be present for the presumed risk to occur at the levels used to set the criteria. The links assumed to be present in the criteria include: (1) Non-degradation in the receiving water - Some regulated pollutants (various PAHs) rapidly break down in receiving waters.

(2) Continued presence in the receiving water at the level of discharge or at the calculated dilution level - Implementation plans and policies give no dilution credit or use very conservative dilution assumptions. As implemented in California, none of the dilution equations take into account far-field effect-, nor the time-averaging effects which in reality typically reduce concentrations to far below those assumed in the risk assessment. The result is as if we assumed that the human endpoint on the risk assessment only ate fish which lived within a few feet of the outfall.

(3) Bioaccumulation in fish or other higher organisms; non-degradation in these organisms - The bioaccumulation assumptions are based on the worst case bioaccumulation encountered in the scientific literature rather than the bioaccumulation actually taking place in commercial species in the waters in question- Not infrequently, tissue samples from food species indicate that less Bioaccumulation is taking place. Another complicating factor is that bioaccumulation factors are derived from steady-state conditions, whereas municipal discharges of chlorinated hydrocarbon carcinogens are usually episodic. Use of steady-state derived water concentration to tissue concentration relationships is especially problematic for wet-weather discharges, as these have durations measured in hours to days, whereas bioconcentration in mature (i.e. legal sized) fish occurs over weeks to months.

(4) Pervasive contamination - Ongoing consumption by humans of contaminated fish (or shellfish) with the level of contamination.

(5) Necessary safety factors - Assumed carcinogenicity or toxicity to humans at 10 or 100 times the frequency experienced by test animals. These safety factors are necessary but their overall effect is to significantly decrease the likely impact of the pollutant (i.e., shift a 10E-6 risk to 10E-7 or 10E-8). EPA's Cancer potency factors are based on an upper bound, i.e. 95 % percentile estimate of the slope.

(6) Non-threshold effects - Carcinogenicity is assumed to have no threshold mechanisms, i.e., there is no low level below which the human body can safely detoxify the carcinogen.

While the use of this chain of events and these assumptions are necessary to identify potential problems, the cumulative uncertainty creates too speculative a result to use for decisions regarding significant expenditures for remedial projects. Better sources of risk information are available, specifically, tissue samples from the organisms presumed to be carrying the risk to humans. What we propose is a three step process prior to controls being mandated for dischargers:

1. numerical criteria to identify potential risks. 2. site specific tissue samples of edible species to identify actual bioaccumulation (as has been done in San Francisco Bay with PCBs and other chemicals). 3. source assessment to determine if prospective controls on point sources provide meaningful reductions.

This approach is within EPA's mandate to set criteria and implement a permit program which meets the goals of the CWA.

San Francisco proposes that the designation of an appropriate level(s) be left to the state in its implementation documents.

Response to: CTR-090-019

EPA disagrees with the commenter that "... bioaccumulation assumptions are based on the worst case bioaccumulation encounter in the scientific literature ...". EPA has and will continue to use the best available science in the selection of the bioaccumulation data for the development of ambient water quality criteria. In the process of selecting bioaccumulation data, all published data are carefully evaluated and bioaccumulation factors are determined using all possible methods. The bioaccumulation data selected in this process for use in the development of water quality criteria represents the best synthesis and consensus of all available scientific information. The commenter also states that "... tissue samples from food species indicate that less bioaccumulation is taking place." However, no supporting information was provided nor were citations from the scientific literature provided. EPA disagrees with the commenter. EPA has and will continue to use the best available science in the selection of the bioaccumulation data for the development of ambient water quality criteria. The commenter further suggests that bioaccumulation factors developed using long term average concentrations in fish and the water are inappropriate for developing ambient water quality criteria for persistent bioaccumulative chemicals. EPA disagrees with the commenter. For human health, EPA uses lifetime consumption rates in setting acceptable doses/exposures for bioaccumulative chemicals and to be consistent with the dose/exposure basis, bioaccumulation factors must be developed using long term average concentrations as well. Regarding the commenter's statements on the chemical degradation of various PAHs, refer to the response to CTR-060-014.

Regarding the commenter's statements on risk assumptions, EPA uses risk methods consistent with published risk assessment guidelines that are available in both EPA reports and peer reviewed literature [e.g., Guidelines for Mutagenicity Assessment (Federal Register, Vol. 51, September 24, 1986), Final Guidelines for Developmental Toxicity Risk Assessment (Federal Register, Vol. 56, December 5, 1991), Integrated Risk Information System (IRIS) - On-line]. EPA acknowledges the commenter's proposed three-step process. When EPA promulgates criteria, it uses CWA Section 304(a) criteria guidance. EPA does not perform site-specific risk assessments; the Agency relies on protective assessments that apply to the nation as a whole. This is consistent with EPA's approach to the National Toxics Rule (NTR), of which this CTR is a part. A State or Tribe has the flexibility to utilize site-specific data when available in its assessments and decision-making process.

Comment ID: CTR-095-001b
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-20
C-21
C-14

Comment: In regard to the numeric water quality standards criteria for California surface water, they have been revealed by environmental groups to be insufficiently protective and environmentally unjust. The proposed new rules assume fish ingestion of 6.5 grams per day. In reality, consumption of fish in some communities can be as high as 1 pound per day. This level of consumption is especially likely among subsistence fishers.

Please prevent toxic pollution in California's bays by making more protective standards that consider all toxic pollutants and consider the fish consumption habits of subsistence anglers.

Response to: CTR-095-001b

Regarding the issue of fish consumption, refer to the response to CTR-002-002a on this same issue.

Comment ID: CTR-097-001a
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-14

Comment: I am writing to urge you to more stringent - and more protective - water quality standards for California surface water. The proposed standards are too weak and discriminatory in their effects.

Lastly, the proposed standards are discriminatory in their effects in that they assume consumption of only 6.5 grams of fish per day per person. Many poorer communities catch and eat fish for subsistence - as much as a pound per day per person (more than sixty what the EPA estimates!) placing them at greater risk. The standards should be set to protect everybody, including those who happen to be poor and/or eat a significant amount of fish.

Please set the standards to protect us all and move us closer to the goals of the Clean Water Act, that our waters be safely fishable and swimmable.

Response to: CTR-097-001a

Regarding the issue of fish consumption, refer to the response to CTR-002-002a on this same issue.

Comment ID: CTR-099-001a
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-17a Methodologies Human Health

References:
Attachments? N
CROSS REFERENCES C-17b

Comment: This letter is to comment on the water quality standards for California surface water. It is my strongly held opinion that the proposed standards do not meet the minimum legal requirements of protecting health, let alone other aspects of the environment. The numbers should be adjusted to lower MAC's by roughly an order of magnitude.

Response to: CTR-099-001a

EPA disagrees. EPA believes that the criteria are fully protective of aquatic life and human health. The comment offers no evidence that the criteria are not protective.

Comment ID: CTR-102-001a
Comment Author: Bryan Gordon
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/10/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-17b

Comment: Please ensure that the Federal water quality standards provide the maximum protection for people as well as the animals that inhabit our state's waterways.

Thank you for protecting America's waterways and the Americans and American animals that come into contact with them.

Response to: CTR-102-001a

EPA acknowledges the comment.

Comment ID: CTR-104-004b
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-09a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-104-004b

See response to CTR-016-008.

Comment ID: CTR-105-002a
Comment Author: Heather Catherine Park Tausig
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/13/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-21

Comment: The maximum levels proposed for mercury, dioxin, and thirteen other pollutants have been identified by respected environmental advocacy groups as (1) insufficiently protective, and (2) environmentally unjust, potentially increasing the cancer risks for subsistence fishers, who are, in large part, people of color.

The standards must be established at a level that makes California waters truly "fishable," and not just "fishable if you don't object to cancer."

Thank you for your consideration.

Response to: CTR-105-002a

See response to CTRH-001-010 (Category C-21; Legal Concerns).

Comment ID: CTR-106-004b
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES C-09a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-106-004b

See response to CTR-016-008.

Comment ID: CTR-110-001
Comment Author: Judith A. Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/02/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: I have recently been reading about some proposed new quality standards for pollutants of California surface waters. I feel very concerned about these proposed standards, as they appear to be more lenient toward pollutants than the existing regulations. I believe very strongly that our surface water is of serious concern to the millions of Californians who use this water every day. In particular, to children and elderly who are more vulnerable to toxins. There is growing evidence that water pollutants lead to cancer and other serious illnesses. I urge you to create more protective standards for our water. The people of this country are being exposed to potentially serious harm by toxicities in our water supply and I hope that more stringent standards can and will be implemented.

Thank you for allowing me to express my concern.

Response to: CTR-110-001

See response to CTR-002-003 (Category C-24; Site-Specific Criteria).

Comment ID: CTRH-001-024e
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-17a Methodologies Human Health
References:
Attachments? N
CROSS REFERENCES g-02
g-05

c-22
c-24a

Comment: MS. PLA: My name is Michelle Pla. I'm with the Public Utilities Commission, City and County of San Francisco.

I made the comment on my card that I also said that I would try to be constructive, and so I'm going to follow my mentor here, Phil Bobel, and say that there are some things in this rule that we're very pleased to see.

We're very pleased to see use of the latest scientific information, particularly the use of latest IRIS, I-R-I-S, numbers-for human health. We're very pleased that you're using dissolved versus total recoverable form for the metals.

We're very pleased to see recognition of the water effects ratios. We're pleased to see recognition for a multi-tiered mixing zone for acute and chronic human health effects and hope that the state pays particular attention to that.

We do have a problem with the way you've described compliance schedules and hope to be working strictly by the state on that as well. We think that the five-year system is fairly shortsighted, and -we can't even do FMDSLs in five years.

Response to: CTRH-001-024e

EPA acknowledges the commenter's support for the aspects of the rule mentioned in the comment. With respect to compliance schedules, see response to CTR-002-010b (Category G-02; Compliance Schedules).

Subject Matter Code: C-17b Methodologies Aquatic Life

Comment ID: CTR-002-004b
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? Y
CROSS REFERENCES C-17a

Comment: B. The criteria do not control pollution that harms fishing, and aquatic life.

Adoption of EPA's proposed criteria values will result in less control of toxic pollutants that exceed state criteria values in large parts of San Francisco Bay. Examples of this problem are shown in tables 3 through 6 for mercury, copper, nickel and PAH measured in 1995 at monitoring stations shown on a map of San Francisco Bay (Figure 1). The EPA-proposed criteria would allow:

- mercury violations triggered by state criteria values through much of the northern reach of the Bay. EPA-proposed criteria trigger violations only at the Petaluma river mouth and in South Bay). Bay-wide, 8 of 15 state criteria-triggered violations (53%) are allowed by EPA criteria.

- copper violations triggered by state criteria (4.9 ug/L total) throughout the northern reach of the Bay. EPA'S 3.1 ug/L dissolved value triggers violations only in the Petaluma river and in' South Bay. Bay-wide, 15 of 25 state-triggered violations (60%) are allowed by EPA criteria,

- nickel violations triggered by state criteria throughout most of the northern and southernreaches of the Bay. EPA's 8.2 ug/L dissolved value triggers violations at the Petaluma river mouth and one South Bay slough. Bay-wide, 20 of the 22 water quality standards violations (91%) triggered by the 7.1 ug/L criterion are allowed by EPA criteria,

- PAH violations triggered by state criteria at Coyote Creek and the Petaluma River mouth, EPA-proposed criteria trigger 4 violations for benzo(a)pyrene and indeno(1,2,3-cd)pyrene while state criteria trigger 40 violations for these compounds and 6 other PAHS.

Though EPA criteria do not control mercury except at the Petaluma River and in South Bay, a state human health advisory cites mercury contamination,(*6) and demonstrates that mercury restricts fishing uses Bay-wide. A severe threat and possible harm to aquatic life of the Bay's entire southern reach is evidenced by reduced abundance of all species known to be most vulnerable to copper toxicity, while these same species thrive in otherwise similar estuaries with less copper and nickel pollution.(*1) (*2) EPA criteria do not control copper and nickel in most of this area. Nor do EPA criteria control PAHs which -- with PCBs -- cause toxic effects in starry flounder in Central Bay.(*4)

Further, EPA'S proposed criteria include no criteria for 16 dioxin compounds that are included in the state dioxin criterion for TCDD equivalents.(*10) (*21) These 16 compounds are 6 dibenzo-paradioxins chlorinated in the 2,3,7, and 8 positions (except for 2,3,7,8-TCDD which is included in the EPA criterion), and 10 dibenzofurans chlorinated in the 2,3,7 and 8 positions. Under the state criteria, these 16

compounds and 2,3,7,8-TCDD are assigned toxicity equivalence factors as discussed in the proposed rule. Under the state criterion all these compounds are limited: if only 2,3,7,8-TCDD is present it cannot exceed 0.014 pg/L; if only OCDD is present it cannot exceed 14 pg/L; and if a mixture of dioxins is present the sum of their toxicities cannot exceed 0.014 pg/L. By failing to use toxicity equivalents and then failing to propose separate criteria for these 16 compounds, EPA is essentially deregulating 16 of the most toxic chemicals known to science even though these dioxins harm fishing uses, as shown by the health advisory discussed above. (*6)

The EPA criteria do not control toxics that threaten and harm the Bay, fishing and public health.

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.
(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten other estuaries. Communities for a Better Environment (CBE). July, 1992.
(*4) Spies et al., (2 papers), 1988: Effects of organic contaminants on reproduction of the starry flounder Platichthys stellatus in San Francisco Bay, I., Hepatic contamination and mixed-function oxidase (MFO) activity during the reproductive season. Marine Biology 98: 181-189; and II. Reproductive success of fish captured in San Francisco Bay and spawned in the laboratory. Marine Biology 98: 191-200. Excerpt including abstracts.
(*6) Cal. EPA, 1994. Health advisory on catching and eating fish, interim sport fish advisory for San Francisco Bay. December, 1994.
(*10) California State Water Resources Control Board, 1991. California Enclosed Bays and Estuaries Plan; water quality control plan for enclosed bays and estuaries in California. 91-13WQ. April, 1991. Excerpt including adopted water quality criteria and definition of terms.
(*21) California State Water Resources Control Board, 1997. Staff technical report, Division of Water Quality, Petitions of CBE, San Francisco BayKeeper, and Tosco Corporation for review of Order No. 95-138 of the San Francisco Bay Regional Water Quality Control Board. Office of Chief Counsel [OCC File Nos. A-983 and A-983(A)].

Response to: CTR-002-004b

EPA disagrees with the comment. EPA sets its criteria values at concentrations that will protect aquatic life or human health, based on the evaluation of the toxicity of the pollutants. Aquatic life criteria are expected to protect at least 95 percent of all genera, based on prediction from measured toxicological values. EPA's approach is a longstanding policy; EPA has used this approach to deriving aquatic life criteria since 1980. Criteria concentrations are not selected either to match existing concentrations in particular California waterbodies, or match criteria concentrations previously used by the state.

EPA does not believe that the information provided by the comment can be used reasonably to evaluate whether criteria concentrations protect aquatic life uses. Whether EPA's criteria are higher or lower than criteria previously used by the state are not germane to whether EPA's criteria protect aquatic life uses.

The observations that certain aquatic taxa are impaired in South Bay cannot validly be interpreted to indicate whether EPA's criteria are or are not protective. The cause or causes of impairment in South Bay are in fact not known. The concentrations of many contaminants are correlated with each other and with other occurrence of other stresses. Because of the presence of so many confounding factors, the information on South Bay cannot be used to derive criteria or to judge their validity.

EPA did not derive its criteria concentrations by considering whether the existing concentrations in

particular California waterbodies would or would not attain criteria concentrations. Rather EPA derived its criteria from toxicity data indicating that concentrations that are necessary to protect aquatic life. The comment offers no definitive toxicological or ecological evidence that the criteria are not protective.

The preamble discusses why the only dioxin compound included in the rule is 2,3,7,8-TCDD, which is the only dioxin compound that is a priority pollutant.

Comment ID: CTR-026-002a
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-27; C-29

Comment: 2. PARTIAL PROTECTION BY THE PROPOSED AQUATIC LIFE CRITERIA (FRESHWATER OR SALTWATER)

On page 42168, the proposed rule includes the following language: "EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time." The CTR goes on to state that this approach results in only a "small possibility" of substantial overprotection or underprotection. Obviously, it is underprotection that is of concern to the DFG. The DFG has very serious concerns that criteria are being proposed that protect "most" of the species "most" of the time. We are aware of the protocols that require a minimum of eight specified families be used to develop criteria and that it may be difficult to determine criteria that are one hundred percent protective; however, this does not preclude the real possibility that certain designated uses and aquatic organisms will not be maintained, and or protected, as a result of the proposed criteria. The DFG is also concerned that criteria and protocols developed for specific constituents do not take into account the additive or synergistic effects that contaminant combination may have on aquatic organisms. Another factor that needs to be considered is bioaccumulation, as well as the effect this may have on organisms at higher trophic levels.

As trustee of all the fish and wildlife resources in the State, it is our agency's responsibility to ensure appropriate protection of all fish and wildlife resources, not just "most", and this includes adequate water quality standards. Due to our concerns and the very real possibility of underprotection to aquatic organisms and designated uses, the DFG believes that it may be appropriate to derive the criteria as proposed, and subsequently develop some additional safety factors for inclusion. It is our understanding that this approach was used in the formulation of water quality objectives for protection of aquatic organisms in the California Ocean Plan. In the short term, the safety factor could possibly be realized by the development of a comprehensive biological monitoring program to determine whether the proposed criteria are indeed fully protective.

Response to: CTR-026-002a

EPA disagrees with the comment. EPA believes that incorporating the type of safety factor requested in

the comment would be arbitrary and would be difficult to defend scientifically. In particular EPA does not believe such a safety factor could be defended as being necessary for the protection of aquatic life. The commenter provides no data demonstrating that the criteria do not protect aquatic life.

The phrase "most of the species...most of the time" generally means a high percentage of species, a very high percentage of time. Aquatic life criteria are expected to protect at least 95 percent of all genera, based on prediction from measured toxicological values. In most streams, the duration and frequency goals result in attainment of criteria more than 99 percent of time. Past application of aquatic life criteria indicate that this level of protection will protect all aquatic life uses of a waterbody. Considering the variability of natural stresses on all species in a waterbody, EPA can find no basis in data or analysis for a concern that its goals for criteria concentrations and attainment time would not protect aquatic life uses. Because EPA's aquatic life criteria are derived using an appropriately conservative methodology, there is no need to develop the safety factors suggested by the comment.

See response to CTR-026-002b for discussion of the additive or synergistic concerns.

Comment ID: CTR-026-003a
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: 3 . TOXICITY DATABASE USED TO DEVELOP CRITERIA

The CTR indicates that the criteria being proposed are based upon a review of the most recent literature and toxicity data bases. The DFG is concerned that the databases utilized by EPA may not be as comprehensive as they could be with respect to inclusion of toxicity studies on a wide variety indigenous species found in State waters. Furthermore, data included in such databases such as EPA's AQUIRE have been found, in some instances, to be less than acceptable. Obviously we would like to see the criteria based on the most recent and scientifically sound toxicity data available. The DFG believes that it would be beneficial to describe in more detail the literature and databases utilized by EPA in development of the proposed criteria.

Also a discussion on appropriate and acceptable methodologies for data collection needs to be provided. It is not only important that the databases utilized by EPA be as comprehensive as possible, with respect to the inclusion of toxicity studies on a wide variety of indigenous species found in State waters. It is also important to know how the data was developed so that it won't be misinterpreted. For example, DFG would prefer using data that was derived from sampling whole organisms rather than edible filets if we were looking at bioaccumulation, biomagnification, or other types of food chain issues. Most predators don't limit their diet to only the edible portions of a prey organism. Sampling only the edible portions of an organism could lead to faulty conclusions.

Finally, with regards to the development of chronic toxicity standards or criteria based on a straight

percentage of the determined acute toxicity level, we would like to participate in any process that attempts to establish chronic levels in that manner.

Response to: CTR-026-003a

The derivation of each aquatic life criteria concentration is explained in detail in the criteria documents and in the 1995 update document, all of which were publicly available. This information was not repeated in the preamble of the proposed rule.

EPA does not agree with the comment about the comprehensiveness of the toxicity database. At the time the criterion document for each pollutant was developed, a comprehensive search of the literature was performed. The comment has offered no literature citations that EPA missed. Regarding the comment on the database AQUIRE, this database was never intended to include only the data that EPA would use for criteria development. EPA agrees that for purposes of developing criteria, some of the data in AQUIRE is "less than acceptable." However, EPA would not and has not used such data in development of the rule's criteria.

Bioaccumulation factors developed from data on edible portions of aquatic organisms have been used in criteria designed to prevent the edible portions of fish or shellfish from exceeding FDA action levels, and to prevent human health risks.

EPA encourages the commenter to participate in State adoption of water quality objectives, which after approval, would supersede these federal criteria.

Comment ID: CTR-029-002b
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-17a; A; C-22; C-27; C-29

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published

guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the published guidance documents is "insignificant"(*4); however, in light of the current contamination problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be underprotective because additive and synergistic effects were not considered; and because the effects on wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).
(*5) Id. at 42168.
(*6) Id. at 42172.

Response to: CTR-029-002b

EPA disagrees with the comment, with respect to incorporation of weaker criteria. EPA incorporated its latest criteria values into the proposed and final rule. EPA believes that these criteria are fully protective, and are the most scientifically defensible available at this time. The commenter offers no evidence that these criteria are not protective.

EPA disagrees with the assertion that "EPA acknowledges that total recoverable metals criteria...consider sediment, food-chain effects and other fate-related issues." The preamble to the proposed rule (62 FR 42172) has no such acknowledgment. Total recoverable metals criteria do not consider sediment, food-chain, or fate. Rather, EPA has acknowledged that a state may consider such factors in risk management decisions affecting water quality programs and standards. See also response to CTR-26-004.

See response to CTR-026-002b regarding additive or synergistic issues.

Comment ID: CTR-031-002c
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES F; C-17a; J; V

Comment: 2. Since the preamble implies that CTR criteria may be applied in NPDES permits for municipal storm water dischargers as numeric effluent limitations, the proposed rule is flawed with regard to: a) setting attainable, scientifically valid criteria in a manner consistent with state and federal regulatory approaches; b) assessing the potential economic impact on the public served by municipal storm water dischargers; c) assessing environmental impacts pursuant to the National Environmental Policy Act and the Endangered Species Act; and d) providing for the coordinated review and evaluation of the proposed CTR in conjunction with the proposed State Implementation Plan.

Response to: CTR-031-002c

EPA disagrees with item a). The commenter offers no evidence to support this alleged flaw.

Comment ID: CTR-031-004b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES C-17a; I

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

ii. Scientific Defensibility of Standards

Municipal storm water discharges require a uniquely different scientific as well as regulatory approach.

The episodic nature of storm flow events; the huge variances in flow volume, rate, timing, concentrations, and loads; the variability in receiving waters; and organism tolerance for and recovery from episodic exposure need to be taken into account in developing standards.

In a July 1992 memorandum addressing a Combined Sewer Overflow/Wet Weather workshop, Tudor Davies, Director of EPA's Office of Science and Technology wrote: "Changes being considered in the aquatic criteria development methodology to enhance the scientific defensibility of the criteria would be applicable to both constant and to wet weather discharges. One such change undergoing consideration is a change in the duration and frequency of exposure assumptions to make criterion more toxicologically realistic.

EPA has begun this work and is apparently nearing completion. With EPA's own Science and Technology office recognizing the inadequacy of the current approach to setting criteria relative to wet weather discharges, it must be concluded any attempt to apply the CTR criteria to municipal stormwater system discharges is ill-founded and likely inconsistent with the CWA.

Response to: CTR-031-004b

EPA agrees that the specified numeric criteria concentrations, chronic averaging period, and allowable frequency may not be completely appropriate for every possible application of each criterion. For this reason, the proposed and final rules incorporate provisions for the Water-Effect Ratio for modifying the criteria concentrations for site-water conditions. The final rule also incorporates a provision that the State of California, with EPA approval, after public notice and comment, may use alternative, scientifically defensible, averaging periods and allowable frequencies. When the numeric values are coupled with these provisions, EPA believes that the rule provides criteria that are fully applicable to all types of discharges, including storm water where appropriate.

Comment ID: CTR-037-002
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: 2. EPA has used its 1985 Guidelines to develop the criteria designed to protect aquatic life and its uses proposed in this rule. However, EPA has used new decision criteria in this rule that are not part of the 1985 Guidelines or any addendum of the Guidelines. Examples include the use of test results where measured concentrations were reported rather than for tests where concentrations were not reported, regardless of whether the test was flow through; and the use of the lowest SMAV or SMCV as the GMAV or GMCV when SMAVs or SMCVs varied by more than a factor of five within a genus. EPA should not be "making the rules up as they go" and should be amending the Guidelines as changes are necessary. Changes to the methods used to develop criteria must be made public in an organized fashion to facilitate consistent development of criteria across the country. EPA may find that if these new decision criteria were applied to all criteria that they too would change. Changes to the Guidelines

without formal documentation introduces too much variability into the water quality criteria program and does not insure that all regulatory agencies will acknowledge and implement the changes. EPA should follow the Guidelines that they have developed until new methods are available.

Response to: CTR-037-002

EPA agrees that the derivation of some of the criteria for the rule used certain decision criteria that were not part of the 1985 Guidelines. These included a preference for results from flow-through tests with measured concentrations, and setting the GMAV at the lowest SMAV where SMAVs differ by more than a factor of five. These decision criteria are used in the derivation of the GLI criteria, although they are also not part of the GLI Guidelines (40 CFR 132). EPA believes that the preference for flow-through measured tests is reasonable because the toxicant exposure has greater certainty in such tests. Provided that experimental variability had little to do with accounting for observed differences in SMAVs, then setting the GMAV equal to the lowest SMAV might likewise be reasonable, if the intent were to protect all tested species within the genus in such situations. These changes do not constitute changes to the national Guidelines. EPA believes that it is not bound by the 1985 Guidelines where there is a reasonable scientific basis for deviating from the Guidelines.

Comment ID: CTR-037-003a
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: 3. EPA has deleted data from several databases without indicating the reason for the deletions. This introduces the same problem as that described in #2 above, and results in variability in how water quality criteria are developed. Additionally, stakeholders need to know why data is deleted so that these decision criteria can be used in the development of defensible site-specific criteria. EPA should provide their reasoning for deleting data that was once believed acceptable so that this same reasoning can be used to update current criteria and to develop new sound criteria.

Response to: CTR-037-003a

EPA disagrees. The commenter did not identify particular data that were at issue. EPA believes that the derivation of criteria was fully explained in the 1995 Updates and in the original criteria documents, both of which were included in the public record for the proposed rule.

Comment ID: CTR-065-002c
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:

Document Date: 09/26/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES A; C-17a

Comment: PROPOSED RULE ALLOWS SIGNIFICANT AND UNACCEPTABLE INCREASES IN TOXIC POLLUTANT CONCENTRATIONS IN BAYS AND ESTUARIES

Our initial review indicates that the proposed criteria for a number of toxic constituents are unacceptably high and will allow more pollution of bays and estuaries by several orders of magnitude. If adopted as proposed, the CTR will allow a 900% increase of dioxin, 140% increase of PCBS, 325% increase of mercury, 2760% increase of zinc, 23,000% increase of lead, and a stunning 430 million % increase for total PAH, some of the most problematic pollutants in San Diego Bay. The CTR only improves (i.e. strengthens) criteria for only 3 of 64 pollutants. This does not square with new studies that show reasons for concern about the synergistic and long-term effects of exposures to these toxic pollutants. In sum, the CTR proposes weaker criteria for 58% of the pollutants and no change for 37% of the criteria. This kind of action will not bring us closer to our goal of cleaner water containing healthier organisms in the future.

Response to: CTR-065-002c

EPA disagrees. EPA did not derive its criteria concentrations with the intent of matching existing concentrations in particular California waterbodies. EPA derived its criteria based on toxicity data indicating concentrations that are necessary to protect aquatic life. In most waterbodies having impairment of aquatic life, there are particular pollutants or other factors that are causing a stress. The concentrations of all other contaminants not causing stress are below their criteria. The comment's observation that existing concentrations are below the criteria in some waterbodies does not provide a reasonable basis for setting or judging a criterion intended to be necessary for the protection of aquatic life.

Comment ID: CTR-065-004
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: EHC DOES NOT SUPPORT THE "MOST OF THE SPECIES, MOST OF THE TIME" TEST

EHC is VERY concerned about the EPA.proposing criteria to protect "most of the species and their uses most of the time". This is tantamount to condoning and facilitating marine life destruction through regulation. It is a terrible policy and should be abandoned. We are allowing polluting industries and dischargers. to bombard our marine resources with pollutants that result in multiple chemical exposures

of which we know very little of the, cumulative and synergistic effects.

Further, what is the EPA's definition of "most"? Is it 99.99%, 75% or 51%? Will estuarine environments survive standards that could be argued need only protect half of the organisms? This is completely unacceptable. EPA promulgated standards should be protective of all the living creatures 'in and' near the waters of the state. If we err, let us err on the side of protection. Although there is much that is unknown about impacts of multiple pollutants on marine organisms, one thing is for sure: once the damage is done it is hard to undo. One look at DDT- and PCB contamination in California waters should serve as an adequate reminder.

Discharging known, toxic pollutants into the marine environment is not a right, it is a privilege. The privilege should be granted only when the discharge does not harm the marine environment. Instead of trying to closely walk the ever unknowable line of exact protection, EPA should propose standards that assure complete protection so that bays, oceans, and inland waters containing all of their species, all of the time can be passed to the next generation.

Response to: CTR-065-004

Comment ID: CTR-099-001b
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: This letter is to comment on the water quality standards for California surface water. It is my stronly held opinion that the proposed standards do not meet the minimum legal requirements of protecting health, let alone other aspects of the environment. The numbers should be adjusted to lower MAC's by roughly an order of magnitude.

Response to: CTR-099-001b

EPA disagrees. EPA believes that is the criteria are fully protective of designated aquatic life uses. The commenter offers no evidence that the criteria are not protective.

EPA agrees that with the comment that a criterion that would protect only half of all the aquatic organisms would be unacceptable. However, EPA finds no evidence, within the comment or elsewhere, indicating that its criteria yield so little protection.

EPA criteria are derived such that they would be expected to protect at least 95 percent of the genera, based on prediction from measured toxicological values, a very high percentage (usually more than 99 percent) of the time. This very high level of protection is sufficient to protect aquatic life uses.

Comment ID: CTR-102-001b
Comment Author: Bryan Gordon
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/10/97
Subject Matter Code: C-17b Methodologies Aquatic Life
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: Please ensure that the Federal water quality standards provide the maximum protection for people as well as the animals that inhabit our state's waterways.

Thank you for protecting America's waterways and the Americans and American animals that come into contact with them.

Response to: CTR-102-001b

EPA acknowledges the comment.

Subject Matter Code: C-17c Meth.New Human Health Meth.

Comment ID: CTR-035-023
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-17c Meth.New Human Health Meth.
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42177 --New Human Health Criteria Methodology Please clarify when the new human health criteria methodology will be available, when EPA will be promulgating revised criteria as a result of the new methodology, and how those will be incorporated into the CTR and ultimately into permits. Will the criteria being adopted in this rule automatically be updated, or will EPA update them through subsequent rulemakings? If it is EPA's intent to modify the criteria in the CTR without undertaking a full rulemaking process, then those changes must be analyzed now, including an analysis of the costs and benefits of the different criteria. Also, please clarify whether, if specific criteria are changed within 5 years of adoption of the CTR, it is EPA's intent that compliance schedules already placed into permits would be extended if necessary to meet lower criteria?

Response to: CTR-035-023

Any changes to the CTR as a result of the new human health criteria methodology would be done through rulemaking to stay, withdraw, or amend the CTR. The draft revisions to the methodology for deriving ambient water quality criteria for the protection of human health were published in the Federal Register on August 14, 1998. A 120-day public comment period closed on December 14, 1998. The draft methodology revisions are available at the U.S. EPA National Center for Environmental Publications and Information (NCEPI), 11029 Kenwood Road, Cincinnati, OH 45242 or (513) 489-8190. They also may be downloaded from the EPA Office of Science and Technology's internet site (http://www.epa.gov/OST/humanhealth).

The most recent Federal action establishes the Agency's current water quality criteria. To date, the most recent Federal recalculation of 304(a) criteria occurred in the CTR. These 22 CTR criteria, plus the previously published 78 criteria, are the Agency's recommended human health criteria. As such, they will continue to be used as the basis for Agency decisions, both regulatory and nonregulatory, until EPA revises and reissues chemical-specific criteria. For example, EPA intends to use these criteria: (1) as guidance to States and Tribes for use in establishing water quality standards; (2) as the basis for EPA promulgation of water quality standards; (3) in establishing NPDES water quality-based permit limits, where the criteria have been adopted by a State or Tribe or promulgated by EPA; and (4) for all other purposes of Section 304(a) criteria under the Act.

EPA views the criteria program as constantly evolving. When the AWQC Methodology Revisions are final, any chemical-specific 304(a) criteria published using the revised methodology will be considered the Agency's most current recommended 304(a) criteria. EPA notes revisions of existing 304(a) criteria prior to the finalization of the revised methodology may be undertaken and are not precluded. Until such time as EPA re-evaluates a chemical, subjects the criteria to appropriate peer review, and subsequently

publishes revised chemical-specific 304(a) criteria, the existing recommended 304(a) criteria remain in effect.

States and Tribes have three options when adopting water quality criteria for which EPA has published 304(a) criteria. They can establish numerical values based on 304(a) criteria, 304(a) criteria modified to reflect site specific conditions, or other scientifically defensible methods. When States or Tribes revise their water quality criteria to correct deficiencies identified in a Federal promulgation, EPA will assess the scientific defensibility of the criteria in terms of the Agency's most recent recommended water quality criteria. Once new or revised 304(a) criteria are published by EPA, the Agency expects States and Tribes to adopt new or revised water quality criteria into their water quality standards consistent with the three options discussed above. EPA emphasizes it will be reviewing State and Tribal water quality standards to assess the need for new or revised water quality criteria. EPA believes five years from the date of publication of new or revised 304(a) criteria is a reasonable time frame by which States and Tribes should take action. This period is intended to accommodate those States and Tribes which have begun a triennial review and wish to complete the actions they have underway, deferring initiating adoption of new or revised water quality criteria until the next triennial review.

Subject Matter Code: C-18 Conversion Factors

Comment ID: CTR-035-017
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-18 Conversion Factors
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42172 -- Acute/Chronic Saltwater Conversion Factors for Metals We question the validity of the assumption that acute saltwater conversion factors for metals can be substituted for chronic. EPA should further explain and document the basis for substituting acute saltwater conversion factors for chronic saltwater conversion factors.

Response to: CTR-035-017

Because EPA's previous criteria guidance had been expressed as total recoverable metal rather than dissolved, EPA developed conversion factors that account for the possible presence of particulate metal in the laboratory toxicity tests used to develop the total recoverable criteria. EPA has used the best data available to it for estimating the percentage of dissolved metal in the toxicity test waters which support the derivation of its criteria. The commenter provides no evidence that the application of saltwater acute conversion factors to saltwater chronic criteria is inappropriate. Nor does the commenter offer an alternative solution. EPA believes its assumptions regarding chronic conversion factors are reasonable; EPA believes that using dissolved metals criteria for water quality standards better approximates the bioavailable metals in the water column and better approximates metals toxicity than do criteria based on total recoverable metal. Based on the close similarity between the measured conversion factors for freshwater acute and chronic toxicity tests, and absent any other information to the contrary, it is reasonable to expect that saltwater acute and chronic conversion factors would be similar to each other.

Subject Matter Code: C-19 FDA Action Levels

Comment ID: CTR-016-006
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-19 FDA Action Levels
References:
Attachments? Y
CROSS REFERENCES

Comment: Calculation of Final Residual Values Based on FDA Action Levels

The Regional Board agrees with EPA's assessment that it is inappropriate to use FDA Action Levels to develop criteria intended to be protective of aquatic life; at the same time, we question the appropriateness of using Action Levels as the basis for criteria intended to be protective of human health. In 1991, Board staff reviewed all historical Federal Register documents pertaining to the Action Levels dating back to the early '60s. In that review, we found that the majority of Action Levels FDA was using in 1991 were derived from studies conducted by pesticide manufacturers in the '60s. These studies characterized the expected residual level of pesticides in meat and poultry following application of pesticides on grain according to manufacturer's specifications. The implicit presumption on FDA's part was that the marginal health risks posed by pesticide residues were negligible compared to the benefits associated with pesticide-aided food production. We sincerely hope that the FDA has revised its methodology for deriving Action Levels since 1991, but do not believe that a predetermined percentage of food on the market is an acceptable factor to include in the derivation of environmentally protective criteria. Based on our findings, we encourage EPA not to use any Action Level until it has passed a level of technical review comparable to other risk-based federal environmental criteria.

Response to: CTR-016-006

None of EPA's Section 304(a) human health criteria, including the criteria that are being promulgated in today's rulemaking, are derived using FDA action levels.

Subject Matter Code: C-20 Scope Prty Toxic Poll. List

Comment ID: CTR-025-001b
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? Y
CROSS REFERENCES C-16

Comment: Proposed California Toxic Rule

The Metropolitan Water District of Southern California (Metropolitan) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (U.S.EPA) proposed California Toxics Rule(CTR). Metropolitan, through its 27 member agencies, supplies nearly 60% of the drinking water used by approximately 16 million people living in the six-county region of Southern California. Our sources of supply are surface waters from Northern California and the Colorado River.

The water quality criteria proposed in the CTR are of critical importance to Metropolitan and other drinking water suppliers. These criteria create the basis for source water protection activities which are the first line of defense for ensuring a safe drinking water supply. Further, the criteria help protect aquatic species, including the unique aquatic resources of the Bay-Delta. The health of the Bay-Delta ecosystem and waters tributary to the Delta is linked to the amount of water available for export and thus directly affects water supply reliability of the exporting water agencies such as Metropolitan. Lastly, the CTR criteria affect the ability of water suppliers to operate and maintain their facilities.

Metropolitan recognizes that the CTR is only required to address the Clean Water Act's "priority pollutants". We note, however, that many of the drinking water contaminants regulated under the Federal and/or California Safe Drinking Water Acts (SDWA) are not among the priority pollutants. Table 1 lists the drinking water chemical constituents regulated under the California SDWA which are not priority pollutants. (The California SDWA regulates a broader set of contaminants than the Federal SDWA and provides the appropriate regulatory comparison since the CTR pertains solely to California.) Drinking water beneficial, uses cannot be fully protected without water quality criteria for all California SDWA regulated contaminants. Metropolitan requests that U.S. EPA consider including human health criteria for the contaminants listed in Table 1 as part of the CTR.

Response to: CTR-025-001b

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance the discharge or presence of which could reasonably be expected to interfere with the designated uses of state waters. The promulgation of pollutants that are not identified as priority toxic pollutants (i.e, those pollutants that are not contained in the CWA Section 307(a) list) are outside of the scope of today's rule.

Comment ID: CTR-026-008
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES

Comment: 8. ADDITIONAL CRITERIA

The proposed rule would establish freshwater aquatic organism acute criteria for 24 constituents, freshwater aquatic organism chronic criteria for 28 constituents, saltwater aquatic organism acute criteria for 23 constituents, and saltwater aquatic organism chronic criteria for 27 constituents. The DFG agrees that establishment of criteria for these constituents will go a long way towards protecting fish and wildlife resources. However, we also believe that criteria for additional constituents would further strengthen the proposed rule. To this end, the DFG recommends that acute and chronic toxicity criteria be established for chlorine and ammonia. As a starting point, the EPA 1986 Gold Book has fresh and saltwater criteria guidance developed for both constituents. With respect to acute and chronic toxicity, the CTR should develop criteria similar to that which exists in the California Ocean Plan. From an overall toxicity standpoint, setting acute and chronic criteria would better address the additive or synergistic effects that individual constituent criteria fail to take into account.

Response to: CTR-026-008

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance and where those pollutants could reasonably be expected to interfere with the designated uses of state waters. Neither ammonia nor chlorine are identified as priority toxic pollutants in CWA Section 307(a) and are thus outside of the scope of today's rule. This is consistent with EPA's action in the National Toxics Rule 57 FR 60848 (Dec 22, 1992). See p. 60852, col. 2; 60856-60859.

EPA, however, recognizes the detrimental impacts of ammonia, chlorine, and other toxins on aquatic ecosystems, and encourages states, including California, to adopt criteria for these and other pollutants so that the designated uses of state waters can be fully protected (the CWA and Water Quality Standards Regulation requires states to adopt water quality standards, which includes water quality criteria, sufficient to protect the designated uses of their waters). States may also use their narrative criteria to prevent toxic effects caused by pollutants, such as ammonia and chlorine, in instances where a state does not have numeric criteria in place or to supplement their numeric criteria.

Comment ID: CTR-058-009
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA

Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? Y
CROSS REFERENCES

Comment: MTBE. WSPA supports EPA's decision not to set criteria based on secondary or organo-leptic considerations and to remain focused on setting criteria to protect human health and aquatic life.

Given the controversy surrounding use of MTBE, particularly in California, WSPA supports an open, objective and comprehensive scientific discussion of the issues and possible solutions. In fact, WSPA is supporting (with EPA and API) a detailed study of ambient aquatic toxicity data on MTBE in surface waters, with a goal to agree on appropriate water quality criteria to protect aquatic life. It is appropriate to allow this study to run its course, at which time EPA and the states can examine the data and set criteria based on sound science.

Other stakeholders may raise concerns about the carcinogenicity of MTBE. However, EPA (the agency charged with deciding whether MTBE is a carcinogen) has not taken an official position on this issue. The data which suggest that it might be (e.g., Belpoggi et al.) provide, at best, only weak evidence and are highly controversial from a methodological standpoint. It is imperative that EPA carefully review the evidence and decide the matter in an appropriate forum. Certainly, this rulemaking is not the appropriate forum.

In the interim, water quality officials are already well-empowered to address concerns of taste and odor when needed. Establishing an MTBE criterion in this rulemaking will not enhance protection of drinking water supplies.

Response to: CTR-058-009

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance and the discharge or presence of which could reasonably be expected to interfere with the designated uses of state waters. MTBE is not identified as a priority toxic pollutant in CWA Section 307(a) and is thus outside of the scope of today's rule. Additionally, EPA acknowledges the support for the Agency in not promulgating criteria that are based on organoleptic considerations. This is consistent with the NTR. See 57 FR 60873.

Comment ID: CTR-061-006
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:

Attachments? Y
CROSS REFERENCES

Comment: Page 42162, second column, near the top, does not provide a reliable discussion about how the Priority Pollutant list was developed. It was a court-ordered consent decree that was not internally peer-reviewed by the US EPA, or reviewed by the technical community or the public concerned with these issues. The Priority Pollutant list as promulgated and implemented has proven to be a significant detriment to proper water pollution control efforts in the US since it focuses resources on a number of chemicals that have limited significance to public health and the environment and allows regulatory agencies, dischargers, etc. to ignore the vast arena of hazardous or detrimental chemicals that exist in various types of wastes and point and non-point source stormwater runoff that can and, in some instances, do cause real water quality impacts.

Response to: CTR-061-006

EPA believes that the derivation of the Section 307(a) priority toxic pollutant list is outside of the scope of today's rule. Additionally, EPA disagrees that the current Section 307(a) list of priority toxic pollutants is a detriment to water pollution control. The Agency believes that the establishment of criteria for priority toxics pollutants represents significant progress in controlling the discharge of toxins to the nation's waters and will result in many improvements in protecting water resources and in achieving the fishable/swimmable goals of the Clean Water Act. EPA maintains that the control of toxic pollutants in ambient waters is fundamental in a number of Clean Water Act programs, including permitting programs, protection of contaminant levels in fish and shellfish, improvements in marine, coastal, and inland surface water quality, contamination of sediments, pollution prevention, and in ecological protection.

While EPA agrees that there may be other chemicals that adversely impact environmental protection, EPA notes that states do have the authority to develop and adopt criteria for pollutants that are not contained on the 307(a) list in order to protect the designated uses of their waters. The Water Quality Standards Regulation (see 40 CFR 131) requires all states, including California, to adopt criteria that will provide sufficient coverage to protect the designated uses of their waters. Furthermore, where a state has not adopted sufficient coverage of numeric criteria to protect the designated uses, the state may utilize its narrative criteria to derive criteria for pollutants to supplement the numeric criteria.

Comment ID: CTR-065-006b
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES P

Comment: TOXICITY TESTING

EHC strongly supports inclusion of acute and chronic toxicity tests. However, it is very important that

chlorine and ammonia be added to the list of constituents.

Response to: CTR-065-006b

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B). Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance and where those pollutants could reasonably be expected to interfere with the designated uses of state waters. Neither ammonia nor chlorine are identified as priority toxic pollutants in CWA Section 307(a) and are thus outside of the scope of today's rule. This is consistent with EPA's action in the National Toxics Rule 57 FR 60848 (Dec 22, 1992). See p. 60852, col. 2; 60856-60859.

EPA, however, recognizes the detrimental impacts of ammonia, chlorine, and other toxins on aquatic ecosystems, and encourages states, including California, to adopt criteria for these and other pollutants so that the designated uses of state waters can be fully protected (the CWA and Water Quality Standards Regulation requires states to adopt water quality standards, which includes water quality criteria, sufficient to protect the designated uses of their waters). States may also use their narrative criteria to prevent toxic effects caused by pollutants, such as ammonia and chlorine, in instances where a state does not have numeric criteria in place or to supplement their numeric criteria.

Comment ID: CTR-090-005
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

The criteria includes many toxicants which are not known to cause problems in the waters; many are banned substances. On the other hand, substances which are known to be problems and which are being released in large amounts are not included in the proposed criteria;

Response to: CTR-090-005

EPA believes that the derivation of the Section 307(a) priority toxic pollutant list is outside of the scope

of today's rule. Furthermore, EPA disagrees that the criteria promulgated in today's rule are not to known to cause problems in ambient waters. See response to CTR-061-006. The criteria are based on laboratory studies showing harm to human health or aquatic life. Further, because permit limits are incorporated into NPDES permits only for constituents having a reasonable potential to exceed water quality standards, a discharger does not receive a limit in its permit unless the discharge contains the pollutant. Thus existence of criteria does not translate into unnecessary permit limits.

Comment ID: CTR-090-016
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Outdated priority pollutant list - p 42162. B. Statutory and Regulatory Background (paragraphs 3,4) - As noted in the preamble, the 1978 priority pollutant list has not been updated since January 1981. This has several important implications for this rule-making:

1. The absence of criteria for significant toxicants - Chemical usage changes over time. New chemical intermediates and products are continually being developed and brought to market. Pesticides, in particular, have a relatively short commercial existence. Of the approximately eighteen pesticides and metabolites on the priority pollutant list, all but two are now banned or significantly restricted. Newer, or otherwise non-listed, pesticides are not covered by the CTR even though there is evidence of their presence in surface waters and adverse impacts. The Pollutant Policy Document (SWRCB, May 1990 final draft) noted that the San Joaquin drains an agricultural area which may receive as much as 23 million kilograms of pesticides annually. In the river, it noted that, "Consistently detected are 2,4-D, atrazine, simazine, dacthal and diazinon." Yet this proposed rule contains criteria for none of these pesticides. Of particular importance is diazinon. Approximately 2,000,000 pounds are sold annually in California with about half going to agriculture and half to residential users. Monitoring by Alameda County has tied it to toxicity in some county creeks. Diazinon appears in all of Palo Alto's creeks at levels that -may be of concern (Fish and Game recommends 80 ppt to protect aquatic life and Palo Alto has detected it at up to 400 ppt.).

Although this pesticide is subject to hydrolysis and eventually breaks down, the process may take four to six months. More significantly, the U.S. Geological Survey has tracked pulses of this pesticide down the San Joaquin and Sacramento and into San Francisco Bay. During the USGS study, water samples from the San Joaquin were toxic for 12 consecutive days to the water flee, Ceriodaphia dubia. (USGS, Water Fact Sheet, Diazinon Concentrations in the Sacramento and San Joaquin Rivers and San Francisco Bay, California, February 1993, K. Kuivila, 1993). The USGS report noted that other pesticides (chlorpyrifos, methidathion, and carbaryl) were also routinely detected in the samples and may have contributed to the toxicity. These other pesticides also do not have EPA criteria.

The Central Valley Regional Water Quality Control Board has detected diazinon, chlorpyrifos, fonofos, and carbaryl at concentrations toxic to Ceriodaphnia. In fact, the principal conclusion of their two and

half year study was that a 43 mile stretch of the San Joaquin River was toxic to Ceriodaphnia about half the time (Insecticide Concentrations and Invertebrate Bioassay Mortality in Agricultural Return Water from the San Joaquin Basin, CVRWQCB, December 1995). Other chemicals, methyl tertiary butyl ether (WBE), for example, a fuel additive, and related compounds are now showing up in California drinking water supply reservoirs and appear to be persistent

These unregulated toxicants are may be a significant water quality problem in California surface waters yet EPA has not found it appropriate to issue criteria for them. The excuse for inaction for all of these constituents cannot be that they have only recently appeared or have not been evaluated. Although MTBE is relatively new, in 1973, the National Academy of Sciences issued a guideline for diazinon of 9 ppt for the protection of aquatic life. More recently the California Department of Pesticide Regulation proposed quantitative response limits (QRLS) for diazinon, chlorpyrifos, and methidathion.

The CALFED program is proposing to spend a billion dollars over the next 20 years for water course and riparian habitat enhancements in the Delta. This effort will be undermined unless steps are taken to reduce toxicity from agricultural drainage.

The Clean Water Act in Section 303(c)(4) allows the Administrator to issue a standard in any case where it is necessary to meet the requirements of the Act. If there ever was an obvious, overwhelming need for standards, this is it. EPA needs to work with the State and agricultural interests to develop effective programs to control the release of pesticides to the inland surface waters and Bays and Estuaries of California

Response to: CTR-090-016

See response to CTR-090-005.

Comment ID: CTR-090-017
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: 2. Criteria for no longer relevant toxicants - Listing chemicals which no longer have relevance to water quality is not as serious as omitting chemicals which are important. Listing irrelevant toxicants does, however, waste resources since these chemicals are routinely placed in NPDES permits with both effluent limits and mandated monitoring regardless of whether they have ever been detected. The result is permits with impressive lists of priority pollutants which give the false impression that they are comprehensive and therefore protective of the receiving waters.

For each chemical included in this rule-making EPA should demonstrate that the chemical is present either in effluents or receiving waters at concentrations which cause or have the reasonable Potential to cause, or contribute to an excursion above any criteria published by EPA under Section 304. The

adoption of irrelevant criteria is not "necessary to support such, designated uses," 303(c)(2)(B), and therefore can be omitted.

The information on which toxicants are present should be readily available since EPA receives the NPDES monitoring reports and state water quality assessments. By limiting the rule-making to real constituents of concern, we can - begin to focus on those toxic chemicals which are damaging the biota or threatening human health.

Response to: CTR-090-017

See response to CTR-090-005.

Comment ID: CTR-095-001a
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES C-17a; C-21; C-14

Comment: In regard to the numeric water quality standards criteria for California surface water, they have been revealed by environmental groups to be insufficiently protective and environmentally unjust. The proposed new rules assume fish ingestion of 6.5 grams per day. In reality, consumption of fish in some communities can be as high as 1 pound per day. This level of consumption is especially likely among subsistence fishers.

Please prevent toxic pollution in California's bays by making more protective standards that consider all toxic pollutants and consider the fish consumption habits of subsistence anglers.

Response to: CTR-095-001a

See response to CTR-061-006. With respect to fish consumption see responses to CTR-002-002a and CTR-002-005a (Category C-14; Fish or Water Consumption).

Comment ID: CTR-100-001
Comment Author: Michael A. McBride
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/04/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES

Comment: Great progress has been made in the last twenty years to clean our polluted streams, rivers and oceans. Please keep the pressure on the polluters by creating more protective standards that consider all toxic pollutants of concern. Thank you for your time and please let me know your thoughts.

Response to: CTR-100-001

See response to CTR-061-006.

Comment ID: CTR-101-001b
Comment Author: Cheesemans' Ecology/Brd Safari
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 10/06/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES C-14

Comment: We would like to thank the EPA for accepting comments on its proposed numeric water quality standards criteria for California surface water. We urge the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-101-001b

See response to CTR-061-006. With respect to fish consumption, see response to CTR-109-001a (Category C-14; Fish or Water Consumption).

Comment ID: CTR-105-001a
Comment Author: Heather Catherine Park Tausig
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/13/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES C-14

Comment: I understand that the EPA is currently accepting comments on its proposed numeric water quality standards criteria for California surface water. I am writing to urge the EPA support the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-105-001a

See response to CTR-061-006. With respect to fish consumption, see response to CTR-109-001a (Category C-14; Fish or Water Consumption).

Comment ID: CTR-109-001b
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES C-14

Comment: The new water quality standards the EPA is proposing for California surface waters disturbs me greatly. There are several problems with the proposed rules. First, in establishing standards for mercury, dioxin, PCBs, and other contaminants, the proposed new rules assume fish consumption at 6.5 grams per day yet consumption of fish in certain communities can be as high as one pound per day, over 60 times more than estimated by the EPA. Please don't underestimate fish consumption by people of different races and cultures.

Please prevent the toxic pollution of California waters by creating more protective standards that consider all toxic pollutants and all consumers of fish. Thank you.

Response to: CTR-109-001b

See response to CTR-061-006. With respect to fish consumption, see response to CTR-109-001a (Category C-14; Fish or Water Consumption).

Comment ID: CTRH-001-016
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-20 Scope Prty Toxic Poll. List
References:
Attachments? N
CROSS REFERENCES

Comment: As you know -- you should know -- EPA approved methyl tert-butyl ether, MTBE, a gasoline additive, creating the fastest-growing chemical market in the world, without any analysis of water quality effects. In addition to evidence of widespread groundwater and drinking water contamination, MTBE has been found many of our state's surface waters.

Will EPA not propose a criterion for MTBE? Why did they not propose one in this rule?

Response to: CTRH-001-016

See response to CTR-058-009.

Subject Matter Code: C-21 Legal Concerns

Comment ID: CTR-002-005b
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES C-14

Comment: C. Criteria for the pollutants of most concern do not provide equal protection for people of color and are not supportable by science.

EPA cannot show that its weaker proposed criteria will protect fishing and aquatic life from dioxin-like compounds, mercury, and copper. Further, EPA's proposal to allow greater health risks for subsistence fishers fails to provide equal protection under the law and is contrary to the President's Executive Order on Environmental Justice.

The proposed criteria provide unequal protection for people of color who fish for food. EPA admits in the proposal that: "There may be subpopulations within a state, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish.. ." Indeed, ample data show that some people exercise their fishing rights to "use" Bay waters byeating up to a pound (450 grams) per day of fish from San Francisco Bay, and most of them are people of color.(*8) EPA's discussion then goes on to admit that it is proposing to provide less protection for these subsistence anglers: "[I]ndividuals that ingest ten times more of a carcinogenic pollutant than is assumed in derivation of the criteria at a [one excess cancer in a million] risk level will be protected to a [one in 100,000] level, which EPA has historically considered to be adequately protective." However, people who eat a pound per day eat seventy times more, and pages 8- 11 and 8-12 of EPA's economic analysis admit people eat 16 times more, than the 6.5 grams (1/70th of a pound) of Bay fish per day assumed in EPA's criteria. EPA's own calculations show present cancer threats of nearly 1 in 1,000 for some Bay anglers at these higher consumption levels. Thus, EPA itself predicts that its proposal will result in lesser, inadequate protection for people of color who rely on Bay-caught fish for food.

(*8) Previously unpublished data from a 1993-4 survey of 500 anglers using South and Central San Francisco Bay by Communities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994.(excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence..

Response to: CTR-002-005b

See response to CTR-002-005a (Category C-14; Fish and Water Consumption).

Comment ID: CTR-002-009
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES

Comment: D. EPA's proposals fail to meet federal laws and regulations.

Proposed criteria would revise water quality standards contrary to law and regulations. Pursuant to 40 CFR section 131.22(c) revised water quality criteria must protect existing uses under 40 CFR section 131.12 (a)(1), and shall support the most sensitive designated use of Bay waters based on sound scientific rationale, under 40 CFR section 131.11(a)(1). However, EPA criteria for pollutants shown in Table 2 above do not meet these tests, as shown by sections II A, B, and C of these comments.

Inappropriate rejection of scientifically sound criteria for 16 dioxin compounds accumulation, and mercury and copper field data results in criteria which allow pollutant levels shown to threaten or harm aquatic life and the fishing public. Human health criteria do not protect people who eat up to a pound of Bay fish per day because EPA assumes people eat only 6.5 grams of these fish per day. In this crucial analysis, protecting the most sensitive use must mean protecting people who eat as much as a pound of fish per day (seventy times more than 6.5 grams), and more often than not are people of color fishing for food as well as recreation.(*8) The criteria do not protect designated uses of Bay waters for fishing and propagation of aquatic life- based on sound science.

Even if EPA argues that some of the pollutants for which it proposes weaker criteria attain levels necessary to achieve water quality standards and protect fishing, aquatic life and wildlife, under 40 CFR 131.12(a)(2) EPA cannot allow water quality to be degraded because this is not "necessary to accommodate important economic or social development." At EPA's request, CBE has supplied evidence showing that long-term economic benefits to the manufacturing base resulted from pollution prevention measures driven by the implementation of state criteria more stringent than EPA's proposal with zero dilution effluent limits. The economy of this area, Silicon Valley, grew substantially at the same time and this growth was led by the industries involved in this effort. Although we are concerned that EPA seems to have arbitrarily rejected evidence that the most "stringent" criteria implementation resulted in economic benefit rather than cost, we trust EPA will agree there is no evidence that weakening these criteria is needed for economic or social reasons.

(*8) Previously unpublished data from a 1993-4 survey of 500 anglers using South and Central San Francisco Bay by Conununities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994.(excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence..

Response to: CTR-002-009

EPA disagrees with this comment. The CTR criteria are based on sound science and are protective of the most sensitive uses of waters in California, in compliance with 40 CFR 131.11(a)(1) and 131.22(c). The criteria are based on the uses which the State itself has designated: the CTR does not adopt or modify any use designations. The scientific bases for the CTR criteria are set forth in The California Toxics Rule Administrative Record Matrix.

As to some of the CTR criteria which this commenter claims will allow increases in pollution of San Francisco Bay, this commenter's concerns are no longer applicable. EPA's decision to not promulgate final CTR criteria for those waters where there are EPA-approved San Francisco Basin Plan criteria in effect addresses those CTR criteria which this commenter compares unfavorably to existing Bay Basin Plan criteria. (See response to CTR-016-001.)

As to those CTR criteria which the commenter compares unfavorably with ISWP and EBEP criteria, see response to CTR-002-003.

The commenter's implication that adoption of the CTR violates anti-degradation provisions in EPA's regulations is misplaced. In the first place, it is not appropriate to compare CTR criteria with California's ISWP and EBEP criteria for purposes of determining whether degradation of water quality may result from adoption of the CTR. The California criteria do not exist for purposes of making such a comparison, since the ISWP and EBEP were rescinded in 1994. Secondly, the adoption of criteria sufficient to protect designated uses is not an action which in and of itself results in any change in water quality. The implementation of such criteria may raise anti-degradation issues in specific instances in the future, but this rulemaking does not.

With respect to the commenter's concern about certain people eating more fish than 6.5 grams/day, see response to CTR-002-005a (Category C-14; Fish and Water Consumption).

Comment ID: CTR-005-006a
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES S; R

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and also taking into consideration their use and value for navigation (See CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern. For those identified waters, states must adopt criteria for such toxic pollutants applicable to sufficient to protect the designated use"(See 40 CFR 131.1 1 (a)(2)).

Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-005-006a

See responses to CTR-036-005, CTR 035-012a, and CTR 005-007a.

With respect to EPA's compliance with E.O. 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act, see the preamble to the final rule, EPA's economic analysis conducted pursuant to the order, and the record for the rule. EPA notes that the water quality criteria only have an impact when the permit authority finds that a discharge has the reasonable potential to violate water quality standards. EPA based its economic analysis on two scenarios, a high end scenario and a low end scenario. The high end established baseline concentrations as being equal to existing permit limits, whether or not the pollutant was detected in the effluent. This provides and upper bound because most facilities typically discharge below their permit limit. The low end scenario is based on actual data about what pollutants are present in the effluent and the actual concentrations of the dischargers in the effluent.

Comment ID: CTR-005-008b
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: 7. Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Pablo Bay in the vicinity of the District's discharge, or alternatively EPA should state in the Preamble that the Regional Board should: (1) allow a dilution credit for the District based on modeling studies; and (2) apply metals translator determined based on EPA procedures from the results of the Regional Monitoring Program. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the analysis of costs and benefits performed by the District (see Attachment 1), EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation criteria that will allow the current discharge to continue. The District has performed dilution studies (see Attachment 2) and performed reasonable potential analyses using dilution and metals translators (see Attachments 3 and 4). These show that with the use of these implementation provisions, the proposed criteria can be achieved in-stream. Without EPA specifying that dilution studies and metals translators should be utilized in the District's case, it is possible that the CTR could impose enormous costs on the District (and the small entities it serves) without providing any environmental benefit. In that case, the CTR would be

inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-005-008b

See response to CTR-005-008a (Category C-24; Site-Specific Criteria).

Comment ID: CTR-007-004
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: 3. The District requests that in the Final CTR, a provision be placed in the rule that grants a waiver to the water quality criteria or that the approach is shifted to a risk based approach where an agency or responsible party engages in cleanup or remediation activities.

Response to: CTR-007-004

EPA disagrees with this comment. The CTR does not include implementation provisions because this rule's intent is to implement section 303(c)(2)(B) of the CWA for California. EPA believes that implementation of these provisions is appropriately left to the state. To the extent that this commenter is proposing implementation provisions that are consistent with CWA requirements, such provisions may be considered by the State for inclusion in its implementation plan. 40 CFR 131.11. See also response to CTR 042-007a. Further, designation of uses is primarily left to the states. In this rule, EPA is simply establishing criteria necessary to protect the designated uses. Use designation may consider economics. If a state wishes to designate a use that is not a CWA section 101(a) use, the state must conduct a use attainability analysis to determine that the use is not attainable.

Comment ID: CTR-010-003
Comment Author: Save San Francisco Bay Assoc.
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA's proposal also does not comply with the federal Clean Water Act and is certain to stir up

a hornet's nest of protest if moved forward. The proposals also restrict the ability of the public and concerned agencies from involvement in ensuring standards are complied with. U.S. environmental policy is often hamstrung by the short-term, corporate bottom line influence to the detriment of the vast majority. Ultimately such short-sightedness will result in not only a continued worsening quality of life for the general public, but also in a loss of economic competiveness to those industries and countries able to profit from pollution prevention.

Though the mission of the U.S. EPA is to protect the environment, the California Toxics Rule harms the environment. The proposed criteria should be revised before being adopted. We would welcome the opportunity to discuss these issues with you, along with other concerned parties. We would also appreciate a response to this letter.

Response to: CTR-010-003

EPA disagrees with this comment.

First, concerning the ability of the public and concerned agencies to be involved in ensuring that standards are complied with, EPA reaffirms that the CTR is an adoption of criteria, and it does not include implementation provisions. The State is responsible for the application of CTR criteria to point and non-point sources. The State is currently developing a plan for implementation of the CTR criteria, following its own public participation requirements (Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, September 11, 1997). Furthermore, as the State applies CTR criteria in specific actions that it will take in the future, such as issuing discharge permits, the public can pursue applicable participation opportunities as they arise. The commenter has not explained how the rule will impair the ability of the public and concerned agencies to ensure standards are complied with.

Secondly, EPA cannot respond specifically to the comment regarding the influence of "the short-term, corporate bottom line" on federal environmental policy, as there is no support for this conclusory statement. Although Executive Order 12866 and the Unfunded Mandates Reform Act require EPA to estimate the costs of certain rules (rules deemed "significant under the E.O., and rules that require "Federal mandates" that may result in expenditures in excess of 100 million/year under UMRA, the E.O. and UMRA do not override applicable law. Under the CWA, economics or cost benefit analysis is not a basis for adopting water quality criteria. See CWA section 303(c), 40 CFR 131.11. See response to CTR-042-007a. For a discussion of the Regulatory Flexibility Act, see the preamble to the final rule. The CTR fully complies with all of these requirements.

Comment ID: CTR-020-002
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES

Comment: 1. General Comments

A. Applicability of the Rule is Overly Broad

The CTR applies the various water quality criteria to "all waters of the United States" regardless of the actual aquatic life or beneficial uses present. EPA specifically disclaimed any need to individually assess hydrologic unit needs as mandated by the Porter-Cologne Act and the court decision overturning the Inland Surface Waters Plan ("ISWP"). In effect, this means that the CTR will be applied in an overly broad manner, particularly with respect to storm water discharges, as the criteria designed for high quality wann and cold water fisheries will be applied to storm water ditches which the Agency may classify as intermittent streams pursuant to the Regional Water Quality Control Board's (the "Regional Board") "tributary policy" (i.e., tributaries are presumed to contain the same uses as designated main streams). Such water bodies are dry other than during precipitation events and cannot maintain sensitive aquatic life uses. These water bodies have not been classified for specific use protection, and approved Basin Plans allow consideration of site-specific factors in determining actual use protection needs.

EPA's Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses (1985) ("National Guidelines") specify that criteria must be applied in the manner in which they were derived to provide reasonable and appropriate protection. Federal water quality regulations (40 CFR Part 131) also specify that water quality criteria must be necessary to protect the beneficial uses. Thus, EPA lacks authority to establish water quality criteria that are more restrictive than necessary to ensure that actual uses will be protected. The Agency's attempt to apply stringent water quality criteria to water bodies that either have no reasonable likelihood of maintaining sensitive aquatic life or have not been classified by the state to protect such uses is arbitrary and capricious. In addition, application of stringent human health ingestion-based and fish tissue criteria to receiving waters that lack a potable water supply use or that cannot support a game fishery is clearly not consistent with the National Guidelines and is unnecessarily restrictive. Similarly, pursuant to the Porter-Cologne Act and applicable case law, EPA may not enact requirements that would otherwise be unlawful under California law.

As the Porter-Cologne Act would not allow such action (i.e., overly broad use designations) on the part of the State's Water Quality Control Boards, EPA needs to restrict the application of the CTR to circumstances where the water quality criteria are reasonably applicable. Thus, the proposed criteria for aquatic life should only be applied to perennial streams and not to intermittent watercourses that primarily exist during rainfall events. Human health criteria that include a water ingestion component should only be applied to water bodies that have a demonstrated capability to provide potable water, and application of the criteria should be at the water intake (which would allow for loss of pollutant in the environment and documented pollutant reduction achieved by the water treatment facility). Applying the ingestion-based criteria at appropriate water intake points will help to avoid the assumption that surface waters are consumed without treatment, as such an assumption is not lawful under the Safe Drinking Water Act.

Response to: CTR-020-002

EPA disagrees with this comment. EPA must adopt criteria in accordance with the requirements of the CWA. As a federal agency, EPA is not subject to the requirements of the Porter-Cologne Act, which is State law, nor to the State court decision which overturned the ISWP and EBEP.

Regarding the failure to individually assess the needs of hydrologic units, such an undertaking would amount to adoption of site-specific criteria. It is beyond the scope of the CTR to adopt site-specific

criteria for individual pollutants and/or water bodies, based on localized information and data. As explained in the preamble to the proposed CTR, and further discussed in the response to CTR-003-006, et al., EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR where such State criteria are in effect.

EPA further disagrees that the CTR criteria will be applied "in an overly broad manner," based on EPA'sfailure to consider the actual uses of specific water bodies. The CTR does not modify or adopt any uses for any waters. Rather, the CTR adopts criteria for waters of the United States in California to protect aquatic life and human health uses already designated by the State. It is not arbitrary or capricious for EPA to rely on uses designated by the State in accordance with its own laws. Commenters may seek to have the State modify or eliminate uses for particular water bodies; however, EPA cautions that the State is subject to the requirements of 40 CFR 131.10 if it undertakes to do so.

Finally, EPA disagrees that it lacks authority "to establish water quality criteria that are more restrictive than necessary to ensure that actual uses will be protected." (Emphasis added.) The term "actual uses" is an undefined term, but the commenter clearly uses it to describe uses that differ from designated uses. EPA has the authority as well as the legal obligation to adopt criteria which protect the designated uses, however, even if such uses require a greater level of protection than existing uses. 40 CFR 131.5(a)(2); 131.6(c); 131.11(a). If an existing use (as defined in CWA regulations) is less sensitive than the designated use, then the appropriate initial response is not to adopt less stringent criteria to protect the less sensitive use. That would not be allowed unless the designated use itself had been modified. The State may undertake to modify designated uses, including, in some instances, downgrading some uses, in accordance with 40 CFR 131.10, but no such action has been taken which would affect the adoption of the final CTR.

Comment ID: CTR-031-003a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES I-03

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal storm water dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

i. Attainability of Standards

The statutory premise of the CWA is to provide water quality for protection and propagation of aquatic life, wildlife, and recreation wherever attainable. The CWA therefore establishes a reality test in that objectives must be attainable.

The proposed CTR criteria can not be attained by municipal storm water dischargers. The District treats through detention and retention all but 1% of its urban runoff on an annual average basis. Nonetheless, its urban runoff discharges, after detention, would exceed proposed dissolved copper, lead, and zinc criteria. Concentrations would need to be reduced by 67%-95% to meet the proposed chronic criteria. No storm water best management practices, including conventional end-of-pipe storm water treatment facilities (i.e., detention systems), are believed to be able to achieve these levels of reductions for these constituents.

Response to: CTR-031-003a

EPA disagrees with this comment. There is no authority for revising the proposed CTR criteria based on the considerations cited in this comment. Water quality criteria adopted pursuant to CWA section 303 must be based on sound science and must protect the designated uses of the water bodies to which they apply. 40 CFR 131.11. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Attainability issues may be considered in accordance with CWA section 303 in designating or modifying uses for those water bodies; however, the CTR does not undertake to modify or adopt any uses for waters in California. Scientific validity of criteria is based on ambient conditions, not on dischargers. The scientific bases for the CTR criteria are set forth in The California Toxics Rule Administrative Record Matrix.

In raising the question of storm water dischargers' ability to attain CTR standards, this comment apparently relies on language in CWA section 402(p) which requires storm water dischargers to reduce pollutants only to the maximum extent practicable (MEP). MEP, however, is a point source permitting standard; it does not apply to the adoption of ambient water quality criteria. Moreover, EPA has interpreted the MEP standard as applying only to technology-based permit requirements. It does not affect the requirement of CWA section 301(b)(1)(C) that CWA permits include limitations necessary to meet water quality standards. Memorandum from E. Donald Elliot, Assistant Administrator and General Counsel, to Nancy J. Marvel, Region 9, dated January 9. 1991.

Comment ID: CTR-034-010b
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-28

Comment: * SCAP recommends that EPA defer adoption of criteria contained in the draft CTR which are typically below detection limits. While we understand EPA's rationale for setting criteria that may

not be detectable based on EPA's determination of the criteria needed to adequately protect aquatic life and human health, we believe that EPA has not fulfilled its duties under the Clean Water Act, Unfunded Mandates Act, and E.O. 12866. In accordance with federal water quality standards regulations, EPA is required to review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use (see 40 CFR section 131.11). Thus, if the pollutant has not been detected, there is no basis for determining whether the chemical is adversely affecting water quality or the attainment of designated uses.

Further, EPA cannot make an accurate determination of the costs and benefits of promulgating CTR criteria for those criteria that are below detection levels. It is quite likely that detection limits for some substances will improve in the near future, and dischargers previously projecting full attainment will no longer be able to comply. For instance, a SCAP member agency was issued an NPDES permit in the early 1990s containing effluent limits for a number of toxic pollutants. In this agency's case, lindane was not being detected at the time of permit issuance (and the detection level was higher than the permit limit). Yet, in the following years, the detection level dropped and this agency began to experience exceedences of the permit limit. Lindane cannot be readily controlled at the source by normal industrial waste source control methods because it is in widespread use by consumers. Therefore, the only reliable option for the POTW to come into compliance may be to add end-of-pipe treatment, a very expensive proposition. This scenario is likely to happen again with many of the criteria being proposed in the CTR. The potential compliance costs could be high, yet the Economic Analysis for the draft CTR could not estimate such costs. For all of the above reasons, EPA should defer adoption of these criteria until they can be detected and EPA can more fully determine the potential economic impacts of promulgation of the CTR. Instead, we recommend that a watershed approach be used to address these pollutants (see below).

Response to: CTR-034-010b

EPA disagrees with the commenter that it should defer promulgating water quality criteria below detection limits or that such promulgation is in any way inconsistent with the CWA, UMRA, or E.O. 12866. EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by the States at concentrations necessary to protect the designated use. Given this requirement, consideration of analytical detectibility is not an appropriate factor to consider when calculating water quality criteria to protect designated uses since they are not related to actual environmental impacts. As EPA stated in the preamble to the National Toxics Rule, 57 FR 60876, col. 1, this has been the Agency's longstanding position. See also 57 FR 60870. EPA's criteria are based on scientific information about a pollutant's toxic effects, without regard to analytical methods or techniques. The criteria are based on the concentrations that either cause toxic effects to aquatic life or to human health. EPA's criteria development methods for aquatic life are generally based on laboratory analyses with sensitive aquatic life. The results from these tests are analyzed by mathematical procedures outlined in EPA's criteria guidelines. EPA's human health criteria are developed from protocols generally using toxicity studies on laboratory animals such as mice and rats. Thus, because the criteria are based on data showing toxic effects, EPA does not believe that the analytical detection limit should determine the basis for the criteria.

The water quality standards established in this rule are not self implementing; they will be applied by the State in developing total maximum daily loads, wasteload allocations to point sources, (which may be used to develop NPDES permit limits) and load allocations to nonpoint sources. The sensitivity of analytical methods is relevant for determining compliance with water-quality based permit limits. The permit authority, here the State of California, establishes the analytical methodology to be used for

determining compliance with the permit limit. EPA has issued guidance on how constituents with water quality criteria below the sensitivity of official analytical methods (i.e., those listed in 40 CFR Part 136) are established in permits. See Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States, memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors and NPDES State Directors, May 21, 1990. This guidance presents a model for addressing toxic pollutants which have criteria recommendations less than current detection limits and it is applicable to other criteria as well. The guidance explains that standard analytical methods may be used for determining compliance with permit limits but not for establishing water quality criteria or permit limits. Also, EPA's Great Lakes Guidance Procedure 8 specifies that where the water quality-based effluent limit is lower than the pollutant's quantification level, the quantification level is the method for determining compliance with the limit. This approach is mandated by the CWA, which requires that permit contain WQBELs as necessary to achieve standards. (CWA section 301). Neither EPA nor the States are authorized to set WQBELs at higher levels simply because of technical difficulties in measuring compliance. See NRDC. v. EPA, 859 F.2d 156, 208 (D.C. Cir. 1988)("Congress did not intend to tie compliance with water quality-based effluent limitations to the capabilities of any given level of technology."] It should also be noted that by the time criteria are converted into permit limitations after calculating total maximum daily loads, waste load allocations and load allocations, the actual permit limit may be in the range of standard analytical methods cited by EPA in 40 CFR Part 136.

EPA also establishes water quality criteria for many chemicals of concern because they biomagnify in the tissue and organs of fish (e.g., mercury and PCBs) to levels that can adversely effect aquatic life, wildlife and human health. Fish tissue information can be used to determine if the water body is attaining water quality standards even when the water quality criteria and instream pollutant concentrations are below detectable levels. For chemicals that are not highly bioaccumulative but have criteria below detectable levels, fate and transport (mass balance) models can be used to predict instream pollutant concentrations and attainment of water quality criteria and designated uses. This information with other field observed data showing stress or adverse effects on the biological community serve as an earlier warning to the public that water quality is being degraded and steps must be taken if the designated use for the water body is to be protected and maintained.

The decision to maintain a designated use or to downgrade the water body to a lower use designation is a place-based decision that must rest solely in the hands of the local community, elected officials and other stakeholders that use the water resource affected by such decisions. Therefore, the importance of adopting statewide numeric water quality criteria to protect designated uses (e.g., fishable, swimmable) is not predicated on costs or benefits but on the public's "right-to-know" and participate in decision-making affecting their water resources. Congress understood this and in CWA sections 303 and 304 preserved the public's right-to-know about the condition and safety of the waters they use for food, drinking, recreation and commerce. See responses to CTR-036-005 and CTR-O42-007a.

With respect to EPA's compliance with UMRA and E.O. 12866, see the preamble to the final rule andEPA's Regulatory Impact Analysis conducted for the rule. Although analytical detection limits may improve in the future, EPA has reasonably estimated the costs of the rule in the regulatory impact analysis based on the best available data about how permit limits might change under the final rule. EPA evaluated the costs of attaining permit limits derived from CTR criteria but maintains that the costs associated with attaining effluent limits that are less than detectable levels are speculative and EPA's methods may tend to overstate costs. Nevertheless, EPA estimated costs under a high scenario using assumptions about how much pollutant reduction would be required even when it had "no" effluent data indicating the presence of the pollutant in the discharge or that the control strategy was actually necessary.

EPA's estimates of costs include control technology costs for pollutant reduction that would be required to reduce pollutant levels to the MDL as well as pollutant minimization programs to reduce the pollutant level to below the MDL. EPA's estimates reflect the goal of reducing all potential sources of the pollutant necessary to maintain the final effluent quality discharged to the receiving water to a level at or below the permit limit. The costs for pollutant minimization programs include both capital and O&M costs to find sources and implement reduction control strategies. EPA estimated these costs both for direct municipal and industrial dischargers as well as for indirect discharges to publicly owned treatment works (POTWs). Thus, EPA accounted for all anticipated costs to the extent feasible, even in situations were potential "hidden" pollutant loads may exist below detectable levels.

The issue of potential hidden loads raised by commenters on the CTR is not new. In 1994, EPA evaluated a sample of nine POTWs in the Great Lakes Basin using super-clean and high-resolution analytical methods (many of which were experimental) to determine whether, in fact, there was a substantial hidden pollutant load of bioaccumulative chemicals of concern (BCC). This study was undertaken because the regulated community in the basin raised concerns regarding the potential presence of mercury and other BCCs just below current Part 136 methods and the associated costs to remove these potential hidden loads. EPA assumed BCCs to be ubiquitous in the Great Lakes Basin at major POTWs because of the historical widespread use of these chemicals and well documented problems in the basin. Therefore, EPA concentrated its sampling efforts on POTWs which have less control of the potential sources of BCCs being discharged to their collection system than industrial dischargers.

In this study, EPA found the infrequent presence of BCCs (38 detections in 477 observations, approximately 8%) in POTW effluents. Of BCC's detected, mercury was detected at each of the POTWs (either as total mercury or methyl mercury). The concentrations of mercury found in POTW effluents were above EPA's most stringent ambient water quality criterion for the Great Lakes Basin in five of the nine samples taken. Where effluent concentrations exceeded the ambient criterion, however, they did so by small amounts, indicating that pollutant minimization programs (PMPs) would more than likely control mercury discharges to the levels required to comply with permit limits. The results of the study, when extrapolated to the universe of 316 POTWs in the Great Lakes Basin, indicates that the median concentration of mercury in all effluents is 0.99 ppt, the 75th percentile is 5.14 ppt, and the 95th percentile is 55.0 ppt.

These results indicate substantial compliance with permit limits significantly more stringent than those expected from CTR-based criteria and would not indicate substantial additional costs if the facilities were required to demonstrate compliance through analytical methods with lower MDLs. Furthermore, the study demonstrates that hidden pollutant loads do not exist at the levels once thought even for highly contaminated areas. This information is important when evaluating the economic analysis for the CTR because it indicates that the estimated costs at the high end of the cost range for the CTR, which accounts for controlling hidden pollutant loads were no effluent data exists may never materialize should analytical methods improve in the future.

EPA has also identified a number of locations where pollutant minimization programs have either been highly effective in reducing pollutant loads or have been implemented but have had inadequate time to determine results. For example, the Inland Empire Utilities Agency, serving the Chino Basin with three POTWs, has successfully reduced lindane in its effluents to permit limits through education of health authorities and pet service providers on effective alternatives to lindane-based products for lice and flea control. A similar program is being implemented at a facility in Arizona. The Western Lake Superior Sanitary District's (WLSSD) efforts to reduce mercury levels in their effluent include diverting

incinerator scrubber water; implementing external source identification studies and subsequent control programs at a pulp and paper mill, dental facilities, and medical facilities and laboratories; and conducting extensive public education and outreach, including mercury collection under a bounty program. As of 1996, WLSSD had successfully reduced mercury concentrations at their waste water treatment plant by more than 74% from 1990 dry sludge levels (from 4.50 ppm to 1.15 ppm) and by more than 97% from 1990 effluent levels (from 0.58 ppb to 0.015 ppb). The following are some additional examples of pollution prevention activities undertaken by facilities in the State of California:

* Replaced a sewer running through an arsenic-contaminated Superfund site (City of Palo Alto, California Regional Water Quality Control Plant).

* Allowed diversion of residential graywater containing mercury for use as on-site irrigation (City of Palo Alto, California Regional Water Quality Control Plant).

* Developed BMPs with medical facilities/offices about the use of mercury, handling of mercury-containing wastes, management of mercury-containing reagents, prevention and response for mercury spills, nonmercury analytical methodologies, and nonmercury-containing equipment (City of Palo Alto, California Regional Water Quality Control Plant).

* Educated pharmacists on mercury-containing products (City of Palo Alto, California Regional Water Quality Control Plant).

* Developed BMPs addressing mercury-containing equipment and reagent handling in laboratories (City of Palo Alto, California Regional Water Quality Control Plant).

* Published and distributed a BMP booklet to local pottery studios, schools, and art supply stores (City of Palo Alto, California Regional Water Quality Control Plant).

* Reduced the local discharge limit for nickel (applicable primarily to metal finishers) (City of Palo Alto, California Regional Water Quality Control Plant).

* Educated photo processors and medical and dental offices processing x-rays on silver use and disposal (City of Palo Alto, California Regional Water Quality Control Plant).

As a final point, EPA does not wish to delay or defer any further having ambient criteria for toxics as required under section 303(c)(2)(B) of the CWA. California is the only state in the nation without such numeric limits and it is important in order to meet the requirements of the CWA to bring California into compliance with the CWA by promulgation of this rule.

Comment ID: CTR-035-012a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N

Comment: 1. Comments on Proposed Rule A. General Comments p. 42166-67 --Legal Basis

EPA argues that:

EPA does not believe that it is necessary to support the criteria proposed today on a pollutant-specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA section 304(a) criteria guidance there is a 'discharge or presence' of that pollutant which could reasonably 'be expected to interfere with' the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) to the CWA.

Contrary to EPA's argument, we believe that the requirement in Section 303 of the CWA that States adopt water quality standards where there is a discharge or presence of toxic pollutants in the affected waters which could reasonably expected to interfere with designated uses, applies to EPA. EPA's claim that such a review would impose an "enormous administrative burden" is not compelling, since States, in their adoption of water quality standards, must perform this pollutant specific review of each stream segment under the express terms of Section 303(c)(2)(B). EPA's own regulations require that, in promulgating water quality standards for a State, EPA is subject to "the same policies, procedures, analyses, and public participation requirements established for States in these regulations" (40 CFR section 131.22). The regulations require States to "review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(40 CFR section 131.11)(emphasis added). Thus, the regulations regarding the adoption of water quality standards do not suggest that States adopt uniform water quality standards for every water body merely because there may be a large amount of work required to determine the appropriate water quality standards for each water body. We especially believe this issue to be pertinent to pollutants for which the proposed CTR criteria are below detection levels. We therefore recommend that EPA defer the adoption of criteria for constituents which are below detection limits until such time as data are available demonstrating that particular toxic pollutants are being discharged to specific water bodies at levels to warrant concern. The pollutants in this category include the following: aldrin, alpha-BHC, beta-BHC, chlordane, 4,4'-DDD, 4,4'-DDT, 4,4'-DDE, dieldrin, 2,3,7,8-TCDD (dioxin), endosulfan I, endosulfan II, endrin, endrin aldehyde, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, PCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, hexachlorobenzene, n-nitrosodi-n-propylamine, pentachlorophenol, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chaysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd)pyrene. EPA, upon determining that promulgation of a 303(c)(2)(B) criterion is necessary, should promulgate the criterion on a water body-specific basis. Also, EPA would need to conduct an economic impact analysis at that time. Finally, as with the CTR, EPA must pursue adoption of these criteria through a rulemaking process, allowing opportunities for public review and comment in accordance with the Clean Water Act and Administrative Procedures Act.

Response to: CTR-035-012a

EPA disagrees with the commenter. See response to CTR-036-005. In addition to the response outlined above, the commenter cites EPA regulations at 40 CFR 131.11 and 131.22 arguing that the regulation

constrains how EPA may implement CWA section 303(c)(2)(B) . The regulation cited by the commenter with respect to toxics control, 131.11, however, was part of the 1983 water quality standards regulations (48 Fed. Reg. 51400, Nov. 8, 1983), which preceded by several years enactment of CWA section 303(c)(2)(B) as part of the 1987 Amendments to the CWA. EPA did not amend the regulations after enactment of section 303(c)(2)(B), but instead issued guidance interpreting how the provision couldbe implemented by states consistently with the statute. Availability of the guidance was published in the Federal Register at 54 Fed. Reg. 346 (Jan. 5, 1989) and discussed at length in the preamble to the final National Toxics Rule at 57 Fed. Reg. 60848, 60853 (Dec. 22, 1992). In this guidance, EPA stated that states could implement CWA section 303(c)(2)(B) in three different ways, as specified by its 1989 Program Guidance for Implementing Section 303(c)(2)(B):

Option 1. Adopt statewide numeric criteria in State Water Quality Standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

Option 2. Adopt chemical-specific numeric criteria for priority toxic pollutants that are the subject of EPA section 304(a) criteria guidance, where the State determines based on available information that the pollutants are present or discharged and can reasonably be expected to interfere with designated uses.

Option 3.Adopt a procedure to be applied to a narrative water quality standard provision prohibiting toxicity in the receiving waters. Such procedures would be used by the State in calculating derived numeric criteria which must be used for all purposes under section 303(c) of the CWA.

In this rule, EPA has adopted the first approach. In addition, EPA has gathered information on the presence of toxic pollutants in the waters of the State to the extent possible, but does not believe it is necessary to demonstrate impairment of the water before applying ambient criteria to the water for the reasons stated in See response to CTR-036-005. However, because EPA has chosen an approach consistent to the guidance it gave the states, EPA has applied the same requirement of scientific defensibility it would require of states, and because EPA has allowed for public comment on the rule, EPA has applied the same policies, procedure, analyses and public participation requirements it established for States in Part 131.

Finally, with respect to detection levels, see responses to CTR-034-010b; CTR-005-009; CTR011-002; CTR-013-004; CTR-020-020; CTR-021-005b; CTR-027-004; CTR-030-009; CTR033-003a; CTR-034-010a; CTR-035-005; CTR-035-012b.

Comment ID: CTR-036-005
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: Authority for EPA to Adopt Statewide Criteria

Contrary to what EPA asserts, it cannot promulgate statewide water quality criteria for priority toxic pollutants without considering whether the discharge or presence of such pollutants will interfere with the specific designated uses of those California waters that are covered by the criteria. Under Section 303(c)(4)(B) of the CWA, EPA is permitted to "promptly prepare and publish proposed regulations setting forth a revised or new water quality standard for the navigable waters involved in any case where [EPA] determines that a revised or new standard is necessary to meet the requirements of [the CWA]." 33 U.S.C. section 1313(c)(4)B). However, a water quality standard consists of both "the designated uses of the navigable waters involved" and the "water quality criteria for such waters based upon such uses." 33 U.S.C. section 1313(c)(2)(A).

Here, EPA has proposed water quality criteria for California waters, not water quality standards. More importantly, EPA has failed to develop such criteria "based upon" the designated uses of these waters. EPA has not determined whether these criteria pollutants are present in all California waters. EPA attempts to argue that there is evidence in the record indicating the presence of priority toxic pollutants throughout the waters of the States, yet EPA admits that the evidence is "not necessarily complete (62 Fed. Reg. 42160, 72167) nor has EPA determined whether the discharge or presence of these pollutants "could reasonably be expected to interfere with" the designated uses of such waters, as is required under CWA Section 303(c)(2)(B). See 33 U.S.C. section 1313(c)(2)(B).

EPA argues that it would be an "enormous administrative burden" for it to determine on a "water body-by-water body basis" whether the discharge or presence of the priority toxic pollutants could reasonably be expected to interfere with the designated use of affected waters. [62 Fed. Reg. 42160, 42166]. EPA further asserts that interpreting Sections 303(c)(2)(B) and (c)(4) to require it to perform "such a cumbersome pollutant specific effort on each stream bed" in California would render Section 303(c) meaningless [Id. at 42167]. Finally, EPA claims that based on the statutory language, purpose and legislative history of Section 303(c), it is empowered to act swiftly and promptly when it determines that new or revised standards are necessary to comply with the CWA, and thus it may disregard the strictures of CWA Section 303(c)(2)(B). Id.

Unfortunately, these arguments ignore the plain meaning of Section 303(c). EPA must (1) promulgate water quality standards, not water quality criteria, when it determines that such standards are necessary to meet the requirements of the CWA, and (2) develop these water quality standards taking into account the designated uses of the waters to which such standards are being applied. 33 U.S.C. sections 1313(c)(2), (4).

Moreover, the call to prompt action contained in section 3043(c)(4) cannot be read in a way that transforms the remaining provisions of Section 303(c) into mere surplusage. Despite EPA's assertion that the "numerous deadlines" imposed by Section 303(c) require it to ignore the demands of Section 303(c)(2)(B), there in fact is no specific time frame within which EPA must promulgate a new or revised water quality standard when it acts pursuant to section 303(c)(4). Thus, the requirements that EPA act "promptly" govern the manner, not the time frame, in which it must act.

Nor can the legislative history of Section 303(c) be used to ignore the express language and plain meaning of section 303(c)(2)(B). When a statute is plain and unambiguous on its face there is no need to look to legislative history as a guide to its meaning [Tennessee Valley Authority v. Hill, 437 U.S. 153 (1978)]. The requirement of Section 303(c)(2)(B) to determine whether the "discharge or presence" of priority toxic pollutants "could reasonably be expected to interfere with" the designated uses of affected waters is not ambiguous, even juxtaposed with the requirement that EPA act "promptly". Congress may

have wanted EPA to act promptly, but it equally wanted EPA to act within the constraints of Section 303(c).

In short, Congress's supposed quest for swift action is not enough to ignore the plain language of Section 303(c). Legislative history may be considered where the plain meaning of statute produces an absurd result, but it may not be considered where it merely produces a "cumbersome" one.

Response to: CTR-036-005

EPA disagrees with the comment. EPA interprets section 303(c)(4)(B) to give EPA authority to act if the State fails to act by promulgate ambient water quality criteria pursuant to section 303(c)(2)(B) for water bodies with either human health or aquatic life uses designated by the state for pollutants for which EPA has issued national section 304(a) recommended criteria guidance. As EPA has reiterated throughout the rulemaking record, EPA's strong preference would have been for the state to take the lead in promulgating these criteria. Pursuant to section 303(c)(4)(B), the State's failure to take such action after its standards were invalidated in state court constitutes a failure to meet the requirements of the Act under CWA section 303(c)(2)(B). Further, EPA is acting consistent with its authority because as explained below, the criteria in the rule are ambient criteria that define attainment of the designated uses, and they will result in additional controls on dischargers only where necessary to protect the designated uses.

EPA disagrees with the comment that it has somehow violated the CWA by promulgating water quality criteria instead of "water quality standards." EPA's regulations explain that there are three components to water quality standards, designated uses; water quality criteria to protect those uses, and an antidegradation policy. See 40 CFR Part 131.6. In the rule, EPA is promulgating one component of water quality standards because this is what the state has failed to do. The CWA's reference to water quality standards, a broader authority encompassing designated uses, criteria to protect those uses and an antidegradation policy, does not preclude EPA from issuing one component of standards, water quality criteria.

EPA disagrees that it has failed to develop such criteria "based upon" the designated uses of such waters. The criteria in the rule are based on protection of human health (either through ingestion of drinking water or drinking water and organisms) or aquatic life (saltwater or freshwater) which relate directly to the uses designated by the State of California for the waterbody. The State has designated the waters covered by this rule for a number of uses related to recreation, drinking water and aquatic life. The State always retains the discretion to change the designated uses of the State, as long as it meets the criteria set forth in 40 CFR 131.10. These criteria define what is necessary to protect the designated use. In essence, EPA's interpretation of section 303(c)(2)(B) of the CWA means that if the discharge or presence of the pollutant exceeds the criteria values, the discharge or presence of the pollutant would interfere with the designated uses of the waterbody.

As these are ambient criteria, they do not in and of themselves require control of a discharge. The ambient criteria are implemented in two ways -- to point sources through NPDES permits for direct dischargers (that may be based on wasteload allocations in impaired waters) or pretreatment standards for indirect discharges (both of which are enforceable limits) and through load allocations for non-point sources (which are not enforceable under the Clean Water Act, but which represent the portion of a receiving waters receiving capacity attributable to a non-point source that would attain applicable water quality standards). Under the NPDES regulations, the ambient criteria promulgated in the rule are applied in NPDES permits as effluent limitation control only if the uncontrolled discharge of a particular pollutant has a "reasonable potential" to exceed applicable water quality criteria. EPA defines

"reasonable potential" in its regulations as where a discharge is projected or calculated to cause an excursion above a water quality standard based on a number of factors including, as a minimum, the four factors listed in 40 CFR 122.44(d)(1)(ii). Absent that determination, the criteria in and of themselves have no impact. Thus, EPA's promulgation of criteria for all water bodies in California that currently have no numeric criteria for toxic pollutants criteria for protecting the designated use ensures a safety net that does not impose any needless burden or costs on any dischargers. (EPA made this point in describing its guidance implementing section 303(c)(2)(B), 57 Fed. Reg. 60853 col. 1 (Dec. 22, 1992)). If EPA were to interpret section 303(c)(2)(B) to compel it to prove conclusively that all of the priority pollutants are present in all California waters, this would impose a huge resource burden on EPA with no substantive benefit in terms of environmental protection. In fact, if EPA were not to have perfect information upon which to base a determination that current discharges are impairing designated uses, EPA might overlook a waterbody that needs criteria as a basis for controlling discharges. In essence, establishment of these ambient criteria is necessary to establish the benchmark against which the permit authority can make the reasonable potential determination. The commenter's argument that EPA needs to do a more site specific evaluation of whether the discharge of the pollutant "could reasonably interfere" ignores that criteria are not only used to remediate where there is impairment but to prevent it from happening in the first place.

The comment further criticizes EPA's interpretation of the statutory language calling for the states to act within three years of the Act (which was enacted in 1987) coupled with that language in CWA section 303(c)(4) stating that EPA is to act "promptly" does not support EPA's approach to cover all waterbodies. EPA, however, believes that the time frames envisioned by Congress, to put in place ambient criteria for toxic pollutants where EPA had issued recommend criteria under section 304(a) of the CWA for those pollutants, are reasonably considered when interpreting what Congress intended EPA to do. Congress, by linking section 303(c)(2)(B) to the triennial review period, gave states a chance to comply with section 303(c)(2)(B) on their own. To interpret the combination of subsections (c)(2)(B) and (c)(4) as requiring monitoring and analysis to demonstrate impairment before establishing ambient standards would be counter to Congress' goal of putting in place the ambient standards as the foundation for toxics control. Another reason EPA believes that its approach is appropriate is that section 303 establishes a regime whereby EPA's role is one of overseer of the national program, with states taking the primary role for standards. The State of California is better positioned to make local site-specific determinations than is EPA and EPA believes that it is more appropriate to issue state-wide criteria and then to allow the State if it so chooses to establish and submit for approval water quality standards that are based on site-specific considerations. Finally the reference in section 303(c)(2)(B) to section 304(a) criteria suggests that section 304(a) serve as "default" criteria, that once EPA had issued its national section 304(a) criteria recommendations, states were to adopt numeric criteria for those pollutants based on the 304(a) criteria, unless they had other scientifically defensible criteria. Here, California is the only state without such numeric criteria. EPA also notes that this rule follows the approach EPA took nationally in promulgating the National Toxics Rule for states that had failed to comply with CWA section 303(c)(2)(B). 57 Fed. Reg. (Dec. 22, 1992). EPA incorporates the rationale for EPA's action used in the NTR as expressed in the preamble into this final rule.

As the Supreme Court has stated, if a statute is silent or ambiguous on a specific question, a reviewing court must defer to any reasonable construction of that statute by the administering agency. Chevron, U.S.A. v. NRDC, 467 U.S. 837, 843 (1984). Under Chevron, a reviewing court must determine "whether the agency's answer [to the ambiguous question] is based on a permissible construction of the statute." Id. The agency's construction need not be the one the court itself would adopt or the one the court feels would best implement congressional policy. It need only be a reasonable construction of the statutory question at issue. Id. At 844-45. Here, to recognize Congress' desire for timely establishment of numeric criteria for toxics and recognizing that these criteria do not have a regulatory impact unless

reasonable potential for exceeding the criteria is found in a permit-specific context, EPA believes that its approach to implementing section 303(c)(2)(B) is a reasonable construction of the statute.

Comment ID: CTR-038-006a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES E-01c; R; S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, and recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use" (See 40 CFR 131.11(a)(2)). Clearly the intent of both the Clean Water Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, such as the District and the small communities it serves, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-038-006a

EPA disagrees with the comment. See responses to CTR-035-012a and CTR-036-005. For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, see the preamble to the final rule.

Comment ID: CTR-040-011
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

III. Concern: The proposed Rule violates applicable Federal law and regulations

* In proposing a single set of criteria for all fresh waters, the Rule is inconsistent with the CWA and EPA's water quality standard regulations because it has not been determined that these criteria are necessary to avoid interference with designated uses (See Attachment B). The CWA requires that standards be established taking into consideration their use and value, and EPA regulations require consideration of specific water bodies where toxics may be adversely affecting water quality or uses.

Response to: CTR-040-011

EPA disagrees with the comment. See responses to CTR-035-012a and CTR-036-005.

Comment ID: CTR-040-016b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-24d

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

III. Recommendation: Adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for effluent-dominated/effluent-dependent streams.

Available discharge data for effluent-dominated streams in Sacramento indicate that a number of the proposed criteria are not presently being achieved and cannot be achieved with implementation of BMPs or other reasonable controls (See Attachment A). This is also true for many municipal stormwater programs in California.

* The application of the proposed statewide criteria to effluent-dominated waters would force the Sacramento Stormwater Management Program, and other stormwater programs, to remove these discharges, essentially drying up the waters for most of the year. The costs would be significant and the

benefits assessed in EPA's economic analysis (enhanced fishing, passive benefits, and reduced cancer risk) would be zero. The removal of these discharges would likely be detrimental rather than beneficial. The effluent-dependent aquatic and riparian habitat, which previously supported aquatic life and wildlife, would no longer exist.

* Effluent-dominated and effluent-dependent water bodies, which are common in California, require separate and distinct water quality criteria. Such a move is common sense and would be in accordance with the spirit (if not the letter) of Presidential Executive Order 12866 and the Unfunded Mandates Reform Act.

* Additionally, the CWA requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and also taking into consideration their use and value for navigation (See CWA section 303(c)(2)(A)). Consistent with this statutory mandate, EPA regulations require that water quality standards be based on identification of specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use, or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use. Clearly the intent of both the CWA and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question, rather than based on the "one-size-fits-all" approach used in the proposed Rule. This is not the cumbersome task suggested by the Preamble, at least with respect to developing criteria appropriate for effluent-dependent waters. But, even if it were a cumbersome task, the difficulty of complying with the law is not an excuse for noncompliance.

* EPA could fulfill its obligation under the CWA and EPA regulations with respect to effluent-dominated waters simply by proposing criteria for these waters that are generally achievable by present stormwater discharges. Then, using the more stringent statewide criteria as a tracer, control measures and BMPs could be implemented to reduce the discharge of problematic pollutants to the MEP.

Response to: CTR-040-016b

EPA disagrees with this comment. Adoption of aquatic life criteria for effluent-dominated and effluent-dependent waters, based on local information and data, is beyond the scope of the CTR. EPA supports State adoption of such site-specific criteria, however, and intends to stay the CTR after approving any such State-adopted criteria (see response to CTR-003-006, et al.), but EPA cannot undertake to adopt such criteria itself. Even if EPA were to include site-specific criteria in the CTR, such criteria could not be based on considerations as to whether or not they were "reasonably achievable" by dischargers, as proposed in this comment. Water quality criteria must be based on sound scientific rationale and must protect designated uses. Their attainability is not a basis for selecting appropriate criteria. 40 CFR 131.11(a).

The costs (reasonableness) of attainability, which cannot justify adopting criteria that do not protect uses already designated, may be taken into consideration in the designation or modification of uses for individual waterbodies. 40 CFR 131.10. For this reason, EPA believes that this commenter's concerns are misplaced. The suggestion that EPA adopt "separate and distinct water quality criteria" for effluent-dominated and effluent-dependent waters, "tailored to the characteristics of the waters in question," and "reasonably achievable" by dischargers, could be best addressed, initially, through adoption or modification of designated uses. This is also beyond the scope of the CTR, the purpose of which is to adopt numeric toxic pollutant criteria for those waters in California, with designated uses already in place, where there are currently no criteria for these pollutants in effect. The CTR does not

undertake to designate any uses for waters in California or modify any uses already designated by the State.

Also, See responses to CTR-035-012a and CTR-036-005. For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, see the preamble to the final rule.

See also response to CTR-040-016a.

Comment ID: CTR-041-014
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: 1. The California Toxics Rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations.

a. EPA Failed to Adopt Criteria on a Case-by-Case, Pollutant-by-Pollutant Basis.

Section 303 of the Clean Water Act (CWA) requires that whenever a State adopts water quality standards, it "shall adopt criteria for all toxic pollutants listed pursuant to section 1317(a)(1) of this title for which criteria have been published under section 1314(a) of this title, the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." 33 U.S.C. section 1313(c)(2)(B). In other words, criteria only need to be developed where there is a "discharge or presence" of toxic pollutants in the affected waters, which could reasonably be expected to interfere with those designated uses" adopted by the State.(*1) Thus, a water body and pollutant specific determination must be made before criteria are adopted as part of a water quality standard.

In its Preamble to the CTR, EPA stated that:

EPA does not believe that it is necessary to support the criteria proposed today on a pollutant specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA 304(a) criteria guidance there is a "discharge or presence" of that pollutant which could reasonably "be expected to interfere with" the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) of the CWA. 62 Fed. Reg. 42166.

...Thus, to interpret CWA section 303(c)(2)(B) and (c)(4) to require such a cumbersome pollutant specific effort on each stream segment would essentially render section 303(c)(2)(B) meaningless. The provision and its legislative background indicate that the Administrator's determination to invoke her

303(c)(4)(B) authority can be met by a generic finding of inaction by the State without the need to develop pollutant specific data for individual stream segments.

This determination is supported by information in the rulemaking record showing the discharge or presence of priority toxic pollutants throughout the State. While this data is not necessarily complete, it constitutes a strong record supporting the need for numeric criteria for priority toxic pollutants with section 304(a) criteria guidance where the State does not have numeric criteria. 62 Fed. Reg. 42167.

Thus, EPA basically states that it is not necessary for it to make the statutorily-required findings of "discharge or presence" or reasonable expectation of interference with designated uses because it would be a great administrative burden and because swift action is required.

EPA supports its contention that swift action is required by citing the statutory framework and purpose of section 303, and the CWA's legislative history. "In adding section 303(c)(2)(B) to the CWA, Congress understood the existing requirements in section 303(c)(1) for triennial water quality standards review and submissions and in section 303(c)(4)(B) for promulgation. CWA section 303(c) includes numerous deadlines and section 303(c)(4) directs the Administrator to 'act promptly' where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. The legislative history of the provision demonstrates that chief Senate sponsors, including Senators Stafford, Chaffee and others wanted the provision to eliminate State and EPA delays and force quick action." 62 Fed. Reg. 42,167. Thus, EPA rests its entire argument regarding the need for swift action on the existence of the word "promptly" in the section of the statute related to the Administrator's duty to promulgate standards in the absence of approved State standards. It is unclear how EPA can argue that it has acted "promptly" thus far to adopt these new standards since it has been over three years since the State standards were overturned. Arguably, the additional extra time it would have taken to make the statutorily required findings would not have been substantial, and would probably result in less impact on dischargers.

EPA's other argument that such a "cumbersome pollutant specific effort on each stream segment" would "impose an enormous administrative burden" is not compelling. States, in their adoption of water quality standards, must perform this "cumbersome pollutant specific effort on each stream segment" under the express terms of section 303 (c)(2)(B). Therefore, it logically follows that EPA, in promulgating the standards for California, stands in the State's shoes and should be subject to the same requirements imposed upon the State. (*2) Furthermore, EPA's reasoning that it is not required to do something merely because it is "cumbersome" may be subject to a legal challenge that such a determination is "arbitrary and capricious" under the Administrative Procedures Act (5 U-S.C. section 701 et seq.).

(*1) See also 4O C.F.R. part 131.11 (a)(2) ("States must review water quality data and information on discharges to identify specific water bodies where toxic pollutants may be, adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.")

(*2) See accord 40 C.F.R. 131.24(c) regarding EPA promulgation of water quality standards ("In promulgating water quality standards, the Administrator is subject to the same policies, procedures, analyses, and public participation requirement established for States. . .").

Response to: CTR-041-014

EPA disagrees with the comment. See responses to CTR-035-012a and CTR-036-005.

Comment ID: CTR-042-007a
Comment Author: Cal. Dept. of Transportation
SDocument Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES E-01c; S

Comment: 7. The CTR may violate the Administrative Procedures Act, the and Executive Order (E.O.) Unfunded Mandates Reform Act No. 12866.

In the Preamble to the CTR, EPA repeatedly claims that the CTR will not result in expenditures of more than $100 million per year and, therefore, the statutory requirements of the UMRA and E.O. 12866 are not triggered.(*1) Caltrans' annual costs alone and only in Los Angeles will exceed the $100 million annual figure, even assuming the lowest level of treatment. Therefore, EPA's cost assumptions are challengeable as being arbitrary and capricious and in violation of the Administrative Procedures Act.(*2)

Request: Caltrans requests that EPA reconsider its cost estimates based on the comments received during the public comment period.

Caltrans would like to thank EPA for the opportunity to provide comments on this proposed regulation. It is hoped that EPA will consider and address Caltrans' comments in the final version of the CTR. Should you have any questions concerning our comments on the CTR, please feel free to address these questions to Marcia Arrant at (916) 657-5381.

(*1) See CTR, 62 Fed. Reg. at 42,188, and at 42,191 ("EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.")
(*2) See American Iron and Steel Institute v. EPA, 1997 WL 297251 (D.C. Cir., 1497)(the court found that EPA had arbitrarily failed to adequately address cost-justification for its elimination of mixing zones. EPA had estimated the total cost of elimination mixing zones for bioaccumulative chemicals of concern (BCCS) from all dischargers to the Great Lakes at $200,000, without even acknowledging a comment estimating the cost to one town for removal of mercury from its sewage discharge would be approximately $300,000).

Response to: CTR-042-007a

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, see the preamble to the final rule, and EPA's economic analysis for the final rule. For an evaluation of Caltrans' analysis of costs associated with storm water discharges, see response to CTR-040-004 (Category J; Stormwater Economics).

The commenter cited the decision reviewing EPA's Great Lakes' Initiative with respect to eliminating mixing zones for bioaccumulative pollutants of concern. EPA views this decision as remanding the matter to the agency for a failure to respond adequately to a comment as required under the Administrative Procedure Act. The decision did not address or reverse EPA's longstanding interpretation of the CWA that its ambient based water quality criteria must be set at levels necessary to protect the designated use (either aquatic life or human health, or both). The elimination of the mixing zone in the GLI was not a water quality criterion. It was a specific requirement that would have imposed criteria as end-of-pipe effluent limitations for bioaccumulative pollutants where feasible. EPA's current regulations at 40 CFR.131.11 state that criteria must be based on sound scientific rationale and must containsufficient parameters to protect the designated use. Further, such criteria shall be based on EPA's section 304(a) criteria recommendations, EPA's 304(a) criteria recommendations modified to reflect site-specific conditions, or other scientifically defensible methods. From the outset of the water quality standards program, EPA has explained that while economic factors may be considered in designating uses, scientific and technical factors must justify criteria to meet those uses. 44 Fed. Reg. 25,223, -24, 25 (April 30, 1979). When criteria cannot be attained due to economic factors, the state may consider whether a change or "downgrade" the use designation for the waterbody would be appropriate. Id. at 25,224. See. e.g., Mississippi Comm. on Natural Resources v. Costle, 625 F.2d 1269, 1277 (5th Cir. 1980), where the Court addressed whether EPA's action disapproving the state's water quality criterion for dissolved oxygen was arbitrary and capricious because EPA failed to consider economic factors. In affirming EPA's disapproval, the Court stated that

Nevertheless, we are convinced that EPA's construction is correct. See E.I. du Pont de Nemours & Co. v. Train, 430 U.S. 112, at 134-35. Congress itself separated use and criteria and stated that 'the water quality criteria for such waters [shall be] based on such uses. 33 U.S.C. Section 1313(c)(2)(1976). The statute requires EPA to develop criteria 'reflecting the latest scientific knowledge." Id. Section 1314(a)(1)(emphasis added). "The interpretation that criteria were based exclusively on scientific data predates the 1972 amendments. Water Quality Criteria vii (1968). Furthermore, when Congress wanted economics to be considered, it explicitly required it. See Sections 1311(b)(2)(A), 1312(b), 1314(b)(1976).

EPA reiterated this interpretation of the CWA and its implementing regulations in discussing section 304(a) recommended criteria guidance stating that they "are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects" and "do not reflect consideration of economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water." 63 FR 36,742, 36,762 col. 3 (July 7, 1998).

Comment ID: CTR-043-005a
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES E-01c; R; S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters,"states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.1 I (a)(2)). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-043-005a

See responses to CTR-035-012a and CTR-036-005. For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, see the preamble to the final rule, and EPA's economic analysis for the final rule.

Comment ID: CTR-044-006a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES E-01c; R; S

Comment: We have reviewed the proposed CTR and offer the following comments:

5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.11 (a)(2)) (see Exhibit G). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In

failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id.). Moreover, in failing to properly consider the impacts on small entities, such as the City, the rule is inconsistent with the Regulatory Flexibility Act (Id.).

Response to: CTR-044-006a

See responses to CTR-035-012a and CTR-036-005. For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, see the preamble to the final rule.

Comment ID: CTR-044-044
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: LEGAL ANALYSIS OF THE PROPOSED CALIFORNIA TOXICS RULE

1. The California Toxics Rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations.

a. EPA Failed to Adopt Criteria on a Case-by-Case, Pollutant-by-Pollutant Basis.

Section 303 of the Clem Water Act (CWA) requires that whenever a State adopts water quality standards, it "shall adopt criteria for all toxic pollutants listed pursuant to section 1317(a)(1) of this title for which criteria have been published under section 1314(a) of this title, the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." 33 U.S.C. section 1313(c)(2)(B). In other words, criteria only need to be developed where there is a "discharge or presence" of toxic pollutants in the affected waters, which could "reasonably be expected to interfere with those designated uses" adopted by the State.(*1) Thus, a water body and pollutant specific determination must be made before criteria are adopted as part of a water quality standard.

In its Preamble to the CTR, EPA stated that:

EPA does-not believe that it is necessary to support the criteria proposed today on a pollutant specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA 304(a) criteria guidance there is a "discharge or presence" of that pollutant which could reasonably "be expected to interfere with" the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) of the CWA. 62 Fed. Reg. 42166.

Thus, to interpret CWA section 303(c)(2)(B) and (c)(4) to require such a cumbersome pollutant specific effort on each stream segment would essentially render section 303(c)(2)(B) meaningless. The provision and its legislative background indicate that the Administrator's determination to invoke her 303(c)(4)(B) authority can be met by a generic finding of inaction by the State without the need to develop pollutant specific data for individual stream segments. This determination is supported by information in the rulemaking record showing the discharge or presence of priority toxic pollutants throughout the State. While this data is not necessarily complete, it constitutes a strong record supporting the need for numeric criteria for priority toxic pollutants with section 304(a) criteria guidance where the State does not have numeric criteria. 62 Fed. Reg. 42167.

Thus, EPA basically states that it is not necessary for it to make the statutorily-required findings of "discharge or presence" or reasonable expectation of interference with designated uses because it would be a great administrative burden and because swift action is required.

EPA supports its contention that swift action is required by citing the statutory framework and purpose of section 303, and the CWA's legislative history. "In adding section 303(c)(2)(B) to the CWA, Congress understood the existing requirements in section 303(c)(1) for triennial water quality standards review and submissions and in section 303(c)(4)(B) for promulgation. CWA section 303(c) includes numerous deadlines and section 303(c)(4) directs the Administrator to act promptly where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. The legislative history of the provision demonstrates that chief Senate sponsors, including Senators Stafford, Chaffee and others wanted the provision to eliminate State and EPA delays and force quick action." 62 Fed. Reg. 42,167. Thus, EPA rests its entire argument regarding the need for swift action on the existence of the word "promptly" in the section of the statute related to the Administrator's duty to promulgate standards in the absence of approved State standards. It is unclear how EPA can argue that it has acted "promptly" thus far to adopt these new standards since it has been over three years since the State standards were overturned. Arguably, the additional extra time it would have taken to make the statutorily required findings would not have been substantial, and would probably result in less impact on dischargers.

EPA's other argument that such a "cumbersome pollutant specific effort on each stream segment" would "impose an enormous administrative burden" is not compelling. States, in their adoption of water quality standards, must perform this "cumbersome pollutant specific effort on each stream segment" under the express terms of section 303 (c)(2)(B). Therefore, it logically follows that EPA, in promulgating the standards for California, stands in the State's shoes and should be subject to the same requirements imposed upon the State. (*2) Furthermore, EPA's reasoning that it is not required to do something merely because it is "cumbersome" may be subject to a legal challenge that such a determination is "arbitrary and capricious" under the Administrative Procedures Act (5 U.S.C. section 701 et seq.).

(*1) See also 4O C.F.R. section 131.11 (a)(2) ("States must review water quality data and information on discharges to identify specific water bodies where toxic pollutants may be, adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.")

(*2) See accord 40 C.F.R. 131.241(c) regarding EPA promulgation of water quality standards ("In promulgating water quality standards, the Administrator is subject to the same policies, procedures, analyses, and public participation requirement established for States. . .").

Response to: CTR-044-044

Comment ID: CTR-050-001
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the American Petroleum Institute (API), we are submitting the following comments on U.S. EPA's proposal to establish water quality criteria for toxic pollutants for the State of California (62 Fed. Reg. at 42160, Aug. 5, 1997). API is a national trade association representing 300 companies with operations in all facets of the petroleum industry

(exploration, production, refining, and marketing. API has member companies in California as well as member companies in the Midwestern states currently implementing the Great Lakes Initiative. API member companies have experience with many of aspects of the proposed rule which are quite similar to the Great Lakes Initiative.

Many of API's members own and operate facilities in the State of California that discharge wastewater pursuant to NPDES permits. Those facilities will likely be issued new permit limits based on the criteria set forth in the EPA rule, once that rule is issued in final form. Therefore, API has a strong interest in the EPA proposal. Based on its review, API believes that the proposal has substantial legal flaws. Those flaws are described below.

1. EPA is Not Authorized to Impose the Proposed Criteria on a State-wide Basis.

EPA has proposed to impose the new criteria on all-waters in the State of California. EPA claims that it has the authority to impose state-wide criteria because the State's water quality control plans, which contain water quality criteria, have been invalidated by a court. Therefore, according to EPA, the State has not met its obligations under section 303(c)(2)(B) of the Clean Water Act, which requires the State to issue water quality criteria for toxics, "the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Because the State has not taken that action, EPA claims that it must promulgate standards for the State, under section 303(c)(4)(B) of the Act, which requires EPA to act when it determines that "a revised or new standard is necessary to meet the requirements of the Act." (62 Fed. Reg. at 42165).

EPA's position that it may impose state-wide criteria is squarely inconsistent with the plain language and intent of the Clean Water Act. First, Section 303(c)(2)(b) requires that the state must establish criteria for toxics, the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the state as necessary to support such designated uses by requiring that criteria be established for certain toxics, i.e., those which interfere with the designated uses of specified waters, i.e., affected waters, it is clear that Congress intended that criteria be set on a

pollutant specific and stream-specific basis, not according to state geographic boundaries. Uses are designated for particular water bodies. Thus, EPA's position that it need not make any specific findings at all nullifies the clear statutory language of section 303(c)(2)(b) and violates a cardinal principle of statutory construction that each and every word of a provision be given effect.

Response to: CTR-050-001

See responses to CTR-035-012a and CTR-036-005. Further, EPA's interpretation does give effect to each word in CWA section 303(c)(2)(B) because the phrase "discharge or presence of which in the affected waters could reasonably be expect to interfere with those designated uses adopted by the State, as necessary to support such designated uses" reasonably could be interpreted to mean that if the pollutant were discharged, it could interfere with the designated uses. As explained in the above cited comment responses, this is a reasonable interpretation of the CWA given the time frames set forth by Congress and given the practical reality that no water quality based effluent limit must be included in a particular permit unless the State makes a "reasonable potential" determination for a given discharge.

Comment ID: CTR-050-002
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the American Petroleum Institute (API), we are submitting the following comments on U.S. EPA's proposal to establish water quality criteria for toxic pollutants for the State of California (62 Fed. Reg. at 42160, Aug. 5, 1997). API is a national trade association representing 300 companies with operations in all facets of the petroleum industry

(exploration, production, refining, and marketing. API has member companies in California as well as member companies in the Midwestern states currently implementing the Great Lakes Initiative. API member companies have experience with many of aspects of the proposed rule which are quite similar to the Great Lakes Initiative.

Many of API's members own and operate facilities in the State of California that discharge wastewater pursuant to NPDES permits. Those facilities will likely be issued new permit limits based on the criteria set forth in the EPA rule, once that rule is issued in final form. Therefore, API has a strong interest in the EPA proposal. Based on its review, API believes that the proposal has substantial legal flaws. Those flaws are described below.

Second, EPA concedes that it has not made the factual findings to support state-wide application of the proposed standards, i.e., that a particular standard for a particular pollutant on a particular stream is "necessary to meet the requirements of the Act." (62 Fed. Reg. at 42166-42167) In fact, EPA states that its data concerning "discharge or presence" of toxics is "not necessarily complete." (62 Fed. Reg. at 42167) Perhaps, it is this acknowledged lack of supporting data that compels EPA to ignore the language

of section 303(c)(2)(b), which so plainly contradicts the concept of a state-wide applicability of toxic criteria.

Response to: CTR-050-002

See responses to CTR-035-012a and CTR-036-005.

Comment ID: CTR-050-003
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the American Petroleum Institute (API), we are submitting the following comments on U.S. EPA's proposal to establish water quality criteria for toxic pollutants for the State of California (62 Fed. Reg. at 42160, Aug. 5, 1997). API is a national trade association representing 300 companies with operations in all facets of the petroleum industry

(exploration, production, refining, and marketing. API has member companies in California as well as member companies in the Midwestern states currently implementing the Great Lakes Initiative. API member companies have experience with many of aspects of the proposed rule which are quite similar to the Great Lakes Initiative.

Many of API's members own and operate facilities in the State of California that discharge wastewater pursuant to NPDES permits. Those facilities will likely be issued new permit limits based on the criteria set forth in the EPA rule, once that rule is issued in final form. Therefore, API has a strong interest in the EPA proposal. Based on its review, API believes that the proposal has substantial legal flaws. Those flaws are described below.

Third, EPA's claim that it does not have to make pollutant and stream-specific determinations because Congress wanted it to take "quick action" (62 Fed. Reg. at 42167), is not supported by the pertinent statutory provisions which contain no deadlines at all. Section 303(c)(4)(B) merely directs the Agency to act to promptly" and has no explicit connection to section 303(c)(2)(B), which contains the State's obligations to issue criteria for toxicities.

If Congress had wanted to establish a connection between the two statutory provisions, and authorize EPA to take "quick action" to issue state-wide criteria if the State has not acted, Congress could easily have inserted appropriate language in either section 303(c)(2)(B), section 303(c)(4)(B), or both. Congress did not insert such language. Thus, Congress did not authorize the Agency to make an "end run" around the explicit provisions of the statute by issuing state-wide criteria without stream-specific or pollutant-specific findings that such criteria are necessary.

Response to: CTR-050-003

See responses to CTR-035-012a and CTR-036-005.

Comment ID: CTR-050-004
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of the American Petroleum Institute (API), we are submitting the following comments on U.S. EPA's proposal to establish water quality criteria for toxic pollutants for the State of California (62 Fed. Reg. at 42160, Aug. 5, 1997). API is a national trade association representing 300 companies with operations in all facets of the petroleum industry

(exploration, production, refining, and marketing. API has member companies in California as well as member companies in the Midwestern states currently implementing the Great Lakes Initiative. API member companies have experience with many of aspects of the proposed rule which are quite similar to the Great Lakes Initiative.

Many of API's members own and operate facilities in the State of California that discharge wastewater pursuant to NPDES permits. Those facilities will likely be issued new permit limits based on the criteria set forth in the EPA rule, once that rule is issued in final form. Therefore, API has a strong interest in the EPA proposal. Based on its review, API believes that the proposal has substantial legal flaws. Those flaws are described below.

Finally, EPA imposition of state-wide standards is not "necessary to meet the requirements of the Act," as required by Section 303(c)(4)(B). In discussing the potential economic impacts of the proposal, EPA points out that if it did not issue a rule, the State could use its narrative water quality criteria to impose permit limits for toxicities. (62 Fed. Reg. at 42187) EPA fails to recognize that if the state were allowed to use its criteria in this manner, there would be no need for EPA to usurp state authority and federally impose statewide criteria.

For the reasons cited above, EPA's action to propose toxic criteria in the State of California is without legal authority and should be withdrawn.

Response to: CTR-050-004

See responses to CTR-035-012a and CTR-036-005. EPA is promulgating numeric criteria here even though the state could use its narrative to develop water quality based effluent limits in order to meet the requirements of CWA section 303(c)(2)(B). Section 303(c)(2)(B) of the CWA was enacted in 1987 in response to Congress' impatience with the progress in implementation of water quality controls for toxic pollutants for which EPA has national section 304(a) recommended criteria guidance. In enacting section 303(c)(2)(B), Congress required states to adopt numeric criteria. In light of California's failure to have such criteria, EPA's promulgation is implementing Congressional intent.

Comment ID: CTR-050-007a
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES E-01c; R; S

Comment: IV. EPA Has Not Complied With Applicable Regulatory Review Requirements. There are several significant statutes and executive orders that require EPA to undertake analyses of the costs and benefits of its regulations, and to submit the regulations and analyses to other governmental bodies, including the Office of Management and Budget (OMB) and Congress. Those authorities include the Regulatory Flexibility Act, the Small Business Regulatory Enforcement and Fairness Act (SBREFA), the Unfunded Mandates Reform Act, the Congressional Review Act, and Executive Order 12866 (Regulatory Planning and Review). EPA apparently believes that it does not need to comply with any of those requirements for this rulemaking. (62 Fed. Reg. at 42188-42191). API believes that EPA is required to meet those obligations for the proposed criteria, and that the Agency's rationale for avoiding this responsibility has no legal basis.

EPA supports its decision not to comply with the regulatory review statutes by stating that the proposed criteria "by themselves, do not directly impose economic impacts." (62 Fed. Reg. at 42188). EPA admits that when those criteria are combined with the designated uses that have been adopted by the State, and implemented in permit limits, "there may be a cost to some dischargers." (62 Fed. Reg. at 42188) could be substantial; the Agency itself estimates that the compliance cost could be between $15 and $87 million per year.(62 Fed. Reg. at 42189). (That does not include indirect costs to the economy, which would surely put this rule above the $100 million impact threshold specified in several of the regulatory review statutes listed above.) EPA cannot ignore those costs by creating its own interpretation of those statutes in which only "direct" impacts need be considered. There is no support in the statutory language or legislative history for such a reading, and EPA has cited no such support in its Federal Register notice.

There is another problem with EPA's rationale for avoiding regulatory review: if EPA were right that "indirect" impacts do not trigger those reviews, the impacts of this rulemaking are not really "indirect." Those impacts emerge clearly once the proposed criteria are combined with the State's designated uses. Those designations have already been established, so there is nothing uncertain or indefinite about that aspect of the water quality standards. Then, once the standards are completed, the State must implement those standards through permit limits. While there are some decisions that the State must make in determining the proper permit limits, which can influence the size of the compliance costs, EPA can readily determine a range of possible costs. In fact, the Agency has already done so, resulting in the $15 - $87 million cost range discussed above. While those costs may not be fixed with certainty, they are certainly "direct economic impacts". Therefore, even if the Agency were correct in looking at only "direct" impacts, this rulemaking poses such impacts, and EPA must comply with the statutory requirements to conduct and submit cost and benefit analyses of its proposed criteria.

V. CONCLUSION

As explained above, EPA's proposal to issue water quality criteria for toxicities in the State of California suffers from serious legal flaws. API urges the Agency to reconsider its intended course of action in light of the issues raised in these and other public comments. If you have any questions regarding these comments, or would like any additional information, please call Theresa Pugh at 202/682-8036.

Response to: CTR-050-007a

EPA disagrees with the comment. EPA has explained its compliance with E.0. 12866, the Regulatory Flexibility Act (as amended), and the Unfunded Mandates Reform Act in the preamble to the final rule.

With respect to the Regulatory Flexibility Act (RFA), and as stated in the preamble to the proposed and final rules, the RFA requires agencies to assess the economic impact of a rule only on small entities that are subject to the requirements of the rule. Today's rule does not impose any impacts on small entities.

The Regulatory Flexibility Act generally requires federal agencies to prepare a regulatory flexibility analysis (RFA) that describes the impact of a rule on small entities (small businesses, small organizations and small governmental jurisdictions) whenever an agency promulgates a final rule under section 553 of the Administrative Procedure Act, 5 U.S.C. Section 553. 5 U.S.C. Section 604. Under section 605(b) of the Regulatory Flexibility Act, however, if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the statute does not require the agency to prepare an RFA. Pursuant to section 605(b), the Administrator is today certifying that this rule will not have a significant economic impact on a substantial number of small entities for the reasons explained below. Consequently, EPA has not prepared an RFA.

The RFA requires analysis of the economic impact of a rule only on the small entities subject to the rules' requirements. See United States Distribution Companies v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996). ("[N]o [regulatory flexibility] analysis is necessary when an agency determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule," United Distribution at 1170, quoting Mid-Tex Elec. Co-op v. FERC, 773 F.2d 327, 342 (D.C. Cir. 1985) (emphasis added by United Distribution court).) Thus, the RFA requires that any regulatory flexibility analysis prepared for a final rule must include estimates of "the number of small entities to which a rule will apply." 5 U.S.C. Section 604(a)(3). The analysis must also include a description of the recordkeeping, reporting and compliance requirements of the rule, including an estimate of the classes of small entities "which will be subject to the requirements." 5 U.S.C. Section 604(a)(4). In light of these provisions, courts have consistently interpreted the RFA to impose no obligation on an agency to conduct a small entity impact analysis on entities it does not regulate. Motor & Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449, 467 & n.18 (D.C. Cir. 1998).

The U.S. Court of Appeals for the District of Columbia Circuit recently reaffirmed its conclusion that the RFA does not require an agency to prepare an assessment of the economic impact of a rule on small entities that are not directly affected by a rule. American Trucking Association, Inc. v. U.S. Environmental Protection Agency, (D.C. Cir. 1999). In that case, the court determined that EPA was not required to prepare a regulatory flexibility analysis of the economic impact of a rule on small entities when it promulgated air quality standards under the Clean Air Act. There, EPA had certified that the rule would not have a significant impact on small entities because the air standard did not directly impose requirements on small entities and consequently they were not subject to the rule. Under the Clean Air Act, states regulate small entities through state implementation plans that they are required to develop under the Act. States have broad discretion in determining how to achieve compliance with the standards and may choose to avoid imposing any of the burden of complying with the standards on small entities.

The CTR presents a situation very similar to that described in the American Trucking case. It establishes no requirements that are directly applicable to small entities, and so the agency is not required to conduct a regulatory flexibility analysis under the RFA. (See United States Distribution Companies v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996). The Agency is therefore certifying that today's rule will not have a significant economic impact on a substantial number of small entities, within the meaning of the RFA.

Under the CWA water quality standards program, states must adopt water quality standards for their waters that must be submitted to EPA for approval. If the Agency disapproves a state standard and the state does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA has authority to promulgate criteria or standards in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. These state standards (or EPA-promulgated standards) are implemented through various water quality control programs including the National Pollutant Discharge Elimination System (NPDES) program that limits discharges to navigable waters except in compliance with an EPA permit or permit issued under an approved state program. The CWA requires that all NPDES permits must include any limits on discharges that are necessary to meet state water quality standards.

Thus, under the CWA, EPA's promulgation of water quality criteria or standards establishes standards that the state, in turn, implements through the NPDES permit process. The state has considerable discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet the standards. In circumstances where there is more than one discharger to a water body that is subject to water quality standards or criteria, a state also has discretion in deciding on the appropriate limits for the different dischargers. While the state's implementation of federally-promulgated water quality criteria or standards may result indirectly in new or revised discharge limits for small entities, the criteria or standards themselves do not apply to any discharger, including small entities.

EPA recognizes that it has undertaken an economic analysis pursuant to E.O. 12866 for this rule. This analysis, however, makes numerous assumptions and does not necessarily predict how the state will implement the criteria. Thus, the economic analysis represents EPA's best estimate of the implementation costs of the rule given the broad flexibility the state has in implementing the criteria.

The CTR, as explained above, does not itself establish any requirements that are applicable to small entities. As a result of EPA's action here, the State of California will need to ensure that permits it issues comply with the water quality standards established by the criteria in today's rule. In so doing, the State will have a number of discretionary choices associated with permit writing. While California's implementation of today's rule may ultimately result in some new or revised permit conditions for some dischargers, including small entities, EPA's action today does not impose any of these as yet unknown requirements on small entities.

Although the statute does not require EPA to prepare a regulatory flexibility analysis when it promulgates water quality criteria which will establish water quality standards for California, EPA has prepared an assessment of potential economic impact. This evaluation focuses on State and local implementation procedures related to the NPDES permit program. This evaluation is included in a document entitled, Implementation Analysis of Ambient Water Quality Criteria for Priority Toxic Pollutants in California which is part of the administrative record for this rulemaking. This document looks at the many implementation procedures of the NPDES permit program that the State implements to control pollutants from point source discharges. The procedures discussed in the document include: methods to calculate water quality-based effluent limits; mixing zones; site-specific translators for

metals criteria; compliance schedules; effluent trading; water-effect ratios; variances; designated use reclassification; and site-specific criteria. Each of these implementation procedures may have an effect on how water quality standards, based on the criteria in today's rule, will impact NPDES permit holders. Many of these procedures will lessen impacts on regulated entities.

The document also looks at implementation procedures used in the pretreatment program to control pollutant discharges from dischargers that do not discharge directly but introduce pollutants to publicly owned treatment works (POTWs). These dischargers include retail, commercial, and small industrial facilities that discharge to publicly owned treatment works (POTWs). Local entities have significant flexibility to implement their pretreatment programs. These procedures include: methods to calculate local limits (allocation of pollutants); methods of pollution prevention for various specific sources; pretreatment pollutant trading; methods of low cost pollutant reductions; technical assistance to move toward or achieve zero-discharge; cost accounting to drive down levels of discharges; and a few of the regulatory relief options discussed in the direct discharger section, e.g., compliance schedules.

The discussion illustrates the significant amount of flexibility available to the State and local agencies when implementing the NPDES permit program and pretreatment program and emphasizes that appropriate use of the available implementation tools can greatly affect the impact to many direct and indirect dischargers.

EPA recognizes that it has undertaken an economic analysis pursuant to E.O. 12866 for this rule. This analysis, however, makes numerous assumptions and does not necessarily predict how the state will implement the criteria. Thus, the economic analysis represents EPA's best estimate of the costs of the rule given the broad flexibility the state has in implementing the criteria.

Comment ID: CTR-052-021a
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01c; R; S

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should revise the proposed rule and economics analysis such that they are consistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act. Specific citations for these inconsistencies are contained in comments from BADA and CASA/Tri-TAC.

Response to: CTR-052-021a

See responses to CTR-035-012a and CTR-036-005. EPA has explained its compliance with E.0. 12866, the Regulatory Flexibility Act (as amended), and the Unfunded mandates Reform Act in the preamble to the final rule.

Comment ID: CTR-054-014
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES

Comment: The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations (see Attachment 4). In failing to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities (Id.), the rule is inconsistent with the Regulatory Flexibility Act (Id.).

Response to: CTR-054-014

See responses to CTR-035-012a and CTR-036-005. EPA has explained its compliance with E.0. 12866, the Regulatory Flexibility Act (as amended), and the Unfunded mandates Reform Act in the preamble to the final rule.

Comment ID: CTR-054-048
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-21 Legal Concerns
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: LEGAL ANALYSIS OF THE PROPOSED CALIFORNIA TOXICS RULE

1. The California Toxics Rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations.

a. EPA Failed to Adopt Criteria on a Case-by-Case, Pollutant-by-Pollutant Basis.

Section 303 of the Clem Water Act (CWA) requires that whenever a State adopts water quality standards, it "shall adopt criteria for all toxic pollutants listed pursuant to section 1317(a)(1) of this title for which criteria have been published under section 1314(a) of this title, the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." 33 U.S.C. section 1313(c)(2)(B). In other words, criteria only need to be developed where there is a "discharge or presence" of toxic pollutants in the affected waters, which could "reasonably be expected to interfere with those designated uses" adopted by the State.(*1) Thus, a water body and pollutant specific determination must be made before criteria are adopted as part of a water quality standard.

In its Preamble to the CTR, EPA stated that:

EPA does-not believe that it is necessary to support the criteria proposed today on a pollutant specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA 304(a) criteria guidance there is a "discharge or presence" of that pollutant which could reasonably "be expected to interfere with" the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) of the CWA. 62 Fed. Reg. 42166.

Thus, to interpret CWA section 303(c)(2)(B) and (c)(4) to require such a cumbersome pollutant specific effort on each stream segment would essentially render section 303(c)(2)(B) meaningless. The provision and its legislative background indicate that the Administrator's determination to invoke her 303(c)(4)(B) authority can be met by a generic finding of inaction by the State without the need to develop pollutant specific data for individual stream segments. This determination is supported by information in the rulemaking record showing the discharge or presence of priority toxic pollutants throughout the State. While this data is not necessarily complete, it constitutes a strong record supporting the need for numeric criteria for priority toxic pollutants with section 304(a) criteria guidance where the State does not have numeric criteria. 62 Fed. Reg. 42167.

Thus, EPA basically states that it is not necessary for it to make the statutorily-required findings of "discharge or presence" or reasonable expectation of interference with designated uses because it would be a great administrative burden and because swift action is required.

EPA supports its contention that swift action is required by citing the statutory framework and purpose of section 303, and the CWA's legislative history. "In adding section 303(c)(2)(B) to the CWA, Congress understood the existing requirements in section 303(c)(1) for triennial water quality standards review and submissions and in section 303(c)(4)(B) for promulgation. CWA section 303(c) includes numerous deadlines and section 303(c)(4) directs the Administrator to act promptly where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. The legislative history of the provision demonstrates that chief Senate sponsors, including Senators Stafford, Chaffee and others wanted the provision to eliminate State and EPA delays and force quick action." 62 Fed. Reg. 42,167. Thus, EPA rests its entire argument regarding the need for swift action on the existence of the word "promptly" in the section of the statute related to the Administrator's duty to promulgate standards in the absence of approved State standards. It is unclear how EPA can argue that it has acted "promptly" thus far to adopt these new standards since it has been over three years since the State standards were overturned. Arguably, the additional extra time it would have taken to make the statutorily required findings would not have been substantial, and would

probably result in less impact on dischargers.

EPA's other argument that such a "cumbersome pollutant specific effort on each stream segment" would "impose an enormous administrative burden" is not compelling. States, in their adoption of water quality standards, must perform this "cumbersome pollutant specific effort on each stream segment" under the express terms of section 303 (c)(2)(B). Therefore, it logically follows that EPA, in promulgating the standards for California, stands in the State's shoes and should be subject to the same requirements imposed upon the State. (*2) Furthermore, EPA's reasoning that it is not required to do something merely because it is "cumbersome" may be subject to a legal challenge that such a determination is "arbitrary and capricious" under the Administrative Procedures Act (5 U.S.C. section 701 et seq.).

(*1) See also 4O C.F.R. section 131.11 (a)(2) ("States must review water quality data and information on discharges to identify specific water bodies where toxic pollutants may be, adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.")
(*2) See accord 40 C.F.R. 131.241(c) regarding EPA promulgation of water quality standards ("In promulgating water quality standards, the Administrator is subject to the same policies, procedures, analyses, and public participation requirement established for States. . .").

Response to: CTR-054-048

EPA disagrees with the comment. See responses to CTR-035-012a and CTR-036-005.

Comment ID: CTR-055-002a
Comment Author: USS-POSCO Industries
Document Type: Specific Industry
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? Y
CROSS REFERENCES T

Comment: Waste Load Allocation (WLA) is a flawed concept and UPI requests the EPA promulgate conditions for exemption as part of the requirement for compliance with such allocations.

The implementation of CWA Section 303(c)(2)(B) as discussed beginning on page 42184 causes numerous obstacles, both financial and technological, to facilities such as UPI. Our facility will be subject to water quality-based effluent limitations (WQBELs). Therefore, total maximum daily loads (TMDL) and WLAs will be utilized as future discharge permit criteria.

State Task Force recommendations also recognize that the TMDL process can be significantly labor and data intensive. UPI concurs that the TMDL process is significantly labor and data intensive. During the five year period from 1989 through 1993 UPI spent close to a million dollars ($1,000,000) on the studies of point source wasteload performance at its facility. The study was initiated to verify the efficacy of our

waste water treatment system in removing chemical process constituents that were added to the water from the river (Delta) during use of the water as process water. Chain-of-custody and laboratory results for this study were documented in our required monthly self monitoring reports to the RWQCB.

The above study of efficacy of wastewater treatment prior to discharge is summarized in the following attached tables which show averages for three month periods over five full years.

Table 9. Summary of Discharge 001 Gross Mass Loading, lb/day Table 10. Summary of Discharge 001 Net Mass Loading, lb/day Table 11. Summary of Discharge 001 Net Concentrations, ug/l

Each table is shown in two sections. Section A shows the tabulation of results for cadmium (Cd), total chromium (Cr, total), hexavalent chromium (CrE+6), copper (Cu), total iron (Fe, total), dissolved iron (Fe, dissolved), lead (Pb), nickel (Ni) and zinc (Zn). Section B shows the tabulation of results for arsenic (As), mercury (Hg), selenium (Se), silver (Ag), tin (Sn), cyanide, phenolics, polyaromatic hydrocarbons (PAHs), naphthalene, and tetrachloroethylene. All analyses were done using approved standard procedures to determine the total concentration of each chemical. All results that were reported at minimum detection level (MDL) are included in the averages at one half of the reported MDL.

The attached tables illustrate the following: The gross lb/day discharge loadings (Table 9) show certain trends of improvement, eg, CrE+6, for which the process sources had been controlled. Note that since completion of the study compliance samples for CrE+6 during the most recent two year period have been reported at less than MDL. Other decreases, such as shown for Cd, Hg and Pb, are the result of improved analytical test procedures.

The net discharge lb/day loadings (Table 10) and net discharge ug/l concentrations (Table 11) show many results that are at or below zero discharge for many constituents. Other net discharge ug/l concentrations are significantly below the applicable MDLs, which also indicates that the net concentration is essentially zero. This indicates that chemical control for most chemicals is essentially 100% complete and that no process constituents are contained in the permitted discharge, except as noted below.

Exceptions to the above are Cr, Sn, and phenolics for which the net results are significantly above zero.

The above study shows the substantial effort and expenditure that was required to verify performance with respect to chemicals of concern (COCs) for a specific source category (and for several additional chemicals that were added to the COC list). The list of COCs is being expanded to 126 in the proposed regulations, more than six times as large a list as was evaluated in our performance study.

While the use of the Waste Load Allocation (WLA) principle may sound good, it is only good if properly administered. Two criterion should be considered to make the use of WLAs practicable and administratively feasible for both the agencies and the dischargers.:

* The COCs applicable to WLA discharge compliance should be identified by the Administrator for each source category, per Title 33, Section 1316(b)(1).

* Each NPDES Permit Applicant shall analyze and report on chemical listed on the standard permit application every five years to verify which if any discharge chemicals are subject to WLA discharge compliances.

For the above reasons, UPI requests the EPA add the following to the end of Section 131.38(e)(1) of part

131 of Title 40:

"New and existing point source dischargers shall be considered to be in compliance with such WQBELs except for (i) any WQBEL constituent that is identified for the source category pursuant to Section 1316(b)(1) of Title 33, or (ii) any WQBEL constituent which may cause an increase in the receiving water due to such discharge as determined from information contained in the standard required permit application."

Response to: CTR-055-002a

EPA disagrees with this comment. See response to CTR-055-002b (Category T; State Implementation Policy).

Comment ID: CTR-065-003b
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES C-14

Comment: HUMAN HEALTH CRITERIA

EHC is very concerned about the use of 6.5 grams per day of fish tissue as a basis upon which to derive human health criteria. This is not adequate to protect the many thousands of subsistence fishers of California coastal waters. We trust EPA is not in the business of protecting "most of the people, most of the time" as is the indicated goal for marine organisms elsewhere in the CTR (see comments below).

We refer you to a study conducted by the Save San Francisco Bay Association that concluded that fishers of San Francisco Bay consumed 81grams per day in the week prior to the survey with consumption rates as high as 450 grams/day... This element of the CTR must be recalculated at a higher rate of consumption and with a healthy safety margin to accommodate for synergistic and cumulative effects. Further, the Save San Francisco study showed that heads and skin were frequently consumed, the health criteria must reflect these actual eating patterns and practices as well and reflect the cultural diversity of users of the Bays. Since many subsistence fishers are people of color, adoption of this rule could violate the President's Order on Environmental Justice b exposing these populations to increased and undue environmental health risks.

Response to: CTR-065-003b

See response to CTR-065-003a (Category C-14; Fish and Water Consumption).

Comment ID: CTR-095-001c
Comment Author: M. Ruth Uiswander

Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES C-20; C-17a; C-14

Comment: In regard to the numeric water quality standards criteria for California surface water, they have been revealed by environmental groups to be insufficiently protective and environmentally unjust. The proposed new rules assume fish ingestion of 6.5 grams per day. In reality, consumption of fish in some communities can be as high as 1 pound per day. This level of consumption is especially likely among subsistence fishers.

Please prevent toxic pollution in California's bays by making more protective standards that consider all toxic pollutants and consider the fish consumption habits of subsistence anglers.

Response to: CTR-095-001c

See responses to CTR-002-002a, CTR-002-005a, and CTR-058-001 (Subject Matter Code C-13, Risk Level).

Comment ID: CTR-099-004
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: Finally, the timing must be strictly political, since 17 years of delay is unconscionable. Since you advisors must have found it difficult to understand the scientific literature, may I recommend a scientifically accurate book that is accessible to the non-scientist that may explain the dangers and the need for bold action by the EPA. It is Living Downstream - An Ecologist Looks at Cancer and the Environment by Sandra Steingraber, Addison Wesley, NY, 1997.

Response to: CTR-099-004

EPA disagrees with this comment. EPA began work on the CTR in 1994, and only after the State rescinded its ISWP and EBEP. The complexities of this rulemaking have prolonged the CTR process, but EPA is pleased to now be issuing final water quality criteria for toxic pollutants in the State of California.

Comment ID: CTR-105-002b
Comment Author: Heather Catherine Park Tausig
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/13/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: The maximum levels proposed for mercury, dioxin, and thirteen other pollutants have been identified by respected environmental advocacy groups as (1) insufficiently protective, and (2) environmentally unjust, potentially increasing the cancer risks for subsistence fishers, who are, in large part, people of color.

The standards must be established at a level that makes California waters truly "fishable," and not just "fishable if you don't object to cancer."

Thank you for your consideration.

Response to: CTR-105-002b

See response to CTRH-001-010.

Comment ID: CTRH-001-010
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: MR. KARRAS: I'm Greg Karras, K-A-R-R-A-S. I'm with Communities for a Better Environment; I'm a senior scientist.

CBE is a multiracial environmental health and justice organization with 20,000 California members, most of them in the Bay Area. We work with communities imperiled by urban pollution. I represent people who depend upon the environmental health of San Francisco Bay, including people who fish the bay for food.

CBE has worked to clean up the bay for years. We helped EPA establish the first National Estuary Conference and served on the management committee of the San Francisco Estuary Project and signed its consensus plan to protect and restore the bay. We participated in the development of every numeric toxins standard promulgated for the bay, with the possible exception of one adopted by EPA for selenium

in 1992.

We used these standards to leverage toxic prevention that cut toxics of the bay by tons, while netting economic benefits to the manufacturing base and jobs at more than a hundred Bay Area industrial plants. We submitted these data for your work on this proposed rule and we've done a preliminary analysis of the proposal that resulted.

It looks to us as a preliminary matter that EPA's proposed rule today could reverse a decade of environmental policy progress in San Francisco Bay and represent the biggest step backward ever taken for the bay's toxics policies in 25 years under the Clean Water Act. This conclusion is alarming, and this conclusion is surprising.

We hope to find out that we're wrong about that preliminary conclusion. Accordingly, before we make a final judgment, which I understand we need to make by next Friday to submit written comments, I ask that you give CBE and our members, which are the public, important information by answering now or as soon as possible some of our most pressing questions.

On environmental justice, EPA says in its preamble to the proposal that it is EPA's intention to calculate cancer criteria in a way that will provide less protection from cancer for people who rely on locally caught fish for food than it does the average person.

EPA then goes on to say this might still provide adequate protection. However, low-income people of color who fish San Francisco Bay for food are eating up to 60 times more contaminated fish than the state health advisory says is quote, unquote, safe.

And I also note that in Exhibit 8A of your economic analysis, EPA, you say that the hazard from peaks in the mercury and from dioxin in fish consumed in San Francisco Bay exceeds what you consider to be a significant level.

So our first question is simply is EPA proposing to provide the poor --

I should mention, we know from surveys done by several entities in the bay that the vast majority of people who fish the bay and use it for food, rely on it for food, most of them are low-income people and we can determine for sure that the majority are people of color.

So the question is, is EPA proposing to provide poor people and people of color unequal protection under the law?

Response to: CTRH-001-010

See responses to CTR-002-002a and CTR-002-005a (Category C-14; Fish Consumption).

Comment ID: CTRH-001-017
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97

Subject Matter Code: C-21 Legal Concerns
References:
Attachments? N
CROSS REFERENCES

Comment: Finally, this is a daytime hearing. I think the record will show that the vast majority of people who attended this hearing are environmental professionals, and the vast majority of those are people who represent regulated interests and the discharge interests.

The people who are most directly impacted in terms of their health, their livelihood, their ability to work when they're sick, their ability to raise children who don't have slow learning, their rights to fish a clean bay, are not here.

My final question --

And I think it's obvious why many of them are not here. Many of these folks are lower-income people of color, immigrant people, people who are working people, who have the kinds of jobs where it's very difficult for them to ask the boss for time off to attend a hearing of EPA to address fish contamination held at 1:00 p.m. on a Wednesday in the middle of the week.

Will EPA hold a public hearing in the evening on a fishing pier on San Francisco Bay before your proposal is adopted?

Those conclude my questions.

I, again, am serious about getting answers to these now, today, in this hearing or as soon as possible, so that we could make sure that we are as correct as possible in our comments which we will be submitting into the record in writing.

Thank you.

Response to: CTRH-001-017

EPA was unable to hold a public hearing in the evening on the rule. EPA operates during normal business hours. Nevertheless, EPA's intent here is not discriminatory, but rather an administrative necessity in terms of its own staffing, and support mechanisms for its operations. As always, people may submit written comments to EPA if they cannot attend a public hearing.

Subject Matter Code: C-22 Dissolved v. Ttl Recoverable

Comment ID: CTR-004-004c
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES G-05
C-24a
C-09

Comment: Despite the problems addressed above there are provisions of the CTR that SBSA supports, including:

* EPA's policies and guidance regarding the use of mixing zones and dilution

* Use of water effects ratios (WERs) for determining site specific criteria

* Inclusion of metals criteria expressed as dissolved rather than total recoverable

* Allowing permit writers the use of any of the methods in EPA's guidance document on the use of translators

Response to: CTR-004-004c

EPA acknowledges the commenter's support.

Comment ID: CTR-005-003a
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a
C-01a
G-09
G-05
G-04

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as

dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003a

EPA acknowledges the commenter's support.

Comment ID: CTR-007-001
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: The San Diego Unified Port District ("District") supports the general shift from a "Total Recoverables" criterion to a "dissolved" detection method. The District does, however, have a number of concerns with the proposed rule.

Response to: CTR-007-001

EPA acknowledges the commenter's support.

Comment ID: CTR-017-002a
Comment Author: Santa Ana River Discharger Ass
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a

Comment: Because the California Toxics Rule uses the same approach as the UAA in setting water quality objectives for cadmium and copper, SARDA strongly supports the CTR objectives for those metals. We also agree with EPA's written statements acknowledging the binding character of organic carbon and the role it plays in rendering heavy metals non-toxic. We enthusiastically endorse the agency's decision to include Water Effects Ratio as a formal factor to be considered when formulating water quality objectives. It will do much to adjust national criteria to local conditions.

Response to: CTR-017-002a

EPA acknowledges the commenter's support.

Comment ID: CTR-021-002c
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES G-04
C-24a
K-01
G-05
G-02

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; © the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002c

EPA acknowledges the commenter's support.

Comment ID: CTR-026-004
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: 4. DISSOLVED V.S. TOTAL RECOVERABLE METALS CRITERIA

The proposed CTR promulgates the metals criteria as dissolved concentrations instead of the historic use of total recoverable concentrations. The DFG has argued against the use of dissolved concentrations as we believe that they do not rally protect aquatic resources. Chemical constituents of natural waters

affect the biota as essential nutrients and as potential toxicants. These interactions are directly dependent on the chemical speciation of the constituents. While it is generally recognized that only the free concentrations of metals are the toxic component, most laboratories do not have the capability to determine the speciation of the metal. Use of only the dissolved fraction to determine criteria promotes the theory that metals adsorbed to sediments or suspended solids are not biologically available. Additionally, not all species of metal which are detected in the dissolved fraction are biologically available.

Metal complexes in natural waters can be classified into three groups: ion pairs, inorganic complexes, and organic complexes. Complex formation is a reversible reaction of two dissolved species to form a third specie. Free metal ions in solutions are really aquo complexes, the water itself is a ligand that binds metals, and every complexation reaction in water is effectively aligand-exchange reaction. The reaction of a metal with a ligand can be of an electrostatic or covalent nature or both. Speciation tells the fate of metals in the environment (mineral, redox, or bioavailable).

Particulate material is chemically defined as that material retained on a 0.2 u filter. The dissolved fraction is that portion smaller than 5 rim in size, and the colloidal fraction is between 5.0 um and 0.2 um in size. The EPA definition of particulate material is that material retained on a 0.45 um filter. Therefore, inorganic and organic complexed material will be contained in the dissolved fraction. A large portion of the dissolved nickel in south San Francisco Bay is organically complexed (not bioavailable) and remains in the water column for longer than the resident time of the water mass. Currently, most laboratories that will be affected by the proposed change from total recoverable concentrations will not be able to speciate out the free ions from the inorganic ligands and determine the true toxic concentrations of the metal. For example, at a 10E-9 concentration, free copper becomes toxic to aquatic organisms. A single laboratory using the same analytical method, but different analytical conditions, can have different detection windows which provide different speciation information.

Metals retained in the particulate fraction are available to aquatic organisms during the chemical processes of desorption from suspended particles, resuspension via wind mixing and tidal currents, and interstitial-water transport, In addition, the biological processes of ingestion of sediment or suspended solids (e.g., filter feeders, zooplankton, etc.), direct contact transport, and bioaccumulation through the food chain, provide organisms bioavailable metals which are currently retained in the particulate fraction. Average concentrations of particulates are 0.01 ppm in the deep ocean, 10-400 ppm in San Francisco Bay, 50,000 ppm in turbid estuaries, and up to 80 percent in riverine systems. Metals bound to humic acids (freshwater systems) readily dissociate and do not bind for any length of time. In San Francisco Bay, the various forms of selenium are not in equilibrium (surface sediment, water column) and the routes of exposure are additive.

Since the measurement of metals as total recoverable includes that portion associated with sediments or suspended solids, it provides a more accurate (although conservative) descriptor of metal availability in its toxic form. As previously discussed, metals associated with the particulate fraction are available to aquatic organisms through biological and chemical mechanisms. It is now known that metals associated with particulates do not remain permanently associated with the sediments, but rather are transformed into the free ions and become bioavailable. Therefore, the DFG urge the establishment of metal criteria as a total recoverable measurement, at least for the purpose of developing statewide numeric criteria for priority toxic pollutants.

Response to: CTR-026-004

EPA disagrees with the commenter. EPA believes that the scientific evidence indicates that

particulate-bound metals do not contribute toxicity when suspended in the water column, and do not increase in bioavailability if or when settled into sediment. Consequently, EPA believes that to incorporate total recoverable metal criteria into the rule would be an ineffective use of federal, state, and local resources EPA notes that two expert workshops, one in Annapolis in 1993 (58 FR 32131, June 8, 1993) and one in Pensacola in 1996 (Bergman, H.L. and E.J. Dorward-King (eds.), Reassessment of Metals Criteria for Aquatic Life Protection. SETAC Press. Pensacola, FL.. 1997) were held to discuss this issue. Both workshops recommended that EPA express its criteria as dissolved metal. EPA has found the expert workshop recommendations, with their supporting rationale, to be persuasive.

EPA does not believe that the factual material cited in the comment supports the contention that criteria should be expressed as total recoverable. The information provided in the comment merely indicates that metals exist in both dissolved and particulate forms, and that one can conceive of some potential exposure routes involving particulate metals. However, none of the information provided by the comment suggests that particulate potential exposure routes are in fact actually significant when compared to dissolved metals exposure. Consequently, EPA does not believe that any of the information presented in the comment counterbalances the information provided by the above mentioned workshops, supporting use of dissolved metals criteria.

EPA nevertheless agrees with the comment that not all dissolved metal is bioavailable. For this reason, EPA included the Water-Effect-Ratio (WER) in the equation for criteria in the rule to account for varying site-specific toxicity.

Comment ID: CTR-027-012a
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-24a
C-01a
G-09
G-05

Comment: PROVISIONS OF THE PROPOSED RULE WE SUPPORT

Not withstanding the above comments, we believe there are certain elements of the proposed rule with respect to establishing water quality standards that we can support:

* Metal criteria expressed in the dissolved fraction rather than expressed in the total recoverable fraction.

* Metal criteria that are developed as a function of the water-effect-ratio (WER).

* The current proposed human health criterion for mercury.

* The current preamble language regarding metal translators and mixing zones.

We believe the above provisions provide a more acceptable, scientific approach to the water quality-based pollution control approach. We recommend these provisions of the current rule remain as proposed.

Response to: CTR-027-012a

EPA acknowledges the commenter's support.

Comment ID: CTR-029-002d
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES C-17a
C-17b
A
C-27
C-29

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the

published guidance documents is "insignificant"(*4); however, in light of the current contamination problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be under protective because additive and synergistic effects were not considered; and because the effects on wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).

(*5) Id. at 42168.

(*6) Id. at 42172.

Response to: CTR-029-002d

See response to CTR-029-002b.

Comment ID: CTR-032-002b
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
G-09
C-24a
C-24
K
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-034-008
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: * SCAP supports EPA's proposed adoption of criteria for metals expressed as the dissolved fraction rather than as total recoverable metals. We recommend that EPA provide guidance to the State in the Preamble to the CTR stating that the State should also use the dissolved form for metals unless it has been demonstrated that the total recoverable form is necessary to protect aquatic resources found in particular water bodies.

Response to: CTR-034-008

EPA acknowledges the commenter's support for the use of dissolved metals. However, EPA disagrees that it should provide guidance indicating that the State should also use the dissolved form of metals. EPA believes that a state can decide to use a more stringent approach.

Comment ID: CTR-035-002a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES C-01a
C-08a

G-05
G-04
G-09
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002a

EPA agrees with the comment and acknowledges the commenter's support.

Comment ID: CTR-035-016
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42171-42173 -- Dissolved Metals Criteria We support EPA's policy regarding the expression of criteria for metals as the dissolved fraction, rather than as total recoverable metals. We believe that the dissolved fraction more closely approximates the fraction that is bioavailable, and that metals criteria expressed as total recoverable are usually overprotective. We request that EPA include guidance to the State in the Preamble such that, if the State wishes to adopt metals criteria in the total recoverable form, the State must demonstrate, for the particular water bodies, why the total recoverable form is necessary to protect the aquatic resources.

Response to: CTR-035-016

See response to CTR-034-008.

Comment ID: CTR-038-002a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a
C-01a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002a

EPA acknowledges the commenter's support.

Comment ID: CTR-039-003a
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES A

Comment: I . APPLYING DISSOLVED METALS CRITERIA AS PROPOSED VIOLATES THE ANTIDEGRADATION POLICY FOR SAN FRANCISCO BAY AND OTHER WATERS OF THE STATE

The practical effect of EPA's decision to rely on dissolved metals criteria is to allow higher levels of total recoverable metals to be discharged from point sources into San Francisco Bay as well as other waters of the State. Since 1991, many permits in the Bay area and else where have been issued applying the State Water Resources Control Board's technically-based and EPA approved numeric criteria for numerous toxic pollutants. For at least three years, permits throughout the State were required to be issued using the duly-promulgated criteria established by the State Water Resources Control Board ("SWRCB"). After the Sacramento court vacated the criteria on economic grounds, numerous permitting decisions were made by local regional boards and their staffs applying the previously applicable standards using

their best professional judgement ("BPJ") in order to assure the protection of beneficial uses. Each of the permitting decisions based directly or deferentially on the SWRCB's criteria would be more stringent than permits for the same parameters authorized by EPA's proposed rule where a discharger opts to follow the Water Effects Ratio protocol for translating the criteria into a permit limit. BayKeeper would not anticipate that many, if any, dischargers will opt for the default WER of 1.0. Thus, for many regulated dischargers, EPA's proposal will lead to major increases in the total metals they are allowed to discharge into the Bay and other waters of the State. This massive increase in the total pollution proposed to be allowed to be discharged into the Bay and other State waters is completely inconsistent with the State's and EPA's antidegradation policies mandating that existing water quality be maintained and protected. As the State's policy sets forth:

Whenever the existing quality of water is better than the quality established in policies as of the date on which such policies become effective, such existing high quality will be maintained until it has been demonstrated to the State that any change will be consistent with maximum benefit to the people of the State, will not unreasonably affect present and anticipated beneficial use of such water and will not result in water quality less than that prescribed in the policies.

SWRCB Resolution No. 68-16. Under the federal version of the policy:

[w]here the quality of the waters exceed levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water, that quality shall be maintained and protected unless the State finds, after full satisfaction of the intergovernmental coordination and public participation provisions of the State's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development.

40 C.F.R. 131.12(a)(2). The antidegradation policies apply both to permit decisions as well as decisions establishing water quality standards. See, e.g., In The Matter of the Petition of Remmon C. Fay, SWRCB Order No. WQ 86-17 (Nov. 20, 1986). In the case of EPA's proposed rule, throughout California the rule, if adopted, will allow more pollution to be discharged than is currently allowed by permits validly issued to numerous dischargers throughout the State without any consideration of the policies, including the intergovernmental coordination and public participation requirements, required by the antidegradation policies.

Of course, in addition to that procedural problem, BayKeeper is opposed to the proposed reliance on dissolved numbers, especially in the Bay area, because it will in fact allow more pollution to be discharged into the State's waters than is currently allowed today and likely will prove detrimental to beneficial uses. See Comments of Communities For A Better Environment. BayKeeper also is very concerned about the burdens and uncertainty placed on the public by the need for translators in order to apply the dissolved criteria in permit limits that must be based on total recoverable numbers. As noted above, BayKeeper does not anticipate that many dischargers will opt for EPA's proposed WER default of 1.0 BayKeeper views this proposal as an invitation for dischargers to prepare site-specific limitations based on their own studies which will frustrate the public' s ability to participate effectively in the formulation of effluent limits. Further, the proposal will present a moving target for the public to understand and will burden the resources of regional board staff to a degree that may undermine the quality of those site by site determinations.

Response to: CTR-039-003a

EPA does not agree that the criteria adopted by the rule in any way violate antidegradation policies. State and federal antidegradation requirements must still be met. EPA believes that the commenter may

have confused antidegradation concerns with anti-backsliding concerns. Anti-backsliding is a permit issue, not a water quality standards regulatory issue.

EPA also does not agree that use of dissolved metals will prove detrimental to beneficial uses. The commenter provides no evidence to support its assertion, and EPA is not aware of such evidence. EPA acknowledges that the complexity of metals criteria application, which stems from the problem that the same concentration of a metal yields different toxicity in different waters, makes it more difficult for non-experts to understand and participate in the formulation of effluent limits. However, EPA believes that incorporation of the dissolved provision and the water-effect ratio provision is necessary for defense of the scientific validity of most of the metals criteria.

Comment ID: CTR-041-002
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: The District's comments on the proposed CTR are as follows:

1. Items Generally Supported by the District

The District supports a number of the provisions of the proposed rule. That support, however, varies from strong in some cases to a level of grave reservations in other cases. First, the District strongly supports the use of dissolved metals criteria rather than the use of total recoverable metals criteria. The continued use of the dissolved metals approach is a prime example of making a good recommendation based not only on the most recent sound scientific data, but also on the results of both intense national public input and court decisions.

Response to: CTR-041-002

EPA acknowledges the commenter's support.

Comment ID: CTR-041-007b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: 2. Additional Strong Reasons to Maintain use of Dissolved Metals and Mercury Criteria

The District also has significant economic reasons to support the use of dissolved metals and the updated mercury criteria. Previous District studies have shown that adoption of metal criterion as total recoverable would cost the District more than $50 million a year while reducing metal loads in the Sacramento River by several percent. Likewise, if old mercury criteria were adopted it would cost the District over $100 million a year while reducing mercury loads in the Sacramento River by several percent.

Response to: CTR-041-007b

EPA acknowledges the commenter's support.

Comment ID: CTR-042-006
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES

Comment: 6. The CTR should maintain many of the proposed provisions relating to metals criteria.

Caltrans supports the EPA's decision to include metals criteria expressed as dissolved instead of total recoverable; the development of metals criteria as a function of the Water Effect Ratio (WER); the current proposed human health criterion for mercury; and the use of metals translators and mixing zones. Caltrans is of the opinion that these provisions reflect a more sound scientific approach to regulating metals.

Request: Caltrans requests that the provisions described in the preceding paragraph be maintained in the final draft of the CTR.

Response to: CTR-042-006

EPA agrees with the comment and has maintained the provisions.

Comment ID: CTR-043-002a
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a
C-01a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002a

EPA acknowledges the commenter's support.

Comment ID: CTR-044-003a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a
C-01a
G-09
G-05
G-04

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital

improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003a

EPA acknowledges the commenter's support.

Comment ID: CTR-045-004
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

The inclusion of metals criteria expressed as dissolved rather than total recoverable concentrations.

Response to: CTR-045-004

EPA acknowledges the commenter's support.

Comment ID: CTR-052-002a
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-01a
G-09
G-05
G-04

Comment: EPA will recall the State Water Quality Plans Task Forces that included all stakeholders, including EPA. The Authority appreciates the incorporation of many of the consensus recommendations from the Task Forces into the CTR, including:

* Adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a

function of the water-effect ratio

* Adoption of the proposed new human health criterion for mercury

* Preamble discussions regarding metals translators, mixing zones, and interim permit limits

Response to: CTR-052-002a

EPA acknowledges the commenter's support.

Comment ID: CTR-054-002a
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES C-24a

Comment: BADA supports adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio. These changes place the metals criteria on a firmer scientific base than the old State Plans. Moreover, previous BADA studies have shown that adoption of the copper criterion as total recoverable could cost Bay Area POTWs several billion dollars while reducing copper loads to the Bay by only several percent (see Attachment 1). Further, building the water-effect ratio into the criteria will lessen the administrative burden on all parties when it becomes necessary to pursue the development of such a ratio. For these reasons, it would not be in the public interest nor consistent with Presidential Order 12866 or the Unfunded Mandates Reform Act to adopt the metals criteria as total recoverable concentrations or to require approval of a site-specific objective whenever a water-effect ratio is developed.

Response to: CTR-054-002a

EPA acknowledges the commenter's support for the use of dissolved metals criteria.

Comment ID: CTR-056-005
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N

CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* Metals criteria expressed as dissolved rather than total recoverable concentrations,

Response to: CTR-056-005

EPA acknowledges the commenter's support.

Comment ID: CTR-057-006
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: Metals

We support the EPA's intention to adopt metals criteria that are based on dissolved, rather than total recoverable, fractions in the water column. This provision clears up an issue that seemed straight forward but intractable only a few years ago. This provision will also allow the State to make decisions regarding the use of dissolved or total recoverable on a waterbody-specific basis, which we view as appropriate. The City also supports the proposed Rule with respect to applications of the water effect ratio and metal-translator provision (metal-specific partitioning), even though we do not see an immediate application of the latter with respect to our facilities.

Response to: CTR-057-006

EPA acknowledges the commenter's support.

Comment ID: CTR-058-003
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? Y
CROSS REFERENCES

Comment: 2. Dissolved Criteria for Metals. WSPA supports the use of metals criteria based on the dissolved species.

EPA has reviewed the science in this area carefully over the past several years and rightly concluded that dissolved species best reflect the bioavailability of heavy metals in the aquatic environment. That is, metals species which are not available or reactive to aquatic life should not be regulated as toxics. This proposed rule is consistent with EPA's thorough review of this issue.

WSPA believes that EPA will follow this approach in assessing whether waters of the state meet water quality standards based on these criteria. That is, the waters should be judged based on the presence of dissolved or bioavailable metals, not total metals.

Response to: CTR-058-003

EPA agrees with the commenter and acknowledges its support.

Comment ID: CTR-065-005
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: [INDENT]USE OF DISSOLVED CONCENTRATIONS OF METALS WILL UNDERESTIMATE IMPACTS

EHC does not support the use of dissolved concentrations for metals criteria as it will lead to significant underestimation of levels of contamination. Metals in sediments can be bioavailable or could become bioavailable in the future. EHC recommends the use of total recoverable metals as the appropriate basis for metals.

Response to: CTR-065-005

EPA does not agree. See response to CTR-026-004. EPA does not know of any scientific evidence that indicates that metals loading at the criteria levels would eventually or ultimately yield sediment contamination problems. In addition, EPA does not believe that use of total recoverable metals criteria is an effective or appropriate method for protecting sediments from contamination. Instead of basing metals criteria on total recoverable measurements, EPA is proceeding with the development of Equilibrium Partitioning Sediment Guidelines (ESGs) in order to protect sediments, the contamination of which would generally be related to elevated historical loads rather than to the loads allowed after implementation of this rule. EPA has not found the use of total metal concentrations in sediment to be useful or reliable for expressing ESGs. Rather, EPA has used a measure of the sediment's metal enrichment compared against its metal binding (or detoxifying) capacity. EPA's ESGs ensure that there will not be bioavailable metals by determining that the total extractable metal does not exceed total acid

sulfide concentration in the sediment. The ESGs protect against chronic toxicity to benthic organisms from metals in sediment, and can include effects from exposure through pore water and exposure from ingesting sediment.

Comment ID: CTR-066-005
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The inclusion of metals criteria expressed as dissolved rather than total recoverable concentrations.

Response to: CTR-066-005

EPA acknowledges the commenter's support.

Comment ID: CTR-066-019
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: * The proposed metals limits appear to conflict with our current NPDES permit. This will raise questions of our ability to meet the less stringent standards proposed in the CTR. We assume that these new criteria are more scientifically based than four years ago when we negotiated our NPDES permit. Added treatment will surely be required for the four areas of concern we see in the CTR.

Response to: CTR-066-019

EPA acknowledges the concerns about whether the Sanitation District can attain the criteria without added treatment; however, the commenter does not provide EPA with any evidence to support its contentions.

Comment ID: CTR-067-002
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: * OVSD supports EPA's proposed adoption of criteria for metals expressed as the dissolved fraction rather than as total recoverable metals. OVSD recommends that EPA provide guidance to the State in the Preamble to the CTR stating that the State should also use the dissolved form for metals unless it has been demonstrated that the total recoverable form is necessary to protect aquatic resources in a particular water body. This is extremely important because OVSD's current NPDES permit specifies limits for total recoverable metals.

Response to: CTR-067-002

See response to CTR-034-008. Note also that permit limits, per 40 CFR 122.45, must still be expressed in terms of total recoverable metal. When derived from a receiving-water dissolved criterion, total recoverable permit limits are calculated by accounting for the fraction of effluent metal that is or becomes dissolved after discharge.

Comment ID: CTR-077-003
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: Dissolved Criteria for Metals

We support the approach that waters should be judged based on the presence of dissolved or bioavailable metals, not total metals, and therefore agree with EPA's conclusion that metals species which are not available or reactive to aquatic life should not be regulated as toxics. We support the use of this approach in assessing whether waters of the state meet water quality standards based on these dissolved species criteria.

Thank you for your consideration of our comments. We look forward to working with EPA and the state in conjunction with the implementation phase of the California Toxics Rule to ensure a well balanced,

feasible and scientifically sound water quality program.

Response to: CTR-077-003

EPA agrees with the commenter.

Comment ID: CTR-081-002d
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
G-02
G-09
C-01a
C-08a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are performed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. I) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002d

EPA acknowledges the commenter's support with respect to dissolved metals.

Comment ID: CTR-082-003
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Metals criteria be expressed as dissolved fraction rather than total recoverable concentrations.

Response to: CTR-082-003

EPA acknowledges the commenter's support.

Comment ID: CTR-085-006
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* Inclusion of metals criteria expressed as dissolved rather than total recoverable concentrations.

Response to: CTR-085-006

EPA acknowledges the commenter's support.

Comment ID: CTR-086-004b
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
G-09
C-24a
C-24
K-03

G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004b

EPA acknowledges the commenter's support.

Comment ID: CTR-089-001a
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES C-01a
C-08a
G-05
K-01
G-02
G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001a

EPA acknowledges the commenter's support with respect to metals.

Comment ID: CTR-090-002c
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-17a
C-24a
G-05
G-02
G-04

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002c

EPA acknowledges the commenter's support with respect to metals.

Comment ID: CTR-092-002
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Dissolved Metals Criteria

The City supports the promulgation of dissolved concentration criteria for priority pollutant metals. Dissolved metal more closely approximates the bioavailable fraction, and thus toxicity, of metal in the water column than does total recoverable metal. The City believes there may be specific instances whereby risk management decisions (sediment resuspension, bioconcentration, food web issues) could result in scientifically defensible criteria based upon the total recoverable fraction. The City recommends, that any such decision be established with relevant data, sound science, peer review, and involve active public participation.

Response to: CTR-092-002

EPA agrees with the comment.

Comment ID: CTRH-001-003a
Comment Author: Robert Hale
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES C-24a
C-1a

Comment: In summing up -- not summing up, just as a parting shot -- I do appreciate the fact that in working up the toxics rule here that EPA has done certain things which in fact we see as improvements in actually making the standards fit with what we think -- have come to see as perhaps the actual impacts of the stormwater part of this. And by that, I'm referring to the dissolved metals criteria and the water effect ratio in there, and the human health criteria revisions for mercury and the other -- the other items.

I appreciate some of the stuff in there, and -- with the exception of the preamble language. And you really need to get that out of there. We're going to pursue this as far as we have to.

I appreciate your hearing me.

Response to: CTRH-001-003a

EPA acknowledges the commenter's support.

Comment ID: CTRH-001-024c
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable

References:
Attachments? N
CROSS REFERENCES g-02
g-05
c-24a
c-17a

Comment: MS. PLA: My name is Michelle Pla. I'm with the Public Utilities Commission, City and County of San Francisco.

I made the comment on my card that I also said that I would try to be constructive, and so I'm going to follow my mentor here, Phil Bobel, and say that there are some things in this rule that we're very pleased to see.

We're very pleased to see use of the latest scientific information, particularly the use of latest IRIS, I-R-I-S, numbers-for human health. We're very pleased that you're using dissolved versus total recoverable form for the metals.

We're very pleased to see recognition of the water effects ratios. We're pleased to see recognition for a multi-tiered mixing zone for acute and chronic human health effects and hope that the state pays particular attention to that.

We do have a problem with the way you've described compliance schedules and hope to be working strictly by the state on that as well. We think that the five-year system is fairly shortsighted, and -we can't even do FMDSLs in five years.

Response to: CTRH-001-024c

EPA acknowledges the commenter's support with respect to metals.

Comment ID: CTRH-001-032b
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES c-24a
g-5

Comment: I would like to take this time to note that I think it contains some important elements that we agree with and believe are reflective of the impact. These include the uses of dissolved metals and the provisions which will enable the state to use mixing zones and water effects ratios and establish site-specific objectives.

Response to: CTRH-001-032b

EPA acknowledges the commenter's support with respect to metals.

Comment ID: CTRH-001-048
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES

Comment: Particularly in regards to the Bay Area, we are concerned with the EPA's reliance on dissolved numbers, on using a dissolved number for the criteria, and believe that total recoverable would be a more appropriate standard to use.

Total recoverable as proposed, from our initial review, it seems to us that we're going to end up with a lot of existing dischargers that will in fact be allowed to discharge more into the bay, where most, or at least first blush looking at it, most of the metals detected in the bay are present in the dissolved stage, probably attached to sediment, which are a large amount of what's in the bay. It seems that these sediments will disattach themselves and then become dissolved some day.

It seems to me this doesn't take a look at the whole picture, and that is basically carving it off. And it seems to me that the process that led to that wasn't one that was available to all of us to discuss.

It was driven by a case in D.C. and some policy decisions made in Washington, D.C., where here all the permits, of course, are total recoverable units. All of the standards to date that have -- that exist or have been proposed are total recoverable.

Response to: CTRH-001-048

See responses to CTR-039-003a, CTR-065-005, and CTR-026-004.

Comment ID: CTRH-001-057f
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES K-03
C-24a

G-04
G-07
G-09
G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057f

EPA acknowledges the commentor's support with respect to metals.

Comment ID: CTRH-002-011c
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: C-22 Dissolved v. Ttl Recoverable
References:
Attachments? N
CROSS REFERENCES G-02
G-04
K-01

Comment: Now, I'd briefly like to touch on several issues of importance to SCAP members. In addition, we will be submitting written comments before the close of the public comment period.

I'd like to begin by mentioning our support for several provisions included in the draft CTR, and those include the provision authorizing the use of compliance schedules -- although we don't necessarily agree with the time period -- the expression of metals criteria as dissolved rather than totally recoverable, and discussion in the preamble supporting the use of interim limits in permits, while the total maximum daily loads and other special studies are being performed.

Response to: CTRH-002-011c

EPA acknowledges the commentor's support with respect to metals.

Subject Matter Code: C-23 Sediments/Dredged Materials

Comment ID: CTR-007-002
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-23 Sediments/Dredged Materials
References:
Attachments? N
CROSS REFERENCES

Comment: 1. It is the District's understanding that where sediments exceed the CTR's water quality criteria, the sediment could not be put to a beneficial use after dredging. If this is indeed the case, the District would request that some allowance be given to allow dredged sediments to be put to beneficial use.

Response to: CTR-007-002

The purpose of this rule is to establish numeric criteria for those navigable waters in California that do not have water quality criteria for priority toxic pollutants in place and for which EPA has issued section 304 (a) criteria guidance. Specific implementation procedures regarding the disposal and application of dredged sediments are beyond the scope of the rule. The final CTR does not impact California's ability to designate specific uses, including sub-category of uses that allow for disposal of dredged sediments (e.g., artificial wetlands).

Furthermore, EPA notes that through the state 401 certification process, California would determine whether or not disposal of sediments in a particular instance is consistent with the ambient criteria established in the CTR. In addition, any existing State guidelines for approving beneficial reuse of dredged sediments remain in effect.

Comment ID: CTR-077-001
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-23 Sediments/Dredged Materials
References:
Attachments? N
CROSS REFERENCES

Comment: A substantial portion of the membership of the Coalition represent the maritime industry which consists of the six public port authorities and one private port, several vessel carriers, dredging contractor companies, maritime trade unions, shippers, and pilots. The industry is dependent on a safe and navigable waterway system maintained by regular dredging so essential to sustain the Bay as an

international center for trade and commerce.

Dredging applicants must apply for permit approval to dredge and dispose of channel sediment from the federal and state dredging regulatory agencies and are required to evaluate the dredged material to be disposed using a suite of chemical, physical and biological tests. The tests we conduct are very expensive. Due to the high cost, uncertainty and inconclusivity of the test results, essential navigation dredging is often delayed at tremendous expense to the Bay public at large.

Numeric Standards for Pollutants as Applied to Dredged Sediment Physical and Chemical Tests

Our primary concern is what effect will the new water quality standards have on the number of and cost for the sediment physical and chemical tests required for dredging permit approval. Will the Toxics Rule standards alter the current protocol contained in jointly signed Public Notice 93-2 entitled, "Testing Guidelines for Dredged Material Disposal at San Francisco Bay Sites"? We have asked the Sediment Management Unit of EPA and the Dredging Regulatory Unit at the S. F. Bay Regional Water Quality Control Board for an assessment of the effect of the Toxics Rule on the current dredging protocol, and we are waiting for a response from them.

We acknowledge that it is the combined results from all tests for dredging (chemical, physical, and biological) which comprise the overall evaluation of potential sediment toxicity and hence acceptability for discharge at unrestricted or restricted disposal sites. In fact the Testing Guidelines indicate that it is the bioassay responses, as indicators of potential toxicity, that will determine the effect of a proposed discharge of dredged material on the receiving aquatic ecosystem, and that the chemistry standards will not be used as pass/fail standards. However, the Guidelines state in the Response to Comments section that, "however, depending on the contaminants of concern and other factors, elevated chemistry could independently indicate the need for more that the routine Tier II testing..." Thus if the water quality standards become more restrictive, then dredging applicants may have to spend more money to conduct more tests.

Further, we are uncertain as to the environmental relevancy of potential lower water quality standards as they may be applied to dredging discharges because there are often false-positive test results between the chemical and biological tests.

Response to: CTR-077-001

See response to CTR-007-002.

The final CTR does not trigger any additional testing of dredged material. The results of any existing testing requirements may be compared to criteria contained in the CTR, but the CTR itself does not address when sediments need to be tested or specify what constituents need to be tested for.

Even under the 404 guidelines, failing WQC does not in itself trigger any additional testing requirements. The process of evaluating dredged material for proposed open water disposal first involves bulk sediment chemistry analysis (required under 404 guidelines for several purposes) and comparison to any applicable numeric criteria (assuming 100% solubility). To evaluate whether or not narrative criteria (e.g., "no toxics in toxic amounts") are met, the elutriate is subjected to standard bioassays (following allowable dilution) regardless of whether or not there are applicable numeric criteria. In the rare instance that the chemistry is projected to exceed a numeric criterion and an elutriate bioassay is passed, additional elutriate chemistry may be required to confirm the numeric criterion failure. But the need for additional chemical evaluation is independent of the criteria used to compare the results. EPA believes there is no

reason to expect more frequent false positives when comparing elutriate chemistry results to CTR criteria than the criteria previously adopted by California.

Furthermore, EPA notes that through the state 401 certification process, California would determine whether or not disposal of sediments in a particular instance is consistent with the ambient criteria established in the CTR. In addition, any existing State guidelines for approving beneficial reuse of dredged sediments remain in effect.

Comment ID: CTRH-001-021
Comment Author: Jim McGrath
Document Type: Public Hearing
State of Origin: CA
Represented Org: Port of Oakland
Document Date: 09/17/97
Subject Matter Code: C-23 Sediments/Dredged Materials
References:
Attachments? N
CROSS REFERENCES

Comment: MR. McGRATH: Good afternoon. My name is Jim McGrath, Environmental Manager for the Port of Oakland. I'm going to testify about a fairly narrow application of the CTR, one not considered and one I think you need to.

The Port of Oakland has built a facility for removal of dredge material from the marine environment. At completion of dredging of about 1 million cubic yards of contaminated sediment, it's pumped into that facility and dried.

The facility has been constructed as a series of ponds, which physically settle the material but do not provide for treatment. The removals in that facility have ranged about 99.98 percent removal or a little better, depending on how it's being operated.

I think the bottom line for it is the permits in terms of the CTR. The standards that were used for discharge from this facility were those of the basin regional board at the time -- in effect at the time. This rule is dangerous due to the limits contained in the CTR, and the nature of the CTR would prevent that operation.

Our discharge limit is 20 parts per million. The CTR would lower that to 3.1 parts per billion. That cannot be met settling fine grain dredge material, clean or dirty, without treatment.

Thus the application of this rule might prevent not only the Galbraith operation, which is intended to and is effectively removing material presently from the marine environment, but could also prevent beneficial use of dredge material that involved a return discharge to the bay. That includes such projects by the Environmental Protection Agency as Sonoma Baylands, already built, and other projects under consideration.

Now, how does that come about? I think the problem is that the rule has been developed under a conceptual mode of input-output. Stuff comes into the bay; it goes out of the bay.

The real world and the real physics is a little more complicated than that. This gets stored in sediment. We dredge -- we in the maritime industry dredge a small amount of what is stored by the dynamic of the contaminant movement in the water column to the sediment bed and back again. That's substantially more complicated than that. Worse than that, the blinders have been put on by the input-output concept, and the thinking is one of a steady state of input-output.

And the rule doesn't contemplate transient impact due to cleanups of some sort and we're particularly concerned about -- that sediment cleanups and resource enhancement don't fit into the conceptual model used to come up with this rule.

So that's the problem. There is -- there are many different ways to deal with that problem. The waiver or variance process could be expanded to allow special consideration of cleanups or resource enhancement projects. You could apply the risk based on overall project management. I'm sure there are opportunities beyond that.

I want to propose a hypothetical problem in the rule: that a literal application would require for sediment cleanups, physical treatment. Under the Clean Water Act, the standard on dredge material is practicability, and you've got two different regulatory approaches.

If you're talking about cleanup of the sediment in the marine environment, feasibility is an element. And I can tell you from experience, very little contaminated sediment will be dredged if physical treatment rather than settling is going to be required.

Response to: CTRH-001-021

See response to CTR-007-002.

Comment ID: CTRH-001-059
Comment Author: Ellen Johnck
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Planning Coalition
Document Date: 09/17/97
Subject Matter Code: C-23 Sediments/Dredged Materials
References:
Attachments? N
CROSS REFERENCES

Comment: I'm Ellen Johnck, director of the Bay Planning Coalition, a San Francisco Bay planning coalition organization, a membership organization of about 200 members that reflect the maritime industry, shoreline business and industry, several small and large property owners, recreational use and local governments and many counties and cities.

I am here today because I want EPA to understand the far-reaching effect of this particular California Toxics Rule on the broad range of recreational, commercial and environmental uses and users here in the estuary.

One of the major things that we have seen with this California Toxics Rule is that it affects our

international commerce and our trade, which is totally dependent on the navigation channel. We have to dredge about 4 to 5 million cubic yards of material each year from the channel in order to support the Bay's trade and economy.

What this rule will affect will be our terrific program that was initiated in the last several years to try to expand the reuse of dredge material for environmentalpurposes.

In corroborating Mr. McGrath's statements for the Port of Oakland, we discovered that our whole program to restore wetlands of the bay with dredge material actually will not be able to happen because of discharge limits, because the standard could not be met.

And we frankly think that the Environmental Protection Agency needs to look at the whole numeric criteria and how it was devised. It really is not as scientific as that could be, as we look at interaction with the Bay and the properties of the metals attached to it as sediment, therefore, making these metals not necessarily available and having an environmental effect.

So I think my point, number one, is that this -- and I really don't think EPA wants to deter the environment reuse of dredge material -- it will be exceeding the numeric criteria particularly for copper and will deter the environmental reuse of dredge material.

Response to: CTRH-001-059

See response to CTR-007-002.

Subject Matter Code: C-24 Site Specific Criteria

Comment ID: CTR-002-003
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: II. THE EPA PROPOSALS WILL NOT PROTECT FISHING AND OTHER USES OF SAN FRANCISCO BAY WATERS OR PROVIDE EQUAL PROTECTION FOR PEOPLE OF COLOR.

A. The criteria allow more pollution than prior technically-based criteria.

The proposed criteria would replace criteria found to be scientifically sound by the State Water Resources Control Board staff, adopted by the state, and approved by EPA, for San Francisco Bay in the 1991 California Bays and Estuaries Plan,(*10) the 1986 San Francisco Bay Basin Plan,(*11) and the Basin Plan amendment adopting the 1992 Site Specific Copper Objective for San Francisco Bay.(*12) Table I compares the lowest concentration criteria for the 64 toxic pollutants identified by the San Francisco Estuary Project as "pollutants of concern" for the Bay.(*13) The EPA criteria proposal:

*weakens environmental health protection for 37 of these 64 toxic pollutants (58%). It allows greater ambient water concentrations for 30 pollutants, includes new extremely liberal criteria for 4 of the 64 pollutants, and fails to replace previous state criteria for 3 pollutants,

*makes no change for 24 of these 64 pollutants (37%). It includes equivalent criteria for 6 pollutants, and includes no criteria for 18 pollutants which had no state-adopted criteria.

*improves criteria for only 3 of the 64 pollutants (5%). It includes new restrictive criteria for 2 pollutants, and proposes a criterion allowing 200,000 instead of 300,000 ug/L toluene.

The magnitude of increased pollutant concentrations allowed in Bay waters by EPA'S proposal is estimated in Table 2. The first column in this table lists all the toxic pollutants for which EPA proposes more liberal criteria than those adopted by California for the Bay. Footnotes to this column further describe these pollutants. For example: dioxin includes 17 dioxin-like compounds included in the state criterion and current permit limits; and PAH includes the sum of 13 polycyclic aromatic hydrocarbons included in the state's PAH criterion and 8 of these compounds for which EPA proposes criteria.

The second column in Table 2 shows the lowest concentration criteria adopted by California for these pollutants in the Bay, with footnotes indicating the source of these criteria and whether they address human health or aquatic life. The third column shows the corresponding lowest concentration criteria for these pollutants proposed by EPA. Where the EPA-proposed criteria are expressed differently from the state criteria for a pollutant, calculations that more accurately compare the criteria are shown in footnote j to this column. These calculations fall into three general cases:

*Dioxin comparisons - California's dioxin criterion applies to 17 internationally recognized dioxin-like compounds, while EPA's proposal
applies to I only, 2,3,7,8-TCDD. EPA'S chief dioxin scientist and other international experts estimate that the other dioxins account for about 90% of environmental dioxin toxicity.(*14) Thus, EPA's criteria value was multiplied by 10 to estimate the toxicity from California criteria dioxins at EPA's 2,3,7,8-TCDD value of 1,4 pg/IOOL. New data may change the 90% estimate, but not the finding that EPA's proposal is weaker.

*PAH comparisons - California's PAH criterion sums the amounts of 13 compounds, while EPA proposes individual criteria for only 8 of these 13 compounds. EPA criteria values for these 8 compounds were summed for comparison to California's 13-compound criterion. This approach underestimates the amount of PAH allowed by EPA's criteria by assuming a value of zero for each of the 5 compounds which lack EPA-proposed criteria.

*Total versus dissolved metals comparisons - California metals criteria are expressed as total metal while EPA's proposals are often expressed as dissolved metal. Ultra-clean measurements of Bay waters in 1989,(*15) and 1995 (arsenic and chromium)(*3) indicate that total concentrations are often much greater than dissolved concentrations for the same metal, For example, in 5% of Bay samples total copper is at least 3.5 times dissolved copper. At these times dissolved copper levels equal to EPA's 3.1 ug/L criterion correspond to total copper levels of 10.8 ug/L or greater. Ratios for other metals based on this 5% (95th percentile) analysis, which is used by EPA to prevent excursions above criteria more than once in 3 years, are shown in footnote (*j). Analysis of additional data may alter these ratios, but will not change the conclusion that EPA'S proposed dissolved criteria will allow greater water concentrations than total metal criteria.

The estimated magnitude of increased pollutant concentrations allowed in Bay waters by EPA's proposed criteria is shown in the right-hand column of Table 2. EPA's proposal allows 430 million percent more PAH, 23,600% more lead, 3,900% more 1,4-dichlorobenzene, 910% more silver, 900% more dioxin, 630% more chlordane, 340% more DDT, 325% more mercury, 140% more PCBs and 120% more copper in the Bay as compared to state-adopted criteria, based on these estimates. Review of Table 2 also shows that allowable Bay water concentrations would double or more for 18 toxic pollutants in all.

In sum, comparison with the state criteria that would be replaced indicates that EPA's proposed criteria allow increased toxic pollution of San Francisco Bay by at least 37 toxic pollutants representing 58% of the pollutants of concern identified by the San Francisco Estuary Project, allow pollution to increase by about 1,000% or more for extremely toxic pollutants such as dioxin and PAH, and allow pollution to double or worse for 18 toxics including nearly all pollutants known to be of greatest concern in the Bay.

None of the state criteria which the EPA proposals are compared to were set aside because they are scientifically invalid, Rather, some of these criteria, which were adopted in the 1991 Bays and Estuaries Plan, were set aside by a state court on procedural grounds only,(*12) and still form the basis for permit limits written by the state for the Bay.(*21) EPA's proposed criteria allow toxic pollutant concentrations greater than those found by the state to be scientifically appropriate for protection of aquatic life and public health.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH

concentrations in San Francisco Bay waters.
(*10) California State Water Resources Control Board, 1991. California Enclosed Bays and Estuaries Plan; water quality control plan for enclosed bays and estuaries in California. 91-13WQ. April, 1991. Excerpt including adopted water quality criteria and definition of terms.
(*11) California Regional Water Quality Control Board, San Francisco Bay Region, 1986. Water Quality Control Plan, San Francisco Bay Region (2). December, 1986. Excerpt including adopted water quality criteria (objectives) for toxic pollutants in the Bay, and segmentation scheme.
(*12) California Regional Water Quality Control Board, San Francisco Bay Region, 1992. Resolution No. 92-128, adopting an amendment to the water quality control plan and requesting approval from theState Water Resources Control Board. October 21, 1992; and State Water Resources Control Board Workshop Session, April 6 and 7, 1994. Consolidation of the amendments to the water quality control plan for the San Francisco Bay basin regarding a site-specific water quality objective and plan of implementation for copper and addressing nickel. Excerpts including site specific water quality criterion for total copper in San Francisco Bay, and showing that the State Water Resources Control Board staff found "the technical aspects of the site-specific copper objective are valid."
(*13) San Francisco Estuary Project, 1992. State of the estuary, a report on conditions and problems in the San Francisco Bay/Sacramento-San Joaquin Delta estuary. Prepared under cooperative agreement #CE-009486-02 with the U.S. Environmental Protection Agency, by the Association of Bay Area Governments, Oakland, CA. June, 1992. Excerpt including Table 18 (page 163): Pollutants of concern in the Bay/Delta estuary.
(*14) Presentation by Dr. William Farland, EPA, at the May 7, 1997 Workshop on dioxins held by the Regional Water Quality Control Board, San Francisco Bay Region in the Hearing Room of the 'BART headquarters building, Oakland, CA. Excerpt from the RWQCB's tape of the workshop discussing toxicity equivalents data from mechanistic, laboratory and field analyses.
(*15) Flegal et al., 1990. Trace element cycles in the San Francisco Bay estuary: results from a preliminary study in 1989-1990. Final report to the State Water Resources Control Board. Institute of Marine Sciences, U.C. Santa Cruz. Excerpt showing dissolved and total metal concentrations measured in San Francisco Bay waters.
(*21) California State Water Resources Control Board, 1997. Staff technical report, Division of Water Quality, Petitions of CBE, San Francisco BayKeeper, and Tosco Corporation for review of Order No. 95-138 of the San Francisco Bay Regional Water Quality Control Board. Office of Chief Counsel [OCC File Nos. A-983 and A-983(A)].

Response to: CTR-002-003

Overall, EPA disagrees with this comment, which alleges that the CTR "weakens environmental health" for 37 of 64 "pollutants of concern."

Much of the premise for this comment is flawed, because it compares CTR ambient criteria with State and San Francisco Bay Regional Board criteria which are not in effect. The 1991 California Enclosed Bays and Estuaries Plan (EBEP) was rescinded by the State Water Resources Control Board. [Note: California's 1991 Inland Surface Water Plan (ISWP) was rescinded at the same time. Since this comment does not compare CTR criteria to ISWP criteria, however, this response does not address the ISWP.] The State Board returned the 1992 site-specific copper objective for San Francisco Bay to the Regional Board, and it has never taken effect. EPA is now promulgating the CTR to put criteria in place in California where currently there are no applicable EPA-approved criteria in effect, including where criteria were affected by these State actions. The CTR criteria do not revise or replace those State

criteria, because those criteria simply do not exist for CWA purposes.

The commenter also compares CTR criteria to criteria in the 1986 San Francisco Bay Basin Plan. For waters where the criteria that were included in the 1986 amendments to the Water Quality Control Plan for the San Francisco Bay Region (the Basin Plan) and were approved by EPA are still in effect under the 1995 Basin Plan amendments, EPA is not promulgating CTR criteria. The 1986 criteria will therefore remain in effect for those waters. (See response to CTR-016-001.) For those criteria, the commenter's concerns have been addressed.

Another flaw in this comment is that CTR criteria are evaluated for 64 "pollutants of concern" which were identified by the San Francisco Estuary Project. While most of these pollutants are priority pollutants subject to the requirements of CWA section 303(c)(2)(B), 17 are not. The CTR is limited to the promulgation of numeric water quality criteria for priority pollutants, to fully implement section 303(c)(2)(B) in California. It is beyond the scope of the CTR to include other pollutants, even if they are pollutants of concern for the Bay. The commenter may seek to have the State, through its Regional Board, address the possibility of adopting or revising criteria for those non-priority pollutants through its triennial review process, but that approach would not affect the CTR.

With those general observations, EPA responds as follows to the following specific concerns included in this comment:

A. The CTR allows "greater ambient water concentrations" for 30 pollutants

The commenter's discussion of this concern is confusing because only 24 specific pollutants are identified by the commenter (in its Table 2) for this concern, and footnotes for 6 of these indicate that these 6 actually represent enough additional pollutants to make the total number of individual pollutants greater than 30. EPA is responding, therefore, based on the 24 pollutants identified in Table 2.

EPA is "promulgating around" several of these pollutants for those waters of San Francisco Bay where State-adopted, EPA-approved criteria from the 1986 Basin Plan remain in effect, as discussed above. For those waters of San Francisco Bay where EPA is promulgating these 24 criteria, however, EPA agrees that 10 of the 24 CTR criteria in Table 2 (all of the Table 2 criteria, with the exception of nine metals, DDT, endrin, endosulfan, PAHs and dioxins, which are discussed below) would allow greater ambient concentrations than the EBEP criteria would have allowed if it was presently in effect. These CTR criteria, however, are based on sound science, which supports a finding that these criteria are fully protective of the designated uses listed in the CTR. For some criteria, the CTR criteria are based on additional scientific data developed not only since those State criteria were first proposed, but in some cases since the National Toxics Rule (NTR) was adopted by EPA in 1992. The new data further supports the conclusion that the CTR criteria are fully protective of designated uses listed in the CTR. The scientific bases for all of the CTR criteria are set forth in the California Toxics Rule Administrative Record Matrix. See also, National Recommended Water Quality Criteria, 63 Fed.Reg. 68354, December 10, 1998, as corrected, 64 Fed.Reg. 19781, April 22, 1999.

EPA disagrees with the commenter's contention that the CTR will allow increased concentrations of metals in San Francisco Bay. First, EPA notes that the CTR does not include criteria for most metals in much of the San Francisco Bay. Most of the metals criteria in the 1986 Basin Plan (which includes all of the commenter's nine metals, except copper), that were approved by EPA, remain in effect, therefore ambient concentrations for those metals criteria are not affected by the CTR. EPA is, however, promulgating metals criteria for the South Bay (below Dumbarton Bridge) and a saltwater aquatic life copper criterion for waters of the Bay with salinities greater than 5 ppt, because there are no comparable

Basin Plan criteria for those pollutants presently in effect. Since the CTR does include these metals criteria for these waters of San Francisco Bay, EPA has considered the commenter's comparison of ambient concentrations for pollutants in the Bay, which the commenter predicts will result from application of the different metals criteria, and EPA disagrees with those comparisons.

The commenter has compared CTR metals criteria, which are expressed as dissolved metals, with EBEP and copper site-specific criteria, which were expressed as total recoverable metals, by performing a calculation (the "5% analysis") on the CTR metals criteria prior to comparing them with EBEP metals criteria. This is not a recognized basis for comparison between dissolved and total recoverable metals criteria, however, and it is not adequately explained or supported. EPA therefore cannot accept the results of this analysis, which yields greatly exaggerated concentrations of the CTR metals criteria. EPA does not propose an alternative basis for a general comparison between dissolved and total recoverable metals, because the relationship between the two forms of metal varies depending on site-specific and time-specific conditions (which the State must address through the use of translators when implementing the criteria). Instead, EPA relies on sound scientific information which supports the conclusion that the CTR dissolved metals criteria are themselves protective of the designated uses that they are adopted to protect (see the California Toxics Rule Administrative Record Matrix). See also, National Recommended Water Quality Criteria, 63 Fed.Reg. 68354, December 10, 1998, as corrected, 64 Fed.Reg. 19781, April 22, 1999.

EPA also disagrees with the commenter's comparison between CTR criteria and four other EBEP criteria. The commenter compared sums of individual CTR criteria concentrations and compared them with "single" EBEP criteria. The four single EBEP criteria, however, represent four pollutant groups that the State created by combining individual pollutants into groups under the four pollutant names. (The EBEP groups are "DDT", "Endrin", "Endosulfan" and "PAHs".) The CTR, on the other hand, includes individual pollutants without grouping them. The commenter added the concentrations for individual CTR criteria for each of the 4 EBEP criteria groups and compared the sums with the single concentrations for each of the 4 EBEP criteria. This approach resulted in some very questionable comparisons.

For the DDT group, the CTR human health criteria for DDT, DDE and DDD are 0.59 ng/L, 0.59 ng/L and 0.83 ng/L, respectively. The sum of these criteria would be 2.01 (rounded to 2) ng/L, not 2.6 ng/L as the commenter contends. For the PAH group, the sum of the CTR's eight individual criteria would be 392 ng/L, not 135,000,000 ng/L as the commenter contends. For the Endrin group, the commenter has ignored applicable CTR aquatic life criteria. These aquatic life criteria are significantly more stringent than the CTR human health criteria which the commenter used as the sole basis for comparison. Had the commenter compared the EBEP human health criterion for Endrin to the sum of the appropriate CTR criteria for Endrin and Endrin Aldehyde (using the CTR's chronic saltwater aquatic life number for Eldrin and the human health fish consumption number for Endrin Aldehyde), the figures would have shown the CTR to be equivalent to the EBEP criterion, not less stringent.

Notwithstanding these errors, the commenter's approach is simply not a basis for revising the CTR criteria for pollutants in these four groups. As stated above, the comparisons are made to State criteria which are no longer in effect. The CTR is promulgated to put criteria in place where there presently are no State-adopted EPA-approved criteria in effect. The CTR is promulgated to meet the requirements of CWA section 303(c)(2)(B), which requires adoption of numeric criteria only for those toxic pollutants listed pursuant to section 307(a)(1) for which EPA has already adopted section 304(a) criteria. EPA has adopted section 304(a) criteria for the individual pollutants, not for the pollutant groups. As stated in the preamble to the proposed CTR and in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria and intends to stay the CTR when EPA approves such criteria.

The commenter includes a further concern regarding polynuclear aromatic hydrocarbons (PAHs), which is one of these four pollutant groups. The commenter alleges that the CTR includes criteria for eight of the 13 PAHs which are included in the single EBEP criterion for PAHs, and omits the other five. This is not entirely correct. (Even if it were correct, it would not alter the fact that comparing the sum of eight PAHs to a single PAH criterion is invalid.) Of the five pollutants which the commenter alleges are omitted from the CTR, two are, in fact, included in the CTR, but under slightly different names. (Benzo(a)Anthracene (CAS number 56553) and benzo(b)Flouranthene (CAS number 205992) replace the EBEP's 1,2-benzanthracene and 3,4-benzoflouranthene, respectively. The CTR and the EBEP used different naming conventions, but the pollutants are the same chemicals.) It is true, however, that the CTR does not include numeric criteria for three of the 13 PAHs. As discussed in part C and D, below, acenaphthylene, phenanthrene and benz(ghi)perylene are no longer considered carcinogens, and EPA has not developed criteria levels for these toxic pollutants as non-carcinogens. In the absence of such guidance, numeric criteria for these three pollutants are not included in the CTR. [Note: benzo(ghi)Perylene (CAS number 191242) also is the same as one of the EBEP's PAHs (1,12-benzoperylene), but with a different name.] The CTR is consistent with the NTR (40 CFR 131.36 (b)(1)) in regard to all of the PAHs.

It should be further noted that for much of San Francisco Bay, the applicable Basin Plan includes a single criterion for PAHs comparable to the EBEP PAHs criterion, which EPA has previously approved. To the extent that the Basin Plan criterion may be more stringent than the CTR objectives for individual PAHs, it would take precedence over the CTR criteria as a basis for controlling PAHs in the part of the Bay where it applies.

The remaining pollutant among the 24 is "dioxin". The commenter has multiplied the single CTR dioxin criterion by 10 before comparing it with the single EBEP dioxin criterion. The commenter multiplied the CTR criterion for 2,3,7,8-TCDD "to account for...16 other dioxins" before comparing it with the EBEP criterion for "TCDD equivalents". The commenter then concluded that EPA was allowing a 900% increase in "dioxin". EPA disagrees with the 900% figure, because the relationship between this figure and the 16 other dioxins is unexplained. EPA does agree that the CTR could allow for greater concentrations of all dioxins and dioxin-like compounds in San Francisco Bay than the EBEP's dioxin criterion might have allowed, but does not agree that this is inevitable.

The EBEP's single dioxin criterion ("TCDD Equivalents") represented the sum of 17 dioxins and dioxin-like compounds. The CTR, on the other hand, includes a single dioxin criterion for a single dioxin compound (2,3,7,8-TCDD). The numeric values for the two criteria (the ambient concentration limits allowed by the two criteria) are the same.

EPA notes that 2,3,7,8-TCDD is the only EBEPdioxin compound included on the CWA section 307(a)(1) list. It is also the only 307(a)(1)-listed dioxin for which there is a CWA section 304(a) criterion. The CTR is promulgated to meet the requirements of CWA section 303(c)(2)(B), which requires adoption of numeric criteria only for those toxic pollutants listed pursuant to section 307(a)(1) for which EPA has already adopted section 304(a) criteria. EPA is therefore not required to include criteria for any dioxin compound other than 2,3,7,8-TCDD in the CTR. For California waters, if designated or beneficial uses may be impaired by the discharge of other dioxin or dioxin-like compounds, numeric water quality-based effluent limits may be included in NPDES permits through the use of the narrative criterion. EPA strongly encourages the State to adopt either the same national/international convention of toxicity equivalence (TEQ) to account for the presence of other dioxins, furans and other dioxin-like compounds, which the State adopted in its EBEP, or a more recent, comprehensive convention. EPA believes that the State should apply this recognized method for regulating dioxin compounds and believes that this would

address the commenter's concerns.

The EBEP relied on the TEQ convention's nationally/internationally consistent set of toxicity equivalence factors (TEFs) as multipliers for the 17 dioxins, to convert them to the single TCDD Equivalents criterion. Thus, the EBEP's TCDD Equivalents criterion results from the same calculations that EPA believes should be applied to the CTR's 2,3,7,8,-TCDD criterion.

If the State of California did not apply the TEQ convention to the CTR criterion to account for the presence of other dioxins, furans and other dioxin-like compounds, it is possible that, under the CTR, the total concentrations of alldioxin and dioxin-like compounds in the Bay could allowably exceed the EBEP concentration limit even though 2,3,7,8-TCDD by itself does not exceed that limit. For this reason, EPA strongly encourages the State to limit these other compounds through the application of TEQ,.

If the TEQ convention were adopted, and TEF applied to the CTR criterion, the commenter's comparison between the CTR and the EBEP numbers could reasonably conclude that there was no difference between the two. (Alternatively, the commenter might have concluded that the CTR was more inclusive than the EBEP. The commenter refers to 17 dioxin compounds which are included in the EBEP's criterion for TCDD equivalents. The CTR's 2,3,7,8-TCDD criterion is intended to include all dioxins and dioxin-like compounds for which there are TEFs, which are far more than 17.) As long as California applies the national/international TEQ/TEF conventions to implementation of the 2,3,7,8-TCDD criterion in the CTR, as it applied them to implementation of the TCDD Equivalents criterion in the EBEP, then greater concentrations of dioxins will not be allowed to be discharged under the CTR.

B. The CTR includes" new, extremely liberal criteria" for 4 pollutants

This part of the comment is very vague. It appears from the context of this concern, however, that "extremely liberal" means something less than "allows greater ambient water concentrations", for which the preceding group of criteria is criticized. For these four pollutants, the commenter does not allege that the CTR criteria are unprotective of the designated uses. In fact, the CTR criteria for these pollutants (acenapthene, ethylbenzene, antimony and hexachlorobutadiene) are based on recent, sound science which supports the determination that the criteria are protective of the designated uses (see the California Toxics Rule Administrative Record Matrix). See also, National Recommended Water Quality Criteria, 63 Fed.Reg. 68354, December 10, 1998, as corrected, 64 Fed.Reg. 19781, April 22, 1999.

C. The CTR "fails to replace previous state criteria" for 3 pollutants

Of these 3 criteria, one (tributyltin) is not a priority pollutant. This pollutant, as discussed above, is therefore beyond the scope of the CTR, regardless of whether the State had previously adopted statewide criteria for it.

For the other two pollutants (acenaphthylene and phenanthrene), both EPA and the State have previously included human health criteria based on carcinogenicity in proposed or final water quality standards. EPA included such criteria in the 1991 proposed NTR (56 Fed.Reg. 58442-58443), and California adopted them in the 1991 EBEP (EBEP, Table 2 and Appendix 1). However, in the 1992 final NTR, EPA deleted these criteria, having found that there was inadequate toxicity data to assess their carcinogenic potential and that any criteria for these pollutants should therefore be based on

non-carcinogenic effects. Since there were no reference doses to calculate non-carcinogenic criteria for these pollutants, no numeric criteria were included for them in the final NTR. (57 Fed.Reg. 60868, 60887.) There has been no change from this position since 1992, and they are therefore not included in the CTR.

D. The CTR "includes no criteria for 18 pollutants which had no state-adopted criteria"

Of these 18 pollutants, identified in Table 2 of this comment, only two are priority pollutants. The other 16 are beyond the scope of the CTR.

Of the two pollutants which are priority pollutants, benz(ghi)perylene was withdrawn from the final NTR and is therefore not included in the CTR for the same reasons discussed in Part C, above, for acenaphthylene and phenanthrene. For naphthalene, EPA has not published 304(a) criteria. CWA section 303(c)(2)(B), which the CTR is implementing in California, requires that numeric water quality criteria be adopted only for those priority pollutants for which 304(a) criteria have been published, therefore naphtalene is beyond the scope of the CTR.

Comment ID: CTR-003-006
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: 6) In the forward to the rule the suggestion is made that no new SSOs will be approved by USEPA after the rule is promulgated due to lack of resources and the level of effort necessary for such action. Although we appreciate your candor, we do not believe that that is an appropriate response given the potential waste of public and private funds to comply with inappropriate standards.

Response to: CTR-003-006

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has

recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

Comment ID: CTR-004-008
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: Available Regulatory Relief under the California Toxics Rule

The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at. pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility. (*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does riot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Site-Specific Criteria

Another one of the avenues of potential regulatory relief discussed in the Preamble to the CTR is the adoption of site-specific water quality criteria. The Preamble provides that the "State has the discretion to develop site-specific criteria when appropriate e.g., when statewide criteria appear over or under protective of designated uses. The Preamble goes on to explain the site-specific criteria adoption process as follows:

Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants

within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete, the criteria become State law. These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted tinder the State's process and has become State law. CTR Preamble at pg. 42165.

The Preamble explains that the State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of these Basin Plans, some of which contain site-specific criteria, have completed the State review and adoption process and have been submitted to EPA for review and approval. The key to whether or not these site-specific criteria will provide regulatory relief is when the EPA approval/disapproval occurs. Three different timing scenarios and results are possible:

1 . If EPA approves any State-adopted site-specific criteria before promulgation of the final CTR is published, then the EPA Administrator may make a finding, in that final rule that it will be unnecessary to promulgate criteria for the approved site-specific pollutants and associated water bodies.

2. If EPA disapproves any State-adopted site-specific criteria, the proposed statewide criteria contained in the CTR would apply for those pollutants and associated water bodies instead of the site-specific criteria.

3. However, if EPA promulgates statewide federal criteria as proposed in the CTR, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and applications of the more stringent of the two criteria would satisfy both. CTR preamble at pg. 42165.

Thus, the only way less stringent site specific criteria can be used for regulatory relief is if those criteria are approved by EPA prior to the publication of the final CTR. Otherwise, either the CTR or the more stringent of the two (CTR vs. site-specific) criteria apply.

One final note regarding site-specific criteria is that the Preamble to the CTR restricts the ability to use native aquatic life as a way to set site-specific criteria. Instead of allowing a discharger to substitute local species from the receiving waters into which it discharges, the Preamble only allows a discharger to supplement the eight specified families of aquatic life required for criteria development with the addition of native species.(*9) It is doubtful whether this requirement will aid dischargers who are seeking regulatory relief.

(*1) This cost trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario, See EA at pg. 4.

(*2) In addition, pollutant load I reductions word not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*9) "A minimum data set of eight specified families is required for criteria development (details are given in the 1985 Guidelines, page 22). 'f he eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented by the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are

available." CTR Preamble at pg. 42168.

Response to: CTR-004-008

EPA disagrees with this comment. Regarding this commenter's discussion as to how the CTR may relate to State-adopted site-specific criteria, See response to CTR-016-002.

EPA disagrees with the part of this comment which suggests that the preamble to the proposed CTR restricts the use of native aquatic species in setting site-specific criteria. The commenter correctly quotes the preamble to the proposed CTR, however it appears that there must be a misunderstanding on the commenter's part regarding the quoted language. The commenter mistakenly assumes that native species may only be used to "supplement", rather than to "substitute" for species identified by EPA. It has been EPA's consistent position, however, that states may use native species rather than species identified by EPA, provided they do so within the framework of EPA's guidance (which requires the use of a broad spectrum of species, represented by eight families of species), in setting ambient water quality criteria. See Water Quality Standards Handbook: Second Edition (U.S. EPA-823-B-94-005a, August 1994), Chapter 3 (esp section 3.7); "Summary of Revisions to Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 Fed.Reg. 30792, July 29, 1985).

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Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES C-21

Comment: 7. Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Pablo Bay in the vicinity of the District's discharge, or alternatively EPA should state in the Preamble that the Regional Board should: (1) allow a dilution credit for the District based on modeling studies; and (2) apply metals translator determined based on EPA procedures from the results of the Regional Monitoring Program. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the analysis of costs and benefits performed by the District (see Attachment 1), EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation criteria that will allow the current discharge to continue. The District has performed dilution studies (see Attachment 2) and performed reasonable potential analyses using dilution and metals translators (see Attachments 3 and 4). These show that with the use of these implementation provisions, the proposed criteria can be achieved in-stream. Without EPA specifying that dilution studies and metals translators should be utilized in the District's case, it is possible that the CTR could impose enormous costs on the District (and the small entities it serves) without providing any environmental benefit. In that case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the

Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-005-008a

EPA disagrees with the commenter's request that EPA either adopt site-specific copper criteria for San Pablo Bay or state in the preamble that the Regional Board should allow dilution credit and application of a metal translator for the commenter's discharge.

In support of its request for the adoption of "scientifically defensible, reasonably achievable aquatic life criteria for copper" (emphasis added), the commenter has submitted its own analysis of costs and benefits. EPA has conducted an analysis of costs and benefits for this rule pursuant to Executive Order 12866 (see discussion in preamble to final rule); however, the criteria themselves are not based on economic considerations. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA does support State adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in the response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and intends to stay the CTR when EPA has approved such State criteria. In the meantime, in the absence of such criteria for aquatic life for copper in waters of San Francisco Bay, with salinity greater than 5 ppt, EPA is promulgating criteria based on EPA's section 304(a) national marine water copper aquatic life criterion, which is consistent with the requirements of the CWA. (40 CFR Section 131.11(b).) See also responses to CTR-016-001 and -002.

Regarding the suggestion that EPA specify the use of dilution and metals translators for this discharger, EPA disagrees. With the exception of compliance schedules, the CTR does not include implementation provisions; the CTR is promulgated to add numeric criteria for toxic pollutants where they did not exist. The State may address these issues in a separate implementation plan, which it is currently developing. ("Policy for implementation of Toxics Standards for Inland surface Waters, Enclosed Bays and Estuaries of California", released for public comment, September 11, 1997.)

Finally, regarding the commenter's assertion that the CTR could be inconsistent with Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act see the discussion of EPA's compliance with these requirements in the preamble to the final rule.

Comment ID: CTR-008-002
Comment Author: San Luis&Delta-Mendota
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/15/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N

CROSS REFERENCES

Comment: The San Luis & Delta-Mendota Water Authority has entered into a Use Agreement with the Bureau of Reclamation for discharge of drainage water through a portion of the San Luis Drain to the San Joaquin River. A consensus letter to the Central Valley Regional Water Quality Control Board signed November 3, 1995, discussed the selenium water quality objectives in the San Joaquin River, Mud Slough, Salt Slough and wetland channels. The letter states "Please note that the parties have not reached a consensus on the appropriate long-term water quality objectives. However, the parties have committed to participate in a cooperative review process by which to evaluate any new scientific information relative to the subject." This letter was signed by the San Luis & Delta-Mendota Water Authority, the U.S. Bureau of Reclamation, the U.S. Environmental Protection Agency, and the U.S. Fish and Wildlife Service.

The proposed California Toxics Rule should not be adopted without adequately addressing the difference for high-sulfate waters. The Rule should also not be adopted if it undercuts EPA's commitment to the cooperative review of appropriate long-term standards in the San Joaquin River Basin.

Response to: CTR-008-002

EPA disagrees with this comment. Concerning future review of standards in the San Joaquin River Basin, that course of action is in no way precluded by the CTR. As explained in the preamble to the proposed CTR, and further discussed in the response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR where such State criteria are in effect. In the case of the San Joaquin River basin, EPA is committed to cooperative review of site-specific standards. Moreover, where site-specific criteria have already been adopted by the State in accordance with State law, but not yet acted upon by EPA, and those criteria are more stringent than applicable CTR criteria, those are the controlling criteria for CWA purposes within the State even without a stay of the applicable CTR criteria and are thus implementable by the State. (This would not be affected by the "Alaska Rule" which EPA proposed July 9, 1999, 64 Fed.Reg. 37072. See p. 37076.) This is the case with the selenium criterion adopted by the Central Valley Regional Board for Mud and Salt Sloughs and some adjacent basin waters in the Board's 1996 Basin Plan amendment. Since the State must use the most stringent criteria in effect for its water quality programs, the State may use this site-specific selenium criterion notwithstanding the CTR selenium criterion, thus the commenter's concerns should have no practical effect.

EPA has reviewed the information provided concerning the effect of high-sulfate waters on the toxicity of selenium to the extent it applies in the referenced waters. EPA concludes, based on information provided by the U.S. Fish and Wildlife Service (FWS), that this comment provides no basis for changing the numeric selenium criteria contained in the CTR. The letter of October 10, 1997, from Wayne S. White, Field Supervisor, FWS, to Diane Frankel, EPA, responds to the information provided with this comment. (The FWS letter is itself included as a comment on the proposed CTR in the administrative record.) In summary, the FWS letter says that most of the references relied on by this commenter suffer from an inability to transfer laboratory results to the field. They are based on the real but simplified interference between selenate and sulfate. They use relatively high levels of sulfate which are not unrealistic in themselves; however, the reduction in selenium bioaccumulation from selenate that they measure is not elimination of bioaccumulation from that form of selenium. Also, the results apply only to the selenate form of selenium. The other forms of selenium are far more bioaccumulative than selenate, are free of any interference from sulfate and, over time, come to dominate the bioaccumulation process.

Comment ID: CTR-009-003
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: The City is concerned that any site specific objectives have to be implemented through federal rulemaking. The EPA was quite explicit in advising both the State and the regulated community not to expect prompt response from EPA on such requests. The State has a number of watershed projects underway in conjunction with EPA. The expressed lack of potential to ever see the implementation of site-specific requirements based upon the most representative and expansive scientific database for a given watershed have a chilling effect on these efforts. This would beextremely unfortunate because EPA's goal of "place-based" management approaches will suffer a significant set-back in California. Millions of dollars spent on good science to develop the most cost-effective local water quality solutions, may be for naught. This is an unintended negative outcome that the Agency surely does not desire. The City recommends that the final CTR Rule explicitly provide that site specific objectives and requirements for criteria included in the rule can be accomplished through Basin Plan Amendments approved by SWRCB and EPA. Given the sheer size and diversity of California's watersheds and receiving waters, the most effective way to implement appropriate water quality controls is through watershed-specific characterizations implemented by the Regional Boards. Without the ability to affect site-specific objectives in this manner, its tool is undermined if not negated.

Response to: CTR-009-003

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or

rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA further disagrees with any suggestion that the State itself could, in the future, modify CTR criteria. State adoption of site-specific criteria (including site-specific criteria adopted by the Regional Board which have completed the State adoption process) is a separate State action, under State law, which does not modify federal criteria. It would be up to EPA to modify the CTR to "make way" for the State's criteria, once those criteria have been approved by EPA. As discussed above, if the State were to adopt criteria that were more stringent than applicable CTR criteria, those criteria could be effective for CWA purposes within the State under State law, prior to EPA approval of such criteria or modification of the CTR.

Comment ID: CTR-009-006a
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES G-02

Comment: With respect to the provisions in the proposed rule regarding compliance schedules and site-specific objective development and approval/implementation, the City requests verification that these, and all provisions, in the proposed rule apply only to those constituents for which this rule proposes criteria.

Response to: CTR-009-006a

EPA agrees with this comment. The implementation measures contained in the CTR apply to the criteria contained in the rule.

Comment ID: CTR-010-001
Comment Author: Save San Francisco Bay Assoc.
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA's proposed California Toxics Rule is extremely disturbing because it significantly

weakens standards for numerous pollutants of concern in San Francisco Bay. Standards for more than half of the pollutants of concern identified by the S.F. Estuary Project will be weakened, including dioxin, PCB, mercury, PAHs, and chlordane. These pollutants were found in elevated levels in Bay fish by the S.F. Regional Water Board's study on contaminants in fish and resulted in the fish consumption advisory put out by Cal-EPA. Research conducted by Save S.F. Bay Association found people eating two to three times the amount of Bay fish considered safe. EPA's proposal will make this situation much worse and result in higher exposure levels to thousands of people. Moreover, pollution levels for a number of other pollutants will significantly increase, such as lead, copper, zinc, fluoranthene, and many others.

Response to: CTR-010-001

EPA disagrees with this comment. See response to CTR-002-003, which responds in detail to specific concerns regarding pollutant increases in San Francisco Bay, CTR-016-002, which discusses San Francisco Bay Basin Plan criteria which will not be superceded by the final CTR, and CTR-002-002a, which responds to specific concerns regarding fish consumption.

Comment ID: CTR-011-001b
Comment Author: City of Simi Valley
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-011 incorporates by reference letters CTR-027 and CTR-034
Attachments? Y
CROSS REFERENCES C-13
E-01d

Comment: The City of Simi Valley discharges approximately 10 million gallons per day (mgd) of tertiarytreated wastewater (as well as municipal storm water) to the Arroyo Simi, an effluent dependent water body. Through much of the year, Arroyo Simi is dry several miles downstream from the City. The Arroyo Simi Characterization Report, completed by the City in 1995, concluded that the arroyo does not support a significant fishery, and observed only arroyo chub, mosquito fish and blunt-nosed minnow in the stream. Although designated as a potential municipal water supply in the Basin Plan, the arroyo waters are not used for municipal purposes. Effluent monitoring are limited, but available data indicate that the City's discharge may have a reasonable potential to exceed the proposed aquatic life criteria for several metals and the proposed human health criteria for several carcinogens.

Since Simi Valley is largely a residential community with supporting commercial development and little industry, and since the City already has an effective pretreatment program, it is unlikely that pollution prevention efforts would effectively reduce the problematic constituents. More likely, the City would be faced with end-of-pipe treatment controls such as lime precipitation and carbon adsorption to achieve the proposed criteria. The costs would undoubtedly be significant and the benefits relatively minor.

Under these circumstances, it appears reasonable to adopt criteria for Arroyo Simi, and similar effluent dependent waters, that are reasonably achievable without costly end-of-pipe controls and that reflect the actual use of the water (i.e., generally such waters are used for fishing or drinking). One way to address

this issue, consistent with the requirements of the Clean Water Act, would be to adopt specific human health criteria for Arroyo Simi and other effluent dependent streams based on a cancer risk coefficient of 10E-5 or in some cases 10E-4. Based on the limited data collected by the City, risk levels of 10E-4 would have to be adopted for dioxins, aldrin, alpha-BHC and 4,4,-DDD (see Table 1). Risk levels of 10E-5 would be sufficient for chloroform and endoslfan 11 (Id.).

Response to: CTR-011-001b

EPA disagrees that it must or should establish separate criteria for effluent dependent waters in this rule. In establishing water quality criteria for California, EPA is implementing section 303(c)(2)(B) of the CWA which requires adoption of criteria for all toxic pollutants for which EPA has issued criteria guidance and for which the discharge of such pollutants could reasonably be expected to interfere with the designated uses adopted by the state. EPA based the criteria contained in the CTR on its most recent national criteria guidance, which are designed to derive criteria that will be protective of aquatic life and human health. As long as a waterbody currently has a designated use for the protection of aquatic life and/or human health, application of the national 304(a) criteria are appropriate for fulfilling section 303(c)(2)(B). The CTR itself does not adopt uses or modify any uses previously adopted by the State. EPA presumes that the State has designated appropriate uses for its waters. Proposals to revise State-adopted uses must be brought to the State pursuant to its procedures for review of its water quality standards.

That being said, it should nevertheless be understood that EPA does support State adoption os site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR where EPA has approved such State criteria.

With respect to risk level applicable to human health criteria when, as here, EPA establishes a water quality standard, EPA intends in its discretion to use a risk level of 1 x 10-6, although the State may in its discretion choose another risk level for protection of human health, if the State has appropriately consulted the public. As discussed in responses to CTR-011-0001a and CTR-058-001 (Category C-13; Risk Level), EPA follows the risk-level policies of the affected state, when promulgating criteria as regulations.

Comment ID: CTR-016-001
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: Existing State Standards for the San Francisco Bay Region Previously Approved by US EPA

US EPA has asked people commenting on the proposed California Toxics Rule to identify any state-adopted numerical objectives that are still in effect following the decision in the Water Quality

Control Cases, Judicial Council Coordination Proceeding No. JC2610. The San Francisco Bay Regional Board was not a party to that lawsuit. Accordingly, there are several numerical objectives for toxic substances contained in the Water Quality Control Plan for the San Francisco Bay Region (Basin Plan) that remain valid following the court ruling. They were adopted after a full public review process in 1986 and subsequently approved by US EPA in 1987. These objectives are contained in Tables 3-3 and 3-4 of the Basin Plan and are reproduced in an attachment to this letter.

Staff have reviewed these objectives and have determined that many are identical to those proposed in the California Toxics Rule except that the Region's existing standards are expressed as total recoverable and not in the dissolved form. Of those objectives that are not identical, ambient levels of arsenic, lead, and zinc are so far below both existing and proposed standards that the Regional Board does not consider modifying the values a priority. Levels of copper, nickel, mercury, and PAHs, however, are of greater concern in the Region.

In reviewing both the proposed and past US EPA criteria, we have consistently found that site-specific objectives are preferable to more generalized objectives for the complex, dynamic hydrogeological and biogeochemical systems in the San Francisco Bay Estuary. Generalized national criteria development processes seek to minimize the uncertainty of laboratory-based predictions (as in the selection of dissolved criteria) yet do not attempt to reduce any of the environmental uncertainties that arise when laboratory results are extrapolated to extremely complex and variable field conditions. As a result, some of the proposed national criteria are seriously under protective of beneficial uses in San Francisco Bay, while others are overprotective and will ultimately cause compliance problems for dischargers under the existing implementation policies contained in our Basin Plan.

As you are aware, the Regional Board has been working to develop objectives appropriate for San Francisco Bay for copper and nickel since 1988 and is in the process of conducting similar technical analyses for mercury, dioxins, and PAHS. Our technical assessment of the proposed selenium, mercury, and dioxin criteria is presented in greater detail below. The goal of this undertaking is to develop site-specific objectives and pollutant-specific implementation policies for San Francisco Bay.

Because EPA's proposed criteria do not consistently incorporate the most current environmental information, and, in particular do not reflect the complex conditions in the Estuary, we feel it is more appropriate to retain the existing numerical objectives in the Basin Plan and to update them through our regional planning process.

Accordingly, we ask that EPA revise the proposed rule and exclude the existing fresh and salt water pollutant objectives listed in the attachment for waters within the San Francisco Bay Region (as defined in the California Water Code). This exclusion would amend the table on "Water and use classification and Applicable Criteria" to read:

All waters within the San Francisco Bay Region that include a MUN use designation:

* -assigned all criteria in Columns B1 and B2-for all pollutants except for arsenic, chromium (VI), copper, mercury, nickel, silver, and zinc

* -and all criteria in Columns C1 and C2-for all pollutants except for arsenic, cadmium, chromium (VI), lead, mercury, nickel, silver, and zinc

* -and Column D-1-all pollutants

and

All waters within the San Francisco Bay Region that do not include a MUN use designation:

* assigned all criteria in Columns B1 and B2-for all pollutants except for arsenic, chromium (VI), copper, mercury, nickel, silver, and zinc

* and all criteria in Columns C1 and C2-for all pollutants except for arsenic, cadmium, chromium (VI), lead, mercury, nickel, silver, and zinc

* and Column D-2 - all pollutants

It should be noted that this recommended action will result in two saltwater standards for PAHs; one will be a 24-hour average value of 15.0 ppb (the existing objective), the other will be the chronic human health-based federal standard.

Response to: CTR-016-001

EPA has reviewed this comment, as well as the Water Quality Control Plan for the San Francisco Bay Region (Basin Plan), and its amendments, including the 1995 Basin Plan, which the comment addresses. As EPA explained in the preamble to the proposed CTR, EPA intended to amend the text of the final rule to provide that CTR criteria would not apply where there is a site-specific State criterion in effect, approved by EPA, which the State or others identify in comments on the proposed CTR. (62 Fed.Reg. 42165.) This comment has identified such criteria. Based on our review, and discussions with the San Francisco Bay RWQCB, we have determined that those standards for the San Francisco Bay Region for priority toxic substances contained in Tables 3-3 and 3-4 of the 1995 Basin Plan (Tables III-2A and B of the 1986 Basin Plan), are the same as those adopted by the State in 1986 and approved by EPA in 1987, and they remain in effect for those waters of San Francisco Bay where they are presently in effect following final promulgation of the CTR. EPA believes that these are still appropriate criteria values. CTR criteria will therefore not apply to those parameters and waters covered by these San Francisco Bay Region Basin Plan WQS. National Toxics Rule (NTR) criteria for cyanide (40 CFR 131.36(d)(10)) will also continue to apply since the CTR does not supercede the NTR, as it applies in California.

EPA furthermore disagrees that CTR should exclude any of the pollutants proposed in this comment for all waters of San Francisco Bay that have the listed use designations. There are waters of San Francisco Bay (waters of the South Bay below Dumbarton Bridge) for which the criteria addressed in this comment are simply not in effect under the 1995 Basin Plan. CTR criteria are therefore adopted for these waters, and there is no conflict among criteria, since the CTR is filling a gap, not superceding State criteria.

The CTR also applies to any estuarine waters of San Francisco Bay which became subject to different criteria in 1995 when the San Francisco Regional Board eliminated the previously-approved geographic boundary between waters subject to freshwater and saltwater criteria and instead adopted methods for determining, on a salinity basis, where freshwater and saltwater criteria would be applied in San Francisco Bay. Because EPA has not approved the 1995 Basin Plan amendments, and since the 1986 Basin Plan criteria which EPA did approve no longer apply to those waters, EPA adopting CTR criteria for those waters is necessary to implement CWA section 303(c)(2)(B). It is expected, however, that few permits will be affected by this application of CTR criteria.

EPA disagrees that the CTR should exclude all of the pollutant criteria as proposed in this comment. It is beyond the scope of this rule to pick and choose among the CTR criteria which shall apply to waters of

San Francisco Bay on any basis other than whether or not they are subject to an EPA-approved State-adopted criterion, as described above. (For example, under the 1995 Basin Plan, there is currently no criterion for copper in waters of San Francisco Bay with salinity greater than 5 ppt, and EPA therefore will adopt CTR saltwater copper criteria for those San Francisco Bay waters.) Thus, regarding the various pollutants specifically addressed by this commenter, EPA will identify, in the footnotes to section 131.38(b)(1), those criteria which do not supercede EPA-approved San Francisco Bay Region Basin Plan criteria which are presently in effect.

Comment ID: CTR-016-002
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: Development of New Standards by Regional Boards - Clarification of Federal Rulemaking

It is very clear in the proposed rule that it is EPA's intention to promulgate federal standards only where there is an absence of state standards, and that when the state has completed its own process, that EPA intends to stay the proposed rule. At the same time, however, the proposed rule contains the following cautionary language:

"If this proposed rule is still in effect, as with the State adoption of site-specific criteria, EPA would have to undertake rulemaking to make necessary changes to this rule .... EPA, however, cautions California and the public that promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by states. These are optional policies under terms of the federal water quality standards regulation. Except for the water-effect ratio procedure for certain metals, EPA has not incorporated either optional policy, in general, in this proposed rulemaking, that is, EPA has not generally authorized State modifications of federal water quality standards. Each of these types of modifications will, in general, require federal rulemaking on a case-by-case basis to change the federal rule. Because of the time consuming nature of reviewing such requests, limited federal resources, and the need for the Agency to move into other priority program areas in establishing environmental controls, EPA alerts California and the public that a prompt Agency response it unlikely. The best course of action, if such provisions are desired, is for the State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions."

We interpret this language to mean that EPA is not authorizing a modification of the federal standards as part of this rulemaking (except through use of WERs). However, this language suggests that EPA also believes itself to be unable to state standards developed by Regional Boards in a timely manner. We must point out that the site-specific objectives setting process carried out by the Regional Boards in the State of California is not a "modification" of federal standards, but a complete, state standard setting process. Furthermore, the Regional Boards are required and authorized under the CWA and state law to

review and, as appropriate, consider modification of the promulgated standards as they apply to specific water bodies within each region as part of the triennial review process. In both cases, we feel very strongly that EPA is obligated to review state standards developed at the regional level in a timely manner. We also believe that EPA's intent to stay federal standards when the statewide objective setting process is complete should apply equally to state standards adopted by the Regional Boards.

Accordingly, we are asking that EPA specifically clarify its intent with respect to state standards developed by Regional Boards. In addition, we strongly recommend that EPA revise the proposed rulemaking to include a description of conditions under which EPA may initiate a stay of federal standards as part of this rulemaking, thereby alleviating the administrative burden of conducting federal rulemaking changes every time a new state standard is developed and approved.

Response to: CTR-016-002

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that waspart of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA notes that State-adopted criteria (including site-specific criteria) which are less stringent that CTR criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected.

EPA also disagrees with the suggestion that EPA include provisions in this CTR rule to allow EPA to use direct final rulemaking if it stays the CTR, or site-specific portions of the CTR, in the future. Since EPA cannot at this time predict what State criteria would replace CTR criteria when such stays are issued, EPA cannot predict whether such federal rulemakings might appropriately be adopted as direct final rules. Whether EPA meets the criteria for using direct final rulemaking in this context is a decision EPA will make when it undertakes such rulemaking.

Comment ID: CTR-017-001
Comment Author: Santa Ana River Discharger Ass
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: Thank you for the opportunity to provide comments on the recently promulgated California Toxics Rule. The members of the Santa Ana River Dischargers Association (SARDA) are especially appreciative of EPA's effort to review the site-specific water quality objectives (SSOs) proposed for our watershed.

The SSOs for cadmium, copper, lead and ammonia were developed jointly by state and federal regulators in 1992-93. During this period, the Regional Water Quality Control Board - Santa Ana Region held several public hearings to review the merits of the proposed SSOs. As part of the formal procedures to amend the Santa Ana River Basin Plan, the Regional Board received several documents providing scientific evidence that the SSOs would fully protect all designated beneficial uses including aquatic life.

EPA has received several copies of the final report for the Santa Ana River Use-Attainability Analysis. As direct participants in the design and methodology of the study, EPA received draft and final versions of all work papers and reports. In addition, another complete copy of the documents were submitted to the agency as part of the administrative record supporting the State Board decision to approve basin plan amendments adopting the SSOs.

Because the previous copies were submitted nearly four years ago, we believe it would be helpful to submit a new copy for the record. It is our sincere hope that these documents will facilitate EPA's review of the proposed SSOs.

Enclosed are the respective volumes which comprise the UAA Final Report. There are many other pages of written materials supporting the adoption of site-specific water quality objectives previously submitted to EPA and included in the State of California's formal administrative record on the basin plan amendments. If EPA desires additional copies of any of the other documents, SARDA would be pleased to re-submit them as well.

The SSOs proposed for the Santa Ana River are nearly identical to the water quality objectives EPA set forth in the California Toxics Rule. We in SARDA were pleased that EPA's scientists concur in the conclusion that water quality objectives based on dissolved metal concentrationswould fully protect the Santa Ana River. If anything, it appears that the SSOs proposed within the UAA Final Report were conservative. Since then, EPA has sponsored new scientific research which corroborates the original UAA recommendations.

Because the California Toxics Rule uses the same approach as the UAA in setting water quality objectives for cadmium and copper, SARDA strongly supports the CTR objectives for those metals. We also agree with EPA's written statements acknowledging the binding character of organic carbon and the role it plays in rendering heavy metals non-toxic. We enthusiastically endorse the agency's decision to

include Water Effects Ratio as a formal factor to be considered when formulating water quality objectives. It will do much to adjust national criteria to local conditions.

Unlike copper and cadmium, the SSO for lead was based on EPA's "Most-Sensitive Species Methods." As such, SARDA believes that it is more appropriate to adopt the UAA-SSO rather than the CTR formula when setting water quality objectives for lead in the Santa Ana River. Therefore, we urge the agency to join the State Water Resources Control Board in approving the SSO for lead.

Since the UAA was completed, and the basin plan amended, the SARDA agencies have diligently implemented the final recommendations. When chlorine and ammonia were found to be contributing to toxicity in the river, dischargers constructed new facilities to significantly reduce the concentration of these pollutants. Today, SARDA members routinely pass their whole effluent toxicity tests. Annual instream bioassessments, conducted voluntarily by SARDA, consistently demonstrate that our effluent quality fully supports the designated beneficial use.

SARDA is also pleased to report that the concentrations of heavy metals remain well below permitted levels and are often significantly less than historical averages. The fear that SSOs would license widespread increases in pollution never came to pass.

We believe the Santa Ana River UAA was successful in developing more appropriate site-specific objectives as a result of EPA's direct participation in designing, conducting and reviewing the scientific inquiry. The other SARDA agencies join me in thanking EPA's staff for the considerable time and expertise they contributed to this extraordinary effort.

If EPA requires any additional materials, or wishes to discuss the documentation submitted in support of the proposed SSOs, please call me at (909) 797-5119. All of the SARDA agencies are prepared to assist in any way we can. Thank you again for the opportunity to comment on the California Toxics Rule.

Sincerely,

Chairman Santa Ana River Dischargers Association

Response to: CTR-017-001

EPA is pleased to hear the story of success in reducing the toxicity in the Santa Ana River. EPA also appreciates the strong support for the CTR criteria for cadmium and copper, which, as the commenter points out, are nearly identical to the SSOs adopted by the State for the Santa Ana River.

Concerning the site-specific criterion for lead in the Santa Ana River that has been adopted by the State, EPA appreciates the commenter's support of the site-specific criterion over the CTR criterion for protection of fresh water aquatic life. However, EPA has not yet approved this site-specific criterion, and in the absence of EPA-approved State-adopted site-specific criteria, EPA must promulgate CTR criteria to meet the requirements of CWA section 303(c)(2)(B). Nevertheless, where site-specific criteria have already been adopted by the State in accordance with State law, but not yet acted upon by EPA, and those criteria are more stringent than applicable CTR criteria, those are the controlling criteria for CWA purposes within the State even without a stay of the applicable CTR criteria and are thus implementable by the State. (This would not be affected by the "Alaska Rule" which EPA proposed July 9, 1999, 64 Fed.Reg. 37072. See p. 37076.) This is the case with the site-specific criterion for lead adopted by the State for the Santa Ana River. Since the State must use the most stringent criteria in effect for its water quality programs, the State may use this site-specific lead criterion notwithstanding the CTR fresh water

aquatic life criterion for lead, thus the commenter's concerns should have no practical effect.

Comment ID: CTR-020-003
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: B. Site-Specific Modifications

EPA has indicated that it will not allow the state to approve site-specific modifications of the federal criteria regardless of the merit of the situation. The only notable exception is EPA's indication that amendment of these criteria may only be accomplished by a petition for rulemaking which amends the CTR. EPA's self-imposed limitation on CTR modification exacerbates the overly broad nature of the rule and arbitrarily inflicts wasteful expenditures of local resources on meeting objectives that have no actual environmental or public health need. The Agency is authorizing limited waivers to criteria compliance where it can be demonstrated that factors listed in 40 C.F.R. section 131.10(g) apply (e.g., natural conditions prevent attainment of uses). However, these waivers are very limited in scope, are rarely approved, and are not expected to provide relief to the typical circumstances that justify less restrictive criteria (e.g., exposure and organism sensitive assumptions are not relevant, warranting criteria recalculation).

The failure of EPA to build appropriate flexibility into the CTR is contrary to Presidential directives contained in the "Reinventing Environmental Regulation" issued in March 1995. By arbitrarily restricting the ability to modify criteria site-specifically (as outlined in detail in EPA's Water Quality Standards Handbook), EPA will maximize the economic impacts of this rulemaking rather than minimize the costs as required by applicable Executive Office directives and underlying regulatory provisions.

There is no legal or technical basis for restricting the modification of the Section 304(a) criteria. EPA has often referred to the ability to modify federal criteria as the means for ensuring that the criteria are appropriately applied. Similar to the "upset defense" that EPA was directed to include in nationwide effluent guidance to ensure that those requirements were not applied to inappropriate operational conditions, the Agency must grant the State of California the ability to modify the criteria for cause so that the criteria are not applied inappropriately. If this authority is not included in the rule, application of the CTR will clearly be overly broad and will exceed EPA's authority to establish appropriate water quality criteria.

Response to: CTR-020-003

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the

CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA further disagrees with any suggestion that the State itself could, in the future, modify CTR criteria. State adoption of site-specific criteria (including site-specific criteria adopted by the Regional Board which have completed the State adoption process) is a separate State action, under State law, which does not modify federal criteria. It would be up to EPA to modify the CTR to "make way" for the State's criteria, once those criteria have been approved by EPA. As discussed above, if the State were to adopt criteria that were more stringent than applicable CTR criteria, those criteria could be effective for CWA purposes within the State under State law, prior to EPA approval of such criteria or modification of the CTR.

With respect to EPA's compliance with applicable Executive Office directives see the preamble to the final rule.

Comment ID: CTR-021-007
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

4. Need for Expedited Approval of Site-Specific objectives. Sunnyvale is dismayed by the seemingly intransigent position taken by EPA in the preamble to the CTR to the effect that EPA is unlikely to act expeditiously to stay the application of CTR-based criteria with regard to water bodies in California which are covered by future site-specific objectives adopted by California water pollution control agencies and approved by EPA once the CTR becomes a final rule. The Agency's position is inconsistent with its otherwise reasonable and laudable support for local water quality planning efforts. It seems to Sunnyvale that EPA should reward a local planning effort which has complied with all EPA guidance and has produced site-specific water quality objectives which are more appropriate to the affected water body than the state and nationwide criteria in the CTR. What is the reason for EPA's attitude?

EPA has in the past threatened to delay approving state adopted site-specific objectives once a federal promulgation is in place. These threats are generally made when EPA is attempting to urge a state or states to develop state criteria in order to avoid a federal promulgation. However, the principal policy reason to take this position disappears as soon as the statutorily-required criteria have been put in place by EPA. Thereafter, EPA should show support for California's efforts to make appropriate adjustments in EPA's CTR criteria, especially where the adverse impacts of the CTR are being mitigated by the regulatory relief afforded by the State's efforts.

If EPA is concerned about the resources required to go through notice-and-comment rulemaking before it can stay the effect of the CTR, then Sunnyvale urges EPA to seek means to simplify and streamline the EPA rulemaking process. We urge the Agency to apply the lessons learned in the Agency's implementation of the air program in this situation. A proposal by EPA in the final CTR to go directly to final rulemaking to stay the effect of particular CTR criteria would be justified where, in the future, the State and the Agency have complied with the exhaustive EPA guidance on development of scientifically-justifiable site specific water quality objectives. A simple notice of final rulemaking should be amply sufficient to comply with the requirements of the Administrative Procedures Act. We urge the Agency to use the creative resources of the office of General Counsel to explore the merits of this suggestion.

Unless EPA is able to act expeditiously to approve newly-developed site specific criteria, the Agency could be the bottleneck in implementing some highly desirable place-based watershed management planning. Please reconsider your position in this matter in the final rulemaking on the CTR.

Response to: CTR-021-007

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent

than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA also disagrees with the suggestion that EPA include provisions in this CTR rule to allow EPA to use directfinal rulemaking if it stays the CTR, or site-specific portions of the CTR, in the future. Since EPA cannot at this time predict what State criteria would replace CTR criteria when such stays are issued, EPA cannot predict whether such federal rulemakings might appropriately be adopted as direct final rules. Whether EPA meets the criteria for using direct final rulemaking in this context is a decision EPA will make when it undertakes such rulemaking.

Comment ID: CTR-026-006
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: 6. SITE SPECIFIC CRITERIA

The DFG does not object to the development of site-specific criteria provided that they are developed utilizing sound scientific methodologies. The proposed rule indicates that EPA will be reviewing several of the existing site-specific criteria already established in various Basin Plans throughout the State to determine consistency with the proposed rule. The DFG is very interested in participating in the development of site-specific criteria and request that we be included in reviewing any new site-specific proposals or revisiting existing criteria, if that is deemed necessary.

Response to: CTR-026-006

EPA has reviewed and approved some site-specific criteria already established in various Basin Plans throughout the State. The relationship between the CTR and site-specific criteria for the Sacramento River; the San Joaquin River; and the Grassland Water District, San Luis National Wildlife Refuge, and Los Banos State Wildlife Refuge are described in the preamble to the proposed CTR. (62 Fed.Reg. 42165-42166.) For the San Francisco Bay Region, see the response to CTR-016-001. EPA has not acted on any State-adopted site- specific criteria since the proposed CTR was published.

The comment author suggests that the California DFG participate in the development of any new and revised site-specific criteria. We agree with that comment and assume that California's normal process will provide for that participation.

Comment ID: CTR-032-002e
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01; C-22; G-09; C-24a; K; G-04; G-05; G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002e

EPA appreciates this comment which provides general support for the CTR process and for EPA's ongoing efforts to support State water quality standards development.

Comment ID: CTR-032-006b
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-01a

Comment: Mercury Criteria

The District supports the proposed revised human health criteria for mercury based on updated IRIS information. The District also supports EPA's decision (CTR P. 42180) not to apply the bioaccumulation factor (BAF) developed for the Great Lakes Initiative to the CTR mercury criteria. We agree that mercury methylation rates vary widely and are not well understood, particularly for amalgam related mercury. We believe that adoption of a national BAF under consideration as part of the "Mercury Study Report to Congress: SAB Review Draft" is inappropriate for California, particularly for the complex San Francisco Bay system. CDA recommends that EPA direct the State to develop a site specific objective

(SSO) for mercury for San Francisco Bay based on a site specific BAF and data on natural cleanup processes and methylation processes. The proposed CTR criteria should serve as interim criteria until the SSO is developed and adopted.

Response to: CTR-032-006b

EPA appreciates the support by this commenter of the human health criteria for mercury contained in the CTR. To the extent that this commenter goes further and comments on the criteria that might result in the future from EPA's Report to Congress on Mercury (December, 1997), EPA disagrees. EPA does not find it appropriate at this time to direct the State to develop site-specific criteria for mercury for San Francisco Bay (or any other specific waterbody), especially if the purpose is to forestall the application of national criteria that are not yet even defined. That decision is wholly within State authority, however; should they choose to develop site-specific criteria, these criteria would be subject to EPA review and approval based on their individual scientific validity.

Comment ID: CTR-035-014
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: B. Criteria

pp. 42165-42166 -- Site-Specific Criteria We support the process described in the Preamble, whereby the State through its Regional Water Quality Control Boards (RWQCBs) may adopt site-specific criteria as amendments to Basin Plans, which are then subject to approval by the State Water Resources Control Board (SWRCB)and the State's Office of Administrative Law. We strongly urge EPA to make timely determinations for all site-specific criteria currently under review to ensure that appropriate action is taken by EPA before the CTR becomes a final regulation, as well as to conduct timely reviews for those site-specific criteria that may be submitted for approval in the future. We suggest that it is possible to simplify the regulatory process for staying the effect of the final CTR as regards any pollutant for which a site-specific objective has been developed by the State and approved by EPA. If EPA were to state in the final rule that it proposes to approve without further notice and comment any site-specific objective which has gone through the State and EPA approval process, we see no need for additional notice and comment before EPA publishes notice of final rulemaking to modify the CTR. This process is similar to the so-called "parallel processing" procedure used by EPA's air program with respect to the approval of amendments to State Implementation Plans.

We do, however, object to the statement in the Preamble regarding the adoption of site-specificcriteria after the CTR becomes final:

However, if EPA promulgates statewide federal criteria as proposed in this rule, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water

quality program. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both.

Based on EPA's own guidance, we do not believe that it is necessary for EPA to select the more stringent of the two criteria, if the site-specific criteria is less stringent but has been developed in a scientifically defensible manner (EPA, 1994b). In addition, this policy directly contradicts the assumption made in the draft Economic Analysis that an "alternative regulatory approach" would be pursued, including the use of site-specific criteria. A discharger would not pursue the development of site-specific criteria as a regulatory relief option, as was assumed in the Economic Analysis for the CTR, if EPA's policy is to approve only more stringent site-specific criteria. EPA's policy would expressly prohibit site-specific objectives from providing any relief from compliance costs. We therefore recommend that EPA include a policy in the CTR indicating that the Agency will approve site-specific criteria submitted by the State that are scientifically defensible, even if they are less stringent than CTR criteria, particularly if they are necessary to avoid excessive compliance costs.

Response to: CTR-035-014

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA further disagrees with any suggestion that the State itself could, in the future, modify CTR criteria. State adoption of site-specific criteria (including site-specific criteria adopted by the Regional Board which have completed the State adoption process) is a separate State action, under State law, which does not modify federal criteria. It would be up to EPA to modify the CTR to "make way" for the State's criteria, once those criteria have been approved by EPA. As discussed above, if the State were to adopt criteria that were more stringent than applicable CTR criteria, those criteria could be effective for CWA purposes within the State under State law, prior to EPA approval of such criteria or modification of the CTR.

EPA notes that State-adopted criteria (including site-specific criteria) which are less stringent that CTR

criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected.

EPA also disagrees with the suggestion that EPA include provisions in this CTR rule to allow EPA to use direct final rulemaking if it stays the CTR, or site-specific portions of the CTR, in the future. Since EPA cannot at this time predict what State criteria would replace CTR criteria when such stays are issued, EPA cannot predict whether such federal rulemakings might appropriately be adopted as direct final rules. Whether EPA meets the criteria for using direct final rulemaking in this context is a decision EPA will make when it undertakes such rulemaking.

This commenter also urged EPA to act, prior to finalizing the CTR, to approve or disapprove any State-adopted site-specific criteria which had been submitted to EPA but EPA had not yet acted upon. This has not been possible, due to the focus of resources on the CTR itself. However, EPA reiterates that any criterion adopted by the State, and currently in effect under State law, which is more stringent than the comparable CTR criterion, could be used for water quality programs within the State without any stay of the CTR.

Comment ID: CTR-037-001a
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES G-01

Comment: 1. The rule proposes that the more stringent of site-specific and national criteria be used in determining reasonable potential to exceed water quality standards and in development of limits where site-specific criteria have not yet been established. This proposal ignores the scientific basis of a site-specific criterion and that such a criterion is specifically more relevant and appropriate than a national criterion if derived correctly. EPA has acknowledged that national criteria can be more stringent than necessary to protect designated uses because they are designed to protect a wide variety of surface waters, and that a site-specific criterion can be sufficiently protective while being less stringent than a national criterion (Water Effect Ratio Guidance, 1994). This rule is arbitrarily dismissing the use of site-specific criteria which may be more technically defensible than national criteria, while being protective.

Response to: CTR-037-001a

EPA disagrees with this comment. EPA notes that State-adopted criteria (including site-specific criteria) which are less stringent that CTR criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected. The CTR does not preclude state adoption of criteria, including criteria which may be less stringent than CTR criteria. State-adopted criteria(including site-specific criteria) which are less stringent that CTR criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected.

To the extent that this commenter is concerned that the CTR criteria supercede existing State-adopted site-specific criteria which are less stringent than CTR criteria and have not been approved by EPA, EPA agrees that this is the effect of adoption of the CTR, but disagrees that this provides a basis for "promulgating around" such unapproved site-specific criteria. Because EPA has not completed it evaluation of these criteria and EPA needs to have criteria in place to implement section 303(c)(2)(B), EPA has chosen to put in place criteria based on EPA's national section 304(a) criteria recommendations to most efficiently ensure protection for all California waters. EPA will then complete its review of site-specific criteria. To do otherwise would risk that coverage did not occur for some waters should EPA not find the site-specific value to be scientifically defensible. However, as stated in the preamble to the proposed CTR, EPA will make a determination on all State-adopted site-specific criteria which have been submitted to EPA for review. When EPA approves any new or revised State criteria, EPA intends to stay the CTR. It was not possible for EPA to make determinations on pending site-specific criteria prior to the final CTR.

Comment ID: CTR-038-007
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: 6. Separate, site-specific human health criteria for carcinogens should be adopted for Schell Slough based on a 10 (-4) risk level and for Second Napa Slough based on a 10 (-5) risk level. Based on effluent sampling performed by the District, the District would be unable to comply with criteria for numerous carcinogens based on a 10 (-6) risk level (alpha-BHC, gamma-BHC, bromodichloromethane, indeno(1,2,3-cd)pyrene, chlordane, and 4,4'-DDT) without costly end-of-pipe controls. These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the District's discharge would not cause an in-stream exceedance of these criteria in Schell Slough, and at a 10 (-5) risk level, the discharge would not cause an in-stream exceedance in Second Napa Slough. The District does not believe these sloughs are heavily fished and therefore criteria based on 10 (-4) and 10 (-5) risk levels would likely provide greater protection than indicated by the risk levels. The District notes that none of these constituents were identified in EPA's economic analysis as significant contributors to baseline cancer risks for recreational anglers consuming San Francisco Bay fish (see Exhibit 8-7 in EPA's economic analysis).

Response to: CTR-038-007

EPA disagrees that it must or should establish separate, site-specific criteria in this rule for receiving waters where dischargers may be unable to meet the CTR criteria. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses. The CTR itself does not adopt uses or

modify any uses previously adopted by the State. EPA presumes that the State has designated appropriate uses for its waters. Proposals to revise State-adopted uses must be brought to the State pursuant to its procedures for review of its water quality standards.

That being said, it should nevertheless be understood that EPA does support State adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR where EPA has approved such State criteria.

With respect to risk level applicable to human health criteria when, as here, EPA establishes a water quality standard, EPA intends in its discretion to use a risk level of 1 x 10-6, although the State may in its discretion choose another risk level for protection of human health, if the State has appropriately consulted the public. As discussed in responses to CTR-011-0001a and CTR-058-001 (Category C-13; Risk Level), EPA follows the risk-level policies of the affected state, when promulgating criteria as regulations.

The comment that the carcinogens that are asserted to be compliance problems are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming San Francisco Bay fish may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not necessarily mean that the risk from these pollutants do not exist anywhere in the Bay or should not be prevented.

Comment ID: CTR-038-008a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES E-01c; R; S; T

Comment: 7. Separate, sites-specific aquatic life criteria for copper and human health criteria for mercury should be adopted for Schell Slough, or alternatively EPA should specify implementation procedures for these criteria that will preclude unreasonable controls such as end-of-pipe treatment. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the assessment of costs and benefits described in "3" above, EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation procedures that would allow the current discharge to continue (e.g., allowable Mixing zones and averaging periods and, for copper, a translator and water-effect ratio). Again, the District is amenable to continuing to address these constituents through pollution prevention measures and to assessing the actual impacts of these constituents in Schell Slough. Without EPA specifying such implementation procedures in the CTR, it is possible that the CTR could impose significant costs on the District (and the other small communities its serves) without providing a commensurate environmental benefit. In that

case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-038-008a

EPA disagrees with this commenter's suggestion that separate, site-specific criteria for copper and mercury be adopted for Schell Slough, based on considerations of costs and benefits. EPA has conducted an analysis of costs and benefits for this rule pursuant to Executive Order 12866; however, the criteria themselves are not based on economic considerations. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientificvalidity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA does support the State's adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR when EPA has approved such State criteria.

This commenter further suggests that EPA specify implementation procedures for certain criteria as an alternative to the proposed site-specific criteria. The CTR was not intended to include implementation provisions. The CTR is promulgated to add numeric criteria for priority toxic pollutants where they did not exist. To the extent that this commenter is proposing implementation provisions that are not inconsistent with CWA requirements, such provisions may be considered by the State for inclusion in its implementation plan (Draft Policy for Implementation of Toxics Standards for Inland Surface Waters and Enclosed Bays and Estuaries of California, September 11, 1997).

Finally, regarding the commenter's assertion that the CTR could be inconsistent with Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act without further revision (such as suggested by the commenter), see the discussion of EPA's compliance with these requirements in the preamble to the final rule.

Comment ID: CTR-039-001
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: As EPA notes in the preamble to the rule, "adoption of water quality standards is primarily theresponsibility of the states." 62 Fed. Reg. at 42166. In exercising that responsibility, the States have considerable discretion in applying the scientific and technical data available to them. A pervasive concern with the proposed rule is a lack of consistency by EPA in according appropriate deference to the

State of California's prior decisions, already approved by EPA. Where convenient, the proposed rule relies on the State's previous efforts, including for example the State's preference that health risks be based upon a 10-6 risk level and the novel notion of interim permit limits. However, as regards the rule's most important feature and indeed the only raison d'etre for the rule - the numeric criteria - EPA almost completely abandons the State's prior technical determinations on the numeric criteria appropriate for California where the State' s prior decision was more protective of the environment and human health then the currently proposed criteria. This is true for EPA's decision to go from total recoverable metals criteria to dissolved metals criteria, a proposal that is inconsistent with the State's prior approved decision and which will result in significant increases in total pollutants allowed to be discharged into San Francisco Bay and elsewhere in the State. The State's prior decisions also were abandoned for dioxin and mercury, including failing to consider all of the dioxin congeners, failing to consider the bioaccumulation of mercury (a well-documented characteristic of that potent toxic pollutant) and failing to consider the higher rates of fish consumption found in California and in discrete populations of subsistence and recreational anglers.

Response to: CTR-039-001

EPA disagrees with the suggestion that EPA should have deferred to the State's prior WQS decisions, previously approved by EPA. To the extent that the commenter is referring to criteria in the Inland Surface Waters Plan (ISWP) and the Enclosed Bays and Estuaries Plan (EBEP), EPA responds that those were considered along with all of the other scientific information that makes up the record for this rule. However, those statewide plans are no longer in effect, and EPA is not bound by them. EPA adopts criteria based on sound scientific rationale, which protect the designated uses of waters of the United States in California. Additional scientific information has become available for some pollutants since California adopted the ISWP and EBEP in 1991, which forms the basis for adopting CTR criteria which differ from some of the criteria previously adopted for the same waterbodies.

EPA further disagrees with passing statements in this comment criticizing EPA's use of dissolved rather than total recoverable metals, failure to consider all dioxin congeners, failure to consider bioaccumulation of mercury and failure to consider higher rates of fish consumption in California. For a detailed discussion of the points made regarding dioxin, see response to CTR-002-003 and CTR-002-006. Regarding EPA's use of dissolved rather than total recoverable metals see response to CTR-026-004. Regarding bioaccumulative properties of mercury, see CTR-002-007b. Regarding rates of fish consumption, see response to CTR-002-002a and the preamble of the final rule.

To the extent that this comment is referring to site-specific criteria for San Francisco Bay, EPA is revising the final CTR to ensure that EPA-approved State-adopted site-specific criteria shall remain in effect and not be superceded by CTR criteria for the same pollutants for those waters of the Bay where such site-specific criteria are currently in effect. See response to CTR-016-001.

Comment ID: CTR-039-009
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:

Attachments? N
CROSS REFERENCES

Comment: VII. EPA CAN ADJUST ITS PROPOSED RULE TO REFLECT REGIONAL CONDITIONS AND PROTECT USES IN SPECIFIC REGIONS

As EPA notes in the preamble, when it considered the State's 1991 criteria, it approved the proposed criteria for selenium for everywhere in the State except San Francisco Bay and the Delta. 62 Fed. Reg. at 42164. There is no reason that EPA cannot adjust its proposed to rule to reflect the available scientific data that may only be available in certain regions of the State, including for example, data relating to mercury bioaccumulation in San Francisco Bay fish. The concept of treating dischargers from different areas fairly should not be applied so as to punish those regional ecosystems where agencies have been more proactive in collecting necessary data. Rather, dischargers should be treated equally stringently where data from one region indicates that uses are threatened by a particular pollutant throughout the State.

CONCLUSION

In conclusion, BayKeeper is very concerned with the proposed rule. The State obviously must have numeric criteria for toxic pollutants. Great strides have been made, especially in the San Francisco Bay area, to reduce the mass of toxic pollutants entering the Bay. The proposed criteria likely will bring to a halt the most innovative programs to reduce toxic pollution. Instead of promoting innovation and driving dischargers' ability to achieve, some day, the penultimate goal of the Clean Water Act to eliminate all discharges of pollution to the Nation's waters, the proposed rule will only perpetuate mediocre toxic pollution control efforts and fail to reverse the ecological damage from toxic contamination, including dangerous levels of contaminants in fish already observed in Bay fish and the continuing decline of aquatic ecosystems around the State.

BayKeeper appreciates this opportunity to express our views on the proposed rule. If you have any questions, please feel free to call me at 1-800--KEEP-BAY.

Response to: CTR-039-009

EPA disagrees with this comment. In 1991, when EPA took action on the first phase of the Enclosed Bays and Estuaries Plan (EBEP), EPA did not disapprove the salt water aquatic life criterion for selenium. Instead, EPA made it clear that use of that criterion in permits issued for the San Francisco Bay and Delta would be unacceptable. This was consistent with the EBEP provision which stated that more stringent objectives and control measures could be applied by the Regional Boards in some estuarine waters. (Letter of November 6, 1991, to W. Don Maughan, Chairman, State Water Resources Control Board, from Daniel W. McGovern Regional Administrator, EPA RegionIX.) In December 1992, EPA adopted freshwater aquatic life criterion for the San Francisco Bay Estuary as part of the National Toxics Rule (NTR) because the San Francisco Bay Regional board had not itself specified that it would apply the freshwater criterion, consistent with EPA's November 6, 1991 letter. (57 Fed. Reg. 60898.) This was not the promulgation of a site-specific criterion for the San Francisco Bay and Delta, however. Although the freshwater criterion was the same as the freshwater selenium criterion in the Inland Surface Water Plan (ISWP), it was also EPA's national fresh water selenium criterion. As explained in the Preamble to the final NTR (Id.), EPA simply was unable adopt site-specific criteria as part of the NTR. The same is true of the CTR.

As noted in footnotes to the CTR selenium criterion, the CTR does not supercede that provision of the NTR (40 CFR 131.36(d)(10)).

Regarding general concerns included in this comment regarding the effect of the CTR on criteria developed for San Francisco Bay, see responses to CTR-016-001 and CTR-002-003.

Comment ID: CTR-040-050
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does not mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Site Specific Criteria

Another one of the avenues of potential regulatory relief discussed in the Preamble to the CTR is the adoption of site-specific water quality criteria. The Preamble, provides that the "State has the discretion to develop site-specific criteria when appropriate e.g., when statewide criteria appear over- or under-protective of designated uses. The Preamble goes on to explain the site-specific criteria adoption process as follows:

Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete, the criteria become State law. These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted

under the State's process and has become State law. CTR Preamble at pg. 42165.

The Preamble explains that the State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of these Basin Plans, some of which contain site-specific criteria, have completed the State review and adoption process and have been submitted to EPA for review and approval. The key to whether or not these site-specific criteria will provide regulatory relief is when the EPA approval/disapproval occurs. Three different timing scenarios and results are possible:

1. If EPA approves any State-adopted site-specific criteria before promulgation of the final CTR is published, then the EPA Administrator may make a finding in that final rule that it will be unnecessary to promulgate criteria for the approved site-specific pollutants and associated water bodies.

2. EPA disapproves any State-adopted site-specific criteria, the proposed statewide criteria contained in the CTR would apply for those pollutants and associated water bodies instead of the site-specific criteria.

3. However, if EPA promulgates statewide federal criteria as proposed in the CTR, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both. CTR Preamble at pg. 42165.

Thus, the only way less stringent site specific criteria can be used for regulatory relief is if those criteria are approved by EPA prior to the publication of the final CTR. otherwise, either the CTR or the more stringent of the two (CTR vs. site-specific) criteria apply.

One final note regarding site-specific criteria is that the Preamble to the CTR restricts the ability to use native aquatic life as a way to set site-specific criteria. Instead of allowing a discharger to substitute local species from the receiving waters into which it discharges, the Preamble only allows a discharger to supplement the eight specified families of aquatic life required for criteria development with the addition of native species.(*9) It is doubtful whether this requirement will aid dischargers who are seeking regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*9) "A minimum data set of eight specified facilities is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria unsing native species, provided that the broad spectrum represented be the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available." CTR Preamble at pg. 42168.

Response to: CTR-040-050

EPA disagrees with this comment. See response to CTR-004-008.

Comment ID: CTR-041-046
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

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Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete. the criteria become State law. These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted under the State's process and has become State law. CTR Preamble at pg. 42165.

The Preamble explains that the State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of these Basin Plans, some of which contain site-specific criteria, have completed the State review and adoption process and have been submitted to EPA for review and approval. The key to whether or not these site-specific criteria will provide regulatory relief is when the EPA approval/disapproval occurs. Three different timing scenarios and results are possible:

1. If EPA approves any State-adopted site-specific criteria before promulgation of the final CTR is published, then the EPA Administrator may make a finding in that final rule that it will be unnecessary to promulgate criteria for the approved site-specific pollutants and associated water bodies. 2. EPA disapproves any State-adopted site-specific criteria, the proposed statewide criteria contained in the CTR would apply for those pollutants and associated water bodies instead of the site-specific criteria. 3. However, if EPA promulgates statewide federal criteria as proposed in the CTR, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both. CTR Preamble at pg. 42165.

Thus, the only way less stringent site specific criteria can be used for regulatory relief is if those criteria are approved by EPA prior to the publication of the final CTR. Otherwise, either the CTR or the more stringent of the two (CTR vs. site-specific) criteria apply.

One final note regarding site-specific criteria is that the Preamble to the CTR restricts the ability to use native aquatic life as a way to set site-specific criteria. Instead of allowing a discharger to substitute local species from the receiving waters into which it discharges, the Preamble only allows a discharger to supplement the eight specified families of aquatic life required for criteria development with the addition of native species.(*9) It is doubtful whether this requirement will aid dischargers who are seeking regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*9) "A minimum data set of eight specified facilities is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented be the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available." CTR Preamble at pg. 42168.

Response to: CTR-041-046

EPA disagrees with this comment. See response to CTR-004-008.

Comment ID: CTR-043-006a
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:

Attachments? Y
CROSS REFERENCES C-13

Comment: 6. EPA should adopt separate, site-specific human health criteria for Old Alamo Creek based on a 10 (-4) risk level. As previously indicated the City would have to construct costly end-of-pipe controls to comply with the human health criteria for several carcinogens. The subject criteria are based on a cancer risk level of 10 (-6). These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria. The City does not believe Old Alamo Creek is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that none of these carcinogens were identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-043-006a

EPA disagrees with this commenter's suggestion that separate, site-specific human health criteria be adopted for Old Alamo Creek, based on considerations of costs and benefits. EPA has conducted an analysis of costs and benefits for this rule pursuant to Executive Order 12866 (see discussion in preamble to final rule); however, the criteria themselves are not based on economic considerations. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA does support the State's adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR when EPA has approved such State criteria.

With respect to risk level applicable to human health criteria when, as here, EPA establishes a water quality standard, EPA intends in its discretion to use a risk level of 1 x 10-6, although the State may in its discretion choose another risk level for protection of human health, if the State has appropriately consulted the public. As discussed in responses to CTR-011-001a and CTR-058-001 (Category C-13; Risk Level), EPA follows the risk-level policies of the affected state, when promulgating criteria as regulations.

See also response to CTR-043-006b.

Comment ID: CTR-044-007b
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:

Attachments? Y
CROSS REFERENCES C-13

Comment: We have reviewed the proposed CTR and offer the following comments:

6. EPA should adopt separate, site-specific human health criteria for Tule Canal based on a 10 (-4) risk level. Based on effluent sampling, the City would have to construct costly end-of-pipe controls to comply with criteria for aldrin (and perhaps other carcinogens) based on a 10 (-6) risk level. These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria in Tule Canal. The City does not believe Tule Canal is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that aldrin was not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-044-007b

EPA disagrees with this commenter's suggestion that separate, site-specific human health criteria be adopted for Tule Canal, based on considerations of costs and benefits. EPA has conducted an analysis of costs and benefits for this rule pursuant to Executive Order 12866 (see discussion in preamble to final rule); however, the criteria themselves are not based on economic considerations. In accordance with 40 CFR 131.11, criteria must be basedon sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA does support the State's adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and to stay the CTR when EPA has approved such State criteria.

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See also response to CTR-044-007a.

Comment ID: CTR-044-041
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself doesnot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Site Specific Criteria

Another one of the avenues of potential regulatory relief discussed in the Preamble to the CTR is the adoption of site-specific water quality criteria. The Preamble, provides that the "State has the discretion to develop site-specific criteria when appropriate e.g., when statewide criteria appear over- or under-protective of designated uses. The Preamble goes on to explain the site-specific criteria adoption process as follows:

Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete. the criteria become State law. These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted under the State's process and has become State law. CTR Preamble at pg. 42165.

The Preamble explains that the State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of these Basin Plans, some of which contain site-specific criteria, have completed the State review and adoption process and have been submitted to EPA for review and approval. The key to whether or not these site-specific criteria will provide regulatory relief is when the EPA approval/disapproval occurs. Three different timing scenarios and results are possible:

1. If EPA approves any State-adopted site-specific criteria before promulgation of the final CTR is published, then the EPA Administrator may make a finding in that final rule that it will be unnecessary to promulgate criteria for the approved site-specific pollutants and associated water bodies. 2. EPA disapproves any State-adopted site-specific criteria, the proposed statewide criteria contained in the CTR would apply for those pollutants and associated water bodies instead of the site-specific criteria. 3.

However, if EPA promulgates statewide federal criteria as proposed in the CTR, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both. CTR Preamble at pg. 42165.

Thus, the only way less stringent site specific criteria can be used for regulatory relief is if those criteria are approved by EPA prior to the publication of the final CTR. Otherwise, either the CTR or the more stringent of the two (CTR vs. site-specific) criteria apply.

One final note regarding site-specific criteria is that the Preamble to the CTR restricts the ability to use native aquatic life as a way to set site-specific criteria. Instead of allowing a discharger to substitute local species from the receiving waters into which it discharges, the Preamble only allows a discharger to supplement the eight specified families of aquatic life required for criteria development with the addition of native species.(*9) It is doubtful whether this requirement will aid dischargers who are seeking regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*9) "A minimum data set of eight specified facilities is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented be the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available." CTR Preamble at pg. 42168.

Response to: CTR-044-041

Comment ID: CTR-050-005a
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES G-07

Comment: II. EPA Should Allow Variances and Site-Specific modifications.

Beyond the issue of whether EPA has the authority to issue the proposed rule, there are other significant problems with the proposal. For example, the Agency has made the inexplicable decision not to include provisions that would allow for issuance of variances or site-specific modifications to the criteria. This is

despite the Agency's recognition that a variance procedure is an "important procedure to assist the State in effectively implementing water quality standards." (62 Fed. Reg. at 42185). EPA gives absolutely no explanation for its decision not to allow use of this procedure. Moreover, the Agency concedes that "promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger-specific or stream-specific basis. " Instead, an applicant would have to ask EPA to begin a "federal rulemaking on a case-by-case basis to change the federal rule." (62 Fed. Reg. at 42186) EPA makes it quite clear that applicants should not expect any relief from that avenue, because the Agency simply has more important things to do:

Because of the time consuming nature of reviewing such requests, limited federal resources, and the need for the Agency to move into other priority program areas in establishing environmental controls, EPA alerts California and the public that a prompt Agency response is unlikely.

Despite this cavalier dismissal of the need for actually acting on variance and site criteria applications, the Agency does not hesitate to mention those mechanisms in its economic analysis as being available to moderate the impact of the proposed rule. The Agency specifically mentions variances and site-specific criteria when it states that "these implementation procedures can have an effect on how water quality standards, based on today's proposed rule, will impact NPDES permit holders." (62 Fed. Reg. at 42192). In fact, that statement is clearly false, given EPA's decision not to include variance or site-specific criteria procedures in the proposed rule. The Agency should reconsider that decision and insert those provisions.

Response to: CTR-050-005a

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude the issuance of variances from CTR criteria or future state adoption of site-specific criteria.

Variances would modify applicable CTR criteria for individual dischargers. Site-specific criteria would modify CTR criteria for individual waterbodies. Since the State lacks authority to modify federally promulgated CTR criteria itself (See response to CTR-035-014), EPA must approve individual variances and site-specific criteria and stay the applicable CTR criteria to allow these State modification actions to take effect under the CWA. (As stated in the preamble to the proposed CTR, the State must also adopt a variance policy, and EPA must approve the policy, before the State may issue variances to individual dischargers.) EPA stated in the proposed CTR preamble that when the State has completed its own process for modifying criteria, and EPA approves the State's new or revised criteria, EPA does intend to stay the CTR.

Because there is uncertainty as to how the State will implement CTR criteria in individual permits, EPA's economic analysis of the CTR included a wide range of estimated costs and benefits. The analysis was not based on any certainty that variances and site-specific modifications of criteria would be available to every permittee; on the other hand, the analysis assumed that the State was likely to choose implementation provisions that provide some degree of flexibility or relief to point source dischargers. For a discussion of the approach taken in the economics analysis, see the preamble to the final rule.

Comment ID: CTR-051-001
Comment Author: Cal. RWQCB Central Valley Reg.
Document Type: State Government

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: We have reviewed the proposed California Toxics Rule. We have comments about several of the proposed provisions in the Toxics Rule. Many of our concerns are similar to those detailed in the September 25 letter from the Saii, Francisco Bay Regional Water Quality Control Board.

Site Specific Objectives

We are concerned that the language in the proposed Toxics Rule would hamper future Regional Board efforts to establish site specific objectives. EPA cautions California and the public that promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger-specific or stream-specific basis. Also, EPA states that they may be unable to review state developed standards in a timely manner. However, the Regional Boards are required and authorized under the Clean Water Act and state law to review and, as appropriate, consider modification of promulgated standards as they apply to specific water bodies within each region as part of the triennial review process. We suggest that the language in the proposed Toxics Rule be amended to encourage, rather than discourage, development of site specific objectives.

Response to: CTR-051-001

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

Comment ID: CTR-052-008
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: EPA should have considered the CTR specifically as it applies to San Francisco Bay. As noted previously, implementation of the CTR and full compliance by Bay Area POTWs will result in a reduction of between 1-10% of the toxic load on San Francisco Bay. Since 90-99% of the toxic load will still be present from such sources as non-point, riverine, agricultural drainage, acid mines, atmospheric deposition, etc., it is reasonable to conclude that full compliance by POTWs will result in no significant improvement to the Bay. In other words, the benefits will actually approach zero. Annual costs for Bay Area POTWs will range from $130,000,000 to $185,000,000 or more. Such an expenditure for essentially no benefit is clearly not in the best interests of the public or the environment. It is, therefore, reasonable to conclude that in its current form, the CTR should exempt San Francisco Bay, or at least exempt POTWs discharging to the Bay. EPA should acknowledge that Bay Area POTWs have had NPDES permits with effluent limitations for toxic pollutants for many years. Exempting POTWs from the CTR would not have any impact on current standards.

Response to: CTR-052-008

EPA disagrees with this comment. EPA did consider the CTR specifically as it applies to San Francisco Bay, and has modified the CTR accordingly. (See response to CTR-016-001.)

EPA acknowledges that a number of Bay Area POTWs have NPDES permits with effluent limitations for toxic pollutants; however, that information does not serve as justification for exempting the Bay, or certain dischargers to the Bay, from the CTR, where it applies. Water quality standards are developed to protect the designated uses of the waters of the United States, and the standards contained in the CTR are EPA's view of the standards necessary to protect designated uses.. The CTR applies to all sources of toxics discharged to water of the Bay (except where EPA-approved San Francisco Bay Basin Plan criteria apply), not merely to publicly owned treatment works (POTWs). These ambient WQS can also assist in the reduction of pollution from non-point sources, through the TMDL process.

For a discussion of EPA's economic analysis for the CTR in general, see the preamble to the final rule.

Comment ID: CTR-052-017
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria

References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Specify in the Preamble that EPA would support a scientifically defensible, reasonably achievable site specific objective (SSO) for copper for San Francisco Bay. The analysis by Larry Walker used data from the San Francisco Bay Regional Monitoring Plan and concludes that a translator of 1.6 should be used to result in a total recoverable concentration of 5.0 ug/L. Note that this value compares favorably with the existing SSO of 4.9 ug/L. Most of the copper attainability issues, including the Authority's, would be resolved by this approach.

Response to: CTR-052-017

EPA disagrees that EPA should specifically express support for a "scientifically defensible, reasonably achievable" (emphasis added) site-specific criterion for copper in San Francisco Bay, using a translator of 1.6. This comment confuses the adoption of appropriate copper criteria with the approval of a translator to implement such criteria. Translators are implementation mechanisms which are not included in the CTR, but may be adopted by the State.

Regarding the achievability of any criterion for any particular discharger, there is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA supports State adoption of site-specific criteria. As explained in the preamble to the proposed CTR, and further discussed in the response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and intends to stay the CTR where such State criteria are in effect. In the meantime, in the absence of such criteria for aquatic life for copper in waters of San Francisco Bay, with salinity greater than 5 ppt, EPA is promulgating criteria based on EPA's section 304(a) national marine water copper aquatic life criterion, which is consistent with the requirements of the CWA. (40 CFR Section 131.11(b).) See also responses to CTR-016-001 and CTR-016-002.

Comment ID: CTR-053-006
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES

Comment: Heal the Bay expects EPA to continue their participation and leadership in this process, and to be supportive of any State effort to adopt more stringent numeric criteria for specific pollutants. Thank you for your consideration of these comments.

Response to: CTR-053-006

EPA appreciates this comment which provides general support for the CTR process and for EPA's ongoing effortsto support State water quality standards development.

Comment ID: CTR-054-008b
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? Y
CROSS REFERENCES C-02b; E-01c; R; S

Comment: Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Francisco Bay, or alternatively EPA should specify in the Preamble implementation policies for copper that will result in reasonable control measures actions. To comply with the Clean Water Act and EPA regulations, EPA is required to consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act, EPA is required to evaluate regulatory alternatives based on an analysis of costs and benefits. Based on BADA's analysis of costs and benefits, EPA should either adopt copper criteria that are reasonably achievable or alternatively specify implementation policies that will avoid costly end-of-pipe controls. Potential implementation measures that could be specified include use of the following in calculating effluent limitations: actual dilution based on modeling studies; copper translators; probability of compliance less than 99.9%; and water-effect ratios determined for different segments of the Bay. Unless EPA specifies these or similar implementation policies in the rule, it is possible that the CTR could result in significant costs ($12 million per year to $78 million per year) while resulting in minor environmental benefit (a 1% reduction in copper loading to the Bay). In that case, the CTR would violate the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. (see the discussion under Item 11 below.)

Response to: CTR-054-008b

EPA disagrees with the commenter's request that EPA either adopt site-specific copper criteria for San Francisco Bay or, in the CTR preamble, specify the use of certain implementation policies for copper.

In support of its request for the adoption of "scientifically defensible, reasonably achievable aquatic life criteria for copper" (emphasis added), the commenter cites its own analysis of costs and benefits. EPA has conducted an analysis of costs and benefits for this rule pursuant to Executive Order 12866 (see discussion in preamble to final rule); however, the criteria themselves are not based on economic

considerations. In accordance with 40 CFR 131.11, criteria must be based on sound scientific rationale and must protect the designated use. There is no provision for EPA to consider the attainability or the scientific validity of the criteria with regard to specific dischargers or class of dischargers in adopting ambient water quality criteria in the CTR. Economic factors may be considered in designating uses (40 CFR 131.10); however, they may not be used to justify criteria which are not protective of those uses.

That being said, it should nevertheless be understood that EPA supports the adoption of site-specific criteria by the State. As explained in the preamble to the proposed CTR, and further discussed in the response to CTR-016-002, EPA will work with the State to approve acceptable State-adopted criteria (including site-specific criteria) and intends to stay the CTR when EPA has approved such State criteria. In the meantime, in the absence of such criteria for aquatic life for copper in waters of San Francisco Bay, with salinity greater than 5 ppt, EPA is promulgating criteria based on EPA's section 304(a) national marine water copper aquatic life criterion, which is consistent with the requirements of the CWA. (40 CFR Section 131.11(b).) See also responses to CTR-016-001 and CTR 016 -002.

Regarding the suggestion that EPA specify the use of dilution, metals translators and water effect ratios, or similar implementation provisions, EPA disagrees. With the exception of compliance schedules, the CTR does not include implementation provisions; the CTR is promulgated to add numeric criteria for toxic pollutants where they did not exist. The State may address these issues in a separate implementation plan, which it is currently developing. ("Policy for implementation of Toxics Standards for Inland surface Waters, Enclosed Bays and Estuaries of California", released for public comment, September 11, 1997.)

Finally, regarding the commenter's assertion that the CTR could be inconsistent with Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act without further revision (such as suggested by the commenter), see the discussion of EPA's compliance with these requirements in the preamble to the final rule.

See also response to CTR-054-008c.

Comment ID: CTR-054-045
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself doesnot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Site Specific Criteria

Another one of the avenues of potential regulatory relief discussed in the Preamble to the CTR is the adoption of site-specific water quality criteria. The Preamble, provides that the "State has the discretion to develop site-specific criteria when appropriate e.g., when statewide criteria appear over- or under-protective of designated uses. The Preamble goes on to explain the site-specific criteria adoption process as follows:

Periodically, the State through its RWQCBs will adopt site-specific criteria for priority toxic pollutants within respective Basin Plans. These criteria are intended to be effective throughout the Basin or throughout a designated water body. Under California law, these criteria must be publicly reviewed and approved by the RWQCB, the SWRCB, and the State's Office of Administrative Law (OAL). Once this adoption process is complete. the criteria become State law. These criteria must be submitted to the EPA Regional Administrator for review and approval under CWA section 303. These criteria are usually submitted to EPA as part of a RWQCB Basin Plan Amendment, after the Amendment has been adopted under the State's process and has become State law. CTR Preamble at pg. 42165.

The Preamble explains that the State of California has recently reviewed and updated all of its RWQCB Basin Plans. All of these Basin Plans, some of which contain site-specific criteria, have completed the State review and adoption process and have been submitted to EPA for review and approval. The key to whether or not these site-specific criteria will provide regulatory relief is when the EPA approval/disapproval occurs. Three different timing scenarios and results are possible:

1. If EPA approves any State-adopted site-specific criteria before promulgation of the final CTR is published, then the EPA Administrator may make a finding in that final rule that it will be unnecessary to promulgate criteria for the approved site-specific pollutants and associated water bodies. 2. EPA disapproves any State-adopted site-specific criteria, the proposed statewide criteria contained in the CTR would apply for those pollutants and associated water bodies instead of the site-specific criteria. 3. However, if EPA promulgates statewide federal criteria as proposed in the CTR, prior to a decision on any State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both. CTR Preamble at pg. 42165.

Thus, the only way less stringent site specific criteria can be used for regulatory relief is if those criteria are approved by EPA prior to the publication of the final CTR. Otherwise, either the CTR or the more stringent of the two (CTR vs. site-specific) criteria apply.

One final note regarding site-specific criteria is that the Preamble to the CTR restricts the ability to use native aquatic life as a way to set site-specific criteria. Instead of allowing a discharger to substitute local species from the receiving waters into which it discharges, the Preamble only allows a discharger to supplement the eight specified families of aquatic life required for criteria development with the addition

of native species.(*9) It is doubtful whether this requirement will aid dischargers who are seeking regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.
(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.
(*9) "A minimum data set of eight specified facilities is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented be the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available." CTR Preamble at pg. 42168.

Response to: CTR-054-045

Comment ID: CTR-056-015b
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES I-01

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Should clearly recognize within the CTR that the existing, approved Basin Plan for the San Francisco Bay includes requirements specifically designed to address wet weather overflows and grants provisions for exemptions where an inordinate burden would be placed on the discharger relative to the beneficial uses protected. It should also be acknowledged through inclusion in the CTR that the requirements and applicable exemptions previously justified and approved by EPA and the State should not be affected by the proposed rule.

Response to: CTR-056-015b

EPA disagrees that the CTR must specifically acknowledge implementation provisions in the San Francisco Bay Basin Plan which are designed to address wet weather overflows. EPA also disagrees with any suggestion that such provisions be included in the CTR itself. The CTR is promulgated to add numeric criteria for priority toxic pollutants where they did not exist. The CTR does not modify existing Basin Plan implementation provisions, which remain in effect if they were duly adopted under State law,

although the application of Basin Plan compliance schedule provisions may be affected by the compliance schedule provisions in the CTR. (EPA notes, however, that wet weather implementation provisions, which were adopted in the San Francisco Bay Regional Board 1995 Basin Plan amendments, have not been approved by EPA.) Although the State cannot use implementation provisions such as variances to modify federal standards, EPA intends to stay applicable CTR criteria if the State adopts its own criteria and EPA has approved them. (See response to CTR-016-002.) EPA is also working with the State and other stakeholders to address issues related to water quality-based permitting inmunicipal stormwater permits.

See also the response to CTR-016-001.

Comment ID: CTR-057-010c
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES K-01
G-07

Comment: Implementation

Although the proposed Rule discusses implementation issues such as TMDLs, variances, SSOs, and interim permits, it lacks evidence of support for any of these provisions. We believe that this will have the effect of reducing the State's confidence or perceived authority in granting any of these provisions to individual POTWs. For example, Page 42186 of the CTR lists six criteria that must be used by the State to determine the non-attainability of a water quality standard; we are doubtful that any of these criteria would be strictly applicable to our facilities with respect to lindane and DDT. We believe CTR variance criteria should include economic considerations for specific discharger implementation efforts. Unless the EPA provides more support for these provisions, we fear that the State will either not grant us a legitimate variance or will waiver in its commitment to act at all.

Response to: CTR-057-010c

EPA disagrees that the CTR should revise the variance criteria or provide more support for implementation provisions. The CTR is promulgated to add numeric criteria for toxic pollutants in waters of the U.S. in California where they did not exist. The CTR does not modify existing requirements of 40 CFR Part 131, which applies nationally. Those requirements limit the use of variances to six grounds (the six "criteria" referred to by the commenter), which are merely reiterated in the Preamble to the proposed CTR. (62 Fed.Reg. 42186.) The CTR also does not include its own variance provisions. However, the CTR does not modify existing State implementation provisions (including those in Basin Plans), which remain in effect if they were duly adopted under State law (although the application of Basin Plan compliance schedule provisions may be affected by the compliance schedule provisions in the CTR).

Given the scope of the CTR, the economic considerations proposed by the commenter are not relevant. Under the CWA, EPA cannot base numeric values for ambient water quality criteria on economic considerations, therefore EPA cannot "include economic considerations for specific discharger implementation efforts" in this rule. The State may address the implementation issues identified by the commenter, taking economic considerations into account as consistent with the CWA, in the separate implementation plan, which it is currently developing. EPA notes, however, that use of State implementation provisions such as SSOs and variances would require federal rulemaking to modify CTR criteria affected by such actions. See also the responses to CTR-016-002, and CTR-056-015b.

Comment ID: CTR-057-011
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: Similarly, the proposed Rule provides little support with respect to site-specific objectives. It is not clear, for instance, if a POTW could apply for an SSO once the Rule has been promulgated. The State's Site-Specific Objectives Task Force was adamant that SSOs should be an integral part of a priority-pollutant control plan, yet this philosophy is nowhere in evidence in the CTR, In view of this, we believe that the proposed Rule should specify EPA's intentions to review State-approved SSOs without setting deadlines for SSO submittals. This would allow SSOs to be triggered as needed by events not experienced or anticipated at the present time. We therefore recommend that the EPA add statements into the CTR that provide needed direction for the States in issuing decisions dealing with this any similar implementation options.

Response to: CTR-057-011

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any

EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

Comment ID: CTR-060-006
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Site specific water quality criteria

The preamble states that, "EPA ... cautions California and the public that promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger specific or stream-specific basis" and that, "EPA has not incorporated either ... [variance or site-specific criteria development procedures] in this proposed rulemaking, that EPA has not generally authorized State modifications of federal water quality standards" determining that "these types of modifications will, in general, require federal rulemaking on a case by case basis..." (see 62 Fed. Reg. at 42186, Cols. 2 and 3). Otherwise, the federal criteria must be used over a state approved site-specific criteria where it is the more stringent and promulgated before state approval. (see 62 Fed. Reg. at 42165, Col. 3).

However, EPA clarifies that the proposal criteria are not based on a "pollutant-specific, waterbody-by-water body" evaluations. (see 62 Fed. Reg. at 42166, Col. 3 and at 42617, Col. 1). Analysis was conducted, generally speaking, utilizing eight specific families to represent a wide spectrum of aquatic life and which are not necessarily present in water bodies subject to the proposed criteria. (see 62 Fed. Reg. at 42168, Col. 2). Indeed, EPA acknowledges that the proposed criteria rely upon "several individual factors which make the criteria somewhat overprotective or underprotective.' (see 62 Fed. Reg. at 42168, Col. 1).

The proposed rule should incorporate policy and procedures by which site-specific criteria approved by the state (after rule promulgation) may be approved by EPA, though the criteria may be less stringent than in the proposed rule. In addition, the proposed rule should not preclude California from adopting water quality criteria utilizing pollutant-specific, water-body specific or other scientifically sound factors which are less stringent than those in the proposed rule (e.g., beyond WERs) which will prevail when the proposed rule is stayed and ultimately extinguished. Otherwise discharges may be subject to unnecessarily stringent and overprotective effluent limits combined with the application of the

anti-backsliding rule.

Response to: CTR-060-006

EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPAapproves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completed the State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA notes that State-adopted criteria (including site-specific criteria) which are less stringent that CTR criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected.

Comment ID: CTR-086-004e
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01; C-22; G-09; C-24a; K-03; G-04; G-05; G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site

specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004e

EPA appreciates this commenter's support for EPA's ongoing efforts to support State water quality standards development.

Comment ID: CTR-090-018
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24 Site Specific Criteria
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Site-specific criteria - p 42165. State-Adopted Site-Specific Criteria with EPA Approval - This section requests information on previously adopted site-specific criteria. The Basin Plan for the San Francisco Bay Area includes such criteria in narrative form in Chapter 4 (page 4-15, Wet Weather Overflows) in order to implement the Combined Sewer Overflow Control Policy (50 FR 18688).

Response to: CTR-090-018

EPA disagrees with any suggestion that narrative wet weather overflow provisions in the San Francisco Bay Basin Plan be addressed by the CTR. The CTR is promulgated to add numeric criteria for priority toxic pollutants where they did not exist. The CTR does not modify existing Basin Plan implementation provisions, or other narrative Basin Plan provisions, which remain in effect if they were duly adopted under State law. (EPA notes, however, that such provisions, which were adopted in the San Francisco Bay Regional Board 1995 Basin Plan amendments, have not been approved by EPA.)

In inviting commenters to identify existing State site-specific criteria (page 42165 of the preamble to the proposed CTR, 62 Fed.Reg.42160) EPA intended to seek identification only of numeric site-specific criteria. EPA regrets any misunderstanding which omission of the term "numeric" may have caused, but believes that the preamble to the proposed rule clearly explained the scope of the CTR, such that it would be clear that the CTR would not withhold promulgation of numeric criteria in favor of State narrative provisions, nor would the CTR incorporate existing State narrative criteria provisions.

Comment ID: CTR-092-010
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24 Site Specific Criteria

References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: State Adoption of Site Specific Criteria

The preamble recognizes that the State has the discretion to develop site-specific criteria when appropriate for example, when statewide criteria appear over or underprotective of designated uses. Under California law, site specific criteria are adopted as amendments to regional Basin Plans, which are then reviewed by the State Water Resources Control Board (SWRCB) and the Office of Administrative Law. These criteria are then submitted to the, EPA Regional Administrator for review and approval under Clean Water Act Section 303. The City recommends that EPA formally adopt a policy in the CTR to continue and support this regulatory process, specifically during the interim period as the State develops its statewide water quality framework. The City also requests that EPA Region IX conduct prompt reviews of all currently submitted site-specific data, together with timely reviews of site-specific data submitted with these comments and any site-specific data submitted in the future. The City has attached its recently completed site-specific water quality investigation for copper in South San Francisco Bay for formal review by Region IX and inclusion in the record of this rulemaking (Attachment 3).

The City also urges EPA to revise language in the preamble limiting the use of the site-specific criteria process after federal promulgation and prior to a decision on any State adopted site-specific criteria. We also urge EPA to revise the statement that the more stringent of the two criteria would be used for water quality programs, in the event of two promulgations. Such language severely limits this regulatory approach, and State flexibility in the development of scientifically defensible site-specific criteria. The City reiterates its recommendation that EPA develop a viable policy which supports site-specific criteria development, that ensures EPA's continued review and oversight process, and that emphasizes scientific defensibility and not the stringency of the value produced.

Response to: CTR-092-010

0EPA disagrees with this comment. We believe that the commenter misunderstood the cautionary language that was part of the proposed rule. The CTR does not preclude state adoption of criteria after the CTR has been promulgated. As EPA stated in the preamble to the proposed CTR, when the State has completed its own process, and EPA approves the State's new or revised criteria, EPA intends to stay the CTR. Similarly, if the State adopts site-specific criteria (including site-specific Basin Plan criteria adopted by Regional Boards which have completedthe State review and adoption process), and EPA has approved them based on their individual merits, EPA intends to stay that portion of the CTR that applies more general criteria to the specific site. Each individual stay on a site-specific basis would require federal rulemaking on a case-by-case basis, and generally require more detailed effort on the Agency's part than a statewide stay.

Moreover, it is possible that State-adopted criteria could become effective for CWA purposes within the State even prior to EPA approval or rulemaking, although this would change if a rule that EPA has recently proposed is promulgated as proposed. The "Alaska Rule," 64 Fed.Reg. 37072, July 9,1999. Until the Alaska Rule goes final, the State could adopt new or revised standards which are more stringent than the CTR, and those standards would be effective for CWA purposes within the state without any EPA action. Moreover, prior to a final Alaska Rule, the State could adopt statewide standards, and if EPA approved those standards and stayed the CTR based on them, then subsequent site-specific criteria

would apply within the State when adopted by the State without requiring additional EPA approval or rulemaking. If the Alaska Rule becomes final as proposed, however, regardless of whether the CTR has been stayed, only state-adopted criteria which are more stringent than the otherwise applicable standards could be applied within the State, prior to EPA approval of those standards.

EPA notes that State-adopted criteria (including site-specific criteria) which are less stringent that CTR criteria may be approved by EPA and result in a stay of the CTR if such criteria are based on sound scientific rationale which ensures that designated uses will be protected.

This commenter also urged EPA to act, prior to finalizing the CTR, to approve or disapprove any State-adopted site-specific criteria which had been submitted to EPA but EPA had not yet acted upon. This has not been possible, due to the focus of resources on the CTR itself. However, in the final CTR, EPA has made revisions to ensure that EPA-approved State-adopted site-specific criteria shall remain in effect and not be superceded by CTR criteria for the same pollutants for those waters of the Bay where such site-specific criteria are currently in effect. See response to CTR-016-001.

Comment ID: CTRH-001-047
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-24 Site Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: MR. LOZEAU: I'm Michael Lozeau. I'm the executive director of San Francisco Baykeeper and Deltakeeper.

I've done a preliminary review of the rule. But with that in mind, I'm just going to list all our current concerns. I'll start with the simplest perhaps and work my way towards the more complicated ones.

The first thing I noticed in the rule is there's some deference to regional boards, regional board standards that have been issued and approved by EPA. But there's no full listing in the proposed rule, and there's a suggestion that the burden is on the board to come forward and remind EPA of the standards it's already looked at and approved.

I would urge EPA to be proactive about that, so that representatives from regional boards, from all nine regional boards, don't have to make sure that they remind you of the standards that already exist before you perhaps wipe them out with this new rule, especially in the Bay Area where we have a number of standards which have been applied and do exist, which I think would be more appropriate certainly for the Bay Area than a statewide standard.

Response to: CTRH-001-047

EPA believes that it has addressed this comment, particularly with regards to San Francisco Bay. (See responses to CTR-016-001 and CTR 016-002.) EPA approved, State-adopted site-specific criteria for

waterbodies other than San Francisco Bay were not identified in response to the proposed rule, and EPA was unable to obtain a comprehensive listing of such other criteria. For these reasons, EPA has not "promulgated around" any site-specific criteria other than those in San Francisco Bay identified in the final CTR and those discussed in the preamble to the proposed CTR (62 Fed.Reg. 42165-42166), which are also identified in the final CTR. This is consistent with the approach set forth in the Preamble to the proposed CTR. (62 Fed.Reg. 42165.)

Subject Matter Code: C-24a SSC Water Effect Ratios

Comment ID: CTR-003-001
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: 1) The placement of the WER in the equation for the calculation of criteria is an excellent idea which, given affordable implementation methods, should better tailor the criteria to the site. We would, however, appreciate clearer definition as to how this is to be implemented. Will the EPA approve WER study plans and results or is the State the lead agency? Do WER's need to be placed in basin plans or is this similar to total to dissolved ratios which are permitting issues versus objective setting issues?

Response to: CTR-003-001

The rule promulgates a default WER of 1. The rule states that if other than a WER of 1 will be used, it must be developed in accordance with EPA's WER guidance or the State's methodology, after that methodology has been adopted as part of the State's water quality planning process and approved by EPA. WERs developed under one of these processes are not subject to further EPA review and approval.

WERs may be used on a water body basis for a particular pollutant or as part of a permit for an individual discharger for a specific pollutant. EPA encourages the State (and dischargers) to develop and use WERs on a water body basis, since this approach is technically sound, and efficient use of resources, and allowable for the NPDES permitting authority. WERs developed on a water body basis should be included and adopted in the appropriate Regional Water Quality Control Board Basin Plan. WERs that are developed on a permit basis are subject to the NPDES permit approval process.

Comment ID: CTR-004-004b
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES G-05
C-22
C-09

Comment: Despite the problems addressed above there are provisions of the CTR that SBSA supports,

including:

* EPA's policies and guidance regarding the use of mixing zones and dilution

* Use of water effects ratios (WERs) for determining site specific criteria

* Inclusion of metals criteria expressed as dissolved rather than total recoverable

* Allowing permit writers the use of any of the methods in EPA's guidance document on the use of translators

Response to: CTR-004-004b

EPA acknowledges the commenter's support.

Comment ID: CTR-005-003b
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-09
G-05
G-04

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003b

EPA acknowledges the commenter's support.

Comment ID: CTR-017-002b
Comment Author: Santa Ana River Discharger Ass
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:

Attachments? Y
CROSS REFERENCES C-22

Comment: Because the California Toxics Rule uses the same approach as the UAA in setting water quality objectives for cadmium and copper, SARDA strongly supports the CTR objectives for those metals. We also agree with EPA's written statements acknowledging the binding character of organic carbon and the role it plays in rendering heavy metals non-toxic. We enthusiastically endorse the agency's decision to include Water Effects Ratio as a formal factor to be considered when formulating water quality objectives. It will do much to adjust national criteria to local conditions.

Response to: CTR-017-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-020-005
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

2. Water Effects Ratio The preamble explains that the intent of the metals criteria is to control the bioavailable fraction of the metal. Because there is no reliable analytical procedure to measure the bioavailable fraction, most acute and chronic metals criteria are now applied as dissolved criteria and a water effects ratio ("WER") is included as part of the criteria to properly adjust the analytical measurement to reflect the bioavailable fraction. Contrary to the statement that the metals criteria are only intended to address bioavailable metals, the preamble states that acceptance of a WER study is discretionary. This is inappropriate and must be amended in the final rule publication. EPA should not be suggesting that Regional Boards may ignore relevant scientific information.

EPA has also dictated use of the Agency's Interim Guidance on the Determination and Use of Water-Effect Ratios (the "WER Guidance") which is very conservative and costly to follow. Moreover, WER guidance is not designed to address short term events such as storm water discharges. Given that the duration of the tests required to be used greatly exceeds the duration of storm water events, it is apparent that the WER guidance should not be applied to these conditions without considerable modification. The recent Society for Environmental Toxicology and Chemistry ("SETAC") evaluation of EPA metals criteria and implementation policies (entitled "Reassessment of Metals Criteria for Aquatic

Life Protection" [1996]) recommends that whole effluent bioassays using metal sensitive organisms be used to determine the appropriateness of applying EPA's metal criteria to derive stringent effluent limitations. The use of complex and expensive WER tests is not necessary as the use of metal sensitive organisms (such as daphnids), which were originally used to calculate EPA's criteria, will reliably assess whether or not the metals present in the sample are in a bioavailable form. Senior EPA officials were involved in preparing the SETAC recommendation, and the publication is intended to reflect to consensus of the nationally recognized experts on this subject. The Agency has in the past relied upon these same experts in updating the EPA's metals criteria (e.g., the January 1993, EPA-sponsored scientific workshop on the development and implementation of metals criteria in Annapolis, Maryland [the "Annapolis Conference"]).

Because of the excessive cost and time necessary to conduct detailed WER tests in accordance with EPA's published guidance, more simplified and appropriate procedures need to be established. The metals criteria should include a screening procedure which will allow the use of metal sensitive organisms to assess whether or not the metal is in a bioavailable form. If the metal is not bioavailable, then the permitting authority should not establish limitations based upon EPA's criteria.

Response to: CTR-020-005

EPA does not mean to suggest in its language concerning WERs, that California Regional Water Quality Control Boards ignore relevant scientific information. Rather, EPA's intent is simply to clarify that the State has the authority to approve or disapprove site-specific determinations of WER values, derived with methodology approved by EPA.

Additionally, EPA does not mean to suggest that the Agency's "Interim Guidance on the Determination and Use of Water-Effect Ratios" is the only available methodology for determining WERS, as discussed further in the response to CTR-020-006. See also the response to CTR-003-001 for discussion of the general approach for implementation. The commenter wants a simpler EPA WER guidance but does not suggest how to do this and why it would be scientifically defensible.

Comment ID: CTR-020-006
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and support EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. Whle a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omission that should be addressed in the final publication of this rule.

(a) Water Effect Ratio Approach is Mathematically Flawed

As part of the CTR, EPA has required that the Agency's February 22, 1994 water effects ratio procedure be used to appropriately adjust the dissolved metals criteria to reflect the bioavailable fraction. See, WER Guidance. Since the issuance of that document, EPA has prepared an internal evaluation of the reasonableness of the WER Guidance (Delos: "Probabilistic Analysis of the Level of Protection Provided by the Interim Guidance on Determination of Water Effect Ratios" [March 1994]). That analysis found:

...the Guidance procedures tend to produce a lower WER than the unbiased WER... the option favored in the February 22 cover memo to the Guidance is particularly biased (by a factor of 2-4)...

Thus, it is apparent that EPA is aware that the published WER Guidance is flawed and will lead to calculation of unnecessarily restrictive limitations under the most common circumstances where the procedure is applied (low dilution receiving waters). Given this information, it is clearly inappropriate for EPA to mandate the use of the 1994 WER Guidance as the basis for determining all WERs under the CTR.

In addition to those issues identified in EPA's internal review, the procedures outlined in the WER Guidance contain a major, conceptual, technical error that will lead to routine miscalculation of the WER. This error was first brought to EPA's attention in September 1992 by Dr. Herb Allen, one of the nation's leading experts on metals speciation (Exhibit 1).

The basic technical oversight of the WER Guidance is that organometallic complexing manifests itself as a non-linear titration, not a linear ratio. This mode of action was verified decades ago by many researchers. On behalf of EPA, DiToro also verified this phenomenon during EPA's sediment criteria research, and it is the underlying principle in using acid volatile sulfide levels as the indicator of when metals may exhibit toxicity. As discussed in Dr. Allen's most recent analysis (Exhibit 2), metals will not exhibit toxicity where the amount of binding sites is stoichiometrically in excess of the available metal. This is demonstrated by Figure 6 contained in Exhibit 2 for a range of ligand concentrations. Both the acute and chronic criteria will be increased by a specific fixed amount, not a ratio. Thus, the proper way to account for metals inactivation measured by a WER procedure is arithmetically, not multiplicatively.

The error in the appropriate adjustment to the criteria increases as the LC50 used to calculate the WER becomes increasingly greater than the chronic criteria that is being adjusted by the WER. Given that the chronic criteria is always less than the LC50 used to adjust the criteria, EPA's WER procedure will always produce an inappropriately low adjustment factor. The following examples illustrate the magnitude of the error that may occur by using a multiplicative rather than additive approach. The first example is typical of EPA's copper criteria. Where the laboratory derived LC50 is 20 ug/l and the effluent influenced LC50 is 60 ug/l, a WER of three (3) would be calculated. These same data verify that a 40 ug/l copper binding capacity is exhibited by the effluent influenced sample.

Under EPA's procedure, a chronic criteria adjustment to 18 ug/l would occur (assuming 6 ug/l chronic criteria) although the actual chronic endpoint is 46 ug/l based on the titration effect. Thus, EPA's approach is in error by a factor of 2.55 or 155 percent. The criteria calculation error becomes even more dramatic as the acute/chronic ("A/C") ratio is increased. For pollutants such as lead with a high A/C ratio (about 50), the error would easily be a factor of 50 because acute tests are used to calculate the WER. The solution to the problem is straightforward: EPA should inform the public that the binding capability of the mixture should be determined arithmetically (one may geometrically average the results consistent with the acute and chronic criteria development) and add this to the chronic test result to produce the proper instream criteria.

Finally, the WER Guidance is in error in its expensive requirement that WERs be conducted for a series of dilutions under the concern that the WER may decrease more rapidly than the dilution increases. As demonstrated by Dr. Allen in Figure 3, Exhibit 2, organometallic binding is not linear. Binding does not decrease more rapidly or even as rapidly as dilution even for binding agents with relatively low stability constants. Thus, if the pollutant is demonstrated to be non-toxic at low dilution, one may fully expect the pollutant to remain non-toxic as dilution increases. Recognition of this phenomenon can greatly simplify the WER procedures and reduce the exorbitant costs of running all the tests outlined in the WER Guidance.

Based upon these and other concerns, the proposed rule should delete the requirement to utilize the WER Guidance for all WER analyses. As requested and supported by the available technical information, the CTR should allow for use of simplified approached to adjusting the proposed metals criteria.

Response to: CTR-020-006

EPA disagrees that it has mandated or required the of use of the Agency's "Interim Guidance on the Determination and Use of Water-Effect Ratios". As an alternative to following this guidance the rule specifically provides the option of using "other scientifically defensible methods adopted by the State as part of its water quality standards program and approved by EPA."

The commenter recommends use of what could be called a "water-effect difference" (WED), although this particular terminology is not used in the comment. If the test species exhibited effects at concentrations near the criterion, the WED would yield the same result as the WER. If the test species exhibited effects at concentrations significantly above than the criterion, then the WED would yield a different result than the WER. Under certain conditions (e.g., metals interacting with strong binding agents), the WED calculation will yield an accurate result, while the WER will yield an over-protective result. Under other conditions (e.g., metals interacting with weak ligands) the WED will yield an under-protective result, while the WER will yield an accurate result. Analysis of the behavior of EPA's current guidance indicates that it often tends to yield conservative results.

With regard to the issue of the complexity and expense involved in of the WER procedure, EPA has been cooperating with states and dischargers who are experimenting with simplified procedures that yield the essential information using fewer samples ([Date] letter from Evelyn S. MacKnight, EPA Region 3, to James Newbold, Pennsylvania Dept. of Environ. Protection). Furthermore, EPA is developing a biotic ligand modeling approach that will determine the appropriate site-specific criteria adjustment solely from site-specific chemical measurements. Because the state of the science is moving forward in this area, EPA has provided for the use of alternative procedures, and anticipates that future developments will yield procedural improvements approvable under the rule. EPA believes that the current guidance on WERs yields dependable results, but that the upcoming biotic ligand model will simultaneously improve the accuracy of site-specific criteria adjustments (eliminating the above described WER versus WED issue) and simplify their derivation. EPA thus believes that the rule's provisions, coupled with its ongoing scientific development efforts, are directly responsive to the issues raised in the comment.

Comment ID: CTR-021-002b
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale

Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES G-04
C-22
K-01
G-05
G-02

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; (c) the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-027-012b
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-22
C-01a
G-09
G-05

Comment: PROVISIONS OF THE PROPOSED RULE WE SUPPORT

Not withstanding the above comments, we believe there are certain elements of the proposed rule with respect to establishing water quality standards that we can support:

* Metal criteria expressed in the dissolved fraction rather than expressed in the total recoverable fraction.

* Metal criteria that are developed as a function of the water-effect-ratio (WER).

* The current proposed human health criterion for mercury.

* The current preamble language regarding metal translators and mixing zones.

We believe the above provisions provide a more acceptable, scientific approach to the water quality-based pollution control approach. We recommend these provisions of the current rule remain as proposed.

Response to: CTR-027-012b

EPA acknowledges the commenter's support.

Comment ID: CTR-032-002d
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24
K
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002d

EPA acknowledges the commenter's support.

Comment ID: CTR-034-009
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: * SCAP also supports EPA's proposal to include in the proposed rule a default water effects ratio (WER) value of 1.0 unless a site-specific WER is developed, and EPA's policy of allowing the approval of site-specific WERs without a formal rulemaking process to modify the CTR. We also agree with EPA'S policy to allow the development of site-specific WERs in accordance with EPA's technical guidance on WERs or using other scientifically defensible methods.

Response to: CTR-034-009

EPA acknowledges the commenter's support.

Comment ID: CTR-035-002h
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
C-08a
G-05
G-04
G-09
K-01

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002h

EPA acknowledges the commenter's support.

Comment ID: CTR-035-019
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42173-42174 - Application of metals Criteria (Water Effect Ratios) We support EPA's proposal to allow the development of site-specific WERs as set forth in EPA's WER guidance or determined by another scientifically defensible method. We also support the application of the WER on a watershed or water body basis to the extent that it is a technically sound and cost-effective approach. However, we would note that there may be instances where a "site" should be defined to be only a portion of a water body or watershed (e.g. the entire San Francisco Bay should not be considered a single "site"). We strongly endorse the inclusion in the proposed rule of a provision, such as was included in the National Toxics Rule, to create a rebuttable presumption of a default WER value of 1.0, unless a site-specific WER is determined. We understand that to mean that an EPA rulemaking process to adopt site-specific WERs would not be required, and that instead, EPA is "pre-authorizing" the use of correctly applied water effect ratios that are approved by the State. (EPA would still have the opportunity to review each WER through the normal NPDES permit approval process.)

Response to: CTR-035-019

EPA agrees with the commenter's discussion. EPA would approve the methodology. The state would approve the WERs derived in accord with the methodology.

Comment ID: CTR-038-002b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-040-002a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-01a
G-09
G-05

Comment: PROVISIONS SUPPORTED

We support a number of provisions of the Rule, including: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury- and (4) the Preamble discussions regarding metals translators and mixing zones. These provisions provide a firmer scientific base for the water quality-based approach to pollution control and are a marked improvement over the old Inland Surface Waters Plan. We would urge EPA to retain these provisions in the final Rule.

Response to: CTR-040-002a

EPA acknowledges the commenter's support.

Comment ID: CTR-041-003b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES G-09

Comment: Second, the District supports with reservations EPA's proposals on two subjects directly related to dissolved metals criteria, i.e. the proposed guidance on both (1) translators to convert from dissolved metals criteria to total recoverable permit limits and (2) the water-effect ratio (WER) as the method to compare the bioavailability and toxicity of a pollutant in receiving waters and in laboratory waters. Both of these two proposals must be implemented on a site-specific basis using local data, not statewide or watershed-wide data. Translators, however, should be developed whenever a discharger is willing to conduct studies in accordance with EPA-approved methods. The proposed procedure for a default value of 1.0 for a WER should mean that when a site-specific WER is to be determined, an additional EPA rulemaking process would not be required. Instead, this rule should pre-authorize the use of correctly applied WERs that are approved by the State.

Response to: CTR-041-003b

EPA agrees with the comments on translators. EPA does not agree with the comment that WERs cannot be derived on a statewide or watershed-wide basis. Some states have found it useful to pool data from several sites (hydrologically noncontiguous) and project WER values to sites having similar water quality characteristics. Because most pollution control decisions are insensitive to uncertainties in the WER estimation (that is, a range of different possible WER values will yield the same decision), it can be efficient to reserve WER derivations with the greatest site-specificity for those situations where the decision is most sensitive to uncertainties. See also the response to CTR-003-001 for discussion of the general approach for implementing WERs.

Comment ID: CTR-043-002b
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-04
G-05
G-09

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002b

EPA acknowledges the commenter's comment.

Comment ID: CTR-044-003b
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-09
G-05
G-04

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003b

EPA acknowledges the commenter's comment.

Comment ID: CTR-045-005
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WER) allowing RWQCBs and the SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process.

Response to: CTR-045-005

EPA acknowledges the commenter's support.

Comment ID: CTR-049-002
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: We applaud and support USEPA's creation in the draft CTR of a rebuttable presumption for Water Effects Ratios (WERs), allowing the Regional Water Quality Control Boards and the State Water Quality Control Board to develop site-specific WERs that can be approved by USEPA during the NPDES permit approval process. WateReuse believes that this flexible approach would help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-049-002

EPA acknowledges the commenter's support.

Comment ID: CTR-054-002b
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES C-22

Comment: BADA supports adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio. These changes place the metals criteria on a firmer

scientific base than the old State Plans. Moreover, previous BADA studies have shown that adoption of the copper criterion as total recoverable could cost Bay Area POTWs several billion dollars while reducing copper loads to the Bay by only several percent (see Attachment 1). Further, building the water-effect ratio into the criteria will lessen the administrative burden on all parties when it becomes necessary to pursue the development of such a ratio. For these reasons, it would not be in the public interest nor consistent with Presidential Order 12866 or the Unfunded Mandates Reform Act to adopt the metals criteria as total recoverable concentrations or to require approval of a site-specific objective whenever a water-effect ratio is developed.

Response to: CTR-054-002b

See response to comment number CTR-003-001.

Comment ID: CTR-056-006
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* EPA's approach to water effects ratios for determining site specific criteria,

Response to: CTR-056-006

EPA acknowledges the commenter's support.

Comment ID: CTR-056-009
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs) which permit the

RWQCBs and the SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. This approach should lead to the development of appropriate site-specific adjustments for metals criteria, and

Response to: CTR-056-009

EPA acknowledges the commenter's support.

Comment ID: CTR-061-014
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42173, third column, first two paragraphs, discuss the water effects ratio approach for adjusting national criteria. This approach does not adequately or reliably incorporate aquatic chemistry into water quality criteria adjustment. The approach tends to over-regulate because of the failure to equilibrate between the chemical forms in ambient waters and those in the test system. The statement in the third paragraph, "This approach is technically sound, an efficient use of resources... " is not appropriate since it leads to over-regulation of chemical constituents in wastewater and stormwater runoff. Enclosed is a summary report "Regulating Copper in San Francisco Bay: Importance of Appropriate Use of Aquatic Chemistry and Toxicology, " (1997) on the over-regulation of Cu in San Francisco Bay that developed due to the inability of the water effects ratio to develop site-specific criteria that properly reflect the toxicity of Cu in San Francisco Bay waters.

Response to: CTR-061-014

EPA does not agree with the commenter that a reasonably accurate water-effect ratio cannot be derived, either using current guidance or using other scientifically sound procedures allowed by the rule. See response to CTR-020-006.

Comment ID: CTR-066-003
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The water effects ratios philosophy for determining site-specific criteria.

Response to: CTR-066-003

EPA acknowledges the commenter's support.

Comment ID: CTR-066-007
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review ofthe CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by the EPA during the NPDES permit approval process. This approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-066-007

EPA acknowledges the commenter's support.

Comment ID: CTR-081-002b
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES G-04
G-02
C-22
G-09
C-01a
C-08a

G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are perfomed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-085-004
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's approach to water effect's ratios for determining the site-specific criteria.

Response to: CTR-085-004

EPA acknowledges the commenter's support.

Comment ID: CTR-085-008
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WER) allowing the RWQCB and the SWRCB to develop site-specific WER that can be approved by the EPA during the NPDES permit approval process. This approach will help facilitate the development of appropriate site-specific adjustments for metal's criteria.

Response to: CTR-085-008

EPA acknowledges the commenter's support.

Comment ID: CTR-086-004d
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24
K-03
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004d

EPA acknowledges the commenter's support.

Comment ID: CTR-090-002b
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-17a
C-22
G-05
G-02
G-04

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002b

EPA acknowledges the commenter's support.

Comment ID: CTR-092-004
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Application of Metals Criteria

The City supports EPA's proposal to provide for the adjustment of metals criteria through the application of the water-effects-ratio (WER) procedure to ensure that such criteria are appropriate for chemical conditions present in the water body. The City agrees with EPA that ideally, the WER process should be applied on a watershed or water body basis in California. However, the City does have sincere concerns with how a watershed and/or waterbody is defined. The City wishes to be on record that a significant body of sci ' entific information supports the contention that San Francisco Bay South of the Dumbarton Bridge (South San Francisco Bay) constitutes a distinct waterbody for purposes of the WER process. Furthermore, the City recommends that the Rule be revised to allow use of the WER procedure to develop site-specific criteria, without requiring a formal rulemaking process.

Response to: CTR-092-004

EPA recognizes the concerns expressed, but believes that the commenter's concerns may be unfounded. The CTR does not define or restrict the boundaries of any California site, or impede the appropriate definition of such boundaries. The rule also does not require or intend to require that the adoption of site-specific WERs go through a formal rulemaking. See the response to CTR-003-001.

Comment ID: CTR-092-013a
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-02b

Comment: Validity Of The Proposed Copper Criteria For South San Francisco Bay

Attachment 3 to this letter is a technical report entitled "Development of a Site-Specific Water-Effect Ratio for Copper in South San Francisco Bay", dated September 1997 and prepared by the City of San Jose Environmental Services Department.

This attachment is also incorporated as part of our comments and is being submitted for inclusion in the record for this rulemaking. Because EPA is proposing to promulgate water quality criteria for all waterbodies in the State of California, we believe that it is required toconsider site-specific data to the extent that it is available, especially, where, as in the case of the submitted data, it appears that there is a less costly/appropriately protective alternative to the proposed criteria.

Response to: CTR-092-013a

EPA disagrees with the commenter. EPA cannot efficiently include all site-specific data in its rulemaking process. Furthermore, EPA does not believe that it is either technically or administratively advantageous or efficient for the rule to specify particular site boundaries or WERs within such boundaries. Nevertheless, because it is necessary to provide for the use of site-specific data collected either before or after promulgation, the rule expresses the criteria in terms of WER values, which like

water hardness, are specified subsequent to the rulemaking. Thus, the rule has a provision allowing the the state to consider the data cited by the commenter in this context. See the response to CTR-003-001 for discussion of the general approach for implementation.

Comment ID: CTRH-001-003b
Comment Author: Robert Hale
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES C-22
C-1a

Comment: In summing up -- not summing up, just as a parting shot -- I do appreciate the fact that in working up the toxics rule here that EPA has done certain things which in fact we see as improvements in actually making the standards fit with what we think -- have come to see as perhaps the actual impacts of the stormwater part of this. And by that, I'm referring to the dissolved metals criteria and the water effect ratio in there, and the human health criteria revisions for mercury and the other -- the other items.

I appreciate some of the stuff in there, and -- with the exception of the preamble language. And you really need to get that out of there. We're going to pursue this as far as we have to.

I appreciate your hearing me.

Response to: CTRH-001-003b

EPA acknowledges the commenter's support.

Comment ID: CTRH-001-024d
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES g-02
g-05
c-22
c-17a

Comment: MS. PLA: My name is Michelle Pla. I'm with the Public Utilities Commission, City and County of San Francisco.

I made the comment on my card that I also said that I would try to be constructive, and so I'm going to follow my mentor here, Phil Bobel, and say that there are some things in this rule that we're very pleased to see.

We're very pleased to see use of the latest scientific information, particularly the use of latest IRIS, I-R-I-S, numbers-for human health. We're very pleased that you're using dissolved versus total recoverable form for the metals.

We're very pleased to see recognition of the water effects ratios. We're pleased to see recognition for a multi-tiered mixing zone for acute and chronic human health effects and hope that the state pays particular attention to that.

We do have a problem with the way you've described compliance schedules and hope to be working strictly by the state on that as well. We think that the five-year system is fairly shortsighted, and -we can't even do FMDSLs in five years.

Response to: CTRH-001-024d

EPA acknowledges the commenter's support.

Comment ID: CTRH-001-032a
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES c-22
g-5

Comment: I would like to take this time to note that I think it contains some important elements that we agree with and believe are reflective of the impact. These include the uses of dissolved metals and the provisions which will enable the state to use mixing zones and water effects ratios and establish site-specific objectives.

Response to: CTRH-001-032a

EPA acknowledges the commenter's support.

Comment ID: CTRH-001-039a
Comment Author: Robert Reid
Document Type: Public Hearing

State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES G-04
G-02

Comment: I've been saving the good news for last.

Fourth, and by no means last in priority for CASA, we wish to register our support for several parts of the preamble to the CTR.

We support application of interim limits in NPDES permits while TMDLs and other special studies are being performed.

We also support EPA's approach to water effects ratios for determining site-specific criteria.

We also support the inclusion of a provision allowing the compliance schedules in permits in the rule, although we recommend that it be modified to allow the regional boards to include compliance schedules of up to 15 years in permits, if they deem it appropriate.

Thank you for the opportunity to present our views. As I said earlier, we will be submitting detailed comments on the proposed rule by the end of the comment period, which hopefully will be extended in response to our and others' requests.

Response to: CTRH-001-039a

EPA acknowledges the commenter's support.

Comment ID: CTRH-001-057b
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: C-24a SSC Water Effect Ratios
References:
Attachments? N
CROSS REFERENCES K-03
G-04
G-07
G-09
C-22
G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057b

EPA acknowledges the commenter's support.

Subject Matter Code: C-24b SSC Recalculation Procedure

Comment ID: CTR-009-004
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24b SSC Recalculation Procedure
References:
Attachments? Y
CROSS REFERENCES

Comment: At Federal Register, Page 42168, third column, EPA provides that "States may develop site-specific criteria using native species, provided that the broad spectrum represented by the eight families is maintained." In California, as in other arid and semi-arid western states, there are unique aquatic habitats that by their inherent physical chemical and hydrologic nature, are naturally very limited in species diversity as well as density. It would seem that in such cases, what is important and relevant is that the site-specific criteria be most representative of the specific waters and its natural constraints, not that criteria reflect the broad spectrum of species that do not and can not inhabit these waters. The City recommends that the requirement to maintain the eight families broad spectrum be deleted and replaced with a requirement that the site-specific criteria be based upon native species representative of the specific waters in question. In a similar situation, an EPA Administrative Law Judge found that:

"...a proposed test must be reasonably related to determining whether the discharge could lead to real world toxic effects. The Clean Water Act objective to prohibit the discharge of toxic pollutants in toxic amounts concerns toxicity in the receiving waters of the United States, not the laboratory tank."

In the Matter of Metropolitan - Dade County, Miami - Dade Wastewater Authority, NPDES Permit No. Fl, Oct., 1996. Certainly, this precept also applies when establishing a water quality criterion that is intended to protect a specific receiving water. That is, to be relevant to the site-specific waters, the criterion upon which discharge permit limitations are to be developed must be based upon species that are representative of the specific waters. The broad spectrum criteria make sense and are reasonable when applied state-wide. But application of broad spectrum criteria to a site-specific situation would seem to be the antithesis of site-specific water quality controls by definition.

Response to: CTR-009-004

In the CTR, EPA is not promulgating a site-specific criteria methodology. EPA's statement on page 42168 column 2 (not 3) is meant to provide guidance on the derivation of site-specific criteria.

EPA agrees with the general concern that its guidance might be incorrectly interpreted to mean that a site-specific taxonomic data set should have more diversity than the site actually has. EPA does not intend for its guidance to be interpreted in this manner.

Nevertheless, because the Rule does not provide for the Recalculation Procedure, the CTR criteria would continue to apply even if California adopted a Recalculation-based site-specific criterion, unless EPA amended the rule not to apply at that site.

Comment ID: CTR-025-005
Comment Author: Metro. Water Dist. of So. Cal.
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24b SSC Recalculation Procedure
References:
Attachments? Y
CROSS REFERENCES

Comment: The CTR freshwater aquatic life criteria, in general, may not be appropriate for effluent-dominated water bodies and ephemeral streams. Some of these water bodies and the aquatic communities they support exist primarily because of discharges of reclaimed wastewater. Such water bodies are used to transport reclaimed water discharges to a downstream use area and/or are used for the disposal of surplus reclaimed water which occurs when demand is temporarily less than supply. The CTR freshwater aquatic life criteria may create requirements for reclaimed wastewater dischargers which are not economically feasible to meet and could affect the viability of reclamation activities. In Southern California, water reclamation is vital to ensuring a reliable regional water supply.

Response to: CTR-025-005

The commenter here recommends that different uses be adopted for certain waters in California. Designated uses are outside the scope of this rule. EPA has not attempted to determine the beneficial uses or the attainability of designated uses for California in this rule. This rule is to provide criteria for toxic pollutants for California based on the uses established by the State. EPA's criteria will protect these uses.

Comment ID: CTR-082-005
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24b SSC Recalculation Procedure
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Propose that USEPA should accept separate significantly defensible reasonably achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from anthropogenic

sources, such as POTWs (i.e., effluent dependent waters).

Response to: CTR-082-005

EPA does not agree. EPA has not developed separate criteria for effluent-dependent waters because these waters have designated uses for human health and/or aquatic life that correspond to the criteria in the rule. However, the State may consider, and EPA encourages, such criteria developments as part of the State's Phase II of the ISWP/EBWP readoption or as part of its RWQCB Basin Plan updates. In the meantime, EPA's criteria will protect all beneficial uses assigned to each inland surface water and enclosed bay and estuary.

Subject Matter Code: C-24c SSC Santa Ana River

Comment ID: CTR-033-002
Comment Author: San Bernardino Muncpl Wtr Dept
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24c SSC Santa Ana River
References: Letter CTR-033 incorporates by reference letter CTR-020
Attachments? Y
CROSS REFERENCES

Comment: We support the deletion of site specific objectives for cadmium and copper set for in the 1995 Water Quality Control Plan for the Santa Ana River Basin. We believe the site specific objective for lead in the plan is appropriate and should be approved by the U. S. Environmental Protection Agency. This recommendation is premised on the Santa Ana Regional Water Quality Control Board amending the Basin plan to incorporate revised correction factors and recalculations for this metal based upon the most current U.S. EPA guidance and criteria documents.

Response to: CTR-033-002

We agree with the commenter's support of the Regional Water Quality Control Board, Santa Ana River Basin, and its request that we promulgate water quality standards for cadmium and copper in place of the site-specific standards contained in the 1995 Water Quality Control Plan for portions of the Santa Ana River Basin. The final CTR will continue to reflect that position as expressed in the proposed CTR.

EPA also appreciates the commentor's support of the site-specific criterion for lead in portions of the Santa Ana River Basin which the State has adopted and submitted to EPA for approval. However, EPA has not yet approved this site-specific criterion, and in the absence of EPA-approved State-adopted site-specific criteria, EPA must promulgate CTR criteria to meet the requirements of CWA section 303(c)(2)(B). Nevertheless, where site-specific criteria have already been adopted by the State in accordance with State law, but not yet acted upon by EPA, and those criteria are more stringent than applicable CTR criteria, those are the controlling criteria for CWA purposes even without a stay of the applicable CTR criteria and are thus implementable by the State. (This would not be affected by the "Alaska Rule" which EPA proposed July 9, 1999, 64 Fed.Reg. 37072. See p. 37076.) This is the case with the site-specific criterion for lead adopted by the State for certain waters in the Santa Ana River Basin. Since the State must use the most stringent criteria in effect for its water quality programs, the State may use this site-specific lead criterion notwithstanding the CTR fresh water aquatic life criterion for lead, thus the commenter's concerns should have no practical effect.

Subject Matter Code: C-24d SSC Effluent Dependent Wtr

Comment ID: CTR-034-007
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: CRITERIA

* SCAP recommends that EPA adopt separate criteria for water bodies in California that are dependent for all or part of the year on flows from wastewater treatment plants (known as "effluent dependent waters" or EDWs). SCAP believes that there are appropriate ways to modify aquatic life and human health criteria to tailor them to the unique conditions of the EDWs in the arid environment found throughout most of southern California. Potential methods include adjustment of the uncertainty and/or modifying factors used to calculate reference doses (RfDs) for noncarcinogenic human of 10E-4 health criteria, use or 10E-5 risk levels (instead of 10E-6) for carcinogenic human health criteria, adjustment of bioconcentration factors for human health criteria, and the use of site-specific water effects ratios for aquatic life criteria. Further comments regarding these methods are included in Attachment 1.

Response to: CTR-034-007

EPA disagrees that it must or should establish separate criteria for effluent dependent waters in this rule. In establishing water quality criteria for California, EPA is implementing section 303(c)(2)(B) of the CWA which requires adoption of criteria for all toxic pollutants for which EPA has issued criteria guidance and for which the discharge of such pollutants could reasonably be expected to interfere with the designated uses adopted by the state. EPA based the criteria contained in the CTR on its most recent national criteria guidance, which are designed to derive criteria that will be protective of aquatic life and human health. As long as a waterbody currently has a designated use for the protection of aquatic life and/or human health, application of the national 304(a) criteria are appropriate for fulfilling section 303(c)(2)(B). As a policy matter, EPA believes that the CTR, a massive undertaking in and of itself, is an essential first step toward reinstating a strong water quality program in California. Under the Clean Water Act, EPA has no obligation to develop such site-specific criteria or the data upon which such site-specific criteria would be based. If, however, the State wishes to develop site-specific criteria or to change the uses of the waterbody -- pursuant to the regulations at 40 CFR Part 131, and "Region 9's Interim Final Guidance for Modifying and Protecting Effluent-Dependent Ecosystems," EPA would consider and possibly approve such a site specific criterion or such a revision to designated uses.

With respect to risk level applicable to human health criteria when, as here, EPA establishes a water quality standard, EPA intends in its discretion to use a risk level of 1 x 10-6, although the state may in its discretion choose another risk level for protection of human health. If the State has appropriately consulted the public.

With respect to adjustment of bioconcentration factors, the commenter did not explain how or why

bioconcentration factors should be adjusted.

Further, EPA believes that the proposed CTR embodies a number of features that will facilitate the site-specific application of criteria when they are implemented by the state in the future. In proposing an equation rather than a single number for the metals listed in the table in proposed Section 131.38(b)(2) with variables including hardness and water effect ratios (WERs), and in the discussion on the application of metals criteria contained in Section 131.38(c)(4), EPA considers the proposed aquatic life criteria to be highly adjustable to or reflective of site-specific conditions characteristic of EDWs. The inclusion of WERs in these criteria embodies one method of developing water quality objectives for EDWs described in the "Report of the Effluent-Dependent Waters Task Force for Consideration of Issues Related to the Inland Surface Waters Plan" (State Water Resources Control Board, October 1995), which was a broad-based effort to address the specific characteristics of EDWs statewide (see also response to comment number CTR-057-003 below). Another method contained in that report which has been included in the proposed criteria is the use of dissolved metals in lieu of total recoverable metals. Finally, the aquatic life criteria for pentachlorophenol are expressed as a function of pH, allowing for adjustment of the numeric objectives on a site-specific basis.

Furthermore, the above-mentioned report at no point suggests that the resource-intensive task it describes of developing site-specific criteria for EDWs should be carried out by EPA. Rather, on numerous occasions the report recommends that the State or Regional Boards should perform that function. EPA agrees that the appropriate forum for addressing the recommendation in this comment is in subsequent water quality standards revisions carried out by the State, in the adoption of Basin Plans, or in implementation of these criteria in discharge permits or nonpoint source controls.

Potential methods for adjusting criteria for EDWs, with the exception of the inclusion of water effect ratios (WERs) as an optional component of determining appropriate metals criteria, should be applied in the context of State or Regional Board water quality standards-setting actions. EPA's action in promulgating statewide criteria is to reduce risks to all exposed populations, including especially sensitive subpopulations. However, site-specific criteria may be developed subsequently by the State where warranted to provide necessary additional protection, or otherwise to adjust the level of protection as appropriate to reflect site-specific conditions following a Section 304 standards-setting process including the opportunity for public involvement. As described above, EPA has included WERs in the proposed metals criteria listed in the table in Section 131.38(b)(2) for protection of aquatic life.

Comment ID: CTR-035-006
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: EPA should adopt separate, scientifically defensible aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from anthropogenic sources, such as POTWs (i.e. effluent-dependent waters).

Response to: CTR-035-006

See response to CTR-034-007.

Comment ID: CTR-036-009
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: We are concerned that the proposed rule would be equally applicable to effluent-dominated water bodies, particularly in the arid West. In these water bodies habitat is often fully or seasonally dependent on existing discharges and removal, due to redirection and treatment, could result in habitat loss.

Response to: CTR-036-009

For purposes of this rulemaking, EPA is presuming that the State has adequately determined the designated uses for its waters. EPA is merely adding criteria for priority toxic pollutants on a statewide basis sufficient to protect the State's designated uses. EPA believes that a use attainability analysis would provide appropriate means for resolving potential tradeoffs between maintaining discharges to support habitat and meeting stringent effluent standards in a particular waterbody. The results of such an analysis may determine whether site-specific modifications to criteria appropriate. EPA believes that the best forum for conducting these special studies and site-specific analyses is in the context of the statewide revisions of water quality standards and policies for their implementation, undertaken triennially by the State, or in the revision of regional Basin Plans. To assist with these analyses, EPA Region 9 has issued "Guidance for Modifying Water Quality Standards and Protecting Effluent-Dependent Ecosystems," (Interim Final, June 1992). This guidance introduces the "Ecological Benefit Comparison" approach with particular attention to application to EDWs. If it can be demonstrated that using an effluent to maintain riparian and aquatic habitats constitutes a net ecological benefit over removal of the effluent, the guidance describes the circumstances under which a designated but not existing use can be modified or removed. Such an approach may be applied both to aquatic life and to human consumption uses. As was recommended by the Report of the EDWs Task Force, convened by the State in 1995, Statewide plan and regional Basin Plan modifications are the preferred regulatory pathways for conducting and adopting such analyses.

Comment ID: CTR-040-016a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-21

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

III. Recommendation: Adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for effluent-dominated/effluent-dependent streams.

* Available discharge data for effluent-dominated streams in Sacramento indicate that a number of the proposed criteria are not presently being achieved and cannot be achieved with implementation of BMPs or other reasonable controls (See Attachment A). This is also true for many municipal stormwater programs in California.

* The application of the proposed statewide criteria to effluent-dominated waters would force the Sacramento Stormwater Management Program, and other stormwater programs, to remove these discharges, essentially drying up the waters for most of the year. The costs would be significant and the benefits assessed in EPA's economic analysis (enhanced fishing, passive benefits, and reduced cancer risk) would be zero. The removal of these discharges would likely be detrimental rather than beneficial. The effluent-dependent aquatic and riparian habitat, which previously supported aquatic life and wildlife, would no longer exist.

* Effluent-dominated and effluent-dependent water bodies, which are common in California, require separate and distinct water quality criteria. Such a move is common sense and would be in accordance with the spirit (if not the letter) of Presidential Executive Order 12866 and the Unfunded Mandates Reform Act.

* Additionally, the CWA requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and also taking into consideration their use and value for navigation (See CWA section 303(c)(2)(A)). Consistent with this statutory mandate, EPA regulations require that water quality standards be based on identification of specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use, or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use. Clearly the intent of both the CWA and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question, rather than based on the "one-size-fits-all" approach used in the proposed Rule. This is not the cumbersome task suggested by the Preamble, at least with respect to developing criteria appropriate for effluent-dependent waters. But, even if it were a cumbersome task, the difficulty of complying with the law is not an excuse for noncompliance.

* EPA could fulfill its obligation under the CWA and EPA regulations with respect to

effluent-dominated waters simply by proposing criteria for these waters that are generally achievable by present stormwater discharges. Then, using the more stringent statewide criteria as a tracer, control measures and BMPs could be implemented to reduce the discharge of problematic pollutants to the MEP.

Response to: CTR-040-016a

Regarding the first and third recommendations under part III, see the response to CTR-034-007.

Regarding the second recommendation under part III; with respect to the comment about removal of discharges see the response to comment number CTR-036-009 above. Further, with respect to comments that compliance with water quality criteria would incur costs that exceed benefits, EPA believes Sacramento County's has overestimated its incremental expense resulting from implementation of the CTR (for further detail see the response to comment in Section J, "Stormwater Economics," Issue 1). In any case, the Clean Water Act requires the states, or EPA to establish criteria that are protective of the designated uses, regardless of costs. This means that EPA must develop scientifically-based criteria that are protective of designated uses. In existing state water quality standards, however, the designated uses are not refined as suggested in Region 9's Guidance for Modifying and Protecting Effluent Dependent Ecosystems to suggest a use that would have different criteria. Until that is done, EPA is establishing criteria that protect the current designated use.

Regarding the fourth recommendation under part III, see the response to comment number CTR-034-007.

Regarding the fifth recommendation under part III, the Clean Water Act requires EPA to establish criteria that will be protective of designated uses. Establishing criteria for waters based on controls dischargers can currently achieve in their discharges may not ensure that criteria are protective of designated uses.

Comment ID: CTR-042-005
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? Y
CROSS REFERENCES

Comment: 5. The CTR should address effluent dominated waterbodies.

The CTR, as currently proposed, does not recognize that many of the waterbodies in the state are classified as "effluent dominated." In many areas of the state, particularly in Southern California, storm water and wastewater discharges are the primary or only source of water to urban creeks and waterways. To meet CTR criteria on discharges to these waterbodies, zero discharge or advanced treatment technologies may be required. The cost to accomplish this would be substantial and the benefit would be marginal, if not negative. A negative benefit would be realized if the removal of storm water and wastewater discharges to these waterbodies causes damage to the aquatic organisms and wildlife that are supported by and rely upon these effluent dependent waterbodies.

Request: Caltrans requests that the CTR be amended to include separate and distinct water quality criteria for effluent dominated or storm water runoff dependent waterbodies.

Response to: CTR-042-005

Concerning the first paragraph of comment 5, see the response to comment number CTR-036-009 and 040-16a above.

Concerning the second paragraph of comment 5, see the response to comment number CTR-034-007 above.

Comment ID: CTR-043-007
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? Y
CROSS REFERENCES

Comment: 7. EPA should adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from anthropogenic sources. The application of the proposed statewide criteria to waters dominated by discharges from anthropogenic sources would force point source dischargers to remove their discharges, in many cases drying up the waters for most of the year. The costs would be significant and the benefits, at least the benefits assessed in EPA's economic analysis (enhanced fishing, reduced cancer risk, and passive benefits), would be negligible. In fact, the removal of these discharges could be detrimental rather than beneficial. The aquatic and riparian habitat, which previously supported aquatic life and wildlife, would no longer exist. This common type of water body (i.e., effluent dependent waters) demands separate and distinct water quality criteria by any reasonable yardstick, including common sense and the spirit (if not the letter) of Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Additionally, as previously stated, EPA regulations require that water quality standards be based on identification of specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants Applicable to the water body sufficient to protect the designated use." Clearly the intent of these regulations is that water quality standards be tailored to the characteristics of the waters in question, rather than the "one-size-fits-all" approach in the proposed rule. This is not the cumbersome task suggested by the Preamble at least with respect to developing criteria appropriate for effluent dependent waters. But, even if it were a cumbersome task, the difficulty of complying with the law is not an excuse for noncompliance. EPA could fulfill its obligation under the Act and EPA regulations with respect to effluent dependent waters simply by proposing criteria for these waters that are presently achievable by municipal wastewater and stormwater discharges and then using the more stringent statewide criteria as a trigger for development and implementation of controls that will reduce the discharge of problematic pollutants to the maximum extent practical.

Response to: CTR-043-007

See responses to CTR-034-007, CTR-036-009, and CTR-040-016a. See also the responses to comment in the Legal Concerns Category (C-21) including CTR-005-006a, CTR-036-009, CTR-038-006a, and the record for this rule for a discussion about why this rule applies to all waters that do not have water quality criteria for toxic pollutants.

With respect to EPA's compliance with Executive Order (E.O.) 12866, the Regulatory Flexibility Act (RFA), and the Unfunded Mandates Reform Act (UMRA), see the preamble to the final rule.

Comment ID: CTR-044-008
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? Y
CROSS REFERENCES

Comment: We have reviewed the proposed CTR and offer the following comments:

7. EPA should adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from anthropogenic sources. The application of the proposed statewide criteria to waters dominated by discharges from anthropogenic sources--would force point source dischargers to remove their discharges, in many cases drying up the waters for most of the year. The costs would be significant and the benefits, at least the benefits assessed in EPA's economic analysis (enhanced fishing) reduced cancer risk, and passive benefits), would be negligible. In fact, the removal of these discharges could be detrimental rather than beneficial. The aquatic and riparian habitat, which previously supported aquatic life and wildlife, would no longer exist. This common type of water body (i.e., effluent dependent waters) demands separate and distinct water quality criteria by any reasonable yardstick, including common sense and the spirit (if not the letter) of Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Additionally, as previously stated, EPA regulations require that water quality standards be based on identification of specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use." Clearly the intent of these regulations is that water quality standards be tailored to the characteristics of the waters in question, rather than the "one-size-fits-all" approach in the proposed rule. This is not the cumbersome task suggested by the Preamble at least with respect to developing criteria appropriate for effluent dependent waters. Bur, even if it were a cumbersome task, the difficulty of complying with the law is not an excuse for noncompliance. EPA could fulfill its obligation under the Act and EPA regulations with respect to effluent dependent waters simply by proposing criteria for these waters that are presently achievable by municipal wastewater and stormwater discharges and then using the more stringent statewide criteria as a trigger for development and implementation of controls that will reduce the discharge of problematic pollutants to the maximum extent practical.

Response to: CTR-044-008

See responses to CTR-034-007, CTR-036-009, CTR-040-016a, and CTR-043-007.

Comment ID: CTR-049-004
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

2. Adopt separate, scientifically defensible, and achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from recycled water;

Response to: CTR-049-004

See response to CTR-034-007.

Comment ID: CTR-056-011
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Evaluate and adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by dischargers from anthropogenic sources such as POTWs (i.e. effluent-dependant waters).

Response to: CTR-056-011

See response to CTR-034-007.

Comment ID: CTR-057-003
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: Effluent-Dependent Water Bodies

On Page 42164, the proposed Rule states that the EPA disapproved the deferral of water quality objectives in the ISWP for effluent dominated streams (Category "a") and agricultural drainage on the basis of imprecise and overly broad definitions. Since the ISWP was invalidated, the issue of effluent-dependent water bodies (EDW) was analyzed in detail via the State's Public Advisory Task Force process. Through our participation on the EDW Task Force (which included representatives from the EPA), we can confidently state that the issue has since been much better defined and that there is a full consensus that these water bodies need to be recognized in the establishment of water quality criteria.

In developing its list of non-compliant water bodies under the 303(d) provision, the State in essence acknowledged that EDWs are problematic simply because they support beneficial uses that would not otherwise exist without the flows of point and non-point discharges. This situation is compounded by the fact that all waters of the State, regardless of provenance, are classified as potential sources of domestic water supply; again, this is a potential benefit that would not otherwise be possible without effluent discharges, and this benefit should be recognized in the proposed Rule.

From this, we conclude that the proposed Rule is not complete because it does not recognize the importance of EDWs as was conclusively demonstrated by the EDW Task Force. . The EDW concept should not be abandoned, and we strongly urge the EPA to replace its statements on Page 42164 with a brief acknowledgment of the findings and recommendations of the EDW Task Force. We believe that this will provide additional impetus for the State to incorporate EPA-approved EDW provisions in its own plan.

Response to: CTR-057-003

EPA participated in the EDW Task Force with other stakeholders representing the industrial, municipal, storm water, agricultural, environmental, water supply, public health and regulatory sectors. The goal of the Task Force was to develop recommendations for the State Water Resources Control Board (SWRCB) regarding how to provide reasonable protection for appropriate beneficial uses of EDWs. After considering the complexities of the analyses necessary to characterize and determine appropriate water quality objectives for EDWs, the Task Force recommended the following two-step approach to regulating them. The first step is to modify the present designated beneficial uses such that they more accurately reflect actual uses. The second step is to adopt water quality objectives appropriate for each use designation. The needs for developing this approach would be: to define EDWs in the new State plans, to define EDW-specific use categories, to define and categorize all EDWs by use categories in the State, and to adopt appropriate water quality objectives for EDWs. While emphasizing again that this work should be done within the context of either SWRCB or Regional Board standards-setting actions, EPA

acknowledges and agrees with the recommended approach. EPA further notes that the Task Force report also recommends that the SWRCB should develop technical evaluation criteria for a number of the steps identified above, and that the SWRCB should consider convening a technical advisory committee to address these issues. Until the recommended technical evaluation criteria are established and implemented, EPA considers that criteria should be adopted on a statewide basis.

See also response to comment number CTR-034-007 above.

Comment ID: CTR-059-010
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we reconunend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attaimnent of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of water body.

Criteria for Effluent Dependent Waters

As discussed above, the water quality standards regulations (specifically, 40 CFR section 131.11) requires EPA to examine the specific water bodies and uses to be protected before adopting criteria in water quality standards. As EPA is aware, streams and washes in and areas have unique characteristics, and in many locations in southern California, POTW discharges have transformed ephemeral streams into what are essentially perennial streams. These are often referred to as "effluent dependent waters" or EDWs. The impact of this has been to create new riparian habitats that provide valuable ecological benefits. However, this has also raised many questions regarding what water quality standards should be applied to EDWs. For instance, since the use of treated wastewater for drinking water is restricted by the Department of Health Services, it is questionable whether the municipal drinking water designated use (MUN) is appropriate for EDWS. LACSD believes that, based on the requirements of the water quality standards regulations, that EPA has not demonstrated that the proposed CTR criteria are appropriate for EDWs, and that a more appropriate course of action would be for EPA to adopt separate criteria for water bodies in California that are dependent for all or part of the year on flows from wastewater treatment plants.

Appropriate ways to modify aquatic life and human health criteria for EDWs could include adjustment of the uncertainty and/or modifying factors used to calculate reference doses (RfDs) for noncarcinogenic human health criteria, use of 10E-4 or 10E-5 risk levels (instead of 10E-6) for carcinogenic human health criteria, adjustment of bioconcentration factors for hwnan health criteria, the use of site-specific water effects ratios for aquatic life criteria, and the adjustment of the low flow values, frequency of exceedence and/or criteria averaging periods used in deriving or applying the criteria. As an agency that owns and operates numerous treatment plants that discharge into EDWs, and that has a substantial base of knowledge regarding the quality of the effluent and the conditions in the ambient environment in the vicinity of these discharges, we would be pleased to work with EPA to craft water quality criteria for toxic pollutants that are appropriate for EDWs in southern California.

Response to: CTR-059-010

In response to the recommendation that EPA not adopt criteria for effluent dependent waters unless they have been adjusted to reflect the characteristics of this type of water body, see the response to comment number CTR-034-007.

Concerning the comment that water quality standards regulations require EPA to examine specific water bodies and their uses before adopting criteria for them, see response to comment number CTR-040-016a. Concerning what designated uses are appropriate for EDWs, see response to CTR-036-009. See also responses to comment CTR-005-006a, CTR-036-005, and CTR-038-006a in the Legal Concerns Category (C-21). For purposes of this rulemaking, EPA is presuming that the State has adequately determined the designated uses for its waters. EPA is promulgating criteria for priority toxic pollutants on a statewide basis sufficient to protect the State's designated uses.

Concerning appropriate ways to modify aquatic life and human health criteria for EDWs, with the exception of application of water effect ratios (WERs), EPA considers that the methods suggested should be applied in the context of State or Regional Board water quality standards-setting actions. EPA's action in promulgating statewide criteria is to reduce risks to all exposed populations, including especially sensitive subpopulations. However, site-specific criteria may be developed subsequently by the State where warranted to provide necessary additional protection, or otherwise to adjust the level of protection as appropriate to reflect site-specific conditions following a Section 304 standards-setting process including the opportunity for public involvement. As described above, EPA has included WERs in the proposed metals criteria listed in the table in Section 131.38(b)(2) for protection of aquatic life.

With respect to adjusting frequency of exceedence and/or criteria averaging periods, EPA refers the commenter to Appendix D of EPA's "Technical Support Document For Water Quality-Based Toxics Control" (EPA/505/2-90-001, March 1991), in particular to the discussion entitled "Considerations for Proposing Site-Specific Increases or Decreases in the Averaging Frequency of Allowed Excursions." Although more frequent than once-in-three-years excursions might be acceptable in certain situations, where, for example, areas of refuge for aquatic organisms are available or for certain lower-order streams, the converse may also be true depending on the size of the drainage and the persistence of the pollutant in question. As stated previously, EPA considers it inappropriate for EPA to develop site-specific criteria for California EDWs. The averaging periods of EPA proposed criteria for toxics are based on data from nation-wide laboratory toxicity tests. The once-in-three-years frequency of exceedence is based on field data. With the concurrence of EPA, States may adopt site-specific criteria, including potentially different averaging periods and frequencies of allowed excursions, for individual or appropriate categories of water bodies. The kinds of data necessary to justify adoption of such criteria may be determined by reviewing the studies referenced in Appendix D of the Technical Support Document and following procedures described in Chapter 3 of EPA's Water Quality Standards Handbook

(EPA-823-94-005a, August 1994

With regard to the adjustment of low-flow values (although this issue concerns implementation of proposed criteria, and is thus also more appropriate for the State to consider), the once-in-ten-year seven-day average low flow design condition (7Q10) has historical precedent and is part of many States' water quality standards. In addition, this value approximates the same degree of protection as the three-year return interval of the proposed acute and chronic criteria. Given the state of the science, and the limitations of available data, EPA as a matter of policy takes the position that it should assure adequate protection and takes a conservative approach to establishing water quality criteria. This policy is also consistent with and recognizes historic program practices and procedures used by both the Agency and the States in implementing the water quality standards and related implementation programs. (Guidelines for Developing or Revising Water Quality Standards, April 1973, p.7.)

Comment ID: CTR-081-004a
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES C-24e

Comment: * EPA should consider adopting separate, scientifically defensible and reasonably achievable aquatic life criteria for waters that are effluent-dependent for all or part of the year. In addition, the aquatic life criteria should be applied to those waters identified in the Basin Plans instead of "all waters. "

Response to: CTR-081-004a

Concerning the issue of adopting separate aquatic life criteria for effluent-dependent waters, see the response to CTR-034-007.

Concerning the issue of application of those criteria to waters identified in the Basin Plans, EPA considers that, withrespect to protection of aquatic life, the proposed CTR criteria apply to all waters in the State of California except for those covered by the NTR, as amended or those covered by an EPA approved site-specific criterion or basin plan objective. If the aquatic life use designation is considered inappropriate, it may be removed only where a use attainability analysis is conducted and approved, as described further in response to CTR-036-009.

Comment ID: CTR-085-014
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97

Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* The EPA should adopt separate, scientifically defensible, reasonably achievable aquatic life criteria for streams and creeks that are dominated all or part of the year by discharges from anthropogenic sources, such as POTW's (i.e., effluent dependent waters).

Response to: CTR-085-014

See response to CTR-034-007.

Comment ID: CTR-089-006
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Incorporation of the Inland Surface Water Plan Task Force Recommendations

A final issue is whether the draft CTR gave adequate consideration of the recommendations of the state's Inland Surface Water Plan (ISWP) Task Force. The ISWP Task Force was created specifically to address the court-mandated need for multiple-stakeholder input in the state's implementation of the Clean Water Act. The ISWP Task Force included at least two groups (Toxics task force and Effluent Dependent Waterbody task force) specifically charged with making recommendations for the adoption of toxics criteria in the state's inland waters.

The absence of any criteria for toxics in effluent,-dependent waterbodies causes us to wonder how the draft CTR incorporated the recommendations of the ISWP task force. The issue here is that criteria that are too strict may cause dischargers to seek alternative disposal options, which could result in stream wildlife impacts greater than those resulting from substandard water. This issue is paramount in the state's arid regions, where the availability of water of any quality can dictate whether aquatic life exists at all. The rebuttal position that dischargers should be forced to treat the water anyway ignores the fact that, if treated to these standards, the water becomes valuable for other uses such as recycling, which dischargers are legally-entitled to pursue. Indeed, state water policy is to encourage water recycling

efforts specifically to offset the need to import water from the state's less arid regions and the Colorado River Basin.

Response to: CTR-089-006

See the response to CTR-034-007. Concerning incorporation of the Inland Surface Water Plan Task Force Recommendations, see also response to CTR-057-003.

Comment ID: CTR-096-006
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

Specifically, the City submits the following comments:

C. EPA should adopt separate scientifically based aquatic life criteria for rivers that maybe dominated all or part of the year by discharges from anthropogenic sources, such at POTWs (i.e. effluent-dependent waters).

Response to: CTR-096-006

See response to CTR-034-007.

Comment ID: CTRH-002-012
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: However, there are several areas in which we would like to request the EPA make changes. For example, we'd like to see EPA adopting separate aquatic life criteria for streams and creeks in arid areas that are dependent for most or all of their flows on discharges from wastewater treatment facilities.

Response to: CTRH-002-012

See response to CTR-034-007.

Comment ID: CTRH-002-020
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: C-24d SSC Effluent Dependent Wtr
References:
Attachments? N
CROSS REFERENCES

Comment: The final issue that I would like to present concerns the need for recognition in the CTR for effluent dependent waters. Many POTWs in Southern California discharge to waterways that would otherwise be nonexistent during the dry seasons. This has allowed for the establishment of aquatic habitats and other beneficial uses in those waterways. Since it is not an isolated concern, this issue needs to be recognized. If CTR rule-making is limiting itself to establishing a conservative water quality criteria that assures protection of all waters regardless of its condition, then a mechanism needs to be provided in CTR to deal with the EDS issues. EPA cannot simply deny us the designation of Categories A, B and C in the old Inland Surface Water Plan; instead, this issue must be addressed.

Response to: CTRH-002-020

Concerning the first part of this comment see the response to CTR-036-009 above.

Concerning the comment that a mechanism needs to be provided in CTR to deal with the EDW issues, EPA considers that by incorporating variables of hardness, water effect ratios and pH as appropriate into the proposed CTR criteria as described further in response to CTR-034-007 above, it has provided such a mechanism. Beyond such adjustments, criteria would have to be further revised by means of a use attainability or other site-specific analysis, which should be conducted at the State or local level as described in response to the fourth recommendation in CTR-040-016a, above.

Concerning the comment that EPA cannot simply deny California the designation of Categories (a), (b) and (c) in the old Inland Surface Waters Plan: EPA's action in only partially approving California's Inland Surface Waters and Enclosed Bays and Estuaries Plans was to conclude that deferral of adoption of toxics criteria for categories (a) and (b) and the exemption from coverage of category (c) were inconsistent with CWA section 303(c)(2)(B). EPA would be willing, pursuant to its Guidance for Modifying and Protecting Effluent Dependent Ecosystems, to consider application of alternate uses that would lead to less stringent criteria. Thus, EPA did not "deny ... the designation" of EDWs, as is alleged in this comment, as much as disapprove the deferral and exemption of these waters from having any criteria for toxics.

Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses

Comment ID: CTR-013-006b
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References: Letter CTR-013 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES I-04

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

6. The proposed criteria will apply to all inland surface waters and enclosed bays and estuaries, regardless of the designated or attainable uses for a water body. This is of particular concern for waters that only have flows during wet weather events or that are point source effluent dominated water bodies. Blanket application of water quality criteria to all waters without designated uses is inconsistent with Federal and State water quality laws. Water quality standards are made up of two components--designated uses and the appropriate criterion to ensure the designated use can be achieved. Assigning criteria to a water body without first considering the designated uses is inappropriate and could result in over restrictive, unnecessary permit limits potentially resulting in significant compliance costs to a discharger.

It is common in California for urban stormwater runoff discharges to be the primary or only source of waters to urban creeks and waterways, that is, there would be little or no flow during most of the year were it not for urban stormwater or other point source discharges. Given the potential compliance problems for stormwater discharges forcertain constituents (even after a fully implemented BMP program), a municipality could be forced to remove stormwater discharges from the creek. The costs would be significant and the benefit little, if any. In fact, the removal of these discharges would be environmentally damaging to aquatic life and wildlife that were supported by the effluent/runoff dependent waters.

Therefore, the proposed rule should be revised to avoid blanket application of the proposed criteria to all surface waters and to require appropriate beneficial and attainable uses of all waters be determined prior to imposing water quality criteria in the water body. The rule should also be revised to implement separate and distinct water quality criteria for water bodies that are primarily effluent or runoff-dependent.

Response to: CTR-013-006b

As discussed in the preamble, the purpose of today's rule is to establish numeric criteria for those navigable waters in California that do not have criteria for priority toxic pollutants in place. The State has in place specific use designations that were duly adopted by the State through its Regional Water Quality Control Board's Basin Plans which include aquatic life, human health and other uses to be protected in particular waterbodies. Thus, EPA, in this rulemaking, is not revising those use designations established by the State.

Furthermore, EPA encourages the commenter to work with the State in its review and adoption of the Basin Plans to refine those use designations that the commenter believe might be inappropriate. Such review could encompass a use attainability analysis to determine if the designated uses need to be changed to reflect uses that are no longer attainable, provided that the existing uses (those uses established on or after November 28, 1975) are still protected. A use attainability analysis is an assessment of physical, chemical, biological and economic factors that affect the attainment of a use.

Comment ID: CTR-020-017
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

6. Human Health Criteria Application

These stringent criteria, which are based upon the assumption that two liters of water is consumed per day, are specified to apply to all surface waters with a MUN designation. This is a default designation for many waters in the various Basin Plans and means that ditches and other water bodies that clearly have no actual or extremely limited drinking water use potential will be regulated more stringently than tap water for many pollutants. This is an overly broad application of the federal criteria and is unnecessary to ensure appropriate public health protection. EPA should revise the rule to specify that consumption-based criteria will only apply to waters in the vicinity of water intakes which will allow for consideration of fate and transport of pollutants before determining that a potential public health threat exists. Likewise, fish consumption-based criteria should only apply where the Department of Fish & Game determines that there is a reasonable likelihood of the presence of a game fishery. If such a fishery is not present, there will be no human exposure to the pollutants justifying implementation of stringent point or non-point controls.

Response to: CTR-020-017

EPA disagrees that the application of the human health criteria in waters that have a MUN designation is unnecessary to protect public health in California. EPA believes that the application of the human health criteria that considers exposure from both fish and drinking water consumption in waters that have a

MUN designation is appropriate and consistent with State practices and regulatory requirements (Section 131.11 of the Water Quality Standards Regulation requires the adoption of criteria to protect the uses of state waters). The State assigns the MUN designation to waters that are potential or actual drinking water supplies. Since EPA has no intention of changing the uses designated by California in this rulemaking. EPA encourages the commenter to work with the State in its review and adoption of the Basin Plans to refine or modify those use designations that the commenter believe might be inappropriate.

Comment ID: CTR-026-001b
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES A

Comment: 1 . DESIGNATED USES AND ANTIDEGRADATION POLICY

The DFG is concerned with the issues of "designated uses" and an "antidegradation policy" as they apply to the formation of water quality standards. It is our understanding that water quality standards are comprised of, or defined by, three components: 1) designated uses, 2) numeric water quality criteria, and 3) an antidegradation policy. The CTR is not clear on which designated uses are being identified and when they were established. The rule needs to identify what designated uses are being assigned and when these uses were or should be attained. At issue is which uses should be maintained and protected, and what the baseline should be for designating the various beneficial or designated uses for inland freshwater and bay and estuarine waters of the state. We believe that any baseline for applying the antidegradation policy should establish what the quality of the water would have been historically in the absence of human impacts. Under the Porter Cologne Act, the State's primary water quality statute, the dischargeof waste into state waters is not a right but a privilege. Since the discharge of waste is not considered a beneficial use, it should not be permitted in public waters unless it is determined that all beneficial uses, especially publicly entrusted fish and wildlife resources, are fully protected. This is especially true for wetlands throughout the State. The proposed rule is not clear as to when the baseline starts (i.e., historical vs. statutory). The DFG believes that, to the extent practicable, designated uses should be reflective of what has been realized in the past. If the CTR is utilizing a statutory date for which baseline designated uses were identified, then the CTR needs to include a justification for such a date.

With respect to antidegradation, it is not clear whether or not the proposed rule is subject to these requirements. It is our understanding that when a proposed action would allow less stringent criteria than previously proposed or adopted, and if that action would result in more loading of a particular constituent into waters of the State, then an appropriate antidegradation analysis shall be required. It is not clear what process EPA has undertaken to adequately address antidegradation issues related to the proposed new criteria. It may be that the applicability of the antidegradation policies are more pertinent with respect to site-specific criteria that may be included in the final rule. We recommend that the CTR adequately address this issue and apply the antidegradation policy where necessary.

Response to: CTR-026-001b

See response to CTR-013-006b. For a response to antidegradation issues, see response to CTR-026-001a.

The purpose of this rule is to establish numeric criteria for those waters identified in the State's Basin Plans that were duly adopted by California's Regional Water Quality Control Boards that do not have water quality criteria for priority toxic pollutants in place. These Plans have specific use designations for waterbodies that were duly adopted by the State through its Regional WaterQuality Control Boards' basin plans that identify aquatic life and human health uses to be protected in particular waterbodies. EPA, in this rulemaking, is not revising or establishing the use designations for waters contained in the State's Basin Plans. The review of those uses designations established by the State are outside of the scope of today's rule. Furthermore, EPA does not believe that an evaluation of the use designations or a discussion on the dates those uses were assigned is within the scope of this rulemaking action. However, EPA does note that in today's rule and in the proposed rule (see 40 CFR 131.36(d)(1) through (d)(3)), the Agency identifies the water use classifications that are subject to this Federal rule.

Comment ID: CTR-027-007b
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES I-04

Comment: 7. The proposed criteria will apply to all inland surface waters and enclosed bays and estuaries regardless of the designated or attainable uses for a water body. This is of particular concern for waters that only have flows during wet weather events, or that are point source effluent dominated water bodies. Blanket application of water quality criteria to all waters without designated uses is inconsistent with federal and state water quality laws. Water quality standards are made up of two components - designated uses and the appropriate criteria to ensure the designated use can be achieved. Assigning criteria to a water body without first considering the designated uses is inappropriate and could result in overly restrictive, or unnecessary permit limits, potentially resulting in significant compliance costs to a discharger.

It is common in California for urban stormwater runoff discharges to be the primary or only source of waters to urban creeks and waterways; that is, there would be little or no flow during most of the year were it not for man's activities. Given the potential compliance problems for stormwater discharges for certain constituents (even after a fully implemented BMP program) a municipality could be forced to remove stormwater discharges from the receiving water. The costs would be significant and the benefit little, if any. In fact, the removal of these discharges would be environmentally damaging to aquatic life and wildlife that were supported by the effluent/runoff dependent waters.

Recommendation: The proposed rule should be revised to avoid blanket application of the proposed criteria to all surface waters, and to require appropriate beneficial and attainable uses of all waters be determined prior to imposing water quality criteria in the water body. The rule should also be revised to

implement separate and distinct water quality criteria for water bodies that are primarily effluent or runoff dependent waters. An example of such flexibility is the use of a less stringent cancer risk factor such as 10E-4 or 10E-5 for the human health criteria for effluent dominated streams.

Response to: CTR-027-007b

See response to CTR-027-007a.

Comment ID: CTR-035-007
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: EPA should apply the aquatic life criteria only to those waters identified in Regional Water Quality Control Plans ("Basin Plans") as having full aquatic life use designations, rather than to "all waters," in the same way that the human health criteria for water and organisms are applied only to those waters designated in Basin Plans with the municipal drinking water supply, beneficial use ("MUN" use).

Response to: CTR-035-007

See response to CTR-081-004b.

Comment ID: CTR-035-038
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42207 -- Beneficial Use Designations (Applicability of Criteria) We are concerned about what appear to be overly broad statements in the proposed regulation regarding the applicability of the criteria. We recommend that EPA remove the following statement contained in section 131.38(d)(1) of the regulation: "Although the State has adopted several use designations for each of these waters, for purposes of this action, the specific standards to be applied in paragraph (d)(2) of this section are based on the presence in all waters of some aquatic life designation and the presence or absence of the MUN use designation (municipal and domestic supply)" (62 Fed. Reg. 42207) (emphasis added). We also

request that EPA delete from the regulation the statement that begins this paragraph, which states that "Except as specified in paragraph (d)(3) of this section, all waters assigned any aquatic or human health use classifications in the Water Quality Control Plans for the various Basins of the State... are subject to the criteria in paragraph (d)(2) of this section, without exception." We recommend that EPA modify the applicability of the rule to reflect its full evaluation of those specific water bodies where each pollutant is found to be "adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern" (40 CFR section 131.11) (see comments on p. 1-2).

Further, we believe that, contrary to EPA's assertion on p. 42168 of the Preamble that the aquatic life criteria are applicable to all waters of the U.S., the freshwater aquatic life criteria may be inappropriate for application to streams and creeks that are dependent on flows for all or part of the year on discharges from anthropogenic sources, such as POTWs. We request that EPA establish separate, scientifically defensible aquatic life criteria for such water bodies. Several of our comments above have suggested ways that may be appropriate to modify certain types of criteria. Until this issue is addressed, we oppose the application of the criteria contained in the proposed CTR to effluent-dependent waters in the State of California.

Response to: CTR-035-038

See response to CTR-036-005.

Comment ID: CTR-040-018d
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-26;G-03; C-30

Comment: V. Recommendation: Delete all provisions in the Rule that preempt the States flexibility in permitting. The Rule provides specific direction on the adoption of averaging periods, low flow values, effluent limitations for criteria not being adopted as a part of the Rule, and that the aquatic life criteria be applied to all waters irrespective of designated use, etc..

* The Preamble and the Rule's economic analysis make a point that the State has considerable flexibility in establishing permit limitations. In making, that point, EPA implies that the State may implement the criteria in a manner that would have little or no adverse economic impact on dischargers.

* However, the Rule contains a number of implementation provisions that are not required under Section 303(c)(2)(B), but serve to preempt the State's flexibility. These provisions include, but are not necessarily limited to the adoption of averaging periods and low flow values, directives regarding the establishment of effluent limitations for criteria that are not being adopted as a part of the Rule, and application of the aquatic life criteria to all waters irrespective of the designated use.

* Not only does EPA not have a duty to adopt these provisions, but also the provisions are more restrictive than those required by the CWA or EPA regulations, They clearly restrict the State's flexibility. In fact, other states have adopted, and EPA has approved, implementation provisions (e.g., averaging periods and low flow values) which are less restrictive.

* For these reasons, EPA should remove all such implementation provisions from the Rule.

Response to: CTR-040-018d

See response to CTR-081-004b.

Comment ID: CTR-049-005
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

3. Apply the aquatic life criteria to those waters identified in Regional Water Quality Control Plans ("Basin Plans") as having aquatic life uses, rather than to "all waters;" and

Response to: CTR-049-005

See response to CTR-081-004b.

Comment ID: CTR-056-013
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Apply aquatic life criteria to those waters identified in the Regional Water Quality Control Plans (i.e., Basin Plans) as having aquatic life uses, in lieu of adopting criteria for "all waters" of the State.

Response to: CTR-056-013

See response to CTR-081-004b.

Comment ID: CTR-066-012
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requesed changes include the following:

* EPA should apply the aquatic life criteria to those waters identified in Regional Water Quality Control Plans ("Basin Plans") as having aquatic life uses, rather than to "all waters."

Response to: CTR-066-012

See response to CTR-081-004b.

Comment ID: CTR-081-004b
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES C-24d

Comment: * EPA should consider adopting separate, scientifically defensible and reasonably achievable aquatic life criteria for waters that are effluent-dependent for all or part of the year. In addition, the aquatic life criteria should be applied to those waters identified in the Basin Plans instead of "all waters."

Response to: CTR-081-004b

Today's rule applies to those navigable waters in California that do not have numeric criteria for priority toxic pollutants in place. This encompasses waters of the U.S. for which the State has duly adopted use

designations through its Regional Water Quality Control Plans, including those waters that are effluent and flow dependent streams. The criteria in this rule are based generally on EPA's national criteria guidance which are applicable and appropriate for all waters of the U.S. However, if a state finds that the ambient water quality criteria for a waterbody are inappropriate, then EPA's Water Quality Standards Regulation provide for a use attainability analysis and establishment of appropriate use designations.

For waters of the U.S. which have human health uses designated in the Regional Board's Basin Plans, aquatic life is present and fish or other aquatic organisms are being caught and consumed. Therefore aquatic life criteria and human health criteria based on the consumption of fish are applied to those waters except where the State has conducted and EPA has approved a use attainability analysis to remove or modify the aquatic life use or fish consumption use. Furthermore, for waters with a MUN designation, human health criteria that considers exposure from water and fish are applied to those waters. These approaches are consistent with EPA's Water Quality Standards Regulation (40 CFR Part 131) which requires States to include uses identified in Section 101(a) of the Clean Water Act, where attainable, and to establish criteria to protect those use designations.

Comment ID: CTR-082-006
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* USEPA should consider application of the aquatic criteria to be limited to those waters identified in the Regional Water Quality Control plans (Basin Plans) as having aquatic life uses rather than to "all waters."

Response to: CTR-082-006

See response to CTR-081-004b.

Comment ID: CTR-085-015
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses

References:
Attachments? N
CROSS REFERENCES

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* The EPA should apply the aquatic life criteria to those waters identified in Regional Water Control Plans ("Basin Plans") as having aquatic life use, rather than to "all waters."

Response to: CTR-085-015

See response to CTR-081-004b.

Comment ID: CTR-096-007
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-24e SSC Desgntd/Beneficial Uses
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

Specifically, the City submits the following comments:

D. EPA should apply the aquatic life criteria to those waters identified in Regional Water Quality Control Plans ("Basin Plans") as having aquatic life uses, rather than to "all waters".

Response to: CTR-096-007

See response to CTR-081-004b.

Subject Matter Code: C-25 Hardness

Comment ID: CTR-026-005
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-25 Hardness
References:
Attachments? N
CROSS REFERENCES

Comment: 6. TOTAL HARDNESS DEPENDENT FRESHWATER METALS CRITERIA

The DFG does not object to the development of freshwater metals criteria that take into account the effect of total hardness on metals toxicity, with the exception of the comments on criteria development stated above. The DFG does recommend, though, that the proposed rule clarify the tables (page 42169) that reflect this approach. The tables may be viewed as the specific criteria rather than examples of metals criteria based on the total hardness value of 100 mg/l CaCO[subs]3.

Response to: CTR-026-005

EPA acknowledges the commenter's concern that the hardness-dependent metals criteria may be incorrectly misconstrued as single fixed values, particularly since fixed numbers and hardness-dependent numbers appear in the same table. However, footnote "e" of the table explains the hardness dependency. EPA does not know of a better manner in which to present this information, and the commenter did not offer an alternative as to how to make the information clearer to the a casual reader.

Subject Matter Code: C-26 Avrging pds&Exceedence Freq.

Comment ID: CTR-003-002
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: 2) We agree with commentors who argued that a 4-day average period and a once in three year exceedance frequency is unnecessarily restrictive for chronic criteria exceedances. In fact, it would seem reasonable to assume that isolated exceedances of chronic criteria would have no discernable long term effect on a water body. Further, so long as acute criteria are not also exceeded, a rapid recovery period would seem likely, What case studies and/or laboratory results does EPA have to support this finding? Also, what data is EPA relying on for the three year excursion frequency for acute failures? Based on the evidence of recent major environmental calamities, aquatic systems appear to right themselves very quickly after initial cleanup, typically within one year.

Response to: CTR-003-002

See response to CTR-020-014.

Comment ID: CTR-009-007
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: The rule states that the CMC "equals the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time without deleterious effects." What is a "short period of time" defined as? This definition, as it stands, is vague to the point it will require, and be subject to, various interpretations by different entities and individuals. It puts the regulated community in the position of having to make independent judgments as to what the proscribed activity is, case-by-case. This is inappropriate, and will lead to unnecessary conflict. The City recommends that EPA define "short period of time" more precisely, and present the scientific basis for such definition in the final rule.

Response to: CTR-009-007

EPA does not agree that it is necessary to further define "short period of time" within the rule. The reason that it is not numerically specified is that the appropriate averaging period varies from pollutant to pollutant, and is not as well defined as, nor is as important as, the criteria concentrations, which are numerically specified in the rule. EPA is deferring to the State implementation procedures for the application of acute averaging periods into NPDES permit limit calculations, because these implementation procedures primarily involve mixing zone policies, which are at State responsibility, and are not part of this rule.

Comment ID: CTR-020-008
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and supports the EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

4. Averaging Period for Acute Criteria

The proposed rule does not establish a specific averaging period for acute criteria, apparently abandoning the published criteria recommendation that acute criteria should be applied as one hour averages. EPA now states that the exposure time should be "short." While Stockton concurs that a one hour averaging period is not supported by the underlying data and is inconsistent with the permit development procedures in EPA's 1991 Technical Support Document for Water Quality-based Toxics Control ("TSD"), the failure to explain why EPA is no longer recommending a one hour averaging period will lead to confusion and misapplication of the criteria. At a minimum, EPA should explain that "short" means at least 24 hours so that inconsistencies in permitting do not occur.

Thus, the final CTR should discuss the technical basis for this change and identify the acceptable exposure period.

Response to: CTR-020-008

EPA does not agree. The appropriate acute averaging period is not necessarily greater or equal to 24 hours for each of the pollutants. See response to CTR-009-007.

Comment ID: CTR-020-009
Comment Author: City of Stockton
Document Type: Local Government

State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and supports EPA's update of several water qulaity criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed.

(a) EPA's Characterization of Metals as Fast Acting Toxicants is Erroneous

Water quality criteria established pursuant to Section 304(a) of the CWA classify pollutants as acute, chronic, or human health-based depending on the pollutant's mode of toxicological activity. The classification of a pollutant significantly affects the manner in which criteria are applied and effluent limitations are derived. Many factors affect the proper translation of water quality criteria into NPDES permit limits, including modeling, permit averaging periods, low flow return frequency, mixing zones, and assumptions made in the modeling process. In addition, criteria require appropriate "duration" and "frequency of exposure" factors which are directly related to the time required for exposure to a pollutant to elicit a biological response (e.g., mortality). Any arbitrary reduction of the allowable exposure period (or the acceptable return frequency) establishes more stringent criteria than necessary to ensure use protection.

EPA's proposed acute averaging period recommendation (short) has a substantial effect on mixing zone calculations. This policy assumes that short term exposures to concentrations slightly in excess of the acute criteria can produce mortality to swimming or drifting organisms (ie., the "fast acting toxicant assumption"). If 24-48 hour exposures are acceptable, the acceptable and protective mixing zones would increase substantially. This reduces the costs of compliance and the need to construct expensive diffusers except in situations where true acute toxicity concerns exist.

The CWA section 304(a) criteria and EPA's 1991 TSD establish EPA's position on criteria application. As more ftilly set forth below, EPA's assumption that all heavy metals are "fast acting toxicants" is not supported by EPA's recently completed research which was expressly intended to evaluate this issue as part of the February 15, 1995 National Toxics Rule settlement. EPA has recently acknowledged this fact with respect to copper in its Marine Copper Criteria published on April 14, 1995. Consistent with its CWA section 304 mandate, EPA must modify all metals criteria to accurately reflect the latest infon-nation regarding the toxicological rate of action for metals. To do otherwise is arbitrary and capricious, and EPA must provide the public with the results of the recent scientific research about characteristics of each pollutant and their proper averaging period.

Response to: CTR-020-009

EPA does not agree. EPA has not assumed that all toxicants are fast-acting for purposes of applying the CMC to define permit limits. The provisions of the rule were specifically designed not to incorporate such an assumption. EPA is deferring to the State implementation procedures for the application of acute averaging periods into NPDES permit limit calculations.

Comment ID: CTR-020-010
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

(1) Short (One Hour) Acute Averaging Period for Metals is Unnecessarily Restrictive and Without Any Technical Basis

The chronology of EPA's one hour averaging period illustrates a continued adherence to the outdated "fast acting toxicant" assumption that is unsupported. As the following discussion shows, the Agency has acknowledged a dearth of scientific support for the one hour assumption through repeated Freedom of Information Act ("FOIA") requests. Recently EPA released the analytical data underlying its time/toxicity assumptions for metals which confirm metals are not "fast acting."

Acute criteria are generally developed based on 48-96 hour exposures.(*1) In establishing its criteria, EPA arbitrarily reduced "acute" exposures to one hour without any supporting data and continues to assert that the one hour or short acute averaging period is appropriate. Actually, acute criteria underwent two transformations. EPA initially determined the 96 hour no effect concentration to establish the numeric criteria; it then arbitrarily reduced the allowable exposure period from 96 hours to one hour without a corresponding adjustment to the numeric criteria or a determination that this additional adjustment was necessary.

(2) Initial Agency Research on Issue

EPA has been in the process of reconsidering the historically recommended one hour acute averaging period for over eight years. In October 1989, the Agency completed an internal report specifying that existing averaging periods for acute and chronic criteria may be unduly restrictive and that more reasonable approaches may be implemented.(*2)

In response to comments on EPA's 1991 TSD, the Agency admitted that:

The one hour acute averaging period was derived primarily from the data on response time for toxicity to ainmonia, a "fast acting toxicant."(*3)

Research performed by Mancini (1983), cited in the 1991 TSD, verifies EPA's assumption is incorrect.(*4) Erickson (1989) noted that for fathead minnows, copper LC50s increase gradually by a

factor of two (2) between the 96 hour and 12 hour exposure durations. LC50s were ten-fold higher at two to three hours than at 96 hours.(*5) This is hardly a "fast acting" toxicant. Research by Brown (1974) indicated that a one hour exposure of rainbow trout to copper elicited no acute response at twenty times 96-hour LC50 concentrations.(*6)

(3) EPA Commits to Reevaluate the Fast Acting Toxicant Assumption

At the January 1993 Annapolis Conference, EPA and academic scientists, including state regulatory officials, called on the Agency to assess whether overly conservative assumptions are leading to permit limitations which can be orders of magnitude more stringent than needed to protect aquatic life uses. EPA identified several high priority research goals, including the accurate assessment of toxicological kinetics of metals and committed to address whether metals are, in fact, "fast acting" toxicants.(*7)

At a public meeting of EPA's Criteria Review Committee in June 1993, the Science Advisory Board presented copper mortality data that confirmed copper concentrations many orders of magnitude higher than current acute criteria would be required to elicit mortality within a one hour exposure time (Exhibit 3). EPA stated its intention was to utilize such time/mortality studies to derive an appropriate criteria averaging period:

The Committee tentatively intends to incorporate the use of a kinetic model of toxicity into the Guidelines. This model allows more rigorous use of data from toxicity tests, and should better represent the effects of time-varying concentrations occurring in ambient applications... The data on the time course of mortality would yield a rate coefficient indicating how quickly mortality occurs. This rate coefficient would replace the current averaging period.(*8)

Unfortunately, EPA revealed a lack of urgency in addressing the toxicological speed of action issue for metals, leaving many dischargers exposed to unnecessarily stringent requirements. An October 27, 1993 letter from the Assistant Administrator for Water stated:

"...the analysis is not yet complete. Once completed, we will circulate it for public review... Completion, of course, is dependent on available resources, particularly in light of competing statutory and court-ordered mandates."(*9)

Ironically, EPA in the same letter disclosed that the one hour averaging period for metals is a "default value" without any technical basis:

"EPA does not have any specific data on metals discharged near or above criteria levels showing acute impacts in one which is expected to be protective for both fast-acting and slower toxicants."(*10)

In early 1994, EPA asserted it was actively addressing the recommendations made at the Annapolis Conference that toxicant speed of action be revised, and in correspondence to the Pennsylvania League of Cities and Municipalities, the Agency asserted that data analyses were underway at that time:

"You have raised several questions concerning the speed of action of toxic effects of metals. We agree that this issue warrants further investigation. Our plan is to definitively address the issue with a new criteria methodology which will explicitly incorporate data with regard to speed of action on a pollutant-by-pollutant basis. Our present policy is to make a single, conservative assumption on speed of action for all pollutants, in the absence of appropriate data and methodologies to do the pollutant-by-pollutant analysis. We are investigating whether we have sufficient information to issue interim guidance now, modifying this policy on speed of action for some pollutants or classes of

pollutants."(*11)

(4) Results of AnaIysis Confirm Metals Are Not Fast Acting

In a February 28, 1994 response to a FOIA request, EPA acknowledged that data pertaining to toxicity/time relationships for metals are available and that preliminary analyses of available data indicate that the one hour period is unnecessarily conservative:

...the averaging period for copper, zinc, and lead would be about 1 day, while cadmium and arsenite would have an averaging period of about 2.5 days.

... for the above metals [copper, zinc, lead, cadmium, and arsenite] their action can be "fast" in the sense that a short exposure can be lethal, but only at somewhat higher concentrations than those which are lethal for exposures of a day or longer. Even the more fast-acting of the above metals would not require an averaging period as short as a few hours, but a major fraction of a day or longer.(*12)

In an August 22, 1994 letter to Rep. Robert Borski, EPA's Assistant Administrator for Water asserted that the Agency was diligently pursuing completion of studies to better define the toxicological speed of action for metals.

"Consistent with the recommendations from this group, EPA hopes to improve our water quality based approach and better characterize the conservative and nonconservative assumptions associated with the methodology. This would include the guidance addressing fast- and slow-acting metals in the Spring of 1995."(*13)

In September 1994, the EPA Aquatic Life Guidelines Committee met to address issues concerning the derivation of aquatic life criteria, including potential modifications to earlier assumptions related to the speed of action:

"Whereas the 1985 Guidelines use only the survival results at the end of 48- or 96-hour tests, the new framework would also use survival counts taken at various times throughout the tests. These data would be evaluated within the framework of a kinetic-based toxicity model (Mancini, 1983; Erickson, et al., 1989), intended to consider the speed at which effects appear in different individuals and different concentrations."(*14)

From the most recent Agency information available, it is apparent that EPA has completed the studies and re-evaluations of criteria development data necessary to derive appropriate averaging periods for metals. EPA has indicated to at least one state that studies of the toxicological kinetics of metals have been completed and that the Agency has concluded that a 24 hour acute averaging period is protective of aquatic life uses based on those studies, as follows:

"The NJDEP has discussed criteria durations with Charles Delos, Ecological Risk Assessment Branch, Health and Ecological Criteria Division, USEPA, Washington, D.C. Our understanding is that the recent reevaluation of "fast acting" toxicants has been completed for cadmium, chromium, copper, lead, mercury, nickel, silver and zinc. The results of that reevaluation indicate that an acute criteria duration of 24 hours would be protective for these metals."(*15)

EPA acknowledged that a 24 hour acute averaging period is appropriate for copper in its April 14, 1995 Ambient Water Quality Criteria for Copper - Saltwater Copper Addendum. This conclusion was consistent with the evaluation presented by Erickson in 1993 and the subsequent letter to the New Jersey

DEP.

(5) Conclusion

Based on the data provided by EPA pursuant to FOIA, there is no scientific basis to assume all pollutants, particularly metals, are "fast acting" toxicants and that the time period necessary to ensure avoidance of acute impacts is "short." In newly issued marine criteria, the Agency acknowledged that a 24 hour averaging period is appropriate for copper (one of the fastest acting metals) and thus should similarly modify criteria application procedures for other metals to be consistent with the available data. The continued application of a one hour or short averaging period for metals in the CTR is scientifically flawed, inconsistent with the available data, and arbitrary and capricious. EPA should re-propose the CTR with the metals acute averaging periods changed from one hour to 24 hours consistent with the research and EPA's conclusions on the marine copper criteria. To the degree that data are available regarding other constituents, the appropriate acute averaging period should be specified for these criteria. If no information is available and the criteria are based upon 96 hour no effect results, the applicable averaging period should not be less than 24 hours, which constitutes a significant margin of safety given the data available in the record and the 96 hour exposure duration used to establish the acute criteria.

(*1) See, USEPA's Ambient Water Quality Criteria for Copper (1984); Ambient Water Quality Criteria for Cadmium (1984); Ambient Water Quality Criteria for Lead (1984); and Ambient Water Qualily Criteria for Zinc (1997).

(*2) Report on the Feasibility of Predicting the Effects of Fluctuating Concentrations on Aquatic Organisms and Possible Application to Water Quality Criteria USEPA ORD (September 21, 1989).

(*3) EPA's Technical Support Document Responsiveness Summary (1991) at 8.

(*4) Mancini, J. A Method for Calculating Effects on Aquatic Organisms of Time Varying Concentrations. 17 Water Res. 1355-1362 (1983).

(*5) Erickson, R., Kleiner, C., Flandt, J., Highland, T. Report on the Feasibility of Predicting the Effects of Fluctuating Concentrations on Aquatic Organisms and Possible Application to Water Quality Criteria. USEPA Duluth Laboratory (September 1989).

(*6) Brown, V.M., et al. Aspects of Water Quality and the Toxicity of Copper to Rainbow Water Research, Vol. 8, p. 797-803 (1974).

(*7) Memorandum from Martha G. Prothro, USEPA, dated April 1, 1993.

(*8) Aquatic Life Guidelines Status Report No. 3 (June 16, 1993).

(*9) Letter from Robert Perciasepe, USEPA, to Congressman Tim Holden, dated October 25, 1994.

(*10) Id. See also, February 22, 1994 letter and ten attachments from C. Delos (EPA) to Jay Himes (Pennsylvania League of Cities and Municipalities) in response to a FOIA request (attached in part hereto as Exhibit 4).

(*11) Letter from Robert Perciasepe, USEPA, to Jay Himes, Pennsylvania League of Cities and Municipalities, dated March 30, 1994.

(*12) Memorandum from Russell Erickson, USEPA, to Charles Delos, USEPA, in response to FOIA request, dated February 28, 1993.

(*13) Letter from Robert Perciasepe, USEPA, to Congressman Robert A. Borski, dated August 22, 1994.

(*14) Delos, C. "Possible Revisions to EPA's Procedure for Deriving Aquatic Life Criteria." Presented at Water Environment Federation (October, 1994), cited in correspondence dated August 17, 1994 as expressing the Aquatic Life Guidelines Committee's views on criteria revision.

(*15) Letter from Lewis J. Nagy, Assistant Commissioner, Policy and Planning, New Jersey Department of Environmental Protection, to Robert Perciasepe, USEPA, dated May 5, 1995.

Response to: CTR-020-010

EPA does not agree that a "short period of time" equals one hour. In consideration of the developments described in the comment, the one-hour averaging period that EPA had previously specified for the CMC, for example in the 1991 TSD, was not incorporated into the rule. See also responses to CTR-020-009 and CTR-009-007.

Comment ID: CTR-020-014
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

3. Chronic Criteria Averaging Periods

Chronic criteria averaging periods have not been updated despite a commitment by EPA to reevaluate this factor as part of the NTR settlement. EPA acknowledges that the chronic criteria are based primarily upon 28 day or longer tests. The chronic criteria are set at the continuous exposure, no effect level. There is no clear rationale why the continuous-safe exposure period was reduced to four days. This affects the selection of design flow used to apply the criteria (7/Q/10 vs. 30/Q/5) and the manner in which the chronic criteria may be applied to wet weather flows. Given EPA's conclusion that these

criteria establish long term no effect exposure levels, continued use of a four day averaging period is unduly restrictive and inconsistent with EPA's regulatory mandate to only establish criteria and implementing procedures that are "necessary" to protect aquatic life uses (40 C.F.R. section 131.2)

(a) Continued Recommendation of Four Day Averaging Is Inconsistent with the National Guidelines

The National Guidelines and EPA's 1991 TSD recognize that the federally recommended return frequency and low flow (7/Q/10) for applying chronic criteria were based on studies of ecosystems recovering from high exposures (spills) causing acute stress. The application of acute criteria to stringent low flows and use of acute bioassay tests has addressed that concern and prevents acute stress from occurring more frequently than once in ten years. Therefore, it is no longer rational to conclude that minor chronic stress needs to be regulated as rigorously as avoidance of acute stresses (which was one of the underlying purpose of the reduced averaging period and return frequency policy). To a certainty, there is no information in EPA's record showing that exceeding chronic criteria levels over a four day period once in three years has ever been associated with discernible adverse impacts. To the opposite, field studies reported in the 1991 TSD indicate that chronic criteria are very conservative and that longer term exposures which allow four day averages well above the chronic value do not result in adverse impacts on beneficial uses when applied on a once in three year exceedance frequency.

The preamble to the CTR speculates that it is necessary to utilize a four day averaging period to reflect the shorter life span of certain organisms. The only organisms with such short life spans are insects that reproduce rapidly and abundantly. The conservative three year return frequency is not related to the time period necessary for insects to recover from minor chronic stress. This value was based on fish re-population which occurs much more slowly. Accordingly, there is no apparent technical relationship between the underlying basis for the acceptable return frequency and the need to add further conservatism to the chronic averaging period. As the return frequency was based on fish populations, the acceptable averaging period should also reflect that type of organism. Clearly, a thirty day averaging period, consistent with the duration of the chronic tests, should be acceptable and ftilly protective of beneficial uses.

EPA's latest research, which was released pursuant to FOIA requests, indicates that for chronic criteria, a two to five percent exceedance frequency (versus 0.4 percent) should not result in adverse use impacts and would be acceptable. Moreover, as noted above, all research on the standards to permits process confirms that the existing procedures add an additional "level of protection" to conservatively developed criteria. Given this information, EPA should update its chronic criteria application procedures to at least reflect those found approvable - chronic criteria thirty day averaging for Maryland and Colorado

Response to: CTR-020-014

The final rule has been modified to allow the state, with EPA approval subsequent to public comment, to use alternate values for the chronic averaging period and for the exceedance frequency. EPA is certain that the four-day chronic averaging period and three-year return interval provide, at a minimum, a very high degree of protection, as explained in the 1991 Technical Support Document for Water Quality-based Toxics Control. Nevertheless, to allow consideration of current and future developments in the science underlying these parameters, the rule incorporates the flexibility of allowing the State to use of alternate values, with EPA approval, following public comment on any change.

Comment ID: CTR-020-015

Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

4. Statistical Modeling

The proposed rule specifies the exceedance frequency (once in three years) and averaging period and list a number of return flows that may be used to ensure that the specified return frequency is not exceeded. The preamble also discusses the availability of alternate modeling approaches to more directly demonstrate that criteria compliance will occur as intended, such as statistical or probabilistic modeling. However, the CTR itself fails to specify that statistical modeling may be used to apply the criteria. This should be clarified in the final rule.

Response to: CTR-020-015

EPA favors the use of statistical and dynamic modeling and does not intend for the rule to preclude such modeling. In implementing the rule's criteria, the state may employ either steady state design flows or statistical or dynamic modeling.

Comment ID: CTR-035-020
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42174 --Chronic Averaging Period In general, we believe that EPA's proposed use of 4-day averaging periods for chronic (CCC) averaging periods is too short. The averaging period of four days recommended in EPA guidance is much shorter than the toxicity tests upon which the chronic criteria are

based, which is typically 20-30 days. This has the effect of incorporating an additional level of conservatism that has been estimated to be equivalent to a safety factor of two (Delos, 1990). Therefore, EPA should adopt longer averaging periods for chronic criteria for some constituents (for instance, for those metals for which the scientific studies show that metals do not act as fast as the criteria averaging periods would indicate). We recommend that EPA review the toxicity tests used and establish averaging periods that match the effects duration, even if they are different for different criteria. In addition, EPA should provide that any NPDES permits issued after the CTR is finalized should be subject to a reopener to allow for the insertion of a different averaging period in effluent limitations if the ongoing EPA analysis of the chronic design conditions as part of the revisions to the 1985 guidelines (referenced on p. 42174) leads to longer averaging periods.

Response to: CTR-035-020

EPA does not agree that a 4-day chronic averaging period is always too short. This averaging period is primarily based on the shortest duration in which effects appear in the Ceriodaphnia 7-day chronic test. However, EPA agrees that the 4-day chronic averaging period may not be appropriate for all pollutants, and has modified the final rule to allow use of alternate averaging periods. See also responses to CTR-020-014 and CTR-060-012.

Comment ID: CTR-035-028
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42182 -- Averaging Period for Acute Criteria (CMCs) EPA should identify a specific duration for acute (CMC) criteria beyond the current description of "short term" and provide an explanation of this choice. We believe that in many cases (e.g. metals) recent data suggest that the constituents are not as fast-acting as once-believed and that 24-hours is a more appropriate acute averaging period than the 1-hour averaging period previously used. Therefore, we recommend that EPA adjust the acute averaging periods to reflect such information.

Response to: CTR-035-028

See responses to CTR-009-007, CTR-020-010, and CTR-020-014.

Comment ID: CTR-035-031
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42184 -- Frequency of exceedence We believe that adoption in the regulation of the proposed exceedence frequency, once in three years for acute and chronic criteria, should be deferred until EPA completes its review of this issue. As EPA points out, there are numerous scientific issues being reexamined. For streams in and areas, for instance, EPA should consider that annual flooding and scouring may occur, as well as droughts (leading to no flow during the dry season), and the natural communities adapted to these environments may be capable of recovering from such major disturbances in a year or less. Since EPA does not include any evidence in this rulemaking to support the application of this allowable frequency in California, we recommend that EPA not formalize this policy in the CTR.

Response to: CTR-035-031

See response to CTR-020-014.

Comment ID: CTR-036-007a
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES G-03

Comment: We are concerned that EPA has preempted the State's flexibility by establishing averaging periods for applying acute and chronic aquatic life criteria and for establishing low flow conditions that must be used in developing limits based on the proposed criteria. We recommend that such implementation issues remain within State authority.

Response to: CTR-036-007a

See response to CTR-020-009.

Comment ID: CTR-037-007
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.

References:
Attachments? N
CROSS REFERENCES

Comment: 7. EPA is requiring, by rule, that the averaging period for the CMC be 1 hour. However, EPA is also working towards new methods to calculate water quality criteria which acknowledge that the CMC averaging period should probably be closer to 24 hours. This is not being acknowledged in the rule even though the Agency has released this information at various meetings. The one hour averaging period for the CMC is overly stringent and should not be adopted by rule. The averaging period for the CMC being proposed is not technically defensible and arbitrary, therefore it should be removed from the rule until EPA finalizes its study of the issue.

Response to: CTR-037-007

See responses to CTR-020-010 and CTR-020-009.

Comment ID: CTR-037-009
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: 9. EPA is requiring that criteria not be exceeded more than once every three years, on average, EPA, however, is ignoring the fact that this exceedance rate is based on catastrophic events and that minor exceedances require much less time for biological communities to reach their pre-exceedance conditions. This rule is adopting a requirement which often-times will be overly protective with little or no environmental benefit. The basis of the three year exceedance requirement has been acknowledged by EPA's Aquatic Life Criteria Work Group as conservative and unnecessary when exceedances are minor. The rule must be modified to accommodate minor exceedances if justified scientifically. EPA must technically justify the exceedance frequency that it is requiring by rule to insure that resources will not be expended needlessly by permittees.

Response to: CTR-037-009

See response to CTR-020-014.

Comment ID: CTR-040-018a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES G-03
C-30
C-24e

Comment: V. Recommendation: Delete all provisions in the Rule that preempt the States flexibility in permitting. The Rule provides specific direction on the adoption of averaging periods, low flow values, effluent limitations for criteria not being adopted as a part of the Rule, and that the aquatic life criteria be applied to all waters irrespective of designated use, etc..

* The Preamble and the Rule's economic analysis make a point that the State has considerable flexibility in establishing permit limitations. In making, that point, EPA implies that the State may implement the criteria in a manner that would have little or no adverse economic impact on dischargers.

* However, the Rule contains a number of implementation provisions that are not required under Section 303(c)(2)(B), but serve to preempt the State's flexibility. These provisions include, but are not necessarily limited to the adoption of averaging periods and low flow values, directives regarding the establishment of effluent limitations for criteria that are not being adopted as a part of the Rule, and application of the aquatic life criteria to all waters irrespective of the designated use.

* Not only does EPA not have a duty to adopt these provisions, but also the provisions are more restrictive than those required by the CWA or EPA regulations, They clearly restrict the State's flexibility. In fact, other states have adopted, and EPA has approved, implementation provisions (e.g., averaging periods and low flow values) which are less restrictive.

* For these reasons, EPA should remove all such implementation provisions from the Rule.

Response to: CTR-040-018a

EPA does not agree that the averaging periods and low flow values apply to the criteria other than those adopted by this rule. They do not to apply to other State criteria. However, EPA agrees that other averaging periods and exceedence frequencies may be appropriate for the criteria concentrations included in this rule, and has provided for such in the final rule. See response to CTR-020-014.

Comment ID: CTR-060-012
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-26 Avrging pds&Exceedence Freq.
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Over-conservativeness of chronic aquatic criteria due to averaging period

The preamble to the rule (see 62 Fed. Reg. at 42,174, Col. 2) states that most of the toxicity tests used to calculate the chronic criteria were conducted over a 28 day period. However, even though the preamble (see 62 Fed. Reg. at 42,174, Col. 1) acknowledges that "...aquatic organisms can generally tolerate higher concentrations of pollutants over shorter periods of time", EPA proposes in this rule to set the chronic averaging period to 4 days. Consequently, concentrations from longer term (i.e., 28-days) tests, which would generally result in lower concentrations which are considered toxic, are being implemented as 4-day average criteria, even though criteria developed from toxicity tests conducted over a 4-day period would generally result in criteria which are higher. This approach results in criteria that are more restrictive than necessary to protect the state's beneficial uses. The criteria should either: 1) be restated as 28-day average criteria; or 2) be recalculated as criteria representative of 4-day average tests.

Response to: CTR-060-012

The averaging period is shorter than the toxicity tests on which the criterion is based because (a) exposure concentrations in the toxicity tests are nearly constant, (b) exposure concentrations in the field, over the duration of the averaging period, can be rather variable, and (c) variable concentrations yield greater toxicity than a constant concentration equal to the mean of the variable concentrations. Consequently, if the laboratory toxicity tests had employed variable concentrations, the reported effect concentrations (as the mean over the test duration) would be lower than if the test employed constant concentrations. To account for this phenomenon, the criteria averaging period is shorter than the tests on which the criterion is based. Note, however, that EPA is employing flexibility into the rule in order to provide for advances in the state of the science in setting averaging periods. See the response to CTR-020-014.

Subject Matter Code: C-27 Additive/Synergistic Effects

Comment ID: CTR-026-002b
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-27 Additive/Synergistic Effects
References:
Attachments? N
CROSS REFERENCES C-17b
C-29

Comment: 2. PARTIAL PROTECTION BY THE PROPOSED AQUATIC LIFE CRITERIA (FRESHWATER OR SALTWATER)

On page 42168, the proposed rule includes the following language: "EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time." The CTR goes on to state that this approach results in only a "small possibility" of substantial overprotection or underprotection. Obviously, it is underprotection that is of concern to the DFG. The DFG has very serious concerns that criteria are being proposed that protect "most" of the species "most" of the time. We are aware of the protocols that require a minimum of eight specified families be used to develop criteria and that it may be difficult to determine criteria that are one hundred percent protective; however, this does not preclude the real possibility that certain designated uses and aquatic organisms will not be maintained, and or protected, as a result of the proposed criteria. The DFG is also concerned that criteria and protocols developed for specific constituents do not take into account the additive or synergistic effects that contaminant combination may have on aquatic organisms. Another factor that needs to be considered is bioaccumulation, as well as the effect this may have on organisms at higher trophic levels.

As trustee of all the fish and wildlife resources in the State, it is our agency's responsibility to ensure appropriate protection of all fish and wildlife resources, not just "most", and this includes adequate water quality standards. Due to our concerns and the very real possibility of underprotection to aquatic organisms and designated uses, the DFG believes that it may be appropriate to derive the criteria as proposed, and subsequently develop some additional safety factors for inclusion. It is our understanding that this approach was used in the formulation of water quality objectives for protection of aquatic organisms in the California Ocean Plan. In the short term , the safety factor could possibly be realized by the development of a comprehensivebiological monitoring program to determine whether the proposed criteria are indeed fully protective.

Response to: CTR-026-002b

EPA agrees that the numeric values of those criteria that are not expressed as formulas do not account for additive or synergistic effects. However, EPA does not agree that this would mean that the criteria are not sufficient to protect the designated use. EPA has examined the potential for additivity. Data available to EPA suggest that in real world situations, additivity is usually not a significant issue, because most of the toxic stress is usually attributable to a single pollutant, even in systems receiving complex mixtures of discharges from large metropolitan areas.

To illustrate this, consider some 50 samples that EPA collected throughout New York Harbor, an large area extending from the Hudson River to New York Bight, and receiving a large volume of wastewater and runoff from a highly diverse set of discharges, representing a wide range of municipal, industrial, and agricultural activities. Six metals, Ag, Cd, Cu, Ni, Pb, and Zn were measured using clean techniques. For each sample, the toxic equivalents of each metal were calculated as the metal concentration divided by the its criterion. Assuming perfect additivity of toxicity, the toxic equivalents in each sample were added together to obtain the total toxic equivalents. One metal consistently dominated the toxic equivalents in each sample. On average, the combined toxic equivalents of all six metals was only 10 percent greater than the toxic equivalent of the dominant single metal. Among the 50 samples, the maximum ratio of the combined toxic equivalents to the dominant single toxic equivalent was only 19 percent greater than the single dominant toxic equivalent. Consequently, even assuming perfect additivity, the combined contribution of the other metals was minor compared to the contribution of the dominant toxicant.

The comment provides no data indicating that additivity or synergism are in reality significant problems. Nevertheless, the rule's provisions are capable of handling such problems if they exist. First, criteria expressed as formulas with hardness account for the effects of hardness (or lack thereof) and of parameters covarying with hardness. Second, the rule's provision for the water-effect ratio represents the current best technique for adjusting for unknown additive, synergistic, or antagonistic effects, if they exist. Consequently, EPA believes that its criteria are fully protective. Also see response to CTR-026-002a.

Nevertheless, as the commenter represents the State of California, EPA notes that to allay its concerns, if any remain, the State may adopt its own standards more stringent than those promulgated here by EPA.

Comment ID: CTR-029-002e
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-27 Additive/Synergistic Effects
References:
Attachments? N
CROSS REFERENCES C-17a
C-17b
A
C-22
C-29

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The

reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the published guidance documents is "insignificant"(*4); however, in light of the current contamination problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be underprotective because additive and synergistic effects were not considered; and because the effects on wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).

(*5) Id. at 42168.

(*6) Id. at 42172.

Response to: CTR-029-002e

See response to CTR-026-002b.

Subject Matter Code: C-28 Detection Limits

Comment ID: CTR-005-009
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses."

Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. By taking this approach, however, EPA is unable to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act), and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the "safe" approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve down the road, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does not do this, it should evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-005-009

See response to CTR 034-010b and CTR-060-010

EPA disagrees that the Agency should exclude those criteria that are below the method detection limits from this rule. EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by the States at concentrations necessary to protect the designated use. Given this requirement, consideration of analytical detectability is not an appropriate factor to consider when calculating water quality criteria to protect designated uses since they are not related to actual environmental impacts. In consideration of both statutory (CWA Section 303(c)) and regulatory (the Water Quality Standards Regulation at 40 CFR 131.11) requirements that water quality standards, which includes water quality criteria, must be protective of the designated uses of waterbodies, EPA has determined that such consideration of analytical detection limit is not an appropriate factor to consider in developing the water quality criteria component of water quality standards since the detection limits are not related to actual

environmental impacts. This has been EPA's longstanding position since the inception of the water quality standards program in 1965 (see also EPA's discussion on this issue in the National Toxics Rule at 57 FR 60876, 57 FR 60870).

EPA's methodology for deriving aquatic life criteria are primarily based on laboratory bioassays with sensitive aquatic organisms. The results from these tests are analyzed by mathematical procedures outlined in EPA's aquatic life criteria methodology guidelines. EPA's human health criteria are based on protocols generally using toxicity studies performed on laboratory animals such as rats and mice. Thus, EPA's aquatic life and human health criteria are based solely on health effects without regard to chemical analytical methods or techniques. Deleterious effects can occur to both humans and aquatic organisms at concentrations that are below the analytical detection levels.

As previously noted, EPA's Water Quality Standards Regulation requires that criteria be adopted at concentrations that are necessary to protect designated uses. The criteria promulgated today meet that requirement while EPA's policy with respect to regulatory compliance, which is discussed below, takes analytical sensitivity and precision into consideration.

In the preamble of the proposed rule, EPA referenced the Agency's 1990 guidance (Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the united States, memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors and NPDES State Directors) on how water quality based effluent limits for constituents with water quality criteria that are below the sensitivity of official analytical methods can be established. However, EPA acknowledges that in more recent guidance than that cited in the preamble to the proposed rule the Agency recommends use of the Minimum Level (ML) rather than the Method Detection Limit (MDL) for reporting sample results to assess compliance with a water quality based effluent limitation (WQBEL). See Technical Support Document for Water Quality-based Toxics Control, U.S. EPA Office of Water, EPA/505/2-90-001 (March 1991) at page111. The ML, also called the quantification level, is the level at which the entire analytical system gives recognizable mass spectra and acceptable calibration points, i.e., the point at which the method can reliably quantify the amount of pollutant in the sample. More recently, in the Final Great Lakes Water Quality Guidance (see 50 FR 15424, March 23, 1995), EPA included a provision which allowed permitting authorities to utilize the minimum level (ML) for the method specified in the permit to monitor the amount of pollutant in an effluent down to the quantification level. States can use their own procedures to average and otherwise account for monitoring data, e.g., quantifying results below the ML. These results are then used to assess compliance with the WQBEL. See 40 CFR Part 132, Appendix F, Procedure 8.B.

Further, EPA notes that the purpose of today's rule is to establish ambient water quality criteria for priority toxic pollutants in California. Implementation of the criteria, including compliance with water quality based effluent limitations in permits are outside the scope of today's rule. However, the State of California, in its draft implementation procedures for the criteria included in today's rule (entitled "Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California," September 11, 1997) has proposed provisions to address this issue. The State has elected the utilize the minimum levels in determining compliance with WQBELs.

EPA disagrees that there is insufficient data to support the inclusion of priority toxic pollutants in today's rule. In EPA's December 12, 1988 guidance to States on complying with CWA Section 303(c)(2)(B) (Notice of Availability published at 54 FR 346, January 5, 1989), EPA noted that at a minimum, States should adopt criteria for a pollutant if that pollutant was currently present or could potentially be present in State waters the future. EPA's guidance highlighted the Agency's position that any information indicating that a pollutant was discharged or present in a waterbody is justification that a pollutant could

be reasonably expected to interfere with the designated uses, and therefore would need to be included in a State's water quality standards regulation. EPA has determined that adequate information exists in the rulemaking record to show that the priority toxic pollutants in today's rule can be reasonably expected to interfere with the designated uses of waters in California. Moreover, since these criteria are ambient criteria, they do not in and of themselves require control of a discharge. Only where a discharge has a reasonable potential to exceed the water quality criterion would an effluent limit for that pollutant be placed in an NPDES permit. See Response to CTR-003-010b and CTR-036-005.

In promulgating today's rulemaking, EPA is complying with the same Section 303(c)(2)(B) guidance issued to the States. Thus, the lack of widespread monitoring data or data that does not meet analytical detection limitations is not a sufficient basis for excluding numeric criteria for priority toxics from today's rule. As EPA previously stated, consideration of analytical detection limits is not appropriate in establishing criteria. EPA also notes that the commenters did not submit any analyses or information to support the assertion that the coverage of priority toxic pollutants included in today's rule is based on insufficient or reliable data. In addition, EPA further notes that the priority toxic pollutants included in today's rule are the same priority toxic pollutants that the State of California had previously adopted in the Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan to comply with CWA Section 303(c)(2)(B). Thus, the inclusion of the numeric criteria for priority toxic pollutants in today's rule is justified.

EPA disagree with the commenter's assertion that the Agency, by including criteria that are below detection limits, cannot comply with statutory requirements of UMRA, RFA and Executive Order 12866. (See Sections G, I, and J of the preamble for EPA's analysis of this rule's compliance with thesestatutes and the executive order, respectively). EPA notes that the criteria included in today's rule establish ambient water quality criteria in California to comply with CWA Section 303(c)(2)(B) to protect the designated uses of the State's waterbodies. As EPA noted in the responses to comments raised on establishing criteria below detection limits, EPA's policy with respect to regulatory compliance for the criteria takes analytical sensitivity into account.

Comment ID: CTR-011-002
Comment Author: City of Simi Valley
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-011 incorporates by reference letters CTR-027 and CTR-034
Attachments? Y
CROSS REFERENCES

Comment: It is not possible to determine what risk levels would be needed to preclude end-of-pipe treatment for other human health criteria because in most cases the method detection limits exceed the criteria (see Table 2). The City recommends that EPA delay adoption of criteria for these constituents until sufficient detected data is available to assess attainability and perform the economic analysis required by Presidential Order 12866 and the Unfunded Mandates Reform Act. We understand that Section 303 (c)(2)(B) of the Clean Water Act does not require EPA to adopt criteria for constituents that could reasonably be expected to interfere with designated uses. In the absence of data on certain constituents, EPA could easily defend a position not to adopt criteria for those constituents.

Response to: CTR-011-002

See response to CTR-005-009.

Comment ID: CTR-013-004
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

4. The proposed rule adopts criteria for pollutants where the method detection limit exceeds the criteria, and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule contains many criteria in which the criteria are less than current acceptable laboratory detection limit. In other words, if a stormwater sample indicated a non-detect value in its stormwater discharge for certain pollutants, it cannot be determined if the proposed criteria were exceeded or if exceeded, what would be the reductions and costs necessary to achieve compliance.

If the proposed rule is adopted with these criteria, the discharger may find that they are in violation of the criteria, as laboratory techniques are improved in the future. By that time, the discharger has no recourse to require the USEPA to evaluate the cost and benefit of the criteria or alternative criteria. Furthermore, in that event, the discharger may face enforcement action and costly end-of-pipe controls.

We recommend that the USEPA not adopt criteria for any pollutant where the method detection limit exceeds the criteria and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses.

Response to: CTR-013-004

See response to CTR-005-009.

Comment ID: CTR-020-020
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-28 Detection Limits

References:
Attachments? Y
CROSS REFERENCES

Comment: IV. Compliance / Detection Level

The rule specifies that limits may be set below the detection level for a pollutant but that compliance will be determined upon detection level for the pollutant. Thus, a non-detect will be considered in compliance with a permit limitation. The City concurs with the position that a non-detect reading should be considered in compliance with a limitation that is set below the reliable detection level.

Response to: CTR-020-020

See response to CTR-005-009.

Comment ID: CTR-021-005b
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-13
E-01c
R
S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In additon, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to

use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's innovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe that EPA has needlessly failed to comply with many of is legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005b

See response to CTR-005-009.

Comment ID: CTR-027-004
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: 4. The proposed rule adopts criteria for pollutants where the method detection limit exceeds the criteria, and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule contains criteria for many pollutants in which the criteria are less than acceptable laboratory detection limits (e.g. N-Nitrosodi-n-propylamine has an analytical detection limit of 0.5 ppb and the proposed human health criteria of 0.005 ppb). Thus, if a stormwater agency notes a non-detect value in its stormwater discharge for N-Nitrosodi-n-propylamine, it cannot determine if the proposed criterion was exceeded.

Section 303(c)(2)(B) notes that States must adopt numeric criteria for constituents when "...the discharge

or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." However, the proposed rule includes criteria for a number of constituents where there are insufficient detected data to determine whether the discharge of such pollutant could reasonably be expected to interfere with the designated uses. Furthermore, one cannot determine the reduction and costs necessary to achieve compliance.

If the proposed rule is adopted with these criteria, the discharger may find that they are in violation of the criteria as laboratory techniques are improved in the future. By that time the discharger has no recourse to require USEPA to evaluate the cost and benefit of the criteria or alternative criteria. Moreover, in that event, the discharger may face enforcement action and costly end-of-pipe controls.

Recommendation: USEPA should not adopt criteria for any pollutant where the method detection limit exceeds the criteria and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses.

Response to: CTR-027-004

See response to CTR-005-009.

Comment ID: CTR-030-009
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: E. EPA Needs to Clarify its Quantification Discussion and Delete References to the 1990 Dioxin Strategy

EPA states that "the use of analytical detection limits are [sic] appropriate for determining compliance" with the NPDES permit limits. 62 Fed. Reg, at 42,183, col. 3. The use of the term "detection" in that statement, rather than "quantification," may create concision and UWAG urges EPA to use the latter term. Over the past few years, EPA has consistently stated that, for determining compliance with WQBELs calculated at a level below the quantification level, the quantification level will serve as the compliance level. Use of the detection level in that context is entirely inappropriate. Measurements above the detection level, but below the quantification level, are sufficiently reliable to establish the mere presence - but not the amount - of a pollutant in a wastewater sample. Such measurements, therefore, cannot serve as the basis of compliance. Not only has EPA adopted that conclusion,(*3) but the U.S. Court of Appeals for the District of Columbia Circuit just ruled on that very issue by holding:

A standard with which compliance cannot be assessed - and it is agreed that compliance with an effluent limitation set below the level of quantification simply cannot be assessed - is no standard at all for purposes of due process.

American Iron and Steel Institute v. U.S. EPA, 115 F.3d 979, 994 (1997) (AISI).

In addition, EPA's references to its 1990 dioxin strategy document, "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the U.S." (Dioxin Strategy), are troubling. As described below, the Dioxin Strategy contains two significant flaws and thus citation to it may cause confusion in the regulated community. First, the Dioxin Strategy consistently references detection limits, rather than quantification levels. The above discussion explains UWAG's concerns with that approach.

The second major flaw of the Dioxin Strategy is its approval of the application of WQBELs to internal plant waste streams. The Dioxin Strategy states:

Where final, end-of-pipe effluent limitations are determined to be impractical or infeasible to measure, permitting authorities can, in accordance with the requirements of 40 CFR 122.45(h), establish limitations for internal plant waste streams from bleached plant processes.

Dioxin Strategy, p. 20.

As recently clarified by the AISI Court, the Clean Water Act provides no authority for the establishment of anything other than end-of-pipe WQBELS. In AISI, the petitioners challenged EPA's Great Lakes Water Quality Rule, including its requirement that each permit establish a pollutant minimization program (with effluent limitations for internal plant waste streams containing the pollutant) for each pollutant with an end-of-pipe limitation below the level of quantification. Although the Court agreed with EPA that the Clean Water Act allows monitoring of discharges from internal sources, it concluded that EPA could not impose a "point-source WQBEL upon a facility's internal waste streams." 115 F.3d at 996. Thus, the Dioxin Strategy's suggestion that it is appropriate to impose internal waste stream WQBELs is contradicted by the AISI Court.

For the reasons set forth in this subsection, UWAG requests that EPA remove all references to the Dioxin Strategy from the California Water Quality Standards rulemaking. UWAG encourages EPA to reference instead its "Questions and Answers on the Great Lakes Water Quality Guidance-Set 2", dated March 20, 1996 (GLI Q&A-2). In the GLI Q&A-2, the Agency explicitly allowed states to specify - directly within NPDES permits -- that analytical results below the level of quantification may be deemed to be in compliance with the established daily maximum WQBEL, and that zero may be used in lieu of measurements below the quantification level for averaging purposes in evaluating compliance with monthly average WQBELS. GLI Q&A-2, p. 28.

(*3) EPA's official position is that "[q]uantification of measurements below the [quantification level]. . . are [sic] not acceptable. . . . " 61 Fed. Reg. 3412 (col. 1) (Jan. 31, 1996).

Response to: CTR-030-009

See response to CTR-005-009.

Comment ID: CTR-033-003a
Comment Author: San Bernardino Muncpl Wtr Dept

Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-033 incorporates by reference letter CTR-020
Attachments? Y
CROSS REFERENCES E-01n

Comment: Experiments to determine whether a chemical is carcinogenic are performed (on animals) with high concentrations to produce statistically significant results within the time frame of the experiment. The numbers are then extrapolated to determine an estimated "safe" concentration for human populations. All of the factors in the extrapolation process use conservative assumptions (one in a million risk, bioaccumulation potential, carcinogenic potential, etc.) which builds in and multiplies safety factors. For 39 of the constituents in the CTR, the extrapolated criteria levels are below current levels of detection.

The EPA recognizes this as the proposed rule states: "EPA is aware that the criteria proposed today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting water quality criteria since they are not related to actual environmental impacts. The environmental impacts of a pollutant are based on a scientific determination, not a measuring technique that is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. See 1985 Guidelines p. 21. As the methods improve, limits closer to the actual criteria necessary to protect aquatic life and human health become measurable. The Agency does not believe it is appropriate to propose or promulgate criteria that are not sufficiently protective." The rule goes on to add, "the use of detection limits are appropriate for determining compliance with National Pollutant Discharge Elimination System (NPDES) permit limits."

Since the criteria are established on high dosage results that cannot be substantiated at low levels due to statistical significance and inability to see beyond detection limits, the values are predictions. Questions that come to mind are, what would this procedure determine for fat-soluble vitamins A, D and K? In high doses, these vitamins are harmful, though in low dosages, valuable. For constituents below detection, these determinations cannot be scientifically verified by analyses, only mathematically generated based on worst case assumptions. Although caution is warranted when establishing criteria, future unforeseen levels and effects cannot be predicted.

While the EPA believes that compliance determinations are based on detection limits, to assume no cost in the economic analysis for values that are below detection is not a valid assumption. As noted above, the detection limits will be forced to lower levels, and therefore become moving compliance targets without additional economic review should detection's begin to occur.

In summary, the detection levels should serve as the criteria with a "<" designator. The criteria for the affected constituents should be reviewed on a regular basis to reflect current approved analytical techniques, with lower levels promulgated after appropriate economic evaluations.

Response to: CTR-033-003a

See response to CTR-005-009.

Comment ID: CTR-034-010a
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-21

Comment: * SCAP recommends that EPA defer adoption of criteria contained in the draft CTR which are typically below detection limits. While we understand EPA's rationale for setting criteria that may not be detectable based on EPA's determination of the criteria needed to adequately protect aquatic life and human health, we believe that EPA has not fulfilled its duties under the Clean Water Act, Unfunded Mandates Act, and E.O. 12866. In accordance with federal water quality standards regulations, EPA is required to review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use (see 40 CFR section 131.11). Thus, if the pollutant has not been detected, there is no basis for determining whether the chemical is adversely affecting water quality or the attainment of designated uses.

Further, EPA cannot make an accurate determination of the costs and benefits of promulgating CTR criteria for those criteria that are below detection levels. It is quite likely that detection limits for some substances will improve in the near future, and dischargers previously projecting full attainment will no longer be able to comply. For instance, a SCAP member agency was issued an NPDES permit in the early 1990s containing effluent limits for a number of toxic pollutants. In this agency's case, lindane was not being detected at the time of permit issuance (and the detection level was higher than the permit limit). Yet, in the following years, the detection level dropped and this agency began to experience exceedences of the permit limit. Lindane cannot be readily controlled at the source by normal industrial waste source control methods because it is in widespread use by consumers. Therefore, the only reliable option for the POTW to come into compliance may be to add end-of-pipe treatment, a very expensive proposition. This scenario is likely to happen again with many of the criteria being proposed in the CTR. The potential compliance costs could be high, yet the Economic Analysis for the draft CTR could not estimate such costs. For all of the above reasons, EPA should defer adoption of these criteria until they can be detected and EPA can more fully determine the potential economic impacts of promulgation of the CTR. Instead, we recommend that a watershed approach be used to address these pollutants (see below).

Response to: CTR-034-010a

See response to CTR-005-009.

Comment ID: CTR-035-005
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: EPA should defer adoption of criteria for any pollutant where the method detection limit exceeds the objective and there are insufficient reliable data to determine if the pollutant could reasonably be expected to interfere with attainment of designated uses. We believe that because of the inability to detect these substances and the lack of monitoring information indicating water quality use impairment, that EPA has not fulfilled its obligations under the Clean Water Act to conduct a water body-specific analysis of the need to promulgate criteria, nor has EPA fulfilled its obligations under the Unfunded Mandates Act and Executive Order 12866 to analyze the costs and benefits of proposed criteria that cannot be detected or for which insufficient monitoring data are available. We believe that the costs to comply with criteria for organic pollutants that are currently below detection levels could amount to as much as $630 million per year for the POTW sector.

Response to: CTR-035-005

Comment ID: CTR-035-012b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES C-21

Comment: 1. Comments on Proposed Rule A. General Comments p. 42166-67 --Legal Basis

EPA argues that:

EPA does not believe that it is necessary to support the criteria proposed today on a pollutant-specific, water body-by-water-body basis. For EPA to undertake an effort to conduct research and studies of each stream segment or water body across the State of California to demonstrate that for each toxic pollutant for which EPA has issued CWA section 304(a) criteria guidance there is a 'discharge or presence' of that pollutant which could reasonably 'be expected to interfere with' the designated use would impose an enormous administrative burden and would be contrary to the statutory directive for swift action manifested by the 1987 addition of section 303(c)(2)(B) to the CWA.

Contrary to EPA's argument, we believe that the requirement in Section 303 of the CWA that States adopt water quality standards where there is a discharge or presence of toxic pollutants in the affected waters which could reasonably expected to interfere with designated uses, applies to EPA. EPA's claim that such a review would impose an "enormous administrative burden" is not compelling, since States, in their adoption of water quality standards, must perform this pollutant specific review of each stream

segment under the express terms of Section 303(c)(2)(B). EPA's own regulations require that, in promulgating water quality standards for a State, EPA is subject to "the same policies, procedures, analyses, and public participation requirements established for States in these regulations" (40 CFR section 131.22). The regulations require States to "review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(40 CFR section 131.11)(emphasis added). Thus, the regulations regarding the adoption of water quality standards do not suggest that States adopt uniform water quality standards for every water body merely because there may be a large amount of work required to determine the appropriate water quality standards for each water body. We especially believe this issue to be pertinent to pollutants for which the proposed CTR criteria are below detection levels. We therefore recommend that EPA defer the adoption of criteria for constituents which are below detection limits until such time as data are available demonstrating that particular toxic pollutants are being discharged to specific water bodies at levels to warrant concern. The pollutants in this category include the following: aldrin, alpha-BHC, beta-BHC, chlordane, 4,4'-DDD, 4,4'-DDT, 4,4'-DDE, dieldrin, 2,3,7,8-TCDD (dioxin), endosulfan I, endosulfan II, endrin, endrin aldehyde, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, PCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, hexachlorobenzene, n-nitrosodi-n-propylamine, pentachlorophenol, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chaysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd)pyrene. EPA, upon determining that promulgation of a 303(c)(2)(B) criterion is necessary, should promulgate the criterion on a water body-specific basis. Also, EPA would need to conduct an economic impact analysis at that time. Finally, as with the CTR, EPA must pursue adoption of these criteria through a rulemaking process, allowing opportunities for public review and comment in accordance with the Clean Water Act and Administrative Procedures Act.

Response to: CTR-035-012b

See response to CTR-005-009.

Comment ID: CTR-036-006
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: Appropriateness of the Technical Criteria in the CTR

The proposed rule includes a number of technical elements that are of concern.

We are concerned that the proposed rule contains criteria that have concentrations lower than current acceptable laboratory detection limits. We recommend that no criteria be adopted which are below the

detection limits and that no criteria be adopted when insufficient reliable data exists to determine that the pollutant could reasonably be expected to interfere with designated uses.

Response to: CTR-036-006

See response to CTR-005-009.

Comment ID: CTR-037-006
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: 6. EPA states that analytical detection limits are appropriate for determining compliance with NPDES permit limits, which directly conflicts with the Agency's most recent guidance which recommends that MLs be used to determine compliance. This statement completely ignores the issues of analytical variability and uncertainty in data at the MDL and between the MDL and the ML, even though all parties are in consensus that values of high uncertainty should not be used to make compliance decisions. This may be a typographical error, but it needs to be addressed. Furthermore, EPA must consider the analytical limitations of currently approved procedures when adopting criteria, Compliance with criteria can not be determined readily if sufficiently-sensitive approved procedures are not available.

Response to: CTR-037-006

See response to CTR-005-009.

Comment ID: CTR-038-009a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES E-01n
R
S

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could

reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. By taking this approach, however, EPA is unable to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA must not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA must evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits). With respect to the District's discharge and Schell Slough and Second Napa Slough, the criteria in this category include, but are not necessarily limited to, the following : benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chrysene, dibenzo(a,h)anthracene, aldrin, 4,4'-DDD, 4,4'-DDE, dieldrin, endosulfan I, endosulfan II, endosulfan sulfate, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, OCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, and hexachlorobenzene (see Table 3).

Response to: CTR-038-009a

See response to CTR-005-009.

Comment ID: CTR-040-017
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: IV. Recommendation: Do not adopt criteria for any pollutant where the method detection limit exceeds the water quality objective and for which there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses.

* The proposed Rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303(c)(2)(B) of the CWA requires states to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those

designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the CWA and is therefore unnecessary.

* By taking this approach, however, EPA is unable to fulfill its duty under Presidential Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act to assess the costs, benefits, and impacts of the Rule on local governments and other entities.

* While this may be the "safe" approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria.

* For these reasons, EPA must set aside the "play-it-safe" approach and not adopt criteria for those constituents.

* If EPA does not do this, it must evaluate the costs and benefits of the criteria for these constituents, as well as alternative criteria, using, worst case assumptions (discharge levels and ambient levels are at the detection limits).

Response to: CTR-040-017

See response to CTR-005-009.

Comment ID: CTR-041-008a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: 3. Recommend Against Adopting Criteria with Insufficient Detectable Data

The District strongly recommends that the EPA not adopt criteria where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 c(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." EPA has chosen a "safe approach" which clearly goes beyond the Clean Water Act and is clearly unnecessary. This approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small

entities. While this may be the safe approach for EPA, it places dischargers throughout the State at risk.

As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt these criteria, EPA should, prior to that, evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge and ambient levels are at the detection limits). The criteria in this category include the following: Aldrin, Alpha-BHC, Beta-BHC, Chlordane, 4,4'-DDD, 4,4'-DDT, 4,4'-DDE, Dieldrin, Endosulfan I, Endosulfan II, Endrin, Endrin Aldehyde, Heptachlor, Heptachlor Epoxide, Toxaphene, PCB- 1016, PCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, Hexachlorobenzene, N-Nitrosodipropylamine, Pentachlorophenol, Benzo(a)anthracene, Benzo(a)pyrene, Benzo(b)fluoroanthene, Benzo(k)fluoroanthene, Chrysene, Dibenzo(a,h)anthracene, and Indeno(1,2,3-cd)pyrene.

Response to: CTR-041-008a

See response to CTR-005-009.

Comment ID: CTR-042-003
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: 3. The CTR fails to adequately address non-detected pollutants.

In numerous instances, the CTR adopts water quality criteria for pollutants that exceed the method detection limit. In these cases, insufficient data exists to determine if these pollutants will interfere with designated beneficial uses. Without such data, EPA is unable to demonstrate that there is a "discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State" that would require the adoption of water quality standards to support such designated uses. See CWA section 303(c)(2)(B).

Furthermore, without such data, dischargers are unable to determine the controls necessary to meet the CTR criteria. As detection limits are lowered over time through the implementation of new laboratory techniques, dischargers may find that they are in violation of the criteria, are subject to enforcement actions and citizen suits, and must install costly end-of-pipe treatment technologies. This scenario can be avoided if EPA delays the adoption of all criteria that exceed currently available method detection limits.

Request: Caltrans requests that EPA delay the adoption of all CTR water quality criteria that exceed currently available method detection limits until such time that there exists sufficient, detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated beneficial uses.

Response to: CTR-042-003

See response to CTR-005-009.

Comment ID: CTR-043-008
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Additionally, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and consider alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA should evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-043-008

See response to CTR-005-009.

Comment ID: CTR-044-009a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:

Attachments? Y
CROSS REFERENCES E-01c
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "... the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Additionally, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria-and-consider alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA should evaluate the costs and benefits of toxic criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-044-009a

See response to CTR-005-009.

Comment ID: CTR-052-018
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Do not adopt criteria for any pollutant where the method detection limit exceeds the objective. As noted in the second paragraph of B.1, above, attainability issues will likely occur in the future as technology develops lower detection limits. There is no reason to adopt criteria for toxicants than cannot be properly measured. Once proper MDLs exist, each item can be reevaluated and the CTR (or the State Plans) can

be amended. Regulatory agencies must first determine if any of these toxicants are present in the water body to determine if an objective is warranted. The toxicants that should be removed from the CTR include the following: TCDD and equivalents, Hexachlorobenzene, Aldrin, Chlordane, 4,4'-DDT, 4,4'-DDE, 4,4'-DDD, Dieldrin, Endrin, Heptachlor Epoxide, Polychlorinated biphenyls (PCBs), and Toxaphene. There may be other toxicants where MDL is an issue for other POTWS.

Response to: CTR-052-018

See response to CTR-005-009.

Comment ID: CTR-054-009
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Moreover, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the safe approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt these criteria, EPA should, prior to that, evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits). The criteria in this category include the following: Aldrin, Alpha-BHC, Beta-BHC, Chlordane, 4,4'-DDD, 4,4'-DDT, 4,4'-DDE, Dieldrin, Endosulfan I, Endosulfan II, Endrin, Endrin Aldehyde, Heptachlor, Heptachlor Epoxide, Toxaphene, PCB-1016, PCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, TCCD equivalents Hexachlorobenzene, N-Nitroso-di-propylamine, Pentachlorophenol, Benzo(a)anthracene, Benzo(a)pyrene, Benzo(b)fluoroanthene, Benzo(k)fluoroanthene, Chrysene, Dibenzo(a,h)anthracene, and Indeno(1,2,3-cd)pyrene (see Attachment 2).

Response to: CTR-054-009

See response to CTR-005-009.

Comment ID: CTR-056-014
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* NOT adopt criteria for any pollutant where the method detection limits (MDLs) for EPA required analytical procedures defined in 40CFR 136 exceeds the objective. In these cases there is insufficient detectable data to reliably determine if the pollutant of concern could reasonably be expected to interfere with attainment of designated uses. Furthermore, there is no assurance that technological advancements or improved methodology would permit MDLs to be further reduced before interim permit limits became final.

Response to: CTR-056-014

See response to CTR-005-009.

Comment ID: CTR-057-004
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: Analytical Detection Limits

At the time the ISWP was undergoing public review, the City's analytical detection capabilities for trace organics were also being improved. For example, the detection limit for lindane (y-hexachlorocyclohexane) was lowered from 20 ng/L in 1989 to the present detection level of 4 ng/L. At the detection limit of 20 ng/L, the practical quantitation limit (PQL) was 100 ng/L, and lindane had not yet been detected in Tillman effluent. After the new NPDES permit was issued in 1991, the effluent limit for lindane was set at 19 ng/L. With the improvement in the lindane detection limit to 4 ng/L and

the PQL at 20 ng/L, the Tillman plant began to detect lindane consistently at levels of about 30 ng/L for the past 6 years. The plant thus unknowingly inherited a lindane compliance problem. Since the ISWP did not contain a provision for this situation to be addressed, the plant began to experience chronic lindane violations that continue to this day. As described previously in our comments on the EA, the probable cost for treating lindane was estimated to be approximately $40 million per year.

This unanticipated problem, driven by improvements made in analytical methods, should likewise be anticipated in the CTR for criteria that are proposed to be set below PQLs. One possible approach would be to designate these criteria as "target numeric criteria" that would serve as placeholders until such time that improvements to detection levels (which can always be assumed to be achievable) are realized. Practical criteria could be established in the interim based on current method detection levels, which would be adjusted downward to eventually reach the target criteria levels.

Another strong justification for setting appropriate detection limit-specific criteria is based on contingency economic considerations. When "hard" criteria are set below PQLs, no compliance problem at the level between the criteria and the PQLs can be identified and taken into consideration by the EA. The EPA's economic analysis is thus inherently flawed from this point of view, because detection limits effectively represent a level of ignorance (or lack of data) that the EA does not now address.

Response to: CTR-057-004

See response to CTR-005-009.

Comment ID: CTR-059-006a
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c
S

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we recommend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attainment of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of water body.

Criteria Below Detection Limits

We believe that there are fundamental problems with EPA's decision to adopt criteria that are below detection limits. This issue relates to EPA's statutory and regulatory obligations in establishing water quality criteria; namely, that EPA is subject to the same policies, procedures, analyses, and public participation requirements as States pursuant to 40 CFR section 131. These regulations require States to "review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use." (40 CFR section 131.11) For criteria where the method detection limit exceeds the objective, there are inadequate data to determine if the pollutant could reasonably be expected to interfere with attainment of designated uses. We believe that because of the inability to detect these substances and the lack of monitoring information indicating water quality use impairment EPA has not been able to fulfill its obligations to conduct a water body-specific analysis of the need to promulgate criteria.(*1)

(*1)U.S. Environmental Protection Agency, Economic Analysis of the Proposed California Water Quality Toxics Rule, Office of Water (EPA-820-B-96-001, July 1997), p. 8-18.

Second, EPA has not fulfilled its obligations under the Unfunded Mandates Reform Act and Executive Order 12866 to analyze the costs and benefits of promulgating proposed criteria which cannot be detected or for which insufficient monitoring data are available.

Given these deficiencies, we recommend that EPA defer the adoption of criteria for constituents which are below detection limits until such time as EPA has demonstrated that the levels of toxic pollutants being discharged are at a level to warrant concern. As an alternative, EPA could defer to the State for promulgation of criteria for such compounds on a water body-specific basis as part of the State's continuous water quality planning process.

Response to: CTR-059-006a

See response to CTR-005-009.

Comment ID: CTR-060-010
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

EPA needs to clarify its quantification discussion

The preamble to the rule (see 62 Fed. Reg. at 42,183, Col. 3) states that "EPA does believe, however, that the use of analytical detection limits are appropriate for determining compliance with National Pollutant Discharge Elimination System (NPDES) permit limits." SDG&E believes that the use of detection limits for this purpose is inappropriate. First, analytical results that are above the detection limit, but less than the quantitation limit only establish the presence of a analyte, not the actual concentration of the pollutant in the sample. Therefore, results below the quantitation limit do not provide a reliable value for determining compliance with a permit limit. Second, the document ("Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the U.S.") (the "Dioxin Strategy") that is referenced as the basis for using the detection limit for compliance determinations is from May 21, 1990. The Agency has expressed significant changes in its position since that time. For instance, EPA's guidance document dated March 20, 1996 ("Questions and Answers on the Great Lakes Water Quality Guidance-Set 2"; p. 28.) allows states to specify that analytical results below the level of quantification may be deemed to be in compliance with the established water quality-based effluent limitation. Additionally, a U.S. Court of Appeals for the District of Columbia Circuit ruling in 1997 held that:

A standard with which compliance cannot be assessed - and it is agreed that compliance with an effluent limitation set below the level of quantification simply cannot be assessed - is no standard at all for purposes of due process.

American Iron and Steel Institute v. U.S.EPA, 115 F.3d 979, 994 (1997) (AISI).

Rather than reference the Dioxin Strategy, EPA should reference its "Questions and Answers on the Great Lakes Water Quality Guidance-Set 2', dated March 20, 1996.

Response to: CTR-060-010

See response to CTR-005-009.

Comment ID: CTR-066-015b
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: The areas with which we find concerns and the requested changes include the following:

A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Our District finds 34 separate criteria that fall into this category. Lacking this credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures mandates further work prior to the promulgation of the criteria.

Response to: CTR-066-015b

See response to CTR-005-009.

Comment ID: CTR-067-003
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: * OVSD recommends that EPA defer adoption of criteria contained in the draft CTR, which are typically below achievable detection limits. OVSD understands that EPA's rationale for setting criteria below achievable limits is based on EPA's determination of the criteria needed to adequately protect aquatic life and human health. However, if a pollutant has never been detected in OVSD's treatment plant receiving water, there is no basis for determining whether the chemical is adversely affecting water quality or the attainment of designated uses.

Response to: CTR-067-003

See response to CTR-005-009.

Comment ID: CTR-082-009b
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures mandates further work prior to the promulgation of the criteria.

Response to: CTR-082-009b

See response to CTR-005-009.

Comment ID: CTR-085-018b
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* A further problem with the economic analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost analysis or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rule making procedures mandates further work to the promulgation of the criteria.

Response to: CTR-085-018b

See response to CTR-005-009.

Comment ID: CTR-089-003
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Analytical Detection Limits

Criteria for nine pollutants(*1) appear to have been set at levels lower than we can detect in either our laboratory or by commercial laboratories in our region, including those used by the Los Angeles

Regional Water Quality Control Board (RWQCB). While we consistently do not find these pollutants in our discharge, our detection capabilities are limited by the methods available to us for regular monitoring. Some of the proposed limits are so low that our equipment and analytical methods are incapable of detecting them, whether they are present or not. Thus, regardless of the quality of our discharge, there is no practical way to demonstrate compliance with the proposed limits for these nine pollutants.

The Los Angeles RWQCB, which must enforce these limits, is aware of this shortcoming, which applies to both the CTR and the closely-related National Toxics Rule (NTR). Recognizing the "catch-22" inherent to the proposed criteria, they have proposed an alternative, administrative method of compliance. While this alternative will allow us to comply with the CTR in a purely administrative sense, the. fact remains that we cannot actually demonstrate that our discharge meets the proposed criteria for these nine pollutants. This makes our district, the RWQCB and even the USEPA vulnerable to third-party lawsuits and creates a potential for negative public perception and bad press. As recent experience has shown(*2), advocates for public health and the environment are notoriously unforgiving of "administrative compliance". It is also unclear to us whether the administrative remedy proposed by the RWQCB is consistent with the State Implementation Policy for the CTR. This is something we could not determine in the 30 days provided to review the CTR.

(*1) Cadmium, copper, lead, mercury, selenium, silver, chloroform, chlorobromo-methane and dichlorobromomethane

(*2) During the public debates over the reauthorization of the Safe drinking Water Act, the Natural Resources Defense Council aired a number of television and press stories on the safety of public drinking water supplies, based in large part on selective interpretations of NPDES permit conditions and violations. The adoption of pollutant limits that cannot be verified exposes a vary large portion of the water and wastewater industry to allegations of health and environmental risks that can neither be proven or denied.

Response to: CTR-089-003

See response to CTR-005-009.

Comment ID: CTR-090-006
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We

stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

For many of the pollutants the detection limit is above the proposed criteria and there is insufficient water quality data to determine if the constituent could reasonably be expected to interfere with designated uses;

Response to: CTR-090-006

See response to CTR-005-009.

Comment ID: CTR-090-011
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-28 Detection Limits
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: We recommend that EPA:

3. Not adopt criteria for any pollutants where the method detection limit exceeds the objective. Instead these can be trigger points or temporary limits. (see more discussion in attachments)

If these changes cannot be made in the rule, the rule should not be promulgated.

Response to: CTR-090-011

See responses to CTR-004-002 (Category E-01; Cost Analysis) and CTR-034-10b (Category C-21; Legal Concerns).

Comment ID: CTRH-001-020
Comment Author: Phil Bobel
Document Type: Public Hearing
State of Origin: CA
Represented Org: Tri-TAC
Document Date: 09/17/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N

CROSS REFERENCES

Comment: The second point I'll make is about the numeric criteria themselves. There's a number of reasons that we will amplify on in the written comments why we don't believe all of those should be finalized as proposed.

And the example I'd like to deal with here is the group that are below the detection level, where you're proposing a criteria that's substantially below the current detection limit. Dioxin is an example; there are others.

It would be easy to say, and we will say, that because of that situation you weren't able to do an analysis -- an economic analysis, an attainable analysis. You weren't able to tell what impact this would actually have in the real world, because all of the standard setting was below where you had data.

And so how could you possibly know whether or not the standard could be achieved, when it would be achieved, or how much it would cost, or if it could be achieved? We believe that to be a pretty fundamental shortcoming of this whole business, when you're in that area below detection limits.

But there's even a more fundamental thing I'd like the EPA to think about for those pollutants. And that is: Just how are we going to proceed? Even if you manage to get your standard finalized as proposed, what would the next step be, where you've got a standard that's below the detection limits where we can take the normal next steps?

So I think we need more creativity in this area as well. It's an area where we're going to have to all put our heads together and say, "How do we approach the set of pollutants where the level of interest -- the levels at which we're interested in the pollutant is so very low?" Maybe there is some fundamentally different approach we need to take here, and maybe now is a good time to stop, brainstorm about it, do some creative thinking.

I don't think the old -- the TMDR translated to permit limits, that's not the future for those kind of pollutants. It ain't going to work. So now would be a good time to slow down, do some rethinking of how to go about proceeding on those.

So with those two points, I'll stop and thank you for your time.

(Five-minute recess in proceedings.)

Response to: CTRH-001-020

See response to CTR-005-009.

Comment ID: CTRH-001-028
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-28 Detection Limits

References:
Attachments? N
CROSS REFERENCES

Comment: I think Phil had mentioned taking a look at the numeric criteria and things regarding the ones below detection limits. I would agree with that comment. And I think we need to again think outside the box about how we can deal with those issues.

Response to: CTRH-001-028

See response to CTR-005-009.

Comment ID: CTRH-001-038
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: Third point, the basis for adopting a number of the specific criteria, we believe, is inadequate. These criteria fall into several categories. An example of one of these is the establishment of criteria that are below analytic detection limits, mentioned before, as was done for dioxin and a number of other parameters.

Lacking credible data it was not possible to conduct cost-benefit analysis or to determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures mandates further work prior to the establishment of criteria.

Response to: CTRH-001-038

See response to CTR-005-009.

Comment ID: CTRH-002-003
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: C-28 Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: Are the criteria appropriate?

We're concerned that the proposed rule contains criteria that have concentrations lower than the current acceptable laboratory detection limits. We recommend that no criteria be adopted which are below the method detection limits and that no criteria be adopted when insufficient reliable data exists to determine that pollutant could reasonably be expected to interfere with designated uses.

Response to: CTRH-002-003

See response to CTR-005-009.

Subject Matter Code: C-29 Bioaccumulation

Comment ID: CTR-026-002c
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-29 Bioaccumulation
References:
Attachments? N
CROSS REFERENCES C-17b
C-27

Comment: 2. PARTIAL PROTECTION BY THE PROPOSED AQUATIC LIFE CRITERIA (FRESHWATER OR SALTWATER)

On page 42168, the proposed rule includes the following language: "EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time." The CTR goes on to state that this approach results in only a "small possibility" of substantial overprotection or underprotection. Obviously, it is underprotection that is of concern to the DFG. The DFG has very serious concerns that criteria are being proposed that protect "most" of the species "most" of the time. We are aware of the protocols that require a minimum of eight specified families be used to develop criteria and that it may be difficult to determine criteria that are one hundred percent protective; however, this does not preclude the real possibility that certain designated uses and aquatic organisms will not be maintained, and or protected, as a result of the proposed criteria. The DFG is also concerned that criteria and protocols developed for specific constituents do not take into account the additive or synergistic effects that contaminant combination may have on aquatic organisms. Another factor that needs to be considered is bioaccumulation, as well as the effect this may have on organisms at higher trophic levels.

As trustee of all the fish and wildlife resources in the State, it is our agency's responsibility to ensure appropriate protection of all fish and wildlife resources, not just "most", and this includes adequate water quality standards. Due to our concerns and the very real possibility of underprotection to aquatic organisms and designated uses, the DFG believes that it may be appropriate to derive the criteria as proposed, and subsequently develop some additional safety factors for inclusion. It is our understanding that this approach was used in the formulation of water quality objectives for protection of aquatic organisms in the California Ocean Plan. In the short term , the safety factor could possibly be realized by the development of a comprehensivebiological monitoring program to determine whether the proposed criteria are indeed fully protective.

Response to: CTR-026-002c

The commentor is correct in stating that the values EPA is promulgating the California Toxics Rule for the protection of aquatic life are designed to protect most species most of the time. EPA understands the commentor's concern that this does not ensure protection of every species and that for some specific constituents additivity, synergism, and food web accumulation may not be considered. These limitations are a factor of the state of the science in modeling, aquatic toxicology, and chemistry rather than an

oversight by the Agency. In fact, the Agency's strategic planning and goals for the next five to ten years is to move towards criteria and guidance that address these very issues.

If the State believes there are critical species or designated uses that will not be protected by the proposed values, then a site specific criterion can be derived using the species recalculation procedure and the new criterion adopted.

With regards to the approach, the commentor suggests to increase the conservatism of the values by establishing safety factors, this is within the purview of the State. A State may always adopt a scientifically defensible value more stringent than that established by EPA. EPA has not used safety factors in promulgating these criteria, however, because EPA's methodology for deriving aquatic life criteria already incorporates rigorous data analysis procedures, including an extrapolation procedure, designed to protect a very high percentage of species, and to protect nearly all individuals even in species more sensitive than nearly all other species. This yields criteria that are adequately protective of the aquatic life uses designated by the state. Though they have limitations of their own, EPA is very supportive of States establishing biomonitoring programs. Comprehensive biomonitoring programs provide information about the health of aquatic systems that simply cannot be obtained through toxicity testing and chemistry.

Comment ID: CTR-029-002f
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-29 Bioaccumulation
References:
Attachments? N
CROSS REFERENCES C-17a
C-17b
A
C-22
C-27

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm

caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

In Light of Significant Threats to Water Quality, the Proposed Rule Should Contain the Most Stringent Criteria That Are Scientifically Defensible

Many of the criteria in the proposed rule are weaker than criteria in current published guidance. The proposed rule summarily states that the difference between the proposed, weaker criteria and the published guidance documents is "insignificant"(*4); however, in light of the current contamination problems in California's waters today, any move backwards, particularly when spread out over the state, must be viewed as significant.

Any weakening of the criteria should be subject to close scrutiny and the most rigorous analysis, which the proposed rule itself does not do. Among other things, the criteria in the proposed rule may be underprotective because additive and synergistic effects were not considered; and because the effects on wildlife, which can be particularly significant for bioaccumulative chemicals, were ignored.(*5) In addition, the proposed rule contains dissolved rather than total recoverable metals criteria, despite the fact that EPA acknowledges that total recoverable metals criteria are "scientifically defensible" and that they are more protective than dissolved metals criteria because they consider "sediment, food-chain effects and other fate-related issues," rather than simply water column impacts.(*6)

Clean Water Act section 303(c)(2)(B) mandates the development of numeric criteria that will "support such designated uses [that are adopted by the State]." The statistics available on the health of the state's waters indicates that their use already is significantly threatened or impaired by toxics. The strongest criteria supportable by science are necessary to reverse this trend and begin to restore the state's waters.

(*4) 62 Fed. Reg. 42159, 42168 (Aug. 5, 1997).

(*5) Id. at 42168.

(*6) Id. at 42172.

Response to: CTR-029-002f

Economic Analysis: I can't respond to this, not my bailiwick.

As the commentor states, the specific numbers proposed in the rule are not necessarily the same as those in existing criteria documents. The Agency disagrees with the commentor's suggestion that because they are different they are less protective. The Agency believes the values proposed in the rule are sufficiently stringent to protect the designated uses of the waters of California. The proposed values meet the aquatic life criteria derivation requirements and have undergone Agency review and public comment.

EPA understands the commentor's concern that this does not ensure protection of every species and that for some specific constituents additivity, synergism, and bioaccumulation may not be considered. These limitations are a factor of the state of the science in modeling, aquatic toxicology, and chemistry rather than an oversight by the Agency. In fact, the Agency's strategic planning and goals for the next five to ten years is to move towards criteria and guidance that address these very issues.

The metals criteria proposed in the rule are for the dissolved concentration rather than the total recoverable concentration. This is consistent with Agency policy and scientific investigations that the dissolved form of metals is that which most closely reflects the bioavailable fraction of metals in the water column. From modeling and research that has been conducted it is understood that if the dissolved criterion is met in the water column then there should not be metal toxicity in the sediment because the sediment interstitial water cannot contain more metal than the overlying water column (Ankley et al., 1996). This does not preclude small amounts of bioaccumulation of metal but to date we have not been able to demonstrate that the bioaccumulation translates into any toxic effect on higher level consumers (Lee et al., 1998; Hare et al, 1994; Hansen et al., 1996). In other words, the data so far indicates that increased body burden does not translate into increased toxicity.

The dissolved concentration must be translated into a permit limitation which is based on total recoverable. This ensures that acceptable total mass loadings are not exceeded and to ensure that the potential transformation of pollutants in effluents upon entering and mixing with the receiving water are accounted for.. In the very near future, the Agency will be publishing sediment guidelines for metals. These guidelines will compliment the water column values to ensure metals are holistically assessed and addressed.

Ankley, G. T., D. M. Di Toro, et al. (1996). "Technical basis and proposal for deriving sediment quality criteria for metals." Environ. Tox. Chem.15(12): 2056-2066.

Hansen, D.J., J.D. Mahony, W.J. Berry, S. Benyi, J. Corbin, S. Pratt and M.B. Able. 1996. Chronic effect of cadmium in sediments on colonization by benthic marine organisms: An evaluation of the role of interstitial cadmium and acid volatile sulfide in biological availability. Environ. Toxicol. Chem 15:2136-2137.

Hare, L., R. Carignan and M.A. Huerta-Diaz. 1994. A field experimental study of metal toxicity and accumulation by benthic invertebrates; implication for the acid volatile sulfide (AVS) model. Limnol. Oceanogr. 39:1653-1668.

Lee, B.-G., H.-S. Jeon, S.N. Luoma, J.-S. Yi, C.-H. Koh. 1998. Effects of AVS (Acid Volatile Sulfide) on the bioaccumulation of Cd, Ni, and Zn in bivalves and polychaetes. Abstract: 19th Annual Meeting of the Society of Environmental Toxicology and Chemistry. Charlotte, NC.

Comment ID: CTR-097-002
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-29 Bioaccumulation
References:
Attachments? N
CROSS REFERENCES

Comment: The standards are too weak in that they fail to adequately account for the bioaccumulation of mercury in fish tissue. Studies of the Great Lakes indicate that such biaccumulation is four to twenty

times greater than what the EPA projects for California.

Response to: CTR-097-002

The agency disagrees that the proposed criteria fail to adequately account for the bioaccumulation of mercury in fish tissue. The 1980 hg criterion, which is being used nationally until a new national HH criterion is derived, does use what is in effect a BAF (practical bioconcentration factors: PBCF) to account for biomagnification. As stated in the Preamble, the HH criterion is based on an average of "practical bioconcentration factors" for mercury as described in Ambient Water Quality Criteria for Mercury (EPA 440/5-80-058; Pages C-100-101). Because these PCBFs are derived from average mercury residues from commonly consumed aquatic organisms exposed in various water bodies (lakes, rivers, estuaries, oceans) and overall average total mercury concentrations in water, they incorporate potential mercury uptake indirectly from the food chain and directly from water.

Under Section 304 (a) of the Clean Water Act, EPA is required to establish National recommended water quality criteria. As such, the criteria must be applicable across all regions of the United States and, though considered protective of aquatic organisms, are based on central tendencies rather than solely site or State-specific data. However, if the State believe there are critical species or designated uses that may not be sufficiently protected by the National-based promulgated values, a site-specific criterion can be derived using appropriate data and adopted.

Please refer to the response for CTR-002-076 for additional discussion regarding bioaccumulation.

Comment ID: CTR-099-003
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-29 Bioaccumulation
References:
Attachments? N
CROSS REFERENCES

Comment: Then, too, the levels for dioxin and mercury are materials that bioaccumulate. You should know that each consumption up the food chain biomagnifies by a factor of 10. Where are your scientists?

Response to: CTR-099-003

See response to CTR-097-002.

Subject Matter Code: C-30 Narrative Criteria

Comment ID: CTR-038-010
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-30 Narrative Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: 9. EPA should delete recommendations that permit authorities utilize EPA or other criteria that have not been adopted as a part of the CTR as a basis for permit limits under the narrative toxicity criteria for toxics. The Preamble in E.3.b and the rule in footnote n to the criteria listed in 131.38(b)(2) recommend that the permitting authority base permit limits on criteria that are not being adopted as a part of the rule. This is not only unnecessary and inappropriate, but, in essence, it effectively constitutes adoption of those non-CTR criteria without considering costs and benefits or otherwise complying with Federal law and regulations.

Response to: CTR-038-010

EPA is requiring nothing in the CTR in the language cited by the commenter. For pollutants for which no criteria are promulgated as part of this rule, EPA is simply restating that according to existing law under the CWA, not affected by this rule, that permit writers are required to implement the narrative criteria, and that for arsenic, EPA recommends, but does not require, that permit writers may use the value California established for arsenic. EPA is not promulgating a criterion for arsenic in today's rule pending a review of the risk assessment for arsenic. Because the rule is simply restating what is required under existing law, these statements are not a cost of the CTR, but of prior existing law under the CWA and its implementing regulations.

Comment ID: CTR-040-018c
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-30 Narrative Criteria
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-26
G-03
C-24e

Comment: V. Recommendation: Delete all provisions in the Rule that preempt the States flexibility in permitting. The Rule provides specific direction on the adoption of averaging periods, low flow values,

effluent limitations for criteria not being adopted as a part of the Rule, and that the aquatic life criteria be applied to all waters irrespective of designated use, etc..

* The Preamble and the Rule's economic analysis make a point that the State has considerable flexibility in establishing permit limitations. In making, that point, EPA implies that the State may implement the criteria in a manner that would have little or no adverse economic impact on dischargers.

* However, the Rule contains a number of implementation provisions that are not required under Section 303(c)(2)(B), but serve to preempt the State's flexibility. These provisions include, but are not necessarily limited to the adoption of averaging periods and low flow values, directives regarding the establishment of effluent limitations for criteria that are not being adopted as a part of the Rule, and application of the aquatic life criteria to all waters irrespective of the designated use.

* Not only does EPA not have a duty to adopt these provisions, but also the provisions are more restrictive than those required by the CWA or EPA regulations, They clearly restrict the State's flexibility. In fact, other states have adopted, and EPA has approved, implementation provisions (e.g., averaging periods and low flow values) which are less restrictive.

* For these reasons, EPA should remove all such implementation provisions from the Rule.

Response to: CTR-040-018c

EPA has adopted recommendations for averaging periods and low flow values because these are intrinsic to ensuring that the numeric values are protective of the designated use. These factors are part of the ambient condition necessary, see preamble to the proposed CTR and Technical Support Document for Water Quality Based Toxics Control, U.S. EPA 1991, Section 2.3, and Appendix D.

The commenter asserts, but does not provide examples of situations where EPA has approved averaging periods and low flow values that are less restrictive than those incorporated into the final rule. Without specific examples provided, it is difficult for EPA to analyze any distinctions between these situations and the current rule. As a general matter, however, EPA uses the averaging period and low flow value when it promulgates criteria as representing EPA's best scientific judgement about these factors given all the uncertainties in deriving these factors. See Technical Support Document for Water Quality Based Toxics Control, U.S. EPA 1991, Section 2.3, and Appendix D. If a particular state elected to vary from EPA's recommendations, EPA would evaluate the basis presented and the particular facts of a given situation, and might render a different judgement. The commenter provided no specific critiques of the values used or information upon which EPA should base a decision to adjust these factors, and thus EPA has not changed them in response to comment.

Comment ID: CTR-041-011
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-30 Narrative Criteria
References:
Attachments? N

CROSS REFERENCES

Comment: 6. Permit Authorities' Utilization of Criteria Not Adopted as Part of CTR

EPA should delete recommendations that permit authorities utilize EPA or other criteria that have not been adopted as part of the CTR as a basis for permit limits under the narrative toxicity criteria for toxics. The Preamble in E.3.b and the rule in footnote n to the criteria listed in 131.38(b)(2) recommend that the permitting authority base permit limits on criteria that are not being adopted as a part of the rule. This is not only unnecessary and inappropriate, but, in essence, it constitutes adoption of those non-CTR criteria without considering costs and benefits or otherwise complying with Federal law and regulations.

Response to: CTR-041-011

See response to CTR-038-010.

Comment ID: CTR-043-009
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-30 Narrative Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: 9. EPA should delete recommendations that permit authorities utilize EPA or other criteria that have not been adopted as a part of the CTR as a basis for permit limits under the narrative toxicity criteria for toxics. The Preamble in E.3.b and the rule in footnote n to the criteria listed in 131.38(b)(2) recommend that the permitting authority base permit limits on criteria that are not being adopted as a part of the rule. This is not only unnecessary and inappropriate, but, in essence, it constitutes adoption of those non-CTR criteria without considering costs and benefits and without complying with applicable Federal laws and regulations.

Response to: CTR-043-009

See response to CTR-038-010.

Comment ID: CTR-044-010
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-30 Narrative Criteria
References:

Attachments? Y
CROSS REFERENCES

Comment: We have reviewed the proposed CTR and offer the following comments:

9. EPA should delete recommendations that permit authorities utilize EPA or other criteria that have not been adopted as a part of the CTR as a basis for permit limits under the narrative toxicity criteria for toxics. The Preamble in E.3.b and the rule in footnote n to the criteria listed in 131.38(b)(2) recommend that the permitting authority base permit limits on criteria that are not being adopted as a part of the rule. This is not only unnecessary and inappropriate, but, in essence, it constitutes adoption of those non-CTR criteria without considering costs and benefits and without complying with applicable Federal laws and regulations.

Response to: CTR-044-010

See response to CTR-038-010.

Comment ID: CTR-053-002
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-30 Narrative Criteria
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES

Comment: One of Heal the Bay's principle activities is providing comments on NPDES permits for inland, bay and estuary discharges. For years, we have relied on narrative standards and the regional Basin Plan requirements as tools to ensure that inland, bay and estuary discharges were not impacting the beneficial uses of the receiving waters. These tools have proven inadequate for achieving the desired goal of beneficial use protection. This is why numeric criteria, like those in the proposed California Toxics Rule, are so important. The primary obstacle to implementation of the State's ISW/EB&E Plan is the requirement for the State to perform an analysis under the California Environmental Quality Act ("CEQA") for any numeric criteria adopted that is more stringent than Federal criteria. The SWRCB does not have the resources to perform these analysis for the numeric criteria recommended by the task force groups. Therefore, to move implementation of the plans forward, it was agreed that EPA would revise the California Toxics Rule and, simultaneously, the State would develop the implementation policy for the ISW/EB&E Plans. We support this effort because we strongly believe that these plans must be implemented sooner, rather than later, in order to improve impaired water quality throughout California. Therefore, we agree with the California Toxics Rule as it is proposed and do not include detailed comment on the specific criteria for individual pollutants.

Response to: CTR-053-002

EPA appreciates the commenter's support of the proposed rule.

Comment ID: CTR-054-010
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-30 Narrative Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should delete recommendations that permit authorities utilize EPA or other criteria that have not been adopted as a part of the CTR as a basis for permit limits under the narrative toxicity criteria for toxics. The Preamble in E.3.b and the rule in footnote n to the criteria listed in 131.38(b)(2) recommend that the permitting authority base permit limits on criteria that are not being adopted as a part of the rule. This is not only unnecessary and inappropriate, but, in essence, it constitutes adoption of those non-CTR criteria without considering costs and benefits or otherwise complying with Federal law and regulations.

Response to: CTR-054-010

See response to CTR-038-010.

Comment ID: CTR-061-007
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-30 Narrative Criteria
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42162, third column, first full paragraph, states,

"Criteria documents, along with any more recent scientific data and information, may be used to interpret a state's narrative criterion pursuant to 40 CFR 122.44(d)(1)(vi), and serve to establish State and EPA permit discharge limits pursuant to CWA section 301(b)(1)(c) which requires NPDES permits to contain limitations required to implement any applicable water quality standard established in the CWA."

This approach is technically invalid since it tends to over-regulate many of the chemical constituents for which water quality criteria exist and ignores the unregulated or under-regulated constituents.

Response to: CTR-061-007

See response to CTR-038-010.

Subject Matter Code: D Preamble Editorial Comments

Comment ID: CTR-022-001
Comment Author: SWRCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (U.S. EPA) proposed California Toxic Rule (CTR). The State Water Resources Control Board (SWRCB) staff would like to recognize U.S. EPA's tremendous effort in producing the CTR. The SWCB staff are providing you with the following comments:

Page 42160: "Entities discharging pollutants to waters of the United States in California could be indirectly affected by this rulemaking....." Because the Clean Water Act requires that all NPDES permits include limits on discharges that are necessary to meet water quality standards, it appears that entities, such as industry and municipal discharges, could be directly affected by this rulemaking.

Response to: CTR-022-001

EPA disagrees with the commenter that the proposed CTR will directly impact municipal and industrial dischargers. The CTR promulgates water quality criteria which, by themselves, do not impact anyone. It is only when the State of California implements the water quality criteria through its water quality programs that impacts may occur. Different implementation methods can have significantly different impacts. Therefore, EPA's statement that the rule may indirectly impact entities discharging to waters of the U.S. in California is correct.

Comment ID: CTR-022-002
Comment Author: SWRCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (U.S. EPA) proposed California Toxic Rule (CTR). The State Water Resources Control Board (SWRCB) staff would like to recognize U.S. EPA's tremendous effort in producing the CTR. The SWRCB staff are providing you with the following comments:

Page 42163: 3rd column under C. State of California Actions ...last paragraph... "...the Inland Surface Water Plan (ISWP), the Enclosed Bay and Estuary Plan..." should be edited to read ... the Inland Surface Waters Plan (ISWP), the Enclosed Bays and Estuaries Plan.

Response to: CTR-022-002

EPA agrees with the commenter that the name of the State of California's implementation plans, which were invalidated by a State Court ruling, are the "Inland Surface Waters Plan" and the "Enclosed Bays and Estuaries Plan." EPA has made this correction in the preamble to the final rule.

Comment ID: CTR-022-004
Comment Author: SWRCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (U.S. EPA) proposed California Toxic Rule (CTR). The State Water Resources Control Board (SWRCB) staff would like to recognize U.S. EPA's tremendous effort in producing the CTR. The SWRCB staff are providing you with the following comments:

Page 42207: Proposed rule, Section 131.38(d)(1): Please note that the basin plans, in general, identify waters subject to water quality standards in the chapters on beneficial uses. Many basin plans do not specify water quality objectives for the priority toxic pollutants.

Please reword the second and third sentences of this subsection to read:

"These criteria apply to waters identified in the Basin Plans. More particularly, these criteria apply to waters identified in the Basin Plan chapters designating beneficial uses for waters within the region."

Response to: CTR-022-004

EPA agrees with the commenter that the second and third sentences in section 131.38(d)(1) of the rule may be confusing. We have considered your suggestion and modified the language accordingly.

Comment ID: CTR-035-013
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42167 -- No Undue or Inappropriate Burden on the State of California or Its Dischargers

The preamble states that "Today's proposed rule would not impose any undue or inappropriate burden on the State of California or its dischargers." We must disagree with this statement. While EPA's intent with this statement is perhaps to compare California to other States where water quality criteria for toxic pollutants have already been adopted, EPA's own analysis determines that the rule will cost from $15 to 87 million per year to implement which we believe to be a significant underestimate due to numerous uncertainties regarding whole categories of dischargers (i.e. nonpoint sources) and policies for implementation of the rule. Thus, it is both inaccurate and inappropriate for EPA to make the judgement that the rule will not impose an undue or inappropriate burden on the State or its dischargers.

Response to: CTR-035-013

EPA acknowledges the comment concerning the statement in the preamble that the CTR will not impose any undue or inappropriate burden on the State of California and its dischargers. EPA disagrees with the commenter that the statement in the preamble is inappropriate and inaccurate. The CTR promulgates water quality criteria for California that are required by the Clean Water Act under section 303(C)(2)(b), and that had been previously adopted by the State of California and approved by EPA. The State's criteria were rescinded after a State Court found that they had not been adopted in compliance with State law. Every other state in the nation, except California, is in substantial compliance with section 303(C)(2)(b) of the Clean Water Act. Thus, imposing these criteria on the State of California merely puts the State back into the position that it had been in, and into the same position as all other states in the nation. Thus, the criteria do not impose any undue or inappropriate burden.

With respect to the comment that the economic analysis for the proposed rule indicated that the rule would cost between 15 and 87 million dollars per year to implement, EPA acknowledges that the economic analysis indicates that some cost will be associated with how the State implements the CTR criteria into the NPDES permit program. Benefits, however, will also accrue. These costs are not significant pursuant to the language in Executive Order 12866, under which the economic analysis was completed. (See the discussion of costs and benefits in the preamble to the final rule under Executive Order 12866.)

Comment ID: CTR-035-015
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42167-42181 -- Revised / Updated 304(a) Criteria

Please provide a table in the Preamble containing each criterion, indicating each parameter that has been changed since the promulgation in 1992 of the National Toxics Rule, references stating what documents or sources contain the pertinent information and when the changes were made, and directions for obtaining the documentation. This table should incorporate the information in the California Toxics Rule Administrative Record Matrix for human health criteria.

Response to: CTR-035-015

EPA acknowledges the comment that EPA provide a table in the preamble containing each criterion indicating how each had been changed since the National Toxics Rule, including references, documents, sources of information, when any changes were made, and directions for obtaining the information. For the aquatic life criteria, this information was provided in the preamble to the proposed rule and in the Administrative Record, and is again provided in the preamble to the final rule and in the Administrative Record. The preambles discuss and thoroughly explains all significant changes in aquatic life criteria from the National Toxics Rule. The Administrative Record contains all of the water quality criteria documents which explain how each aquatic life criterion was calculated, as well as the document entitled "The 1995 Updates: Water Quality Criteria Documents for the Protection of Aquatic Life in Ambient Water," dated September 1996. This document explains the basis of several recently updated aquatic life criteria.

The preamble also discusses and thoroughly explains several significant changes in human health criteria from the National Toxics Rule. The Administrative Record contains a document entitled The California Toxics Rule Administrative Record Matrix which contains information on the basis of each human health criterion promulgated in the CTR.

The information the commenter is requesting is contained in the preambles and the Administrative Record.

Comment ID: CTR-036-012
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: D Preamble Editorial Comments
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: Equitable Considerations in Proposing the CTR

EPA's promulgation of the California Toxics Rule is unwarranted since California was in the process of revising the Inland Surface Waters Plan and the Enclosed Bays and Estuaries Plan that were overturned by the Superior Court in 1994. California and its water resources would be better served and better

protected by allowing the State Water Board to continue developing its statewide water quality plans unburdened by the strictures of the proposed rule.

EPA's purpose to 'help restore equity among the states; 62 Fed. Reg. 42161, also appears unfounded since the proposed rule differs in a number of ways from the criteria in the National Toxics Rule.

Response to: CTR-036-012

EPA disagrees with the comment that the CTR is unwarranted since California is in the process of revising its statewide plans, and that the State's water resources would be better served by allowing the State to continue its plans unburdened by the strictures of the proposed rule. The State's plans are not being revised; the State's plans are being completely redrafted and repromulgated by the State in compliance with State law, which the State failed to do when it adopted its plans in 1991. Thus, currently the State does not have any statewide plans in place for surface waters or enclosed bays and estuaries to revise. The rescinded plans contained, and thus the State currently lacks, both a comprehensive set of water quality objectives for priority toxic pollutants, as required by the Clean Water Act section 303(C)(2)(b), and implementation plans to implement the resulting water quality standards.

The CTR does not burden the State in any way. The State is intending to readopt its plans in two phases: the first phase will be implementation procedures and the second phase will include water quality objectives for priority toxic pollutants. In fact, the CTR will help restore a comprehensive water quality program to the State of California sooner than the completion of the two phases of the State's plans, since the State will soon complete phase one of its readoption, and EPA has completed its promulgation of the CTR. The CTR, which will create numeric water quality standards, and phase one of the State's plans, which will create implementation, will allow the State to effectively implement numeric water quality standards for priority toxic pollutants for inland surface waters and enclosed bays and estuaries as soon as the State completes phase one of its repromulgation.

When the State completes phase two, the readoption of its water quality objectives, EPA will stay the CTR after its review and approval of the statewide plan. Thus, the CTR does not hinder the State in any way, and in fact helps the State by allowing it to implement numeric water quality standards for toxic pollutants sooner than if EPA had not promulgated the CTR.

The commenter also noted that it appeared that EPA's stated purpose in the preamble to the proposed CTR, that the CTR would restore equity among the states, was unfounded because the proposed rule differed from the National Toxics Rule. EPA disagrees with this comment. The National Toxics Rule applied to several states that were not in substantial compliance with the Clean Water Act at 303(C)(2)(b) at that time. When it was promulgated, all states except those in the National Toxics Rule were in substantial compliance with the Clean Water Act water quality provisions. The State of California was required to rescind its water quality control plans after the finalization of the National Toxics Rule; thus, California became the only state in the nation that was in substantial noncompliance. Thus, the CTR restores equity among the states by restoring numeric water quality standards for toxics to California, as all other states in the nation.

The commenter also noted that the CTR differed in a number of substantial ways from the National Toxics Rule. EPA disagrees with this comment. The criteria in the CTR reflect updated information and do not substantially differ from the criteria in the National Toxics Rule. The CTR criteria reflect EPA's most recent water quality criteria guidance issued under Clean Water Act section 304(a). The preamble discusses these changes in detail. In addition, the Clean Water Act requires states to update their water

quality criteria every three years, and incorporate EPA's most recent 304(a) criteria guidance where appropriate (where a state has not adopted and/or EPA has not approved, different, scientifically-based water quality criteria). Thus, the states are required to incorporate these updates into their own water quality program

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Comment ID: CTR-052-004
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: D Preamble Editorial Comments
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: 1 . EPA has greatly understated the potential impacts of the CTR to the extent that statements in the preamble are completely misleading. On page 42160-1 of the Federal Register, EPA states:

"Potentially Affected Entities: Citizens concerned with water quality in California may be interested in this rulemaking. Entities discharging pollutants to waters of the United States in California could be indirectly affected by this rulemaking since water quality criteria are used to create water quality standards which in turn are used in developing National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities which may ultimately be indirectly affected include:

CATEGORY --- Examples of potentially indirectly affected entities
---------- INDUSTRY --- Industries discharging pollutants to surface waters in California.

MUNICIPALITIES --- Publicly-owned treatment works discharging pollutants to surface waters in California.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding NPDES regulated entities likely to be indirectly affected by this action. This table lists the types of entities that EPA is now aware could potentially be indirectly affected by this action." (emphasis added)

Based on the analysis prepared by BADA, CASA, and Tri-TAC, EPA's own acknowledgement that the CTR is primarily directed toward NPDES permit holders, the above statement is extremely misleading. EPA should be more forthcoming with information that is published in the Federal Register. If the CTR is promulgated in its current form, then the Authority recommends that the above statement be amended to read as follows:

"Affected Entities: Citizens concerned with water quality in California may be interested in this rulemaking. Entities discharging pollutants to waters of the United States in California will be directly affected by this rulemaking since water quality criteria are used to create water quality standards which in turn are used in developing National Pollutant Discharge Elimination System (NPDES) permit limits; Categories and entities which will be directly affected include:

CATEGORY --- Examples of directly affected entities ---------- INDUSTRY --- Industries discharging pollutants to surface waters in California.

MUNICIPALITIES --- Publicly-owned treatment works discharging pollutants to surface waters in California.

OTHER INDUSTRIES AND COMMERCIAL ESTABLISHMENTS --- Industries and commercial establishments discharging pollutants to publicly-owned treatment works.

MEMBERS OF THE PUBLIC --- Members of the public that pay fees to publicly-owned treatment works for wastewater collection and treatment services and/or buy products produced by the entities described as "Industry" or "Other industries and commercial establishments", above.

This table provides a guide for readers regarding NPDES regulated entities that will be directly affected by this action. This table lists the types of entities that EPA is aware will be directly affected by this action."

Response to: CTR-052-004

In response to the comment that the CTR preamble is misleading when it states that municipalities and industries may be indirectly impacted by the rule, see response to CTR-022-001.

Comment ID: CTR-061-015
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: D Preamble Editorial Comments
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42182, second column, first paragraph, uses the term "valence states" for the two forms of Cr. A more appropriate term is "oxidation state" for elements with different numbers ofelectrons in their outer shell. In chemistry, "valence" as a number has a number of different meanings which are not the same as those used in this context.

Response to: CTR-061-015

EPA disagrees with the comment that it has used the term "valance state" incorrectly with respect to its references to Chromium, and that the correct term should be "oxidation state." EPA believes the terms are interchangeable as used in this context; both terms refer to the ability of an atom to combine with other atoms.

Subject Matter Code: E-01 Cost Analysis

Comment ID: CTR-040-020
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES M Re-Open Comment Period

Comment: THE RULE SHOULD BE RE-PROPOSED

The above concerns are fundamental and the recommended modifications necessary to comply with applicable laws and regulations are substantial. For these reasons, we recommend that EPA modify the Rule to account for these and other comments and then re-propose the Rule.

Response to: CTR-040-020

For analysis of the final CTR, EPA updated its Economic Analysis to reflect the most recent data and information for each sample facility and also increased the sample size for minor facilities. Based on this revised analysis, EPA estimated that minor POTWs will incur costs of approximately $5,000 per facility per year under the low cost scenario and $7,800 per facility per year under the high cost scenario. See also response to CTR-058-018.

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-040-022
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Overall Conclusions

When EPA concludes that the costs and benefits of the CTR are of similar magnitude, EPA is comparing apples with oranges.

* The costs are based on the estimated costs of point source controls, which would be required as a

result of the CTR.

* The benefits are based on the assumption that nonpoint source controls, which would not be required as a result of the CTR, will be implemented (nonpoint sources are not regulated under the Clean Water Act).

The Economic Analysis is based on procedures and assumptions that greatly understate costs and benefits.

Based on estimates prepared by municipal wastewater and stormwater organizations, the costs of the CTR could be as high as $8 billion annually, almost two orders of magnitude greater than the high-end costs estimated by EPA ($85 million annually).

Based on case study analyses of benefits by municipal wastewater and stormwater organizations, the benefits of the CTR could be immeasurable and possibly even negative (For example, the CTR could force the removal of treated wastewater and stormwater from effluent dependent waters and thereby destroy the aquatic and riparian habitat created by the discharges). In large part, the absence of benefits is due to the fact (which EPA acknowledges in its analysis) that point sources are minor sources of toxic pollutants, and the fact that the major sources (i.e., the nonpoint sources) are not regulated under the Clean Water Act or the CTR.

EPA inappropriately compares costs for reducing pollutants that would be reduced as a result of the CTR (e.g., metals) with the benefits derived from the reduction of pollutants that will not be controlled as a result of the CTR (e.g., DDT).

EPA should prepare a new economic analysis using the following approach:

* Compare costs for point sources controls with benefits that will result from implementation of those controls using representative case studies.

* Compare costs and benefits on a pollutant-by-pollutant basis.

Response to: CTR-040-022

See responses to CTR-041-018, CTR-054-013a, CTR-040-042, CTR-035-057, CTR-056-018, CTR-021-008, and CTR-021-006b.

Comment ID: CTR-040-023
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Costs

EPA incorrectly asserts that the water quality criteria in the CTR will not directly impose economic impacts. In fact, the CWA requires that NPDES permits contain effluent limits necessary to achieve water quality criteria, and EPA regulations and guidelines (as well as the CTR) specify the methods that must be used to calculate effluent limits. Although the State has some flexibility, the flexibility is limited. The CTR will impose impacts.

Response to: CTR-040-023

See responses to CTR-009-008a, CTR-021-005c, and CTR-056-018.

Comment ID: CTR-041-018
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Overall Conclusions

When EPA concludes that the costs and benefits of the CTR are of similar magnitude, EPA is comparing apples with oranges.

* The costs are based on the estimated costs of point source controls, which would be required as a result of the CTR.

* The benefits are based on the assumption that nonpoint source controls, which would not be required as a result of the CTR will be implemented (nonpoint sources are not regulated under the Clean Water Act).

The Economic Analysis is based on procedures and assumptions that greatly understate costs and overstate benefits.

Based on estimates prepared by municipal wastewater and stormwater organizations, the costs of the CTR could be as high as $8 billion annually, almost two orders of magnitude greater than the high-end costs estimated by EPA ($85 million annually).

Based on case study analyses of benefits by municipal wastewater and stormwater organization, the benefits of the CTR could be immeasurable and possibly even negative (For example, the CTR could force the removal of treated wastewater and stormwater from effluent dependent waters and thereby destroy the aquatic and riparian habitat created by the discharges). In large part, the absence of benefits is due to the fact (which EPA acknowledges in its analysis) that point sources are minor sources of toxic pollutants, and the fact that the major sources (i.e., the nonpoint sources) are not regulated under the

Clean Water Act or the CTR.

EPA inappropriately compares costs for reducing pollutants that would be reduced as a result of the CTR (e.g., metals) with the benefits derived from the reduction of pollutants that will not be controlled as a result of the CTR (e.g., DDT).

EPA should prepare a new economic analysis using the following approach:

* Compare costs for point sources controls with benefits that will result from implementation of those controls using representative case studies.

* Compare costs and benefits on a pollutant-by-pollutant basis.

Response to: CTR-041-018

See responses to CTR-054-013a, CTR-040-042, CTR-035-057, CTR-056-018, and CTR-021-008.

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

Comment ID: CTR-041-019
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Costs

EPA incorrectly asserts that the water quality criteria in the CTR will not directly impose economic impacts. In fact, the CWA requires that NPDES permits contain effluent limits necessary to achieve water quality criteria, and EPA regulations and guidelines (as well as the CTR) specify the methods that must be used to calculate effluent limits. Although the State has some flexibility, the flexibility is limited. The CTR will impose impacts.

Response to: CTR-041-019

See responses to CTR-009-008a, CTR-021-005c, CTR-056-018, and the preamble to the final rule.

Comment ID: CTR-044-013
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Overall Conclusions

When EPA concludes that the costs and benefits of the CTR are of similar magnitude, EPA is comparing apples with oranges.

* The costs are based on the estimated costs of point source controls, which would be required as a result of the CTR.

* The benefits are based on the assumption that nonpoint source controls, which would not be required as a result of the CTR will be implemented (nonpoint sources are not regulated under the Clean Water Act).

The Economic Analysis is based an procedures and assumptions that greatly understate costs and overstate benefits.

Based on estimates prepared by municipal wastewater and stormwater organizations, the costs of the CTR could be as high as $8 billion annually, almost two orders of magnitude greater than the high-end costs estimated by EPA ($85 million annually).

Based on case study analyses of benefits by municipal wastewater and stormwater organization, the benefits of the CTR could be immeasurable and possibly even negative (For example, the CTR could force the removal of treated wastewater and stormwater from effluent dependent waters and thereby destroy the aquatic and riparian habitat created by the discharges). In large part, the absence of benefits is due to the fact (which EPA acknowledges in its analysis) that point sources are minor sources of toxic pollutants, and the fact that the major sources (i.e., the nonpoint sources) are not regulated under the Clean Water Act or the CTR.

EPA inappropriately compares costs for reducing pollutants that would be reduced as a result of the CTR (e.g., metals) with the benefits derived from the reduction of pollutants that will not be controlled as a result of the CTR (e.g., DDT).

EPA should prepare a new economic analysis using the following approach:

* Compare costs for point sources controls with benefits that will result from implementation of those controls using representative case studies.

* Compare costs and benefits on a pollutant-by-pollutant basis.

Response to: CTR-044-013

See responses to CTR-041-018, CTR-054-013a, CTR-040-042, CTR-035-057, CTR-056-018, CTR-021-008, and CTR-021-006b.

Comment ID: CTR-044-014
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Costs

EPA incorrectly asserts that the water quality criteria in the CTR will not directly impose economic impacts. In fact, the CWA requires that NPDES permits contain effluent limits necessary to achieve water quality criteria, and EPA regulations and guidelines (as well as the CTR) specify the methods that must be used to calculate effluent limits. Although the State has some flexibility, the flexibility is limited. The CTR will impose impacts.

Response to: CTR-044-014

See responses to CTR-009-008a, CTR-021-005c, and CTR-056-018.

Comment ID: CTR-047-001
Comment Author: City of Santa Fe Springs
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-047 incorporates by reference letters CTR-013 and CTR-027.
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our storm water program:

1 . The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal storm water discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain

language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-047-001

EPA's criteria for priority toxic pollutants were developed to protect beneficial designated uses. The criteria are independent of considerations about different categories of dischargers. In implementing water quality standards, the State has some degree of flexibility in establishing NPDES permit requirements or best management practices that would be appropriate for small municipal separate storm sewer systems.

Comment ID: CTR-052-003b
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-13
E-02

Comment: However, the Authority is greatly disappointed that EPA chose not to follow the consensus recommendations for many of the most significant issues, including the methodology used for the EA and the choice of using the most conservative carcinogenicity factor for organic pollutants.

Response to: CTR-052-003b

While EPA agrees that the methodology recommended by the State Task Force on Economic Considerations may be one adequate method for the State to calculate the costs and benefits of State adoption and implementation of water quality standards, EPA did not use this method for its own Economic Analysis (EA) for the following reasons:

* EPA's primary responsibility in developing the EA is that it meets the requirements of Executive Order 12866. For program consistency, EPA chose to model the methodology of the EA after the Regulatory Impact Analysis of the Great Lakes Water Quality Guidance which successfully underwent the full Executive Order 12866 process.

* EPA had already established its own methodology and began work on the EA nearly one year before the Task Force began meeting. In light of the substantial resources that EPA already used in its preparation of the EA, EPA could not fundamentally switch the methodology in the middle of the project due to the limited resources that could be spent on the EA. In addition, many task force members acknowledged that the consensus recommendation was a very resource intensive method and it was uncertain whether adequate data currently existed to bring this methodology to completion. EPA did not have the resources nor the data to perform this type of analysis in the time available.

* The State Task Force recommended a methodology, for future analysis by the State, that would gather ambient data to determine waters that were impaired by toxics, and then determine what actions needed to be taken by point and non-point sources to meet new water quality criteria. EPA determined that this methodology may be appropriate for future State analysis, but was not appropriate for EPA's Economic Analysis since EAs under the CWA typically estimate only costs that EPA can implement under the Clean Water Act. Therefore, EPA's EA only calculates potential costs and benefits due to controls on NPDES point sources (excluding wet-weather discharges). EPA believes it may be more appropriate for the State to estimate potential impacts on non-point sources since it has the sole authority for implementing any controls required by non-point sources.

EPA does not agree that its decision to use a 10-6 risk level for carcinogenic pollutants conflicts with any of the State Task Force consensus recommendations. EPA does not observe in the Final Task Force Report, an explicit consensus recommendation of any specific risk level for carcinogenic pollutants.

Comment ID: CTR-054-017
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Overall Conclusions

When EPA concludes that the costs and benefits of the CTR are of similar magnitude, EPA is comparing apples with oranges.

* The costs are based on the estimated costs of point source controls, which would be required as a result of the CTR.

* The benefits are based on the assumption that nonpoint source controls, which would not be required as a result of the CTR will be implemented (nonpoint sources are not regulated under the Clean Water Act).

The Economic Analysis is based an procedures and assumptions that greatly understate costs and overstate benefits.

Based on estimates prepared by municipal wastewater and stormwater organizations, the costs of the CTR could be as high as $8 billion annually, almost two orders of magnitude greater than the high-end costs estimated by EPA ($85 million annually).

Based on case study analyses of benefits by municipal wastewater and stormwater organization, the benefits of the CTR could be immeasurable and possibly even negative (For example, the CTR could force the removal of treated wastewater and stormwater from effluent dependent waters and thereby

destroy the aquatic and riparian habitat created by the discharges). In large part, the absence of benefits is due to the fact (which EPA acknowledges in its analysis) that point sources are minor sources of toxic pollutants, and the fact that the major sources (i.e., the nonpoint sources) are not regulated under the Clean Water Act or the CTR.

EPA inappropriately compares costs for reducing pollutants that would be reduced as a result of the CTR (e.g., metals) with the benefits derived from the reduction of pollutants that will not be controlled as a result of the CTR (e.g., DDT).

EPA should prepare a new economic analysis using the following approach:

* Compare costs for point sources controls with benefits that will result from implementation of those controls using representative case studies.

* Compare costs and benefits on a pollutant-by-pollutant basis.

Response to: CTR-054-017

See responses to CTR-041-018, CTR-054-013a, CTR-040-042, CTR-035-057, CTR-056-018, CTR-021-008, and CTR-021-006b.

Comment ID: CTR-054-018
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Costs

EPA incorrectly asserts that the water quality criteria in the CTR will not directly impose economic impacts. In fact, the CWA requires that NPDES permits contain effluent limits necessary to achieve water quality criteria, and EPA regulations and guidelines (as well as the CTR) specify the methods that must be used to calculate effluent limits. Although the State has some flexibility, the flexibility is limited. The CTR will impose impacts.

Response to: CTR-054-018

See responses to CTR-009-008a, CTR-021-005c, and CTR-056-018.

Comment ID: CTR-059-026
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01g08

Comment: Based on these and other issues discussed in the comments submitted by Tri-TAC & CASA, we strongly urge EPA to revise its Economic Analysis, and recommend that EPA and the SWRCB work together with stakeholders to craft a revised approach that is mutually acceptable. We would be pleased to assist in such an effort.

Response to: CTR-059-026

See response to CTR-034-016.

Comment ID: CTR-091-002a
Comment Author: Abu-Saba, Ganguli, Flegal
Document Type: Environmental Group
State of Origin: CA
Represented Org: Coastal Advocates
Document Date: 09/25/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? N
CROSS REFERENCES E-02

Comment: This comment addresses the mercury criteria for continuous concentration (CCC) proposed in 40 CFR, part 131(*1). The proposed aquatic health and human health criteria do not protect aquatic life or humans from mercury contamination. This is demonstrated by the scientific data presented herein. That information includes published and unpublished results from scientists with established reputations in environmental research.

The aquatic life mercury CCC is proposed to be raised sixty-fold, from the National Toxics Rule standard of 0.012 micrograms per liter (ppb) to 0.770 ppb. The human health criteria is proposed to be raised four-fold, from 0.0 12 ppb to 0.050 ppb. These proposed changes have potentially devastating economic and environmental costs that must be included in the EPA's cost-benefit analysis. Water treatment costs for the metals mercury, silver, and chromium account for 30% of costs projected in the, California Toxics Rule (CTR) economic analysis. However, the long term environmental and economic cost of mercury contamination may far exceed the short term economic savings resulting from an increase in the mercury CCC. This is especially true in California, a mining state that has devoted hundreds of millions of dollars to restoration and enhancement of commercial and sport fisheries by enactment of Proposition 204.

The potential long-term economic and environmental costs of this proposed legislation far exceed any short-term benefits gained by raising the mandatory action level for mercury contamination. A stated goal of the recently passed Proposition 204 legislation is the protection and enhancement of commercial

and sport fishing in the State of California. To that end, hundreds of millions of dollars have been committed to water quality improvement and fish habitat restoration. Increasing the permissible mercury limits will not only hinder those goals, but will likely cause irreversible damage to the environment well into the foreseeable future.

(*1) Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule. U.S. Environmental Protection Agency, Region Nine; U.S. Government Printing Office: Washington D.C., 1997; Federal Register, 62, 42159-42207.

Response to: CTR-091-002a

The aquatic life criteria have been updated using EPA's peer-reviewed and accepted aquatic life methodology. The previous 304(a) criteria guidance value was based on an FDA action level for humans, not on aquatic life protection. As such, the previous criteria are not as appropriate to use as the updated criteria proposed in the CTR. The revised criteria are less stringent than the previous criteria. The human health criteria proposed in the CTR have also been updated using the risk reference dose for methylmercury. The previous 304(a) criteria guidance values were based on the risk reference dose for mercury. The revised human health criteria in the CTR are more stringent than the previous human health criteria guidance.

All water quality standards are comprised of three parts: a designated use, criterion, and an antidegradation requirement. The CTR only proposes criteria. The State of California has adopted designated uses for its water bodies (called beneficial uses) in the Regional Water Board Basin Plans. The State has also adopted antidegradation provisions in each of the Regional Board Basin Plans. These provisions require that water quality in a waterbody cannot be degraded (with narrow exceptions as discussed at 40 CFR 131.12(a) (2) which allow a lowering of water quality if the State finds that it is necessary to accommodate important economic or social development). Thus, if a waterbody has achieved a certain level of cleanliness or is in a pristine condition, discharges are not allowed to degrade the water quality. Therefore, no environmental "cost" or degradation will be incurred as a result of any new or revised water quality criteria in the CTR that may be less stringent than a previously adopted objective or a criteria guidance value. Environmental benefits that have been gained in California fisheries or anywhere else cannot be destroyed.

Comment ID: CTR-107-001
Comment Author: Brian E. Hill
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? Y
CROSS REFERENCES

Comment: This letter is in regards to the U.S. Environmental Protection Agency (EPA) proposing water quality standards for priority toxic pollutants in California. This is referred to as the California Toxics Rule (CTR). Due to the fact that I work in the Water Pollution Control Industry, I am following this

issue very closely. However, this letter is coming from a concerned tax payer.

As you may already know, under provisions of the Clean Water Act every state is required to have water quality standards for priority toxic pollutants. In 1994 California's version of that provision was overturned in State court due to a violation in the implementation of the rule. Subsequently, the U.S. EPA has proposed a rule in order to bring California into compliance. The criteria proposed by the U.S. EPA are extremely stringent and could cost California taxpayers hundreds of millions of dollars.

Response to: CTR-107-001

Although EPA promulgated specific criteria for the State of California under the CTR, EPA promulgated ambient water quality criteria for the entire United States, including California, under the National Toxics Rule (NTR), and the costs of the NTR are borne by dischargers in all NTR States. The [document name] compares the NTR to the CTR and demonstrates that the CTR criteria are rarely, if ever, more stringent than the NTR criteria. Thus, dischargers face a "level playing field" across California and NTR States. See also response to CTR-021-005c.

Comment ID: CTR-107-002a
Comment Author: Brian E. Hill
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01 Cost Analysis
References:
Attachments? Y
CROSS REFERENCES G-02
E-01n

Comment: On September 17, I attended a hearing on the proposed CTR at the EPA's regional office in San Francisco. Here are some key issues from the testimony at that hearing:

* Some of the limits are below normal detection limits, therefore agencies have no background data in order to perform accurate attainability analysis.

* The cost of implementation by the EPA is grossly underestimated. The economic analysis shows a maximum implementation cost of $87 million. If preliminary estimates by publicly owned treatment works (POTW) are correct, implementation of the CTR will far exceed the $100 million provision of the Porter-Cologne Act. If this is the case, feasibility of implementation will be in jeopardy. The City of Merced, CA estimates that their additional cost would be $4 million annually. Merced has a very small treatment facility.

* Robert Reid, speaking on behalf of California Association of Sanitation Agencies (CASA), said that four San Francisco Plants estimate their total implementation costs to be $160 million annually.

* Charles Batts of Bay Area Dischargers Authority (BADA) estimated five BADA POTWs costs to be $12 million per year to meet the strict limit on copper and $56 million per year to meet the organics limit.

* The Regional Water Quality Control Board testified that San Francisco discharges twenty percent of the four percent discharged into the San Francisco Bay by POTWs, noting that POTWs are only a minor part of the volume discharged into the Bay. Thus, the reduction to the prescribed limits would cause a negligible decrease in the total mass of pollutants discharged.

* The City of Sacramento projects a $200 million annual cost will be required to meet the copper limit.

All of the testimony at the hearing echoed these concerns. I am sure that you have access to a transcript. The Clean Water Act has been and is instrumental in cleaning up our rivers, lakes, bay and estuaries. We can continue on this steady path by setting gradual attainable limits and through increased public education. Limits on pollutants should continue to get stricter, but this has to occur on a gradual curve that will not place an unreasonable burden on the individual taxpayer.

Response to: CTR-107-002a

Regarding limits being below detection levels see response to CTR-035-064.

EPA disagrees that costs are underestimated. For further discussion, see responses to CTR-040-039 and CTR-035-011a. EPA also disagrees with the $4 million annual cost estimate for Merced, the $160 million annual estimate for the four San Francisco plants, the BADA POTW cost estimates, and the $200 million cost estimate for copper for the City of Sacramento,however, no supporting data were provided for EPA to be able to evaluate these cost estimates. EPA evaluated the City of Merced facility as one of its sample facilities and estimated costs for Merced to range from $140,000 to $590,000 annually. EPA believes that pollution prevention and process optimization would be sufficient for Merced to ensure compliance with CTR-based limits. EPA also evaluated Sacramento as another sample facility and did not estimate reasonable potential for copper. EPA's cost estimate for Sacramento for the control of lead and mercury ranged from $90,000 to $320,000 annually for pollution prevention and process optimization.

EPA disagrees with the commenter that the decrease in the mass of pollutants discharged to San Francisco Bay would be negligible (as the San Francisco POTW represents only 20% of the 4% that POTWs contribute to the total mass discharged). Commercial and industrial facilities will also be required to meet CTR-based effluent limits which may result in additional reductions in mass discharges. EPA is promulgating the CTR criteria in order to protect human health and the aquatic environment which will benefit from pollutant reductions as is described in the Economic Analysis of the final CTR.

See also responses to CTR-041-018, CTR-038-003, CTR-056-018, CTR-021-005c, and CTR-021-010.

Subject Matter Code: E-01a Baselines

Comment ID: CTR-040-035
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y

CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-040-035

See response to CTR-040-026.

Comment ID: CTR-041-031
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-041-031

See response to CTR-040-026.

Comment ID: CTR-044-026
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-044-026

See response to CTR-040-026.

Comment ID: CTR-054-030
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-054-030

See response to CTR-040-026.

Comment ID: CTR-092-017
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01a Baselines
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #1: Application of the Analysis to San Jose

The derivation of the baseline cost models utilized in the Economic Analysis is detailed and complex. One element of Model 2, the benchmarks for the Low End and High End Cost Scenarios, can be extracted and highlighted as problematic for San Jose. Briefly, the cost of implementation of the CTR is measured by variation, at the low end, between current effluent concentrations and the concentrations which might be allowed by the CTR; and at the high end, by the difference between current permit limits and limits which might be allowed by the CTR.

The high end benchmark assumes that POTW's are already in compliance with their NPDES permit limits so that costs of "new" regulations, e.g. the CTR, can be segmented from "old" regulations, or existing permit compliance costs. In cases where a POTW is not in permit compliance on a particular element, the Model 2 high end benchmark assumes that there is no cost incurred due to federal implementation of the California Toxics Rule. This implies that any costs incurred in meeting the CTR

are really costs of getting into compliance with State regulation.

Questions for EPA on Comment #1

Q. 1 - 1) Did EPA undertake any sensitivity analysis to measure the impact of the high end assumptions on the $87 million high end cost estimate for overall CTR implementation? What if, for analytic purposes, the high end assumption was modified such that costs of attaining permit compliance (for all POTW's who are not in compliance on some element) was considered as a proxy for Rule implementation costs -- what increment of cost would be added to the $87 million estimate?

Q. 1-2) Under the existing assumptions, what share of the $87 million high end cost was attributable to the San Jose/Santa Clara POTW? What was San Jose/Santa Clara's contribution to the low end cost?

Q. 1-3) What would San Jose/Santa Clara POTW contribution be to the modified high end case, under the assumptions stated in Q. 1 - 1, above?

Response to: CTR-092-017

The methodology used to analyze each facility was described in detail in the cost report, Economic Analysis (EA), and technical support document that accompanies the record for the final rule. Following the public comment period for the proposed rule, EPA conducted a revised analysis of the potential costs and benefits of the rule (high scenario costs are estimated to be $61 million). EPA used the same methodology for estimating costs for the final rule but developed a completely updated data set for each of the sample facilities. The updated data represent the most recent three years of data available from public sources for each facility. EPA also considered any data submitted during the public comment period. Therefore, EPA's revised analysis should reflect representative information for each facility. The revised analysis of costs is again presented in detail in the EA and technical support document for the final CTR.

EPA did not estimate the costs for facilities to come into compliance with existing permit limits (see response to CTR-092-019). EPA does not agree with the commenter that this would be a suitable proxy for CTR implementation costs because ensuring compliance with existing permit limits represents costs that facilities would incur regardless of the CTR. Such an estimate would double count those costs attributable to existing state regulations and existing permit limits, instead of accounting for only those costs attributable to the CTR. See response to CTR-092-019.

Nonetheless, if San Jose's costs were evaluated as the commenter suggests (i.e., the cost of attaining permit compliance is used as a proxy for CTR implementation costs), there would be no change from EPA's current cost estimate. Twenty-one of 25 observations for copper are below the CTR-based limitand the existing permit limit. The maximum effluent concentration exceeds the existing permit limit, however, no costs other than pollution prevention costs estimated under EPA's high scenario would be incurred to ensure compliance with the CTR-based limit.

Subject Matter Code: E-01a Baselines

Comment ID: CTR-040-035
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-040-035

See response to CTR-040-026.

Comment ID: CTR-041-031
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-041-031

See response to CTR-040-026.

Comment ID: CTR-044-026
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-044-026

See response to CTR-040-026.

Comment ID: CTR-054-030
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a Baselines
References:
Attachments? N
CROSS REFERENCES

Comment: In its high-end cost scenario, EPA accepted existing permit limits as a baseline even if those permit limits were based on the old State Plans. In fact, permit limits based on the illegal State Plans are themselves illegal and do not constitute an appropriate baseline.

Response to: CTR-054-030

See response to CTR-040-026.

Comment ID: CTR-092-017
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01a Baselines
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #1: Application of the Analysis to San Jose

The derivation of the baseline cost models utilized in the Economic Analysis is detailed and complex.

One element of Model 2, the benchmarks for the Low End and High End Cost Scenarios, can be extracted and highlighted as problematic for San Jose. Briefly, the cost of implementation of the CTR is measured by variation, at the low end, between current effluent concentrations and the concentrations which might be allowed by the CTR; and at the high end, by the difference between current permit limits and limits which might be allowed by the CTR.

The high end benchmark assumes that POTW's are already in compliance with their NPDES permit limits so that costs of "new" regulations, e.g. the CTR, can be segmented from "old" regulations, or existing permit compliance costs. In cases where a POTW is not in permit compliance on a particular element, the Model 2 high end benchmark assumes that there is no cost incurred due to federal implementation of the California Toxics Rule. This implies that any costs incurred in meeting the CTR are really costs of getting into compliance with State regulation.

Questions for EPA on Comment #1

Q. 1 - 1) Did EPA undertake any sensitivity analysis to measure the impact of the high end assumptions on the $87 million high end cost estimate for overall CTR implementation? What if, for analytic purposes, the high end assumption was modified such that costs of attaining permit compliance (for all POTW's who are not in compliance on some element) was considered as a proxy for Rule implementation costs -- what increment of cost would be added to the $87 million estimate?

Q. 1-2) Under the existing assumptions, what share of the $87 million high end cost was attributable to the San Jose/Santa Clara POTW? What was San Jose/Santa Clara's contribution to the low end cost?

Q. 1-3) What would San Jose/Santa Clara POTW contribution be to the modified high end case, under the assumptions stated in Q. 1 - 1, above?

Response to: CTR-092-017

The methodology used to analyze each facility was described in detail in the cost report, Economic Analysis (EA), and technical support document that accompanies the record for the final rule. Following the public comment period for the proposed rule, EPA conducted a revised analysis of the potential costs and benefits of the rule (high scenario costs are estimated to be $61 million). EPA used the same methodology for estimating costs for the final rule but developed a completely updated data set for each of the sample facilities. The updated data represent the most recent three years of data available from public sources for each facility. EPA also considered any data submitted during the public comment period. Therefore, EPA's revised analysis should reflect representative information for each facility. The revised analysis of costs is again presented in detail in the EA and technical support document for the final CTR.

EPA did not estimate the costs for facilities to come into compliance with existing permit limits (see response to CTR-092-019). EPA does not agree with the commenter that this would be a suitable proxy for CTR implementation costs because ensuring compliance with existing permit limits represents costs that facilities would incur regardless of the CTR. Such an estimate would double count those costs attributable to existing state regulations and existing permit limits, instead of accounting for only those costs attributable to the CTR. See response to CTR-092-019.

Nonetheless, if San Jose's costs were evaluated as the commenter suggests (i.e., the cost of attaining permit compliance is used as a proxy for CTR implementation costs), there would be no change from EPA's current cost estimate. Twenty-one of 25 observations for copper are below the CTR-based

limitand the existing permit limit. The maximum effluent concentration exceeds the existing permit limit, however, no costs other than pollution prevention costs estimated under EPA's high scenario would be incurred to ensure compliance with the CTR-based limit.

Subject Matter Code: E-01a02 Cost Diff. for Eff. Limit

Comment ID: CTR-035-058
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a02 Cost Diff. for Eff. Limit
References:
Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis

The report's cost estimates exhibit a number of significant weaknesses, as follows:

* Omission of other 'baseline'' costs may act to artificially reduce USEPA's estimates.

USEPA's baseline adjustment (U.S. EPA, 1997a, page 5-7) implies that the costs associated with meeting existing requirements which are currently not being met should be excluded from the analysis. However, to the extent that these costs are higher than the report's cost limit triggers (e.g., $200/$500), both costs and the benefits associated with them should be eliminated in the analysis. That is, USEPA's assumption that dischargers will not be required to undertake improvements above a certain expense level should be carried through the entire analysis to be consistent. Alternatively, if existing requirements must be met prior to rule compliance, these costs should be estimated and reported.

Response to: CTR-035-058

EPA's economic analysis measures the potential incremental costs and benefits of the rulemaking relative to compliance with current requirements. It is not appropriate for EPA to estimate costs and benefits associated with compliance with current requirements. To the extent that costs were eliminated from the analysis, benefits (loading reductions) were also eliminated from the analysis. That is, EPA did not count benefits without counting the costs of achieving those benefits.

Comment ID: CTR-060-018
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01a02 Cost Diff. for Eff. Limit
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Economic Analysis is deficient

Secondly, it was not clear from the analysis what monitoring data and/or effluent limits were evaluated in comparison to EPA's baseline (i.e., in-plant wastestreams or once-through cooling water or combined discharge of all wastestreams) and what specific methods of compliance modifications were used to estimate compliance costs. If the wastestream evaluated was the gross combined discharge, the estimated costs are potentially severely underestimated. Once through cooling water contains ambient concentrations of pollutants when it is drawn from the source water body. If these same pollutants are the reason why the discharge does not comply with the new criteria, and the plant would have to treat the once-through cooling water to achieve compliance, the costs would be in the hundreds of million of dollars in capital costs to construct the treatment facilities necessary to comply at each power plant.

Response to: CTR-060-018

The analysis of the two sample electric utilities (Pacific Gas and Electric, Hunter's Point and San Diego Gas and Electric, South Bay) does not indicate that ambient water used for cooling would need to be treated because of the CTR. For instance, influent monitoring reports for the Hunter's Point facility indicate that all metals were consistently reported below detection levels with the exception of zinc that was detected, however, not at concentrations of concern. EPA believes that the source of pollutants in electric utilities is low volume waste such as from lubricating and metal cleaning processes. These operations generate low flow, high concentration effluents that are discharged together with cooling waters. In cases of infrequent non-compliance, as with copper at Hunter's Point, process optimization is sufficient to ensure compliance. In cases of more severe non-compliance, waste stream separation and treatment may be recommended.

Subject Matter Code: E-01a03 Model 1 Weaknesses

Comment ID: CTR-035-045
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a03 Model 1 Weaknesses
References:
Attachments? N
CROSS REFERENCES

Comment: B. Cost Analysis p. 2-1 (U.S. EPA, 1997b) - Model I Baseline in Cost Analysis

Model I assumes that, in the absence of the CTR, the State would, pursuant to the NPDES regulations rely on the narrative standards in Basin Plans to establish numeric water quality-based effluent limits in permits. EPA thereby contends that permit limits adopted under Model I could be based on the latest EPA 304(a) criteria. Under this scenario, EPA believes that permit limits would be "nearly identical" to those that would result from implementation of the CTR criteria, and that "the costs and benefits of the CTR would be negligible since implementation of permits under the CTR would not differ significantly from how the State may implement permits under current law." We believe this to be a flawed analysis, and that EPA must delete or modify the Model I baseline. EPA's suggestion that EPA's action has no impacts is equivocal: either EPA is taking an action in proposing the rule or it is not. If it is not taking an action, then it need not propose a rule. If it is taking an action, then this action must have implications. In any case, we believe the analysis is flawed. Under federal regulations (40 CFR section 122.44(d)(iv)), in the absence of the CTR, State permit writers could utilize many more documents than just the 304(a) criteria when adopting permit limits based on narrative standards. These sources of information could easily result in effluent limits that are more or less stringent than the CTR-proposed criteria. Thus, the Model I baseline is fundamentally flawed.

Response to: CTR-035-045

See responses to CTR-035-058 and CTR-021-005c.

EPA believes that the use of 304(a) criteria provides a reasonable estimate of current regulatory requirements because the criteria represent its national recommendations. Additionally, if permit writers deviate from the criteria, they must have a basis for doing so. For example, using field data to modify the criteria on a site-specific basis would require an amendment to the rule.

Comment ID: CTR-035-057
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a03 Model 1 Weaknesses
References:

Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis

The report's cost estimates exhibit a number of significant weaknesses, as follows:

* The assertion that a plausible alternative baseline (i.e., "Model I ") would indicate "no impacts" from the USEPA's rule is weak:

-- Either USEPA is taking an action in proposing the rule, or it is not. If it is not taking an action, then it need not propose a rule. If it is taking an action, then this action must have implications.

-- By definition the baseline cannot be some mythical state action that would occur if USEPA did nothing. The baseline, as described further in the Rule, is current regulation, which at this point reflects no state action in this area. If and when the state issues a regulation, the USEPA Rule can be compared with the state rule to determine benefit and cost differences.

-- The color of money stays the same whether federal or state governments take action. That is, affected parties are indifferent as to who is "scored" with water quality costs.(*5)

-- If there are potentially no costs, there are likewise potentially no benefits, an outcome which is not provided equal credence in the Analysis.

USEPA's Model I approach in this rule is the opposite of the tactic it took in proposing the 1994 State Implementation Plan (SIP) to meet air quality requirements. In Its analysis of this action USEPA provided estimates of SIP costs in the face of no state action, despite the fact that California was required to meet federal air quality standards.

(*5) However, whether the federal or state government is deemed responsible for rule costs may have important legal implications (e.g., different requirements for economic analyses).

Response to: CTR-035-057

See response CTR-040-026.

EPA believes that the potential benefits of the rule are reasonably similar to the potential costs. EPA also notes that, as described in the EA, the estimate of benefits may be underestimated as a result of omitted benefit categories while the estimate of costs was based on assumptions that tend to overstate costs. For example, reductions in noncancer health effects are omitted because there are currently few means of linking consumption of toxic contaminants by humans with cases of systemic effects (as opposed to cancer effects, for which dose-response curves have been estimated). Other omitted benefit categories include instream and near stream recreational activities other than fishing (e.g., boating, swimming, picnicking, and related activities). EPA believes other recreation benefits may be appreciable because these activities have been shown in empirical research to be highly valued, and even modest changes in participation or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (e.g., swimming) and others might increase due to their association with fishing, swimming, or other activities in which the participants might engage.

EPA recognizes that the benefits of the rule will not occur immediately, and has estimated lags in the realization of benefits. However, EPA believes that the standards established by the CTR can be achieved through point source controls and will result in attaining designated uses of the water bodies, and that the estimated benefits are illustrative of the types and potential benefits to be achieved from attaining these uses.

Comment ID: CTR-040-026
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a03 Model 1 Weaknesses
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's Model 1 Scenario erroneously assumes that without the CTR, implementation of the States narrative criterion "would likely result in permit limits that are nearly identical to those that would result from implementation of the CTR criteria." On the contrary, this is highly unlikely based on: (1) the Water Code requirements to consider economics in establishing objectives and adopting permits; (2) the court decision that threw out the same EPA criteria because the State failed to consider economics and other factors by the Water Code; and (3) most basin plans do not contain language that authorizes direct utilization of the criteria in implementing the narrative toxicity objective. In fact, EPA's assertion, quoted above, is contradicted a few paragraphs later: "...since the plans were revoked, permit writers no longer use the criteria contained in the plans." (see page ES-2). In fact, in the three years since the State Plans were rescinded, very few permits have been issued with limits based on EPA criteria.

Response to: CTR-040-026

EPA disagrees with the comment. EPA believes that in the absence of the CTR, implementation of the state narrative criterion would likely result in permit limits nearly identical to those that would result from implementation of the CTR criteria. While it is true that EPA acknowledged in the EA that new effluent limits are not likely to be based on the criteria contained in the old Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan since these plans were withdrawn by the State, EPA has observed that, in several recently issued permits, the State has developed new effluent limits based on EPA recommended 304(a) criteria. EPA's 304(a) criteria are nearly identical to the CTR criteria. Therefore, EPA believes that its statement about the State's use of narrative criteria does not contradict itself as the commenter asserts.

Comment ID: CTR-041-022
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: E-01a03 Model 1 Weaknesses
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's Model 1 Scenario erroneously assumes that without the CTR, implementation of the States narrative criterion "would likely result in permit limits that are nearly identical to those that would result from implementation of the CTR criteria." On the contrary, this is highly unlikely based on: (1) the Water Code requirements to consider economics in establishing objectives and adopting permits; (2) the court decision that threw out the same EPA criteria because the State failed to consider economics and other factors by the Water Code; and (3) most basin plans do not contain language that authorizes direct utilization of the criteria in implementing the narrative toxicity objective. In fact, EPA's assertion, quoted above, is contradicted a few paragraphs later: "...since the plans were revoked, permit writers no longer use the criteria contained in the plans." (see page ES-2). In fact, in the three years since the State Plans were rescinded, very few permits have been issued with limits based on EPA criteria.

Response to: CTR-041-022

See response to CTR-040-026, CTR-035-045, CTR-035-058, and CTR-021-005c.

Comment ID: CTR-044-017
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01a03 Model 1 Weaknesses
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's Model 1 Scenario erroneously assumes that without the CTR, implementation of the States narrative criterion "would likely result in permit limits that are nearly identical to those that would result from implementation of the CTR criteria." On the contrary, this is highly unlikely based on: (1) the Water Code requirements to consider economics in establishing objectives and adopting permits; (2) the court decision that threw out the same EPA criteria because the State failed to consider economics and other factors by the Water Code; and (3) most basin plans do not contain language that authorizes direct utilization of the criteria in implementing the narrative toxicity objective. In fact, EPA's assertion, quoted above, is contradicted a few paragraphs later: "...since the plans were revoked, permit writers no longer use the criteria contained in the plans." (see page ES-2). In fact, in the three years since the State Plans were rescinded, very few permits have been issued with limits based on EPA criteria.

Response to: CTR-044-017

See responses to CTR-040-026 and CTR-035-045.

Comment ID: CTR-054-021
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01a03 Model 1 Weaknesses
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's Model 1 Scenario erroneously assumes that without the CTR, implementation of the States narrative criterion "would likely result in permit limits that are nearly identical to those that would result from implementation of the CTR criteria." On the contrary, this is highly unlikely based on: (1) the Water Code requirements to consider economics in establishing objectives and adopting permits; (2) the court decision that threw out the same EPA criteria because the State failed to consider economics and other factors by the Water Code; and (3) most basin plans do not contain language that authorizes direct utilization of the criteria in implementing the narrative toxicity objective. In fact, EPA's assertion, quoted above, is contradicted a few paragraphs later: "...since the plans were revoked, permit writers no longer use the criteria contained in the plans." (see page ES-2). In fact, in the three years since the State Plans were rescinded, very few permits have been issued with limits based on EPA criteria.

Response to: CTR-054-021

See response to CTR-040-026.

Subject Matter Code: E-01b Cost Triggers

Comment ID: CTR-021-017
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Several fundamental problems exist with the analysis that was conducted in Section 2 "Methodology" of the "Analysis of Potential Costs Related to the Implementation of the California Water Quality Toxics Rule" document. Given flaws in the methodology, the results presented in Appendices I-B, II-B, and IIIB are misleading at best and in some cases incorrect. The following is a summary our comments regarding the methodology used and the results presented.

METHODOLOGY

* Page 2- 10 states: "For any pollutant for which a limit for a toxic pollutant existed in the current NPDES permit for a sample facility, it was assumed that a reasonable potential existed to exceed a CTR based limit and the pollutant was included for further analysis." This is an unreasonable assumption because many local regulators have been resistant to exclude pollutants with no reasonable potential to exceed the permit limit from NPDES permits. In other words, it is very common to find pollutants regulated in NPDES permits which either have not been detected or have been detected in levels significantly below the permit limits. Therefore, assuming that a reasonable potential to exceed the permit limit exists simply because a toxic pollutant is listed in the NPDES permit, is an incorrect assumption. Further, the propagation of this error leads to incorrect economic implications.

Based on the TSD and properly computed effluent limits, a reasonable potential analysis first needs to be conducted for each toxic pollutant to determine a maximum projected effluent quality, and that value then needs to be compared to the CTR based limit to determine if there is a reasonable potential for the limit to be exceeded. If there is a potential for the limit to be exceeded, economic estimates may then be made. In the analysis that was conducted, a reasonable potential to exceed the effluent limit was assumed for each constituent with an effluent limit in the NPDES permit, and potential costs were computed based on the difference between the current and future effluent limits regardless of plant performance. Clearly, this is a flawed, incorrect, and misleading approach,

* WLA[subs]a and WLA[subs]c are based on theoretical partitioning factors. These may or may not be representative of the conditions noted in site specific water bodies. A translator study, conducted specifically for the City of Sunnyvale demonstrates that the relationship between the partition if coefficient and TSS is not nearly as strong as that between the translator and ln(TSS) (the natural logarithm of TSS). WLA would be better computed using a site specific translator, wherever data are available. City of Sunnyvale calculations following guidance described in EPA 823-B-96-007 (The Metals Translator: Guidance for Calculating a total Recoverable Permit Limit from a Dissolved Criterion), demonstrate that significantly different results may be obtained from those presented in Exhibit 2-8 when site specific data are used;

* Another variable which significantly affects the values used to convert from dissolved criteria to total criteria is TSS. The TSS value used to compute the partitioning factor found in Exhibit 2-8 is 15 mg/L, which is lower than any data observed by the City of Sunnyvale between September 1989 and February 1991. Those data indicate that a more representative although still conservative value would be approximately 35 mg/L;

* Summary statistics of the dataset used are needed for each constituent (mean, standard deviation, and coefficient of variation). Further, the full datasets used for the analysis should be included as an appendix so that data trends may be inspected. Typically, as was the case with Sunnyvale but ignored in this analysis, metals concentrations decreased as source control measures have been implemented.

* Identification and exclusion of statistical outliers from the analysis is a critical step which is not addressed in Section 2 "Methodology". Since, the reasonable potential analysis estimates the projected maximum concentration for each constituent on the maximum observed value in the given dataset, identification and exclusion of outliers from the analyses must be considered.

* Table I-B-4 (and II-B-4, and III-B-4) should show the following columns: Reasonable Potential Analysis Projected Maximum Concentration; CTR based WQBEL; Flag; Maximum Observed Concentration; Flag. This structure would make the analyses much clearer. The determination of constituents of potential concern should then be conducted as follows: compute the projected maximum projected concentration for each pollutant, compute conservative estimates of CTR based limits (based on standard translators and TSS values), and compare the CTR based limit to the projected maximum reasonable potential value and the maximum observed concentrations. Constituents of potential concern will be those whose projected maximum concentrations are greater than the CTR based WQBEL.

Further, it needs to be noted that care must be taken to compare the projected maximum concentration with the correct (MDL or AML) CTR limit to determine if a reasonable potential exists to exceed the limit. This will primarily be a function of monitoring frequency. However, it appears that this step was overlooked in the preliminary analyses presented in Appendices I-B, II-B, and III-B. The analyses in those appendices (refer to Table I-B-4) compares the existing limit ("existing high end") to the CTR average monthly limit ("CTR"), and then bases economic extrapolation on that comparison. For example, the current daily limit for silver, 2.3 mg/L is compared to the computed average monthly CTR limit of 1.76 mg/L, and the conclusion is drawn that the City will need to decrease the amount of silver in the effluent. A more reasonable comparison would have been to compare the projected maximum concentration to the proposed CTR daily maximum limit.

* LTAs were computed using the 95%ile for chronic WLAs and the 99%ile for acute WLAs, without an explanation for the apparent disparity. Since in many cases the chronic WLA is lower than the acute WLA, the resultant CTR derived permit limits are based on the 95%ile rather than the 99%ile (e.g. a lower limit than would have been obtained if the 99%ile values were used). In order to determine if a reasonable potential exists for a pollutant to exceed a given permit limitation, consistency is necessary. It is suggested that all computations (reasonable potential analysis and CTR based WQBEL) be based on the same standard, so that the implications of the ensuing comparisons are clear. Further, a 99%ile standard is recommended to more fully account for the lognormal nature of pollutant concentrations in treated water.

* It is stated that "Costs were estimated for any pollutant for which either effluent concentrations or existing permit limitations were greater than the CTR-based WQBEL". As noted above, this analysis should be conducted only on pollutants with a reasonable potential to exceed the CTR-based WQBEL

otherwise economic computations will solely be based on the difference between old and new limits without any consideration to plant performance.

* Finally, high end scenario costs are "Based on the difference between an existing permit limit and the WQBELS". It cannot be overemphasized this is unreasonable, because there may be no reasonable potential to exceed this limit. This methodology implies that simply because an effluent limit is in an NPDES permit, a reasonable potential exists to exceed that limit, which is fundamentally incorrect.

Response to: CTR-021-017

* EPA disagrees with Sunnyvale's comment that it is unreasonable to assume that reasonable potential exists for a pollutant when it has a permit limit in its existing NPDES permit. First, EPA determines whether there is reasonable potential to exceed water quality criteria, not permit limits. Second, EPA acknowledges that the Regional Boards may base the decision to assign reasonable potential on methodologies other than those selected from the Technical Support Document for Water Quality-based Toxics Control (U.S. EPA, 1991). For example, EPA is aware that current permitting practices of some Regional Boards in the State of California include assigning permit limits to pollutants identified in the fish tissue report or pollutants included in the 303(d) list of impaired receiving water bodies. EPA incorporated the presumptions of these particular methodologies by assigning reasonable potential in the high scenario when a permit limit exists.

* Sunnyvale stated that EPA incorrectly based high scenario costs on the difference between an existing permit limit and the CTR-based effluent limit when there may be no reasonable potential to exceed the limit. EPA stands by its methodology to assign reasonable potential in the high scenario because of the existence of a permit limit (see above). EPA's methodology would, if anything, overstate potentialcompliance costs in the high scenario because it assumes that the discharger discharges the pollutant at concentrations of concern and that measures may need to be taken to control the pollutant. That is, EPA's methodology may result in estimates of compliance costs that will not be incurred.

* Sunnyvale also indicated that in the draft analysis, potential costs were computed based on the difference between the current and future effluent limits, regardless of plant performance. This statement is incorrect. Where data are available, cost decisions in the high and low scenarios are based on plant performance. However, in the absence of data, EPA's methodology tends to err on the side of estimating higher costs. EPA's rationale for its cost estimates for Sunnyvale is presented in Appendix B of the Technical Support Document for the final Economic Analysis.

* EPA agrees that site-specific translators for metals would better represent the conditions of site-specific water bodies. Therefore, EPA used site-specific translators in its final Economic Analysis whenever they were available. For example, EPA used a copper site-specific translator of 2.6 for Sunnyvale.

* In the final Economic Analysis, EPA does not use a total suspended solids (TSS) value of 35 mg/L for Sunnyvale. EPA instead used a TSS default value of 15 mg/L, which generally provides a more stringent limit for TSS dependent pollutants than using a TSS value of 35 mg/L. Regardless, TSS does not have an effect on the costs estimated for this particular facility because the two metals with reasonable potential (copper and silver) have metals translators which are not dependent on TSS. EPA used a site-specific translator for copper (2.6) and a default translator value (2) for silver because theoretical partitioning coefficients were not available.

* Sunnyvale requested that summary statistics of the data be presented in the analysis and that effluent

monitoring data be included as an appendix. Presently, the Technical Support Document for the Economic Analysis of the CTR does not include these data. However, the effluent data are publicly available and may be obtained from the Permit Compliance System Database (PCS).

* The revised Economic Analysis does not have a methodology to exclude outliers from the sample during reasonable potential and permit limit derivation. As a result, effluent variability may be greater than what it would be when outliers are extracted from the data set. A greater variability is reflected in larger projected effluent qualities (i.e., greater probability of receiving reasonable potential) and more stringent effluent limits, and, therefore, may result in higher costs. Thus, using all data points for the analysis may result in more conservative (i.e., higher) cost estimates. In addition, in order to fit data to a statistical distribution and to identify outliers, a large enough sample (e.g., greater than 20 observations) is required to ensure accuracy. EPA did not have large data sets for most of the sample facilities in the analysis. Despite this, EPA did try to consider outliers and outdated data by using both a cost decision matrix and best professional judgement to estimate costs. However, because of limited data and conservative assumptions, EPA's estimates may tend to overstate cost impacts.

* Sunnyvale proposed analyzing reasonable potential by comparing the projected effluent quality to the projected CTR-based limit. EPA considers this comparison unnecessary because, in the low scenario, EPA's estimate of reasonable potential is already based on projected effluent quality. EPA's reasonable potential approach compares projected effluent quality against water quality criteria, instead of projected CTR-based limits as recommended by Sunnyvale. Because CTR-based limits for metals are expressed as total concentrations and water quality criteria are dissolved, it is likely that Sunnyvale's methodology will result in fewer pollutants with reasonable potential and smaller costs than EPA's approach. EPA's reasonable potential methodology is based on the Technical Support Document for Water Quality-based Toxics Control (U.S. EPA, 1991) and EPA recognizes that its costing methodology may be moreconservative (i.e., erring on the side of higher costs) than other methodologies that could have been used, such as the one suggested by Sunnyvale.

* Please see response to CTR-021-012 regarding the use of the average monthly limit instead of the maximum daily limit to estimate projected compliance costs. Sunnyvale also has suggested estimating compliance costs by comparing the projected effluent quality to the projected CTR daily maximum limit. EPA does not believe that this comparison would be useful for the analysis, because, in addition to the explanation provided in the response to CTR-021-012, the Agency believes that the use of limited data and statistical procedures to determine compliance is an overly conservative approach. EPA would not use such an approach to establish compliance with water quality based limits or criteria (see CTR-040-004) and greater uncertainty would be introduced into the analysis by estimating costs based on statistically projected values rather than actually measured effluent data.

* Sunnyvale indicated that long-term averages (LTA) were computed using a 95% probability basis for chronic waste load allocations (WLA) and a 99% probability basis for the acute WLAs. This statement is incorrect. Acute and chronic LTAs both were calculated using a 99% probability basis. The probability basis selected for the analysis is provided in Section 5.5.4, Probability Basis (page 110), of the Technical Support Document for Water Quality-based Toxics Control (U.S. EPA, 1991). As indicated in that section, when a permitting authority does not have specific guidance for selection of the probability basis, LTAs are calculated using a 99th percentile level for both chronic and acute LTAs.

* Sunnyvale stated that since, in many cases, the chronic WLA is lower than the acute WLA, the resultant CTR-derived permit limit is based on the 95 percent probability rather than the 99% probability (i.e., a lower limit than would have been obtained if the 99% probability values were used). EPA believes that Sunnyvale has misunderstood the methodology used to derive permit limits. The average

monthly limit (AML) and the maximum daily limit (MDL) both are based on the most stringent (i.e., smaller) of the human health and the aquatic life acute and chronic LTAs. The AML is calculated by multiplying the smallest LTA times a multiplying factor that will result in a concentration that is the 95 th percentile level of a lognormal distribution with an upper bound equal to the chronic WLA. The MDL, on the other hand, is obtained by multiplying the smallest LTA times a multiplying factor that will result in a concentration that is the 99 th percentile level of a lognormal distribution and is less than the acute WLA. In other words, the MDL is greater than the AML mainly because it is calculated to be greater than 99% of the effluent concentrations while the AML is calculated to be greater than only 95% of the effluent concentrations. Refer to Table 5-2, Calculation of Permit Limits (page 103), of the Technical Support Document for Water Quality-based Toxics Control (U.S. EPA, 1991) for a list of multiplying factors at different probability levels. Note that the number of samples per month (n) is also used to calculate the AML.

* Sunnyvale requested that all computations (i.e., multipliers) be based on the same percentile levels in order to maintain consistency. As indicated above, the revised economic analysis of the final CTR uses the 99th percentile level to calculate LTAs. In addition, maximum daily limits (MDL) are also based on the 99th percentile level. The average monthly limits (AML), however, cannot be calculated using the same percentile level because this may result in effluent limits that are not protective of water quality. In particular, when the minimum LTA is the LTA based on chronic criteria, the resulting AML would be equal to the WLA based on chronic criteria. While individual exceedances of the AML are permitted, the WLA should never be exceeded; thus an AML calculated using the same percentile level as the MDL would not ensure compliance with chronic aquatic life criteria.

* Sunnyvale suggested that the projected effluent quality value be based on a 99% confidence level anda 99% probability basis. EPA revised its analysis to calculate projected effluent quality values using these confidence level and probability basis values.

See also responses to CTR-052-003b and CTR-092-017.

Comment ID: CTR-034-014b
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01g08
E-01e
E-01v
J

Comment: * In general, we are pleased that EPA prepared an analysis of the economic impacts of the proposed CTR, and that a major portion of EPA's work focused on determining the potential impacts on POTWs. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Detailed comments can be found in Attachment 2. A few of the areas of concern are listed below:

* Small facilities appear to be under represented in EPA's sample of POTWS, especially for minor dischargers.

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

* The assumptions used to determine cost estimates for indirect dischargers appear to omit a large proportion of potentially affected industries.

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. Statewide, the population is projected to grow by nearly 50% by 2020.

* The use of average cost estimates masks economic impacts on individual dischargers, which may be particularly acute for small communities.

* The economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-034-014b

See responses to CTR-032-004 CTR-035-061, CTR-021-006b, CTR-040-037, CTR-059-018, and CTR-035-048.

Comment ID: CTR-035-047a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES E-01m

Comment: pp. 2-24 - 2-32 (U.S. EPA, 1997b) - Cost Triggers for Alternative Regulatory Approaches The use of the $200 and $500 cost thresholds significantly skewed potential costs downwards by assuming that when those cost thresholds are reached, regulatory relief options would be pursued successfully, despite the fact that dischargers have absolutely no guarantees that such options will be successful, In the Preamble, in fact, EPA indicates that options such as variances and site-specific criteria will rarely, if ever, be granted. In addition, POTW experiences to date in California suggest that it is unlikely that such options will be successful. Thus, the basic premise of the analytic approach used to determine costs needs to be reconsidered. Incidentally, we also believe that the costs attributed to such activities were seriously underestimated. Information we are familiar with suggests that many of the regulatory alternatives EPA examined can cost up to several million dollars (per pollutant) (e.g. TMDLs, UAAs). Thus, we suggest that in the future when calculating the costs for such activities, EPA should use a range where $200,000/pollutant is the low end scenario and $2,000,000/pollutant is the high end scenario.

Response to: CTR-035-047a

See response to CTR-032-004.

Comment ID: CTR-040-033
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if the cost per toxic pound equivalent removed is greater than a certain threshold, the discharger would receive regulatory relief and therefore incur no treatment cost. (It is difficult to understand how EPA could rationalize basing the estimate of CTR costs on the assumption that there would be relief from the CTR if the costs were too high, especially when the CTR itself does not provide for such relief.)

Response to: CTR-040-033

See response to CTR-032-004.

Comment ID: CTR-040-040
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's cost analysis relies on an unofficial yard stick for feasibility and regulatory relief ($200 to $500 per toxic pound equivalent removed) that is different and considerably lower than the official yard stick for feasibility that is set forth in EPA's affordability guidelines. EPA uses its affordability guidelines in considering many forms of regulatory relief (e.g., dedesignation of uses). EPA's affordability guidelines set a much higher threshold. For example under these guidelines, reverse osmosis has shown to be affordable at several large POTWs.

Response to: CTR-040-040

See response to CTR-032-004.

Comment ID: CTR-041-029
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that, if the cost per toxic pound equivalent removed is greater than a certain threshold, the discharger would receive regulatory relief and therefore incur no treatment cost. (It is difficult to understand how EPA could rationalize basing the estimate of CTR costs on the assumption that there would be relief from the CTR if the costs were too high, especially when the CTR itself does not provide for such relief.)

Response to: CTR-041-029

See response to CTR-032-004.

Comment ID: CTR-041-036
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's cost analysis relies on an unofficial yard stick for feasibility and regulatory relief ($200 to $500 per toxic pound equivalent removed) that is different and considerably lower than the official yard stick for feasibility that is set forth in EPA's affordability guidelines. EPA uses its affordability guidelines in considering many forms of regulatory relief (e.g., dedesignation of uses). EPA's affordability guidelines set a much higher threshold. For example under these guidelines, reverse osmosis has shown to be affordable at several large POTWs.

Response to: CTR-041-036

See response to CTR-032-004.

Comment ID: CTR-044-024
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that, if the cost per toxic pound equivalent removed is greater than a certain threshold, the discharger would receive regulatory relief and therefore incur no treatment cost. (It is difficult to understand how EPA could rationalize basing the estimate of CTR costs on the assumption that there would be relief from the CTR if the costs were too high, especially when the CTR itself does not provide for such relief.)

Response to: CTR-044-024

See response to CTR-032-004.

Comment ID: CTR-044-031
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's cost analysis relies on an unofficial yard stick for feasibility and regulatory relief ($200 to $500 per toxic pound equivalent removed) that is different and considerably lower than the official yard stick for feasibility that is set forth in EPA's affordability guidelines. EPA uses its affordability guidelines in considering many forms of regulatory relief (e.g., dedesignation of uses). EPA's affordability guidelines set a much higher threshold. For example under these guidelines, reverse osmosis has shown to be affordable at several large POTWs.

Response to: CTR-044-031

See responses to CTR-032-004 and CTR-045-012b.

Comment ID: CTR-054-028
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that, if the cost per toxic pound equivalent removed is greater than a certain threshold, the discharger would receive regulatory relief and therefore incur no treatment cost. (It is difficult to understand how EPA could rationalize basing the estimate of CTR costs on the assumption that there would be relief from the CTR if the costs were too high, especially when the CTR itself does not provide for such relief.)

Response to: CTR-054-028

See response to CTR-032-004.

Comment ID: CTR-054-035
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's cost analysis relies on an unofficial yard stick for feasibility and regulatory relief ($200 to $500 per toxic pound equivalent removed) that is different and considerably lower than the official yard stick for feasibility that is set forth in EPA's affordability guidelines. EPA uses its affordability guidelines in considering many forms of regulatory relief (e.g., dedesignation of uses). EPA's affordability guidelines set a much higher threshold. For example under these guidelines, reverse osmosis has shown to be affordable at several large POTWs.

Response to: CTR-054-035

See response to CTR-032-004.

Comment ID: CTR-056-018
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Finally, EBMUD has serious concerns about the accuracy of EPA's draft, Economic Analysis, particularly as it pertains to the cost and benefits estimates found in the draft CTR. We believe that the costs of the CTR are significantly underestimated and the benefits are inflated. On the cost side, there are several "flaws" which should be reevaluated:

* The use of assumptions which would tend to underestimate cost.

Response to: CTR-056-018

Based in part on the comments received by EPA on the costs estimated for the proposed CTR, EPA collected new data and information for each of the sample facilities. As a result, EPA revised its estimates of costs and benefits for the final CTR.

A direct comparison of the monetized annual (steady-state) benefits of the CTR and annualized costs shows benefits and costs to be generally commensurate given the uncertainty in the analysis and that several categories of benefits are unmonetized. The low estimate of monetized benefits is $8.7 million per year and the high estimate is $40.8 million per year. Annualized costs are $33.5 million under the low scenario and $61.9 million under the high scenario.

Discounted benefits are lower than discounted costs. However, the assumption that capital is replaced every 10 years likely overstates costs. At the same time, benefits may be understated because some categories are not monetized and full benefits may be realized sooner than 10 or 20 years. Thus, EPA expects that the present value of benefits and costs is more commensurate than shown.

Comment ID: CTR-056-019
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-056 incorporates by reference letter CTR-054

Attachments? N
CROSS REFERENCES

Comment: Finally, EBMUD has serious concerns about the accuracy of EPA's draft, Economic Analysis, particularly as it pertains to the cost and benefits estimates found in the draft CTR. We believe that the costs of the CTR are significantly underestimated and the benefits are inflated. On the cost side, there are several "flaws" which should be reevaluated:

* Assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed CTR, and using this as the basis for removing costs which exceed threshold values.

Response to: CTR-056-019

See response to CTR-032-004.

Comment ID: CTR-059-019
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01b Cost Triggers
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

Response to: CTR-059-019

See response to CTR-032-004.

Comment ID: CTR-082-007b
Comment Author: City of Burbank

Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01b Cost Triggers
References:
Attachments? N
CROSS REFERENCES E-01g08

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* The draft economic analysis seems to have serious flaws. It under-estimates the cost of the draft CTR and overstates the benefits. In the cost analysis USEPA should re-evaluate the representativeness of samples used and the omission of impacts on many factors that contribute to loadings, and hence, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs, and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-082-007b

See response to CTR-032-004.

Subject Matter Code: E-01b01 RegRelief Above Threshold

Comment ID: CTR-066-013b
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01b01 RegRelief Above Threshold
References:
Attachments? N
CROSS REFERENCES E-01g08

Comment: The areas with which we find concerns and the requested changes include the following:

* The draft Economic Analysis has, from our short review, some serious flaws. It underestimates the costs of the draft to implement the CTR and overestimates the benefits. For the cost analysis, EPA should re-evaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings and, therefore, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs; and your assumption that artificially removes costs that exceed threshold values be assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-066-013b

See response to CTR-032-004.

Comment ID: CTR-085-016b
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01b01 RegRelief Above Threshold
References:
Attachments? N
CROSS REFERENCES E-01g08

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* The District agrees with CASA and SCAP that the economic analysis has serious flaws. It underestimates the costs of the draft California Toxics Rule and overestimates the benefits. For the cost analysis, the EPA should evaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings and hence, can be expected to reduce their loadings (i.e., small

indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities and other non-point sources); the incorporation of numerous assumptions that under estimates the costs; and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-085-016b

See response to CTR-032-004.

Comment ID: CTR-092-022b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01b01 RegRelief Above Threshold
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c
E-01y

Comment: Comment #6: General Cost Analysis Concerns

The City of San Jose has several generalized concerns about the costs utilized in the Economic Analysis, which raise questions regarding the validity of that analysis, as follows:

Q.6-1) We believe the real point of undertaking the CTR is to assure water quality throughout State that protects beneficial uses. How can the existing Economic Analysis be sufficient if it does not address the cost of meeting the CTR standards from all sources of discharge? Especially given the amount and cost of aggressive intervention in reducing point source pollution undertaken in California to date?

Q.6-2) Throughout the text of the CTR and within the Economic Analysis, EPA refers repeatedly to the assumption that the State will provide regulatory relief to mitigate severe cost impacts engendered by the CTR. What happens to EPA's cost benefit analysis if even one of those assumptions of regulatory relief is not implemented by the State? While we support EPA's attempt to indicate available regulatory options for the State, local level governments and POTW's have little past experience on which to rationalize acceptance of such assumptions.

Q.6-3) EPA has not estimated the cost to local governments/POTW's/indirect dischargers of securing regulatory relief, nor has that cost been incorporated into the estimate of the CTR impact. How would EPA estimate the cost of securing regulatory relief and how would that additional cost affect the Economic Analysis? Especially since very costly studies may be required in order to qualify for regulatory relief.

Q.6-4) The preamble to the CTR discusses the linkage between the CTR and the National Toxics Rule, and EPA's intent to create a level playing field by setting the CTR standards within the National Toxics Rule Framework. There does not seem to have been a similar attempt to analytically level the playing

field vis a vis implementation costs, however, as no indexing or calibration has been undertaken to account for the cumulative costs of efforts to date (see also Q. 4-3), cost equivalency data is rooted in experience outside California, and simple average costs are used to represent widely variable ranges. How would the CTR cost/benefit relationship be affected by adjusting for California's significant previous efforts on water quality control mechanisms and California cost data?

Response to: CTR-092-022b

See responses to CTR-032-004, CTR-060-019, CTR-004-003, CTR-035-048, and CTR-092-022a.

Subject Matter Code: E-01c Executive Order 12866

Comment ID: CTR-021-005c
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-13
C-28
R
S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's innovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe that EPA has needlesly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water qulaity goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005c

With respect to the Regulatory Flexibility Act (RFA), and as stated in the preamble to the proposed and final rules, the RFA requires agencies to assess the economic impact of a rule only on small entities that are subject to the requirements of the rule. Today's rule does not impose any impacts on small entities.

Under the CWA, states have the primary responsibility for implementing water quality standards. [See e.g., Scott v. City of Hammond, Ind., 741 F.2d 992, 994 (7th Cir. 1984).] Unlike technology-based effluent limitations guidelines which are required to be implemented into NPDES permits, 40 CFR 122. 44(a), and for which EPA conducts regulatory flexibility analyses if the RFA standard is met, states have considerable discretion in developing effluent limits for point sources as necessary to meet water quality standards.

Water quality standards consist of three elements: designated uses, which establish water quality goals for water bodies in the State (which may take into account economic considerations), water quality criteria sufficient to protect those uses (based on science without regard to cost), and an antidegradation policy to maintain water quality. 40 CFR 131.6. Water quality criteria are ambient levels or concentrations or narrative statements representing conditions necessary to protect a designated use. 40 CFR 131.3(b). Once EPA establishes water quality criteria, the end to be achieved, the State has considerable flexibility in determining the means to achieve those ends in NPDES permits, TMDLs and other water quality programs. This flexibility means that while the State's implementation of federally-promulgated water quality criteria may result in new or revised discharge limits being placed on small entities, the criteria themselves apply to water bodies, not to any dischargers, including small entities.

In issuing a permit limit, there are various mechanisms a state may use including: mixing zones, pollutant loading allocations, effluent trading, and water-effect ratios. The State also has the ability to adopt variances, designated use reclassification, and site-specific criteria if appropriate and necessary. Each of these authorities may be applied by the State when it issues an NPDES permit. In addition, the State may have authority to control water quality in other ways independent of the CWA NPDES program, such as establishing controls over non-point sources, water quantity, zoning, best management practices (such as tree planting to lower temperature and runoff or fish ladders to improve fish spawning). These mechanisms, if successful, may affect the need for or substance of a water-quality based effluent limit. Thus, because it is the State that issues the permit and because the State in implementing the criteria may apply any or all of the above authorities, these criteria alone, in and of themselves, do not impact any small entity.

Consistent with this statutorily-mandated division of responsibilities between the states and the federal government under the CWA, EPA in the CTR has set state-wide ambient criteria for toxic pollutants, but has left to the State the primary responsibility for determining how to regulate point source dischargers

and non-point source dischargers tomeet the standards. Thus, EPA's certification of the CTR under section 605(b) of the RFA is consistent with (and a direct consequence of) the design of the CWA.

Further, attempting to apply the RFA analysis to water quality criteria setting does not make sense. Most importantly, this is because water quality criteria apply to the waterbody and must protect the designated use. As such, tailoring water quality criteria to vary depending on the size of a discharging entity is not possible. See Response to Comment CTR 042-007a. Also, because water quality criteria do not apply to small entities, and because states are free to adopt whatever mix of control measures they deem necessary, it is unclear to what extent states will seek discharge reductions from small entities. Finally, the water quality criteria themselves contain no regulatory or informational requirements applicable to small entities and thus cannot be tailored to fit the scale of those entities.

EPA recognizes that it has undertaken an economic analysis pursuant to E.O. 12866 for this rule. This analysis, however, makes numerous assumptions and does not necessarily predict how the state will implement the criteria. Thus, the economic analysis represents EPA's best estimate of the costs of the rule and given the broad flexibility the state has in implementing the criteria, the costs may even be lower. In addition to this analysis, EPA did an analysis of state and local implementation procedures that may have an impact on NPDES permit holders and indirect dischargers, entitled Implementation Analysis of Ambient Water Quality Criteria for Priority Toxic Pollutants in California. These analyses constitute an analysis equivalent to a regulatory flexibility analysis.

EPA believes that CTR criteria by themselves do not directly impose economic impacts. As a result, EPA believes that the rule is not significant within the meaning of Executive Order 12866. Criteria are one of three parts of a water quality standard. A water quality standard is comprised of: a criterion, a designated use, and an antidegradation requirement. The CTR promulgates criteria for priority toxic pollutants. When these criteria are combined with State adopted designated uses and antidegradation requirements, water quality standards will be created. When the State implements these water quality standards, costs may be imposed based on many yet unknown factors including the community's decision that such costs are reasonable and appropriate to protect designated uses. Nevertheless, in the spirit of the intent of E.O. 12866, EPA prepared the EA which looks at the potential costs and benefits of the State's implementation of the resulting water quality standards based on the CTR criteria into the NPDES permit program.

EPA disagrees with the commenter's assertion that EPA may not have complied with Executive Order 12866. EPA fully complied with Section 6(a)(3)(a) of the Executive Order which requires each agency to provide OMB with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions.

EPA categorized the CTR as "not significant" and submitted to OMB, a draft copy of the proposed CTR along with a draft economic analysis. After review of this material, OMB agreed with EPA's determination that the proposed rule was not significant within the meaning of the Executive Order, and waived its 90-day review period for the proposed CTR. EPA performed an economic analysis even though this type of analysis is only required for significant regulatory actions within the scope of section (3)(f)(1) of the Executive Order. Therefore, even though EPA categorized the proposed CTR as "not significant", EPA fulfilled the Executive Order requirements as if it were a significant rule.

For further discussion of how today's rule complies with Executive Order 12866, the Unfunded Mandates Act, and the Regulatory Flexibility Act, see the preamble to the final rule and EPA's economic analysis of the final rule.

Comment ID: CTR-021-006b
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES J
R
S
I-01

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

3. Failure to Address Important Stormwater-Related Issues. In addition to its POTW, Sunnyvale is the owner of a system of storm drains which contribute wet weather flows to the South Bay. We are concerned that the EA entirely neglects the potential impacts of the proposed CTR on the storm drains. The EA entirely omits any meaningful analysis of the costs of bringing storm drains into compliance with the proposed CTR, thereby significantly understating the overall costs of the CTR. We believe that this omission is violative of the Agency's legal obligations under the authorities cited in the preceding paragraph.

In addition, we join in the comments being filed by the various other operators of stormwater collection systems to the effect that EPA has overstated the legal requirements for storm drains to comply with numerical criteria.

Response to: CTR-021-006b

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges) beyond those already being implemented under current state programs. The CTR language allows (consistent with EPA's policy) the practice of applying maximum extent practicable (MEP) to MS4 permits, along with BMPs as effluent limits to meet water quality standards where infeasible or insufficient information exists to develop water quality-based effluent limits. Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place in the State of California. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs. EPA evaluated the comments and analyses submitted by commenters providing costs for controlling nonpoint sources and none of these comments provided a definitive argument that

storm water dischargers cannot achieve compliance with the proposed water quality criteria or that compliance would result in widespread economic impact or hardship.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-040-004.

Comment ID: CTR-031-006c
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES J
R

Comment: b. If the CTR as proposed in the current draft is applied to municipal storm water dischargers so as to require numeric effluent limitations in municipal stormwater permits, the cost to the public will be phenomenal. In the economic analysis of the CTR, EPA failed to consider these costs, and failed to consider the costs to industrial storm water dischargers as well.

The District Is urban storm water drainage system captures through retention 90% of its annual average runoff, and discharges 90% after detention (1% is directly discharged without treatment). The system cost in 1997 dollars is estimated at $500 million.

The only option available to the District to mitigate violations of the proposed criteria would be to expand system storage to capture 100% of average annual runoff. Increasing system storage by 20,000 acre feet (estimated additional storage required for average years), at the current cost of $11,000-$20,00 per acre foot of storage, would result in a capital expenditure of $220,000,000 to $400,000,000.

Even with this exorbitant investment, in approximately half of the rain seasons storage would be exceeded, and 100% of the discharges would be expected to exceed the dissolved metals criteria noted above.

Smaller cities (under 50,000) in California are currently subject to NPDES municipal storm water discharge permits, and many more will be included upon implementation of the Stormwater Phase II program. EPA's failure to assess economic impacts on small cities would appear to be contrary to the requirements of the Federal Regulatory Flexibility Act.

The District includes in its constituency industrial businesses. The District serves these businesses and

assists in the oversight of their pollution prevention and storm water permit compliance efforts. Regardless of EPA' s approach to applying the CTR to municipal storm water permits, industrial storm water dischargers are directly and seriously affected by application of the CTR. EPA's failure to assess these economic impacts on our communities is short-sighted and a breach of good public policy.

Response to: CTR-031-006c

See responses to CTR-021-006b and CTR-040-026. For discussion of the applicability of the Regulatory Flexibility Act to this rule, see the preamble to the final rule.

Comment ID: CTR-035-008f
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01e
E-01d
E-01m
E-01h

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008f

See response to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-035-010
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES

Comment: In summary, we believe that, contrary to EPA's conclusion, the proposed regulation is a significant regulatory action pursuant to Executive Order 12866 and the Unfunded Mandates Reform Act. The CTR may well impose costs that exceed $100 million per year on the regulated community, the majority of which are local public agencies, and this will have a significant impact on local governments. By another measure, by promulgating 190 new criteria for California (for about 70 different pollutants), of which 70 (37%) have been recalculated, modified, or added by EPA since the 1992 promulgation of the National Toxics Rule, the CTR certainly is a "significant regulatory action,"(*1) Further, the Agency fails to make a "reasoned determination that the benefits of the intended regulation justify its costs," as required by Executive Order 12866 or a determination that the Agency selected "the least costly, most cost-effective or least burdensome alternative" as required under the Unfunded Mandates Reform Act. Hence, in our estimation, EPA must completely overhaul the Economic Analysis, and it must be reviewed by the Office of Management and Budget because the CTR is a significant regulatory action.

(*1) These numbers include aquatic life and human health criteria that were promulgated for California in the 1992 NTR but which have been modified or recalculated and are being reproposed in the CTR.

Response to: CTR-035-010

See response to CTR-021-005c.

For a discussion of the Agency's compliance with UMRA and Executive Order (EO) 12866, see the preamble to the final rule. Although EPA was not required to conduct a regulatory impact assessment, EPA chose to conduct one. EPA believes that its analysis has shown that the benefits of the rule justify the costs. However, under the Clean Water Act, water quality criteria are not established based on costs but are based on sound science to protect designated uses of the waters. Further, such criteria are to be based on EPA's section 304(a) criteria recommendations, EPA's 304(a) criteria recommendations modified to reflect site-specific conditions, or other scientifically defensible methods. From the outset of the national water quality standards program, EPA has explained that while economic factors may be considered in designating uses, scientific and technical factors must justify criteria to meet those uses. Also see response to CTR-042-007a.

Comment ID: CTR-035-039
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES

Comment: II. Compliance with Federal Executive Orders and Statutes pp. 42188-42190 -- Executive Order 12866, Regulatory Planning and Review EPA claims that it is not subject to certain requirements of the Executive Order because the Administrator has determined that the CTR is not a "significant regulatory action" within the meaning of Section 3(f)(1) of the E.O. We believe that EPA was incorrect in making this determination, for the following reasons: (1) the annual costs of the CTR will be far in excess of the $ 100 million threshold (see additional discussion below); (2) the CTR will without question materially adversely affect state and local governments; and (3) the CTR is likely to have a material adverse effect on one or more sectors of the economy, with a prime example being Silicon Valley, the heart of America's high technology industry, which happens to be located around the southern portion of San Francisco Bay. EPA itself identifies three sectors that will bear most of the projected costs of implementing the proposed rule. POTWs, chemical and petroleum industries, and metals and transportation equipment (collectively, these three sectors represent 93% and 97% of the annual costs under the low and high cost scenarios, respectively) (U.S. EPA, 1997b, pp. 3-3 and 3-7). We also believe that the proposed CTR is significantly different from rules that have been promulgated previously, including the National Toxics Rule ("NTR") (40 CFR 131.36) and the Great Lakes Initiative ("GLI") (60 Fed. Reg. 15366). While both of these previous rules promulgated water quality criteria for toxic pollutants, many of the criteria included in the CTR have been recalculated since the NTR was -promulgated in 1992 (70, or 37%, have been modified, recalculated, or added), the GLI served a somewhat different purpose than does the CTR (i.e. compliance with the Great Lakes Critical Programs Act of 1990), and, most importantly, those rules did not apply to California.(*2) Therefore, the economic analyses for those rules did not include an analysis of the economic impacts on California.

We believe that EPA also failed to fulfill its obligations under E.O. 12866, as follows: EPA did not seriously explore available regulatory alternatives, including the option of not regulating; EPA did not make a "reasoned determination that the benefits of the intended regulation justify its costs;" and EPA did not take into account the cost of cumulative regulations. In particular, we believe that for pollutants where the criteria are below commonly found laboratory detection levels, EPA did not fulfill its obligation to analyze the potential costs and benefits of the promulgation of these criteria. Because of this lack of compliance with the requirements of E.O. 12866, EPA should select the alternative of not regulating them at this time. As our ability to detect specific chemicals improves, then EPA may proceed with promulgation, provided all legal responsibilities are met. For all of the above-stated reasons, we believe that EPA must revise the CTR, and its economic analysis of the CTR, to comply with E.O. 12866.

(*2) With the exception of the NTR, which partially applied to California. However, the proposed CTR by definition does not duplicate the criteria in the NTR which already apply to California, unless revised criteria are being proposed.

Response to: CTR-035-039

Executive Order (EO) 12866 does not negate the Clean Water Act requirement that States have numeric

criteria for toxic pollutants for which EPA has issued 304(a) guidance. Within EO 12866 there are caveats to the application of the EO including section 1(a): "unless a statute requires another regulatory approach," and section 1(b): "to the extent permitted by law and where applicable."

See responses to CTR-021-005c and CTR-042-007a and the preamble to the final rule for discussions relating to the rule's compliance with EO 12866.

Comment ID: CTR-036-002b
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES J

Comment: Cost to Implement the Proposed Rule

The inclusion of municipal stormwater discharges under the proposed rule renders the economic analysis invalid, noting municipal studies that show that stormwater discharges cannot comply with all of the proposed criteria with anything short of major national or regional product substitutions, or end-of-pipe treatment:

The Fresno Metropolitan Flood Control District conducted an attainability analysis on stormwater discharges from its urbanized area detention basins. The analysis showed that even with pollutant reductions in the basins, the proposed criteria would not be met.

The Sacramento Stormwater Program conducted an attainability analysis and found that even with an aggressive BMP program the urbanized area would not achieve certain of the water quality criteria, and that the cost of treatment would be on the order of $2 billion.

A preliminary attainability analysis conducted by Orange County, based on a limited dataset, indicates similar findings to Fresno and Sacramento in spite of the implementation of a significant BMP program over a multi-year period (see Attachment 2).

A nationwide attainability study, conducted by American Public Works Association in 1992, estimated capital costs and annual operations costs to be $406,734,900,000 and $542,036,700,000. Significantly, these estimates omitted the costs associated with engineering, administration, permitting and land acquisition.

Even if end-of-pipe treatment were to be implemented for all urban stormwater, the contribution of toxic pollutants from this source is so minor (less than 3% according to the economic analysis) that they could not be justified by the marginal water quality benefits achieved. Clearly a rule that is known from the outset to inevitably result in massive expenditures which provide little water quality benefit or inevitable municipal noncompliance is not appropriate for California.

The rulemaking process of the federal government is obligated to fully explore the economic implications of the proposed regulatory action through compliance with Executive Order 12866, the Unfunded Mandates Report Act, of 1995 (the "Reform Act"), and the Regulatory Flexibility Act (the "RFA"). In its economic analysis EPA appears to have understated costs and circumvented these requirements resulting in a lack of disclosure of the true impacts of the Rule.

Executive Order 12866 requires any "significant" federal regulatory action to be referred to the Office of Management and Budget for review before it can be approved. In this context a "significant" action includes one which will "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy". Though admitting that there "may be a cost to some dischargers" to comply with water quality standards which will be derived from these toxics criteria, EPA nonetheless argues that the proposed rule is not a significant action because it "establishes ambient water quality criteria which. by themselves, do not directly impose economic impacts." [62 Fed. Reg. 42188].

First nothing in E.O. 12866 indicates that only actions with direct economic impacts are to be considered by OMB. Second, for EPA to ignore the link between the toxics criteria contained in the proposed rule and the obligations they impose is unfounded.

In short, EPA cannot have it both ways. It cannot indicate that stormwater discharges are subject to the proposed toxics rule and then turn a blind eye toward the costs associated with implementation of this rule. The costs of the proposed rule are direct and significant, greatly exceeding the annual $100 million threshold, and therefore the rule must be submitted to OMB for review.

Response to: CTR-036-002b

See response to CTR-021-005c, CTR- 021-006b and preamble to the final rule.

Comment ID: CTR-038-005a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES R
S

Comment: A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. The District, for example, is a small community having a population of under 50,000 and, in addition, serves several small towns and communities (Sonoma, Glen Ellen, Boyes Hot Springs and Agua Caliente) that would be greatly impacted by the proposed rule.

Response to: CTR-038-005a

See response to CTR-021-005c.

Comment ID: CTR-038-006b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-21
R
S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, and recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use" (See 40 CFR 131.11(a)(2)). Clearly the intent of both the Clean Water Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, such as the District and the small communities it serves, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-038-006b

See responses to CTR-021-005c, CTR-036-005, and the preamble to the final rule.

Comment ID: CTR-038-008b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-24

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Comment: 7. Separate, sites-specific aquatic life criteria for copper and human health criteria for mercury should be adopted for Schell Slough, or alternatively EPA should specify implementation procedures for these criteria that will preclude unreasonable controls such as end-of-pipe treatment. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the assessment of costs and benefits described in "3" above, EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation procedures that would allow the current discharge to continue (e.g., allowable Mixing zones and averaging periods and, for copper, a translator and water-effect ratio). Again, the District is amenable to continuing to address these constituents through pollution prevention measures and to assessing the actual impacts of these constituents in Schell Slough. Without EPA specifying such implementation procedures in the CTR, it is possible that the CTR could impose significant costs on the District (and the other small communities its serves) without providing a commensurate environmental benefit. In that case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-038-008b

See response to CTR-021-005c, the preamble of the final rule.

Comment ID: CTR-040-009c
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES R
S

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* A consequence of the cost/benefit analysis of the Rule are several erroneous conclusions, namely that: (1) this is not a "significant regulatory action" or a major rule (i.e., one which will result in excess of

$100 million annual expenditure) subject to the requirements contained in Presidential Executive Order 12866 and the Unfunded Mandates Reform Act; and (2) this is not a rule that will have a significant economic impact on a substantial number of small entities protected under the Regulatory Flexibility Act.

Response to: CTR-040-009c

See response to CTR-021-005c.

Comment ID: CTR-040-012a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES S

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

III. Concern: The proposed Rule violates applicable Federal law and regulations

* In failing to properly evaluate the Rule's impacts and in failing to adequately consider regulatory alternatives, the Rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (See Attachment B).

Response to: CTR-040-012a

See response to CTR-021-005c.

Comment ID: CTR-041-013a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES R
S

Comment: 8. The proposed Rule is Inconsistent with Applicable Federal Law and Regulations

The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. (See attached Legal Analysis of the Proposed California Toxics Rule) to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id). In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act (Id).

Thank you for the opportunity to provide comments on this important new rule. Please call if you have any questions regarding our letter.

Response to: CTR-041-013a

See responses to CTR-021-005c and CTR-036-005.

Comment ID: CTR-041-015
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES

Comment: 2. The California Toxics Rule is inconsistent with Executive Order 12866 and the Unfunded Mandates Reform Act.

a. Executive Order 12866

Executive Order (E.O.) No. 12866 was decreed by President Clinton on September 30, 1993. This Order governs review of agency regulations and sets standards that federal agencies should use in planning, drafting, and reviewing regulations. E.O. 12866 requires agencies to:

- Assess all of the costs and benefits of available regulatory alternative, including the alternative of not regulating;

- Propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs;

- specify performance objectives, rather than specify the behavior or manner of compliance, to the extent feasible;

- Tailor its regulations to impose the least burden on society, taking into account, among other things,

the cost of cumulative regulations;

- Afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment Period of not less than 60 days;

- Explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

EPA contends that the CTR is not a "significant regulatory action" requiring an economic analysis under the terms of E.O. 12866.(*3) This contention by EPA is erroneous since BADA's attainability analysis shows that the cost to BADA alone may exceed the $100 million cut-off for determining whether a rule is a "significant regulatory action."

Furthermore, the standard for becoming a "significant-regulatory action" is, among other things, that the proposed rule is likely to have annual effect on the economy of $ 100 million or more, OR adversely affect in a material way the economy, the environment, or local governments. Thus, EPA should not be able to allege that this is not a "significant regulatory action" because the CTR will be likely to adversely affect the economy and local governments even if the $100 million cut-off were not met.

Moreover, EPA failed to seriously explore available regulatory alternatives, including an option of not regulating; did not make a "reasoned determination that the benefits of the intended regulation justify its costs;" did not allow a 60-day comment period; and did not seriously take into account the cost of cumulative regulations.

(*3) See 62 Fed. Reg. 42,188 (Aug, 5,1997)("It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order (E.O.) 12866 and is therefore not subject to OMB review").

Response to: CTR-041-015

See responses to CTR-021-005c, CTR-001-001, and CTR-035-001.

Comment ID: CTR-042-007b
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-21
S

Comment: 7. The CTR may violate the Administrative Procedures Act, the and Unfunded Mandates Reform Act (UMRA) Executive Order (E.O.) No. 12866.

In the Preamble to the CTR, EPA repeatedly claims that the CTR will not result in expenditures of more than $100 million per year and, therefore, the statutory requirements of the UMRA and E.O. 12866 are not triggered.(*1) Caltrans' annual costs alone and only in Los Angeles will exceed the $100 million annual figure, even assuming the lowest level of treatment. Therefore, EPA's cost assumptions are challengeable as being arbitrary and capricious and in violation of the Administrative Procedures Act.(*2)

Request: Caltrans requests that EPA reconsider its cost estimates based on the comments received during the public comment period.

Caltrans would like to thank EPA for the opportunity to provide comments on this proposed regulation. It is hoped that EPA will consider and address Caltrans' comments in the final version of the CTR. Should you have any questions concerning our comments on the CTR, please feel free to address these questions to Marcia Arrant at (916) 657-5381.

(*1) See CTR, 62 Fed. Reg. at 42,188, and at 42,191 ("EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.")

(*2) See American Iron and Steel Institute v. EPA, 1997 WL 297251 (D.C. Cir., 1997)(the court found that EPA had arbitrarily failed to adequately address cost-justification for its elimination of mixing zones. EPA had estimated the total cost of elimination mixing zones for bioaccumulative chemicals of concern (BCCS) from all dischargers to the Great Lakes at $200,000, without even acknowledging a comment estimating the cost to one town for removal of mercury from its sewage discharge would be approximately $300,000).

Response to: CTR-042-007b

With respect to the commenter's criticism of the GLI decision, see CTR-042-007a. See CTR-021-005c for an explanation of how the Economic Analysis for the final CTR complies with EO 12866 and UMRA.

Cost estimates provided in the California Department of Transportation (Caltrans) analysis of compliance with the CTR may mix best management practices (BMPs) implementation costs to comply with local storm water permits with new compliance costs resulting from the CTR. EPA's Economic Analysis only evaluates the incremental impact of the water quality standards for toxics compared to the baseline program to avoid a double counting of costs (and benefits). For a detailed discussion of Caltrans' comments, see CTR-040-004.

Comment ID: CTR-043-005b
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:

Attachments? Y
CROSS REFERENCES C-21
R
S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters,"states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.1 I (a)(2)). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-043-005b

See responses to CTR-021-005c and CTR-036-005, and the preamble to the final rule.

Comment ID: CTR-044-006b
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-21
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where

toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.11 (a)(2)) (see Exhibit G). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id.). Moreover, in failing to properly consider the impacts on small entities, such as the City, the rule is inconsistent with the Regulatory Flexibility Act (Id.).

Response to: CTR-044-006b

See responses to CTR-021-005c, CTR-036-005, and the preamble to the final rule.

The NOAA data included five bays (San Diego, Humboldt, Monterey, Santa Monica, and San Pedro), two of which are actually covered by the CTR (San Diego and Humboldt). EPA assumed that the data for the nonenclosed bays generally will be applicable to enclosed bays. If EPA had excluded those bays not covered by the rule, the attribution assumption for point sources would actually be higher (see EA, Chapter 7). For example, for urban bays, the toxic-weighted average contribution of point sources is higher for the enclosed bay covered by the rule (San Diego Bay; 91%) compared to the nonenclosed bays (Santa Monica and San Pedro, at 88% and 83%, respectively). EPA employed toxicity-weighting to estimate relative source contribution because the toxicity of the discharge, more than volume, will influence its impact on receiving waters. The California 1996 303(d) report lists both point and nonpoint sources as probable sources of pollution for Santa Monica Bay. The list of pollutants and stressors for Santa Monica Bay includes metals, DDT, and PCBs.

Comment ID: CTR-044-009b
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-28
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S

Comment: We have reviewed the proposed CTR and offer the following comments:

8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "... the discharge or presence of which in the affected waters could

reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Additionally, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria-and-consider alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA should evaluate the costs and benefits of toxic criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-044-009b

See responses CTR-044-033, CTR-021-005c, CTR-004-002, CTR-005-009, and CTR-035-064.

EPA defined toxic-impaired waters as waters rated medium or poor quality for at least one or more toxic pollutant or group of pollutants. EPA acknowledged that this definition may result in an overestimate of toxic-impairment (EA Chapter 8). However, the rating of these waters corresponds to EPA's categories of 'not fully supporting' and 'partially supporting' designated uses. The existence of waters not supporting and only partially supporting designated uses is indicative of the need for and benefits associated with pollution controls.

Comment ID: CTR-044-045
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES B Comment Period

Comment: 2. The California Toxics Rule is inconsistent with Executive Order 12866 and the Unfunded Mandates Reform Act.

a. Executive Order 12866

Executive Order (E.O.) No. 12866 was decreed by President Clinton on September 30, 1993. This Order governs review of agency regulations and sets standards, that federal agencies should use in planning, drafting, and reviewing regulations. E.O. 12866 requires agencies to:

- Assess all of the costs and benefits of available regulatory alternatives, including the alternative of not regulating;

- Propose or adopt a regulation only upon a reasoned determination that the benefits of the intended

regulation justify its costs;

- Specify performance objectives, rather than specify the behavior or manner of compliance, to the extent feasible;

- Tailor its regulations to impose the least burden on society, taking into account, among other things, the cost of cumulative regulations;

- Afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days;

- Explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

EPA contends that the CTR is not a "significant regulatory action" requiring an economic analysis under the terms of E.O. 12866. This contention by EPA is erroneous since the standard for becoming a "significant-regulatory action" is that the proposed rule is likely to have annual effect on the economy of $100 million or more, OR adversely affect in a material way the economy, the environment, or local governments. Thus, EPA should not be able to allege that this is not a "significant regulatory action" because the CTR will be likely to adversely affect the economy and local governments even if the $100 million cut-off were not met.

Moreover, EPA failed to seriously explore available regulatory alternatives, including an option of not regulating; did not make a "reasoned determination that the benefits of the intended regulation justify its costs;" did not allow a 60-day comment periods, and did not seriously take into account the cost of cumulative regulations.

Response to: CTR-044-045

See responses to CTR-021-005c and the preamble to the final rule.

Comment ID: CTR-045-012b
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES E-01d

Comment: Based on our analysis of the impact of the proposed CTR, we will need to utilize reverse osmosis to meet the proposed CTR limits for copper. Based on this modification, we estimate that our potential annualized costs for compliance will be approximately $900,000. These costs are significantly higher than EPA's estimated costs per plant of $27,000 per year to $480,000 per year. Thus, we strongly believe that the draft Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-045-012b

EPA received a number of comments regarding the ability of existing treatment technologies to meet CTR-based WQBELs for a wide variety of pollutants. The CTR, consistent with the Clean Water Act (CWA) and the National Pollutant Discharge Elimination System (NPDES) program, does not direct facilities on how to comply with permit requirements. Therefore, each regulated facility can consider a variety of options to comply with permit requirements. In estimating compliance costs, EPA selected control options for the sample facilities by taking into consideration treatment feasibility and cost.

In an effort to ensure consistency in estimating the general types of controls that would be necessary for a sample facility to comply with the final CTR, as well as to integrate into the cost analysis the alternatives available through CWA and NPDES permit programs, EPA developed and utilized a decision matrix. The underlying assumption of the decision matrix is that a facility will examine least-cost alternatives prior to incurring the expense and potential liabilities associated with constructing end-of-pipe treatment facilities. Additionally, for the low scenario only, EPA assumes that where current treatability data indicate that end-of-pipe treatment cannot achieve the WQBEL, a regulatory alternative measure, such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, etc., will be utilized.

Under the decision matrix, EPA considered costs for minor treatment plant operation and facility changes first. Where it was not technically feasible to simply adjust existing operations, waste minimization/pollution prevention controls were considered; however, these controls were selected only where they were considered feasible based on EPA's understanding of the processes at a facility. In general, detailed treatment and manufacturing process information is not available in NPDES permit files. Therefore, EPA's assessment of feasibility was primarily based upon best professional judgement using general knowledge of industrial and municipal operations. If waste minimization was deemed not feasible to reduce pollutant levels to those needed to comply with the final Guidance criteria, EPA considered a combination of waste minimization/pollution prevention and simple treatment. If these relatively low-cost controls could not achieve the CTR-based WQBELs, then, finally, EPA assigned costs for end-of-pipe treatment.

It should be noted that under the low scenario, EPA provided one additional cost assumption. Before assuming that treatment would be installed by the facility, EPA first considered whether or not the treatment had been shown to achieve the requisite effluent concentration, and evaluated the relationship between the cost of adding the treatment versus other types of remedies or controls. If EPA concluded that treatment was not technically feasible, or that other remedies or controls would be more feasible than installing end-of-pipe treatment, EPA assumed that a facility would alternatively pursue regulatoryoptions for relief from the WQBEL. When EPA assumed that facilities would pursue a regulatory alternative, no end-of-pipe treatment cost was estimated for a facility; however, a nominal cost for efforts to reduce the pollutant using best available control methodologies was included. Where regulatory alternatives were utilized, EPA did not take credit for any load reduction for any pollutant for which regulatory alternatives were assumed. Finally, EPA estimated and included the typical cost to facilities pursuing alternatives to CTR-based WQBELs. These costs may include activities such as additional monitoring, performing special studies, etc., to support facilities' requests for alternatives to CTR-based WQBEL.

EPA's revised per plant cost estimates are $61,000 to $325,000 per year for POTWs for the low and high cost scenarios in its Economic Analysis of the final CTR. These costs are based on analyzing a sample of facilities and extrapolating to the whole universe of POTWs. Because these values represent averages for the universe of facilities throughout the state, it is possible that costs may be higher for some facilities

and that others may have very low or zero costs.

Given Sausalito-Marin City Sanitary District's (SMCSD) effluent concentration of 22 ug/L and the proposed CTR limit provided in the comment of 15.3 ug/L, a 30.4% loading reduction would be required. Since SMCSD does not provide other details of its current operations, it is not possible for EPA to evaluate whether reverse osmosis is the only feasible option which would ensure compliance with the CTR-based limit. However where sample facilities commented that they would need to install reverse osmosis and provided data to that effect, EPA's analysis of that data found that reverse osmosis would not be necessary.

Comment ID: CTR-050-007b
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? N
CROSS REFERENCES C-21
R
S

Comment: IV. EPA Has Not Complied With Applicable Regulatory Review Requirements. There are several significant statutes and executive orders that require EPA to undertake analyses of the costs and benefits of its regulations, and to submit the regulations and analyses to other governmental bodies, including the Office of Management and Budget (OMB) and Congress. Those authorities include the Regulatory Flexibility Act, the Small Business Regulatory Enforcement and Fairness Act (SBREFA), the Unfunded Mandates Reform Act, the Congressional Review Act, and Executive Order 12866 (Regulatory Planning and Review). EPA apparently believes that it does not need to comply with any of those requirements for this rulemaking. (62 Fed. Reg. at 42188-42191). API believes that EPA is required to meet those obligations for the proposed criteria, and that the Agency's rationale for avoiding this responsibility has no legal basis.

EPA supports its decision not to comply with the regulatory review statutes by stating that the proposed criteria "by themselves, do not directly impose economic impacts." (62 Fed. Reg. at 42188). EPA admits that when those criteria are combined with the designated uses that have been adopted by the State, and implemented in permit limits, "there may be a cost to some dischargers." (62 Fed. Reg. at 42188) could be substantial; the Agency itself estimates that the compliance cost could be between $15 and $87 million per year.(62 Fed. Reg. at 42189). (That does not include indirect costs to the economy, which would surely put this rule above the $100 million impact threshold specified in several of the regulatory review statutes listed above.) EPA cannot ignore those costs by creating its own interpretation of those statutes in which only "direct" impacts need be considered. There is no support in the statutory language or legislative history for such a reading, and EPA has cited no such support in its Federal Register notice.

There is another problem with EPA's rationale for avoiding regulatory review: if EPA were right that "indirect" impacts do not trigger those reviews, the impacts of this rulemaking are not really "indirect."

Those impacts emerge clearly once the proposed criteria are combined with the State's designated uses. Those designations have already been established, so there is nothing uncertain or indefinite about that aspect of the water quality standards. Then, once the standards are completed, the State must implement those standards through permit limits. While there are some decisions that the State must make in determining the proper permit limits, which can influence the size of the compliance costs, EPA can readily determine a range of possible costs. In fact, the Agency has already done so, resulting in the $15 - $87 million cost range discussed above. While those costs may not be fixed with certainty, they are certainly "direct economic impacts". Therefore, even if the Agency were correct in looking at only "direct" impacts, this rulemaking poses such impacts, and EPA must comply with the statutory requirements to conduct and submit cost and benefit analyses of its proposed criteria.

V. CONCLUSION

As explained above, EPA's proposal to issue water quality criteria for toxicities in the State of California suffers from serious legal flaws. API urges the Agency to reconsider its intended course of action in light of the issues raised in these and other public comments. If you have any questions regarding these comments, or would like any additional information, please call Theresa Pugh at 202/682-8036.

Response to: CTR-050-007b

See responses to CTR-050-007a, CTR-021-005c, and the preamble to the final rule.

Comment ID: CTR-052-021b
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-21
R
S

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should revise the proposed rule and economics analysis such that they are consistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act. Specific citations for these inconsistencies are contained in comments from BADA and CASA/Tri-TAC.

Response to: CTR-052-021b

See responses to CTR-009-008a and CTR-021-005c.

Comment ID: CTR-054-008c
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES C-02b
C-24
R
S

Comment: Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Francisco Bay, or alternatively EPA should specify in the Preamble implementation policies for copper that will result in reasonable control measures actions. To comply with the Clean Water Act and EPA regulations, EPA is required to consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act, EPA is required to evaluate regulatory alternatives based on an analysis of costs and benefits. Based on BADA's analysis of costs and benefits, EPA should either adopt copper criteria that are reasonably achievable or alternatively specify implementation policies that will avoid costly end-of-pipe controls. Potential implementation measures that could be specified include use of the following in calculating effluent limitations: actual dilution based on modeling studies; copper translators; probability of compliance less than 99.9%; and water-effect ratios determined for different segments of the Bay. Unless EPA specifies these or similar implementation policies in the rule, it is possible that the CTR could result in significant costs ($12 million per year to $78 million per year) while resulting in minor environmental benefit (a 1% reduction in copper loading to the Bay). In that case, the CTR would violate the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. (see the discussion under Item 11 below.)

Response to: CTR-054-008c

See responses CTR-054-013a, CTR-021-005c, CTR-056-018, CTR-042-007a, and the preamble to the final rule.

Comment ID: CTR-054-049
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-040 incorporates by reference letter CTR-027

Attachments? Y
CROSS REFERENCES B Comment Period

Comment: 2. The California Toxics Rule is inconsistent with Executive Order 12866 and the Unfunded Mandates Reform Act.

a. Executive Order 12866

Executive Order (E.O.) No. 12866 was decreed by President Clinton on September 30, 1993. This Order governs review of agency regulations and sets standards, that federal agencies should use in planning, drafting, and reviewing regulations. E.O. 12866 requires agencies to:

- Assess all of the costs and benefits of available regulatory alternatives, including the alternative of not regulating;

- Propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs;

- Specify performance objectives, rather than specify the behavior or manner of compliance, to the extent feasible;

- Tailor its regulations to impose the least burden on society, taking into account, among other things, the cost of cumulative regulations;

- Afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days;

- Explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

EPA contends that the CTR is not a "significant regulatory action" requiring an economic analysis under the terms of E.O. 12866. This contention by EPA is erroneous since the standard for becoming a "significant-regulatory action" is that the proposed rule is likely to have annual effect on the economy of $100 million or more, OR adversely affect in a material way the economy, the environment, or local governments. Thus, EPA should not be able to allege that this is not a "significant regulatory action" because the CTR will be likely to adversely affect the economy and local governments even if the $100 million cut-off were not met.

Moreover, EPA failed to seriously explore available regulatory alternatives, including an option of not regulating; did not make a "reasoned determination that the benefits of the intended regulation justify its costs;" did not allow a 60-day comment periods, and did not seriously take into account the cost of cumulative regulations.

Response to: CTR-054-049

See response to CTR-021-005c.

Comment ID: CTR-055-003

Comment Author: USS-POSCO Industries
Document Type: Specific Industry
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References:
Attachments? Y
CROSS REFERENCES

Comment: UPI requests Office of Management and Budget (OMB) review of the subject reputation in accord with Executive Order (E.O.) 12866.

The EPA has not fully considered the impact and cost of Waste Load Allocation (WLA) for industrial facilities and for publicly owned treatment works (POTWs), even though the EPA supports the State Task Force conclusion which recognized that the development of Total Maximum Daily Load (TMDL) criteria was "significantly labor and data intensive" and that a "collaborative effort by....stockholders, could distribute work and associated costs". Costs were not properly determined for this significant effort or for the even larger compliance effort required for dischargers.

UPI has considered technologies and costs for compliance with the proposed regulation, recognizing that total maximum daily loads (TMDLs) would apply for a number of water quality-based effluent limitations (WQBELS) likely to be applicable to the receiving water at our facility.

UPI has determined that the only assured means of compliance with the proposed regulation is by use of equipment and operating methods that would eliminate discharge. Technologies for control are difficult, but appear to be feasible. The installed cost of such facilities at a plant such as ours which began operation early this century and contains numerous old installations was estimated at more that $25,000,000 when it was evaluated about five years ago. Such a cost for our facility when extended over just a few of the 56 major industrial facilities and 128 POTWs identified in California by the EPA would mandate OMB review of the subject regulation.

Response to: CTR-055-003

See response to CTR-021-005c. EPA disagrees with the commenter's statement that TMDLs would result in significant compliance costs. The use of TMDLs in developing permit limits would only reduce the cost impacts on facilities evaluated under the CTR because costs would not be borne solely by the point source dischargers. If EPA were to evaluate implementation costs using the TMDL process, it would allocate load reductions between point and nonpoint sources to take advantage of the most cost-effective mix of controls possible. EPA's current costing approach is conservative, erring towards higher costs by assuming that point sources would bear the cost burden alone. With a TMDL process, the result would be a more cost-effective mix between nonpoint and point source dischargers which could conceivably reduce the incremental impact on point source dischargers once current nonpoint source control programs are fully implemented.

Comment ID: CTR-059-002a
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES R
S

Comment: The Sanitation Districts disagree with EPA's assertions that the CTR is not a significant regulatory action under Executive Order 12866 or the Unfunded Mandates Reform Act, and that EPA is not required to comply with the Regulatory Flexibility Act because the CTR establishes no requirements applicable to small entities. We believe the potential costs for POTWs to comply with the CTR criteria would far exceed the $ 100 million threshold, based on the fact that we estimate that the potential costs for seven Sanitation Districts' facilities to comply with the CTR to be nearly $150 million per year. Clearly, many of the 304 other POTWs in the State will also incur costs, as, will other NPDES permittees, indirect dischargers, stormwater dischargers, and nonpoint sources. Thus, EPA's cost figure of $15 - $87 million per year is simply not a credible estimate. Also, it is quite clear that the CTR is likely to adversely affect local governments, including over 40 small communities located in our service area, and that it is significantly different from other federal regulations previously promulgated in California. We believe that EPA has not complied with the mandates of Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. Accordingly, EPA must revise the economic analysis and it must be reviewed by the Office of Management and Budget and then EPA must select the most cost-effective and least burdensome regulatory alternative.

Response to: CTR-059-002a

EPA disagrees with LACSD's $150 million cost estimate, however EPA is not able to evaluate LACSD's estimate because LACSD does not provide monitoring data or any other details with which EPA can perform it's own analysis or evaluate LACSD's methodology. Based on EPA's analysis, costs to POTWs for the entire state range from $7.8 million to $41.6 million, much less than LACSD's $150 million cost estimate. See response to CTR-021-005c and the preamble for a discussion of how EPA's economic analysis meets the requirements of EO 12866, the UMRA, and the RFA.

Comment ID: CTR-059-004a
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES M

Comment: As others have commented, we also encourage EPA to build on its efforts over the past year to coordinate with the State Water Resource Control Board (SWRCB). In particular, we recommend that in the future the two agencies take such steps as the use of simultaneous comment periods, joint preparation

of the economic analysis, and joint final promulgation, much as the "CAL-FED" agencies are doing. Simultaneous comment periods would greatly facifitate review by the public. Development of a joint economic analysis would greatly reduce the time and resources expended by the two regulatory agencies, as well as by stakeholders. Most importantly, EPA and the SWRCB should adopt the CTR and the State's Implementation Policy at the same time. This will eliminate uncertainties for permit writers and the regulated community as to how the CTR should be implemented, and encourage greater statewide consistency in the implementation of the CTR.

Response to: CTR-059-004a

See responses to CTR-034-016.

Comment ID: CTR-059-006b
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-28
S

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we reconunend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attaimnent of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of water body.

Criteria Below Detection Limits

We believe that there are fundamental problems with EPA's decision to adopt criteria that are below detection limits. This issue relates to EPA's statutory and regulatory obligations in establishing water quality criteria; namely, that EPA is subject to the same policies, procedures, analyses, and public participation requirements as States pursuant to 40 CFR section 131. These regulations require States to "review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use." (40 CFR section 131.11) For criteria where the method detection limit exceeds the objective, there are inadequate data to determine if the pollutant could reasonably be expected to interfere with attainment of designated uses. We believe

that because of the inability to detect these substances and the lack of monitoring information indicating water quality use impairment EPA has not been able to fulfill its obligations to conduct a water body-specific analysis of the need to promulgate criteria.(*1)

(*1)U.S. Environmental Protection Agency, Economic Analysis of the Proposed California Water Quality Toxics Rule, Office of Water (EPA-820-B-96-001, July 1997), p. 8-18.

Second, EPA has not fulfilled its obligations under the Unfunded Mandates Reform Act and Executive Order 12866 to analyze the costs and benefits of promulgating proposed criteria which cannot be detected or for which insufficient monitoring data are available.

Given these deficiencies, we recommend that EPA defer the adoption of criteria for constituents which are below detection limits until such time as EPA has demonstrated that the levels of toxic pollutants being discharged are at a level to warrant concern. As an alternative, EPA could defer to the State for promulgation of criteria for such compounds on a water body-specific basis as part of the State's continuous water quality planning process.

Response to: CTR-059-006b

See responses to CTR-021-005c and CTR-005-009.

Comment ID: CTR-059-015a
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES S

Comment: Executive, Order 12866 and Unfunded Mandates Reform Act

The Sanitation Districts disagree with EPA's assertion that the CTR is not a significant regulatory action under Executive Order 12866 or the Unfunded Mandates Reform Act. We believe that the potential costs for POTWs to comply with the CTR criteria could far exceed the $ 100 million threshold, based on the fact that we estimate that the potential costs of seven Sanitation Districts' facilities to comply with the CTR could be nearly $150 million per year. Clearly, many of the 304 other POTWs in the State will also incur costs, as will other NPDES permittees, indirect dischargers, stormwater dischargers, and nonpoint sources. Thus, EPA's cost figure of $15 - $87 million per year is simply not a credible estimate. Also, it is quite clear that the CTR is likely to adversely affect local governments, and that it is significantly different from other federal regulations previously promulgated in California. Therefore, we believe that EPA has not complied with the mandates of E.O. 12866 and the Unfunded Mandates Reform Act, and that the economic analysis must be revised, and EPA must select the most cost-effective and least burdensome regulatory alternative. In addition, the Office of Management and Budget should review the economic analysis and the rule before it is promulgated, as required by Section 6 of E.O. 12866.

Response to: CTR-059-015a

See responses to CTR-021-005c and CTR-059-002a.

Comment ID: CTR-090-012a
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES S

Comment: The PUC is aware that the Clean Water Act does not require and in fact does not allow for economic considerations in meeting water quality requirements. However, other policies and regulatory mandates (Executive Order 12866 and the Unfunded Mandates Reform Act) require that we disclose to the public the cost of meeting water quality requirements. There is no doubt that there will be costs that California must bear to produce water quality. We must assure the public that the costs will produce benefits. We are not confident that this proposed rule can do that.

Response to: CTR-090-012a

See response to CTR-021-005c.

Comment ID: CTR-092-016a
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES R
S

Comment: Introductory Comment

EPA states in the Executive Summary (page ES-2) to the Economic Analysis that:

"EPA did not calculate costs for any program for which it does not have enforceable authority ... (nor) for NPDES sources which are not typically subject to numeric WQBELs....."

From a national policy perspective, this narrowing, of the focus of the Economic Analysis may be a

justifiable approach to cost benefit analysis. Local government, however, is not able to disregard the potential cost effects of the CTR on urban and agricultural runoff. Those potential costs will have to be defrayed with proceeds from the same pool of local rate payers responsible for paying for point source pollutant removal programs. In California, those ratepayers have made clear both their support for environmental protection and their reluctance to pay more than is necessary for that protection. A narrow definition of those costs included in the CTR Economic Analysis continues the pattern of fragmenting responsibility and authority for the protection of waterways, which in turn hinders creation and implementation of holistic strategies which would best serve the environment at least cost.

Questions for EPA on the Introductory Comment

Q.-1) If not EPA, who has the responsibility to define the aggregated costs of all water quality-related regulations?

Q.-2) San Jose's reading of federal policy initiatives (which include, but are not limited to, the Regulatory Flexibility Act, Executive Order 12866, and the Unfunded Mandates Reform Act) indicates that EPA is empowered to analyze the economic impact of federal regulations in a way that addresses both aggregated cost impacts as well as the fiscal reality of local level government. Why was this not accounted for in the current analysis?

Response to: CTR-092-016a

See response to CTR-021-005c.

Comment ID: CTR-092-022a
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c Executive Order 12866
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01b01
E-01y

Comment: Comment #6: General Cost Analysis Concerns

The City of San Jose has several generalized concerns about the costs utilized in the Economic Analysis, which raise questions regarding the validity of that analysis, as follows:

Q.6-1) We believe the real point of undertaking the CTR is to assure water quality throughout the State that protects beneficial uses. How can the existing Economic Analysis be sufficient if it does not address the cost of meeting the CTR standards from all sources of discharge? Especially given the amount and cost of aggressive intervention in reducing point source pollution undertaken in California to date?

Q.6-2) Throughout the text of the CTR and within the Economic Analysis, EPA refers repeatedly to the assumption that the State will provide regulatory relief to mitigate severe cost impacts engendered by the CTR. What happens to EPA's cost benefit analysis if even one of those assumptions of regulatory relief is not implemented by the State? While we support EPA's attempt to indicate available regulatory options for the State, local level governments and POTW's have little past experience on which to rationalize acceptance of such assumptions.

Q.6-3) EPA has not estimated the cost to local governments/POTW's/indirect dischargers of securing regulatory relief, nor has that cost been incorporated into the estimate of the CTR impact. How would EPA estimate the cost of securing regulatory relief and how would that additional cost affect the Economic Analysis? Especially since very costly studies may be required in order to qualify for regulatory relief.

Q.6-4) The preamble to the CTR discusses the linkage between the CTR and the National Toxics Rule, and EPA's intent to create a level playing field by setting the CTR standards within the National Toxics Rule Framework. There does not seem to have been a similar attempt to analytically level the playing field vis a vis implementation costs, however, as no indexing or calibration has been undertaken to account for the cumulative costs of efforts to date (see also Q. 4-3), cost equivalency data is rooted in experience outside California, and simple average costs are used to represent widely variable ranges. How would the CTR cost/benefit relationship be affected by adjusting for California's significant previous efforts on water quality control mechanisms and California cost data?

Response to: CTR-092-022a

See responses to CTR-032-004, CTR-060-019, CTR-004-003. amd CTR-035-048.

Because implementation is the responsibility of the state, EPA does not control, nor does it know, what the cost impacts of implementing the CTR will be.

Subject Matter Code: E-01c01 $100M Threshold

Comment ID: CTR-034-003
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c01 $100M Threshold
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: LEGAL ISSUES - Executive Order 12866, Unfunded Mandates Reform Act, Regulatory Flexibility Act

* SCAP disagrees with EPA's assertion that the CTR is not a significant regulatory action under Executive Order 12866. We believe that the potential costs of complying with NPDES permit limits based on the CTR criteria alone could far exceed the $100 million threshold. The CTR can also be considered a significant rule because it will "materially affect" one or more sectors of the economy, it will adversely affect local governments, and it is significantly different from other federal regulations previously promulgated in California.

Response to: CTR-034-003

See response to CTR-021-005c.

Comment ID: CTR-035-044a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES E-01d01
J

Comment: pp. 42188-42189 - Potential Costs Do Not Meet the $100 Million Threshold Under E 0. 12866 (also see discussion above) As noted on p. 42188, one component of the definition of a "significant regulatory action" is that the rule may have an annual effect on the economy of $100 million or more. EPA states on p.42189 that "the annualized potential costs that direct and indirect dischargers may incur as a result of State implementation of permit limits based on water quality standards using today's proposed criteria are estimated to be between $15 million and $87 million." We believe that this range significantly underestimates the potential costs that may be realized from the implementation of this rule. This belief is based on the numerous assumptions used by EPA that would have served to underestimate

potential costs, including assumptions about regulatory flexibility that are clearly contradicted in the Preamble to the rule itself. These issues are further enumerated in Attachment 2, which contains an analysis prepared by the environmental economics firm, M. Cubed. Furthermore, we strongly believe that EPA has a duty to look at a full range of potential costs that may be incurred, and not just to look at the costs under optimistic assumptions. This duty is especially acute in light of the uncertainties of how the CTR will be implemented by the State.

We examined the potential costs for the POTW sector to determine the reasonableness of EPA's cost estimates. Our preliminary analysis indicates that for 23 major POTWs the annualized costs could reach $400 million.(*3) This estimate includes the cost to construct and operate end-of-pipe treatment processes where these would be necessary to achieve projected effluent limits. Unlike the EPA cost estimates, we have assumed that regulatory relief options may not be available, and that, based on the pollutants causing compliance problems, pollution prevention and treatment plant optimization might not be sufficient to reliably achieve compliance. Thus, we feel that this estimate reflects a more accurate depiction of the potential POTW "high-end" compliance costs that could result from the draft CTR. Based on this analysis, we believe that EPA should re-analyze the potential costs for POTWs to meet water quality-based effluent limits based on the criteria in the CTR.

As noted on p. ES-2 of the Economic Analysis (U.S. EPA, 1997a), EPA estimated only the costs to point sources, and did not estimate the potential costs for compliance for nonpoint source dischargers, despite the fact that the majority of water bodies in California are impaired due to nonpoint source discharges (SWRCB, 1996). In addition, EPA failed to estimate the costs of compliance for wet weather dischargers, such as municipal and industrial stormwater dischargers. These omissions also lead us to believe that the potential total costs of the rule are far greater than $100 million. EPA must correct these deficiencies and redo the Economic Analysis.

(*3) Backup information for these cost estimates is available upon request.

Response to: CTR-035-044a

See response to CTR-021-005c.

Comment ID: CTR-035-056b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES E-01c02
E-01p

Comment: Introduction

On behalf of CASA and Tri-TAC, M.Cubed reviewed the U.S. Environmental Protection Agency 's

(USEPA) Economic Analysis (Analysis), as well as the report's underlying benefit and cost data and analyses. M.Cubed's overall reaction is that policy makers and the regulated community can place little confidence in either the benefit or cost analyses -- the uncertainties and broad assumptions contained in these analyses largely undermines their findings. Based on the information provided by USEPA, M.Cubed's judgement is that the proposed California Toxics Rule (Rule) will result in multi-million dollar annual costs -- and have substantial impacts on individual publicly-owned treatment works (POTWS) and dischargers -- and may result in no noticeable benefits to public health or the environment. A critique of specific weaknesses in the cost and benefit analyses is provided below.

Weaknesses in Overall Report Findings

The Analysis' overall findings exhibit a number of flaws, as follows:

USEPA's estimates indicate that Rule costs outweigh benefits, both on an annualized and present value basis. USEPA's claim that comparison "...of both annualized benefits and costs and discounted benefits and costs indicates that the monetized benefits of the CTR are of the same general magnitude as the costs" is simply not true (U.S. EPA, 1997a, page 9-2). For example, using USEPA's comparison of a twenty-year phase-in of benefits at a 3 percent discount rate against a ten-year phase-in of costs at a 7 percent discount rate, or benefits of between approximately $20 to $600 million against costs of about $180 million to $1 billion (setting aside the significant weaknesses in the analysis; differences in the probabilities of low or high outcomes; and questions over the appropriate discount rate to apply)(*2) indicates a low cost scenario which is nine times higher than the estimated benefits, and a high cost scenario which is almost twice as high as benefits.(*3)

Executive Order 12866, which requires the economic review, defines "significant regulatory action" as one that is likely to "adversely affect ... a sector of the economy." Yet, although the USEPA finds that two sectors will incur the majority of the regulatory costs POTWs and chemical/petroleum products -- it provides no analysis of whether or not these costs are "significant" to these sectors. Likewise, USEPA does not examine the potential costs or their implications to small businesses (e.g., health care providers; automobile repair shops), small communities, or non-significant industrial users (SIUs) in general (i.e., industries that are regulated by POTWs through local ordinances, rather than under federal rules)

USEPA's conclusion that the use of different risk levels would not significantly influencecompliance costs is not supported by its data. Based on USEPA's own data, use of a 10E-5 risk level for carcinogens would induce a 25 percent cost savings relative to a 10E-6 risk level under the low cost scenario, with a 3 percent change in pollutant loadings.(*4)

(*2) Noticeable benefits seem unlikely to emerge in the near term, if at all, due to the persistence of existing contaminants in the environment, while costs will be incur-red over one to two decades. Use of a lower discount rate for benefits would reflect the greater value future generations may place on environmental amenities, an assumption which is open to debate.

(*3) The large differences between benefits and costs is mirrored by the wide range in estimated pollution reduction. Under USEPA's low scenario, only.63 million toxic pounds- equivalent are expected to be reduced under the rule, compared to a high scenario reduction of 7 million pounds equivalent. That is, reductions under the high scenario are eleven times higher than under the low scenario.

(*4) Under the high cost scenario cost reductions are less than I percent, with a 7 percent change in pollutant loadings.

Response to: CTR-035-056b

See response to CTR-021-005c.

Comment ID: CTR-045-013
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? Y
CROSS REFERENCES

Comment: The proposed regulation is a significant regulatory action because it may well impose costs that are greater than $100 million per year on the regulated community, the majority of which are local public agencies. Regardless of the dollar amount, it is likely to adversely affect in a material way the economy, the environment, or local governments.

Response to: CTR-045-013

See response to CTR-021-005c.

Comment ID: CTR-066-017
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* The proposed CTR is a significant regulatory action because it will impose costs that are greater than $100 million per year on the regulated community, the majority of which are local public agencies. Regardless of the dollar amount, it is likely to adversely affect in a material way the economy, the environment, or local governments.

Response to: CTR-066-017

See response to CTR-021-005c.

Comment ID: CTR-082-011
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* It should be noted that proposed regulation is a significant regulatory action, because it may well impose costs that are greater than $100,000,000 per year on the regulated community. Regardless of the dollar amount, it is likely to adversely affect in a material way the economic environment a local government.

Response to: CTR-082-011

See response to CTR-021-005c.

Comment ID: CTR-084-002a
Comment Author: City of Redding
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES S

Comment: ISSUES OF CONCERN

The Unfunded Mandates Act of 1995, 62 FR 42191. The City of Redding disagrees with the conclusion that the proposed rule does not result in expenditures by state or local governments in aggregate of $100 million or more in any one year. The strict water quality criteria in the proposed rule would directly cause the state to adopt more stringent standards for dischargers, which would then require the local dischargers to implement exorbitant and costly measures against our users.

Regarding unfunded mandates, the City of Redding believes that the state and local governments would have no alternative in implementing this federal rule than to enforce exorbitant and costly measures

against our users. Therefore, the proposed rule would directly cause significant burden and costs to state and local governments.

Response to: CTR-084-002a

See response to CTR-021-005c.

Comment ID: CTR-096-003a
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c01 $100M Threshold
References:
Attachments? N
CROSS REFERENCES J-05

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

3. The cost implications of these numerical standards are estimated to exceed $100 million to the City of Modesto alone, thereby triggering the President's Executive Order 12866 requiring a more detailed and comprehensive cost-benefit assessment of these proposed standards.

Specifically, the City submits the following comments:

E. Under the proposed rule, Best Management Practices (BMPS) are recommended for compliance with the California Toxic Rule. BMPs may include a variety of processes. Each of these processes may have an associated construction and operation cost. For the City of Modesto, due to the design of the wastewater and stormwater collection systems, it may cost between $25 million to $50 million to construct acceptable BMPS. Existing BMPs may not reduce the pollutant level below that listed in the proposed CRT. Therefore, it is our opinion that construction costs presented in the California Toxic Rule are significantly under estimated. Constructed treatment facilities for wastewater and storm water, beyond BMPS, could exceed $1 00 million for Modesto alone. In addition, annual operation and maintenance costs for BMPs and treatment facilities exceed $1,000,000.

In summary, the proposed regulation is significant because it may well impose costs that are greater than $100 million per year on the regulated community, the majority of which are local public agencies. Regardless of the dollar amount, it is likely to adversely affect, in a material way, the economy, the environment, and local governments.

Thank you in advance for consideration of my comments on the CTR.

Response to: CTR-096-003a

See response to CTR-021-005c.

Subject Matter Code: E-01c02 Bnfts do not Balance Cost

Comment ID: CTR-005-005
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? Y
CROSS REFERENCES

Comment: 4. The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated.

The District's analysis demonstrates that actual costs may be an order of magnitude greater than EPA's $500/lb threshold and the benefits may be nil. A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. For example, the District serves the City of Novato which has a population under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-005-005

See responses to CTR-005-004, CTR-054-013a, CTR-021-005c, CTR-040-029a, and CTR-042-007a.

The standards established in the CTR apply to certain California waterbodies. EPA currently only applies water quality based effluent limits to point sources, and thus the estimate of post-regulation cost reflects only the potential impact of controls on point sources. EPA's benefits analysis is based on an assumption that other controls may also be required of other sources in the future (e.g., under state of law for non-point sources). As controls on other sources are implemented (e.g., remediation of contaminated sediments; best management practices to control storm water discharges, EPA expects that concentrations in fish tissue will decline further and that the standards established by the CTR to protect human health can be achieved.

EPA also believes that the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which is based on only a small sample of point source dischargers. Baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San

Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample and, thus, EPA's analysis may underestimate the risk reduction impact on point sources.

Comment ID: CTR-029-004a
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES E-02e

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

The Proposed Rule's Economic Analysis Over-Emphasizes Costs and Under reports the Benefits of Improving Water Quality Throughout the State

By EPA's own admission, the proposed rule's economic analysis over-reports costs and under-reports benefits. Specifically, the proposed rule states that "cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because the analysis tended to use conservative assumptions."(*8) Conversely, "numerous categories of potential or likely benefits have been omitted" from the analysis, and these omitted benefits "are likely to be significant contributors" to an "appreciable underestimation" of the overall benefits of the rule.(*9) Categories left out of the benefits analysis include improvements in water-related, non-fishing recreation, improvements in land recreation, and improvements in human health resulting from reducing non-cancer risk."(*10)

CMC believes it is possible to quantify many of these omitted benefits to obtain a more accurate picture of the importance of this rule. For example, a recent Santa Monica Bay Restoration Project Study found that people swimming close to storm drains face a 50% increase in their risk of contracting a variety of

non-cancer ills such as gastroenteritis and ear and other infections. At a minimum, EPA's analysis could capture the benefits of improved water quality in terms of avoided sick days and avoided medical costs for such users.

CMC also believes that the economics analysis should consider other categories of benefits not mentioned at all in the proposed rule. For example, Governor Wilson's March 1997 planning document, California's Ocean Resources: An Agenda for the Future, finds that industries that depend on healthy coastal and ocean waters contribute $17.3 billion to the state's economy each year and support 370,000 jobs. The majority of this total, $10 billion, is from tourism, which is not mentioned in the proposed rule but which could benefit greatly from improved water quality. Such omitted benefits should be examined in order to have a more balanced economic analysis.

The adequacy of the proposed rule's economic analysis is important to the long-term implementation of the rule. As reported by EPA, "[t]he allegation that the State did not sufficiently consider economics when adopting Water quality objectives ... was an important issue in the litigation" that resulted in the rescission of the Enclosed Bays and Estuaries Plan and the Inland Surface Waters Plan.(*11) Moreover, an accurate description of the benefits of the proposed rule is critical to obtaining funding and public support for swift implementation of the numeric criteria. CMC thus requests that the benefits analysis be updated where possible to parallel the acknowledged "conservative" approach used in estimating the costs of the proposed rule.

(*8) Id. at 42189.

(*9) Id. at 42190.

(*10) Id.

(*11) Id. at 42165.

Response to: CTR-029-004a

The benefits of water quality improvements are highly site specific and difficult to monetize due to limitations in benefits methodology and accurate data on society's values for these improvements. For example, there are currently few means of linking consumption of toxic contaminants by humans with cases of systemic effects (as opposed to cancer effects, for which dose-response curves have been estimated). As another example, the contingent valuation (CV) is the only method for estimating passive use values, and CV surveys require substantial resources to conduct. As a result, there is limited data and information with which to estimate the benefits of the proposed rule. Since these values are not known, a parallel conservative approach is not possible. EPA presented the information on the limitations of the analysis (e.g., costs may be overstated and benefits may be understated) to assist decision makers in evaluating the results.

Illnesses contracted from swimming, such as those evaluated in the study of storm water drains in Santa Monica Bay, typically result from exposure to pathogens that will not be regulated under the CTR. Noncancer effects from the toxic pollutants that will be reduced by the rule are difficult to quantify because of a lack of information on the link between concentrations in the environment and potential cases of systemic effects.

EPA's analysis does not cover all benefit categories as the commenter notes, however, the evaluation of

all categories of benefits in a constructive manner is beyond the scope of this analysis, thus EPA has done the best possible analysis given the time and budget constraints. EPA believes that had all the benefit categories been fully evaluated, the monetized benefits for this rule would have increased significantly. However, secondary benefits (e.g., tourism) or economic impacts embody the successive rounds of spending in an economy that result from the primary benefits of a regulation. These secondary benefits (or impacts) are estimated based on the analysis of data on interindustry linkages within a region. Although these impacts may be of relevance to policy makers, the inclusion of secondary benefits may be inappropriate. This is because under conditions of reasonably full employment, the resources placed into support services (or diverted from complying entities) would be diverted from (or redirected toward) other productive purposes (i.e., net jobs would not be created or lost for otherwise unemployed individuals but, rather, workers would be drawn to or away from other jobs). Thus, these secondary impacts represent a transfer or redistribution of resources rather than changes in real economic activity.

Comment ID: CTR-032-008b
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01u

Comment: Economic Analysis

The District supports CASA/Tri-TAC's conclusions that the Economic Analysis has significant technical weaknesses, is based on a large number of assumptions and minimal empirical data, and that it almost certainly understates costs and overestimates benefits. There is a critical need for a sound economic analysis. We also agree with their recommendation that EPA and the SWRCB undertake a collaborative process with interested members of the public to revise the Economic Analysis based on guidelines in the Economic Considerations Task Force Report.

Response to: CTR-032-008b

See responses to CTR-056-018 and CTR-092-017.

Comment ID: CTR-035-043
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES

Comment: III. Economic Analysis A. General Comments p. 9-2 (U.S. EPA, 1997a) - EPA Finds that Benefits Are of Same General Magnitude as Costs

Whether the monetized benefits and costs are compared on an annualized basis, or on a total, discounted basis, we disagree with EPA's conclusion that the benefits are of the same magnitude as the costs. When looked at in terms of a twenty-year phase-in of benefits at a 3 percent discount rate and a ten-year phase-in of costs at a 7 percent discount rate, in the low cost scenario, the costs are nine times higher than the benefits; in the high cost scenario, the costs are nearly twice as high as the benefits. Thus, we think that EPA should disclose in its conclusions and inthe summary contained in the Preamble to the CTR that the costs appear to outweigh the benefits. Thus, as discussed above, we believe EPA has to demonstrate that the benefits outweigh the costs, as required under E.O. 12866.

Response to: CTR-035-043

See responses to CTR-021-005c, CTR-032-004, CTR-004-003, CTR-040-039, and CTR-021-006b.

Comment ID: CTR-035-056a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES E-01c01
E-01p

Comment: Introduction

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Weaknesses in Overall Report Findings

The Analysis' overall findings exhibit a number of flaws, as follows:

USEPA's estimates indicate that Rule costs outweigh benefits, both on an annualized and present value basis. USEPA's claim that comparison "...of both annualized benefits and costs and discounted benefits and costs indicates that the monetized benefits of the CTR are of the same general magnitude as the

costs" is simply not true (U.S. EPA, 1997a, page 9-2). For example, using USEPA's comparison of a twenty-year phase-in of benefits at a 3 percent discount rate against a ten-year phase-in of costs at a 7 percent discount rate, or benefits of between approximately $20 to $600 million against costs of about $180 million to $1 billion (setting aside the significant weaknesses in the analysis; differences in the probabilities of low or high outcomes; and questions over the appropriate discount rate to apply)(*2) indicates a low cost scenario which is nine times higher than the estimated benefits, and a high cost scenario which is almost twice as high as benefits.(*3)

Executive Order 12866, which requires the economic review, defines "significant regulatory action" as one that is likely to "adversely affect ... a sector of the economy." Yet, although the USEPA finds that two sectors will incur the majority of the regulatory costs - POTWs and chemical/petroleum products -- it provides no analysis of whether or not these costs are "significant" to these sectors. Likewise, USEPA does not examine the potential costs or their implications to small businesses (e.g., health care providers; automobile repair shops), small communities, or non-significant industrial users (SIUs) in general (i.e., industries that are regulated by POTWs through local ordinances, rather than under federal rules)

USEPA's conclusion that the use of different risk levels would not significantly influence compliance costs is not supported by its data. Based on USEPA's own data, use of a 10E-5 risk level for carcinogens would induce a 25 percent cost savings relative to a 10E-6 risk level under the low cost scenario, with a 3 percent change in pollutant loadings.(*4)

(*2) Noticeable benefits seem unlikely to emerge in the near term, if at all, due to the persistence of existing contaminants in the environment, while costs will be incur-red over one to two decades. Use of a lower discount rate for benefits would reflect the greater value future generations may place on environmental amenities, an assumption which is open to debate.

(*3) The large differences between benefits and costs is mirrored by the wide range in estimated pollution reduction. Under USEPA's low scenario, only.63 million toxic pounds- equivalent are expected to be reduced under the rule, compared to a high scenario reduction of 7 million pounds equivalent. That is, reductions under the high scenario are eleven times higher than under the low scenario.

(*4) Under the high cost scenario cost reductions are less than 1 percent, with a 7 percent change in pollutant loadings.

Response to: CTR-035-056a

EPA disagrees with the commenter's claim that costs outweight benefits. In the Economic Analysis of the final CTR, EPA estimates that benefits may range from $6.9 million to $74.7 million per year and costs may range from $33.5 million to $61.0 million per year. EPA believes that benefits are underestimated due to EPA's inability to monetize all categories of benefits. See also responses to CTR-056-018, CTR-029-004b, and CTR-035-057.

Regarding the issue of whether the CTR imposes significant costs on the chemical/petroleum product andPOTW industries, see the response to CTR-042-007a. Based on 40 CFR.131.11, EPA is supposed to base current criteria on sound science and the criteria must contain sufficient parameters to protect the designated uses. From the outset of the national water quality standards program, EPA has explained that while economic factors may be considered in designating uses, scientific and technical factors must form the basis for the criteria to meet those uses. However, in the spirit of EO 12866, EPA has evaluated the cost impact of the CTR on the regulated community.

EPA disagrees with the commenter that the use of different risk levels significantly influences compliance costs. Under EPA's revised low scenario, there is a 3% difference in costs and under the high scenario, there is a 10% difference in costs between the alternative 10E-5 risk level scenario and the CTR-based 10E-6 risk level scenario. Cost increments should be compared to benefits increments, not loading reductions, for a more realistic evaluation of the impact of risk levels. EPA believes that monetized benefits might be commensurate with the cost increase resulting from the lower risk level and EPA believes that costs may be overstated in the high scenario.

See also response to CTR-021-005c.

Comment ID: CTR-035-064
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES

Comment: Weakness in cost analysis The report cost estimates exhibit a number of significant weaknesses, as follows:

* Although USEPA claims that its estimates most likely overstate potential costs, the Analysis isbased on a large number of assumptions that could act to understate rule related expenditures. Table One identifies some of these assumptions.

Table One Other Major Technical Assumptions Which Could Significantly Impact the Cost Analysis

Assumption / Potential Impact on Analysis

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"If all monitoring data reported for a facility were reported as below analytical detection levels, even if the reported detection limit was above EPA-approved analytical detection levels, it was assumed that no reasonable potential existed to exceed CTR-based WQBELS." (U.S. EPA, 1997b, page 2-13)

RWQCB's permitting policies could undermine this assumption, thereby inducing greater impacts than assumed in the analysis (e.g., lindane in the City of Los Angeles).

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The low-cost scenario assumes "no cost" after costs exceed $200 per toxic pounds equivalent; high-cost threshold is assumed to be $500 per toxic pounds.

If relief not given, costs would be substantially higher. Relief is estimated to cost $200,000 per facility,

despite a potential range of $20,000-$1,000,000 per pollutant. Since "the facility ultimately must achieve the CTR based WQBEL" (U.S.EPA, 1997b, page 2-31) under this method costs should properly be extended to the future (e.g, discounted). Relief provision isn't balanced with benefit reductions.

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USEPA claims that "minor dischargers are not expected to incur significant impacts as a result of State implementation of CTR water quality criteria." (US, EPA, 1997b, page ES-1).

This statement appears to be based on a sample of three minor dischargers, an insufficient sample to reflect the entire population of these dischargers.

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Between 10 to 30 percent of indirect dischargers could be affected by pretreatment requirements.

This percentage is based on a Great Lakes study, with no reason to believe similar patterns exist in California, Although pre-treatment costs are very industry-specific, USEPA's data is solely based on two California cases: Compliance period may not allow for optimal use of pretreatment; optimization; or end-of-pipe treatments.

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Assumes that costs are incremental (e.g., that rule compliance would result in distinct investment from past or future behavior).

Could require the need to reorganize capital or operating expenditures, resulting in higher costs. The costs of existing unmet standards should be considered.

"...assumed that all sludges generated would be nonhazardous..that sludge would be disposed of in municipal landfills..."

"...potential costs associated with storing and transporting sludge were not considered." (U.S. EPA, 1997b, page 2-35)

Average per-facility process "optimization" costs were assumed to be $100,000, and to be fully effective in obtaining targeted reductions.

This is an optimistic assumption.

Depreciation and the cost of capital where not included in the O&M costs. Financing assumed to be available.

Some (small) POTWs may have difficulty obtaining lowcost financing, particularly as a result of

Proposition 218.

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"...detailed treatment and manufacturing process information was not available in the NPDES permit files, ...the assessment of feasibility was based primarily upon best professional judgement using general knowledge of industrial and municipal operations." (U.S.EPA, 1997b, page 2-30)

Use of generalized knowledge may act to under- or over-estimate file costs to specific POTWs and dischargers.

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Technical assumptions in the case studies (e.g., treatment of process waters; optimization) merit engineering review.

Examination of case-specific costs could result in different estimates.

Response to: CTR-035-064

See also responses to CTR-032-004, CTR-040-024, CTR-040-029a, CTR-040-036, CTR-059-018, and CTR-060-019.

EPA acknowledges that as permit limits are established below analytical detection levels, ambient water quality background data also may be below analytical detection levels, which may make analysis of use attainability more difficult. However, in accordance with the procedures recommended in Water Quality Standards Handbook, Second Edition (U.S. EPA 1994), analysis of use attainability encompasses evaluating physical and biological indicators as well as the ability to meet water quality criteria.

The commenter's statement that, under EPA's analysis, no reasonable potential is assigned to pollutants with projected effluent limits below detection levels is inaccurate. In EPA's high scenario, pollutants with projected CTR-based limits below detection levels are assigned reasonable potential and analyzed for potential compliance costs if they have an existing NPDES permit limit. The fact that a Regional Board assigns a permit limit to a pollutant reported below detection level indicates that the Board may require further controls to ensure compliance. In the Economic Analysis, EPA estimates that facilities would implement pollution prevention or waste minimization programs in order to achieve compliance with limits below method detection levels.

For the City of Los Angeles POTW, EPA determined reasonable potential to exceed water qualitycriteria for lindane because a (1991) permit limit exists and discharge data show reasonable potential to exceed CTR criteria. EPA did not estimate compliance costs, however, because the existing permit limit is as stringent as the projected CTR-based permit limit.

Comment ID: CTR-038-004d
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h
E-01m

Comment: 4. The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. The District's analysis demonstrates that actual costs may be an order of magnitude greater than EPA's $500/lb threshold and that the benefits are very small.

Response to: CTR-038-004d

See responses to CTR-054-013a, CTR-032-004, CTR-021-008, and CTR-040-029a.

Comment ID: CTR-040-008a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01m
E-02c

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* Estimates of potential costs are severely constrained due to certain assumptions including the assumption that regulatory relief from the Rule will be granted if costs are in excess of certain thresholds.

* Estimates of potential benefits are exaggerated by assuming, that the proposed water quality criteria

will actually be achieved in receiving water bodies. This will not result from the implementation of the Rule because the Rule is only addressing permitted discharges to the receiving water bodies.

* The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated.

Response to: CTR-040-008a

See responses to CTR-054-013a, CTR-032-004, and CTR-056-018.

Comment ID: CTR-040-042
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA improperly lumps all criteria together in estimating costs and benefits. The result is that the pollutant reductions that form the basis for most of the costs (chromium, mercury, silver and toluene) are not generally the same pollutants that form the basis for most of the benefits (DDT, PCBs, mercury and dioxin). The cost-benefit analysis should be done on a pollutant-by-pollutant basis and it should be done on the basis of the pollutants that will be reduced as a result of the CTR.

Response to: CTR-040-042

For a discussion of the estimation of benefits and costs for individual pollutants see response to CTR-044-033.

To calculate potential human health risk reduction benefits, EPA first calculated baseline risk levels using actual contaminant concentrations found in fish tissue. EPA then multiplied the baseline risk levels by the estimated reduction in loadings expected to result from the implementation of point source controls and by the relative contribution of point source loadings to total loadings. For DDT, EPA estimated a 68.8% reduction in point source loadings under the high end cost estimate and a 0% reduction in point source loadings under the low end cost estimate. EPA's estimate of human health benefits reflects these estimated reductions. For example, potential cancer-related benefits to recreational anglers range from $0 to $4.2 million for freshwater resources and total $0 for San Francisco Bay.
In addition, the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample.

Comment ID: CTR-041-038
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES

Comment: EPA improperly lumps all criteria together in estimating costs and benefits. The result is that the pollutant reductions that form the basis for most of the costs (chromium, mercury, silver and toluene) are not generally the same pollutants that form the basis for most of the benefits (DDT, PCBs, mercury and dioxin). The cost-benefit analysis should be done on a pollutant-by-pollutant basis and it should be done on the basis of the pollutants that will be reduced as a result of the CTR.

Response to: CTR-041-038

See responses to CTR-040-042 and CTR-044-033.

Comment ID: CTR-043-004e
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? Y
CROSS REFERENCES E-01g
E-01h
E-01m
E-02c

Comment: 4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution;

(2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements;

(3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and

(4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed

water quality criteria) that will not result from the rule.

The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act.

Response to: CTR-043-004e

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-056-018, and CTR-059-018.

Comment ID: CTR-044-005e
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h01
E-01m
E-02c
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005e

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, and CTR-040-029a.

Comment ID: CTR-044-033
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES

Comment: EPA improperly lumps all criteria together in estimating costs and benefits. The result is that the pollutant reductions that form the basis for most of the costs (chromium, mercury, silver and toluene) are not generally the same pollutants that form the basis for most of the benefits (DDT, PCBs, mercury and dioxin). The cost-benefit analysis should be done on a pollutant-by-pollutant basis and it should be done on the basis of the pollutants that will be reduced as a result of the CTR.

Response to: CTR-044-033

See response to CTR-054-013a.

Although a small subset of toxic pollutants are responsible for cancer risk reduction benefits, EPA anticipates ecosystem-wide benefits (e.g., noncancer risk reductions, ecologic benefits) from controlling a range of toxic pollutants. EPA did estimate human health benefits on a pollutant-specific basis. For other benefit categories, EPA estimated potential benefits based on toxic-weighted loading reductions to account for the different toxicities of the pollutants.

EPA recognizes the persistence of some of the substances addressed by the CTR (e.g., DDT and PCBs) and the impact of this persistence on the realization of benefits. In the EA (Chapter 9), EPA accounted for this lag by assuming 10- and 20-year phase-in periods for benefits in its comparison of present value benefits and costs.

In addition, EPA believes that point source controls can factor into pollutant reduction scenarios, although the cost-effectiveness of point and nonpoint source controls are likely to be highly site specific. Potential "hidden" loads (contaminant concentrations which are not currently measured because they are below detection levels) from point sources may also be occurring and may increase the potential benefits of point source controls. In addition, point source loadings reductions will reduce future sediment contamination and, thereby, reduce the need for costly site-specific sediment remediation in the future. Therefore, the CTR can be viewed as both reducing current environmental risks (yielding benefits) by reducing current loadings, and reducing future environmental cleanup costs.

Comment ID: CTR-054-037
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES

Comment: EPA improperly lumps all criteria together in estimating costs and benefits. The result is that the pollutant reductions that form the basis for most of the costs (chromium, mercury, silver and toluene) are not generally the same pollutants that form the basis for most of the benefits (DDT, PCBs, mercury and dioxin). The cost-benefit analysis should be done on a pollutant-by-pollutant basis and it should be done on the basis of the pollutants that will be reduced as a result of the CTR.

Response to: CTR-054-037

See responses to CTR-040-042 and CTR-044-033.

Comment ID: CTRH-001-037a
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES E-01q03
E-01h02

Comment: Second, the interaction between the CTR and the state's implementation policy is particularly important given our second concern, which is namely that the EPA's economic evaluation underestimates the costs and overestimates the benefits of implementing this rule.

Our concern about the cost estimates is based on the fact that the cost analysis appears to undervalue the magnitude of difficulty dischargers will have complying with permits issued based on this rule.

We are also concerned that the cost estimates for various compliance activities such as source control and treatment process optimization made in the case studies are overly optimistic and not reflective of the true actions that will need to be taken to insure compliance.

Overall, we are concerned that the expenditures that may be necessary for many POTWS to comply with the CTR will be large, these costs may not be matched by commensurate benefits, and that EPA has not analyzed whether point source controls are in fact a cost-effective way to achieve water quality standards.

Our preliminary analysis for just five agencies in the Bay Area to comply with the proposed standard for copper alone could amount to more than $60 million per year -- 60 million. This number would be far higher if calculated for every pollutant listed in the CTR for the entire POTW industry in California.

Since this estimate would undoubtedly exceed the high end of the range contained in EPA's analysis, we believe it is necessary for EPA to redo the economic analysis to fully comply with its legal responsibilities.

In addition, revised economic analysis is necessary to provide a sound basis for the State to use in its analysis of the economic impacts of the implementation policy.

Response to: CTRH-001-037a

See responses to CTR-041-018, CTR-035-057, CTR-056-018, CTR-004-003, and CTR-040-039.

Comment ID: CTRH-002-016a
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: E-01c02 Bnfts do not Balance Cost
References:
Attachments? N
CROSS REFERENCES E-01h

Comment: And finally, I'd like to comment on the analysis of the economic impact of the CTR. We believe that the analysis does not portray a reasonable picture of what the potential costs and benefits may result from the promulgation of this CTR. In our opinion, the cost analysis contains many flawed assumptions that result in severe underestimation of the total potential costs, and we're particularly concerned about the use of process optimization and how it was relied upon.

Likewise, the benefits, while admittedly difficult to estimate, appear tenuous at best. The bottom line is that we are concerned that this analysis does not properly reveal that the CTR can lead to requirements for large expenditures by POTWs in Southern California with questionable benefits to the environment. We recommend that EPA carefully redo its economic analysis to portray a more accurate picture of the potential costs and benefits.

Thank you again for this opportunity. We look forward to submitting our comments in writing.

Response to: CTRH-002-016a

See responses CTR-054-013a, CTR-035-057, CTR-056-018, and CTR-004-003.

Subject Matter Code: E-01d Direct Dischargers

Comment ID: CTR-011-001c
Comment Author: City of Simi Valley
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01d Direct Dischargers
References: Letter CTR-011 incorporates by reference letters CTR-027 and CTR-034
Attachments? Y
CROSS REFERENCES C-13
C-24

Comment: The City of Simi Valley discharges approximately 10 million gallons per day (mgd) of tertiarytreated wastewater (as well as municipal storm water) to the Arroyo Simi, an effluent dependent water body. Through much of the year, Arroyo Simi is dry several miles downstream from the City. The Arroyo Simi Characterization Report, completed by the City in 1995, concluded that the arroyo does not support a significant fishery, and observed only arroyo chub, mosquito fish and blunt-nosed minnow in the stream. Although designated as a potential municipal water supply in the Basin Plan, the arroyo waters are not used for municipal purposes. Effluent monitoring are limited, but available data indicate that the City's discharge may have a reasonable potential to exceed the proposed aquatic life criteria for several metals and the proposed human health criteria for several carcinogens.

Since Simi Valley is largely a residential community with supporting commercial development and little industry, and since the City already has an effective pretreatment program, it is unlikely that pollution prevention efforts would effectively reduce the problematic constituents. More likely, the City would be faced with end-of-pipe treatment controls such as lime precipitation and carbon adsorption to achieve the proposed criteria. The costs would undoubtedly be significant and the benefits relatively minor.

Under these circumstances, it appears reasonable to adopt criteria for Arroyo Simi, and similar effluent dependent waters, that are reasonably achievable without costly end-of-pipe controls and that reflect the actual use of the water (i.e., generally such waters are used for fishing or drinking). One way to address this issue, consistent with the requirements of the Clean Water Act, would be to adopt specific human health criteria for Arroyo Simi and other effluent dependent streams based on a cancer risk coefficient of 10E-5 or in some cases 10E-4. Based on the limited data collected by the City, risk levels of 10E-4 would have to be adopted for dioxins, aldrin, alpha-BHC and 4,4,-DDD (see Table 1). Risk levels of 10E-5 would be sufficient for chloroform and endoslfan 11 (Id.).

Response to: CTR-011-001c

See responses to CTR-004-003, CTR-021-008, and CTR-056-018.

Comment ID: CTR-035-008c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01e
E-01m
E-01h
E-01c

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008c

See responses to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-035-061
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis The report's cost estimates exhibit a number of significant weaknesses, as follows:

* The Analysis does not account for changes in discharges over time. Changes in the volume and characteristics of discharges resulting from demographic,(*9) economic, and policy trends are ignored in the analysis. For example, existing economic conditions may lead to greater discharge volumes; electric industry restructuring in California may induce different operating patterns among the state's generators (e.g., Hunter's Point), and air quality rules may alter petroleum refining processes (e.g., reformulated gasoline). These impacts may be region- (e.g,, Silicon Valley) or industry-specific.

(*9) For example, the state may add another six million Californians between 1996 and 2005. See Center for Continuing Study of the California Economy, California County Projections, 1997 Edition.

Response to: CTR-035-061

EPA estimated annual (steady-state) benefits and annualized costs as well as 20- and 30-year streams of benefits and costs to account for the differences in the time frame for experiencing benefits and costs (i.e., up-front capital cost and a phase-in of benefits). EPA did not forecast economic, demographic, or policy changes across these time periods. Such a forecast would involve a great deal of uncertainty. However, EPA does not foresee changes in these variables negatively impacting the anticipated ratio of benefits and costs. Rather, EPA believes that future increases in population and economic activity will most likely increase the benefits of achieving standards for toxic pollutants in California waters compared to the cost of controls.

Comment ID: CTR-045-012a
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? Y
CROSS REFERENCES E-01c

Comment: Based on our analysis of the impact of the proposed CTR, we will need to utilize reverse osmosis to meet the proposed CTR limits for copper. Based on this modification, we estimate that our potential annualized costs for compliance will be approximately $900,000. These costs are significantly higher than EPA's estimated costs per plant of $27,000 per year to $480,000 per year. Thus, we strongly believe that the draft Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-045-012a

See responses to CTR-056-018 and CTR-045-012b.

Comment ID: CTR-052-006
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d Direct Dischargers
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: EPA has greatly underestimated the costs of compliance in the EA. Information developed by CASA and Tri-TAC for just 23 POTWs indicates that annualized costs for those facilities may reach $400,000,000. These are the 23 plants that have had the opportunity to fullyreview their effluent data. Using this cost data, and extrapolating it for all affected California POTWs leads to a potential cost ranging from $570,000,000 to $995,000,000, depending on the assumptions used.

Response to: CTR-052-006

EPA disagrees with the $400 million cost estimate, however, neither EBDA nor CASA/Tri-TAC provide any details of the CASA/Tri-TAC analysis (e.g., names of the 23 major POTWs, the pollutants assigned costs, and cost estimation methodology), thus EPA cannot evaluate the $400 million cost estimate. In CASA/Tri-TAC's comment, Attachment 1 notes that CASA "assumed that regulatory relief options may not be available, and that, based on the pollutants causing compliance problems, pollution prevention and treatment plant optimization might not be sufficient to reliably achieve compliance." However, CASA/Tri-TAC did not provide any data substantiating this assumption. EPA's cost estimate in the Economic Analysis (EA) of the final CTR for all California POTWs affected by this rule ranges from $7.8 million to $41.6 million in the low and high cost scenarios, respectively. EPA stands by it's cost estimates provided in the EA of the final CTR which is based on available permit, permit application, and effluent monitoring data evaluated using a cost decision methodology which allowed for a case-by-case evaluation of costs for a sample set of facilities.

See also response to CTR-040-039.

Comment ID: CTR-052-011
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d Direct Dischargers
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Impact on East Bay Dischargers Authority Ratepayers

The Authority and its member agencies serve approximately 700,000 people in southern and eastern Alameda County. Using an annualized cost of $44,257,000 results in an annual cost of $63.22 per person per year. Using an average of 3.25 persons per household results in an annual cost of $205.48 per household per year. Current sewer rates for Authority agencies are as low as $113 per year. Compliance

with the CTR would result in a new sewer rate of $318.48, or an increase of 282%. Clearly, the costs do not justify the benefits.

Response to: CTR-052-011

EPA disagrees with the $44 million annualized cost estimate for Alameda County, however, EBDA does not provide any details of how this cost was estimated (e.g., pollutants requiring reductions, pollutant concentrations, treatments required), thus EPA could not evaluate the cost estimate. EPA's cost estimate in the economic analysis of the final CTR for all California POTWs ranges from $7.8 million to $41.6 million annually in the low and high cost scenarios, respectively. EPA stands by it's cost estimates provided in the EA of the final CTR which is based on available permit, permit application, and effluent monitoring data evaluated using a cost decision methodology which allowed for a case-by-case evaluation of costs for a sample set of facilities.

See also responses to CTR-056-018 and CTR-005-004.

Comment ID: CTR-066-016
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* Based on our very preliminary analysis of the impacts of the proposed CTR, we will need to add at a minimum reverse osmosis treatment at the regional plant to meet the rulemaking. Based on this modification, we estimate that our potential annualized costs for compliance will be $10,250,000. These costs are significantly higher than EPA's estimated costs per plant of $27,000 per year to $480,000 per year. Based upon this finding, we strongly believe that the draft Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-066-016

See responses to CTR-056-018 and CTR-045-012b.

Comment ID: CTR-081-005b
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d Direct Dischargers

References:
Attachments? N
CROSS REFERENCES E-01d

Comment: * Based on the comments at the hearing of September 17, and our own estimates, the EPA's economic analysis has serious flaws and does not reflect the full costs for implementation of the CTR. The comments of the California Association of Sanitation Agencies should be given significant weight in this regard.

* For example, the WCA plants will not be able to meet the new criteria for copper, lead, and nickel, as well as some organics. This is true even after maximizing source control, pollution prevention, and process control improvements. Both our plants would need additional "end-of-pipe" treatment, such as reverse osmosis.

* Based on our analysis of the proposed CTR, we will need to implement reverse osmosis in order to meet the requirements of the proposed CTR. Based on this, we estimate that our potential annualized costs for compliance will be $11,220,000. These costs are significantly higher than EPA's estimated costs per plant of $27,000 to $480,000 per year. Thus, we believe strongly that the draft Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-081-005b

EPA disagrees that its Economic Analysis (EA) underestimates costs. West County Agency does not provide the details of their $11.2 million cost estimate, thus EPA cannot evaluate its validity or conduct its own analysis. Based on EPA's sample of 14 POTWs in California, EPA predicts that the state-wide cost impact on POTWs would range from $7.8 million to $41.6 million per year. See the EA for details on the EPA's methodology and costs.

See responses to CTR-056-018, CTR-004-003, and CTR-045-012b.

Comment ID: CTR-082-010
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Based on our analysis the impact of the USEPA proposed CTR will need significant in-plant

modifications, changes in effluent disinfection practices, and possibly incorporating nitrification and de-nitrification processes to fully comply with the proposed CTR. Based on these modifications, we estimate that our potential annualized costs for compliance will be around $5,900,000. These costs are significantly higher than USEPA's estimated costs per plant of $27,000 to $480,000 per year. Therefore we strongly believe that the draft economic analysis significantly underestimates the potential statewide costs associated with adopting the CTR and should be revised.

Response to: CTR-082-010

See responses to CTR-056-018 and CTR-045-012b.

Comment ID: CTR-085-019
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

Based on the District's analysis of the impact of the proposed California Toxies Rule, the District will need to add reverse osmosis to existing treatment processes to meet the proposed California Toxics Rule. Based on this modification, it is estimated that our potential annual costs for compliance will be $2.97 million, including retirement of capital. This cost is significantly higher than the EPA's estimated costs per plant of $27,000 per year to $480,000 per year. Thus we strongly believe that the draft economic analysis significantly underestimates the potential costs associated with adoption of the California Toxics Rule and should be revised.

Response to: CTR-085-019

See responses to CTR-056-018 and CTR-045-012b.

Comment ID: CTR-089-005
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Adequacy of the Economic Analysis

We are, quite frankly, astounded that the draft CTR asserts negligable economic impacts as a result of the proposed regulations. Even a cursory examination of the criteria contained in the draft CTR suggest economic impacts well-beyond those assumed by the US EPA's economic model. These include over $650,000 in estimated annualized costs to abandon existing chlorine disinfection facilities and replace them with some other disinfection method such as ultra-violet radiation or ozone, or the addition of GAC filters or air-stripping towers. Each of these modifications may create new and additional compliance problems with other state and federal regulatory requirements and standards, with unknown costs to mitigate them. Clearly the potential magnitude of these economic impacts argues against the use of a generalized model for estimating statewide impacts.

SUMMARY

We hope these comments will help to make the final CTR a better document and a better law. Overall, the draft CTR reflects substantial thought and effort on how best to implement the Clean Water Act's mandate of reducing pollutant discharges to the nation's receiving waters. The draft CTR clearly advances this goal, but our hope is that those agencies and parties most-directly affected by it will be allowed additional time to review it to their satisfaction. We strongly encourage a more detailed assessment of the actual economic impacts that could result from these new regulations. The ability of public utilities to fund new projects has never been lower, and every rate increase requires sound and well-founded justification. No ratepayer should be asked to shoulder the cost of new regulations without a clear and detailed explanation of what it is going to cost, and what benefits will result. State mandated costs require state funding.

We appreciate this opportunity to comment on the draft California Toxics Rule. Please do not hesitate call myself or Dr. Randal Orton in our Resource Conservation and Public Outreach Department to tell us how we can help you further.

Response to: CTR-089-005

EPA disagrees with the $650,000 cost estimate to install a new disinfection method or additional treatment that will control chlorination/disinfection byproducts (DBPs) as EPA did not estimate that any sample facilities would need to install new equipment in order to ensure compliance with CTR-based effluent limits for DBPs. Of the 27 sample facilities examined, EPA assigned costs to 7 facilities for process optimization and to 4 facilities for pollution prevention efforts to control DBPs. EPA's estimated costs for process optimization for the sample facilities range from $25,000 to $230,000 depending on the size of the facility. Estimates for pollution prevention included costs for other, non-disinfection related pollutants and ranged from $50,000 to $2 million.

See response to CTR-035-061 and CTR-003-013.

Comment ID: CTRH-001-027
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: E-01d Direct Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: We're very concerned about the economic analysis. We understand that you can -- this is based on federal orders, executive order and some legislation, in that this is not the normal thing that you do, but we're really concerned that there are some really real significant flaws here.

I'm also very concerned that there's some real misleading of the people of California of what it's going to cost the water bodies in the state to meet these levels. And to say that you think it's going to be 84 million a year is entirely misleading.

It really concerns me that people are going to glom on that number, say, "Gee, this isn't going to cost us much," if you believe that economic analysis. There's very few sources of pollution which you address with the $84 million. It is not looking at the sources and not looking at actually getting those water bodies to those levels. So I would really recommend that you be really careful about those numbers.

Put yourself in my situation. We know in San Francisco that we're going to have a problem meeting aldrin peaks (phonetic) and the dioxin.

We think -- we don't have exact numbers on this right now, but we think that if we have to go to a worst-case scenario -- in other words, if we cannot meet those numbers with source control, we cannot meet those numbers by alternatives, we'll have to -- have to go to carbon or something like this. That could cost $100 million in -- up to 100 million in coastal costs, and $1 million in O & M a year.

Now, I'm going to go to my board of supervisors and say, "Please allow me to pass a bond issue so that I can meet these discharge requirements for discharge to the San Francisco Bay." We're not talking about the Pacific ocean now, just the bay.

And they say to me, "If we give you that money to build those facilities, will the people that fish in the San Francisco Bay, that live in San Francisco, be able to eat the fish?"

And I'm going to say no. I can't guarantee that, because we're a minor source. We're less than 20 percent of 4 percent of the total sources of discharge to San Francisco Bay.

So I think you need to be careful about how you throw these numbers around, because it's going to put us in a position of never being able to do anything either.

You need to think about this economic analysis, because I don't think it's real. And I don't think the benefits that you've shown either are very real, and we'll make more extensive comments in our written form on that.

Response to: CTRH-001-027

See responses to CTR-054-013a, CTR-035-057, and CTR-038-003.

Subject Matter Code: E-01d01 Cost Estmte by Commenter

Comment ID: CTR-005-004
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES

Comment: 3. The proposed rule could cost the District between $2.7 and $7.1 million per year without providing significant benefits. The current Basin Plan for San Francisco Bay does not allow dilution for shallow water dischargers. A review of the Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, September 12, 1997, indicates that the draft policy would allow the current Basin Plan dilution policy to continue. Under the zero dilution policy and other historic permitting practices of the San Francisco Bay Regional Board (e.g., the Board has not considered translators in establishing permit limits), the District would be unable to comply with the proposed copper criteria for aquatic life protection (CMC and CCC), the proposed nickel criterion for aquatic life protection (CCC), and the proposed human health criterion for mercury.

The District, in 1996, made a thorough analysis of the costs and benefits of complying with the proposed copper criterion of 3.1 ug/I dissolved copper and the 4.9 ug/l site-specific objective developed by the Regional Board staff. That analysis indicated that the least costly alternative to comply with these objectives would be to construct a deep water outfall at a capital cost of $28 million and a total annual cost of $2.7 million. This would have the effect of doubling our current sewer service charges. The deep water outfall would not reduce the mass of copper discharged to the Bay. The sole benefit would be to achieve the copper criterion in the immediate vicinity of the outfall (the area affected is on the order of 0.6 acres).

The next most cost-effective alternatives were to go to land disposal or reverse osmosis treatment, both of which would have a total annual cost of $7.1 million. These alternatives would reduce the mass of copper discharged to San Pablo Bay by only 0. 16%. The cost per toxic pound equivalent removed for the deep water outfall is infinite, since no copper would be removed. If one were to assume that the copper discharged to deep water is removed, the cost per toxic pound equivalent removed would be $8,470/lb. For the alternatives that actually remove copper from the Bay, the cost per toxic pound equivalentremoved would be $22,300/lb for land disposal and $28,500/lb for reverse osmosis. The detailed report containing this analysis is presented in Attachment 1.

In conclusion, the adoption of the proposed copper criteria for San Pablo Bay could, under the high-end cost scenario of State implementation, result in very high costs without providing any significant water quality benefit. The District would concur that the low-end cost scenario could be zero (i.e., if the Regional Board were to allow a dilution credit and metals translators).

Response to: CTR-005-004

The Novato Sanitary District estimate is out of the range of the costs EPA estimated for the same

industrial category and within the same range of discharge flow. However, the information submitted by the District is not sufficient to compare the facility with sample facilities of the same industrial category and flow range because existing permit limits for copper, nickel and mercury are not indicated in the comment supporting documentation. However, review of the NPDES permit issued in 1992, which was to expire in 1997, indicates that final effluent limits for copper, nickel and mercury are 2.9 ug/L, 8.3 ug/L, and 0.03 ug/L, respectively. Even though Novato was not a sample facility evaluated by EPA, it appears that these limits are likely to be more stringent than CTR-based limits that would be calculated for this facility using standard U.S. EPA implementation procedures such as those EPA assumed for the CTR EA. In the case of nickel, for example, the most stringent CTR criterion (dissolved) is 8.2 ug/L and a metal translator would be used to convert this criterion to total. Consequently, the CTR-based criterion would likely be less stringent than the existing limit and no costs would be attributed to the rule. In the case of mercury, the 1992 limit of 0.03 ug/L is already more stringent than a projected CTR-based limit of 0.05 ug/L.

If a facility chooses to calculate permit limits with consideration of metal translators or water effect ratios, the facility will not likely need to implement high cost alternatives such as deep water outfall, land disposal, or reverse osmosis. Moreover, U.S. EPA is aware that the use of metal translators to implement water quality criteria for metals does not constitute a regulatory relief alternative under the proposed Inland Surface Waters Policy. In practice, the use of metals translators may be a standard step for the calculation of effluent limits in the State of California and consistent with EPA's policy concerning the implementation of dissolved water quality criteria.

EPA did not calculate a per household cost as part of the CTR analysis. By dividing the POTW portion of the revised high-end cost estimate ($41.6 million) by the State's current estimated number of households in California (11.1 million) results in an estimated cost of $3.75 per household per year. It is unknown, however, whether all of the costs incurred by POTWs would be passed directly on to households. Nonetheless, EPA believes that $3.75 per year is not an unreasonable rate increase to protect the waters of the State of California.

See also responses to CTR-005-001 and CTR-040-031.

Comment ID: CTR-035-044b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? N
CROSS REFERENCES E-01c01
J

Comment: pp. 42188-42189 - Potential Costs Do Not Meet the $100 Million Threshold Under E 0. 12866 (also see discussion above) As noted on p. 42188, one component of the definition of a "significant regulatory action" is that the rule may have an annual effect on the economy of $100 million or more. EPA states on p.42189 that "the annualized potential costs that direct and indirect dischargers may incur as a result of State implementation of permit limits based on water quality standards using today's

proposed criteria are estimated to be between $15 million and $87 million." We believe that this range significantly underestimates the potential costs that may be realized from the implementation of this rule. This belief is based on the numerous assumptions used by EPA that would have served to underestimate potential costs, including assumptions about regulatory flexibility that are clearly contradicted in the Preamble to the rule itself. These issues are further enumerated in Attachment 2, which contains an analysis prepared by the environmental economics firm, M. Cubed. Furthermore, we strongly believe that EPA has a duty to look at a full range of potential costs that may be incurred, and not just to look at the costs under optimistic assumptions. This duty is especially acute in light of the uncertainties of how the CTR will be implemented by the State.

We examined the potential costs for the POTW sector to determine the reasonableness of EPA's cost estimates. Our preliminary analysis indicates that for 23 major POTWs the annualized costs could reach $400 million.(*3) This estimate includes the cost to construct and operate end-of-pipe treatment processes where these would be necessary to achieve projected effluent limits. Unlike the EPA cost estimates, we have assumed that regulatory relief options may not be available, and that, based on the pollutants causing compliance problems, pollution prevention and treatment plant optimization might not be sufficient to reliably achieve compliance. Thus, we feel that this estimate reflects a more accurate depiction of the potential POTW "high-end" compliance costs that could result from the draft CTR. Based on this analysis, we believe that EPA should re-analyze the potential costs for POTWs to meet water quality-based effluent limits based on the criteria in the CTR.

As noted on p. ES-2 of the Economic Analysis (U.S. EPA, 1997a), EPA estimated only the costs to point sources, and did not estimate the potential costs for compliance for nonpoint source dischargers, despite the fact that the majority of water bodies in California are impaired due to nonpoint source discharges (SWRCB, 1996). In addition, EPA failed to estimate the costs of compliance for wet weather dischargers, such as municipal and industrial stormwater dischargers. These omissions also lead us to believe that the potential total costs of the rule are far greater than $100 million. EPA must correct these deficiencies and redo the Economic Analysis.

(*3) Backup information for these cost estimates is available upon request.

Response to: CTR-035-044b

See responses to CTR-021-005c, CTR-032-004, CTR-004-003, CTR-040-039, and CTR-021-006b.

Comment ID: CTR-038-003
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES

Comment: As background, the Sonoma Valley County Sanitation District (District) provides secondary

treatment of wastewater from the towns and communities of Sonoma, Glen Ellen, Boyes, Hot Springs and Aqua Caliente. These are small residential communities with supporting commercial development and only two significant industrial users, a winery and a State hospital. The plant serves a combined population of approximately 26,000, has a capacity of 3.0 million gallons per day (mgd). Between November 1 and April 30 of each year, the plant discharges effluent to the upper end of Schell Slough. During the remainder of the year the effluent is reclaimed for agricultural irrigation. Schell Slough extends approximately 5 miles downstream from the discharge before it terminates at its confluence with Second Napa Slough. Approximately 5.7 miles of waterways connects the Schell Slough system / Second Napa Slough confluence to both the Napa River and San Pablo Bay.

Under the Basin Plan dilution policy, the treatment plant discharge to Schell Slough does not receive a dilution credit, and as a result receiving water criteria are applied directly as effluent limitations in our permit. The District has conducted a dilution analysis using a model of Schell Slough and downstream waters (see attachment). The analysis found that during periods of low natural runoff, the discharge receives a 1:1 dilution about 3 miles downstream and a 10:1 dilution shortly after entering Second Napa Slough 5 miles downstream.

The District has implemented a pollution prevention program. As a result of a corrosion control program implemented by our agency, copper levels in the plant effluent have been reduced from over 40 ug/l several years ago to between 10 and 20 ug/l today. Based on studies conducted by the Novato Sanitary District, which has the same water supply and similar effluent copper levels, it can be concluded that the remaining copper levels in the Sonoma plant effluent are largely the result of corrosion of copper pipes in local households and businesses. Thus, there are no feasible pollution prevention measures that can be taken to bring about further source reduction of copper.

The District has recently conducted an effluent monitoring program to assess compliance with EPA-recommended water quality criteria, using clean sampling techniques and appropriate QA/QC. We are conscious of the difficulty of analyzing for certain constituents and have taken precautions to ensure that we get accurate results. For example, in the case of mercury, we are using ultra clean sampling techniques and sending our samples to Frontier GeoScience, the recognized national expert in mercury analysis. This sampling program has identified several significant attainability problems with respect to the proposed CTR criteria.

3. The proposed rule could cost the District approximately $7 million per year without providing commensurate environmental benefits. The current Basin Plan for San Francisco Bay does not allow dilution for shallow water dischargers. A review of the Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, September 12, 1997, indicates that the draft policy would allow the current Basin Plan dilution policy to continue. Under the zero dilution policy and other historic permitting practices of the San Francisco Bay Regional Board (e.g., the Board has not considered translators in establishing permit limits), the District would be unable to comply with the proposed aquatic life criteria for copper (CMC and CCC) and the proposed human health criteria for mercury, alpha-BHC, gamma-BHC (lindane) and bromodichloro-methane (see Table 1). Based on constituents detected in 1 or 2 of the 6 samples, one PAH (indeno (1,2,3-cd)pyrene) and several pesticides (chlordane, 4,4'-DDT, and endrin) may also present attainability problems (see Table 2). To achieve the CTR criteria for these constituents would require reductions of greater than 80% for copper and reductions of between 49% and 75% for mercury, and between 83% and 98% for alpha-BHC and gamma BHC. Such reductions would require tertiary lime precipitation and reverse osmosis for mercury and copper and carbon adsorption for the organics. The costs of these facilities for a 3.0 mgd plant would be on the order of $7 million per year ($5 million per year for lime precipitation and reverse osmosis and $2 million per year for carbon adsorption)(see Table 4).(*1) This compares to the present

District budget for all functions of approximately $5 million per year. These costs would have no measurable benefit on San Francisco Bay proper because the District's discharge constitutes such a small portion (less than 1%) of the municipal discharge to the Bay and according to the EPA economic analysis, point source discharges contribute only 1% to 11% of the total toxic loading to the Bay. Thus, the District contributes between 0.01% and 0.1% of the toxic pollutant load to the Bay. The sole benefit of the costly end-of-pipe facilities necessary to achieve compliance with the CTR criteria would be to achieve the criteria in Schell Slough, before it enters Second Napa Slough. The District is willing to pursue source control and other reasonable measures to reduce the discharge of these constituents, but the costs necessary to achieve the proposed CTR criteria in-stream do not appear commensurate with the benefits. Although the District has not calculated the cost per toxic pound equivalent that would be removed by such facilities, the cost would likely exceed by an order of magnitude the $200 - $500 cost triggers for regulatory relief, which EPA used in its economic analysis.

(*1) The District's current permit contains a number of effluent limits based on the old State Plans. However, those effluent limits are not legally enforceable in that they were based on water quality . plans that were determined by the court to be illegal. For that reason, it would be inappropriate for EPA to assume that adoption of criteria similar to those in the old State Plans would have no effect on the District.

Response to: CTR-038-003

The Sonoma Valley County Sanitation District (District) stated that the CTR could cost the District approximately $7 million per year without providing commensurate environmental benefits. This estimate is based on the assumption that projected CTR-based permit limits would be derived using historic Regional Board permitting practices, which do not provide dilution and do not use metal translators to derive permit limits. The District estimated that tertiary lime precipitation and reverse osmosis would be required for mercury and copper, and that carbon adsorption would be required for organic constituents such as alpha-BHC, gamma-BHC (lindane), bromodichloromethane, indeno (1,2,3-cd)pyrene, chlordane, 4,4'-DDT, and endrin.

The documentation the District provided, however, is not sufficient for EPA to determine whether the District's estimate is consistent with EPA's estimates for sample facilities of the same industrial category and flow range. In particular, the District would need to provide facility engineering data, existing permit limits, and effluent data for the pollutants of concern. The documentation submitted by the District provides only maximum effluent concentrations. EPA is aware, for example, that other dischargers to San Francisco Bay tributaries (e.g., Novato District) have been assigned copper and mercury NPDES limits that are more stringent than projected CTR-based effluent limits (see response to CTR-005-001). When existing effluent limits are as stringent or more stringent than projected CTR-based limits, no costs are attributed to the CTR because the State has the authority under the Clean Water Act to implement water quality standards in a more stringent manner than is required under federal regulations and guidance.

EPA also noted that the District's analysis was based on effluent data that were reported between November 1996 and April 1997 (6 months) and comprise only six observations per pollutant. These effluent data are limited and may not reflect typical discharge conditions. A drought during a particular year, for example, may induce people to use more pesticides; thus impacting effluent quality. Such may be the case in the use of alpha-BHC and gamma-BHC (lindane) which were detected in the effluent at concentrations greater than the projected CTR-based limits. Estimates based on effluent data collected over three consecutive years would be more appropriate in establishing the most effective compliance

strategy. Despite the limited information submitted with the District's comment, EPA believes that the District's estimate is based on implementation assumptions that are different from EPA's assumptions which follow the Technical Support Document for Water Quality-based Toxics Control (EPA, 1991). If the District is analyzed using EPA's methodology and implementation procedures, the facility's potential compliance costs will most likely be insignificant.

With respect to the District's comment that it is not feasible to implement pollution prevention measures for further source reduction of copper, EPA acknowledges that source reduction alternatives may, indeed, not be feasible for all dischargers and pollutants. In the case of copper, for example, the information submitted by the District suggests that its most cost-effective compliance strategy would be to develop a site-specific metal translator and a water-effect ratio. According to the CTR, these two implementationoptions are acceptable and would not result in significant costs. However, significant costs that result from nonstandard implementation practices should not be attributed to the CTR as is done in the District's analysis.

EPA disagrees with the District's assumption that tertiary lime precipitation and reverse osmosis would be necessary for mercury compliance. The District indicated that the facility receives discharges from a State hospital. EPA has information on mercury levels form hospitals, clinical laboratories, and medical waste incinerators which indicates that hospital facilities discharge mercury at levels up to 15 ppb (EPA compiled two documents which are available in the record for this rule: Overview of Pollution Prevention Approaches at POTWs and Pollution Prevention at POTWs, Resources List). There are some potential other sources which could also be addressed with pollution prevention programs to assure a facility would be in compliance with projected CTR-based limits. Based on EPA's costing methodology, pollution prevention is assumed sufficient for compliance when a pollutant is reported below method detection levels and the projected effluent limit is below method detection levels.

The District also indicated that four organic constituents, indeno(1,2,3-cd)pyrene, chlordane, 4,4'-DDT, and endrin were detected in one or two samples at concentrations greater than projected CTR-based limits. Based on EPA's costing methodology, one or two exceeding values out of six total observations would not be conclusive enough to assume treatment costs. Because the available data is not sufficient to justify addition of treatment, and because the District does not indicate having pursued any source reduction efforts for organic constituents (i.e., no information is provided in the comment), EPA estimates that pollution prevention would be a reasonable pollution control strategy for organic constituents. Examples of the successes of POTWs awareness and education campaigns regarding the use and discharge of products containing toxic substances are presented in EPA's Overview of Pollution Prevention Approaches at POTWs and Pollution Prevention at POTWs Resource List, which are available in the record for this rulemaking.

EPA also noted that the District's $7 million annual cost estimate was based on capital costs that are considerably higher than those estimated by EPA. EPA's costs are based on those found in the Treatability Manual Volume IV, Cost Estimating (U.S. EPA, 1980) and adjusted to current dollars using an Engineering News Record index of 1.9. The District indicated that the total capital costs for a reverse osmosis and chemical precipitation system would be $18.9 million compared to EPA's estimate of $5.7 million. EPA believes that its capital cost estimates are reasonable.

Finally, EPA disagrees with the District's statement that compliance costs for point source dischargers will not have measurable benefits on San Francisco Bay because of the relatively small toxic load contribution compared with nonpoint sources. EPA believes that controls on point source dischargers will contribute to attaining standards in the water body. As controls on nonpoint sources are also implemented, the water quality standards can be achieved. However, should the State determine through

a total maximum daily load (TMDL) allocation that controls on nonpoint sources are a more cost-effective approach to achieving standards, the State can redistribute the allocations through the TMDL process. Also note that it is the toxicity of the discharge that is important. That is, even a small discharge can result in increased risks, sediment contamination, and toxics loading.

See also responses to CTR-032-004, CTR-056-018, CTR-045-012b, CTR-040-026, and CTR-040-031.

Comment ID: CTR-041-009
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? N
CROSS REFERENCES

Comment: 4. Critique of SRCSD Case Study

General

The findings of the Sacramento case study are summarized in Appendix I-C.

The summary analysis flags three pollutants: mercury, aldrin and alpha-BHC as having a reasonable potential to exceed projected CTR-based WQBELs. Projections are then performed to determine a compliance cost related to achieving reductions necessary to comply with the CTR - based limits. This is accomplished by establishing a pound-equivalent reduction needed for each pollutant and relating this to estimated costs (taken from the " . . Great Lakes Water Quality Guidance (April, 1993)). From this a cost-effectiveness ratio is established. For Sacramento, the data used results in a fairly low (favorable) cost-effectiveness ($1.30/annual toxic load equivalent).

A review of the Sacramento case revealed significant problems with the data and assumptions used to derive the cost-effectiveness ratio. These have resulted in a gross underestimate of the ratio and bring to question the validity of the entire analysis. The main problems were use of questionable data without qualification and unsubstantiated assumptions in the cost to achieve compliance. The following details the concerns specific to each pollutant identified.

Mercury

In the analysis a pound-equivalent for mercury was determined using the following:

Regional Plant design flow of 181 mgd. Maximum single effluent mercury concentration of 0.360 ppb. Toxic Weight factor of 500

The total mercury discharge loading is then calculated by applying the design flow of the Regional Treatment Plant and the maximum effluent mercury concentration. It is further assumed this maximum value occurs on a daily basis resulting in a calculated 198 pounds mercury per year (or 99,177 pound

equivalents). This method severely overstates the amount of mercury potentially discharged or even existing in the system. A more appropriate method would be to use the mean concentration to calculate toxic-pound equivalence Further, the 0.360 ppb value has previously been identified as an outlier.

Aldrin and Alpha BHC

The use of either of these compounds in the analysis is questionable based on a qualified review of the data.

The compound alpha-BHC has never been detected in all effluent testing performed. Due to the use of different analytical laboratories over the years, the laboratory detection level has varied. However, through 1996 only 1 case out of 41 samples had a detection level above the listed CTR-based limit. It was this one case that was used to perform the pound-equivalent evaluation and cost analysis for reduction for the Sacramento case study. However, based on sampling it is doubtful as to whether this pollutant is present in the plant wastestreams, since the results of testing using low-level detection limits has demonstrated nondetects significantly below the CTR-based limit. A similar case is made for Aldrin which has been detected only once in the effluent in all testing performed.

The case study applied the highest detection levels for each compound to determine the pound-equivalent reduction necessary to achieve compliance. Once again this grossly overestimates the amount of pollutants in the system. Further, it is stated in the case study that these compounds will be controlled through pollution prevention/waste minimization and a cost of $400,000 assigned for both pollutants. The overstated pound-equivalent coupled with the unsubstainated cost for control yields a relatively low cost-effectiveness ratio. However, it should be noted that both these compounds have been banned for at least a decade and therefore do not lend themselves to the techniques of pollution prevention since there is no identified point source.

Response to: CTR-041-009

See response to CTR-004-003.

EPA calculated pollutant loading reductions for each facility by calculating the difference between the baseline effluent concentration and the projected CTR-based effluent limitation. The approach for calculating the load reductions, therefore, varied depending on the costing scenarios.

For the low scenario, the following assumptions were used: No reduction was assumed if the difference between the baseline value and the CTR limitation was negative. If the existing effluent concentration was above the MDL but the CTR-based limit was below the MDL, the CTR-based limit, or one-half of the MDL (whichever produces a smaller load reduction) was used for the CTR-based effluent limitation. If the maximum reported effluent concentration exceeded the existing permit limit, high scenario assumptions were employed.

For the high scenario, the following assumptions were used: If all effluent data for a pollutant were reported below detection levels, the method detection level (MDL) was used as the maximum observed concentration. If the maximum observed concentration was below the CTR-based limitation, no loading reductions were considered. If the difference between the baseline value (existing permit limit or effluent concentration) and the CTR limitation was negative, zero reduction was assumed. If both the CTR-based WQBEL and the existing permit limit were below the analytical MDL, one-half of the difference between the existing permit limit and the CTR-based limit was used to estimate the pollutant load reduction. If the existing permit limit (or effluent concentration in the absence of a permit limit)

was above the MDL, but the CTR limit was below the MDL, the CTR-based limit, or one-half of the MDL (whichever produced a smaller load reduction) was used for calculating pollutant load reductions.

To determine the reduction in loadings, EPA converted the difference between the most stringent existing permit limit (or the maximum reported effluent concentration) and the most stringent CTR-based effluentlimit (concentration) to pounds per year by multiplying this difference by the facility's average daily flow rate (design flow rate for municipal dischargers). EPA calculated annual pollutant loading reductions for each of the pollutants analyzed at each sample facility for which costs were estimated. The average load reduction then was calculated across sample facilities within each discharge category and extrapolated to the universe of facilities by multiplying the average load reduction by the total number of facilities in the category (EPA extrapolated facility specific costs similarly).

As indicated above, where pollutant monitoring data indicate detectable quantities of a pollutant, EPA used maximum effluent concentrations to estimate both pollutant loading and potential costs. Under this scenario, the methodology may result in overstating pollutant loadings and benefits. However, the assumption will also overstate compliance costs to reduce pollutant discharge concentrations. EPA chooses to err on the side of overstating costs to ensure that all potential costs are counted. EPA disagrees with the commenter's opinion that pollution prevention is not an appropriate treatment for these pollutants merely because they have been banned for some time. Lingering stockpiles or residential use of banned substances may still be releasing these pollutants into the environment and an aggressive pollution prevention program including source controls and public education should be successful in controlling these substances.

One exception, however, occurs under the low scenario. Where the Agency assumed that a facility would pursue regulatory relief, rather than end-of-pipe treatment, no load reduction is credited to the facility, while a nominal cost is incurred to pursue the regulatory relief. In other words, costs increase with no concurrent benefits.

Comment ID: CTR-044-004
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES

Comment: As background, the City of Woodland is a small community with a population of 43,250. We operate a 6.0 million gallon per day (mgd) secondary treatment plant which discharges to Tule Canal, a constructed agricultural drain located within the Yolo Bypass. Tule Canal is an effluent dependent water body. Except for periods when the Sacramento River overflows into the bypass, Tule Canal flows are dependent upon agricultural drainage and the plant effluent. During most of the year, canal flows are dominated by agricultural drainage.

In 1994, the City conducted an effluent and receiving water quality assessment. The purpose of the assessment was to characterize toxic pollutant levels in the plant effluent and the receiving water,

determine effluent dilution, and assess whether the discharge, had a reasonable potential to cause or contribute to an exceedance of either existing or potential water quality objectives for toxic pollutants. The toxic pollutant sampling was conducted using clean sampling techniques and proper QA/QC. In 1996, a supplementary sampling monitoring program was conducted to gather additional data on several of the toxic pollutants of concern. Based on the combined results of the 1994 and 1996 monitoring programs, the City concluded that there may be a reasonable potential for exceedance of several existing and potential toxic pollutant objectives (including aldrin). In that same year, the City developed a water quality compliance strategy to address the problematic toxic pollutants (see Exhibit A).

We have reviewed the proposed CTR and offer the following comments:

3. The proposed rule could cost the City approximately $1.3 million annually without providing commensurate environmental benefits. The Regional Board does not allow the City a dilution credit and therefore we would have to achieve the aldrin criteria (and possibly other criteria) in our undiluted effluent. This would require that maximum observed aldrin levels (0.01 ug/l) be reduced by 98.6% (to 0.00014 ug/l). A reduction of this magnitude is not feasible through pollution prevention because only 4% of the aldrin has been identified as coming from industrial sources. Residential sources account for 55% and other unidentified sources account for 41 % (see Exhibit C). The least costly alternative for achieving an effluent limitation based on the aldrin criteria would be to remove the discharge from Tule Canal and construct a 7-mile outfall to the Sacramento River (where significant dilution exists). This would have a total present worth cost of $9.4 million (see Exhibit A, Tables 5 and 6). This would translate to an annual cost of $1.3 million per year (at 7% over 10 years) and would require about a 50% increase in monthly sewer service charges. This substantial cost would not produce measurable benefit on Tule Canal in that the canal is dominated by agricultural drainage, which contains pesticides and other toxic pollutants. For example, Tule Canal mercury levels upstream of the plant discharge have been measured at levels of 0.15 ug/l, three times the proposed CTR criterion for mercury (see Exhibit A, page 5). Irrespective of this, the City has developed a source control strategy for aldrin and other pollutants of concern (see Exhibit D). A major element of the strategy is the implementation of a pesticides outreach program, now underway (see Exhibit E).

Response to: CTR-044-004

EPA disagrees with the City of Woodland that a $9.4 million construction project would be required to ensure compliance with the CTR-based limit for aldrin because pollution prevention cannot feasibly ensure compliance with the CTR-based limit. The City of Woodland's own analysis of aldrin effluent monitoring data (Larry Walker Associates, WPCF Water Quality Compliance Strategy, Task 14.4, November 1996) states that "significant uncertainty exists as to the actual amounts present." Aldrin was detected above the detection level of 0.006 ug/L only twice out of 13 data points (0.0063 ug/L and 0.01 ug/L). Since sampling data for aldrin are limited and generally reflect that aldrin is not detected, EPA would assign pollution prevention to ensure that aldrin levels remain below detection levels and in compliance with the CTR-based limit. Woodland's current pollution prevention program involves education and outreach, methods which can be successful in reducing residential and miscellaneous inputs of aldrin to the system. However, if Woodland's public education and outreach program does not produce the desired result, Woodland may need to better identify miscellaneous sources (41% of aldrin sources based on the Larry Walker report) for source control or other pollution prevention measures in order to control aldrin levels.

See responses to CTR-056-018 and CTR-021-008.

EPA acknowledges that it was unable to monetize all categories of potential benefits from the rule. EPA

provided a qualitative description of the expected benefits and those unmonetized benefits that may contribute most substantially to total benefits in the final Economic Analysis of the CTR.

Comment ID: CTR-052-005b
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01i

Comment: EPA has greatly understated the potential attainability problems associated with the CTR. This also includes numerous erroneous assumptions made in the EA, such as those described by BADA, CASA/Tri-TAC, and M.Cubed. Larry Walker Associates prepared an Attainability Analysis for the BADA agencies, copy attached. That analysis concluded that BADA agencies will not be able to comply with effluent standards for copper, nickel, pesticides (Aldrin and Heptachlor), and PAHs [Benzo(a)Pyrene, Dibenzo(a,h)Anthracene, and lndeno(1,2,3-cd)Pyrene]. Removals ranging from approximately 20% to nearly 90% will be required. Without major revisions to the CTR, the cost for compliance will be more than $130,000,000 annually. These costs represent only the BADA agencies. Actual costs for all POTW dischargers to San Francisco Bay would be at least an additional 40%, bringing the total annual cost for San Francisco Bay ratepayers to more than $185,000,000 on a strictly flow proportional basis. Since the non-BADA POTWs are significantly smaller, capital costs would actually increase due to loss of economy of scale. Therefore, actual costs for San Francisco Bay could easily exceed $200,000,000 per year - all for the sole purpose of removing between 1-10% of the "Estimated Share of Toxic Loadings Attributable to Point Source."(*1)

(*1) United States Environmental Protection Agency, Office of Water 4301, EPA-820-B-96-001, July 1997, Economic Analysis of the Proposed California Water Quality Toxics Rule, Executive Summary, Page ES-10, Exhibit ES-3. Estimated Share of Toxic Loadings to California Surface Waters Attributable to Point Sources.

Response to: CTR-052-005b

See responses to CTR-040-039 and CTR-052-005a.

Comment ID: CTR-052-010
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter

References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Cost Estimates for East Bay Dischargers Authority Compliance with the CTR

The following table summarizes the costs for compliance with the CTR. The costs are based on data and methodology used in the EA.

Pollutant	Remedy	Capital Cost ($M)	Annual O&M ($M)	Annualized Costs ($M)	
copper	pollution prevention	NA	NA	0.057	
organics	carbon adsorption	116.4	19.4	44.2	
TOTAL		116.4	19.4	44.26	

Response to: CTR-052-010

See responses to CTR-032-004 and CTR-060-019.

Comment ID: CTR-054-005
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES

Comment: The proposed CTR contains several criteria that could result in annual costs for BADA agencies alone of between $68 million and $134 million per year. BADA has conducted an attainability analysis based on effluent data collected by BADA agencies over the past several years, ambient data collect as a part of the Regional Monitoring Program, and the current Basin Plan dilution policies. Both the effluent and ambient data were collected using clean sampling techniques and analyzed using proper QA/QC procedures. An initial review of the State Implementation Policy indicates that the policy would not result in any loosening of the current Basin Plan dilution policy and, in fact, could result in a more restrictive policy.(*1) BADA's attainability analysis also assumed that an additional 10% reduction in problematic pollutants could be achieved through pollution prevention. The CTR economic analysis assumed a 10% to 25% reduction through pollution prevention, but BADA agencies have been implementing pollution prevention for years and would not expect significant additional reductions beyond those already achieved. All BADA agencies have extensive public education and pollution prevention programs and several have won national awards for their source control programs. BADA's analysis assumed that the Regional Board would accept and utilize metals translators developed in

accordance with EPA procedures. BADA used the RMP ambient data to develop the metals translators. BADA's analysis assumed lime precipitation would be utilized where metals removal was necessary and carbon absorption would be utilized where organics removal was necessary. BADA evaluated two lime precipitation scenarios, the addition of lime to primary tanks as EPA assumed in its economic analysis and tertiary lime treatment. BADA evaluated the cost of tertiary lime treatment because we believe EPA's assumption regarding the efficacy and cost of primary lime addition to be overly optimistic. BADA does not believe it is possible to achieve the low effluent values required to comply with the copper criteria through addition of lime to the primaries. Further, BADA believes EPA was incorrect in assuming that lime could be added to primaries without significant capital cost. Adding lime to primaries, at a minimum, would greatly increase the amount of sludge produced, thereby necessitating additional sludge handling and processing facilities. For these reasons, consultants have generally recommended tertiary lime treatment to achieve the effluent copper levels required to achieve the proposed criteria. Finally, BADA's analysis used 1996 costs, amortized at 7% interest over ten years, just as EPA did in its analysis. In estimating the cost of lime addition to the primaries, BADA used EPA's costs for lime treatment. The results of BADA's attainability analysis are presented in Attachment 2. The analysis shows that after pollution prevention all five BADA agencies would have problems complying with one or more of the proposed criteria. Three agencies would have problems with dissolved copper criteria for protection of aquatic life and two agencies would have problems with carcinogen criteria for protection of human health (aldrin, PAHs, or heptachlor). The estimated annual cost to achieve compliance varies between $68 million and $134 million per year depending on the assumption regarding lime treatment. The lower cost was based on EPA's assumption that lime could be added to the primaries to achieve the effluent limits without any capital cost. The higher cost was based on the assumption that tertiary lime treatment would be necessary to achieve the effluent limits. The lower costs include $12 million per year for lime treatment to achieve the copper effluent limitations and $56 million per year for carbon absorption treatment to achieve the effluent limitations based on carcinogens. The higher costs include $78 million per year for lime treatment and $56 million per year for carbon absorption treatment. Again, this is not a worst case scenario in that BADA assumed translators would be allowed (even though the Regional Board has not made it a practice to accept translators) and assumed continuation of the present dilution policy (even though the Draft State Implementation Policy would allow the Regional Board to deny dilution credits for deepwater dischargers).

(*1) For example, on page 13, the Draft Implementation Policy states: "The RWQCB shall consider denying or significantly limiting a mixing zone and dilution credit if the discharge contains pollutants that are carcinogenic, mutagenic, teratogenic, persistent, bioccumulative, or attractive to aquatic organisms." Literally all POTW discharges contain pollutants such as mercury that are bioccumulative and materials such as chloroform that are carcinogenic. Thus, the Draft Implementation Policy would allow the San Francisco Bay Regional Board to eliminate the 10: 1 dilution credit currently afforded to deep water dischargers.

Response to: CTR-054-005

EPA disagrees with BADA's cost estimates. EPA estimated costs to POTWs for the entire state of from $7.8 million to $41.6 million annually compared to BADA's estimate of $68 million to $134 million annually. As BADA points out in its comment, EPA uses a different standard when assigning pollution prevention costs (see response to CTR-004-003 for a discussion of EPA's methodology for applying pollution prevention costs). EPA's analysis assumes that facilities will try to meet CTR-based limits using the least cost option and, for loading reductions between 10% and 25%, EPA believes that pollution prevention or process optimization are the more likely options over end-of-pipe treatment.

In EPA's economic analysis for the final CTR, it assigned both lime addition to primary tanks and tertiary lime treatment based on individual facilities' existing treatment, CTR-based limits, and required loading reductions (see the response to CTR-040-032). EPA did consider sludge disposal where relevant and estimated residuals removal costs for those facilities.

The differences in load reductions (and thus the treatments considered necessary to meet CTR-based limits) between BADA and EPA's analyses result from different baselines in the two analyses. BADA uses a 99.9% probability estimate for metals and the maximum observed concentration for organics as its baseline to estimate loading reductions. EPA uses the existing NPDES permit limit or, in the absence of an existing limit, the maximum effluent concentration to estimate loading reductions which are then considered when assigning costs to reach the necessary load reductions.

EPA did not assign costs mechanically based on unrealistic guidelines and statistical procedures to predict worst-case effluent quality as a means for determining compliance as was done in the BADA analysis. EPA's cost decision matrix allowed for the consideration of the available data in the context of detection limits, facility processes, and potential irregularities in plant operations which might result in abnormally high data. EPA believes that it's methodology is more accurate in its evaluation of data and its estimation of costs than the BADA methodology.

See also responses to CTR-054-013a, CTR-021-008, CTR-040-029a, CTR-056-018, and CTR-040-031.

Comment ID: CTR-056-020
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Given the limited time available to respond to the proposed CTR, an attainability assessment for one pollutant, copper, as the primary pollutant of concern for EBMUD was conducted (it should be noted that the District also has concerns over organic pollutants where detection limits are greater than the proposed criteria). The analysis was conducted and is presented as percentage reductions necessary to reach three levels of probability for achieving 4-day average limits:

* 95% Probability would require a 0 to 7% copper reduction. The District believes that such reductions could be achieved within 0 to 5 years by continued focus on pollution prevention measures. Current costs for pretreatment are approximately $570,000/year, and the cost of pollution prevention approximately $546,000/year.

* 99% and 99.9% Probability would require up to a 19% and 30% reduction respectively; this could only be attained through advanced treatment facilities beyond that which presently exists.

Since 1974, influent copper loadings have been reduced from 318 kg/day to 17 kg/day in 1996 (i.e.

94.7%). Pollution Prevention efforts since 1988 have resulted in a 39% reduction from 28 kg/day to 17 kg/day. In 1996 wastewater treatment resulted in a further reduction to an average effluent discharge of 5.2 kg/day. To reduce the discharge of copper by an additional 30% from 5.2 kg/day to 3.64 kg/day would result in a capital cost of $42 million and an annual O&M cost of $5 million per year. This is based on the assumption of having to treat approximately 30% of the plant flow (i.e. 22 MGD) to remove copper using the lime precipitation process. This estimate compares closely with an independent estimate of $39.2 million capital cost and $4.6 million per year operating cost performed at EBMUD's request by the consulting firm of Larry Walker & Associates.

If the EBMUD information is an example, there can be no doubt that the $15 to $87 million per year EPA cost estimate, which is supposed to have included debt service on capital investments, is a gross understatement of the true costs statewide.

Response to: CTR-056-020

See response to CTR-004-003.

Comment ID: CTR-059-001
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Historical monitoring data for the seven water WRPs have shown that plant effluent concentrations will not reliably meet the proposed CTR criteria for mercury, lindane and four trihalomethanes (bromoform, chlorodibromomethane, chloroform and dichlorobromomethane). Our preliminary evaluation of the feasibility of employing source control or pollution prevention as the principal compliance strategy indicates that these options are likely to yield only very small reductions in loadings for these pollutants. Thus, to ensure reliable compliance with the CTR, reverse osmosis (RO) at the Sanitation Districts' seven WRPs would be necessary. The preliminary cost estimate for providing RO at each of the seven WRPs is significant. The total annualized cost is approximately $148 million. To put this into perspective, the addition of RO treatment would double or triple the single family home sewer system rates for the areas serviced by these facilities.

Response to: CTR-059-001

EPA is not able to evaluate LACSD's assessment that reverse osmosis (RO) is required at each of the WRPs which are not in compliance with the CTR-based limits because LACSD does not provide monitoring data or any other details with which EPA can perform an analysis. Thus, EPA disagrees with LACSD's $148 million cost estimate for the WRPs. EPA estimates that costs to POTWs for the entire state will range from $7.8 million to $41.6 million. See responses to CTR-045-012b, CTR-004-003, and CTR-005-004.

Comment ID: CTR-067-006b
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? N
CROSS REFERENCES R

Comment: * The EPA should reevaluate their determination under the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities. OVSD would be classified as a small entity, serving a population of 25,000, and would be significantly affected by the CTR. OVSD would have to further treat our effluent with reverse osmosis in order to comply with proposed CTR criteria, specifically for copper, nickel, zinc, lindane, and trihalomethanes; modifications to the existing plant would result in estimated increased annualized costs of $1.98 million. These costs are significantly higher than EPA's estimated costs per plant of $27,000 to $480,000 per year. In addition, EPA must consider that OVSD's contingent of small businesses potentially will be affected by the proposed rule through increased regulation of their discharges, increased sewer discharge fees, or product bans. Thus we strongly believe that the EPA's Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-067-006b

See responses to CTR-021-005c, CTR-056-018, and CTR-045-012b.

Comment ID: CTR-070-002b
Comment Author: Sewerage Agency of Sthrn Marin
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES E-01w

Comment: Economic analysis The attached table shows that implementation of the proposed limits will result in the reduction of SASM's copper limit from 37 ug/l to 12 ug/I. It is expected that reverse osmosis will be the most economical method to reach this level and that the cost of this operation will be approximately $550,000 per year. This equates to a 30% increase in SASM's budget. This cost is also higher than EPA's estimated costs of $27,000 to $480,000 per plant per year. It appears that the Economic Analysis underestimates the potential statewide cost and should be revised.

Response to: CTR-070-002b

See responses to CTR-045-012b and CTR-070-002a.

Comment ID: CTR-111-001
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 02/19/98
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? Y
CROSS REFERENCES

Comment: As discussed in the February 12, 1998 telephone conversation between Mr. Mitchell of your office and William Straub of my staff, enclosed for your information and use is a copy of an April 1992 report summarizing anticipated compliance efforts and costs that the City compiled in response to the State Water Resources Control Board's 1991 adoption of the Inland Surface Waters (ISWP). Although the compliance costs were estimated specifically for our DC Tillman Water Reclamation plant in Van Nuys, we believe that per-MGD unit costs are valid for our Los Angeles-Glendale Water Reclamation Plant as well (the estimated costs are summarized on Pages 11 and 12 of the report's Executive Summary).

As indicated in our oral and written comments (September 18, 1997 public hearing and September 26, 1997 letter), the proposed California Toxics Rule's July 1997 Economic Analysis (EA), based in part on the Tillman facility as a case study, misrepresented the true compliance cost impact to the City. The EA, in effect, compared the proposed criteria to the waste discharge requirements of the Tillman plant's existing NPDES permit and concluded that the cost impact would be minimal. However, the plant's 1991 permit was based on the ISWP, which itself anticipated the criteria contained in the proposed Rule. The Tillman plant was the only POTW in the region to be repermitted using these criteria; because of mounting POTW discontent following ISWP adoption, (which ultimately led to the invalidation of the ISWP in 1994), all other POTW permits were renewed using Basin Plan objectives, PQLs and National Toxics Rule criteria. The 1991 Tillman NPDES permit renewal resulted in immediate compliance problems for the plant, and for this reason we believe that the EA cost figures should consider the cost impacts of the proposed Rule from a pre-1991 point of view. The enclosed report approaches these costs from that perspective.

Updated cost estimates for the City's Tillman and Los Angeles-Glendale reclamation plants were recently prepared by the Bureau's Industrial Waste Management Division in response to the release of the proposed Rule. These include:

* Process optimization. Operational modifications to the Tillman and Los Angeles-Glendale plants necessitated by the proposed Rule involve capital costs in the range of millions of dollars and annual O&M costs between $50,000 to $200,000 per plant.

* Pollution Prevention/Waste Optimization. Based on past outreach programs and pollution prevention studies, the proposed Rule would cost about $500,000. In view of the present industrial discharger compliance rate (better than 95%), this effort might have only a marginal beneficial impact.

* Pretreatment Program. Based on studies conducted in the early 1990's, the cost of each pollutant requiring local limits development is about $15,000. Tables I and 2 (attached) summarize constituents which would be problematic under the proposed Rule. The cost of new local limits development for these pollutants would exceed $250,000.

The EA also did not include actual costs incurred by the City resulting from compliance studies required by the Los Angeles Regional Water Quality Control Board. These included:

* A numerical chronic toxicity limitation that resulted in 5 years of toxicity testing costing in excess of $200,000 (other POTWs in the area were granted narrative toxicity limits);

* Industrial source-controllability studies costing $110,000 for methylene chloride, lindane and other pesticides that were determined to be of domestic origin and therefore not controllable by the plant;

* Numerous and ongoing efforts on the part of the Bureau of Sanitation to obtain relief from the Los Angeles Regional Water Quality Control Board based on plant performance data demonstrating that ISWP-based limits were neither equitable nor achievable. We would greatly appreciate your consideration of these costs and the estimated costs contained in the enclosed report with respect to EA revision. If you should have any questions, or wish to discuss actual compliance costs incurred since 1991 in greater detail, please contact William Straub at (213) 485-1820.

Response to: CTR-111-001

See response to CTR-040-026.

Comment ID: CTRH-001-044
Comment Author: Charles Batts
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: E-01d01 Cost Estmte by Commenter
References:
Attachments? N
CROSS REFERENCES

Comment: I don't want to go into what's presented in writing, but as a discharger, our first evaluative criteria of this rule was attainability.

Our analysis is based on the information from our member agencies, and it indicates that the ability of publicly owned treatment works to meet all the criteria is seriously questionable.

For the record, all the dischargers in BADA have extensive public education programs. We have pollution prevention programs. We have award-winning source control programs.

We base our analysis on using actual data that we filed with NPDES permits over the last two years and current regulatory criteria. All the agencies would have attainability problems.

Three agencies would have problems with dissolved copper, three agencies with the organic/carcinogenic compounds. And in fact, we believe as the detection limit approaches permit limits, that all agencies would violate the carcinogenic requirement.

At present, there is no data on these constituents in the environment, in the receiving waters, or in our influents. Most of the data is nondetectable, because of the limits of detection.

It assumes that pollution prevention can identify and control these organic compounds at below parts per trillion. That is highly speculative.

Despite the assumption made in the plan of regulatory relief, treatment has been the method used to remove pollutants from our waste water effluent. If the agencies have to remove copper by relying on lime precipitation, using EPA's own numbers which contain no capital cost for handling the solid material and sludge generated, which is no minor problem, would require considerable capital cost. It would cost our agencies on a yearly basis $12 million.

To remove the organics that is required, it would require probably using technology like powdered activated carbon, and based on EPA estimates for this process, the cost to those agencies, just the three, would be $56 million a year.

We believe that other of our agencies would probably be added as detection limits and the reporting limits are lowered, since MLs would offer only temporary relief, until the detection limits show that these organics are pervasive in the environment.

So just this attainability cost -- based on data of the last two years for five agencies serving three and a half million people in the Bay Area, the cost is $68 million a year. That approaches the maximum cost projected for the state.

If we look at the projected benefits of the increased treatment and cost to our taxpayers, with point dischargers being less than 10 percent of the loading, and the lack of looking at the benefits analysis, we tend to lead people to believe that waters would meet these criteria based on just control of point sources. Actual or passive, one has to wonder what the benefits really are to the public.

If BADA agencies increase treatment to remove copper, for example, an additional 2,400 pounds of copper would be removed per year. That's about a 1 percent benefit to San Francisco. Since there is no data on carcinogenics we are talking about parts per trillion here -- the benefits become even more specious.

This analysis has not factored in more restrictive ambient background concentrations, water effect ratios, water hardness, et cetera. The hope of holding out ambiguous regulatory relief as a method of avoiding treatment costs does not seem consistent with the general trend of regulations, despite the mood of Congress or the public in general.

BADA agencies appreciate the work of EPA staff on the California Toxics Rule. We are willing to provide further data or case studies, if needed, to improve this document.

We have already, and will in the future, optimize and improve the treatment operations, increase pollution prevention and participate in studies to better define the course of action that should be taken to improve the environment and human health.

I thank you for letting me comment.

Response to: CTRH-001-044

See responses to CTR-054-013a, CTR-045-011, CTR-032-004, CTR-056-018, CTR-004-003, CTR-040-039, CTR-040-032, CTR-035-064, and CTR-029-015.

EPA acknowledged that increased angling activity at sites experiencing reductions in toxic contaminants may reflect a shift in activity from substitute sites rather than a net increase. Because EPA could not account for substitute sites in this analysis, EPA estimated lower bound benefits of $0 (i.e., assuming no net increases in activity; see Chapter 8 of EA).

Subject Matter Code: E-01e Indirect Dischargers

Comment ID: CTR-021-011
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01e Indirect Dischargers
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The CTR Inappropriately Extrapolates the Results of Copper and Nickel Industrial Mass Audits to Project the Measures, Cost and Feasibility of Compliance with Organics Limits

The CTR cites the mass audit studies conducted by Sunnyvale and San Jose for copper and nickel as the basis for the estimated $61,526 cost per significant industrial user (indirect discharger) affected by new permit limits. It is a significant extrapolation, if not distortion, to use the results of those studies to project pollution prevention and waste minimization costs for other constituents, particularly trace organics. Those studies did not address organics and there is minimal basis for assuming that the types of measures recommended to address copper and nickel, and therefore costs, and the number of affected industries (CTR assumes 10-30% of total SIUs) bears any relationship to the costs and numbers of organics from local sanitary sewer dischargers. The measures identified in the mass audits were also the easiest and most cost-effective to implement. In the instances where there were additional potential control measures identified, they were considerably more expensive. EPA ignores non-SIUs which may represent up to as much as 75% of POTW regulated industries.

Response to: CTR-021-011

See the response to CTR-040-037.

EPA disagrees with the commentor's assertion that the costs for San Jose and Sunnyvale cannot be used to extrapolate costs to indirect users at other POTWs. The procedures for identifying indirect sources contributing specific pollutants to POTWs and developing and implementing a source control plan to minimize these discharges are similar for all types of pollutants. Additionally, similar to San Jose and Sunnyvale, metals were the primary pollutants of concern for POTWs evaluated in the cost analysis. Apart from these studies, EPA has no data upon which to establish facility-level compliance costs for indirect dischargers. To account for this uncertainty, EPA has revised its assumption regarding the percentages of indirect dischargers that may incur these costs. The percentage of facilities that may incur these costs was revised from the initial estimate of from 10% to 30% to a new estimate of from 30% to 70%. EPA believes that these new estimates are highly conservative (i.e. tend to overestimate costs).

Average per facility investment costs for industrial participants were estimated using the mass audit studies for copper and nickel pollution prevention projects with paybacks of less than five years. The average cost per indirect discharger was estimated to be $61,526 or $15,000 per year at an interest rate of 7 percent and over a period of five years. The total annual costs to the indirect discharger population in California then were estimated by multiplying the annualized cost ($15,000) by the total number of potentially affected indirect dischargers.

Under the MAS, the pounds removed by the pollution prevention projects with paybacks of less than five years were 560 pounds per year for copper and 148 pounds per year for nickel. Since neither San Jose nor Sunnyvale required nickel reductions under the water quality criteria in the final CTR, EPA did not consider pounds removed. Both San Jose and Sunnyvale did require copper reductions under the high-end cost analysis. For San Jose, copper reductions required to comply with the WQBEL equaled approximately 746 non-toxic-weighted pounds per year, however, for Sunnyvale, required reductions equaled 87 pounds per year. Thus, the MAS indicates that copper reductions would be adequate to meet Sunnyvale's required loading reductions, however, they would not be adquate to meet San Jose's required loading reductions.

EPA estimated the costs for POTWs to implement waste minimization/pollution prevention programs which included capital costs for source controls for indirect dischargers. This double counting of costs associated with waste minimization/pollution prevention will cover any new or additional pollutant reduction that is required of a POTW or indirect discharger to meet the WQBEL. The double counting may be more than enough as 90% reduction is not necessary under the rule, even in San Jose's case. Only a small additional redcution is required, thus, this additional capital could be used to reduce the copper load with controls at indirect dischargers.

Comment ID: CTR-034-014c
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e Indirect Dischargers
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01g08
E-01b
E-01v
J

Comment: * In general, we are pleased that EPA prepared an analysis of the economic impacts of the proposed CTR, and that a major portion of EPA's work focused on determining the potential impacts on POTWs. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Detailed comments can be found in Attachment 2. A few of the areas of concern are listed below:

* Small facilities appear to be under represented in EPA's sample of POTWS, especially for minor dischargers.

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

* The assumptions used to determine cost estimates for indirect dischargers appear to omit a large proportion of potentially affected industries.

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. Statewide, the population is projected to grow by nearly 50% by 2020.

* The use of average cost estimates masks economic impacts on individual dischargers, which may be particularly acute for small communities.

* The economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-034-014c

See responses to CTR-032-004, CTR-035-061, CTR-021-006b, CTR-040-037, CTR-059-018, and CTR-035-048.

Comment ID: CTR-035-008b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e Indirect Dischargers
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01d
E-01m
E-01h
E-01c

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008b

See responses to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-035-049
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e Indirect Dischargers
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 2-38 - 2-39 (US EPA, 1997b) -- Cost Estimates for Indirect Dischargers By only including Significant Industrial Users (SIUs), EPA drastically underestimated the costs to indirect dischargers to POTWs, and thus to many of the industries of the State. EPA ignores non-SIUs, which may amount to as many as two-thirds of the permitted industries discharging to a POTW. EPA also does not take into account the businesses that POTWs might have to start regulating, such as dentists for source control of mercury, auto repair shops for metals, and veterinarians for pesticides used for flea control (e.g. lindane, diazinon), which could cumulatively number in the thousands. EPA also used assumptions about indirect dischargers based on an analysis of compliance costs for the Great Lakes Initiative, which showed that between 8 and 44 percent of indirect dischargers could be affected by new permit limits on POTWS. EPA used a range of 10 to 30 percent, based on that analysis. EPA appears to have done no analysis of California industries see what the distribution is by SIC code, and then determined what adjustments might be necessary to use a comparison to the Great Lakes States industrial base. Without this, there is simply no evidence that the assumptions used have anyvalidity for the California economy. For instance, at least in some parts of California, a higher proportion of industries are indirect dischargers than is the case elsewhere in the country. Additionally, to estimate individual indirect discharger costs, EPA used figures based on studies in San Jose and Sunnyvale. EPA provides no rationale for extrapolating from a single area and a few limited types of industries to the wide range industries in California, which may have very different products, treatment processes, and waste streams. To do a credible cost analysis, EPA must thoroughly examine the impacts of the CTR on indirect dischargers in California.

Response to: CTR-035-049

See responses to CTR-021-011 and CTR-040-037.

Comment ID: CTR-041-010c
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e Indirect Dischargers

References:
Attachments? N
CROSS REFERENCES E-01n
E-01m
E-01g

Comment: 5. Concerns Regarding Economic Analysis

The District also has several significant concerns with the Economic Analysis that was performed for the proposed rule. Concerns about the cost estimates made for both the District and the state are presented here. (See attached Review of EPA's Economic Analysis of the Proposed California Water Quality Toxics Rule.) Overall, the District believes that problems with the Economic Analysis are serious enough that is should be redone. As stated above in our analysis of assumed costs at the SRWTP, the use of questionable data without qualification combined with unsubstantiated assumptions regarding costs to achieve compliance resulted in a gross underestimate in the cost-effectiveness ratio. The District's first concern is that if the types of problems found in our Case Study are widespread in other studies, the complete analysis is suspect.

In addition to the analysis of the District's facilities, there are several other points which have been used by EPA to lead to a potentially serious understatement of actual costs. The key assumptions involved are that: 1) no costs would occur if either no monitoring data presently exists or if that data is below analytical detection levels; 2) no treatment costs would occur whenever EPA's initial estimates showed high costs, due to successful regulatory relief; 3) no costs are included for nonpoint sources such as municipal stormwater management systems; and 4) no costs are included for indirect dischargers to the District's system that are not large enough to be considered a Significant Industrial User (SIU).

Regarding the first assumption, the District has found that there is pressure from many sides, including the Safe Drinking Water Act, to both increase the number of constituents being monitored and to lower detection levels to meet numeric criteria set by EPA and the state. To assume that monitoring of these new constituents will not lead to any treatment cost increases is simply unrealistic. Similarly, the second assumption about absolute success in every pursuit of regulatory relief is also overly optimistic. There are no guarantees that pursuit of regulatory relief will be successful in any situation, and EPA indicates elsewhere in the preamble that options such as variances and site-specific criteria will rarely, if ever, be granted.

The third and fourth key assumptions ignore present dominating trends and facts, i.e. that. prevention and control of pollutants at their sources, including very small indirect dischargers, storm runoff, and other nonpoint sources are now the major focus of EPA's wastewater programs nationally. While we agree that these management steps should be taken, there will be significant costs attached to the implementation of these steps that cannot be ignored.

Combined with concerns the District has heard from other sources such as the California Association of Sanitation Agencies (CASA), it appears that EPA has failed to make "a reasoned determination that the benefits of the intended regulation justify its costs." Therefore the District believes that the Agency is obligated to redo the draft Economic Analysis.

Response to: CTR-041-010c

See responses to CTR-032-004, CTR-021-006b, CTR-040-037, and CTR-003-011.

Comment ID: CTR-056-022a
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01e Indirect Dischargers
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES S

Comment: EBMUD perceives there to be a significant overall economic impact resulting from CTR, contrary to the conclusions reached by EPA. Because the cost may exceed $100 million annually on the regulated community (the majority of which are publicly owned agencies), it appears that pursuant to Executive Order 12,866 and the Unfunded Mandates Reform Act, the CTR can be considered a significant regulatory action which is likely to adversely affect the economy of many regions of the State, the environment and/or local governments. EBMUD is also of the opinion that EPA failed to make a, "...reasoned determination that the benefits of the intended regulation justify its costs," and is obligated to redo the draft Economic Analysis and submit it for review by the Office of Management and Budget.

Response to: CTR-056-022a

See response to CTR-021-005c.

Comment ID: CTR-092-020
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e Indirect Dischargers
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #4: Policy Assumptions re Indirect Dischargers

On page 2-38 of the Analysis of Potential Costs it states:

"...it was assumed that many POTW's will select the option of controlling discharges to their collection system as a cost-effective means to comply with permit limits".

Questions for EPA on Comment #4:

The specifics of San Jose/Santa Clara's copper limit and permit performance, as detailed below, raise

several global economic analysis methodological questions. For example, in the case

a) substantial, costly, pollution prevention and pre-treatment programs are already in place for most Indirect Dischargers; b) the emphasis on point sources has reduced influent concentrations to the Plant to levels where there is no longer a significant correlation of influent concentrations to effluent concentrations; c) 90% of copper is routinely removed from the influent at the San Jose/Santa Clara POTW, making further source control only marginally effective; and d) the POTW's wastewater effluent can be proven to be very close to CTR criteria. on average; yet e) portions of the receiving waters do not meet the suggested criteria, it seems capricious and arbitrary to assume that POTW's will opt to make Indirect Dischargers responsible for additional costs, as the source of the bulk of the copper is clearly not from the Indirect Dischargers, and the attainment of the CTR criteria in the receiving water will not occur by asking these sources to make further reductions.

Q.4-1) How many of the Indirect Dischargers are operating in a POTW environment where EPA's assumption would be appropriate? How many are not?

Q.4-2) How would the EPA estimates of POTW costs vs. Indirect Dischargers cost change if this assumption about cost effectiveness were changed?

Q.4-3) With respect to costs, have any measures been employed in this analysis to recognize cumulative costs of efforts undertaken to date? To identify where dischargers (indirect or direct) are on the scale of operating economies? To identify if point source pollution reduction efforts have been successful, thus spending additional monies will be only minimally productive?

Response to: CTR-092-020

The City of San Jose (San Jose) challenges the economic analysis methodology based on its particular experience in the control of toxic substances. In particular, San Jose states that because major pollution prevention efforts have already been conducted at the San Jose/Santa Clara POTW, pollution prevention is not expected to be a successful alternative for compliance with the projected CTR-based copper limit. EPA disagrees with San Jose's statement and addresses specific concerns in the following paragraphs.

San Jose indicates that although San Jose/Santa Clara facility's copper effluent concentration can be shown to be very close to the CTR-based limit, portions of the receiving water do not meet the suggested standard. EPA agrees with San Jose that the San Jose/Santa Clara facility's copper effluent concentrations are reported most often in compliance with the projected CTR-based limit, thus, estimated compliance costs are not sizable. EPA considers, however, San Jose's statement regarding some portions of the receiving water not being in compliance to be vague. If portions of the receiving water would not meet water quality standards when the San Jose/Santa Clara discharge is in compliance with its CTR-based permit limit, then a TMDL may need to be developed for the water body to ensure water quality protection. If the TMDL shows that water quality standards violations are caused by neighboring sources, then these sources would need to be controlled and related costs would not be attributed to the San Jose/Santa Clara facility.

San Jose states that it seems capricious and arbitrary to assume that POTWs will opt to make indirect dischargers responsible for pollution control costs when this may not be the case. EPA believes that San Jose's statement is inaccurate. The EPA's Economic Analysis estimates a statewide cost and is based on assumptions that apply to the majority of dischargers. If an individual facility, such as San Jose, believes that further controls on indirect dischargers are not necessary, then this specific situation would need to be addressed by the facility in a different manner. In order to account for this situation, EPA

assumed in its economic analysis that 30% of indirect dischargers would be impacted in the high scenario and 70% of indirect dischargers would be impacted in the low scenario which reflects that a greater proportion of the implementation costs would fall on POTWs under the high scenario. Nonetheless, EPA believes that the largest portion of toxic constituents received by POTWs are from indirect dischargers, thus pollution prevention, including source control efforts, will be able to ensure compliance with projected CTR-based limits.

Regarding San Jose's question about how many indirect dischargers would be targeted to reduce toxic discharges to POTWs (Q.4-1), EPA did not have adequate information to evaluate all individual indirect dischargers as part of its economic analysis, thus EPA is not able to give numerical estimates of the exact number of indirect dischargers discharging to POTWs that will be affected by this rule. However, to compensate for data limitations, EPA increased its estimate of indirect dischargers affected by the CTR from 10% to 30% used in the proposal to 30 to 70% used in the economic analysis for the final rule. EPA believes that this assumption dramatically overstates the number of dischargers affected by the CTR, but has done so to ensure that costs remain conservative, i.e., erring on the side of higher costs.

San Jose's second question (Q.4-2) is incomplete and, thus, EPA cannot prepare a response. San Jose is asking how costs would change if the assumptions used to estimate indirect costs were different, however San Jose does not indicate what the new assumptions would be. There are numerous other assumptions which could be employed to estimate indirect costs, however EPA cannot address them all and feels thatthe methodology used in the Economic Analysis was reasonable.

In response to San Jose's third question (Q.4-3), EPA did consider documented pollution prevention efforts implemented by the sample facilities in its evaluation and estimation of costs. However, having a successfully implemented pollution prevention program does not automatically disqualify a facility from being assigned pollution prevention costs in EPA's economic analysis. In the case of San Jose, effluent concentrations for copper and silver are reported below projected CTR-based effluent limits for all except one data point. Under this high compliance rate, addition of treatment is not justified, and EPA estimates that the facility would implement a pollution prevention program to ensure continued compliance (e.g., by addressing intermittent discharges). In addition, it should be noted that a pollution prevention program implemented to achieve an existing limit, although successful, may not necessarily comprise the same activities and level of effort as a program that would be implemented to ensure compliance with a new and more stringent limit (i.e., a CTR-based effluent limit).

See also response to CTR-004-003.

Subject Matter Code: E-01e01 Sunnyvale/San Jose

Comment ID: CTR-059-020
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e01 Sunnyvale/San Jose
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The assumptions used to determine cost estimates for indirect dischargers, such as only considering significant industrial users (SlUs), assuming that only 10 to 30 percent of the SlUs would be required to implement control measures, and estimating that the average cost per indirect discharger would be just $15,000 per year, appear to omit a large proportion of potentially affected industries and drastically underestimate potential costs.

Response to: CTR-059-020

See responses to CTR-021-011 and CTR-040-037.

Comment ID: CTR-092-018
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e01 Sunnyvale/San Jose
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #2: Estimation of Costs for Indirect Dischargers

[Re: Page 4-9 of the Economic Analysis; also Page 2-38 of the "Analysis of Potential Costs Related to the Implementation of the California Water Quality Toxics Rule"]

The methodology for estimating costs of implementing the CTR for all the Indirect Dischargers in the state relies on data from the October 1994 Mass Audit Studies (MAS) prepared by indirect dischargers for the San Jose/Santa Clara and Sunnyvale POTW'S. The pages cited above state that "...the average cost per indirect discharger was estimated to be $61,526 or $15,000 per year..."; the former figure being a raw project cost, and the latter, an annualized payment, assuming 5 year amortization at a 7% interest.

Our review of the San Jose/Santa Clara (only)-related MAS data, as tallied in the October 1994 report, presents a very different "average" picture. Specifically, the average per facility project cost figure which can be documented is $135,017 for both copper and nickel projects. Using the same financing assumptions as EPA, that raw cost would generate an annualized cost per facility of more than $30,000 per year.

We believe that these findings cast serious doubt on how the data were interpreted and then utilized for the estimate of costs to Indirect Dischargers. The City has further strong concerns about the validity of using data for projects related to only two priority pollutants (copper and nickel) to represent costs, statewide, for the multitude of pollutants which Indirect Dischargers (and the City) may now be faced with compliance on, given implementation of the CTR.

Of further concern is that the range of project costs for San Jose/Santa Clara Indirect Dischargers is from $2,940 to $928,100 per facility for copper removal projects and $500 to $543,565 per facility for nickel removal projects. Use of a single average cost to represent these widely variable ranges substantially obscures the real cost impacts on the local level and on individual businesses.

Questions for EPA on Comment #2:

Q.2- 1) Based on the San Jose/Santa Clara MAS data which was given to EPA, as cited above, how could the inclusion of Sunnyvale data with San Jose/Santa Clara MAS data bring the average raw cost per facility down from approximately $135,000 to just over $61,500?

Q.2-2) Given the MAS data cited above, it seems unreasonable to allow an average figure to serve as a proxy for costs for Indirect Dischargers statewide. Did EPA undertake some sensitivity analysis to explain the impact of a widely variable range of potential project costs and how that would affect costs to individual Indirect Dischargers as well as costs to the group of Indirect Dischargers?

Q.2-3) How did EPA test for the validity of using data focused on the costs of removing only two priority pollutants by the Indirect Dischargers in one Northern California subregion to represent Indirect Dischargers, with all possible combinations of pollutants as priorities, throughout the State?

Q.2-4) Did EPA determine that the number of pounds of pollutants removed under the five year payback scenario would be sufficient to meet the CTR standards? If not, then perhaps that scenario should be tested, as it may be necessary for the Indirect Dischargers to move to the next level of removal projects analysis (the 90% removal scenario). The per pound costs of doing so can be shown to increase by a factor of over 30 times, which will have a substantial effect on the per facility cost of meeting the CTR and, therefore, change the conclusions of the current analysis.

Response to: CTR-092-018

See responses to CTR-021-011 and CTR-035-048.

Subject Matter Code: E-01e02 No Costs for Non-SIUs

Comment ID: CTR-040-037
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e02 No Costs for Non-SIUs
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's estimates for indirect dischargers is confined to "significant industrial users" (SlUs) and ignores small industrial and commercial establishments that can be sources of toxic pollutants (e.g., vehicle service businesses, printers, dentists, etc.). In most cases, where toxic pollutants exist at levels of concern in effluent, they are not the result of SIU discharges; they are from either residential or commercial sources.

Response to: CTR-040-037

Since non-SIUs are typically not the focus of POTW regulatory programs, the Agency has assumed that the costs to control discharges from non-SIUs will be born primarily by the POTW. EPA's consideration of non-SIUs, therefore, is built into the waste minimization costs allocated to POTWs. For example, the waste minimization costs assumed for POTWs include components such as source identification, outreach and training, and source reduction strategies. These measures have been used successfully by POTWs to reduce discharges of specific pollutants from non-SIUs (e.g., mercury, silver) without imposing costly end-of-pipe treatment.

Comment ID: CTR-041-033
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e02 No Costs for Non-SIUs
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimates for indirect dischargers is confined to "significant industrial users" (SlUs) and ignores small industrial and commercial establishments that can be sources of toxic pollutants (e.g., vehicle service businesses printers, dentists, etc.). In most cases, where toxic pollutants exist at levels of concern in effluent, they are not the result of SIU discharges; they are from either residential or commercial sources.

Response to: CTR-041-033

See response to CTR-040-037.

Comment ID: CTR-043-003
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e02 No Costs for Non-SIUs
References:
Attachments? Y
CROSS REFERENCES

Comment: As background, the City of Vacaville owns and operates two wastewater treatment plants. The Easterly Plant has a capacity of 10 million gallons per day (mgd) and discharges to Old Alamo Creek, an effluent-dependent stream with little or no natural flow during much of the year. The Gibson Canyon Creek Plant has a capacity of 1.4 mgd and discharges to a small creek with the same name. The City has reviewed the proposed CTR with respect to its potential impact on the Easterly Plant. Because the Gibson Canyon Creek Plant serves two industrial dischargers, the City did not evaluate it with respect to the proposed CTR. Additionally, due to the City's population (< 100,000) stormwater has not been monitored for toxic pollutants. However, based on the Easterly Plant review, the City is concerned about the potential impact of the proposed rule on the City's municipal wastewater and on future stormwater operations.

Since 1993, the City has conducted an effluent and receiving water quality assessment with respect to the Easterly Plant. The purpose of the assessment was to characterize toxic pollutant levels in the plant effluent and the receiving water and to determine whether the discharge had a reasonable potential to cause or contribute to an exceedance of either existing or potential water quality objectives for toxic pollutants. The results of this assessment have formed the basis for the City's review of the proposed CTR.

3. The proposed rule could cost the City approximately $4.2 million annually without providing commensurate environmental benefits. The Regional Board does not allow the City a dilution credit and therefore we would have to achieve the CTR criteria in our undiluted effluent. A review of our effluent data indicates we would be unable to attain effluents based on the human health criteria for three carcinogens -- gamma-BHC, chloroform, and dibromochloromethane (see Attachment). The reductions in effluent levels necessary to achieve these criteria vary between 27% for gamma-BHC to 88% for dibromochloromethane. These types of reductions would not be achievable through pollution prevention. Thus, end-of-pipe treatment would be required, most likely carbon adsorption. Using EPA's estimate of costs for a 10 mgd carbon adsorption facility for the City of Merced case study, the capital cost of the facility would be $10.7 million and the annual cost would be $4.2 million (7%, 10 years). It is questionable whether this substantial cost would bring about much benefit in an effluent-dependent stream.

Response to: CTR-043-003

See responses to CTR-021-008, CTR-056-018, CTR-004-003, and CTR-021-008.

Comment ID: CTR-044-028
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e02 No Costs for Non-SIUs
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimates for indirect dischargers is confined to "significant industrial users" (SlUs) and ignores small industrial and commercial establishments that can be sources of toxic pollutants (e.g., vehicle service businesses printers, dentists, etc.). In most cases, where toxic pollutants exist at levels of concern in effluent, they are not the result of SIU discharges; they are from either residential or commercial sources.

Response to: CTR-044-028

See response to CTR-040-037.

Comment ID: CTR-054-032
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01e02 No Costs for Non-SIUs
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimates for indirect dischargers is confined to "significant industrial users" (SlUs) and ignores small industrial and commercial establishments that can be sources of toxic pollutants (e.g., vehicle service businesses printers, dentists, etc.). In most cases, where toxic pollutants exist at levels of concern in effluent, they are not the result of SIU discharges; they are from either residential or commercial sources.

Response to: CTR-054-032

See response to CTR-040-037.

Subject Matter Code: E-01e03 No Savings from Poll. Red

Comment ID: CTR-092-019
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01e03 No Savings from Poll. Red
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #3: Net Costs of MAS Projects

The EPA document entitled "Analysis of Potential Costs Related to the Implementation of the California Water Quality Toxics Rule" describes the agency's interpretation of the Mass Audit study information provided by the City of San Jose for use in preparing the CTR. On page 2-39 of that document it states that:

"The studies concluded that substantial discounted net savings could accrue to their indirect industrial dischargers by implementing pollution reduction projects for which the payback period is five years or less."

Questions for EPA on Comment #3:

Q.3- 1) Isn't this statement appropriate only if the indirect discharger(s) accepts the analyst's financing and business operation assumptions, i.e. that project costs were annualized and then offset by annual operating savings? Even then would there be net savings before project costs were completely offset in approximately five years?

Q.3-2) For those dischargers who chose to pay for pollution reduction projects from current operating monies, isn't the time gap between cost offset and accumulated operating savings even longer? Is there not also the additional, (uncalculated) cost of the opportunity cost of business capital?

Q-3-3) San Jose's findings were that, for the aggregate of MAS dischargers, on an undiscounted, per pound of pollutant removed basis, there were net costs for the copper removal projects, not net savings, which effectively lengthened the payback period. How were these findings incorporated into this analysis?

Q.3-4 San Jose further found that the per pound savings (again undiscounted) for the nickel removal projects would hardly be considered substantial for most large indirect dischargers. How did EPA define "substantial"?

Response to: CTR-092-019

EPA's analysis does not include the costs of coming into compliance with existing permit limits as part of CTR compliance costs because these costs will be incurred regardless of the implementation of the CTR. In EPA's revised economic analysis of the final CTR, San Jose's high-end and low-end costs are

estimated to be $300,000 per year and $57,000 per year, respectively. The extrapolated costs attributed to San Jose in the high and low scenarios are $750,000 and $140,000, respectively, or 1.2% and 0.5% of the total projected annual costs.

For sites included in the San Jose mass audit study (MAS) that reported a payback of 5 years or less, the MAS reports aggregate total costs (over 5 years or less) for copper projects of $2.5 million compared to an annual operating cost savings of $1.7 million, resulting in an average overall payback period of 1.5 years. The MAS also reports aggregate total costs for nickel projects of $1.7 million versus an annual operating cost savings of $2.3 million for an average overall payback period of 0.75 years (MAS, 1994). The MAS does not consider alternate financing or accounting practices. In using the San Jose MAS costs, EPA did not consider that any savings would be realized and financed the entire costs at seven percent over the five years. Factoring in the operating cost savings would have resulted in lower costs over this same period.

EPA believes that the O&M savings for the nickel removal projects for most large indirect dischargers are too speculative and specific to dischargers in the South Bay area to apply to other POTWs throughout California, thus EPA discounted the savings component to add a measure of conservatism when estimating costs to the indirect discharger population.

Reference: City of San Jose, San Jose/Santa Clara Water Pollution Control Plant, 1994. Industrial Mass Audit Studies Summary Report.

CALIFORNIA TOXICS RULE
RESPONSE TO COMMENTS REPORT

VOLUME II

December 1999

Prepared by:

U.S. Environmental Protection Agency
Office of Science and Technology
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Washington, D.C. 20460

and

U.S. Environmental Protection Agency
Region 9
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Subject Matter Code: E-01g Sample Facilities

Comment ID: CTR-021-008
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01g Sample Facilities
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: EOA submits the following comments on the Draft California Toxics Rule on behalf of the City of Sunnyvale. Sunnyvale owns and operates a 29.5 mgd advanced secondary municipal wastewater treatment plant that discharges into the extreme South San Francisco Bay. Sunnyvale has had in place for several years comprehensive source control, pollution prevention, and waste minimization programs.

The San Francisco Bay Regional Water Quality Control Board (RWQCB) considers Sunnyvale a shallow water discharger and does not allow dilution credit in calculating effluent limits. As such Sunnyvale faces considerable difficulties in complying with end-of-the-pipe limits for copper and potentially several toxic organics that have proposed criteria lower than the analytical detection limit.

One of the key items contained in the CTR that directly impacts Sunnyvale is the effluent limit attainability analysis and cost of compliance for Sunnyvale contained in the Analysis of Economic Costs Technical Support Document and Appendix. The methodology is flawed, a number of assumptions (including basic facts) are incorrect and thus lead to erroneous results. Reliance on an incorrect analysis of the City of Sunnyvale WPCP and then extrapolation of this analysis to other California dischargers will lead to other erroneous and misleading results and conclusions.

The EPA Sunnyvale Case Study Did Not Follow EPA's TSD and Did Not Use Current Available Effluent Data and thus Contains Erroneous Conclusions

Attachment no. 1 to this memo contains a detailed analysis of deficiencies in EPA's analysis of the Sunnyvale Case Study, specifically an evaluation of Sunnyvale's compliance with calculated CTR based effluent limits (Analysis of Potential Costs TSD Appendices I-B, 11-B, II I-B). It is not clear why EPA did not employ a more straight-forward 1991 TSD based approach (Chapters 3 and 5) starting with a reasonable potential analysis based on actual data followed by effluent limit calculation. Some of the fundamental assumptions behind the approach used are flawed, leading to erroneous conclusions, some overly conservative, some not.

For example from Table I-B-4, silver was reported to be a problem since the calculated CTR limit (1.76 ug/L) was less than the current limit (2.3 ug/L) , even though the maximum historic effluent value (1.6 ug/L) was less than either limit. The CTR analysis also appears to be confusion over effluent limit averaging periods since the CTR limit of 1.76 ug/L is derived from a one day maximum toxicity based criterion yet the limit is described as a monthly average limit. Current NPDES permits in the San Francisco Bay Region do not have monthly average limits for silver. The CTR should explain how the proposed 3.8 ug/L daily maximum limit is considered protective of aquatic life.

Response to: CTR-021-008

To estimate costs related to implementation of the CTR, EPA selected a sample of point source dischargers for evaluation to represent the universe of point source dischargers to inland waters, enclosed bays, and estuaries. As described in SAIC and Jones and Stokes Associates (1997), this sample was selected based on a number of factors, including type of facility, geographic location, etc. Available dilution was not considered in selecting a sample.

However, dilution factors used to calculate water quality-based effluent limits (WQBELs) were based on the dilution allowed within the current waste discharge requirements for each sample facility. Of the 20 sample facilities, only four were provided with dilution factors; WQBELs for the remaining facilities were based on a dilution of zero. When this sample is extrapolated to the universe, over 94% of point source dischargers are estimated to not be allowed dilution. EPA believes that this is a highly conservative estimate that will likely overestimate potential costs.

Reference: SAIC and Jones and Stokes Associates, Inc. 1997. Analysis of Potential Costs Related to the Implementation of the California Toxics Rule. Prepared for U.S. EPA, Office of Science and Technology and U.S. EPA Region IX, May 5.

Comment ID: CTR-021-014
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01g Sample Facilities
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Attachment 1 - Comments on "Sunnyvale Facility Summary" Appendices

ANALYSES-

As discussed in the above memo, a fundamental methodological assumption was incorrect causing bias in the ensuing technical and economic analyses. Therefore, detailed comment on the results are for the most part inappropriate. In addition, the entire analyses conducted for the City of Sunnyvale apparently utilized a dataset containing effluent data from 1991 through 1993 when more appropriate recent data (1994-1996) should have been used. However, as an illustration of how the results are biased, the following points are presented:

Appendix I-B:

Appendix I-B states that "The existing permit limits and/or the maximum reported concentrations of silver, endrin, pentachlorophenol, 1,2-dichlorobenzene, chlorodibromomethane, and toluene are less stringent than the projected CTR-based limits (see Table I-B-4)". The following discussion addresses each of those constituents:

* Silver: The CTR based average monthly limit is 1.76 mg/L and the maximum daily limit is 3.8 mg/L. The current daily maximum limit is 2.3 mg/L. Based on a reasonable potential analysis (Attachment - 2) of plant performance data from 1994 through 1996, the projected maximum concentration is lower than the CTR based average monthly limit.

* 1,2-dichlorobenzene, and toluene: The CTR based average monthly limit for each of these constituents decreased below the current effluent limit, therefore they were cited as requiring additional removal for compliance. However the City's reasonable potential analysis of plant performance data from 1993 through 1996 indicates that there is no reasonable potential to exceed the CTR based limit (i.e. values were orders of magnitude below the proposed limits).

* Endrin and Pentachlorophenol: The CTR based average monthly limit for pentachlorophenol decreased from 8.2 mg/L to 7.4 mg/L, triggering its inclusion in the CTR evaluation. During the time period of 1993 through 1996, 16 samples were analyzed at a detection limit of 10 mg/L, all of which were reported below detectable levels. Endrin was never detected in the effluent, but the available detection limits were above the CTR based effluent limit.

* Chlorodibromomethane: Currently, THMs are regulated for the City of Sunnyvale at a level of 480 mg/L as an average monthly limit for Total THMs. A reasonable potential analysis of plant performance data from 1993 through 1996 indicates that there is a reasonable potential to exceed the CTR based limit of 34 mg/L.

* Copper should have been flagged as a pollutant with reasonable potential to exceed the limit. A reasonable potential analysis of plant performance data will show that there is areasonable potential for copper to exceed the maximum daily CTR based limit of 9.27 mg/L and the average monthly limit of 5.55 mg/L. The analysis summarized in Table I-B-3, only compares the proposed site specific objective of a maximum daily limit of 4.9 mg/L to the CTR based average monthly limit of 5.55 mg/L.

* Dichlorobromomethane: This is similar to chlorodibromomethane in that a reasonable potential analysis will demonstrate that there is a reasonable potential for this constituent to exceed the CTR based average monthly limit.

Appendix II-B:

Appendix II-B states that "The existing permit limits and/or the maximum reported concentrations of silver, endrin, pentachlorophenol, and 1,2-dichlorobenzene, are less stringent than the projected CTR based limits (see Table II-B-4)". Refer to the discussion above for an interpretation of effluent concentrations for each of these pollutants.

Response to: CTR-021-014

Sunnyvale stated that the technical and economical analysis is biased because of an incorrect fundamental assumption and because the effluent data used for Sunnyvale (1991-1993) were not recent. Since Sunnyvale has disagreed with many of the methodological assumptions used for the analysis, it is difficult to determine to which specific assumption Sunnyvale is referring. Sunnyvale also raised questions regarding issues such as assigning reasonable potential in the high scenario based on existence of permit limits and the use of the projected average monthly limit to assess compliance. EPA's responses to these questions follow.

* EPA's revised Economic Analysis included the use of effluent data that were reported between January 1995 and December 1997. These were the most recent data available at the time the analysis

was completed.

* Analysis of silver effluent data indicate that this pollutant does not have reasonable potential to exceed a CTR-based limit. Thus, no compliance costs are necessary in the low scenario. However, pollution control costs are necessary in the high scenario because the existing permit limit is less stringent than the projected CTR-based limit. As indicated in the Economic Analysis, EPA determines reasonable potential to exceed CTR-based limits in the high scenario if a pollutant has an existing permit limit or if the projected effluent quality based on the facility effluent data is greater than CTR-based limits. EPA recognizes that this is a conservative assumption that may overstate costs in the high scenario if a pollutant is limited in a permit but is not actually present in the effluent.

* 1,2-dichlorobenzene and toluene do not have reasonable potential to exceed water quality criteria andthus no associated compliance costs in the low scenario of the revised Economic Analysis. However, reasonable potential and compliance costs are assigned in the high scenario because existing permit limits for these pollutants are less stringent than the projected CTR-based limits. The rationale behind this assumption is the same as for silver (see above).

* Endrin is not listed as a pollutant of concern in the revised Economic Analysis. In the low scenario, reasonable potential is not assigned because, as Sunnyvale also indicated, the pollutant is consistently reported below detection levels. In the high scenario, no costs are assigned because the existing limit is as stringent as the projected CTR-based limit. Sunnyvale indicated that although endrin was detected in the effluent, the detection level is greater than the projected CTR-based effluent limit suggesting that controls may be necessary. However, since the existing permit limit is as stringent as the CTR-based projected limit, any compliance costs are attributable to the existing limit and not the CTR.

* In the revised Economic Analysis, pentachlorophenol is assigned compliance costs in the high scenario and not in the low scenario. This is because the existing permit limit is less stringent than the projected CTR-based limit and all available effluent data are below detection levels. As shown in the cost decision matrix presented in the Economic Analysis, EPA assumes that addition of treatment is not justified when effluent data are inconclusive or limited.

* No pollution control costs are estimated for chlorodibromomethane and dichlorobromomethane in the revised Economic Analysis. The existing NPDES permit does not include limits for these constituents. In addition, no recent effluent monitoring data (1995 to 1997) were available. Although, Sunnyvale indicated that it had completed reasonable potential analyses for chlorodibromomethane and dichlorobromomethane, it did not provide these analyses to EPA.

* Please see the response to CTR-021-004 for a detailed discussion of EPA's response to the issues the commenter raises regarding copper.

* In the revised Economic Analysis, the reduced risk level scenario for silver, endrin, pentachlorophenol, and 1,2-dichlorobenzene (Appendix II-B) is identical to the base scenario. Thus, the above responses are also applicable to the Appendix II-B comments Sunnyvale submitted.

Comment ID: CTR-035-059
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g Sample Facilities
References:
Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis

The report's cost estimates exhibit a number of significant weaknesses, as follows:

* No evidence is presented that the selected case studies reflect the overall population of affected parties. Although a stratified sample approach appears to reflect sound basis from which to estimate costs, USEPA provides no explanation as to how the case study areas were selected- no evidence that the impacted population is statistically "normal"(*6) and no informationindicating that the sample size is sufficient to make generalizations (e.g., 7 percent of the major POTW NPDES permittees; 1 percent of the minor NPDES permmittees). Likewise the analysis points to significant diversity in how Regional Water Quality Boards treat permits, with potentially concomitant cost implications. Excluding a few high-cost parties from the sample, and ignoring regional Board behavior, could falsely indicate that total Rule costs are less than $100 million a year.

An alternative sampling approach could focus on the presence and distribution of affected pollutants, rather than the impacted entities. Since costs to control metals and mercury are estimated to account for almost 60 percent of total annual costs,(*7) examination of the presence of these pollutants in different state regions could provide a basis for alternative cost estimates.(*8) Or, to account for different regional water quality conditions and Regional Board behavior, sampling could be done by water body.

(*6) In fact, the provided data implies that a handful of dischargers may be responsible for the great majority of costs.

(*7) This estimate in itself may be suspect, as organics may account for a larger proportion of the contaminants than indicated by USEPA.

(*8) This approach would require a great deal more information about existing pollutant characteristics and distribution. However, such knowledge would seem to be a critical precursor to rule development.

Response to: CTR-035-059

See responses to CTR-021-005c and CTR-059-018.

Comment ID: CTR-041-010d
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g Sample Facilities

References:
Attachments? N
CROSS REFERENCES E-01n
E-01m
E-01e

Comment: 5. Concerns Regarding Economic Analysis

The District also has several significant concerns with the Economic Analysis that was performed for the proposed rule. Concerns about the cost estimates made for both the District and the state are presented here. (See attached Review of EPA's Economic Analysis of the Proposed California Water Quality Toxics Rule.) Overall, the District believes that problems with the Economic Analysis are serious enough that is should be redone. As stated above in our analysis of assumed costs at the SRWTP, the use of questionable data without qualification combined with unsubstantiated assumptions regarding costs to achieve compliance resulted in a gross underestimate in the cost-effectiveness ratio. The District's first concern is that if the types of problems found in our Case Study are widespread in other studies, the complete analysis is suspect.

In addition to the analysis of the District's facilities, there are several other points which have been used by EPA to lead to a potentially serious understatement of actual costs. The key assumptions involved are that: 1) no costs would occur if either no monitoring data presently exists or if that data is below analytical detection levels; 2) no treatment costs would occur whenever EPA's initial estimates showed high costs, due to successful regulatory relief; 3) no costs are included for nonpoint sources such as municipal stormwater management systems; and 4) no costs are included for indirect dischargers to the District's system that are not large enough to be considered a Significant Industrial User (SIU).

Regarding the first assumption, the District has found that there is pressure from many sides, including the Safe Drinking Water Act, to both increase the number of constituents being monitored and to lower detection levels to meet numeric criteria set by EPA and the state. To assume that monitoring of these new constituents will not lead to any treatment cost increases is simply unrealistic. Similarly, the second assumption about absolute success in every pursuit of regulatory relief is also overly optimistic. There are no guarantees that pursuit of regulatory relief will be successful in any situation, and EPA indicates elsewhere in the preamble that options such as variances and site-specific criteria will rarely, if ever, be granted.

The third and fourth key assumptions ignore present dominating trends and facts, i.e. that. prevention and control of pollutants at their sources, including very small indirect dischargers, storm runoff, and other nonpoint sources are now the major focus of EPA's wastewater programs nationally. While we agree that these management steps should be taken, there will be significant costs attached to the implementation of these steps that cannot be ignored.

Combined with concerns the District has heard from other sources such as the California Association of Sanitation Agencies (CASA), it appears that EPA has failed to make "a reasoned determination that the benefits of the intended regulation justify its costs." Therefore the District believes that the Agency is obligated to redo the draft Economic Analysis.

Response to: CTR-041-010d

See responses to CTR-032-004, CTR-021-006b, CTR-040-037, and CTR-003-011.

Comment ID: CTR-043-004a
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g Sample Facilities
References:
Attachments? Y
CROSS REFERENCES E-01h
E-01m
E-02c
E-01c02

Comment: 4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution;

(2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements;

(3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and

(4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule.

The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act.

Response to: CTR-043-004a

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-056-018, and CTR-059-018.

Comment ID: CTR-092-014
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g Sample Facilities
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y

CROSS REFERENCES

Comment: EPA's Economic Analysis

Attachment 4 to this letter, are detailed comments by the City on EPA's Economic Analysis of the costs and benefits that are anticipated from adoption of the CTR. This attachment is also incorporated as part of our comments and is being submitted for inclusion in the record for this rulemaking.

Although the City initially supported a waiver of OMB review of the CTR, we are very concerned with the number of uncertainties and erroneous assumptions contained in the Economic Analysis. We are particularly concerned with EPA's interpretation of the San Jose/Santa Clara facility data as it relates to the cost and attainability of limits based on the proposed copper and nickel criteria. We are also extremely concerned with the use of this data to draw conclusions about costs and compliance with for other pollutants or other facilities. Finally, we are also concerned that the State may attempt to use or rely on the Economic Analysis in promulgating its implementation plan.

We understand the difficulty of performing such an analysis, but we also believe that the importance of a complete, thorough and supportable Economic Analysis cannot be overstated. As discussed in more detail in Attachment 4, the Economic Analysis does not fully account for all costs and the benefits, nor does the Analysis accurately calculate and analyze the costs and benefits that are presented. As indicated above, EPA's conclusions about costs and benefits cannot be validated at this time due to uncertainties about State implementation of the Rule.

Response to: CTR-092-014

See responses to CTR-021-011 and CTR-040-037.

Subject Matter Code: E-01g01 Low or Zero Dilution

Comment ID: CTR-108-001
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 10/31/97
Subject Matter Code: E-01g01 Low or Zero Dilution
References:
Attachments? Y
CROSS REFERENCES

Comment: On behalf of Dr. Ing Yih Cheng, I am sending you copies of tables which described the constituents of concern with respect to CTR at Los Angeles-Glendale Water Reclamation Plant, Terminal Island Wastewater Treatment Plant, and Donald C. Tillman Water Reclamation Plant. Detailed information regarding the concern constituents at each plant will be forwarded to you sometimes next week.

If you have any questions regarding these tables please call me at (310)524-1171.

Response to: CTR-108-001

See response to CTR-092-017.

Subject Matter Code: E-01g02 Another EA for Sample Fac

Comment ID: CTR-052-014
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g02 Another EA for Sample Fac
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Revise the Economics Analysis. The EA should be revised to incorporate the updated and more representative cost data provided by POTWs. The benefits analysis should also be revised using the methodology recommended by M.Cubed and others. EPA should use data more representative of California, rather than relying on questionable data from a Ph.D. dissertation. The EA should also include sub-sections specific for San Francisco Bay and effluent dependent water bodies.

Response to: CTR-052-014

See response to CTR-021-008.

To update its analysis for the final CTR, and in response to comments, EPA collected the most recent publicly available data for all facilities included in the cost analysis, including permits, fact sheets, permit applications, and discharge monitoring data. Data submitted as a part of the public comments were also reviewed and considered.

Comment ID: CTR-057-001
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g02 Another EA for Sample Fac
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to submit comments on the proposed California Toxics Rule (CTR). As we indicated in our oral comments at the September 18, 1997 public meeting, the City of Los Angeles is primarily concerned about the adequacy of your agency's cost/benefit analysis (particularly with respect to the Tillman Water Reclamation Plant case study). Although we highlight this issue in the following comments, we have a number of additional concerns regarding other important matters raised by the proposed Rule that are also presented. We strongly urge the EPA to consider these comments and

recommendations, especially with regard to revision of the economic analysis.

Overview of Affected Facilities

The City owns and operates three treatment facilities that would be impacted by the proposed Rule:

DC Tillman Water-Reclamation Plant. This 80-MGD facility is located in Van Nuys and provides tertiary-treated reclaimed water that is essential for current and planned reuse projects (irrigation, recreation and wildlife habitat) and aquatic wildlife support (via discharges to natural portions of the Los Angeles River). A major water reclamation project (East Valley Water Recycling Project), currently under construction, will deliver up to 30 MGD of flow to groundwater recharge basins and industrial users in the San Fernando Valley. The plant's service area comprises a population of approximately 1 million people.

Los Angeles-Glendale Water Reclamation Plant. This 20-MGD capacity plant (partly owned by the City of Glendale) supplies tertiary-treated reclaimed water for several industrial and irrigation uses, while discharges to the Los Angeles River support natural portions of the Los Angeles River. The plant's service area includes portions of the cities of Los Angeles and Glendale, comprising a total served population of approximately 250,000 people.

Terminal Island Treatment Plant. This 30-MGD facility, located in San Pedro was recently upgraded to tertiary capability via the addition of deep-bed effluent filters. This plant is the site of a major water reclamation project which will ultimately supply advanced-treated (microfiltration/reverse osmosis) effluent to nearby oil refineries and support industries. The plant serves a population of about 300,000 people.

The combined annual operation and maintenance cost of these facilities is approximately $15 million. As the City is also expanding its Hyperion Treatment Plant to full-secondary capability, the incurred costs of this and other capital-improvement efforts have severely restricted the City's ability to invest in additional projects without placing additional financial burdens on rate payers in the City. Consequently, the benefits (as well as the costs) of the CTR as identified in the EPA's economic analysis were examined closely.

Comments

While the CTR proposes criteria and provisions having a broad range of impacts to POTWS, we have identified a number of issues that we are primarily concerned with. These are discussed individually in the following statements.

Economic Analysis

In view of the substantial capital and O&M investment that the City's treatment facilities represent, our primary concern of course is the proposed Rule's Economic Analysis (EA) and the misleading impression it makes with respect to the Rule's probable cost. Overall, we believe that the CTR presents the EA as a conclusive statement of cost based on two model approaches, of which neither represents an accurate assessment of the true costs to POTWs. The first model provides what is essentially a "no cost" scenario, while the second approach results in a high-end amortized cost of only $86.6 million per year State-wide. This number (rounded to $100 million) and the methods utilized in its derivation is highly suspect as a basis for the Office of Management and Budget's declaration that the Rule will not significantly impact State dischargers. The figure was based for the most part on the EPA's investigations of several case

studies in which detailed cost analyses were conducted for POTWs deemed to be "problematic;" that is, treatment facilities whose performance histories indicated the possibility that the proposed Rule would have significant cost impacts.

These case studies included our Tillman facility, which since 1991 has undergone a uniquely painful experience with respect to NPDES compliance as a direct result of priority-pollutant rule promulgation. As you are likely aware, the plant's NPDES permit was renewed in September 1991 shortly after the State's adoption of the Inland Surface Waters Plan (ISWP), which itself imposed priority-pollutant criteria identical with or similar to those included in the proposed Rule. To our knowledge, our plant was the only one in the region that suffered the fate of having to comply with a water quality control plan that was subsequently invalidated by the State Superior Court.

Following the ISWP's April 1991 adoption and renewal of the NPDES permit, our plant immediately experienced compliance difficulties with respect to chronic toxicity, copper, lindane, DDT, methylene chloride, and numerous other trace organic compounds. In April 1992, we completed a 6-month study investigating the probable cost of ISWP compliance for the Tillman facility. In view of the staggeringly high costs we identified (see following summary), we initiated ongoing and costly efforts to identify and implement industrial source controls; from this, we reduced methylene chloride down to compliance levels but we determined that many of the problem constituents are not source-controllable. Consequently, in 1993 we initiated a process with the Los Angeles Regional Water Quality Control Board to obtain relief in the form of a modification of the NPDES permit. Since that time, and even in view of the 1995 invalidation of the ISWP, we have been unsuccessful in negotiating what we feel are justified revisions to the NPDES permit.

EPA's cost estimates in the Tillman EA take none of this into account. The EPA instead treats the plant's NPDES as a compliance baseline from which comparisons with the CTR are made. As a result, it was a foregone conclusion that the EPA would not find any significant cost impacts to the plant due to the proposed Rule, as the Rule's criteria are already effectively contained in the plant's NPDES permit! Our 1992 cost estimates (see attached summary sheets) translate into an annual amortization and O&M cost of approximately $36 million. An updated estimate ($40 million) conducted on the basis of the proposed Rule confirms the magnitude of these costs.

When we described this situation at the September 18 public meeting, we were advised by the national EPA representative to seek variances for problem constituents. While these variances can alleviate Tillman's non-compliance issue, this approach does not address the compliance cost underestimation issue. In view of this, we believe that the EA is fundamentally flawed from the Tillman plant's perspective and therefore in need of substantial revision. Furthermore, this is not a moot point given the fact that the State intends to adopt a revised version of the ISWP, as it is our belief that EPA recognition of the probable true costs of CTR compliance would have a major effect on ISWP implementation provisions. We believe that a more objective assessment of the CTR's cost impact would also provide a more realistic evaluation of the Rule's environmental benefits, which by comparison appear to be overestimated in the EA.

The City therefore respectfully requests the EPA to revise the economic assessment and to amend the Tillman EA to reflect the true cost of compliance. Given the somewhat unfortunate timing of the proposed Rule with the State's own Draft Implementation Policy (which we have only begun to analyze), we further request that the EPA consider working in collaboration with the State and the public members of the State's Economic Considerations Task Force to develop mutually agreed-upon approaches needed to revise the EA.

Miscellaneous comments:

* The EA refers to a 10-year amortization schedule (Pages 4-2 and 9-3), but Exhibit 9-2 (the cost benefit comparison) refers to equipment purchases at 1 and 16 years (a 15-year amortization schedule).

* The statements in the last row of Exhibit 8-21 casts considerable doubt on the overall adequacy of the EA with respect to benefits.

* The EA avoids the issue of cross-media pollutant transfer and the associated costs. Spent activated carbon and reverse-osmosis brine are wastes representing real disposal problems.

Response to: CTR-057-001

See responses to CTR-021-005c, CTR-040-026, CTR-021-004, and CTR-054-033.

EPA corrected this discrepancy in its revised analysis.

Subject Matter Code: E-01g03 Cost Effectiveness Ratio

Comment ID: CTR-040-039
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's estimate of cost-effectiveness ($8 - $12 per toxic pound equivalent) is considerably lower than the estimates prepared by others. The Bay Area Dischargers Association and the Novato Sanitary District calculated unit costs for copper removal to be in excess of several thousand dollars per toxic pound equivalent removed.

Response to: CTR-040-039

In response to comments received by EPA on the economic analysis that accompanied the proposed CTR, EPA collected additional data for the sample facilities. EPA also revised its estimate of potential compliance costs attributable to the CTR.

EPA's low estimate of total annualized costs of the final CTR is $33.5 million per year and its high estimate is $61.0 million per year. The low and high estimates vary based on whether effluent data or permit limits are used to assess the need for additional controls. They also vary based on whether or not alternative regulatory approaches, such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc., are considered under certain circumstances. EPA believes that its estimates of costs and benefits are sound.

EPA believes that several general observations can be made regarding studies submitted by commenters and how they differ from the EPA cost study for the final CTR. Many commenters assumed that the mere presence of a pollutant would result in costs to comply with a CTR-based WQBEL. It should be noted that the presence of a pollutant in an ambient inland water, enclosed bay, or estuary does not require permitting authorities to establish a WQBEL for that pollutant. The establishment of a permit limit is appropriate only where the permitting authority determines that a pollutant is likely to be present, and that the pollutant concentration has a "reasonable potential" to cause or contribute to an exceedance of the applicable water quality standard. Where the pollutant is not likely to be present, or is not present at levels that have reasonable potential to cause or contribute to a water quality standard exceedance, a WQBEL may not be necessary.

The majority of cost estimates provided by commenters include the costs for the addition of end-of-pipe treatment to achieve proposed CTR-based WQBELs. This was particularly the case when WQBELs were expected to be below analytical detection levels. EPA disagrees that end-of-pipe treatment is necessary to achieve CTR-based WQBELs in all cases. As discussed in SAIC (1995), there are documented cases where waste minimization or source control techniques have been used to comply with existing permit limits established below detection levels. Other examples include the Western Lake Superior Sanitary District (WLSSD), who after evaluating the costs involved to meet more stringent WQBELs for mercury

with end-of-pipe treatment, concluded that pollution prevention techniques were the preferable control strategy. As a result, WLSSD published a guide designed to "assist wastewater treatment plant staff with creating and implementing their own mercury reduction projects." As a result of the efforts of WLSSD, effluent mercury levels were found to decrease from 0.58 parts per billion (ppb) to 0.015 ppb.

Although waste minimization or source controls are not always applicable, EPA assumes in its low estimate of costs that a facility would first evaluate whether process changes or modifications are feasible, prior to incurring costs for adding treatment.

In addition, many commenters assumed that compliance would be based on the WQBEL, regardless of whether it is below the analytical method detection level (MDL). This is not consistent with current practice. Instead, the State may use the "minimum level" (ML) (as defined in 40 CFR Part 136) as the required compliance point where a permit limit is established at a value below the MDL. The ML is a value at which the limited parameter can be accurately quantified, and is always greater than or equal to the MDL. To ensure that its cost estimates were conservative (i.e., erring on the side of higher costs), EPA used the MDL as the compliance level. Although EPA used the pollutant MDL for costing purposes, the Agency acknowledges that estimating treatment costs for WQBELs below the MDL is speculative and likely unrealistic.

Finally, many of the commenters included costs related to installation of treatment for storm water discharges. As further described in the responses to CTR-021-008 and CTR-040-004, EPA believes that the final CTR will not significant affect the current storm water program being implemented by the State, which includes the requirement to develop best management practices to control pollutants in storm water discharges. As such, EPA believes that inclusion of end-of-pipe treatment costs for storm water are inappropriate.

Reference: SAIC. 1995. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. Prepared for U.S. EPA, Office of Science and Technology, March 13.

Comment ID: CTR-041-035
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of cost-effectiveness ($8 - $12 per toxic pound equivalent) is considerably lower than the estimates prepared by others. The Bay Area Dischargers Association and the Novato Sanitary District calculated unit costs for copper removal to be in excess of several thousand dollars per toxic pound equivalent removed.

Response to: CTR-041-035

See response to CTR-040-039.

Comment ID: CTR-044-030
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of cost-effectiveness ($8 - $12 per toxic pound equivalent) is considerably lower than the estimates prepared by others. The Bay Area Dischargers Association and the Novato Sanitary District calculated unit costs for copper removal to be in excess of several thousand dollars per toxic pound equivalent removed.

Response to: CTR-044-030

See response to CTR-040-039.

Comment ID: CTR-054-013a
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References:
Attachments? Y
CROSS REFERENCES E-01q01
E-01m
E-02l

Comment: The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule (see Attachment 3). The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. BADA's analysis shows that its member agencies alone could be faced with costs in excess of $100 million per year to achieve effluent limits based on the copper, PAH, heptachlor and aldrin criteria. BADA's analysis also indicates that the benefits associated with this

expenditure will be difficult to measure. Copper loadings will be reduced by 1% and the level of compliance for PAH's and heptachlor will remain unchanged at its present high level. Certainly these benefits will not measurably improve the fishing experience or measure the number of fisherman in the Bay, significantly reduce the cancer cases, or improve property values or other nonuse benefits, as estimated in EPA's economic analysis. A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. BADA agencies provide service to a number of small communities with populations under 50,000 people that could be greatly impacted by the proposed rule.

Response to: CTR-054-013a

EPA believes that the sample of dischargers selected adequately represents the various types of direct dischargers in the state. EPA would have considered any and all information submitted by a discharger that did not think it was adequately represented by the sample facilities.

See responses to CTr-021-008, CTR-059-018, CTR-040-029a, CTR-032-004, CTR-056-018, and CTR-021-005c.

The commenter is referring to the estimate of total potential benefits in the analysis of benefits document. In EPA's EA for the proposed (and final) rule, only the portion of benefits expected to be achieved by implementing controls on point source dischargers are counted. EPA recognizes that the proposed standards will not be achieved in some cases by controlling point sources alone. EPA's assumptions regarding the attribution of benefits to the rule are described in the EA for the proposed rule in Chapter 7.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA believes that controls on point source dischargers will, in many cases, contribute to attaining standards in a given water body. As controls on other sources are also implemented, the water quality standards can be achieved. However, the total maximum daily load (TMDL) process is provided to address cost-ineffectiveness as it pertains to point or nonpoint sources. For example, if controls on nonpoint sources are a more cost-effective approach to achieving standards, the State can redistribute the load allocations through the TMDL process.

EPA did not include values for water- and land-related benefits other than fishing, but noted that potential benefits may be underestimated because these benefit categories are not included. As described in the EA (See Chapter 8), EPA believes that these benefits may be appreciable because such recreational activities (e.g., boating, swimming, picnicking, and related activities) have been shown in empirical research to be highly valued, and even modest changes in participation or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (e.g., swimming) and others might increase due to their association with fishing, swimming, or other activities in which the participants might engage.

Comment ID: CTR-054-034
Comment Author: Bay Area Dischargers Associati

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of cost-effectiveness ($8 - $12 per toxic pound equivalent) is considerably lower than the estimates prepared by others. The Bay Area Dischargers Association and the Novato Sanitary District calculated unit costs for copper removal to be in excess of several thousand dollars per toxic pound equivalent removed.

Response to: CTR-054-034

See response to CTR-040-039.

Comment ID: CTR-056-016
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Finally, EBMUD has serious concerns about the accuracy of EPA's draft, Economic Analysis, particularly as it pertains to the cost and benefits estimates found in the draft CTR. We believe that the costs of the CTR are significantly underestimated and the benefits are inflated. On the cost side, there are several "flaws" which should be reevaluated:

* The representativeness of the sample used is questionable and should be reconsidered.

Response to: CTR-056-016

See responses to CTR-056-018 and CTR-059-018.

Comment ID: CTR-056-017
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97

Subject Matter Code: E-01g03 Cost Effectiveness Ratio
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Finally, EBMUD has serious concerns about the accuracy of EPA's draft, Economic Analysis, particularly as it pertains to the cost and benefits estimates found in the draft CTR. We believe that the costs of the CTR are significantly underestimated and the benefits are inflated. On the cost side, there are several "flaws" which should be reevaluated:

* The omission of those impacts on those "dischargers" which contribute to loading such as: small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities and non-point sources, and therefore would be expected to reduce their loading.

Response to: CTR-056-017

See responses to CTR-056-018, CTR-021-006b, and CTR-040-037.

Subject Matter Code: E-01g04 AMLs vs. MDLs

Comment ID: CTR-021-010
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01g04 AMLs vs. MDLs
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The CTR Analysis Incorrectly Evaluates Permit Compliance By Using an Average Monthly Effluent Limit Rather than the California Regional Board's Maximum Effluent Limit

The EPA analysis assumes that the limit to be achieved, either 4.9 or the potential CTR limit of 5.55 ug/L is a monthly average limit. The current state NPDES permit cites the limit as a 1-day average limit, based on the San Francisco Basin Plan's 1-hour marine water quality objective.

Sunnyvale's 1994-1996 weekly effluent copper data (155 data points) had a mean of 4.3 ug/L, but a maximum of 9 ug/L, a 99%tile of 8.9 ug/L and a 95%tile of 7.0 ug/L.

The CTR economic analysis (Appendix Table I-B-3) calculated average monthly limits (AML) of 5.5 ug/L and maximum daily limits (MDL) of 9.27 ug/L for copper. EPA needs to specify if the State is currently in error in its interpretation and implementation of effluent limits in this manner. Furthermore, the CTR should clarify if this means that it is acceptable for States to calculate and include monthly average (30-day) limits in NPDES permits based on the proposed CCC criteria and the TSD based methodology used in the economic analysis (and similarly daily average limits based on the proposed CMC criteria).

Based on current State permits the economic analysis must be corrected since the threshold for determining whether or not additional measures would be required to comply with the CTR is based on a comparison with average, not maximum values. As noted above, unless EPA is redefining the chronic averaging period as monthly instead of 4-day (or 1-day), Sunnyvale can not achieve a 4.9 or 5.5 ug/L copper effluent limit (WPCP effluent is above this limit approximately 30-40% of the time). Other dischargers to San Francisco Bay that aren't allowed dilution credit face the same compliance problem and will require additional treatment to meet a 1 or 4-day limit in that range. Therefore, extrapolation of the CTR analysis to other dischargers is not appropriate an d will lead to erroneous results and misleading conclusions.

Response to: CTR-021-010

This comment refers to Sunnyvale's previous one-day average copper limit. The previous permit limit was based on the underlying national criteria (saltwater) in effect at that time [2.9 ug/L for both the chronic aquatic life (CCC) and acute aquatic life (CMC)]. The State was not in error in implementing the above criteria as a one-day average limit. In the CTR, the saltwater copper CMC has been revised to 4.8 ug/L dissolved and the CCC has been revised to 3.1 ug/L dissolved. The revised CCC should not be implemented directly as a one-day average. EPA recommends that the State calculate both average

monthly limits and maximum daily limits based on the chronic and acute criteria using the U.S. EPA Technical Support Document (TSD) approach (1991). Therefore, EPA used the TSD approach in the Economic Analysis to estimate facility compliance with CTR-based WQBELs.

Reference: U.S. EPA. 1991. Technical Support Document for Water Quality-based Toxics Control. EPA/505/2-90-001

Subject Matter Code: E-01g05 Effluent Data

Comment ID: CTR-040-027
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g05 Effluent Data
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a discharger has no effluent data that the discharger will not incur costs as a result of the CTR.

Response to: CTR-040-027

If a discharger had no effluent data, EPA did not automatically assume that the discharger would have no costs as a result of the CTR. When effluent data was available, however, EPA used the method in EPA's Technical Support Document for Water Quality-based Toxics Control (1991) to determine reasonable potential and then followed the methodology (i.e., the cost-decision matrix) described in the Economic Analysis (EA) of the final CTR to estimate costs. In the abscence of data under the high scenario, reasonable potential was assumed if the discharger had an existing permit limit for a pollutant and EPA then estimated costs using the methodology described in the EA. See also response to CTR-003-011.

Comment ID: CTR-041-023
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g05 Effluent Data
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a discharger has no effluent data that the discharger will not incur costs as a result of the CTR.

Response to: CTR-041-023

See response to CTR-003-011.

Comment ID: CTR-044-018
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g05 Effluent Data
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a discharger has no effluent data that the discharger will not incur costs as a result of the CTR.

Response to: CTR-044-018

See response to CTR-003-011.

Comment ID: CTR-054-022
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g05 Effluent Data
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a discharger has no effluent data that the discharger will not incur costs as a result of the CTR.

Response to: CTR-054-022

See response to CTR-003-011.

Comment ID: CTR-093-001

Comment Author: City of Merced
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: E-01g05 Effluent Data
References:
Attachments? Y
CROSS REFERENCES

Comment: Pursuant to our conversations following the California Toxics Rule (CTR) hearing of 17 September, find enclosed 1994, 1995, and 1996 data from priority pollutant monitoring at the City of Merced Wastewater Treatment Facility. It is our understanding that the information will be utilized to refine the economic impact analysis from the City of Merced Case Study.

One qualification we submit regarding the enclosed data is that cyanide, dutifully reported as having been detected in POTW effluent in 1994 and 1995, was likely not actually present. It has been demonstrated that nitrogen interference during cyanide analysis of chlorinated samples will often result in falsely positive results. To prevent this, EPA has approved a sulfamic acid scrubbing procedure to counter the interference. That procedure was not practiced by our analyzing laboratories until 1996. No contributor of cyanide has been identified in Merced, and, it has never been detected either at the influent or primary effluent of our plant. The sulfamic acid scrubbing procedure was incorporated in the analytical procedures during 1996, and there have been no detections of cyanide in POTW effluent since.

If there are any questions please do not hesitate to contact me at (209) 385-8693.

Response to: CTR-093-001

EPA has removed cyanide from its economic analysis for the final CTR because EPA's analysis of existing data and facility information resulted in no determinations of reasonable potential for cyanide.

Subject Matter Code: E-01g06 Reasonable Potential

Comment ID: CTR-021-016
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01g06 Reasonable Potential
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Appendix Ill-B states that "The existing permit limits and/or the maximum reported concentrations of copper, nickel, silver, endrin, 1,2-cichlorobenzene, chlorobenzene, chlorodichloromethane, and toluene are less stringent than the projected CTR-based limits".

* Copper: A reasonable potential analysis of plant performance data indicates that there is a reasonable potential under these grossly conservative and misleading assumptions to exceed both the CTR based maximum daily limit and the average monthly limit.

* Nickel, silver, and zinc: A reasonable potential analysis of plant performance data indicates that under these grossly conservative and misleading assumptions there is no reasonable potential to exceed the CTR based maximum daily limit. However, if the projected maximum concentrations are compared to the CTR based average monthly limit, there is a reasonable potential for the effluent concentrations to exceed these limits.

* Organic compounds: See notes for Appendix I-B above.

Response to: CTR-021-016

EPA revised its EA including the use of more recent data. In the revised EA, nickel, silver, and zinc have reasonable potential in the high-end scenario because the facility has existing permit limits, however no load reductions are estimated for these pollutants in either the low- or high-end scenarios.

See also responses to CTR-052-014 and CTR-021-017.

Subject Matter Code: E-01g08 Discharger Representation

Comment ID: CTR-034-014a
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01b
E-01e
E-01v
J

Comment: * In general, we are pleased that EPA prepared an analysis of the economic impacts of the proposed CTR, and that a major portion of EPA's work focused on determining the potential impacts on POTWs. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Detailed comments can be found in Attachment 2. A few of the areas of concern are listed below:

* Small facilities appear to be under represented in EPA's sample of POTWS, especially for minor dischargers.

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

* The assumptions used to determine cost estimates for indirect dischargers appear to omit a large proportion of potentially affected industries.

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. Statewide, the population is projected to grow by nearly 50% by 2020.

* The use of average cost estimates masks economic impacts on individual dischargers, which may be particularly acute for small communities.

* The economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-034-014a

See responses to CTR-032-004, CTR-035-061, CTR-021-006b, CTR-040-037, CTR-059-018, and CTR-035-048.

Comment ID: CTR-035-008a
Comment Author: Tri-TAC/CASA

Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01e
E-01d
E-01m
E-01h
E-01c

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008a

See responses to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-035-046a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01g09

Comment: pp. 2-4 - 2-9 (U.S. EPA, 1997b) -- Sampling Strategy In general terms, we support EPA's methodology of stratified sampling to determine costs, although it is not clear whether the POTW sample was stratified appropriately. We believe that inadequate evidence is presented that the sample of case studies reflects the overall population of POTWs, and that extrapolation based on the sample would truly reflect total POTW costs. Little explanation is provided as to how the case study facilities were selected, and little evidence is presented demonstrating the validity of extrapolating from the small sample to the impacted population of POTWs. In particular, we believe that minor facilities were under-represented, and that it is invalid to assure that none of the 185 minor POTWs will incur any costs. We also believe that larger samples of facilities from 0-10 MGD and from 10-100 MGD also would be necessary to obtain valid estimates of POTW costs. In addition, by assuming that existing facilities that contain effluent limits for toxic pollutants were representative facilities and using them as the basis for extrapolation to the universe of potentially affected facilities, EPA may have failed to include a major category of costs. By ignoring the costs of those facilities meeting their current permit limits, EPA is assuming that the facilities they are extrapolating to have similar current permit limits, which was not demonstrated to be the case. Therefore, EPA should reexamine the use of this assumption in the analysis of POTW costs.

Response to: CTR-035-046a

EPA believes that the sample facilities adequately represent the universe of facilities in California. Facilities within the sample demonstrate both compliance and non-compliance with projected CTR limits and, although the sample may not exactly represent the actual proportion of facilities not in compliance with limits, EPA believes that the overall economic analysis uses conservative cost estimation techniques which actually overstate costs. See also response to CTR-059-018.

Comment ID: CTR-035-063
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis The report's cost estimates exhibit a number of significant weaknesses, as follows:

* Potential impacts on non-point sources merit greater attention than given them in the Analysis. Since non-point sources (e.g., mining/mine tailings; agricultural drainage/runoff; urban runoff/stormwater) are responsible for the great majority of potentially harmful discharges, they will almost certainly be affected by the proposed Rule. Likewise, these sources must be addressed if the benefits estimated by USEPA are to be obtained. Greater examination of these costs would be no more speculative than many of the benefit estimates shown in the report.

Response to: CTR-035-063

See response to CTR-021-006b.

Comment ID: CTR-038-004a
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? Y
CROSS REFERENCES E-01h
E-01m
E-01c02

Comment: 4. The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. The District's analysis demonstrates that actual costs may be an order of magnitude greater than EPA's $500/lb threshold and that the benefits are very small.

Response to: CTR-038-004a

See responses to CTR-054-013a, CTR-032-004, CTR-021-008, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-040-024
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA erroneously assumes that minor POTW dischargers (i.e., those with a permitted flow of less than 1.0 mgd) will not incur significant impacts as a result of the CTR.

Response to: CTR-040-024

For analysis of the final CTR, EPA updated its Economic Analysis to reflect the most recent data and information for each sample facility and also increased the sample size for minor facilities. Based on this revised analysis, EPA estimated that minor POTWs will incur costs of approximately $5,000 per facility per year under the low cost scenario and $7,800 per facility per year under the high cost scenario. See also response to CTR-058-018.

Comment ID: CTR-041-020
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that minor POTW dischargers (i.e., those with a permitted flow of less than 1.0 mgd) will not incur significant impacts as a result of the CTR.

Response to: CTR-041-020

See responses to CTR-059-018 and CTR-040-024.

Comment ID: CTR-044-005a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? Y
CROSS REFERENCES E-01h01
E-01m
E-02c
E-01c02
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an

additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005a

See responses CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-056-018, CTR-059-018, and CTR-035-046a.

Comment ID: CTR-044-015
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that minor POTW dischargers (i.e., those with a permitted flow of less than 1.0 mgd) will not incur significant impacts as a result of the CTR.

Response to: CTR-044-015

See response to CTR-040-024.

Comment ID: CTR-045-009a
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? Y
CROSS REFERENCES E-01h
E-01m

Comment: The draft Economic Analysis has serious flaws. It underestimates the costs of the draft CTR and overestimates the benefits. For the cost analysis, EPA should reevaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings, and hence, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs; and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-045-009a

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTR-049-006a
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01h
E-01m

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

4. Review and correct existing flaws in the current "Economic Analysis."

With respect to the Economic Analysis conducted by USEPA, we are concerned that it underestimates the cost of the proposed CTR rule while overestimating its benefits. We suggest that USEPA re-evaluate (1) the representativeness of the sample used; (2) the omission of impacts on many sectors that contribute to loadings; (3) the incorporation of a variety of assumptions that underestimate costs; and (4) the assumption to artificially remove costs that exceed threshold values by incorrectly assuming that regulatory relief measures will be granted. For the benefits analysis, USEPA should utilize more California-specific and recent information. A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures requires, in our opinion, further work prior to the promulgation of the criteria.

Response to: CTR-049-006a

See responses CTR-045-011, CTR-032-004, CTR-056-018, CTR-021-006b, CTR-059-018, and CTR-052-014.

Comment ID: CTR-054-019
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that minor POTW dischargers (i.e., those with a permitted flow of less than 1.0 mgd) will not incur significant impacts as a result of the CTR.

Response to: CTR-054-019

See responses to CTR-059-018 and CTR-040-024.

Comment ID: CTR-059-018
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Economic Analysis

The Sanitation districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* Small facilities appear to be under-represented in EPA's sample of POTWs, especially for minor dischargers.

Response to: CTR-059-018

EPA acknowledges that evaluating the impact of each individual direct discharger to inland waters, enclosed bays, and estuaries within the State of California would be the most accurate method to determine impacts of the CTR. However, the resources that would be required to perform such an analysis for each of the over 1,241 direct dischargers are beyond the resources typically available for

development of environmental regulations. EPA would have considered well-documented information submitted in comments.

In developing the methodology for estimating the compliance costs for the proposed CTR, time and budget constraints limited EPA's costing review to a subset of the regulated community. However, EPA believes that the sample selected adequately represents the various types of direct dischargers in the State.

EPA acknowledges that minor dischargers were under sampled as compared to the major dischargers. However, by definition, under the NPDES permit program, facilities classified as minor would not be expected to discharge toxic pollutants in toxic amounts. Since the CTR addresses only toxic pollutants, EPA would not expect significant, if any, impact to minor dischargers.

In analyses of the final CTR, EPA increased the sample of minors by five randomly selected facilities to bolster its analysis. EPA estimated costs of $872 per minor facility under the low scenario, and $2,682 per minor facility under the high scenario due to the CTR.

EPA also replaced Silvergate with South Bay in the sample in order to improve the estimate of the impacts of the CTR on the electric utility industry. The draft CTR cost analysis included costs for Silvergate, but the facility had closed and the data available were over five years old. The addition of South Bay, an electric utility facility with no costs, to the sample results in a more realistic, lower overall cost estimate for the electric utility industry.

Comment ID: CTR-059-023a
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES J

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The Economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-059-023a

See response to CTR-021-006b.

Comment ID: CTR-060-017
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Economic Analysis is deficient

EPA's economic analysis evaluated a number of discharger categories to estimate the potential costs associated with the adoption of these criteria. One discharger category was electric utilities which evaluated the costs to power plants. EPA's analysis of the electric utility category was deficient for at least two reasons. First, the analysis included two relatively small power plants. Specifically, the assessment included Pacific Gas & Electric's Hunter Point Power Plant (HPPP) and SDG&E's Silver Gate Power Plant (SGPP). Both the HPPP and SGPP are relatively small plants (generating capacities are approximately 396 MW and 230 MW, respectively). The SGPP is no longer in operation and its NPDES permit was rescinded in 1995. In fact, the economic analysis did not evaluate costs to the SGPP because it had not operated for several years. Both PG&E and SDG&E have plants affected by this rule which are larger (e.g., Pittsburgh at 2,060 MW and South Bay Power Plant at 709 MW). Consequently, the cost estimates for the entire category were based on only one small facility representing one water body and are therefore not likely to be representative of the actual costs that will be incurred by electric utilities.

Response to: CTR-060-017

See response to CTR-059-018.

Comment ID: CTR-066-013a
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01b01

Comment: The areas with which we find concerns and the requested changes include the following:

* The draft Economic Analysis has, from our short review, some serious flaws. It underestimates the costs of the draft to implement the CTR and overestimates the benefits. For the cost analysis, EPA should re-evaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings and, therefore, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs; and your assumption that artificially removes costs that exceed threshold values be assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-066-013a

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTR-082-007a
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01b
B Comment Period

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* The draft economic analysis seems to have serious flaws. It under-estimates the cost of the draft CTR and overstates the benefits. In the cost analysis USEPA should re-evaluate the representativeness of samples used and the omission of impacts on many factors that contribute to loadings, and hence, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs, and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-082-007a

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTR-085-016a
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES E-01b01

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* The District agrees with CASA and SCAP that the economic analysis has serious flaws. It underestimates the costs of the draft California Toxics Rule and overestimates the benefits. For the cost analysis, the EPA should evaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings and hence, can be expected to reduce their loadings (i.e., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities and other non-point sources); the incorporation of numerous assumptions that under estimates the costs; and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-085-016a

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTRH-001-058
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: E-01g08 Discharger Representation
References:
Attachments? N
CROSS REFERENCES

Comment: There are some things that we do have some concerns with, and that is the uncertainties and assumptions made in the economic analysis.

Although the City strongly believes that California needs certainty in its water quality program process as well as implementation, we are concerned about the potential precedents being set by some uncertainties and assumptions in the federal economic analysis of cost and benefits.

Although the City supported the OMB waiver in order to expedite the standards program promulgation process in California, we are very concerned with what may be potential faults in the federal analysis that

could be carried over to the state planning process.

There are differences between the federal and state acceptance processes. Where the state process requires a much more in-depth analysis of cost incurred by any state water quality planning process, the City believes greater attention should be placed upon nonpoint source control program costs, potential costs that could be incurred to meet criteria now set below detectability, as well as any hidden costs that may be associated with some of the uncertainties and assumptions in the federal financial analysis.

Again, the City will provide much greater detail in its written comments by the end of next week. We thank you for the opportunity to comment and look forward to working with you in the future.

Thank you.

Response to: CTRH-001-058

See responses to CTR-045-011, CTR-02-006b, CTR-021-004, and CTR-004-002.

Subject Matter Code: E-01g09 Affected Facilities

Comment ID: CTR-021-004
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01g09 Affected Facilities
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

1. The Inadequacies of the EA. Sunnyvale is gravely concerned that the EA has significantly missed the mark in assessing Sunnyvale's potential costs to comply with the criteria in the CTR. As pointed out in greater detail in the EOA Letter, the methodology used in the EA is fraught with analytical errors and unfounded assumptions, leading to many unanswered questions regarding the costs which Sunnyvale may face in coming into compliance with CTR-based effluent limitations. Accordingly, Sunnyvale urges EPA in the strongest terms not to use Sunnyvale as a representative facility to extrapolate cost information to the remainder of California until the EA is re-done. Use of the EA analysis at this point will result in erroneous, unfounded and misleading results which would be a disservice to EPA's ethical and legal obligations.

We are particularly concerned about the EA's unsupported assumption that Sunnyvale can easily close the gap between current discharge levels for copper and the CTR level for that metal merely by more stringent application of source controls. Sunnyvale already has one of the most stringent source control programs in the U.S., developed after years of careful analysis and in cooperation with the Regional Water Quality Control Board and representatives of a vigorous and concerned environmental community. The available effluent improvements from this avenue have long ago been achieved. The misplaced assumption in the EA tends to grossly and arbitrarily understate costs associated with compliance, particularly the potential for requiring reverse osmosis as the only availablemeans of achieving concentration levels seemingly mandated by the proposed CTR.

Further, we strongly urge EPA to make clear that the overall methodology and approach used in the EA is neither appropriate nor legally sufficient for use by the State of California in promulgating its implementation plan or in promulgating State criteria for the pollutants addressed in the CTR. The gross inadequacies in the EA, which are depicted in the CASA/Tri-TAC letter, could not withstand judicial scrutiny under California's Porter-Cologne Act.

Response to: CTR-021-004

The City of Sunnyvale states that its present source control program is one of the most stringent in the country and that reverse osmosis would be required for compliance with a CTR-based effluent limit for

copper. EPA's revised cost analysis for Sunnyvale indicates that the facility is in compliance with the CTR-based effluent limit for copper and that the addition of reverse osmosis is not justified. As indicated in the Technical Support Document for the Economic Analysis of the Final CTR, the City of Sunnyvale reported one discharge observation for copper between January 1995 and December 1997 above the projected effluent limit for copper (8.03 ug/L). This single exceedance was 8.4 ug/L which is only 4% above the CTR-based permit limit. EPA believes that this violation frequency and the magnitude of the violation do not justify addition of reverse osmosis. Moreover, the projected pollutant loading reduction would likely have minimum pollution control costs. These costs would be associated with controlling discharges of copper using pollution prevention, or by optimizing existing processes (e.g., individual units performance under peak flows or critical conditions) at the POTW.

Note that EPA calculated the projected effluent limit for the City of Sunnyvale using a metal translator factor of 2.6 and a saltwater dissolved criterion of 3.1 ug/L. Additionally, the projected limit used was adjusted using statistical methods to account for effluent variability and different averaging periods. The resulting effluent limit is comparable to the copper limit established in the 1998 NPDES permit issued to the facility (8.6 ug/L).

The State is not required to use the EPA's Economic Analysis (EA) in promulgating its proposed implementation plan. While EPA and the State have worked very closely to gather the data necessary to develop their respective economic analyses, the State's economic analysis for its proposed implementation plan is different than EPA's. The State tailored the information gathered and reported in the EPA's EA to reflect the specific proposed policies in the State plan.

Although EPA disagrees with commenters that claim that EPA's EA is inappropriate for use by the State, EPA does believe that the State is under no obligation to use EPA's EA and may choose alternative methodologies for its economic analysis in support of State water quality policy or regulation.

See responses to CTR-021-017 and CTR-035-011a.

Comment ID: CTR-035-046b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g09 Affected Facilities
References:
Attachments? N
CROSS REFERENCES E-01g08

Comment: pp. 2-4 - 2-9 (U.S. EPA, 1997b) -- Sampling Strategy In general terms, we support EPA's methodology of stratified sampling to determine costs, although it is not clear whether the POTW sample was stratified appropriately. We believe that inadequate evidence is presented that the sample of case studies reflects the overall population of POTWs, and that extrapolation based on the sample would truly reflect total POTW costs. Little explanation is provided as to how the case study facilities were selected, and little evidence is presented demonstrating the validity of extrapolating from the small sample to the impacted population of POTWs. In particular, we believe that minor facilities were under-represented, and that it is invalid to assure that none of the 185 minor POTWs will incur any costs. We also believe

that larger samples of facilities from 0-10 MGD and from 10-100 MGD also would be necessary to obtain valid estimates of POTW costs. In addition, by assuming that existing facilities that contain effluent limits for toxic pollutants were representative facilities and using them as the basis for extrapolation to the universe of potentially affected facilities, EPA may have failed to include a major category of costs. By ignoring the costs of those facilities meeting their current permit limits, EPA is assuming that the facilities they are extrapolating to have similar current permit limits, which was not demonstrated to be the case. Therefore, EPA should reexamine the use of this assumption in the analysis of POTW costs.

Response to: CTR-035-046b

See responses to CTR-059-018 and CTR-040-024.

Comment ID: CTR-035-048
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01g09 Affected Facilities
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 2-36 - 2-37 (U.S. EPA, 1997b) -- Use of Average Cost Estimates for Extrapolation EPA's use of average costs to estimate individual POTW costs masks a significant range in expenditures, indicating that some communities will be much more significantly impacted than others. By using averages for extrapolation rather than the full range, total cost estimates are likely to be severely underestimated.

Response to: CTR-035-048

EPA selected sample facilities in order to represent different industry categories, but also various facility sizes with different flow magnitudes. For example, EPA analyzed POTW facilities which fell into three flow categories representing facilities serving very large, medium, and small communities. Costs were averaged for the sample facilities within each flow category for an industry type and then extrapolated to the universe of facilities which matched the industry type and the range in flow for that flow category. Thus, costs calculated for facilities operating in very large communities would not be applied to facilities serving very small communities. See also response to CTR-059-018.

Subject Matter Code: E-01g10 Toxic Pound Equivalents

Comment ID: CTR-052-012
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01g10 Toxic Pound Equivalents
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Cost per Toxic Pound Removed

Removal of copper by pollution prevention methods would be marginally cost effective. Pollution prevention of 10% of the Authority's annual copper load would result in a removal of 262 pounds per year from the Bay. Using the toxic weight factor from the EA, 0.47 results in a removal of 123 toxic pounds. Using the annual cost of $56,952 from the Larry Walker analysis results in a removal cost of $462 per pound. This approaches the high end of $500 per pound cited by EPA.

Removal of organics would not be cost effective. No toxic weights are listed for the PAHS, so this analysis is only for Heptachlor, which has a toxic weight of 4,100. Assuming that carbon adsorption removes 95% of the Heptachlor, and using the maximum recorded value of 0.018 ug/L results in the following:

(0.95)(0.018 ug/L)(4,100)(65 MGD)(365 days/year)(8.34 lbs/gal)(1 mg/l000 ug)=

13,872 toxic pounds per year

Using the annualized cost for carbon adsorption of $44,200,000 per year results in a removal cost of $3,186 per toxic pound. This figure is 6-16 times the threshold cost range cited by EPA of $200-$500 per toxic pound. In actual practice, the costs would even be higher since much of the data is non-detect with MDLs as low as 0.007 ug/L.

Response to: CTR-052-012

See response to CTR-004-003.

Subject Matter Code: E-01h Treatment Assumptions

Comment ID: CTR-003-011
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: 11) What justification does the EPA have for assuming that, "If all monitoring data reported for a facility were reported as below analytical detection levels, even if the reported detection limit was above EPA approved analytical method detection levels, it was assumed that no reasonable potential existed to exceed CTR-based WQBELs".? Can permit holders make the same assumption to assess reasonable potential when applying for new permits?

Response to: CTR-003-011

The NPDES permit regulations in 40 CFR 122.44(d) and 123.25 require that WQBELs be derived for toxic pollutants that are discharged at a level that has a reasonable potential to exceed water quality standards. EPA believes that the approach used to determine reasonable potential to exceed CTR-based effluent limitations in its economic analysis was reasonable. This is particularly the case for the high cost scenario. Under this scenario, when any pollutant for which a limit for a toxic pollutant already existed in the current NPDES permit for a sample facility, it was assumed that a reasonable potential existed to exceed a CTR-based limit and the pollutant was included for further analysis. For pollutants that were not limited in the existing permit for a sample facility, but were detected in the effluent (as reported in the permit application, or as a result of special monitoring conditions contained in the NPDES permit), an analysis was conducted to determine if a reasonable potential existed to exceed CTR-based limits using the method recommended in EPA's Technical Support Document for Water Quality-based Toxics Control (1991). If all monitoring data reported for a facility were reported as below analytical detection levels, even if the reported detection limit was above EPA-approved analytical method detection levels, EPA assumed that no reasonable potential existed to exceed CTR-based WQBELs. Although EPA acknowledged in its economic analysis that this assumption could underestimate the impact of implementing the CTR, it most likely reflects the actual procedures that would be used by the State Regional Water Quality Control Boards (RWQCBs) because the discharger would not be subject to enforcement at any level below quantifiable analytical detection levels.

In estimating potential costs associated with the final rule, EPA also made an effort to ensure that all relevant and current information related to the possible presence of a pollutant in a sample facility discharge was collected. Specifically, all current information and data (including permits, fact sheets, permit applications, and other relevant discharge information) were updated and verified for each sample facility. In addition, each of the State RWQCBs were contacted to provide comments and additional information as necessary to ensure accurate reflection of current permit requirements and discharge conditions. Finally, permit and monitoring data submitted as a part of the public comments were reviewed and considered.

Reference: U.S. EPA. 1991. Technical Support Document for Water Quality-based Toxics Control. EPA/505/2-90-001

Comment ID: CTR-003-013
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: 13) The City has reviewed those sections of the economic impact report which dealt directly with it's treatment plant. Although we have not had the time to address directly the cost impacts, we can comment on the assumptions that were used. EPA finds that we may have problems meeting metals objectives and suggests that they can be solved by chemically assisted clarification and additional pollution prevention/ waste minimization controls. It should be noted that the City has used both of these techniques for many years. With minor exceptions for waste minimization, it is unlikely that further reductions can be attained by either method. Waste minimization is cited as the answer to potential problems with chloroform. EPA needs to be aware that chloroform is a byproduct of the wastewater treatment process where chlorine disinfection is involved. Waste minimization will not help. It would be more appropriate to assume that the disinfection process would need to change to ultra violet or a similar non-chlorinated method. Capital costs would likely range around three to four million dollars with operating costs near one million dollars per year.

Response to: CTR-003-013

See response to CTR-004-003.

EPA agrees that chloroform is most likely a disinfection by-product (DBP) in wastewater treatment plants that use chlorination as the means for disinfection and that UV is an alternative technology that eliminates the presence of chloroform in the effluent. However, it should be noted that process optimization in the chlorination units is a viable and relatively low-cost pollution control alternative that can be used to reduce the discharge of chloroform and other DBPs (Truax, 1992; U.S. EPA, 1992; U.S. EPA, 1990) to levels in compliance with projected CTR-based limits. Process optimization is used to control DBPs in the final economic analysis of the CTR.

References:

Truax, Dennis D. 1992. "Optimization of Wastewater Treatment Plant Systems". Water Environment Research. 64(4): 400-02.

U.S. EPA. 1992. Standardized Costs for Water Supply Distribution Systems. Gummerman, R., Burris, B., and Burris D. EPA 600/R-92/009. Cincinnati, OH.

U.S. EPA. 1990. Optimized Water Treatment Plant Performance with the Composite Correction

Program. Summary Report. EPA 600/8-90/017. Cincinnati, OH.

Comment ID: CTR-021-009
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The Estimated CTR Plant Optimization Compliance Costs for Sunnyvale are Under Estimated by One to Two Orders of Magnitude (10 to 100 times low)

The projected average cost per POTW under the high-end scenario of $480,000 per year (p. 4-12) is low by a factor of 10 to 100 based on Sunnyvale's situation and analysis (as cited in Appendix I-B-11). There is no support provided for the key assumption that "many of the sample facilities already possessed treatment processes that could be enhanced potentially to achieve CTR-based effluent limits" and "Therefore increased O&M was assumed adequate to comply with CTR-based effluent limits (as opposed to installing new treatment equipment). (p. 4-13).

Secondary treatment facilities with dual media filtration, such as Sunnyvale, are not specifically designed for metals or toxic organics removal. The removals that occur are an incidental function of the secondary biological treatment and solids separation processes. It is not technically possible to "dial-in" an additional 10-25% as has been assumed, particularly for facilities such a Sunnyvale, that already have low influent concentrations due to past implementation extensive source control, pollution prevention, and waste minimization measures. The presumption regarding plant optimization apparently mistakenly assumes that percent removal is a linear function instead of an asymptotic one. It is much more difficult to remove an additional 10-25% when the effluent contains only 5-10 ug/l versus say 20-50 ug/L when more of the copper is likely particulate (associated with solids) versus soluble and more amenable to removal through potential chemical addition to enhance solids removal.

Sunnyvale already achieves 85-90% metals removal and the majority of metals remaining are in the dissolved form. This information was submitted to EPA, as input for the Case Study, in an EOA September 23, 1996 memo (incorporated herein by reference). As stated in that memo, the low-end treatment option (high lime treatment) with an annual cost of $9.8 million, was not guaranteed to consistently achieve a 4.9 ug/L copper effluent limit. Only the reverse osmosis based treatment option, at $42.1 million per year could likely produce effluent in the 4.9 ug/L copper range, since this is a maximum limit (i.e. never to be exceeded) not an average limit as incorrectly assumed in the CTR (see below). EPA need to provide, in the CTR, the specific plant performance data, apparently from the RREL Treatability Database, that supports the contention that minor levels ($100,000) of plant optimization can achieve the proposed low part per billion metals concentrations.

Response to: CTR-021-009

See responses to CTR-021-017 and CTR-004-003.

Comment ID: CTR-035-008e
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01e
E-01d
E-01m
E-01c

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008e

See responses to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-038-004b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:

Attachments? Y
CROSS REFERENCES E-01g08
E-01m
E-01c02

Comment: 4. The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. The District's analysis demonstrates that actual costs may be an order of magnitude greater than EPA's $500/lb threshold and that the benefits are very small.

Response to: CTR-038-004b

See responses to CTR-054-013a, CTR-032-004, CTR-021-008, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-040-032
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that effluent metals levels can be reduced to the low levels necessary to ensure compliance without any capital costs, by adding lime to existing primary tanks.

Response to: CTR-040-032

The U.S. EPA Treatability Database indicates that chemical precipitation with addition of lime is a technology capable of removing metals at the concentrations and loading reductions required. For example, several treatment plants have reached concentrations of 7.7 ug/L for copper based on a pilot study (CTR-based level for copper is 8.03 ug/L) and 0.46 ug/L for silver (CTR-based level for silver is 1.51 ug/L) (U.S.EPA RREL). Some of the sample facilities already have a clarification system in place, therefore, only capital costs for the lime feeding and conveying system need to be considered. For facilities without clarifiers, the capital cost of a primary clarifier is also included in EPA's cost estimates. EPA's cost estimates are based on EPA's Treatability Manual (1980) and are adjusted for inflation.

References: U.S. EPA. 1980. Treatability Manual, Volume IV, Cost Estimating. U.S. EPA Risk Reduction Engineering Laboratory (RREL). Cincinnati, Ohio. Treatability Database.

Comment ID: CTR-040-038
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA may have greatly underestimated the cost of metals removal. EPA assumed that significant metals reductions could be achieved without any capital costs by adding lime to existing primary sedimentation tanks. But, this would increase the amount of primary sludge produced (as much as 5 times at high lime dosages) and could therefore necessitate additional sludge handling costs. Further, there is no evidence that addition of lime to the primary sediment tanks could achieve the low effluent levels required to achieve some of the metals criteria (e.g., the saltwater copper criteria). Most engineers who have addressed this issue have assumed that tertiary lime treatment would be necessary. In the Bay Area Dischargers Association analysis, tertiary limetreatment was six times the cost of primary lime addition.

Response to: CTR-040-038

See response to CTR-040-032.

Comment ID: CTR-041-028
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that effluent metals levels can be reduced to the low levels necessary to ensure compliance without any capital costs, by adding lime to existing primary tanks.

Response to: CTR-041-028

See response to CTR-040-032.

Comment ID: CTR-041-034
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: EPA may have greatly underestimated the cost of metals removal. EPA assumed that significant metals reductions could be achieved without any capital costs by adding lime to existing primary sedimentation tanks. But, this would increase the amount of primary sludge produced (as much as 5 times at high lime dosages) and could therefore necessitate additional sludge handling costs. Further, there is no evidence that addition of lime to the primary sediment tanks could achieve the low effluent levels required to achieve some of the metals criteria (e.g., the saltwater copper criteria). Most engineers who have addressed this issue have assumed that tertiary lime treatment would be necessary. In the Bay Area Dischargers Association analysis, tertiary lime treatment was six times the cost of primary lime addition.

Response to: CTR-041-034

EPA assigned separate costs for residuals removal (including sludge) where it was appropriate. EPA did not add any residuals removal costs to Sacramento Regional Wastewater Treatment Plant in association with the process optimization study that was assigned in EPA's cost estimate for the facility. EPA disagrees that lime addition cannot meet the CTR-based limits; see response to CTR-040-032.

Comment ID: CTR-043-004b
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? Y
CROSS REFERENCES E-01g
E-01m
E-02c
E-01c02

Comment: 4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution;

(2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements;

(3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and

(4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule.

The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act.

Response to: CTR-043-004b

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-056-018, and CTR-059-018.

Comment ID: CTR-044-023
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that effluent metals levels can be reduced to the low levels necessary to ensure compliance without any capital costs, by adding lime to existing primary tanks.

Response to: CTR-044-023

See response to CTR-040-032.

Comment ID: CTR-044-029
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA

Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: EPA may have greatly underestimated the cost of metals removal. EPA assumed that significant metals reductions could be achieved without any capital costs by adding lime to existing primary sedimentation tanks. But, this would increase the amount of primary sludge produced (as much as 5 times at high lime dosages) and could therefore necessitate additional sludge handling costs. Further, there is no evidence that addition of lime to the primary sediment tanks could achieve the low effluent levels required to achieve some of the metals criteria (e.g., the saltwater copper criteria). Most engineers who have addressed this issue have assumed that tertiary lime treatment would be necessary. In the Bay Area Dischargers Association analysis, tertiary lime treatment was six times the cost of primary lime addition.

Response to: CTR-044-029

See response to CTR-040-032.

Comment ID: CTR-045-009b
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01m

Comment: The draft Economic Analysis has serious flaws. It underestimates the costs of the draft CTR and overestimates the benefits. For the cost analysis, EPA should reevaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings, and hence, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of numerous assumptions that underestimate costs; and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-045-009b

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTR-049-006b
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01m

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

4. Review and correct existing flaws in the current "Economic Analysis."

With respect to the Economic Analysis conducted by USEPA, we are concerned that it underestimates the cost of the proposed CTR rule while overestimating its benefits. We suggest that USEPA re-evaluate (1) the representativeness of the sample used; (2) the omission of impacts on many sectors that contribute to loadings; (3) the incorporation of a variety of assumptions that underestimate costs; and (4) the assumption to artificially remove costs that exceed threshold values by incorrectly assuming that regulatory relief measures will be granted. For the benefits analysis, USEPA should utilize more California-specific and recent information. A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures requires, in our opinion, further work prior to the promulgation of the criteria.

Response to: CTR-049-006b

See responses CTR-045-011, CTR-032-004, CTR-056-018, CTR-021-006b, CTR-059-018, and CTR-052-014.

Comment ID: CTR-054-027
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that effluent metals levels can be reduced to the low levels necessary to ensure compliance without any capital costs, by adding lime to existing primary tanks.

Response to: CTR-054-027

See response to CTR-040-032.

Comment ID: CTR-054-033
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: EPA may have greatly underestimated the cost of metals removal. EPA assumed that significant metals reductions could be achieved without any capital costs by adding lime to existing primary sedimentation tanks. But, this would increase the amount of primary sludge produced (as much as 5 times at high lime dosages) and could therefore necessitate additional sludge handling costs. Further, there is no evidence that addition of lime to the primary sediment tanks could achieve the low effluent levels required to achieve some of the metals criteria (e.g., the saltwater copper criteria). Most engineers who have addressed this issue have assumed that tertiary lime treatment would be necessary. In the Bay Area Dischargers Association analysis, tertiary lime treatment was six times the cost of primary lime addition.

Response to: CTR-054-033

See response CTR-040-032.

In estimating compliance costs for facilities, EPA included costs associated with solid waste disposal costs as part of operation and maintenance costs for sample facilities.

Comment ID: CTR-086-003
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: E-01h Treatment Assumptions
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: CDA is a strong supporter of water quality and human health protection. CDA's primary goals in commenting on the draft CTR are to request that mercury criteria be based on sound science and that mercury regulation be implemented via a watershed management, phased TMDL-type approach.

CDA is particularly concerned that the CTR does not adequately assess the economic impacts on indirect dischargers nor the extent to which there will be measurable water quality benefits solely from adoption of the proposed mercury criteria for point sources.

Economic Analysis

CDA supports CASA/Tri-TAC's conclusions that the Economic Analysis has significant technical weaknesses, is based on a large number of assumptions and minimal empirical data, and that it understates costs and overestimates benefits. The analysis found that mercury reductions of 80.4% and 51.7% would be required under the high-end and low-end scenarios, respectively. The economic analysis needs to evaluate costs and feasibility of attainability based on actual treatment plant mercury removal performance data with associated detection limits. It also needs to evaluate costs under the scenario that dilution credit would be eliminated when calculating effluent limits for bioaccumulative constituents of concern, such as mercury, for deepwater dischargers within or capable of impacting mercury nonattaininent areas.

Response to: CTR-086-003

EPA did examine detailed treatment information and pollutant removal performance data at the sample facilities to evaluate the feasibility and potential costs of meeting CTR-based WQBELs. EPA estimated that seven facilities would incur costs to meet the CTR-based effluent limits for mercury. When this information was limited, the assessment of pollutant removal feasibility was also based upon the reviewing engineer's best professional judgement using general knowledge of industrial and municipal operations.

Dilution factors used to calculate water quality based effluent limits were based on the dilution allowed within the current waste discharge requirements for each sample facility. Of the 20 sample facilities, only four were provided with dilution factors. WQBELs for the remaining facilities were based on a dilution of zero. When this sample is extrapolated to the universe, over 94% of point source dischargers are estimated to not be allowed dilution. EPA believes that this is a highly conservative estimate that will likely overestimate potential costs.

Comment ID: CTRH-002-016b
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: E-01h Treatment Assumptions
References:
Attachments? N
CROSS REFERENCES E-01c2

Comment: And finally, I'd like to comment on the analysis of the economic impact of the CTR. We

believe that the analysis does not portray a reasonable picture of what the potential costs and benefits may result from the promulgation of this CTR. In our opinion, the cost analysis contains many flawed assumptions that result in severe underestimation of the total potential costs, and we're particularly concerned about the use of process optimization and how it was relied upon.

Likewise, the benefits, while admittedly difficult to estimate, appear tenuous at best. The bottom line is that we are concerned that this analysis does not properly reveal that the CTR can lead to requirements for large expenditures by POTWs in Southern California with questionable benefits to the environment. We recommend that EPA carefully redo its economic analysis to portray a more accurate picture of the potential costs and benefits.

Thank you again for this opportunity. We look forward to submitting our comments in writing.

Response to: CTRH-002-016b

See responses CTR-054-013a, CTR-035-057, CTR-056-018, and CTR-004-003.

Subject Matter Code: E-01h01 25% Reduction Assumption

Comment ID: CTR-040-029b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h01 25% Reduction Assumption
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01q01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-040-029b

See response to CTR-040-029a.

Comment ID: CTR-041-025b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h01 25% Reduction Assumption
References:
Attachments? N
CROSS REFERENCES E-01q01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-041-025b

See response to CTR-040-029a.

Comment ID: CTR-044-005b
Comment Author: City of Woodland

Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01h01 25% Reduction Assumption
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01m
E-02c
E-01c02
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005b

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-044-020b
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01h01 25% Reduction Assumption
References:
Attachments? N
CROSS REFERENCES E-01q01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is

anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-044-020b

See response to CTR-040-029a.

Comment ID: CTR-054-024b
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01h01 25% Reduction Assumption
References:
Attachments? N
CROSS REFERENCES E-01q01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-054-024b

See response to CTR-040-029a.

Subject Matter Code: E-01h02 Unit Cost Assumptions

Comment ID: CTRH-001-037c
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: E-01h02 Unit Cost Assumptions
References:
Attachments? N
CROSS REFERENCES E-01c02
E-01q03

Comment: Second, the interaction between the CTR and the state's implementation policy is particularly important given our second concern, which is namely that the EPA's economic evaluation underestimates the costs and overestimates the benefits of implementing this rule.

Our concern about the cost estimates is based on the fact that the cost analysis appears to undervalue the magnitude of difficulty dischargers will have complying with permits issued based on this rule.

We are also concerned that the cost estimates for various compliance activities such as source control and treatment process optimization made in the case studies are overly optimistic and not reflective of the true actions that will need to be taken to insure compliance.

Overall, we are concerned that the expenditures that may be necessary for many POTWS to comply with the CTR will be large, these costs may not be matched by commensurate benefits, and that EPA has not analyzed whether point source controls are in fact a cost-effective way to achieve water quality standards.

Our preliminary analysis for just five agencies in the Bay Area to comply with the proposed standard for copper alone could amount to more than $60 million per year -- 60 million. This number would be far higher if calculated for every pollutant listed in the CTR for the entire POTW industry in California.

Since this estimate would undoubtedly exceed the high end of the range contained in EPA's analysis, we believe it is necessary for EPA to redo the economic analysis to fully comply with its legal responsibilities.

In addition, revised economic analysis is necessary to provide a sound basis for the State to use in its analysis of the economic impacts of the implementation policy.

Response to: CTRH-001-037c

See responses to CTR-041-018, CTR-035-057, CTR-056-018, CTR-004-003, and CTR-040-039.

Subject Matter Code: E-01i Alternative Cost Analysis

Comment ID: CTR-003-012
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01i Alternative Cost Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: 12) The cost analysis suggests that there is little difference between the cost of using a risk level of 10E-6 versus 10E-5. The reason for that is in all likelihood the fact that many of these criteria are below the detection level at both risk levels. Under the assumptions used their would be no cost to either scenario.

Response to: CTR-003-012

As part of its revised cost analysis, EPA estimated the changes in estimated costs and pollutant load reductions based on the lower risk level of 10-5. Under the low scenario, costs decrease by $1.1 million, approximately 11% less than the costs based on the higher risk level. Under the high scenario, annual costs decrease by $5.8 million, also an 11% decrease from the costs based on a 10-6 risk level. Pollutant load reductions attributable to use of a lower risk level are estimated to decrease by approximately 4% and 1% under the low and high scenarios, respectively. The relatively low sensitivity of costs to the change in risk level primarily is related to the fact that most of the potential costs related to implementing the CTR are being driven by metals. Changes in risk levels for carcinogens primarily affect organic pollutants.

Comment ID: CTR-021-015
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01i Alternative Cost Analysis
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Appendix III-B:

The analysis conducted in Appendix III-B is essentially the same as that shown in the previous appendices, except that it is assumed that the dissolved criteria converts directly to a total criteria (translator =I). The implication of this is methodological assumption that 100% of the total pollutants discharged in the effluent are in dissolved form. Results from this appendix represent an absolute worst

case, are misleading and inappropriate. It has been shown that the assumptions used to generate the analysis in Appendix I-B (TSS, translator values, and 95%tile values for chronic WLAs) are already highly conservative.

Response to: CTR-021-015

The criteria for metals in the proposed rule are expressed in the dissolved form. Permitting regulations, however, require that permit limits be set in terms of total recoverable metals concentrations. Therefore, permit writers must "translate" dissolved criteria to derive total recoverable permit limits which can be done through a variety of methods. The preferred methodology employs site-specific information to derive the translator. However, since not all site-specific information was available, the base case analysis used a second method, the theoretical partitioning relationship, to estimate the translator. According to recent EPA guidance on translators, this method usually tends to overstate the stringency of the derived permit limit compared to the site-specific method, although it will sometimes understate the stringency (U.S. EPA, 1996). A third method is to simply use the total recoverable criteria that are derived by dividing the dissolved criteria by the conversion factor. This method is very conservative and will, in nearly all cases, result in more stringent permit limits compared to the site-specific method.

EPA performed a sensitivity analysis to estimate the effect of the use of total recoverable criteria on CTR-based WQBELs, total costs, and load reductions. CTR-based WQBELs are calculated using the same methods described in Chapter 4 of EPA's Economic Analysis, except that total recoverable criteria are used in place of dissolved criteria for metals. The analysis shows that a significant increase in costs can be expected by using total recoverable criteria, as compared to the costs of the theoretical partitioning approach used in the base case analysis. Potential annual costs under the low scenario are $62.4 million per year, an approximately two-fold increase over the estimates in the low base case analysis. Under the high scenario, total costs are estimated to be nearly $325 million per year, over five times the cost estimates in the base case analysis. Potential load reductions are estimated to increase by approximately 14% over the low base case scenario, and by nearly 7% under the high scenario. Using conversion factors as translators would result in significantly higher costs per toxic pound-equivalent removed than the base case analysis. The cost-effectiveness of the low scenario is $50 per toxic pound-equivalent removed compared to $31 per toxic pound-equivalent removed in the base case analysis. The cost-effectiveness of the high scenario is $111 per toxic pound-equivalent removed compared to $22 per toxic pound-equivalent removed in the base case analysis.

Although the cost effectiveness for this translator sensitivity analysis is reasonable, EPA believes that the costs estimated from this analysis greatly overstate true costs. EPA expects that in cases where a facility may incur substantial economic impacts due to an effluent limit for a metal, there will be strong incentives for the facility or the state to develop site-specific data, which will result in more realistic translators, thus reducing potential economic impacts. EPA believes that the cost estimates developed using the theoretical partitioning approach in the base case are more realistic than the cost estimates from this sensitivity analysis.

Reference: U.S. EPA. 1996. The Metals Translator: Guidance for Calculation of a Total Recoverable Permit Limit From a Dissolved Criteria.

Comment ID: CTR-052-005a
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01i Alternative Cost Analysis
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01d01

Comment: EPA has greatly understated the potential attainability problems associated with the CTR. This also includes numerous erroneous assumptions made in the EA, such as those described by BADA, CASA/Tri-TAC, and M.Cubed. Larry Walker Associates prepared an Attainability Analysis for the BADA agencies, copy attached. That analysis concluded that BADA agencies will not be able to comply with effluent standards for copper, nickel, pesticides (Aldrin and Heptachlor), and PAHs [Benzo(a)Pyrene, Dibenzo(a,h)Anthracene, and lndeno(1,2,3-cd)Pyrene]. Removals ranging from approximately 20% to nearly 90% will be required. Without major revisions to the CTR, the cost for compliance will be more than $130,000,000 annually. These costs represent only the BADA agencies. Actual costs for all POTW dischargers to San Francisco Bay would be at least an additional 40%, bringing the total annual cost for San Francisco Bay ratepayers to more than $185,000,000 on a strictly flow proportional basis. Since the non-BADA POTWs are significantly smaller, capital costs would actually increase due to loss of economy of scale. Therefore, actual costs for San Francisco Bay could easily exceed $200,000,000 per year - all for the sole purpose of removing between 1-10% of the "Estimated Share of Toxic Loadings Attributable to Point Source."(*1)

(*1)United States Environmental Protection Agency, Office of Water 4301, EPA-820-B-96-001, July 1997, Economic Analysis of the Proposed California Water Quality Toxics Rule, Executive Summary, Page ES-10, Exhibit ES-3. Estimated Share of Toxic Loadings to California Surface Waters Attributable to Point Sources.

Response to: CTR-052-005a

EPA disagrees with the annual compliance cost estimate of $130 million taken from an attainability analysis performed for BADA. This figure represents the higher of two estimates presented in the BADA analysis and corresponds to the use of tertiary lime addition. The lower cost estimate ($68 million) presented in the analysis is based on lime addition to primary tanks. The attainability analysis also uses the costs for the City of Merced from EPA's economic analysis of the proposed CTR as a basis for estimating carbon adsorption costs.

In EPA's revised economic analysis, EPA no longer estimates that the City of Merced will need to add costly granular activated carbon (a cost of $4.2 million annually) to comply with CTR-based limits. EPA's revised analysis indicates that pollution prevention and process optimization (a cost of $594,000 annually) should be sufficient to ensure compliance with CTR-based limits. If EPA's revised cost estimate were used, the BADA cost estimates would be significantly lower because $56 million of both estimates is based on the old Merced cost estimate.

The BADA analysis also provides an estimate of costs for San Jose, one of the sample facilities in EPA's detailed cost analysis. The BADA analysis estimates costs of $7.75 million to $54.07 million for copper reductions (nickel reductions are included in the pollution prevention costs for copper). BADA

estimated a 54% reduction for copper and a 5% reduction for nickel. EPA's analysis contained a 17% required reduction for copper and none for nickel with estimated annual costs of approximately $300,000 for pollution prevention under the high cost scenario.

The differences in load reductions between BADA and EPA's analyses result from the different baselines in the two analyses. BADA uses a 99.9% probability estimate for metals and the maximum observed concentration for organics as its baseline to estimate loading reductions. EPA uses the existing NPDES permit limit or, in the absence of an existing limit, the maximum effluent concentration to estimateloading reductions which are then considered when assigning costs to reach the necessary load reductions.

BADA's analysis assumed pollution prevention costs for reductions of up to 10%, whereas EPA considered pollution prevention an option for reductions of up to 25%. EPA believes that a 25% loading reduction is a more realistic cap for pollution prevention efforts than 10%. EPA's analysis assumes that facilities will try to meet CTR-based limits using the least cost option and, for loading reductions between 10% and 25%, EPA believes that pollution prevention or process optimization are the more likely options over end-of-pipe treatment.

EPA did not assign costs mechanically based on unrealistic guidelines and statistical procedures to predict worst-case effluent quality as a means for determining compliance as was done in the BADA analysis. EPA's cost decision matrix allows for the consideration of the available monitoring and permit data in the context of detection limits, facility processes, and potential irregularities in plant operations which might result in abnormally high data. EPA believes that its methodology is more appropriate for assessing data and estimating costs than that used by BADA.

See also response to CTR-040-039.

Comment ID: CTR-052-009
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01i Alternative Cost Analysis
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: IMPACTS ON THE AUTHORITY AND ITS MEMBER AGENCIES

Attainability Analysis. The Attainability analysis performed by Larry Walker Associates and Authority staff concludes that the Authority will not be able to comply with effluent limitations for copper, heptachlor, Dibenzo(a,h)Anthracene, and possibly Benzo(a)Anthracene. The following table summarizes compliance issues and solutions.

Pollutant	% Removal Required	Remedy
Copper	8-9	Pollution Prevention
Heptachlor	88	Carbon Adsorption
Dibenzo(a,h)Anthracene	30	Carbon Adsorption

Benzo(a)Anthracene 10 Pollution Prevention?

In addition, it is unknown whether future compliance issues would arise for numerous pollutants where the current Method Detection Limits (MDL) are above the anticipated effluent limitations. As noted previously, EPA's assumption that non-detect data equals compliance, and therefore, no costs is not justified. Only POTWs with the most resources have real data or many pesticides and PAHS. Smaller facilities tend to have nothing but non-detect data. Since the Authority and other BADA agencies have detected these pollutants, it is reasonable to assume that other agencies would if they used lower detection limits. Therefore, it is logical to assume that once technology provides lower detection limits, other compliance issues will arise.

Response to: CTR-052-009

See responses to CTR-003-011 and CTR-004-002.

Comment ID: CTR-059-027
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01i Alternative Cost Analysis
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01g08

Comment: Attainability Analysis

Based on our review of the CTR, at least seven of the Sanitation Districts' Water Reclamation Plants (WRPS) would be affected by the proposed rule. They include the Pomona WRP (15 MGD(*1)), the Whittier Narrows (15 WRP), the San Jose Creek WRP (100 MGD), the Los Coyotes WRP (37.5 MGD), the Long Beach WRP (25 MGD), the Saugus WRP (6.5 MGD) and the Valencia WRP (12.6 MGD). The seven WRPs treat mainly residential and commercial waste, with less than 10% of the influent coming from industrial sources. On an annual basis, over 38% of the reclaimed water is reused for applications including groundwater recharge, landscape irrigation and industrial uses. The remainder is discharged to inland surface waters that are effluent dependent water bodies. The existing and potential designated uses of the receiving waters are diverse and include groundwater recharge, water recreation, warm fresh water habitat, wildlife habitat; commercial and sport fishing; wildlife habitat; rare, threatened or endangered species; and spawning, reproduction, and early development.

A preliminary review of historical monitoring data has shown that plant effluent concentrations of mercury, lindane and four trihalomethanes (bromoform, chlorodibromomethane, chloroform and dichlorobromomethane) frequently exceed the proposed CTR criteria at each of the seven plants. Further evaluations were conducted to determine if loading reductions could be achieved through source control or pollution prevention options and/or treatment.

Source Control and Pollution Prevention Options

The Sanitation Districts' industrial waste pretreatment program was established to ensure that all treatment facilities are able to comply with waste discharge requirements; to protect the public and the environment; and to protect personnel and facilities from potentially harmful industrial wastes. To achieve these objectives, a systemwide pretreatment program was created in 1972. The program presently regulates an extensive and varied industrial base consisting of 3,300 industries, of which 1,335 are Significant Industrial Users (SlUs).

For the CTR constituents of concern, our review has shown that there is very little potential for achieving additional reductions in pollutant loadings through source control or pollution prevention. In the case of mercury, we estimate that only 4% of the influent mercury loadings are from industrial sources. Thus, reductions of the mercury industrial contribution to meet the proposed CTR criteria would be ineffective. The same is true for other POTWs in California. For example, a 1997 study(*2) conducted for the City of Palo Alto demonstrated that the primary sources of mercury to the Palo Alto Regional Water Quality Control Plant were from residents (46%), the water supply (22%), dentists (9%), permitted industries (4%), storm water inflow (3%), employee-related human waste (30%), Stanford University (30%) and other sources (1%). None of the regulated dischargers in the Palo Alto service area used mercury in any manufacturing process. In addition, a study conducted for the Central Contra Costa Sanitary District, which serves an estimated population of 236,200, showed that over 11 pounds per year of mercury were discharged by residential sources including human waste, laundry greywater, thermometers, contact lens solution, household products and food waste. Since residential contributions of mercury are so significant, there are very limited options for control other than educational outreach programs and/or implementation of best management practices, which may have limited effectiveness yet can be costly to develop and implement.

In the case of lindane, pollution prevention is also not feasible. The primary sources of lindane can be traced to consumer products such as flea shampoos for pets and human lice shampoo. Traditional methods of source control such as permitting or the application of best management practices would not be practical or effective. The only viable source control alternative would be a ban on constuner products that use lindane as an active agent. This approach would require the cooperation of federal and state agencies, and the manufacturers of the commercial products. Since these products have a legitimate use for public health protection, some substitute product would need to be provided. Presumably, EPA would need to determine if replacements for lindane were more or less environmentally friendly in terms of overall water quality protection,

Trihalomedwes (THMs) are another example of where source control is not feasible option. Current maximum contaniinant levels allow for chloroform, bromoform, chlorodibromomethane and dichlorobromomethane concentrations up to 100 ug/L in drinking water that is used upstream and discharged to POTWs. The average concentration of THMs in the influent to the Sanitation Districts' water reclamation plants ranges from 2 ug/L to 10 mg/L, well below the drinking water standard, yet above the proposed CTR criteria. We believe that the drinking water supply accounts for almost the entire loading. Since local water supplies are in compliance with drinking water standards, no further source control options are viable.

Based on this assessment, it is apparent that EPA drastically underestimated the costs of the CTR by assuming that in many cases compliance could be achieved through source reduction or pollution prevention. EPA's assertion that 10 to 25 percent reductions in current discharge levels is "insignificant," and would be fully addressed by low-cost waste reduction strategies clearly does not take into consideration the fact that much of the priority pollutant loading to POTWs comes from residential and commercial sources rather than industrial sources.(*4) The former are considerably more diverse and

numerous, and not easily controlled.

Since it is unlikely that source control or pollution prevention measures by themselves will ensure compliance with the CTR, advanced treatment at the Sanitation Districts' seven WRPs would be required. Our preliminary evaluation of viable treatment options indicates that reverse osmosis (RO) would be needed to remove the constituents of concern. Although other forms of advanced treatment such as air stripping and/or carbon adsorption could be used to reduce lindane and trihalomethane concentrations in the treated wastewater to acceptable levels, they would be ineffective for treating mercury. Thus, RO was selected based on its ability to effectively treat mercury, lindane and the trihalomethanes.

The preliminary cost estimate for providing RO treatment at each of the seven WRPs is significant. For exwnple, just the estimated capital investment (including construction, engineering and administrative costs) alone exceeds $470 million collectively for the seven plants.(*5) When amortized over IO years at a 7% interest rate, the capital investment is approximately $68 million per year. After including the estimated annual operation and maintenance costs of approximately $79 million, the total annualized cost for RO treatment at the seven WRPs is approximately $148 million. To put this estimated cost into perspective, the addition of RO treatment would double the single family home service charge rate for the Sanitation Districts' Joint Outfall System (JOS) service area and triple the service charge rate for the Santa Clarita Valley Joint Sewerage System (SCVJSS) service area.(*6)

Further investigation into the amount of wastewater requiring treatment at each facility and the optimal combination of treatment will be performed in an effort to fine tune the cost estimates. It is likely that if RO treatment is added, only a portion of each plant's wastewater flow would be treated and subsequently blended with non-RO treated wastewater to meet the proposed limits. Itis also possible that the optimum advance treatment system may include carbon adsorption, air stripping and RO. For the two WRPs in the SCVJSS, additional costs will be incurred for providing facilities for brine disposal associated with the RO treatment process. Preliminary cost estimates indicate that the capital costs for a brine line would be $45 million, corresponding to an amortized cost of $6.4 million per year over I 0 years at a 7% interest rate. Further work is nee" to refine these and the other estimates. Although the cost estimates presented are somewhat preliminary, they are believed to accurately represent the order of magnitude of cost for the Sanitation Districts to achieve attainment with the proposed CTR criteria.

(*1) Design capacities are indicated for each plant.

(*2) EIP Associates. Mercury Source Identification. August 1997.

(*3) Larry Walker Associates. Residential Metals Study. May 1994.

(*4) U.S. General Accounting Office, "Water Pollution: Nonindustrial Wastewater Pollution Can Be Better Managed" (GAO/RCED-92-40, December 1991), Ch. 2. Treatment Options and Costs

(*5) The RO costs estimates (including capital and operation and maintenance) are based on information obtained from Orange County's Water Factory 21 facility and the 1982 Orange and Los Angeles Counties Water Reuse Study Facilities Plan.

(*6) The treatment figures represent the total population and number of businesses actually served by the seven WRPs. However, it should be noted that the plants service separate treatment systems. Five of the WRPs are part of the Joint Outfall System (JOS), which serves a total of 5 million people and over 3,300 permitted industries. Because the rates for these plants are calculated based on the costs for the entire

system, which includes the Joint Water Pollution Control Plant, increases in rates due to installation of new treatment systems would be home by all users of the JOS. This would, of course, result in lower costs on a sewage unit basis (i.e., per household), although far more people would experience rate increases. The remaining two WRPs provide treatment for the Santa Clarita area, which has a significantly lower population than the JOS. The service charge rates for this area are 57% higher that those of the JOS, so any rate increases would have a disproportionately high impact on those communities.

Response to: CTR-059-027

LACSD dismisses pollution prevention as "costly to develop and implement" in favor of reverse osmosis, a very expensive treatment technology. EPA disagrees that pollution prevention cannot be effective in reducing pollutant loadings from sources other than industrial sources. EPA compiled two documents, Overview of Pollution Prevention Approaches at POTWs and Pollution Prevention at POTWs, a Resource List (available in the record for this rulemaking), which identify successful programs to reduce mercury and lindane through public education and source controls. EPA believes that facilities will employ lower-cost alternatives such as pollution prevention before resorting to expensive additional treatment processes to achieve CTR-based limits, such as reverse osmosis. The trihalomethanes that occur in concentrations above CTR-based criteria but below drinking water standards are disinfection byproducts and may be manageable through process optimization (see response to CTR-003-013).

See responses to CTR-040-029a, CTR-056-018, CTR-004-003, CTR-045-012b, CTR-005-004, CTR-054-033, and 059-001.

Comment ID: CTR-092-021
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01i Alternative Cost Analysis
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Comment #5: Related Issues on Policy Assumptions

(Re: Page I-A-11 of the "Technical Support Document (Appendices)" for the "Analysis of Potential Costs Related to Implementation of the California Water Quality Toxics Rule)

The page cited above presents an Alternative Analysis for the City of San Jose with regard to the discharge quality of the San Jose/Santa Clara POTW effluent compared to that which would be permissible under the CTR for copper. The text states:

"Note that for the exception of outlying values, the average concentrations are low and within the range of the potential CTR limits."

It is precisely those outlying values which cause the San Jose/Santa Clara POTW to be in noncompliance

with its NPDES permit. It seems circular at best for EPA to take specific note of the very factors which create non-compliance with the permit and then assume them away and determine that San Jose/Santa Clara will have no cost of meeting the CTR copper criteria because our costs are really those of complying with the permit standard -- which does not except outlying values.

The cited text further states that "To achieve these reductions, the City is assumed to prefer an aggressive pollution prevention program by targeting specific industries and focusing on commercial dischargers." Note that this has already been undertaken and is insufficient, to allow compliance with expected permit limits.

Questions for EPA on Comment #5:

Q.5-1) As alluded to earlier in the comment regarding application of the analysis to San Jose, we are concerned that the assumptions incorporated in the Model #2 high end scenario understate the actual costs of meeting the CTR. Does EPA support the exclusion of outlying values in the State's calculation of compliance? How would the high end costs change were San Jose/Santa Clara to be considered in compliance, thus incremental costs would analytically accrue to the CTR?

Q.5-2) What evidence brought EPA to the conclusion that the City would "prefer an aggressive ... focusing on commercial dischargers"? How would changing that assumption affect the costs of implementing the CTR?

Response to: CTR-092-021

EPA disagrees with the commenter that the high scenario understates costs. EPA believes that the high scenario actually overstates costs because the high scenario is based on existing permit limits and not effluent data. If effluent data is actually below the existing limit, as it is for San Jose, then compliance costs may be overstated. EPA does not support the exclusion of outlying values in assessing compliance. In fact, EPA considers all data including outliers when it is estimating treatment requirements. However EPA does not include the costs for facilities to come into compliance with existing permit limits because these costs would be incurred even without the CTR. EPA estimated costs for San Jose to move from compliance with existing permit limits to the CTR-based limits, thus the high scenario cost estimate for San Jose would not change if San Jose were considered in compliance.

EPA's revised cost analysis for San Jose no longer mentions an "aggressive pollution prevention program." Under the revised cost analysis, the required reductions are low (17% for copper, 0% for silver, and 2% for chloroform). Thus, EPA assigned pollution prevention for the metals and process optimization for chloroform to ensure compliance with CTR-based limits. EPA's revised cost estimates for San Jose are $296,000 under the high scenario and $57,000 under the low scenario.

See also response to CTR-092-019.

Subject Matter Code: E-01j

Comment ID: CTR-069-002b
Comment Author: CA Bus Prop Ass & Bldg Ind Ass
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01j
References:
Attachments? N
CROSS REFERENCES J-01

Comment: Additionally, CBIA and CBPA are concerned with the findings in the "Economic Analysis of the Proposed California Water Quality Toxics Rule." The acknowledgment by EPA in the economic analysis that "the water quality criteria in this rule may also have an indirect effect on sources not permitted under the NPDES program or not subject to numeric water quality-based effluent Emits is extremely troublesome. Sources not permitted under the NPDES program include nonpoint sources and wet weather discharges such as runoff from farms and urban areas. The economic analysis continues by stating that "any potential effect on these sources is unknown at this time" and that "the State may ask or require these sources to implement best management practices or participate in a comprehensive watershed management approach. Since the economic analysis only focuses on the costs to point source dischargers and not non-point discharges, CBIA and CBPA believe that the potential economic impact of the proposed rule is greater than identified in the economic analysis.

We thank you for your consideration of these comments.

Response to: CTR-069-002b

See response to CTR-021-006b.

Subject Matter Code: E-01l UMRA - Economic Comments

Comment ID: CTR-059-024
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01l UMRA - Economic Comments
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01g08

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The Economic Analysis presents a very weak analysis of potential benefits, which is based on limited information about ambient water quality conditions. Due to this weakness, combined with the paucity of information in the literature regarding the benefits from marginal improvements in water quality, the benefits analysis does a poor job of evaluating the marginal benefits that would result from the implementation of the CTR.

Response to: CTR-059-024

See response to CTR-003-010.

Subject Matter Code: E-01m Regulatory Relief

Comment ID: CTR-003-007
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: 7) The economic analysis assumes that where the proposed criteria cannot be economically met, the EPA or State will take some action such as setting new criteria which will result in no cost to the discharger. This is totally inappropriate. First there is no assurance that relief can or will be given. At a minimum, studies will have to be performed to support a proposed action. The cost of such studies can and historically have been significant, ranging from hundreds of thousands to millions of dollars per study. These costs are borne by the effected communities not the EPA or State. Most importantly, the EPAs position that once promulgated, they do not have the resources to modify this rule in a timely manner, is in contradiction to this assumption.

Response to: CTR-003-007

See responses to CTR-032-004 and CTR-060-019.

Note also that, because there is no assurance that specific dischargers will receive regulatory relief, EPA estimated potential compliance costs under the assumption that none of the facilities with significant costs would be allowed alternative regulatory approaches (i.e., the high scenario).

Comment ID: CTR-032-001
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: Las Gallinas Valley Sanitary District (District) submits the following comments on the proposed California Toxics Rule. The District owns and operates a 2.9 mgd advanced secondary municipal wastewater treatment plant that discharges into northern San Francisco Bay. The San Francisco Bay Regional Water Quality Control Board (RWQCB) considers the District a shallow water discharger and does not allow dilution credit in calculating effluent limits. As such, the District faces considerable difficulties in complying with end-of-the-pipe limits for copper, mercury and potentially

several toxic organics that have proposed objectives lower than the currently available analytical detection limits.

The District has had in place for several years, comprehensive source control, pollution prevention and waste minimization programs similar to those of much larger dischargers. While we continue to look for ways to improve our programs, we believe that we have passed the point of diminishing returns and that there is not a significant potential for additional pollutant removal via these mechanisms. The vast majority of copper loading, as in the case of most Bay area shallow water dischargers, is from the potable water supply and corrosion of residential copper plumbing. Plant optimization is being investigated but to date also does not appear to promise more than marginal increases in particulate copper removal, at moderate to significant costs.

Therefore, contrary to the conclusions of the CTR economic analysis, we do not believe that implementation of additional pollution prevention measures and/or plant optimization are viable mechanisms for the District to achieve current or proposed CTR criteria. Regulatory relief, as we have requested during our NPDES permit renewal process, is required.

Response to: CTR-032-001

The Las Gallinas Valley Sanitary District (District) did not provide enough information for EPA to analyze whether pollution control measures and/or process optimization would be viable mechanisms for compliance with CTR-based limits. In particular, the facility would need to provide facility engineering data and existing permit limit information and effluent data for copper and mercury. Such specific data are required to determine how the economic analysis assumptions and methodology (e.g., cost decision matrix) would apply to this particular facility. Despite this, review of the comment letter suggests that the District presently is not in compliance with existing effluent limits for copper and mercury and that regulatory relief already has been requested for these constituents. Information submitted by the Novato Sanitary District, another wastewater treatment plant discharging to northern San Francisco Bay and classified as a shallow water discharger, indicates that the present effluent limits for copper and mercury are 2.9 ug/L and 0.03 ug/L. As indicated in the response to CTR-005-001, these limits are likely to be more stringent than permit limits calculated using CTR criteria and EPA's methodology (e.g., which uses dissolved criteria and metals translators). Although the information submitted by the District is not sufficient to fully evaluate their comments, EPA believes that it is likely that the CTR would not result insignificant costs because existing discharge limits seem to be more stringent than CTR-based limits. Nonetheless, the decision to grant regulatory relief is not a federal responsibility, but a place-based decision that must rest solely in the hands of the local community, elected officials, and other stakeholders that use the water resource affected by such decisions.

See also response to CTR-004-003.

Comment ID: CTR-032-004
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-032 incorporates by reference letter CTR-035

Attachments? N
CROSS REFERENCES

Comment: The use of the $200 and $500 per toxic-pound equivalent of pollutant removed cost thresholds significantly skewed potential costs downward by assuming that when those cost thresholds are reached, regulatory relief options would be pursued successfully. The CTR should include an evaluation of costs assuming regulatory relief is not made available. While the District supports the various regulatory relief options referenced, such as site specific objectives and watershed based phased TMDLs, dischargers have absolutely no guarantees that such regulatory relief will indeed be provided. Furthermore, regulatory relief conveys a negative connotation to these actions; most are more accurately viewed as "sound science", actions that should be taken anyway in pursuit of more technically defensible objectives and limits that will fully protect water quality.

Response to: CTR-032-004

As described in the EA that accompanied the proposed CTR (SAIC and Jones and Stokes Associates, 1997), EPA assumed that regulatory alternatives such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc., are considered under certain circumstances. Specifically, under the low-end scenario, regulatory alternatives were assumed necessary if the cost for a sample facility exceeded $200 per toxic pounds-equivalent (in practice, regulatory relief mechanisms are available even when costs are below $200 per toxic pounds-equvalent).

EPA assumes that a facility, when faced with the challenge of meeting water quality-based effluent limitations (WQBELs) based on CTR criteria, will select the most cost-effective controls, including regulatory alternatives. In fact, this has been the case in California, where several major POTWs have performed studies in pursuit of regulatory alternatives such as metals translators and site-specific criteria, rather than install costly controls to comply with WQBELs. EPA acknowledges that the actual cost-effectiveness value will vary by facility depending upon many factors, including the characteristics and volume of discharge, the receiving water, etc. However, EPA disagrees that the cost trigger is unrealistic, as these avenues of regulatory relief do exist and are employed to implement the water quality standards program.

Nonetheless, in the high-end estimate developed for the cost analysis accompanying the final CTR, no cost trigger was used and, thus, EPA's high-end cost estimate did not include the use of a regulatory alternative for any sample facility.

Reference: SAIC and Jones and Stokes Associates, Inc. 1997. Analysis of Potential Costs Related to the Implementation of the California Toxics Rule. Prepared for U.S. EPA, Office of Science and Technology and U.S. EPA Region IX, May 5.

Comment ID: CTR-035-008d
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief

References:
Attachments? N
CROSS REFERENCES E-01g08
E-01e
E-01d
E-01h
E-01c

Comment: Finally, we have serious concerns about the accuracy of the draft Economic Analysis and the estimates of the costs and benefits of the draft CTR (see detailed comments in Attachments I and 2). Our primary concerns related to the cost analysis include 1) that the case studies on which the cost analysis is based do not adequately represent the actual population of POTWs in California; 2) the omission of costs that could be incurred by many sectors that contribute to overall loadings, and, hence, can be expected to have to reduce their loadings (e.g., non-SIU indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources of CTR-regulated pollutants); 3) the use of numerous assumptions that underestimate costs; and 4) the capricious removal of costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the lack of any proposed regulatory relief trigger in the proposed regulation.

To illustrate the degree of underestimation of costs for the POTW sector alone, we looked at potential compliance costs for the POTW sector. We found that the potential costs for 23 major POTWS. on an annualized basis, may reach $400 million. We believe that this analysis demonstrates that the potential cost consequences of compliance with effluent limits based on the proposed CTR criteria would easily exceed the $ 100 million annual cost threshold, especially when the costs of all 313 POTWs in the State are estimated. Thus, we believe that EPA must conclude that the proposed CTR could have significant economic impacts on local governments.

Response to: CTR-035-008d

See responses to CTR-021-005c, CTR-032-004, CTR-040-039, CTR-021-006b, CTR-040-037, and CTR-059-018.

Comment ID: CTR-035-047b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES E-01b

Comment: pp. 2-24 - 2-32 (U.S. EPA, 1997b) - Cost Triggers for Alternative Regulatory Approaches The use of the $200 and $500 cost thresholds significantly skewed potential costs downwards by assuming that when those cost thresholds are reached, regulatory relief options would be pursued successfully, despite the fact that dischargers have absolutely no guarantees that such options will be successful, In the Preamble, in fact, EPA indicates that options such as variances and site-specific criteria will rarely, if

ever, be granted. In addition, POTW experiences to date in California suggest that it is unlikely that such options will be successful. Thus, the basic premise of the analytic approach used to determine costs needs to be reconsidered. Incidentally, we also believe that the costs attributed to such activities were seriously underestimated. Information we are familiar with suggests that many of the regulatory alternatives EPA examined can cost up to several million dollars (per pollutant) (e.g. TMDLs, UAAs). Thus, we suggest that in the future when calculating the costs for such activities, EPA should use a range where $200,000/pollutant is the low end scenario and $2,000,000/pollutant is the high end scenario.

Response to: CTR-035-047b

See responses to CTR-032-004 and CTR-060-019.

Comment ID: CTR-038-004c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h
E-01c02

Comment: 4. The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. The District's analysis demonstrates that actual costs may be an order of magnitude greater than EPA's $500/lb threshold and that the benefits are very small.

Response to: CTR-038-004c

See responses to CTR-054-013a, CTR-032-004, CTR-021-008, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-040-008b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief

References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01c02
E-02c

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* Estimates of potential costs are severely constrained due to certain assumptions including the assumption that regulatory relief from the Rule will be granted if costs are in excess of certain thresholds.

* Estimates of potential benefits are exaggerated by assuming, that the proposed water quality criteria will actually be achieved in receiving water bodies. This will not result from the implementation of the Rule because the Rule is only addressing permitted discharges to the receiving water bodies.

* The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated.

Response to: CTR-040-008b

See responses to CTR-054-013a, CTR-032-004, and CTR-056-018.

Comment ID: CTR-040-031
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that permit authorities will accept metals translators when there is no history of such acceptance in California.

Response to: CTR-040-031

EPA disagrees. The State has used metals translators in the Santa Ana River in a case in which it

adopted site-specific dissolved criteria for metals. Since the CTR would establish dissolved metals criteria on a statewide basis, EPA expects that the State will accept appropriate translator studies to convert from dissolved criteria to total recoverable permit limits. The State indicated that it would accept the use of defensible translator studies in its Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (September 11, 1997, p. 10).

Comment ID: CTR-040-036
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's assumption that dischargers would pursue source control, treatment plant optimization, and regulatory relief prior to constructing end-of-pipe facilities conflicts with the 5-year maximum compliance schedule allowed by the CTR. In most cases (e.g., in the Merced POTW case study) it would take 5 years to plan, design, obtain approvals, arrange financing, and construct end-of-pipe facilities. A discharger could not pursue such non-structural controls and still be assured to meeting a 5-year compliance schedule.

Response to: CTR-040-036

EPA's compliance schedule in the final rule would allow the State flexibility in establishing compliance schedules for dischargers. EPA amended the final CTR to include a provision whereupon the compliance schedule provision will sunset in five years or when the State adopts its own compliance schedule provision in the State Implementation Policy and, if EPA approves the schedule, EPA will then act to stay the EPA compliance schedule provision for the CTR. This change to the CTR will give the State discretion to develop an appropriate compliance schedule policy for California.

Comment ID: CTR-040-041
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Many of the types of regulatory relief identified as possible in the analysis (and in the Preamble to the CTR) do not really constitute relief and/or are not available to dischargers under the

CTR (see Attachment B-1).

Response to: CTR-040-041

See response to CTR-032-004.

Comment ID: CTR-041-010b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES E-01n
E-01e
E-01g

Comment: 5. Concerns Regarding Economic Analysis

The District also has several significant concerns with the Economic Analysis that was performed for the proposed rule. Concerns about the cost estimates made for both the District and the state are presented here. (See attached Review of EPA's Economic Analysis of the Proposed California Water Quality Toxics Rule.) Overall, the District believes that problems with the Economic Analysis are serious enough that is should be redone. As stated above in our analysis of assumed costs at the SRWTP, the use of questionable data without qualification combined with unsubstantiated assumptions regarding costs to achieve compliance resulted in a gross underestimate in the cost-effectiveness ratio. The District's first concern is that if the types of problems found in our Case Study are widespread in other studies, the complete analysis is suspect.

In addition to the analysis of the District's facilities, there are several other points which have been used by EPA to lead to a potentially serious understatement of actual costs. The key assumptions involved are that: 1) no costs would occur if either no monitoring data presently exists or if that data is below analytical detection levels; 2) no treatment costs would occur whenever EPA's initial estimates showed high costs, due to successful regulatory relief; 3) no costs are included for nonpoint sources such as municipal stormwater management systems; and 4) no costs are included for indirect dischargers to the District's system that are not large enough to be considered a Significant Industrial User (SIU).

Regarding the first assumption, the District has found that there is pressure from many sides, including the Safe Drinking Water Act, to both increase the number of constituents being monitored and to lower detection levels to meet numeric criteria set by EPA and the state. To assume that monitoring of these new constituents will not lead to any treatment cost increases is simply unrealistic. Similarly, the second assumption about absolute success in every pursuit of regulatory relief is also overly optimistic. There are no guarantees that pursuit of regulatory relief will be successful in any situation, and EPA indicates elsewhere in the preamble that options such as variances and site-specific criteria will rarely, if ever, be granted.

The third and fourth key assumptions ignore present dominating trends and facts, i.e. that. prevention and control of pollutants at their sources, including very small indirect dischargers, storm runoff, and other nonpoint sources are now the major focus of EPA's wastewater programs nationally. While we agree that these management steps should be taken, there will be significant costs attached to the implementation of these steps that cannot be ignored.

Combined with concerns the District has heard from other sources such as the California Association of Sanitation Agencies (CASA), it appears that EPA has failed to make "a reasoned determination that the benefits of the intended regulation justify its costs." Therefore the District believes that the Agency is obligated to redo the draft Economic Analysis.

Response to: CTR-041-010b

See responses to CTR-032-004, CTR-021-006b, CTR-040-037, and CTR-003-011.

Comment ID: CTR-041-027
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that permit authorities will accept metals translators when there is no history of such acceptance in California.

Response to: CTR-041-027

See response to CTR-040-031.

Comment ID: CTR-041-032
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's assumption that dischargers would pursue source control, treatment plant optimization, and regulatory relief prior to constructing end-of-pipe facilities conflicts with the 5-year maximum compliance schedule allowed by the CTR. In most cases (e.g., in the Merced POTW case study) it would take 5 years to plan, design, obtain approvals, arrange financing, and construct end-of-pipe facilities. A discharger could not pursue such non-structural controls and still be assured to meeting a 5-year compliance schedule.

Response to: CTR-041-032

See responses to CTR-040-036 and CTR-032-004.

Comment ID: CTR-041-037
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Many of the types of regulatory relief identified as possible in the analysis (and in the Preamble to the CTR) do not really constitute relief and/or are not available to dischargers under the CTR (see Attachment 3-1).

Response to: CTR-041-037

See responses to CTR-032-004 and CTR-060-019.

Comment ID: CTR-043-004c
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? Y
CROSS REFERENCES E-01g
E-01h
E-02c
E-01c02

Comment: 4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution;

(2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements;

(3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and

(4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule.

The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act.

Response to: CTR-043-004c

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-044-005c
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h01
E-02c
E-01c02
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water

quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005c

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, and CTR-056-018.

Comment ID: CTR-044-022
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that permit authorities will accept metals translators when there is no history of such acceptance in California.

Response to: CTR-044-022

See response to CTR-040-031.

Comment ID: CTR-044-027
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's assumption that dischargers would pursue source control, treatment plant optimization,

and regulatory relief prior to constructing end-of-pipe facilities conflicts with the 5-year maximum compliance schedule allowed by the CTR. In most cases (e.g., in the Merced POTW case study) it would take 5 years to plan, design, obtain approvals, arrange financing, and construct end-of-pipe facilities. A discharger could not pursue such non-structural controls and still be assured to meeting a 5-year compliance schedule.

Response to: CTR-044-027

See response to CTR-040-036.

Comment ID: CTR-044-032
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Many of the types of regulatory relief identified as possible in the analysis (and in the Preamble to the CTR) do not really constitute relief and/or are not available to dischargers under the CTR (see Attachment 3-1).

Response to: CTR-044-032

See responses to CTR-032-004 and CTR-060-019.

Comment ID: CTR-045-009c
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h

Comment: The draft Economic Analysis has serious flaws. It underestimates the costs of the draft CTR and overestimates the benefits. For the cost analysis, EPA should reevaluate the representativeness of the sample used; the omission of impacts on many sectors that contribute to loadings, and hence, can be expected to have to reduce their loadings (e.g., small indirect dischargers, municipal and industrial stormwater dischargers, agricultural activities, and other nonpoint sources); the incorporation of

numerous assumptions that underestimate costs; and the assumption to artificially remove costs that exceed threshold values by assuming that regulatory relief measures will be granted, despite the fact that they are not automatically granted through triggers included as part of the proposed regulation.

Response to: CTR-045-009c

See responses to CTR-032-004, CTR-056-018, CTR-021-006b, and CTR-059-018.

Comment ID: CTR-049-006c
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES E-01g08
E-01h

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

4. Review and correct existing flaws in the current "Economic Analysis."

With respect to the Economic Analysis conducted by USEPA, we are concerned that it underestimates the cost of the proposed CTR rule while overestimating its benefits. We suggest that USEPA re-evaluate (1) the representativeness of the sample used; (2) the omission of impacts on many sectors that contribute to loadings; (3) the incorporation of a variety of assumptions that underestimate costs; and (4) the assumption to artificially remove costs that exceed threshold values by incorrectly assuming that regulatory relief measures will be granted. For the benefits analysis, USEPA should utilize more California-specific and recent information. A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures requires, in our opinion, further work prior to the promulgation of the criteria.

Response to: CTR-049-006c

See responses CTR- 045-011, CTR-032-004, CTR-056-018, CTR-021-006b, CTR-059-018, and CTR-052-014.

Comment ID: CTR-054-013c
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? Y
CROSS REFERENCES E-01g03
E-01q01
E-02l

Comment: The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule (see Attachment 3). The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. BADA's analysis shows that its member agencies alone could be faced with costs in excess of $100 million per year to achieve effluent limits based on the copper, PAH, heptachlor and aldrin criteria. BADA's analysis also indicates that the benefits associated with this expenditure will be difficult to measure. Copper loadings will be reduced by 1% and the level of compliance for PAH's and heptachlor will remain unchanged at its present high level. Certainly these benefits will not measurably improve the fishing experience or measure the number of fisherman in the Bay, significantly reduce the cancer cases, or improve property values or other nonuse benefits, as estimated in EPA's economic analysis. A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. BADA agencies provide service to a number of small communities with populations under 50,000 people that could be greatly impacted by the proposed rule.

Response to: CTR-054-013c

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-056-018, and CTR-059-018.

Comment ID: CTR-054-026
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that permit authorities will accept metals translators when there is no history of such acceptance in California.

Response to: CTR-054-026

See response to CTR-040-031.

Comment ID: CTR-054-031
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's assumption that dischargers would pursue source control, treatment plant optimization, and regulatory relief prior to constructing end-of-pipe facilities conflicts with the 5-year maximum compliance schedule allowed by the CTR. In most cases (e.g., in the Merced POTW case study) it would take 5 years to plan, design, obtain approvals, arrange financing, and construct end-of-pipe facilities. A discharger could not pursue such non-structural controls and still be assured to meeting a 5-year compliance schedule.

Response to: CTR-054-031

See response to CTR-040-036.

Comment ID: CTR-054-036
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m Regulatory Relief
References:
Attachments? N
CROSS REFERENCES

Comment: Many of the types of regulatory relief identified as possible in the analysis (and in the Preamble to the CTR) do not really constitute relief and/or are not available to dischargers under the CTR (see Attachment 3-1).

Response to: CTR-054-036

See response to CTR-032-004.

Comment ID: CTR-086-006
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: E-01m Regulatory Relief
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: The use of the $200 and $500 per toxic pound-equivalent cost thresholds significantly skewed potential costs downward by assuming that when those cost thresholds are reached regulatory relief options would be pursued successfully. The CTR should include an evaluation of costs assuming regulatory relief is not made available. While CDA supports the various regulatory relief options referenced, such as site specific objectives and watershed based phased TMDLS, dischargers, and by inference indirect dischargers, have absolutely no guarantees that such regulatory relief will indeed be provided. Furthermore, regulatory relief conveys a negative connotation to these actions; most are more accurately viewed as "sound science", actions that should be taken anyway in pursuit of more technically defensible objectives and limits that will fully protect water quality.

Response to: CTR-086-006

See response to CTR-032-004.

Subject Matter Code: E-01m02 Success in Reg. Relief

Comment ID: CTR-090-003
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01m02 Success in Reg. Relief
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

* The costs section of the economic analysis is extremely flawed; if this rule is adopted and the State Implementation Policy does not allow for regulatory relief the cost of compliance to point sources dischargers will be orders of magnitude more than the amount stated in the proposed rule.

Response to: CTR-090-003

See responses to CTR-032-004 and CTR-056-018.

Subject Matter Code: E-01m03 Cost of WERs

Comment ID: CTR-060-019
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01m03 Cost of WERs
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Economic Analysis is deficient

Additionally, the metals criteria are expressed as the dissolved concentration of the metal andhave been derived from toxicity tests conducted in laboratory water that is relatively pure. Many bays and estuaries, especially back bays and estuaries contain significant concentrations of suspended organic matter. Ambient levels of organic matter can bind much of the bioavailable portion of the metal and reduce the overall toxicity due to the metal. To account for this effect, the rule allows for the use of water effects ratios (WERs) (in addition to translators) in calculating water quality based effluent limits. This may be a viable option for some dischargers to achieve compliance with the proposed criteria. However, the cost to establish a WER could be significant. EPRI(*16) has estimated that the typical costs for a basic WER study for an acute metal criterion could range from $20,000 to $50,000. To develop a WER for a chronic criterion or to address spatial or seasonal variability can substantially increase the costs. It is not clear whether the economic analysis reflects the cost to the regulated community of having to develop WERs that will effectively increase the water quality based effluent limits. This cost should be added into the economic analysis.

(*16) Implementation Manual for the Water-Effect Ratio (WER)", EPRI Report No. TR-107144, November, 1996, page 3-5.

Response to: CTR-060-019

Based upon estimates provided in SAIC (1995), the Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance, the typical cost to facilities pursuing alternative regulatory approaches to CTR-based WQBELs is $200,000 per pollutant. The $200,000 per pollutant cost represents the mid-range of costs for a number of alternative regulatory approaches and was usd for the economic analysis of the CTR. EPA Regional Offices and States estimate that alternative approaches range from $20,000 for criteria modifications to $1,000,000 per pollutant for phased-TMDLs. These costs reflect costs associated with additional monitoring, performing special studies, and other activities, to support requests from facilities for relief from the CTR-based WQBEL. EPA estimates that the cost of calculating water-effects ratio (WER) is comparable to this typical cost.

Reference: SAIC. 1995. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. Prepared for U.S. EPA, Office of Science and Technology, March 13.

Subject Matter Code: E-01n Detection Limits

Comment ID: CTR-003-008
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: 8) USEPA has assumed in both it's low and high end cost scenario that if monitoring data for potential chemical constituents were reported as below detection limits then there would be no cost of compliance for these constituents. The City of Riverside has 35 constituents from the list of proposed criteria, applicable to its receiving water use designations, whose limits and effluent concentrations are below analytical detection levels in our matrix. The potential cost for the City to remove even one of these constituents , should it be detected as technology improves, could exceed the projected costs of this rule for the entire state. Given that this is the case for most if not all POTWs in the State, it does not seem appropriate to implement standards for which the ability to comply is not and cannot be known. The constituents of concern at our plant are: cadmium, chromium (VI), copper, lead, mercury, selenium, silver, thallium, asbestos, dioxin, acrylonitrile, benzidine, benzo(a) anthracene, benzo(a) pyrene, benzo(b) fluoranthene, benzo (k) fluorenthene, chrysene, dibenzo (a,h) anthracene, (3,3) dichlorobenzidine, 1,2-diphenylhydrazine, hexachlorobenzene, indeno (1,2,3-cd) pyrene, aldrin, alpha-BHC, chlordane, 4,4'-DDT, 4,4'-DDE, 4,4'-DDD, dieldrin, endrin, heptachlor, heptachlor epoxide, PCBS, toxaphene. The compliance status of several other constituents would be in question if the human health criteria for consumption of "Water and Organisms" is used versus organisms only. Given the extremely low levels at which many of the criteria are set and unless the EPA is proposing a nation wide product ban, it is quite likely that one or more of these chemicals will show up in a POTW effluent at levels above the standards. The EPA should either remove from consideration criteria for which compliance cannot be determined or assume that it is being exceeded for the purpose of the economic analysis.

Response to: CTR-003-008

See responses to CTR-003-011 and CTR-004-002.

Comment ID: CTR-004-002
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: SBSA has a comprehensive effluent monitoring program for metals and organics. Since the inception of the SBSA Pretreatment Program in 1975 and the operation of advanced treatment technology in 1982 there has been a significant reduction in influent and effluent pollutant loading. The more recent Pollution Prevention Program has also contributed to reduced pollutant loading. Even with the substantial reductions achieved in the past there will be severe attainability problems resulting specifically from the adoption of the proposed CTR criteria. Monitoring data from January 1996 through August 1997 shows noncompliance with six (6) metals; copper, lead, mercury, nickel, silver, and zinc. For samples from 1993 to the present there are nine (9) organics and twenty-two (22) pesticides that have proposed objectives below detection limits. There is no mechanism to assess the ability or cost of achieving compliance with these limits.

Response to: CTR-004-002

In recent years, many States have promulgated water quality criteria for various toxic pollutants that are more restrictive than the level of analytical detection. Implementation of these existing water quality criteria by many States do take into account the ability to detect the pollutant in the waste stream. For example, some States determine compliance with limits established below method detection limits (MDL) based on the minimum level (ML), where available. When a promulgated ML is not available, compliance with that limit may be based on the MDL or the practicable quantitation level (PQL).

To ensure that its cost estimates were conservative (i.e., erring on the side of higher costs), EPA used the MDL as the compliance level. Although EPA based compliance determination on the MDL, the Agency acknowledges that estimating treatment costs for WQBELs below the MDL is speculative and likely unrealistic.

However, EPA does believe that aggressive pollutant prevention/waste minimization practices, combined with conventional end-of-pipe treatment, can effectively reduce all detectable amounts of particular pollutants of concern from the discharge, resulting in compliance with WQBELs below detection levels. EPA agrees that some facilities will want to ensure compliance with WQBELs below detection levels through the use of additional or enhanced end-of-pipe treatment. EPA believes that appropriate costswere included in the cost analysis by including costs for both pollution prevention/waste minimization techniques (such as material substitution, process modification, and/or recycling, reuse, or treatment of internal waste streams) and end-of-pipe treatment. Where the pollutant is present at detectable levels, and where the facility implements control measures directed specifically at eliminating these pollutants, the controls will likely result in reduction of the pollutant to below the level of detection. Because there is no evidence that reductions cannot reach a level in compliance with WQBELs, EPA has no reason to believe that its assumption of compliance is not reasonable. EPA compiled two documents, Overview of Pollution Prevention Approaches at POTWs and Pollution Prevention at POTWs, a Resource List (available in the record for this rulemaking), which identify successful programs to reduce mercury and lindane through public education and source controls. See also response to CTR-034-010b.

Comment ID: CTR-021-013
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale

Document Date: 09/25/97
Subject Matter Code: E-01n Detection Limits
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The CTR Analysis of POTW Compliance with Organics is Based on the Flawed Assumption that Analytical Detection Limits Will Not Improve and thus POTW Plants that Currently Meet the Proposed Organic Effluent because Effluent Monitoring Results are Less than the Detection Limit will Meet the Limits into the Future

A significant number of organic compounds contained in the CTR have detection limits greater than the proposed criteria. For example, endrin and pentachlorophenol are the two cited in the Sunnyvale economic analysis. A significant and potentially costly incorrect assumption of the "Analysis of Potential Costs ... " document was that if all values were reported as below the detection limit, there would be no costs attributable to implementing the CTR. This dismisses a very likely scenario, namely that analytical detection limits will improve over time and that some of these organics may then be detected in the effluent.

If this occurs, POTWs will most likely be facing installation of Granular Activated Carbon (GAC) for low level organics removal, as was recommended for the City of Merced in the CTR Economic Analysis appendix. There are no assurances that the proposed pollution prevention and waste minimization measures would be effective in reducing levels to the extent required. Reverse osmosis (RO) is not extremely effective at removing many of these organics to these low levels so even if Sunnyvale had installed RO for trace metals removal, it would still be facing use of GAC for organics compliance. This would cost approximately $12 million/year for the 29.5 mgd Sunnyvale plant based on the over $4 million/year estimate for the 10 mgd Merced plant.

Response to: CTR-021-013

See responses to CTR-004-003, CTR-003-011, and CTR-004-002.

Comment ID: CTR-033-003b
Comment Author: San Bernardino Muncpl Wtr Dept
Document Type: Water District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n Detection Limits
References: Letter CTR-033 incorporates by reference letter CTR-020
Attachments? Y
CROSS REFERENCES C-28

Comment: Experiments to determine whether a chemical is carcinogenic are performed (on animals) with high concentrations to produce statistically significant results within the time frame of the experiment. The numbers are then extrapolated to determine an estimated "safe" concentration for human populations. All of the factors in the extrapolation process use conservative assumptions (one in a million risk, bioaccumulation potential, carcinogenic potential, etc.) which builds in and multiplies safety

factors. For 39 of the constituents in the CTR, the extrapolated criteria levels are below current levels of detection.

The EPA recognizes this as the proposed rule states: "EPA is aware that the criteria proposed today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting water quality criteria since they are not related to actual environmental impacts. The environmental impacts of a pollutant are based on a scientific determination, not a measuring technique that is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. See 1985 Guidelines p. 21. As the methods improve, limits closer to the actual criteria necessary to protect aquatic life and human health become measurable. The Agency does not believe it is appropriate to propose or promulgate criteria that are not sufficiently protective." The rule goes on to add, "the use of detection limits are appropriate for determining compliance with National Pollutant Discharge Elimination System (NPDES) permit limits."

Since the criteria are established on high dosage results that cannot be substantiated at low levels due to statistical significance and inability to see beyond detection limits, the values are predictions. Questions that come to mind are, what would this procedure determine for fat-soluble vitamins A, D and K? In high doses, these vitamins are harmful, though in low dosages, valuable. For constituents below detection, these determinations cannot be scientifically verified by analyses, only mathematically generated based on worst case assumptions. Although caution is warranted when establishing criteria, future unforeseen levels and effects cannot be predicted.

While the EPA believes that compliance determinations are based on detection limits, to assume no cost in the economic analysis for values that are below detection is not a valid assumption. As noted above, the detection limits will be forced to lower levels, and therefore become moving compliance targets without additional economic review should detection's begin to occur.

In summary, the detection levels should serve as the criteria with a "<" designator. The criteria for the affected constituents should be reviewed on a regular basis to reflect current approved analytical techniques, with lower levels promulgated after appropriate economic evaluations.

Response to: CTR-033-003b

See responses to CTR-004-002 and CTR-005-009.

Comment ID: CTR-038-009b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? Y
CROSS REFERENCES C-28
R
S

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. By taking this approach, however, EPA is unable to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA must not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA must evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits). With respect to the District's discharge and Schell Slough and Second Napa Slough, the criteria in this category include, but are not necessarily limited to, the following : benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chrysene, dibenzo(a,h)anthracene, aldrin, 4,4'-DDD, 4,4'-DDE, dieldrin, endosulfan I, endosulfan II, endosulfan sulfate, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, OCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, and hexachlorobenzene (see Table 3).

Response to: CTR-038-009b

See responses to CTR-021-005c and CTR-004-002.

Comment ID: CTR-041-008b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES C-28

Comment: 3. Recommend Against Adopting Criteria with Insufficient Detectable Data

The District strongly recommends that the EPA not adopt criteria where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such

pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 c(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." EPA has chosen a "safe approach" which clearly goes beyond the Clean Water Act and is clearly unnecessary. This approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the safe approach for EPA, it places dischargers throughout the State at risk.

As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt these criteria, EPA should, prior to that, evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge and ambient levels are at the detection limits). The criteria in this category include the following: Aldrin, Alpha-BHC, Beta-BHC, Chlordane, 4,4'-DDD, 4,4'-DDT, 4,4'-DDE, Dieldrin, Endosulfan I, Endosulfan II, Endrin, Endrin Aldehyde, Heptachlor, Heptachlor Epoxide, Toxaphene, PCB- 1016, PCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, Hexachlorobenzene, N-Nitrosodipropylamine, Pentachlorophenol, Benzo(a)anthracene, Benzo(a)pyrene, Benzo(b)fluoroanthene, Benzo(k)fluoroanthene, Chrysene, Dibenzo(a,h)anthracene, and Indeno(1,2,3-cd)pyrene.

Response to: CTR-041-008b

See response to CTR-004-002 and CTR-005-009.

Comment ID: CTR-041-010a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES E-01m
E-01e
E-01g

Comment: 5. Concerns Regarding Economic Analysis

The District also has several significant concerns with the Economic Analysis that was performed for the proposed rule. Concerns about the cost estimates made for both the District and the state are presented here. (See attached Review of EPA's Economic Analysis of the Proposed California Water Quality Toxics Rule.) Overall, the District believes that problems with the Economic Analysis are serious enough that is should be redone. As stated above in our analysis of assumed costs at the SRWTP, the use of questionable data without qualification combined with unsubstantiated assumptions regarding costs to achieve compliance resulted in a gross underestimate in the cost-effectiveness ratio. The District's first

concern is that if the types of problems found in our Case Study are widespread in other studies, the complete analysis is suspect.

In addition to the analysis of the District's facilities, there are several other points which have been used by EPA to lead to a potentially serious understatement of actual costs. The key assumptions involved are that: 1) no costs would occur if either no monitoring data presently exists or if that data is below analytical detection levels; 2) no treatment costs would occur whenever EPA's initial estimates showed high costs, due to successful regulatory relief; 3) no costs are included for nonpoint sources such as municipal stormwater management systems; and 4) no costs are included for indirect dischargers to the District's system that are not large enough to be considered a Significant Industrial User (SIU).

Regarding the first assumption, the District has found that there is pressure from many sides, including the Safe Drinking Water Act, to both increase the number of constituents being monitored and to lower detection levels to meet numeric criteria set by EPA and the state. To assume that monitoring of these new constituents will not lead to any treatment cost increases is simply unrealistic. Similarly, the second assumption about absolute success in every pursuit of regulatory relief is also overly optimistic. There are no guarantees that pursuit of regulatory relief will be successful in any situation, and EPA indicates elsewhere in the preamble that options such as variances and site-specific criteria will rarely, if ever, be granted.

The third and fourth key assumptions ignore present dominating trends and facts, i.e. that. prevention and control of pollutants at their sources, including very small indirect dischargers, storm runoff, and other nonpoint sources are now the major focus of EPA's wastewater programs nationally. While we agree that these management steps should be taken, there will be significant costs attached to the implementation of these steps that cannot be ignored.

Combined with concerns the District has heard from other sources such as the California Association of Sanitation Agencies (CASA), it appears that EPA has failed to make "a reasoned determination that the benefits of the intended regulation justify its costs." Therefore the District believes that the Agency is obligated to redo the draft Economic Analysis.

Response to: CTR-041-010a

See responses to CTR-032-004, CTR-021-006b, CTR-040-037, and CTR-003-011.

If pressure from the Safe Drinking Water Act results in increases in monitoring of constituents or lowering of detection levels, any associated costs should not be attributed to this rule but would be attributed to actions taken under drinking water regulations. To account for those costs under this rule would be double counting because a cost analysis of drinking water rules would already have accounted for those costs. From the outset of the national water quality standards program, EPA has explained that while economic factors may be considered in designating uses, scientific and technical factors must justify the criteria to meet those uses. Additionally, with regard to benefits justifying costs, Executive Order 12866 states in section 1(b) that this is limited "to the extent permitted by law and where applicable." See also response to 042-007a.

Comment ID: CTR-045-011
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: Several criteria are below current analytical detection. It was therefore not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance.

Response to: CTR-045-011

EPA acknowledges the limitations of detection levels for certain bioaccumulative pollutants. However, indirect dischargers to municipal treatment plants often have detectable levels of these pollutants. Similarly, within industrial plants, discharges are often detectable prior to treatment. Once detectable sources are identified, mass balance methods can be used to determine if the facility is discharging at concentrations that exceed instream water quality standards. Fish tissue concentrations can also be used as an indicator that discharges may be causing an exceedance of standards.

Comment ID: CTR-066-015a
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES C-28

Comment: The areas with which we find concerns and the requested changes include the following:

A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Our District finds 34 separate criteria that fall into this category. Lacking this credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures mandates further work prior to the promulgation of the criteria.

Response to: CTR-066-015a

See response to CTR-045-011.

Comment ID: CTR-067-004a
Comment Author: Ojai Valley Sanitary District

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES K

Comment: * In addition, EPA cannot make an accurate determination of the costs and benefits of promulgating CTR criteria for those criteria that are below achievable detection limits. Because detection limits for some pollutants will most likely improve in the near future, dischargers who are reporting regulatory compliance with current detection limits may not be in compliance when lower detection limits are achievable. OVSD (and likely other dischargers as well) have historically been required to report pollutant results with little regard to the detection limit achieved by the contract laboratory conducting the testing. This may have led to EPA's grossly under estimating the cost impact of the CTR. Detection limits of many priority pollutants identified in the CTR are actually lower than those achieved during recent special testing of OVSD's effluent to identify low pollutant levels. Therefore, the potential compliance costs to our commercial and residential dischargers could be significant, yet the Economic Analysis for the draft CTR could not estimate such costs. As a more reasonable alternative, OVSD recommends that a watershed approach be used to address these pollutants. OVSD's receiving water (the Ventura River) is currently managed using the watershed approach.

Response to: CTR-067-004a

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from pollutants in inland surface waters, enclosed bays, and estuaries in California. For example, in addition to discharges from point sources, toxic pollutants are also potentially contributed from other sources such as industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, urban and agricultural runoff, hazardous waste and Superfund sites, municipal landfills, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in many of these areas.

EPA believes that in certain parts of California, nonpoint sources and other diffuse sources of pollution are responsible for significant amounts of the loadings of some pollutants of concern. Where such continuing contribution of toxic pollutants by these sources occurs, increased controls by point sources may not lead to cost-effective environmental improvement.

EPA encourages all States and Tribes to implement water quality protection programs on a watershed basis. EPA's Watershed Protection Approach is based on the assumption that water quality and ecosystem problems are most efficiently managed at the watershed level rather than an individual water body or discharger level. However, the decision to regulate at the watershed level rests with the State and will be dependent upon many site-specific factors applicable to the watershed (e.g., number andtypes of pollutant sources).

EPA also recommends that States and Tribes establish total maximum daily loads (TMDLs) when dealing with difficult environmental problems, for example, persistent, ubiquitous pollutants and water quality impacts resulting in large part from nonpoint sources and lack of data and scientific uncertainty. Wasteload and load allocations recommended by a TMDL may be based on a reasonable expectation that

water quality standards will be met in a reasonable period of time after appropriate controls are put in place. When there is a reasonable expectation that standards will be achieved in a reasonable period of time, TMDLs may schedule implementation activities, including collecting performance data, that would result in a more cost-effective control strategy and lower costs than the methodology used to estimate compliance costs for the CTR.

See also response to CTR-004-002.

Comment ID: CTR-070-003
Comment Author: Sewerage Agency of Sthrn Marin
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: Other impacts Significant impacts may also result from dramatic reductions in discharge limits for PAH'S. Calculated discharge limits for SASM are an order of magnitude lower than the detection limits currently used for SASM effluent.

Response to: CTR-070-003

While it is true that SASM's estimates indicate significant required loading reductions (86% to 91%) based on current and projected effluent limits, the maximum effluent concentration is below detection levels indicating that the pollutants have never been detected. SASM does not provide detailed effluent data or describe existing treatment processes, thus EPA cannot estimate CTR-based limits for this facility nor assess whether additional treatment is required or pollution prevention or process optimization would be sufficient to ensure compliance with CTR-based limits. Because the pollutants have never been detected, EPA would most likely estimate zero costs under its low scenario and, under its high scenario, would probably include costs for pollution prevention or process optimization (depending on the facts relevant for the particular facility) for these pollutants as a result of the CTR.

Comment ID: CTR-082-009a
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES C-28
B Comment Period

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* A further problem with the analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost-benefit analyses or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rulemaking procedures mandates further work prior to the promulgation of the criteria.

Response to: CTR-082-009a

See responses to CTR-045-011 and CTR-005-009.

Comment ID: CTR-085-018a
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES C-28

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* A further problem with the economic analysis relates to the establishment of criteria that are below analytical detection. Lacking credible data, it was not possible to conduct cost analysis or determine that any set of control measures would or could lead to compliance. This fundamental inability to utilize established rule making procedures mandates further work to the promulgation of the criteria.

Response to: CTR-085-018a

See response to CTR-045-011.

Comment ID: CTR-107-002c
Comment Author: Brian E. Hill
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? Y
CROSS REFERENCES E-01

G-02

Comment: OnSeptember 17, I attended a hearing on the proposed CTR at the EPA's regional office in San Francisco. Here are some key issues from the testimony at that hearing:

* Some of the limits are below normal detection limits, therefore agencies have no background data in order to perform accurate attainability analysis.

* The cost of implementation by the EPA is grossly underestimated. The economic analysis shows at maximum implementation cost of $87 million. If preliminary estimates by publicly owned treatment works (POTW) art correct, implementation of the CTR will far exceed the $100 million provision of the Porter-Cologne Act. If this is the case, feasibility of implementation will be in jeopardy. The City of Merced, CA estimates that their additional cost would be $4 million annually. Merced has a very small treatment facility.

* Robert Reid, speaking on behalf of California Association of Sanitation Agencies(CASA), said that four San Francisco Plants estimate their total implementation costs to be $160 million annually.

* Charles Batts of Bay Area Dischargers Authority (BADA) estimated five BADA POTWs costs to be $12 million per year to meet the strict limit on copper and $56 million per year to meet the organics limit.

* The Regional Water Quality Control Board testified that San Francisco discharges twenty percent of the four percent discharged into the San Francisco Bay by POTWS, noting that POTWs are only a minor part of the volume discharged into the Bay. Thus, the reduction to the prescribed limits would cause a negligible decrease in the total mass of pollutants discharged.

* The City of Sacramento projects a $200 million annual cost will be required to meet the copper limit.

All of the testimony at the hearing echoed these concerns. I am sure that you have access to a transcript. The Clean Water Act has been and is instrumental in cleaning up our rivers, lakes, bay and estuaries. We can continue on this steady path by setting gradual attainable limits and through increased public education. Limits on pollutants should continue to get stricter, but this has to occur on a gradual curve that will not place an unreasonable burden on the individual taxpayer.

Response to: CTR-107-002c

See responses to CTR-107-002a, CTR-041-018, CTR-038-003, CTR-056-018, CTR-021-010, CTR-021-005c, CTR-040-039, CTR-035-011a, and CTR-035-064.

Comment ID: CTRH-002-019
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N

CROSS REFERENCES

Comment: Another point we would like to make with respect to the economic analysis deals with the fact that this analysis ignores a potential cause related to compliance for criteria that are being set at below-method detection limits. Again, using Tillman as a case study, the limit on lindane was specified at 19 parts per trillion in the Inland Surface Water Plan. And at the time of promulgation of ISWP, no lindane was detected in the Tillman effluent. However, soon after the new permit was issued, better analytical methods for lindane became available, and subsequently we found Tillman to be consistently in non-compliance. Since that time, Tillman has had lindane concentrations of around 30 parts or so in excess of the permit limit of 19, and the cost for lindane compliance was an unexpected factor that we were forced to address because of better detection limits of lindane, not because Inland Surface Water Plan did not address the issue.

So I think on -- on the other hand that, you know, we can say that no economic analysis could be or need to be performed when the only data available are non-detects. But this issue is real and we are experiencing that. EPA minimally must provide a mechanism to incorporate this scenario into the economic process as they occur.

Response to: CTRH-002-019

See responses to CTR-045-011 and CTR-035-064.

Comment ID: CTRH-002-022
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: E-01n Detection Limits
References:
Attachments? N
CROSS REFERENCES

Comment: MS. FRANKEL: I have just one question. If I could ask you -- I missed the first thing that you had mentioned. You said that you were putting in some treatment to comply with the existing permit?

DR. CHENG: In the case of lindane, we would have to go to really drastic measures. And no, we have not. We are still in noncompliance. And while we were contemplating on project to deal with the lindane case back in 1994, that was about the time that Inland Surface Water Plan was rescinded, and therefore we were basically taking the approach "wait and see what happens" without spending hundreds of millions of dollars. I think -- I believe the figure was $200 million to go through our own whatever necessary to remove lindane.

I might as well mention, at that time methylene chloride is a similar case. But the City in good faith effort pursue all avenues, and actually we were able to bring the methylene chloride issue to compliance through very aggressive retreatment program. So we're very proud of that, and that supports the EPA's program in source control and a lot of other things.

But we believe, in our case, that the case of lindane, we have exhausted all of the industrial potential dischargers and it comes to perhaps home use, head lice treatment, doing shampoo, that type of thing. And since 1992 we have entertained request with state consumer product affair regulations to see if they could do something about it. But these are the type of things that are beyond our capabilities other than putting in real expensive treatment. And I hope you understand why we are so concerned with the detection limits and making the need to be provided as these things will occur because scientists are going to make progress and we're going to find where we didn't think there was a problem.

MR. MORRIS: The other comment you made is that the cost when the limit is below the quantitation level - -

DR. CHENG: Yes.

MR. MORRIS: -- and the analysis does to a certain extent look at those types of costs. In the high-end scenario, it is a limit-to-limit analysis. So if you look at the WQBEL for PCBS, let's say, the typical WQBEL for PCBs is the quantitation level; the WQBEL for the CTR will be below the quantitation level. In those, if there was a difference between those two limits which are below the quantitation level, we would cost the treatment to give the current statement to ours. So there is an element in there that deals with WQBELs below quantitation.

We've done similar type analysis for other rule-making; but you've got to understand that, when you do those, they're highly speculative because a lot of times you don't really know if it's there or not. And when we do these types of regulations in other parts of the country, a lot of times the dischargers and the municipalities say the same thing. We've all got this pollutant. You can't quite see it because it's right below the detection level.

What we've done in the past when we go out in the field and try to find these pollutants, they don't really exist. So I guess what I'm saying to do is that when we spend a lot of money going out to try to identify whether or not you have it, the likelihood is it's like mercury which is fairly ubiquitous. What we're finding is they're down under a part per billion for dischargers.

DR. CHENG: Thank you. I understand what you're saying and I highly respect your economic analysis because I'm an economist. However, maybe I have not made the case real clear.

The case about lindane is real clear. Back in 1991, I believe our detection limit was about 200 parts per trillion. Nobody had detected anything using the bestmethod. Criteria was set at 19 for the highest WP, but it's just such a coincidence that my labs were getting better, using capillary pollens and all these other things, and better control of even the gas chromatograph injection techniques; but now we go below 19 and all of a sudden we found out that we are about 30. It's real. It's generating permit violations every month just about. So I can recall only maybe a handful of months throughout the six- or seven-year period that we were not exceeding the 19.

So while I can appreciate that there are case histories where it's just a big worry that the sky might fall, in this case the sky has fallen. And so I would like to just make it clear that I have not gone through your analysis to fully understand about WQBEL and how you do it, but perhaps one practitioner's point of view, the cost that we assess to comply with lindane, for example, is in the hundreds of million of dollars, and because the only technology based on what we know was based on something like reverse osmosis, is that something that through the economic analysis will be washed out?

MR. MORRIS: If in our analysis we have a permit limit for that pollutant and the state's permit limit and you're violating that limit, we would not take the hit for you getting into compliance with your current state permit limit.

DR. CHENG: I understand EPA's approach and EPA's policy. However, it does behoove us to recognize that it is an unfair situation. The legal basis for Inland Surface Water Plan is not there. And can we not -- Looking at the books I see it.

MR. MORRIS: I think that in your particular case, if you truly have this problem and you're truly looking at the kind of economic impacts that you say you're going to RO, or whatever you need to get to this limit, I would apply for a variance. I would continue to aggressively implement and apply for a variance and lay the facts on the table and, let's say, look at them, make a decision. But I think that requires going public, putting the data on the table, showing them what you've done, showing that its -- you can't find the source, it's ubiquitous, and there is no way you can take it out other than going to plant treatment. But the public has to review the facts and make a decision.

DR. CHENG: I appreciate very much your suggestion indeed, since the City of L.A. has been basically trying its best to address all pollution concerns. We are confident that it is -- We are concerned that it's got to be addressed one way or another.

Response to: CTRH-002-022

See responses to CTR-045-011, CTR-032-004, CTR-060-019, CTR-040-026, and CTR-035-064.

EPA agrees that benefits are likely to be highly site specific. However, sites likely to experience a disproportionate share of the benefits are also likely to incur a disproportionate share of the costs.

In addition, once water quality standards are in place, sites that are currently less impacted by toxic pollutants may experience cost savings by preventing future cleanup costs. That is, it may be more cost-effective to prevent toxic pollutants from entering surface waters than to clean up and remediate the impacts once toxic pollutants are released. However, should the State determine through a total maximum daily load (TMDL) allocation that controls on nonpoint sources are a more cost-effective approach to achieving standards, the State can redistribute the allocations through the TMDL process.

The range of estimated benefits in part reflects the range in loadings reductions that may result from point source controls given the flexibility in State implementation procedures. The decision as to which implementation procedures will be employed, and therefore what costs and benefits will result, will be made by state and local entities for specific locations.

Subject Matter Code: E-01n01 Non-Detects, No Cost

Comment ID: CTR-040-028
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n01 Non-Detects, No Cost
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if monitoring data was available but all values were reported as below analytical detection levels, that the discharger will not incur costs as a result of the CTR.

Response to: CTR-040-028

If a discharger had no effluent data, EPA did not automatically assume that the discharger would have no costs as a result of the CTR. When effluent data was available, however, EPA used the method in EPA's Technical Support Document for Water Quality-based Toxics Control (1991) to determine reasonable potential and then followed the methodology (i.e., the cost-decision matrix) described in the Economic Analysis (EA) of the final CTR to estimate costs. In the abscence of data under the high scenario, reasonable potential was assumed if the discharger had an existing permit limit for a pollutant and EPA then estimated costs using the methodology described in the EA. See also response to CTR-003-011.

Comment ID: CTR-041-024
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n01 Non-Detects, No Cost
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if monitoring data was available but all values were reported as below analytical detection levels, that the discharger will not incur costs as a result of the CTR.

Response to: CTR-041-024

See response to CTR-003-011 and CTR-005-009.

Comment ID: CTR-044-019
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01n01 Non-Detects, No Cost
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if monitoring data was available but all values were reported as below analytical detection levels, that the discharger will not incur costs as a result of the CTR.

Response to: CTR-044-019

See response to CTR-003-011.

Comment ID: CTR-054-023
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01n01 Non-Detects, No Cost
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if monitoring data was available but all values were reported as below analytical detection levels, that the discharger will not incur costs as a result of the CTR.

Response to: CTR-054-023

See response to CTR-003-011.

Subject Matter Code: E-01o Background Levels

Comment ID: CTR-003-010
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01o Background Levels
References:
Attachments? N
CROSS REFERENCES

Comment: 10) In general we were impressed by the level of effort used in the economic analysis. However the paucity of data at levels sensitive enough to characterize the compliance status of the waters and the underlying assumptions used in their place, completely overshadowed it's finer points. For example, the use of zero for the ambient receiving water background concentration in the absence of reported numbers is not appropriate for chemicals typically found in the environment but may be appropriate for exotic chemicals if their use is non-existent in the area. Given the extremes in potential costs involved here, it would have been appropriate to run the analysis once under the assumption that it is zero and again assuming that it equals the detection level for that chemical.

Response to: CTR-003-010

For analysis of the final CTR, EPA collected the most recent publicly available data and information for each of the sample facilities including permits fact sheets, permit applications and monitoring data. Data submitted as a part of the public comments were also reviewed and considered. However, because only four of the sample facilities are allowed dilution, EPA applied the CTR criteria directly as effluent limits for most of the sample facilities (i.e., since no dilution was provided, background data did not affect the stringency of the effluent limit).

Subject Matter Code: E-01p Risk Level Costs

Comment ID: CTR-035-050
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01p Risk Level Costs
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 5-1 - 5-2 (U.S. EPA, 1997b) -- Analysis of 10E-5 Risk Level for Carcinogens We disagree with EPA's conclusion that "the changes in estimated costs and pollutant load reductions based on the lower risk level of 10E-5 are minimal." In fact, under the low cost scenario, the analysis shows that there would be >25 percent cost savings, with only a 3 percent lowering in pollutant reductions. We believe that analysis demonstrates that it is probably cost-effective to lower the risk level for carcinogens. However, given the equivocal results for the high cost scenario, we recommend that EPA re-analyze the impacts of modifying the risk level, and look not only at the attainability and cost analysis, but analyze the actual change in risk levels that would result, given the uncertainty factors that are built into the criteria. Based on all of the conservative assumptions included in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk from using lower risk levels. EPA should factor this uncertainty into the risk assessment, along with population exposure, when evaluating risk levels for the human health criteria.

Response to: CTR-035-050

See response to CTR-003-011.

Comment ID: CTR-035-056c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01p Risk Level Costs
References:
Attachments? N
CROSS REFERENCES E-01c02
E-01c01

Comment: Introduction

On behalf of CASA and Tri-TAC, M.Cubed reviewed the U.S. Environmental Protection Agency 's (USEPA) Economic Analysis (Analysis), as well as the report's underlying benefit and cost data and analyses. M.Cubed's overall reaction is that policy makers and the regulated community can place little

confidence in either the benefit or cost analyses -- the uncertainties and broad assumptions contained in these analyses largely undermines their findings. Based on the information provided by USEPA, M.Cubed's judgement is that the proposed California Toxics Rule (Rule) will result in multi-million dollar annual costs -- and have substantial impacts on individual publicly-owned treatment works (POTWS) and dischargers -- and may result in no noticeable benefits to public health or the environment. A critique of specific weaknesses in the cost and benefit analyses is provided below.

Weaknesses in Overall Report Findings

The Analysis' overall findings exhibit a number of flaws, as follows:

USEPA's estimates indicate that Rule costs outweigh benefits, both on an annualized and present value basis. USEPA's claim that comparison "...of both annualized benefits and costs and discounted benefits and costs indicates that the monetized benefits of the CTR are of the same general magnitude as the costs" is simply not true (U.S. EPA, 1997a, page 9-2). For example, using USEPA's comparison of a twenty-year phase-in of benefits at a 3 percent discount rate against a ten-year phase-in of costs at a 7 percent discount rate, or benefits of between approximately $20 to $600 million against costs of about $180 million to $1 billion (setting aside the significant weaknesses in the analysis; differences in the probabilities of low or high outcomes; and questions over the appropriate discount rate to apply)(*2) indicates a low cost scenario which is nine times higher than the estimated benefits, and a high cost scenario which is almost twice as high as benefits.(*3)

Executive Order 12866, which requires the economic review, defines "significant regulatory action" as one that is likely to "adversely affect ... a sector of the economy." Yet, although the USEPA finds that two sectors will incur the majority of the regulatory costs -POTWs and chemical/petroleum products -- it provides no analysis of whether or not these costs are "significant" to these sectors. Likewise, USEPA does not examine the potential costs or their implications to small businesses (e.g., health care providers; automobile repair shops), small communities, or non-significant industrial users (SIUs) in general (i.e., industries that are regulated by POTWs through local ordinances, rather than under federal rules)

USEPA's conclusion that the use of different risk levels would not significantly influencecompliance costs is not supported by its data. Based on USEPA's own data, use of a 10E-5 risk level for carcinogens would induce a 25 percent cost savings relative to a 10E-6 risk level under the low cost scenario, with a 3 percent change in pollutant loadings.(*4)

(*2) Noticeable benefits seem unlikely to emerge in the near term, if at all, due to the persistence of existing contaminants in the environment, while costs will be incur-red over one to two decades. Use of a lower discount rate for benefits would reflect the greater value future generations may place on environmental amenities, an assumption which is open to debate.

(*3) The large differences between benefits and costs is mirrored by the wide range in estimated pollution reduction. Under USEPA's low scenario, only.63 million toxic pounds- equivalent are expected to be reduced under the rule, compared to a high scenario reduction of 7 million pounds equivalent. That is, reductions under the high scenario are eleven times higher than under the low scenario.

(*4) Under the high cost scenario cost reductions are less than I percent, with a 7 percent change in pollutant loadings.

Response to: CTR-035-056c

See responses to CTR-021-005c, CTR-056-018, and CTR-003-012.

Comment ID: CTR-052-016
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01p Risk Level Costs
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Specify carcinogenicity risk factor of 10E-5 . EPA should acknowledge that a significant portion of the attainability, cost, and benefit issues can be addressed by the simple modification of the carcinogenicity risk factor. EPA should clearly state that the criteria are based on a risk factor of 10E-5, and strongly urge its use by the State in its Implementation Plan. As noted in the analysis by Larry Walker Associates, Authority and BADA attainability and cost issues are essentially resolved if the criteria are based on a risk factor of 10E-5. In addition, existing permit limits and high level of compliance remain in place.

Response to: CTR-052-016

See response to CTR-003-012.

Subject Matter Code: E-01q Source Reduction

Comment ID: CTR-004-003
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01q Source Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: Industrial source control and pollution prevention activities cannot be relied on to achieve the reductions that may be needed. The Sources of Pollutants of Concern and Waste Minimization Plan study, conducted by SBSA in 1992, identified that most of the pollutants of concern are not from industrial or commercial users. Complete elimination of industrial and commercial discharges would not resolve the compliance problems. The conceptual cost estimate for metals and organics removal treatment (reverse osmosis) technology at SBSA is around $18 million dollars per year.

Response to: CTR-004-003

EPA agrees that pollution prevention may not be applicable or effective in all circumstances. Before estimating costs for the final Great Lakes Water Quality Guidance, which was used as the basis of pollution prevention cost estimates for the CTR, EPA attempted to collect additional data related to the cost and effectiveness of pollution prevention techniques for the pollutants being regulated under the final Guidance. The result of these efforts, which generally constituted an extensive review of the EPA Pollution Prevention Information Clearinghouse (PPIC), indicated that limited documentation was available regarding the effectiveness of pollution prevention to remove many of the pollutants included in the CTR. The limited information did, however, suggest that facilities could eliminate toxic constituents from their operations using pollution prevention techniques such as raw materials substitution and process modifications (EPA, 1992; EPA, 1994).

In estimating costs for the CTR, EPA used a decision matrix for purposes of estimating the types of controls and costs associated with these controls to avoid unjustified use of waste minimization/pollution prevention techniques to achieve CTR water quality-based effluent limits (WQBELs). Under the decision matrix, waste minimization/pollution prevention was considered only after consideration of modifying existing treatment systems to achieve CTR-based WQBELs. Further, waste minimization/pollution prevention controls were considered when the production process or source generating the pollutant was amenable to pollution prevention techniques, and when addition of treatment was not justifiable. Three cases where EPA assumed that the addition of treatment would not be justified are detailed below.

1. Existing discharge data indicate that the pollutant is most often in compliance with projected CTR-based effluent limits. The reported maximum effluent concentration or existing permit limit does not reflect standard discharge levels. For instance, treatment costs were not assigned to pollutants reported above detection levels only once in three years. A pollutant was considered most often in compliance with projected limits if sufficient data were available and approximately 80% or more of the observations were already in compliance with the projected permit limit.

2. Discharge monitoring data are inconclusive to assume treatment costs. It was assumed that a facility would not add treatment without having sound proof that it was needed. Treatment was not selected if discharge monitoring data were not available or very limited (i.e., 1 or 2 data points), discharge data were not recent (i.e., previous to 1993) or did not reflect existing operating conditions, in particular when operating practices described in a recently re-issued permit indicated the decrease in the discharge of pollutants.

3. The pollutant loading reduction is insignificant in terms of percentage load reduction (i.e., 10-25%).

As an alternative to the use of waste minimization/pollution prevention, EPA also considered the use of the flexibility provided through the National water quality standards and NPDES programs (i.e., alternative regulatory approaches such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc.) as a control alternative in estimating costs for the CTR. However, the use of alternative regulatory approaches was limited to only those facilities under the low-end scenario where the estimated cost was disproportionately high as compared to the resulting estimated pollutant reduction.

References:

U.S. EPA. 1992. Pollution Prevention Options in Metal Fabricated Products Industries; A Bibliographic Report. EPA/560/8-92/001A. Washington, DC. Pages 20 - 23.

U.S. EPA. 1994. 33/50 Program Company Profiles: Reduction Highlights. EPA-745-K-94-017. Washington, DC. Pages 2, 4, and 7.

Comment ID: CTR-021-012
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: E-01q Source Reduction
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The CTR Incorrectly Extrapolates Assumptions Regarding the Effectiveness of the City's Source Control Program Regarding Metals Control Measures that Leads to Erroneous Conclusions Regarding Compliance with Projected CTR Effluent Limits

CTR Appendix I-B-1 1 refers to Sunnyvale's 1994 Local Limits Compliance Strategy report relative to an alternative analysis of copper compliance. The appendix asserts thatimplementation of the City's recommended pollution prevention and source control activities "is believed to be sufficient to the 4.9 ug/L limit" and that costs to achieve a 5.5 ug/L CTR limit would range from $400,000 to $2,000,000. The City's reports do not support this conclusion, but rather indicate that the WPCP would probably not attain the limits. It is important to note that since the 1994 report, the City has fully implemented the copper control measures recommended in that report and the effluent quality is above the 4.9 or 5.5 ug/l

level 30-40% of the time. As described elsewhere in this memo, the CTR authors continue to confuse compliance with a non-existent monthly average limit with the actual daily maximum limit which cannot be exceeded on any day.

The majority of copper now entering the treatment plant is from the local water supply, from corrosion of residential copper plumbing. This is not a source that is under the control of the City although the City has worked with the water purveyors to help optimize their corrosion control efforts. This CTR appendix needs to be corrected to reflect Sunnyvale has implemented the "reasonable control measures" and there is no basis for assuming that further pollution control measures will achieve copper compliance.

Response to: CTR-021-012

EPA's revised Economic Analysis of the CTR does not include the alternative analysis for copper compliance that was presented in the draft version (Appendix I-B-1 of the Technical Support Documentdated May 5, 1997). Therefore, Sunnyvale's comments regarding the feasibility of this cost estimate are no longer applicable. In it's revised cost analysis, EPA used dissolved water quality criteria for copper and assumed that the criteria would be implemented using metals translators (EPA used a site specific translator of 2.6 for copper). Effluent quality data for copper indicate that the facility is in compliance with CTR criteria (only one effluent data point collected between 1995 and 1997 was above the CTR-based limit). Thus, EPA concluded that a pollution prevention program was sufficient to ensure compliance with the CTR-based limit and estimated costs for this program.

In addition, Sunnyvale asserted that EPA confused compliance with a nonexistent monthly average limit with the actual daily maximum limit. The methodology EPA used to derive permit limits for the draft and final economic analyses of the CTR establishes that for each pollutant assumed to have reasonable potential, a maximum daily limit and an average monthly limit are calculated. This is a standard NPDES permitting requirement and is detailed in the Technical Support Document for Water Quality-based Toxics Control (U.S. EPA, 1991). For the final Economic Analysis, EPA used the average monthly limit as the projected CTR-based limit because it is the most stringent limitation imposed on this facility. EPA estimated pollution control costs based on individual violations of the average monthly limit, as if the average monthly limit was a maximum daily limit. As a result of these assumptions, EPA's estimates are more conservative than those based on maximum daily limits.

EPA recommends referring to Box 5-2, "Calculating Permit Limits Based on Two-Value Wasteload Allocation," (page 100) of the Technical Support Document for Water Quality-based Toxics Control, for a step by step explanation of EPA's methodology.

See also the response to CTR-021-017.

Comment ID: CTR-035-062
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q Source Reduction
References:
Attachments? N

CROSS REFERENCES

Comment: Weaknessesin Cost Analysis The report's cost estimates exhibit a number of significant weaknesses, as follows:

* The Analysis assumes a very loose and highly effective trigger for use of low-cost waste minimization/pollution prevention techniques. USEPA asserts that 10 to 25 percent reductions in current discharge levels is "insignificant," and would be fully addressed by low-cost waste reduction strategies.(*10) Little data is provided to support this assertion. Individual POTWs and dischargers may already be implementing all feasible low cost techniques; or these techniques may be insufficient to obtain the necessary reductions. As indicated by USEPA itself, "...without process-specific information, it is unknown if waste minimization is technically feasible." (U.S. EPA, 1997b, page 2-33).

(*10) It is equally plausible that it will be extremely expensive to obtain an additional one to ten pounds per day of reductions, such as may be required in the City of San Jose.

Response to: CTR-035-062

See response to CTR-004-003.

Comment ID: CTR-040-030
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q Source Reduction
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a constituent only occasionally exceeds a calculated effluent limit,that the effluent limit can be achieved through source control even if the required reduction is on the order of 90% to 99% (as was done in the analysis of mercury and aldrin for the Sacramento POTW case study).

Response to: CTR-040-030

The results of the final CTR cost analysis indicate that aldrin is no longer a pollutant of concern for the Sacramento POTW. These results support the draft analysis in that no major costs should be associated with aldrin removal. No reasonable potential to exceed was concluded because no permit limit exists for aldrin and because the constituent was recorded consistently below detection levels during the last three years of monitoring (twenty-one observations).

Mercury criteria are 0.05 ug/l for freshwater and 0.05 ug/l for saltwater. In analysis of the final CTR, the required reduction for mercury is 72%. EPA still assumes that pollution prevention/waste minimization will be sufficient to comply with CTR limits. Forty-nine observations were made at the discharge from 1994 to 1997, and only three observations were recorded slightly above the proposed CTR limit. Since the facility is capable of complying with the proposed limit 95% of the time, EPA expects that the facility would find more cost-effective methods to comply with the CTR limit, and not incur the expense of adding treatment process units. See also response to CTR-004-003.

Comment ID: CTR-041-026
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q Source Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a constituent only occasionally exceeds a calculated effluent limit, that the effluent limit can be achieved through source control even if the required reduction is on the order of 90% to 99% (as was done in the analysis of mercury and aldrin for the Sacramento POTW case study).

Response to: CTR-041-026

See response to CTR-040-030.

Comment ID: CTR-044-021
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01q Source Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a constituent only occasionally exceeds a calculated effluent

limit, that the effluent limit can be achieved through source control even if the required reduction is on the order of 90% to 99% (as was done in the analysis of mercury and aldrin for the Sacramento POTW case study).

Response to: CTR-044-021

See response to CTR-040-030.

Comment ID: CTR-054-025
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q Source Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that if a constituent only occasionally exceeds a calculated effluent limit, that the effluent limit can be achieved through source control even if the required reduction is on the order of 90% to 99% (as was done in the analysis of mercury and aldrin for the Sacramento POTW case study).

Response to: CTR-054-025

See response to CTR-040-030.

Subject Matter Code: E-01q01 25% Assumption

Comment ID: CTR-040-029a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q01 25% Assumption
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01h01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-040-029a

EPA acknowledges that the effectiveness of source controls and process optimization techniques will vary from facility-to-facility, and will depend upon many factors, including for example, the volume of discharge, the type of manufacturing process used, and the inputs to the production process. However, EPA believes that, on average, assuming that reductions of less than 25% can be controlled by the use of source controls or process optimization is reasonable. EPA considered minor, low-cost modifications or adjustments of existing treatment feasible if the literature indicated that the existing treatment process could achieve the revised WQBEL and if the additional pollutant reduction was relatively small (e.g., 10% to 25% of current discharge levels). EPA assumes that prior to incurring capital expenditures, most facilities will evaluate low-cost alternatives for pollutant reduction.

It should be noted that in the analysis of costs for the Economic Analysis for the final CTR, EPA performed a literature search to verify the costs associated with treatment process optimization. As a result of this effort, EPA revised upward its estimate of process optimization costs to a range of $60,000 to $233,000 depending upon the general type of treatment processes being used at a facility and the volume of discharge. These estimates include costs for performing a process optimization study, as well as process modifications.

See also response to CTR-004-003.

Comment ID: CTR-041-025a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q01 25% Assumption
References:

Attachments? N
CROSS REFERENCES E-01h01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-041-025a

See response to CTR-040-029a.

Comment ID: CTR-044-020a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01q01 25% Assumption
References:
Attachments? N
CROSS REFERENCES E-01h01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-044-020a

See response to CTR-040-029a.

Comment ID: CTR-054-013b
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q01 25% Assumption
References:
Attachments? Y
CROSS REFERENCES E-01g03
E-01m
E-02l

Comment: The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule (see Attachment 3). The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. BADA's analysis shows that its member agencies alone could be faced with costs in excess of $100 million per year to achieve effluent limits based on the copper, PAH, heptachlor and aldrin criteria. BADA's analysis also indicates that the benefits associated with this expenditure will be difficult to measure. Copper loadings will be reduced by 1% and the level of compliance for PAH's and heptachlor will remain unchanged at its present high level. Certainly these benefits will not measurably improve the fishing experience or measure the number of fisherman in the Bay, significantly reduce the cancer cases, or improve property values or other nonuse benefits, as estimated in EPA's economic analysis. A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. BADA agencies provide service to a number of small communities with populations under 50,000 people that could be greatly impacted by the proposed rule.

Response to: CTR-054-013b

See responses to CTR-021-008, CTR-040-029a, CTR-032-004, CTR-054-013a, CTR-056-018, CTR-021-005c, and CTR-059-018.

Comment ID: CTR-054-024a
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01q01 25% Assumption
References:
Attachments? N
CROSS REFERENCES E-01h01

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that POTWs can achieve a 25% reduction through source control and an additional 25% reduction through treatment plant optimization.

Response to: CTR-054-024a

See response to CTR-040-029a.

Subject Matter Code: E-01q03 Unit Cost Assumption

Comment ID: CTRH-001-037b
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: E-01q03 Unit Cost Assumption
References:
Attachments? N
CROSS REFERENCES E-01c02
E-01h02

Comment: Second, the interaction between the CTR and the state's implementation policy is particularly important given our second concern, which is namely that the EPA's economic evaluation underestimates the costs and overestimates the benefits of implementing this rule.

Our concern about the cost estimates is based on the fact that the cost analysis appears to undervalue the magnitude of difficulty dischargers will have complying with permits issued based on this rule.

We are also concerned that the cost estimates for various compliance activities such as source control and treatment process optimization made in the case studies are overly optimistic and not reflective of the true actions that will need to be taken to insure compliance.

Overall, we are concerned that the expenditures that may be necessary for many POTWS to comply with the CTR will be large, these costs may not be matched by commensurate benefits, and that EPA has not analyzed whether point source controls are in fact a cost-effective way to achieve water quality standards.

Our preliminary analysis for just five agencies in the Bay Area to comply with the proposed standard for copper alone could amount to more than $60 million per year -- 60 million. This number would be far higher if calculated for every pollutant listed in the CTR for the entire POTW industry in California.

Since this estimate would undoubtedly exceed the high end of the range contained in EPA's analysis, we believe it is necessary for EPA to redo the economic analysis to fully comply with its legal responsibilities.

In addition, revised economic analysis is necessary to provide a sound basis for the State to use in its analysis of the economic impacts of the implementation policy.

Response to: CTRH-001-037b

See responses to CTR-041-018, CTR-035-057, CTR-056-018, CTR-004-003, and CTR-040-039.

Subject Matter Code: E-01r Economic Variances

Comment ID: CTR-035-060
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01r Economic Variances
References:
Attachments? N
CROSS REFERENCES

Comment: Weaknesses in Cost Analysis The report's cost estimates exhibit a number of significant weaknesses, as follows:

* USEPA's use of averages to estimate individual POTW costs may mask significant expense variations. For example, some facilities may experience the great majority of total costs, while others may face less significant expenses. Likewise, the Analysis does not address costs associated with maintaining reliable water quality levels in the face of time or weather-related variations in discharges, such as peak loading.

Response to: CTR-035-060

See responses to CTR-035-061 and CTR-035-048.

Subject Matter Code: E-01s 2ndary,Indirect Cost Impact

Comment ID: CTR-009-008a
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01s 2ndary,Indirect Cost Impact
References:
Attachments? Y
CROSS REFERENCES E-02o
E-02c

Comment: The City does not agree with the economic analysis. It is incomplete and misrepresents the actual costs and benefits. The analysis does not include costs of expensive AWT to meet more stringent limits based upon the proposed criteria. It does not include the first second, and third order costs to the community, individuals and businesses, of the economic dislocations resulting from huge capital costs, especially for small and economically distressed communities, that divert scarce resources from other priorities or out of the area. It does not include cost impact assessments to low and fixed-income households - ignoring the economic aspects of environmental justice. The benefits assessments make vast unsupported assumptions about the benefits of reductions in constituent concentrations that are barely, if even, measurable, and assigns unrealistic contingent valuations to these assumed benefits. The cost analyses does not follow EPA's own economic assessment guidance (which, itself, is fatally flawed). These points were brought up during the Task Force meetings in 1995 and 1996, but were dismissed outright by EPA. The City hereby raises these issues for the formal record.

The City of Thousand Oaks appreciates the opportunity to comment on the proposed California Toxics Rule.

Sincerely,

Donald H. Nelson Public Works Director

Response to: CTR-009-008a

EPA's own economic assessment guidance (Interim Economic Guidance for Water Quality Standards, EPA-823-B-95-002, March 1995) is intended to assist States and applicants in understanding the economic factors that may be considered, and the types of tests that can be used to determine if a designated use cannot be attained, if a variance can be granted, or if degradation of high-quality water is warranted. In order to remove a designated use or obtain a variance, or if degradation of high-quality water is warranted, the state or discharger must demonstrate that attaining the designated use would result in substantial and widespread economic and social impacts. Although EPA is responsible for approving a State's water quality standards, the State is responsible for interpreting the circumstances of each case and determining where there are substantial and widespread economic and social impacts, or where important social and economic development would be precluded.

Estimating the economic impact of the CTR in California requires a detailed econometric model of the region's economy. EPA did not conduct such an analysis of the rule and the Clean Water Act does not

require such a analysis (see CTR-042-007a). However, for a similar toxics rule in the Great Lakes Basin, an econometric analysis was performed independent of the regulatory impact analysis for the Council of Great Lakes Governors (The Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness. DRI/McGraw-Hill, San Francisco, California, July 1993). This analysis showed a minimal impact of the rule on the region's economy for a worst case scenario, a scenario with costs far exceeding those estimated by EPA. Manufacturing output was estimated to fall by between 0.008% and 0.337% over a range of four scenarios evaluated, while personal income loss was estimated at between 0.002% and 0.094% for these scenarios. As a result, the study authors concluded that the impact of the rule on the region's economy would be "nearly imperceptible." Thus, similar controls on toxic pollutants have been shown to be affordable in other regions of the country.

EPA agrees that the contingent valuation method (CVM) elicits an individual's stated willingness to pay or accept compensation. The benefit-cost comparisons in EAs are prepared to inform the public and policy makers. Thus, the strengths and weaknesses of all aspects of the EA, including methodologies for estimating benefits, need to be made clear so that readers are aware of the limits and uncertainties. However, a 1993 Blue Ribbon Panel convened by the National Oceanic and Atmospheric Administration (NOAA) evaluated CVM and found it to be an appropriate methodology for measuring values. It is also the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values and has withstood Federal Court review for its use in litigation contexts.

Additionally, much of the criticism of CVM is conceptual rather than based on empirical research. Where CVM can be compared to other research techniques (e.g., use values estimated by the travel cost methodology or the hedonic price method), CVM is shown to yield similar values (see Brookshire et al., 1982 and Smith et al., 1986). Additionally, in several field experiments, actual purchase decisions were compared to hypothetical purchase decisions (Bishop and Heberlein, 1978 and Dickie et al., 1987). In all of these studies, hypothetical behavior was sufficiently predictive of actual behavior that researchers concluded meaningful values could be obtained for benefit-cost analysis or damage assessment.

Bishop, R.C. and T.A. Heberlein. 1978. Measuring values of extra-market goods: Are indirect measures biased? American Journal of Agricultural Economics 61(5): 926-930.

Brookshire, D., M. Thayer, W.D. Schulze, and R. d'Arge. 1982. Valuing public goods: A comparison of the survey and hedonic approaches. American Economic Review 72(1): 165-177.

Comment ID: CTRH-001-023
Comment Author: Julio Guerra
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Merced
Document Date: 09/17/97
Subject Matter Code: E-01s 2ndary,Indirect Cost Impact
References:
Attachments? N
CROSS REFERENCES

Comment: And one final point that I would like to make is that the management of the City of Merced is really looking hard at ending our discharge to surface waters because of the uncertainties of how much it

is going to cost in enforcement liability with the California Toxics Rule.

If that would happen, we would be doing a disservice to a thriving ecosystem. And I believe that the economic impact of people having to cease discharges because of the regulations should be taken into account as part the economic analysis.

Thank you.

Response to: CTRH-001-023

See response to CTR-021-008.

Subject Matter Code: E-01u Economic Consid. Task Force

Comment ID: CTR-032-008a
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01u Economic Consid. Task Force
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01c02

Comment: Economic Analysis

The District supports CASA/Tri-TAC's conclusions that the Economic Analysis has significant technical weaknesses, is based on a large number of assumptions and minimal empirical data, and that it almost certainly understates costs and overestimates benefits. There is a critical need for a sound economic analysis. We also agree with their recommendation that EPA and the SWRCB undertake a collaborative process with interested members of the public to revise the Economic Analysis based on guidelines in the Economic Considerations Task Force Report.

Response to: CTR-032-008a

See responses to CTR-056-018 and CTR-034-016.

Comment ID: CTR-034-016
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01u Economic Consid. Task Force
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: * Based on these and other issues discussed in the attachments, we strongly urge EPA to revise its Economic Analysis, and recommend that EPA and the SWRCB work together with stakeholders to craft a revised approach that is mutually acceptable. We would be pleased to assist in such an effort.

Response to: CTR-034-016

EPA has worked very closely with the State to develop the results of the Economic Analysis (EA). The Agency considered all comments and information regarding the EA that accompanied the proposed CTR and revised the EA, as appropriate. In the post proposal process, EPA also met with stakeholders, as

requested, to discuss their concerns regarding the EA and made revisions, where necessary. EPA did not want to alter the EA methodology without another round of public comment which likely would have resulted in enormous additional costs and more delays. This was not justifiable given that the methodology was sound and the criteria are science, and not economically, based.

Comment ID: CTR-035-011a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? N
CROSS REFERENCES M
B Comment Period

Comment: EPA's Economic Analysis is important not only for EPA's rulemaking, but for the SWRCB's promulgation of the State's Implementation Policy. Without significant improvements, we do not believe that EPA's Economic Analysis would comply with the requirements of the state Porter-Cologne Act if used by the SWRCB to support the State Proposal. We propose that EPA and the SWRCB undertake a collaborative process with interested members of the public to revise the Economic Analysis, based on methodologies and assumptions Jointly agreed 91 upon. Such a process was recommended by the Economic Considerations Task Force convened by the SWRCB in 1995, based on the process used in the Bay-Delta process. Guidelines for embarking on a collaborative process were proposed in the Task Force Report (SWRCB, 1995, Section VIII). We believe that this process could result in a mutually acceptable and defensible analysis that both EPA and the SWRCB could use to satisfy their respective rulemaking requirements for economic analysis.

Based on the extensiveness of the modifications we believe EPA should make to both the proposed rule and the accompanying Economic Analysis, we request that EPA re-propose the rule for public review and comment before publishing the CTR as a final rule.

Response to: CTR-035-011a

See responses to CTR-021-004 and CTR-034-016.

The EA is part of a Federal action that is not subject to the requirements of the Porter-Cologne Act. The State, in the development of its Implementation Plan, is solely responsible for compliance with the requirements of the Porter-Cologne Act and other relevant State statutes. EPA is unable to comment on whether or not the State's future actions will withstand potential judicial review. However, EPA stands by its economic analysis as being an appropriate estimate of the costs likely to be incurred by California facilities as a result of implementation of the CTR.

Comment ID: CTR-045-014
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA and SWRCB should undertake a collaborative process with interested members of the public to revise the Economic Analysis, based on methodologies and assumptions jointly agreed upon, similar to the process recommended by the SWRCB's Economic Considerations Task Force.

Response to: CTR-045-014

See responses to CTR-021-004 and CTR-034-016.

Comment ID: CTR-049-007
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? N
CROSS REFERENCES

Comment: The accuracy of the Economic Analysis as contained in the CTR is extremely important. As such, we encourage the USEPA and the SWRCB to undertake a collaborative process with interested members of the public to revise the existing Economic Analysis to be based on methodologies and assumptions which are jointly agreed upon.

We respectfully submit these comments to the draft CTR for your consideration. If you should have any questions about WateReuse or the remarks contained in this correspondence, please feel free to contact me at (916) 442-2746 or our Executive Director Peter MacLaggan at (619) 523-4661. Thank you for your continued support of recycled water.

Response to: CTR-049-007

See responses to CTR-021-004 and CTR-034-016.

Comment ID: CTR-056-023
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/22/97
Subject Matter Code: E-01u Economic Consid. Task Force
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Because of the importance of the Economic Analysis, EBMUD and many other public agencies affected by the CTR believe that EPA and the SWRCB should adhere to the recommendation of the SWRCB's Economic Considerations Task Force convened by the SWRCB in 1995, and use a collaborative process in cooperation with interested members of the public to revise the Economic Analysis based on methodologies and assumptions jointly agreed upon. We believe that such a process will result in a mutually acceptable and defensible analysis that can satisfy the respective rulemaking requirements for an economic analysis.

Response to: CTR-056-023

See responses to CTR-021-004 and CTR-034-016.

Comment ID: CTR-066-018
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* Because of the importance of the Economic Analysis, EPA and the SWRCB should undertake a collaborative process with interested members of the regulated community and public to revise the analysis, based on methodologies and assumptions jointly agreed upon, similar to the process recommended by the SWRCB's Economic Considerations Task Force.

Response to: CTR-066-018

See responses to CTR-021-004 and CTR-034-016.

Comment ID: CTR-082-012
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97

Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Because of the importance of the economic analysis USEPA and SWRCB should undertake a collaborative process with interested members of the public to revise the economic analysis based on the methodologies and assumptions jointly agreed upon similar to the process recommended by the SWRCB's Economic Consideration Task Force.

Response to: CTR-082-012

See responses to CTR-021-004 and CTR-034-016.

Comment ID: CTR-096-009
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01u Economic Consid. Task Force
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

Specifically, the City submits the following comments:

I. Lastly, because of the importance of the economic analysis, EPA and the SWRCB should undertake a collaboration process with interested members of the public to revise the Economic Analysis, based on methodologies and assumptions jointly agreed upon, similar to the process recommended by the SWRCB's Economic Considerations Task Force.

Response to: CTR-096-009

See responses to CTR-021-004 and CTR-034-016.

Subject Matter Code: E-01v Discharge Over Time

Comment ID: CTR-034-014d
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-01v Discharge Over Time
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES E-01g08
E-01b
E-01e
J

Comment: * In general, we are pleased that EPA prepared an analysis of the economic impacts of the proposed CTR, and that a major portion of EPA's work focused on determining the potential impacts on POTWs. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Detailed comments can be found in Attachment 2. A few of the areas of concern are listed below:

* Small facilities appear to be under represented in EPA's sample of POTWS, especially for minor dischargers.

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

* The assumptions used to determine cost estimates for indirect dischargers appear to omit a large proportion of potentially affected industries.

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. Statewide, the population is projected to grow by nearly 50% by 2020.

* The use of average cost estimates masks economic impacts on individual dischargers, which may be particularly acute for small communities.

* The economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-034-014d

See responses to CTR-032-004, CTR-035-061, CTR-021-006b, CTR-040-037, CTR-059-018, and CTR-035-048.

Comment ID: CTR-059-021
Comment Author: Los Angeles County Sanit. Dist

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01v Discharge Over Time
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. For example, in Los Angeles County the population is projected to grow to nearly 13 million (36%) by 2020.

Response to: CTR-059-021

See response to CTR-035-061.

Subject Matter Code: E-01w Cost per Facility

Comment ID: CTR-005-001
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: E-01w Cost per Facility
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Ms. Frankel:

The Novato Sanitary District (District) thanks you for the opportunity to comment on the proposed California Toxics Rule (CTR). Unfortunately, we had insufficient time to analyze all aspects of the rule and the supporting economic analysis. This letter summarizes the comments based on our review to date.

As background, the District has two tertiary treatment plants (each with secondary treatment plus nitrification and filtration) which discharge through a common outfall to the shallow waters of San Pablo Bay. As a shallow water discharger, we are not allowed a dilution credit under the current Basin Plan and receiving water criteria are generally incorporated directly into our permit as effluent limits. The District has a population of approximately 57,000 and is basically residential in nature with supporting commercial development. We have no significant industrial dischargers to our system. We have established an aggressive pollution prevention program targeted primarily at copper (corrosion control and vehicle services control programs), and as a result our effluent copper levels have been reduced significantly (from over 50 ug/l several years ago to generally between 10 and 20 ug/l.

Sampling of residential and commercial discharges to our sewer system has established that influent copper levels are equivalent to residential copper levels and that 87% of the copper loading is attributable to tap water (the result of corrosion of copper pipes). The local water agency has already implemented a corrosion control project. Pursuant to the District's request, the agency has increased the pH beyond that required by the lead and copper rule to achieve maximum potential reduction of corrosivity. Our effluent monitoring has for several years employed clean sampling techniques and appropriate QA/QC. In the case of mercury, for example, we have been using Frontier GeoScience, the recognized expert in mercury analysis.

The District has evaluated low-cost alternatives for improving copper removals at the least efficient of our two treatment plants and concluded that addition of chemicals without significant capital improvements would not be effective. The District has further determined that significantimprovement in copper removals (although far less than needed to achieve compliance) would require capital improvements of $2.8 million and total annual costs of $480,000.

Response to: CTR-005-001

The Navato Sanitary District states that capital improvements of $2.8 million total and annual costs of $480,000 would be required for the District to achieve significant copper removal at one of its wastewater treatment plant facilities. Moreover, the district indicates that this investment will not be

sufficient to achieve compliance levels.

Review of the information submitted by the District is not sufficient to determine if the costs estimated by the District are consistent with the estimates obtained for sample facilities of the same industrial category and flow range. The existing permit limit for copper is not indicated in the documentation submitted by the District. Review of the NPDES Permit issued in 1992, which was to expire in 1997, indicates that a final copper permit limit of 2.9 ug/L was to become effective in April 11, 1996. This limit is more stringent than a limit calculated using CTR criteria for a facility with the characteristics of the Novato Sanitary District. Therefore, if the 1992 final permit limit were used to assess existing (baseline) conditions, it is unlikely that the Novato Sanitary District would show any cost as a result of the CTR.

Additionally, the cost estimates submitted by the District seem to be based on compliance with an estimated permit limit of 2.9 ug/L. These costs are included in the amendment request for the copper effluent limit submitted by the District to the California Regional Water Quality Control Board on January 31, 1996. A CTR-based permit limit for a facility with the characteristics of the Novato Sanitary District facility would use a 3.1 ug/L dissolved criteria for copper. Metal translators could also be used to derive permit limits and, if desired, the facility could complete a water effect ratios study which may result in a less stringent limit. For example, based on studies completed by the Regional Board and the City of San Jose (a San Francisco Bay discharger), water effect ratios for the Bay range between 1.7 and 3. Additionally, a metal translator of 3.2 could be calculated based on the U.S. EPA theoretical partitioning coefficient and an assumed total suspended solids (TSS) concentration of 20 mg/L. The resulting permit using CTR criteria and accepted implementation procedures would result in a limit of 16.8 ug/L for copper in comparison to the 2.9 ug/l limit the District used for its cost estimates.

Based on the above considerations, EPA does not believe the District cost estimates are comparable withthe estimates obtained for the economic analysis of the CTR.

Comment ID: CTR-059-022
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01w Cost per Facility
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The use of average cost estimates masks economic impacts on individual dischargers.

Response to: CTR-059-022

See response to CTR-035-048.

Comment ID: CTR-070-002a
Comment Author: Sewerage Agency of Sthrn Marin
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-01w Cost per Facility
References:
Attachments? Y
CROSS REFERENCES E-01d01

Comment: Economic analysis The attached table shows that implementation of the proposed limits will result in the reduction of SASM's copper limit from 37 ug/l to 12 ug/l. It is expected that reverse osmosis will be the most economical method to reach this level and that the cost of this operation will be approximately $550,000 per year. This equates to a 30% increase in SASM's budget. This cost is also higher than EPA's estimated costs of $27,000 to $480,000 per plant per year. It appears that the Economic Analysis underestimates the potential statewide cost and should be revised.

Response to: CTR-070-002a

SASM does not describe their existing treatment processes or provide detailed effluent data, thus EPA is not able to estimate a CTR-based effluent limit or evaluate whether process optimization is a viable alternative to reverse osmosis for controlling copper concentrations. EPA estimated that process optimization would be sufficient for the City of Colton (a secondary treatment wastewater sample facility with 9.9 MGD) to meet its estimated CTR-based limit for copper which require a loading reduction of less than 25%. EPA revised its cost estimates for the final CTR and now estimates that per facility costs for POTWs range from $61,000 to $325,000.

See response to CTR-045-012b.

Comment ID: CTR-081-005a
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01w Cost per Facility
References:
Attachments? N
CROSS REFERENCES E-01d

Comment: * Based on the comments at the hearing of September 17, and our own estimates, the EPA's economic analysis has serious flaws and does not reflect the full costs for implementation of the CTR. The comments of the California Association of Sanitation Agencies should be given significant weight in this regard.

* For example, the WCA plants will not be able to meet the new criteria for copper, lead, and nickel, as well as some organics. This is true even after maximizing source control, pollution prevention, and process control improvements. Both our plants would need additional "end-of-pipe" treatment, such as reverse osmosis.

* Based on our analysis of the proposed CTR, we will need to implement reverse osmosis in order to meet the requirements of the proposed CTR. Based on this, we estimate that our potential annualized costs for compliance will be $11,220,000. These costs are significantly higher than EPA's estimated costs per plant of $27,000 to $480,000 per year. Thus, we believe strongly that the draft Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-081-005a

EPA disagrees that its Economic Analysis (EA) underestimates costs. West County Agency does not provide the details of their $11.2 million cost estimate, thus EPA cannot evaluate its validity or conduct its own analysis. Based on EPA's sample of 14 POTWs in California, EPA predicts that the state-wide cost impact on POTWs would range from $7.8 million to $41.6 million per year. See the EA for details on the EPA's methodology and costs.

See responses to CTR-056-018, CTR-004-003, and CTR-045-012b.

Subject Matter Code: E-01y Cost of Efforts to Date

Comment ID: CTR-092-022c
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-01y Cost of Efforts to Date
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c
E-01b01

Comment: Comment #6: General Cost Analysis Concerns

The City of San Jose has several generalized concerns about the costs utilized in the Economic Analysis, which raise questions regarding the validity of that analysis, as follows:

Q.6-1) We believe the real point of undertaking the CTR is to assure water quality throughout State that protects beneficial uses. How can the existing Economic Analysis be sufficient if it does not address the cost of meeting the CTR standards from all sources of discharge? Especially given the amount and cost of aggressive intervention in reducing point source pollution undertaken in California to date?

Q.6-2) Throughout the text of the CTR and within the Economic Analysis, EPA refers repeatedly to the assumption that the State will provide regulatory relief to mitigate severe cost impacts engendered by the CTR. What happens to EPA's cost benefit analysis if even one of those assumptions of regulatory relief is not implemented by the State? While we support EPA's attempt to indicate available regulatory options for the State, local level governments and POTW's have little past experience on which to rationalize acceptance of such assumptions.

Q.6-3) EPA has not estimated the cost to local governments/POTW's/indirect dischargers of securing regulatory relief, nor has that cost been incorporated into the estimate of the CTR impact. How would EPA estimate the cost of securing regulatory relief and how would that additional cost affect the Economic Analysis? Especially since very costly studies may be required in order to qualify for regulatory relief.

Q.6-4) The preamble to the CTR discusses the linkage between the CTR and the National Toxics Rule, and EPA's intent to create a level playing field by setting the CTR standards within the National Toxics Rule Framework. There does not seem to have been a similar attempt to analytically level the playing field vis a vis implementation costs, however, as no indexing or calibration has been undertaken to account for the cumulative costs of efforts to date (see also Q. 4-3), cost equivalency data is rooted in experience outside California, and simple average costs are used to represent widely variable ranges. How would the CTR cost/benefit relationship be affected by adjusting for California's significant previous efforts on water quality control mechanisms and California cost data?

Response to: CTR-092-022c

See responses to CTR-032-004, CTR-060-019, CTR-004-003, CTR-035-048, and CTR-092-022a.

Comment ID: CTRH-002-018
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: E-01y Cost of Efforts to Date
References:
Attachments? N
CROSS REFERENCES

Comment: DR. CHENG: Hi. My name is Ing-Yih Cheng. I'm here today representing the City of Los Angeles, Department of Public Works, Bureau of Sanitation. City of Los Angeles has three treatment plans that are being affected by CTR. They are Tillman Water Reclamation Plant, Los Angeles-Glendale Water Reclamation Plant, and the Terminal Island Treatment Plant. We appreciate the opportunity to testify on the proposed CTR. We have three issues to briefly address because of time limitations, and a more detailed written comment will be forthcoming.

The first and foremost issue concerns with the economic analysis that you have performed on the Tillman plant. When the State Inland Surface Water Plan came out in 1991, the City conducted probable cause assessment for the Tillman plant. The study was completed in April 1992 after a new ISWP-based NPDES permit had been issued. A comparison between this detailed study and EPA economic analysis showed that your economic analysis underestimated the cost required for compliance by orders of magnitude. And the reason for this is because EPA's EA compared CTR to essentially ISWP requirements, since the NPDES permit limits reflect ISWP limits criteria. This is inherently unfair because it ignores treatment costs for those constituents that we are yet to be in full compliance with. We have discussed this matter with our attorney who has advised us to exhaust all legal remedies and hold EPA to the requirement that it prepare a legally defendable economic analysis. We will be glad to make details of our cost estimates available to you, if you like. And on the basis of this comment for one plant alone, we object to EPA's finding that CTR is not a significant rulemaking.

Response to: CTRH-002-018

See responses CTR-021-005c and CTR-035-058.

Subject Matter Code: E-02 Benefits Analysis

Comment ID: CTR-034-015
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: * The Economic Analysis presents a very weak analysis of potential benefits, which is based on limited information about ambient water quality conditions. Due to this weakness, combined with the paucity of information in the literature regarding the benefits from marginal improvements in water quality, the benefits analysis does a poor job of evaluating the marginal benefits that would result from the implementation of the CTR.

* The Economic Analysis suggests that reductions attributable to point source reductions may be de minimis. For instance, most of the public health benefits appear to be associated with a small number of contaminants, most of which are not discharged in significant quantities by point source dischargers. Cancer risks, for example are dominated by four contaminants, two of which - DDT and PCBs - are probably more the result of historic loadings than due to ongoing point source inputs.

Response to: CTR-034-015

Water quality improvements often involve thresholds such as action levels for fish consumption advisories. However, water quality regulations often contribute only a portion of the improvement needed to surpass a threshold. Although individuals may (or may not) have a willingness to pay for incremental steps toward crossing a threshold, when the threshold is surpassed (e.g., fish consumption advisories are lifted), every action that contributed to the effort should be allocated a portion of the benefits. This was accomplished for the CTR by allocating a portion of the total toxic-free benefits (proportional to the reduction in loadings) to the implementation of point source controls under the CTR.

EPA analyzed potential reductions for over forty toxic pollutants that may be discharged by point sources. EPA expects that reductions in these toxics will lead to a variety of benefits including ecological, health, and recreational benefits. Although certain health risks such as cancer are indeed dominated by only a few toxic contaminants that may not be greatly reduced by point source controls, reductions of these toxics are, nevertheless, expected to yield reductions in cancer cases as well as systemic health risks. EPA expects the annual reduction in cancer cases among recreational anglers after implementation of the CTR to range from 0.0 to 0.1 for San Francisco Bay and 0.0 to 0.8 for freshwater resources. EPA also analyzed the post-CTR hazard quotients (HQ) for systemic risks among recreational anglers with high consumption rates. The HQ for PCBs may be reduced from 11.31 to 5.44 for San Francisco Bay anglers and from 7.02 to 3.28 for freshwater anglers.

Comment ID: CTR-035-071
Comment Author: Tri-TAC/CASA

Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: * As indicated in Table Two, much of the benefit estimates are based on little or no empirical data.

Table Two Benefit Areas with Little or No Empirical Foundation Variable/Issue Empirical Evidence

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"Water quality conditions in many State waters have not been fully assessed, and assessments of waters that have been evaluated often do not contain monitoring data that is extensive or detailed enough to determine whether the waterbody meets all of the proposed criteria." (U.S. EPA, 1997d, page 1-5)

In many cases there is limited information about water quality conditions, and as a result the need for, and benefits associated with, pollution reductions is substantially unknown.

****

"EPA found no available studies of the value to California anglers of reducing toxic contamination in surface waters." (U.S. EPA, 1997a, page ES-12).

Fishing-related benefits are based on a single out of-state report which estimated "...the value of reducing toxic contaminants in a popular boat fishery that has experienced widespread and highly publicized contamination and fish consumption advisories" (U.S. EPA, 1997a, page 8-17). This analysis most likely bears little or no relation to California conditions, and should not be used as the sole basis for benefits estimation.

****

Assumes that the proposed rules will result in "appreciable" increases in water- and land-related recreation apart from fishing.

No evidence is presented that boaters, swimmers, hunters or others will increase their use of California's resources because of a marginal change in pollutant load.

****

Assumes the rule would likely engender some "passive use" benefits.

Passive use benefits estimates are based on a 13-year old analysis which may bear little relevance to the Rule. The supporting data for this benefit category is so poor as to forgo any quantification of it.

****

Uses effluent concentration data from the Sacramento County POTW to analyze freshwater resources.

"...may not be representative of effluent from other facilities" (U.S. EPA, 1997a, page 7-6).

****

Assumes San Francisco Bay discharges have not changed over the last decade.

The Analysis is based on ten-year old data which may not be representative of current conditions.

****

"Reductions in toxics may contribute to improved conditions for the successful recovery of federal and State threatened and endangered species..."

No evidence is provided supporting this claim.

****

Assumes relative point/non-point source contribution to particular contaminants based on limited data.

"None of the data sources ... definitely estimates the relative point source contribution of PCBS, dioxin, pesticides, or mercury..." (U.S. EPA, 1997d, page 7-32).

****

Response to: CTR-035-071

EPA defined toxic-impaired waters as waters rated medium or poor quality for at least one or more toxic pollutant or group of pollutants. EPA acknowledged that this definition may result in an overestimate of toxic-impairment (EA Chapter 8). However, the rating of these waters corresponds to EPA's categories of 'not fully supporting' and 'partially supporting' designated uses. The existence of waters not supporting and only partially supporting designated uses is indicative of the need for and benefits associated with pollution controls.

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA did not include values for water- and land-related benefits other than fishing, but noted that potential benefits may be underestimated because these benefit categories are not included. As described in the EA (Chapter 8), EPA believes that these benefits may be appreciable because such recreational activities (e.g., boating, swimming, picnicking, and related activities) have been shown in empirical research to be highly valued, and even modest changes in participation or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (e.g., swimming) and others might increase due to their association with fishing, swimming, or other activities in which the
participants might engage.

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. Research also indicates that these values are at least half as great as recreational values, such that if they are potentially applicable to a policy action, providing a rough approximation is preferable, with proper caveats, to omitting them from the analysis of benefits and costs. EPA believes that the studies used to calculate the ratio of passive use to use value are applicable to the CTR (see also comment and response CTR-026-009). Therefore, EPA applies a ratio of 0.5 to obtain an estimate of passive use values for households with active recreational anglers. Based on a review of the literature, EPA believes that non-angling household do indeed have a passive use value. To determine a lower-bound estimate of passive use values for non-angling households, EPA assumed that the value may be 30% of the value for angling households. For analysis of the final CTR, EPA revised the upper-bound estimate assuming that the passive use value of non-angling households may be 90% of those for angling households. This revision is based on a study by Loomis et al. (1991), who estimated the benefits of improved fishery, wetland, and waterfowl resources in the San Joaquin Valley to users and nonusers residing in California.

By multiplying a ratio of passive use to use value by recreational fishing values, which EPA apportioned to reflect the relative contribution of point sources, EPA also accounted for attribution in its estimate of passive use values.

For the EA that accompanied the proposal, EPA conducted an extensive search of the literature for more recent data or information related to the relative contributions of various sources to water quality impairments. In the EA accompanying the proposal, EPA solicited additional data, however, none was received. In revising the EA for the final rulemaking, EPA conducted an additional extensive search of the literature and research efforts at California universities for relevant information. EPA has incorporated any new information into the revised EA for the final rule.

EPA provided a qualitative description of the potential impacts of toxics on ecological resources and the potential benefits from reducing toxic loadings to the state's water resources (see Chapter 6 of the EA that accompanied the proposed rule). As stated in that chapter, EPA performed a qualitative assessment of the ecologic benefits of the proposed rule (IEC, 1996), rather than a contaminant-specific quantitative

assessment of the magnitude and extent of benefits accruing for each affected aquatic system. However, without performing a complete quantitative analysis, EPA concluded that potential ecologic benefits from implementation of the CTR may include:

* Reductions in toxics loadings are expected to contribute to improved conditions for California fish spawning and/or migration in bays/harbors and estuaries, lakes, rivers and streams, and saline lakes.

* Reductions in bioaccumulative chemicals of concern that may currently affect fish and wildlife throughout the state, including selenium, mercury, PCBs, dioxins, and chlorinated pesticides.

* Reductions in toxics may contribute to improved conditions for the successful recovery of federal and State threatened and endangered species, such as the delta smelt, desert pupfish, California brown pelican, bald eagle, California clapper rail, California tiger salamander, and western snowy plover.

* Reductions in toxics may reduce adverse toxics-related impacts on aquatic and terrestrial wildlife in two important areas of California: the San Francisco Bay watershed and the Central Valley (see Case Studies in [U.S. EPA, 1997]).

* Reductions in the concentrations of both selenium and pesticides in the waters that feed the Salton Sea may contribute to improved conditions for the restoration and maintenance of currently declining populations of wildlife, including threatened and endangered species such as the California brown pelican, peregrine falcon, bald eagle, Yuma clapper rail, and desert pupfish (see Case Studies in [U.S. EPA, 1997]).

* Improved water quality and associated improvements in survival, growth, and reproductive capacity of aquaticand aquatic-dependent organisms may contribute to the increased stability, resilience, and overall health of numerous ecosystems throughout California, and may contribute to protecting, restoring, and maintaining California's ecological diversity.

EPA used ranges to address the uncertainty in the relative point source contribution of different contaminants. These ranges were based on toxic-weighted pollutant loads so that the results could not be driven by pollutants with little impact on the environment or public health. EPA also solicited additional or updated data and information on this issue in the EA but did not receive any. In revising the EA for the final rulemaking, EPA conducted an additional extensive search of the literature and research efforts at California universities for relevant information. EPA has incorporated any new information into the revised EA for the final rule.

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Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: * Likewise, as indicated in Table Three, the benefits analysis is based on a number of assumptions which may act to overstate benefits.

Table Three Other Major Technical Assumptions Which Could Affect Benefits Estimates

Assumptions Potential Impact on Analysis

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"The benefits estimates in this report represent the total benefits expected to occur once water quality control programs have been fully implemented by California and water quality criteria have been achieved for toxic pollutants." (U.S. EPA, 1997d, page 1-8)

Cost analysis explicitly includes exemptions (cost thresholds) to rule attainment. Likewise, non-point sources are excluded. Both of these factors indicate that water quality criteria will not be achieved, and certainly not at the estimated cost.

****

Assumes anglers are aware of toxic contamination in waters that have no fish consumption advisories.

No empirical evidence provided on behavioral responses, if any, to actual or perceived public health concerns.

****

Assumes "potential benefits for all California waters affected by toxics, not just those waters under fishing consumption advisories" (U.S. EPA, 1997a, page 8-17).

May overstate benefits related to point source reductions, as most of the fishing contaminants are related to non-point sources.

****

Assumes little substitution among fishing sites.

Estimates of the value of increased fishing participation most likely overstates angler behavior as a result of substitution between fishing sites.

****

Assumes one-to-one benefit from reduction in toxics.

Other factors (e.g., habitat alteration) may pose more serious threats to the environment, and partially negate rule benefits. For example, complete reductions in point source pollution is meaningless if the water body's habitat has been substantially disturbed by development.

****

Response to: CTR-035-072

The commenter is referring to the estimate of total potential benefits in the analysis of benefits document. In EPA's EA for the proposed (and final) rule, only the portion of benefits expected to be achieved by implementing controls on point source dischargers are counted. EPA recognizes that the proposed standards will not be achieved in some cases by controlling point sources alone. EPA's assumptions regarding the attribution of benefits to the rule are described in the EA for the proposed rule in Chapter 7.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA Chapter 8). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to CTR-035-009a.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

Behavioral responses to public health concerns and pollution have been documented in the literature. For example, as shown in the table below, anglers in the Great Lakes region report taking fewer fishing trips, changing fishing locations, and changing cooking methods in response to fish consumption advisories. EPA revised it's analysis to include this information.

References

Fiore, B.J., H.A. Anderson, L.P. Hanrahan, L.J. Olson, and W.C. Sonzogni. 1989. Sport Fish Consumption and Body Burden Levels of Chlorinated Hydrocarbons: A Study of Wisconsin Anglers.

Archives of Environmental Health. 44(2):82-88.

Knuth, B.A. and N.A. Connelly, and M.Z. Shapiro. 1993. Angler Attitudes and Behavior Associated with OhioRiver Health Advisories. Prepared by the Human Dimensions Behavior Research Unit of the Department of Natural Resources of the New York State College of Agriculture and Life Sciences. HDRU Series No. 93-6. July. 163 pp.

Knuth, B.A. and N.A. Connelly. 1992. Is New York's Health Advisory on Fish Consumption Making a Difference? Coastlines. 22(4):4-5.

Silverman, W.M. 1990. Michigan's Sport Fish Consumption Advisory: A Study in Risk Communication. Thesis. University of Michigan, Ann Arbor. May. 103 pp.

Vena, J.E. 1992. Risk Perception, Reproductive Health Risk and Consumption of Contaminated Fish in a Cohort of New York State Anglers. Research Program in Occupational and Environmental Health, State University of New York at Buffalo. 67 pp.

West, P.C., J.M. Fly, R. Marans, F. Larkin, and D. Rosenblatt. 1993. 1991-92 Michigan Sport Anglers Fish Consumption Study. Executive Summary. University of Michigan, Natural Resource Sociology Lab. Technical Report #6. Ann Arbor, Michigan.

Behavioral Responses of Anglers to Fish Consumption Advisories

Study	Location	Reported Behavioral Response
Fiore et al. (1989)	Lake Michigan and Green Bay, Wisconsin	57% Reported changing fishing habits and/or fish consumption
Knuth, Connelly, and Shapiro (1993)	Ohio River	37% Took fewer trips
		26% Changed fishing locations
		26% Changed species sought
		22% Changed cleaning methods
		17% Changed size of fish consumed
		13% Changed cooking methods
Vena (1992)	Lake Ontario, New York	53% Ate less fish
		31% Changed preparation methods
		30% Changed fishing locations
		20% Changed species sought
		16% No longer ate fish
		16% Took fewer trips
Silverman (1990)	Lake St. Clair	56% Ate less fish
	Detroit River	56% Changed cleaning methods
	Lake Erie	41% Ate smaller fish
		31% Changed fishing locations
		31% Ate different species

		28% Changed cooking methods 21% Fished for different species 10% Took fewer fishing trips
Knuth and Connelly (1992)	New York	70% Ate less fish 40% Cooked fish differently 17% No longer ate sport caught fish
West et al. (1993)	Michigan	86% Cooked fish differently (Great Lakes anglers) 80% Ate less fish (Great Lakes anglers) 75% Cleaned fish differently 46% Ate less fish (overall) 27% Cooked fish differently (overall)

Although the standards established by the CTR apply to the waterbody (i.e., inland surface waters and enclosed bays and estuaries) EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA acknowledged that increased angling activity at sites experiencing reductions in toxic contaminants may reflect a shift in activity from substitute sites rather than a net increase. Because EPA could not account for substitute sites in this analysis, EPA estimated lower bound benefits of $0 (i.e., assuming no net increases in activity; see EA, Chapter 8).

EPA believes that where appropriate habitat, species, and other conditions exist, yet waters are impaired by toxic pollutants, the standards established by the CTR will result in attaining designated uses. At sites where designated uses are also impaired by factors such as habitat alteration, exotic species, or inadequate flows, these conditions may have to be corrected to fully attain the use. Notwithstanding, even if a receiving water does not fully attain its use because of other factors, this does not justify further degrading the water body by failing to reduce loadings of toxic pollutants.

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Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y

CROSS REFERENCES

Comment: ATTACHMENT: 3 - 2 A Criteria Review of: "Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study"(*1)

Introduction This dissertation is primarily concerned with examining economic models of natural resource valuation. Specifically, two models were examined, the travel cost method and the contingent valuation method. The main purpose of this dissertation was to apply these probabilistic choice models to a new data set and examine their performance against one another. In this study, the main use of contingent valuation modeling is to provide alternative value estimates for comparison to the values produced by the travel cost model. The data set examined consisted of two sets of surveys completed by a total of 513 anglers in Wisconsin. One set of surveys examined Wisconsin anglers who fished for trout and salmon in the Great Lakes (274 respondents), while the second set examined those who fished for trout and salmon in inland waters other than the Great Lakes (239 respondents). The primary concern of this critique lies in the application of some of Lyke's findings to the benefits analysis of EPA's California Toxics Rule(*2). Specifically, EPA uses Lyke's results in calculating the potential benefits accrued by California fisheries attributable to the implementation of the California Toxics Rule.

The Models Two models are used in analyzing the data. The first is the travel cost model which links travel costs and fishing success to angler decisions of where to fish. The second model is from a class of questioning methods known as contingent valuation. The travel model estimates non-market value from observable behavior (e.g. distance traveled to fishing sites) while the contingent valuation method simply measures attitudes (the willingness to pay to use a fishing site) not economic behavior per se. This critique is primarily concerned with the contingent valuation questions found in the surveys. These questions measured respondents valuation of their fishing experience (a valuation of the fishery) in relation to toxic contamination. The responses to these questions provide the basis for EPAs valuation of the improved fishing experience for California anglers after implementation of the California Toxics Rule.

Sample Design Data The contingent valuation model data are taken from two mail surveys of anglers who held fishing licenses in 1988 and fished in 1989. This study only examined the behavior and views of anglers who fish for trout and salmon. Millions of trout and salmon are planted in Wisconsin waters annually and catching them is a popular pastime. However, most of these fish are hatchery raised and as such represent a major expense for the state fisheries agency. To help defray these costs, the state requires a special trout and salmon stamp on the licenses of anglers who catch these fish. This added cost might deter some anglers, who then would not be in the "angler population" examined in this study. Also, since anglers who fish primarily for trout and salmon are willing to pay more to catch these prized gamefish, they may be more conscientious in returning questionnaires that "typical" anglers. Both these factors may cause overestimates of fisheries value in this study. This critique is primarily concerned with the data provided by Wisconsin anglers who were identified as having fished the Great Lakes for trout and salmon in 1989. This set consisted of 274 useable questionnaires (out of a possible 368 anglers).

Results Contingent valuation results were generated from responses to direct questions about the value of a given resource (in this case the Great Lakes sport fisheries). The contingent valuation models are applied to value the Wisconsin Great Lakes sport fisheries under current conditions as well as for hypothetial scenarios where contaminants are removed from the fishery and where native lake trout populations are rehabilitated. There is no travel cost model alternative to measuring these values. Lyke determined that the current value (in 1989 dollars) of the Great Lakes Fishery was $339.43/angler/year (with a standard error of $53.17). The value of a hypothetically "contaminant free" fishery to anglers

was $377.18/angler/year (with a standard error of $64.60). These values can be found in Table 15 (pg. 169) of Lyke's dissertation. It appears that EPA uses these values to estimate the potential increase in value to California fisheries with the implementation of the California Toxics Rule. EPA estimates an 11.1 percent to 31.3 percent in value to fisheries following the application of the California Toxics Rule and the subsequent elimination of toxicants from affected waterbodies. These estimated increases appear to be drawn from the values presented by Lyke. There is an 11.1 percent increase in worth when the mean value of current conditions are compared to the mean value of the hypothetical "contaminant free" conditions. There is a 31.8 percent increase in worth when the lower end (mean value minus the standard error) of the value for current conditions is compared to the mean value of the "contaminant free" conditions.

Conclusions:

1.) There is a lack of data on the value anglers in California place upon reducing toxic contamination to fisheries, so EPA used the increase in values produced by Lyke's model. However, the increases in value which Lyke shows are based on the responses of 274 individual anglers to only two contingent valuation questions in a mail survey containing a total of 64 questions. This is clearly a very small sample of the population of Wisconsin anglers and may have caused some bias in the analysis. This was probably a representative sample of anglers but not a random sample of anglers.

2.) Only anglers who fished for trout and salmon in the Wisconsin Great Lakes were surveyed. These anglers may not be representative of the typical Wisconsin Great Lakes angler, and this data does not show any valuation for any fishery other than trout and salmon.

3.) It is not clear how EPA derived the upper limit of their potential increase in fisheries value (31.3 percent). It is possible that EPA used the "contaminant free" mean ($377. 18/angler/year) and compared that to the low end value (mean minus the standard error) of the value of the fishery under current conditions ($286.26/angler/year), yielding an increase in value of 31.8 percent. Another portion of Lyke's analysis actually shows "contaminant free" fisheries to be valued lower than the current "contaminated" fishery. Inland fishing anglers who fish for trout and salmon were less willing to pay for a contaminant free fishery. The mean value of the inland fishery under current conditions ($720.12/angler/year) compared to the mean value of a "contaminant free" inland fishery ($597.42/angler/year) yields a loss in value of 17 percent.

4.) There is no evidence than any portion of Lyke's dissertation has undergone peer review outside the University of Wisconsin-Madison. An extensive literature search found no peer reviewed journal publications by the author. Without proper peer review, its methods and conclusions must remain in doubt.

5.) The degree and extent to which individual Great Lakes fishing sites and fisheries are contaminated by toxicants was not considered in this study. Therefore, it is unclear how well the study's findings can be applied to "contaminated" fisheries in California.

6.) Contingent valuation measures the attitudes of anglers, not their behavior. More specifically, it measures an anglers stated willingness to pay or compensate, not the actual behavior of paying or compensating.

(*1) Lyke, Audrey J., Dissertation submitted to the Graduate School of the University of Wisconsin-Madison, 1993.

(*2) U.S. EPA Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule. June 1997.

Response to: CTR-040-052

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA p. 8-17). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to Issue 3.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

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EPA agrees that the contingent valuation method (CVM) elicits an individual's stated willingness to pay or accept compensation. The benefit-cost comparisons in EAs are prepared to inform the public and policy makers. Thus, the strengths and weaknesses of all aspects of the EA, including methodologies for estimating benefits, need to be made clear so that readers are aware of the limits and uncertainties. However, a 1993 Blue Ribbon Panel convened by the National Oceanic and Atmospheric Administration (NOAA) evaluated CVM and found it to be an appropriate methodology for measuring values. It is also the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values and has withstood Federal Court review for its use in litigation contexts.

Additionally, much of the criticism of CVM is conceptual rather than based on empirical research. Where CVM can be compared to other research techniques (e.g., use values estimated by the travel cost methodology or the hedonic price method), CVM is shown to yield similar values (see Brookshire et al., 1982 and Smith et al., 1986). Additionally, in several field experiments, actual purchase decisions were compared to hypothetical purchase decisions (Bishop and Heberlein, 1978 and Dickie et al., 1987). In all of these studies, hypothetical behavior was sufficiently predictive of actual behavior that researchers concluded meaningful values could be obtained for benefit-cost analysis or damage assessment.

Bishop, R.C. and T.A. Heberlein. 1978. Measuring values of extra-market goods: Are indirect measures biased? American Journal of Agricultural Economics 61(5): 926-930.

Brookshire, D., M. Thayer, W.D. Schulze, and R. d'Arge. 1982. Valuing public goods: A comparison of the survey and hedonic approaches. American Economic Review 72(1): 165-177.

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Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
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References:

Attachments? N
CROSS REFERENCES

Comment: ATTACHMENT: B - 2 A Criteria Review of: "Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study"(*1)

Introduction This dissertation is primarily concerned with examining economic models of natural resource valution. Specifically, two models were examined, the travel cost method and the contingent valuation method. The main purpose of this dissertation was to apply these probabilistic choice models to a new data set and examine their performance against one another. In this study, the main use of contingent valuation modeling is to provide alternative value estimates for comparison to the values produced by the travel cost model. The data set examined consisted of two sets of surveys completed by a total of 513 anglers in Wisconsin. One set of surveys examined Wisconsin anglers who fished for trout and salmon in the Great Lakes (274 respondents), while the second set examined those who fished for trout and salmon in inland waters other than the great lakes (239 respondents). The primary concern of this critique lies in the application of some of Lyke's findings to the benefits analysis of EPA's California Toxics Rule(*2). Specifically, EPA uses Lyke's results in calculating the potential benefits accrued by California fisheries attributable to the implementation of the California Toxics Rule.

The Models Two models are used in analyzing the data. The first is the travel cost model which links travel costs and fishing success to angler decisions of where to fish. The second model is from a class of questioning methods known as contingent valuation. The travel model estimates non-market value from observable behavior (e.g. distance traveled to fishing sites) while the contingent valuation method simply measures attitudes (the willingness to pay to use a fishing site) not economic behavior per se. This critique is primarily concerned with the contingent valuation questions found in the surveys. These questions measured respondents valuation of their fishing experience (a valuation of the fishery) in relation to toxic contamination. The responses to these questions provide the basis for EPAs valuation of the improved fishing experience for California anglers after implementation of the California Toxics Rule.

Sample Design Data The continent valuation model data are taken from two mail surveys of anglers who held fishing licenses in 1988 and fished in 1989. This study only examined the behavior and views of anglers who fish for trout and salmon. Millions of trout and salmon are planted in Wisconsin waters annually and catching them is a popular pastime. However, most of these fish are hatchery raised and as such represent a major expense for the state fees agency. To help defray these costs, the state requires a special trout and salmon stamp on the licenses of anglers who catch these fish. This added cost might deter some anglers, who then would not be in the "angler population" examined in this study. Also, since anglers who fish primarily for trout and salmon are willing to pay more to catch these prized gamefish, they may be more conscientious in returning questionnaires than "typical" anglers. Both these factors may cause overestimates of fisheries value in this study. This critique is primarily concerned with the data provided by Wisconsin anglers who were identified as having fished the Great Lakes for trout and salmon in 1989. This set consisted of 274 useable questionnaires (out of a possible 368 anglers).

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Conclusions:

1.) There is a lack of data on the value anglers in California place upon reducing toxic contamination to fisheries, so EPA used the increase in values produced by Lyke's model. However, the increases in value which Lyke shows are based on the responses of 274 individual anglers to only two contingent valuation questions in a mail survey containing a total of 64 questions. This is clearly a very small sample of the population of Wisconsin anglers and may have caused some bias in the analysis. This was probably a representative sample of anglers but not a random sample of anglers.

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5.) The degree and extent to which individual Great Lakes fishing sites and fisheries are contaminated by toxicants was not considered in this study. Therefore, it is unclear how well the study's findings can be applied to "contaminated" fisheries in California.

6.) Contingent valuation measures the attitudes of anglers, not their behavior. More specifically, it measures an anglers stated willingness to pay or compensate, not the actual behavior of paying or compensating.

(*1) Lyke, Audrey J., Dissertation submitted to the Graduate School of the University of

Wisconsin-Madison, 1993.

(*2) U.S. EPA Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule. June 1997.

Response to: CTR-041-048

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA Chapter 8). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to CTR-035-009a.)

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters.

However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

EPA agrees that the contingent valuation method (CVM) elicits an individual's stated willingness to pay or accept compensation. The benefit-cost comparisons in EAs are prepared to inform the public and policy makers. Thus, the strengths and weaknesses of all aspects of the EA, including methodologies for estimating benefits, need to be made clear so that readers are aware of the limits and uncertainties. However, a 1993 Blue Ribbon Panel convened by the National Oceanic and Atmospheric Administration (NOAA) evaluated CVM and found it to be an appropriate methodology for measuring values. It is also the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values and has withstood Federal Court review for its use in litigation contexts.

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Bishop, R.C. and T.A. Heberlein. 1978. Measuring values of extra-market goods: Are indirect measures biased? American Journal of Agricultural Economics 61(5): 926-930.

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U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

Comment ID: CTR-044-043
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02 Benefits Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: ATTACHMENT: 3 - 2 A Criteria Review of: "Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study"(*1)

Introduction This dissertation is primarily concerned with examining economic models of natural

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(*1) Lyke, Audrey J., Dissertation submitted to the Graduate School of the University of Wisconsin-Madison, 1993.

(*2) U.S. EPA Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule. June 1997.

Response to: CTR-044-043

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obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA p. 8-17). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

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U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

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Brookshire, D., M. Thayer, W.D. Schulze, and R. d'Arge. 1982. Valuing public goods: A comparison of the survey and hedonic approaches. American Economic Review 72(1): 165-177.

Comment ID: CTR-052-003c
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02 Benefits Analysis
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-13
E-01

Comment: However, the Authority is greatly disappointed that EPA chose not to follow the consensus recommendations for many of the most significant issues, including the methodology used for the EA and the choice of using the most conservative carcinogenicity factor for organic pollutants.

Response to: CTR-052-003c

While EPA agrees that the methodology recommended by the State Task Force on Economic Considerations may be one adequate method for the State to calculate the costs and benefits of State adoption and implementation of water quality standards, EPA never agreed that it would use this method for its own Economic Analysis (EA) for the following reasons:

* EPA's primary responsibility in developing the EA is that it meets the requirements of Executive Order 12866. For program consistency, EPA chose to model the methodology of the EA after the Regulatory Impact Analysis of the Great Lakes Water Quality Guidance which successfully underwent the full Executive Order 12866 process.

* EPA had already established its own methodology and began work on the EA nearly one year before the Task Force began meeting. EPA could not abruptly switch the methodology in the middle of the project due to the limited resources that could be spent on the EA. In addition, many task force members acknowledged that the consensus recommendation was a very resource intensive method and it was uncertain whether adequate data currently existed to bring this methodology to completion. EPA did not have the resources nor the data to perform this type of analysis in the time available.

* The State Task Force recommended a methodology, for future analysis by the State, that would gather ambient data to determine waters that were impaired by toxics, and then determine what actions needed to be taken by point and non-point sources to meet new water quality criteria. EPA determined that this methodology may be appropriate for future State analysis, but was not appropriate for EPA's Economic Analysis since EAs under the CWA typically estimate only costs that EPA can enforce under the Clean Water Act. Therefore, EPA's EA only calculates potential costs and benefits due to controls on NPDES point sources (excluding wet-weather discharges). EPA believes it may be more appropriate for the State to estimate potential impacts on non-point sources since it has the sole authority for enforcing any controls required by non-point sources.

EPA does not agree that its decision to use a 10-6 risk level for carcinogenic pollutants conflicts with any of the State Task Force consensus recommendations. EPA does not observe in the Final Task Force Report, an explicit consensus recommendation of any specific risk level for carcinogenic pollutants.

Comment ID: CTR-052-007
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02 Benefits Analysis
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
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Comment: EPA has greatly overstated the cost to benefit ratio. The EA concludes that the costs and benefits are nearly equal, which implies a cost to benefit ratio approaching unity, i.e. costs divided by benefits is about 1. The critique prepared by M.Cubed indicates that this is quite faulty, in that costs range from two to nine times the benefits as developed by EPA. Others have noted that the benefits are

also very questionable. Using the costs from No. 3, above, and EPA's high-end benefits, results in costs that are anywhere from 4.6 to 11 times the benefits. No rational person would ever spend that kind of money for such little benefit.

Response to: CTR-052-007

EPA believes that the potential benefits of the rule are reasonably similar to the potential costs. EPA also notes that, as described in the EA, the estimate of benefits may be underestimated as a result of omitted benefit categories while the estimate of costs was based on assumptions that tend to overstate costs. For example, reductions in noncancer health effects are omitted because there are currently few means of linking consumption of toxic contaminants by humans with cases of systemic effects (as opposed to cancer effects, for which dose-response curves have been estimated). Other omitted benefit categories include instream and near stream recreational activities other than fishing (e.g., boating, swimming, picnicking, and related activities). EPA believes other recreation benefits may be appreciable because these activities have been shown in empirical research to be highly valued, and even modest changes in participation or user values could lead to sizable benefits statewide. Some of these activities can be closely associated with water quality attributes (e.g., swimming) and others might increase due to their association with fishing, swimming, or other activities in which the participants might engage.

Comment ID: CTR-054-047
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: ATTACHMENT: 3 - 2 A Criteria Review of: "Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study"(*1)

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Conclusions:

1.) There is a lack of data on the value anglers in California place upon reducing toxic contamination to fisheries, so EPA used the increase in values produced by Lyke's model. However, the increases in value which Lyke shows are based on the responses of 274 individual anglers to only two contingent valuation questions in a mail survey containing a total of 64 questions. This is clearly a very small sample of the population of Wisconsin anglers and may have caused some bias in the analysis. This was probably a representative sample of anglers but not a random sample of anglers.

2.) Only anglers who fished for trout and salmon in the Wisconsin Great Lakes were surveyed. These

anglers may not be representative of the typical Wisconsin Great Lakes angler, and this data does not show any valuation for any fishery other than trout and salmon.

3.) It is not clear how EPA derived the upper limit of their potential increase in fisheries value (31.3 percent). It is possible that EPA used the "contaminant free" mean ($377. 18/angler/year) and compared that to the low end value (mean minus the standard error) of the value of the fishery under current conditions ($286.26/angler/year), yielding an increase in value of 31.8 percent. Another portion of Lyke's analysis actually shows "contaminant free" fisheries to be valued lower than the current "contaminated" fishery. Inland fishing anglers who fish for trout and salmon were less willing to pay for a contaminant free fishery. The mean value of the inland fishery under current conditions ($720.12/angler/year) compared to the mean value of a "contaminant free" inland fishery ($597.42/angler/year) yields a loss in value of 17 percent.

4.) There is no evidence than any portion of Lyke's dissertation has undergone peer review outside the University of Wisconsin-Madison. An extensive literature search found no peer reviewed journal publications by the author. Without proper peer review, its methods and conclusions must remain in doubt.

5.) The degree and extent to which individual Great Lakes fishing sites and fisheries are contaminated by toxicants was not considered in this study. Therefore, it is unclear how well the study's findings can be applied to "contaminated" fisheries in California.

6.) Contingent valuation measures the attitudes of anglers, not their behavior. More specifically, it measures an anglers stated willingness to pay or compensate, not the actual behavior of paying or compensating.

(*1) Lyke, Audrey J., Dissertation submitted to the Graduate School of the University of Wisconsin-Madison, 1993.

(*2) U.S. EPA Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule. June 1997.

Response to: CTR-054-047

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA p. 8-17). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish

populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to Issue 3.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA agrees that the contingent valuation method (CVM) elicits an individual's stated willingness to pay or accept compensation. The benefit-cost comparisons in EAs are prepared to inform the public and policy makers. Thus, the strengths and weaknesses of all aspects of the EA, including methodologies for estimating benefits, need to be made clear so that readers are aware of the limits and uncertainties.

However, a 1993 Blue Ribbon Panel convened by the National Oceanic and Atmospheric Administration (NOAA) evaluated CVM and found it to be an appropriate methodology for measuring values. It is also the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values and has withstood Federal Court review for its use in litigation contexts.

Additionally, much of the criticism of CVM is conceptual rather than based on empirical research. Where CVM can be compared to other research techniques (e.g., use values estimated by the travel cost methodology or the hedonic price method), CVM is shown to yield similar values (see Brookshire et al., 1982 and Smith et al., 1986). Additionally, in several field experiments, actual purchase decisions were compared to hypothetical purchase decisions (Bishop and Heberlein, 1978 and Dickie et al., 1987). In all of these studies, hypothetical behavior was sufficiently predictive of actual behavior that researchers concluded meaningful values could be obtained for benefit-cost analysis or damage assessment.

Bishop, R.C. and T.A. Heberlein. 1978. Measuring values of extra-market goods: Are indirect measures biased? American Journal of Agricultural Economics 61(5): 926-930.

Brookshire, D., M. Thayer, W.D. Schulze, and R. d'Arge. 1982. Valuing public goods: A comparison of the survey and hedonic approaches. American Economic Review 72(1): 165-177.

Comment ID: CTR-090-008
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

The propose rule will cost more than EPA estimates, will not be applicable to those discharges that are of most concern and which interfere with the designated uses and therefore the rule will produce less benefits than EPA estimates.

Response to: CTR-090-008

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source

share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

Comment ID: CTR-091-002b
Comment Author: Abu-Saba, Ganguli, Flegal
Document Type: Environmental Group
State of Origin: CA
Represented Org: Coastal Advocates
Document Date: 09/25/97
Subject Matter Code: E-02 Benefits Analysis
References:
Attachments? N
CROSS REFERENCES E-01

Comment: This comment addresses the mercury criteria for continuous concentration (CCC) proposed in 40 CFR, part 131(*1). The proposed aquatic health and human health criteria do not protect aquatic life or humans from mercury contamination. This is demonstrated by the scientific data presented herein. That information includes published and unpublished results from scientists with established reputations in environmental research.

The aquatic life mercury CCC is proposed to be raised sixty-fold, from the National Toxics Rule standard of 0.012 micrograms per liter (ppb) to 0.770 ppb. The human health criteria is proposed to be raised four-fold, from 0.0 12 ppb to 0.050 ppb. These proposed changes have potentially devastating economic and environmental costs that must be included in the EPA's cost-benefit analysis. Water treatment costs for the metals mercury, silver, and chromium account for 30% of costs projected in the, California Toxics Rule (CTR) economic analysis. However, the long term environmental and economic cost of mercury contamination may far exceed the short term economic savings resulting from an increase in the mercury CCC. This is especially true in California, a mining state that has devoted hundreds of millions of dollars to restoration and enhancement of commercial and sport fisheries by enactment of Proposition 204.

The potential long-term economic and environmental costs of this proposed legislation far exceed any short-term benefits gained by raising the mandatory action level for mercury contamination. A stated goal of the recently passed Proposition 204 legislation is the protection and enhancement of commercial and sport fishing in the State of California. To that end, hundreds of millions of dollars have been committed to water quality improvement and fish habitat restoration. Increasing the permissible mercury limits will not only hinder those goals, but will likely cause irreversible damage to the environment well into the foreseeable future.

(*1) Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule. U.S. Environmental Protection Agency, Region Nine; U.S. Government Printing Office: Washington D.C., 1997; Federal Register, 62, 42159-42207.

Response to: CTR-091-002b

The aquatic life criteria have been updated using EPA's peer-reviewed and accepted aquatic life

methodology. The previous 304(a) criteria guidance value was based on an FDA action level for humans, not on aquatic life protection. As such, the previous criteria are not as appropriate to use as the updated criteria proposed in the CTR. The revised criteria are less stringent than the previous criteria.

The human health criteria proposed in the CTR have also been updated using the risk reference dose for methylmercury. The previous 304(a) criteria guidance values were based on the risk reference does for mercury. The revised human health criteria in the CTR are more stringent than the previous human health criteria guidance.

All water quality standards are comprised of three parts: a designated use, and criterion, and an antidegradation policy. The CTR only proposes criteria. The State of California has adopted designated uses for its water bodies (called beneficial uses) in the Regional Water Board Basin Plans. The State has also adopted antidegradation provisions in each of the Regional Board Basin Plans. These provisions require that water quality in a waterbody cannot be degraded (with narrow exceptions as discussed at 40 CFR 131.12(a) (2) which allow a lowering of water quality if the State finds that it is necessary to accommodate important economic or social development). Thus, if a waterbody has achieved a certain level of cleanliness or is in a pristine condition, discharges are not allowed to degrade the water quality. Therefore, no environmental "cost" or degradation will be incurred as a result of any new or revised water quality criteria in the CTR that may be less stringent than a previously adopted objective or a criteria guidance value. Environmental benefits that have been gained in California fisheries or anywhere else cannot be destroyed.

See response to CTR-002-007b.

Subject Matter Code: E-02c Overstated Benefits

Comment ID: CTR-009-008b
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? Y
CROSS REFERENCES E-02o
E-01s

Comment: The City does not agree with the economic analysis. It is incomplete and misrepresents the actual costs and benefits. The analysis does not include costs of expensive AWT to meet more stringent limits based upon the proposed criteria. It does not include the first second, and third order costs to the community, individuals and businesses, of the economic dislocations resulting from huge capital costs, especially for small and economically distressed communities, that divert scarce resources from other priorities or out of the area. It does not include cost impact assessments to low and fixed-income households - ignoring the economic aspects of environmental justice. The benefits assessments make vast unsupported assumptions about the benefits of reductions in constituent concentrations that are barely, if even, measurable, and assigns unrealistic contingent valuations to these assumed benefits. The cost analyses does not follow EPA's own economic assessment guidance (which, itself, is fatally flawed). These points were brought up during the Task Force meetings in 1995 and 1996, but were dismissed outright by EPA. The City hereby raises these issues for the formal record.

The City of Thousand Oaks appreciates the opportunity to comment on the proposed California Toxics Rule.

Sincerely,

Donald H. Nelson Public Works Director

Response to: CTR-009-008b

EPA's own economic assessment guidance (Interim Economic Guidance for Water Quality Standards, EPA-823-B-95-002, March 1995) is intended to assist States and applicants in understanding the economic factors that may be considered, and the types of tests that can be used to determine if a designated use cannot be attained, if a variance can be granted, or if degradation of high-quality water is warranted. In order to remove a designated use or obtain a variance, or if degradation of high-quality water is warranted, the state or discharger must demonstrate that attaining the designated use would result in substantial and widespread economic and social impacts. Although EPA is responsible for approving a State's water quality standards, the State is responsible for interpreting the circumstances of each case and determining where there are substantial and widespread economic and social impacts, or where important social and economic development would be precluded.

Estimating the economic impact of the CTR in California requires a detailed econometric model of the region's economy. EPA did not conduct such an analysis of the rule. However, for a similar toxics rule in

the Great Lakes Basin, an econometric analysis was performed independent of the regulatory impact analysis for the Council of Great Lakes Governors (The Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness. DRI/McGraw-Hill, San Francisco, California, July 1993). This analysis showed a minimal impact of the rule on the region's economy for a worst case scenario, a scenario with costs far exceeding those estimated by EPA. Manufacturing output was estimated to fall by between 0.008% and 0.337% over a range of four scenarios evaluated, while personal income loss was estimated at between 0.002% and 0.094% for these scenarios. As a result, the study authors concluded that the impact of the rule on the region's economy would be "nearly imperceptible." Thus, similar controls on toxic pollutants have been shown to be affordable in other regions of the country.

Comment ID: CTR-035-009b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? N
CROSS REFERENCES E-02f

Comment: We also question the estimates of the benefits derived in the draft Economic Analysis, and believe that more recent information specific to California should be collected and used. In particular, for most of the benefits, estimates are based on a comparison with waters which are completely free of contaminants or unimpaired, which is unrealistic. There is also little evaluation of the marginal benefits of the proposed rule (i.e. the benefits that would be realized as a result of marginal changes in contamination levels). While presumably achievement of the full reductions necessary to meet the CTR criteria in ambient waters is EPA's goal, EPA itself acknowledges that few of the benefits of the CTR are likely to be realized through point source controls, and the Agency fails to demonstrate how the water quality criteria promulgated by the CTR will be achieved.

Response to: CTR-035-009b

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

Water quality improvements often involve thresholds such as action levels for fish consumption advisories. However, water quality regulations often contribute only a portion of the improvement needed to surpass a threshold. Although individuals may (or may not) have a willingness to pay for incremental steps toward crossing a threshold, when the threshold is surpassed (e.g., fish consumption advisories are lifted), every action that contributed to the effort should be allocated a portion of the benefits. This was accomplished for the CTR by allocating a portion of the total toxic-free benefits (proportional to the reduction in loadings) to the implementation of point source controls under the CTR.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-035-065b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? N
CROSS REFERENCES E-02k

Comment: Weaknesses in Benefits Analysis

USEPA's benefits analysis is even weaker than its cost evaluation. For example:

* Although there is evidence that the Rule could result in no benefits in the near-term due to long-term environmental persistence of existing contamination, the Analysis does a poor job of highlighting this potential outcome. For example, there is some likelihood that benefits could truly be zero, while under no circumstances will Rule implementation be costless. Likewise, USEPA's use of ranges to express potential benefit values may mislead readers into believing that the estimated high benefits are as likely to be achieved as the low benefits, when in fact the probability that different benefit levels will actually be achieved varies greatly from low to high.

Response to: CTR-035-065b

The range of estimated benefits in part reflects the range in loadings reductions that may result from point source controls given the flexibility in State implementation procedures. The decision as to which

implementation procedures will be employed, and therefore what costs and benefits will result, will be made by state and local entities for specific locations.

Comment ID: CTR-035-068
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? N
CROSS REFERENCES

Comment: * Most of the benefits estimates are based on a comparison with waters which are "completely unimpaired", "contaminant free," or "completely free of pollutants that may threaten human health." Even if point source reductions are fully obtained, California's waters will remain polluted from non-point sources and contaminants already in the environment for the foreseeable future. In fact, it is unlikely that most state waters will ever be completely unimpaired, and the use and non-use values associated with complete purity may be considerably higher than the more likely outcome of long-term small-scale contamination.

Response to: CTR-035-068

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-040-008c
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01c02
E-01m

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* Estimates of potential costs are severely constrained due to certain assumptions including the assumption that regulatory relief from the Rule will be granted if costs are in excess of certain thresholds.

* Estimates of potential benefits are exaggerated by assuming, that the proposed water quality criteria will actually be achieved in receiving water bodies. This will not result from the implementation of the Rule because the Rule is only addressing permitted discharges to the receiving water bodies.

* The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated.

Response to: CTR-040-008c

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA does not believe that estimates of potential costs are constrained due to assumptions regarding regulatory relief from the Rule. Although EPA considered an industry category cost threshold under the low cost scenario, beyond which a facility was assumed to pursue regulatory relief, no such assumption was used for the high cost scenario. That is, under the high scenario all necessary pollutant reductions were assumed to be achieved through either treatment or a waste control program (e.g. waste minimization pollution prevention).

Comment ID: CTR-040-043
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Benefits

The benefits analysis overstates benefits by assuming an end (i.e., achievement of the water quality criteria) that will not result from the CTR. The CTR will impact point sources, which EPA acknowledges are only a small portion of the toxic pollutant load (3% of the load to freshwater and 1%-11% of the load

to San Francisco Bay). The major sources of toxic pollutants, nonpoint sources, are not regulated under the Clean Water Act or the CTR.

Response to: CTR-040-043

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Although the standards established by the CTR apply to the waterbody (i.e., inland surface waters and enclosed bays and estuaries), EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

Comment ID: CTR-041-039
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Benefits

The benefits analysis overstates benefits by assuming an end (i.e., achievement of the water quality criteria) that will not result from the CTR. The CTR will impact point sources, which EPA acknowledges are only a small portion of the toxic pollutant load (3% of the load to freshwater and 1 %-11% of the load to San Francisco Bay). The major sources of toxic pollutants, nonpoint sources, are not regulated under the Clean Water Act or the CTR.

Response to: CTR-041-039

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-043-004d
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? Y
CROSS REFERENCES E-01g
E-01h
E-01m
E-01c02

Comment: 4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution;

(2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements;

(3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and

(4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule.

The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act.

Response to: CTR-043-004d

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA does not believe that estimates of potential costs are constrained due to assumptions regarding regulatory relief from the Rule. Although EPA considered an industry category cost threshold under the low cost scenario, beyond which a facility was assumed to pursue regulatory relief, no such assumption was used for the high cost scenario. That is, under the high scenario all necessary pollutant reductions were assumed to be achieved through either treatment or a waste control program (e.g. waste minimization pollution prevention).

EPA's EA, which uses many conservative costing assumptions, indicates that the cost of the State implementing water quality standards based on the proposed criteria in the CTR is likely to be below

$100 million per year. Benefits are also estimated to be below $100 million per year. These estimates indicate that the action is not "significant" under E.O. 12866, under the provision concerning annual effects on the economy.

Criteria, by themselves, do not directly impose economic impacts. Criteria are one of three parts of a water quality standard. A water quality standard is comprised of: a criterion, a designated use, and an antidegradation policy. California currently has a narrative criterion stating that there shall be no toxic in toxic amounts. Pursuant to this narrative criterion, which are the basis for this rule. Under this scenario, the rule would have no costs. Under the second scenario, assumes that without this rule, the current permit conditions for point sources would continue in the future. Under this second scenario, EPA assessed a range of potential costs that would be incurred for point sources to meet these criteria - the low end being based on current effluent concentrations, the high end being based on current permit limits. [Pursuant to this analysis, it has been determined that this is not a significant regulatory action subject to OMB review.] See the preamble for the final rule.

The Unfunded Mandates Reform Act of 1995 (UMRA) in general requires federal agencies to assess the effects of their regulatory actions on State and local governments, and on the private sector. The agency must prepare a written statement including a cost-benefit analysis for actions with a "federal mandate" that may result in expenditures to State and local governments, in the aggregate, or to the private sector of $100 million or more in any one year. The CTR does not contain any federal mandate that may result in expenditures by State and local governments, or the private sector, of $100 million or more in any one year. The CTR imposes no direct enforceable duties on the State, local or private sector; rather the rule promulgates water quality criteria which, when combined with State-adopted designated uses and antidegradation requirements, will create water quality standards. The CTR does not directly regulate or affect any entity and therefore is not subject to the requirements of UMRA. See the preamble to the final rule.

See also response to CTR-050-007a.

Comment ID: CTR-044-005d
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? Y
CROSS REFERENCES E-01g08
E-01h01
E-01m
E-01c02
R
S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005d

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA does not believe that estimates of potential costs are constrained due to assumptions regarding regulatory relief from the Rule. Although EPA considered an industry category cost threshold under the low cost scenario, beyond which a facility was assumed to pursue regulatory relief, no such assumption was used for the high cost scenario. That is, under the high scenario all necessary pollutant reductions were assumed to be achieved through either treatment or a waste control program (e.g. waste minimization pollution prevention).

EPA's EA, which uses many conservative costing assumptions, indicates that the cost of the State implementing water quality standards based on the proposed criteria in the CTR is likely to be below $100 million per year. Benefits are also estimated to be below $100 million per year. These estimates indicate that the action is not "significant" under E.O. 12866, under the provision concerning annual effects on the economy.

California currently has a narrative criterion stating that there shall be no toxic in toxic amounts. Pursuant to this narrative criterion, which are the basis for this rule. Under this scenario, the rule would have no costs. Under the second scenario, assumes that without this rule, the current permit conditions for point sources would continue in the future. Under this second scenario, EPA assessed a range of potential costs that would be incurred for point sources to meet these criteria - the low end being based on current effluent concentrations, the high end being based on current permit limits. [Pursuant to this analysis, it has been determined that this is not a significant regulatory action subject to OMB review.] See the preamble for the final rule.

The Unfunded Mandates Reform Act of 1995 (UMRA) in general requires federal agencies to assess the effects of their regulatory actions on State and local governments, and on the private sector. The agency must prepare a written statement including a cost-benefit analysis for actions with a "federal mandate" that may result in expenditures to State and local governments, in the aggregate, or to the private sector of $100 million or more in any one year. The CTR does not contain any federal mandate that may result in expenditures by State and local governments, or the private sector, of $100 million or more in any one year. The CTR imposes no direct enforceable duties on the State, local or private sector; rather the rule

promulgates water quality criteria which, when combined with State-adopted designated uses and antidegradation requirements, will create water quality standards. The CTR does not directly regulate or affect any entity and therefore is not subject to the requirements of UMRA. See preamble to the final rule.

See also the response to CTR-050-007a.

Comment ID: CTR-044-034
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Benefits

The benefits analysis overstates benefits by assuming an end (i.e., achievement of the water quality criteria) that will not result from the CTR. The CTR will impact point sources, which EPA acknowledges are only a small portion of the toxic pollutant load (3% of the load to freshwater and 1 %-11% of the load to San Francisco Bay). The major sources of toxic pollutants, nonpoint sources, are not regulated under the Clean Water Act or the CTR.

Response to: CTR-044-034

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-054-038
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:

Attachments? N
CROSS REFERENCES

Comment: Review of EPA's Analysis of Potential Benefits

The benefits analysis overstates benefits by assuming an end (i.e., achievement of the water quality criteria) that will not result from the CTR. The CTR will impact point sources, which EPA acknowledges are only a small portion of the toxic pollutant load (3% of the load to freshwater and 1 %-11% of the load to San Francisco Bay). The major sources of toxic pollutants, nonpoint sources, are not regulated under the Clean Water Act or the CTR.

Response to: CTR-054-038

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-061-018
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02c Overstated Benefits
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42190, bottom of the first and all of the second and third columns, discuss benefits. This discussion on the benefits of achieving these criteria is superficial, at best. There is no way to reliably estimate the improvement in the real water quality - beneficial uses arising from the adoption of these criteria since the database needed to relate the exceedances of the criteria to real water quality use-impairments does not exist. Many of the exceedances that are now occurring are "administrative" exceedances related to overly protective approaches dictated by the US EPA that have been and will likely continue to be used in implementing the criteria into discharge limits.

Response to: CTR-061-018

EPA defined toxic-impaired waters as waters rated medium or poor quality for at least one or more toxic pollutant or group of pollutants. EPA acknowledged that this definition may result in an overestimate of toxic-impairment (EA Chapter 8). However, the rating of these waters corresponds to EPA's categories of

'not fully supporting' and 'partially supporting' designated uses. The existence of waters not supporting and only partially supporting designated uses is indicative of the need for and benefits associated with pollution controls.

Subject Matter Code: E-02d Passive Use Value

Comment ID: CTR-026-009
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02d Passive Use Value
References:
Attachments? N
CROSS REFERENCES

Comment: 9. ECONOMIC ANALYSIS

The document entitled "Economic Analysis of the Proposed California Water Quality Toxics Rule" examines in large part the benefits and costs of changes in water quality due to point source dischargers implementation actions using the CTR-based water quality standards. This comment addresses the approach to quantifying benefits know as "passive use values" held by the public. We believe that a "rule of thumb" ratio of 50% or 0.5 for passive use values to active use values is overly conservative and leads to a significant understatement of the potential benefits of water quality improvements.

The CDFG has recently hired Dr. John Loomis (Colorado State University, Fort Collins) to establish such a passive use to active use value ratio, for small scale changes in the quality and/or quantity of natural resources and the services they provide to the public. Dr. Loomis conducts a comprehensive review of the resource economics literature and provided a conservative estimate of 1.43 versus the 0.50 used in the Economic Analysis performed for the CTR. We believe that should the US EPA attempt to quantify passive use benefits of the CTR, that a more appropriate use value ratio (or rule of thumb) is 1.43 rather than the 0.5 currently used in the analysis.

Response to: CTR-026-009

EPA reviewed the recent review by Dr. John Loomis referenced by the commenter (Loomis, 1997). Dr. Loomis conducted this review for application to the California Type A Model for simplified damage assessments under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980.

Dr. Loomis compiled studies from several previous reviews, including Fisher and Raucher (1984), Bishop et al. (1993), and Brown (1993). Each study used different approaches for calculating the ratio of passive use to use values, including comparison of use and passive use values, relying on respondents to prorate their willingness to pay between use and passive use components, and obtaining values when respondents are asked to assume active use is zero. Dr. Loomis notes that the prorating approach can yield higher estimates of the ratio than other approaches. He calculated his ratio of 1.43 by averaging across ratios calculated by all methods employed, after excluding outliers (three studies showing ratios of greater than 6) and studies involving unique resources or endangered species (studies involving bald eagles, grizzly bears, whooping cranes, and Mono Lake were not deemed appropriate for application to small oil spills).

As described in the EA accompanying the proposed CTR, in applying a rule of thumb such as the ratio of

passive use to use values, it is important to consider the extent to which the primary research efforts have evaluated resources and changes in resource conditions that are reasonably comparable to the CTR (see Chapter 8 EA). EPA considered the studies evaluated by Fisher and Raucher (1984) and which indicated a ratio of 0.5 more applicable to the CTR than studies indicating potentially higher ratios. For example, a study by Sanders et al. (1990) indicated a ratio of approximately 1.8 or 1.9, however, the results are based on the value of preserving several free-flowing river segments in Colorado from the development of dams and other major, irreversible hydrological modifications.

Dr. Loomis' review also includes studies that value environmental changes substantially different from those expected under the CTR. For example, a study by Haefele, et al (1992) estimates the total value of forest quality in high elevation spruce forests. This study contributes ratios of 10.74 and 6.7 to Dr. Loomis' review. A study by King et al (1988) , which contributed a ratio of 7.57, estimated the value of a herd of desert bighorn sheep. In addition, Dr. Loomis excluded studies of unique resources and endangered species (e.g., bald eagles) because of a lack of applicability to small oil spills; unique resources and endangered species are of relevance to the CTR.

Dr. Loomis' review of the ratio EPA applied to estimate passive use benefits for the CTR indicates that this ratio may be conservatively estimated. However, for the CTR, EPA used a less conservative application of the ratio compared to previous applications. That is, the selected ratio is typically multiplied by use values (e.g., recreational angling values for the CTR, nonconsumptive use values for the CERCLA Type A Model) to estimate passive use values. This application may be conservative because, in effect, passive use values are only being counted for resource users. To include passive use values for nonusers in its analysis of benefits for the CTR, EPA estimated passive use values for nonangling California households.

References

Bishop, R. M. Welsh, and S. Press. 1993. The CERCLA Type-A Natural Resource Damage Assessment Model for the Great Lakes Environment. Vol. 1, Draft.

Brown, T. 1993. Measuring Non-use Values: A Comparison of Recent Contingent Valuation Studies, in Benefits and Cost Transfers in Natural Resource Planning, Sixth Interim Report, J.C. Bergstrom, Compiler. Department of Agricultural and Applied Economics, University of Georgia, Athens, Georgia.

Fisher, A. and R. Raucher. 1984. Intrinsic Benefits of Improved Water Quality: Conceptual and Empirical Perspectives, Advances in Micro-Economics, V.K. Smith and A.D. Witte, eds. Vol. 3, JAI Press, Greenwich, CT.

Haefele, M., R.Kramer, and T. Holmes. 1992. Estimating the Total Value of Forest Quality in High Elevation Spruce Forests, in The Economic Value of Wilderness: Proceedings of the conference. GTR SE-78, Southern Forest Experiment Station. U.S. Forest Service, Asheville, NC.

King, D.A. , D.J. Flynn, and W.W. Shaw. 1988. Total and Existence Values of a Herd of Desert Bighorn Sheep. Benefits and Costs in Natural Resource Planning, Interim Report. Western Regional Research Publication W-133.

Loomis, J. 1997. Calculation of Nonuse Value Ratios and Documentation for the California Type A Model. Department of Agricultural and Resource Economics, Colorado State University, Fort Collins, CO.

Sanders, L.D., R.G. Walsh, and J.B. Loomis. 1990. "Toward Empirical Estimation of the Total Value of Protecting Rivers." Water Resources Research. 26(7):1345-1357.

Comment ID: CTR-035-055
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02d Passive Use Value
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 8-24 - 8-27 (U.S. EPA, 1997a) -- Passive Use Benefits The Economic Analysis assumes that a substantial portion of the benefits would accrue from passive use benefits (about 60% for the low end estimate and 70% for the high end estimate). We believe that, based on the number and type of assumptions required, and the reliance on studies of other types of passive use benefits (e.g. avoidance of mining activities or building a dam), these estimates are extremely tenuous. None of the studies cited examined the marginal benefits of incremental improvements in concentrations of toxic pollutants, nor were any of the studies based in California. Furthermore, it does not appear that EPA apportioned the passive use benefits attributable to improvements in water quality that will occur as a result of the CTR, as was done for other benefit categories. We recommend that the inclusion of quantitative estimates be reconsidered for passive use benefits, and, at most, only that portion representing the benefits attributable to the CTR be included.

Response to: CTR-035-055

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. Research also indicates that these values are at least half as great as recreational values, such that if they are potentially applicable to a policy action, providing a rough approximation is preferable, with proper caveats, to omitting them from the analysis of benefits and costs. EPA believes that the studies used to calculate the ratio of passive use to use value are applicable to the CTR (see also comment and response CTR-026-009).

Therefore, EPA applies a ratio of .5 to obtain an estimate of passive use values for those households that have active recreational anglers. Based on a review of the literature, EPA believes that non-angling household do indeed have a passive use value. To determine a lower-bound estimate of passive use values for non-angling households, EPA assumed that the value may be 30% of the value for angling households. For analysis of the final CTR, EPA revised the upper-bound estimate assuming that the passive use value of non-angling households may be 90% of those for angling households. This revision is based on a study by Loomis et al. (1991), who estimated the benefits of improved fishery, wetland, and waterfowl resources in the San Joaquin Valley to users and nonusers residing in California.

By multiplying a ratio of passive use to use value by recreational fishing values, which EPA apportioned to reflect the relative contribution of point sources, EPA also accounted for attribution in its estimate of passive use values.

Comment ID: CTR-040-047
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02d Passive Use Value
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's estimate of passive use benefits ($36.3 million annually under the high-end scenario and 70% of the total estimated benefits) is erroneous. First, it is based on an unsupported assumption that non-use values (e.g., property values) are depressed in California because of pollution. Second, it is based on the assumption that the water quality criteria will be achieved as a result of the CTR, which as previously stated, is not the case.

Response to: CTR-040-047

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. EPA believes that these studies are applicable to the CTR. EPA also believes that its assessment of toxic impairment of California, based on data and information compiled by the State Water Resource Control Boards, is reasonably accurate.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of the State's actions that may control other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-041-043
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02d Passive Use Value
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of passive use benefits ($36.3 million annually under the high-end scenario and 70% of the total estimated benefits) is erroneous. First, it is based on an unsupported assumption that non-use values (e.g., property values) are depressed in California because of pollution. Second, it is based on the assumption that the water quality criteria will be achieved as a result of the CTR, which as previously stated, is not the case.

Response to: CTR-041-043

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. EPA believes that these studies are applicable to the CTR. EPA also believes that its assessment of toxic impairment of California, based on data and information compiled by the State Water Resource Control Boards, is reasonably accurate.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of the State's actions that may control other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-044-038
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02d Passive Use Value
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of passive use benefits ($36.3 million annually under the high-end scenario and 70% of the total estimated benefits) is erroneous. First, it is based on an unsupported assumption that non-use values (e.g., property values) are depressed in California because of pollution. Second, it is based on the assumption that the water quality criteria will be achieved as a result of the CTR, which as previously stated, is not the case.

Response to: CTR-044-038

As described in the EA (p. 8-22), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. EPA believes that these studies are applicable to the CTR. EPA also believes that its assessment of toxic impairment of California, based on data and information compiled by the State Water Resource Control Boards, is reasonably accurate.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-054-042
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02d Passive Use Value

References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of passive use benefits ($36.3 million annually under the high-end scenario and 70% of the total estimated benefits) is erroneous. First, it is based on an unsupported assumption that non-use values (e.g., property values) are depressed in California because of pollution. Second, it is based on the assumption that the water quality criteria will be achieved as a result of the CTR, which as previously stated, is not the case.

Response to: CTR-054-042

As described in the EA (p. 8-22), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. EPA believes that these studies are applicable to the CTR. EPA also believes that its assessment of toxic impairment of California, based on data and information compiled by the State Water Resource Control Boards, is reasonably accurate.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Subject Matter Code: E-02e Include Omitted Benefits

Comment ID: CTR-029-004b
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02e Include Omitted Benefits
References:
Attachments? N
CROSS REFERENCES E-01c02

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

The Proposed Rule's Economic Analysis Over-Emphasizes Costs and Under reports the Benefits of Improving Water Quality Throughout the State

By EPA's own admission, the proposed rule's economic analysis over-reports costs and under-reports benefits. Specifically, the proposed rule states that "cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because the analysis tended to use conservative assumptions."(*8) Conversely, "numerous categories of potential or likely benefits have been omitted" from the analysis, and these omitted benefits "are likely to be significant contributors" to an "appreciable underestimation" of the overall benefits of the rule.(*9) Categories left out of the benefits analysis include improvements in water-related, non-fishing recreation, improvements in land recreation, and improvements in human health resulting from reducing non-cancer risk."(*10)

CMC believes it is possible to quantify many of these omitted benefits to obtain a more accurate picture of the importance of this rule. For example, a recent Santa Monica Bay Restoration Project Study found that people swimming close to storm drains face a 50% increase in their risk of contracting a variety of non-cancer ills such as gastroenteritis and ear and other infections. At a minimum, EPA's analysis could capture the benefits of improved water quality in terms of avoided sick days and avoided medical costs for such users.

CMC also believes that the economics analysis should consider other categories of benefits not mentioned at all in the proposed rule. For example, Governor Wilson's March 1997 planning document, California's Ocean Resources: An Agenda for the Future, finds that industries that depend on healthy coastal and ocean waters contribute $17.3 billion to the state's economy each year and support 370,000 jobs. The majority of this total, $10 billion, is from tourism, which is not mentioned in the proposed rule but which could benefit greatly from improved water quality. Such omitted benefits should be examined in order to have a more balanced economic analysis.

The adequacy of the proposed rule's economic analysis is important to the long-term implementation of the rule. As reported by EPA, "[t]he allegation that the State did not sufficiently consider economics when adopting Water quality objectives ... was an important issue in the litigation" that resulted in the rescission of the Enclosed Bays and Estuaries Plan and the Inland Surface Waters Plan.(*11) Moreover, an accurate description of the benefits of the proposed rule is critical to obtaining funding and public support for swift implementation of the numeric criteria. CMC thus requests that the benefits analysis be updated where possible to parallel the acknowledged "conservative" approach used in estimating the costs of the proposed rule.

(*8) Id. at 42189.

(*9) Id. at 42190.

(*10) Id.

(*11) Id. at 42165.

Response to: CTR-029-004b

EPA acknowledges that it was unable to monetize all categories of potential benefits from the rule. EPA provided a qualitative description of the expected benefits and those unmonetized benefits that may contribute most substantially to total benefits.

Illnesses contracted from swimming, such as those evaluated in the study of storm water drains in Santa Monica Bay, typically result from exposure to pathogens that will not be regulated under the CTR. Noncancer effects from the toxic pollutants that will be reduced by the rule are difficult to quantify because of a lack of information on the link between concentrations in the environment and potential cases of systemic effects.

Secondary benefits (e.g., tourism) or economic impacts embody the successive rounds of spending in an economy that result from the primary benefits of a regulation. These secondary benefits (or impacts) are estimated based on the analysis of data on interindustry linkages within a region. Although these impacts may be of relevance to policymakers, the inclusion of secondary benefits may be inappropriate. This is because under conditions of reasonably full employment, the resources placed into support services (or diverted from complying entities) would be diverted from (or redirected toward) other productive purposes (i.e., net jobs would not be created or lost for otherwise unemployed individuals but, rather, workers would be drawn to or away from other jobs). Thus, these secondary impacts represent a transfer or redistribution of resources rather than changes in real economic activity.

The benefits of water quality improvements are highly site specific and difficult to monetize due to

limitations in benefits methodology and accurate data on society's values for these improvements. For example, there are currently few means of linking consumption of toxic contaminants by humans with cases of systemic effects (as opposed to cancer effects, for which dose-response curves have been estimated). As another example, the contingent valuation (CV) is the only method for estimating passive use values, and CV surveys require substantial resources to conduct. As a result, there is limited data and information with which to estimate the benefits of the proposed rule. Since these values are not known, a parallel conservative approach is not possible. EPA presented the information on the limitations of the analysis (e.g., costs may be overstated and benefits may be understated) to assist decisionmakers in evaluating the results.

Comment ID: CTR-092-023a
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02e Include Omitted Benefits
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-02l
E-02q

Comment: Comment #7: General Benefit Analysis Concerns

The benefit analysis undertaken by EPA uses old, out-of-state data which does not appear applicable to California. A major concern with this analysis is that the benefit recipients are only a subset of those impacted by the costs. Another is that the benefits accrue to the public at large; costs, on the other hand, to the extent that CTR-implementation costs are borne by Indirect Dischargers (as assumed by EPA in the copper situation) accrue to businesses.

Further, the benefit measurements of "angling day" are only useful if they represent a net increase in fishing activity -- if all that improving waterway quality does is create additional sites where safe fishing can occur, without increasing the overall amount of fishing that occurs, there is no net gain, there is only substitution between comparable sites. The value of benefits which occur because of substitution between fishing sites must be subtracted from the value which occurs from increased fishing. This has not been done in the EPA analysis, thus benefits are overstated.

Further, no stratification is evident to account for importation of out-of-state fishers -- including benefit value of attracting new anglers from other states to California fishing sites is irrelevant to an analysis of costs/benefits of implementing the CTR for California.

Questions for EPA on Comment #7:

Q.7 - 1) If the concerns stated above were appropriately addressed, what would be the impact on EPA's benefits analysis? Our concern relates to the need to examine levels of regulation in comparison to benefits obtained, i.e. cost-effectiveness.

Q.7 - 2) Executive Order 12866, in recognition that quantification of benefits is very difficult, is quite

explicit about addressing qualitative benefits wherever possible why wasn't that done in this analysis?

Response to: CTR-092-023a

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Although it is true that the direct costs of the regulation are borne by municipal and industrial dischargers while the benefits accrue to the public at large, it is also true that in generating the discharges, the benefits (cost savings) accrued to businesses and municipalities while the costs (decreased utility associated with water resources) were borne by the public. Ultimately, benefits and costs are borne throughout society (e.g., costs are borne directly by municipal and industrial dischargers but indirectly by the public who pays for their products and services).

EPA acknowledged that increased angling activity at sites experiencing reductions in toxic contaminants may reflect a shift in activity from substitute sites rather than a net increase. Because EPA could not account for substitute sites in this analysis, EPA estimated lower bound benefits of $0 (i.e., assuming no net increases in activity; see EA, Chapter 8).

EPA's estimate of the relevant angling population is based on resident California anglers (see Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule, Draft, December 20, 1996, pp. 3-23, 3-35 to 3-36).

EPA revised its economic analysis in response to comments and to reflect any new data or changes to the proposal.

(EPA revised.....already part of text)....The estimated cost-effectiveness of the rule is expected to range from $22/lb-eq to $31/lb-eq. EPA expects the total annual, monetized benefits from implementation of the CTR to range from $8.7 to $40.8 million dollars.

Chapter 6 of the EA (Qualitative Assessment of Potential Ecological Benefits) provides a qualitative discussion of potential ecological benefits. EPA also provided a qualitative discussion of important benefit categories that it was not able to quantify or monetize (see the EA that accompanied the proposed rule, Chapter 8).

Subject Matter Code: E-02f Use More Recent Data

Comment ID: CTR-035-009a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? N
CROSS REFERENCES E-02c

Comment: We also question the estimates of the benefits derived in the draft Economic Analysis, and believe that more recent information specific to California should be collected and used. In particular, for most of the benefits, estimates are based on a comparison with waters which are completely free of contaminants or unimpaired, which is unrealistic. There is also little evaluation of the marginal benefits of the proposed rule (i.e. the benefits that would be realized as a result of marginal changes in contamination levels). While presumably achievement of the full reductions necessary to meet the CTR criteria in ambient waters is EPA's goal, EPA itself acknowledges that few of the benefits of the CTR are likely to be realized through point source controls, and the Agency fails to demonstrate how the water quality criteria promulgated by the CTR will be achieved.

Response to: CTR-035-009a

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

Water quality improvements often involve thresholds such as action levels for fish consumption

advisories. However, water quality regulations often contribute only a portion of the improvement needed to surpass a threshold. Although individuals may (or may not) have a willingness to pay for incremental steps toward crossing a threshold, when the threshold is surpassed (e.g., fish consumption advisories are lifted), every action that contributed to the effort should be allocated a portion of the benefits. This was accomplished for the CTR by allocating a portion of the total toxic-free benefits (proportional to the reduction in loadings) to the implementation of point source controls under the CTR.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-035-051b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? N
CROSS REFERENCES E-02g
E-02k

Comment: C. Benefits Analysis pp. 5-7 - 5-8 (U.S. EPA, 1997a) -- Attribution of Benefits to the Control of Point Sources

We applaud EPA's effort to analyze and report the proportion of the total benefits that might accrue due to the implementation of controls on point source NPDES dischargers in the benefits analysis (although we believe that this apportionment should have been carried through to the estimates of passive use benefits). We believe that it is appropriate to state the benefits that can be attributed to the estimated expenditures. We recognize, however, that there are many limitations in this approach, and that better data are needed. For instance, the pollutant loadings data used in this analysis were old and outdated (specifically, the Davis and NOAA studies contained data that are 10-15 years old). We urge EPA to update these studies with more recent data for the final Economic Analysis.

We believe that the benefits analysis illustrates that, in many instances, point source controls will not produce significant benefits. For instance, this is illustrated by the fact that the projected health benefits of the CTR in reducing both cancer and baseline systemic risks are minimal (see pp, 8-11 - 8-16, (U.S. EPA, 1997a)). Another example is illustrated by an examination of those water bodies for which fish consumption advisories have been issued. For those included on the State's 303(d) list, except for San Francisco Bay, the causes of impairment are largely listed by the SWRCB as nonpoint sources, including mining or resource extraction, agricultural drainage or runoff, urban stormwater runoff, or other unspecified nonpoint sources (SWRCB, 1996).

In addition, the analysis of benefits should highlight more clearly the fact that there may be little or no benefits in the near-term due to long-term environmental persistence of existing contamination. As EPA itself acknowledges on p. 5-8 (U.S. EPA, 1997a), "historical loads may, in some instances, be the predominant source of toxics-related water quality problems. In such instances, efforts to control current

discharges may be of relatively limited effectiveness and value." It is well-documented that some substances, such as DDT and PCBs, which have been banned for two or more decades, still persist in the environment; thus, the likelihood of the CTR substantially reducing loadings and producing benefits is minimal.

Response to: CTR-035-051b

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. Research also indicates that these values are at least half as great as recreational values, such that if they are potentially applicable to a policy action, providing a rough approximation is preferable, with proper caveats, to omitting them from the analysis of benefits and costs. EPA believes that the studies used to calculate the ratio of passive use to use value are applicable to the CTR (see also comment and response CTR-029-009).

Therefore, EPA applies a ratio of .5 to obtain an estimate of passive use values for those households that have active recreational anglers. Based on a review of the literature, on studies that estimate resource values fo users and non-users (see the revised economic analysis), EPA believes that non-angling household do indeed have a passive use value. To determine a lower-bound estimate of passive use values for non-angling households, EPA assumed that the value may be 30% of the value for angling households. For analysis of the final CTR, EPA revised the upper-bound estimate assuming that the passive use value of non-angling households may be 90% of those for angling households. This revision is based on a study by Loomis et al. (1991), who estimated the benefits of improved fishery, wetland, and waterfowl resources in the San Joaquin Valley to users and nonusers residing in California.

By multiplying a ratio of passive use to use value by recreational fishing values, which EPA apportioned to reflect the relative contribution of point sources, EPA also accounted for attribution in its estimate of passive use values.

For the EA that accompanied the proposal, EPA conducted an extensive search of the literature for more recent data or information related to the relative contributions of various sources to water quality impairments. In the EA accompanying the proposal, EPA solicited additional data, however, none was received. In revising the EA for the final rulemaking, EPA conducted an additional extensive search of the literature and research efforts at California universities for relevant information. EPA has incorporated any new information into the revised EA for the final rule.

The standards established in the CTR apply to all waterbodies. EPA currently only applies water quality based effluent limits to point sources, and thus the estimate of post-regulation risk levels reflect only the potential impact of controls on point sources. However, controls will also be required of other sources in the future. As controls on other sources are implemented (e.g., remediation of contaminated sediments; best management practices to control storm water discharges and runoff from agricultural land), EPA expects that concentrations in fish tissue will decline further and that the standards established by the CTR to protect human health can be achieved.

EPA also believes that the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point sources effluents, however, the facilities discharging these pollutants may not be included in the sample.

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA recognizes the persistence of some of the substances addressed by the CTR (e.g., DDT and PCBs) and the impact of this persistence on the realization of benefits. In the EA (Chapter 9), EPA accounted for this lag by assuming 10- and 20-year phase-in periods for benefits in its comparison of present value benefits and costs.

In addition, EPA believes that point source controls can factor into pollutant reduction scenarios, although the cost-effectiveness of point and nonpoint source controls are likely to be highly site specific. Potential "hidden" loads (contaminant concentrations which are not currently measured because they are below detection levels) from point sources may also be occurring and may increase the potential benefits of point source controls. In addition, point source loadings reductions will reduce future sediment contamination and, thereby, reduce the need for costly site-specific sediment remediation in the future. Therefore, the CTR can be viewed as both reducing current environmental risks (yielding benefits) by reducing current loadings, and reducing future environmental cleanup costs.

Comment ID: CTR-045-010
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? Y
CROSS REFERENCES

Comment: For the benefits analysis, EPA should utilize more California-specific and recent information.

Response to: CTR-045-010

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Comment ID: CTR-056-021
Comment Author: East Bay Municipal Util. Dist.

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-02f Use More Recent Data
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Regarding the benefits analysis, EPA should use more recent information and information specific to the state of California to develop their assessment of the value of the benefits resulting from the implementation of the CTR. We believe that by considering these two factors alone, the benefit value is more likely to be on the low side of the $1.5 to $51.7 million/year estimate provided by EPA. Also, a consideration which was not included as an adverse side-effect of enhancing beneficial uses of inland surface waters and enclosed bays and estuaries is the increased pollutant loading along the margins of the water body linked to increased recreational activities (e.g. increased pollution associated with recreational boating).

Response to: CTR-056-021

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

EPA believes that the environmental impacts of the pollutants regulated by the CTR far exceed those associated with recreational boating, and that pollutants generated by boating are already regulated to ensure minimal impacts on water resources.

Comment ID: CTR-066-014
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* With regard to the benefits analysis, we believe EPA should utilize more California-specific and recent information.

Response to: CTR-066-014

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Comment ID: CTR-082-008
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* For the benefits analysis, EPA should utilize more California-specific and recent information.

Response to: CTR-082-008

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Comment ID: CTR-085-017
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: E-02f Use More Recent Data
References:
Attachments? N
CROSS REFERENCES

Comment: The District supports the following positions of CASA and SCAP where changes need to be

made in the proposed California Toxics Rule:

* For the benefit analysis, the EPA should utilize more California-specific and recent information.

Response to: CTR-085-017

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Subject Matter Code: E-02g Benefits & Poll. Reduction

Comment ID: CTR-035-051a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References:
Attachments? N
CROSS REFERENCES E-02f
E-02k

Comment: C. Benefits Analysis pp. 5-7 - 5-8 (U.S. EPA, 1997a) -- Attribution of Benefits to the Control of Point Sources

We applaud EPA's effort to analyze and report the proportion of the total benefits that might accrue due to the implementation of controls on point source NPDES dischargers in the benefits analysis (although we believe that this apportionment should have been carried through to the estimates of passive use benefits). We believe that it is appropriate to state the benefits that can be attributed to the estimated expenditures. We recognize, however, that there are many limitations in this approach, and that better data are needed. For instance, the pollutant loadings data used in this analysis were old and outdated (specifically, the Davis and NOAA studies contained data that are 10-15 years old). We urge EPA to update these studies with more recent data for the final Economic Analysis.

We believe that the benefits analysis illustrates that, in many instances, point source controls will not produce significant benefits. For instance, this is illustrated by the fact that the projected health benefits of the CTR in reducing both cancer and baseline systemic risks are minimal (see pp, 8-11 - 8-16, (U.S. EPA, 1997a)). Another example is illustrated by an examination of those water bodies for which fish consumption advisories have been issued. For those included on the State's 303(d) list, except for San Francisco Bay, the causes of impairment are largely listed by the SWRCB as nonpoint sources, including mining or resource extraction, agricultural drainage or runoff, urban stormwater runoff, or other unspecified nonpoint sources (SWRCB, 1996).

In addition, the analysis of benefits should highlight more clearly the fact that there may be little or no benefits in the near-term due to long-term environmental persistence of existing contamination. As EPA itself acknowledges on p. 5-8 (U.S. EPA, 1997a), "historical loads may, in some instances, be the predominant source of toxics-related water quality problems. In such instances, efforts to control current discharges may be of relatively limited effectiveness and value." It is well-documented that some substances, such as DDT and PCBs, which have been banned for two or more decades, still persist in the environment; thus, the likelihood of the CTR substantially reducing loadings and producing benefits is minimal.

Response to: CTR-035-051a

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. Research also indicates that these values are at least half as great as recreational values, such that if they are potentially applicable to a policy action,

providing a rough approximation is preferable, with proper caveats, to omitting them from the analysis of benefits and costs. EPA believes that the studies used to calculate the ratio of passive use to use value are applicable to the CTR (see also comment and response CTR-026-009).

Therefore, EPA applies a ratio of .5 to obtain an estimate of passive use values for those households that have active recreational anglers. Based on a review of the literature, EPA believes that non-angling household do indeed have a passive use value. To determine a lower-bound estimate of passive use values for non-angling households, EPA assumed that the value may be 30% of the value for angling households. For analysis of the final CTR, EPA revised the upper-bound estimate assuming that the passive use value of non-angling households may be 90% of those for angling households. This revision is based on a study by Loomis et al. (1991), who estimated the benefits of improved fishery, wetland, and waterfowl resources in the San Joaquin Valley to users and nonusers residing in California.

By multiplying a ratio of passive use to use value by recreational fishing values, which EPA apportioned to reflect the relative contribution of point sources, EPA also accounted for attribution in its estimate of passive use values.

For the EA that accompanied the proposal, EPA conducted an extensive search of the literature for more recent data or information related to the relative contributions of various sources to water quality impairments. In the EA accompanying the proposal, EPA solicited additional data, however, none was received. In revising the EA for the final rulemaking, EPA conducted an additional extensive search of the literature and research efforts at California universities for relevant information. EPA has incorporated any new information into the revised EA for the final rule.

The standards established in the CTR apply to all California inland surface waters and enclosed bays and estuaries. EPA currently only applies water quality based effluent limits to point sources, and thus the estimate of post-regulation risk levels reflect only the potential impact of controls on point sources. However, controls will also be required of other sources in the future. As controls on other sources are implemented (e.g., remediation of contaminated sediments; best management practices to control storm water discharges and runoff from agricultural land), EPA expects that concentrations in fish tissue will decline further and that the standards established by the CTR to protect human health can be achieved.

EPA also believes that the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point sources effluents, however, the facilities discharging these pollutants may not be included in the sample.

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA recognizes the persistence of some of the substances addressed by the CTR (e.g., DDT and PCBs) and the impact of this persistence on the realization of benefits. In the EA (Chapter 9), EPA accounted for this lag by assuming 10- and 20-year phase-in periods for benefits in its comparison of present value

benefits and costs.

In addition, EPA believes that point source controls can factor into pollutant reduction scenarios, although the cost-effectiveness of point and nonpoint source controls are likely to be highly site specific. Potential "hidden" loads (contaminant concentrations which are not currently measured because they are below detection levels) from point sources may also be occurring and may increase the potential benefits of point source controls. In addition, point source loadings reductions will reduce future sediment contamination and, thereby, reduce the need for costly site-specific sediment remediation in the future. Therefore, the CTR can be viewed as both reducing current environmental risks (yielding benefits) by reducing current loadings, and reducing future environmental cleanup costs.

Comment ID: CTR-035-066
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: * The Analysis suggests that the proposed reductions in point source discharges may not result in any benefits. As indicated by USEPA, "...the estimates presented here do not make direct causal links between point source controls and the stated benefits..."

Response to: CTR-035-066

EPA recognizes that the benefits of the rule will not occur immediately, and has estimated lags in the realization of benefits. However, EPA believes that the standards established by the CTR can be achieved through point source controls and will result in attaining designated uses of the water bodies, and that the estimated benefits are illustrative of the types and potential benefits to be achieved from attaining these uses.

Comment ID: CTR-040-044
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's estimate of reduced cancer benefits ($5.3 million annually under the high-end scenario)

is suspect because the analysis does not show that the pollutant upon which the benefits are based (DDT) will be reduced (or sufficiently reduced) as a result of the CTR to lead to the estimated reduction in cancer cases.

Response to: CTR-040-044

To calculate potential human health risk reduction benefits, EPA first calculated baseline risk levels using actual contaminant concentrations found in fish tissue. EPA then multiplied the baseline risk levels by the estimated reduction in loadings expected to result from the implementation of point source controls and by the relative contribution of point source loadings to total loadings. For DDT, EPA estimated a 68.8% reduction in point source loadings under the high end cost estimate and a 0% reduction in point source loadings under the low end cost estimate. EPA's estimate of human health benefits reflects these estimated reductions. For example, potential cancer-related benefits to recreational anglers range from $0 to $4.2 million for freshwater resources and total $0 for San Francisco Bay.

In addition, the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample.

Comment ID: CTR-041-040
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of reduced cancer benefits ($5.3 million annually under the high-end scenario) is suspect because the analysis does not show that the pollutant upon which the benefits are based (DDT) will be reduced (or sufficiently reduced) as a result of the CTR to lead to the estimated reduction in cancer cases.

Response to: CTR-041-040

To calculate potential human health risk reduction benefits, EPA first calculated baseline risk levels using actual contaminant concentrations found in fish tissue. EPA then multiplied the baseline risk levels by the estimated reduction in loadings expected to result from the implementation of point source controls and by the relative contribution of point source loadings to total loadings. For DDT, EPA estimated a 68.8% reduction in point source loadings under the high end cost estimate and a 0% reduction in point source loadings under the low end cost estimate. EPA's estimate of human health benefits reflects these estimated reductions. For example, potential cancer-related benefits to recreational

anglers range from $0 to $4.2 million for freshwater resources and total $0 for San Francisco Bay.

In addition, the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample.

Comment ID: CTR-044-035
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of reduced cancer benefits ($5.3 million annually under the high-end scenario) is suspect because the analysis does not show that the pollutant upon which the benefits are based (DDT) will be reduced (or sufficiently reduced) as a result of the CTR to lead to the estimated reduction in cancer cases.

Response to: CTR-044-035

To calculate potential human health risk reduction benefits, EPA first calculated baseline risk levels using actual contaminant concentrations found in fish tissue. EPA then multiplied the baseline risk levels by the estimated reduction in loadings expected to result from the implementation of point source controls and by the relative contribution of point source loadings to total loadings. For DDT, EPA estimated a 68.8% reduction in point source loadings under the high end cost estimate and a 0% reduction in point source loadings under the low end cost estimate. EPA's estimate of human health benefits reflects these estimated reductions. For example, potential cancer-related benefits to recreational anglers range from $0 to $5.3 million for freshwater resources and total $0 for San Francisco Bay.

In addition, the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample.

Comment ID: CTR-054-039
Comment Author: Bay Area Dischargers Associati

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02g Benefits & Poll. Reduction
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of reduced cancer benefits ($5.3 million annually under the high-end scenario) is suspect because the analysis does not show that the pollutant upon which the benefits are based (DDT) will be reduced (or sufficiently reduced) as a result of the CTR to lead to the estimated reduction in cancer cases.

Response to: CTR-054-039

To calculate potential human health risk reduction benefits, EPA first calculated baseline risk levels using actual contaminant concentrations found in fish tissue. EPA then multiplied the baseline risk levels by the estimated reduction in loadings expected to result from the implementation of point source controls and by the relative contribution of point source loadings to total loadings. For DDT, EPA estimated a 68.8% reduction in point source loadings under the high end cost estimate and a 0% reduction in point source loadings under the low end cost estimate. EPA's estimate of human health benefits reflects these estimated reductions. For example, potential cancer-related benefits to recreational anglers range from $0 to $5.3 million for freshwater resources and total $0 for San Francisco Bay.

In addition, the risk reducing impact of the regulation on point sources may not be fully illustrated by EPA's analysis which reflects only a small sample of point source dischargers. That is, although baseline risk levels are based on actual fish tissue concentrations, post-regulation risk levels are estimated by examining the potential for reducing loadings at a sample of facilities. Pollutants responsible for much of the baseline health risk at specific sites, such as popular fishing areas in San Francisco Bay, may be found in point source effluents, however, the facilities discharging these pollutants may not be included in the sample.

Subject Matter Code: E-02h Un-Enclose,Enclose Bay Data

Comment ID: CTR-035-053
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02h Un-Enclose,Enclose Bay Data
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 7-12 - 7-14 (U.S. EPA, 1997c) -- Extrapolation from Non-Enclosed Bays to Enclosed Bays

EPA assumed that the data from the 1988 NOAA study on 5 bays (San Diego, Humboldt, Monterey, Santa Monica, and San Pedro) could be readily extrapolated for enclosed bays. We believe that there are serious flaws in this approach, and that the data for the non-enclosed bays should be removed from the data set. We are most familiar with Santa Monica Bay, which has been heavily studied, including several specialized studies since that time. The basic problem with including data such as that for Santa Monica Bay in the data set is that the mass loading data are undoubtedly dominated by data for 2 large ocean discharge POTWs (each greater than or equal to 350 MGD), which would likely not be allowed to discharge into enclosed bays, thus skewing the assumptions towards a greater influence from POTWs on these bays than really occurs. If EPA examines the SWRCB's 1996 303(d) list, information is provided for many of these water bodies indicating what types of discharges are the likely sources of the pollution problems, which we believe will confirm this.

Response to: CTR-035-053

The NOAA data included five bays (San Diego, Humboldt, Monterey, Santa Monica, and San Pedro), two of which are actually covered by the CTR (San Diego and Humboldt). EPA assumed that the data for the nonenclosed bays generally will be applicable to enclosed bays. If EPA had excluded those bays not covered by the rule, the attribution assumption for point sources would actually be higher (see EA, p. 7-4). For example, for urban bays, the toxic-weighted average contribution of point sources is higher for the enclosed bay covered by the rule (San Diego Bay; 91%) compared to the nonenclosed bays (Santa Monica and San Pedro, at 88% and 83%, respectively). EPA employed toxicity-weighting to estimate relative source contribution because the toxicity of the discharge, more than volume, will influence its impact on receiving waters. The California 1996 303(d) report lists both point and nonpoint sources as probable sources of pollution for Santa Monica Bay. The list of pollutants and stressors for Santa Monica Bay includes metals, DDT, and PCBs.

Comment ID: CTR-035-070
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: E-02h Un-Enclose,Enclose Bay Data
References:
Attachments? N
CROSS REFERENCES

Comment: * Even more than the cost analysis, benefits would appear to be site-specific. Uses of water bodies varies considerable, as does the contribution of point, non-point, and natural sources to toxic contamination. As a result, there is likely a mismatch between the total estimated benefits, and the distribution of these benefits throughout the state, as well as the costs of obtaining water body-specific benefits (e.g., costs could be disproportionately felt in areas with little benefit).

For example, USEPA's assumptions about urban bays other than San Francisco are based on a National Oceanic and Atmospheric Administration (NOAA) report that examined five bays: Humboldt, Monterey, San Diego, San Pedro, and Santa Monica, of which only Humboldt and San Diego are covered by the Rule. USEPA assumption that the data for the non-enclosed bays is generally applicable to enclosed bays may not be supportable as a result of differences in dilution factors and the contribution of non-point sources.

Response to: CTR-035-070

EPA agrees that benefits are likely to be highly site specific. However, sites likely to experience a disproportionate share of the benefits are also likely to incur a disproportionate share of the costs.

In addition, once water quality standards are in place, sites that are currently less impacted by toxic pollutants may experience cost savings by preventing future cleanup costs. That is, it may be more cost-effective to prevent toxic pollutants from entering surface waters than to clean up and remediate the impacts once toxic pollutants are released. However, should the State determine through a total maximum daily load (TMDL) allocation that controls on nonpoint sources are a more cost-effective approach to achieving standards, the State can redistribute the allocations through the TMDL process.

The NOAA data included five bays (San Diego, Humboldt, Monterey, Santa Monica, and San Pedro), two of which are actually covered by the CTR (San Diego and Humboldt). EPA assumed that the data for the nonenclosed bays generally will be applicable to enclosed bays. If EPA had excluded those bays not covered by the rule, the attribution assumption for point sources would actually be higher (see EA, p. 7-4). For example, for urban bays, the toxic-weighted average contribution of point sources is higher for the enclosed bay covered by the rule (San Diego Bay; 91%) compared to the nonenclosed bays (Santa Monica and San Pedro, at 88% and 83%, respectively). EPA employed toxicity-weighting to estimate relative source contribution because the toxicity of the discharge, more than volume, will influence its impact on receiving waters. The California 1996 303(d) report lists both point and nonpoint sources as probable sources of pollution for Santa Monica Bay. The list of pollutants and stressors for Santa Monica Bay includes metals, DDT, and PCBs.

Subject Matter Code: E-02i Impaired Waters Assumptions

Comment ID: CTR-035-054
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02i Impaired Waters Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: p. 8-18 (U.S. EPA, 1997a) --Assumptions Regarding Impaired Waters EPA explains on p. 8-18 how it extrapolated from the State's 305(b) Report to create estimates for all waters. We believe that EPA should have consulted the SWRCB to determine the general locations of unassessed/unmonitored waters so that logical assumptions could be made. Assumptions about water quality conditions would be very different, for instance, if they are mostly Central Valley agricultural drains than if they are streams in the Sierra Nevada or northern California mountains.

Response to: CTR-035-054

EPA did consult with SWRCB staff concerning appropriate assumptions about unassessed waters. The SWRCB considered EPA's assumptions reasonable for estimating the extent of toxic impairment in unassessed waters.

Comment ID: CTR-040-046
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02i Impaired Waters Assumptions
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: The value of recreational angling was multiplied by 50% to obtain $4.3 million annually for passive use benefits. The Wisconsin study, therefore, was the basis for $12.9 million, or 2.5% of the $51.7 million in total benefits.

EPA's estimate of increased angler participation ($1 .5 million annually under the high-end scenario) is based on the unsupported assumption that reducing pollution causes more people to fish. It is just as likely that it does not.

Response to: CTR-040-046

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA Chapter 8). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to CTR-035-009a.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

Comment ID: CTR-041-042
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02i Impaired Waters Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: The value of recreational angling was multiplied by 50% to obtain $4.3 million annually for passive use benefits. The Wisconsin study, therefore, was the basis for $12.9 million, or 2.5% of the $51.7 million in total benefits.

EPA's estimate of increased angler participation ($1.5 million annually under the high-end scenario) is based on the unsupported assumption that reducing pollution causes more people to fish. It is just as likely that it does not.

Response to: CTR-041-042

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA Chapter 8). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to CTR-035-009a.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

Comment ID: CTR-044-037

Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02i Impaired Waters Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: The value of recreational angling was multiplied by 50% to obtain $4.3 million annually for passive use benefits. The Wisconsin study, therefore, was the basis for $12.9 million, or 2.5% of the $51.7 million in total benefits.

EPA's estimate of increased angler participation ($1.5 million annually under the high-end scenario) is based on the unsupported assumption that reducing pollution causes more people to fish. It is just as likely that it does not.

Response to: CTR-044-037

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA p. 8-17). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to Issue 3.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final

Report, April 15.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

Comment ID: CTR-054-041
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02i Impaired Waters Assumptions
References:
Attachments? N
CROSS REFERENCES

Comment: The value of recreational angling was multiplied by 50% to obtain $4.3 million annually for passive use benefits. The Wisconsin study, therefore, was the basis for $12.9 million, or 2.5% of the $51.7 million in total benefits.

EPA's estimate of increased angler participation ($1.5 million annually under the high-end scenario) is based on the unsupported assumption that reducing pollution causes more people to fish. It is just as likely that it does not.

Response to: CTR-054-041

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA p. 8-17). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million

and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to Issue 3.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

Subject Matter Code: E-02k Long-Term Contamination

Comment ID: CTR-035-051c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02k Long-Term Contamination
References:
Attachments? N
CROSS REFERENCES E-02g
E-02f

Comment: C. Benefits Analysis pp. 5-7 - 5-8 (U.S. EPA, 1997a) -- Attribution of Benefits to the Control of Point Sources

We applaud EPA's effort to analyze and report the proportion of the total benefits that might accrue due to the implementation of controls on point source NPDES dischargers in the benefits analysis (although we believe that this apportionment should have been carried through to the estimates of passive use benefits). We believe that it is appropriate to state the benefits that can be attributed to the estimated expenditures. We recognize, however, that there are many limitations in this approach, and that better data are needed. For instance, the pollutant loadings data used in this analysis were old and outdated (specifically, the Davis and NOAA studies contained data that are 10-15 years old). We urge EPA to update these studies with more recent data for the final Economic Analysis.

We believe that the benefits analysis illustrates that, in many instances, point source controls will not produce significant benefits. For instance, this is illustrated by the fact that the projected health benefits of the CTR in reducing both cancer and baseline systemic risks are minimal (see pp, 8-11 - 8-16, (U.S. EPA, 1997a)). Another example is illustrated by an examination of those water bodies for which fish consumption advisories have been issued. For those included on the State's 303(d) list, except for San Francisco Bay, the causes of impairment are largely listed by the SWRCB as nonpoint sources, including mining or resource extraction, agricultural drainage or runoff, urban stormwater runoff, or other unspecified nonpoint sources (SWRCB, 1996).

In addition, the analysis of benefits should highlight more clearly the fact that there may be little or no benefits in the near-term due to long-term environmental persistence of existing contamination. As EPA itself acknowledges on p. 5-8 (U.S. EPA, 1997a), "historical loads may, in some instances, be the predominant source of toxics-related water quality problems. In such instances, efforts to control current discharges may be of relatively limited effectiveness and value." It is well-documented that some substances, such as DDT and PCBs, which have been banned for two or more decades, still persist in the environment; thus, the likelihood of the CTR substantially reducing loadings and producing benefits is minimal.

Response to: CTR-035-051c

As described in the EA (Chapter 8), research provides empirical evidence of the passive use values associated with improved water quality and fisheries. Research also indicates that these values are at least half as great as recreational values, such that if they are potentially applicable to a policy action,

providing a rough approximation is preferable, with proper caveats, to omitting them from the analysis of benefits and costs. EPA believes that the studies used to calculate the ratio of passive use to use value are applicable to the CTR (see also comment and response CTR-026-009).

Therefore, EPA applies a ratio of .5 to obtain an estimate of passive use values for those households that have active recreational anglers. Based on a review of the literature, EPA believes that non-angling household do indeed have a passive use value. To determine a lower-bound estimate of passive use values for non-angling households, EPA assumed that the value may be 30% of the value for angling households. For analysis of the final CTR, EPA revised the upper-bound estimate assuming that the passive use value of non-angling households may be 90% of those for angling households. This revision is based on a study by Loomis et al. (1991), who estimated the benefits of improved fishery, wetland, and waterfowl resources in the San Joaquin Valley to users and nonusers residing in California.

By multiplying a ratio of passive use to use value by recreational fishing values, which EPA apportioned to reflect the relative contribution of point sources, EPA also accounted for attribution in its estimate of passive use values.

For the EA that accompanied the proposal, EPA conducted an extensive search of the literature for more recent data or information related to the relative contributions of various sources to water quality impairments. In the EA accompanying the proposal, EPA solicited additional data, however, none was received. In revising the EA for the final rulemaking, EPA conducted an additional extensive search of the literature and research efforts at California universities for relevant information. EPA has incorporated any new information into the revised EA for the final rule.

Although the standards established by the CTR apply to all sources, EPA's analysis examined only the portion of benefits expected to be achieved by controlling point sources. EPA estimated the point source share of benefits based on data and information on the relative contribution of all sources to toxic loadings in California waters. Although point sources may account for only a small portion of the load in some waters, they may account for relatively larger portions at some sites, and point source controls will contribute to meeting standards in the water bodies.

EPA recognizes the persistence of some of the substances addressed by the CTR (e.g., DDT and PCBs) and the impact of this persistence on the realization of benefits. In the EA (Chapter 9), EPA accounted for this lag by assuming 10- and 20-year phase-in periods for benefits in its comparison of present value benefits and costs.

In addition, EPA believes that point source controls can factor into pollutant reduction scenarios, although the cost-effectiveness of point and nonpoint source controls are likely to be highly site specific. Potential "hidden" loads (contaminant concentrations which are not currently measured because they are below detection levels) from point sources may also be occurring and may increase the potential benefits of point source controls. In addition, point source loadings reductions will reduce future sediment contamination and, thereby, reduce the need for costly site-specific sediment remediation in the future. Therefore, the CTR can be viewed as both reducing current environmental risks (yielding benefits) by reducing current loadings, and reducing future environmental cleanup costs.

Comment ID: CTR-035-065a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02k Long-Term Contamination
References:
Attachments? N
CROSS REFERENCES E-02c

Comment: Weaknesses in Benefits Analysis

USEPA's benefits analysis is even weaker than its cost evaluation. For example:

* Although there is evidence that the Rule could result in no benefits in the near-term due to long-term environmental persistence of existing contamination, the Analysis does a poor job of highlighting this potential outcome. For example, there is some likelihood that benefits could truly be zero, while under no circumstances will Rule implementation be costless. Likewise, USEPA's use of ranges to express potential benefit values may mislead readers into believing that the estimated high benefits are as likely to be achieved as the low benefits, when in fact the probability that different benefit levels will actually be achieved varies greatly from low to high.

Response to: CTR-035-065a

The range of estimated benefits in part reflects the range in loadings reductions that may result from point source controls given the flexibility in State implementation procedures. The decision as to which implementation procedures will be employed, and therefore what costs and benefits will result, will be made by state and local entities for specific locations.

Subject Matter Code: E-02l Marginal Impacts/Benefits

Comment ID: CTR-035-052
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02l Marginal Impacts/Benefits
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 6-1 - 6-12 (U.S. EPA, 1997a) -- Assessment of Potential Ecological Benefits

EPA should state in the Economic Analysis that there may not be a one-to-one relationship between benefits and reductions in toxic pollutants, due to the fact that factors such as habitat alteration, competition from invasive exotic species, inadequate flows, hydrologic modification, channelization, and other disturbances, may pose serious threats to ecological resources, and may undermine or partially negate the benefits of the rule.

Response to: CTR-035-052

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA acknowledges that applying Lyke's results to all California waters affected by toxics may overstate potential benefits (see EA Chapter 8). Anglers may or may not be aware of toxic contamination in the absence of fish consumption advisories. EPA acknowledges the limitations in the application of Lyke's research. However, EPA chose this approach to provide illustration of the potential magnitude of recreational angling values rather than leave this important benefit category unmonetized.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA first applied Lyke's research in its analysis of the potential benefits of the Great Lakes Water Quality Guidance. Calculation of the range of results is explained in U.S. EPA (1993). Lyke estimated the Wisconsin Great Lakes open water sport fishery to be worth between $339 and $424 per licensed angler, resulting in an estimated consumer surplus associated with the fishery of between $66.6 million

and $83.3 million annually. Lyke obtained values for a contaminant-free fishery ranging from $7.4 million to $26.1 million per year, with the range in results attributable to whether a linear or constant elasticity of scale functional form is used in the estimation. These results reflect between 11.1% and 31.3% of the value of the fishery under current conditions, which is the range of values EPA used in analysis of the CTR.

EPA acknowledges that Lyke-based benefits represent a substantial portion of total benefits and supports these benefits estimates. (See also comment and response to CTR-035-009a.)

U.S. EPA, 1993. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. Final Report, April 15.

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

EPA agrees that the contingent valuation method (CVM) elicits an individual's stated willingness to pay or accept compensation. The benefit-cost comparisons in EAs are prepared to inform the public and policy makers. Thus, the strengths and weaknesses of all aspects of the EA, including methodologies for estimating benefits, need to be made clear so that readers are aware of the limits and uncertainties. However, a 1993 Blue Ribbon Panel convened by the National Oceanic and Atmospheric Administration (NOAA) evaluated CVM and found it to be an appropriate methodology for measuring values. It is also the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values and has withstood Federal Court review for its use in litigation contexts.

Additionally, much of the criticism of CVM is conceptual rather than based on empirical research. Where CVM can be compared to other research techniques (e.g., use values estimated by the travel cost methodology or the hedonic price method), CVM is shown to yield similar values (see Brookshire et al., 1982 and Smith et al., 1986). Additionally, in several field experiments, actual purchase decisions were compared to hypothetical purchase decisions (Bishop and Heberlein, 1978 and Dickie et al., 1987). In all of these studies, hypothetical behavior was sufficiently predictive of actual behavior that researchers

concluded meaningful values could be obtained for benefit-cost analysis or damage assessment.

Bishop, R.C. and T.A. Heberlein. 1978. Measuring values of extra-market goods: Are indirect measures biased? American Journal of Agricultural Economics 61(5): 926-930.

Brookshire, D., M. Thayer, W.D. Schulze, and R. d'Arge. 1982. Valuing public goods: A comparison of the survey and hedonic approaches. American Economic Review 72(1): 165-177.

Comment ID: CTR-035-067
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02l Marginal Impacts/Benefits
References:
Attachments? N
CROSS REFERENCES

Comment: * The benefits analysis does a poor job of evaluating the marginal impacts of the proposed rule. For example, "...even low contaminant concentrations in water, sediment, or diet may impair fitness, produce adverse-physiological effects that lead to death, or lower long-term survivability in the wild." Likewise, related to environmental benefits:

-- Only a qualitative description of ecologic benefits is provided because of.. (4) uncertainty regarding the extent to which the CTR will result in toxics loading reductions significant enough (relative to the contribution of historical and ongoing point and nonpoint loadings) to generate changes in ambient concentration and ecosystem health (U.S.EPA, 1997a, page 6-10).

Benefits are unlikely to be linear, but rather related to threshold changes in the environment.

Response to: CTR-035-067

EPA provided a qualitative description of benefits to supplement its quantitative analysis, acknowledging that even low concentrations of toxics in water, sediment, or diet may impair fitness or produce adverse physiological effects that can lead to death or lower long-term survivability in the wild (see EA Chapter 6).

Comment ID: CTR-054-006
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02l Marginal Impacts/Benefits
References:
Attachments? Y

Comment: The benefits accruing from these costs would be minimal. The addition of lime treatment at three BADA agency plants to remove copper would have the effect of reducing copper loads to the Bay by 2,400 lbs/year (see Attachment 2). To put this in perspective, this is about 1 % of the total copper load to the Bay based on the Regional Board's 1993 Copper Wasteload Allocation. The cost per toxic pound equivalent removed would be between $2,300/lb and $14,800/lb, the former based on EPA's assumption regarding the cost and effectiveness of primary lime addition and the latter based on the assumption that tertiary lime treatment would be necessary. Further, the RMP has generally shown that the dissolved copper criteria is generally achieved in the Bay, with the exception of occasional exceedances in the extreme South Bay and the Petaluma River. Of 216 measurements made over 9 RMP sampling events, only about 10% of the samples exceeded the proposed criteria, with the highest single value recorded being 5.93 ug/l. Loading data is unavailable for the organics, but the RMP data show that there were no exceedances at any station for heptachlor and one of the problematic PAHs and that the other two problematic PAHs were exceeded in less than 3% of the samples. Like copper, the PAH exceedances occurred in the South Bay and the Petaluma River. Hence, reduction of PAHs in the one deep water discharger with attainability problems would not change the current level of compliance. The RMP did not analyze for aldrin. EPA's economic analysis based benefits estimates on improved fishing experience and increased angler participation, reduced cancer risks, and nonuse values associated with compliance with all water quality standards. A 1% reduction in copper loading to the Bay would not trigger any of these benefits, nor would controls that do not result in any change in the present level of compliance in Bay waters of PAHs and heptachlor criteria. Irrespective of the fact that the RMP-measured level of compliance with the subject PAHs is 97% and with heptachlor is 100%, EPA's cancer risk analysis identifies heptachlor as contributing 0.1% to the baseline cancer risks for anglers consuming Bay fish and does not list any PAH (see Economic Analysis Exhibit 8-7). In conclusion, adoption of the proposed criteria, while potentially imposing considerable costs on BADA agencies, would have very little beneficial impact on the Bay. Copper loading would be reduced by 1% and PAH compliance would remain unchanged at 97% to 100%.

Response to: CTR-054-006

As part of its revised cost analysis, EPA estimated the changes in estimated costs and pollutant load reductions based on the lower risk level of 10-5. Under the low scenario, costs decrease by $1.1 million, approximately 11% less than the costs based on the higher risk level. Under the high scenario, annual costs decrease by $5.8 million, also an 11% decrease from the costs based on a 10-6 risk level. Pollutant load reductions attributable to use of a lower risk level are estimated to decrease by approximately 4% and 1% under the low and high scenarios, respectively. The relatively low sensitivity of costs to the change in risk level primarily is related to the fact that most of the potential costs related to implementing the CTR are being driven by metals. Changes in risk levels for carcinogens primarily affect organic pollutants.

EPA believes that controls on point source dischargers will, in many cases, contribute to attaining standards in a given water body. As controls on other sources are also implemented, the water quality standards can be achieved. However, the total maximum daily load (TMDL) process is provided to address cost-ineffectiveness as it pertains to point or nonpoint sources. For example, if controls on nonpoint sources are a more cost-effective approach to achieving standards, the State can redistribute the load allocations through the TMDL process.

EPA recognizes that the benefits of the rule will not occur immediately, and has estimated lags in the

realization of benefits. However, EPA believes that the standards established by the CTR can be achieved through point source controls and will result in attaining designated uses of the water bodies, and that the estimated benefits are illustrative of the types and potential benefits to be achieved from attaining these uses.

The U.S. EPA Treatability Database indicates that chemical precipitation with addition of lime is a technology capable of removing metals at the concentrations and loading reductions required. For example, several treatment plants have reached concentrations of 7.7 ug/L for copper based on a pilot study (CTR-based level for copper is 8.03 ug/L) and 0.46 ug/L for silver (CTR-based level for silver is 1.51 ug/L) (U.S.EPA RREL). Some of the sample facilities already have a clarification system in place, therefore, only capital costs for the lime feeding and conveying system need to be considered. For facilities without clarifiers, the capital cost of a primary clarifier is also included in EPA's cost estimates. EPA's cost estimates are based on EPA's Treatability Manual (1980) and are adjusted for inflation.

References: U.S. EPA. 1980. Treatability Manual, Volume IV, Cost Estimating. U.S. EPA Risk Reduction Engineering Laboratory (RREL). Cincinnati, Ohio. Treatability Database.

Comment ID: CTR-054-013d
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02l Marginal Impacts/Benefits
References:
Attachments? Y
CROSS REFERENCES E-01g03
E-01q01
E-01m

Comment: The economic analysis is seriously flawed. The major flaws include: (1) failing to do an appropriate sampling of dischargers; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule (see Attachment 3). The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. BADA's analysis shows that its member agencies alone could be faced with costs in excess of $100 million per year to achieve effluent limits based on the copper, PAH, heptachlor and aldrin criteria. BADA's analysis also indicates that the benefits associated with this expenditure will be difficult to measure. Copper loadings will be reduced by 1% and the level of compliance for PAH's and heptachlor will remain unchanged at its present high level. Certainly these benefits will not measurably improve the fishing experience or measure the number of fisherman in the Bay, significantly reduce the cancer cases, or improve property values or other nonuse benefits, as estimated in EPA's economic analysis. A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a

rule that affects small entities protected under the Regulatory Reform Act. BADA agencies provide service to a number of small communities with populations under 50,000 people that could be greatly impacted by the proposed rule.

Response to: CTR-054-013d

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

EPA considers Lyke's scenario (waters completely free of contaminants that may threaten human health) to be similar to a scenario in which all California waters meet the water quality standards established by the CTR. EPA has no information to show that these standards cannot be achieved. Thus, EPA used Lyke's results to estimate the total potential benefits of achieving standards. However, since point source controls alone may not be sufficient to achieve the standards throughout California, EPA allocated only a portion of the total benefits to the CTR.

EPA agrees that the study site for Lyke's research is substantially different from California waters. However, EPA's search of the literature indicated that there is no similar research for California or other more similar waters. Therefore, EPA applied Lyke's results to provide decisionmakers with information on the types and potential magnitude of the benefits from water quality improvements, rather than leaving this important benefit category unmonetized. EPA has no information to determine whether California residents may value toxic-free waters more or less than Wisconsin residents.

In addition, EPA believes that Lyke's scenario does not capture another component of potential value to current anglers that may result as reduced levels of toxic pollutants result in healthier sport fish populations. Lyke's survey asked anglers to consider a fishery that is free of contaminants that may threaten human health. However, fish are more sensitive than humans to some classes of toxic pollutants and fish populations may increase as contamination is reduced. To the extent that reducing toxic contamination results in a more satisfying angling experience in terms of increasing catch rates, achieving water quality standards may result in an increase in value to current anglers beyond that associated with reducing human health concerns.

Comment ID: CTR-092-023b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02l Marginal Impacts/Benefits
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-02e
E-02q

Comment: Comment #7: General Benefit Analysis Concerns

The benefit analysis undertaken by EPA uses old, out-of-state data which does not appear applicable to

California. A major concern with this analysis is that the benefit recipients are only a subset of those impacted by the costs. Another is that the benefits accrue to the public at large; costs, on the other hand, to the extent that CTR-implementation costs are borne by Indirect Dischargers (as assumed by EPA in the copper situation) accrue to businesses.

Further, the benefit measurements of "angling day" are only useful if they represent a net increase in fishing activity -- if all that improving waterway quality does is create additional sites where safe fishing can occur, without increasing the overall amount of fishing that occurs, there is no net gain, there is only substitution between comparable sites. The value of benefits which occur because of substitution between fishing sites must be subtracted from the value which occurs from increased fishing. This has not been done in the EPA analysis, thus benefits are overstated.

Further, no stratification is evident to account for importation of out-of-state fishers -- including benefit value of attracting new anglers from other states to California fishing sites is irrelevant to an analysis of costs/benefits of implementing the CTR for California.

Questions for EPA on Comment #7:

Q.7 - 1) If the concerns stated above were appropriately addressed, what would be the impact on EPA's benefits analysis? Our concern relates to the need to examine levels of regulation in comparison to benefits obtained, i.e. cost-effectiveness.

Q.7 - 2) Executive Order 12866, in recognition that quantification of benefits is very difficult, is quite explicit about addressing qualitative benefits wherever possible why wasn't that done in this analysis?

Response to: CTR-092-023b

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to promulgating the final rule.

Although it is true that the direct costs of the regulation are borne by municipal and industrial dischargers while the benefits accrue to the public at large, it is also true that in generating the discharges, the benefits (cost savings) accrued to businesses and municipalities while the costs (decreased utility associated with water resources) were borne by the public. Ultimately, benefits and costs are borne throughout society (e.g., costs are borne directly by municipal and industrial dischargers but indirectly by the public who pays for their products and services).

EPA acknowledged that increased angling activity at sites experiencing reductions in toxic contaminants may reflect a shift in activity from substitute sites rather than a net increase. Because EPA could not account for substitute sites in this analysis, EPA estimated lower bound benefits of $0 (i.e., assuming no net increases in activity; see EA, Chapter 8).

EPA's estimate of the relevant angling population is based on resident California anglers (see Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule, Draft, December 20, 1996, pp. 3-23, 3-35 to 3-36).

EPA revised its economic analysis in response to comments and to reflect any new data or changes to the proposal. The estimated cost-effectiveness of the rule is expected to range from $22/lb-eq to $31/lb-eq. EPA expects the total annual, monetized benefits from implementation of the CTR to range from $8.7 to $40.8 million dollars.

Chapter 6 of the EA (Qualitative Assessment of Potential Ecological Benefits) provides a qualitative discussion of potential ecological benefits. EPA also provided a qualitative discussion of important benefit categories that it was not able to quantify or monetize (see the EA that accompanied the proposed rule, Chapter 8).

Subject Matter Code: E-02m Few Pollutant Mask Analysis

Comment ID: CTR-035-069
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02m Few Pollutant Mask Analysis
References:
Attachments? N
CROSS REFERENCES

Comment: * Most of the public health benefits appear to be associated with a small number of contaminants, acting to mask the benefit cost analysis. For example, cancer risks are dominated by four contaminants, two of which -- DDT and PCBs -- may be substantially unrelated to ongoing point sources. In other words, while costs are associated with reductions in a wide range of toxic materials, benefits may be derived from a small subset of these toxins, most of which are primarily related to non-point sources or historical contamination.

Response to: CTR-035-069

EPA analyzed potential reductions for over forty toxic pollutants that may be discharged by point sources. EPA expects that reductions in these toxics will lead to a variety of benefits including ecological, health, and recreational benefits. Although certain health risks such as cancer are indeed dominated by only a few toxic contaminants that may not be greatly reduced by point source controls, reductions of these toxics are, nevertheless, expected to yield reductions in cancer cases as well as systemic health risks. EPA expects the annual reduction in cancer cases among recreational anglers after implementation of the CTR to range from 0.0 to 0.1 for San Francisco Bay and 0.0 to 0.8 for freshwater resources. EPA also analyzed the post-CTR hazard quotients (HQ) for systemic risks among recreational anglers with high consumption rates. The HQ for PCBs may be reduced from 11.31 to 5.44 for San Francisco Bay anglers and from 7.02 to 3.28 for freshwater anglers.

Comment ID: CTR-059-025
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02m Few Pollutant Mask Analysis
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01g08

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The Economic Analysis suggests that reductions attributable to point source reductions may be de minimis. For instance, most of the public health benefits appear to be associated with a small number of contaminants, most of which are not discharged in significant quantities by point source dischargers. Cancer risks, for example, are dominated by four contaminants, two of which -- DDT and PCBs -- are mainly the result of historic discharges rather than due to ongoing point source inputs.

Response to: CTR-059-025

EPA analyzed potential reductions for over forty toxic pollutants that may be discharged by point sources. EPA expects that reductions in these toxics will lead to a variety of benefits including ecological, health, and recreational benefits. Although certain health risks such as cancer are indeed dominated by only a few toxic contaminants that may not be greatly reduced by point source controls, reductions of these toxics are, nevertheless, expected to yield reductions in cancer cases as well as systemic health risks. EPA expects the annual reduction in cancer cases among recreational anglers after implementation of the CTR to range from 0.0 to 0.1 for San Francisco Bay and 0.0 to 0.8 for freshwater resources. EPA also analyzed the post-CTR hazard quotients (HQ) for systemic risks among recreational anglers with high consumption rates. The HQ for PCBs may be reduced from 11.31 to 5.44 for San Francisco Bay anglers and from 7.02 to 3.28 for freshwater anglers.

Subject Matter Code: E-02o Analysis from Wisconsin

Comment ID: CTR-009-008c
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: E-02o Analysis from Wisconsin
References:
Attachments? Y
CROSS REFERENCES E-02c
E-01s

Comment: The City does not agree with the economic analysis. It is incomplete and misrepresents the actual costs and benefits. The analysis does not include costs of expensive AWT to meet more stringent limits based upon the proposed criteria. It does not include the first second, and third order costs to the community, individuals and businesses, of the economic dislocations resulting from huge capital costs, especially for small and economically distressed communities, that divert scarce resources from other priorities or out of the area. It does not include cost impact assessments to low and fixed-income households - ignoring the economic aspects of environmental justice. The benefits assessments make vast unsupported assumptions about the benefits of reductions in constituent concentrations that are barely, if even, measurable, and assigns unrealistic contingent valuations to these assumed benefits. The cost analyses does not follow EPA's own economic assessment guidance (which, itself, is fatally flawed). These points were brought up during the Task Force meetings in 1995 and 1996, but were dismissed outright by EPA. The City hereby raises these issues for the formal record.

The City of Thousand Oaks appreciates the opportunity to comment on the proposed California Toxics Rule.

Sincerely,

Donald H. Nelson Public Works Director

Response to: CTR-009-008c

EPA's own economic assessment guidance (Interim Economic Guidance for Water Quality Standards, EPA-823-B-95-002, March 1995) is intended to assist States and applicants in understanding the economic factors that may be considered, and the types of tests that can be used to determine if a designated use cannot be attained, if a variance can be granted, or if degradation of high-quality water is warranted. In order to remove a designated use or obtain a variance, or if degradation of high-quality water is warranted, the state or discharger must demonstrate that attaining the designated use would result in substantial and widespread economic and social impacts. Although EPA is responsible for approving a State's water quality standards, the State is responsible for interpreting the circumstances of each case and determining where there are substantial and widespread economic and social impacts, or where important social and economic development would be precluded.

Estimating the economic impact of the CTR in California requires a detailed econometric model of the region's economy. EPA did not conduct such an analysis of the rule. However, for a similar toxics rule in

the Great Lakes Basin, an econometric analysis was performed independent of the regulatory impact analysis for the Council of Great Lakes Governors (The Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness. DRI/McGraw-Hill, San Francisco, California, July 1993). This analysis showed a minimal impact of the rule on the region's economy for a worst case scenario, a scenario with costs far exceeding those estimated by EPA. Manufacturing output was estimated to fall by between 0.008% and 0.337% over a range of four scenarios evaluated, while personal income loss was estimated at between 0.002% and 0.094% for these scenarios. As a result, the study authors concluded that the impact of the rule on the region's economy would be "nearly imperceptible." Thus, similar controls on toxic pollutants have been shown to be affordable in other regions of the country. In addition, all of the United States, with exception of California, has implemented CWA section (c)(2)(3).

Comment ID: CTR-040-045
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02o Analysis from Wisconsin
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA's estimate of increased value of recreational angling ($8.6 million annually under the high-end scenario) is highly suspect:

* It is based on a Ph.D. dissertation that does not appear to have been subjected to outside peer review (no paper has been found in a peer-reviewed journal). The primary focus of the dissertation was the evaluation, using Wisconsin anglers, of a travel cost model to value changes in environmental quality. A secondary purpose as to evaluate a contingent valuation model todetermine the increased value of fishing in pollutant-free waters. The dissertation was based on two surveys of Wisconsin anglers, one set of anglers who fished for trout and salmon in the Great Lakes and another set who fished for the same fish in inland waters. The surveys contained 64 questions, only two of which addressed the increased value of recreational angling in pollutant-free water, There were 274 respondents to the Great Lakes survey and 239 respondents to the inland waters survey. (see Attachment B-2)

* EPA seems to have selectively used the dissertation. For example, EPA used the results of the Great Lakes survey (which showed an 11.1% increase in value based on mean values) but did not use the inland waters survey (which actually showed a reduction in value with pollutant-free water). This of course raises questions about the validity of the survey and the values present in the dissertation. Further, in estimating the high-end benefits, EPA appears to have used the pollutant-free mean value and compared that to the low-end polluted water value (mean value minus the standard error). It is not clear why EPA would have done this.

* This approach assumes that the current value of recreational angling in California is impaired as a result of pollution. That may be the case in some waters of the State, but it is certainly not the case in the vast majority of the State's waters.

* This approach also assumes that the CTR will result in pollutant-free water, which, as stated previously, is not the case.

Response to: CTR-040-045

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of the States's actions that may control other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-041-041
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02o Analysis from Wisconsin
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of increased value of recreational angling ($8.6 million annually under the high-end scenario) is highly suspect:

* It is based on a Ph.D. dissertation that does not appear to have been subjected to outside peer review (no paper has been found in a peer-reviewed journal). The primary focus of the dissertation was the evaluation, using Wisconsin anglers, of a travel cost model to value changes in environmental quality. A secondary purpose as to evaluate a contingent valuation model to determine the increased value of fishing in pollutant-free waters. The dissertation was based on two surveys of Wisconsin anglers, one set of anglers who fished for trout and salmon in the Great Lakes and another set who fished for the same fish in inland waters. The surveys contained 64 questions, only two of which addressed the increased value of recreational angling in pollutant-free water, There were 274 respondents to the Great Lakes survey and 239 respondents to the inland waters survey. (see Attachment 3-2)

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Lakes survey (which showed an 11.1 % increase in value based on mean values) but did not use the inland waters survey (which actually showed a reduction in value with pollutant-free water). This of course raises questions about the validity of the survey and the values present in the dissertation. Further, in estimating the high-end benefits, EPA appears to have used the pollutant-free mean value and compared that to the low-end polluted water value (mean value minus the standard error). It is not clear why EPA would have done this.

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* This approach also assumes that the CTR will result in pollutant-free water, which, as stated previously, is not the case.

Response to: CTR-041-041

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of the State's action that may control other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-044-036
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02o Analysis from Wisconsin
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of increased value of recreational angling ($8.6 million annually under the high-end scenario) is highly suspect:

* It is based on a Ph.D. dissertation that does not appear to have been subjected to outside peer review (no paper has been found in a peer-reviewed journal). The primary focus of the dissertation was the evaluation, using Wisconsin anglers, of a travel cost model to value changes in environmental quality. A secondary purpose as to evaluate a contingent valuation model to determine the increased value of fishing in pollutant-free waters. The dissertation was based on two surveys of Wisconsin anglers, one set of anglers who fished for trout and salmon in the Great Lakes and another set who fished for the same fish in inland waters. The surveys contained 64 questions, only two of which addressed the increased value of recreational angling in pollutant-free water, There were 274 respondents to the Great Lakes survey and 239 respondents to the inland waters survey. (see Attachment 3-2)

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* This approach also assumes that the CTR will result in pollutant-free water, which, as stated previously, is not the case.

Response to: CTR-044-036

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

EPA estimated the percentage of California waters impaired by toxic pollutants based on water quality assessments developed by the State Water Resources Control Boards. EPA defined toxic-impaired waters as those rated medium or poor for one or more toxic pollutants or group of pollutants. Research (e.g., Lyke, 1993) indicates that the recreational value of water resources may be substantially enhanced by reducing toxic contamination.

EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Comment ID: CTR-054-040
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02o Analysis from Wisconsin
References:
Attachments? N
CROSS REFERENCES

Comment: EPA's estimate of increased value of recreational angling ($8.6 million annually under the high-end scenario) is highly suspect:

* It is based on a Ph.D. dissertation that does not appear to have been subjected to outside peer review (no paper has been found in a peer-reviewed journal). The primary focus of the dissertation was the evaluation, using Wisconsin anglers, of a travel cost model to value changes in environmental quality. A secondary purpose as to evaluate a contingent valuation model to determine the increased value of fishing in pollutant-free waters. The dissertation was based on two surveys of Wisconsin anglers, one set of anglers who fished for trout and salmon in the Great Lakes and another set who fished for the same fish in inland waters. The surveys contained 64 questions, only two of which addressed the increased value of recreational angling in pollutant-free water, There were 274 respondents to the Great Lakes survey and 239 respondents to the inland waters survey. (see Attachment 3-2)

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* This approach also assumes that the CTR will result in pollutant-free water, which, as stated previously, is not the case.

Response to: CTR-054-040

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

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EPA's analysis presents only the portion of the total potential benefits that can be achieved by controlling point sources. EPA expects additional benefits will accrue as a result of controlling other sources. EPA has no reason to believe that the standards established by the CTR cannot be achieved.

Subject Matter Code: E-02o01 No Peer Review Reference

Comment ID: CTR-090-004
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: E-02o01 No Peer Review Reference
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

The benefits section of the economic analysis is extremely flawed; the data used to develop the benefits section is highly questionable, some of which has not been peer reviewed (see BADA comments);

Response to: CTR-090-004

EPA acknowledges that Lyke's study has not been published in a peer reviewed journal and that she obtained some inconsistent results. EPA applied Lyke's research to illustrate the types and potential magnitude of the benefits from water quality improvements. EPA conducted an extensive search of the literature for additional studies that provide indication of the potential magnitude of the benefits from reducing concentrations of toxic pollutants in California surface waters. The results of EPA's search are described in the EA that accompanies the final rule.

Subject Matter Code: E-02q Benefits to Public at Large

Comment ID: CTR-092-023c
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: E-02q Benefits to Public at Large
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-02e
E-02l

Comment: Comment #7: General Benefit Analysis Concerns

The benefit analysis undertaken by EPA uses old, out-of-state data which does not appear applicable to California. A major concern with this analysis is that the benefit recipients are only a subset of those impacted by the costs. Another is that the benefits accrue to the public at large; costs, on the other hand, to the extent that CTR-implementation costs are borne by Indirect Dischargers (as assumed by EPA in the copper situation) accrue to businesses.

Further, the benefit measurements of "angling day" are only useful if they represent a net increase in fishing activity -- if all that improving waterway quality does is create additional sites where safe fishing can occur, without increasing the overall amount of fishing that occurs, there is no net gain, there is only substitution between comparable sites. The value of benefits which occur because of substitution between fishing sites must be subtracted from the value which occurs from increased fishing. This has not been done in the EPA analysis, thus benefits are overstated.

Further, no stratification is evident to account for importation of out-of-state fishers -- including benefit value of attracting new anglers from other states to California fishing sites is irrelevant to an analysis of costs/benefits of implementing the CTR for California.

Questions for EPA on Comment #7:

Q.7 - 1) If the concerns stated above were appropriately addressed, what would be the impact on EPA's benefits analysis? Our concern relates to the need to examine levels of regulation in comparison to benefits obtained, i.e. cost-effectiveness.

Q.7 - 2) Executive Order 12866, in recognition that quantification of benefits is very difficult, is quite explicit about addressing qualitative benefits wherever possible why wasn't that done in this analysis?

Response to: CTR-092-023c

EPA was not able to locate more relevant or more recent data or research for the analysis. EPA solicited relevant data and information in the EA and proposal. In addition, in response to comments, EPA conducted an extensive search of the literature for any additional recent, California-specific data or information applicable to the benefits analysis. EPA reviewed and evaluated all data and information submissions, and the results of the literature search, and revised the EA and CTR as appropriate prior to

promulgating the final rule.

Although it is true that the direct costs of the regulation are borne by municipal and industrial dischargers while the benefits accrue to the public at large, it is also true that in generating the discharges, the benefits (cost savings) accrued to businesses and municipalities while the costs (decreased utility associated with water resources) were borne by the public. Ultimately, benefits and costs are borne throughout society (e.g., costs are borne directly by municipal and industrial dischargers but indirectly by the public who pays for their products and services).

EPA acknowledged that increased angling activity at sites experiencing reductions in toxic contaminants may reflect a shift in activity from substitute sites rather than a net increase. Because EPA could not account for substitute sites in this analysis, EPA estimated lower bound benefits of $0 (i.e., assuming no net increases in activity; see EA, Chapter 8).

EPA's estimate of the relevant angling population is based on resident California anglers (see Analysis of the Potential Benefits Related to Implementation of the California Toxics Rule, Draft, December 20, 1996, pp. 3-23, 3-35 to 3-36).

EPA revised its economic analysis in response to comments and to reflect any new data or changes to the proposal.

(EPA revised.....already part of text)....The estimated cost-effectiveness of the rule is expected to range from $22/lb-eq to $31/lb-eq. EPA expects the total annual, monetized benefits from implementation of the CTR to range from $8.7 to $40.8 million dollars.

Chapter 6 of the EA (Qualitative Assessment of Potential Ecological Benefits) provides a qualitative discussion of potential ecological benefits. EPA also provided a qualitative discussion of important benefit categories that it was not able to quantify or monetize (see the EA that accompanied the proposed rule, Chapter 8).

Subject Matter Code: F Endangered Species Act

Comment ID: CTR-001-009a
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: F Endangered Species Act
References:
Attachments? N
CROSS REFERENCES J-06

Comment: THE PROPOSAL VIOLATES THE NATIONAL ENVIRONMENTAL POLICY ACT AND ENDANGERED SPECIES ACT, AND WOULD USURP THE ROLE OF CONGRESS AND THE STATE AND REGIONAL BOARDS

Major environmental impacts of controls could also be foreseen if the water quality standards of the proposed CTR were to apply as numeric effluent limitations or wasteload allocations. This would result in the requirement to prepare an EIS in connection with the proposed rule. (*13) In effect, substantial end-of-pipe treatment facilities on the same order of magnitude as existing POTWs in the Bay Area could be necessary.

Given the scale and location of the facilities that would be required, significant wetland, endangered species and other environmental impacts could occur. EPA must fully evaluate these impacts of the proposed rule before the rule is promulgated. (*14)

A more expansive application of the WQS also would usurp the basin planning process to the extent that the regional boards have included textual discussions of how ambient water quality criteria are to be implemented, particularly with respect to MS4s. The San Francisco Basin Plan states generally that WQS are to be addressed by MS4s through escalating BMPS. EPA has not taken action to disapprove the San Francisco Basin Plan and cannot implicitly repeal portions of that plan through inconsistent preamble language in the currently proposed rule.

Congress has already addressed this significant public policy question and the agency cannot shed its Congressional leash and arrogate legislative power. This is particularly true given the massive expenditures of public funds that could be implicated under at least the more expansive view of what EPA has proposed. We elect our representatives in Congress to balance these major questions, such as the matter of whether local funds should be siphoned from schools, police, infrastructure, etc., to fund storm water controls at the scale necessary to meet WQS regardless of cost. Congress has determined in Section 402(p) that MS4s need only adopt controls to reduce pollutants in storm water to the maximum extent practicable, and to effectively prohibit non-storm water discharges to the storm water system, rather than being subjected to infeasible or exorbitantly expensive numeric effluent limitations.(*15)

(*13) To the extent that the CTR will force development of end of-pipe treatment systems, promulgation of the CTR will represent a major federal action significantly affecting the quality of the human environment under the National Environmental Policy Act, triggering the requirement to develop an

environmental impact statement to support the rule.

(*14) Commenters have been limited in their ability to present specific information on the question of endangered species, wetland and other environmental impacts given the short comment period on the proposal and EPA's refusal to extend that comment period.

(*15) In Sections 402(p)(5) and (6)f Congress also directed that the approach to meeting water quality standards should MEP-level controls on major dischargers fall short would be to study and expand the scope of the program to include additional dischargers. No mention is made of subjecting major MS4s to more stringent controls. In fact, the regulations are expressly required to target stormwater discharges, other than those discharges described in paragraph (2) [major MS4S], to be regulated to protect water quality - 33 U.S.C. section 1342(p)(6) (Emphasis added).

Response to: CTR-001-009a

With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, Comment CTR-040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

The purpose of the CTR is to fill the current gaps in water quality criteria in inland surface waters and enclosed bays and estuaries. Any existing provisions in a State Basin Plan that have been approved by the State and EPA would not be negated by the preamble discussion in the CTR.

Regarding the application of MEP under section 402(p) of the CWA see response to CTR-040-004.

See also response to CTR-001-009b (Category J-06; Stormwater Economics).

Comment ID: CTR-012-001
Comment Author: Fish and Wildlife Service
Document Type: Federal Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: F Endangered Species Act
References:
Attachments? N
CROSS REFERENCES

Comment: This is in response to the Environmental Protection Agency's (EPA) August 5, 1997, publication of the Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule (Proposed Rule) (Federal Register Vol. 62, No. 150, pages 42159-42208). The Fish and Wildlife Service (Service) provides the following comments specific to EPA's statutory obligations pursuant to section 7 of the Endangered Species Act of 1973, as amended (Act).

Section L of the Proposed Rule states that consultation pursuant to section 7 of the Act will occur. Section 7 of the Act directs that Federal agencies prepare a biological assessment for a proposed action that may affect a listed species, however, to date the Service has not received a biological assessment on the Proposed Rule. The Service has specific concerns regarding selenium, mercury, dissolved metals and PCP and their effects on listed species. Preliminary review indicates that adverse impacts to listed species may occur, therefore, we anticipate that the EPA will formally consult with the Service regarding this proposed rule making process, and will wait until formal section 7 consultation has been completed before finalizing the proposed rule.

The Service looks forward to the opportunity to work with you and our staff on this consultation and appreciates the efforts to date to evaluate the effects of the proposed action on listed species. If you have any questions regarding this response please contact Ms. Maria Boroja at (916) 979-2749.

Response to: CTR-012-001

The US Fish and Wildlife Service (FWS) and US National Marine Fisheries Service initiated formal consultation in a letter to EPA dated November 28, 1997, after reviewing the biological evaluation that EPA submitted to them on October 27, 1997. These documents and others pertaining to the formal consultation process are part of the administrative record of the CTR. EPA completed this process [in October 1999].

Comment ID: CTR-031-002a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: F Endangered Species Act
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES C-17a
C-17b
J
V

Comment: 2. Since the preamble implies that CTR criteria may be applied in NPDES permits for municipal storm water dischargers as numeric effluent limitations, the proposed rule is flawed with regard to: a) setting attainable, scientifically valid criteria in a manner consistent with state and federal regulatory approaches; b) assessing the potential economic impact on the public served by municipal storm water dischargers; c) assessing environmental impacts pursuant to the National Environmental Policy Act and the Endangered Species Act; and d) providing for the coordinated review and evaluation of the proposed CTR in conjunction with the proposed State Implementation Plan.

Response to: CTR-031-002a

With respect to comments about storm water dischargers, see response to comment CTR-013-003 (Category J; Stormwater Economics).

With respect to comments about NEPA and ESA, see response to CTR-031-002e (Category V; Collaborative Approach). With respect to the comment about coordination with the State Implementation Plan, see response to CTR-031-008b (Category V; Collaborative Approach).

Comment ID: CTR-031-007a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: F Endangered Species Act
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES J-04

Comment: C. If the CTR as proposed in the current draft is applied to municipal storm water dischargers as numeric effluent limitations, new end-of -pipe facilities will result. The impact of these facilities on the environment in general, and endangered species in particular, must therefore be specifically reviewed pursuant to the National Environmental Policy Act and Endangered Species Act.

End-of-pipe facilities would be required for municipal storm water dischargers in their attempt to meet the subject criteria. Storm water facilities must be located in the lowest topographic areas, which contain many of our most valuable and already diminished wetland habitats. This readily foreseeable environmental consequence of the CTR, if directly applied to municipal storm water dischargers, should not be ignored.

Response to: CTR-031-007a

With respect to ESA, EPA has completed consultation as required by Section 7 of the ESA. With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, CTR-040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

Comment ID: CTR-034-006
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: F Endangered Species Act
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: LEGAL ISSUES -- Executive Order 12866, Unfunded Mandates Reform Act, Regulatory Flexibility Act

* SCAP requests that EPA publish in the Federal Register for public review and comment a full discussion of the CTR criteria and implementation provisions that could be affected through the Endangered Species Act Section 7 consultation process with the U.S. Fish and Wildlife service and National Marine Fisheries Service. Additionally, prior to finalizing the CTR, EPA should provide an opportunity for the public to comment on the Biological Evaluation, Biological Opinion, including Reasonable and Prudent Alternatives, and EPA's proposed decisions regarding the Biological Opinion.

Response to: CTR-034-006

The administrative record for the CTR contains documents concerning the ESA consultation. The record contains EPA's biological evaluation and the FWS's and NMFS's biological opinion. The Services' biological opinion is not subject to public comment, rather EPA's proposed rule is subject to comment. Persons wishing to comment on how the rule would affect threatened and endangered species had adequate opportunity to do so during the comment period.

Comment ID: CTR-035-042
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: F Endangered Species Act
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42192 of preamble & pp. 5-42 - 5-52 (U.S. EPA, 1997c) - The Endangered Species Act EPA should provide a full discussion in the Preamble of the criteria and implementation provisions that could be affected through the consultation process with the U.S. Fish and Wildlife Service and National Marine Fisheries Service. In addition, EPA should provide an opportunity for public comment on the Biological Evaluation, Biological Opinion, including any Reasonable and Prudent Alternatives, and EPA's proposed decisions regarding the Biological Opinion, before the CTR is finalized, This will allow in parties to provide information to EPA that may be relevant to Agency decision making about the impacts of the CTR on threatened and endangered species.

Response to: CTR-035-042

See response to CTR-034-006.

Comment ID: CTR-059-017
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/26/97
Subject Matter Code: F Endangered Species Act
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Endangered Species Act

LACSD requests that EPA publish in the Federal Register for public review and comment a full discussion of the CTR criteria and implementation provisions that could be affected through the Endangered Species Act Section 7 consultation process with the U.S. Fish and Wildlife Service and National Marine Fisheries Service. Additionally, prior to finalizing the CTR, EPA should provide an opportunity for the public to comment on the Biological Evaluation, Biological Opinion, including Reasonable and Prudent Alternatives, and EPA's proposed decisions regarding the Biological Opinion.

Response to: CTR-059-017

See response to CTR-034-006.

Comment ID: CTRH-001-009b
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: F Endangered Species Act
References:
Attachments? N
CROSS REFERENCES J-6

Comment: Lastly, it's been fairly well documented by EPA testimony before the Congress and by other state stakeholders' concerns about the end-of-pipe mandate, because the end-of-pipe facilities that must be constructed in effect create substantial damage to the riparian and other waters of the U.S. that are of primary concern to us.

With that potential, then certainly NEPA and the Endangered Species Act would require an evaluation of the impact associated with a rule causing or leading to those impacts. And again, the current rule does not consider that nor any of the cost or other impacts related to stormwater programs.

So there is a huge consistency or inconsistency problem that we think must be corrected for the rule to be consistent with the statutes and with your executive orders.

Thank you.

Response to: CTRH-001-009b

With respect to ESA, EPA has completed consultation as required by Section 7 of the ESA. With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, CTR-040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

Subject Matter Code: G-01 Reasonable Potential

Comment ID: CTR-032-002a
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-01 Reasonable Potential
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-22
G-09
C-24a
C-24
K
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002a

EPA appreciates the commenter's support for the preamble language on State implementation. However, EPA wishes to clarify that for reasonable potential analysis, the CTR preamble did not explicitly recommend any specific method of calculating reasonable potential including those methods chosen by the State Task Force. The State of California as the implementing authority has the discretion to choose any method that meets the requirements of the Clean Water Act. EPA does support the State's consideration of State Task Force recommendations in selecting implementation procedures including reasonable potential methodology.

Comment ID: CTR-037-001b
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-01 Reasonable Potential
References:

Attachments? N
CROSS REFERENCES C-24

Comment: 1. The rule proposes that the more stringent of site-specific and national criteria be used in determining reasonable potential to exceed water quality standards and in development of limits where site-specific criteria have not yet been established. This proposal ignores the scientific basis of a site-specific criterion and that such a criterion is specifically more relevant and appropriate than a national criterion if derived correctly. EPA has acknowledged that national criteria can be more stringent than necessary to protect designated uses because they are designed to protect a wide variety of surface waters, and that a site-specific criterion can be sufficiently protective while being less stringent than a national criterion (Water Effect Ratio Guidance, 1994). This rule is arbitrarily dismissing the use of site-specific criteria which may be more technically defensible than national criteria, while being protective.

Response to: CTR-037-001b

The proposed rule does not by its own terms dictate whether a particular site-specific criterion or a national criterion should be used in a reasonable potential analysis. The reasonable potential analysis to determine whether a discharger needs a water quality-based effluent limit is based on the criterion that applies to the waterbody. EPA agrees that when an approved state site-specific criterion applies to a particular pollutant for a specific waterbody and EPA determines that it need not adopt a criterion for that pollutant and site in the final rule, the State site-specific criterion should be the criterion upon which the reasonable potential analysis is based.

If EPA promulgates statewide federal criteria before a decision to approve a State-adopted site-specific criteria, the more stringent of the two criteria would be used for water quality programs. Both federal and State water quality programs must be satisfied, and application of the more stringent of the two criteria would satisfy both. The CTR does not preclude future State adoption of site-specific criteria. However, a state-adopted site-specific criterion would become the sole criterion upon which a reasonable potential analysis is based only after EPA approves the criterion and also stays or withdraws the corresponding CTR criterion to the specific site.

Comment ID: CTR-086-004a
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: G-01 Reasonable Potential
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES C-22
G-09
C-24a
C-24
K-03
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004a

EPA appreciates the commenter's support for the preamble language on State implementation. However, EPA wishes to clarify that for reasonable potential analysis, the CTR preamble did not explicitly recommend any specific method of calculating reasonable potential including those methods chosen by the State Task Force. The State of California as the implementing authority has the discretion to choose any method that meets the requirements of the Clean Water Act. EPA does support the State's consideration of State Task Force recommendations in selecting implementation procedures including reasonable potential methodology.

Comment ID: CTR-090-010a
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-01 Reasonable Potential
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES K-01

Comment: We recommend that EPA:

2. Include in the rule an implementation proposal which states that before a criteria is put into a permit there must first be: an assessment that the pollutant could reasonably interfere with the designated uses of the water; a comprehensive TMDL is done which includes all sources of pollutants to the water body; and a reasonable potential analysis is completed for point source dischargers. Only then, after all of these analyses are completed by the state or EPA should the criteria be converted to a permit limit with the appropriate implementation factors.

Response to: CTR-090-010a

The implementation procedures suggested by the commenter are beyond the scope of this rule. Implementation of water quality standards through various regulatory and non-regulatory tools is primarily a State responsibility.

Generally, a permit limit that implements a criterion for a pollutant will only be considered when it has already been determined that limiting the level of the pollutant is necessary to protect the designated use.

This determination occurs during the standard-setting process. EPA agrees that when multiple sources (point and nonpoint) impact a waterbody, a comprehensive TMDL is the preferred regulatory tool under the CWA for determining how best to achieve any necessary load reduction to the waterbody so as to attain water quality standards. When a TMDL has been conducted, the wasteload allocation (WLA) in the TMDL for a discharger would be basis for developing water quality-based effluent limits. When the TMDL includes a WLA for a discharger, a separate reasonable potential analysis to determine whether or not a WQBEL is needed would in most cases be redundant (although in rare cases, it may be that the level of the pollutant in the discharger's effluent is so much less than the level allowed by a WLA/WQBEL that even under worst case conditions the effluent would not exceed the WQBEL; in these cases, permitting authority would have the discretion not to include a limit.).

As recognized in the preamble to the proposed rule, the TMDL process "can be significantly labor and data intensive." 62 FR at 42185. Delaying WQBELs until TMDLs are completed would be inconsistent with the Clean Water Act and would unnecessarily delay attainment of water quality goals. The CWA requires imposition ofWQBELs whenever technology-based limits are insufficient to attain water quality standards [301(b)(1)(C) and 402], whether or not a TMDL has been completed for that pollutant. Under federal regulations, permitting authorities must analyze whether a discharger would cause or have the reasonable potential to cause or contribute to an exceedance of water quality standards [Section 122.44(d)(1)(i) , and if so, impose a WQBEL that derives from and implements the standard [Section 122.44(d)(1)(vii)]. Permitting authorities need to consider a number of factors related to the characteristics of the effluent and receiving water (including other sources that influence the background levels of pollutants in the receiving water) in making these determinations. [see, e.g., Section 122.44(d)(1)(ii)].

Subject Matter Code: G-02 Compliance Schedules

Comment ID: CTR-002-010b
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES A

Comment: The proposed implementation plan allowing compliance schedules for effluent limits to attain the criteria to be placed in permits may not pass the antidegradation test either. CBE believes EPA recognizes that permit schedules which allow continued impairment of fishing and aquatic life uses are improper (See e.g., section 1311(b)(1)(C), section 1314(l)(1)(D), section 1342(o)(1) and (3) and section 1313(d)(4)(A) of the Clean Water Act). In the alternative case, however, a schedule allowing discharge of these persistent pollutants to waters attaining the criteria will result in the accumulation of pollutants and will degrade water quality. This degradation is unnecessary as the state has accommodated important economic and social development for years while placing compliance schedules in administrative enforcement orders, and is thus impermissible under 40 CFR section 131.12(a)(2). Indeed, existing California dischargers have been made aware of the need to meet similar or more restrictive criteria since at least 1991, and further extension of time for more pollution should be done through schedules in enforcement orders. Any desire to avoid the administrative effort of continuing to prepare these enforcement orders is easily outweighed by the public interests in clean water and public participation afforded.

In sum, EPA'S. weaker criteria shown in Table 2 do not protect designated uses of water based on sound scientific rationale, and even if this were true for some toxics in some areas of the Bay, the weaker criteria are not necessary to allow important economic or social development. Therefore, revision of water quality standards by adopting these criteria would not meet the tests set forth by 40 CFR section 131.11(a)(1) and section 131.12 and the Clean Water Act provisions these regulations implement, Further, incorporating schedules allowing polluters to harm fishing and aquatic life in water quality standards and effluent limits is improper, and there is no legitimate need for schedules allowing degradation of water quality and restricting public participation to be in permits instead of putting them in administrative enforcement orders as is done today. Thus EPA's proposal may, by failing to provide equal protection for people of color who fish for food and unfairly restricting public participation, also conflict with the Executive Order on environmental justice and civil rights law.

Response to: CTR-002-010b

The Clean Water Act authorizes the use of compliance schedules for meeting water quality standards. Section 303(e), governing the continuing planning process for water quality standards, states that the Administrator shall approve continuing planning processes that have, among other things, effluent limitations and schedules of compliance. See CWA section 303(e)(3)(A) and (F). Congress recognized the practical need for compliance schedules to allow dischargers the time necessary to install treatment to comply with effluent limitations. Other portions of the CWA contemplate that some time is practically necessary in order to allow dischargers time to meet new effluent limits, e.g. section 304(l), providing for

three years to meet water quality based limits in waters that are impaired, and section 301(b)(2), relating to technology-based limits. EPA's implementing regulations also contemplate schedules of compliance. See 40 CFR Section 130.5(1) and (6) which provide that each state must describe the process for developing effluent limitations and schedules of compliance and for establishing and assuring adequate implementation of new or revised water quality standards, including schedules of compliance.

The Environmental Appeals Board has held that an NPDES permit could not contain a compliance schedule unless the State explicitly authorizes such a compliance schedule in state law or regulation. See Star-Kist Caribe, Inc. (NPDES Appeal No. 88-5, May 26, 1992; Earlier Order, April 16, 1990). This holding clearly recognizes that compliance schedules are authorized under the Clean Water Act as part of the state's water quality standards. Further, EPA notes that because parties may challenge particular effluent limitations in particular permit proceedings, they may comment on specific proposed permits and then challenge such permits if they believe that EPA's granting of additional time in a particular context is arbitrary and capricious.

The question at issue in authorizing a compliance schedule is how long is reasonably necessary to meet the water-quality based effluent limit contained in a permit. As is consistent with the Great Lakes Guidance, EPA is authorizing five years as the outside limit for a compliance schedule, but expects permit authorities to use shorter compliance schedules wherever possible, or not to use compliance schedules where they are not necessary. Thus authorizing a compliance schedule does not mean each discharger will be allowed up to that amount of time; rather the permit authority will need to make a judgment about what is technically feasible for the dischargers to come into compliance. Further, recognizing that permit reissuance depends on where in the permit cycle the dischargers is, the rule provides that, in effect, the discharger may have up to ten years from the effective date of the rule to come into compliance with permit limits.

The regulated community commented that the compliance schedule was too short, while some environmental commenters argued that there should be no compliance schedule at all. Here, EPA balanced the prior existing compliance schedule time applied by the State of California, which for the Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan was up to ten years and concerns from some dischargers that meeting the limits will take at least five years with EPA's view that the criteria be met as expeditiously as possible.

EPA believes that more than three years may be needed in some circumstances for a variety of reasons. EPA is concerned that in some cases, dischargers may need to implement new state-of-the art treatment technologies or pollution prevention programs. Also, evaluation, design and implementation of facility-wide comprehensive pollution prevention strategies involving product substitution, process line changes may require more than three years. Further, as discussed in the preamble to the proposed rule, the technical and administrative process of modifying and implementing revised requirements for numerous industrial users at POTWs, as well as planning budgeting and undertaking new construction to change treatment processes at a municipal treatment works may take more than three years. 62 Fed. Reg. 42187 (Aug. 5, 1997). Thus, EPA finds that a compliance schedule of five years is reasonable for the CTR.

EPA further notes that its permit regulations allow the use of interim limitations in conjunction with a compliance schedule or other mechanism such as a variance. 40 CFR 122.47.

With respect to comments suggesting that EPA's criteria do not protect designated uses see response to CTR-002-003 (Category C-24; Site-Specific Criteria). With respect to the comment that the CTR may degrade water quality in violation of antidegradation policy see CTR-002-010a (Category A;

Antidegradation) and CTR-039-004 (Category C-14;Fish/Water Consumption).

With respect to comments concerning environmental justice see response to CTR-002-005a (Category C-14; Fish/Water Consumption).

Comment ID: CTR-009-002
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: The City concurs with the five year compliance schedule and variance provisions, and the EPA's recommendation that the State include such provisions in its water quality standards regulations as broadly and flexibly as the law allows.

Response to: CTR-009-002

EPA appreciates these comments providing support of EPA's positions on compliance schedules and variances.

Comment ID: CTR-009-006b
Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: With respect to the provisions in the proposed rule regarding compliance schedules and site-specific objective development and approval implementation, the City requests verification that these, and all provisions, in the proposed rule apply only to those constituents for which this rule proposes criteria.

Response to: CTR-009-006b

The compliance schedule allowance only applies to pollutants listed in the CTR. This rule does not address site-specific criteria development.

Comment ID: CTR-013-007b
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES I-05

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

7. The proposed rule provides only a five-year compliance schedule to achieve compliance with the proposed water quality criteria. Again, setting aside the issue of whether water quality standards actually apply to municipal stormwater discharges, municipal stormwater programs are long-term, BMP-based programs. Because of this, it will take many years for a municipality to realize any water quality benefits in the receiving waters. The preamble to the proposed rule addresses all wet weather discharges together in one discussion. Municipal stormwater programs should be discussed and treated separately from all other wet weather and point source discharges. These are unique programs and cannot be placed in a "one-size fits all" regulatory program. The proposed rule needs to account for the nature of stormwater discharges by allowing more time for the MS4 long-term, BMP, source control program approach to take place for controlling pollutants in stormwater discharges.

We recommend that the rule be revised to provide a longer compliance schedule and to provide more flexible regulatory relief for MS4 dischargers who have fully complied with the MEP discharge standards but cannot achieve compliance within the established compliance schedule. At a minimum, the CTR should follow the recommendation of the State Task Force on the Inland Surface Water Plan to provide a 15-year compliance schedule.

Response to: CTR-013-007b

EPA is unwilling to extend the compliance period beyond five years because it has not received specific information indicating under what specific circumstances more than five years would be necessary to meet permit limits. Some municipalities supported the five year compliance schedule, while others argued that it was not sufficiently long. With respect to municipal stormwater discharges, permits are expected to require implementation of BMPs as the effluent limitations and that these BMPs are feasible within five years. Compliance schedules relate to what is necessary to meet the requirements of a particular permit limitation and EPA believes that meeting these limits is feasible within five years.

EPA supports the State in adopting a statewide provision independent of or as part of the current effort to readopt statewide water quality control plans, or in adopting individual basin-wide compliance schedule provisions through its nine Regional Water Quality Control Boards (RWQCBs). The State and RWQCBs have broad discretion to adopt a provision, including discretion on reasonable lengths of time for final compliance with WQBELs. EPA recognizes that practical time frames within which to set interim goals may be necessary to achieve meaningful, long-term improvements in water quality in

California.

EPA would prefer that the State authorize a compliance schedule provision but recognizes that it may not be able to complete this action for some time after promulgation of the CTR. Thus, EPA has chosen to promulgate the rule with a sunset provision which states that the authorizing compliance schedule provision will cease or sunset on September 30, 2004, or in approximately five years. However, if the State Board adopts, and EPA approves, a statewide authorizing compliance schedule provision prior to that time, EPA will expeditiously act to stay the authorizing compliance schedule provision in today's rule. Additionally, if a Regional Board adopts, and the State Board adopts and EPA approves, a Regional Board authorizing compliance schedule provision, EPA will act to stay today's provision for the appropriate or corresponding geographic region in California. At that time, the State Board's or Regional Board's authorizing compliance schedule provision will govern the ability of the State regulatory entity to allow a discharger to include a compliance schedule in a discharger's NPDES permit.

At this time, two RWQCBs have adopted an authorizing compliance schedule provision as an amendment to their respective Basin Plans during the Boards' last triennial review process. The Basin Plans have been adopted by the State and have come to EPA for approval. Thus, the Basin Plans' provisions are effective for the respective Basins. If and when EPA approves of either Regional Basin Plan, EPA will expeditiously act to amend the CTR, staying its compliance schedule provision, for the appropriate geographic region.

Comment ID: CTR-015-006
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: Schedules of Compliance (FR p. 42187, Preamble section F.5.)

It is mentioned that one Regional Board has adopted an authorizing compliance schedule provision in its Basin Plan and that, if the Agency includes a authorizing compliance schedule provision in this Rule, that Regional Board's provision will be recognized and effective. How would other Regional Boards get similar provisions into their Basin Plans, and what is the State Board's function, after this Rule is finalized? This discussion is confusing, as California state law already authorizes the use of schedules of compliance (Porter-Cologne Water Quality Act, Article 4, section 13263(c); California Code of Regulations, Title 23, Division 3, Chapter 91 section 2235.2). The discussion implies that, if the Agency does not include an authorizing compliance schedule provision in this Rule, that compliance schedules would not be allowed, which could impact the State Board's existing general authority and associated policies.

Response to: CTR-015-006

The CTR pre-empts any state law unless the state law is more stringent (Clean Water Act, Section 510).

The compliance schedule allowance in the CTR will be applicable wherever the CTR applies. If a Basin Plan includes a criteria (objective) for pollutant to which the CTR either does not apply or is less stringent, that Basin Plan must allow for compliance schedules in order for a compliance schedule to be included in the permit.

EPA would prefer that the State authorize a compliance schedule provision but recognizes that it may not be able to complete this action for some time after promulgation of the CTR. Thus, EPA has chosen to promulgate the rule with a sunset provision which states that the authorizing compliance schedule provision will cease or sunset on September 30, 2004, or in approximately five years. However, if the State Board adopts, and EPA approves, a statewide authorizing compliance schedule provision prior to that time, EPA will expeditiously act to stay the authorizing compliance schedule provision in today's rule. Additionally, if a Regional Board adopts, and the State Board adopts and EPA approves, a Regional Board authorizing compliance schedule provision, EPA will act to stay today's provision for the appropriate or corresponding geographic region in California. At that time, the State Board's or Regional Board's authorizing compliance schedule provision will govern the ability of the State regulatory entity to allow a discharger to include a compliance schedule in a discharger's NPDES permit.

At this time, two RWQCBs have adopted an authorizing compliance schedule provision as an amendment to their respective Basin Plans during the Boards' last triennial review process. The Basin Plans have been adopted by the State and have come to EPA for approval. Thus, the Basin Plans' provisions are effective for the respective Basins. If and when EPA approves of either Regional Basin Plan, EPA will expeditiously act to amend the CTR, staying its compliance schedule provision, for the appropriate geographic region.

Comment ID: CTR-016-003
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: State Compliance Schedule Provisions

We support the inclusion of compliance schedule provisions and would like EPA to clarify the statement that "any appropriately adopted Basin Plan amendment concerning a compliance schedule would also be effective for the Basin." In 1995, our Basin Plan was formally amended to include a compliance schedule provision (p. 4-14, (f)--see attached). The state review and approval process of those amendments has been completed and we have submitted the amendments to EPA for approval.

Our interpretation is that the regional compliance schedule provisions adopted in Basin Plans would take precedence over any compliance schedule provisions promulgated in the final rule by EPA and that EPA will either formally approve our Basin Plan prior to final rulemaking, or amend the proposed rule such that state-adopted compliance schedule provisions automatically take precedence at the time the final step in the approval process has been completed.

Response to: CTR-016-003

See response to CTR-015-006.

Comment ID: CTR-020-021
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: V. Schedules of Compliance

The CTR specifies that schedules of compliance are authorized, but only if the Basin Plan specifically allows the inclusion of schedules in permits. While the City generally agrees that schedules of compliance should be available for new requirements, we disagree that the authority for schedules of compliance must be specifically stated in a Basin Plan. The Porter-Cologne Act itself authorizes schedules of compliance and pursuant to the decision in the Star-kist Caribe, Inc., NPDES Appeal No. 88-5 (may 26, 1992), such authorization is sufficient to allow a schedule of compliance. Stockton agrees that a schedule of at least five years should be allowed. For complex pollution situations such as those related to storm waters, a longer period of compliance should be allowed because the available methods for pollution reduction will take much longer to implement and assess. As EPA allows up to twenty years for compliance for combined sewer overflows (a similar wet weather problem), a twenty-year period should be specified for storm waters.

Response to: CTR-020-021

See response to CTR-015-006.

Comment ID: CTR-021-002f
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES G-04
C-24a
C-22
K-01
G-05

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; (c) the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002f

EPA appreciates these comments providing support for EPA's allowance of compliance schedules in NPDES permits.

Comment ID: CTR-022-003
Comment Author: SWRCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (U.S. EPA) proposed California Toxic Rule (CTR). The State Water Resources Control Board (SWRCB) staff would like to recognize U.S. EPA's tremendous effort in producing the CTR. The SWRCB staff are providing you with the following comments:

Pages 42188 and 42208: State Compliance Schedule Provisions: The preamble indicates, if the CTR is adopted with compliance schedule provisions, any appropriately adopted basin plan provision authorizing compliance schedules would also be effective for the basin. We support this approach; however, it is not reflected in the wording of proposed Section 131.38(e).

In fact, at least two Regional Water Quality Control Boards have included compliance schedule provisions in their basin plans. These provisions allow compliance schedules of up to ten years in permits. In this respect the basin plan provisions are less stringent than the proposed rule. While the proposed rule states that "...where shorter schedules of compliance are prescribed or schedules of compliance are prohibited by law, those provisions shall govern", the rule does not clarify that existing basin plan provisions authorizing longer schedules are also effective.

Response to: CTR-022-003

See responses to CTR-013-007b and CTR-015-006.

Comment ID: CTR-027-008b
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES I-05

Comment: 8. The proposed rule provides only a five-year compliance schedule to achieve compliance with the proposed water quality criteria. Again setting aside the issue of whether water quality standards actually apply to municipal stormwater discharges, municipal stormwater programs are long term BMP based programs. The proposed rule fails to recognize this, addressing all wet weather discharges together in one discussion. Municipal stormwater programs should be discussed and treated separately from all other wet weather and point source discharges. These are unique programs and cannot be placed in a "one-size fits all" regulatory program. The proposed rule needs to account for the nature of stormwater discharges by allowing more time for the MS4 long-term, BMP, source control program approach to take place for controlling pollutants in stormwater discharges.

The compliance schedule in the proposed rule discourages a watershed approach to improving water quality. The development and implementation of a watershed plan requires many years and many stakeholder involvements. However, the short compliance schedule in the CTR would actually encourage the discharger to forgo the watershed approach and address its toxicity issues separately and more expeditiously.

Recommendation: The rule should allow the State to establish compliance schedules. Short of this flexibility, the rule should be revised to provide a longer compliance schedule and to provide more flexible regulatory relief for MS4 dischargers who have fully complied with the MEP discharge standards but cannot achieve WQBELs compliance within the established compliance schedule. At a minimum, the CTR should follow the recommendation of the State Task Force on the Inland Surface Water Plan to provide a 15-year compliance schedule. Also provisions should be made for a longer compliance schedule when dischargers use a watershed approach to control toxic pollutants.

Response to: CTR-027-008b

See response to CTR-013-007b.

Further, in response to comments that EPA adopt a 15-year compliance schedule in order to accommodate schedules for developing TMDLS, EPA disagrees. The schedule for developing TMDLs is not relevant to compliance schedules; they are two totally separate issues. Compliance schedules address how long it will take in terms of technical or financial feasibility to meet an effluent limit established in an NPDES permit; they do not affect when the permit is issued. Moreover, while states may be adopting schedules for adopting TMDLs that extend up to 15 years, NPDES permits continue to be issued, even if this means they are issued before the TMDL is established for a particular waterbody. To do otherwise would be to stop the NPDES program until TMDLs are established. With regard to a situation in which a TMDL or watershed management program for the waterbody are scheduled for completion after the original compliance schedule has lapsed and justifiable delays in meeting WQBELs

arise, the discharger may apply for a variance from the water quality standard if the State develops an authorizing variance provision and the discharger meets the conditions set forth under 40 CFR 131.10(g).

The outside limit of ten years from the effective date of the rule means that dischargers whose permit is not renewed until the end of the ten year time frame will not be able to obtain a compliance schedule. EPA believes that this provision is nevertheless fair and reasonable for several reasons. First, based on the State's Implementation Plan [Reg. 9 put in correct title], EPA expects that the State will be able to reissue permits before the expiration of the ten year periods. Even if the State cannot do this, EPA thinks that ten years notice gives dischargers sufficient time to plan for meeting water quality based effluent limits, particularly given that the rest of the country has been subject since at least 1992 to such water quality standards either under state law or the National Toxics Rule ("NTR"). EPA promulgated the NTR for all states that did not have adequate criteria for toxic pollutants for which EPA had issued CWA section 304(a) criteria guidance.) Dischargers may also have sufficient notice because the State issued to many dischargers NPDES permits based on either the State's Inland Surface Waters Plan and Enclosed Bays and Estuaries Plan or narrative criteria similar to criteria in today's rule. Further, EPA also does not want to create an incentive for dischargers to have their permits re-issued later rather than sooner. Given the concern to have a level playing field among California dischargers, and those across the country who have all been subject to water quality criteria at least since 1992, EPA believes it is reasonable to cut off the compliance schedule for every discharger by ten years after the effective date of the rule.

Comment ID: CTR-030-004a
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES G-04
I

Comment: D. EPA's Endorsement of Five-Year Compliance Schedules and Interim Permit Limits for Modifications is Appropriate

UWAG strongly supports EPA's recognition that modifications necessary to comply with new or more stringent effluent limitations may necessitate the use of five-year compliance schedules. 62 Fed. Reg. at 42,187, col. 3. UWAG believes, however, that in certain circumstances a longer compliance schedule may be appropriate. Steam electric facilities that need retrofits to meet water quality-based effluent limits (WQBELS) often require extensive engineering design and testing prior to the actual retrofit. Additionally, nuclear facilities must ensure that any design changes are compatible with Nuclear Regulatory Commission regulations. Therefore, the availability of five-year compliance schedules is certainly well-justified. Further, EPA should consider whether longer compliance schedules should be available, at least in some limited circumstances.

Additionally, UWAG strongly supports EPA's approval of interim permit limits for use in permit modifications. This flexibility will allow dischargers to stay in compliance while necessary process or

design changes are carried out.

Response to: CTR-030-004a

EPA appreciates these comments providing support for its compliance schedule provisions. With respect to EPA's decision on compliance schedule length see response to CTR-002-010b.

Comment ID: CTR-031-005a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES I

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

iii. State Flexibility and Authority

The CTR states, "The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are other Federally-adopted and State-adopted numeric toxics criteria when applied to the same use classifications..." p. 42206

This language supports State Water Resources Control Board decisions and the San Francisco Basin Plan which have made it clear that municipal storm water dischargers need to address water quality standards only through the implementation, and escalation as necessary, of best management practices. As noted previously, the language of this section must be better supported in the preamble.

Notwithstanding the above statement on page 42206, the CTR actually diminishes state flexibility in implementing the rule and is inconsistent with state compliance schedules. The CTR mandates implementation limits on the state and implies a 5-year limit on compliance.

A five-year compliance schedule for municipal storm water dischargers is entirely inconsistent with the State's, EPA'S, and Phase II stakeholder's understanding of the unique challenges of storm water permitting. The draft Phase II regulation submitted to OMB includes a comprehensive reevaluation of storm water programs after two permit terms, and recommends no added best management practices or

changes in the Phase II program until such evaluation and research are completed.

Response to: CTR-031-005a

See response to CTR-013-007b.

Comment ID: CTR-032-002i
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
K
G-04
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002i

EPA appreciates these comments providing support for its compliance schedule provisions.

Comment ID: CTR-034-013
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N

CROSS REFERENCES

Comment: * SCAP endorses the inclusion in the draft CTR of a provision authorizing the use of compliance schedules in NPDES permits. We agree with the rationale for its inclusion, since immediate and full compliance by dischargers simply is not always possible or practicable. We strongly urge EPA, however, to consider modifying this provision to authorize the issuance of permits containing compliance schedules of up to 15 years. While schedules that long need not always be granted, we believe that including the authority in the CTR would allow greater flexibility in crafting control strategies as EPA and the State implement watershed-based approaches, and would foster greater opportunities to pursue pollution prevention avenues before moving to extreme measures, such as advanced end-of-pipe treatment.

Response to: CTR-034-013

See response to CTR-027-008b.

Comment ID: CTR-035-037
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42187-42188 -- Schedules of Compliance We support the inclusion in the CTR of a provision authorizing the use of compliance schedules in permits, as authorized by the Clean Water Act. We agree with EPA's statement in the Preamble explaining the need for compliance schedule authorization, "because of the potential for existing dischargers to have new or more stringent effluent limitations, under the final rule, for which immediate compliance would not be possible or practicable." However, periods of time longer than 5 years may sometimes be necessary and appropriate. Consistent with the 1990 Starkist-Caribe Order, EPA has full authority to promulgate a compliance schedule provision, and there is no limitation in the Clean Water Act on the length of such a provision (U.S. EPA, 1990a). Therefore, based on the consensus recommendation of the Permitting and Compliance Issues Task Force, we urge EPA to allow up to 15 years for water quality standards to be met and to include a provision in the regulation stating that compliance schedules in NPDES permits for achievement of final effluent limitations based on the water quality criteria being promulgated may not extend beyond the compliance deadline for the standards (SWRCB, 1995, Part VI). The 5-year time frame assumes that a rapid response through source control, treatment plant operational changes, and/or major structural improvements is possible. However, once a decision is made to proceed with a project, planning, financing, design and construction can take more than 5 years. Further, we believe that a longer time frame may be suitable in cases where TMDLs are necessary and/or a watershed management program is underway but not complete. In such cases, it may make more sense for dischargers to pursue actions other than end-of-pipe treatment, such as monitoring, pollution prevention programs, water-effect ratio studies, investigation of pollutant trading opportunities, etc. (We also would like to point out that, in such cases, interim limits may be more appropriate than final effluent limits with compliance schedules.) This

is particularly true for pollutants which are not easily controlled (short of adding advanced treatment) through traditional industrial waste controls, and which must be reduced through new and innovative means (for instance, public education programs, installation of BMPs, etc.). A 15-year time frame is also consistent, we believe, with the guidance to EPA Regions issued by Assistant Administrator for Water Robert Perciasepe in August 1997, which directs States to submit schedules for developing TMDLs for all listed waters over an 8 to 13 year time period (U.S. EPA, 1997d). As this time frame does not include the implementation of measures to comply with Waste Load Allocations and Load Allocations to be developed through the TMDL process, we believe that even the 15-year time frame is optimistic for meeting water quality standards in all impaired water bodies, especially given the small number initiated in California to date and the large number of water bodies listed as impaired on California's 303(d) list.(*1)

(*1) 386 water bodies were listed by the state of California on the 303(d) list as of 1996 (SWRCB, 1996). Many of these water bodies were listed for multiple pollutants or stressors.

Response to: CTR-035-037

See response to CTR-027-008b.

Comment ID: CTR-036-010a
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES I

Comment: We are concerned that the five-year compliance period for stormwater discharges to meet the criteria is untenable. The linkage between the application of best management practices and water quality benefits is long term and will thus be hard to demonstrate. Even in a direct product substitution situation, such as the removal of leaded gasoline from fuels, data from Orange County shows a very slow and long-term reduction in lead concentrations in our water bodies over multiple years.

Response to: CTR-036-010a

See response to CTR-013-007b.

Comment ID: CTR-038-012
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: 11. EPA should provide for a compliance schedule of 15 years, consistent with the recommendation of the State Plan Public Task Forces, where dischargers with potential compliance problems are pursing watershed management and other reasonable activities. The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to: monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies; translator studies; water-effect ratio studies; risk assessments; TMDL studies; investigation of pollutant trading opportunities; and conduct of watershed management studies. On the other hand, the proposed rule states that dischargers should generally be able to comply with the rule within 3 years and, at most, will be allowed a maximum of 5 years from the issuance of a permit to comply. These are obviously conflicting principles. Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the CTR should allow permit authorities to defer placement of final effluent limits based on CTR criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces. Also, consistent with the Task Force recommendations, the CTR should allow up to 15 years from the date of the rule to achieve compliance rather than the 10 years allowed in the proposed CTR. Such a provision would have the result of encouraging dischargers to participate in activities, such as watershed management, that will further the goals of the Clean Water Act, The presently proposed rule would have the effect of discouraging such activities.

Response to: CTR-038-012

See responses to CTR-013-07b and CTR-027-008b.

Comment ID: CTR-039-007
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of San Francisco BayKeeper, its Stockton-based DeltaKeeper project, San Diego BayKeeper and Santa Monica BayKeeper (hereinafter "BayKeepeer"), I am submitting these comments for consideration in finalizing EPA's proposed rule establishing water quality criteria for priority toxic pollutants for the waters of the State of California. The need for numeric criteria for priority toxic pollutants was identified by Congress ten years ago when, in October, 1987, it enacted amendments to the Clean Water Act mandating that States issue such criteria by not later than October 18, 1990. The State of California adopted a portion of the mandated criteria in April, 1991, which, in large part, EPA

approved. However, even that partial compliance was thwarted by the Sacramento Superior Court's overly broad decision vacating the State's decision based solely on a flawed economic analysis purportedly required by State law.

Now, seven years later, although appreciative of the complexity of the task required by Congress, BayKeeper is deeply concerned that EPA's proposed rule to cure the State's violation will undermine permit limits promulgated throughout the Bay area and other regions, allowing more pollution to be discharged to San Francisco Bay and other state waters in violation of the State and EPA's antidegradation policies. BayKeeper also is very concerned that EPA is promulgating criteria for mercury, dioxin and 13 other pollutants which are based on drastic underestimates of the quantity of fish consumed by recreational and subsistence anglers throughout the State of California. BayKeeper also believes that at this late date, the proposal to allow compliance schedules which could delay for up to ten years compliance with permit effluent limitations based upon the proposed criteria is inappropriate given the already seven year delay suffered by California's aquatic ecosystems and the people who depend upon the health of those systems for food and recreation.

V. EPA SHOULD NOT INCLUDE AUTHORITY FOR COMPLIANCE SCHEDULES IN ITS PROPOSED CRITERIA

As noted above, the proposed criteria, good or bad, are now seven years late. However, the State did have some criteria established for a three year period between 1991 and 1994. Thus, the regulated community has had ample notice of the criteria to come. indeed, a significant number of dischargers have been subject to permits based on approved criteria for upwards of five years. There is no scientific reason for EPA to perpetuate the delay and cause the State's aquatic ecosystems to further suffer toxic contamination that Congress mandated be addressed by October of 1990. Compliance schedules would be inconsistent with Congress' mandate. Moreover, compliance schedules would not be fair to those dischargers who already have been required to comply with the State's criteria issued in 1991. EPA should strike the compliance schedule authority from the proposed rule and leave the question of the need for compliance schedules to the State.

Response to: CTR-039-007

With respect to EPA's decision to include a compliance schedule, see response to CTR-002-010b. With respect to the relationship between EPA's compliance schedule and State adopted compliance schedules, see response to CTR-015-006. With respect to the comment that the CTR may degrade water quality in violation of antidegradation policy, see responses to CTR-002-010a (Category A; Antidegradation) and CTR-039-004 (Category C-14; Fish/Water Consumption). With respect to the comments on fish consumption, see response to CTR-002-002a (Category C-14; Fish/Water Consumption).

Comment ID: CTR-040-019
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y

CROSS REFERENCES

Comment: VI. Recommendation: Provide for a compliance schedule of 15 years, consistent with the recommendation of the State Plan Public Task Forces, where dischargers with potential compliance problems are pursuing watershed management and other reasonable actions.

* The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to: monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies; translator studies, water-effect ratio studies; risk assessments; TMDL studies; investigation of pollutant trading opportunities; and watershed management studies.

* On the other hand, the proposed Rule states that dischargers should generally be able to comply with the Rule within 3 years and, at most, will be allowed a maximum of 5 years from the issuance of a permit to comply. These are obviously conflicting principles.

* Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the Rule should allow permit authorities to defer placement of effluent limits based on Rule criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces.

* Also, consistent with the State Plan Public Task Force's recommendations, the Rule should allow up to 15 years from the date of its promulgation to achieve compliance rather than the 10 years currently proposed. Such a provision would have the result of encouraging dischargers to participate in activities, such as watershed management and development of TMDLs, that will further the goals of the CWA. (In other documents, EPA has acknowledged that the TMDL process may take 8 - 13 years). The Rule, as it is presently proposed, will have the effect of discouraging such activities.

Response to: CTR-040-019

See response to CTR-027-008b.

Comment ID: CTR-041-012
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: 7. EPA Should Provide a Compliance Schedule of Fifteen Years

EPA should provide for a compliance schedule of fifteen years, consistent with the recommendation of the State Plan Public Task Forces, where dischargers with potential compliance problems are pursuing

watershed management and other reasonable activities. The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to; monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies, translator studies; water-effect ratio studies, risk assessments; TMDL studies; investigation of pollutant trading opportunities; and conduct of watershed management studies. On the other hand, the proposed rule states that dischargers should generally be able to comply with the rule within three years and, at most, will be allowed a maximum of five years from the issuance of a permit to comply. These are obviously conflicting principles. Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the CTR should allow permit authorities to defer placement of final effluent limits based on CTR, criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces. Also, consistent with the Task Force recommendations, the CTR should allow up to fifteen years from the date of the rule to achieve compliance rather than the five years allowed in the proposed CTR. Such a provision would have the result of encouraging dischargers to participate in activities, such as watershed management, that will further the goals of the Act. The presently proposed rules will have the effect of discouraging such activities.

Response to: CTR-041-012

See response to CTR-027-008b.

Comment ID: CTR-043-010
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: 10. EPA should provide for a compliance schedule of 15 years, consistent with the recommendation of the State Plan Public Task Forces. The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to: monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies; translator studies; water-effect ratio studies; risk assessments; TMDL studies; investigation of pollutant trading opportunities; and conduct of watershed management studies. On the other hand, the proposed rule states that dischargers should generally be able to comply with the rule within 3 years and, at most, will be allowed a maximum of 5 years from the issuance of a permit to comply. These are obviously conflicting principles. Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the CTR should allow permit authorities to defer placement of final effluent limits based on CTR criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces. Also, consistent with the Task Force recommendations, the CTR should allow up to 15 years from the date of the rule to achieve compliance rather than the 5 years allowed in the proposed CTR. Such a provision would have

the result of encouraging dischargers to participate in activities, such as watershed management, that will further the goals of the Act. The presently proposed rule would have the effect of discouraging such activities.

Response to: CTR-043-010

See response to CTR-027-008b.

Comment ID: CTR-044-011
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: We have reviewed the proposed CTR and offer the following comments:

10. EPA should provide for a compliance schedule of 15 years, consistent with recommendation of the State Plan Public Task Forces. The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to: monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies; translator studies; water-effect ratio studies; risk assessments; TMDL studies; investigation of pollutant trading opportunities; and conduct of watershed management studies. On the other hand, the proposed rule, states that dischargers should generally be able to comply with the rule within 3 years and, at most, will be allowed a maximum of 5 years from the issuance of a permit to comply. These are obviously conflicting principles. Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the CTR should allow permit authorities to defer placement of final effluent limits based on CTR criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces. Also, consistent with the Task Force recommendations, the CTR should allow up to 15 years from the date of the rule to achieve compliance rather than the 5 years allowed in the proposed CTR. Such a provision would have the result of encouraging dischargers to participate in activities, such as watershed management, that will further the goals of the Act. The presently proposed rule would have the effect of discouraging such activities.

Response to: CTR-044-011

See response to CTR-027-008b.

Comment ID: CTR-045-003
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA

Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

The inclusion of a provision to allow compliance schedules in permits. It is suggested that this provision be modified to allow Regional Water Quality Control Boards (RWQCBS) to include compliance schedules of up to 15 years in permits, if they deem it appropriate.

Response to: CTR-045-003

See response to CTR-027-008b.

Comment ID: CTR-052-020
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should provide for compliance schedules of up to 15 years. This would be consistent with the consensus recommendation of the State Plan Public Task Forces, and allow dischargers the necessary flexibility to develop cost effective solutions prior to considering end-of-pipe treatment options.

Response to: CTR-052-020

See response to CTR-027-008b.

Comment ID: CTR-053-004
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and

the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES

Comment: We also agree with the concerns of our colleagues regarding the allowance of compliance schedules in permits to meet the California Toxics Rule. Compliance schedules are required in enforcement orders for any exceedance of numeric criteria. We, therefore, agree with and incorporate by reference CBE's comments on compliance schedules.

Response to: CTR-053-004

See response to CTR-002-010b.

Comment ID: CTR-054-012
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should provide for a compliance schedule of 15 years, consistent with the recommendation of the State Plan Public Task Forces, where dischargers with potential compliance problems are pursing watershed management and other reasonable activities. The Preamble discusses a number of reasonable and responsible actions that a discharger might pursue to address toxic pollutants including, but not limited to: monitoring of sources, discharges and ambient waters; development of best management practices; development of pollution prevention programs; optimizing treatment plant operations for toxics removal; dilution studies; translator studies; water-effect ratio studies; risk assessments; TMDL studies; investigation of pollutant trading opportunities; and conduct of watershed management studies. On the other hand, the proposed rule states that dischargers should generally be able to comply with the rule within 3 years and, at most, will be allowed a maximum of 5 years from the issuance of a permit to comply. These are obviously conflicting principles. Where dischargers are pursuing reasonable and responsible actions, such as those previously listed, the CTR should allow permit authorities to defer placement of final effluent limits based on CTR criteria in permits, and instead provide for interim permit limits consistent with the recommendations of the State Plan Public Task Forces. Consistent with the Task Force recommendations, the CTR should allow up to 15 years from the date of the rule to achieve compliance rather than the 5 years allowed in the proposed CTR. Such a provision would have the result of encouraging dischargers to participate in activities, such as watershed management, that will further the goals of the Act. The presently proposed rules will have the effect of discouraging such activities.

Response to: CTR-054-012

See response to CTR-027-008b.

Comment ID: CTR-056-010
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* The inclusion in the rule of a provision allowing compliance schedules in NPDES permits (although this provision should be modified to enable RWQCBs to include compliance schedules of up to 15 years in permits if it is determined to be appropriate).

Response to: CTR-056-010

See response to CTR-027-008b.

Comment ID: CTR-058-007
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES

Comment: Compliance Schedules. WSPA supports EPA's recognition of the need for granting appropriate but flexible compliance schedules, with timeframes up to and including five years. This is especially true in cases when treatment technology is not available and must be developed to deal with a specific pollutant which has not been regulated in the permit previously.

WSPA members have detailed and intimate personal experience with the struggle and timeframe needed to come into compliance with highly restrictive and challenging water-quality based effluent limitations (WQBELs). WPSA and the SFRWQCB have collaborated on the detailed studies (which include studies of the significant secondary impacts) needed to meet the very stringent selenium limits set for Bay Area refineries. Selenium is a contaminant which typically occurs in refinery wastewaters at concentrations much less than 0.5 mg/L (roughly the practical level for heavy metal treatment technology when our studies begin). Its chemistry is very complex and was not well understood when industry began its studies.

The timeframe for the selenium studies and compliance schedule is as follows:

1. 3rd quarter 1992: WSPA members begin meeting to develop technology to meet RWQCB refinery selenium limits. Studies begin approximately the end of 1992.

2. 2nd quarter 1993: WSPA invites the RWQCB to participate in the selenium studies. Annual interim reports to RWQCB are made.

3. 3rd quarter 1995. The consolidated WSPA technology studies are completed and reported to the RWQCB.

4. 1995/1996. Individual refineries pilot the technology(ies) of their choice.

5. July 31, 1998: compliance deadline for new limits; meanwhile interim limits apply.

RWQCB staff participated in our assessment and development of available technology options. One of the primary reasons for the technology studies was to pursue alternatives to the iron coprecipitation process because this process generates vast quantities of potentially "toxic" solid waste (using California definitions). In addition to the WSPA coordinated studies, two refineries actively pursued other promising technologies specific to their facilities. These technologies were ultimately dropped due to technical deficiencies. Evaluating the alternatives took time and was a valuable part of the study even though, in the end, they did not workable results. In any case, the refineries still anticipate meeting the compliance deadline. We think the regulatory community would agree with us that even given the significant resources devoted to assessing the efficacy and appropriateness of various technologies, these studies take time to do well. However, to address complex and difficult WQBELS, this anecdote illustrates the need for permit writers to have the flexibility to work with dischargers on compliance schedules which in some cases may be very lengthy.

The use of compliance schedules is amply supported by existing regulations and practice, and makes for a practical approach to achieving the goals of the Act.

Response to: CTR-058-007

Comment ID: CTR-059-013
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: The Sanitation Districts supports the inclusion in the draft CTR of a provision authorizing the use of compliance schedules in NPDES permits. We agree with the rationale for its inclusion, since immediate and full compliance by dischargers simply is not generally possible or practicable. We strongly urge EPA, however, to consider modifying this provision to authorize the issuance of permits

containing compliance schedules of up to 15 years. We believe that including the authority in the CTR would foster greater opportunities to pursue pollution prevention avenues before moving to extreme measures, such as advanced end-of-pipe treatment. The ability to allow longer compliance schedules is especially critical, we believe, to the success of watershed management projects and the development of TMDLs (especially phased TMDLs).

Response to: CTR-059-013

See response to CTR-027-008b.

Comment ID: CTR-060-005
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Compliance Periods No Longer than 5 Years

The preamble and rule describe the use of compliance schedules by existing dischargers where they find that they cannot immediately comply with a new more restrictive water quality based effluent limit (see 62 Fed. Reg. at 42187, Col. 1-3; and 62 Fed. Reg. at 42208, Col. 1-3). SDG&E supports the use of compliance schedules. However, the preamble and rule limit the term of compliance schedules to five years from the issuance of the new effluent limit. This duration may not be adequate where a TMDLA/VLA/LA process is necessary or may not accommodate the time needed to investigate alternative compliance methods, develop and obtain approval of site specific criteria, design and engineer necessary modifications to the facility and to obtain necessary financing. The SWRCB's Task Forces' Final Report ("Reports of the Public Advisory Task Forces to the State Water Resources Control Board Regarding the Development of the Inland Surface Waters Plan and the Enclosed Bays and Estuaries Plan"; October, 1995) recommended the use of compliance periods up to 15 years. SDG&E recommends that the rule be modified to allow for up to 15 year durations for compliance schedules.

Response to: CTR-060-005

See response to CTR-027-008b.

Comment ID: CTR-066-004
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The inclusion of a provision allowing compliance schedules in permits in the rule, although the provision should be modified to allow the Regional Water Quality Control Boards (RWQCBs) to include compliance schedules of up to 15 years in permits if they deem it appropriate.

Response to: CTR-066-004

See response to CTR-027-008b.

Comment ID: CTR-067-005
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: * Having just completed an eight (8) year, twenty-eight (28) million dollar project to meet more stringent effluent limits, OVSD strongly endorses the inclusion in the draft CTR of a provision authorizing compliance schedules of up to 15 (fifteen) years in NPDES permits. Tremendous effort and time are required for a POTW to sample for and identify potential pollutants, negotiate the permit(s) with the applicable regulatory agencies, perform the necessary environmental studies to determine the impact of the pollutant(s) observed, identify potential solutions/mitigation measures and their costs, and then to design and build additional treatment facilities. Although 15 (fifteen) years may not always need to be granted, allowing the flexibility of extended compliance schedules would be very beneficial to OVSD (and other POTWs) and the Regional Water Quality Control Boards. This is true not only for the reasons stated above, but also because extended compliance schedules would allow time for the development and implementation of the relatively new watershed-based management approach.

Response to: CTR-067-005

See response to CTR-027-008b.

Comment ID: CTR-081-002c
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
C-22
G-09
C-01a
C-08a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are performed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002c

See response to CTR-027-008b.

Comment ID: CTR-082-002
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* The inclusion of a provision allowing compliance schedules in permits in the rule, should be modified

to allow the Regional Water Quality Control Board's (RWQCB's) to include compliance schedule of up to 15 years if they deem it is appropriate.

Response to: CTR-082-002

See response to CTR-027-008b.

Comment ID: CTR-085-005
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The inclusion of a provision allowing compliance schedules in permits in the rule although the provisions should be modified to allow the Regional Water Quality Control Boards (RWQCB) to include compliance schedules of up to 15 years in permits if they deem it appropriate.

Response to: CTR-085-005

See response to CTR-027-008b.

Comment ID: CTR-086-004i
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
K-03
G-04
G-05

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004i

See response to CTR-027-008b.

Comment ID: CTR-089-001f
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
C-08a
G-05
K-01
G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001f

EPA appreciates these comments for providing support for EPA's allowance of compliance schedules in NPDES permits.

Comment ID: CTR-090-002e
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-17a
C-24a
C-22
G-05
G-04

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002e

See response to CTR-027-008b.

Comment ID: CTR-090-024
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Compliance Schedules -- The PUC supports the use of compliance schedules as part of the NPDES permit process, however, we oppose establishing any ceiling in the CTR for the duration of such schedules. If water shed based solutions are to be implemented, these will require a much as a 10 to 15 years to begin to show significant results. it would be most unwise to burden small contributors of toxicants with large expenses, until such time as the efficacy of water shed approaches can be established in the specific water sheds.

Even in cases where there is a clear and immediate indication that a POTW will have to undertake significant process upgrading to achieve CTR based WQBEL effluent limitations, the five year period for compliance is simply unrealistic. It would be difficult for a municipality or regional sanitation agency to arrange financing, plan and undertake CEQA procedures, design, construct and run process shake down within five years for any major wastewater project.

Rather than incorporate a compliance schedule ceiling in the CTR, the CTR should simply state that compliance schedules can be established by the RWQCBs on a case by case basis.

Response to: CTR-090-024

See response to CTR-027-008b. With respect to the relationship between EPA's compliance schedule and State adopted compliance schedules see response to CTR-015-006.

Comment ID: CTR-092-009
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Schedules of Compliance

The City endorses compliance schedules as an interim sequence of events which lead to compliance with water quality-based effluent limitations. The City further supports the authorizing compliance schedule provision contained in the CTR but advocates a period of 15 years to comply with such limitations. The 15 year time period is consistent with 1997 guidance issued by Assistant Administrator Robert Perciasepe regarding the development of TMDLs over an 8 to 13 year timeframe.

Response to: CTR-092-009

See response to CTR-027-008b.

Comment ID: CTR-095-004
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N

CROSS REFERENCES

Comment: Also, it is unconscionable to postpone compliance with the new proposals for up to 10 years. This is unacceptable. Facts must be faced and prevention measures to taken now. Cancer is epidemic! We must act!

Response to: CTR-095-004

See response to CTR-002-010b.

Comment ID: CTR-104-003
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: "Compliance schedules" could postpone compliance for up to 10 years. There has already been a 7 year delay in reaching this proposal stage, so further procrastination is completely unacceptable.

Response to: CTR-104-003

See response to CTR-002-010b.

Comment ID: CTR-106-003
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: "Compliance schedules" could postpone compliance for up to 10 years. There has already been a 7 year delay in reaching this proposal stage, so further procrastination is completely unacceptable.

Response to: CTR-106-003

See response to CTR-002-010b.

Comment ID: CTR-107-002b
Comment Author: Brian E. Hill
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? Y
CROSS REFERENCES E-01
E-01n

Comment: On September 17, I attended a hearing on the proposed CTR at the EPA's regional office in San Francisco. Here are some key issues from the testimony at that hearing:

* Some of the limits are below normal detection limits, therefore agencies have no background data in order to perform accurate attainability analysis.

* The cost of implementation by the EPA is grossly underestimated. The economic analysis shows at maximum implementation cost of $87 million. If preliminary estimates by publicly owned treatment works (POTW) art correct, implementation of the CTR will far exceed the $100 million provision of the Porter-Cologne Act. If this is the case, feasibility of implementation will be in jeopardy. The City of Merced, CA estimates that their additional cost would be $4 million annually. Merced has a very small treatment facility.

* Robert Reid, speaking on behalf of California Association of Sanitation Agencies(CASA), said that four San Francisco Plants estimate their total implementation costs to be $160 million annually.

* Charles Batts of Bay Area Dischargers Authority (BADA) estimated five BADA POTWs costs to be $12 million per year to meet the strict limit on copper and $56 million per year to meet the organics limit.

* The Regional Water Quality Control Board testified that San Francisco discharges twenty percent of the four percent discharged into the San Francisco Bay by POTWS, noting that POTWs are only a minor part of the volume discharged into the Bay. Thus, the reduction to the prescribed limits would cause a negligible decrease in the total mass of pollutants discharged.

* The City of Sacramento projects a $200 million annual cost will be required to meet the copper limit.

All of the testimony at the hearing echoed these concerns. I am sure that you have access to a transcript. The Clean Water Act has been and is instrumental in cleaning up our rivers, lakes, bay and estuaries. We can continue on this steady path by setting gradual attainable limits and through increased public education. Limits on pollutants should continue to get stricter, but this has to occur on a gradual curve that will not place an unreasonable burden on the individual taxpayer.

Response to: CTR-107-002b

See response to CTR-107-002a.

Comment ID: CTR-109-004
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: Fourth, the proposed new rule also contemplates "compliance schedules" could postpone up to ten years compliance with the proposed new rule.

Response to: CTR-109-004

See response to CTR-002-010b.

Comment ID: CTR-110-003
Comment Author: Judith A. Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/02/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: Also, anti-pollutant compliance schedules need to be immediate and continuing, not ten years from now.

Response to: CTR-110-003

See response to CTR-002-010b.

Comment ID: CTRH-001-011
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N

CROSS REFERENCES

Comment: Next, compliance schedule.

EPA appears to be saying that it is only allowing state authorities to decide whether to put compliance schedules in permits which grant permission to pollute over the established criteria for up to 10 years.

However, we know that when the Unocal refinery here sued and paid the state authorities for permission to dump excess selenium for five years, EPA joined CBE, the City of San Francisco, the City of Richmond and others in court to support the public's right to protect our bay and protect our health.

Our question here is, has EPA waffled in its commitment to support our rights to be involved in a meaningful way in enforcement of water quality standards to protect our health?

Response to: CTRH-001-011

See response to CTR-002-010b.

Comment ID: CTRH-001-024a
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES g-05
c-22
c-24a
c-17a

Comment: MS. PLA: My name is Michelle Pla. I'm with the Public Utilities Commission, City and County of San Francisco.

I made the comment on my card that I also said that I would try to be constructive, and so I'm going to follow my mentor here, Phil Bobel, and say that there are some things in this rule that we're very pleased to see.

We're very pleased to see use of the latest scientific information, particularly the use of latest IRIS, I-R-I-S, numbers-for human health. We're very pleased that you're using dissolved versus total recoverable form for the metals.

We're very pleased to see recognition of the water effects ratios. We're pleased to see recognition for a multi-tiered mixing zone for acute and chronic human health effects and hope that the state pays particular attention to that.

We do have a problem with the way you've described compliance schedules and hope to be working strictly by the state on that as well. We think that the five-year system is fairly shortsighted, and -we can't even do FMDSLs in five years.

Response to: CTRH-001-024a

See response to CTR-027-008b.

Comment ID: CTRH-001-039c
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES C-24a
G-04

Comment: I've been saving the good news for last.

Fourth, and by no means last in priority for CASA, we wish to register our support for several parts of the preamble to the CTR.

We support application of interim limits in NPDES permits while TMDLs and other special studies are being performed.

We also support EPA's approach to water effects ratios for determining site-specific criteria.

We also support the inclusion of a provision allowing the compliance schedules in permits in the rule, although we recommend that it be modified to allow the regional boards to include compliance schedules of up to 15 years in permits, if they deem it appropriate.

Thank you for the opportunity to present our views. As I said earlier, we will be submitting detailed comments on the proposed rule by the end of the comment period, which hopefully will be extended in response to our and others' requests.

Response to: CTRH-001-039c

See response to CTR-027-008b.

Comment ID: CTRH-001-052
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper

Document Date: 09/17/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: The compliance schedules, I would definitely question the need. There was a question reflected earlier, whether we need compliance schedules authorized by this federal rule.

It seems to me that EPA is trying to fix an absence of criteria. We have been waiting a long time for these criteria. They were supposed to be in place in -- it was '93, I think. The deadline, technically speaking, is about four years behind, and will probably be five by the time it's done.

To have another ten years before we actually see any results is a little frustrating, so I for one don't think compliance schedules, whether the agencies, for better or worse -- and with some help from the dischargers, they have not been able to issue the criteria required by federal law. And I guess the uncertainty of that delay should go to the benefit of the bay and all the waters of the state. So on compliance schedules, I think at this point they are a little bit too late, especially in the standards.

That's not to say in particular instances that the individual boards can't figure out ways of using enforcement authority to devise rational schedules where people for whatever reason have not been able to adjust the facilities to meet new standards.

But in the standards themselves, I think history shows that is not something that's going to cripple the various industries and dischargers, that it can be adjusted through enforcement processes.

Response to: CTRH-001-052

See response to CTR-002-010b.

Comment ID: CTRH-002-011a
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES G-04
C-22
K-01

Comment: Now, I'd briefly like to touch on several issues of importance to SCAP members. In addition, we will be submitting written comments before the close of the public comment period.

I'd like to begin by mentioning our support for several provisions included in the draft CTR, and those include the provision authorizing the use of compliance schedules -- although we don't necessarily agree

with the time period -- the expression of metals criteria as dissolved rather than totally recoverable, and discussion in the preamble supporting the use of interim limits in permits, while the total maximum daily loads and other special studies are being performed.

Response to: CTRH-002-011a

See response to CTR-027-008b.

Comment ID: CTRH-002-014
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: G-02 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES

Comment: And on compliance schedule time frames, we'd like to see that those are consistent with the State's proposal.

Response to: CTRH-002-014

See response to CTR-015-006.

Subject Matter Code: G-03 Design/Minimum Flows

Comment ID: CTR-003-004
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-03 Design/Minimum Flows
References:
Attachments? N
CROSS REFERENCES

Comment: 4) The use of the "harmonic mean flow" adds yet another level of conservatism to the standard setting process. As the response to the toxin is assumed linear with respect to concentration and additive over time, the use of this statistic seems inappropriate and overprotective.

Response to: CTR-003-004

EPA disagrees that the use of the harmonic mean flow is inappropriate and overprotective. Carcinogens, unlike non-carcinogens, do not have a threshold concentration where effects are only observed above certain concentrations. Exposure to carcinogens is best estimated by determining lifetime average exposure because carcinogens, as illustrated by the supporting toxicity data in the criteria documents, show a linear relationship of dose versus response. In other words, as exposure increases over time, a greater incidence of effects are observed. This means that exposure is cumulative over time. The human health criteria for carcinogens are based on the assumption of average exposure over a seventy year period (life expectancy assumption). The harmonic mean is the running average of all the flow data on record for a particular stream. EPA believes that averaging the entire flow record best approximates lifetime exposure. Thus, the Agency recommends the harmonic mean flow for determining long term exposure estimates when using steady-state modeling. EPA also notes that the final CTR does allow alternative flows to be used where supported by data and approved by EPA after EPA publishes for public comment a notice proposing such a change (40 CFR 131.38(d)(1)(iv)) . Appropriate dynamic modeling is one such alternative that EPA would approve. The final CTR maintains the harmonic mean flow as the design flow for human health criteria for carcinogens. EPA also notes the commentor did not provide an alternative to the harmonic mean flow.

Further discussion on the basis for the harmonic mean flow is contained in the Technical Support Document for Water Quality-based Toxics Control (section 4.6 and Appendix D) and in "Design Stream Flows Based on Harmonic Means," Lewis A. Rossman, Jr. of Hydraulic Engineering, Vol. 116, No. 7, July 1990.

Comment ID: CTR-020-016
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-03 Design/Minimum Flows

References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

5. Application of Criteria at Return Flows

The rule specifies that the criteria should be applied under various design flows that properly represent the acceptable exposures that may occur in the environment. Consistent with the National Guidelines, EPA recognized that it is inappropriate and unnecessary to apply the criteria in a "never to exceed" manner. Clearly, the information underlying the selection of the return frequency of once in three years, which was conservatively derived, demonstrates that periodic exceedance of the criteria is acceptable. However, in the rule, EPA states that these flows should only be used if the Regional Board has expressly determined that water quality criteria apply only above certain flows. Absent such a statement from the Regional Board, the criteria apply at all flows and no exceedance, no matter how minor, would be allowed. This provision (which will clearly lead to overly stringent application of criteria) is arbitrary and capricious.

If EPA is to adopt criteria and implementation procedures in place of state action, that regulatory package must be complete and appropriate considering the regulation as a whole. EPA is well aware that few Regional Boards have established specific return flows because the issue is addressed on a case-by-case basis. Moreover, as no specific flow is set to apply to wet weather events, the CTR would lead to the absurd conclusion that storm waters, prior to mixing with any surface waters, must comply with stringent water quality criteria.

EPA may not knowingly establish procedures that will lead to unnecessarily restrictive application of the criteria unrelated to actual use protection needs. The final rule should specify the criteria will only be applied to flows exceeding the design stream flows specified in the rule.

Response to: CTR-020-016

EPA disagrees that the low flow provisions in this rule are arbitrary and capricious. EPA notes that under the Water Quality Standards Regulation (see 40 CFR 131.13), States may adopt discretionary policies that affect the implementation of their water quality standards. Such policies may include the establishment of low flow provisions and are subject to EPA review and approval. However, where a State has not specified low flow provisions and has determined that the application of the criteria at all flows is appropriate State policy, EPA will defer to the State's expressed policy. This approach is consistent with Section 510 of the Clean Water Act which preserves State authority to adopt provisions for its waters that are more stringent than required by EPA.

Furthermore, EPA disagrees with the commenter's assertion that if a State's criteria apply at all flows, the

criteria could never be exceeded. EPA's aquatic life criteria are based on three interrelated components which include magnitude, duration, and frequency. EPA's longstanding position is that the criteria may not be exceeded more than once every three years on the average. This recurrence frequency takes into consideration the rates of ecological recovery from severe environmental stresses. Further discussions on this issue is contained in EPA's Technical Support Document for Water Quality-based Toxics Control (Chapter 2 and Appendix D).

Comment ID: CTR-027-005a
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-03 Design/Minimum Flows
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES T

Comment: 5. The proposed rule restricts the State's regulatory flexibility in permitting by establishing averaging periods and low flow conditions, and directives regarding establishing effluent limits for criteria not being adopted as part of the CTR. USEPA has preempted the State's flexibility by establishing averaging periods for applying acute and chronic aquatic life and human health criteria, and by establishing low flow conditions that must be used in developing limits based on proposed criteria. These are implementation issues that should remain with the State regulatory authority.

Recommendation: The rule should be revised to delete all provisions that preempt the State's regulatory flexibility.

Response to: CTR-027-005a

EPA disagrees that the flow provisions contained in the final rule will limit State flexibility.

First, EPA notes that the State of California may develop alternative design flows for its waters provided that those alternative flows are scientifically defensible and protective of the designated uses of State waters. Such alternative flows will be subject to EPA review, approval, and public comment. However where the State has not adopted low flow provisions, the design flows specified in today's rule shall be implemented to ensure that the criteria will be implemented appropriately to provide environmental and human health protection.

As noted in the preamble of today's rule, EPA's Technical Support Document for Water Quality-based Toxics Control (the TSD) also recommends the use of dynamic models to perform wasteload allocations. EPA is clarifying that today's rule provides the State of California with the flexibility to utilize dynamic models to implement the federal criteria. The dynamic modeling techniques, as outlined in the TSD, will allow enable the determination of wasteload allocations that will meet the criteria in today's rule.

Comment ID: CTR-035-029
Comment Author: Tri-TAC/CASA

Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-03 Design/Minimum Flows
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42182-42183 -- Low Flow Values for Streams and Rivers We recommend that EPA not adopt the design flow values (e.g. 1Q10 or 1B3 for aquatic life acute criteria) for the CTR criteria. The values specified are not always appropriate. For instance, EPA proposes that the harmonic mean flow be applied with human health criteria for carcinogens. In contrast, EPA's Technical Support Document (U.S. EPA, 1991) states:

"However, for situations involving seasonally variable effluent discharge rates, hold-and-release treatment systems, and effluent-dominated sites, the harmonic mean may not be appropriate, In these cases, the effluent load and downstream flow are not independent (i.e., they are correlated). Modeling techniques can calculate an average daily concentration over a long period of time are more appropriate to determine the long-term exposure in these cases." Therefore, we recommend that EPA include these values in the Preamble as guidance instead of in the rule itself.

Response to: CTR-035-029

EPA agrees that the low flow values specified in the rule may not be appropriate in all instances as noted in the Agency's Technical Support Document for Water Quality-based Toxics Control (the TSD). Furthermore, EPA noted in the proposed rule (see section 131.38(c)(2)(ii)) that the low flows would apply in waters suitable for the establishment of low flow return frequencies such as free flowing streams and rivers. However, in general, EPA supports these flows as being appropriate in a majority of situations. Additionally, as noted in the preamble of today's rule, EPA is clarifying that today's rule provides the State of California with the flexibility to utilize dynamic modeling (as an alternative to steady state modeling) in implementing the criteria contained in today's rule. Therefore, EPA will retain the design flows as proposed, as these flows will ensure adequate implementation of the criteria included in today's rule in cases where the State does not have design flows in place or where the State does not utilize dynamic modeling.

Comment ID: CTR-036-007b
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-03 Design/Minimum Flows
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES C-26

Comment: We are concerned that EPA has preempted the State's flexibility by establishing averaging periods for applying acute and chronic aquatic life criteria and for establishing low flow conditions that must be used in developing limits based on the proposed criteria. We recommend that such implementation issues remain within State authority.

Response to: CTR-036-007b

See response to CTR-027-005a.

Comment ID: CTR-037-005
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-03 Design/Minimum Flows
References:
Attachments? N
CROSS REFERENCES

Comment: 5. EPA is requiring, by rule, that 1Q10 and 7Q10 receiving water flows be developed to implement acute and chronic water quality standards. This will therefore eliminate any flexibility that the State wishes to use when calculating reasonable potential to exceed standards and water quality-based limits. This will also limit permittees as to the approaches that can be used when modeling mixing zones. The use of 1Q10 and 7Q10 values is arbitrary and is not related in any way to how water quality criteria are developed or protection of the environment. These statistics were adopted merely because they were already in use by other programs and were therefore easily obtained. Use of these statistics does not recognize unique qualities of California's or any other states's waters, and therefore does not preclude overly stringent regulation. EPA must justify with data why these particular flows are required to implement water quality standards and why designated uses will not be protected if these flows are not used in NPDES permitting.

Response to: CTR-037-005

See response to CTR-027-005a. EPA disagrees that the 1Q10 and 7Q10 values are arbitrary. The hydrological basis for these flows were taken directly from EPA's Technical Support Document for Water Quality-based Toxics Control (See TSD, Appendix D for further information).

Comment ID: CTR-040-018b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-03 Design/Minimum Flows
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y

CROSS REFERENCES C-26; C-30; C-24e

Comment: V. Recommendation: Delete all provisions in the Rule that preempt the States flexibility in permitting. The Rule provides specific direction on the adoption of averaging periods, low flow values, effluent limitations for criteria not being adopted as a part of the Rule, and that the aquatic life criteria be applied to all waters irrespective of designated use, etc..

* The Preamble and the Rule's economic analysis make a point that the State has considerable flexibility in establishing permit limitations. In making, that point, EPA implies that the State may implement the criteria in a manner that would have little or no adverse economic impact on dischargers.

* However, the Rule contains a number of implementation provisions that are not required under Section 303(c)(2)(B), but serve to preempt the State's flexibility. These provisions include, but are not necessarily limited to the adoption of averaging periods and low flow values, directives regarding the establishment of effluent limitations for criteria that are not being adopted as a part of the Rule, and application of the aquatic life criteria to all waters irrespective of the designated use.

* Not only does EPA not have a duty to adopt these provisions, but also the provisions are more restrictive than those required by the CWA or EPA regulations, They clearly restrict the State's flexibility. In fact, other states have adopted, and EPA has approved, implementation provisions (e.g., averaging periods and low flow values) which are less restrictive.

* For these reasons, EPA should remove all such implementation provisions from the Rule.

Response to: CTR-040-018b

See response to CTR-027-005a.

Comment ID: CTRH-001-034c
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: G-03 Design/Minimum Flows
References:
Attachments? N
CROSS REFERENCES I-08; I-05

Comment: Thirdly, I'd like to touch upon implementation of the rule. My understanding is that the state's Inland Surface Waters and Enclosed Bays and Estuaries Plan will address implementation of the CTR. With this in mind, the CTR should serve as an enabling rule and allow the state and the dischargers flexibility in the implementation of objectives contained in the rule.

As I touched upon earlier in my opening remarks, EPA has included some enabling provisions in this rule that we support, such as use and determination of mixing zones and water effects ratios. From the stormwater perspective, we believe other important enabling provisions must be included to allow for regional flexibility in the implementation of our stormwater programs.

For example, enabling provisions should be included to allow flexibility in establishing compliance schedules for stormwater discharges and should allow flexibility for site-specific establishment of low-flow conditions and wet weather standards, and ranges of human health criteria depending on the use of individual receiving waters.

Response to: CTRH-001-034c

See response to CTR-027-005a.

Subject Matter Code: G-04 Interim Limits

Comment ID: CTR-003-005
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: 5) The concept of interim permit limits is a worthy one which we hope you retain.

Response to: CTR-003-005

EPA appreciates these comments providing support for EPA's discussion of interim limits in the preamble of the proposed CTR. EPA addressed some implementation issues in the preamble to the proposed rule to illustrate the discretion available to the State in its issuance of permits and effluent limits, however, this implementation issue is outside the scope of the rule. EPA supports the State's consideration of stakeholder Task Force recommendations in developing the State's policy (Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California) regarding interim limits. However, EPA is not recommending any specific method of calculating interim limits because EPA does not intend to limit the State's discretion in implementing the Clean Water Act.

Comment ID: CTR-005-003f
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-09
G-05

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003f

See response to CTR-003-005.

Comment ID: CTR-021-002a
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-24a
C-22
K-01
G-05
G-02

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; © the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002a

See response to CTR-003-005.

Comment ID: CTR-030-001
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: Comments of the Utility Water Act Group on the Proposed California Water Quality Standards

The Utility Water Act Group (UWAG)(*1) submits these comments on EPA's proposed Water Quality Standards for the State of California, published in the Federal Register on August 5, 1997. (62 Fed. Reg. 42,160) (the California proposal). UWAG is interested in the proposed regulation because: (1) UWAG member companies in California will be directly affected by the proposed changes to the California water quality standards; and (2) many of the issues raised in the proposal have national implications, particularly as they relate to general implementation of the NPDES program.

As detailed in Section I below, UWAG finds many parts of the proposal reasonable and sensible, and endorses EPA's intentions as to those parts. However, as explained in Section 11, the proposal sets forth some propositions that are erroneous or technically deficient, and others that may lead to inappropriate implications or misinterpretations.

I. ISSUES UWAG SUPPORTS

A. UWAG Approves of Interim Permit Limits When a TMDL Study is Incomplete

UWAG agrees with EPA that interim permit limits - where WQBELs have otherwise been justified - are appropriate for pollutants that are the subject of an ongoing TMDL/WLA/LA or other special study. 62 Fed. Reg. at 42,185, col. 2. UWAG also agrees that past performance and future uncertainty are appropriate factors - although not the only possibly relevant factors to consider in determining interim permit limits. UWAG wishes to emphasize, however, that permit writers must not be encouraged to impose any WQBELS, including interim WQBELS, until they have obtained sufficient and reliable data with which to conclude that the discharge has a reasonable potential of causing an excursion of water quality standards. In short, EPA should emphasize in the final rule that interim limitations are not intended to supersede the obligation of a permit writer to perform a reasonable potential determination as a prerequisite to imposing a WQBEL.

(*1) UWAG is an association of 73 individual electric utilities and three national trade associations of electric utilities, the Edison Electric Institute, the National Rural Electric Cooperative Association, and the American Public Power Association. The individual utility companies operate power plants and other facilities that generate, transmit, and distribute electricity to residential, commercial, industrial, and institutional customers. The Edison Electric Institute is the association of the nation's investor-owned electric utilities. The National Rural Electric Cooperative Association is the association of nonprofit electric cooperatives supplying central station service through generation, transmission and distribution of electricity to rural areas of the United States. The American Public Power Association is the national trade association that represents publicly owned electric utilities in the United States. UWAG's purpose is to participate on behalf of its members in EPA's rulemakings under the CWA and in litigation arising from those rulemakings.

Response to: CTR-030-001

EPA agrees that the permit writer must have a reasonable basis to conclude whether the discharger has "reasonable potential" for causing or contributing to an excursion of an objective prior to setting water quality-based effluent limits. EPA addressed some implementation issues in the preamble to the proposed rule to illustrate the discretion available to the State in its issuance of permits and effluent limits, however, this implementation issue is outside the scope of the rule.

Comment ID: CTR-030-004b
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES G-02
I

Comment: D. EPA's Endorsement of Five-Year Compliance Schedules and Interim Permit Limits for Modifications is Appropriate

UWAG strongly supports EPA's recognition that modifications necessary to comply with new or more stringent effluent limitations may necessitate the use of five-year compliance schedules. 62 Fed. Reg. at 42,187, col. 3. UWAG believes, however, that in certain circumstances a longer compliance schedule may be appropriate. Steam electric facilities that need retrofits to meet water quality-based effluent limits (WQBELS) often require extensive engineering design and testing prior to the actual retrofit. Additionally, nuclear facilities must ensure that any design changes are compatible with Nuclear Regulatory Commission regulations. Therefore, the availability of five-year compliance schedules is certainly well-justified. Further, EPA should consider whether longer compliance schedules should be available, at least in some limited circumstances.

Additionally, UWAG strongly supports EPA's approval of interim permit limits for use in permit modifications. This flexibility will allow dischargers to stay in compliance while necessary process or design changes are carried out.

Response to: CTR-030-004b

See response to CTR-003-005.

Comment ID: CTR-032-002g
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
K

G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002g

See response to CTR-003-005.

Comment ID: CTR-034-012a
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES K-01

Comment: * SCAP supports EPA's discussion in the Preamble regarding the use of interim permit limits while Total Maximum Daily Loads.(TMDLs) and other special studies are being performed. We strongly urge EPA to support the use of the SWRCB Permitting Task Force's recommended approach for deriving interim permit limits.

Response to: CTR-034-012a

See response to CTR-003-005.

Comment ID: CTR-035-002e
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N

CROSS REFERENCES C-22
C-01a
C-08a
G-05
G-09
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002e

See response to CTR-003-005.

Comment ID: CTR-035-033
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42185 -- Interim Limits We support the inclusion of the provision in the Preamble which supports the use of interim limits in NPDES permits while TMDLs and other special studies are being performed. We endorse the recommendation of the Permitting and Compliance Issues Task Force that interim effluent limits be calculated based on past performance plus future uncertainty (SWRCB 1995, Part VI). While recognizing that the State has discretion in determining how effluent limits are calculated, we recommend that EPA strengthen its statement of support for this approach by recommending its use to State permitting authorities.

Response to: CTR-035-033

See response to CTR-003-005.

Comment ID: CTR-038-002d
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-05
G-09

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002d

See response to CTR-003-005.

Comment ID: CTR-039-008
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: VI. EPA'S SUGGESTION THAT "INTERIM PERMIT LIMITS" MAY BE ACCEPTABLE IS WITHOUT AUTHORITY IN THE LAW

EPA refers to a suggestion of the State's Permitting Task Force that performance-based interim permit limits may be appropriate where a TMDL/WLA/LA is underway but not yet completed. 62 Fed. Reg. at 42185. This innovative concept has one fatal flaw --- there is no authority for such limits in the Clean Water Act. Indeed, the notion of an interim limit is inconsistent with other important features of the Act.

First, by definition, an effluent limitation must be designed to meet all applicable water quality standards. Interim limits, by definition, would not be designed to assure compliance with standards. Where a

TMDL is underway and presumably pertinent to a Proposed "interim" limit, the waterbody by definition is not meeting an applicable standard. An interim limit, by definition, is deferring the limit which would be required of the particular discharger to meet that standard.

Second, interim limits are a veiled attempt to sidestep the regulatory restrictions placed on compliance schedules. Where authorized, compliance schedules are limited to 5 years and must include interim steps if they are longer than one year. "Interim" limits is simply a way of creating a compliance schedule without the appropriate label. As a result, the proposal appears to contemplate potentially open-ended schedules with none of the limited safeguards provided by compliance schedules. In other words, an interim limit is nothing but an illegal compliance schedule. When included in conjunction with a compliance schedule, as set forth in another section of the proposed rule, BayKeeper is not concerned with the notion of an interim effluent limit (albeit, as noted above, neither is appropriate for inclusion in this proposed rule). 62 Fed. reg. 42208.

Third, the need for interim limits in order to wait for unfinished TMDLs is an extremely flimsy policy reason for creating a new genre of permit limits. Section 303(d), 33 U.S.C. section 1313(d) has required TMDLS for well over a decade. States, including California, as well as EPA simply have refused to comply with that legal obligation. Simply because the agencies have chosen to ignore Congress' mandate is not a valid reason for EPA or the State of California to undermine other sections of the Act, such as the process for establishing effluent limits and compliance schedules.

The reference to interim limits while waiting for TMDLs included in the preamble should be stricken. Should the State choose to authorize compliance schedules, that should be the only process by which a discharger can defer compliance with a water quality-based effluent limit. There is no reason that a schedule of a couple of years but not greater than 5 years would not be ample time to complete a required TMDL process.

Response to: CTR-039-008

EPA disagrees that there is no authority for interim limits in the Clean Water Act.

See response to CTR-002-010b (Category G-02; Compliance Schedules).

Comment ID: CTR-041-006a
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES G-05

Comment: Fifth, the District supports the preamble discussion on both interim permit limits and mixing zones as valid implementation procedures. In addition, however, the District specifically endorses the State's Permitting Task Force recommendations on these two subjects: (1) that interim effluent limits be

calculated based on past performance plus future uncertainty, and (2) that the State Water Resources Control Board (SWRCB) should allow the establishment of both acute and chronic mixing zones.

Response to: CTR-041-006a

See response to CTR-003-005.

Comment ID: CTR-043-002d
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-01a
G-05
G-09

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002d

See response to CTR-003-005.

Comment ID: CTR-044-003f
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-09
G-05

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003f

See response to CTR-003-005.

With respect to the comment about the economic impact of the old criterion for mercury 0.012 ug/l, EPA has not evaluated these costs since the CTR does not promulgate a mercury criteria of 0.012 ug/l.

Comment ID: CTR-045-002
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

The application of interim limits in NPDES permits while Total Daily Maximum Loads (TMDLS) and other special studies are being performed.

Response to: CTR-045-002

See response to CTR-003-005.

Comment ID: CTR-052-002e

Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-09
G-05

Comment: EPA will recall the State Water Quality Plans Task Forces that included all stakeholders, including EPA. The Authority appreciates the incorporation of many of the consensus recommendations from the Task Forces into the CTR, including:

* Adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio

* Adoption of the proposed new human health criterion for mercury

* Preamble discussions regarding metals translators, mixing zones, and interim permit limits

Response to: CTR-052-002e

See response to CTR-003-005.

Comment ID: CTR-054-004c
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? Y
CROSS REFERENCES G-09
G-05

Comment: BADA supports the Preamble discussions regarding metals translators, mixing zones, and interim permit limits. Translators and mixing zones will provide a better scientific basis for the application of the criteria and will go a long way toward protecting against the imposition of unnecessary or unreasonable controls. Interim permit limits will allow dischargers faced with potential attainability problems to pursue reasonable actions, such as pollution prevention, treatment plant optimization, pollutant trading, TMDLS, etc. prior to being faced with final effluent limitations. BADA endorses the recommendation of the State Plan Public Task Forces on the issue of interim limits.

Response to: CTR-054-004c

See response to CTR-003-005.

Comment ID: CTR-056-002
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* The application of interim limits in NPDES permits while establishing TMDLs or conducting other special studies,

Response to: CTR-056-002

See response to CTR-003-005.

Comment ID: CTR-059-012
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Interim Permit Limits

The Sanitation Districts applaud EPA on the inclusion of the provision in the Preamble which supports the use of interim limits in NPDES permits while TMDLs and other special studies are being performed. We endorse the recommendation of the SWRCB Permitting and Compliance Issues Task Force that interim effluent limits be calculated based on past performance plus future uncertainty.

Response to: CTR-059-012

See response to CTR-003-005.

Comment ID: CTR-060-001
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E SUPPORTS

EPA has included in the proposed CTR provisions which are reasonable and with which SDG&E supports. These include:

Interim limits

The preamble discusses the use of interim numeric limits during the time which TMDL/WLA/LA or other special studies are underway but not completed (see 62 Fed. Reg. at 42185, Col. 2). SDG&E agrees that interim limits are appropriate and supports their use. Also, interim limits should be set such that existing discharges can maintain compliance during the interim period.

Response to: CTR-060-001

See response to CTR-003-005.

Comment ID: CTR-066-002
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The application of interim limits in NPDES permits while TMDLs and the other special studies that are scientifically supported are being performed.

Response to: CTR-066-002

See response to CTR-003-005.

Comment ID: CTR-081-002a
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES C-24a
G-02
C-22
G-09
C-01a
C-08a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are performed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. I) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002a

See response to CTR-003-005.

Comment ID: CTR-085-003
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The application of interim limits in NPDES permits while Total Maximum Daily Loads (TMDL) and other special studies are being performed.

Response to: CTR-085-003

See response to CTR-003-005.

Comment ID: CTR-085-012
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The use of interim permit limits with Total Maximum Daily Loads and other special studies are being performed.

Response to: CTR-085-012

See response to CTR-003-005.

Comment ID: CTR-086-004g
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
K-03
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004g

See response to CTR-003-005.

Comment ID: CTR-090-002f
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-17a
C-24a
C-22
G-05
G-02

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002f

See response to CTR-003-005.

Comment ID: CTR-092-006
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-04 Interim Limits
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Interim Limits

The City supports the concept of interim numeric permit limits when a TMD or other special investigation is underway but not yet completed. The City supports the discussion of factors applicable to the derivation of interim numeric permit limits, specifically past treatment performances, future uncertainty, receiving water body attainment and water quality. The City further encourages flexibility and innovation as illustrated by the concept of effluent "trigger concentrations".

Response to: CTR-092-006

See response to CTR-003-005.

Comment ID: CTRH-001-039b
Comment Author: Robert Reid
Document Type: Public Hearing
State of Origin: CA
Represented Org: CASA
Document Date: 09/17/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES C-24a
G-02

Comment: I've been saving the good news for last.

Fourth, and by no means last in priority for CASA, we wish to register our support for several parts of the preamble to the CTR.

We support application of interim limits in NPDES permits while TMDLs and other special studies are being performed.

We also support EPA's approach to water effects ratios for determining site-specific criteria.

We also support the inclusion of a provision allowing the compliance schedules in permits in the rule,

although we recommend that it be modified to allow the regional boards to include compliance schedules of up to 15 years in permits, if they deem it appropriate.

Thank you for the opportunity to present our views. As I said earlier, we will be submitting detailed comments on the proposed rule by the end of the comment period, which hopefully will be extended in response to our and others' requests.

Response to: CTRH-001-039b

See response to CTR-003-005.

Comment ID: CTRH-001-057c
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: G-04 Interim Limits
References:
Attachments? N
CROSS REFERENCES K-03
C-24a
G-07
G-09
C-22
G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057c

See response to CTR-003-005.

Comment ID: CTRH-002-011b
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: G-04 Interim Limits
References:

Attachments? N
CROSS REFERENCES G-02
C-22
K-01

Comment: Now, I'd briefly like to touch on several issues of importance to SCAP members. In addition, we will be submitting written comments before the close of the public comment period.

I'd like to begin by mentioning our support for several provisions included in the draft CTR, and those include the provision authorizing the use of compliance schedules -- although we don't necessarily agree with the time period -- the expression of metals criteria as dissolved rather than totally recoverable, and discussion in the preamble supporting the use of interim limits in permits, while the total maximum daily loads and other special studies are being performed.

Response to: CTRH-002-011b

See response to CTR-003-005.

Subject Matter Code: G-05 Mixing Zones&Dilution Credit

Comment ID: CTR-004-004a
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES C-24a; C-22; C-09

Comment: Despite the problems addressed above there are provisions of the CTR that SBSA supports, including:

* EPA's policies and guidance regarding the use of mixing zones and dilution

* Use of water effects ratios (WERs) for determining site specific criteria

* Inclusion of metals criteria expressed as dissolved rather than total recoverable

* Allowing permit writers the use of any of the methods in EPA's guidance document on the use of translators

Response to: CTR-004-004a

See response to CTR-004-009.

Comment ID: CTR-004-009
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: Alternative Mixing Zones

One of the few avenues that may actually provide some regulatory relief is mixing zones. The Preamble to the CTR describes a mixing zone as a limited area or volume of water where initial dilution of a discharge takes place and where water quality standards can be exceeded. Mixing zones have been applied in the water quality standards program since its inception. The present water quality standards regulations allows states to adopt acute and chronic mixing zones as a matter of state discretion, so long

as the state's mixing zone protects the designated uses. See 40 C.F.R. section 131.13.

The Preamble recognizes that several California Regional Water Quality Control Boards have adopted mixing zone provisions in their respective Basin Plans. These mixing zone provisions can be applied to discharges to water bodies to which water quality standards based on the criteria contained in this proposed rule will apply once this mile becomes final. See CTR Preamble at pg. 42185. The problem arises for the proposal or adoption of new mixing zones where one is not currently authorized under an existing Basin Plan. The Preamble sets out numerous restrictions on the use of mixing zones, as follows:

A mixing zone should be established to ensure that the zone will riot impair the integrity of the water body as a whole, the zone will not cause lethality to passing organisms, and, considering- likely pathways of exposure, that there are no significant human health risks. For application of two-number aquatic life criteria, as proposed in this rule, there may be up to two types of mixing zones. In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met, The chronic criterion is met at the edge of the second mixing zone. However, since both aquatic life and human health criteria are proposed in today's rule, the state may establish independent mixing zone policies for each. For any particular pollutant from anyparticular discharge, the magnitude, frequency, duration and mixing zone associated with each of the type of criteria may determine which one most limits the allowable discharge. Id.

The other potential problem arises because state-adopted mixing- zones are subject to EPA review and approval . See 40 C.F.R. section 131.13. Because EPA approval is required, the question arises whether a federal rulemaking would accompany approval of mixing zones as it does with approval of state variances (which are also authorized under 40 C.F.R. section 131.13). If so, this would greatly restrict the utility of new or alternative mixing zones as an avenue for regulatory relief.

(*1) This cost trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario, See EA at pg. 4.

(*2) In addition, pollutant load I reductions word not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

Response to: CTR-004-009

Mixing zone and dilution policies and implementation procedures are used by States to establish water quality based discharge limitations that protect the integrity of a waterbody as a whole, but provide permittees a reasonable avenue of relief by allowing ambient concentrations above water quality criteria in small areas near outfalls. EPA is not promulgating a mixing zone and dilution policy for California as part of this rulemaking. This is because EPA maintains that the decision regarding whether to adopt a mixing zones and dilution policy is made at the discretion of the State (see 40 CFR 131.13). While adopting a mixing zone and dilution policy is an area of State discretion, EPA retains authority to review and approve or disapprove policies which affect the application and implementation of water quality standards.

The CTR preamble reiterates existing EPA guidance contained in the Technical Support Document for Water Quality-based Toxics Control (1991) and the Water Quality Standards Handbook (1993) regarding the use of mixing zones and dilution by States. In accordance with this guidance, allowable mixing zone characteristics should be established to ensure that: (1) mixing zones do not impair the integrity of the

water body as a whole; (2) there is no lethality to organisms passing through the mixing zone; and (3) there are no significant health risks, considering likely pathways of exposure. To assist States in establishing appropriate mixing zones and dilution policies and procedures, EPA-Headquarters has periodically issued technical guidance on this topic. National EPA guidance can be found in the Technical Support Document for Water Quality-based Toxics Control (1991), the Water Quality Standards Handbook (1983 and 1993) and Quality Criteria for Water (the "Red Book", 1976). Other sources of information and guidance include Water Quality Criteria 1972 (the "Blue Book", National Academy of Sciences). At minimum, State mixing zone and dilution policies must be consistent with the EPA water quality standards regulation which requires the protection of designated uses. EPA received a majority of comments in support of the mixing zone and dilution discussion in the CTR preamble, which includes a review of the application of mixing zones and dilution in setting allowable discharge limitations based on acute, chronic, and human health criteria using a multi-tiered approach.

As discussed previously, under EPA's water quality standards regulation, States may adopt policies authorizing the use of mixing zones and dilution in setting TMDLs and water quality based effluent limitations (see 40 CFR 131.13). Pursuant to federal regulation, the decision regarding whether to allow mixing zones and dilution is made by individual States (i.e., States may elect to allow or to prohibit mixing zones/dilution for purposes of water quality based permitting). Where a State elects to allow mixing zones and dilution, the State must include an authorizing policy in its water quality standards regulation (e.g., see Water Quality Control Plan for Ocean Waters of California, California Ocean Plan, State Water Resources Control Board, 1997). Where a mixing zone and dilution policy is not sufficiently specific for EPA to adequately evaluate its implementation, the State must also establish procedures to be followed in implementing its mixing zone and dilution policy. Such mixing zone and dilution policies and implementation procedures are subject to EPA review and approval, as new or revised water quality standards (see 40 CFR 131.13). Courts have held that EPA is not required to undertake notice and comment procedures before approving State water quality standards. City ofAlbuquerque v. Browner, 865 F. Supp. 733 (D. N.M. 1993) (The Court noted that EPA is specifically required to provide notice and take comment before issuing federal water quality standards under section 303(b) and held that '[i]f Congress wanted the agency to provide additional notice upon approving state standards, it could have included that language in Section 303(c)(1)," aff'd, 97 F.3d 415, 425, n. 15 (10th Cir. 1996), cert. denied, 1997 US LEXIS 6709 (Nov. 10, 1997). State decisions regarding the application of mixing zones and dilution to specific point source discharges are subject to EPA review through the NPDES permitting process.

EPA will continue to support the State's establishment of technically defensible mixing zone and dilution policies and implementation procedures, consistent with EPA's water quality standards regulations and guidance, and their application in setting TMDLs and water quality based effluent limitations for acute, chronic, and human heath criteria.

Therefore, since EPA will approve reasonable implementation of mixing zones, EPA believes its Economic Analysis properly included mixing zones as one of several areas of potential regulatory relief for dischargers.

Comment ID: CTR-005-003e
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:

Document Date: 09/23/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES C-22; C-24a; C-01a; G-09; G-04

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003e

See response to CTR-004-009.

Comment ID: CTR-015-004
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: Mixing Zones (FR p.42185, Preamble section F.3.)

Mixing zones are defined by states. At this time, California does not have mixing zones at any state-level plan (Note: they were in the plans that were rescinded). The Agency mentions that several Regional Boards have mixing zone provisions in Basin Plans. The Agency states that it will recognize those provisions as they are applied to the water quality criteria contained in the Rule. Will the Agency recognize mixing zones should other Regional Boards adopt provisions from this time forward, especially if the State Board does not adopt a state-wide mixing zone definition and associated provisions in a timely manner, or at all?

Response to: CTR-015-004

In the absence of a state-wide policy on mixing zones, EPA will recognize any mixing zone provision that has been adopted by the Regional Board within its basin plan consistent with State law and is approved by EPA as consistent with the Clean Water Act.

Comment ID: CTR-020-019
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA

Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES

Comment: III. Mixing Zones

The CTR specifies that mixing zones are allowed on a case-by-case basis if authorized by the applicable Basin Plan and approved by the Regional Board for individual permits. In general, the rule should state that consideration of mixing should also apply to storm waters where dilution is certain to exist.

Response to: CTR-020-019

The State has discretion to allow (or deny) mixing zones in ambient waters that would apply to any NPDES discharger including storm water.

Comment ID: CTR-021-002e
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES G-04; C-24a; C-22; K-01; G-02

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; (c) the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002e

See response to CTR-004-009.

Comment ID: CTR-027-012e
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-22; C-24; C-01a; G-09

Comment: PROVISIONS OF THE PROPOSED RULE WE SUPPORT

Not withstanding the above comments, we believe there are certain elements of the proposed rule with respect to establishing water quality standards that we can support:

* Metal criteria expressed in the dissolved fraction rather than expressed in the total recoverable fraction.

* Metal criteria that are developed as a function of the water-effect-ratio (WER).

* The current proposed human health criterion for mercury.

* The current preamble language regarding metal translators and mixing zones.

We believe the above provisions provide a more acceptable, scientific approach to the water quality-based pollution control approach. We recommend these provisions of the current rule remain as proposed.

Response to: CTR-027-012e

See response to CTR-004-009.

Comment ID: CTR-032-002h
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01; C-22; G-09; C-24a; C-24; K; G-04; G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim

limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002h

See response to CTR-004-009.

Comment ID: CTR-035-002d
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES C-22; C-01a; C-08a; G-04; G-09; K-01; C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002d

See response to CTR-004-009.

Comment ID: CTR-035-034
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42185 -- Mixing Zones We support the inclusion of the discussion in the Preamble which allows mixing zones for acute and chronic criteria. As EPA notes, the Permitting and Compliance Issues Task Force recommended that the SWRCB allow the establishment of both acute and chronic mixing zones. We recommend that EPA support the establishment of technically defensible mixing zones that protect beneficial uses, consistent with EPA's water quality standards regulation.

Response to: CTR-035-034

See response to CTR-004-009.

Comment ID: CTR-038-002e
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES C-22; C-24a; C-01a; G-04; G-09

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002e

See response to CTR-004-009.

Comment ID: CTR-040-002d
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-24a; C-01a; G-09

Comment: PROVISIONS SUPPORTED

We support a number of provisions of the Rule, including: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury- and (4) the Preamble discussions regarding metals

translators and mixing zones. These provisions provide a firmer scientific base for the water quality-based approach to pollution control and are a marked improvement over the old Inland Surface Waters Plan. We would urge EPA to retain these provisions in the final Rule.

Response to: CTR-040-002d

See response to CTR-004-009.

Comment ID: CTR-040-051
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does not mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Alternative Mixing Zones

One of the few avenues that may actually provide some regulatory relief is mixing zones. The Preamble to the CTR describes a mixing zone as a limited area or volume of water where initial dilution of a discharge takes place and where water quality standards can be exceeded. Mixing zones have been applied in the water quality standards program since its inception. The present water quality standards regulations allows states to adopt acute and chronic mixing zones as a matter of state discretion, so long as the state's mixing zone protects the designated uses. See 40 C.F.R. section 131.13.

The Preamble recognizes that several California Regional Water Quality Control Boards have adopted mixing zone provisions in their respective Basin Plans. These mixing zone provisions can be applied to discharges to water bodies to which water quality standards based on the criteria contained in this proposed rule will apply once this rule becomes final. See CTR Preamble at pg. 42185. The problem

arises for the proposal or adoption of new mixing zones where one is not currently authorized under an existing Basin Plan. The Preamble sets out numerous restrictions on the use of mixing zones, as follows:

A mixing zone should be established to ensure that the zone will not impair the integrity of the water body as a whole, the zone will not cause lethality to passing organisms, and, considering likely pathways of exposure, that there are no significant human health risks. For application of two-number aquatic life crime as proposed in this rule, there may be up to two types of mixing zones. In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met. The chronic criterion is met at the edge of the second mixing zone. However, since both aquatic life and human health criteria are proposed in today's rule, the State may establish independent mixing zone policies for each. For any particular pollutant from any particular discharge, the magnitude, frequency, duration and mixing zone associated with each of the type of criteria may determine which one most limits the allowable discharge. Id.

The other potential problem arises because state-adopted mixing zones are subject to EPA review and approval, See 40 C.F.R. section 131.13. Because EPA approval is required, the question arises whether a federal rulemaking would accompany approval of mixing zones as it does with approval of state variances (which are also authorized under 40 C.F.R. section 131.13). If so, this would greatly restrict the utility of new or alternative mixing zones as an avenue for regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.
(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

Response to: CTR-040-051

See response to CTR-004-009.

Comment ID: CTR-041-006b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES G-04

Comment: Fifth, the District supports the preamble discussion on both interim permit limits and mixing zones as valid implementation procedures. In addition, however, the District specifically endorses the State's Permitting Task Force recommendations on these two subjects: (1) that interim effluent limits be calculated based on past performance plus future uncertainty, and (2) that the State Water Resources Control Board (SWRCB) should allow the establishment of both acute and chronic mixing zones.

Response to: CTR-041-006b

See response to CTR-004-009.

Comment ID: CTR-041-047
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself doesnot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Alternative Mixing Zones

One of the few avenues that may actually provide some regulatory relief is mixing zones. The Preamble to the CTR describes a mixing zone as a limited area or volume of water where initial dilution of a discharge takes place and where water quality standards can be exceeded. Mixing zones have been applied in the water quality standards program since its inception. The present water quality standards regulations allows states to adopt acute and chronic mixing zones as a matter of state discretion, so long as the state's mixing zone protects the designated uses, See 40 C.F.R. section 131.13.

The Preamble recognizes that several California Regional Water Quality Control Boards have adopted mixing zone provisions in their respective Basin Plans. These mixing zone provisions can be applied to discharges to water bodies to which water quality standards based on the criteria contained in this proposed rule will apply once this rule becomes final. See CTR Preamble at pg. 42185. The problem arises for the proposal or adoption of new mixing zones where one is not currently authorized under an existing Basin Plan. The Preamble sets out numerous restrictions on the use of mixing zones, as follows:

A mixing zone should be established to ensure that the zone will not impair the integrity of the water

body as a whole, the zone will not cause lethality to passing organisms, and, considering likely pathways of exposure, that there are no significant human health risks. For application of two-number aquatic life crime as proposed in this rule, there may be up to two types of mixing zones. In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met. The chronic criterion is met at the edge of the second mixing zone. However, since both aquatic life and human health criteria are proposed in today's rule, the State may establish independent mixing zone policies for each. For any particular pollutant from any particular discharge, the magnitude, frequency, duration and mixing zone associated with each of the type of criteria may determine which one most limits the allowable discharge. Id.

The other potential problem arises because state-adopted mixing zones are subject to EPA review and approval, See 40 C.F.R. section 131,13. Because EPA approval is required, the question arises whether a federal rulemaking would accompany approval of mixing zones as it does with approval of state variances (which are also authorized under 40-C.F.R. section 131.13). If so, this would greatly restrict the utility of new or alternative mixing zones as an avenue for regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

Response to: CTR-041-047

See response to CTR-004-009.

Comment ID: CTR-043-002e
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES C-22; C-24a; G-01a; G-04; G-09

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002e

See response to CTR-004-009.

Comment ID: CTR-044-003e
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES C-22; C-24a; C-01a; G-09; G-04

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003e

See response to CTR-004-009.

With respect to the comment about the economic impact of the old criterion for mercury 0.012 ug/l, EPA has not evaluated these costs since the CTR does not promulgate a mercury criteria of 0.012 ug/l.

Comment ID: CTR-044-042
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself doesnot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Alternative Mixing Zones

One of the few avenues that may actually provide some regulatory relief is mixing zones. The Preamble to the CTR describes a mixing zone as a limited area or volume of water where initial dilution of a discharge takes place and where water quality standards can be exceeded. Mixing zones have been applied in the water quality standards program since its inception. The present water quality standards regulations allows states to adopt acute and chronic mixing zones as a matter of state discretion, so long as the state's mixing zone protects the designated uses, See 40 C.F.R. section 131.13.

The Preamble recognizes that several California Regional Water Quality Control Boards have adopted mixing zone provisions in their respective Basin Plans. These mixing zone provisions can be applied to discharges to water bodies to which water quality standards based on the criteria contained in this proposed rule will apply once this rule becomes final. See CTR Preamble at pg. 42185. The problem arises for the proposal or adoption of new mixing zones where one is not currently authorized under an existing Basin Plan. The Preamble sets out numerous restrictions on the use of mixing zones, as follows:

A mixing zone should be established to ensure that the zone will not impair the integrity of the water body as a whole, the zone will not cause lethality to passing organisms, and, considering likely pathways of exposure, that there are no significant human health risks. For application of two-number aquatic life crime as proposed in this rule, there may be up to two types of mixing zones. In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met. The chronic criterion is met at the edge of the second mixing zone. However, since both aquatic life and human health criteria are proposed in today's rule, the State may establish independent mixing zone policies for each. For any particular pollutant from any particular discharge, the magnitude, frequency, duration and mixing zone associated with each of the type of criteria may determine which one most limits the allowable discharge. Id.

The other potential problem arises because state-adopted mixing zones are subject to EPA review and approval, See 40 C.F.R. section 131,13. Because EPA approval is required, the question arises whether a federal rulemaking would accompany approval of mixing zones as it does with approval of state variances (which are also authorized under 40-C.F.R. section 131.13). If so, this would greatly restrict

the utility of new or alternative mixing zones as an avenue for regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

Response to: CTR-044-042

See response to CTR-004-009.

Comment ID: CTR-045-008
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

EPA's policies and guidance regarding the application of mixing zones and dilution credits.

Response to: CTR-045-008

See response to CTR-004-009.

Comment ID: CTR-052-002d
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-22; C-01a; G-09; G-04

Comment: EPA will recall the State Water Quality Plans Task Forces that included all stakeholders, including EPA. The Authority appreciates the incorporation of many of the consensus recommendations

from the Task Forces into the CTR, including:

* Adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio

* Adoption of the proposed new human health criterion for mercury

* Preamble discussions regarding metals translators, mixing zones, and interim permit limits

Response to: CTR-052-002d

See response to CTR-004-009.

Comment ID: CTR-052-019
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should mandate that the State Board continue to use defensible dilution credits. Only if documented human health and/or aquatic toxicity problems are shown to exist in specific segments of water bodies should the State and Regional Boards be allowed to consider modifications to continued use of dilution credits.

Response to: CTR-052-019

EPA does not believe that it is appropriate to mandate that the State use dilution credits or mixing zones because these decisions are most appropriately addressed at the State and local level. The State has discretion to make modifications to its mixing zone policy based on any scientific or policy grounds as long as the modifications are consistent with State and Federal law. The State is not required to limit modifications to its mixing zone policy only to those cases where human health or toxicity problems are shown to exist in specific segments of water bodies. States may always be more stringent than EPA in adopting water quality standards. See section 510 of the Clean Water Act.

Comment ID: CTR-054-004b
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES G-09; G-04

Comment: BADA supports the Preamble discussions regarding metals translators, mixing zones, and interim permit limits. Translators and mixing zones will provide a better scientific basis for the application of the criteria and will go a long way toward protecting against the imposition of unnecessary or unreasonable controls. Interim permit limits will allow dischargers faced with potential attainability problems to pursue reasonable actions, such as pollution prevention, treatment plant optimization, pollutant trading, TMDLS, etc. prior to being faced with final effluent limitations. BADA endorses the recommendation of the State Plan Public Task Forces on the issue of interim limits.

Response to: CTR-054-004b

See response to CTR-004-009.

Comment ID: CTR-054-046
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself doesnot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Alternative Mixing Zones

One of the few avenues that may actually provide some regulatory relief is mixing zones. The Preamble to the CTR describes a mixing zone as a limited area or volume of water where initial dilution of a

discharge takes place and where water quality standards can be exceeded. Mixing zones have been applied in the water quality standards program since its inception. The present water quality standards regulations allows states to adopt acute and chronic mixing zones as a matter of state discretion, so long as the state's mixing zone protects the designated uses, See 40 C.F.R. section 131.13.

The Preamble recognizes that several California Regional Water Quality Control Boards have adopted mixing zone provisions in their respective Basin Plans. These mixing zone provisions can be applied to discharges to water bodies to which water quality standards based on the criteria contained in this proposed rule will apply once this rule becomes final. See CTR Preamble at pg. 42185. The problem arises for the proposal or adoption of new mixing zones where one is not currently authorized under an existing Basin Plan. The Preamble sets out numerous restrictions on the use of mixing zones, as follows:

A mixing zone should be established to ensure that the zone will not impair the integrity of the water body as a whole, the zone will not cause lethality to passing organisms, and, considering likely pathways of exposure, that there are no significant human health risks. For application of two-number aquatic life crime as proposed in this rule, there may be up to two types of mixing zones. In the zone immediately surrounding the outfall, neither the acute nor the chronic criterion is met. The acute criterion is met at the edge of this zone. In the next mixing zone, the acute, but not the chronic, criterion is met. The chronic criterion is met at the edge of the second mixing zone. However, since both aquatic life and human health criteria are proposed in today's rule, the State may establish independent mixing zone policies for each. For any particular pollutant from any particular discharge, the magnitude, frequency, duration and mixing zone associated with each of the type of criteria may determine which one most limits the allowable discharge. Id.

The other potential problem arises because state-adopted mixing zones are subject to EPA review and approval, See 40 C.F.R. section 131,13. Because EPA approval is required, the question arises whether a federal rulemaking would accompany approval of mixing zones as it does with approval of state variances (which are also authorized under 40-C.F.R. section 131.13). If so, this would greatly restrict the utility of new or alternative mixing zones as an avenue for regulatory relief.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

Response to: CTR-054-046

See response to CTR-004-009.

Comment ID: CTR-056-007
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97

Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* EPA's policy regarding and guidance on the application of mixing zones and dilution credits,

Response to: CTR-056-007

See response to CTR-004-009.

Comment ID: CTR-058-008
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? Y
CROSS REFERENCES

Comment: 7. Mixing Zones. WSPA supports EPA's recognition of the use of mixing zones.

In proposing the rule, EPA has recognized the appropriate role of mixing zones in setting and achieving WQBELS. EPA regulations, policy and guidance (e.g., the Technical Support Document for WQBELS) amply support their use in protecting receiving water.

WPSA supports the use of sound science in determining mixing zones and the actual degree of mixing achieved by today's engineered diffusers in establishing mixing zones and dilution credit. EPA should encourage states and regulators to make use of sound science, rather than arbitrary dilution factors, in establishing mixing zones. To this end WSPA supports additional EPA outreach to the states and state regulators to achieve a comfort level with using sound science and avoiding arbitrary decisions.

Response to: CTR-058-008

See response to CTR-004-009.

Comment ID: CTR-060-002
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E SUPPORTS

EPA has included in the proposed CTR provisions which are reasonable and with which SDG&E supports. These include:

Mixing zones

Acute and chronic mixing zones play an important role in the implementation of water quality based effluent limits. SDG&E supports EPA's inclusion of the use of mixing zones in the proposed rule (see 62 Fed. Reg. at 42206, Col. 2).

Response to: CTR-060-002

See response to CTR-004-009.

Comment ID: CTR-066-010
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support are as follows:

* EPA's policies and guidance regarding the application of mixing zones and dilution credits.

Response to: CTR-066-010

See response to CTR-004-009.

Comment ID: CTR-077-002
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97

Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: Mixing Zone Policy

According to the Guidelines, the Mixing zone calculations as applied to dredge sediment testing are performed in accordance with the "Green Book" (EPA/Corps 1991). We support EPA's recognition of the use of mixing zones in the Toxics Rule.

Response to: CTR-077-002

See response to CTR-004-009.

Comment ID: CTR-081-002h
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES G-04; C-24a; G-02; C-22; G-09; C-01a; C-08a

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are perfomed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002h

See response to CTR-004-009.

Comment ID: CTR-085-011
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97

Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's policies and guidance regarding the application of mixing zones and dilution credits.

Response to: CTR-085-011

See response to CTR-004-009.

Comment ID: CTR-086-004h
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01; C-22; G-09; C-24a; C-24; K-03; G-04; G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004h

See response to CTR-004-009.

Comment ID: CTR-089-001d
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:

Attachments? N
CROSS REFERENCES C-22; C-01a; C-08a; K-01; G-02; G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001d

See response to CTR-004-009.

Comment ID: CTR-090-002d
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-17a; C-24a; C-22; G-02; G-04

Comment: There are many features of the proposed rule which we strongly endorse, specifically:

* the use of the latest IRIS values for human health criteria, it is essential that the criteria be based on the latest scientific and environmental information;

* recognition that the dissolved fraction of metals, rather than the total recoverable, better reflect the aquatic toxicity of metals;

* recognition that for certain metals (e.g. copper and zinc) ambient water chemistry is critical in determining toxicity thereby endorsing the Water Effects Ratio;

* recognition and strong endorsement of the multi-tiered mixing zones for acute, chronic and human health effects; and

* recognition of interim limits and compliance schedules as appropriate implementation strategies,

Response to: CTR-090-002d

See response to CTR-004-009.

Comment ID: CTR-092-007
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Mixing Zones

The City fully supports the discussion and allowance of mixing zones for both acute and chronic criteria in accordance with EPA's water quality standards program. The establishment of mixing zones should be allowed in those instances where designated uses remain unimpaired, where the zone does not result in lethal doses to resident organisms, and where human health aspects are adequately protected.

Response to: CTR-092-007

See response to CTR-004-009.

Comment ID: CTRH-001-022b
Comment Author: Julio Guerra
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Merced
Document Date: 09/17/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES G-07

Comment: There are good things in here regarding the variances and the recognition of the existence of ephemeral streams. And the naturally occurring pollution, you know, has to be taken into account when it actually applies to water quality standards.

I would observe in that regard that the NPDES program recognizes that intake credits may sometimes be appropriately applied to adjust effluent limits. But in the NPDES language it states that that only can occur when you discharge into the same water body that you take the water from.

In our case, of course, we use groundwater. And, as an example, it may contain arsenic. And the arsenic isn't really removed from the water before it is discharged to surface water. We don't fit the mold of being authorized those intake credits, because we're not discharging into the same water body that we draw water from.

Response to: CTRH-001-022b

EPA recognizes that a same body of water demonstration may be more difficult for a municipality using groundwater; however, groundwater as a category is not excluded necessarily from eligibility for a same body of water determination. EPA's rationale for intake credits is based on two guiding principles: 1) the source water and receiving water are hydrologically connected; and, 2) that the pollutant would have ended up in the receiving water had the man-induced removal and reintroduction of the pollutant not occurred. If a same body of water determination cannot be made, there are other more appropriate forms of flexibility for inter-water body transfers of pollutants where the discharger is unable to comply with its new or more stringent water quality-based effluent limit, e.g., variances, compliance schedules.

Comment ID: CTRH-001-024b
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES g-02; c-22; c-24a; c-17a

Comment: MS. PLA: My name is Michelle Pla. I'm with the Public Utilities Commission, City and County of San Francisco.

I made the comment on my card that I also said that I would try to be constructive, and so I'm going to follow my mentor here, Phil Bobel, and say that there are some things in this rule that we're very pleased to see.

We're very pleased to see use of the latest scientific information, particularly the use of latest IRIS, I-R-I-S, numbers-for human health. We're very pleased that you're using dissolved versus total recoverable form for the metals.

We're very pleased to see recognition of the water effects ratios. We're pleased to see recognition for a multi-tiered mixing zone for acute and chronic human health effects and hope that the state pays particular attention to that.

We do have a problem with the way you've described compliance schedules and hope to be working strictly by the state on that as well. We think that the five-year system is fairly shortsighted, and -we can't even do FMDSLs in five years.

Response to: CTRH-001-024b

See response to CTR-004-009.

Comment ID: CTRH-001-032c
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA

Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES C-22; C-24a

Comment: I would like to take this time to note that I think it contains some importantelements that we agree with and believe are reflective of the impact. These include the uses of dissolved metals and the provisions which will enable the state to use mixing zones and water effects ratios and establish site-specific objectives.

Response to: CTRH-001-032c

See response to CTR-004-009.

Comment ID: CTRH-001-057g
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: G-05 Mixing Zones&Dilution Credit
References:
Attachments? N
CROSS REFERENCES K-03; C-24a; G-04; G-07; G-09; C-22

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057g

See response to CTR-004-009.

Subject Matter Code: G-06 NWQI

Comment ID: CTR-061-020
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-06 NWQI
References:
Attachments? Y
CROSS REFERENCES

Comment: National Water Quality Inventory

At the September 17,1997 hearing on the proposed CTR, the US EPA Region 9 made available on the table in the hearing room a copy of the US EPA Fact Sheet "National Water Quality Inventory: 1994 Report to Congress" (1995) evidently to try to convince the hearing participants that the adoption of the proposed CTR criteria was necessary to protect the Nation's waters from the impact of toxics that are regulated by the proposed CTR. Shortly after the release of that report to Congress, I conducted a review of the procedures used by the US EPA and the states in determining the presence of so-called "impaired" waters and found that the Agency had again used unreliable procedures for designating impaired waters. Enclosed is a copy of a report, "Unreliable Reporting of Water Quality Impairment by the US EPA's National Water Quality Inventory," Feb (1996) that I have prepared on this issue. The Agency dictates to the states that they must list as impaired any waterbody for which there is an exceedance of a water quality criterion more than once in three years. The Agency ignores the well-known fact that many of the exceedances are administrative, arising from the overly protective nature of the criteria that results from the failure of the criteria and the water effects ratio approach to properly incorporate the aquatic chemistry of the regulated constituents into assessing potential toxicity to aquatic life. The actual amount of real use-impaired waters of concern to the public is far less than that predicted by the US EPA "Fact Sheet."

Response to: CTR-061-020

First, EPA notes that the National Water Quality Inventory Reports (also referred to as the CWA Section 305(b) report) and the guidance used by States and Indian Tribes for developing these reports are outside of the scope of today's rule. The Agency will, however, take the commenter's concerns under advisement and consider those concerns expressed in the review of the Section 305(b) guidance for preparing the reports which EPA jointly develops with States and Indian Tribes.

Subject Matter Code: G-07 Variances

Comment ID: CTR-004-007
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

Comment: Available Regulatory Relief under the California Toxics Rule

The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at. pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility. (*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does riot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Water Quality Standard Variances/ Designated Use Modifications

The Preamble to the CTR discusses variances as a form of regulatory relief that might be pursued by dischargers. See 62 Fed.Rec,. 42,185-6. The Preamble provides that States may adopt a statewide policy (or Regional Boards may adopt Basin-wide policies) to allow water quality standard variances for individual dischargers. The variance Policy Would allow the State or Regional Board to grant a variance to an individual permittee from a water quality standard,(*5) which is the basis of a water quality-based effluent limitation in a permit. However, there are some serious restrictions placed oil tile use of variances. The following lays out these restrictions:

* Variances are not allowed for new or recommencing dischargers.

* Variances are discharger and pollutant specific. In other words, the water quality standard variance applies only to the permittee requested the variance and only to the pollutant or pollutants specified in the variance.

* Once a variance has been approved by the State, it must be submitted to EPA for approval. - EPA will only approve variances if consistent with the substantive requirements set out at 40 CFR Part 131 for

removing a designated use.(*6)

* EPA will only approve state variances if specific provisions are included.(*7)

* EPA would have to tinder-take a federal rulemaking to make the necessary changes to this rule to allow for State-approved variances. The Preamble explains this restriction as follows:

EPA, however, cautious California and the public that promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by states. These are optional policies under terms of the federal water quality standards regulation. Except for tire water-effect ratio procedure for certain metals, EPA has not incorporated either optional policy, in general, in this proposed rulemaking, that is, EPA has not generally authorized State modifications of federal water quality. Each of these types of modifications will, in general, require federal rulemaking on a case by case basis to change the federal rule. Because of the time consuming nature of reviewing such requests, limited federal resources, and the need for the Agency to move into other priority program areas in establishing environmental controls, EPA alerts California and the public that a prompt Agency response is unlikely. The best course of action, if such provisions are desired, is for the State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions.(*8)

Because of all of the restrictions placed on their use, variances are not really a viable option for regulatory relief. The only way for variances to be a viable option would be for EPA to incorporate a variance policy into the proposed rule that would authorize State modifications of federal water quality standards.

(*1) This cost trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario, See EA at pg. 4.

(*2) In addition, pollutant load I reductions word not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*4) EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 at pg. 20 (April 1991) (Emphasis added).

(*5) The variance would allow the permittee time to achieve reasonable progress towards attaining a specific water quality based effluent limitation, without violating CWA section 402(a)(1), which requires that NPDES permittees meet all applicable water quality standards. See 62 Fed.Reg, 42185-6. A variance does not effect the corresponding water quality standard fur the water body receiving the discharge. Variances are designed to preserve the underlying water quality standard over the long term, while providing flexibility to individual dischargers in complying with peanut limits based on the standards. When a variance is granted, the discharger is assured compliance during the term of a variance, as long as all variance conditions are met. Id.

(*6) Specifically, the State's policy must require the inclusion of a demonstration that a water quality standard is unattainable, based on one or more of the following grounds: 1. Naturally occurring pollutant concentrations prevent the attainment of the water quality standard; 2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the water quality standard, unless these

conditions may be compensated for by the discharge of sufficient volume of effluent to enable the standard to be met without violating State water conservation requirements; 3. Human-caused conditions or sources of pollution prevent the attainment of the water quality standard and cannot be remedied, or would cause more environmental damage to correct than to leave in place; 4. Dams, diversions or other types of hydrologic modifications preclude the attainment of a water quality standard, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the standard; 5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of the water quality standard; or 6. Controls more stringent than those required by CWA sections 30 1 (b) and 306 would result in substantial and widespread economic and social impact.

(*7) The required provisions are as follows: 1. The State will include each individual variance as part of its water quality standard or water quality plan; 2. The variance will include documentation that treatment more advanced than that required by CWA section 301(b) and 306 has been carefully considered, and that alternative effluent control strategies have been evaluated; 3. The underlying, more stringent criterion will be maintained and will be binding on all other dischargers; 4. The discharger who will be given a variance for one particular constituent will be required to meet the applicable criteria for other constituents; 5. The variance will be granted for a specific period of time and must be rejustified upon expiration, but at least every three years; 6. Reasonable progress will be made towards meeting the underlying standards; 7. The variance will not likely jeopardize the continued existence of any threatened or endangered species listed under Section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat; and 8. The variance will be subjected to public notice, comment, and hearing. See CWA section 303(c)(t) and 40 CFR 131.20. The public notice should contain a clear description of the impact of the variances upon achieving the water quality standard in the water body.

(*8) See CTR Preamble at pg. 42195-6. Further guidance on variance policies is provided in EPA's 1994 Water Quality Standards Handbook, Chapters 2 and 5 (EPA 823-B-94-005a, August 1994).

Response to: CTR-004-007

EPA disagrees that variances are not a viable option for regulatory relief for dischargers. The ability of States to develop site specific criteria or to grant variances and exceptions to water quality standards are optional procedures that are available to States (See 40 CFR 131.11(b)(ii) and 131.3). It is neither a statutory nor a regulatory requirement to develop site specific criteria or to issue variances.

Since the criteria in this rule are Federal criteria that are applicable in the State, the State cannot unilaterally establish site-specific criteria or issue variances to the Federal rule. Such provisions are still available to the State, but are more cumbersome as it requires the State to meet all the regulatory requirements for developing such procedures, but then EPA would need to undertake a Federal rulemaking process on a case by case basis in order to effectuate changes to the rule in accordance with the Administrative Procedures Act. EPA emphasizes that this is a strong reason for California to act to adopt its own numeric criteria even after this Federal promulgation action is taken.

The basis for assuming that regulatory relief would be available under certain circumstances for purposes of estimating costs is explained in the economic analysis for this rule. Note that EPA's high end cost estimate assumed that no regulatory relief would be available to dischargers.
See also response to comment CTR-032-004 (Category E-01m).

Comment ID: CTR-015-005
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

Comment: Variances (FR p. 42185, Preamble section F.3.)

The Agency describes the procedures and demonstrations that any state-adopted variance policy must contain, and also states that the Agency must approve the policy. Additionally, should any variance from a water quality criterion subsequently result from the state policy, it is indicated that a federal rulemaking must occur to recognize each variance from the Rule. Is this true? Agency "approval" is required, according to the Agency's Water Quality Standards Handbook (1994). If the Agency approves a state variance policy, then actions under the policy should follow the policy procedures, whether the criteria are federal or state. The last part of these statements essentially denies modifications to the water quality criteria. The Agency is effectively removing the flexibility which seems to be under the purview of the state.

Response to: CTR-015-005

See response to CTR-004-007.

Comment ID: CTR-035-035
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42185-42186 -- Variances The Preamble encourages the SWRCB to adopt a policy allowing dischargers to apply for variances, but stops short of adopting a provision in the CTR allowing variances. EPA further states that the granting of variances will require a federal rulemaking on a case-by-case basis, and that "a prompt Agency response is unlikely." As with site-specific criteria, we object, on the one hand, to EPA's assumption in the cost analysis that regulatory relief mechanisms such as variances will not only be available but will be granted to dischargers, while on the other hand EPA essentially states that it does not intend to grant variances. We believe these approaches conflict, and that EPA must resolve these inconsistencies before finalizing the CTR- Therefore, we strongly urge EPA

to include a provision in the CTR authorizing the issuance of variances. However, we recommend that EPA provide flexibility in variance procedures to allow for such things as variances without federal rulemaking requirements, and consideration of multiple discharger (or water body) variances, consistent with the policy of fostering collaborative, watershed-based solutions to water quality problems.

Response to: CTR-035-035

See response to CTR-005-009

Comment ID: CTR-040-049
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-07 Variances
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does not mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Water Quality Standard Variances/ Designated Use Modifications

The Preamble to the CTR discusses variances as a form of regulatory relief that might be pursued by dischargers. See 62 Fed. Reg. 42,185-6. The Preamble provides that States may adopt a statewide policy (or Regional Boards may adopt Basin-wide policies) to allow water quality standard variances for individual dischargers. The variance policy would allow the State or Regional Board to grant a variance to an individual permittee from a water quality standard,(*5) which is the basis of a water quality-based effluent limitation in a permit. However, there are some serious restrictions placed on the use of variances. The following lays out these restrictions:

* Variances are not allowed for new or recommencing dischargers. * Variances are discharger and pollutant specific. In other words, the

water quality standard variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. * Once a variance has been approved by the State, it must be submitted to EPA for approval. - EPA will only approve variances if consistent with the substantive requirements set out at 40 CFR Part 131 for removing a designated use.(*6) - EPA will only approve state variances if specific provisions are included.(*7) - EPA would have to undertake a federal rulemaking to make the necessary changes to this rule to allow for State-approved variances, The Preamble explains this restriction as follows:

EPA, however, cautions California and the public that promulgation of this federal rule removes most of the flexibility available to the State for modifying it standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by states. These are optional policies under terms of the federal water quality standards regulation. Except for the water-effect ratio procedure for certain metals, EPA has not incorporated either optional policy, in general, in this proposed rulemaking, that is, EPA has not generally authorized State modifications of federal water quality standards. Each of these types of modifications will, in general, require federal rulemaking on a case by case basis to change the federal rule. Because of the time consuming nature of reviewing such requests, limited federal resources, and the need for the Agency to move into other priority program areas in establishing environmental controls, EPA alerts California and the public that a prompt Agency response is unlikely. The best course of action, if such provisions are desired, is for the State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions. (*8)

Because of all of the restrictions placed on their use, variances are not really a viable option for regulatory relief. The only way for variances to be a viable option would be for EPA to incorporate a variance policy into the proposed rule that would authorize State modifications of federal water quality standards.

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*5) The variance would allow the permittee to achieve reasonable progress towards attaining a specific water quality-based effluent limitation, without violating CWA section 402(a)(1), which requires that NPDES permittees meet all applicable water quality standards, See 62 Fed.Reg. 42185-6. A variance does not effect the corresponding water quality for the water body receiving the discharge. Variances are designed to preserve the underlying water quality standard over the long term, while providing flexibility to individual dischargers in complying with permit limits based on the standards. When a variance is granted, the discharger is assured compliance during the term of a variance, as long as all variance conditions are met. Id.

(*6) Specifically, the State's policy must require the inclusion of a demonstration that a water quality standard is unattainable, based on one or more of the following grounds:

1. Naturally occurring pollutant concentrations prevent the attainment of the water quality standard; 2.

Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the water quality standard, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable the standard to be met without violating State water conservation requirements; 3. Human-caused conditions or sources of pollution prevent the attainment of the water quality standard and cannot be remedied, or would cause more environmental damage to correct than to leave in place; 4. Dams, diversions or other types of hydrologic modifications preclude the attainment of a water quality standard, and it is not feasable to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the standard; 5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of the water quality standard; or 6. Controls more stringent than those required by CWA sections 301(b) and 306 would result in substantial and widespread economic and social impact.

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(*8) See CTR Preamble at pg. 42185-6. Further guidance on variance policies is provided in EPA's 1994 Water Quality Standards Handbook, Chapters 2 and 5 (EPA 823-B-94-005a, August 1994).

Response to: CTR-040-049

See Response to CTR-035-035.

Comment ID: CTR-041-045
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

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Response to: CTR-041-045

See Response to CTR-004-007.

Comment ID: CTR-044-040
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

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Response to: CTR-044-040

See response to CTR-004-007.

Comment ID: CTR-050-005b
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES C-24

Comment: II. EPA Should Allow Variances and Site-Specific modifications.

Beyond the issue of whether EPA has the authority to issue the proposed rule, there are other significant problems with the proposal. For example, the Agency has made the inexplicable decision not to include provisions that would allow for issuance of variances or site-specific modifications to the criteria. This is despite the Agency's recognition that a variance procedure is an "important procedure to assist the State in effectively implementing water quality standards." (62 Fed. Reg. at 42185). EPA gives absolutely no explanation for its decision not to allow use of this procedure. Moreover, the Agency concedes that "promulgation of this federal rule removes most of the flexibility available to the State for modifying its standards on a discharger-specific or stream-specific basis. " Instead, an applicant would have to ask EPA to begin a "federal rulemaking on a case-by-case basis to change the federal rule." (62 Fed. Reg. at 42186) EPA makes it quite clear that applicants should not expect any relief from that avenue, because the Agency simply has more important things to do:

Because of the time consuming nature of reviewing such requests, limited federal resources, and the need for the Agency to move into other priority program areas in establishing environmental controls, EPA alerts California and the public that a prompt Agency response is unlikely.

Despite this cavalier dismissal of the need for actually acting on variance and site criteria applications, the Agency does not hesitate to mention those mechanisms in its economic analysis as being available to moderate the impact of the proposed rule. The Agency specifically mentions variances and site-specific criteria when it states that "these implementation procedures can have an effect on how water quality standards, based on today's proposed rule, will impact NPDES permit holders." (62 Fed. Reg. at 42192). In fact, that statement is clearly false, given EPA's decision not to include variance or site-specific criteria procedures in the proposed rule. The Agency should reconsider that decision and insert those provisions.

Response to: CTR-050-005b

See response to CTR-035-035.

Comment ID: CTR-054-044
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES

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(*5) The variance would allow the permittee to achieve reasonable progress towards attaining a specific water quality-based effluent limitation, without violating CWA section 402(a)(1), which requires that NPDES permittees meet all applicable water quality standards, See 62 Fed.Reg. 42185-6. A variance does not effect the corresponding water quality for the water body receiving the discharge. Variances are designed to preserve the underlying water quality standard over the long term, while providing flexibility to individual dischargers in complying with permit limits based on the standards. When a variance is granted, the discharger is assured compliance during the term of a variance, as long as all variance conditions are met. Id.

(*6) Specifically, the State's policy must require the inclusion of a demonstration that a water quality standard is unattainable, based on one or more of the following grounds:

1. Normally occurring pollutant concentrations prevent the attainment of the water quality standard; 2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the water quality standard, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable the standard to be met without violating State water conservation requirements; 3. Human-caused conditions or sources of pollution prevent the attainment of the water quality standard and cannot be remedied, or would cause more environmental damage to correct than to leave in place; 4. Dams, diversions or other types of hydrologic modifications preclude the attainment of a water quality standard, and it is not feasable to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the standard; 5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of the

water quality standard; or 6. Controls more stringent than those required by CWA sections 301(b) and 306 would result in substantial and widespread economic and social impact.

(*7) The required provisions are as follows: 1. The State will include each individual variance as part of its water quality standard or water quality plan; 2. The variance will include documentation that treatment more advanced than that required by CWA section 301(b) and 306 has been carefully considered, and that alternative effluent control strategies have been evaluated; 3. The underlying, more stringent criterion will be maintained and will be binding on all other discharges; 4. The discharger who will be given a variance for one particular constituent will be required to meet the applicable criteria for other constituents; 5. The variance will be granted for a secific period of time and must be rejustified upon expiration, but at least every three years; 6. Reasonable progress will be made towards meeting the underlying standards; 7. The variance will not likely jeopardize the continued existence of any threatened or endangered species listed under Section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat; and 8. The variance will be subjected to public notice, comment and hearing. See CWA section 303(c)(1) and 40 CFR 131.20. The public notice should contain a clear description of the impact of the variance upon achieving the water quality standard in the water body.

(*8) See CTR Preamble at pg. 42185-6. Further guidance on variance policies is provided in EPAs 1994 Water Quality Standards Handbook, Chapters 2 and 5 (EPA 823-B-94-005a, August 1994).

Response to: CTR-054-044

See response to CTR-004-007.

Comment ID: CTR-057-010b
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES K-01; C-24

Comment: Implementation

Although the proposed Rule discusses implementation issues such as TMDLs, variances, SSOs, and interim permits, it lacks evidence of support for any of these provisions. We believe that this will have the effect of reducing the State's confidence or perceived authority in granting any of these provisions to individual POTWs. For example, Page 42186 of the CTR lists six criteria that must be used by the State to determine the non-attainability of a water quality standard; we are doubtful that any of these criteria would be strictly applicable to our facilities with respect to lindane and DDT. We believe CTR variance criteria should include economic considerations for specific discharger implementation efforts. Unless the EPA provides more support for these provisions, we fear that the State will either not grant us a legitimate variance or will waiver in its commitment to act at all.

Response to: CTR-057-010b

See response to CTR-004-007.

Furthermore, the six criteria that are used as a basis for a variance does include economic considerations (see preamble of the proposed rule 62 FR 42186, August 5, 1997 and the Water Quality Standards Regulation at 131.10(g)). The requirements for issuing a variance are the same as those for downgrading or removal of a designed use. Discussions on alternative justifications for variances are outside the scope of today's rule.

Comment ID: CTR-090-020
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-07 Variances
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Variances This procedure described in the preamble is unduly cumbersome and unrealistic. Particular problems we see with this approach are:

Time limit - The proposed policy requires that variances be granted for not more than three years, after which they must be re-justified. This policy is not reasonable when applied to a major municipal wastewater construction program which may have a variance as an integral part of the facility planning process. Does it make sense to reanalyze a fundamental design premise every three years for a wastewater system that may have cost hundreds of millions and taken decades to construct. Although review of facility plans is appropriate in some cases, following the laborious process every three years as described in this proposal would have no benefit since there is no feasible way to instantly change a completed wastewater system.

Regulatory justification - EPA has modeled the variance procedure on the portion of the regulations established to provide for removal of a designated use. What is left out of the preamble is a justification for using this model for the additional requirements added to the procedure. Why, in the first place does EPA need to establish a variance procedure. The Clean Water Act requires the state have standards which 'shall be such as to protect the public health and welfare, enhance the quality of water and serve the purposes of this chapter." Each Basin Plan in California already has a variance policy which meet this statutory requirement and which is currently in effect. We propose that there is no need for the variance procedure in this rule-making.

Conflict with the fundamental premise of state water quality standards The major problem with the proposed variance procedure is that it is in conflict with the underlying premise upon which the standards were originally developed. The standards in California were developed to be applied to permanent dischargers such as POTWs and industrial discharges. The state explicitly recognized that the standards were inappropriate for intermittent discharges such as combined sewer overflows. Because the standards were not appropriate for CSOs, the state intended that the variance procedure be used. Taking as an

example, the Ocean Plan standards applied to the first San Francisco permits, the SWRCB made the following statement:

... it is patiently clear that it was realized it inappropriate to apply Ocean Plan standards strictly to combined waste and stormwater discharges. The record indicates further, that rather than address this problem in the 1978 Ocean Plan amendments, directly, it was decided to deal with such problems on a case-by-case basis via the exception mechanism. [Order No. WQ 79-16].

The same argument applies to stormwater discharges. Since most such discharges will violate the current standards during at least some period during the discharge, it is obvious that the intent of those developing the standards was not to apply them to intermittent discharges in the same manner as they are applied to permanent discharges. Until the standards are changed, the variance process is the only available mechanism to reconcile the standards with these discharges.

In order to minimize paperwork, and to provide more meaningful public participation, we suggest that all remaining variances be handled has part of the Basin Plan process ,(by watershed and discharger class) rather than on an individual NPDES permit basis.

We further request that all existing variances be incorporated into the CTR by reference. This could be handled by listing the currently applicable Basin Plans and adding language to the effect that "...all variances issued pursuant to these plans are incorporated into the CTR by reference." San Francisco has variances and/or site-specific discharge standards associated with its wet-weather control facilities (RWQCB(2) Order 94-149 as amended by Order 96-117, Southeast WPCP, and Order 95-039, Northpoint and Southeast Sewerage Zones).

Response to: CTR-090-020

EPA disagrees that a three year time limit for variances is unreasonable. The variance represents a change in the applicable water quality criteria. Variances are optional components of a state's water quality standards. As noted in the preamble, EPA's policy on variances is that variance are granted for a specific period of time and must be rejustified upon expiration but at least every three years. The three year rejustification is derived from the triennial review requirements of CWA Section 303. Section 303 requires States to hold hearings for the purpose of reviewing and, if necessary, revising their water quality standards.

EPA notes that the Agency is not including or establishing a variance procedure for California in this rule. Rather, the preamble of the rule explains minimum requirements for State adopted variance provisions. As previously noted, such provisions are optional policies that states in general adopt to assist in the implementation of their NPDES permit program. See response to CTR-004-007.

Comment ID: CTR-092-008
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-07 Variances
References: Letter CTR-092 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Variances

The City strongly supports the application of variances as an important regulatory procedure to assist the State in implementing its water quality standards program. The City further encourages the State to formally adopt a variance provision that allows variances for individual dischargers. This procedure would provide a valuable tool to allow a permittee to achieve reasonable progress toward attainment of a water quality based effluent limitation without violating applicable water quality standards.

Response to: CTR-092-008

EPA takes no position as to whether the State adopts a variance provisions in its water quality standards.

Comment ID: CTRH-001-022a
Comment Author: Julio Guerra
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Merced
Document Date: 09/17/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES G-05

Comment: There are good things in here regarding the variances and the recognition of the existence of ephemeral streams. And the naturally occurring pollution, you know, has to be taken into account when it actually applies to water quality standards.

I would observe in that regard that the NPDES program recognizes that intake credits may sometimes be appropriately applied to adjust effluent limits. But in the NPDES language it states that that only can occur when you discharge into the same water body that you take the water from.

In our case, of course, we use groundwater. And, as an example, it may contain arsenic. And the arsenic isn't really removed from the water before it is discharged to surface water. We don't fit the mold of being authorized those intake credits, because we're not discharging into the same water body that we draw water from.

Response to: CTRH-001-022a

EPA acknowledges the commenter's support for the discussions on variances that are contained in the preamble of the rule. See response to CTR-004-007.

Comment ID: CTRH-001-057d
Comment Author: Dave Tucker

Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: G-07 Variances
References:
Attachments? N
CROSS REFERENCES K-03; C-24a; G-04; G-09; C-22; G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057d

EPA acknowledges the commenter's support for variances, However, EPA is not including a variance procedure in today's rule. See response to CTR-004-007.

Subject Matter Code: G-08 State Policy

Comment ID: CTRE-004-001b
Comment Author: Victor Valley Wastewater Auth.
Document Type:
State of Origin: CA
Represented Org:
Document Date: 09/11/97
Subject Matter Code: G-08 State Policy
References:
Attachments? N
CROSS REFERENCES B

Comment: The Victor Valley Wastewater Reclamation Authority (VVWRA) respectfully requests that the comment period deadline be extended for the California Toxics Rule (CTR). The current comment period deadline is September 26, 1997. We request that the latter deadline be extended for at least 60 days so that we can fully evaluate the potential impact on VVWRA

The reasons for our request are as follows:

1. VVWRA discharges to the Mojave River, which is considered by the Lahontan RWQCB as an impaired waterway. Although portions of the Mojave exhibit year-round surface flow, the River directly above VVWRA does not exhibit consistent surface flow. However, the Lahontan RWQCB considers the Mojave an underflow stream, which is often considered as surface flow. Whether an underflow stream would be considered under the CTR for receiving stream dilution has yet to be determined;

2. It is difficult if not impossible to evaluate the impacts of a proposed regulation without considering the mechanism by which it will be implemented. The SWRCB is not expected to release the implementation plan until September 12, 1997. Therefore, VVWRA takes exception to the imposition of a regulation with an undefined implementation plan;

3. Because of the latter unknowns and the complexity of the regulation V has not had sufficient time to evaluate the potential economic impacts, if any, of the proposed regulation.

Response to: CTRE-004-001b

See response to CTR-009-001.

Subject Matter Code: G-09 Translators

Comment ID: CTR-004-004d
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES G-05
C-24a
C-22

Comment: Despite the problems addressed above there are provisions of the CTR that SBSA supports, including:

* EPA's policies and guidance regarding the use of mixing zones and dilution

* Use of water effects ratios (WERs) for determining site specific criteria

* Inclusion of metals criteria expressed as dissolved rather than total recoverable

* Allowing permit writers the use of any of the methods in EPA's guidance document on the use of translators

Response to: CTR-004-004d

EPA appreciates the commenter's support for its discussion of metals translators in the preamble of the proposed CTR.

Comment ID: CTR-005-003d
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: G-09 Translators
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-05
G-04

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-005-003d

See response to CTR-004-004d.

Comment ID: CTR-027-012d
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-22
C-24
C-01a
G-05

Comment: PROVISIONS OF THE PROPOSED RULE WE SUPPORT

Not withstanding the above comments, we believe there are certain elements of the proposed rule with respect to establishing water quality standards that we can support:

* Metal criteria expressed in the dissolved fraction rather than expressed in the total recoverable fraction.

* Metal criteria that are developed as a function of the water-effect-ratio (WER).

* The current proposed human health criterion for mercury.

* The current preamble language regarding metal translators and mixing zones.

We believe the above provisions provide a more acceptable, scientific approach to the water quality-based pollution control approach. We recommend these provisions of the current rule remain as proposed.

Response to: CTR-027-012d

See response to CTR-004-004d.

Comment ID: CTR-030-008
Comment Author: Utility Water Act Group

Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:
Attachments? Y
CROSS REFERENCES

Comment: D. EPA's Discussion of the Chemical Translator Guidance Should be Clarified

EPA appropriately includes its recently completed Chemical Translator Guidance (The Metals Translator: Guidance for Calculating a Total Recoverable Permit Limit From a Dissolved Criterion (EPA 823-B-96-007, June 1996) (Translator Guidance) in the rulemaking record and notes the importance of having mechanisms to "translate" between dissolved metal in ambient waters and total recoverable metal in effluent. 62 Fed. Reg. at 42,173, col. 2. But EPA's discussion of only certain provisions of the Translator Guidance creates an implication that only those portions of the Translator Guidance are applicable to this rulemaking. For example, the proposal requires use of conversion factors for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved criterion in the water column. The Translator Guidance provides greater flexibility; it states: "[A] translator is required to derive a total recoverable permit limit from a dissolved criterion" but caveats this statement with the following footnote:

As a reasonable worst case, however, it may be assumed that metal in the receiving environment would be biologically available to the same extent as during toxicity testing; and the conversion factors may be used as translators if a site-specific translator is not developed. In that case, the water quality criterion that already has been multiplied by the conversion factor would be divided by the conversion factor.

Translator Guidance, p. 5, n. 6.

Therefore, to avoid any implication that only part of the Translator Guidance is applicable to this rulemaking, UWAG requests that EPA make general reference to the translator Guidance and approve, without reservation, its entire contents.

Response to: CTR-030-008

EPA clarifies that the State in implementing its policy on translators may consider the entire contents of the guidance. EPA did not intend to imply that only a portion of the guidance could be used by the State to implement CTR criteria.

Comment ID: CTR-032-002c
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References: Letter CTR-032 incorporates by reference letter CTR-035

Attachments? N
CROSS REFERENCES G-01
C-22
C-24a
C-24
K
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002c

See response to CTR-004-004d.

Comment ID: CTR-035-002f
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
C-08a
G-05
G-04
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being

performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002f

See response to CTR-004-004d.

Comment ID: CTR-035-018
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42173 -- Translators for Dissolved to Total Recoverable Metals Limits We support EPA's guidance to RWQCBs that they may use any of the methods described in EPA's guidance document on the use of translators (U.S. EPA, 1996b). We believe that the development of site-specific translators should be allowed in those cases where a discharger is willing to conduct the studies in accordance with EPA-approved methods. As such, we believe the recommendation that the State "adopt a statewide policy on the use of translators so that the most appropriate method or methods are used consistently within California" is unnecessary, and this recommendation should be deleted from the Preamble.

Response to: CTR-035-018

EPA believes its recommendation that the State "adopt a statewide policy on the use of translators so that the most appropriate method or methods are used within California" is useful. This recommendation does not preclude the State from allowing dischargers to conduct site-specific translator studies in accordance with EPA methods if the State so chooses within its discretion to write NPDES permits. In fact, in its proposed implementation policy, the State's expressed its acceptance of site-specific translator methods.

Comment ID: CTR-038-002f
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:

Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-04
G-05

Comment: 2. The following provisions of the rule are supported (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Response to: CTR-038-002f

See response to CTR-004-004d.

Comment ID: CTR-040-002c
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-24a
C-01a
G-05

Comment: PROVISIONS SUPPORTED

We support a number of provisions of the Rule, including: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury- and (4) the Preamble discussions regarding metals translators and mixing zones. These provisions provide a firmer scientific base for the water quality-based approach to pollution control and are a marked improvement over the old Inland Surface Waters Plan. We would urge EPA to retain these provisions in the final Rule.

Response to: CTR-040-002c

See response to CTR-004-004d.

Comment ID: CTR-041-003a
Comment Author: Sacramento Reg Cnty Sanit Dist

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES C-24a

Comment: Second, the District supports with reservations EPA's proposals on two subjects directly related to dissolved metals criteria, i.e. the proposed guidance on both (1) translators to convert from dissolved metals criteria to total recoverable permit limits and (2) the water-effect ratio (WER) as the method to compare the bioavailability and toxicity of a pollutant in receiving waters and in laboratory waters. Both of these two proposals must be implemented on a site-specific basis using local data, not statewide or watershed-wide data. Translators, however, should be developed whenever a discharger is willing to conduct studies in accordance with EPA-approved methods. The proposed procedure for a default value of 1.0 for a WER should mean that when a site-specific WER is to be determined, an additional EPA rulemaking process would not be required. Instead, this rule should pre-authorize the use of correctly applied WERs that are approved by the State.

Response to: CTR-041-003a

EPA agrees that translators derived using site-specific methods are generally preferable to a generic method using statewide or regional data. However, the State is the lead authority with respect to NPDES permit implementation and may choose any method that is consistent with the Clean Water Act. In its proposed implementation policy, the State expressed its acceptance of site-specific translator methods.

Comment ID: CTR-043-002f
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
G-01a
G-04
G-05

Comment: 2. The following provisions of the rule are supported: (1) adoption of metals criteria as dissolved concentrations; (2) expression of the metals criteria as a function of the water-effect ratio; (3) adoption of the proposed new human health criterion for mercury; and (4) the Preamble discussions regarding metals, translators, mixing zones and interim permit limits.

Response to: CTR-043-002f

See response to CTR-004-004d.

Comment ID: CTR-044-003d
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References:
Attachments? Y
CROSS REFERENCES C-22
C-24a
C-01a
G-05
G-04

Comment: We have reviewed the proposed CTR and offer the following comments:

2. The following provisions of the rule are supported:

(1) adoption of metals criteria as dissolved concentrations;

(2) expression of the metals criteria as a function of the water-effect ratio;

(3) adoption of the proposed new human health criteria for mercury; and

(4) the Preamble discussions regarding metals translators, mixing zones, and interim permit limits.

Were the old human health criterion for mercury (0.012 ug/ l) to be adopted, the City would have to remove its discharge from Tule Canal and go to land disposal. The capital cost to do this would be $22.1 million and the total present worth cost would be $23.1 million (see Exhibit B, Required Capital improvements and Costs for Beryllium and Mercury). This would translate to an annual cost of $3.1 million per year (at 7% over 10 years) and would require that monthly sewer service charges be increased by more than 100%.

Response to: CTR-044-003d

See response to CTR-004-004d.

With respect to the comment about the economic impact of the old criterion for mercury of 0.012 ug/l, EPA has not evaluated these costs since the CTR does not promulgate a mercury criteria of 0.012 ug/l.

Comment ID: CTR-052-002c
Comment Author: East Bay Dischargers Authority

Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-22
C-01a
G-05
G-04

Comment: EPA will recall the State Water Quality Plans Task Forces that included all stakeholders, including EPA. The Authority appreciates the incorporation of many of the consensus recommendations from the Task Forces into the CTR, including:

* Adoption of the metals criteria as dissolved concentrations and the expression of the criteria as a function of the water-effect ratio

* Adoption of the proposed new human health criterion for mercury

* Preamble discussions regarding metals translators, mixing zones, and interim permit limits

Response to: CTR-052-002c

See response to CTR-004-004d.

Comment ID: CTR-054-004a
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-09 Translators
References:
Attachments? Y
CROSS REFERENCES G-05
G-04

Comment: BADA supports the Preamble discussions regarding metals translators, mixing zones, and interim permit limits. Translators and mixing zones will provide a better scientific basis for the application of the criteria and will go a long way toward protecting against the imposition of unnecessary or unreasonable controls. Interim permit limits will allow dischargers faced with potential attainability problems to pursue reasonable actions, such as pollution prevention, treatment plant optimization, pollutant trading, TMDLS, etc. prior to being faced with final effluent limitations. BADA endorses the recommendation of the State Plan Public Task Forces on the issue of interim limits.

Response to: CTR-054-004a

See response to CTR-004-004d.

Comment ID: CTR-056-008
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: G-09 Translators
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* EPA's guidance to Regional Water Quality Control Boards stating that they may use any of the methods described in EPA's guidance document on the use of translators ["The Metals Translator: Guidance for Calculating a Total Recoverable Permit Limit from a Dissolved Criterion," EPA 823-B-96-007, June 1996],

Response to: CTR-056-008

See response to CTR-004-004d.

Comment ID: CTR-060-009
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

EPA's chemical translator guidance should be clarified

EPA describes in the preamble (see 62 Fed. Reg. at 42,173, Col. 2) the importance of permitting authorities of having the ability to translate between dissolved metals in ambient waters and total recoverable metal in effluent and refers to its Chemical Translator Guidance document "The Metals

Translator. Guidance for Calculating a Total Recoverable Permit Limit From a Dissolved Criterion"(EPA 823-B-96-007, June 1996) (the "Translator Guidance"). However, the preamble describes only certain provisions of the translator guidance document, implying that other portions may not be applicable to California. EPA should clarify the translator guidance document is applicable in its entirety to California.

Additionally, the preamble should specifically identify, as the Translator Guidance indicates in footnote No. 6 on Page 5, that, in the absence of a site-specific translator, the conversion factor should be used as the translator.

Response to: CTR-060-009

See response to CTR-030-008.

Comment ID: CTR-066-006
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The guidance to RWQCBs that they may use any of the methods described in EPA's guidance document on the use of translators.

Response to: CTR-066-006

See response to CTR-004-004d.

Comment ID: CTR-081-002e
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
G-02

C-22
C-01a
C-08a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are performed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. I) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002e

See response to CTR-004-004d.

Comment ID: CTR-085-007
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's guidance to RWQCB's that they may use any of the methods described in the EPA's guidance document on the use of translators.

Response to: CTR-085-007

See response to CTR-004-004d.

Comment ID: CTR-086-004c
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent

Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
C-24a
C-24
K-03
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004c

See response to CTR-004-004d.

Comment ID: CTR-089-001g
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
C-08a
G-05
K-01
G-02

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the

CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001g

See response to CTR-004-004d.

Comment ID: CTR-092-003
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-09 Translators
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Translators to Convert from Dissolved Metals Criteria to Total Recoverable-Permit Limits

The City supports EPA's discussion of the metals translation process contained in "The Metals Translator, Guidance, for Calculation of a Total Recoverable Limit From a Dissolved Criterion" (EPA 823-B-96-007, June 1996). The City supports the use of EPA's translator methods by Regional Water Quality Control Boards to develop water quality-based permit limits. The Cityalso supports EPA's encouragement for the development of a statewide policy on the use of translators and for the consistency of their use statewide.

Response to: CTR-092-003

See response to CTR-004-004d.

Comment ID: CTRH-001-045b
Comment Author: Charles Batts
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES B

Comment: We would ask the EPA to extend the comment period to encourage further comments.

We would encourage you to look at actual agencies' calculations, that all translators be reviewed to ensure accuracy, even if special studies are required by individual dischargers.

Response to: CTRH-001-045b

EPA will review translator methods used by the State as a part of EPA's usual NPDES permit review process.

Comment ID: CTRH-001-049
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES

Comment: The notion of translators is a scary one to me in terms of what that means for any given permit process. You're talking about a very complicated permit process at that point, and I don't expect certainly the dischargers to pass up that opportunity. I would expect to see a very complicated permit process for every single one of the criteria that you have proposed here, unless you include a total recoverable number.

Response to: CTRH-001-049

EPA believes translators for metals is an appropriate tool for converting from dissolved metals criteria to total recoverable permit limits. Dissolved criteria are applicable only to a subset of priority toxic pollutants and would not be applicable to all criteria in the final rule. While the use of translators may make the permit process somewhat more complex, in some cases, EPA believes this extra effort will be worthwhile and will allow the State to develop the most appropriate effluent limits for metals discharges.

EPA's basis for using dissolved metals is described in the preamble to the proposed CTR at 62 Fed. Reg. 42171 (Aug. 5, 1997), the preamble to the final rule, and in the administrative record to the final rule (PLACEHOLDER FOR DOCUMENT TITLE).

Comment ID: CTRH-001-057e
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: G-09 Translators
References:
Attachments? N
CROSS REFERENCES K-03
C-24a
G-04
G-07

C-22
G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057e

See response to CTR-004-004d.

Subject Matter Code: G-10 Pretreatment

Comment ID: CTR-096-004a
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: G-10 Pretreatment
References:
Attachments? N
CROSS REFERENCES R

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

4. The environmental consequences of the necessary treatment facilities and changes in operating practices to meet these discharg5 standards is very significant and has not been addressed in promulgating the proposed rule.

Specifically, the City submits the following comments:

F. A comparison of the Water Quality Standards (WQS) used by its City during the Local Limits Study and the proposed WQS is shown in Table 1. There is a little variation in limits for cadmium, copper, nickel, and zinc as these values are dependent on receiving stream hardness. The values shown in Table I for the City were developed using a hardness of 170 mg/l as CaCO3 while the standards from the CTR are based on 100 mg/l as CaCO3. The WQS from the CTR are actually expressed as dissolved fractions. A factor of I has been used to convert from dissolved to total fractions for the comparison to take place.

Table 1

Comparison of Water Quality Standards

	City Report		WQS		1996		1997	
	Chronic	Acute	Chronic	Acute				
Arsenic, ppb	190.0	360.0	150.0	340.0	Cadmium, ppb	1.7	7.1	2.2
4.3	Chromium, ppb	10.0	15.0	11.0	16.0	Copper, ppb	19.0	29.0	9.0
13.0	Nickel, ppb	250.0	2200.0	52.0	470.0	Zinc, ppb	170.0	180.0	
120.0	120.0	Mercury, ppb	N/A	2.1	.77	1.4			

Table 1 indicates that the City's Local Limits for arsenic, cadmium, chromium, and zinc would have little difficulty meeting the CTR. However, limits for copper, nickel and mercury may be drastically impacted. This impact in developing a stricter local limit may result in an economic hardship to many small business enterprises that currently do metal plating. These businesses may be forced to close down due to the implementation of these limits. Modesto experiences a chronic unemployment rate above 12%, and economic development is critical to this community.

Response to: CTR-096-004a

The commenter has not provided enough information to enable EPA to respond to the assertion that metal plating businesses in Modesto may endure economic hardship and be forced to close down due to implementation of the CTR.

The commenter's derivation of 1997 WQS in Table 1 appears to be based on the CTR criteria. This is a "worst case scenario" since it does not address possible adjustments (all allowable for implementation of the CTR) for dilution, hardness, and translation from dissolved criteria to total recoverable effluent limits, all of which could result in an effluent limit for the POTW that may be less stringent than the levels indicated in Table 1. In addition, the commenter did not provide information on how local limits for indirect dischargers (such as metal plating businesses) would be calculated nor any data on historical discharge levels of pollutants from metal plating businesses. Therefore, EPA cannot come to any conclusion whether the implementation of CTR water quality criteria could have an adverse economic impact on Modesto's metal plating businesses or force the businesses to close.

EPA notes that the comment regarding the stringency of proposed aquatic life mercury criteria is no longer relevant since EPA is not promulgating a final aquatic life mercury criteria in the final CTR.

Subject Matter Code: G-11 Intake Credits

Comment ID: CTR-084-001
Comment Author: City of Redding
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: G-11 Intake Credits
References:
Attachments? N
CROSS REFERENCES

Comment: ISSUES OF CONCERN

F. 3. Implementation, 62 FR 42185. Total Maximum Daily Load (TMDL's) should not be required if water quality criteria for a water body segment are exceeded due to discharges from upstream dischargers who operate with federal waivers or variances to water quality standards.

F. 3. Implementation, 62 FR 42184. The proposed California Toxics Rule (CTR) does not specifically afford municipal credits for pollutants in the intake water supply. The City of Redding is concerned about how the proposed CTR will be implemented with regard to upstream acid mine dischargers who are operating with federal waivers to water quality standards. If credits for pollutants in the intake water supply were intended, they should be specifically included in the current proposal under F. 3. Implementation, to allow public comment at this time.

BACKGROUND

Previous Task Force and Sacramento River Watershed Program discussions and recommendations to the EPA have focused on acid mine discharges (AMDs) to the Sacramento River, as sources that are largely unregulated and contribute great amounts of metals to the river. The City of Redding has annually commented in our pretreatment program reports, on the deleterious affect of upstream heavy metal discharges from Iron Mountain Mine (IMM) into the Sacramento River and the downstream City water supply.

Prior to classification as a superfund site, IMM had previously been under a NPDES permit issued by the Central Valley Regional Water Quality Control Board. A review of a fact sheet by EPA on Iron Mountain Mine Superfund Site (May 1996) indicates the IMM site: under Superfund law, requires EPA cleanup actions to comply with all federal and state environmental requirements or of applicable or relevant and appropriate requirements" (ARARs), but allows a waiver of those requirements for interim actions such as collection and treatment of IMM Slickrock Creek flows. Although the interim actions will provide an environmental improvement, they are not expected to achieve full compliance with all of these environmental requirements. The fact sheet references that the ARARs waiver for "Interim Measures" is provided for under 40 CFR 300.430 (f)(1)(ii)(C)(1) and invited comment on whether it would be appropriate to rely on a waiver of these standards on the basis of "technical impracticability" under 40CFR 300.430 (f)(1)(ii)(C)(3).

Presently and for an indefinite period of time, IMM will remain without water quality criteria (WQC) compliance requirements. Additionally, it appears that there will be no enforcement actions against IMM

for failure to comply with WQC requirements. Apparently, this will not be the case for municipalities downstream of this and other AMDs on the Sacramento River according to the proposed CTR.

Monitoring of heavy metal concentrations in the Sacramento River by the City of Redding, indicate IMM interim actions implemented to date have produced an environmental improvement; however, the Sacramento River still violates water quality criteria proposed in the CTR. The very fact that the river will continue to experience violations of the proposed water quality criteria makes continuous POTW NPDES compliance impossible during AMDs upstream excursions of these same criteria. It would be unfair and cost prohibitive to require downstream POTW's to comply with increased water quality standards, where the water body quality has been significantly degraded because of the actions or inactions of the federal and state regulators on upstream discharges.

The City of Redding discharges back into the same water source (Sacramento River) from which it receives its primary municipal intake water. Wastewater discharge compliance with the proposed WQC would be very problematic, as ambient Sacramento River concentrations of heavy metals can fluctuate widely and be higher than the proposed WQC during any given river monitoring event. In contrast to theoretical models which assume the worst case scenario occur during low river flows, the upper Sacramento River commonly experiences the highest metal concentrations during high winter flows.

Even though the City of Redding does not have NPDES permit limits for metals at the current time, we must assume it will some day. Therefore, the above issue is significant and in need of comment at this time.

SUMMARY

Federal Regulations contained within the proposed CTR prohibit the discharge of toxic constituents in toxic concentrations. Iron Mountain Mine, as a superfund site discharger to the Sacramento River, will not fall under the proposed CTR due to the federal waiver granted to them in 1996. The proposed CTR should address the issue of effluent limit adjustments based upon intake water concentrations from upstream AMDs and provide a means of implementing a fair and affordable approach to adjust or provide relief to municipalities whose sources of water are already at or above the proposed water quality criteria. The City of Redding believes it is urgent that U.S. E.P.A. include in the preparation of the final California Toxics Rule, effluent limit adjustments based upon intake water ambient concentrations due to AMDs or other upstream toxics for all applicable water bodies found within the State of California.

Therefore, we request that language be added to the proposed rule as follows, "Any discharger downstream of a water body which has been granted a federal or state variance or waiver, and whose primary source of water supply is impaired by such shall be allowed credit in their NPDES discharges by either 1) an extension of that variance or waiver to affected downstream dischargers and/or 2) allowing intake credits to affected downstream dischargers."

If you have any questions, please contact Wastewater Superintendent Stephen Craig at (916) 224-6063 or Industrial waste Supervisor Richard Elliott at (916) 224-6050.

Response to: CTR-084-001

The State has discretion to use implementation tools such as appropriate intake credits to apply to dischargers that have poor intake or receiving water which is beyond their control. Implementation of water quality standards through various regulatory and non-regulatory tools is primarily a State responsibility and is beyond the scope of the CTR. Since the proposed CTR was issued, the State

released a draft Policy for Implementation of Toxic Water Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, September 11, 1997. The draft policy included a provision for intake water credits (See pp. V-60-V-70). EPA has provided a copy of your comments to the State Water Resources Control Board for consideration.

Subject Matter Code: H Paperwork Reduction Act

Comment ID: CTR-019-004b
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/25/97
Subject Matter Code: H Paperwork Reduction Act
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES I

Comment: THE PROPOSED RULE DOES NOT COMPLY WITH THE PAPERWORK REDUCTION ACT

The preamble states at page 42192 that the CTR "requires no new or additional information collection." It is difficult to believe that a rule which, unless modified, may effectively require end-of-pipe treatment of storm water discharges would not require any "additional information collection." For example, simply a demonstration that WQBEL's are infeasible requirements for either municipal storm water permits would necessarily require an significant amount of additional data collection and reporting. USEPA should have conducted a full analysis of the potential information gathering requirements of the CTR before proposing this rule.

The preamble to the proposed rule sets forth in detail the various efforts that USEPA employed to obtain public input on the CTR. However, to our knowledge, none of the cities on whose behalf we are submitting these comments, nor any of the other cities which we represent were contacted by EPA in advance of the proposed rulemaking or given a reasonable opportunity to participate.

In closing, we join in the requests made by other local governmental entities that the proposed rule be modified to exclude any application to storm water discharges to municipal separate storm sewer systems.

RICHARDS, WATSON & GERSHON 333 So. Hope Street, 38th Floor Los Angeles, California 90071

John J. Harris

Response to: CTR-019-004b

EPA disagrees with the commenter that the proposed CTR does not comply with the Paperwork Reduction Act, and that the CTR will impose new, additional requirements on storm water dischargers. The preamble states that the action requires no new or additional information collection subject to the Paperwork Reduction Act. The CTR promulgates water quality criteria for priority toxic pollutants. The State is required to implement water quality criteria through its water quality control programs, specifically through the NPDES permit program. The State implements water quality-based effluent limitations or WQBELs in NPDES permits for any pollutant for which reasonable potential exists. Thus, the CTR does not directly place any requirements on any discharger.

Reporting and monitoring requirements already exist for all NPDES dischargers, including storm water dischargers, under the NPDES regulations. The CTR does not impose any additional reporting or monitoring requirements. As noted above, the CTR promulgates criteria for toxic pollutants, and the State will use the criteria in developing water quality-based effluent limitations in NPDES permits for the pollutants where reasonable potential exists. The rule does not impose any additional reporting or monitoring burden on any discharger.

The CTR poses no direct information collection burden on the State of California. The CTR places an indirect burden for reviewing and revising the toxic pollutants that were promulgated. (See the National Toxics Rule discussion of the Paperwork Reduction Act at 57 FR 60848, Tuesday, December 22, 1992.) The general Water Quality Standards regulations Information Collection Request (ICR) estimated an average indirect burden on respondents (States) for reviewing and revising water quality criteria, and toxics criteria are merely a subset of those criteria. Thus, the CTR poses no direct burden, and any indirect burden on the State for a required triennial review has been estimated and updated in the general Water Quality Standards.

EPA acknowledges the comment concerning EPA's outreach to the public for input. In 1995, EPA sent out a newsletter to all interested parties, including all NPDES permit holders in the State of California, soliciting comments and attendance at public meetings. EPA held two public meetings on August 24, 1995 in San Francisco, where again comments were solicited from the discharger community, including storm water dischargers. In addition, EPA attended each of the State's Task Force Meetings for the development of the new statewide implementation plan; the storm water discharger community was invited to attend all of these meetings. EPA was available to the public for questions and answers on both the CTR and the State's proposed implementation. Reasonable opportunity existed for the storm water community to submit input on the CTR.

Subject Matter Code: I Stormwater/Wet Weather Flows

Comment ID: CTR-019-004a
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES H

Comment: THE PROPOSED RULE DOES NOT COMPLY WITH THE PAPERWORK REDUCTION ACT

The preamble states at page 42192 that the CTR "requires no new or additional information collection." It is difficult to believe that a rule which, unless modified, may effectively require end-of-pipe treatment of storm water discharges would not require any "additional information collection." For example, simply a demonstration that WQBEL's are infeasible requirements for either municipal storm water permits would necessarily require an significant amount of additional data collection and reporting. USEPA should have conducted a full analysis of the potential information gathering requirements of the CTR before proposing this rule.

The preamble to the proposed rule sets forth in detail the various efforts that USEPA employed to obtain public input on the CTR. However, to our knowledge, none of the cities on whose behalf we are submitting these comments, nor any of the other cities which we represent were contacted by EPA in advance of the proposed rulemaking or given a reasonable opportunity to participate.

In closing, we join in the requests made by other local governmental entities that the proposed rule be modified to exclude any application to storm water discharges to municipal separate storm sewer systems.

RICHARDS, WATSON & GERSHON 333 So. Hope Street, 38th Floor Los Angeles, California 90071

John J. Harris

Response to: CTR-019-004a

EPA's EA, which uses many conservative costing assumptions, indicates that the cost of the State implementing water quality standards based on the proposed criteria in the CTR is likely to be below $100 million per year. Benefits are also estimated to be below $100 million per year. These estimates indicate that the action is not "significant" under E.O. 12866, under the provision concerning annual effects on the economy.

Criteria, by themselves, do not directly impose economic impacts. Criteria are one of three parts of a water quality standard. A water quality standard is comprised of: a criterion, a designated use, and an

antidegradation requirement. The CTR promulgates criteria for priority toxic pollutants. When these criteria are combined with State adopted designated uses and antidegradation requirements, water quality standards will be created. When the State implements these water quality standards, costs may be imposed. However, in the spirit of the intent of E.O. 12866, EPA prepared the EA which looks at the costs and benefits of the State's implementation of the resulting water quality standards based on the CTR criteria into the NPDES permit program.

The Unfunded Mandates Reform Act of 1995 (UMRA) in general requires federal agencies to assess the effects of their regulatory actions on State and local governments, and on the private sector. The agency must prepare a written statement including a cost-benefit analysis for actions with a "federal mandate" that may result in expenditures to State and local governments, in the aggregate, or to the private sector of $100 million or more in any one year. The CTR does not contain any federal mandate that may result in expenditures by State and local governments, or the private sector, of $100 million or more in any one year. The CTR imposes no direct enforceable duties on the State, local or private sector; rather the rule promulgates water quality criteria which, when combined with State-adopted designated uses and antidegradation requirements, will create water quality standards. The CTR does not directly regulate or affect any entity and therefore is not subject to the requirements of UMRA.

The Regulatory Flexibility Act in general requires federal agencies to describe the impact of their regulatory actions on small entities as part of the rulemaking. If the Administrator certifies that the action will not have a significant economic impact on a substantial number small entities, the agency is not required to prepare the analysis. The Administrator certified in the proposed rule, and is certifying again today that the rule will not have a significant economic impact on a substantial number of small entities. EPA's promulgation of water quality criteria will assist the State in establishing water quality standards. The State will, in turn, implement the resulting water quality standards in its water quality regulatory programs such as the NPDES permit program. The State has discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet those standards. While the State's implementation of water quality standards based on federally-promulgated criteria may result in new or revised discharge limits being placed on small entities, the criteria or standards themselves to not apply to any discharger, including small entities. Thus, EPA's action today does not impose any of these as yet unknown requirements on small entities.

As described in EA that accompanied the proposed CTR (SAIC and Jones and Stokes Associates, 1997), EPA assumed that regulatory alternatives such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc., are considered under certain circumstances. Specifically, under the low-end scenario, regulatory alternatives were assumed necessary if the cost for a sample facility exceeded $200 per toxic pounds-equivalent.

EPA assumes that a facility, when faced with the challenge of meeting water quality-based effluent limitations (WQBELs) based on CTR criteria, will select the most cost-effective controls, including regulatory alternatives. In fact, this has been the case in California, where several major POTWs have performed studies in pursuit of regulatory alternatives such as metals translators and site-specific criteria, rather than install costly controls to comply with WQBELs. EPA acknowledges that the actual cost-effectiveness value will vary by facility depending upon many factors, including the characteristics and volume of discharge, the receiving water, etc. However, EPA disagrees that the cost trigger is unrealistic, as it was reasonably based upon the highest reported cost-effectiveness values for industry categories subject to effluent limitations guidelines and standards.

Nonetheless, in the high-end estimate developed for the cost analysis accompanying the final CTR, no cost trigger was used and, thus, EPA's high-end cost estimate did not include the use of a regulatory

alternative for any sample facility.

Reference: SAIC and Jones and Stokes Associates, Inc. 1997. Analysis of Potential Costs Related to the Implementation of the California Toxics Rule. Prepared for U.S. EPA, Office of Science and Technology and U.S. EPA Region IX, May 5.

Comment ID: CTR-030-004c
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References:
Attachments? Y
CROSS REFERENCES G-02
G-04

Comment: D. EPA's Endorsement of Five-Year Compliance Schedules and Interim Permit Limits for Modifications is Appropriate

UWAG strongly supports EPA's recognition that modifications necessary to comply with new or more stringent effluent limitations may necessitate the use of five-year compliance schedules. 62 Fed. Reg. at 42,187, col. 3. UWAG believes, however, that in certain circumstances a longer compliance schedule may be appropriate. Steam electric facilities that need retrofits to meet water quality-based effluent limits (WQBELS) often require extensive engineering design and testing prior to the actual retrofit. Additionally, nuclear facilities must ensure that any design changes are compatible with Nuclear Regulatory Commission regulations. Therefore, the availability of five-year compliance schedules is certainly well-justified. Further, EPA should consider whether longer compliance schedules should be available, at least in some limited circumstances.

Additionally, UWAG strongly supports EPA's approval of interim permit limits for use in permit modifications. This flexibility will allow dischargers to stay in compliance while necessary process or design changes are carried out.

Response to: CTR-030-004c

EPA dropped its proposed five year compliance schedule from the final CTR. Based on public comments, EPA has determined that, in California, establishment of a compliance schedule is an implementation issue. Thus, the State should have discretion to establish a compliance schedule subject to EPA approval.

Comment ID: CTR-031-004c
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES C-17a
C-17b

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

ii. Scientific Defensibility of Standards

Municipal storm water discharges require a uniquely different scientific as well as regulatory approach. The episodic nature of storm flow events; the huge variances in flow volume, rate, timing, concentrations, and loads; the variability in receiving waters; and organism tolerance for and recovery f rom episodic exposure need to be taken into account in developing standards.

In a July 1992 memorandum addressing a Combined Sewer Overflow/Wet Weather workshop, Tudor Davies, Director of EPA's Office of Science and Technology wrote: "Changes being considered in the aquatic criteria development methodology to enhance the scientific defensibility of the criteria would be applicable to both constant and to wet weather discharges. One such change undergoing consideration is a change in the duration and frequency of exposure assumptions to make criterion more toxicologically realistic.

EPA has begun this work and is apparently nearing completion. With EPA's own Science and Technology office recognizing the inadequacy of the current approach to setting criteria relative to wet weather discharges, it must be concluded any attempt to apply the CTR criteria to municipal stormwater system discharges is ill-founded and likely inconsistent with the CWA.

Response to: CTR-031-004c

EPA believes the CTR is consistent with current State and federal regulatory approaches. Regarding the comment that the CTR is not coordinated with the State Implementation Procedures, the CTR and the State Implementation Plan have been coordinated by EPA and the State in order to be made effective in a similar timeframe. In addition, EPA will review the State Implementation Policy for consistency with the Clean Water Act.

The comment regarding NEPA and ESA review assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in Comment ID CTR-001-002, EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

EPA's interim policy regarding application of the CTR to storm water dischargers is described in response to Comment ID CTR-001-002. The issue raised here is more one of how criteria are implemented for storm water dischargers and not the criteria themselves, which are developed to be protective of aquatic life and human health. In addition, the criteria are biologically based and, as such, if applied with the appropriate duration and frequency for storm water events, reflect a biologically-based approach.

Comment ID: CTR-031-005b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES G-02

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

iii. State Flexibility and Authority

The CTR states, "The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are other Federally-adopted and State adopted numeric toxics criteria when applied to the same use classifications..." p. 42206

[INDENT]This language supports State Water Resources Control Board decisions and the San Francisco Basin Plan which have made it clear that municipal storm water dischargers need to address water quality standards only through the implementation, and escalation as necessary, of best management practices. As noted previously, the language of this section must be better supported in the preamble.

Notwithstanding the above statement on page 42206, the CTR actually diminishes state flexibility in implementing the rule and is inconsistent with state compliance schedules. The CTR mandates implementation limits on the state and implies a 5-year limit on compliance.

A five-year compliance schedule for municipal storm water dischargers is entirely inconsistent with the State's, EPA'S, and Phase II stakeholder's understanding of the unique challenges of storm water permitting. The draft Phase II regulation submitted to OMB includes a comprehensive reevaluation of

storm water programs after two permit terms, and recommends no added best management practices or changes in the Phase II program until such evaluation and research are completed.

Response to: CTR-031-005b

See response to CTR-040-004.

EPA believes the CTR is consistent with current State and federal regulatory approaches. Regarding the comment that the CTR is not coordinated with the State Implementation Procedures, the CTR and the State Implementation Plan have been coordinated by EPA and the State in order to be made effective in a similar timeframe. In addition, EPA will review the State Implementation Policy for consistency with the Clean Water Act.

The comment regarding NEPA and ESA review assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in Comment ID CTR-001-002, EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

Comment ID: CTR-036-008
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: We are concerned that the proposed rule precedes actions to evaluate wet weather flows by EPA Headquarters and the establishment of an appropriate scientific approach for stormwater compliance.

Response to: CTR-036-008

EPA's interim policy regarding application of the CTR to storm water dischargers is described in response to Comment ID CTR-001-002. The issue raised here is more one of how criteria are implemented for storm water dischargers and not the criteria themselves, which are developed to be protective of aquatic life and human health. In addition, the criteria are biologically based and, as such, if applied with the appropriate duration and frequency for storm water events, reflect a biologically-based approach.

Comment ID: CTR-036-010b
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES G-02

Comment: We are concerned that the five-year compliance period for stormwater discharges to meet the criteria is untenable. The linkage between the application of best management practices and water quality benefits is long term and will thus be hard to demonstrate. Even in a direct product substitution situation, such as the removal of leaded gasoline from fuels, data from Orange County shows a very slow and long-term reduction in lead concentrations in our water bodies over multiple years.

Response to: CTR-036-010b

EPA dropped its proposed five year compliance schedule from the final CTR. Based on public comments, EPA has determined that, in California, establishment of a compliance schedule is an implementation issue. Thus, the State should have discretion to establish a compliance schedule subject to EPA approval.

Comment ID: CTR-042-004
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References:
Attachments? Y
CROSS REFERENCES

Comment: 4. The CTR criteria are not appropriate for application to storm water discharges.

In addition to the fact that the CTR criteria are not applicable to municipal storm water discharges, the water quality criteria proposed in the CTR are also based on the continuous or steady flows associated with wastewater discharges. As such, these criteria may not be applicable to the intermittent flows associated with storm water discharges. It is Caltrans understanding that EPA Headquarters is currently reviewing the applicability of water quality criteria to wet weather discharges. Currently, there exists no published scientific study assessing the impacts of storm water discharges on the designated beneficial uses of receiving waters. Given the variability of storm water flows, discharge points, pollutant quantities, and quality, EPA might consider a different approach to adopting criteria that takes into consideration this variability.

Requests:

Caltrans requests that the CTR criteria not be applied to municipal storm water discharges.

Response to: CTR-042-004

See response to CTR-040-004.

Every two years, the California State Water Resources Control Board (SWRCB) submits a report on the State's water quality to the U.S. EPA pursuant to Section 305(b) of the Federal Clean Water Act. These reports present water quality assessment information compiled by California's nine Regional Water Quality Control Boards. SWRCB (1996) indicates that urban runoff and storm sewers are major and moderate sources of impairment of beneficial uses in estuaries, lakes and reservoirs, rivers and streams, and wetlands. The extent of this impairment is shown in the table below.

Sizes of Waters Impaired by Urban Runoff and Storm Sewers by Contribution to Impairment

Waterbody Type (Units)	Major^1	Moderate and Minor^2
Estuaries(Acres)	899	52,552
Lakes and Reservoirs (Acres)	120,320	7,985
Rivers and Streams (Miles)	92	1,620
Wetlands, Freshwater (Acres)	1	58,316
Wetlands, Tidal (Acres)	0	184

Source: SWRCB (1996).
1. A major contributor is a source that is either the only one responsible for nonsupport of any designated use or it predominates over other sources.
2. A moderate contributor is a source that is the only one responsible for partial support of any use, predominates over other sources of partial support, or is one of multiple sources of nonsupport that have a significant impact on designated use attainment. A minor contributor is a source that is one of multiple sources responsible for nonsupport or partial support and is judged to contribute relatively little to this nonattainment.

State Water Resources Control Board (SWRCB). 1996. California 305(b) Report on Water Quality. Prepared as Required in Clean Water Act Section 305(b). August.

Comment ID: CTRH-002-006a
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: I Stormwater/Wet Weather Flows
References:
Attachments? N
CROSS REFERENCES J

Comment: Does the California Toxics Rule meet the legal requirements of the Clean Water Act and other federal policies and laws?

Previous municipal stormwater speakers have questioned, as we have, EPA's interpretation of Section 402(p) of the Clean Water Act. In addition, the California Toxics Rule raises significant questions regarding its conformance with other federal policies and laws including Executive Order 12866, the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, and the authority for EPA to adopt blanket criteria without considering the designated uses of such waters as required under the Clean Water Act.

To give you just one example, I'd like to briefly compare the California Toxics Rule with the compliance of Executive Order 12866:

Under Executive Order 12866, any "significant" federal regulatory action must be referred to the Office of Management and Budget for review before it can be approved. In this context, a "significant" action includes one which will "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy." Though admitting that there "may be a cost to some dischargers" to comply with the water quality standards that will be derived from these toxics criteria, the EPA nonetheless argues that the proposed rule is not a significant action because it "establishes ambient water quality criteria which, by themselves, do not directly impose economic impacts."

First, nothing in Executive Order 12866 indicates that only actions with direct economic impacts are to be considered by OMB. Second, for the EPA to ignore the link between the toxics criteria in the proposed rule and the obligations being imposed is very questionable. Is EPA conceding that State and regional water boards may simply ignore these criteria when promulgating water quality standards and issuing permits? Nothing in the preamble indicates that EPA views these criteria as merely advisory.

Despite stating that Executive order 12866 is not applicable, EPA goes on to include an economic analysis which purports to demonstrate that the proposed rule will result in a net economic benefit. The problem with this analysis is that it completely ignores the enormous cost that municipalities will bear if they are forced to bring their stormwater discharges into compliance with these toxics criteria. For example, a 1990 study conducted for the Sacramento Stormwater Program estimated that it would cost nearly $2 billion to implement a treatment program to achieve the water quality criteria proposed in the former Inland Surface Water Plan. Costs to comply with the proposed toxics criteria would be similar, if not higher, than those proposed in the Inland Surface Water Plan. Ultimately, the costs of compliance may reach into the ten of billions of dollars.

In short, EPA cannot have it both ways. It cannot state that stormwater discharges are subject to the proposed toxics rule and then turn a blind eye toward the costs associated with the implementation of this rule. The costs of the proposed rules are direct and significant, and therefore the rule must be submitted to OMB for review.

We have comparable concerns with the other federal laws that I cited previously, and we will elaborate on them in our written comments.

Response to: CTRH-002-006a

As with all NPDES storm water program rules, the CTR gives operators the flexibility to implement controls and measures as they deam appropriate to achieve the goals of the rule. MS4 operators can employ professional expertise, innovation or industry standards, and their previously-demonstrated legal authoriy (MS4 application, part 2 requirement) to achieve MEP (and to pay for it, if necessary), with the goal being cost-effective compliance with the CTR. WQS are considered in the CTR, as the rule allows the State to develop site-specific criteria when appropriate (see also the response to CTR-020-001 and

CTR-040-004).

Subject Matter Code: I-01 Application Sec 301 vs. MEP

Comment ID: CTR-001-003
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: SECTION 402(P) ONLY SUBJECTS MUNICIPAL SEPARATE STORM SEWER SYSTEMS TO MAXIMUM EXTENT PRACTICABLE ("MEP") LEVEL CONTROLS

The implementation approach adopted by the State and Regional Boards is compelled by Section 402(p) of the Clean Water Act, which directs that a distinction to be drawn between industrial and municipal dischargers, and subjects municipal systems only to those controls that reflect pollution reductions to the maximum extent practicable.

Section 402(p)(3)(A) of the Clean Water Act as amended in 1987 provides that:

Permits for discharges associated with industrial activity shall meet all applicable provisions of this section and section (301).

42 U.S.C. 1342(p)(3)(A) (Emphasis Added).

In contrast to Section 402(p)(3)(A), which makes industrial storm water sources subject to "section 301," Section 402(p)(3)(B) provides that MS4 discharges need only satisfy the dual requirements of: (1) effective prohibition of non-storm water discharges, and (2) controls to reduce the discharge of pollutants in storm water to the maximum extent practicable ("MEP"). 33 U.S.C. S 1342(p)(3)(B). That subsection contains no cross reference to Section 301 as is found in the industrial discharge provision.

Section 301(b)(1)(C) sets a "timetable for achievement of objectives" that directs "point sources" to achieve "any more stringent limitation, including those necessary to . . . implement any applicable water quality standard established pursuant to (the CWA (such as the CTR)]" by July 1, 1977. 42 U.S.C. S 1311(b)(1))(C). This section has been cited by EPA as a basis for imposing numeric effluent limitations exceeding MEP-level controls on municipal storm water systems.

Yet, until the addition of Section 402(p) in 1987, municipal storm water systems were not subject to a NPDES permitting requirement. To read Section 301(b)(1)(C) as applying to municipal storm water systems would necessitate the retroactive application of Section 402(p), since under that reading such systems would have been required to address water quality standards ten years before the provision was added to the Act.

An interpretation of the statute resulting in such retroactive application would be strongly disfavored in the absence of clear Congressional intent to establish such retroactivity. N.J. Singer, Sutherland on Statutory Construction, S 41.04 (Sands 5th ed. 1993) ("Sutherland") ("Retrospective operation is not

favored by the courts however, and a law will not be construed as retroactive unless the act clearly, by express language or necessary implication, indicates that the legislature intended a retroactive application.").

However, Section 402(p) avoids this problem by expressly describing the applicability of Section 301, distinguishing between industrial storm water sources (which were always subject to Sections 402 and 301 and are confirmed by the 1987 Amendments to remain subject to Section 301), and municipal storm water sources (which were not subject to Section 402 prior to the 1987 Amendments and are only subject to MEP-level controls). The applicability provisions of Section 402(p) are also accommodated directly in Section 301(b)(1)(C), which only requires the achievement of "applicable" water quality standards. (*3)

The express applicability provisions of Section 402(p) also eliminate any argument that Congress intended to make Section 402(p) retroactively applicable to municipal storm water systems, thereby requiring such systems to have achieved water quality standards ten years previously. Not only is evidence lacking of any Congressional intent to make the provision retroactive, any argument of such intent is definitively rebutted by the clear distinction in Section 402(p) between industrial and municipal storm water systems.

Under standard rules of statutory construction, the more specific provision (402(p)) prevails over the more general provision (301(b)), and the express reference to Section 301 for one category of dischargers (industrial) precludes implication of the same reference for another category of dischargers (municipal) that is specifically addressed and does not contain such a reference. (*4) In other words, while Section 402(p) arguably makes the water-quality-related provisions of Section 301 applicable to industrial discharges, the Clean Water Act establishes a distinct system for MS4s that relies on the prohibition of non-storm water discharges and escalating best management practices.

EPA in the preamble to its 1990 storm water regulations acknowledged the statutory distinction in stating that:

The Act clarified that permits for discharges associated with industrial activity must meet all of the applicable provisions of section 402 and section 301 including technology and water quality based standards. However, the new Act makes significant changes to the permit standards for discharges from municipal storm sewers . . . . The approach is tiered in that storm water discharges associated with industrial activity must comply with sections 301 and 402 of the CWA . . . but permits for discharges from municipal separate storm sewer systems must require controls to reduce the discharge of pollutants to the maximum extent practicable . . . .

55 Fed. Reg. 47992-94 (November 16, 1990).

It is therefore important that the CTR confirm the implementation provisions of the 1995 Basin Plan and corresponding State Board decisions, and conform to the distinction set forth in Section 402(p) of the Clean Water Act. There is no authority under the Act for subjecting municipal storm sewer systems to control obligations exceeding the MEP standard.

(*3) Section 301(a), by reference, also requires compliance with Section 302, which provides that where a discharge:

would interfere with the attainment or maintenance of that water quality in a specific portion of the

navigable waters which shall assure protection of public health, public water supplies, agricultural and industrial uses, and the protection and propagation of a balanced population of shellfish, fish and wildlife, and allow recreational activities in and on the water, effluent limitations (including alternative effluent control strategies) for such point source or sources shall be established which can reasonably be expected to contribute to the attainment or maintenance of such water quality.

33 U.S.C. S 1312(a). Such "alternative effluent control strategies" which "can reasonably be expected to contribute" to this goal are generally comparable in description to the MEP standard.

(*4) In any event, Section 302 expressly allows "alternative effluent control strategies" and only requires limitations "reasonably" anticipated to "contribute" to meeting objectives. Similarly, EPA's regulations for the issuance of NPDES permits simply require the "imposition of conditions [that] ensure compliance with the applicable water quality requirements of all affected States.,, 40 C.F.R. S 122.4(d). For the San Francisco Bay Area, those requirements are expressed in the 1995 Basin Plan, which explicitly states that numerical water quality objectives are infeasible and provides for the sort of escalating management practices required under the NPDES permit for the ACCWP. The approach is also contemplated by EPA's regulations which state that NPDES permits should include " - . . best management practices to control or abate the discharge of pollutants when: . . . (2) Numeric effluent limitations are infeasible . . . . I, 40 C.F.R. S 122.44(k).

Response to: CTR-001-003

This comment is outside the scope of this rule which concerns what criteria should apply to California waters. The rule is distinct from the issue of whether storm water dischargers must comply with water quality standards. The issue raised by the commenter has been addressed by EPA's storm water program in other contexts. EPA disagrees with the comments. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c.

Comment ID: CTR-001-005
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: INCONSISTENT AND AMBIGUOUS LANGUAGE IN THE PREAMBLE SUGGESTING A DIFFERENT RESULT MUST BE REMOVED

Reaffirmation of the provisions in Section 402(p) that make municipal storm water systems subject only to MEP-level controls is critically important since a number of statements in the preamble are either expressly, or ambiguously, overbroad. For example, the preamble states that:

Point source and nonpoint source allocations are established so that predicted receiving water concentrations do not exceed water quality standards.

Page 42185. As discussed above, there is no authority in the Clean Water Act for imposing wasteload allocations on municipal storm water systems that require more than MEP-level controls. Likewise, the following statement could be read to impermissibly substitute numeric effluent limitations for the MEP control standard:

National Pollutant Discharge Elimination System (NPDES) permits for wet weather point source discharges must include limits necessary to implement applicable water quality standards, through application of water quality-based effluent limitations of WQBELS.

Page 42186. Other statements in the preamble are somewhat less direct but nonetheless problematic.

When these proposed federal criteria take effect, they will create legally applicable water quality standards in the State of California for inland surface waters, enclosed bays and estuaries for all purposes and programs under the CWA.

Page 42160. Similarly, the following statement at page 42162 could be read in an overbroad manner as applied to MS4 discharges:

CWA section 301(b)(1)(C) . . . requires NPDES permits to contain limitations required to implement any applicable water quality standard established in the CWA.

So long as this "implementation" occurs through adoption of MEP-level BMPs, the result may be correct, but it is correct only because 402(p) subjects MS4s to the MEP standard, rather than due to the provisions of Section 301(b)(1)(C), which only apply to industrial and not municipal storm water systems under the applicability scheme established in Section 402(p).

Likewise, the apparently broad statement at page 42184 that:

If a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric or narrative water quality criteria, the permitting authority must develop permit limits as necessary to meet water quality standards.

must be qualified as applied to MS4s by the distinction set forth by Congress in Section 402(p). From the same statutory language of Section 402(p) comes the corollary that wasteload allocations reflecting reductions beyond MEP do not apply to municipal storm water discharges. (*6)

Any attempt to subject MS4s to controls exceeding the MEP standard would be unauthorized, and the statements in the preamble suggesting such a result must be removed. (*7)

(*6) The limited time allowed by the proposed rule for compliance schedules also does not adequately accommodate the MEP standard, since it may not be practicable (or even possible) to meet NELs or WLAs within the deadlines allowed under the proposal. The rule should allow compliance schedules for as long as necessary to meet the requirements using MEP-level controls.

We note in this regard that the proposed State Implementation Policy would provide that:

In no event shall a schedule of compliance for point source discharges, including stormwater discharges, exceed 10 years from the date of adoption of this Policy.

Draft SIP at 17. This provision would violate both Section 402(p) of the Clean Water Act and the cost-benefit balancing provisions of the Porter Cologne Act discussed below, to the extent that compliance within ten years could not be achieved through MEP-level controls.

(*7) We recognize that there is useful language in the discussion of "Wet Weather Flows" at page 42186-87, which states:

EPA recognizes that it is commonly infeasible to express (water quality based effluent limitations or] WQBELs as numeric limits for wet weather discharges and that in such cases best management practices ("BMPs") may serve as WQBELs . . . . It is therefore anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather discharges, NPDES permits, when the permitting authority determines that it is infeasible to express WQBELS as numeric limits.

We agree that MS4 permits should be established on the basis of BMPS. But EPA's discussion at page 42187 still fails to implement Section 402(p) to the extent that the agency would evaluate the feasibility of "expressing" numeric WQBELS rather than "satisfying" or "meeting" WQBELS. Section 402(p) only requires MS4s to adopt controls to the MEP level. It is the practicability of controls that is central to this system, not just the practicability of writing permits. The discussion at page 42187 should therefore be modified to acknowledge directly that MS4s are only required under Section 402(p) to adopt MEP level controls, regardless of whether it would be "feasible" from an administrative standpoint to write permits containing NELs or WLAS.

Response to: CTR-001-005

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c.

Comment ID: CTR-001-011
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: CONCLUSION

The most fundamental concern of the ACCWP is that any decision to subject MS4 dischargers to numeric effluent limitations and/or wasteload allocations that could trigger extensive collection and

end-of-pipe treatment facilities should take place directly and openly, rather than implicitly through ambiguously drafted regulation and preamble discussion. The ACCWP believes that it is currently in full compliance with its Clean Water Act obligations, through the adoption and implementation of a Storm Water Management Plan that has won numerous awards.

Only controls to the maximum extent practicable are required under Clean Water Act Section 402(p), and the State and Regional Boards are likewise precluded from adopting draconian control measures under analogous limitations of the state Porter Cologne Act.

These are not just nettlesome roadblocks to EPA action, but instead reflect a considered determination made by the legislative branch of both the state and federal governments that resources need only be devoted to this subject to the extent practicable. Given the magnitude of the public expenditures that would be involved statewide from numeric effluent limitations and/or reductions to meet wasteload allocations more stringent than achievable from MEP-level controls, and the fact that Congress has already addressed the matter in Section 402(p), a decision of this type and magnitude cannot be made administratively.

If EPA's intention is to conform its rule to Section 402(p), it should do so clearly and cleanly and remove the conflicting statements in the proposed rule's preamble that suggest a different result.

Response to: CTR-001-011

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-013-001
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. With regard to stormwater permits, the USEPA states in the preamble that:

NPDES permits for wet weather point source discharge must include limits necessary to implement applicable water quality based standards, through application of water quality-based effluent limitations or WQBELS. When this rulemaking is complete, these (numeric) criteria will be used to determine water quality standards in California and will, therefore, be the basis of WQBELs in NPDES permits for wet weather point sources. (Page 42186)

We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewer systems (MS4s) into Section 410(p) (3) (B) of the Clean Water Act. To date, we are unaware of any USEPA regulation which has taken the noted position.

The Preamble goes on to state: "It is ... anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather discharges' NPDES permits, when the permitting authorities determines that it is infeasible to express WQBELs as numeric limits." Although this statement is intended to soften the earlier position, the difficulty for municipalities is that even with an aggressive BMP-based program, a municipality will likely not be able to comply with the proposed water quality standards. This was found in the analysis conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District. If this is the case, the permitting agency would be required to develop a permit with WQBELs that essentially require end-of-pipe treatment of stormwater and the municipalities would face significant costs for complying with the limits.

We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-013-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-014-001
Comment Author: City of Lakewood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-014 incorporates by reference letters CTR-013 and CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality

standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410 (p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to Clarify that MS4s arc not required to comply with water quality standards.

Response to: CTR-014-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-019-001a
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES J

Comment: We recognize that the basic purpose for the proposed rule is to establish water quality criteria for priority toxic pollutants for point source discharges. However, in proposing to extend that criteria to storm water discharges, it is clear that EPA has not fully assessed the potential impact of such an extension on local governmental agencies, nor the complete lack of feasibility of attempting to apply numeric effluent standards to discharges to municipal separate storm sewer systems ("MS4s"), or the enormous cost of such an effort which would potentially require a complete reengineering and if not reconstruction of MS4s in California to include end-of-pipe treatment.

Our comments should be considered in the proper context. The cities which we represent are acutely aware of the problems associated with pollution from... urban runoff. Their residents and businesses share a common concern to preserve and enhance the water quality of our bays, rivers, estuaries and the Pacific Ocean. Our cities are fully committed to doing what they reasonably can to achieve these objectives. Our cities have been working with staff of the State Water Resources Control Board ("SWRCB") and its Regional Water Quality Control Boards ("RWQCB's") to develop effective storm water management programs under current municipal NPDES permits which comply with state and federal law. However, the proposed rule does not appear to reflect or recognize that individual cities' fiscal and administrative resources for implementing unfunded mandates are limited. Of all governmental agencies in California involved in the process, the many small cities which we represent are the least suited to bear the brunt of the responsibility for controlling pollution from urban runoff.

The primary portion of the proposed rule that has caused concern among our cities is the statement at

pages 42186-42187 of preamble that:

"When this rulemaking is complete, these criteria will be used to determine water-quality standards in California and will therefore be the basis of WQBELs in NPDES permits for wet weather point sources. However, EPA recognizes that it is commonly infeasible to express WQBELs as numeric limits for wet weather discharges and that in such cases best management practices ("BMPs") may serve as WQBELS. (Emphasis added.)

Our concern is further heightened by the comment at page 42187 of preamble that:

"It is therefore anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather dischargers' NPDES permits, when the permitting authority determines that it is infeasible to express WQBELS as numeric limits." (Emphasis added.)

The comments appear to indicate that in any further municipal NPDES permitting situations, the proposed rule potentially can be interpreted to require the implementation of WQBELs unless an analysis is prepared determining the infeasibility of each of the WQBELs as numeric limits.

As applied to storm water discharges, WQBELs are almost by definition infeasible. It should also be kept in mind that it is not the cities themselves that are the sources of stormwater pollution; municipal facilities have not been identified, to our knowledge, as being significant sources of contaminated urban runoff. Rather, the sources of this type of pollution, to the extent they can be identified, appear to be primarily the result of hydrological changes brought about by urbanization. These are activities over which cities have very little practical control. Nevertheless, the cities and counties of California are bearing the full and financially unassisted responsibility of ending stormwater pollution themselves.

We agree with the comments of the County of Los Angeles and the ACCWP that EPA's effort to apply numeric effluent limits to municipal storm water discharges is in direct conflict with the plain language of Congress in adopting the "maximum extent practicable" standard for controlling pollution in storm water discharges to a MS4. The proposed rule as applied to wet weather flows is also clearly inconsistent with both the EPA Is and the SWRCB's approach of addressing this problems through the adoption of Best Management Practices ("BMP's").

As noted in the SWRCB's own Municipal Storm Water Best Management and Practices Guidebook, "the sources of storm water pollution are extensive, ill-defined and highly variable." The State Board previously determined in its order entitled "In the Matter of Petition of Natural Resources Defense Council, Inc. for Review of Waste Discharge Requirements Order No. 90-079," Order No. WQ 91-04 (May 16, 1991), that:

"We find here also that the approach of the Regional Board requiring the dischargers to implement a program of best management practices which will reduce pollutants and runoff and prohibiting non-storm water discharges, is appropriate and proper. We base our conclusion on the difficulty of establishing numeric effluent limitations which have a rational basis, the lack of technology available to treat storm water discharges at the end of the pipe, the huge expense such treatment would entail, and the level of pollutant reduction which we anticipate from the Board's regulatory program. We feel compelled to note here our agreement with the Regional Board that this permit does truly represent a massive undertaking." (Emphasis added.)

As discussed in detail in the technical comments filed in response to the proposed rule, the EPA has not

explained how the proposed numeric effluent guidelines can be achieved through the implementation of BMP's. Under the circumstances, the ultimate result of the application of the rule to storm water discharges would be end of pipe treatment controls.

However, the EPA has already recognized, as the SWRCB, that end of pipe treatment controls for storm water discharges are technically unfeasible and unreasonable. The EPA has recognized that "it was not the intent of Congress to acquire municipal permits to required end of pipe treatment technology but to implement a comprehensive stormwater management program to reduce the discharge of pollutants from municipal storm sewer systems." 55 Fed.Reg., p. 48038 (November 16, 1990).

Each of our cities strongly believe that the proposed rule must be modified to clearly state that numeric effluent guidelines do not and will not apply to discharges to the municipal separate sewer systems.

Response to: CTR-019-001a

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-021-006e
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES J
E-01c
R
S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

3. Failure to Address Important Stormwater-Related Issues. In addition to its POTW, Sunnyvale is the owner of a system of storm drains which contribute wet weather flows to the South Bay. We are concerned that the EA entirely neglects the potential impacts of the proposed CTR on the storm drains. The EA entirely omits any meaningful analysis of the costs of bringing storm drains into compliance with the proposed CTR, thereby significantly understating the overall costs of the CTR. We believe that this omission is violative of the Agency's legal obligations under the authorities cited in the preceding paragraph.

In addition, we join in the comments being filed by the various other operators of stormwater collection systems to the effect that EPA has overstated the legal requirements for storm drains to comply with numerical criteria.

Response to: CTR-021-006e

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For further discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, see the preamble to the final rule.

Comment ID: CTR-024-001
Comment Author: City of Hawthorne
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-024 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-024-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-027-001
Comment Author: California SWQTF
Document Type: Storm Water Auth.

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: MAJOR ISSUES

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. In the preamble to the proposed rule, US EPA suggests that the numeric water quality standards in the CTR will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. With regard to stormwater permits, USEPA states in the preamble that:

NPDES permits for wet weather point source discharge must include limits necessary to implement applicable water quality based standards, through application of water quality-based effluent limitations or WQBELS. When this rulemaking is complete, these (numeric) criteria will be used to determine water quality standards in California and will therefore be the basis of WQBELs in NPDES permits for wet weather point sources. (Page 42186)

We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 420(p)(3)(B) of the Clean Water Act. To date we are unaware of any USEPA regulation, which has taken the position in the proposed rule. Furthermore, the basis for USEPA's position is primarily the "Elliot memo". This memo is an internal memorandum and has not been subject to public or judicial review. Further discussion regarding this issue is found in the responses to the CTR by the Alameda Countywide Clean Water Program, County of Orange and County of Sacramento, which are incorporated herein by reference.

The Preamble goes on to state: "It is ....anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather discharges' NPDES permits, when the permitting authority determines that it is infeasible to express WQBELs as numeric limits." Although this statement appears to soften the earlier position, the difficulty for municipalities is that even with an aggressive BMP based program, a municipality will likely not be able to comply with the proposed water quality standards. We point to the analysis conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District. If this is the case, the permitting agency could likely be required to develop a permit with WQBELs that essentially require end-of-pipe treatment of stormwater and the municipalities would face significant costs for complying with the limits (see following discussion regarding economic analysis).

Recommendation: USEPA should modify the Preamble statement to clarify that MS4s are only required to satisfy the MEP standard, and are not obligated to adopt controls beyond MEP-levels to achieve water quality standards.

Response to: CTR-027-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation

of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-030-010
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? Y
CROSS REFERENCES

Comment: F. EPA Should Provide a Consistent Standard for Application of BMPs to Wet Weather Flows

UWAG applauds EPA's recognition that "it is commonly infeasible to express WQBELs as numeric limits for wet weather discharges and that in such cases best management practices (BMPS) may serve as WQBELS." 62 Fed. Reg. at 42, 186-87. But EPA also obscures the standard for determining when use of BMPs is appropriate by stating:

It is ... anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather discharges' NPDES permits, when the permitting authority determines that it is infeasible to express WQBELs as numeric limits.

62 Fed. Reg. at 42,187, col. 1. This statement differs from the standard EPA proposed in a recently released question and answer document (61 Fed. Reg. 57,425 (Nov. 6, 1996)) on wet weather flows. According to the question and answer document, permitting authorities may use alternative permit conditions "where numeric water quality-based effluent limitations are determined to be unnecessary or infeasible." Id. at 57,426, col. I (emphasis added). Thus, EPA has narrowed the applicability of BMPs to wet weather flows for purposes of the California proposal. If EPA wants to promote consistent treatment of wet weather flows, it should modify the proposed preamble to the California water quality standards to reflect that the permitting authority may apply BMPs or other alternative permit conditions whenever a numeric WQBEL is unnecessary or infeasible.

Furthermore, EPA should explicitly state that the permitting authority bears the burden of showing that a numeric WQBEL for a wet weather flow is feasible or necessary. Since EPA admits that such limitations are "commonly infeasible," the permittee should not bear the burden of proving numeric limits unnecessary or infeasible.

Response to: CTR-030-010

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-031-001a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES I-02

Comment: 1. The preamble of the proposed CTR, and therefore the apparent intended application of the rule, is inconsistent with the Clean Water Act.

Several broad, ambiguous statements in the preamble of the proposed rule imply that Clean Water Act section 301 requirements apply to all dischargers, including municipal stormwater systems. These presumptions must be qualified to recognize the clear intent of Congress and plain language of the CWA, section 402(p) which clearly require municipal storm water dischargers only to adopt controls to reduce pollutants in storm water to- the maximum extent practicable and to eliminate non-storm water discharges. The section's intent is demonstrated through the application of section 301 requirements, and related application of numeric effluent limitations or wasteload allocations in NPDES permits, to industrial stormwater discharges only.

EPA is obviously aware of Congress's intent as to municipal storm water discharge requirements. EPA included in its published draft Phase I municipal storm water regulations a quote from the Congressional Record of October 16, 1986, citing that intent.

Without a clear citation of the provisions of CWA section 402(p), the preamble to the proposed rule appears to be an attempt to codify the Elliot memorandum of January 9, 1991, and to create via this rule a result not authorized by Congress.

In order to eliminate this fundamental legal flaw in the proposed CTR, and eliminate the potential for future misinterpretation and controversy, each of the following statements from the preamble (at a minimum) must be clarified and/or qualified so that they do not appear to override or retract CWA section 402(p).

"When these proposed federal criteria take effect, they will create legally applicable water quality standards ... in California ... for all purposes and programs under the CWA." [p. 42160. This statement must include recognition that for municipal storm water dischargers, the CWA objectives can be addressed through best management practices, implemented to the maximum extent practicable (MEP), as established by CWA section 402(p).]

"CWA section 301(b)(1)(C) ... requires NPDES permits to contain limitations required to implement any applicable water quality standard established in the CWA." [p. 42162. The text should note that section 301 (b) (1) (c) does not apply to municipal storm water dischargers, as established through section 402(p).]

"If a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric

or narrative water quality criteria, the permitting authority must develop permit limits as necessary to meet water quality standards." (P. 42184. Again, for municipal storm water dischargers, the preamble and CTR must make clear the MS4 permits must: address this CWA objective through the MEP requirement.]

"Point source and nonpoint source allocations are established so that predicted receiving water concentrations do not exceed water quality standards." [p. 42185.1; and

"[NPDES] permits for wet weather point source dischargers must include limits necessary to implement applicable water quality standards, through application of water quality-based effluent limitations or WQBELs." [p. 42186. These two statements are only correct as applied to industrial storm water dischargers; numeric effluent limitations or wasteload allocations can not be legally, reasonably, or practically applied to municipal storm water discharges.]

Response to: CTR-031-001a

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-035-036
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42186-42187 -- Wet Weather Flows Consistent with a recommendation by the Permitting and Compliance Issues Task Force, we recommend that EPA include language in the Preamble stating that, for permits such as stormwater permits that do not generally contain quantitative effluent limits but instead require the implementation of control measures and best management practices, compliance shall be determined based on the degree of implementation of the required control measures and the reduction of pollutants to the maximum extent practicable (SWRCB, 1995, Part VI).

Response to: CTR-035-036

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-036-001

Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: Applicability of Criteria to Municipal Stormwater Discharges

In the preamble to the proposed rule, EPA assumes without discussion that these criteria for priority toxic pollutants apply to municipal stormwater discharges. Specifically, the preamble states, "When this rulemaking is complete, these criteria will be used to determine water quality standards in California and will therefore be the basis of WQBELs [Water Quality-Based Effluent Limitations] in NPDES permits for wet weather point sources." [62 Fed. Reg. 431861.

We note for the record, however, that the applicability of WQBELs to municipal stormwater discharges is an issue which has not yet been resolved. Under Section 402(p)(3)(A) of the Clean Water Act ("CWA"), permits for industrial stormwater discharges must comply with the applicable provisions of the CWA concerning effluent limitations. [33 U.S.C. section 1342(p)(3)(A)]. In contrast, permits for municipal Stormwater discharges are only required to ensure reduction of the pollutant discharges "to the maximum extent possible." [33 U.S.C. section 1342(p)(3)(B)].

In the preamble, EPA acknowledges that it is "commonly infeasible" to express WQBELs as numeric limits for wet weather discharges and that in such cases best management practices (BMPs) "may serve as WQBELS." [62 Fed. Reg. 42186-871.] Implicit in that acknowledgment is the assumption that the application of WQBELs to municipal stormwater discharges remains appropriate and that numeric limits can be imposed on such discharges at some time in the future. We believe such an assumption is wrong and is directly contradicted by the plain language of Section 402(p). The distinction drawn between industrial stormwater discharges and municipal stormwater discharges under that Section are real and cannot be ignored by EPA in adopting the proposed rule.

Conclusions

The proposed California Toxics Rule in its current form has many flaws, with respect to its presumption of applicability to municipal stormwater discharges. The comments provided above indicate a need to substantially revise the rule and assure conformance with federal policies and laws. Consideration should also be given to allowing the State of California to resume control over rule promulgation. As a result, the County of Orange recommends that the rule not be adopted at this time and that discussions be initiated with municipal stormwater dischargers through the California Stormwater Task Force to resolve the many issues raised.

Response to: CTR-036-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges,

see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-040-003
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

1. Concern: The Rule, as presently proposed, appears to require discharges from municipal stormwater programs to meet water quality based effluent limits (WQBELs).

* Reference Section--Preamble, page 42186 of the Federal Register under "4. Wet Weather Flows." This language appears to replace the municipal stormwater BMP standard established in the Clean Water Act (CWA) section 402(p)(3)(B), that municipal stormwater programs "shall require controls to reduce the discharge of pollutants to the maximum extent practicable (MEP)..."

* Many of the urban streams in Sacramento County are effluent dominated during storm events. Thus, the flow in these urban streams is primarily stormwater. if WQBELs apply to municipal stormwater, then stormwater discharges to many county urban streams will have to meet the numeric water quality criteria proposed in the Rule.

* If the Rule intends that municipal stormwater discharges will be required to meet WQBELS, the Rule will force the Sacramento Stormwater Management Program to implement end-of-pipe treatment.

Response to: CTR-040-003

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-042-001
Comment Author: Cal. Dept. of Transportation
Document Type: State Government

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? Y
CROSS REFERENCES

Comment: The California Department of Transportation (Caltrans) submits the following comments on the proposed California Toxics Rule ("CTR") relative to its status as a NPDES storm water discharge permit holder. As this proposed rule could have serious financial impacts on storm water dischargers, Caltrans welcomes the opportunity to provide comments to EPA that could decrease the impact of this rule while still affording a similar level of environmental benefit. It is our hope that you will give serious consideration to the following comments:

1. The CTR improperly applies water quality-based effluent limits to municipal storm water discharges.

The Preamble to the CTR discusses application of the rule to wet weather discharges by stating:

NPDES permits for wet weather point source discharges must include limits necessary to implement applicable water quality standards, through the application of water quality-based effluent limitations or WQBELS. Section 301(b)(1)(C) of the CWA, 33 U.S.C. 1311(b)(1)(C); see also Memorandum of E. Donald Elliot, Assistant Administrator and General Counsel, to Nancy J. Marvel, Region 9, dated January 9, 1991. When this rulemaking is complete, these criteria will be used to determine water quality standards in California and will therefore be the basis for WQBELs in NPDES permits for wet weather point sources.

62 Fed. Reg. 42,186 (Aug. 5, 1997). The position taken by EPA in this excerpt, namely that WQBELs must be applied to all wet weather discharges, is inconsistent with the plain language of the Clean Water Act ("CWA"). The CWA at section 402(p)(3)(B)(iii) specifically states that permits for discharges from municipal storm sewers "shall require controls to reduce the discharge of pollutants to the maximum extent practicable." Unlike industrial storm water dischargers, which are required to "meet all applicable provisions of this section and section 1311 of this title" (See section 402(p)(3)(A)), municipal storm water dischargers, such as Caltrans, must only reduce the discharge of pollutants to the Maximum Extent Practicable ("MEP"). The Preamble language mistakenly applies the WQBEL requirements of section 301 to municipal storm water dischargers when it is clear that Congress never intended for municipal dischargers to meet this more stringent standard.

Request: Caltrans respectfully requests that the Preamble be modified to clarify that municipal storm water discharges are not required to meet water quality standards, but must only control discharges to the MEP.

Response to: CTR-042-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-056-015a
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES C-24

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Should clearly recognize within the CTR that the existing, approved Basin Plan for the San Francisco Bay includes requirements specifically designed to address wet weather overflows and grants provisions for exemptions where an inordinate burden would be placed on the discharger relative to the beneficial uses protected. It should also be acknowledged through inclusion in the CTR that the requirements and applicable exemptions previously justified and approved by EPA and the State should not be affected by the proposed rule.

Response to: CTR-056-015a

The purpose of the CTR is to fill the current gaps in water quality criteria in inland surface waters, enclosed bays, and estuaries. Any existing exemptions in a State Basin Plan that have been approved by the State and EPA would not be negated by the CTR.

Comment ID: CTR-060-011
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

Application of effluent limits/BMPs to stormwater

The preamble (see 62 Fed. Reg. at 42,186, Col. 3) states that: 1) NPDES permits "...for wet weather point source discharges must include limits necessary to implement applicable water quality standards,

through application of water quality-based effluent limits or WQBELs"; and 2) "...these criteria will ... be the basis of WQBELs in NPDES permits for wet weather point sources". The preamble further recognizes that "it is commonly infeasible to express WQBELs as numeric limits for wet weather discharges and that in such cases best management practices (BMPS) may serve as WQBELS." (see 62 Fed. Reg. at 42,186-87). However, the standard for determining when the use of BMPs is appropriate is different from that provided in a recent Federal Register notice (see 61 Fed. Reg. 57425-29) "Questions and Answers Regarding Implementation of an Interim Permitting Approach for Water Quality-Based Effluent Limitations in Storm Water Permits" (the "Notice"). Whereas the Notice states that permitting authorities may use alternative permit conditions "where numeric water quality-based effluent limitations are determined to be unnecessary or infeasible." Id. at 57,426, col. 1 (emphasis added), the preamble to the CTR indicates that BMPs may only be used where it is determined that "...it is infeasible to express WQBELs as numeric limits."

EPA should revise the preamble to the CTR to state that BMPs or other alternative permit conditions may be utilized whenever a numeric WQBEL is unnecessary or infeasible.

Furthermore, EPA should explicitly state that the permitting authority bears the burden of showing that a numeric WQBEL for a wet weather flow is feasible or necessary. Since EPA admits that such limitations are "commonly infeasible," the permittee should not bear the burden of proving numeric limits unnecessary or infeasible.

Response to: CTR-060-011

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-062-001
Comment Author: City of Downey
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-062 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

1 . The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the U.S. EPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewer systems (MS4s) into section 41 0 (p) (3) (B) of the Clean Water Act. We

recommend that the U.S. EPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-062-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-071-001
Comment Author: City of Rosemead
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-071 incorporates by reference letter CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

1 . The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA. the numeric water quality standards in the California Toxic Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 41 0(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-071-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-072-001
Comment Author: City of Bell Gardens
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP

References: Letter CTR-072 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxic Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 41 0(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-072-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-073-001
Comment Author: City of Paramount
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-073 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxic Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 41 0(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-073-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-074-001
Comment Author: City of San Gabriel
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-074 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

1. The Application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410 (p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-074-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-075-001
Comment Author: City of El Monte
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-075 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program;

I. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410(p)(3)(B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-075-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-076-001
Comment Author: City of Cudahy
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-076 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR) , which are of major impact to our stormwater program:

1. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the maximum extent practicable standard for municipal separate storm sewers systems (MS4s) into section 410(p)(3)(B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are, not required to comply with water quality standards.

Response to: CTR-076-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-078-001
Comment Author: City of Maywood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-078 incorporates by reference letter CTR-013
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

I. The application of water quality standards to calculate water quality-based effluent limits for NPDES permits for municipal Stormwater discharges. As proposed by the USEPA, the numeric water quality standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the maximum extent practicable,, standard for municipal separate storm sewers systems (MS4s) into section 410(p)(3)(B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-078-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-079-001
Comment Author: City of Glendale
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-079 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

1. The application of water quality standards to calculate water quality based effluent limits for NPDES permits for municipal stormwater discharges. As proposed by the USEPA, the numeric water quality

standards in the California Toxics Rule will be used to calculate water quality-based effluent limitations for all NPDES permits issued by the State. We believe that this position is inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard for municipal separate storm sewers systems (MS4s) into section 410(p) (3) (B) of the Clean Water Act. We recommend that the USEPA modify the Preamble to clarify that MS4s are not required to comply with water quality standards.

Response to: CTR-079-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-087-001
Comment Author: Morrison & Foerster LLP
Document Type: Storm Water District
State of Origin: CA
Represented Org: SCVURPPP
Document Date: 09/24/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-087 incorporates by reference letters CTR-001 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: Members of the SCVURPPP strongly endorse and fully incorporate by this reference, the comments being submitted to you on the California Toxics Rule ("CTR") by the State Storm Water Quality Task Force, the Alameda Countywide Clean Water Program, and other municipal stormwater programs located throughout California. As those comments make clear at greater length, Congress's directive in Clean Water Act section 402(p)(3)(B) requires that the Agency expressly exclude municipal stormwater permits from the scope of proposed section 131.38(e)(1). Specifically, this section of the rule should be modified to state: "It is presumed that new and existing point source dischargers except for municipal stormwater dischargers, will promptly comply with any new or more restrictive water quality-based effluent limitations ("WQBELs") based on the water quality criteria set forth in this [rule]."

As other commenters have made clear, the Agency's current position in the CTR's preamble which "presumes" that municipal stormwater discharges are subject to water quality-based effluent limitations ("WQBELs") flies in the face of the plain language used by Congress in enacting section 402(p)(3)(B) of the Clean Water Act. It also ignores the contrast that Congress drew in the statute between the NPDES permitting requirements specifically delineated for municipal stormwater discharges and those expressly made applicable to stormwater discharges "associated with industrial activities." cf. 33 U.S.C. 1342(p)(3)(B) with 33 U.S.C. 1342(p)(3)(A). While best management practices ("BOPS") are certainly more appropriate tools for permit writers to use in stormwater permits than numeric effluent limitations, when it comes to municipal stormwater permits, Congress clearly required that such permit requirements be derived from section 402(p)(3)(B)(iii)'s maximum extent practicable standard, not through WQBELs based on the type of numeric water quality standards being promulgated in the CTR.

Response to: CTR-087-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c.

Comment ID: CTR-090-014
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Impacted Facilities - p 42160. Potentially Affected Facilities--- This list should include separate storm water systems and combined sewer systems in addition to POTWS. The preamble is vague as to whether these facilities must eventually comply with water quality criteria. If municipal wet-weather discharges must comply with strict application of the CTR, the potential infrastructure costs of compliance for metropolitan areas will be considerable. San Francisco spent $1 billion to address wet weather pollution. Assuming comparable per capita costs ($1,300 pc), and an urbanized population of 25,000,000 in California, wet weather capital costs could run over $32,000,000,000. Annual amortization costs (I = 5%) would exceed, $2,500,000,000. Even if only 5% of urbanized areas needed to use structural solutions for wet weather discharges, annual costs would be in the order of $125,000,000. It is essential that EPA decide whether it expects wet weather discharges to comply with the numerical standards and then state this assumption explicitly. EPA is doing a disservice to the public ff it maintains this dichotomy in the document: (1) an assumption in its economic analysis that storm water will not need substantial controls to meet the requirements of the rule-making, and (2) the position that this rule-making will promote the attainment of those designated uses adopted by the state.

Response to: CTR-090-014

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTR-092-011
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References: Letter CTR-092 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Application of Rule to Municipal Stormwater Dischargers

The CTR does not clearly state how the establishment of these criteria is intended to be implemented to municipal stormwater dischargers. The City opposes to any scenario that would directly apply numerical water quality objectives to this permitted program. The Rule needs to be revised to clearly state that the criteria established by the rule will not be used to calculate numeric water quality based effluent limitations for municipal storm water dischargers.

If the Rule were to result in the imposition of numeric water quality based effluent limitations on municipal storm water dischargers, it would be inconsistent with the plain language used by Congress in incorporating the "maximum extent practicable" standard into Section 402(p)(3)(B) of the Clean Water Act. Revision of the Rule to clearly state that it will not result in the imposition of numeric water quality based effluent limits on the Municipal storm water dischargers is also necessary to conform the rule with EPA's Economic Analysis, which assumes that the Rule will have no economic impact on these dischargers. EPA's failure to assess the costs of bringing municipal storm water dischargers into compliance with numeric water quality based effluent limits would represent a substantial violation of its legal requirements under Executive Order 12866, the Unfunded Mandates Reform Act of 1995 (2 U.S.C.A. 1511 et seq.), and the Regulatory Flexibility Act (5 U.S.C.A. 601 et seq.).

Specific areas of the Rule that need to be revised to clarify application of the rule to municipal storm water dischargers are Section F4 of the preamble, relating to wet weather flows and Section 131.38(e)(1). The discussion of the "unfeasibility" of imposing numeric limits for wet weather dischargers in the preamble is not an adequate statement that numeric limits will not be imposed. Moreover, the Rule itself states that it "presumed" that new and existing point source dischargers will promptly comply with any new or more restrictive water quality based effluent limits based on the water quality criteria set forth in this section. In order to be consistent with the Economic analysis, the Rule should explicitly state that it can only be used to establish BMP's as WQBEL's for municipal stormwater dischargers.

Response to: CTR-092-011

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTRE-002-002
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/18/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N

CROSS REFERENCES

Comment: As you heard from speaker after speaker yesterday, the urban stormwater dischargers are justifiably concerned about the confusing situation that exists today where they are being informed by the US EPA that NPDES-permitted urban stormwater runoff will be subject to having to meet water quality standards (objectives) in the receiving waters for the stormwater runoff during the time of runoff and after through a process of ever-increasingly more stringent and expensive BMPS. As I testified at the hearing and as is well understood in the field, the US EPA "Gold Book" water quality criteria, including those being promulgated under the California Toxics Rule, were not designed to address short-term, episodic events of the type that routinely occur in stormwater runoff from urban areas and highways. As a result, administrative exceedances of the California Toxics Rule criteria can readily occur without any real impairment of the designated beneficial uses for the receiving waters for the stormwater runoff. By real impairment I mean an altered number, types and/or characteristics of aquatic life in the receiving waters for the runoff.

There have been a sufficient number of studies conducted now to document that it will indeed be rare that the constituents which occur in urban stormwater runoff from residential and commercial areas are in toxic, available forms for a sufficient duration in the receiving waters for the ninoff to be adverse to aquatic life. As long as the US EPA persists with its improperly developed and adopted Independent Applicability policy, where chemical criteria/standards have to be met, even if appropriately conducted studies show that the constituents of concern such as heavy metals in urban stormwater runoff, are in non-toxic, non-available forms, the urban stormwater dischargers face the situation of ultimately having to spend large amounts of public funds to achieve administrative exceedances of inappropriate criteria/standards for urban stormwater runoff with no expected improvement in the real beneficial uses of waterbodies in which the exceedances occur that are of concern to the public who must ultimately pay for the control programs.

The administrative exceedances arise from well-known, technically invalid, inappropriate approaches that were adopted by the US EPA in the 1980s for implementing the "Gold Book" criteria that the Agency under various administrations has yet to address. Even today, based on discussions at the US EPA's Multi-Regional Water Quality Criteria and Standards meeting that was held at the end of August 1997 in St. Louis, Missouri, the Agency is still unwilling to address in a meaningful way the problems in regulating urban stormwater runoff water quality. For the Agency to announce, as it did at this meeting, that wet weather issues are no longer part of the ANPRM represents a serious deficiency in the Agency's current policy that must be corrected.

Response to: CTRE-002-002

EPA disagrees with the comments. The ANPRM and the scope of section 402(p) are outside the scope of the rule. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTRH-001-001a
Comment Author: Robert Hale
Document Type: Public Hearing

State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES J

Comment: MR. HALE: Good afternoon. My name is Robert Hale and I'm the chairman of the California Stormwater Quality Task Force which is located at 951 Turner Court, Suite 300, in Hayward.

This task force is a statewide organization representing municipal separate storm sewer systems that hold National Pollutant Discharge Elimination System, NPDES, permits to discharge stormwater.

My comments today are on behalf of the -- principally on behalf of that task force. I also am chairman of the management committee of the Alameda Countywide Clean Water Program. I will make some comments with respect to Alameda County.

As proposed by EPA, the preamble language, which is the principal point here in referring to numeric effluent limitations and water quality based effluent limitations, is clearly inconsistent with the plain language used by Congress in incorporating the maximum extent practicable standard into Section 402(p)(3)(B) of the Clean Water Act.

You may argue that this reference is only in the preamble and not in the main text of the rule; but it's my understanding, however, that the preamble itself is supposed to explain and clarify the meaning of the rule and the Clean Water Act. This proposed language would instead appear to be trying to change one of the fundamental points of the Clean Water Act.

The reason I think this point is fundamental is that the cost to society, and to our county in this case and to the states, is an important consideration. Congress considers the entirety of the tasks that the country has to do, rather than going for broke on one issue such as stormwater quality.

In short, the Congress balances the larger picture, and the language in Section 402(p)(3)(B) actually reflects that balance. I believe that Section 402(p) says what it says for a good reason. The only economically feasible means of achieving water quality standards is through best management practices.

To illustrate this point, I work in Alameda County as chairman of the Clean Water Program there, and I did some rough calculations here. We often get storms as much as 2 inches in a 24-hour period. That's several times a winter. If you had a one-day storm, as I figure it, that will work out to 5 billion gallons of runoff water.

To treat this much water, if we were driven to this sort of the extreme case by the language in the preamble -- and I'm not talking about the text of the rule so much as the language in that preamble -- if it were to drive us in this extreme case to have -- to do end-of-pipe treatment for our discharges in order to meet the standards that are there, and to keep up -- basically keep up with the storms, which often come one behind the other within a couple days, it would necessitate building dozens, perhaps more, treatment plants of substantial size and would necessitate the use or acquisition of valuable industrial properties on the margins of the bay. Which I just did a little separate figuring here; I'm figuring it costs about $3 a gallon to treat -- to secondarily treat sanitary sewage and about $4 a gallon to store it.

I estimate that a storm of this size -- to be able to handle a storm of this size would cost between 35 and $50 billion for Alameda County alone. This is for a population of l.35 million residents.

And this does not account for the acquisition of property needed to do this, assuming we could store it in facilities or properties we already own. And it also does not account for the secondary treatment. In fact, we might have some difficulty achieving the standards that are in the rule.

And there's a way you can express this getting down to the nuts and bolts of it, which I like to do. I did some rough estimates of the size of the Oakland Coliseum, and if you were to use structures the size of the Oakland Coliseum for storing this water from one of these storms, I figured it would come out to -- you'd need 50 of them to store the runoff from this one storm that I've got here.

And I know some of you might be thinking about how the A's are doing right now and this might not be a bad idea. We can, say, think about leaving an extra one there for the A's and Raiders and build 50 more of them.

But the point is, we're talking about a tremendous investment in the infrastructure here, and it's very difficult for us to keep up with.

So let's see. Just a few more points here.

So we're not really talking about upgrades to existing delivery and treatment systems. We would have to start from scratch and build pumping systems, conveyance systems, to build an entire infrastructure. The cost would be prohibitive for us in Alameda County. This is a -- sort of one of the worst-case scenarios. And I think that the economic rule -- or the economic analysis in the rule doesn't do this justice.

So --

MR. MORRIS: Have you done any modelling?

MR. HALE: This is strictly back-of-the-envelope type calculations at this point. I don't know whether or not -- what discharges the storm concentrations would result in.

The first question I have on modeling is to see what these discharges of stormwater with these effluent concentrations -- under the storm conditions if we would be -- would have a higher flow than the drought flow condition which was modeled.

When you have a storm event, the stream conditions are different, the hydrology is different, the modeling characteristics. We could work out the scenario. And it's true that when you've got a huge storm, water fires right out the bay and out the Golden Gate. We might even probably need to talk about that and work on that.

Response to: CTRH-001-001a

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs,

see response to CTRH-002-006a.

Comment ID: CTRH-001-004
Comment Author: Alan Waltner
Document Type: Public Hearing
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/17/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: MR. WALTNER: Thank you.

Good afternoon. My name is Alan Waltner and I have served as counsel to the Alameda Countywide Clean Water Program for seven years now, through the first and second rounds of NPDES permits and also the 1995 Basin Plan amendments for the San Francisco Bay area. I'll be following up on Robert Hale's comments he presented about the practical issues we're worried about.

Our concern fundamentally is a set of inconsistent statements in the preamble regarding how this rule would apply to municipal stormwater dischargers. At one point, for example, it states that alternate anticipated criteria may apply through simply best management practices, which is happening currently.

At other points in the preamble it suggests that we would have to do whatever it takes to make wasteload reductions under a waste allocation system or water-based numeric effluent limitations that would be keys to the standards. And depending on which of those interpretations you apply, the difference is significant.

Right now we're doing best management practices under the criteria of Section 402(p), that we have to do all that we can to the maximum extent practicable, and we estimate addressing pollution in stormwater for Alameda County to cost somewhere in the approximate neighborhood of 10 million a year, if I'm right.

It we had to do whatever it took, it -- by initial analysis, if we had to do whatever it took to provide a wasteload reduction that would be a proportionate share -- actually, copper mostly -- by end-of-pipe treatment of the entire stormwater flow of the county to produce the proportionate reductions, and you start coming up with figures in the range of $60 billion from Alameda County.

So it's incredibly important for us that the preamble language be clarified or -- and we think in a way that's consistent with Section 402(p), that the municipal stormwater systems only need to do appropriate MEP level controls.

Now, industrial stormwater dischargers under Section 402(p) may be subject to 301 and the numeric effluent limitations waste water quality standards. There is a clear distinction in Section 402(p) between the treatment of the industrial stormwater dischargers and the municipal stormwater dischargers. We think you need to maintain that distinction.

Now, I've noted that the regulation itself seemed to preserve the existing implementation policy of the State Water Resources Control Board. The policy of the State Water Resources Control Board simply requires implementation of BMPs to comply with 402(p) criteria. And to the extent that the rule keeps that implementation policy in place, then we're simply continuing what we're doing, the implementing of BMPs. That is something that we've already bought into and recognized we're obligated to do.

But if some of the significant statements in the preamble language were to prevail and we should have to do whatever it takes to provide proportionate wasteload reductions, it would lead to significant disruption and other legal problems that violate the description of Section 402(p) review procedures for the 1995 Basin Plan.

In that sense you would be impliedly repealing that implementation which would violate the review of the EPA subject to the 1995 Basin Plan, because it's impliedly repealing the implementation provision that we only have to do best management practices.

I think the bottom line is we're asking for EPA to clarify that Section 402(p) is what controls in this situation when applied to municipal stormwater dischargers, that we are obligated to keep pursuing maximum extent practicable controls, but that Congress has concluded there shouldn't be a requirement that we do whatever it takes, regardless of cost. And again, the costs are substantial to meet these numbers.

Thank you.

Response to: CTRH-001-004

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTRH-001-006
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: MR. HARRISON: Doug Harrison, General Manager of the Fresno Metro Flood Control District. I also happen to serve currently as a member of EPA's Wet Weather Advisory Committee and as liaison for FACA to the Stormwater Phase II FACA, so I've had the benefit of some additional exposure to some of these issues of concern recently.

I would endorse the comments of concern that Mr. Waltner just described. We're going to address these in written comments, but I wanted to touch verbally today on some that stand out, that flow from those concerns.

We agree with the concern that the preamble appears to try to codify the Elliott memorandum of 1991 and as to produce a result that was not intended by Congress in the 1987 Act amendments.

There are references on pages 42184, 186 and 187 of your preamble where these concerns arise, where you fail to address the clear language spelled out in the Clean Water Act that relates to municipal stormwater systems. We think for the rule to resolve this deficiency that there needs to be some clarification specifically addressed.

We believe that EPA itself is aware of the congressional intent with respect to the language in Section 402(p) as that relates to the municipal systems. In its draft stormwater regulations of October 1986, EPA included specific language that cited quite clearly the congressional intent and the understanding of that intent as it related to municipal systems and the issues around the permittings of those municipal stormwater systems.

Response to: CTRH-001-006

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTRH-001-031
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: MR. BRENT: Good afternoon.

I thank you for this opportunity to speak on the proposed rule. I'm Dave Brent, vice chairman of the California State Water Quality Task Force and supervisor of the City of Sacramento's stormwater management facility. I've been supervisor of the City of Sacramento's Stormwater Management Program for the past six years.

My comments are representative of at least nine major metropolitan stormwater programs in California, all with active stormwater management programs through the State Water Quality Task Force. You will also be provided with comments down in Los Angeles tomorrow.

We would echo Bob Hale and Doug Harrison. I think it's important that you hear from the state water interests, the State Water Quality Task Force on stormwater and the technical elements of the CTR itself.

This said, there are four major concerns that the State Water Quality Task Force and the Sacramento Stormwater Program have with this proposed CTR.

The first concern is the discussion in the preamble that states that the municipal stormwater permits must include limits necessary to implement applicable water quality standards. This approach continues the erosion of Congress's intent in the 1987 Clean Water Act amendments as implemented in Part 402(p) of 40 CFR, that applied the MEP standard, maximum extent practicable, to municipal stormwater discharges.

While the proposed rule appears as if it may recognize this MEP standard by giving the permit writers flexibility to express effluent limits as best management practices when the permitting authority determines that it is infeasible to express numeric limits, it doesn't come out and say what the regulations clearly require, that municipal stormwater dischargers must effectively control non stormwater discharges and control the discharges of pollutants to the maximum extent practicable.

In short, we believe that the preamble should not mince words and should clearly state that stormwater -- municipal stormwater discharges are subject to MEP.

Response to: CTRH-001-031

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTRH-001-040
Comment Author: Kathy Russick
Document Type: Public Hearing
State of Origin: CA
Represented Org: Sacremento Co. Stormwater
Document Date: 09/17/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: MS. RUSSICK: Kathy Russick, speaking on behalf of the Sacramento County Stormwater Quality Section, who is one of four member agencies of the Sacramento Stormwater Management Program, the other agencies being the cities of Sacramento, Galt and Folsom.

And I would like to note that many of the challenges facing the Sacramento Stormwater Program which I raise here are also the same challenges facing other stormwater programs in the state.

Specifically, I will be addressing today the concern raised by these stormwater agencies that the California Toxics Rule will require municipal stormwater programs in California to meet numeric water quality limits.

The interpretation of the rule that we are -- this interpretation of the rule we are concerned with was discussed last week at a state Stormwater Quality Task Force meeting. We discussed it with a representative of the State Water Resources Control Board and he confirmed the interpretation specifically that municipal stormwater programs will have to implement ever-escalating BMPs until the numeric discharge limits are achieved.

Response to: CTRH-001-040

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTRH-002-001
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: My name is Chris Crompton and I'm the manager of environmental resources for the Orange County Public Facilities and Resources Department. My office address is 10852 Douglass Road, Anaheim, California.

Today I'm presenting comments on the draft California Toxics Rule on behalf of the County of Orange and the Orange County Flood District. The County of Orange is the principal permittee on municipal stormwater permits for Orange County. These permits cover stormwater discharges for the county, flood district, and 31 incorporated cities.

In the main, the County of Orange supports the comments presented on behalf of the California Stormwater Quality Task Force by Chairman Robert Hale at the public hearing in San Francisco yesterday and by other municipal speakers from Sacramento County and Fresno. The County has been an active participant in the Task Force and in the development of those comments. Today I will be presenting our general concerns regarding the California Toxics Rule as it applies to our municipal stormwater quality management program. More detailed written comments on the proposed rule are being prepared for inclusion in the public record.

Our written comments will focus on challenging a number of basic assumptions in the California Toxics

Rule. In brief, we're going to be questioning the following:

Are the criteria applicable to municipal stormwater discharges?

In the preamble to the proposed rule, EPA assumes that these criteria for priority toxic pollutants apply to municipal stormwater discharges. We note for the record, however, that the applicability of water quality based effluent limits on municipal stormwater discharges has not been resolved. The Clean Water Act only requires dischargers of municipal stormwater to reduce pollutants "to the maximum extent practicable."

As noted in the Task Force testimony yesterday, in the preamble, EPA assumes that the application of water quality based effluent limits to stormwater discharges is appropriate and that the numerical limits can be imposed on such discharges sometime in the future. We believe that this assumption is incorrect and is directly contradicted by the plain language of Section 402(p) of the Clean Water Act.

Response to: CTRH-002-001

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTRH-002-008
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: I-01 Application Sec 301 vs. MEP
References:
Attachments? N
CROSS REFERENCES

Comment: We recommend deletion of the staff interpretation of the applicability of water quality based effluent standards to municipal stormwater discharges presented in the preamble.

Response to: CTRH-002-008

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Subject Matter Code: I-02 Elliott Memorandum

Comment ID: CTR-001-006
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-02 Elliott Memorandum
References:
Attachments? N
CROSS REFERENCES

Comment: THE ELLIOT MEMORANDUM SHOULD BE RESCINDED, RATHER THAN CODIFIED, IN THE CALIFORNIA TOXICS RULE

As support for much of the problematic language in the preamble to the CTR, EPA cites a January 9, 1991, memorandum from E. Donald Elliot to Nancy J. Marvel, Region 9 ("Elliot memorandum") which concluded that water quality based numeric effluent limitations apply to storm water discharges.

The Elliot memorandum contains a number of critical flaws and should be rescinded. Any attempt to rely on the Elliot memorandum in the proposed CTR, or to codify the Elliot memorandum, would subject the CTR to challenge based on these flaws.

The Elliot memorandum acknowledges that: "Section 402(p)(3) is clearly intended to draw a distinction between the requirements on industrial and municipal storm water discharges." Elliot memorandum at page 3. (*8) However, the memorandum derails by assuming an erroneous and contrary conclusion:

Section 402(a)(1) requires that all NPDES permits comply with the applicable provisions of section 301. This includes compliance with appropriate technology-based standards and effluent limits (sections 301(b)(1)(B), 301(b))2)). Permits must include "any more stringent limitation" necessary to meet WQS. Section 301(b)(1)(C).

Elliot memorandum at page 2. The critical flaw in this conclusion is that Section 402(p) establishes the applicability of Section 301, making Section 301 applicable only to industrial, and not municipal, storm water systems. Section 402(a) does not override, or conflict with, the applicability provisions of Section 402(p). In fact, by referring only to "applicable requirements under section 301," Section 402(a) acknowledges that not all "requirements" of Section 301 are applicable to all NPDES permits issued under Section 402. Among the limitations on such applicability are those set forth in Section 402(p).

The analysis in the Elliot memorandum also ignores a number of critical rules of statutory construction. First, as discussed above, the Elliot memorandum's reading of the statute would result in the retroactive application of Section 301(b)(1)(C) to municipal storm water systems, despite the absence of any evidence of Congressional intent to have created a retroactive system (and, in fact, despite the evidence in Section 402(p) to the contrary).

Second, the Elliot memorandum ignores the maxim that expresio unius est exclusio alterius ("to express one thing is to exclude all others"). Sutherland, supra, at S 47.23. The maxim applies to the interpretation of Section 402(p) in at least two ways. First, by making MEP-level controlsthe standard for municipal

storm water systems, other control approaches (such as water quality based effluent limitations) are excluded. Second, by making Section 301 applicable only to industrial storm water discharges, the application of Section 301 to municipal storm water discharges is excluded.

The maxim is closely related to the "plain meaning" rule. Here, Section 402(p) plainly states that MS4s are only subject to MEP-level controls. Section 402(p) does not leave open any possibility that MS4s might be subject to more stringent water quality based effluent limitations.

The Elliot memorandum also violates the plain meaning rule by applying the broad principles of the Act to override the statute's express provisions in Section 402(p). Likewise, extrinsic factors not appearing on the face of a statute cannot be used to override the express statutory language or create an ambiguity. Sutherland, supra, at Section 46.04.

The Elliot memorandum vainly seeks salvation by citing Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984) ("Chevron") in support of its flawed analysis. However, only where the statute is ambiguous does the doctrine described in Chevron come into play. Yet Section 402(p) is unambiguous and exclusive in its application of MEP-level controls to MS4s.

As summarized by the D.C. Circuit in American Petroleum Inst. v. EPA, 52 F.3d 1113, 1119 (D.C. Cir. 1995):

Under the Chevron doctrine, a court reviewing an agency's interpretation of a statute it administers must first determine whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, the review ends there for the court must give effect to the unambiguously expressed intent of Congress. Id. at 842-43. If the court determines that Congress has not directly addressed the precise issue, however, it then goes to the second step of the review to determine whether the agency's interpretation is based on a permissible construction of the statute. Id. at 843.

52 F.3d at 1117. Here, the precise issues of: (1) the control technology standard to be met by MS4s, and (2) the applicability of Section 301, have been addressed in the statute. EPA is not, as the Elliot memorandum argues, free to substitute its preferred result for the approach selected by Congress. (*9)

Rather than addressing these critical flaws in its analysis, the Elliot memorandum spends considerable time pursuing a red herring, arguing that the plain meaning of Section 402(p) (limiting MS4 control standards to the MEP level) would impliedly repeal Section 301 (which EPA argues makes all dischargers subject to more stringent water quality based effluent limitations). The Elliot memorandum argues that this would "read Section 402(p)(3)(B) as overriding 301(b)(1)(C)." Elliot memorandum at page 4. Yet Section 402(p) did not "impliedly repeal" or "override" Section 301; Section 402(p) actually confirmed the operation of Section 301 as applied to industrial storm water systems. The fact that Section 402(p) created a distinction between two categories of dischargers is perfectly ordinary. Congress routinelydelineates the applicability of statutes without resulting in "implied repeals" of the delineated provisions. EPA's argument (that making MS4s subject to water quality based effluent limitations exceeding MEP-level controls is necessary to avoid an implied repeal of Section 301) is specious.

The analysis in the Elliot memorandum is flawed and the memorandum's conclusion is only arguably correct as applied to storm water discharges associated with industrial activity. Municipal dischargers need only address water quality standards through MEP-level reductions (*10) The Elliot memorandum should not be relied upon or codified by EPA in the CTR, but instead should be expressly revoked given its demonstrated lack of merit.

(*8) The Elliot memorandum also states that:

Section 402(p) also specified the levels of control to be incorporated into storm water permits. Permits for discharges associated with industrial activity are to require compliance with all applicable provisions of Sections 301 and 402 of the CWA, i.e., all technology-based and water quality-based requirements. Section 402(p)(3)(A). By contrast, permits for discharges from municipal separate storm sewers "shall require controls to reduce the discharge of pollutants to the maximum extent practicable" ("MEP"). Section 402(p)(3)(B)(iii).

Elliot memorandum at page 2.

(*9) Moreover, the protection of the Chevron doctrine cannot be invoked without including the agency interpretation in a regulation. In Chevron, the Supreme Court found that Congress had left a gap for EPA to fill through rulemaking on the technical definition of "stationary source" under the Clean Air Act, and that EPA's regulations filling that gap were within the permissible range of discretion intended by Congress. Chevron held that where a statute includes a broad definition, the very breadth of the definition implies a delegation to the agency to fill the gap in a manner consistent with the goals and purposes of the statute. Yet the position in the Elliot memorandum has never been incorporated in a regulation; agency staff pronouncements of lesser stature are ineligible for the deference that Chevron would provide.

Finally, EPA's interpretation is inconsistent, both as between the Elliot memorandum and the Interim Permitting Policy, and even within the Elliot memorandum. In a closing footnote EPA acknowledges that:

There may be some municipal separate storm sewer systems which are unable to meet even the three-year compliance date in their permits. The Agency retains the discretion to issue an administrative order fixing a schedule for compliance if compliance is not achieved in that three-year period.

Elliot memorandum at 5. The basis for this inconsistent position contemplating discharges in excess of water quality based effluent limitations is not stated. More importantly, any deference under Chevron is limited where EPA's own interpretation has been inconsistent.

(*10) The ACCWP also objects to the indirect way in which this issue is being presented. The Elliot memorandum was issued without benefit of any public comment, and no EPA regulation has ever put forward for judicial review the positions taken in the Elliot memorandum. EPA owes it to the state and local agencies that will be affected by this rule to act in a more straightforward manner. If EPA is going to put the position taken in the Elliot memo forward as official policy binding on permit decisions, the agency should do Bo in a judicially reviewable form so that government agencies that would be affected by the positions taken in the memorandum have a fair opportunity to seek a judicial determination of the validity of that approach.

Response to: CTR-001-006

See response to CTR-040-004.

Comment ID: CTR-031-001b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-02 Elliott Memorandum
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES I-01

Comment: 1. The preamble of the proposed CTR, and therefore the apparent intended application of the rule, is inconsistent with the Clean Water Act.

Several broad, ambiguous statements in the preamble of the proposed rule imply that Clean Water Act section 301 requirements apply to all dischargers, including municipal stormwater systems. These presumptions must be qualified to recognize the clear intent of Congress and plain language of the CWA, section 402(p) which clearly require municipal storm water dischargers only to adopt controls to reduce pollutants in storm water to- the maximum extent practicable and to eliminate non-storm water discharges. The section's intent is demonstrated through the application of section 301 requirements, and related application of numeric effluent limitations or wasteload allocations in NPDES permits, to industrial stormwater discharges only.

EPA is obviously aware of Congress's intent as to municipal storm water discharge requirements. EPA included in its published draft Phase I municipal storm water regulations a quote from the Congressional Record of October 16, 1986, citing that intent.

Without a clear citation of the provisions of CWA section 402(p), the preamble to the proposed rule appears to be an attempt to codify the Elliot memorandum of January 9, 1991, and to create via this rule a result not authorized by Congress.

In order to eliminate this fundamental legal flaw in the proposed CTR, and eliminate the potential for future misinterpretation and controversy, each of the following statements from the preamble (at a minimum) must be clarified and/or qualified so that they do not appear to override or retract CWA section 402(p).

"When these proposed federal criteria take effect, they will create legally applicable water quality standards ... in California ... for all purposes and programs under the CWA." [p. 42160. This statement must include recognition that for municipal storm water dischargers, the CWA objectives can be addressed through best management practices, implemented to the maximum extent practicable (MEP), as established by CWA section 402(p).]

"CWA section 301(b)(1)(C) ... requires NPDES permits to contain limitations required to implement any applicable water quality standard established in the CWA." [p. 42162. The text should note that section 301 (b) (1) (c) does not apply to municipal storm water dischargers, as established through section 402(p).]

"If a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a numeric or narrative water quality criteria, the permitting authority must develop permit limits as necessary to

meet water quality standards." (P. 42184. Again, for municipal storm water dischargers, the preamble and CTR must make clear the MS4 permits must: address this CWA objective through the MEP requirement.]

"Point source and nonpoint source allocations are established so that predicted receiving water concentrations do not exceed water quality standards." [p. 42185.1; and

"[NPDES] permits for wet weather point source dischargers must include limits necessary to implement applicable water quality standards, through application of water quality-based effluent limitations or WQBELs." [p. 42186. These two statements are only correct as applied to industrial storm water dischargers; numeric effluent limitations or wasteload allocations can not be legally, reasonably, or practically applied to municipal storm water discharges.]

Response to: CTR-031-001b

See response to CTR-040-004.

Comment ID: CTR-040-014a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-02 Elliott Memorandum
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES J

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

I. Recommendation: Modify the Preamble statement that indicates municipal wet weather discharges must comply with water quality standards or WQBELs (Preamble pages 42186-42187).

* It is not a requirement of the CWA or EPA that wet weather discharges must meet water quality criteria. If it were, the adverse economic impact on municipal stormwater programs would be enormous. The CWA, at best, is ambiguous on this issue; EPA regulations do not address it; and the Elliott memorandum, which appears to be the primary basis for EPA's position on this issue, is not a legitimate basis for such a position. The Elliott memorandum is an internal EPA memorandum and; therefore, is not an independent interpretation of the CWA. The Elliott memorandum does not constitute EPA policy and is based upon a false premise and an inaccurate reading of the preamble to EPA's 1988 proposed stormwater regulations. The Elliot memorandum contains other erroneous conclusions that have never been applied to municipal stormwater permits (e.g., that municipal stormwater dischargers must comply with water quality standards within three years of permit issuance).

* EPA has routinely approved municipal stormwater NPDES permits that have not included requirements to comply with water quality standards (e.g., Tulsa, OK; Greesnboro, NC; Denver, CO; Portland, OR; Cedar/Green (Seattle), WA; Sarasota County, FL; and Phoenix, AZ).

* If EPA does not modify the Preamble statement to clarify that municipal stormwater dischargers are not required to comply with these water quality standards, then EPA must include the cost of the structural controls necessary for compliance in its economic analysis and, using these costs, address the requirements of Presidential Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act.

Response to: CTR-040-014a

See response to CTR-040-004.

Subject Matter Code: I-02a Applying WQBELs, Stormwater

Comment ID: CTR-001-002
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-02a Applying WQBELs, Stormwater
References:
Attachments? N
CROSS REFERENCES

Comment: I represent the Alameda Countywide Clean Water Program ("ACCWP") in a variety of matters regarding the ACCWP Storm Water Management Plan ("SWMP") and associated National Pollutant Discharge Elimination System ("NPDES") permit. The ACCWP is a consortium of the fourteen cities in Alameda County, the County, the Alameda County Flood Control and Water Conservation District, and Zone 7 of the Alameda County Flood Control District. Those agencies have joined together in a coordinated approach to storm water management and control, and are the co-permittees under an NPDES permit that recently was reissued by the San Francisco Bay Regional Water Quality Control Board ("RWQCB").

This letter provides comments of the ACCWP on legal issues raised by the August 5, 1997, proposed rule regarding "Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California." 62 Fed. Reg. 42160 ("California Toxics Rule" or "CTR"). By copy of this letter to the State Water Resources Control Board ("SWRCB"), we also provide comments on the SWRCB's parallel implementation rule, proposed September 12, 1997. Comments on the scientific and technical issues raised by the proposed CTR will be submitted separately. (*1)

BACKGROUND

Local governments recognize that they have a key role in addressing the contribution of municipal storm water discharges to water quality problems and the ACCWP takes that role very seriously. During the first five years of the program, for example, ACCWP members adopted comprehensive storm water management ordinances and have undertaken a broad range of initiatives to reduce storm water pollution. This program has won numerous awards, including EPA's 1994 National Second Place Award for the Outstanding Municipal Storm Water Control Program.

However, important practical constraints are faced by municipal dischargers which, unlike most industrial sources, cannot simply cease discharging. First is the chronic problem of limited resources, which has been exacerbated by the recent passage of Proposition 218 in California constraining the fee-based revenue sources upon which the ACCWP members generally have relied.

Second, municipal discharges have limited authority over the products and activities that contribute to storm water pollution. For example, home garden care pesticides have been identified as a significant contributor to toxicity in storm water runoff, but municipalities are preempted from regulating those pesticides directly and must rely instead on public information campaigns. Similarly, copper from brake linings is also of concern, but local governments cannot direct the formulation of brake linings.

Third, there are limited opportunities for end-of-pipe storm water discharge controls, and such controls would be both costly and environmentally damaging. See, In re Citizens for a Better Environment, et al, SWRCB, WQ 91-03, at 51-52 ("Treatment techniques such as wet-detention basins also require large land areas to contain high volume, variable storm flows. These techniques therefore result in extremely high costs . . . . The impacts of holding large amounts of storm water for treatment may also pose potential adverse environmental impacts".)

Since such storm water treatment plants generally would need to be constructed at the downstream end of storm water flows, they would need to be located adjacent to the San Francisco Bay. However, many of the undeveloped sites adjacent to the Bay are constrained by wetland and endangered species concerns, as well as presenting potentially significant open space, energy, visual, odor, noise and other impacts. Given siting constraints in the substantially developed inner San Francisco Bay Area, it may not even be possible to site the substantial storm water collection, transportation, storage and treatment facilities that might be needed to produce pollutant reductions of the magnitude assumed by EPA in the proposed rule.

As a result of the constraints faced by municipal storm water systems, existing water quality criteria in the San Francisco Basin Plan historically have been implemented in the context of NPDES permits for storm water systems through escalating best management practices ("BMPs"), rather than through numeric effluent limitations ("NELs") or wasteload allocations ("WLAs"). The reason for this is that NELs and WLAs currently are infeasible for municipal separate storm sewer systems ("MS4s").

This implementation policy was first embodied in the 1986 Basin Plan, which retained considerable permitting discretion for nonpoint source controls, and did not require municipal permittees to meet numerical water quality objectives. See, In re Citizens for a Better Environment, et al, SWRCB, WQ 91-03, at ii.

The 1995 Basin Plan, at pages 4-14 and 4-15, continued and clarified this implementation policy, stating that:

Since both the sources of pollutants in stormwater discharges and the points of dischargeare diffuse, and the methods of reducing pollutants in stormwater discharges are in the development stage, water quality-based numerical effluent limitations are not feasible at this time. Instead, stormwater permits will include requirements to prevent or reduce discharges of pollutants that cause or contribute to violations of water quality objectives . . . . If this first phase does not result in attainment of water quality objectives, the Regional Board will consider permit conditions that may require implementation of additional control measures.

This implementation policy has also been recognized by the State Board, "Storm water permits for MS4s must achieve compliance with water quality objectives, but they may do so by requiring the implementation of BMPS." SWRCB Order 96-13 at 11.

The Basin Plan's approach is consistent with EPA policy, reflected in EPA's August 26, 1996, "Interim Permitting Approach for Water Quality-Based Effluent Limitations in Storm water Permits" published at 61 Fed. Reg. 43761 et seq. ("EPA Interim Permitting Policy"). The EPA Interim Permitting Policy:

uses best management practices (BMPS) in first-round storm water permits, and expanded or better-tailored BMPs in subsequent permits, where necessary, to provide for the attainment of water quality standards.

Numeric effluent limitations are not required under the EPA Interim Permitting Policy (*2)

The current NPDES permit for the ACCWP was developed under this approach, by requiring the dischargers to carry out the SWMP while providing for annual improvements through a work plan process.

Any attempt to make water quality standards for San Francisco Bay directly applicable to municipal storm water dischargers as numeric effluent limitations would conflict with these carefully considered provisions of the Basin Plan and State Board implementation policy.

(*1) As you know, several storm water systems have requested additional time to comment on the proposed rule, a request in which the ACCWP has joined. Additional time is particularly important given the interdependence between the CTR and the recently proposed "Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California," ("State Implementation Policy" or "SIP") released by the SWRCB on September 12, 1997, just two weeks before the comment deadline an the CTR. The way in which the CTR is implemented is central to its effects on storm water dischargers, as discussed below. Unfortunately, the State Implementation Policy does not fully correct or moderate the critical problems created by the proposed CTR.

(*2) See also, EPA, May 3, 1996, "Draft Language for Interim Permitting Approach for Water Quality-Based Effluent Limitations in Storm Water Permits." EPA also indicates in the draft policy that neither the statute nor EPA regulations require numeric effluent limitations in municipal storm water permits, and that BMPs can substitute for such numeric limitations.

Response to: CTR-001-002

See response to CTR-040-004.

Comment ID: CTR-001-004
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-02a Applying WQBELs, Stormwater
References:
Attachments? N
CROSS REFERENCES

Comment: THE REGULATION SHOULD MORE CLEARLY CONFIRM THE CURRENT IMPLEMENTATION POLICY, AND CONFLICTING LANGUAGE IN THE PREAMBLE SHOULD BE REMOVED

At the outset, we note that the actual language of the proposed regulation appears to be appropriately qualified, stating that:

The criteria established in this section are subject to the State's general rules of applicability in the same way and to the same extent as are other Federally-adopted and State adopted numeric toxics criteria when

applied to the same use classifications . . . .

Page 42206, Proposed Section 131.38(c). As discussed above, State Board decisions in California and the San Francisco Basin Plan have made clear that MS4s need address WQS only through the implementation of escalating BMPS, all within the framework of the MEP standard.

Unfortunately, the recently proposed State Implementation Policy ("SIP',) is inconsistently drafted regarding this point. The state policy does, in Section 5.1, state that:

It is the intent of the SWRCB, in adopting this Policy, that the implementation of priority pollutant criteria/objectives and other requirements of this Policy through NPDES permits for storm water shall be consistent with the requirements of the existing SWRCBand RWQCB storm water program.

Draft State Implementation Policy at 5.1. In Chapter 5.1 of the Functional Equivalent Document ("FED") supporting the SIP, existing policy is correctly described as follows:

The RWQCBs have adopted NPDES storm water permits for MS4s . . . The MS4 permits require the discharger to develop and implement a Storm Water Management Plan whose goal is to reduce the discharge of pollutants to the maximum extent practicable (MEP). KEP is the performance standard specified in Section 402(p) of the Clean Water Act. Components of the storm water management plan address public education and outreach; illicit connection/illegal discharge detection and elimination; fiscal resources; monitoring; and the best management practices (BMPS) which will be utilized. To date, the efforts of the municipalities subject to MS4 permits have been focused on implementation of BMPs to reduce pollutants, rather than on treatment of storm water to remove pollutants.

FED at V-117 (Emphasis Added, Italics in Original). The FED goes on to state that:

Because of the nature of storm water discharges and the typical lack of information on which to base numeric water quality based effluent limitations, it has not been feasible for the SWRCB to establish numeric effluent limitations for storm water permits.

FED at V-118. The policy alternative selected in the proposed SIP is described as follows:

The existing NPDES storm water permits contain narrative objectives, rather than the numeric limits found in the more conventional NPDES permits. Compliance with these narrative objectives is a function of the dischargers' timely and effective implementation of the management practices and programs identified in the storm water management plan (MS4 permits) or the storm water pollution prevention plan (industrial/construction permits).

FED at V-119.

Despite this carefully drafted language in the FED, general statements included in the SIP suggest that WQS may need to be translated into NELs or WLAS, regardless of whether those NELs or WLAs can be satisfied by MEP-level controls. Draft SIP at 2, 910. This would violate the approach of Clean Water Act Section 402(p), as well as requirements of the Porter Cologne Act described below. (*5)

We request confirmation of the statements in the proposed rulemaking that MS4s only need to address WQS through the adoption of BMPs reflecting MEP-level controls, and that EPA does not intend that the state apply the proposed WQS as numeric effluent limitations or as the basis for wasteload allocations. Specifically, we request that EPA include language similar to that quoted above from the FED in the final

rule, and/or the preamble to the final rule.

(*5) The SIP at page 10 has particularly problematic language which states that:

Regardless of which method is used for deriving water quality-based effluent limitations, the calculated water quality-based effluent limitations shall be compared to the technology-based effluent limitations for the pollutant, and the most protective of the two types of limitations shall be included in the [permit].

This language could be read to suggest that NELS or WLAs could override the MEP standard of Section 402(p), which would violate both the Clean Water Act and porter Cologne Act.

Response to: CTR-001-004

See response to CTR-040-004.

Comment ID: CTR-020-001
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-02a Applying WQBELs, Stormwater
References:
Attachments? Y
CROSS REFERENCES

Comment: City of Stockton, California Comments on the Proposed "California Toxics Rule" 62 Fed. Reg. 42160-42207 (August 5, 1997)

The City of Stockton (the "City" or "Stockton") operates both wastewater and storm water facilities which discharge to waters of the United States. Consequently, the City is directly impacted by the Environmental Protection Agency's ("EPA" or the "Agency") proposed rulemaking. The following provides the City of Stockton's comments on the California Toxics Rule ("CTR" or the "rule") (62 Fed. Reg. 42160-42207).

As was the case with the prior National Toxics Rule ("NTR"), this proposal only addresses toxic pollutants listed pursuant to Section 307(a) of the Clean Water Act ("CWA") (approximately 126 pollutants). Conventional and non-conventional pollutants (such as ammonia, chlorine, iron, aluminum and color) are not addressed under this rule proposal. In addition, this proposal does not address whole effluent toxicity. The CTR addresses not only applicable water quality criteria (acute, chronic and human health) but also implementation methodologies such as the appropriate design instrearn flows to apply in developing permit limits (e.g., 7/Q/10, 30/Q/5, harmonic mean). Based upon the preamble to the proposed rule, the proposed water quality criteria will apply to both point source and non-point source discharges such as storm water. Due to the qualifying language contained in the rule, it is not apparent that criteria application will be uniform throughout the state and will depend somewhat on existing Basin Plan provisions.

Contrary to the rule preamble, the City does not believe that this regulatory proposal reflects the latest scientific information regarding proper application of the proposed criteria. Due to the expansive application of human health-related criteria to all streams designated as MUN (which is a default use designation under the Basin Plans) and the failure to allow site-specific modification to reflect actual use conditions, the potential receiving waters classified as exceeding human health criteria will be greatly exaggerated (e.g., stringent water ingestion and fish consumption-based criteria will be applied to ditches and intermittent streams). Consequently, the cost impact associated with this rule will be significantly greater than it otherwise should be.

In particular, the application of the criteria to storm water discharges will produce widespread non-compliance with the proposed criteria for common metals such as zinc, copper, and lead and will trigger the need for extensive implementation of costly technologies, unrelated to actual environmental needs. Therefore, the City respectfully submits that the CTR needs to be restricted in scope, updated to include more recent information regarding the expected impact of pollutants on the environment, and revised to allow utilization of relevant site-specific information to avoid misapplication of limited local resources. The following presents an overview of the proposed rule and identifies issues of concern from both storm water and wastewater discharge perspectives.

Response to: CTR-020-001

See response to CTR-040-004.

Comment ID: CTR-020-022
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-02a Applying WQBELs, Stormwater
References:
Attachments? Y
CROSS REFERENCES

Comment: VI. Application of Criteria to Wet Weather Flows is Inappropriate

The CTR specifically states that all toxies criteria apply to wet weather flow events and storm water discharges. EPA further states that it is unlikely that specific effluent limits will be established because such limits are "infeasible." Regardless of EPA's position concerning the ability to establish specific effluent limits, it is apparent that application of the proposed criteria to storm water discharges either through effluent limits or receiving water limits will place virtually all storm waters in violation of the CTR. Thus, municipalities and water conservation districts will be exposed to citizen suits and civil penalties under state and federal law. As a result, major expenditures of local resources would be required to eliminate violations of the proposed criteria, even where it is apparent that there is no actual environmental harm. Because the rule fails to assess the significant economic impact associated with application of the criteria to storm waters and there is no information in the record supporting that it is necessary to meet the criteria in storm waters to adequately protect the environment, the CTR should specifically exempt storm waters from the criteria application. The legal and technical basis for this request is discussed below.

Few, if any, of the EPA criteria were designed to apply to storm water-related events, The criteria assume that extended exposure to the pollutants of concern will occur, that sensitive organisms are present, and that the form of pollutant and water chemistry used to conduct the laboratory studies underlying the criteria are similar to the receiving water conditions. All of these assumptions are known to be in error for storm water discharges, as follows:

* Exposures will be intermittent, variable and generally far shorter than the exposure used to establish the acute criteria (96 hours) and certainly far less than any chronic or human health based criteria (30 days to 70 years). EPA's "fast acting toxicant" evaluations confirm that short duration exposures may often be an order of magnitude higher than longer term exposures without causing adverse impacts (see, Section II.A.4.a.1 above). Thus, direct application of the criteria (with or without a mixing zone) will produce unnecessarily restrictive requirements.

* Water chemistry in storm water is dramatically different than the typical pristine water used to assess pollutant impacts in the criteria tests (e.g., Lake Superior water). EPA has routinely acknowledged that water chemistry significantly impacts the effect of pollutants in the environment, and elevated TOC and TSS levels will significantly mitigate the toxicity of a wide range of metals and organics. (See, 62 Fed. Reg. 42175). The National Guidelines require modification of the criteria when it is apparent that the criteria will be overprotective as is the case in this circumstance.

* Sensitive organisms such as daphnids and salmonids, which often drove the criteria document calculations (e.g., metals criteria) cannot inhabit most receiving waters and certainly will not be present in intermittent streams. Turbulent high flow conditions alone would destroy fragile daphnids. Applying criteria to protect species that cannot possible exist in the receiving waters is clearly unnecessary.

* Guidance documents related to the translation of water quality criteria into permit limitations are not designed to address intermittent wet weather conditions. Criteria modification procedures mandated to apply to metals (WER Guidance) cannot be applied to short term, highly variable, intermittent exposure conditions without a major restructuring of the guidance documents.

* Permitting guidance recommended for usage with the CTR (e.g., (1991) TSD) does not have a wet weather analysis component and the statistical procedures are not applicable due to the lack of continuous discharge and infrequency of discharge conditions. The only comparable information contained in the TSD relates to mixing zones wherein the TSD states that environmental impacts cannot be properly assessed unless the time period of exposure is accurately considered due to the known dose/response relationships of various pollutants. EPA has also acknowledged that "[T]he human health risks of a substance cannot be determined with any degree of confidence unless a dose/response relationship is quantified" (62 Fed. Reg. 42175). As data on the short term dose/response is not included in the published criteria and the TSD procedures do not specify how to assess intermittent short term pollutant exposures to compare such exposures to longer term criteria, there is no objective basis upon which to apply even the acute criteria to storm water events.

Given the lack of experience of permitting authorities in properly applying water quality criteria to short term events, it is essential that EPA clarify that the proper application of criteria to wet weather events must account for the time period of exposure, the organisms present, and the different characteristics of the water in comparison to EPA laboratory studies. Absent the establishment of specific procedures to ensure that the criteria will be properly applied to the unique circumstances of storm events, EPA should not extend application of the criteria to wet weather events.

Application of metals criteria to storm water discharges will be particularly problematic as EPA is now recommending that the actual hardness of the receiving water be used and there is no assurance that dilution with receiving waters will be considered. Most of EPA's metals criteria assume that a metal becomes infinitely toxic as hardness approaches zero. This is not based on a detailed database of organism sensitivity at low hardness but is an artifact of the hardness/toxicity model that reasonably reflects the toxicity of metals under typical hardness conditions (50-200 mg/l). Storm water events, however, do not fit within the typical conditions that formed the basis of the current metals criteria.

The hardness of rain water is quite low and will result in extremely low limits if applied to storm waters. Hardness levels increase as the storm water contact time with the ground increases. However, prior to mixing with surface waters, it is not unusual to encounter hardness values in the 20 mg/l range. This produces extremely low acute and chronic criteria for a host of metals, most notable copper, zinc, and lead. For these parameters, the calculated criteria will range from less than 1 ppb to 30 ppb. Thus, application of the CTR criteria to storm waters would lead to the conclusion that most storm waters are an acute toxicity threat to the environment even though a more accurate application of the criteria would lead to an opposite conclusion for metals. This is not a minor difference in results and, unless corrected, will trigger the need for expensive biological testing to prove the obvious -- metals in storm waters are not toxic.

In addition to the concerns regarding application of metals criteria, it is apparent that there is no rational basis for applying long term human health criteria to short term storm water events. EPA should clarify that long term human health-based criteria (which assume 30 day to 70 year exposures) often based on long term bioaccumulation do not apply to short term storm water discharge events. This will prevent misapplication of the criteria that would otherwise occur under the Agency's proposal.

In summary, EPA should revise the scope of the CTR to specify that the criteria do not apply to storm water situations and that site-specific decisions on the need for reduction of pollutants in storm waters will be conducted.

Response to: CTR-020-022

See response to CTR-040-004.

Comment ID: CTR-087-002
Comment Author: Morrison & Foerster LLP
Document Type: Storm Water District
State of Origin: CA
Represented Org: SCVURPPP
Document Date: 09/24/97
Subject Matter Code: I-02a Applying WQBELs, Stormwater
References: Letter CTR-087 incorporates by reference letters CTR-001 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: Moreover, the Agency's position on the application of WQBELs to municipal stormwater discharges rests on a flawed internal opinion circulated from the General Counsel's office to Region 9's legal counsel in January 1991 (the so-called "Elliot Memo") which ignores the plain language of the statute and simply assumes that Congress's clear language was ambiguous. It has never before been

endorsed by the Administrator or been subjected to public comment process or the potential for judicial review. Therefore, if EPA wishes to try to make the Elliot Memo the law through the CTR, it first needs to go to Congress to amend the Act's unambiguous NPDES permitting requirements for municipal stormwater discharges.

Response to: CTR-087-002

See response to CTR-040-004.

Subject Matter Code: I-03 Applicability of Criteria

Comment ID: CTR-007-003
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: 2. Under the proposed rule, it is unclear whether Best Management Practices or the water quality criteria will be used to assess stormwater discharges.

Response to: CTR-007-003

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-013-005
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

5. The proposed criteria were established based on typical, steady flow wastewater discharges, and may not be applicable to wet weather flows. The USEPA in Washington is currently reviewing the applicability of present water quality criteria to wet weather discharges. Given the quantity of stormwater discharges, flow conditions in the receiving waters, the numerous discharge points, and variability in discharge quality, there is no published scientific approach for assessing the impacts of such discharges on designated uses.

We recommend that the rule not apply to MS4s until the USEPA has completed its study on the applicability of water quality criteria to MS4 discharges.

Response to: CTR-013-005

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-027-006
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: 6. The proposed criteria were established based on typical, steady flow wastewater discharges, which may not be applicable to wet weather flows. USEPA in Washington is currently reviewing the applicability of present water quality criteria to wet weather discharges. Given the quantity of stormwater discharges, flow conditions in the receiving waters, the numerous discharge points, and variability in discharge quality, there is no published scientific approach for assessing the impacts of such discharges on designated uses.

Recommendation: The rule should not apply to MS4s until USEPA has completed its study on the applicability of water quality criteria to MS4 discharges.

Response to: CTR-027-006

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-031-003b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES C-21

Comment: If the proposed rule is carefully and sufficiently modified to affirm a commitment by EPA to effect only its Congressional authorization as established by CWA section 402(p), then EPA's failure to assess municipal storm water dischargers" ability to attain the proposed standards and associated economic and environmental impacts may be set aside at this time. However, if EPA persists in maintaining the CTR as drafted in this regard, the ambiguities presented in the preamble demand serious consideration and analyses as follows.

a. Many of the criteria are not attainable or scientifically valid with regard to municipal stormwater dischargers, nor is the proposed approach consistent with an appropriate delegation of authority to the State.

i. Attainability of Standards

The statutory premise of the CWA is to provide water quality for protection and propagation of aquatic life, wildlife, and recreation wherever attainable. The CWA therefore establishes a reality test in that objectives must be attainable.

The proposed CTR criteria can not be attained by municipal storm water dischargers. The District treats through detention and retention all but 1% of its urban runoff on an annual average basis. Nonetheless, its urban runoff discharges, after detention, would exceed proposed dissolved copper, lead, and zinc criteria. Concentrations would need to be reduced by 67%-95% to meet the proposed chronic criteria. No storm water best management practices, including conventional end-of-pipe storm water treatment facilities (i.e., detention systems), are believed to be able to achieve these levels of reductions for these constituents.

Response to: CTR-031-003b

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a.

Comment ID: CTR-037-008
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N

CROSS REFERENCES

Comment: 8. EPA states that NPDES permits for wet weather point source discharges must include limits in order to implement water quality standards, and that the water quality criteria presented in the rule will be used to develop WQBELs in NPDES permits for these sources. EPA does not address the exposure issues associated with using surface water quality standards developed using tests lasting 2-60 or more days to draw conclusions on discharges lasting minutes to hours. WERF has conducted research recently which shows clearly that the impact due to exposure of minutes is orders of magnitude less than the impact observed following days of exposure. Use of water quality standards to regulate most stormwater discharges is overly stringent and protective, which will ultimately result in the expenditure of resources on controls which offer no benefit. EPA should be responsible for justifying the use of water quality standards with stormwater discharges with data and illustrating why they are necessary to protect and support designated uses. The use of these standards under these conditions is arbitrary, at best.

Response to: CTR-037-008

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-061-005a
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? Y
CROSS REFERENCES C-17

Comment: Additional Comments

Presented below are some specific comments on statements made in the proposed CTR Federal Register.

Page 42160, third column, near the bottom, municipal stormwater dischargers should be added to the list of NPDES dischargers who have an interest in this rule. If anything, they probably will be affected more than any other entity.

Page 42161, third column, first paragraph, states,

"Numeric criteria for toxic pollutants allow the State and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Numeric criteria also provide

a more precise basis for deriving water quality-based effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits to control toxic pollutant discharges."

That statement is somewhat unreliable and misleading.

While it is bureaucratically simpler for regulatory agencies to numerically compare concentrations found in an effluent or in ambient waters with a chemical concentration-based water quality criterion, the claim made in the quoted statement is not necessarily true. In fact, rarely is the exceedance of numeric criteria a reliable basis for assessing the impacts of constituents on human health or the environment. While it may be more precise, it can be highly inaccurate. This is one of the areas that needs to be corrected by the US EPA where biological effects-based approaches are used, rather than chemical-based approaches for regulating such impacts as aquatic life toxicity for potentially toxic constituents.

Response to: CTR-061-005a

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-096-001a
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N
CROSS REFERENCES C-17

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

1. The numerical standards are ambiguous or incomplete to address the variety of operating conditions under which discharges to waters of the United State occur.

Specifically, the City submits the following comments:

A. California's receiving waters have a very wide diversity of hydraulic and environmental conditions. The numerical standards do not take into account the wide range of rainfall patterns, storm durations, irrigation flows and power generation flows that are the current aquatic habitat. California's rivers are highly regulated, highly managed. The proposed regulations neither address this variety, nor provide a means by which numerical standards can be readily developed to address such variety.

B. The California Toxic Rule presents new water quality standards for the State of California. This rule

presents water quality standards for all water bodies within the state. Water quality standards as presented in this rule would apply to all environmental conditions (dry and wet weather). During wet weather, conditions in the receiving streams can be extremely variable due to the quality and quantity of stormwater. Treatment plants generally have hydraulic capacity to process twice the average dry weather flow received. Water quality standards were developed based on dry weather conditions. Therefore, numerical water quality standards should not need to be achieved during storm events. If water quality standards need to be achieved during storm conditions, it is suggested that new standards be developed to account for the changes in environmental conditions.

Response to: CTR-096-001a

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria with regard to WQBELs and storm water discharges, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTRE-002-004
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/18/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: As you may or should know, the urban stormwater dischargers are not claiming that there are no water quality problems associated with their discharges. It appears that there may be real water quality problems in urban stormwater discharges due to chemicals, such as the organophosphate pesticides principally known at this time, diazinon and chlorpyrifos, which the US EPA either, in the case of chlorpyrifos for which there is a water quality criterion, has failed to implement a criterion or, for diazinon, has yet failed to develop a criterion. I understand that finally after years of delay where it has been well known by the US EPA that diazinon was causing widespread aquatic life toxicity, the Agency is now beginning again to formulate a water quality criterion for this chemical.

Even with the development of these criteria, however, it does not mean that they would be enforced. The chlorpyrifos situation is a prime example of where there is well-known aquatic life toxicity in many communities' stormwater runoff, yet the Agency, including US EPA Region 9, has failed to admit publicly that there is a problem, much less act to control the problem. A situation could readily develop where stormwater dischargers are required under CTR to spend massive amounts of public funds building "50 Oakland Coliseums" just to store stormwater runoff in Alameda County from a storm magnitude that occurs more frequently than once in three years because of administrative exceedances of several CTR-regulated heavy metals in the stormwater runoff which have been repeatedly found to be in non-toxic, non-available forms, including the dissolved forms. yet could have the treated stormwater discharge to San Francisco Bay be highly toxic due to unregulated or inadequately regulated

organophosphate pesticides. This is an artifact of the inappropriate approaches used by the Agency of focusing on chemicals, rather than chemical impacts, i.e. potential toxicants rather than toxicity.

Response to: CTRE-002-004

The scope of today's rule is to establish numeric criteria to bring California into compliance with CWA Section 303(c)(2)(B): Section 303(c)(2)(B) requires adoption of numeric criteria for priority toxic pollutants contained in CWA Section 307(a) for which EPA has issued Section 304(a) criteria guidance if those pollutants could reasonably be expected to interfere with the designated uses of state waters. The promulgation, implementation, and control of pollutants that are not identified as priority toxic pollutants (i.e, those pollutants that are not contained in CWA Section 307(a)) are outside of the scope of today's rule. Diazinon and chloropyrifos, the pollutants referenced by the commenter, are not contained toxic pollutants under CWA Section 307(a) and are thus outside of the scope of this rulemaking.

However, EPA notes that the CWA and Water Quality Standards Regulation requires all states, including California, to adopt water quality standards (which includes water quality criteria) sufficient to protect the designated uses of their waters. This requirement necessitates State adoption of criteria that are not included in the CWA Section 307(a) list. In addition, states may also use their narrative criteria to prevent toxic effects caused by pollutants that are not identified as priority toxic pollutants, such as those pollutants mentioned by the commenter, in instances where a state does not have numeric criteria in place or to supplement the numeric criteria

For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004. See also response to CTR-001-003.

Comment ID: CTRH-001-007
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: Even if it could be successfully argued that the CTR as drafted is applicable to the stormwater dischargers, we believe that the criteria is flawed. During one recent meeting of the Water Quality Standards Work Group of FACA, EPA headquarters staff made a presentation that reminded us of the language of the Act, which seems to establish a test of attainability -- a reality test, if you will -- that the objectives must be attainable.

We also have extensive data from the NURP program and the NPDES permits that suggest that through monitoring it was demonstrated that the criteria are not attainable, the concerns that you heard from the

two previous speakers. It is documented that episodic stormwater flows vary greatly the ability to handle -- in things like recovery times and so forth.

And I would also note a 1992 memo that was produced by Tudor Davis of the Office of Science and Technology, reporting on the CSO Wet Weather Panel that focused on some of these, and the fact that while they concluded it was not necessarily appropriate to produce a separate set of criteria just for wet weather conditions, that what the criteria did have to do is to be applied to both duration and the frequency and magnitude -- frequency and magnitude.

The EPA began this work shortly thereafter and brought to the Urban Wet Weather FACA the individual who is doing this work of application to the aquatic life criteria of these variables. The criteria analysis was to have been completed by September/October of this year.

We have to conclude that if the criteria as proposed in the current CTR proposal is in fact to be interpreted to include stormwater, that there are these inconsistencies that need to be addressed.

Certainly there's awareness at EPA of the limitations of BMP programs regarding attainment of CWA objectives and criteria.

The Phase II draft rule that is now before OMB for review provides for a complete comprehensive stormwater program evaluation in 13 years from the date of the adoption of that final rule, which is scheduled for March of '99. And that program definition included Phase I to Phase II programs, and goes on to state that there should be no additional BMPs required until that evaluation is completed.

It appears to limit flexibility -- would tend to limit state flexibility. We have concern about that, and also that it appears to limit the compliance schedule to 5 years. EPA has already cited the need to go to a 10-year evaluation after two permit terms for the entire stormwater program.

We have run models in our community FMFCD stormwater system. We capture 90 percent of all runoff in the community and keep it. It never gets to the waters of the U.S. The remaining 10 percent, we treat 90 percent of it through extensive detention.

Response to: CTRH-001-007

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTRH-001-061
Comment Author: Fred Lee
Document Type: Public Hearing
State of Origin: CA
Represented Org:
Document Date: 09/17/97
Subject Matter Code: I-03 Applicability of Criteria
References:

Attachments? N
CROSS REFERENCES

Comment: MR. LEE: My name is Fred Lee, L-E-E.

I want to focus on one aspect of the discussions today, and that is the urban stormwater and highway stormwater runoff issues. These are of concern to me. I'm particularly concerned about this issue in applying these criteria to regulating stormwater runoff and the ultimate goal mandated by the Clean Water Act.

I have been involved in criteria and standards development since the 60s, I helped EPA develop its current approach as a peer reviewer for agencies for the so-called gold book criteria, which is still basically the approach being used today to promulgate these criteria.

There is no question, if you understand how the current criteria were developed, that they tend to significantly over regulate urban stormwater runoff. This will result in massive expenditures as we approach the goal of achieving water quality standards in stormwaters.

This is a well-known problem. Everyone knows this is a problem, but everybody says, "Well, apply BMPs for a while." And that's no man's land. what's that really mean and what's MEP mean and so forth?

When I looked at that rule, I said we really missed the boat by not discussing what it's going to cost to apply these criteria to urban stormwater as an ultimate goal where you have no measure for exceedence for five years. That's Clean Water Act requirements.

We've got to get these figures on the table and we've got to start to understand where we're heading for as a goal with respect to applying these criteria as ultimate goals for urban stormwater.

It's -- there may be situations it's 1 to 2 dollars per person per day in the regulated communities. That's the kind of cost we're talking about for achieving Clean Water Act requirements, with no more than one exceedence for constituents, as we've heard, such as copper and lead, zinc, et cetera -- 1 to 2 dollars per person.

We don't have lands to store this water in order to provide treatment, so it's -- to me, it's a matter for EPA as part of this rule to do a proper economic analysis of what it's going to cost the public actually to process ever-increasing BMPs until we get to the goal.

It's a serious mistake. We're talking about a massive bill for this country. And what are we going to get? We'll get a lot of over regulation because criteria are not applicable to this kind of situation.

We need different kind of criteria, and this has been well discussed; we understand that needs to be done obviously.

Response to: CTRH-001-061

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality

criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Comment ID: CTRH-002-024
Comment Author: Gary Hildebrand
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Dept of Public Works
Document Date: 09/19/97
Subject Matter Code: I-03 Applicability of Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: My name is Gary Hildebrand. I'm with the Los Angeles County Department of Public Works, and I'm the stormwater permit program manager for Los Angeles County. I'm here representing the principal permittee for the L.A. County Municipal Stormwater Permit Program which is the largest municipal stormwater permit program in the nation. We have over 86 permittee cities in our program. We cover over a 3,000-square-mile watershed which contains like 9 million people. We also have a 3,000-mile-plus urban storm drain network that permittees must maintain.

First, I'd like to express our support and agreement with the comments expressed at the public hearing yesterday in San Francisco by Mr. Bob Hale, the chairman of the California Stormwater Quality Task Force, and also the other municipal stormwater program representatives, both there and at the hearing today.

Then I would like to provide some additional comments that are concerned to our municipal stormwater program. First off, compliance with the proposed criteria for stormwater discharges may be impractical. The proposed criteria was established for typical steady flow point source discharges and are not applicable to the wet weather flows. Quantity of stormwater discharges, slow conditions and receding waters, the numerous discharge points and the variability in discharge quality, there is no published scientific approach to determine the compliance with water quality criteria for stormwater runoff from a municipal storm drain system. Until such an approach is accepted and published by a regulatory agency, it should not be applicable to municipal stormwater discharges.

Response to: CTRH-002-024

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of the scientific validity of CTR criteria, see response to CTR-031-004c. For a discussion of the relationship between criteria, standards, effluent limitations and implementation costs, see response to CTRH-002-006a. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to CTR-013-003 and CTR-040-004.

Subject Matter Code: I-04 Site-Specific Criteria

Comment ID: CTR-013-006a
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-04 Site-Specific Criteria
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES C-24e

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

6. The proposed criteria will apply to all inland surface waters and enclosed bays and estuaries, regardless of the designated or attainable uses for a water body. This is of particular concern for waters that only have flows during wet weather events or that are point source effluent dominated water bodies. Blanket application of water quality criteria to all waters without designated uses is inconsistent with Federal and State water quality laws. Water quality standards are made up of two components--designated uses and the appropriate criterion to ensure the designated use can be achieved. Assigning criteria to a water body without first considering the designated uses is inappropriate and could result in over restrictive, unnecessary permit limits potentially resulting in significant compliance costs to a discharger.

It is common in California for urban stormwater runoff discharges to be the primary or only source of waters to urban creeks and waterways, that is, there would be little or no flow during most of the year were it not for urban stormwater or other point source discharges. Given the potential compliance problems for stormwater discharges forcertain constituents (even after a fully implemented BMP program), a municipality could be forced to remove stormwater discharges from the creek. The costs would be significant and the benefit little, if any. In fact, the removal of these discharges would be environmentally damaging to aquatic life and wildlife that were supported by the effluent/runoff dependent waters.

Therefore, the proposed rule should be revised to avoid blanket application of the proposed criteria to all surface waters and to require appropriate beneficial and attainable uses of all waters be determined prior to imposing water quality criteria in the water body. The rule should also be revised to implement separate and distinct water quality criteria for water bodies that are primarily effluent or runoff-dependent.

Response to: CTR-013-006a

See response to CTR-040-004.

Comment ID: CTR-027-007a
Comment Author: California SWQTF

Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-04 Site-Specific Criteria
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES C-24e

Comment: 7. The proposed criteria will apply to all inland surface waters and enclosed bays and estuaries regardless of the designated or attainable uses for a water body. This is of particular concern for waters that only have flows during wet weather events, or that are point source effluent dominated water bodies. Blanket application of water quality criteria to all waters without designated uses is inconsistent with federal and state water quality laws. Water quality standards are made up of two components - designated uses and the appropriate criteria to ensure the designated use can be achieved. Assigning criteria to a water body without first considering the designated uses is inappropriate and could result in overly restrictive, or unnecessary permit limits, potentially resulting in significant compliance costs to a discharger.

It is common in California for urban stormwater runoff discharges to be the primary or only source of waters to urban creeks and waterways; that is, there would be little or no flow during most of the year were it not for man's activities. Given the potential compliance problems for stormwater discharges for certain constituents (even after a fully implemented BMP program) a municipality could be forced to remove stormwater discharges from the receiving water. The costs would be significant and the benefit little, if any. In fact, the removal of these discharges would be environmentally damaging to aquatic life and wildlife that were supported by the effluent/runoff dependent waters.

Recommendation: The proposed rule should be revised to avoid blanket application of the proposed criteria to all surface waters, and to require appropriate beneficial and attainable uses of all waters be determined prior to imposing water quality criteria in the water body. The rule should also be revised to implement separate and distinct water quality criteria for water bodies that are primarily effluent or runoff dependent waters. An example of such flexibility is the use of a less stringent cancer risk factor such as 10E-4 or 10E-5 for the human health criteria for effluent dominated streams.

Response to: CTR-027-007a

See response to CTR-040-004.

Comment ID: CTRH-002-025
Comment Author: Gary Hildebrand
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Dept of Public Works
Document Date: 09/19/97
Subject Matter Code: I-04 Site-Specific Criteria
References:
Attachments? N
CROSS REFERENCES

Comment: The next and the proposed criteria will apply to Inland Surface Waters, Enclosed Bays, and Estuaries regardless of the designatable or attainable uses for water -- this is a particular concern that only flows during wet weather events or that are dominated water bodies.

There are many situations in our area where early stormwater runoff discharges to local creeks and waterways are the primary or only source of waters. There would be flow under most of the year were it not for discharges. Given the stormwater discharges and compliance problems with certain decisions, this would be even after a fully implementing BMP program. The municipality could be forced to remove the discharge from the creek constantly without benefit. In fact, removal of these discharges could be environmentally unsound given the wildlife that are supported by the effluent and/or runoff-dependent waters.

Response to: CTRH-002-025

The commenter feels that in situations where a municipality is unable to achieve compliance with CTR in an intermittent stream, they will be forced to continuously remove the discharge from the stream. EPA does not mandate removal of runoff as part of a storm water management plan, rather the upgrading / addition of BMPs to lower pollutant loadings. Commenter is right in that wildlife may be dependent on the intermittent flows which are totally of storm water origin. But it must be noted that the flora and flauna may also be similarly imperiled by toxics contained in the storm water effluent.

Subject Matter Code: I-05 Compliance Schedules

Comment ID: CTR-013-007a
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-05 Compliance Schedules
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES G-02

Comment: In addition, we would like to emphasize the following concerns for which greatly impact the Los Angeles County Stormwater Program:

7. The proposed rule provides only a five-year compliance schedule to achieve compliance with the proposed water quality criteria. Again, setting aside the issue of whether water quality standards actually apply to municipal stormwater discharges, municipal stormwater programs are long-term, BMP-based programs. Because of this, it will take many years for a municipality to realize any water quality benefits in the receiving waters. The preamble to the proposed rule addresses all wet weather discharges together in one discussion. Municipal stormwater programs should be discussed and treated separately from all other wet weather and point source discharges. These are unique programs and cannot be placed in a "one-size fits all" regulatory program. The proposed rule needs to account for the nature of stormwater discharges by allowing more time for the MS4 long-term, BMP, source control program approach to take place for controlling pollutants in stormwater discharges.

We recommend that the rule be revised to provide a longer compliance schedule and to provide more flexible regulatory relief for MS4 dischargers who have fully complied with the MEP discharge standards but cannot achieve compliance within the established compliance schedule. At a minimum, the CTR should follow the recommendation of the State Task Force on the Inland Surface Water Plan to provide a 15-year compliance schedule.

Response to: CTR-013-007a

See response to CTR-030-004c.

Comment ID: CTR-027-008a
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-05 Compliance Schedules
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES G-02

Comment: 8. The proposed rule provides only a five-year compliance schedule to achieve compliance with the proposed water quality criteria. Again setting aside the issue of whether water quality standards actually apply to municipal stormwater discharges, municipal stormwater programs are long term BMP based programs. The proposed rule fails to recognize this, addressing all wet weather discharges together in one discussion. Municipal stormwater programs should be discussed and treated separately from all other wet weather and point source discharges. These are unique programs and cannot be placed in a "one-size fits all" regulatory program. The proposed rule needs to account for the nature of stormwater discharges by allowing more time for the MS4 long-term, BMP, source control program approach to take place for controlling pollutants in stormwater discharges.

The compliance schedule in the proposed rule discourages a watershed approach to improving water quality. The development and implementation of a watershed plan requires many years and many stakeholder involvements. However, the short compliance schedule in the CTR would actually encourage the discharger to forgo the watershed approach and address its toxicity issues separately and more expeditiously.

Recommendation: The rule should allow the State to establish compliance schedules. Short of this flexibility, the rule should be revised to provide a longer compliance schedule and to provide more flexible regulatory relief for MS4 dischargers who have fully complied with the MEP discharge standards but cannot achieve WQBELs compliance within the established compliance schedule. At a minimum, the CTR should follow the recommendation of the State Task Force on the Inland Surface Water Plan to provide a 15-year compliance schedule. Also provisions should be made for a longer compliance schedule when dischargers use a watershed approach to control toxic pollutants.

Response to: CTR-027-008a

See response to CTR-030-004c.

Comment ID: CTRH-001-034b
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: I-05 Compliance Schedules
References:
Attachments? N
CROSS REFERENCES I-08
G-03

Comment: Thirdly, I'd like to touch upon implementation of the rule. My understanding is that the state's Inland Surface Waters and Enclosed Bays and Estuaries Plan will address implementation of the CTR. With this in mind, the CTR should serve as an enabling rule and allow the state and the dischargers flexibility in the implementation of objectives contained in the rule.

As I touched upon earlier in my opening remarks, EPA has included some enabling provisions in this rule that we support, such as use and determination of mixing zones and water effects ratios. From the

stormwater perspective, we believe other important enabling provisions must be included to allow for regional flexibility in the implementation of our stormwater programs.

For example, enabling provisions should be included to allow flexibility in establishing compliance schedules for stormwater discharges and should allow flexibility for site-specific establishment of low-flow conditions and wet weather standards, and ranges of human health criteria depending on the use of individual receiving waters.

Response to: CTRH-001-034b

With respect to compliance schedules see response to CTR-030-004c.

The final CTR also provides flexibility for site-specific flow conditions. EPA notes that the State of California may develop alternative design flows for its waters provided that those alternative flows are scientifically defensible and protective of the designated uses of State waters. Such alternative flows will be subject to EPA review and approval. However where the State has not adopted low flow provisions, the design flows specified in today's rule shall be implemented to ensure that the criteria will be implemented appropriately to provide environmental and human health protection.

As noted in the preamble of today's rule, EPA's Technical Support Document for Water Quality-based Toxics Control (the TSD) also recommends the use of dynamic models to perform wasteload allocations. EPA is clarifying that today's rule provides the State of California with the flexibility to utilize dynamic models in establishing low flow designs. The dynamic modeling techniques, as outlined in the TSD, will enable the determination of wasteload allocations that will meet the criteria in today's rule without using a single, worst-case concentration based on a critical condition.

EPA disagrees that it must or should establish ranges of criteria depending on the use of individual receiving waters. In establishing water quality criteria for California, EPA is implementing section 303(c)(2)(B) of the CWA which requires adoption of criteria for all priority toxic pollutants for which EPA has issued criteria guidance and for which the discharge of such pollutants could reasonably be expected to interfere with the designated uses adopted by the state. EPA based the criteria contained in the CTR on its recent national criteria guidance, which are designed to protect aquatic life and human health. As long as a waterbody currently has a designated use for the protection of aquatic life and/or human health, application of the section 304(a) criteria is appropriate for fulfilling section 303(c)(2)(B). As a policy matter, EPA believes that the CTR, a massive undertaking in and of itself, is an essential first step toward reinstating a strong water quality program in California. Under the CWA, EPA has no obligation to develop such site-specific criteria or the data upon which such site-specific criteria would be based. If, however, the State wishes to develop site-specific criteria or to change the uses of the waterbody, pursuant to the regulations at 40 CFR Part 131, EPA would consider and possibly approve such a site specific criterion.

Comment ID: CTRH-002-026
Comment Author: Gary Hildebrand
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Dept of Public Works
Document Date: 09/19/97
Subject Matter Code: I-05 Compliance Schedules

References:
Attachments? N
CROSS REFERENCES

Comment: The last thing, the proposed rule provides only a five-year compliance schedule for a discharger to achieve the proposed criteria. Municipal stormwater programs are long-term programs that could take many years to fully implement and to realize any water quality benefits. Limiting municipal stormwater discharges to a five-year compliance schedule is inappropriate and impracticable.

The preamble to the proposed rule addresses all wet weather discharges. This should be discussed and treated separately from all other weather and point sources charges. These are unique programs and cannot be placed in a one size-fits-all category. The proposed rule needs to account for the nature of stormwater discharges but needs to allow a longer compliance schedule to account for the long-term BMP source control program approach. The proposed rule and corresponding compliance schedule discourages a watershed approach to improving water quality. The development and implementation of a watershed plan requires many years and various involvement. However, the CTR with a short compliance schedule would actually encourage the watershed approach and address toxicity issues separately and a little more expeditiously. The CTR should follow the recommendations of the State Task Force on the Inland Surface Water Plan than propose a 15-year schedule for full compliance.

Again, we'll be following up with written comments covering our oral testimony today. Thank you.

Response to: CTRH-002-026

See response to CTR-030-004c.

Subject Matter Code: I-07 Attainability of Criteria

Comment ID: CTR-040-005
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-07 Attainability of Criteria
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

1. Concern: The Rule, as presently proposed, appears to require discharges from municipal stormwater programs to meet water quality based effluent limits (WQBELs).

* Attaining sufficient pollutant reduction through source control and other reasonable measures can be infeasible because many sources of pollutants are extremely difficult or impossible to control. This situation is illustrated by the Sacramento Stormwater Management Program's recent experience in evaluating sources of lead in Sacramento County. This past year the Sacramento Stormwater Program conducted an intense effort to evaluate lead, an identified high priority stormwater constituent of concern for the Program. A major part of the effort was to identify all potential sources of lead to stormwater. Approximately 50 individual sources of lead were identified. The next step was to determine which of these sources could be controlled considering the nature of the sources, practicality of controlling the sources, legal jurisdiction of the permittees, etc. Only a portion of the sources identified could be addressed through source control and BMPs. Some examples of sources that are difficult or impossible to control are: naturally occurring lead in soil, aircraft fuel (which does not come in unleaded form), automobile emissions (which still contain some lead), abrasion of road striping paint, and abrasion of tires.

Response to: CTR-040-005

See response to CTR-040-004.

Comment ID: CTR-096-002
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-07 Attainability of Criteria

References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

2. Scientific data is lacking to show that impairments to waters of the United States are occurring during storm events.

Response to: CTR-096-002

Every two years, the California State Water Resources Control Board (SWRCB) submits a report on the State's water quality to the U.S. EPA pursuant to Section 305(b) of the Federal Clean Water Act. These reports present water quality assessment information compiled by California's nine Regional Water Quality Control Boards. SWRCB (1996) indicates that urban runoff and storm sewers are major and moderate sources of impairment of beneficial uses in estuaries, lakes and reservoirs, rivers and streams, and wetlands. The extent of this impairment is shown in the table below.

Sizes of Waters Impaired by Urban Runoff and Storm Sewers by Contribution to Impairment

Waterbody Type (Units)	Major^1	Moderate and Minor^2
Estuaries(Acres)	899	52,552
Lakes and Reservoirs (Acres)	120,320	7,985
Rivers and Streams (Miles)	92	1,620
Wetlands, Freshwater (Acres)	1	58,316
Wetlands, Tidal (Acres)	0	184

Source: SWRCB (1996).
1. A major contributor is a source that is either the only one responsible for nonsupport of any designated use or it predominates over other sources.
2. A moderate contributor is a source that is the only one responsible for partial support of any use, predominates over other sources of partial support, or is one of multiple sources of nonsupport that have a significant impact on designated use attainment. A minor contributor is a source that is one of multiple sources responsible for nonsupport or partial support and is judged to contribute relatively little to this nonattainment.

State Water Resources Control Board (SWRCB). 1996. California 305(b) Report on Water Quality. Prepared as Required in Clean Water Act Section 305(b). August.

Subject Matter Code: I-08 SWRCB Flexibility&Authority

Comment ID: CTR-001-010
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: I-08 SWRCB Flexibility&Authority
References:
Attachments? N
CROSS REFERENCES

Comment: EPA SHOULD ADDRESS ALL OF THE FACTORS THAT THE STATE WOULD ADDRESS UNDER THE PORTER COLOGNE ACT IN ESTABLISHING AN IMPLEMENTATION POLICY FOR MS4S

In promulgating water quality standards, EPA "is subject to the same policies, procedures, analyses, and public participation requirements established for States . . . ." 40 C.F.R. Section 131.22(c). If EPA is to stand in the shoes of the State Board in this activity, it needs to address the fundamental statutory criteria for basin plan amendments, which limits the Regional Board to adopting only those objectives that "will ensure the reasonable protection of beneficial uses and the prevention of nuisance . . . [taking into account] . . . economic considerations . . . [and] the need for developing housing within the region." Water Code Section 13241.

Under state law, the definition of water quality objectives incorporates this requirement of reasonableness, by defining objectives to mean "the limits or levels of water quality constituents or characteristics which are established for the reasonable protection of beneficial uses of water or the prevention of nuisance within a specific area." Water Code Section 13050(h).

All basin plans must implement the basic policies of Water Code Section 13000, which states that "activities and factors which may affect the quality of the waters of the state shall be regulated to attain the highest water quality which is reasonable, considering all demands being made and to be made on those waters and the total values involved, beneficial and detrimental, economic and social, tangible and intangible."

At the permitting stage, water code Section 13263(a) provides for the case-by-case consideration of site specific beneficial uses and objectives in every instance: "(discharge requirements] shall take into consideration the beneficial uses to be protected, the water quality objectives reasonably required for that purpose . . . and the provisions of Section 13241."

Even if EPA considers itself exempt from the application of these provisions of the Porter Cologne Act when it adopts water quality standards for California, by including inflexible standards that do not allow for the future consideration of costs as required by Section 13241, EPA is putting the Regional and State Boards on a collision course with these requirements when future Basin Plan and permitting decisions are made. Adequate flexibility must be included in the regulation, at minimum by preserving existing basin plan and State Board implementation policies, so that these state law requirements can be satisfied when basin planning and permitting decisions are made in the future.

Response to: CTR-001-010

EPA disagrees with this comment. EPA must adopt criteria in accordance with the requirements of the CWA. The quoted regulation means that EPA will follow the same policies, procedures, analyses, and public participation requirements as it requires for states under the CWA. The regulation does not mean that the CWA's provisions are negated by state law. As EPA explained in the CTR response to CTR-042-007a, while economic factors may be considered in designating uses, they may not be used to justify criteria that are not protective of those uses. As a Federal agency, EPA is not subject to the requirements of the Porter-Cologne Act.

The CTR does not interfere with the State's discretion to develop implementation policies including basin planning activities and permitting decisions. Federal law does allow the State to consider economics in decisions regarding changes in designated uses and variances.

Comment ID: CTRH-001-034a
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: I-08 SWRCB Flexibility&Authority
References:
Attachments? N
CROSS REFERENCES I-05; G-03

Comment: Thirdly, I'd like to touch upon implementation of the rule. My understanding is that the state's Inland Surface Waters and Enclosed Bays and Estuaries Plan will address implementation of the CTR. With this in mind, the CTR should serve as an enabling rule and allow the state and the dischargers flexibility in the implementation of objectives contained in the rule.

As I touched upon earlier in my opening remarks, EPA has included some enabling provisions in this rule that we support, such as use and determination of mixing zones and water effects ratios. From the stormwater perspective, we believe other important enabling provisions must be included to allow for regional flexibility in the implementation of our stormwater programs.

For example, enabling provisions should be included to allow flexibility in establishing compliance schedules for stormwater discharges and should allow flexibility for site-specific establishment of low-flow conditions and wet weather standards, and ranges of human health criteria depending on the use of individual receiving waters.

Response to: CTRH-001-034a

See response to CTRH-001-034b.

Subject Matter Code: I-09 Pesticides in Runoff

Comment ID: CTR-061-001
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-09 Pesticides in Runoff
References:
Attachments? Y
CROSS REFERENCES

Comment: Please find enclosed an original and two copies, and a computer disk, of my comments on the draft "US EPA 40 CFR Part 131 Water Quality Standards for the State of California" as proposed on Tuesday, August 5, 1997. As indicated, I find significant problems with the proposed approach set forth in the draft CTR for regulating some "toxics" in California waters. I also find problems with some of the criteria in that they do not represent the information on the constituents' potential impacts on the beneficial uses of waterbodies. If adopted as proposed, the CTR will lead to massive waste of public and private funds in the construction of unnecessary treatment works for domestic and industrial wastewaters and especially urban and highway stormwater runoff, in an effort to try to meet water quality standards based on the CTR proposed criteria in discharges and ambient waters without a significant improvement of real water quality/beneficial uses of waterbodies of concern to the public who must pay for the over-regulation. The proposed CTR fails to address the most important cause of real ambient-water toxicity in California, organophosphate pesticides in urban and agricultural stormwater runoff. The Agency needs to shift its toxics control program from control of chemical constituents that in some situations can be toxic, to the control of ambient water toxicity in ambient waters.

Response to: CTR-061-001

EPA disagrees. The CTR establishes the pollutant levels in ambient waters necessary to protect beneficial designated uses. Establishing numeric criteria for ambient water bodies does not limit the discretion of the permit writer to use appropriate and flexible tools such as mixing zones or translators for dissolved metals in establishing effluent limits. In addition, if a discharger believes the CTR criterion is inappropriately restrictive or overprotective of the designated use, the discharger can request the State and EPA to approve a site-specific criterion or to downgrade the designated use.

Subject Matter Code: I-10 CSO Policy

Comment ID: CTR-090-021
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: I-10 CSO Policy
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Wet weather flows - p 42186 - This section needs to be rewritten to incorporate the policy for combined sewer systems as described in EPA's Combined Sewer Overflow Control Policy. The policy includes two specific approaches for assessing compliance with water quality standards and these are not addressed in this rule-making.

Response to: CTR-090-021

See response to CTR-040-004.

Subject Matter Code: J Storm Water Economics

Comment ID: CTR-001-007
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: SIGNIFICANT ECONOMIC IMPACTS WOULD RESULT FROM THE APPLICATION OF WATER QUALITY STANDARDS AS NUMERIC EFFLUENT LIMITATIONS OR WASTELOAD ALLOCATIONS

If EPA intends that the WQS have a more direct effect on the permitting for MS4s, the implications are significant. in particular, the economic analysis supporting the proposed CTR would be dramatically incomplete. Massive expenditures would be required if storm water systems essentially were required to meet the same numerically based treatment standards as being considered for POTWs. The expenditures that would result from such an approach are being addressed in more detail in other MS4 comments, and will not be repeated here.

However, we note that the economic impact analysis that EPA prepared to support the proposed rule assumes that the regulation would have no economic impact on MS4s. (*11) If MS4s are subjected to NELs or WLAs as a result of the rule, significant economic impacts would result. Even if water quality based effluent limitations are based on BMPS, they would have an economic impact if they represent controls more extensive than the maximum extent practicable criteria of Section 402(p). EPA's economic analysis also provides no basis for estimating the costs to MS4s, since the "representative" dischargers analyzed in the economic analysis do not include any storm water systems. The economic analysis does not include these costs and it would be arbitrary to adopt a rule that would have these implications without considering those costs. (*12)

(*11) Likewise, the economic analysis supporting the State Implementation Policy excluded consideration of the costs to municipal storm water systems, on the theory that "the proposed Policy does not impose new regulatory requirements and, therefore, no additional costs are anticipated (i.e., . . . storm water . . .)" SIP at VIII-33. Elsewhere the SIP urges that: "The SWRCB is making no changes in the existing storm water program at the SWRCB and RWQCB. For these reasons, this cost analysis did not consider the storm water proposed Policy issue." Id. at VIII-43. These municipal costs were excluded even though the benefits calculations assumed that the proposed water quality standards would be achieved and that, with respect to San Francisco Bay, the share of toxic loadings attributable to nonpoint sources is estimated to range from 90% to 99% of the total. SIP at VIII-25. It is fundamental that "you can't get something for nothing" and the conflicting assumptions in the SIP, which parallel assumptions in the economic analysis of the CTR, are simply arbitrary.

(*12) Also, since EPA stands in the shoes of the state in adopting these criteria the action would violate the cost balancing elements of the Porter Cologne Act, as discussed below. At minimum, to the extent

that the rule creates an inflexible obligation to implement the criteria with respect to MS4s without complying with Porter Cologne Act requirements, it would set the State and Regional Boards on a collision course with those requirements at the Basin Plan and NPDES permitting phases.

Response to: CTR-001-007

EPA did not ascribe benefits or costs of controlling storm water discharges in the proposed or final Economic Analysis. EPA believes that many storm water dischargers can avoid violation of water quality standards through application of best management practices that are already required by current storm water permits. This conclusion is supported by EPA's analysis of the data submitted by several commenters (see response to CTR-040-004). EPA articulated its position on the use of BMPs in storm water permits in the Interim Permitting Approach for Water Quality Based Effluent Limitations in Storm Water Permits (61 FR 43761, August 19, 1996).

The commenter claims that even with the application of current BMPs, its storm water dischargers would still violate water quality standards due to the CTR criteria. The commenter appears to assume that the storm water discharge would be subject to numeric water quality based effluent limits which would be equivalent to the criteria values and applied as effluent limits never to be exceeded, or calculated in the same manner that effluent limits are calculated for other point sources, such as POTWs. The commenter then appears to assume that such WQBELs would then require the construction of very costly end-of-pipe controls.

EPA contends that neither scenario is valid with regards to developing WQBELs for storm water discharges or establishing compliance with WQBELs. EPA acknowledges that wet weather discharges are technically difficult to model and evaluate financially, because they are intermittent and highly variable. Wet weather discharges also occur under more diverse hydrologic or climatic conditions than continuous discharges from industrial or municipal facilities, which are evaluated under critical low flow or drought conditions. If the EPA had enough data to completely characterize all the conditions and do the necessary modelling, WQBELs would be developed using dynamic models to account for the intermittent loadings and exposures from the storm water discharges. In the absence of this data, EPA will continue to advocate the use of BMPs, as discussed in the CTR preamble. Therefore, EPA believes there is inadequate information at the current time to conclude whether the CTR will have any cost impact on storm water dischargers. Until that information is available, it is premature to project that storm water dischargers would be subject to strict numeric WQBELs and would incur any costs beyond those for which they are already legally responsible under the Clean Water Act. EPA will continue to work with the State to implement storm water permits that comply with water quality standards with an emphasis on pollution prevention and best management practices rather than costly end-of-pipe controls.

See also response to CTR-040-004.

EPA disagrees that the CTR must meet the requirements of the Porter Cologne Act. As a Federal agency, EPA is not subject to the requirements of the Porter-Cologne Act, which is State law. See also response to CTR-020-002 (Category C-21; Legal Issues).

Comment ID: CTR-013-003
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

3. The economic analysis used by The USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. Again, setting aside the issue of WQBELS for MS4s, the economic analysis is inadequate. Under Executive Order 12866, the USEPA must determine whether the CTR is "significant" and subject to OMB review. One of the criteria in assessing whether a proposed regulation is significant is to determine if it has an adverse affect resulting in an annual cost of $100 million or more. To address this criterion, the USEPA estimated the cost and benefit of the proposed regulations. Based on this analysis, the USEPA determined that the CTR was not a "significant regulatory action."

In its economic analysis, the USEPA's entire focus of the compliance cost was on the point sources which included Public-Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). This assumption appears to be applied to both municipal and industrial stormwater interests. We point to studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district which show this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance.

It may be argued that an MS4 would seek regulatory relief from the criteria before incurring the cost of end-of-pipe treatment. While this is probably a reasonable assumption, the economic analysis failed to address the cost for either treatment, BMP program, or regulatory relief for MS4s. As a result, the overall cost for compliance is significantly underestimated. By assigning zero cost to the MS4s for compliance, the cost benefit analysis is severely flawed.

We recommend that the USEPA not implement the proposed criteria to MS4 discharges without an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-013-003

EPA disagrees with the comment that its economic analysis is flawed or incomplete.

EPA did not include benefits or costs of controlling storm water discharges in the proposed or final Economic Analysis. EPA believes that many storm water dischargers can avoid violation of water quality standards through application of best management practices that are already required by current

storm water permits. This conclusion is supported by EPA's analysis of the data submitted by several commenters (see response to CTR-040-004). EPA articulated its position on the use of BMPs in storm water permits in the Interim Permitting Approach for Water Quality Based Effluent Limitations in Storm Water Permits (61 FR 43761, August 19, 1996).

The commenter claims that even with the application of current BMPs, its storm water dischargers would still violate water quality standards due to the CTR criteria. The commenter appears to assume that the storm water discharge would be subject to numeric water quality based effluent limits which would be equivalent to the criteria values and applied as effluent limits never to be exceeded, or calculated in the same manner that effluent limits are calculated for other point sources, such as POTWs. The commenter then appears to assume that such WQBELs would then require the construction of very costly end-of-pipe controls.

EPA contends that neither scenario is valid with regards to developing WQBELs for storm water discharges or establishing compliance with WQBELs. EPA acknowledges that wet weather discharges are technically difficult to model and evaluate financially, because they are intermittent and highly variable. Wet weather discharges also occur under more diverse hydrologic or climatic conditions than continuous discharges from industrial or municipal facilities, which are evaluated under critical low flow or drought conditions. If the EPA had enough data to completely characterize all the conditions and do the necessary modelling, WQBELs would be developed using dynamic models to account for the intermittent loadings and exposures from the storm water discharges. In the absence of this data, EPA will continue to advocate the use of BMPs, as discussed in the CTR preamble. Therefore, EPA believes there is inadequate information at the current time to conclude whether the CTR will have any cost impact on storm water dischargers. Until that information is available, it is premature to project that storm water dischargers would be subject to strict numeric WQBELs and would incur any costs beyond those for which they are already legally responsible under the Clean Water Act. EPA will continue to work with the State to implement storm water permits that comply with water quality standards with an emphasis on pollution prevention and best management practices rather than costly end-of-pipe controls.

With respect to the studies conducted by the County of Sacramento and Fresno Metropolitan Flood district see response to CTR-040-004.

Comment ID: CTR-013-008b
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

8. The proposed rule applies to all current and future MS4 dischargers, including small communities.

The small communities will be significantly impacted by the proposed rule. In Los Angeles County, 77 of the 85 co-permittee cities are communities with a population of less than 100,000. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies, however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities, however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*2), it indicates that there are no small entities to be impacted by the rule and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Therefore, unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*2) Federal Register, August 5, 1997, Vol. 62, No. 150, Page 42191

Response to: CTR-013-008b

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-014-003
Comment Author: City of Lakewood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-014 incorporates by reference letters CTR-013 and CTR-027

Attachments? N
CROSS REFERENCES

Comment: 3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-014-003

See response to CTR-013-003.

Comment ID: CTR-014-004b
Comment Author: City of Lakewood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-014 incorporates by reference letters CTR-013 and CTR-027

Attachments? N
CROSS REFERENCES R

Comment: 4. The proposed rule applies to all current and future MS4 dischargers, including small communities. These small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*1) it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase 11. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Thank you for this opportunity to comment on the proposed CTR. Respectfully,

Lisa Ann Rapp Director of Public Works

(*1) Federal Register, August 5, 1997, Vol. 62, No. 150, Page 42191

Response to: CTR-014-004b

See response to CTR-013-008b.

Comment ID: CTR-018-001
Comment Author: Ventura Countywide SWQMP
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: I would like to take this opportunity to submit in writing the specific concerns of the municipal stormwater program in Ventura County that I expressed on September 18, 1997 at the Public Hearings on the subject proposed rule.

In August of 1994, a countywide municipal NPDES permit was issued to the Ventura County Flood Control District, the County of Ventura and the ten cities in Ventura County. We are now entering the fourth year of our permit term.

At the time the eleven municipalities in Ventura County applied for the stormwater permit, only three were actually required to do so. The other eight entered the program voluntarily. In reality, five of these co-permittees would not even be required to be covered under Phase II, since their populations range from 8 to 30,000.

The Ventura Countywide Stormwater Quality Management Program was formulated to achieve compliance with the maximum extent practicable discharge standard through the use of Best Management Practices (BMPs). While the primary goal and driving force of the program is to achieve compliance with water quality standards, the economic and technological feasibility of achieving all of the proposed criteria is not practical given the diverse nature of an urbanized area, the number of discharge points and the numerous sources of pollutants for urban runoff.

Under our monitoring program, we have collected urban runoff water quality data for the past four years. The attainability analysis-using this data has indicated that even if a BMP program was fully implemented at exorbitant expense, we may not be able to achieve compliance with proposed criteria for copper, lead, zinc, thallium, nickel, and silver.

The alternative to BMP implementation would be to collect and treat stormwater discharges. Stormwater regulations make it clear that municipal stormwater permits are to implement programs to address the sources of pollutants, not to provide end of pipe treatment.

Although the cost of compliance with this rule will significantly impact all communities, the cost could be even more significant and prohibitive for the smaller ones that have made a proactive choice to apply for permit coverage. Currently, in Ventura County, we are spending approximately $5.00 per capita to implement a BMP based program. Yet the economic analysis concludes that the maximum cost of implementing the California Toxics Rule in California, for all dischargers, will be approximately $2.50 to $3.00 per person. We believe that the economic analysis for the proposed rule has not accurately evaluated the financial impact to municipalities, particularly the smaller ones.

Thank you for the opportunity to provide comments to the proposed rule. If you have any questions or would like to discuss these comments further, feel free to call me at (805)654-2040,

Response to: CTR-018-001

See responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-019-001b
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES I-01

Comment: We recognize that the basic purpose for the proposed rule is to establish water quality criteria for priority toxic pollutants for point source discharges. However, in proposing to extend that criteria to storm water discharges, it is clear that EPA has not fully assessed the potential impact of such an extension on local governmental agencies, nor the complete lack of feasibility of attempting to apply numeric effluent standards to discharges to municipal separate storm sewer systems ("MS4s"), or the enormous cost of such an effort which would potentially require a complete reengineering and if not reconstruction of MS4s in California to include end-of-pipe treatment.

Our comments should be considered in the proper context. The cities which we represent are acutely aware of the problems associated with pollution from... urban runoff. Their residents and businesses share a common concern to preserve and enhance the water quality of our bays, rivers, estuaries and the Pacific Ocean. Our cities are fully committed to doing what they reasonably can to achieve these objectives. Our cities have been working with staff of the State Water Resources Control Board ("SWRCB") and its Regional Water Quality Control Boards ("RWQCB's") to develop effective storm water management programs under current municipal NPDES permits which comply with state and federal law. However, the proposed rule does not appear to reflect or recognize that individual cities'

fiscal and administrative resources for implementing unfunded mandates are limited. Of all governmental agencies in California involved in the process, the many small cities which we represent are the least suited to bear the brunt of the responsibility for controlling pollution from urban runoff.

The primary portion of the proposed rule that has caused concern among our cities is the statement at pages 42186-42187 of preamble that:

"When this rulemaking is complete, these criteria will be used to determine water-quality standards in California and will therefore be the basis of WQBELs in NPDES permits for wet weather point sources. However, EPA recognizes that it is commonly infeasible to express WQBELs as numeric limits for wet weather discharges and that in such cases best management practices ("BMPs") may serve as WQBELS. (Emphasis added.)

Our concern is further heightened by the comment at page 42187 of preamble that:

"It is therefore anticipated that WQBELS, including those necessary to meet the criteria set forth in this proposed rule, will be expressed as BMPs in wet weather dischargers' NPDES permits, when the permitting authority determines that it is infeasible to express WQBELS as numeric limits." (Emphasis added.)

The comments appear to indicate that in any further municipal NPDES permitting situations, the proposed rule potentially can be interpreted to require the implementation of WQBELs unless an analysis is prepared determining the infeasibility of each of the WQBELs as numeric limits.

As applied to storm water discharges, WQBELs are almost by definition infeasible. It should also be kept in mind that it is not the cities themselves that are the sources of stormwater pollution; municipal facilities have not been identified, to our knowledge, as being significant sources of contaminated urban runoff. Rather, the sources of this type of pollution, to the extent they can be identified, appear to be primarily the result of hydrological changes brought about by urbanization. These are activities over which cities have very little practical control. Nevertheless, the cities and counties of California are bearing the full and financially unassisted responsibility of ending stormwater pollution themselves.

We agree with the comments of the County of Los Angeles and the ACCWP that EPA's effort to apply numeric effluent limits to municipal storm water discharges is in direct conflict with the plain language of Congress in adopting the "maximum extent practicable" standard for controlling pollution in storm water discharges to a MS4. The proposed rule as applied to wet weather flows is also clearly inconsistent with both the EPA Is and the SWRCB's approach of addressing this problems through the adoption of Best Management Practices ("BMP's").

As noted in the SWRCB's own Municipal Storm Water Best Management and Practices Guidebook, "the sources of storm water pollution are extensive, ill-defined and highly variable." The State Board previously determined in its order entitled "In the Matter of Petition of Natural Resources Defense Council, Inc. for Review of Waste Discharge Requirements Order No. 90-079," Order No. WQ 91-04 (May 16, 1991), that:

"We find here also that the approach of the Regional Board requiring the dischargers to implement a program of best management practices which will reduce pollutants and runoff and prohibiting non-storm water discharges, is appropriate and proper. We base our conclusion on the difficulty of establishing numeric effluent limitations which have a rational basis, the lack of technology available to treat storm water discharges at the end of the pipe, the huge expense such treatment would entail, and the level of

pollutant reduction which we anticipate from the Board's regulatory program. We feel compelled to note here our agreement with the Regional Board that this permit does truly represent a massive undertaking." (Emphasis added.)

As discussed in detail in the technical comments filed in response to the proposed rule, the EPA has not explained how the proposed numeric effluent guidelines can be achieved through the implementation of BMP's. Under the circumstances, the ultimate result of the application of the rule to storm water discharges would be end of pipe treatment controls.

However, the EPA has already recognized, as the SWRCB, that end of pipe treatment controls for storm water discharges are technically unfeasible and unreasonable. The EPA has recognized that "it was not the intent of Congress to acquire municipal permits to required end of pipe treatment technology but to implement a comprehensive stormwater management program to reduce the discharge of pollutants from municipal storm sewer systems." 55 Fed.Reg., p. 48038 (November 16, 1990).

Each of our cities strongly believe that the proposed rule must be modified to clearly state that numeric effluent guidelines do not and will not apply to discharges to the municipal separate sewer systems.

Response to: CTR-019-001b

See response to CTR-040-004.

Comment ID: CTR-019-002a
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES S

Comment: UNFUNDED MANDATED PROGRAMS

One of the express purposes of the Unfunded Mandates Reform Act of 1995 is "to end the imposition, in the absence of full consideration of Congress of Federal mandates on State, local and tribal governments without adequate Federal funding, in a manner that may displace other essential State, local and tribal governmental priorities." 2 U.S.C. section 1501(2). The proposed rule in its current form seems to have been drafted without regard to its fiscal impact on cities. The rule could require treatment of storm water discharges, despite the fact that no funding mechanism, nor any assistance, financial or otherwise, is being provided to the cities by either USEPA or the State of California. If the USEPA wishes to impose these treatment programs, it needs to provide funds to pay for their implementation.

We believe that USEPA's analysis under the Unfunded Mandates Reform Act of 1995 that the CTR will not result in an expenditure in the aggregate of more than $100,000,000.00 a year is wrong. As pointed

by other local government entities which have submitted comments, the USEPA appears to assume that a BMP program will lead to compliance with numeric effluent guidelines and that there will be no associated additional costs for the BMP program. However, the economic analysis does not appear to analyze the potential cost of end of pipe treatment controls and analyze in any sort of detail what sort of BMP's would be necessary to achieve numeric effluent guidelines for the toxic pollutants. The economic analysis itself acknowledges that under its existing NPDES stormwater permit, the cities and counties of the Los Angeles area plan to spend $15,000,000 annually on public education in a program to curb illegal dumping. That cost estimate was based upon the analysis by the SWRCB of the 1990 permit. The actual costs of implementing all of the programs under the 1990 permit have been considerably more. For example, the cost estimates prepared by the San Gabriel Valley COG in connection with the LA. County permit, estimated implementation costs at $8.98 per person per year. The City of Long Beach estimated that it was already spending, as of early 1996, $12.4 million a year and that the estimated costs of implementing the programs under the current permit adopted in July 1996 would be another $3.4 million or about $16.1 million total. That number extrapolated to approximately $38.35 per person per year. The comparative cost numbers prepared by the Santa Monica Bay Restoration Project in connection with the existing Los Angeles permit estimated an average cost of dedicated stormwater program funding of $3.34 a month per household or approximately $13.36 per person per year. Using that number as a base, a city with a population of approximately $40,000 people can expect to spend $500,000 a year under its current stormwater programs. Extrapolating those numbers over the State of California, it is quite clear that the costs of implementing the existing stormwater program are in the hundred of millions of dollars a year.

Considering these economic analyses, it is quite clear that the financial impact of requiring end of pipe treatment controls or other means to achieve numeric effluent guidelines would quite easily exceed $100 million a year.

The foregoing numbers, of course, do not include potential increased costs to residents, business and industry complying with the discharge prohibitions and other requirements under the City's current municipal permits nor does the EPA's economic analysis calculate the potential costs to regulated dischargers, that is, business and industries required to either obtain an individual NPDES stormwater permit or who are covered under a general permit by filing a notice of intent.

Necessarily, the expenditure of such large amounts of money is an important public policy question, particularly in a situation where neither the State of California nor the federal government has been willing to provide any meaningful source of funds to local agencies to carry out these programs.

Response to: CTR-019-002a

See response to CTR-013-003.

With respect to EPA's compliance with UMRA see the preamble to the final rule.

Comment ID: CTR-019-003a
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97

Subject Matter Code: J Storm Water Economics
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES R

Comment: THE PROPOSED RULE DOES NOT COMPLY WITH THE REGULATORY FLEXIBILITY ACT

USEPA's analysis under the Regulatory Flexibility Act and Executive Order No. 12866 that the CTR will not affect a significant number of small entities is simply wrong. Most of the cities which we represent have populations of less than 20,000; many have less than 10,000. As noted by the County of Los Angeles, 77 of the co-permittee cities have populations of less than 100,000. Many of these cities are primarily residential and with limited tax revenues. Nevertheless the proposed CTR would impose the same financial requirements on these cities as would be imposed on larger entities. These cities do not receive funds from either the State of California or the federal government for their storm water programs or other urban runoff control measures.

Response to: CTR-019-003a

EPA believes it properly described the potential impact of the implementation of the CTR on storm water discharges in the preamble to the proposed CTR and in its Economic Analysis (for further discussion see responses to CTR-013-003 and CTR-040-004). EPA believes it is in full compliance with its legal obligations under Executive Order 12866 (see response to CTRH-002-006a; Category I: Stormwater/Wet Weather Flows), the Regulatory Flexibility Act (see response to CTR-013-008b).

Comment ID: CTR-021-006a
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyva
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c
R
S
I-01

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

3. Failure to Address Important Stormwater-Related Issues. In addition to its POTW, Sunnyvale is the

owner of a system of storm drains which contribute wet weather flows to the South Bay. We are concerned that the EA entirely neglects the potential impacts of the proposed CTR on the storm drains. The EA entirely omits any meaningful analysis of the costs of bringing storm drains into compliance with the proposed CTR, thereby significantly understating the overall costs of the CTR. We believe that this omission is violative of the Agency's legal obligations under the authorities cited in the preceding paragraph.

In addition, we join in the comments being filed by the various other operators of stormwater collection systems to the effect that EPA has overstated the legal requirements for storm drains to comply with numerical criteria.

Response to: CTR-021-006a

EPA believes it properly described the potential impact of the implementation of the CTR on storm water dischargers in the preamble to the proposed CTR and in its Economic Analysis (for further discussion see responses to CTR-013-003 and CTR-040-004). EPA believes it is in full compliance with its legal obligations under Executive Order 12866 (see response to CTRH-002-006a; Category I: Stormwater/Wet Weather Flows), the Regulatory Flexibility Act (see response to CTR-013-008b), and the Unfunded Mandates Act (see preamble to the final rule).

Comment ID: CTR-024-003
Comment Author: City of Hawthorne
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-024 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: 3. The economic analysis used by The USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA Is economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost of a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-024-003

See response to CTR-013-003.

Comment ID: CTR-024-004b
Comment Author: City of Hawthorne
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-024 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: 4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*1), it indicates that there are no small entities to be impacted by the rule, and therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*1) Federal Register, August 5, 1997, Vol. 62, No. 150, page 42191

Response to: CTR-024-004b

See response to CTR-013-008b.

Comment ID: CTR-027-003
Comment Author: California SWQTF
Document Type: Storm Water Auth.

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: 3. The economic analysis used by USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. Again setting aside the issue of WQBELs for MS4s, the economic analysis is inadequate. Under Executive Order 12866 USEPA must determine whether the CTR is "significant" and subject to OMB review. One of the criteria in assessing whether a proposed regulation is significant is to determine if it has an adverse effect resulting in an annual cost of $100 million or more. To address this criterion USEPA estimated the cost and benefit of the proposed regulations. Based on this analysis USEPA determined that the CTR was not a "significant regulatory action".

USEPA used two different economic models in assessing the CTR. The model that proved more applicable consisted of an analysis that focused on direct compliance costs (such as capital costs and O&M for end-of-pipe control, indirect source control, (e.g. pretreatment programs) pollution prevention, monitoring and costs for pursuing alternative methods of compliance). However, the entire focus of the compliance cost was on the point sources with individual NPDES permits, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in USEPA's analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP program (over and above what an MS4 has in place already). This assumption appears to be applied to both municipal and industrial stormwater interests. We point to studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District which show this to be incorrect, i.e. an aggressive BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for an aggressive BMP program is significant and would increase much more substantially if an MS4 was required to construct end-of-pipe treatment for compliance.

It may be argued that an MS4 would seek regulatory relief from the criteria before incurring the cost of end-of-pipe treatment. Even assuming such relief would be forthcoming, the economic analysis failed to address the cost for treatment, or for a BMP program, or for seeking regulatory relief for MS4s. As a result the overall cost for compliance is significantly underestimated. By assigning zero cost to the MS4s for compliance, the cost benefit analysis is severely flawed.

Recommendation: USEPA should not implement the proposed criteria until such time an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-027-003

See response to CTR-013-003.

Comment ID: CTR-027-009b

Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES R

Comment: 9. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems if the proposed criteria are adopted. While most small communities have not conducted discharge characterization studies; it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless EPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule (*3), USEPA indicates that no small entities are impacted by the rule, and, therefore, USEPA did not need to complete an analysis required under the Act. USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. USEPA should have conducted an analysis on the economic impacts to smaller communities.

Recommendation: Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be promulgated until USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*3) Federal Register, August 5, 1997, Vol. 62, No. 150, page 42191

Response to: CTR-027-009b

See response to CTR-013-008b.

Comment ID: CTR-027-010
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N

CROSS REFERENCES

Comment: 10. The proposed rule failed to address the economic impacts it may have on industrial stormwater dischargers. Industrial stormwater dischargers that are currently regulated by a stormwater permit, and all future industrial dischargers that will come into the program under Phase II will be required to comply with the proposed criteria. Cost of compliance with the proposed criteria for certain industries may be prohibitive, yet USEPA did not address this potential impact in its economic analysis. In addition many of these industries are small entities that should be addressed under the Regulatory Flexibility Act.

Recommendation: The proposed rule should not be promulgated until USEPA conducts an adequate economic analysis that addresses the economic impact the rule may have on industrial stormwater dischargers, including the impact to small industries.

Response to: CTR-027-010

EPA believes it that it has conducted an adequate analysis which addresses industrial stormwater dischargers and that the CTR must be promulgated under the Clean Water Act. For further discussion see responses to CTR-013-003 and CTR-013-008b.

Comment ID: CTR-028-001b
Comment Author: City of Folsom
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-028 incorporates by reference letter CTR-040
Attachments? N
CROSS REFERENCES R

Comment: The City is a small community with a population of less than 50,000. We volunteered to participate in the Sacramento Stormwater Management Program as a co-permittee on the NPDES permit because we understood that it was a BMP-based program aimed at reducing the discharge of pollutants to the maximum extent practicable. We are very concerned with the CTR's Preamble statement that municipal stormwater agencies must comply with effluent limitations based on water quality criteria. As the County has stated in its comments, this will result in enormous costs without producing significant environmental benefits.

We are also concerned that the EPA Administrator has certified that the CTR will have no effect on small entities such as the City. Based on the estimated compliance costs prepared by the County and the statewide estimates prepared by the California Storm Water Quality Task Force, the CTR will have significant economic effects on small communities throughout the State. For example, our proportional share of the countywide costs to comply with effluent limitations, based on the proposed water quality criteria, could be over $10 million per year.

We urge EPA to reconsider its position that municipal stormwater discharges must comply with water quality standards. EPA should remove the Preamble statement or clarify that municipal stormwater

discharges are only required to reduce the discharge of pollutants to the maximum extent practicable.

Alternatively, EPA must revise its economic analysis to include the costs to municipal stormwater agencies and the EPA Administrator must withdraw her certification and, pursuant to the requirements of the Regulatory Flexibility Act, assess the economic impacts of the CTR on small entities.

Response to: CTR-028-001b

See response to Comment CTR-013-003, CTR-013-008b, and CTR-040-004.

Comment ID: CTR-031-002d
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES F
C-17a
C-17b
V

Comment: 2. Since the preamble implies that CTR criteria may be applied in NPDES permits for municipal storm water dischargers as numeric effluent limitations, the proposed rule is flawed with regard to: a) setting attainable, scientifically valid criteria in a manner consistent with state and federal regulatory approaches; b) assessing the potential economic impact on the public served by municipal storm water dischargers; c) assessing environmental impacts pursuant to the National Environmental Policy Act and the Endangered Species Act; and d) providing for the coordinated review and evaluation of the proposed CTR in conjunction with the proposed State Implementation Plan.

Response to: CTR-031-002d

See response to CTR-013-003.

With respect to comments about the Endangered Species Act see response to CTR-031-002e (Category V; Collaborative Approach). With respect to the comment about coordination with the State Implementation Plan see response to CTR-031-008b (Category V; Collaborative Approach).

Comment ID: CTR-031-006a
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics

References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES R
E-01c

Comment: b. If the CTR as proposed in the current draft is applied to municipal storm water dischargers so as to require numeric effluent limitations in municipal stormwater permits, the cost to the public will be phenomenal. In the economic analysis of the CTR, EPA failed to consider these costs, and failed to consider the costs to industrial storm water dischargers as well.

The District Is urban storm water drainage system captures through retention 90% of its annual average runoff, and discharges 90% after detention (1% is directly discharged without treatment). The system cost in 1997 dollars is estimated at $500 million.

The only option available to the District to mitigate violations of the proposed criteria would be to expand system storage to capture 100% of average annual runoff. Increasing system storage by 20,000 acre feet (estimated additional storage required for average years), at the current cost of $11,000-$20,00 per acre foot of storage, would result in a capital expenditure of $220,000,000 to $400,000,000.

Even with this exorbitant investment, in approximately half of the rain seasons storage would be exceeded, and 100% of the discharges would be expected to exceed the dissolved metals criteria noted above.

Smaller cities (under 50,000) in California are currently subject to NPDES municipal storm water discharge permits, and many more will be included upon implementation of the Stormwater Phase II program. EPA's failure to assess economic impacts on small cities would appear to be contrary to the requirements of the Federal Regulatory Flexibility Act.

The District includes in its constituency industrial businesses. The District serves these businesses and assists in the oversight of their pollution prevention and storm water permit compliance efforts. Regardless of EPA' s approach to applying the CTR to municipal storm water permits, industrial storm water dischargers are directly and seriously affected by application of the CTR. EPA's failure to assess these economic impacts on our communities is short-sighted and a breach of good public policy.

Response to: CTR-031-006a

With respect to the commenter's estimate of its stormwater costs see response to CTR-040-004. With respect to EPA's compliance with the Regulatory Flexibility Act see response to CTR-013-008b.

Comment ID: CTR-034-014e
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N

CROSS REFERENCES E-01g08
E-01b
E-01e
E-01v

Comment: * In general, we are pleased that EPA prepared an analysis of the economic impacts of the proposed CTR, and that a major portion of EPA's work focused on determining the potential impacts on POTWs. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Detailed comments can be found in Attachment 2. A few of the areas of concern are listed below:

* Small facilities appear to be under represented in EPA's sample of POTWS, especially for minor dischargers.

* The cost triggers used as regulatory relief thresholds are unrealistic, and are not consistent with EPA regulations and policies.

* The assumptions used to determine cost estimates for indirect dischargers appear to omit a large proportion of potentially affected industries.

* The Economic Analysis does not take into account projected population and industrial growth over time, which may influence effluent quality and quantity. Statewide, the population is projected to grow by nearly 50% by 2020.

* The use of average cost estimates masks economic impacts on individual dischargers, which may be particularly acute for small communities.

* The economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-034-014e

For analysis of the final CTR, EPA updated its Economic Analysis to reflect the most recent data and information for each sample facility and also increased the sample size for minor facilities. Based on this revised analysis, EPA estimated that minor POTWs will incur costs of approximately $5,000 per facility per year under the low cost scenario and $7,800 per facility per year under the high cost scenario.

EPA acknowledges that evaluating the impact of each individual direct discharger to inland waters, enclosed bays, and estuaries within the State of California would be the most accurate method to determine impacts of the CTR. However, the resources that would be required to perform such an analysis for each of the over 1,241 direct dischargers are beyond the resources typically available for development of environmental regulations. Therefore, in developing the methodology for estimating the compliance costs for the proposed CTR, time and budget constraints limited EPA's costing review to a subset of the regulated community. However, EPA believes that the sample selected adequately represents the various types of direct dischargers in the State.

EPA acknowledges that minor dischargers were sampled less frequently as compared to the major dischargers. However, by definition, under the NPDES permit program, facilities classified as minor would not be expected to discharge toxic pollutants in toxic amounts. Since the CTR addresses only

toxic pollutants, EPA would not expect significant, if any, impact to minor dischargers.

In analyses of the final CTR, EPA increased the sample of minors by five randomly selected facilities to bolster its analysis. EPA estimated costs of $872 per minor facility under the low scenario, and $2,682 per minor facility under the high scenario due to the CTR.

EPA also replaced Silvergate with South Bay in the sample in order to improve the estimate of the impacts of the CTR on the electric utility industry. The draft CTR cost analysis included costs for Silvergate, but the facility had closed and the data available was over five years old. The addition of South Bay, an electric utility facility with no costs, to the sample results in a more realistic, lower overall cost estimate for the electric utility industry.

As described in EA that accompanied the proposed CTR (SAIC and Jones and Stokes Associates, 1997), EPA assumed that regulatory alternatives such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc., are considered under certain circumstances. Specifically, under the low-end scenario, regulatory alternatives were assumed necessary if the cost for a sample facility exceeded $200 per toxic pounds-equivalent.

EPA assumes that a facility, when faced with the challenge of meeting water quality-based effluent limitations (WQBELs) based on CTR criteria, will select the most cost-effective controls, including regulatory alternatives. In fact, this has been the case in California, where several major POTWs have performed studies in pursuit of regulatory alternatives such as metals translators and site-specific criteria, rather than install costly controls to comply with WQBELs. EPA acknowledges that the actual cost-effectiveness value will vary by facility depending upon many factors, including the characteristics and volume of discharge, the receiving water, etc. However, EPA disagrees that the cost trigger is unrealistic, as it was reasonably based upon the highest reported cost-effectiveness values for industry categories subject to effluent limitations guidelines and standards.

Nonetheless, in the high-end estimate developed for the cost analysis accompanying the final CTR, no cost trigger was used and, thus, EPA's high-end cost estimate did not include the use of a regulatory alternative for any sample facility.

Reference: SAIC and Jones and Stokes Associates, Inc. 1997. Analysis of Potential Costs Related to the Implementation of the California Toxics Rule. Prepared for U.S. EPA, Office of Science and Technology and U.S. EPA Region IX, May 5.

EPA disagrees with the commenter's assertion that the costs for San Jose and Sunnyvale cannot be used to extrapolate costs to indirect users at other POTWs. The procedures for identifying indirect sources contributing specific pollutants to POTWs and developing and implementing a source control plan to minimize these discharges are similar for all types of pollutants. Additionally, similar to San Jose and Sunnyvale, metals were the primary pollutants of concern for POTWs evaluated in the cost analysis. Apart from these studies, EPA has no data upon which to establish facility-level compliance costs for indirect dischargers. To account for this uncertainty, EPA has revised its assumption regarding the percentages of indirect dischargers that may incur these costs. The percentage of facilities that may incur these costs was revised from the initial estimate of from 10% to 30% to a new estimate of from 30% to 70%. EPA believes that these new estimates are highly conservative (i.e. tend to overestimate costs).

Average per facility investment costs for industrial participants were estimated using the mass audit studies for copper and nickel pollution prevention projects with paybacks of less than five years. The average cost per indirect discharger was estimated to be $61,526 or $15,000 per year at an interest rate of

7 percent and over a period of five years. The total annual costs to the indirect discharger population in California then were estimated by multiplying the annualized cost ($15,000) by the total number of potentially affected indirect dischargers.

Under the MAS, the pounds removed by the pollution prevention projects with paybacks of less than five years were 560 pounds per year for copper and 148 pounds per year for nickel. Since neither San Jose nor Sunnyvale required nickel reductions, EPA did not consider pounds removed. Both San Jose and Sunnyvale did require copper reductions under the high-end cost analysis. For San Jose, required reductions equaled approximately 746 non-toxic-weighted pounds per year, however, for Sunnyvale, required reductions equaled 87 pounds per year. Since the industrial facilities to which the MAS results were applied are not as large as the San Jose facility (160 million gallons per day) whose reduction requirements exceed the MAS results, EPA estimated that load reductions from implementing the pollution prevention projects would be adequate.

EPA estimated annual (steady state) benefits and annualized costs. EPA also compared, 20- and 30-years streams of benefits and costs to account for differences in the schedule for experiencing benefits and costs (up-front capital cost and a phase-in of benefits). EPA did not forecast economic, demographic, or policy changes over these time periods. However, EPA does not expect changes in these variables to negatively impact the anticipated ratio of benefits and costs. Instead, EPA believes that increased population and economic activity in the future would likely increase the benefits of achieving standards for toxic pollutants in California waters compared to the cost of controls.

EPA selected sample facilities in order to represent different industry categories, but also various facility sizes with different flow magnitudes. For example, EPA analyzed POTW facilities which fell into three flow categories representing facilities serving very large, medium, and small communities. Costs were averaged for the sample facilities within each flow category for an industry type and then extrapolated to the universe of facilities which matched the industry type and the range in flow for that flow category. Thus, costs calculated for facilities operating in very large communities would not be applied to facilities serving very small communities.

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is either unknown at this time or not a result of this rule. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs that are distinct from the CTR.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive. Until this information is available, it is premature to project that the sources would incur any costs beyond those for which they are already responsible under current regulations of the Clean Water Act.

See also responses to CTR-013-003 and CTR-040-004.

Comment ID: CTR-035-044c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES E-01c01
E-01d01

Comment: pp. 42188-42189 - Potential Costs Do Not Meet the $100 Million Threshold Under E 0. 12866 (also see discussion above) As noted on p. 42188, one component of the definition of a "significant regulatory action" is that the rule may have an annual effect on the economy of $100 million or more. EPA states on p.42189 that "the annualized potential costs that direct and indirect dischargers may incur as a result of State implementation of permit limits based on water quality standards using today's proposed criteria are estimated to be between $15 million and $87 million." We believe that this range significantly underestimates the potential costs that may be realized from the implementation of this rule. This belief is based on the numerous assumptions used by EPA that would have served to underestimate potential costs, including assumptions about regulatory flexibility that are clearly contradicted in the Preamble to the rule itself. These issues are further enumerated in Attachment 2, which contains an analysis prepared by the environmental economics firm, M. Cubed. Furthermore, we strongly believe that EPA has a duty to look at a full range of potential costs that may be incurred, and not just to look at the costs under optimistic assumptions. This duty is especially acute in light of the uncertainties of how the CTR will be implemented by the State.

We examined the potential costs for the POTW sector to determine the reasonableness of EPA's cost estimates. Our preliminary analysis indicates that for 23 major POTWs the annualized costs could reach $400 million.(*3) This estimate includes the cost to construct and operate end-of-pipe treatment processes where these would be necessary to achieve projected effluent limits. Unlike the EPA cost estimates, we have assumed that regulatory relief options may not be available, and that, based on the pollutants causing compliance problems, pollution prevention and treatment plant optimization might not be sufficient to reliably achieve compliance. Thus, we feel that this estimate reflects a more accurate depiction of the potential POTW "high-end" compliance costs that could result from the draft CTR. Based on this analysis, we believe that EPA should re-analyze the potential costs for POTWs to meet water quality-based effluent limits based on the criteria in the CTR.

As noted on p. ES-2 of the Economic Analysis (U.S. EPA, 1997a), EPA estimated only the costs to point sources, and did not estimate the potential costs for compliance for nonpoint source dischargers, despite the fact that the majority of water bodies in California are impaired due to nonpoint source discharges (SWRCB, 1996). In addition, EPA failed to estimate the costs of compliance for wet weather dischargers, such as municipal and industrial stormwater dischargers. These omissions also lead us to believe that the potential total costs of the rule are far greater than $100 million. EPA must correct these deficiencies and redo the Economic Analysis.

(*3) Backup information for these cost estimates is available upon request.

Response to: CTR-035-044c

In response to comments received by EPA on the economic analysis that accompanied the proposed CTR, EPA collected additional data for the sample facilities. EPA also revised its estimate of potential compliance costs attributable to the CTR.

EPA's low estimate of total annualized costs of the final CTR is $33.5 million per year and its high estimate is $61.0 million per year. The low and high estimates vary based on whether effluent data or permit limits are used to assess the need for additional controls. They also vary based on whether or not alternative regulatory approaches, such as phased total maximum daily loads/water quality assessments, site-specific criteria modifications, standards variances, metals translators, etc., are considered under certain circumstances. EPA believes that its estimates of costs and benefits are sound.

EPA believes that several general observations can be made regarding studies submitted by commenters and how they differ from the EPA cost study for the final CTR. Many commenters assumed that the mere presence of a pollutant would result in costs to comply with a CTR-based WQBEL. It should be noted that the presence of a pollutant in an ambient inland water, enclosed bay, or estuary does not require permitting authorities to establish a WQBEL for that pollutant. The establishment of a permit limit is appropriate only where the permitting authority determines that a pollutant is likely to be present, and that the pollutant concentration has a "reasonable potential" to cause or contribute to an exceedance of the applicable water quality standard. Where the pollutant is not likely to be present, or is not present at levels that have reasonable potential to cause or contribute to a water quality standard exceedance, a WQBEL may not be necessary.

The majority of cost estimates provided by commenters include the costs for the addition of end-of-pipe treatment to achieve proposed CTR-based WQBELs. This was particularly the case when WQBELs were expected to be below analytical detection levels. EPA disagrees that end-of-pipe treatment is necessary to achieve CTR-based WQBELs in all cases. As discussed in SAIC (1995), there are documented cases where waste minimization or source control techniques have been used to comply with existing permit limits established below detection levels. Other examples include the Western Lake Superior Sanitary District (WLSSD), who after evaluating the costs involved to meet more stringent WQBELs for mercury with end-of-pipe treatment, concluded that pollution prevention techniques were the preferable control strategy. As a result, WLSSD published a guide designed to "assist wastewater treatment plant staff with creating and implementing their own mercury reduction projects." As a result of the efforts of WLSSD, effluent mercury levels were found to decrease from 0.58 parts per billion (ppb) to 0.015 ppb.

Although waste minimization or source controls are not always applicable, EPA assumes in its low estimate of costs that a facility would first evaluate whether process changes or modifications are feasible, prior to incurring costs for adding treatment.

In addition, many commenters assumed that compliance would be based on the WQBEL, regardless of whether it is below the analytical method detection level (MDL). This is not consistent with current practice. Instead, the State may use the "minimum level" (ML) (as defined in 40 CFR Part 136) as the required compliance point where a permit limit is established at a value below the MDL. The ML is a value at which the limited parameter can be accurately quantified, and is always greater than or equal to the MDL. To ensure that its cost estimates were conservative (i.e., erring on the side of higher costs),

EPA used the MDL as the compliance level. Although EPA used the pollutant MDL for costing purposes, the Agency acknowledges that estimating treatment costs for WQBELs below the MDL is speculative and likely unrealistic.

Finally, many of the commenters included costs related to installation of treatment for storm water discharges. As further described in the responses to CTR-021-008, CTR-013-003 and CTR-040-004, EPA believes that the final CTR will not significantly affect the current storm water program being implemented by the State, which includes the requirement to develop best management practices to control pollutants in storm water discharges. As such, EPA believes that inclusion of end-of-pipe treatment costs for storm water are inappropriate.

With respect to EPA's analysis of nonpoint source dischargers see response to CTR-034-014e.

Reference: SAIC. 1995. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. Prepared for U.S. EPA, Office of Science and Technology, March 13.

Comment ID: CTR-036-002a
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES E-01c

Comment: Cost to Implement the Proposed Rule

The inclusion of municipal stormwater discharges under the proposed rule renders the economic analysis invalid, noting municipal studies that show that stormwater discharges cannot comply with all of the proposed criteria with anything short of major national or regional product substitutions, or end-of-pipe treatment:

The Fresno Metropolitan Flood Control District conducted an attainability analysis on stormwater discharges from its urbanized area detention basins. The analysis showed that even with pollutant reductions in the basins, the proposed criteria would not be met.

The Sacramento Stormwater Program conducted an attainability analysis and found that even with an aggressive BMP program the urbanized area would not achieve certain of the water quality criteria, and that the cost of treatment would be on the order of $2 billion.

A preliminary attainability analysis conducted by Orange County, based on a limited dataset, indicates similar findings to Fresno and Sacramento in spite of the implementation of a significant BMP program over a multi-year period (see Attachment 2).

A nationwide attainability study, conducted by American Public Works Association in 1992, estimated capital costs and annual operations costs to be $406,734,900,000 and $542,036,700,000. Significantly, these estimates omitted the costs associated with engineering, administration, permitting and land acquisition.

Even if end-of-pipe treatment were to be implemented for all urban stormwater, the contribution of toxic pollutants from this source is so minor (less than 3% according to the economic analysis) that they could not be justified by the marginal water quality benefits achieved. Clearly a rule that is known from the outset to inevitably result in massive expenditures which provide little water quality benefit or inevitable municipal noncompliance is not appropriate for California.

The rulemaking process of the federal government is obligated to fully explore the economic implications of the proposed regulatory action through compliance with Executive Order 12866, the Unfunded Mandates Report Act, of 1995 (the "Reform Act"), and the Regulatory Flexibility Act (the "RFA"). In its economic analysis EPA appears to have understated costs and circumvented these requirements resulting in a lack of disclosure of the true impacts of the Rule.

Executive Order 12866 requires any "significant" federal regulatory action to be referred to the Office of Management and Budget for review before it can be approved. In this context a "significant" action includes one which will "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy". Though admitting that there "may be a cost to some dischargers" to comply with water quality standards which will be derived from these toxics criteria, EPA nonetheless argues that the proposed rule is not a significant action because it "establishes ambient water quality criteria which. by themselves, do not directly impose economic impacts." [62 Fed. Reg. 42188].

First nothing in E.O. 12866 indicates that only actions with direct economic impacts are to be considered by OMB. Second, for EPA to ignore the link between the toxics criteria contained in the proposed rule and the obligations they impose is unfounded.

In short, EPA cannot have it both ways. It cannot indicate that stormwater discharges are subject to the proposed toxics rule and then turn a blind eye toward the costs associated with implementation of this rule. The costs of the proposed rule are direct and significant, greatly exceeding the annual % 100 million threshold, and therefore the rule must be submitted to OMB for review.

Response to: CTR-036-002a

EPA believes it properly described the potential impact of the implementation of the CTR on storm drains in the preamble to the proposed CTR and in its Economic Analysis (for further discussion see response to CTR-013-003). With respect to the analyses by the Fresno Metropolitan Flood District and the Sacramento Stormwater program see response to CTR-040-004. EPA believes it is in full compliance with its legal obligations under Executive Order 12866 (see response to CTRH-002-006a; Category I: Stormwater/Wet Weather Flows), the Regulatory Flexibility Act (see the preamble to today's rule, response to CTR-013-008b, and CTR-050-007a), and the Unfunded Mandates Act (see the preamble to today's rule and response to CTR-036-006a).

Comment ID: CTR-036-003b
Comment Author: County of Orange
Document Type: Local Government

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES S

Comment: EPA also has failed to meet its obligations under the Unfunded Mandates Reform Act of 1995 (the "Reform Act"). As with E.O. 12866, the Reform Act requires federal agencies to assess the effects of their regulatory actions on state, local and tribal governments, and on the private sector [U.S.C. section 1531]. Among other things, the Reform Act requires the preparation of a cost-benefit analysis and the examination of a range of alternatives, whenever the proposed action may result in expenditures in excess of $100 million [2 U.S.C. sections 1532, 1535]. In addition, the Reform Act contains a number of specific requirements where an action may significantly or uniquely impact small governments [2 U.S.C. section 1533].

EPA asserts again that it does not have to comply with the Reform Act because the proposed rule "imposes no direct enforceable duties on the State or any local government or on the private sector." [62 Fed. Reg 42160, 42191]. For the reasons discussed earlier, this assertion is without merit. As EPA acknowledges, these criteria will serve as the basis for any water quality standards promulgated by the State, which in turn will be binding on. local government and private industry. Unless EPA is prepared to view these criteria as being optional, it therefore cannot in good conscience state that they do not create an enforceable duty. Given this, EPA must comply with the mandates of the Reform Act

Response to: CTR-036-003b

With respect to EPA's compliance with UMRA see response to CTR-036-006a (Category S:UMRA) and the preamble to the final rule.

Comment ID: CTR-036-004a
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES R

Comment: Finally, EPA has not met its duties under the Regulatory Flexibility Act (the "RFA"). Under the RFA, federal agencies are required to conduct an initial regulatory flexibility analysis ("IRFA") describing the impact of a proposed regulatory action on small entities. Once more relying on the claim that the proposed rule does not establish criteria that are directly applicable to small entities, EPA states that the mandates of RFA do not apply [62 Fed. Reg. 41160, 42191-92].

This position is contrary to both the letter and the spirit of the RFA. The fact that the toxics criteria contained in the proposed rule must be translated into water quality standards and, in turn, NPDES permit effluent limitations, does not negate the fact that the burden of complying and implementing such toxics criteria ultimately will be borne by individual municipalities and business entities. As noted above, the costs to municipalities alone could run into billion of dollars placing a severe strain on their budgets and forcing them to divert funds currently allocated to other important municipal services, including public safety.

Moreover, EPA's statement that "California will have a number of discretionary choices associated with permit writing" is disingenuous and ironic in light of EPA's rationale for issuing the proposed rule. The toxics criteria will necessarily narrow the State's discretion in issuing NPDES permits and in establishing effluent limits for such permits. If EPA had meant for the State to have any serious discretion, it would not be promulgating these criteria in the first place.

Response to: CTR-036-004a

The purpose of the CTR is to fill the current gaps in water quality criteria in inland surface waters, enclosed bays, and estuaries. EPA disagrees that the State will not have substantial discretion in issuing NPDES permits under the rule. The CTR establishes pollutant levels necessary to protect designated uses. Establishing numeric criteria in the CTR does not limit the discretion of permit writers to use appropriate and flexible tools such as mixing zones or translators for dissolved metals criteria in establishing effluent limits. In addition, if a discharger believes the CTR criterion is inappropriately overprotective of the designated use, the discharger can request the State and EPA to approve a site-specific criterion or to downgrade the designated use.

Comment ID: CTR-040-004
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

1. Concern: The Rule, as presently proposed, appears to require discharges from municipal stormwater programs to meet water quality based effluent limits (WQBELs).

* The enclosed attainability analysis (See Attachment A) demonstrates that implementation of an

aggressive BMP-based program will cost on the order of $20 million per year. And, despite the implementation of ever escalating BMPs, the Sacramento Stormwater Management Program will not achieve several of the proposed aquatic life criteria (for copper, lead, and zinc) and human health criteria (for PAHs).

Response to: CTR-040-004

EPA disagrees with the commenter's interpretation of the language regarding wet weather discharges in the proposed CTR, and has clarified the language in the section of the CTR that discusses the applicability of the rule to wet weather discharges. EPA believes that the CTR language allows the practice of applying maximum extent practicable (MEP) to MS4 permits, along with best management practices (BMPs) as effluent limits to meet water quality standards where infeasible or insufficient information exists to develop WQBELs.

Section 402(p)(3)(B) requires municipal separate storm water systems to 1) prohibit non-storm water discharges, and 2) reduce the discharge of pollutants in storm water to MEP. The Agency has purposely not defined MEP to allow municipalities flexibility in designing pollution control measures. MEP is a dynamic performance standard which requires the municipality to demonstrate permit compliance in many ways including the use of BMPs, proper maintenance of their BMPs, and ongoing assessment of BMP performance in reducing pollutant discharges. EPA has determined that, where sufficient information does not exist on which to base WQBELs, or where infeasible, the use of BMPs is consistent with the requirement that municipal storm water programs require controls to reduce the discharge of pollutants to MEP in order to attain and maintain water quality standards.

EPA articulated its position on the use of BMPs in storm water permits in the Interim Permitting Approach For Water Quality-Based Effluent Limitations In Storm Water Permits signed by the Assistant Administrator for Water, Robert Perciasepe on August 1, 1996 (61 FR 43761, August 19, 1996). The policy focuses on the question of the applicability of WQBELs to MS4 permits, and whether or not numeric effluent limitations are required, or could be represented by other control mechanisms such as BMPs. The policy affirms the use of best management practices as a means to attain water quality standards in storm water permits. The policy reads as follows:

In response to recent questions regarding the type of water quality-based effluent limitations that are most appropriate for National Pollutant Discharge Elimination System (NPDES) storm water permits, the Environmental Protection Agency (EPA) is adopting an interim permitting approach for regulating wet weather storm water discharges. Due to the nature of storm water discharges, and the typical lack of information on which to base numeric water quality-based effluent limitations (expressed as concentration and mass), EPA will use an interim permitting approach for NPDES storm water permits.

The interim permitting approach uses best management practices (BMPs) in first-round storm water permits, and expanded or better-tailored BMPs in subsequent permits, where necessary, to provide for the attainment of water quality standards. In cases where adequate information exists to develop more specific conditions or limitations to meet water quality standards, these conditions or limitations are to be incorporated into storm water permits, as necessary and appropriate.

This interim permitting approach is not intended to affect those storm water permits that already include appropriately derived numeric water quality-based effluent limitations. Since the policy only applies to water quality-based effluent limitations, it is not intended to affect technology-based limitations, such as those based on effluent guidelines or the permit writer's best professional judgement, that are incorporated into storm water permits.

Each storm water permit should include a coordinated and cost-effective monitoring program to gather necessary information to determine the extent to which the permit provides for attainment of applicable water quality standards and to determine the appropriate conditions or limitations for subsequent permits. Such a monitoring program may include ambient monitoring, receiving water assessment, discharge monitoring (as needed), or a combination of monitoring procedures designed to gather necessary information.

This interim permitting approach applies only to EPA; however, EPA also encourages authorized States and Tribes to adopt similar policies for storm water permits. This interim permitting approach provides time, where necessary, to more fully assess the range of issues and possible options for the control of storm water discharges for the protection of water quality. This interim permitting approach may be modified as a result of the ongoing Urban Wet Weather Flows Federal Advisory Committee policy dialogue on this subject.

EPA also reviewed the attached report entitled "Technical Report Assessing the Attainability of Water Quality Criteria Proposed in the California Toxics Rule," a report prepared for Sacramento County Stormwater Management Program by Larry Walker Associates (LWA). In response, EPA has the following concerns and comments regarding various aspects of the report and its conclusions.

General Limitations of the Analysis

* LWA do not provide the raw data upon which they base their conclusions regarding potential compliance problems with the proposed CTR water quality criteria. Without the raw data, EPA could not fully assess the validity of the analysis.

* The data may not be representative of the storm water discharges to the American and Sacramento Rivers. Most samples were collected for first-flush events, usually one hour or less in duration. As a result, the in stream exposure period is probably one hour at most, which corresponds to the exposure period for acute criteria, not chronic criteria as used in the LWA analysis.

* LWA report that applying BMPs to storm water would not result in attainment of criteria as proposed in the CTR. However, LWA focus on the most stringent (and unlikely) scenario for attainability of criteria (i.e., applying chronic criteria with no allowance for dilution). According to LWA's own analysis, BMPs would nearly achieve compliance under the scenario of applying acute criteria and dilution factors to storm water flows. If mathematical errors in LWA's Table's 11 and 12 are corrected, the analysis demonstrates compliance with acute criteria for even the 99.91 percentile values of copper, lead, and zinc in the Sacramento River, and for lead in the American River, with no additional treatment.

* The analysis also may not be reflective of the compliance scenario for other California waters. The metals criteria are based on a low hardness value for the American River (25 mg/l as CaCO3). This hardness value is lower than any of the hardness values observed for the economic analysis of sample facilities throughout California. As a result, the criteria for the American River are very stringent (i.e., criteria become more stringent with lower hardness) compared to criteria for California waters in general.

* LWA compare the concentration of the dissolved fraction of metals in the discharge to the instream criterion values expressed as dissolved metals to assess compliance. This approach may be overly stringent because it does not account for the partitioning of dissolved metals present in the discharge to suspended solids present in receiving waters (particularly during a storm event when suspended solids are elevated). Thus, less dissolved metals may be available in the water column than LWA's analysis

would estimate. In addition, this is not the approach that is used to determine compliance under the NPDES program. The NPDES regulations require all permit limits for metals to be expressed in terms of "total recoverable metals" [40 CFR 122.45]. In order to determine whether a discharge would meet NPDES permit limits developed to protect water quality, the instream criteria should not be used directly, but should be converted to a water quality-based effluent limit (WQBEL) using the EPA standards-to-permits procedures. The development of WQBELs expressed as total recoverable metals accounts for the partitioning of dissolved metals (present in the discharge) to suspended solids that are present in the receiving water. EPA used this approach in its cost evaluations.

* Cost estimates provided in the LWA analysis for complying with the CTR appear to mix BMP implementation costs to comply with Sacramento's storm water permit with new compliance costs resulting from the CTR. EPA's economic analysis only evaluates the incremental impact of the water quality standards for toxics compared to the baseline program to avoid a double counting of costs (and benefits).

Specific Data and Sampling Issues

* LWA calculated average event mean concentrations (AEMC) to represent the entire urbanized drainage area of Sacramento County. Samples were combined to calculate AEMCs (based on contributions of 95% commercial/residential and 5% industrial) utilizing three sampling locations. Although LWA indicate that both grab and composite samples were collected to estimate the AEMCs, as well as annual loadings, it is unclear how the different sample types were used. According to the EPA's Guidance Manual For The Preparation of Part 2 of the NPDES Permit Applications for Discharges From Municipal Separate Storm Sewer Systems (EPA 833-B-92-002), an event mean concentration (EMC) is determined from analyses of flow-weighted composite samples. In order to qualify as a valid sample, the storm event must be sampled for at least three hours, or for the entire storm if the event lasts less than three hours. Of great importance in such derivations is consistency in methodology, i.e., the first method employed must always be employed to ensure that results can be compared. LWA do not provide any information to confirm the consistency of sampling procedures.

* LWA completed a discharge characterization project (DCP) for storm water discharges in 1996 (not included as part of commenter's submission). LWA state that the DCP evaluated all urban runoff monitoring data available. However, it is not clear whether the data set used for the DCP was the same as that analyzed for the current report, or whether it was more extensive. LWA state that the DCP used "statistical modeling" (unnamed methodology) to "characterize and estimate" mass loadings. They also state that data on heavy metals, conventional and non-conventional pollutants were "updated for 1996/1997 data. However, they do not report which procedures governed the "update," whether the data sets were consistent, or under what circumstances they were sampled and analyzed. EPA believes that this lack of information makes it impossible to evaluate the methodologies used to extrapolate the data set and draw conclusions as to its appropriateness in demonstrating nonattainability of toxic criteria. In addition, LWA cite a "robust statistical method" for deciding whether to use detection limit values for nondetect data. This method is not described.

* It appears from Charts 1 through 5 presented in the report, that LWA use a limited data set (not included as part of commenter's submission) for each of the pollutants of concern, and use statistical projections to predict "worst case" (i.e., 95th, 99th, and 99.91th percentiles) discharge values. These predicted discharge concentrations are then used to assess whether instream criteria would be met. This is an extremely conservative approach that would not be used by EPA to establish compliance with water quality-based effluent limits or water quality criteria. To assess the potential for metals and organics to exceed aquatic life and human health criteria during intermittent, high flow, storm water episodes, a

complex dynamic modeling effort would be required. This procedure is highly data intensive, and is beyond the scope of this costing analysis; nevertheless, it should have been employed in the LWA analysis to accurately determine the potential for exceedances of criteria. The generalized technical approach for assessing compliance with the applicable criteria is described in EPA's Technical Support Document for Water Quality-Based Toxics Control (March 1991). For typical point sources, this is performed by developing wasteload allocations (using steady-state models, under low flow conditions) and developing WQBELs based on these wasteload allocations. The process of developing wasteload allocations and WQBELs that would be protective of applicable criteria during storm events is significantly more difficult, and is not described in current EPA guidance. The EPA Center for Exposure Assessment Modeling (CEAM), located at the National Exposure Research Laboratory in Athens, Georgia, maintains and distributes environmental simulation models and databases for urban and rural nonpoint sources. Information on dynamic models and their use for storm water modeling can be obtained through CEAM.

Cost Methodology Issues

* It is unclear why Tables 7 and 7a were included in the analysis. These tables appear to present costs associated with the implementation of the BMPs required by the current Sacramento MS4 permit. They are, therefore, distinct from any incremental attainment costs associated with treatment of storm water due to water quality criteria. The potential costs resulting from the alternative of collecting and treating all storm water prior to discharge are summarized in Figure C, however, no details, explanatory notes, or assumptions are presented in support of this estimate.

* Figure B states that capital costs range from $160 to $187 million. However, EPA notes that only the higher value is presented in the summary. The choice to use only the higher value is not explained. It appears that the difference in the values results from the assumed level of engineering and other costs (50% of capital costs, as opposed to 30%, see Table 7). Other published sources have traditionally used a percentage more consistent with the lower of the two values referenced in Table 7 (see, for example, Estimating Costs for the Economic Benefits of RCRA Noncompliance, U.S. EPA, March 1997, page 1-4, where the percentage increase due to engineering and inspection, contractor's overhead and profit, and contingency is 35%).

Other Methodological Issues

* LWA do not clearly state what proportion of the County's runoff enters the American River versus the Sacramento River. LWA base their presentation largely on discharges to the American River which has a two-fold lower hardness concentration, resulting in the most stringent metals criteria. As noted above, a hardness value of 25 mg/l (as CaCO3) is on the very low end of the range for receiving waters considered in the CTR analysis.

* LWA focus their presentation on the "no dilution" scenario. However, both the American and Sacramento Rivers provide substantial dilution (reducing runoff concentrations by 51% and 86%, respectively). The analysis developed in the LWA report summarizes the results of this evaluation in Tables 11 and 12. In presenting the data, the LWA evaluation incorrectly calculates the dilution provided by the Sacramento River. When correctly calculated, the analysis indicates that the acute criteria for all of the metals would be met at the 99.91 percentile value in the Sacramento River. In addition the acute criterion for lead would be met for the American Rivers. Furthermore, compliance with copper and zinc criteria would practically be achieved assuming dilution and implementation of BMPs (i.e., 70% reduction of copper and zinc by BMPs). In their assessment of instream mixing, the LWA analysis used ambient background pollutant concentrations presented in Tables 11 and 12. While

all other values are indicated as "dissolved" concentrations, no such note is provided for the background data. If these values are expressed as total metals it would overestimate the background load and thus underestimate the available assimilative capacity of the stream.

* Similarly, the LWA does not account for in-stream dilution in its evaluation of the potential for PAH compounds and pentachlorophenol to exceed human health criteria. In its evaluation, LWA again projects worst case (i.e., 95th, 99th, and 99.91th percentile) storm water concentration values and compares these values directly to ambient human health criteria. This approach significantly overestimates the potential for exceeding these criteria. Human health criteria are developed assuming a lifetime exposure to the pollutant at a daily ingestion rate of 2 liters of drinking water and ingestion of an assumed mass of aquatic organisms. To account for such long term exposures, EPA permitting procedures recommend using typical stream flows (e.g., harmonic mean) in developing wasteload allocations. The calculated wasteload allocations are also assumed to represent long-term averages (i.e., average monthly permit limits) rather than maximum daily values. Depending on the available dilution, this approach generally results in WQBELs much higher (i.e., less stringent) than the actual criterion values. Based on LWA projections, it appears that even a small allowance for dilution would resolve the compliance concerns or pentachlorophenol. The potential for compliance concerns identified by LWA for PAH compounds could only be accurately determined based on the results of the dynamic modeling assessment previously discussed.

* In calculating the allowable discharge concentration (Ce) for lead and zinc, LWA used detection level values for ambient background concentrations even though no lead or zinc were measured. Since background concentrations may actually be significantly lower than the detection level, this may result in an overly stringent Ce (and thus more costly to achieve).

Comments from the Fresno Metropolitan Flood Control District (Fresno) and the California Department of Transportation (Caltrans)

EPA also reviewed comments submitted by the Fresno Metropolitan Flood Control District (Fresno) and the California Department of Transportation (Caltrans) on the CTR provisions relating to storm water. In response, EPA has the following concerns and comments regarding various aspects of the submissions and their conclusions. Some of these issues are addressed in the above review of LWA's submission and are so referenced.

General Limitations of the Analysis

* Neither Fresno nor Caltrans provide the raw data upon which they base their conclusions regarding potential compliance problems with the proposed CTR water quality criteria. Without the raw data, EPA could not fully assess the validity of the analysis.

* Caltrans' data came from eight storm events at three urban freeway sites in the Los Angeles area, but the sampling methodology is not specified (i.e., first flush, peak, outfall, street, etc.). The data may not be representative of the storm water discharges for all Caltrans facilities. Fresno does not specify the sampling methodology nor the number of sites or storm events sampled.

* Fresno reports that applying BMPs (including end-of-pipe) to storm water would not result in attainment of criteria as proposed in the CTR. However, Fresno presents a stringent (and unlikely) scenario for attainability of criteria (i.e., applying chronic criteria).

* Caltrans reports that applying source reduction and nonstructural BMPs will not provide the reduction

necessary to meet the criteria. End-of-pipe treatment would be required. Although acute criteria are used in this analysis, no data or estimates are provided to demonstrate that BMPs would not result in reductions needed to comply with properly developed WQBELs.

* The analysis also may not be reflective of the compliance scenario for other California waters.

* Fresno and Caltrans compare the concentration of the dissolved fraction of metals in the discharge to the instream criterion values expressed as dissolved metals to assess compliance. See the response to LWA for EPA's discussion of the problems with this approach.

* Cost estimates provided in the Fresno and Caltrans analysis for complying with the CTR may mix BMP implementation costs to comply with local storm water permits with new compliance costs resulting from the CTR. EPA's economic analysis only evaluates the incremental impact of the water quality standards for toxics compared to the baseline program to avoid a double counting of costs (and benefits).

Specific Data and Sampling Issues

* Caltrans specifies that consistent procedures were used at all three sampling sites, but it does not specify the exact methodology (i.e., sampling duration, first flush, etc.). Of great importance in data analysis is consistency in methodology, i.e., the first method employed must always be employed to ensure that results can be compared.

Fresno does not describe its sampling procedures or methodology.

* Caltrans uses a limited data set (not included as part of commenter's submission) for each of the pollutants of concern, and uses statistical projections to predict "worst case" (i.e., 99.91th percentile) discharge values. These predicted discharge concentrations are then used to assess whether in stream criteria would be met. This is an extremely conservative approach that would not be used to establish compliance with water quality-based effluent limits or water quality criteria because compliance is based on measured values and not on statistically derived worst case values.

Summary and Recommendations

The LWA report was based on storm water data collected at outfalls discharging to the American and Sacramento Rivers. The report did not provide the raw data, nor did it provide detailed information on how these data were collected. The primary scenario described in the report (i.e., comparing projected worse case discharge concentrations directly to chronic aquatic life and human health criteria with no allowance for dilution) is highly conservative in comparison with the water quality-based permitting and compliance procedures that would be implemented by EPA. The LWA analysis also did not consider the equilibrium partitioning of dissolved and total metals that may occur instream during a storm event. An ancillary analysis summarized in the LWA report compared the maximum projected discharge concentrations (99.91 percentile values) of copper, lead, and zinc to the acute aquatic life criteria accounting for dilution. If errors are corrected in the LWA spreadsheet, the LWA data indicate that there would be no compliance problems for these parameters in the Sacramento River, and that BMPs would likely result in compliance in the American River. While the LWA analysis provides information that could be useful in determining "reasonable potential" for possible WQBEL development, the approach is not consistent with water quality-based permitting procedures or EPA's approach to compliance assessment.

To accurately determine whether additional treatment would be necessary to control storm water discharges to the American and Sacramento Rivers, EPA would conduct a comprehensive modeling effort to develop appropriate WQBELs. The WQBELs (for organics and total metals), would be developed using dynamic models to account for the intermittent loadings and exposures from the storm water discharges. EPA recognizes that the determination of appropriate WQBELs for storm water outfalls is a difficult modeling effort that requires intensive data collection and verification. The LWA report has not utilized this approach, and the necessary level of effort is not within the scope of the agency's CTR analysis.

In summary, the CTR language allows (consistent with EPA's policy) the practice of applying MEP to MS4 permits, along with BMPs as effluent limits to meet water quality standards where infeasible or insufficient information exists to develop WQBELs. Neither the LWA report, nor the Fresno and Caltrans comments, provide a definitive argument that storm water dischargers cannot achieve compliance with the proposed water quality criteria or that compliance would result in widespread economic impact or hardship. Although none of the three comment submissions discussed above provide the raw data used for their analyses for EPA to fully assess the validity of the analyses, their methodology does not assess compliance with WQBELs as would be developed by EPA. In particular, the assessments do not account for dilution or the partitioning of dissolved metals to suspended solids present in the receiving waters. LWA and Caltrans also do not apply the appropriate criteria in assessing compliance and use statistical projections to predict "worst case" discharge concentrations, an approach that would not be used to establish compliance with WQBELs or water quality criteria. In addition, LWA's estimated costs do not accurately portray the incremental expense to Sacramento County resulting from implementation of the CTR, that is, the costs attributable to the CTR criteria that are over and above the cost of implementing the current storm water program.

Comment ID: CTR-040-006
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

1. Concern: The Rule, as presently proposed, appears to require discharges from municipal stormwater programs to meet water quality based effluent limits (WQBELs).

* In order to achieve WQBELS, it will be necessary to intercept all of the urban runoff from the Sacramento metropolitan area (including that discharged to urban streams and the American River),

transport it to an area near the Sacramento River for equalizing storage and subsequent end-of-pipe treatment, and then discharge it to the Sacramento River (See Attachment A), The capital cost of this structural control program is estimated to be on the order of $2.5 billion. Amortizing that cost over a 20-year period, at 7% interest and including annual operation and maintenance costs, the total annual cost to bring Sacramento urban stormwater into compliance with the proposed criteria is on the order of $260 million per year.

* Even this enormously expensive end-of-pipe treatment will not guarantee achievement of the proposed criteria (e.g., PAH removals of 99% may not be achievable with the proposed end-of-pipe treatment which formed the basis of the cost estimate).

Further, as indicated in the attainability analysis provided in Attachment A, this $260 million per year program may not result in any net environmental benefits. Extensive ambient river monitoring over the past five years has shown that copper, lead, and zinc levels in the American and Sacramento Rivers generally comply with the proposed criteria and are not significantly impacted by stormwater discharges (PAH data are not available). On the other hand, the removal of stormwater discharges from the urban streams would likely have a negative environmental impact. It would lead to destruction of the aquatic and riparian habitat which currently exists. Thus, this $260 million per year program would not lead to any of the types of benefits that formed the basis of EPA's benefits analysis, including fishing use benefits, reduced cancer benefits, or passive benefits. In this case, the cost is $260 million per year and there may be no net environmental benefits. Therefore, pursuant to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act, -EPA should consider alternative criteria for copper, lead, zinc and PAHs for those waters in the Sacramento area.

Response to: CTR-040-006

See response to CTR-040-004.

Comment ID: CTR-040-007
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* Consideration of any costs to urban stormwater dischargers is not included in the analysis.

Response to: CTR-040-007

See response to CTR-013-003.

Comment ID: CTR-040-010a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES R

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

* The cities of Folsom and Galt, co-permittees in our stormwater program, both have populations less than 50,000. Their costs associated with complying with the effluent limitations proposed in the Rule would be significant (on the order of $10 million annually for each city). Therefore, the EPA Administrator's certification that the Rule would have no effect on small entities, pursuant to the requirements of the Regulatory Flexibility Act, is incorrect.

Response to: CTR-040-010a

See response to CTR-013-008b.

Comment ID: CTR-040-014b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES I-02

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

I. Recommendation: Modify the Preamble statement that indicates municipal wet weather discharges must comply with water quality standards or WQBELs (Preamble pages 42186-42187).

* It is not a requirement of the CWA or EPA that wet weather discharges must meet water quality criteria. If it were, the adverse economic impact on municipal stormwater programs would be enormous. The CWA, at best, is ambiguous on this issue; EPA regulations do not address it; and the Elliott memorandum, which appears to be the primary basis for EPA's position on this issue, is not a legitimate basis for such a position. The Elliott memorandum is an internal EPA memorandum and; therefore, is not an independent interpretation of the CWA. The Elliott memorandum does not constitute EPA policy and is based upon a false premise and an inaccurate reading of the preamble to EPA's 1988 proposed stormwater regulations. The Elliot memorandum contains other erroneous conclusions that have never been applied to municipal stormwater permits (e.g., that municipal stormwater dischargers must comply with water quality standards within three years of permit issuance).

* EPA has routinely approved municipal stormwater NPDES permits that have not included requirements to comply with water quality standards (e.g., Tulsa, OK; Greesnboro, NC; Denver, CO; Portland, OR; Cedar/Green (Seattle), WA; Sarasota County, FL; and Phoenix, AZ).

* If EPA does not modify the Preamble statement to clarify that municipal stormwater dischargers are not required to comply with these water quality standards, then EPA must include the cost of the structural controls necessary for compliance in its economic analysis and, using these costs, address the requirements of Presidential Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act.

Response to: CTR-040-014b

EPA believes the applicability of water quality standards to storm water discharges is outside the scope of the rule. See response to CTR-001-003. With respect to the comment about potential costs to municipal storm water dischargers see responses to CTR-040-004 and CTR-021-006a.

Comment ID: CTR-047-003
Comment Author: City of Santa Fe Springs
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-047 incorporates by reference letters CTR-013 and CTR-027.
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our storm water program:

3. In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-047-003

See response to CTR-013-003.

Comment ID: CTR-047-004a
Comment Author: City of Santa Fe Springs
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-047 incorporates by reference letters CTR-013 and CTR-027.
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our storm water program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittee to MS4 permits. Many of the larger municipalities in California have conducted storm water discharge characterization studies. These studies have shown that there are common pollutants associated with storm-water discharges from urbanized areas that could result in compliance problems with the proposed criteria . Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-047-004a

See response to CTR-013-008b.

Comment ID: CTR-059-023b
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01g08

Comment: Economic Analysis

The Sanitation Districts commends EPA for preparing an analysis of the economic impacts of the proposed CTR, and for selecting POTWs for half of the case studies. We believe that EPA is correct in thinking that POTWs are likely to experience major impacts as a result of the promulgation of the CTR. However, we believe that this analysis is based on improper assumptions and inaccurate cost estimates, resulting in unconvincing conclusions. Our own attainability and cost analysis indicates that there are indeed fundamental flaws in the cost analysis. A few of the areas of concern are listed below:

* The Economic Analysis ignores the costs that may be incurred by stormwater dischargers and nonpoint sources to reduce loadings so that CTR criteria may be met in ambient waters.

Response to: CTR-059-023b

See response to CTR-013-003.

Comment ID: CTR-061-002
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? Y
CROSS REFERENCES

Comment: By far, the greatest deficiency with the CTR is the US EPA's failure to include a properly conducted economic analysis associated with the application of these criteria into standards governing the regulation of urban area and highway stormwater runoff-associated constituents. The application of these criteria to this situation will result in significant unnecessary expenditures for chemical constituent control in an effort to try to achieve the criteria values when implemented as standards for receiving waters for urban area and highway stormwater runoff.

Response to: CTR-061-002

See response to CTR-013-003.

Comment ID: CTR-061-003
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? Y
CROSS REFERENCES

Comment: Overall Comments The California Toxics Rule (CTR), as proposed, is significantly deficient in providing an economic analysis that includes information on the cost, and an assessment of the water quality benefits, of ultimately having to meet state water quality standards based on CTR proposed criteria in the receiving waters for urban area and highway stormwater runoff. Without this information, the public, regulatory agencies and the regulated community cannot understand the significant technical deficiencies that exist in the US EPA CTR proposed rulemaking. The CTR should not be finalized until this information has been developed and provided to the public for review and comment. Urban stormwater discharge representative-speaker after speaker at the September 17, 1997 hearing on the proposed CTR was justifiably concerned about the confusing situation that exists today; they are being informed by the US EPA that NPDES-permitted urban stormwater runoff will be subject to meeting water quality standards (objectives) in the receiving waters for the stormwater runoff during the time of runoff and after through a process of ever-increasingly stringent and expensive BMPS.

As I testified at the September 17, 1997 hearing, it is well-understood in the stormwater runoff water quality management field that the US EPA "Gold Book" water quality criteria, including those being promulgated under the California Toxics Rule, are not designed to address short-term, episodic discharges of chemical constituents of the type that routinely occur in stormwater runoff from urban areas and highways. As a result, "administrative" exceedances of the proposed California Toxics Rule criteria can readily occur without any real impairment of the designated beneficial uses of the receiving waters for the stormwater runoff. By real impairment of aquatic life-related beneficial uses I mean alteration of the number, types and/or characteristics of desirable forms of aquatic life in the receiving waters for the runoff, that are of concern to the public who must ultimately pay for the control of chemical constituents in the stormwater runoff.

There has been a sufficient number of studies conducted on the characteristics of urban and highway

stormwater runoff to document that it will indeed be rare that the constituents present in urban stormwater runoff from residential and commercial areas are in toxic, available forms for a sufficient duration and magnitude in the receiving waters for the runoff to be adverse to aquatic life. As long as the US EPA persists with its improperly developed and adopted Independent Applicability Policy (by which chemical criteria/standards have to be met even if appropriately conducted studies show that the constituents of concern, such as heavy metals in urban stormwater runoff, are in non-toxic, unavailable forms) urban stormwater runoff water quality managers face ultimately having to spend large amounts of public funds to avoid "administrative" exceedances of inappropriate criteria/standards for urban stormwater runoff, with no expected improvement in the real beneficial uses of the waterbodies that are of concern to the public who must ultimately pay for the control programs.

Problems with "administrative" exceedances arise from what are well-known to be technically invalid and inappropriate approaches adopted by the US EPA in the 1980s for implementing the "Gold Book" criteria, that the Agency under various administrations has yet to address. These issues are discussed in the attached papers and in references provided therein. Even today, based on discussions at the US EPA's Multi-Regional Water Quality Criteria and Standards meeting that was held at the end of August 1997 in St. Louis, Missouri, the Agency is still unwilling to address in a meaningful way the problems in regulating urban stormwater runoff water quality. For the Agency to announce, as it did at that meeting, that wet-weather water quality management issues are no longer part of the ANPRM for water quality standards, represents a serious deficiency in the Agency's current policy that must be corrected if the public is to be protected from wasting large amounts of funds constructing structural BMPs to work toward achieving CTR-based water quality standards in the receiving/discharge waters for urban stormwater runoff.

As was pointed out by several speakers at the CTR hearing held on September 17, 1997, the US EPA Region 9 and US EPA headquarters made a significant error in developing the California Toxics Rule where those responsible chose to ignore the massive costs that regulated urban stormwater dischargers will ultimately have to bear as part of implementing the California Toxics Rule. I believe that if this matter were taken to the courts, the urban dischargers could force US EPA Region 9/Washington, D.C. to do a proper economic analysis of the cost of ultimately having to achieve water quality standards (objectives) based on CTR criteria. The fact that there is some ill-defined period of time during which the standards/criteria can be met through BMPS does not change the ultimate cost that will have to be borne by the public. It is my assessment that these costs will be on the order of at least $1 to $2 per person per day forever for the regulated communities.

Several of the urban stormwater dischargers who testified at the September 17, 1997 hearing reported that their preliminary cost estimates were even greater than those that I projected since not only would they have to construct and operate large treatment works to capture, store and treat urban stormwater runoff so that no more than one exceedance of a criterion/standard occurs every three years, but also they would have to acquire land near waterbodies where such treatment works could be developed. Representatives of Alameda County estimated that more than 50 facilities each the size of the Oakland Coliseum would have to be constructed to store the stormwater runoff from a two-inch, one-day storm. The construction of such facilities in near shore areas of Alameda County on San Francisco Bay might be justified if there were reason to believe that they would solve real, significant water quality use-impairments of San Francisco Bay occurring due to urban stormwater runoff-derived constituents that exceed proposed CTR criteria for protection of aquatic life. However, the fact is that after extensive study, none of the heavy metals in Bay Area urban stormwater discharges has been found to be in toxic, available forms that are causing real water quality use-impairments. Basically, the expenditures of dollars per person per day for the regulated community-dwellers that are now dictated by the Clean Water Act and the US EPA's Independent Applicability Policy arise from the US EPA's failing to address

the obvious, significant problems with the application of the "Gold Book" and now proposed CTR criteria to urban stormwater runoff-associated constituents.

I have found that the urban stormwater runoff water quality managers are not claiming that there are no water quality problems associated with their stormwater discharges. It appears that there may be real water quality problems in urban stormwater discharges due to chemicals such as the organophosphate pesticides (e.g., diazinon and chlorpyrifos) for which the US EPA has either failed to develop a criterion (diazinon) or has failed to implement an existing criterion (chlorpyrifos). I understand that finally, after years of delay during which it has been well-known by the US EPA that diazinon was causing widespread aquatic life toxicity, the Agency is now beginning again to formulate a water quality criterion for this chemical. Additional summary information on the organophosphate pesticide issue is presented in the attached paper, "Diazinon and Chlorpyrifos as Urban Stormwater Runoff Associated Pollutants," June (1997)

It is important to understand that the development of criteria for chemicals such as diazinon does not mean that those criteria will be properly implemented or enforced. The chlorpyrifos situation is an example; chlorpyrifos has been well-known to cause aquatic life toxicity in many communities' stormwater runoff, yet the Agency, including US EPA Region 9, has failed to admit publicly that there is a problem, much less act to control the toxicity problem. Under the current regulatory approach, stormwater dischargers could be required under CTR to spend massive amounts of public funds building "50 Oakland Coliseums" just to store stormwater runoff in Alameda County from a storm magnitude that occurs more frequently than once in three years because of administrative Exceedances of several CTR-regulated heavy metals in the stormwater runoff (which have been repeatedly found to be in non-toxic, unavailable forms, including the dissolved forms), while the treated stormwater discharge to San Francisco Bay could be highly toxic due to unregulated or inadequately regulated organophosphate pesticides. This is an artifact of the inappropriate approaches used by the Agency of focusing on chemicals rather than chemical impacts, i.e., on potential toxicants rather than toxicity. While this approach is bureaucratically simple to administer, it is technically invalid and can lead to a massive waste of public funds in implementing stormwater runoff water quality management programs.

Urban stormwater runoff water quality management is in chaos. This situation has been well-understood for at least five years. While attempts are being made to address these issues through the US EPA headquarters' various wet-weather committees, thus far the fundamental issue that was raised at the September 17, 1997 hearing by urban stormwater discharger after discharger, i.e., ultimately having to achieve water quality standards based on CTR criteria in the receiving waters for the discharge through ever-increasingly stringent BMPS, has not been adequately addressed. While the proposed CTR does not specify a time period over which the BMP ratcheting-down process will occur, there can be no doubt that time period will be set by the courts through litigation brought by environmental groups who will assert that an NPDES-permitted stormwater discharger is not making adequate progress toward achieving the ultimate goal of only one violation of a water quality standard every three years for regulated constituents. Because of the uncertainty of how the courts will handle this matter, stormwater dischargers could be faced with having to achieve water quality standards in the discharge waters within five to ten years. Clearly there is need now to understand the costs and true water quality benefits associated with achieving these standards as part of adopting the CTR as it is applied to regulating urban stormwater runoff water quality.

I have published extensively on these issues. Many of my papers and reports on this topic are available from my web site (http://members.aol.com/gfredlee/gfl.htm).

It is my recommendation that US EPA Region 9 and US EPA headquarters postpone any adoption of

the California Toxics Rule until the US EPA properly presents and discusses the potential costs and the potential water quality benefits in terms of real improvements in designated beneficial uses of receiving waters that will likely accrue as the result of regulated urban stormwater discharges' ultimately having to comply with water quality standards based on CTR criteria. The US EPA Region 9 should allow the stormwater dischargers the opportunity to provide information on the costs and benefits arising from applying these criteria to stormwater discharges as required by the Clean Water Act when it becomes clear that BMPS of the type that are readily available today will not eliminate the administrative Exceedances of water quality standards numerically equal to the aquatic life criteria set forth in the CTR. After allowing the urban stormwater dischargers to provide this information, the US EPA then should develop an economic analysis that reliably presents and discusses these issues. This CTR review process is the necessary first step to correcting the significant chaos that now exists in the urban stormwater runoff water quality management field.

Response to: CTR-061-003

See response to CTR-013-003 and CTR-040-004.

Comment ID: CTR-061-017
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42186, third column, last paragraph and page 42187, first column, first paragraph discuss the application to wet-weather loads. The proposed US EPA criteria will tend to significantly over-regulate wet-weather flows such as urban area and highway stormwater runoff. It is estimated that these costs are on the order of $1 to $2 per person per day. This issue is discussed in the attached papers and in other papers on my web site.

Response to: CTR-061-017

See response to CTR-013-003.

Comment ID: CTR-061-019
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? Y

CROSS REFERENCES

Comment: Comments on Economic Analysis of the Proposed Water Quality Toxics Rule

Page ES-2, second paragraph, "Scope of Economic Analysis," states, "In addition, EPA does not calculate costs for NPDES sources which are not typically subject to American WQBEL's including sources required to hold NPDES permits stormwater permit and other wet weather dischargers."

This is a significant deficiency in the cost analysis which makes the CTR largely unreliable. As long as NPDES stormwater dischargers are required to work toward the goal of achieving water quality standards in the receiving waters for stormwater runoff, the cost of achieving these standards must be included in evaluating the potential economic impacts of adopting these criteria. While most NPDES wastewater discharges meet or are close to meeting these criteria at the edge of a mixing zone for the discharge, NPDES-permitted stormwater dischargers in Phase I as well as the soon-to-be-released Phase 2 are not yet even beginning to effectively comply with the requirement of meeting water quality standards in the stormwater runoff during wet-weather runoff events. While it is unknown at this time what the situation will actually be in the future with respect to compliance with water quality standards for NPDES-regulated urban and highway stormwater runoff, until there is a clear, unequivocal policy adopted that exempts urban area and highway stormwater runoff from meeting these criteria, the costs of meeting such standards must be included in a proper evaluation of the cost of implementing these criteria.

Response to: CTR-061-019

See response to CTR-013-003.

Comment ID: CTR-062-003
Comment Author: City of Downey
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-062 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

3. The economic analysis used by the U.S. EPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The U.S. EPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in the U.S. EPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the U.S. EPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP program (over and above what an MS4 has in place already).

Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP-program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The U.S. EPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers in conducted and assessed.

Response to: CTR-062-003

See response to CTR-013-003.

Comment ID: CTR-062-004a
Comment Author: City of Downey
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-062 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 discharges, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the U.S. EPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the U.S. EPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the U.S. EPA did not need to complete an analysis required under the Act. The U.S. EPA neglected to address small MS4 communities in California that are currently subject to MS4 permits, and those smaller communities that may be impacted through Phase II. The U.S. EPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the U.S. EPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-062-004a

See response to CTR-013-008b.

Comment ID: CTR-071-003
Comment Author: City of Rosemead
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-071 incorporates by reference letter CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan, Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-071-003

See also response to CTR-013-003.

Comment ID: CTR-071-004a
Comment Author: City of Rosemead
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-071 incorporates by reference letter CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-071-004a

See response to CTR-013-008b.

Comment ID: CTR-072-003
Comment Author: City of Bell Gardens
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-072 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial

treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-072-003

See response to CTR-013-003.

Comment ID: CTR-072-004a
Comment Author: City of Bell Gardens
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-072 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits, Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-072-004a

See response to CTR-013-008b.

Comment ID: CTR-073-003
Comment Author: City of Paramount
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-073 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-073-003

See response to CTR-013-003.

Comment ID: CTR-073-004a
Comment Author: City of Paramount
Document Type: Local Government
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-073 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits, Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-073-004a

See response to CTR-013-008b.

Comment ID: CTR-074-003
Comment Author: City of San Gabriel
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-074 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control District shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-074-003

See response to CTR-013-003.

Comment ID: CTR-074-004a
Comment Author: City of San Gabriel
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-074 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the

proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicated that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-074-004a

See response to CTR-013-008b.

Comment ID: CTR-075-003
Comment Author: City of El Monte
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-075 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program;

3. The economic analysis used by The USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-related community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works(POTWs), industrial treatment facilities, and industrial users discharging to POTWS. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to M84 dischargers is conducted and assessed.

Response to: CTR-075-003

See response to CTR-013-003.

Comment ID: CTR-075-004a
Comment Author: City of El Monte
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-075 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program;

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly affected by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule:, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-075-004a

See response to CTR-013-008b.

Comment ID: CTR-076-003
Comment Author: City of Cudahy
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: J Storm Water Economics
References: Letter CTR-076 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

3. The economic analysis used by The USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-076-003

See response to CTR-013-003.

Comment ID: CTR-076-004a
Comment Author: City of Cudahy
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-076 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharge from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small

communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

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Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-076-004a

See response to CTR-013-008b.

Comment ID: CTR-078-003
Comment Author: City of Maywood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-078 incorporates by reference letter CTR-013
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

3. The economic analysis used by The USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater-regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in USEPA analysis is the cost for the stormwater program to comply with the proposed

In its analysis, the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program (over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-078-003

See response to CTR-013-003.

Comment ID: CTR-078-004a
Comment Author: City of Maywood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-078 incorporates by reference letter CTR-013
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studied have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

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Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-078-004a

See response to CTR-013-008b.

Comment ID: CTR-079-003
Comment Author: City of Glendale

Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-079 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

3. The economic analysis used by the USEPA is flawed and inadequately addresses the impacts of the CTR on the stormwater regulated community. The USEPA's economic analysis focused entirely on the compliance cost of point sources, which included Public Owned Treatment Works (POTWs), industrial treatment facilities, and industrial users discharging to POTWs. A major omission in the USEPA analysis is the cost for the stormwater program to comply with the proposed criteria.

In its analysis the USEPA appears to assume that a BMP program will lead to compliance and that there is no associated cost for a BMP Program over and above what an MS4 has in place already). Studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control district shows this to be incorrect, i.e., a BMP program cannot comply with the proposed criteria. Furthermore, these studies show that the cost for a BMP program is significant and would increase substantially if an MS4 was required to construct end-of-pipe treatment for compliance. The USEPA should not implement the proposed criteria to MS4 discharges until such time as an adequate economic analysis addressing the true impacts to MS4 dischargers is conducted and assessed.

Response to: CTR-079-003

See response to CTR-013-003.

Comment ID: CTR-079-004a
Comment Author: City of Glendale
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-079 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES R

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in

California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

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Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-079-004a

See response to CTR-013-008b.

Comment ID: CTR-080-001
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J Storm Water Economics
References: Letter CTR-080 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: The City of Los Angeles is hereby transmitting its comments regarding the proposed California Toxics Rule (CTR). I would like to begin by stating that the City currently spends an average of $28 million annually on its Stormwater Management Program. The majority of Program activities are guided by the Los Angeles County Municipal Stormwater Permit, which dictates the use of Best Management Practices to control pollutants to the maximum extent practicable. We are primarily concerned with how the CTR may impact the Stormwater Management Program.

* The City recommends that a parallel economic analysis be conducted to address the impacts of the CTR on the stormwater-regulated community.

Response to: CTR-080-001

See response to CTR-013-003.

Comment ID: CTRE-002-003
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/18/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: As was pointed out by several speakers at the hearing yesterday, US EPA Region 9 and US EPA headquarters made a significant error in developing the California Toxics Rule where they chose to ignore the massive costs that regulated urban stormwater dischargers will ultimately have to bear as part of implementing the California Toxics Rule. From my perspective, and I do not speak for any discharger, I believe that if this matter were taken to the courts, the urban dischargers could force US EPA Region 9/Washington, D.C. to do a proper economic analysis of the cost of ultimately having to achieve water quality standards (objectives) based on CTR criteria. The fact that there is some ill-defined period of time during which the standards/criteria can be met through BMPs does not change the ultimate cost that will have to become by the public. It is my assessment that these costs will be on the order of at least $1 to $2 per person per day forever for the regulated communities.

Several of the urban stormwater dischargers who testified at yesterday's hearing reported that their preliminary cost estimates were even greater than those that I projected since not only would they have to construct and operate large treatment works to capture, store and treat urban stormwater runoff so that no more than one exceedance of a criterion/standard occurs every three years, but also they would have to acquire land near waterbodies where such treatment works could be developed. As you heard, Alameda County estimated that over 50 facilities the size of the Oakland Coliseum would have to be constructed to store the stormwater runoff from a two-inch, one-day storm. While the construction of such facilities in near shore areas of Alameda County on San Francisco Bay might be justified if there was reason to believe that they would solve real, significant water quality use impairments of San Francisco Bay that are occurring due to urban stormwater runoff-derived constituents that exceed proposed CTR criteria for protection of aquatic life, the facts are that after extensive study, none of the heavy metals in Bay Area urban stormwater discharges had been found to be in toxic, available form. Basically, the expenditures of dollars per -person per day for the regulated community dwellers that are now dictated by the Clean Water Act and the US EPA's Independent Applicability Policy arise from the US EPA failing to address the obvious, significant problems with the application of the "Gold Book" and now proposed CTR criteria to urban stormwater runoff-associated constituents.

Response to: CTRE-002-003

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs

due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-040-004.

Comment ID: CTRH-001-001b
Comment Author: Robert Hale
Document Type: Public Hearing
State of Origin: CA
Represented Org: CA Stormwater Task Force
Document Date: 09/17/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES I-1

Comment: MR. HALE: Good afternoon. My name is Robert Hale and I'm the chairman of the California Stormwater Quality Task Force which is located at 951 Turner Court, Suite 300, in Hayward.

This task force is a statewide organization representing municipal separate storm sewer systems that hold National Pollutant Discharge Elimination System, NPDES, permits to discharge stormwater.

My comments today are on behalf of the -- principally on behalf of that task force. I also am chairman of the management committee of the Alameda Countywide Clean Water Program. I will make some comments with respect to Alameda County.

As proposed by EPA, the preamble language, which is the principal point here in referring to numeric effluent limitations and water quality based effluent limitations, is clearly inconsistent with the plain language used by Congress in incorporating the maximum extent practicable standard into Section 402(p)(3)(B) of the Clean Water Act.

You may argue that this reference is only in the preamble and not in the main text of the rule; but it's my understanding, however, that the preamble itself is supposed to explain and clarify the meaning of the rule and the Clean Water Act. This proposed language would instead appear to be trying to change one of the fundamental points of the Clean Water Act.

The reason I think this point is fundamental is that the cost to society, and to our county in this case and to the states, is an important consideration. Congress considers the entirety of the tasks that the country has to do, rather than going for broke on one issue such as stormwater quality.

In short, the Congress balances the larger picture, and the language in Section 402(p)(3)(B) actually

reflects that balance. I believe that Section 402(p) says what it says for a good reason. The only economically feasible means of achieving water quality standards is through best management practices.

To illustrate this point, I work in Alameda County as chairman of the Clean Water Program there, and I did some rough calculations here. We often get storms as much as 2 inches in a 24-hour period. That's several times a winter. If you had a one-day storm, as I figure it, that will work out to 5 billion gallons of runoff water.

To treat this much water, if we were driven to this sort of the extreme case by the language in the preamble -- and I'm not talking about the text of the rule so much as the language in that preamble -- if it were to drive us in this extreme case to have -- to do end-of-pipe treatment for our discharges in order to meet the standards that are there, and to keep up -- basically keep up with the storms, which often come one behind the other within a couple days, it would necessitate building dozens, perhaps more, treatment plants of substantial size and would necessitate the use or acquisition of valuable industrial properties on the margins of the bay. Which I just did a little separate figuring here; I'm figuring it costs about $3 a gallon to treat -- to secondarily treat sanitary sewage and about $4 a gallon to store it.

I estimate that a storm of this size -- to be able to handle a storm of this size would cost between 35 and $50 billion for Alameda County alone. This is for a population of l.35 million residents.

And this does not account for the acquisition of property needed to do this, assuming we could store it in facilities or properties we already own. And it also does not account for the secondary treatment. In fact, we might have some difficulty achieving the standards that are in the rule.

And there's a way you can express this getting down to the nuts and bolts of it, which I like to do. I did some rough estimates of the size of the Oakland Coliseum, and if you were to use structures the size of the Oakland Coliseum for storing this water from one of these storms, I figured it would come out to -- you'd need 50 of them to store the runoff from this one storm that I've got here.

And I know some of you might be thinking about how the A's are doing right now and this might not be a bad idea. We can, say, think about leaving an extra one there for the A's and Raiders and build 50 more of them.

But the point is, we're talking about a tremendous investment in the infrastructure here, and it's very difficult for us to keep up with.

So let's see. Just a few more points here.

So we're not really talking about upgrades to existing delivery and treatment systems. We would have to start from scratch and build pumping systems, conveyance systems, to build an entire infrastructure. The cost would be prohibitive for us in Alameda County. This is a -- sort of one of the worst-case scenarios. And I think that the economic rule -- or the economic analysis in the rule doesn't do this justice.

So --

MR. MORRIS: Have you done any modelling?

MR. HALE: This is strictly back-of-the-envelope type calculations at this point. I don't know whether or not -- what discharges the storm concentrations would result in.

The first question I have on modeling is to see what these discharges of stormwater with these effluent concentrations -- under the storm conditions if we would be -- would have a higher flow than the drought flow condition which was modeled.

When you have a storm event, the stream conditions are different, the hydrology is different, the modeling characteristics. We could work out the scenario. And it's true that when you've got a huge storm, water fires right out the bay and out the Golden Gate. We might even probably need to talk about that and work on that.

Response to: CTRH-001-001b

EPA disagrees with the comments. See response to CTR-001-003. For a discussion of EPA's evaluation of studies concerning costs associated with achieving water quality criteria for storm water discharges, see responses to Comments CTR-013-003 and CTR-040-004. For a discussion of the scientific validity of CTR criteria, See response to CTR-031-004c.

EPA disagrees with the cost estimates provided by the commenter as EPA does not believe that storage and treatment of stormwater would be required to ensure compliance with the CTR. See response to CTR-021-006b.

Comment ID: CTRH-001-029
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: We're going to submit more responses in written comments having to do with other issues such as wet weather. I would really encourage you to listen carefully to those who have experience in building wet weather facilities.

We know it costs $4 a gallon for storage. We know the latest cost of building treatment facilities is about $3 a gallon, so those are real numbers. And so I think you do need to pay attention to the wet weather issue as well.

Response to: CTRH-001-029

See response to CTR-021-006b and CTR-001-007.

Comment ID: CTRH-001-033
Comment Author: Dave Brent
Document Type: Public Hearing
State of Origin: CA

Represented Org: CA Water Qual. Task Force
Document Date: 09/17/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: Second, we are concerned that the compliance cost for the stormwater programs to meet the objectives of the proposed rule will be significant. Already the city spends about $1.2 million to implement a program that services 400,000 people.

Unfortunately, even with the proactive stormwater programs implemented in the State of California, BMP programs will probably fall short of the water quality standard for several of the constituents included in the rule. And in cases where objectives are achieved, it will take several years.

As my counterpart and co-permittee from Sacramento County, Kathy Russick will describe, the City of Sacramento has estimated cost for compliance based on five of the constituents in the CTR: copper -- dissolved copper, dissolved lead and dissolved zinc, pentachlorophenol and PAHs.

These costs -- this study indicates that the costs will be very extreme to even come close to meeting those objectives and the objectives -- and this is from six years of monitoring data and six years of a proactive BMP program, so we are basing this on fact. And again, Kathy will elaborate on this in her discussion.

And also the analysis -- economic analysis focuses only on POTW discharges, not industrial discharges. Again, with the costs we're seeing for stormwater compliance, we feel that the analysis falls short and that EPA should revisit the economic analysis and include not only the cost for municipal stormwater programs to comply, but also the cost for the industrial stormwater programs.

Response to: CTRH-001-033

The commenter claims that BMP programs will fall short of the water quality standards for several pollutants included in the CTR. EPA disagrees with the commenter and believes that BMP programs, when properly implemented, will be sufficient to ensure compliance with CTR-based standards.

See also the response to CTR-021-006b, CTR-001-007, and the preamble to the final rule.

Comment ID: CTRH-001-054
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: In closing, in terms of some of the comments made by especially the municipal stormwater

programs, first, I'd like to just make a comment that economic analysis might be required by executive order, but it isn't required by the Clean Water Act; that standards, in fact, cannot include any kind of economic consideration in terms of coming up with a scientifically based number.

The Act mandates a scientifically based number. State level doesn't do that, but the federal level is quite clear. And you have no authority to include in your numbers an economic criteria. So I'll just remind you of that, to -- just to balance off the comments today with -- not exactly balance. At least one person said that.

And also in terms of the storm -- fears of the stormwater programs, they're quite fearful of the language in here. I would simply remind folks, 402(p) under the permits section doesn't rewrite 303D, formulate the TMDLs and load allocation requirements. It doesn't rewrite the need for permits to go beyond best available technology or whatever they need to do to meet the criteria- it doesn't rewrite 301.

So 402(p) takes a back seat effectively to a situation where you had a violation of standards in the ambient water. Those permits would by definition be subject to a particular regional board's discretion to revise them as proposed.

I don't think any realistic look at the future indicates that all the permits will be rewritten with numerical effluent limits, given the magnitude of that program. I would just put in my word of reason that there's really nothing to be afraid of. The South Bay has a stormwater program, and in Santa Clara County we have a stormwater program that looks like every other municipal stormwater program in the area.

And I think that's about it.

Response to: CTRH-001-054

EPA agrees with the commenter that criteria must be science-based and are established so as to ensure the protection of designated uses of California waters. EPA performed an Economic Analysis of the implementation of the rule to determine the potential economic impact of the CTR, not to establish standards or criteria. Also see response to CTR-042-007a.

Comment ID: CTRH-002-005
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: EPA also failed to address the impacts of the proposed rule on industrial stormwater discharges. This rule could significantly impact industries in a municipal area that is subject to stormwater permits.

Response to: CTRH-002-005

See response to CTR-021-006b and CTR-001-007.

Comment ID: CTRH-002-006b
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES I

Comment: Does the California Toxics Rule meet the legal requirements of the Clean Water Act and other federal policies and laws?

Previous municipal stormwater speakers have questioned, as we have, EPA's interpretation of Section 402(p) of the Clean Water Act. In addition, the California Toxics Rule raises significant questions regarding its conformance with other federal policies and laws including Executive Order 12866, the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, and the authority for EPA to adopt blanket criteria without considering the designated uses of such waters as required under the Clean Water Act.

To give you just one example, I'd like to briefly compare the California Toxics Rule with the compliance of Executive Order 12866:

Under Executive Order 12866, any "significant" federal regulatory action must be referred to the Office of Management and Budget for review before it can be approved. In this context, a "significant" action includes one which will "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy." Though admitting that there "may be a cost to some dischargers" to comply with the water quality standards that will be derived from these toxics criteria, the EPA nonetheless argues that the proposed rule is not a significant action because it "establishes ambient water quality criteria which, by themselves, do not directly impose economic impacts."

First, nothing in Executive Order 12866 indicates that only actions with direct economic impacts are to be considered by OMB. Second, for the EPA to ignore the link between the toxics criteria in the proposed rule and the obligations being imposed is very questionable. Is EPA conceding that State and regional water boards may simply ignore these criteria when promulgating water quality standards and issuing permits? Nothing in the preamble indicates that EPA views these criteria as merely advisory.

Despite stating that Executive order 12866 is not applicable, EPA goes on to include an economic analysis which purports to demonstrate that the proposed rule will result in a net economic benefit. The problem with this analysis is that it completely ignores the enormous cost that municipalities will bear if they are forced to bring their stormwater discharges into compliance with these toxics criteria. For example, a 1990 study conducted for the Sacramento Stormwater Program estimated that it would cost nearly $2 billion to implement a treatment program to achieve the water quality criteria proposed in the former Inland Surface Water Plan. Costs to comply with the proposed toxics criteria would be similar, if

not higher, than those proposed in the Inland Surface Water Plan. Ultimately, the costs of compliance may reach into the ten of billions of dollars.

In short, EPA cannot have it both ways. It cannot state that stormwater discharges are subject to the proposed toxics rule and then turn a blind eye toward the costs associated with the implementation of this rule. The costs of the proposed rules are direct and significant, and therefore the rule must be submitted to OMB for review.

We have comparable concerns with the other federal laws that I cited previously, and we will elaborate on them in our written comments.

Response to: CTRH-002-006b

See response to CTRH-002-006a.

EPA established criteria in order to comply with the requirements of the Clean Water Act. In order for such criteria to achieve their intended purpose, the implementation scheme must be such that the final results protect aquatic life and human health. EPA disagrees that designated uses are not considered. It is through the implementation of the CTR that site-specific factors of water bodies and discharging facilities (e.g., hardness, pH, stream flows, or site-specific criteria studies) are considered and designated uses are protected.

EPA disagrees with the commenter that municipalities will bear "enormous" costs to bring their stormwater discharges into compliance with the CTR criteria, however, EPA was not able to evaluate the commenter's compliance cost estimate of "tens of billions of dollars" because the commenter did not provide a methodology or any data for EPA to evaluate. Also see response to CTR-021-006b, CTR-021-005c, and the preamble to the final rule.

Comment ID: CTRH-002-009
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: We recommend that EPA conduct an economic analysis to assess the full impacts of the wet weather discharge requirements of the proposed rule and further evaluate the actual benefits of implementation of the rule.

The County of Orange encourages EPA to work cooperatively with California municipal stormwater stakeholders to resolve these issues. Through the California Stormwater Quality Task Force, the municipal stormwater dischargers have demonstrated our ability to work cooperatively with the EPA and State Water Resources Control Board to develop mutually effective solutions to facilitate implementation of the stormwater program. Such intergovernmental coordination is needed to develop a feasible

program to protect the environment.

Response to: CTRH-002-009

See responses to CTR-021-006b and CTR-034-016.

Comment ID: CTRH-002-017
Comment Author: Alex Sheydayi
Document Type: Public Hearing
State of Origin: CA
Represented Org: Ventura Co. Flood Control
Document Date: 09/18/97
Subject Matter Code: J Storm Water Economics
References:
Attachments? N
CROSS REFERENCES

Comment: MR. SHEYDAYI: Good afternoon. I'm Alex Sheydayi of the Ventura County Flood Control District, and I'm here to speak on behalf of the Ventura County Management Program.

Before I make my comments, I would also like to express my -- our program's support for the comments that were made by Mr. Crompton earlier and also by our speakers in San Francisco that spoke on behalf of the Municipal Water Quality Management Programs statewide.

Our program -- The permit for our program was issued in August of '94. And our program basically consists of 12 permittees in the flood control district which is the municipality and the municipal permittee which is the County of Ventura and ten cities in the county.

At the time that we applied for the stormwater permit, only three municipalities in the county were required to do so. The others entered the program voluntarily in order to maintain a uniform program countywide. Currently, of the 12 corporate permittees, five corporate permittees would not even be required to have permits under Phase 20 because they have populations far west than that required for Phase 20. So you can see we have very small communities that are participating in the program voluntarily.

The commission earlier stated that one of the reasons many of the corporate permittees entered the program voluntarily is to maintain a uniform program countywide. And one of the incentives for doing that was the fact that the program was a BMP-driven program to comply with the requirements of a permit to the maximum extent practicable under the Clean Water Act.

We have also recently completed a four-year monitoring program and, using the information from the monitoring program, we have attainability of the data that we have collected for our program. This attainability data indicates that even if we comply -- apply the BMP program to the maximum extent possible, the expenditure of radial funds, we would still not be able to meet the requirements of the proposed criteria for several of the metals and other constituents, which would then -- of course, our program would go into a treatment mode for stormwater discharges. We believe that this was going to be very costly for us, particularly very costly for smaller communities who don't have the base to spread the cost of such an expense over their population.

Our programs, like so many other municipal programs in California, were based on implementation of programs to address source of weakness, not to provide the treatment. Just to give you an idea of why we concur with the other speakers concerning the economic analysis and the fallacy of the economic analysis, let me just give you a very quick example of the cost that we are currently incurring. We are currently spending $5 per -- for every man, woman, and child in Ventura County to implement a BMP-based program. And yet if you'll look at the pages that were presented in the CTR of the maximum $87 million statewide, the number will be approximately two and a half to three dollars for every person in California to implement the CTR — not just the stormwater dischargers, but for all dischargers statewide. So we think that there is something wrong with this whole analysis if we are currently exceeding the cost of the assumptions made in the analysis for compliance with CTR.

We also, as I said earlier, believe that the analysis should take into consideration the size of the communities, and as Mr. Crompton mentioned earlier, most of the municipal programs in California are very small communities and the cost of applying the treatment would be very, very difficult for them to comply with.

That's the end of my comment. I thank you for the opportunity to speak.

MR. MORRIS: Are you going to submit the data and the analyses that you did that show why -- You said you have a lot of data. Are they going to --

MR. SHEYDAYI: We are not going to submit them on the comments. We are going to be submitting that data -- It's still relatively in raw form, but we will be submitting that data to the regional board with our annual report in November.

MR. MORRIS: If you could get me or send me a copy or Diane a copy of the data and how you calculated your WQBEL, your permit limit based on the new criteria, that would be useful. I'd like to see how you did that.

MR. SHEYDAYI: Okay. We'll send you whatever we can put together.

MR. MORRIS: I think there is a misconception that people have to implement the criteria for stormwater dischargers at the drought low condition and the 7QlO condition. That's not the case. When we issue a permit, you keep that limit for a stormwater discharge, you usually model the condition that occurs in. If you do it right, that gives you a model that gives you concentration in the receiving water and the duration of the exposure of that concentration, and then you'll compare that to the criterion and flood flow or rain flow or storm flow. Right? Usually you have enough to keep your WQBEL below the criteria and you don't see the effects. If you do a good model, you shouldn't have any impact.

If you look across the country, across the U.S., there are many, many states that have standards on the books, water quality standards that are far more stringent than the numbers we're promulgating or proposing to promulgate in Southern California. If you look at their standards, you won't see any black boxes on the end of those stormwater discharges. Nobody builds treatment for stormwater treatment in this country. They've been implementing standards for 15 years. California is no different.

Response to: CTRH-002-017

The costs attributable to the CTR are only those incremental costs which will be incurred to go from compliance with existing permits to compliance with more stringent CTR-based limits. EPA's revised

cost estimates from the Economic Analysis range from $33.5 million to $61.0 million annually. The commenter compares BMP costs of $5 per person to potential CTR compliance costs, however, this is not relevant because CTR costs are incremental costs and are not based on the costs of existing programs. See also responses to CTR-021-006b and CTR-035-048.

Subject Matter Code: J-01 MS4s/CSOs/Industries Costs

Comment ID: CTR-013-002
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Lost Angeles County Stormwater Program:

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant costs with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, thus requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA for the following reasons:

The preamble to the Federal stormwater regulations(*2) clearly indicates that it was not the intent of Congress to require municipal permits to require end-of-pipe treatment technology but to implement a comprehensive stormwater management program to reduce the discharge of pollutants from municipal storm sewer systems.

If municipal stormwater discharges are required to comply with the proposed rule, end-of-pipe treatment or zero discharge would be the only alternatives to achieve compliance. This would result in major capital expense to construct the collection and treatment facilities. In addition, this may result in other more significant environmental impacts, such as destruction of wetlands and wildlife habitats.

We recommend that the proposed rule not apply to MS4 discharges. However, if the USEPA should continue to impose the proposed rule to MS4s, the rule should be revised to specifically address compliance issues and resolution to those issues for MS4 discharges that adequately reflect the intent of Congress when it implemented the municipal stormwater program.

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*2) Federal Register, November 16, 1990, Vol. 55, No. 222, Page 48038

Response to: CTR-013-002

See response to CTR-040-004.

Comment ID: CTR-014-002
Comment Author: City of Lakewood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-014 incorporates by reference letters CTR-013 and CTR-027

Attachments? N
CROSS REFERENCES

Comment: 2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to achieve compliance which would provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-014-002

See response to CTR-040-004.

Comment ID: CTR-024-002
Comment Author: City of Hawthorne
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-024 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: 2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and Fresno Metropolitan Flood Control

District, stormwater discharges being controlled through aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-024-002

See response to CTR-040-004.

Comment ID: CTR-027-002
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: 2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to possibly achieve compliance which would only provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant costs with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of pipe treatment would be necessary. Even then, certain criteria, e.g. PAHs, cannot be attained through typical treatment BMPs. In the case of Sacramento, a capital cost of $2.5 billion was required to provide treatment. The annual cost, including operation and maintenance, for such an arrangement was $444 million. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat all stormwater discharges. This is unreasonable, and not consistent with intent of the CWA for the following reasons:

* The preamble to the Federal stormwater regulations (*1) clearly indicates that it was not the intent of Congress to require municipal permits to require end-of-pipe treatment technology, but to implement a comprehensive stormwater management program to reduce the discharge of pollutants from municipal storm sewer systems.

If municipal stormwater discharges are required to comply with the proposed rule, end-of-pipe treatment or zero discharge would be the only alternatives to achieve compliance. Extrapolating the Sacramento cost for end-of-pipe treatment to a population of $22 million (*2) results in an annual cost of $7 billion. In addition to the significant compliance costs, there are other issues that could make such alternatives infeasible.

- Fully developed communities may not have the vacant land available to construct collection and treatment facilities. Acquisition of developed land would be very expensive.

- Going to zero discharge or constructing and operating collection and treatment facilities may result in other more significant environmental impacts, such as destruction of wetlands and wildlife habitats.

- Technologies to treat not only the quantity of stormwater but to reduce toxic pollutants to low concentrations are not currently available.

* As noted in the economic analysis to the proposed rule, EPA estimates that only 3% of the total load of toxic pollutants to fresh waters of the State are from point source discharges, which include municipal stormwater discharges. Since point source discharges contribute a small percentage of the total toxic pollutant load, reducing the toxic pollutants in stormwater would result in only marginal water quality improvements in the waters the proposed criteria are intended to protect. The costs to implement a BMP based program alone to address toxic pollutants, without considering end-of-pipe treatment, are significant and not justified when compared to the marginal water quality benefits to be achieved.

Recommendation: The proposed rule should not apply to MS4 discharges. However, if USEPA should continue to impose the proposed rule to MS4s, the rule should be revised to specifically address an resolve these compliance issues, as they apply to MS4 discharges, in a manner consistent with the intent of Congress when it adopted the requirements of the municipal stormwater program.

(*1) Federal Register, November 16, 1990, Vol. 55, No. 222, page 48038.

(*2) Based on 1990 census data.

Response to: CTR-027-002

See response to CTR-040-004.

Comment ID: CTR-040-034
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that municipal stormwater dischargers can achieve the criteria with no-cost BMPs.

Response to: CTR-040-034

See response to CTR-013-003.

Comment ID: CTR-041-030
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that municipal stormwater dischargers can achieve the criteria with no-cost BMPs.

Response to: CTR-041-030

See response to CTR-013-003.

Comment ID: CTR-044-025
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that municipal stormwater dischargers can achieve the criteria with no-cost BMPs.

Response to: CTR-044-025

See response to CTR-013-003.

Comment ID: CTR-054-029
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References:
Attachments? N
CROSS REFERENCES

Comment: Although EPA goes to great length to label its cost analysis as "conservative" the analysis is anything but conservative:

* It is not conservative to assume that municipal stormwater dischargers can achieve the criteria with no-cost BMPs.

Response to: CTR-054-029

See response to CTR-013-003.

Comment ID: CTR-062-002
Comment Author: City of Downey
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-062 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-062-002

See response to CTR-040-004.

Comment ID: CTR-069-002a
Comment Author: CA Bus Prop Ass & Bldg Ind Ass
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References:
Attachments? N
CROSS REFERENCES E-01j

Comment: Additionally, CBIA and CBPA are concerned with the findings in the "Economic Analysis of the Proposed California Water Quality Toxics Rule." The acknowledgment by EPA in the economic analysis that "the water quality criteria in this rule may also have an indirect effect on sources not permitted under the NPDES program or not subject to numeric water quality-based effluent limits is extremely troublesome. Sources not permitted under the NPDES program include nonpoint sources and wet weather discharges such as runoff from farms and urban areas. The economic analysis continues by stating that "any potential effect on these sources is unknown at this time" and that "the State may ask or require these sources to implement best management practices or participate in a comprehensive watershed management approach. Since the economic analysis only focuses on the costs to point source dischargers and not non-point discharges, CBIA and CBPA believe that the potential economic impact of the proposed rule is greater than identified in the economic analysis.

We thank you for your consideration of these comments.

Response to: CTR-069-002a

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive. Until this information is available, it is premature to project that the sources would incur any costs beyond those for which they

are already responsible under the current regulations of the Clean Water Act.

Comment ID: CTR-071-002
Comment Author: City of Rosemead
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-071 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-071-002

See response to CTR-040-004.

Comment ID: CTR-072-002
Comment Author: City of Bell Gardens
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-071 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-072-002

See response to CTR-040-004.

Comment ID: CTR-073-002
Comment Author: City of Paramount
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-073 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-073-002

See response to CTR-040-004.

Comment ID: CTR-074-002

Comment Author: City of San Gabriel
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-074 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

2.The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-074-002

See response to CTR-040-004.

Comment ID: CTR-075-002
Comment Author: City of El Monte
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-075 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program;

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to M84s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District,

stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-075-002

See response to CTR-040-004.

Comment ID: CTR-076-002
Comment Author: City of Cudahy
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-076 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR) , which are of major impact to our stormwater program:

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-076-002

See response to CTR-040-004.

Comment ID: CTR-078-002
Comment Author: City of Maywood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-078 incorporates by reference letter CTR-013
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-078-002

See response to CTR-040-004.

Comment ID: CTR-079-002
Comment Author: City of Glendale
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-079 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

2. The application of water quality standards to MS4 stormwater discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require stormwater agencies to incur significant cost with minimal improvement in water quality. Based on studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, stormwater discharges being controlled through an aggressive BMP based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its stormwater discharges. This is unreasonable and is

not consistent with the intent of the CWA.

Response to: CTR-079-002

See response to CTR-040-004.

Comment ID: CTR-087-003
Comment Author: Morrison & Foerster LLP
Document Type: Storm Water District
State of Origin: CA
Represented Org: SCVURPPP
Document Date: 09/24/97
Subject Matter Code: J-01 MS4s/CSOs/Industries Costs
References: Letter CTR-087 incorporates by reference letters CTR-001 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: Finally, even if the Elliot Memo were not incorrect (and, given the plain language of the statute, it clearly is), EPA's position that WQBELs may be applied in municipal stormwater permits requires that it conduct an economic analysis of the proposed rule's potential impact on municipal stormwater dischargers. In this regard, it makes no difference whether WQBELs are expressed as numeric effluent limitations or in the form of BMPS. For if BMPs must be calculated on the basis of the numeric criteria contained in the proposed CTR rather than on section 402(p)(3)(B)(iii)'s maximum extent practicable standard, they are likely to have significant economic consequences -- consequences the Agency has failed to even attempt to analyze in its proposal.

Members of the SCVURPPP look forward to EPA revising its proposal to address the comments contained in this letter and those offered by their fellow municipal stormwater dischargers.

Please contact me at the telephone number listed above if you have any questions concerning the matters covered by this letter or wish to discuss them further.

Response to: CTR-087-003

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or

drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-040-004.

Subject Matter Code: J-02 RFA - Small Entity Cost

Comment ID: CTR-001-008a
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: J-02 RFA - Small Entity Cost
References:
Attachments? N
CROSS REFERENCES R

Comment: EPA'S PROPOSAL VIOLATES THE REGULATORY FLEXIBILITY ACT

Several of the member agencies of the ACCWP have populations less than 50,000 (Piedmont, Emeryville, Albany) and will be significantly affected by the proposed rule if it results in the adoption of NELs or WLAs in the permit for their discharges. These "small entities" under the Regulatory Flexibility Act ("RFA") are entitled to both initial and final regulatory flexibility analyses under the RFA.

EPA's finding that a substantial number of small entities will not be significantly affected by the proposed rule is arbitrary and capricious given this demonstrated impact. A substantial number of municipalities less than 50,000 in population are currently covered by NPDES permits for their storm water discharges. In addition, EPA's upcoming Phase II storm water regulations may substantially expand the universe of small municipalities that will be subject to NPDES permits and, through those permits, to the provisions of the CTR.

Neither the ACCWP, the ACCWP's member agencies or, to our knowledge, any other storm water system that will be subject to this rule, was contacted by EPA in advance of the proposed rulemaking and given a reasonable opportunity to participate in the rulemaking as required by 5 U.S.C. section 609(a). In addition, as a "covered agency" under 5 U.S.C. section 609, EPA must process the proposed rule in accordance with the provisions of that section, including the convening of a review panel, but apparently has failed to do so.

Response to: CTR-001-008a

See response to CTR-001-008b, CTR-050-007a, and the preamble to the final rule.

Comment ID: CTRH-001-005a
Comment Author: Alan Waltner
Document Type: Public Hearing
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/17/97
Subject Matter Code: J-02 RFA - Small Entity Cost
References:
Attachments? N
CROSS REFERENCES R

Comment: If you go beyond best management practices, you're impliedly eliminating those provisions of the 1995 Basin Plan. I think it would clearly violate the Regulatory Flexibility Act, since you haven't considered the costs of controls.

If, again, our dischargers had to do whatever it took, our members had to do whatever it took -- and in fact, several of our dischargers are small entities under the Regulatory Flexibility Act: the City of Emeryville, the City of Albany, the City of Piedmont.

The NPDES permits small entities and municipalities under 50,000 in number. If they had to do whatever it took to provide the waste allocations without consideration of the economic impact, those entities, because of the practical problems of needing 50 coliseums of storage in the Bay Area and the practical considerations that plague us -- and the only place you could put that is by the bay, where you have a serious problem with requirements under the Endangered Species Act.

To the extent you're standing in the shoes of the state in promulgating these standards, you violate the cost/benefit balances provision of the Porter Cologne Act.

Response to: CTRH-001-005a

See responses to CTR-001-008b, CTR-050-007a, CTR-035-011a, and the preamble to the final rule.

Comment ID: CTRH-001-008b
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: J-02 RFA - Small Entity Cost
References:
Attachments? N
CROSS REFERENCES R

Comment: Looking at the results of our monitoring and your criteria, we'll have to achieve another 70 to 90 percent reduction in pollutants in order to be in compliance. That means we'd have to increase our storage volume to 20,000 acre feet just to handle average annual runoff we have underway right now.

That's a price tag of $220 million to $400 million to try to stay in compliance with the current criteria if you interpret the rule to apply to us -- 220 million. And then we can't prevent major storm events in our community, storm impacts that cause a discharge, in which case 100 percent of the discharges would exceed -- would be out of compliance, even though we were retaining 100 percent of the average annual rainfall.

We think that raises a problem with the Regulatory Flexibility Act, both in terms of the cost analysis itself and the impact that accrues to small communities, certainly with respect to the executive order. Just in our case alone the $100 million limit is in serious trouble, dealing with compliance with a five-year schedule just in our community with the possibility of $80 million per year of expense. That does not include O & M cost in that system.

Response to: CTRH-001-008b

EPA disagrees with the commenter's cost estimates, because EPA does not believe that additional storage capacity will need to be constructed to comply with the CTR. However, no details of the cost estimate were provided, thus, EPA could not evaluate the estimated cost. See also response to CTR-001-008b, CTR-040-004, and CTR-050-007a.

Comment ID: CTRH-002-004
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: J-02 RFA - Small Entity Cost
References:
Attachments? N
CROSS REFERENCES

Comment: Is the economic analysis appropriate?

Most of the municipal stormwater permittees in Orange County are communities of less than 100,000 in population. I might add that most of the permittees in California are small communities.

Based on our monitoring data and studies conducted by others, it is reasonable to assume that stormwater discharges from these small communities would be faced with the same compliance issues as the large and medium municipalities. EPA failed to address this potential impact in its economic analysis of the proposed rule.

Response to: CTRH-002-004

See responses to CTR-001-008b, CTR-050-007a, and the preamble to the final rule.

Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP

Comment ID: CTR-031-007b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES F

Comment: C. If the CTR as proposed in the current draft is applied to municipal storm water dischargers as numeric effluent limitations, new end-of -pipe facilities will result. The impact of these facilities on the environment in general, and endangered species in particular, must therefore be specifically reviewed pursuant to the National Environmental Policy Act and Endangered Species Act.

End-of-pipe facilities would be required for municipal storm water dischargers in their attempt to meet the subject criteria. Storm water facilities must be located in the lowest topographic areas, which contain many of our most valuable and already diminished wetland habitats. This readily foreseeable environmental consequence of the CTR, if directly applied to municipal storm water dischargers, should not be ignored.

Response to: CTR-031-007b

With respect to ESA, EPA has completed consultation as required by Section 7 of the ESA. With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, Comment CTR-040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

Comment ID: CTR-042-002
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References:
Attachments? Y
CROSS REFERENCES

Comment: 2. If municipal storm water dischargers are required to meet water quality standards, this will result in the need for installation of expensive end-of-pipe treatment.

As explained in Attachment A included with these comments, Caltrans storm water discharges will, in many instances, be unable to comply with the proposed CTR numeric water quality criteria. In fact, as shown in Attachment A, falling rainwater (which acts as a mechanism for atmospheric deposition) cannot comply with the CTR criteria. As graphically illustrated in Figures 11 and 12 of Attachment A, the concentration of pollutants in the falling rainwater is a substantial fraction of the concentration of those pollutants found in storm water runoff. This demonstrates that atmospheric deposition may be a large source of pollutants in storm water.

The conclusion contained in Attachment A further states that if Caltrans is required to comply with the water quality standards proposed in the CTR, it will be forced to install costly end-of-pipe treatment.

Application of the necessary treatment technologies statewide for all of Caltrans facilities and rights-of-way equates to an astronomical cost. These costs were not even considered in EPA's Economic Analysis for the CTR.

Requests:

* Caltrans requests that EPA clarify the language of the CTR Preamble to state that municipal storm water dischargers must only implement BMPs to reduce the discharge of pollutants to the MEP.

* If the Preamble is not adjusted as requested above, EPA must adjust the costs contained in its Economic Analysis to reflect the potential cost to Caltrans and other municipal storm water dischargers that may be required to meet water quality standards by implementing BMPs and/or advanced treatment technologies.

Response to: CTR-042-002

See response to CTR-040-004.

Comment ID: CTR-047-002
Comment Author: City of Santa Fe Springs
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References: Letter CTR-047 incorporates by reference letters CTR-013 and CTR-027.
Attachments? N
CROSS REFERENCES

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our storm water program:

2. The application of water quality standards to MS4 storm water discharges would result in end-of-pipe treatment to reasonably achieve compliance and provide limited environmental benefit. Putting aside the issue of whether water quality standards apply to MS4s, the CTR as presently proposed will require storm water agencies to incur significant cost with minimal improvement in water quality. Based on

studies conducted by the County of Sacramento and the Fresno Metropolitan Flood Control District, storm water discharges being controlled through an aggressive BMP-based program could not be certain of achieving the proposed water quality criteria. To achieve the criteria, end-of-pipe treatment would be necessary. It is reasonable to assume that other municipalities throughout California where special studies have not been conducted will not be able to meet the proposed criteria as well, requiring public agencies throughout California to collect and treat its storm-water discharges. This is unreasonable and is not consistent with the intent of the CWA.

Response to: CTR-047-002

See response to CTR-040-004.

Comment ID: CTR-080-002
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References: Letter CTR-080 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES

Comment: The City of Los Angeles is hereby transmitting its comments regarding the proposed California Toxics Rule (CTR). I would like to begin by stating that the City currently spends an average of $28 million annually on its Stormwater Management Program. The majority of Program activities are guided by the Los Angeles County Municipal Stormwater Permit, which dictates the use of Best Management Practices to control pollutants to the maximum extent practicable. We are primarily concerned with how the CTR may impact the Stormwater Management Program.

* The City is concerned that the application of water quality standards to municipal separate storm sewers, may result in end-of-pipe treatment. There are issues regarding the feasibility and environmental benefits of such treatment.

Response to: CTR-080-002

See response to CTR-040-004.

Comment ID: CTRH-001-042
Comment Author: Kathy Russick
Document Type: Public Hearing
State of Origin: CA
Represented Org: Sacremento Co. Stormwater
Document Date: 09/17/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References:
Attachments? N

CROSS REFERENCES

Comment: As Dave Brent of the City of Sacramento mentioned already, we have evaluated the numeric limits proposed in the rule against six years of our stormwater programs' monitoring data. We have identified five constituents that will be a problem -- where we will likely have a problem in meeting the numeric discharge limits: copper, zinc, lead, PAHs and pentachlorophenol. These also show up as problem constituents for other stormwater programs in the state as well.

We evaluated the reductions that we could attain through intense BMP and source control efforts and determined that, if implemented, we still could not reduce the concentration of these constituents enough to meet the numeric limits. And this leads us inevitably to end-of-pipe treatment.

I would like to illustrate for you the obstacles that a stormwater program faces in meeting numeric limits. This past year the Sacramento Stormwater Program conducted an intense effort to evaluate specifically lead, a high-priority stormwater constituent of concern for us as well as EPA.

A major part of our effort was to identify all potential sources of lead to stormwater in Sacramento County. We identified about 50 individual sources of lead. So the next step in our effort was to determine which of these sources of lead we could actually control considering the nature of the sources, the practicality of controlling the sources, and the legal jurisdiction of our respective agencies, et cetera.

Only a portion of the sources that we identified we could address through source control and BMPs within our program. An example of some of those sources that we have no or very limited control over are: soil erosion, the natural soil erosion that just happens, not to do with construction; aircraft fuel emissions -- by the way, aircraft fuel does not come in unleaded form; automobile emissions, which still contain some lead; abrasion of road striping paint; and the abrasion of tires. These are to name a few.

Our program is now in the process of incorporating practical control measures that we did identify for lead into the various implementation elements of our program, particularly our Industrial Management Program, though we realize that we can only get at a portion of the lead sources in our stormwater.

I would like to note that we are initiating a similar source identification/source control effort for copper this year and anticipate similar results as we experienced for lead, that we will be able to address only a portion of the sources of copper in our stormwaters.

We, the Sacramento Stormwater Program, are not just throwing up our hands and giving up on controlling the problem constituents in our area. We are pursuing control measures and implementing BMPs to address those sources that we can address. And we are committed to continuing this effort.

We are implementing ever-escalating BMPs. We are striving toward maximum extent practicable in accordance with the Clean Water Act. But we have limited control over the pollution of our stormwater.

Now, after looking at lead sources in Sacramento, we are again back to end-of-pipe treatment. We're pushed to end-of-pipe treatment.

The price tag that has been estimated for end-of-pipe treatment for Sacramento County is $2 billion. That, amortized over 20 years, is $200 million per year. End-of-pipe treatment for municipal stormwater programs was never the intent of the Clean Water Act.

Plus, what would be achieved overall if we did end-of-pipe treatment in Sacramento County? The County makes up only a fraction of the Sacramento River watershed, and while we would spend $2 billion on end-of-pipe treatment, the majority of the stormwater occurring within the entire watershed would go unchecked.

In conclusion, I emphasize that the target of municipal programs should be maintained as the maximum extent practicable. If this is indeed the intent of the California Toxics Rule, then clarify that in the rule.

I would like to thank you for the opportunity to speak on behalf of Sacramento County today.

Response to: CTRH-001-042

EPA disagrees with the commenter's cost estimate of $2 billion because EPA does not believe that end-of-pipe treatment will be required to comply with the CTR. However, no details of the cost estimate were provided, thus, EPA could not evaluate the estimated cost. See also response to CTR-040-004.

Comment ID: CTRH-001-060b
Comment Author: Ellen Johnck
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Planning Coalition
Document Date: 09/17/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References:
Attachments? N
CROSS REFERENCES B

Comment: Secondarily and thirdly -- these two are tied together, the whole -- all our members that comply and have to secure the stormwater permits, we have been looking at how much it would cost us to build facilities to do some kind of end-of-pipe treatment to actually meet some of these numeric criteria for stormwater.

We don't think the economic evaluation that EPA has done is valid. Basically, there are a lot of shortcomings to it, and you have already heard today some of the numbers. The actual amount of money needed to build new facilities is way beyond the $86 million estimate that you have indicated in your analysis.

And based on this very serious economic evaluation shortcoming, I am recommending that at least a 30-day time limit be provided so that you can hear from the permit applicants regarding the statement to show you what the costs really are, and we'd like some more time to do that.

Those are essentially the substance of my comments today. Thank you.

Response to: CTRH-001-060b

See response to CTR-040-004.

Comment ID: CTRH-002-002
Comment Author: Chris Compton
Document Type: Public Hearing
State of Origin: CA
Represented Org: County of Orange
Document Date: 09/18/97
Subject Matter Code: J-04 End-of-Pipe Treatment v. BMP
References:
Attachments? N
CROSS REFERENCES

Comment: Are the criteria attainable?

Orange County has developed and implemented a municipal stormwater quality management plan (also known as the Drainage Area Management Plan) which is applicable countywide. The Drainage Area Management Plan identifies a number of BMPs that address the major source categories of urban stormwater pollutants. These BMPs have been reviewed and approved by the respective regional water quality control boards. However, we have conducted a preliminary attainability analysis and have determined that, after considerable cost to fully implement a BMP-based program, it may not achieve compliance with proposed criteria for dissolved metals without regional or national product substitutions.

Although substantial public resources have been committed to implementation of this program, the municipal stormwater discharges in Orange County seem unlikely to attain all of the proposed criteria within the required compliance period. The alternative would be to collect and treat stormwater discharges as described in the Task Force testimony yesterday.

In addition to the capital cost, construction of these facilities would result in the displacement of jobs and housing as well as a loss of habitat. We believe that Congress intended municipal stormwater permits to implement programs to address sources of pollutants, not to provide end-of-pipe treatment to meet the numerical criteria.

Response to: CTRH-002-002

See response to CTR-040-004.

Subject Matter Code: J-05 BMPs Inability to Comply

Comment ID: CTR-040-025
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-05 BMPs Inability to Comply
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: EPA erroneously assumes that municipal stormwater dischargers can comply with the water quality criteria with BMPs and that BMPs do not cost money. Both assumptions are incorrect as evidenced by attainability analyses performed by several municipal stormwater dischargers.

Response to: CTR-040-025

See response to CTR-040-004.

Comment ID: CTR-041-021
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-05 BMPs Inability to Comply
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that municipal stormwater dischargers can comply with the water quality criteria with BMPs and that BMPs do not cost money. Both assumptions are incorrect as evidenced by attainability analyses performed by several municipal stormwater dischargers.

Response to: CTR-041-021

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-040-004.

Comment ID: CTR-044-016
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: J-05 BMPs Inability to Comply
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that municipal stormwater dischargers can comply with the water quality criteria with BMPs and that BMPs do not cost money. Both assumptions are incorrect as evidenced by attainability analyses performed by several municipal stormwater dischargers.

Response to: CTR-044-016

See response to CTR-040-004.

Comment ID: CTR-054-020
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-05 BMPs Inability to Comply
References:
Attachments? N
CROSS REFERENCES

Comment: EPA erroneously assumes that municipal stormwater dischargers can comply with the water quality criteria with BMPs and that BMPs do not cost money. Both assumptions are incorrect as evidenced by attainability analyses performed by several municipal stormwater dischargers.

Response to: CTR-054-020

EPA did not include benefits or costs of controlling nonpoint sources or storm water dischargers in its estimates of benefits and costs of the CTR. EPA believes that the final rule will not have a direct effect on sources not permitted under the NPDES program (e.g., nonpoint sources) or NPDES sources not typically subject to numeric water quality-based effluent limits (e.g., wet weather discharges). Any potential indirect effect on nonpoint sources and wet weather discharges, such as runoff from farms, urban areas, and abandoned mines, and contaminated sediment, is unknown at this time. Many of the programs developed to control nonpoint sources and wet weather discharges are already in place. Costs due to these programs have already been incurred or will soon be incurred owing to existing federal, State, and local environmental programs.

EPA also acknowledges that nonpoint sources and wet weather discharges are technically difficult to model and evaluate costs because they are intermittent and highly variable. Nonpoint source and wet weather discharges also occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which are evaluated under critical low flow or drought conditions. Thus, evaluating agricultural nonpoint source discharges and storm water discharges and their effects on the environment is highly site-specific and data intensive.

See also response to CTR-001-002.

Comment ID: CTR-096-003b
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: J-05 BMPs Inability to Comply
References:
Attachments? N
CROSS REFERENCES E-01c01

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

3. The cost implications of these numerical standards are estimated to exceed $100 million to the City of Modesto alone, thereby triggering the President's Executive Order 12866 requiring a more detailed and comprehensive cost-benefit assessment of these proposed standards.

Specifically, the City submits the following comments:

E. Under the proposed rule, Best Management Practices (BMPS) are recommended for compliance with the California Toxic Rule. BMPs may include a variety of processes. Each of these processes may have an associated construction and operation cost. For the City of Modesto, due to the design of the wastewater and stormwater collection systems, it may cost between $25 million to $50 million to construct acceptable BMPS. Existing BMPs may not reduce the pollutant level below that listed in the proposed CRT. Therefore, it is our opinion that construction costs presented in the California Toxic Rule are significantly under estimated. Constructed treatment facilities for wastewater and storm water, beyond BMPS, could exceed $1 00 million for Modesto alone. In addition, annual operation and maintenance costs for BMPs and treatment facilities exceed $1,000,000.

In summary, the proposed regulation is significant because it may well impose costs that are greater than $100 million per year on the regulated community, the majority of which are local public agencies. Regardless of the dollar amount, it is likely to adversely affect, in a material way, the economy, the environment, and local governments.

Thank you in advance for consideration of my comments on the CTR.

Response to: CTR-096-003b

With respect to wet-weather compliance with the CTR see response to CTR-040-004. With respect to EPA's compliance with E.O. 12866 see CTRH-002-006a (Category I; Stormwater/Wet Weather Discharges).

Subject Matter Code: J-06 NEPA

Comment ID: CTR-001-009b
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: J-06 NEPA
References:
Attachments? N
CROSS REFERENCES F

Comment: THE PROPOSAL VIOLATES THE NATIONAL ENVIRONMENTAL POLICY ACT AND ENDANGERED SPECIES ACT, AND WOULD USURP THE ROLE OF CONGRESS AND THE STATE AND REGIONAL BOARDS

Major environmental impacts of controls could also be foreseen if the water quality standards of the proposed CTR were to apply as numeric effluent limitations or wasteload allocations. This would result in the requirement to prepare an EIS in connection with the proposed rule. (*13) In effect, substantial end-of-pipe treatment facilities on the same order of magnitude as existing POTWs in the Bay Area could be necessary.

Given the scale and location of the facilities that would be required, significant wetland, endangered species and other environmental impacts could occur. EPA must fully evaluate these impacts of the proposed rule before the rule is promulgated. (*14)

A more expansive application of the WQS also would usurp the basin planning process to the extent that the regional boards have included textual discussions of how ambient water quality criteria are to be implemented, particularly with respect to MS4s. The San Francisco Basin Plan states generally that WQS are to be addressed by MS4s through escalating BMPs. EPA has not taken action to disapprove the San Francisco Basin Plan and cannot implicitly repeal portions of that plan through inconsistent preamble language in the currently proposed rule.

Congress has already addressed this significant public policy question and the agency cannot shed its Congressional leash and arrogate legislative power. This is particularly true given the massive expenditures of public funds that could be implicated under at least the more expansive view of what EPA has proposed. We elect our representatives in Congress to balance these major questions, such as the matter of whether local funds should be siphoned from schools, police, infrastructure, etc., to fund storm water controls at the scale necessary to meet WQS regardless of cost. Congress has determined in Section 402(p) that MS4s need only adopt controls to reduce pollutants in storm water to the maximum extent practicable, and to effectively prohibit non-storm water discharges to the storm water system, rather than being subjected to infeasible or exorbitantly expensive numeric effluent limitations.(*15)

(*13) To the extent that the CTR will force development of end of-pipe treatment systems, promulgation of the CTR will represent a major federal action significantly affecting the quality of the human environment under the National Environmental Policy Act, triggering the requirement to develop an environmental impact statement to support the rule.

(*14) Commenters have been limited in their ability to present specific information on the question of endangered species, wetland and other environmental impacts given the short comment period on the proposal and EPA's refusal to extend that comment period.

(*15) In Sections 402(p)(5) and (6)f Congress also directed that the approach to meeting water quality standards should MEP-level controls on major dischargers fall short would be to study and expand the scope of the program to include additional dischargers. No mention is made of subjecting major MS4s to more stringent controls. In fact, the regulations are expressly required to target stormwater discharges, other than those discharges described in paragraph (2) [major MS4s], to be regulated to protect water quality - 33 U.S.C. section 1342(p)(6) (Emphasis added).

Response to: CTR-001-009b

With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, Comment CTR-040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

The purpose of the CTR is to fill the current gaps in water quality criteria in inland surface waters and enclosed bays and estuaries. Any existing provisions in a State Basin Plan that have been approved by the State and EPA would not be negated by the preamble discussion in the CTR.

Regarding the application of MEP under section 402(p) of the CWA see response to CTR-040-004.

Comment ID: CTRH-001-009a
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: J-06 NEPA
References:
Attachments? N
CROSS REFERENCES F

Comment: Lastly, it's been fairly well documented by EPA testimony before the Congress and by other state stakeholders' concerns about the end-of-pipe mandate, because the end-of-pipe facilities that must be constructed in effect create substantial damage to the riparian and other waters of the U.S. that are of primary concern to us.

With that potential, then certainly NEPA and the Endangered Species Act would require an evaluation of the impact associated with a rule causing or leading to those impacts. And again, the current rule does not consider that nor any of the cost or other impacts related to stormwater programs.

So there is a huge consistency or inconsistency problem that we think must be corrected for the rule to be consistent with the statutes and with your executive orders.

Thank you.

Response to: CTRH-001-009a

Subject Matter Code: K Watershed Approach

Comment ID: CTR-021-003
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Sunnyvale has long been an advocate of watershed planning at the local level, and it is an enthusiastic charter participant in the Watershed Planning Initiative for the South Bay (the "WPI"). We believe that the WPI has significant potential to set the pace for "place-based" watershed management planning throughout the San Francisco Bay area, if not in California. The CTR-based criteria, particularly those for metals, will form the starting point for the water modeling which will lead to a TMDL and a wasteload allocation/load allocation for the South Bay. Accordingly, we have devoted significant time and resources to the joint efforts of our sister cities in the South Bay to work with EPA, the Regional Water Quality Control Board, affected industry, and the environmental community to make the WPI work. We believe that the WPI will be a credit to EPA's leadership and willingness to devote the considerable resources required.

In conclusion, we are entirely supportive of many of EPA's innovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe that EPA has needlessly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-003

EPA appreciates the commenter's support and significant participation in the Watershed Planning Initiative for the South Bay.

Comment ID: CTR-032-002f
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N

CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

The District supports EPA's use of "sound science" and current data in developing the proposed criteria in the California Toxics Rule (CTR). The District strongly supports language in the Preamble that references and endorses recommendations of the State Task Forces including use in permitting of:

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-032-002f

EPA appreciates the commenter's support of the preamble language concerning the State's use of innovative TMDL processes such as effluent trading.

Comment ID: CTR-032-007
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: Watershed Management Based Permitting Approach

Since POTWs are only responsible for contributing 1-10% of the toxics mass loading (including copper and mercury) to San Francisco Bay (CTR P. 7-7 EA) it makes economic sense to focus limited public resources on identification of larger and potentially more cost-effective sources to control. The District strongly believes that future permits should be developed using a comprehensive watershed management based approach, consistent with various EPA guidance including the August 1997 Robert Perciasepe TMDL Policy memorandum and the San Francisco Bay Regional Board's July 1997 Watershed Management Initiative Guidance.

The District supports the watershed approach where before additional control measures are imposed on point source dischargers, other potential sources of copper and mercury in the watershed that impact the receiving water need to be identified, quantified, and evaluated as to the potential cost of control

measures. Effluent trading should be permitted and encouraged where it is demonstrated to be a more cost effective pollutant reduction technique than additional point source treatment. We support the use of interim limits with compliance schedules linked to completion of special studies, in situations such as ours where compliance with final mercury and copper limits is not feasible and additional information is required to develop technically defensible and attainable final limits.

Response to: CTR-032-007

EPA appreciates District's support of the watershed management approach and its use in developing permits. However, EPA does not agree that the watershed approach should be applied in such a manner that would preclude additional point source controls until the impact of other sources of pollutants are "... identified, quantified, and evaluated as to the potential cost of control measures." We believe that TMDL development can be an effective tool to conduct such an evaluation and that TMDLs will be a component of many effective watershed management strategies.

EPA agrees with the District that pollutant trading can be a cost effective means of attaining compliance with water quality standards. EPA believes that TMDLs can provide the necessary analytical framework to implement a trading program. EPA will continue to encourage the State to evaluate such programs and will work with the State to ensure that such programs are designed equitably and do not result in the creation of "hot" spots in the watershed (See Draft Framework for Watershed-Based Trading, U.S. EPA 1996).

Comment ID: CTR-034-011
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: * As noted in our testimony at the September 18 public hearing, SCAP recommends that EPA describe in the Preamble the Agency's strategy for using a watershed management approach for controlling toxic pollutant inputs to the environment. This is particularly appropriate for pollutants which come primarily from nontraditional sources, are in the ambient environment primarily as a result of historical discharges (e.g. DDT, PCBs), and/or are difficult or very costly to control using end-of-pipe treatment. We believe that it is also appropriate to adopt a watershed approach for pollutants which are known to cause environmental harm - due to bioaccumulation, or other characteristics - but which are below detection levels.

Response to: CTR-034-011

EPA acknowledges the comment suggesting that it describe in the preamble the watershed management approach for controlling toxic pollutants into the environment. We believe that a detailed discussion of the watershed management approach is more appropriate in documents dedicated to the topic. Several documents already exist including EPA's Draft Framework for Watershed-Based Trading, dated May

1996, and EPA's Guidance for Water Quality-based Decisions: the TMDL Approach, dated April 1991. The preamble to the CTR contains information specific to the promulgation of the CTR. EPA appreciates the commenter's request for information and hopes that the documents listed above are informative.

Comment ID: CTR-035-003
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References:
Attachments? N
CROSS REFERENCES

Comment: Third, with respect to the criteria proposed for adoption in the draft CTR and implementation issues discussed in the preamble to the CTR, we wish to make the following recommendations to EPA.

- Consistent with EPA's Watershed Approach Framework and NPDES Watershed Strategy, EPA should describe in the Preamble the Agency's strategy for implementing a watershed management approach to achieve the CTR criteria in California, particularly since, as EPA's Economic Analysis for the CTR found, many -- if not most of the criteria will not be achieved solely with point source controls (U.S. EPA, 1996a and 1994a).

Response to: CTR-035-003

EPA acknowledges the comment suggesting that it include and describe in the preamble its strategy for implementing a watershed approach to achieve water quality standards based on CTR criteria. Please see response to CTR-034-011. The watershed approach is a flexible approach which may vary widely between water bodies in different situations. Since the State will create and implement a watershed management approach, EPA cannot prescribe an approach or strategy for the State to achieve water quality standards based on CTR criteria for all California water bodies. Various EPA publications exist for states and dischargers to use in developing strategies best suited for particular water quality situations for specific water bodies. These publications include those the commenter noted. EPA supports the State's use of a watershed management approach to implement CTR-based water quality standards for particular water bodies and pollutants.

Comment ID: CTR-036-011
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040

Attachments? N
CROSS REFERENCES

Comment: We are concerned that the proposed rule reflects a reversal to the comrnand-and-control approach of water quality regulation and marks a policy shift away from the community-driven 'watershed' approach that EPA has been promoting. Orange County has a number of fledgling 'watershed' programs that we feel offer potential to effectively prioritize the approaches to be taken on a watershed-specific basis.

Response to: CTR-036-011

EPA disagrees with the comment that the CTR reflects a reversal to the command and control approach and marks a policy shift away from the watershed approach. The CTR merely sets into place water quality criteria for the State of California. These criteria, combined with the State-adopted beneficial uses, create water quality standards which are necessary to set bench marks for the State's water quality control programs, strategies, and approaches. The methods used to achieve the standards will continue to be through NPDES permits and other State programs, including programs which may utilize the watershed management approach. EPA continues to encourage and support the State's use of the watershed management approach to achieve water quality standards in various water quality control programs, and for appropriate situations.

Comment ID: CTR-059-014
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES

Comment: Watershed Management

The Sanitation Districts recommend that EPA describe in the Preamble the Agency's strategy for using a watershed management approach for controlling toxic pollutant inputs to the environment. This is particularly appropriate for pollutants which come primarily from nontraditional sources, are in the ambient environment primarily as a result of historical discharges (e.g. DDT, PCBs), and/or are difficult or very costly to control using end-of-pipe treatment. We also believe that a watershed approach is the appropriate way to address pollutants which are known to cause environmental harm -- due to bioaccumulation, or other characteristics -- but which are below detection levels. We particularly encourage EPA to use a flexible watershed-based approach in implementing the CTR in the types of situations described above, where a point source-oriented command-and-control strategy is not likely to be effective.

Response to: CTR-059-014

In response to the comment that EPA should describe in its preamble the watershed management approach to achieve CTR-based water quality standards, please see response to CTR-035-003.

Comment ID: CTR-067-004b
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K Water Shed Approach
References:
Attachments? N
CROSS REFERENCES E-01n

Comment: * In addition, EPA cannot make an accurate determination of the costs and benefits of promulgating CTR criteria for those criteria that are below achievable detection limits. Because detection limits for some pollutants will most likely improve in the near future, dischargers who are reporting regulatory compliance with current detection limits may not be in compliance when lower detection limits are achievable. OVSD (and likely other dischargers as well) have historically been required to report pollutant results with little regard to the detection limit achieved by the contract laboratory conducting the testing. This may have led to EPA's grossly under estimating the cost impact of the CTR. Detection limits of many priority pollutants identified in the CTR are actually lower than those achieved during recent special testing of OVSD's effluent to identify low pollutant levels. Therefore, the potential compliance costs to our commercial and residential dischargers could be significant, yet the Economic Analysis for the draft CTR could not estimate such costs. As a more reasonable alternative, OVSD recommends that a watershed approach be used to address these pollutants. OVSD's receiving water (the Ventura River) is currently managed using the watershed approach.

Response to: CTR-067-004b

In response to the comment that EPA should use a watershed approach to address CTR-based water quality standards, please see response to CTR-035-003.

Comment ID: CTR-083-002
Comment Author: Fairfield-Suisun Sewer Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K Water Shed Approach
References: Letter CTR-083 incorporates by reference letters CTR-035 and CTR-054
Attachments? N
CROSS REFERENCES

Comment: * The District supports EPA Headquarters' Watershed Approach Framework and NPDES Watershed Strategy. We believe the CTR should address the EPA Region IX strategy for implementing

this management approach for pollutants with attainability issues. This is particularly crucial when regulating bioaccumulative pollutants, such as mercury. Region IX's commitment to this approach will insure appropriate consideration is given to watershed management strategies by State agencies when implementing the CTR.

Response to: CTR-083-002

EPA acknowledges the commenter's support for the watershed management approach. However, in response to the comment that EPA address the watershed management approach in the CTR for pollutants with attainability problems, please see response to CTR-035-003. EPA continues to support the State's use of the watershed management approach where appropriate.

Comment ID: CTRH-002-015
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: K Water Shed Approach
References:
Attachments? N
CROSS REFERENCES

Comment: We suggest that EPA give consideration to using a watershed management approach to achieve the clean water goals for controlling toxic pollutant inputs into the environment rather than the traditional "command and control" approach, and that a strategy for doing this be included in the preamble to the rule. This is particularly appropriate for pollutants which come primarily from nontraditional sources and are difficult or very costly to control using end-of-pipe treatment.

Response to: CTRH-002-015

EPA agrees with the comment that the watershed management approach should be used for controlling toxic pollutants in certain situations. Please see response to CTR-035-003.

Subject Matter Code: K-01 TMDLs

Comment ID: CTR-004-006
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES

Comment: Available Regulatory Relief under the California Toxics Rule

The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at. pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility. (*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does riot mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Total Maximum Daily Loads (TMDLS)

The majority of the discussion of TMDLs contained in the Preamble to the CTR is merely a reiteration of the requirements of the Clean Water Act (CWA) and the existing regulations. See CTR at pg. 42185-6; see accord 33 U.S.C. Section 1313(d)(1)(C) and 40 C.F.R. Section 130.7. However, the Preamble discussion also contains recommendations regarding the implementation of TMDLs that merit some review.

First, EPA recommends that, since the TMDL process can be significantly labor and data intensive, collaborative efforts to establish TMDLs on water quality limited water bodies should be pursued. EPA envisions that this collaborative effort by dischargers, the State, EPA, and other stakeholders, could distribute work and associated costs between the interested parties, as well as shorten the overall time necessary to complete the analyses. See CTR at pg. 42185-6. This language attempts to alter the current statutory and regulatory language requiring that States must perform TMDLS, which are then submitted for EPA approval. If EPA is now proposing to allow other entities or coalitions to be able to establish TMDLS, this authority must be placed in the language of the rule itself, if not in an amendment to the CWA.

Second, EPA recommends innovative alternatives to traditional "pounds per day" TMDLS. The regulations and EPA guidance reviewed regarding TMDLs did not mention whether TMDLs had to be established as "pounds per day," The regulations define of "load" as "an -amount of matter, . . that is introduced into a receiving water" (40 C.F.R. Section 130.2(c)) and discuss TMDLs in terms of either mass per time, toxicity, or other appropriate measure" (40 C.F.R. Section 130.2(I)). These definitions seem to be flexible enough to allow for EPA's recommended alternatives to "traditional pounds per day TMDLS."

A third recommendation pertained to effluent or pollutant trading. In the Preamble to the CTR, EPA encourages innovative approaches such as effluent trading as a method to attain and/or maintain water quality standards. The Preamble at page 42185 describes effluent trading as follows:

Effluent trading allows sources that can control pollutants beyond compliance with current requirements to sell or trade credits for its excess reduction to in other source unable to control its own pollutants is effectively or as efficiently. The goal of an effluent trading program is to achieve similar or improved environmental results in a more cost-effective manner than under current regulatory structures. EPA's most current policy on effluent trading is summarized in the "Policy Statement for Effluent Trading in Watersheds" which was issued in January of 1996 and which reiterates President Clinton's commitment to effluent trading as expressed in the March 16, 1995 report on "Reinventing Environmental Regulation." The Policy states that the "EPA will work cooperatively with key stakeholders to find sensible, innovative ways to meet water quality standards quicker and at less cost than traditional approaches alone." The policy outlines several different types of trades that may take place. These trades include but are not limited to the following; (1) Intra-plant trading between outfalls within one facility; (2) pretreatment trading between indirect industrial point sources that discharge to a POTW; (3) point to point source trading, point to nonpoint source trading, and nonpoint to nonpoint source trading.

The existing regulations and EPA guidance relating to TMDLs already contemplate some form of pollutant trading.(*3) However, the regulations currently do not specifically allow the degree of trading outlined in the Preamble. To clarify that this is now EPA policy, EPA should propose language to that effect within the regulatory language itself.

The final recommendation EPA makes related to TMDLs addresses the use of interim permit limits when a TMDL/WLA/LA or other special study is underway but not completed. The Preamble gives guidance on how interim limits should be calculated. EPA states that "past performance and future uncertainty can be considered as factors in determining interim permit limits; however, permitting authorities may consider other factors, particularly factors concerning the water quality of the receiving water body and the overall goal to attain the water quality standard." EPA further states that it supports innovative ideas such as using specific method for determining interim limits and "trigger" concentrations above which corrective action would be necessary. Furthermore, EPA notes that the State, as the permitting authority, has broad discretion in determining how interim permit limits should be ascertained in different situations. CTR Preamble at pg. 42184-5. This language is helpful, but it should be placed into the rule so that it has the force of law and may be utilized as such.

As a Final note regarding the use of TMDLs as a form of regulatory relief, it should be noted that theuse of less restrictive effluent limitations based on TMDLs and interim limits is limited by the TMDL process itself as well as the antibacksliding provisions of the CWA. EPA guidance recognized these facts in its TMDL guidance with the following statement:

In developing a TMDL it is important to keep in mind certain constraints on the WLA [wasteload allocation] portion that are imposed by antibacksliding regulatory provisions. The WLA will normally

result in new or more stringent water quality-based limits than those contained in a previously issued permit. In a limited number of cases, however, it is conceivable that less stringent water quality-based limits could result. In these cases, permit limits must conform to the antibacksliding provisions contained in section 402(o) of the CWA. (*4)

(*1) This cost trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario, See EA at pg. 4.

(*2) In addition, pollutant load reductions word not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*3) See 40 C.F.R. Section 130.2(I) ("If Best Management Practices (BMPS) or other nonpoint source pollution controls make more stringent load allocations practicable, then wasteload allocations can be made less stringent. Thus, the TMDL process provides for nonpoint source control tradeoffs."); see also EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 it pg. 51 (April 1991).

(*4) EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 at pg. 20 (April 1991) (Emphasis added)

Response to: CTR-004-006

EPA does not agree that a collaborative approach to TMDL development described in the preamble to the proposed CTR requires a change in statutory or regulatory language. Currently, the State's process for TMDL approval includes amendment of the affected Regional Board's Basin Plan, which requires approval by the State Water Resources Control Board and the Office of Administrative Law, prior to submital to EPA. The collaborative approach which EPA supports does not allow any other entity beside the State to establish TMDLs. The basis for the TMDL (e.g. the technical work) can be performed by other entities. That technical work can then be submitted by the State to EPA as part of the supporting documentation of the State-established TMDL.

EPA agrees with the commentor that current Federal regulations provide for flexibility in the manner that TMDLs are expressed. The commentor asserts that regulations do not specifically allow the degree of trading outlined in the preamble to the proposed rule. The current regulations do not prohibit the trading described in the preamble. TMDLs can provide the necessary analytical framework to ensure that trades are equitable and do not result in the creation of "hot spots".

With respect to TMDLs as a form of regulatory relief, the commentor asserts that EPA guidance indicates that little relief can occur for the waste load allocation portion of the TMDL due to anti-backsliding provisions of section 402(o) of the Clean Water Act. EPA believes that section 303(d)(4) of the Clean Water Act specifically allows for less restrictive effluent limits as long as such limits are consistent with an approved TMDL. However, these issues concerning TMDLs are outside the scope of this rule, and the rules concerning TMDLs may change.

In response to the commentor's discussion concerning the different regulatory relief approaches that EPA discusses in its Economic Analysis, please see response to CTR-032-004.

Comment ID: CTR-021-002d
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES G-04; C-24a; C-22; G-05; G-02

Comment: Sunnyvale is very supportive of many fine concepts advanced in the proposed CTR, and we join with CASA/Tri-TAC in complimenting the Agency on its proposed positions with regard to such matters as: (a) the use of interim effluent limitations in NPDES permits during the pendency of TMDL and other special studies; (b) the allowance of water effects ratios in adjusting the criteria for metals without the necessity for additional rulemaking to establish site-specific objectives; (c) the use of the dissolved state for the metals criteria; (d) the use of cooperative, intergovernmental, and stakeholder-involved approaches towards the development of TMDLs;(e) the allowance of dilution for both chronic and acute pollutants; and (f) the allowance of compliance schedules in NPDES permits.

Response to: CTR-021-002d

EPA appreciates the commenter's support of EPA's preamble discussion concerning the State's use of cooperative approaches toward the development of TMDLs.

Comment ID: CTR-034-012b
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-04

Comment: * SCAP supports EPA's discussion in the Preamble regarding the use of interim permit limits while Total Maximum Daily Loads.(TMDLs) and other special studies are being performed. We strongly urge EPA to support the use of the SWRCB Permitting Task Force's recommended approach for deriving interim permit limits.

Response to: CTR-034-012b

EPA appreciates the commenter's support of the discussion in the preamble concerning the State's use of interim permit limits while TMDLs or other special studies are being developed. EPA supports the State's consideration of the stakeholder Task Force recommendations to help deal with these issues.

Comment ID: CTR-035-002g
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES C-22; C-01a; C-08a; G-05; G-04; G-09; C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002g

EPA appreciates the commenter's support of the discussion in the preamble concerning the State's use of interim permit limits while TMDLs or other special studies are being developed.

Comment ID: CTR-035-032a
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES K-03

Comment: C. Implementation Issues pp. 42184-42185 -- Total Maximum Daily Loads (TMDLs) We agree with EPA's statements in the Preamble in support of the recommendations of the Permitting and Compliance Issues Task Force regarding the benefits of collaborative approaches to developing TMDLs. We also endorse the State's and EPA's policy to allow innovative alternatives to traditional "pounds per day" TMDLs, and suggest that EPA expand this reference in the Preamble to include the concept of "quantifiable targets," under which TMDLs could be expressed as a mass loading, a concentration, a

percent reduction, an ecosystem improvement, or a degree of implementation of a control measure (such as a best management practice) (see SWRCB, 1995, Part VI).

EPA also encourages the use of innovative approaches such as effluent trading, within the TMDL framework. While we support the concept of effluent trading, we do have concerns about how EPA intends for it to be implemented. For instance, in comments submitted to EPA on September 6, 1996 on EPA's Draft Framework for Watershed-Based Trading (May 1996), we pointed out that the proposed framework was overly prescriptive and, as a result, would likely significantly restrict watershed-based trading in California. A few of the barriers to trading we identified in the draft framework include: provisions limiting the duration of trades to the five year term of NPDES permits; limitations on the effect of trades on existing effluent limits, compliance schedules or enforcement actions; discouragement of trading for toxic pollutants; and inequitable requirements for point sources to demonstrate a "reasonable assurance" that a trade will be successful. We recommend that EPA include language in the Preamble to the CTR emphasizing a flexible approach to both TMDLs and effluent trading; that trading is voluntary for all involved parties; and that interim limits will be placed in NPDES permits while the necessary ambient data arc gathered and analytical tools are developed.

Response to: CTR-035-032a

EPA appreciates the commenter's support of the preamble discussion concerning the State's use of cooperative approaches toward the development of TMDLs and concerning the State's use of innovative alternatives to traditional "pounds per day" TMDLs. The commenter suggests that EPA expand the reference to include the concept of "quantifiable targets", under which "TMDLs could be expressed as a mass loading, a concentration, a percent reduction, an ecosystem improvement, or a degree of implementation of a control measure". Currently, TMDLs must be established to implement the applicable water quality standard and may be expressed in terms of mass per time, toxicity, or other appropriate measure (40 CFR 130.2(i)). Other appropriate measures include mass loading, concentration, or other indicators. The analysis supporting the TMDL must describe how the TMDL will result in the attainment of water quality standards; numeric targets are usually included in calculations to interpret applicable standards and provide the basis for TMDL calculations. Although implementation of control measures or best management practices (BMPs) will often be a component of the State's TMDL implementation plan, degree of BMP implementation will not suffice as a TMDL because this approach does not clearly demonstrate that water quality standards will be attained. Moreover, since the manner of BMP implementation often determines the effectiveness of the BMP (i.e. there is a high degree of uncertainty in the effectiveness of the BMP), the use of such a "quantifiable target" would require the use of a prohibitively large margin of safety and thus, may be infeasible. These issues, however, are beyond the scope of the CTR, and rules for TMDLs may change.

The commenter also recommends that EPA include language in the preamble emphasizing a flexible approach to both TMDLs and effluent trading; that trading is voluntary for all parties; and that interim limits will be placed in NPDES permits while the necessary data and analytical tools are developed. The preamble to the proposed rule summarized the available flexibility in both TMDLs and effluent trading, as well as supported the State's use of interim permit limits during the development of TMDLs. EPA agrees that effluent trading should be voluntary and believes that TMDLs can provide the analytical framework to support trades. However, as noted above, this is beyond the scope of the CTR, and rules for TMDLs may change.

Comment ID: CTR-040-048

Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits." EA at.pg. 4 (emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does not mention any of the methods of regulatory relief. Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

Total Maimum Daily Loads (TMDLs)

The majority of the discussion of TMDLs contained in the Preamble to the CTR is merely a reiteration of the requirements of the Clean Water Act (CWA) and the existing regulations. See CTR at pg. 42185-6; see accord 33 U.S.C. section 1313(d)(1)(C) and 40 C.F.R. section 130.7. However, the Preamble discussion also contains recommendations regarding the implementation of TMDLs that merit some review.

First, EPA recommends that, since the TMDL process can be significantly labor and data intensive, collaborative efforts to establish TMDLs on water quality limited water bodies should be pursued. EPA envisions that this collaborative effort by dischargers, the State, EPA, and other stakeholders, could distribute work and associated costs between the interested parties, as well as shorten the overall time necessary to complete the analysis. See CTR at pg. 42185-6. This language attempts to alter the current statutory and regulatory language requiring that States must perform TMDLs, which are then submitted for EPA approval. If EPA is now proposing to allow other entities or coalitions to be able to establish TMDLs, this authority must be placed in the language of the rule itself, if not in an amendment to the CWA.

Second, EPA recommends innovative alternatives to traditional "pounds per day" TMDLs. The regulations and EPA guidance reviewed regarding TMDLs did not mention whether TMDLs had to be established as "pounds per day." The regulations define of "load" as "an amount of matter . . . that is introduced into a receiving water" (40 C.F.R. section 130.2(e)) and discuss TMDLs in terms of either mass per time, toxicity, or other appropriate measure" (40 C.F.R. section 130.2(i)). These definitions

seem to be flexible enough to allow for EPA's recommended alternatives to "traditional pounds per day TMDLs."

A third recommendation pertained to effluent or pollutant trading. In the Preamble to the CTR, EPA encourages innovative approaches such as effluent trading as a method to attain and/or maintain water quality standards. The Preamble at page 42185 describes effluent trading as follows:

Effluent trading allows sources that can control pollutants beyond compliance with current requirements to sell or trade credits for its excess reduction to another source unable to control its own pollutants as effectively or as efficiently. The goal of an effluent trading program is to achieve similar or improved environmental results in a more cost-effective manner than under current regulatory structures. EPA's most current policy on effluent trading is summarized in the "Policy Statement for Effluent Trading in Watersheds" which was issued in January of 1996 and which reiterates President Clinton's commitment to effluent trading as expressed in the March 16, 1995 report on "Reinventing Environmental Regulation." The Policy states that "EPA will work cooperatively with key stakeholders to find sensible, innovative ways to meet water quality standards quicker and at less cost than traditional approaches alone." The policy outlines several different types of trades that may take place. These trades include but are not limited to the following: (1) Intra-plant trading between outfalls within one facility; (2) pretreatment trading between indirect industrial point sources that discharge to a POTW; (3) point to point source trading, point to nonpoint source trading, and nonpoint to nonpoint source trading.

The existing regulations and EPA guidance relating to TMDLs already contemplate some form of pollutant trading.(*3) However, the regulations currently do not specifically allow the degree of trading outlined in the Preamble. To clarify that this is now EPA policy, EPA should propose language to that effect within the regulatory language itself.

The final recommendation EPA makes related to TMDLs addresses the use of interim permit limits when a TMDL/WLA/LA or other special study is underway but not completed. The Preamble gives guidance on how interim limits should be calculated. EPA states that "pastperformance and future uncertainty can be considered as factors in determining interim permit limits, however, permitting authorities may consider other factors, particularly factors concerning the water quality of the receiving water body and the overall goal to attain the water quality standard." EPA further states that it supports innovative ideas such as using specific method for determining interim limits and "trigger" concentrations above which corrective action would be necessary. Furthermore, EPA notes that the State, as the permitting authority, has broad discretion in determining how interim permit limits should be ascertained in different situations. CTR Preamble at pg. 42184-5. This language is helpful, but it should be placed into the rule so that it has the force of law and may be utilized as such.

As a final note regarding the use of TMDLs as a form of regulatory relief, it should be noted that the use of less restrictive effluent limitations based on TMDLs and interim limits is limited by the TMDL process itself as well as the antibacksliding provisions of the CWA. EPA guidance recognized these facts in its TMDL guidance with the following statement:

In developing a TMDL it is important to keep in mind certain constraints on the WLA [wasteload allocation] portion that are imposed by antibacksliding regulatory provisions. The WLA will normally result in new or more stringent water quality-based limits that those contained in a previously issued permit. In a limited number of cases, however, it is conceivable that less stringent water quality-based limits could result. In these cases, permit limits must conform to the antibacksliding provisions contained in section 402(o) of the CWA.(*4)

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*3) See 40 C.F.R. section 130.2(i) ("If Best Management Practices (BMPs) or other nonpoint source pollution controls make more stringent load allocations practicable, then wasteload allocations can be made less stringent. Thus, the TMDL process provides for nonpoint source control tradeoffs."); see also EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 at pg. 51 (April 1991).

(*4) EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 at pg. 20 (April 1991) (emphasis added).

Response to: CTR-040-048

In response to the commenter's discussion concerning TMDLs with respect to the collaborative approach, alternatives to traditional "pounds per day" TMDLs, effluent and/or pollutant trading, and the use of interim permit limits, see response to CTR-004-006.

Comment ID: CTR-041-044
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits. EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

The types of alternative regulatory approaches assumed available for dischargers in California include phased total maximum daily loads (TMDLs), water quality standard variances, site-specific criteria, change in designated use, and alternative mixing zones. EA at pg. 4-5. The following sections will discuss each of EPA's proposed methods for regulatory relief and explain whether or not these methods can truly be used to provide relief from the CTR-based permit limits as anticipated by EPA. It should be noted that the actual language of the rule itself does not mention any of the methods of regulatory relief.

Therefore, this analysis will be based solely upon the language contained in the Preamble to the CTR.

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First, EPA recommends that, since the TMDL process can be significantly labor and data intensive, collaborative efforts to establish TMDLs on water quality limited water bodies should be pursued. EPA envisions that this collaborative effort by dischargers, the State, EPA, and other stakeholders, could distribute work and associated costs between the interested parties, as well as shorten the overall time necessary to complete the analysis. See CTR at pg. 42185-6. This language attempts to alter the current statutory and regulatory language requiring that States must perform TMDLs, which are then submitted for EPA approval. If EPA is now proposing to allow other entities or coalitions to be able to establish TMDLs, this authority must be placed in the language of the rule itself, if not in an amendment to the CWA.

Second, EPA recommends innovative alternatives to traditional "pounds per day" TMDLs. The regulations and EPA guidance reviewed regarding TMDLs did not mention whether TMDLs had to be established as "pounds per day." The regulations define of "load" as "an amount of matter that is introduced into a receiving water (40 C.F.R. section 130.2(e)) and discuss TMDLs in terms of either mass per time, toxicity, or other appropriate measure" (40 C.F.R. section 130.2(i)). These definitions seem to be flexible enough to allow for EPA's recommended alternatives to "traditional pounds per day TMDLs."

A third recommendation pertained to effluent or pollutant trading. In the Preamble to the CTR, EPA encourages innovative approaches such as effluent trading as a method to attain and/or maintain water quality standards. The Preamble at page 42185 describes effluent trading as follows:

Effluent trading allows sources that can control pollutants beyond compliance with current requirements to sell or trade credits for its excess reduction to another source unable to control its own pollutants as effectively or as efficiently. The goal of an effluent trading program is to achieve similar or improved environmental results in a more cost-effective manner than under current regulatory structures. EPA's most current policy on effluent trading is summarized in the "Policy Statement for Effluent Trading in Watersheds" which was issued in January of 1996 and which reiterates President Clinton's commitment to effluent trading as expressed in the March 16, 1995 report on "Reinventing Environmental Regulation." The Policy states that "EPA will work cooperatively with key stakeholders to find sensible, innovative ways to meet water quality standards quicker and at less cost than traditional approaches alone." The policy outlines several different types of trades that may take place. These trades include but are not limited to the following: (1) Intra-plant trading between outfalls within one facility; (2) pretreatment trading between indirect industrial point sources that discharge to a POTW; (3) point to point source trading, point to nonpoint source trading, and nonpoint to nonpoint source trading.

The existing regulations and EPA guidance relating to TMDLs already contemplate some form of pollutant trading.(*3) However, the regulations currently do not specifically allow the degree of trading outlined in the Preamble. To clarify that this is now EPA policy, EPA should propose language to that effect within the regulatory language itself.

The final recommendation EPA makes related to TMDLs addresses the use of interim permit limits when a TMDL/WLA/LA or other special study is underway but not completed. The Preamble gives guidance on how interim limits should be calculated. EPA states that "past performance and future uncertainty can be considered as factors in determining interim permit limits, however, permitting authorities may consider other factors, particularly factors concerning the water quality of the receiving water body and the overall goal to attain the water quality standard." EPA further states that it supports innovative ideas such as using specific method for determining interim limits and "trigger" concentrations above which corrective action would be necessary. Furthermore, EPA notes that the State, as the permitting authority, has broad discretion in determining how interim permit limits should be ascertained in different situations. CTR Preamble at pg, 42184-5. This language is helpful, but it should be placed into the rule so that it has the force of law and may be utilized as such.

As a final note regarding the use of TMDLs as a form of regulatory relief, it should be noted that the use of less restrictive effluent limitations based on TMDLs and interim limits is limited by the TMDL process itself as well as the antibacksliding provisions of the CWA. EPA guidance recognized these facts in its TMDL guidance with the following statement:

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Response to: CTR-041-044

In response to the commenter's discussion concerning TMDLs with respect to the collaborative approach, alternatives to traditional "pounds per day" TMDLs, effluent and/or pollutant trading, and the use of interim permit limits, see response to CTR-004-006.

Comment ID: CTR-044-039
Comment Author: City of Woodland
Document Type: Local Government

State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES

Comment: The Preamble to the California Toxics Rule (CTR), and the rules accompanying Economic Analysis (EA), place a great deal of emphasis on the ability of dischargers to use alternative regulatory approaches to comply with CTR criteria if the cost of treatment technology was prohibitively expensive. For example, the EA assumes that, if the estimated annualized cost for removing a pollutant exceeded a cost trigger,(*1) "dischargers would explore the use of alternative regulatory approaches to comply with CTR-based effluent limits. EA at.pg. 4(emphasis added). Based on this assumption, no treatment cost was estimated for the facility.(*2)

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Response to: CTR-044-039

In response to the commenter's discussion concerning TMDLs with respect to the collaborative approach, alternatives to traditional "pounds per day" TMDLs, effluent and/or pollutant trading, and the use of interim permit limits, see response to CTR-004-006.

Comment ID: CTR-054-043
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES

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the requirements of the Clean Water Act (CWA) and the existing regulations. See CTR at pg. 42185-6; see accord 33 U.S.C. section 1313(d)(1)(C) and 40 C.F.R. section 130.7. However, the Preamble discussion also contains recommendations regarding the implementation of TMDLs that merit some review.

First, EPA recommends that, since the TMDL process can be significantly labor and data intensive, collaborative efforts to establish TMDLs on water quality limited water bodies should be pursued. EPA envisions that this collaborative effort by dischargers, the State, EPA, and other stakeholders, could distribute work and associated costs between the interested parties, as well as shorten the overall time necessary to complete the analysis. See CTR at pg. 42185-6. This language attempts to alter the current statutory and regulatory language requiring that States must perform TMDLs, which are then submitted for EPA approval. If EPA is now proposing to allow other entities or coalitions to be able to establish TMDLs, this authority must be placed in the language of the rule itself, if not in an amendment to the CWA.

Second, EPA recommends innovative alternatives to traditional "pounds per day" TMDLs. The regulations and EPA guidance reviewed regarding TMDLs did not mention whether TMDLs had to be established as "pounds per day." The regulations define of "load" as "an amount of matter that is introduced into a receiving water (40 C.F.R. section 130.2(e)) and discuss TMDLs in terms of either mass per time, toxicity, or other appropriate measure" (40 C.F.R. section 130.2(i)). These definitions seem to be flexible enough to allow for EPA's recommended alternatives to "traditional pounds per day TMDLs."

A third recommendation pertained to effluent or pollutant trading. In the Preamble to the CTR, EPA encourages innovative approaches such as effluent trading as a method to attain and/or maintain water quality standards. The Preamble at page 42185 describes effluent trading as follows:

Effluent trading allows sources that can control pollutants beyond compliance with current requirements to sell or trade credits for its excess reduction to another source unable to control its own pollutants as effectively or as efficiently. The goal of an effluent trading program is to achieve similar or improved environmental results in a more cost-effective manner than under current regulatory structures. EPA's most current policy on effluent trading is summarized in the "Policy Statement for Effluent Trading in Watersheds" which was issued in January of 1996 and which reiterates President Clinton's commitment to effluent trading as expressed in the March 16, 1995 report on "Reinventing Environmental Regulation." The Policy states that "EPA will work cooperatively with key stakeholders to find sensible, innovative ways to meet water quality standards quicker and at less cost than traditional approaches alone." The policy outlines several different types of trades that may take place. These trades include but are not limited to the following: (1) Intra-plant trading between outfalls within one facility; (2) pretreatment trading between indirect industrial point sources that discharge to a POTW; (3) point to point source trading, point to nonpoint source trading, and nonpoint to nonpoint source trading.

The existing regulations and EPA guidance relating to TMDLs already contemplate some form of pollutant trading.(*3) However, the regulations currently do not specifically allow the degree of trading outlined in the Preamble. To clarify that this is now EPA policy, EPA should propose language to that effect within the regulatory language itself.

The final recommendation EPA makes related to TMDLs addresses the use of interim permit limits when a TMDL/WLA/LA or other special study is underway but not completed. The Preamble gives guidance on how interim limits should be calculated. EPA states that "past performance and future uncertainty can be considered as factors in determining interim permit limits, however, permitting authorities may

consider other factors, particularly factors concerning the water quality of the receiving water body and the overall goal to attain the water quality standard." EPA further states that it supports innovative ideas such as using specific method for determining interim limits and "trigger" concentrations above which corrective action would be necessary. Furthermore, EPA notes that the State, as the permitting authority, has broad discretion in determining how interim permit limits should be ascertained in different situations. CTR Preamble at pg, 42184-5. This language is helpful, but it should be placed into the rule so that it has the force of law and may be utilized as such.

As a final note regarding the use of TMDLs as a form of regulatory relief, it should be noted that the use of less restrictive effluent limitations based on TMDLs and interim limits is limited by the TMDL process itself as well as the antibacksliding provisions of the CWA. EPA guidance recognized these facts in its TMDL guidance with the following statement:

In developing a TMDL it is important to keep in mind certain constraints on the WLA [wasteload allocation] portion that are imposed by antibacksliding regulatory provisions. The WLA will normally result in new or more stringent water quality-based limits that those contained in a previously issued permit. In a limited number of cases, however, it is conceivable that less stringent water quality-based limits could result. In these cases, permit limits must conform to the antibacksliding provisions contained in section 402(o) of the CWA.(*4)

(*1) This coat trigger is $200 per toxic pounds-equivalent for a facility under the low-end scenario, and $500 per toxic pounds-equivalent for a category of dischargers under the high-end scenario. See EA at pg. 4.

(*2) In addition, pollutant load reductions were not calculated or credited for any pollutant for which an alternative regulatory approach was pursued. Id.

(*3) See 40 C.F.R. section 130.2(i) ("If Best Management Practices (BMPs) or other nonpoint source pollution controls make more stringent load allocations practicable, then wasteload allocations can be made less stringent. Thus, the TMDL process provides for nonpoint source control tradeoffs."); see also EPA, Guidance for Water Quality-based Decisions: The TMDL Process, EPA Doc. No. 440/4-91-001 at pg. 51 (April 1991).

Response to: CTR-054-043

In response to the commenter's discussion concerning TMDLs with respect to the collaborative approach, alternatives to traditional "pounds per day" TMDLs, effluent and/or pollutant trading, and the use of interim permit limits, see response to CTR-004-006.

Comment ID: CTR-057-010a
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K-01 TMDLs
References:

Attachments? N
CROSS REFERENCES G-07; C-24

Comment: Implementation

Although the proposed Rule discusses implementation issues such as TMDLs, variances, SSOs, and interim permits, it lacks evidence of support for any of these provisions. We believe that this will have the effect of reducing the State's confidence or perceived authority in granting any of these provisions to individual POTWs. For example, Page 42186 of the CTR lists six criteria that must be used by the State to determine the non-attainability of a water quality standard; we are doubtful that any of these criteria would be strictly applicable to our facilities with respect to lindane and DDT. We believe CTR variance criteria should include economic considerations for specific discharger implementation efforts. Unless the EPA provides more support for these provisions, we fear that the State will either not grant us a legitimate variance or will waiver in its commitment to act at all.

Response to: CTR-057-010a

EPA disagrees with the comment that although the preamble discusses implementation issues, it lacks evidence of support for any of them. The CTR preamble section to the proposed rule entitled "Implementation" discusses EPA's general policy on TMDLs, variances, and interim permit limits. EPA's intention for including the discussions is to clearly state that it supports the State's appropriate use of the action as an implementation tool, not to discourage the use of the action in any way. EPA does not believe that its discussion in the preamble would discourage the State in any way, and in fact would facilitate the appropriate use of the provision.

Comment ID: CTR-058-011
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? Y
CROSS REFERENCES

Comment: TMDLs. WSPA recognizes that the law requires the state to adopt TMDLs for those waters which fail water quality standards and are listed on the 303(d) list. WSPA supports the TMDL process based on the following approach:

* Waters should only be listed after careful review of the standards and careful assessment of actual water quality. WPSA does not support the universal application of "independent applicability". In some cases independent applicability is appropriate but in many cases it is overkill and EPA should give states flexibility in applying it. * For metals and many organics, the decision to list should be based on the bioavailable (e.g., dissolved) fraction, not total. * A careful process of prioritization should be encouraged. Also, reasonable schedules for implementing TMDL programs must be established. EPA and the states should be moving expeditiously to set such schedules so that the courts do not take the decision-making process out of their hands. * Today, nearly everybody recognizes that non-point sources

rather than point sources are the major problem for most impaired waters. EPA should supply additional tools to the states for dealing with nonpoint sources, and EPA should encourage the emphasis on those sources, whether point or nonpoint, which are the major source of the problem. * Resolution of TMDLs into load and waste load allocations should be based on sound science. Allocations and permit limits should not be largely a political response to the perceived problem. * The relative impact of more stringently regulating point sources should be considered in establishing a strategy. For example, if point sources are 10% of the problem, it may be inappropriate to call for a 50% reduction in their discharges if a 5% overall reduction will have no meaningful impact-on improving the receiving water quality. WSPA believes that airborne deposition in some cases plays a significant role in water quality, and that regulating point sources in such scenarios is often unlikely to produce meaningful results. TMDLs should instead focus on situations where a real impact on receiving water quality can be made through regulation of dischargers (point or nonpoint).

Response to: CTR-058-011

The commenter, in discussing TMDLs, states that waters should only be listed under section 303(d) after a review of the water quality standards and an assessment of "actual water quality". Issues concerning TMDLs are outside the scope of the CTR, and rules concerning TMDLs may change. However, the State should regularly review applicable water quality standards, but EPA does not believe that such a review is a required as part of the decision to list a water body. With respect to the issue of "independent applicability", the statute and regulations require the State to list waters when water quality standards are not being met. In the case of numeric water quality standards, the State may be able to determine whether water quality standards are being met solely on the basis of ambient water column data. In the case of narrative standards, the State may need to consider other available physical, toxicological, and biological data.

It appears that the commenter believes that some 303(d) listing decisions have been based on "best professional judgement" with no supporting ambient data. Although professional judgment plays an important role in any water quality assessment, EPA agrees that decisions to list waters generally should be based on available physical, chemical, and biological data. The commenter and other interested stakeholders can make a substantial contribution to the collection of monitoring data to support the State's assessment of water quality.

The commenter also states that the decision to list should be based on the bioavailable (e.g. dissolved) fraction, not the total, of metals and many organics. As noted above, the State's decision to add a water body/pollutant to the 303(d) list is based on whether the applicable water quality standard is being exceeded. National guidance on 303(d) listing does not allow waters to be excluded from consideration based on the manner in which existing applicable standards are expressed or the fact that standards revisions are currently underway.

EPA agrees with the commenter that a careful process for prioritization and schedules for implementing the TMDL program should be established. The EPA- approved State guidelines for the 1998 303(d) list update provide for specific criteria to guide prioritization. The State will develop a schedule for completion of TMDLs for all 303(d) listed water bodies (see 1998 Clean Water Act 303(d) Listing Guidelines for California).

EPA agrees with the commenter that additional tools should be provided to the State to address nonpoint source pollution problems. EPA's "Clean Water Action Plan" provides a framework for coordination of Federal activities, especially as it relates to nonpoint source problems. Lastly, as noted above, TMDLs and issues concerning TMDLs are outside the scope of the CTR, and rules and policies concerning

TMDLs may change.

Comment ID: CTR-086-001b
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES Q

Comment: CDA's primary concerns are with the potential for additional regulation of wastewater discharges from dental offices to POTWS. Several municipalities in the Bay Area, including the City of San Francisco, have informed CDA that dentist offices are considered a source of mercury discharges to municipal sewer systems, and under the Basin Plan will be subject to additional regulation when lower effluent limits are imposed in municipal NPDES permits. Yet, very little is known about the fate, transport, bioavailability and overall water quality impacts of amalgam related mercury.

CDA in cooperation with San Francisco, has developed a comprehensive program of pollution prevention practices (best management practices) for dental offices that has been distributed statewide and is in the process of being implemented. Yet efforts continue by municipalities in parts of the State, such as San Francisco Bay, to impose increasingly stringent and costly controls on dental offices. Within the current point source regulatory structure. POTWs that have mercury compliance problems, or perceive that they might have if the criteria become more stringent (e.g. through loss of dilution credit), are forced to continue to look "upstream" for additional sources to control, until such time, as recommended, as a more comprehensive watershed based approach is allowed.

CDA is a strong supporter of water quality and human health protection. CDA's primary goals in commenting on the draft CTR are to request that mercury criteria be based on sound science and that mercury regulation be implemented via a watershed management, phased TNML-type approach. CDA is particularly concerned that the CTR does not adequately assess the economic impacts on indirect dischargers nor the extent to which there will be measurable water quality benefits solely from adoption of the proposed mercury criteria for point sources.

Watershed Management Based Approach

Data show that there are elevated levels of mercury in San Francisco Bay waters, sediments, and some fish tissue. It is critical to have a better understanding of watershed-wide mercury inputs, fate, transport, and biogeochemical transformations affecting the San Francisco Bay food chain and human health, and the feasibility and costs of alternative control measures, before imposing potentially onerous control measures (through POTWS) on indirect dischargers, such as dentists, that may not provide measurable water quality or human health benefits.

Since POTWs are only responsible for contributing 1-10% of the toxics mass loading (including mercury) to San Francisco Bay (p. 7-7 EA) it makes economic sense to focus limited public resources on identification of larger and potentially more cost-effective sources to control. Since dentists likely

represent a very minor and declining fraction of the mercury loading to POTWs (due to implementation of BMPs and substitution of non-mercury based compounds for mercury containing dental amalgam), it makes even more public policy sense to fully evaluate and prioritizeall sources and controls before pursuing additional control measures on indirect dischargers such as dentists. This needs to be conducted on a watershed basis, consistent with various EPA guidance including the August 1997 Robert Perciasepe TMDL Policy memorandum and the San Francisco Bay Regional Board's July 1997 Watershed Management Initiative Guidance.

Response to: CTR-086-001b

In response to the comments concerning the scientific basis of the mercury criteria, the TMDL approach for mercury in San Francisco Bay, and the economic assessment of impacts on indirect dischargers, see response to CTR-086-001a. In response to the comment concerning the watershed management approach to mercury in the Bay, the State has listed mercury in San Francisco Bay on its 303(d) list and has targeted completion of a TMDL for mercury in the foreseeable future.

EPA supports the State's decision and schedule to complete a detailed TMDL for mercury for the San Francisco Bay, and EPA agrees with the commenter that it makes good public policy to evaluate and prioritize sources of and controls for mercury coming into the Bay as soon as possible.

Comment ID: CTR-089-001e
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES C-22; C-01a; C-08a; G-05; G-02; G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001e

EPA appreciates the commenter's support of EPA's preamble discussion of TMDL guidance and flexibility.

Comment ID: CTR-090-010b
Comment Author: C&C of SF, Public Utl. Commis.

Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES G-01

Comment: We recommend that:

2. Include in the rule an implementation proposal which states that before a criteria is put into a permit there must first be: an assessment that the pollutant could reasonably interfere with the designated uses of the water; a comprehensive TMDL is done which includes all sources of pollutants to the water body; and a reasonable potential analysis is completed for point source dischargers. Only then, after all of these analyses are completed by the state or EPA should the criteria be converted to a permit limit with the appropriate implementation factors.

Response to: CTR-090-010b

EPA agrees with the commenter that a reasonable potential analysis as well as a determination that the pollutant could reasonably interfere with the designated uses of the water body before a permit limit is placed in a permit for a particular pollutant. The State completes these analyses before a permit limit is placed in a permit. EPA does not agree with the comment that a comprehensive TMDL must be completed on a particular water body for a particular pollutant before the permit limit is placed in a permit for that pollutant. The State is required to protect the beneficial uses of its waters, and thus is required to implement water quality-based effluent limits for particular pollutants which it has knowledge are contributing to preventing the achievement of beneficial uses. EPA agrees, however, that a TMDL for a pollutant may be necessary to comprehensively address a particular problem in a water body.

Comment ID: CTR-092-005
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: K-01 TMDLs
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Total Maximum Daily Loads (TMDL)

The City firmly endorses language in the preamble discussing the merits of a collaborative approach toward the establishment of TMDLs on water quality limited water bodies. The City agrees that this approach could better distribute costs and resources between regulators and the regulated community, as well as shorten the time necessary to complete the modeling analysis. The City supports innovative alternatives to the traditional TMDL approach of "pounds per day" and encourages the concept of

effluent trading as a method to aftain or maintain water quality compliance. The City further encourages EPA to better define these and related programs in order to facilitate the TMDL process.

Response to: CTR-092-005

EPA appreciates the commenter's support of EPA's preamble discussions concerning the State's use of cooperative approaches toward the development of TMDLs, the State's use of innovative alternatives to the traditional "pounds per day" TMDL, and the concept of effluent trading. Additional guidance concerning these concepts can be found in EPA documents which discuss the TMDL process and the water management approach.

Comment ID: CTRH-002-011d
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: K-01 TMDLs
References:
Attachments? N
CROSS REFERENCES G-02; G-04; C-22

Comment: Now, I'd briefly like to touch on several issues of importance to SCAP members. In addition, we will be submitting written comments before the close of the public comment period.

I'd like to begin by mentioning our support for several provisions included in the draft CTR, and those include the provision authorizing the use of compliance schedules -- although we don't necessarily agree with the time period -- the expression of metals criteria as dissolved rather than totally recoverable, and discussion in the preamble supporting the use of interim limits in permits, while the total maximum daily loads and other special studies are being performed.

Response to: CTRH-002-011d

EPA appreciates the commenter's support of EPA's preamble discussion concerning the State's use of interim permit limits while TMDLs and other special studies are being completed.

Subject Matter Code: K-02 Watershed Permitting

Comment ID: CTR-090-023a
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-02 Watershed Permitting
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES Q

Comment: An Alternative Strategy to Implement the CTR - The CTR will likely result in massive public and private expenditures without yielding measurable or significant environmental benefits. Costs can be significantly reduced with regulatory flexibility and the cost analysis assumes that regulatory relief will be forthcoming when costs become excessive. However, nothing in the preamble nor anything in the State's implementation plan indicates a willingness to provide regulatory relief. On the contrary, the draft rule establishes an unusually cumbersome variance procedure while theState's draft proposal sets out very conservative procedures for WQBELs and waste load allocations (WLAs).

For these reasons, we recommend a go slow approach to both promulgating and implementing the CTR for those toxicants where the best evidence indicates that non-permitted sources are the predominant sources. This approach would:

1. Use the concept of temporary standards based on liberal assumptions such as use of a CRF of 10E-4 or 10E-4.5 until such time that a) problems in tissue concentrations are established; and b) loadings are established within the watershed. 2. Require permitted sources, including storm water sources to thoroughly characterize their discharges for the watershed specific problem contaminants. 3. Require permitted sources including storm water that discharge nontrivial amounts of problem toxicants to participate in or financially support ambient monitoring programs. 4. Require permitted sources including storm water sources, to undertake all reasonable source control efforts for any problem toxicants in their discharge.

The above efforts will continue through the development of Watershed based control measures, including TMDLs where required. For complex watershed the TMDL process could be lengthy, up to 10 years or more.

Such approaches were discussed in the preamble of the Great Lakes Initiative (589 FR 72, April 16, 1993), and are further discussed in a September 10, 1997 EPA HQ draft memorandum "A Watershed Approach for the Achievement of Water Quality Objectives." (Attachment 1) The temporary limits approach would also obviate the massive administrative burdens contained in the proposed variance procedures.

Response to: CTR-090-023a

EPA disagrees with the comment that the CTR will likely result in massive public and private expenditures without yielding significant environmental benefits. The CTR establishes water quality criteria for priority toxic pollutants; these criteria, combined with State adopted beneficial uses, will

create badly needed ambient water quality standards for California's surface waters including fresh and estuarine waters. The State then must implement these standards into its various water quality control programs, including the Federally mandated NPDES permit program. EPA agrees with the comment that costs of implementation of water quality standards into the NPDES permit program may be reduced with more flexible procedures. EPA described several methods in the preamble to the CTR that are available to provide flexibility in the NPDES permit program. EPA does not agree that these methods are cumbersome. The variance procedure outlined in the preamble may be considered somewhat complex, but the procedure does provide relief to those who are willing to undertake the analyses to show its applicability to a particular situation.

EPA appreciates the detailed comment concerning an alternative strategy for implementing CTR-based water quality standards in California. However, the State has the responsibility of implementing the CTR-based standards. Thus, the alternative implementation concepts described in the comment should be considered by the State in its adoption of the statewide implementation plan. For example, the commenter suggests that temporary standards based on liberal assumptions be used until loadings are established in the watershed; that permitted sources thoroughly characterize their discharges for specific problem contaminants; that permitted sources of problem pollutants participate or financially support ambient monitoring programs, and undertake source control efforts. The commenter's suggestions should be considered by the State in its implementation of water quality standards programs.

Subject Matter Code: K-03 Watershed/Effluent Trading

Comment ID: CTR-035-032b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-03 Watershed/Effluent Trading
References:
Attachments? N
CROSS REFERENCES K-01

Comment: pp. 42184-42185 -- Total Maximum Daily Loads (TMDLs) We agree with EPA's statements in the Preamble in support of the recommendations of the Permitting and Compliance Issues Task Force regarding the benefits of collaborative approaches to developing TMDLs. We also endorse the State's and EPA's policy to allow innovative alternatives to traditional "pounds per day" TMDLs, and suggest that EPA expand this reference in the Preamble to include the concept of "quantifiable targets," under which TMDLs could be expressed as a mass loading, a concentration, a percent reduction, an ecosystem improvement, or a degree of implementation of a control measure (such as a best management practice) (see SWRCB, 1995, Part VI).

EPA also encourages the use of innovative approaches such as effluent trading, within the TMDL framework. While we support the concept of effluent trading, we do have concerns about how EPA intends for it to be implemented. For instance, in comments submitted to EPA on September 6, 1996 on EPA's Draft Framework for Watershed-Based Trading (May 1996), we pointed out that the proposed framework was overly prescriptive and, as a result, would likely significantly restrict watershed-based trading in California. A few of the barriers to trading we identified in the draft framework include: provisions limiting the duration of trades to the five year term of NPDES permits; limitations on the effect of trades on existing effluent limits, compliance schedules or enforcement actions; discouragement of trading for toxic pollutants; and inequitable requirements for point sources to demonstrate a "reasonable assurance" that a trade will be successful. We recommend that EPA include language in the Preamble to the CTR emphasizing a flexible approach to both TMDLs and effluent trading; that trading is voluntary for all involved parties; and that interim limits will be placed in NPDES permits while the necessary ambient data arc gathered and analytical tools are developed.

Response to: CTR-035-032b

This comment was fully answered under CTR-035-032a.

Comment ID: CTR-061-016
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: K-03 Watershed/Effluent Trading
References:

Attachments? Y
CROSS REFERENCES

Comment: Page 42185, second column, first paragraph, discusses effluent trading issues. It is important in effluent trading to properly incorporate aquatic chemistry and toxicology into developing the trade arrangements. This issue is discussed in papers on my web site.

Response to: CTR-061-016

EPA agrees with the comment that it is important in effluent trading to properly incorporate aquatic chemistry and toxicology in developing trade arrangements. EPA, in its Draft Framework for Watershed-Based Trading (USEPA, May 1996), states that pollutant chemistry must be reviewed before appropriate trading arrangements can be completed. EPA contemplates that such analyses will be conducted before the State approves any effluent trading arrangements.

Comment ID: CTR-086-004f
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: K-03 Watershed/Effluent Trading
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES G-01
C-22
G-09
C-24a
C-24
G-04
G-05
G-02

Comment: Regulatory Flexibility and Relief

CDA supports language in the CTR Preamble that references and endorses recommendations of the State Task Forces including in part the use of.

* reasonable potential analyses * dissolved metals criteria * translators * water effects ratios * site specific objectives * innovative TMDL processes such as effluent trading * performance based interim limits * chronic and acute mixing zones, and * compliance schedules in NPDES permits.

Response to: CTR-086-004f

EPA appreciates the commenter's support of EPA's preamble discussion concerning the State's use of innovative TMDL processes including effluent trading.

Comment ID: CTRH-001-057a
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: K-03 Watershed/Effluent Trading
References:
Attachments? N
CROSS REFERENCES C-24a
G-04
G-07
G-09
C-22
G-05

Comment: Some of the flexibility that the City highly supports is the water effect ratio investigations to adjust statewide criteria to site-specific conditions; the interim limits concept while special studies are being conducted by the dischargers and other entities; a variance procedure to allow dischargers to achieve progress toward effluent limit attainment without violating applicable water quality standards; dissolved criteria for metals to reflect the toxicological conditions; translators to adjust dissolved criteria to total permit limitations; trading programs to attain and maintain water quality; and a mixing zone that reflects true instream pollutant conditions and that protects beneficial uses.

Response to: CTRH-001-057a

EPA appreciates the commenter's support of EPA's preamble discussion concerning the State's use of effluent trading programs to attain and maintain water quality.

Subject Matter Code: L Anti-Backsliding

Comment ID: CTR-030-002
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: L Anti-Backsliding
References:
Attachments? Y
CROSS REFERENCES

Comment: B. UWAG Strongly Supports EPA's Position on the Application of Antibacksliding During Compliance Periods

UWAG applauds the Agency's decision to recognize that the antibacksliding provisions of section 402(o) of the Clean Water Act "do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations." 62 Fed. Reg. at 42,189, col. 2. Permittees should not be subject to antibacksliding provisions until the limits in question come into force at the expiration of the compliance schedule.

Response to: CTR-030-002

EPA acknowledges this support and notes that its position regarding the application of Clean Water Act antibacksliding provisions in the CTR remains unchanged from that of the proposed rule.

Comment ID: CTR-060-003
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: L Anti-Backsliding
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E SUPPORTS

EPA has included in the proposed CTR provisions which are reasonable and with which SDG&E supports. These include:

Anti-backsliding during interim limits

The preamble states that the anti-backsliding requirements of CWA Section 402(0) do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations (see

62 Fed. Reg. at 42188, Col. 2). SDG&E supports EPA's interpretation.

Response to: CTR-060-003

EPA acknowledges this support and notes that its position regarding the application of Clean Water Act antibacksliding provisions in the CTR remains unchanged from that of the proposed rule.

Subject Matter Code: M Re-Open Comment Period

Comment ID: CTR-005-010
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: 9. EPA should modify the CTR to reflect these and other comments and then repropose the rule. The above concerns are fundamental and the recommended modifications necessary to comply with applicable laws and regulations are substantial. For these reasons, the District recommends that EPA modify the rule to account for these and other comments and then re-propose the rule.

Again, the District appreciates the opportunity to comment on the proposed rule. Please contact me if you have any questions or if you need additional information

Sincerely,

Thomas S. Selfridge Deputy Manager-Engineer

Response to: CTR-005-010

In response to the comment to re-propose and re-open the public comment period based on the commenter's comments, EPA has responded substantively to the comments elsewhere in this comment response document. EPA has determined that none of the changes EPA has made warrants re-proposing and re-opening the comment period.

Comment ID: CTR-013-009
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-013 incorporates by reference letter CTR-027

Attachments? N
CROSS REFERENCES

Comment: In addition we would like to emphasize the followin concerns which greatly impact the Los Angeles County Stormwater Program:

9. The rule should not be adopted as proposed. It should be revised and then reproposed. The above comments and concerns are fundamental and the recommended modifications are necessary for MS4s to achieve compliance with the proposed water quality criteria. We recommend that the USEPA modify the rule to account for the above comments and other comments received from other MS4 dischargers and then redistribute the rule for further review and comment.

Thank you, again for this opportunity. If you have any questions, or would like to discuss these comments or issues further, please contact Gary Hildebrand at (626) 458-5948, Monday through Thursday, 7:00 a.m. to 5:30 p.m.

Response to: CTR-013-009

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-027-013a
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES O

Comment: OFFER OF ASSISTANCE

We appreciate the opportunity to provide comments to the proposed rule. Overall, we believe the rule should not be adopted as proposed. We would recommend that USEPA modify the rule and redistribute the rule for further review and comment.

During the development of the proposed rule, USEPA failed to meet with the California Stormwater Task Force or any other California group of MS4 dischargers to discuss the propose rule. We believe such a meeting would have been very beneficial for USEPA and the MS4 dischargers. We extend an offer to meet with EPA and other interested parties to resolve the above issues, and other significant issues prior to finalizing the rule.

Thank you again for this opportunity, if you have any questions or would like to discuss these comments or issues further please contact me at (510) 670-5563.

Response to: CTR-027-013a

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010. EPA was receptive to stakeholder issues concerning the CTR, during its development. For example, EPA sent out a newsletter to all stakeholders inviting discussion, including the storm water interest groups, during the development of the CTR; EPA also attended all of the State task force groups concerning the State's proposed implementation plan and was available for

discussion of issues at those meetings. EPA subsequently met with several stakeholder groups during the development of the CTR. Stakeholders concerned with storm water did not approach EPA during this time. Since the time the CTR was proposed, to ensure impartiality, EPA has limited its involvement with all stakeholder groups who wish to solely discuss the CTR and its finalization. Stakeholders concerned with storm water issues have approached EPA subsequent to the CTR proposal, and EPA has met with them to discuss permit and compliance issues. EPA is available to meet with you further concerning permits and compliance issues.

Comment ID: CTR-031-010
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-031 incorporates by reference CTR-027
Attachments? N
CROSS REFERENCES

Comment: Above all, the District urges the EPA to: 1) incorporate language consistent with CWA section 402(p) into the proposed CTR, and 2) circulate the redrafted rule for further review and comment. This will also provide for review by those concerned to ensure that the proposed CTR when joined with the proposed State Plan does not lead to further inconsistencies.

Response to: CTR-031-010

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-034-017
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: Again, we appreciate the opportunity to comment on the proposed California Toxics Rule. Due to the significant nature of the changes proposed, we request that EPA re-propose the CTR for public review and comment. Thank you for your consideration of our comments.

Response to: CTR-034-017

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-035-011b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? N
CROSS REFERENCES E-01u

Comment: EPA's Economic Analysis is important not only for EPA's rulemaking, but for the SWRCB's promulgation of the State's Implementation Policy. Without significant improvements, we do not believe that EPA's Economic Analysis would comply with the requirements of the state Porter-Cologne Act if used by the SWRCB to support the State Proposal. We propose that EPA and the SWRCB undertake a collaborative process with interested members of the public to revise the Economic Analysis, based on methodologies and assumptions Jointly agreed 91 upon. Such a process was recommended by the Economic Considerations Task Force convened by the SWRCB in 1995, based on the process used in the Bay-Delta process. Guidelines for embarking on a collaborative process were proposed in the Task Force Report (SWRCB, 1995, Section VIII). We believe that this process could result in a mutually acceptable and defensible analysis that both EPA and the SWRCB could use to satisfy their respective rulemaking requirements for economic analysis.

Based on the extensiveness of the modifications we believe EPA should make to both the proposed rule and the accompanying Economic Analysis, we request that EPA re-propose the rule for public review and comment before publishing the CTR as a final rule.

Response to: CTR-035-011b

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-038-013
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: 12. EPA should modify the CTR to reflect these and other comments and then re-propose the rule. The above concerns are fundamental and the recommended modifications necessary to comply with applicable laws and regulations are substantial. For these reasons, the District recommends that EPA modify the rule to account for these and other comments and then repropose the rule.

Response to: CTR-038-013

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-043-011
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: 11. EPA should modify the CTR to reflect these and other comments and then repropose the rule. The above concerns are fundamental and the recommended modifications necessary to comply with applicable laws and regulations are substantial. For these reasons, the City recommends that EPA modify the rule to account for these and other comments and then repropose the rule.

Response to: CTR-043-011

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-044-012
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: We have reviewed the proposed CTR and offer the following comments:

11. EPA should modify the CTR to reflect these and other comments and then repropose the rule. The above concerns are fundamental and the recommended modifications necessary to comply with

applicable laws and regulations are substantial. For these reasons, the City recommends that EPA modify the rule to account for these and other comments and then re-propose the rule.

Response to: CTR-044-012

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-052-022
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should modify the CTR and EA to reflect these and other comments and then re-propose the rule. The concerns cited by the Authority and other POTW organizations are genuine, and the recommended modifications necessary to resolve cost and attainability issues, as well as to insure EPA's compliance with applicable laws and regulations.

Response to: CTR-052-022

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-053-001
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES

Comment: The State of California has been without an ISW/EB&E Plan for too long because of administrative process and litigation delays. It Is imperative for the protection and enhancement of the beneficial uses of the receiving waters of the State that these plans be implemented as soon as possible.

Response to: CTR-053-001

In response to the comment requesting that the State implement its new statewide water quality plans as soon as possible, EPA agrees with the comment. However, the State must comply with its administrative process requirements which take time. EPA believes the State is making progress and moving toward finalizing its implementation plans.

Comment ID: CTR-054-016
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should modify the CTR to reflect these and other comments and then repropose the rule. The above concerns are fundamental and the recommended modifications necessary to comply with applicable laws and regulations are substantial. For these reasons, BADA recommends that EPA modify the rule and its economic analysis to account for these and other comments and then re-propose the rule.

Response to: CTR-054-016

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-059-004b
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c

Comment: As others have commented, we also encourage EPA to build on its efforts over the past year to coordinate with the State Water Resource Control Board (SWRCB). In particular, we recommend that in the future the two agencies take such steps as the use of simultaneous comment periods, joint preparation of the economic analysis, and joint final promulgation, much as the "CAL-FED" agencies are doing. Simultaneous comment periods would greatly facifitate review by the public. Development of a joint economic analysis would greatly reduce the time and resources expended by the two regulatory agencies, as well as by stakeholders. Most importantly, EPA and the SWRCB should adopt the CTR and the

State's Implementation Policy at the same time. This will eliminate uncertainties for permit writers and the regulated community as to how the CTR should be implemented, and encourage greater statewide consistency in the implementation of the CTR.

Response to: CTR-059-004b

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010. In response to the comment that EPA and the State should jointly prepare an economic analysis and jointly finalize the CTR water quality criteria and the State implementation plan, EPA is proposing criteria an the State is proposing an implementation plan so that the State will have a comprehensive water quality control program in place as soon as possible. EPA and the State have coordinated on the criteria and implementation plan so that EPA believes the two phases of the program will work well together. However, it is more efficient for each agency to move forward with its part, to complete each phase as soon as possible.

Comment ID: CTR-059-005
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Finally, due to the extensive nature of the proposed changes to the rule and the economic analysis, we request that EPA re-publish the CTR and economic analysis for public comment before finalizing the regulation.

Response to: CTR-059-005

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010.

Comment ID: CTR-067-007
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: M Re-Open Comment Period
References:
Attachments? N
CROSS REFERENCES R

Comment: Based on these issues, OVSD strongly urges EPA to revise its Economic Analysis, and recommend that EPA and the SWRCB work together with stakeholders to develop a revised approach that is mutually acceptable. Due to the significant nature of the changes proposed, OVSD requests EPA re-propose the CTR for public review and comment. We appreciate the opportunity to comment on the proposed CTR, as well as your consideration of our comments.

Response to: CTR-067-007

In response to the comment requesting that EPA re-propose and re-open the public comment period, please refer to response to CTR-005-010. In response to the comment that EPA work together to develop a revised approach, EPA did not substantially revise the CTR and thus, re-proposal is not warranted.

Subject Matter Code: O Offer of Assistance/Review

Comment ID: CTR-027-013b
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: O Offer of Assistance/Review
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES M

Comment: OFFER OF ASSISTANCE

We appreciate the opportunity to provide comments to the proposed rule. Overall, we believe the rule should not be adopted as proposed. We would recommend that USEPA modify the rule and redistribute the rule for further review and comment.

During the development of the proposed rule, USEPA failed to meet with the CaliforniaStormwater Task Force or any other California group of MS4 dischargers to discuss the propose rule. We believe such a meeting would have been very beneficial for USEPA and the MS4 dischargers. We extend an offer to meet with EPA and other interested parties to resolve the above issues, and other significant issues prior to finalizing the rule.

Thank you again for this opportunity, if you have any questions or would like to discuss these comments or issues further please contact me at (510) 670-5563.

Response to: CTR-027-013b

EPA did not meet with the commenter during the development of the California Toxics Rule because the commenter did not ask for a meeting to discuss the rule during this time period. EPA did hold a public meeting on August 2, 1995 which provided an opportunity for all groups, including storm water dischargers, to ask questions or express concerns about the CTR. Since the proposal and subsequent to the commenter's request to meet with EPA, EPA did meet with the California Water Quality Task Force to discuss a related issue to CTR; language in current stormwater permits regarding water quality standards. In addition, EPA held two public hearings, September 18, 1997 in San Francisco and September 19, 1997 in Los Angeles. EPA believes it does understand the concerns of the California Water Quality Task Force and MS4 dischargers as expressed through its written and verbal comments on the CTR. EPA addresses these comments elsewhere in the response to comment document for the rule.

Comment ID: CTR-040-001
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: O Offer of Assistance/Review

References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: OUR PROGRAM

The County is one of four agencies comprising the Sacramento Stormwater Management Program. The other three agencies are the cities of Sacramento, Folsom, and Galt. The Sacramento Stormwater Management Program began in June 1990. Since its inception, the Sacramento Stormwater Program has developed into a high quality stormwater program which is being recognized this year by EPA through its first place award to both the County and City of Sacramento in EPA's outstanding Stormwater Management Program, municipal category.

OUR INTERESTS

The comments that follow are based on our interests that the Rule, the Preamble, and the Rule's accompanying analyses accomplish the following goals:

1. Allow municipal stormwater programs to continue their focus on reduction of pollutants to the maximum extent practicable.

2. Satisfy the requirements of applicable Federal laws and regulations.

3. Provide incentives for reasonable actions to address toxic pollutants from all sources within a watershed.

We believe these interests are compatible with those of EPA and other interested par-ties, and we offer to work with all parties to craft a Rule that satisfies these interests.

Response to: CTR-040-001

EPA believes the CTR is consistent with the goals stated in the comments.

Comment ID: CTR-040-021
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: O Offer of Assistance/Review
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: OFFER TO ASSIST

Again, we appreciate the opportunity to comment on the proposed Rule. We extend an offer to sit down with EPA and other interested parties to resolve these and other significant issues prior to finalizing the

Rule.

Response to: CTR-040-021

See response to CTR-040-001.

Subject Matter Code: P Whole Effluent Toxicity

Comment ID: CTR-057-008
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: P Whole Effluent Toxicity
References:
Attachments? N
CROSS REFERENCES

Comment: Toxicity

While we acknowledge the need for improved sampling and testing protocols for acute and chronic toxicity, we are concerned about the extent of EPA's awareness with respect to test variability and test acceptability criteria. The effects of test organism age and health and variations in effluent quality over the testing period introduce many variables into toxicity assessment results; these variations can only be accounted for through statistical methods of data analysis. Consequently, we believe that the EPA should provide for the use of narrative toxicity criteria when site-specific conditions merit them. Similarly, the use of non-local test species should be viewed with caution since this introduces another variable into the test results. Narrative criteria can also be justified in view of the need for additional toxicity research on standard test species with respect to type of pollutant, especially chlorination by-products and ammonia.

Response to: CTR-057-008

The CTR did not propose either narrative or numeric toxicity criteria, and therefore, issues related to WET are outside the scope of this rule.

Comment ID: CTR-065-006a
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: P Whole Effluent Toxicity
References:
Attachments? N
CROSS REFERENCES C-20

Comment: TOXICITY TESTING

EHC strongly supports inclusion of acute and chronic toxicity tests. However, it is very important that chlorine and ammonia be added to the list of constituents.

Response to: CTR-065-006a

With respect to your comment on the inclusion of acute and chronic toxicity testing, the CTR did not propose either narrative or numeric toxicity testing criteria. As required by Section 303(c)(2)(B), the CTR proposed numeric water quality criteria for priority toxic pollutants, as identified at CWA section 307(a) and for which the Agency has issued CWA section 304(a) criteria guidance. Whole effluent toxicity limits are not within the ambit of section 303(c)(2)(b) and thus are outside the scope of this action.

EPA agrees that acute and chronic toxicity testing is an important component of the water quality-based toxics control program. In EPA's water quality standards regulations, 40 CFR 131.11, EPA encourages states to adopt both numeric and narrative criteria. Narrative criteria can be the basis for limiting toxicity in waste discharges where a specific pollutant can be identified as causing or contributing to the toxicity but there are no numeric criteria in the state standards, or where toxicity cannot be traced to a particular pollutant. Section 131.11(a)(2) requires states to develop implementation procedures to explain how it will ensure the narrative toxic criteria are met.

Subject Matter Code: Q Nonpoint Sources

Comment ID: CTR-086-001a
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: Q Nonpoint Sources
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES K-01

Comment: CDA's primary concerns are with the potential for additional regulation of wastewater discharges from dental offices to POTWS. Several municipalities in the Bay Area, including the City of San Francisco, have informed CDA that dentist offices are considered a source of mercury discharges to municipal sewer systems, and under the Basin Plan will be subject to additional regulation when lower effluent limits are imposed in municipal NPDES permits. Yet, very little is known about the fate, transport, bioavailability and overall water quality impacts of amalgam related mercury.

CDA in cooperation with San Francisco, has developed a comprehensive program of pollution prevention practices (best management practices) for dental offices that has been distributed statewide and is in the process of being implemented. Yet efforts continue by municipalities in parts of the State, such as San Francisco Bay, to impose increasingly stringent and costly controls on dental offices. Within the current point source regulatory structure. POTWs that have mercury compliance problems, or perceive that they might have if the criteria become more stringent (e.g. through loss of dilution credit), are forced to continue to look "upstream" for additional sources to control, until such time, as recommended, as a more comprehensive watershed based approach is allowed.

CDA is a strong supporter of water quality and human health protection. CDA's primary goals in commenting on the draft CTR are to request that mercury criteria be based on sound science and that mercury regulation be implemented via a watershed management, phased TNML-type approach. CDA is particularly concerned that the CTR does not adequately assess the economic impacts on indirect dischargers nor the extent to which there will be measurable water quality benefits solely from adoption of the proposed mercury criteria for point sources.

Watershed Management Based Approach

Data show that there are elevated levels of mercury in San Francisco Bay waters, sediments, and some fish tissue. It is critical to have a better understanding of watershed-wide mercury inputs, fate, transport, and biogeochemical transformations affecting the San Francisco Bay food chain and human health, and the feasibility and costs of alternative control measures, before imposing potentially onerous control measures (through POTWS) on indirect dischargers, such as dentists, that may not provide measurable water quality or human health benefits.

Since POTWs are only responsible for contributing 1-10% of the toxics mass loading (including mercury) to San Francisco Bay (p. 7-7 EA) it makes economic sense to focus limited public resources on identification of larger and potentially more cost-effective sources to control. Since dentists likely represent a very minor and declining fraction of the mercury loading to POTWs (due to implementation

of BMPs and substitution of non-mercury based compounds for mercury containing dental amalgam), it makes even more public policy sense to fully evaluate and prioritizeall sources and controls before pursuing additional control measures on indirect dischargers such as dentists. This needs to be conducted on a watershed basis, consistent with various EPA guidance including the August 1997 Robert Perciasepe TMDL Policy memorandum and the San Francisco Bay Regional Board's July 1997 Watershed Management Initiative Guidance.

Response to: CTR-086-001a

The commentor's concerns that the CTR would disproportionately impact dental offices makes assumptions about the implementation of the CTR. The implementation of the CTR includes issues that are outside the scope of this rule. The purpose of the CTR is to establish ambient criteria, which define the constituent concentrations that represent a quality of water that supports a particular use. EPA recognizes that both point (including indirect industrial discharges to POTWs) and nonpoint sources may contribute to exceedence of water quality criteria. While EPA encourages the State to take a watershed approach and consider the total and relative loadings from, and the most effective means of controlling, both point and nonpoint sources in developing programs to ensure that criteria are met, the purpose of the CTR is to establish the criteria themselves; not to provide, nor impose, tools for achieving the criteria. The State has primacy in developing its own implementation procedures. The State's proposed implementation procedures can be found in "Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California," September 11, 1997. The State plans to issue a final policy shortly after promulgation of the CTR.

EPA believes that the Economic Analysis does adequately address economic impacts on indirect dischargers based on the use of available data. The EA used available data from San Jose and Sunnyvale based on those cities' projections of pretreatment controls for copper and nickel from industrial sources. EPA's analysis makes reasonable estimates given the uncertainty of whether NPDES permit limits will become more stringent and how POTWs would implement controls on industrial or commercial discharges to POTWs. As stated in the EA, the States and POTWs have a great deal of discretion in implementing these criteria.

Regarding the commentor's request that mercury criteria be based on sound science see responses to category C-1.

Comment ID: CTR-090-007
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: Q Nonpoint Sources
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Major Concerns About the Proposed Criteria and Rule

1. The Proposal is Based on Poor Data and Will Not Result in Better Water Quality for California. We

stated that our own attainability analysis and that of BADA show that San Francisco,) will be impacted by this rule. Unfortunately, due to the short time for review, the poor quality of data and basis for statements and assumptions in the proposal and the problem with detection limits we cannot specifically say what will be the cost to Sari Francisco. One analysis tell us it could be $2.3 million per year annualized costs and another analysis tells us it could be much more. We strongly recommend major revision to the proposal and the economic analysis before final promulgation for the following reasons:

This rule will be applied to point source dischargers with NPDES permits and all EPA and State data confirm that the major sources of many of the pollutants of concern in the major waters of California are not point discharges.

Response to: CTR-090-007

The comment claiming the CTR will have a disproportionate burden on point sources deals with implementation of the CTR which is outside the scope of this rule. The purpose of the CTR is to establish ambient criteria, which define the constituent concentrations that represent a quality of water that supports a particular use. EPA discusses the legal bases for the rule in the preamble and elsewhere in the comment response document for the rule. EPA recognizes that both point and nonpoint sources may contribute to exceedence of water quality criteria. While EPA encourages the State to take a watershed approach and consider the total and relative loadings from, and the most effective means of controlling, both point and nonpoint sources in developing programs to ensure that criteria are met, the purpose of the CTR is to establish the criteria themselves; not to provide, nor impose, tools for achieving the criteria. The State has primacy in developing its own implementation procedures. The State's proposed implementation procedures can be found in "Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California," September 11, 1997. The State plans to issue a final policy shortly after promulgation of the CTR.

Regarding the uncertainty of the costs to San Francisco, EPA agrees that economic impacts, due to the the uncertain manner in how the CTR will be implemented by on a site-specific basis, are difficult to predict. However, EPA believes its Economic Analysis provides a reasonable range of potential costs to sample facilities given the available data and the uncertainty of site-specific implementation.

Comment ID: CTR-090-015
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: Q Nonpoint Sources
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Source of toxicants - Benefits from adoption of this rule may be minimal as the most serious water quality problems are caused by non-point sources not subject to WQBEL in NPDES permits. For example, the Benefits Document depicts the seven northern California water bodies that currently have DHS health advisories. These water bodies are:

1. Lake Nacimiento 2. Guadalupe and other Santa Clara County Reservoirs 3. Lake Herman 4. Lake Berryessa 5. Clear Lake 6. Kesterton National Wildlife Refuge/Grassland Area 7. San Francisco Bay

The first five areas are all areas contaminated by mercury from historical mercury mines. Between the late nineteenth century to about 1965, the central coast ranges from San Luis Obispo County north to Lake County provided 70% of the domestic production of elemental mercury. The dominant ore was cinnabar, (HgS) which was found typically in shallow deposits within serpentine and other Franciscan formation rocks. Many abandoned mercury mines with their attendant calcined waste dumps and contaminated main facilities are found throughout this area. Construction and maintenance of access roads to these mines could also mobilize considerable mercury through increased erosion.

Natural releases of mercury either through seismic or geothermal activity may be a significant portion of the mercury problem in some parts of Clear Lake. Sediment deposits dated to 8,800 years ago show mercury concentrations up to 65 mg/kg. Geothermal activity also occurs within the catchment for Lake Beryessa.

(For a good discussion of the mercury problem in the Coast Ranges, see Hood, Michael, etal, Mining Waste Study -Final Report, University of California, Berkeley, July 1, 1988, prepared for the SWRCB, pages 243, et seq. and pages 275 et seq.).

No part of this mercury problem can be attributed to either POTWs or currently active industries. Nor will anything in the CTR provide additional tools to assist in the remediation of the correctable portions of these mercury problems.

The sixth site is Kesterson Reservoir, contaminated by selenium, from surface and sub-surface agricultural drains. Again state efforts to remediate this problem are underway and will not change as a result of the CTR.

The seventh area is San Francisco Bay. Portions of the Bay have elevated levels of mercury, PCBS, dioxin and pesticides. EPA acknowledges that NPDES permitted point sources typically account for between 4 % and 1 1 % of most of the problematic toxicants.

Whether these percentages hold true for the chlorinated organic compounds is difficult to establish as many potential sources are not well characterized due to analytical problems. Nevertheless, it is unlikely that POTWs and industrial point sources are anything other thanminor contributors of the chlorinated hydrocarbon compounds of greatest concern.

The major sources for most of the problem toxicants in the Bay, are, agriculture, abandoned mines, historical contaminated sediments and both urban and nonurban runoff. These major sources will be very difficult, and in some cases impossible, to control. Therefore, even if permitted point sources achieve full compliance with the CTR, only negligible (<10%) improvement in Bay water quality will result. The CTR must address this critical issue: which toxic pollutants prevent California waters from achieving CWA goals and objectives and what isthe source of these toxicants. This assessment is necessary to determine ff EPA has met its obligations to promulgate new water quality standards necessary to meet the requirements of the Act. [CWA section 303(c)(4)]

Response to: CTR-090-015

See response to CTR-090-007 (first paragraph).

Comment ID: CTR-090-023b
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: Q Nonpoint Sources
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES K-02

Comment: An Alternative Strategy to Implement the CTR - The CTR will likely result in massive public and private expenditures without yielding measurable or significant environmental benefits. Costs can be significantly reduced with regulatory flexibility and the cost analysis assumes that regulatory relief will be forthcoming when costs become excessive. However, nothing in the preamble nor anything in the State's implementation plan indicates a willingness to provide regulatory relief. On the contrary, the draft rule establishes an unusually cumbersome variance procedure while theState's draft proposal sets out very conservative procedures for WQBELs and waste load allocations (WLAs).

For these reasons, we recommend a go slow approach to both promulgating and implementing the CTR for those toxicants where the best evidence indicates that non-permitted sources are the predominant sources. This approach would:

1. Use the concept of temporary standards based on liberal assumptions such as use of a CRF of 10E-4 or 10E-4.5 until such time that a) problems in tissue concentrations are established; and b) loadings are established within the watershed. 2. Require permitted sources, including storm water sources to thoroughly characterize their discharges for the watershed specific problem contaminants. 3. Require permitted sources including storm water that discharge nontrivial amounts of problem toxicants to participate in or financially support ambient monitoring programs. 4. Require permitted sources including storm water sources, to undertake all reasonable source control efforts for any problem toxicants in their discharge.

The above efforts will continue through the development of Watershed based control measures, including TMDLs where required. For complex watershed the TMDL process could be lengthy, up to 10 years or more.

Such approaches were discussed in the preamble of the Great Lakes Initiative (589 FR 72, April 16, 1993), and are further discussed in a September 10, 1997 EPA HQ draft memorandum "A Watershed Approach for the Achievement of Water Quality Objectives." (Attachment 1) The temporary limits approach would also obviate the massive administrative burdens contained in the proposed variance procedures.

Response to: CTR-090-023b

See response to CTR-090-023b (first paragraph).

Subject Matter Code: R RFA/SBREFA

Comment ID: CTR-001-008b
Comment Author: Law Offices of Alan C. Waltner
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/22/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES J-02

Comment: EPA'S PROPOSAL VIOLATES THE REGULATORY FLEXIBILITY ACT

Several of the member agencies of the ACCWP have populations less than 50,000 (Piedmont, Emeryville, Albany) and will be significantly affected by the proposed rule if it results in the adoption of NELs or WLAs in the permit for their discharges. These "small entities" under the Regulatory Flexibility Act ("RFA") are entitled to both initial and final regulatory flexibility analyses under the RFA.

EPA's finding that a substantial number of small entities will not be significantly affected by the proposed rule is arbitrary and capricious given this demonstrated impact. A substantial number of municipalities less than 50,000 in population are currently covered by NPDES permits for their storm water discharges. In addition, EPA's upcoming Phase II storm water regulations maysubstantially expand the universe of small municipalities that will be subject to NPDES permits and, through those permits, to the provisions of the CTR.

Neither the ACCWP, the ACCWP's member agencies or, to our knowledge, any other storm water system that will be subject to this rule, was contacted by EPA in advance of the proposed rulemaking and given a reasonable opportunity to participate in the rulemaking as required by 5 U.S.C. section 609(a). In addition, as a "covered agency" under 5 U.S.C. section 609, EPA must process the proposed rule in accordance with the provisions of that section, including the convening of a review panel, but apparently has failed to do so.

Response to: CTR-001-008b

The Regulatory Flexibility Act generally requires federal agencies to prepare a regulatory flexibility analysis (RFA) that describes the impact of a rule on small entities (small businesses, small organizations and small governmental jurisdictions) whenever an agency promulgates a final rule under section 553 of the Administrative Procedure Act, 5 U.S.C. Section 553. 5 U.S.C. Section 604. Under section 605(b) of the Regulatory Flexibility Act, however, if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the statute does not require the agency to prepare an RFA. Pursuant to section 605(b), the Admininstrator is today certifying that this rule will not have a significant economic impact on a substantial number of small entities for the reasons explained below. Consequently, EPA has not prepared an RFA.

The RFA requires analysis of the economic impact of a rule only on the small entities subject to the rules' requirements. See United States Distribution Companies v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996). ("[N]o [regulatory flexibility] analysis is necessary when an agency determines that the rule will not have

a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule," United Distribution at 1170, quoting Mid-Tex Elec. Co-op v. FERC, 773 F.2d 327, 342 (D.C. Cir. 1985) (emphasis added by United Distribution court).) Thus, the RFA requires that any regulatory flexibility analysis prepared for a final rule must include estimates of "the number of small entities to which a rule will apply." 5 U.S.C. Section604(a)(3). The analysis must also include a description of the recordkeeping, reporting and compliance requirements of the rule, including an estimate of the classes of small entities "which will be subject to the requirements." 5 U.S.C. Section 604(a)(4). In light of these provisions, courts have consistently interpreted the RFA to impose no obligation on an agency to conduct a small entity impact analysis on entities it does not regulate. Motor & Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449, 467 & n.18 (D.C. Cir. 1998).

The U.S. Court of Appeals for the District of Columbia Circuit recently reaffirmed its conclusion that the RFA does not require an agency to prepare an assessment of the economic impact of a rule on small entities that are not directly affected by a rule. American Trucking Association, Inc. v. U.S. Environmental Protection Agency, (D.C. Cir. 1999). In that case, the court determined that EPA was not required to prepare a regulatory flexibility analysis of the economic impact of a rule on small entities when it promulgated air quality standards under the Clean Air Act. There, EPA had certified that the rule would not have a significant impact on small entities because the air standard did not directly impose requirements on small entities and consequently they were not subject to the rule. Under the Clean Air Act, states regulate small entities through state implementation plans that they are required to develop under the Act. States have broad discretion in determining how to achieve compliance with the standards and may choose to avoid imposing any of the burden of complying with the standards on small entities.

The CTR presents a situation very similar to that described in the American Trucking case. It establishes no requirements that are directly applicable to small entities, and so the agency is not required to conduct a regulatory flexibility analysis under the RFA. (See United States Distribution Companies v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996). The Agency is therefore certifying that today's rule will not have a significant economic impact on a substantial number of small entities, within the meaning of the RFA.

Under the CWA water quality standards program, states must adopt water quality standards for their waters that must be submitted to EPA for approval. If the Agency disapproves a state standard and the state does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA has authority to promulgate criteria or standards in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of the Act. These state standards (or EPA-promulgated standards) are implemented through various water quality control programs including the National Pollutant Discharge Elimination System (NPDES) program that limits discharges to navigable waters except in compliance with an EPA permit or permit issued under an approved state program. The CWA requires that all NPDES permits must include any limits on discharges that are necessary to meet state water quality standards.

Thus, under the CWA, EPA's promulgation of water quality criteria or standards establishes standards that the state, in turn, implements through the NPDES permit process. The state has considerable discretion in deciding how to meet the water quality standards and in developing discharge limits as needed to meet the standards. In circumstances where there is more than one discharger to a water body that is subject to water quality standards or criteria, a state also has discretion in deciding on the appropriate limits for the different dischargers. While the state's implementation of federally-promulgated water quality criteria or standards may result indirectly in new or revised discharge limits for small entities, the criteria or standards themselves do not apply to any discharger, including small entities.

EPA recognizes that it has undertaken an economic analysis pursuant to E.O. 12866 for this rule. This analysis, however, makes numerous assumptions and does not necessarily predict how the state will implement the criteria. Thus, the economic analysis represents EPA's best estimate of the implementation costs of the rule given the broad flexibility the state has in implementing the criteria.

The CTR, as explained above, does not itself establish any requirements that are applicable to small entities. As a result of EPA's action here, the State of California will need to ensure that permits it issues comply with the water quality standards established by the criteria in today's rule. In so doing, the State will have a number of discretionary choices associated with permit writing. While California's implementation of today's rule may ultimately result in some new or revised permit conditions for some dischargers, including small entities, EPA's action today does not impose any of these as yet unknown requirements on small entities.

Although the statute does not require EPA to prepare a regulatory flexibility analysis when it promulgates water quality criteria which will establish water quality standards for California, EPA has prepared an assessment of potential economic impact. This evaluation focuses on State and local implementation procedures related to the NPDES permit program. This evaluation is included in a document entitled, Implementation Analysis of Ambient Water Quality Criteria for Priority Toxic Pollutants in California which is part of the administrative record for this rulemaking. This document looks at the many implementation procedures of the NPDES permit program that the State implements to control pollutants from point source discharges. The procedures discussed in the document include: methods to calculate water quality-based effluent limits; mixing zones; site-specific translators for metals criteria; compliance schedules; effluent trading; water-effect ratios; variances; designated use reclassification; and site-specific criteria. Each of these implementation procedures may have an effect on how water quality standards, based on the criteria in today's rule, will impact NPDES permit holders. Many of these procedures will lessen impacts on regulated entities.

The document also looks at implementation procedures used in the pretreatment program to control pollutant discharges from dischargers that do not discharge directly but introduce pollutants to publicly owned treatment works (POTWs). These dischargers include retail, commercial, and small industrial facilities that discharge to publicly owned treatment works (POTWs). Local entities have significant flexibility to implement their pretreatment programs. These procedures include: methods to calculate local limits (allocation of pollutants); methods of pollution prevention for various specific sources; pretreatment pollutant trading; methods of low cost pollutant reductions; technical assistance to move toward or achieve zero-discharge; cost accounting to drive down levels of discharges; and a few of the regulatory relief options discussed in the direct discharger section, e.g., compliance schedules.

The discussion illustrates the significant amount of flexibility available to the State and local agencies when implementing the NPDES permit program and pretreatment program and emphasizes that appropriate use of the available implementation tools can greatly affect the impact to many direct and indirect dischargers.

See also response to CTR-050-007a (Category C-21; Legal Concerns) and the preamble to the final rule.

Comment ID: CTR-005-006c
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA

Represented Org:
Document Date: 09/23/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-21; S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and also taking into consideration their use and value for navigation (See CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern. For those identified waters, states must adopt criteria for such toxic pollutants applicable to sufficient to protect the designated use"(See 40 CFR 131.1 1 (a)(2)).

Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-005-006c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-013-008a
Comment Author: County of Los Angeles
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-013 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following concerns which greatly impact the Los Angeles County Stormwater Program:

8. The proposed rule applies to all current and future MS4 dischargers, including small communities.

The small communities will be significantly impacted by the proposed rule. In Los Angeles County, 77 of the 85 co-permittee cities are communities with a population of less than 100,000. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies, however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities, however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*2) it indicates that there are no small entities to be impacted by the rule and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Therefore, unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*2) Federal Register, August 5, 1997, Vol. 62, No. 150, Page 42191.

Response to: CTR-013-008a

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-014-004a
Comment Author: City of Lakewood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-014 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: 4. The proposed rule applies to all current and future MS4 dischargers, including small communities. These small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume

that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*1), it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Thank you for this opportunity to comment on the proposed CTR. Respectfully,

Lisa Ann Rapp Director of Public Works

(*1) Federal Register, August 5, 1997, Vol. 62, No. 150, Page 42191

Response to: CTR-014-004a

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-019-003b
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036

Attachments? N
CROSS REFERENCES J

Comment: THE PROPOSED RULE DOES NOT COMPLY WITH THE REGULATORY FLEXIBILITY ACT

USEPA's analysis under the Regulatory Flexibility Act and Executive Order No. 12866 that the CTR will not affect a significant number of small entities is simply wrong. Most of the cities which we represent have populations of less than 20,000; many have less than 10,000. As noted by the County of Los Angeles, 77 of the co-permittee cities have populations of less than 100,000. Many of these cities are

primarily residential and with limited tax revenues. Nevertheless the proposed CTR would impose the same financial requirements on these cities as would be imposed on larger entities. These cities do not receive funds from either the State of California or the federal government for their storm water programs or other urban runoff control measures.

Response to: CTR-019-003b

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-021-005d
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-13; C-28; E-01c; S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by

the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's innovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe tht EPA has needlessly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005d

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

With respect to detection limits see response to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). With respect to the selection and economic analysis of risk levels for carcinogens see responses to CTR-021-005a (Category C-13; Risk Level) and CTR-021-005c (Category E-01c; Executive Order 12866).

Comment ID: CTR-021-006c
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES J; E-01c; S; I-01

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectaton that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

3. Failure to Address Important Stormwater-Related Issues. In addition to its POTW, Sunnyvale is the owner of a system of storm drains which contribute wet weather flows to the South Bay. We are concerned that the EA entirely neglects the potential impacts of the proposed CTR on the storm drains. The EA entirely omits any meaningful analysis ofthe costs of bringing storm drains into compliance with

the proposed CTR, thereby significantly understating the overall costs of the CTR. We believe that this omission is violative of the Agency's legal obligations under the authorities cited in the preceding paragraph.

In addition, we join in the comments being filed by the various other operators of stormwater collection systems to the effect that EPA has overstated the legal requirements for storm drains to comply with numerical criteria.

Response to: CTR-021-006c

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

EPA believes it properly described the potential impact of the implementation of the CTR on storm drains in the preamble to the proposed CTR and in its Economic Analysis. For further discussion see responses to CTR-013-003 and CTR-040-004 (Category J; Stormwater Economics).

Comment ID: CTR-023-001
Comment Author: City of Los Alamitos
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-023 incorporates by reference letters CTR-027 and CTR-036
Attachments? N
CROSS REFERENCES

Comment: The City of Los Alamitos is particularly concerned that, in promulgating the California Toxics Rule, US EPA has neglected its responsibilities under the Regulatory Flexibility Act (RFA). Specifically, the proposed rule does not present any analysis of its impact on a small entity such as the City of Los Alamitos (Population - 12,425) as required by the RFA.

As a small entity regulated under the municipal stormwater permitting requirements of the Clean Water Act, the proposed rule making will have a profound impact on the City of Los Alamitos. This impact now needs to be explicitly understood before further action is taken on the California Toxics Rule.

Response to: CTR-023-001

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-024-004a
Comment Author: City of Hawthorne
Document Type: Local Government
State of Origin: CA

Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-024 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: 4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule(*1), it indicates that there are no small entities to be impacted by the rule, and therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*1) Federal Register, August 5, 1997, Vol. 62, No. 150, page 42191

Response to: CTR-024-004a

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-027-009a
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES J

Comment: 9. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems if the proposed criteria are adopted. While most small communities have not conducted discharge characterization studies; it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless EPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule (*3), USEPA indicates that no small entities are impacted by the rule, and, therefore, USEPA did not need to complete an analysis required under the Act. USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. USEPA should have conducted an analysis on the economic impacts to smaller communities.

Recommendation: Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be promulgated until USEPA has complied with the requirements of the Regulatory Flexibility Act.

(*3) Federal Register, August 5, 1997, Vol. 62, No. 150, page 42191

Response to: CTR-027-009a

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-027-011
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES

Comment: 11. The proposed rule appears to violate applicable Federal law and regulations. As indicated in the above comments, it appears that the proposed rule is inconsistent with the Regulatory Flexibility Act by not considering the impacts on small entities. The rule also appears to be in conflict with the Clean Water Act by proposing a single set of criteria for all fresh waters instead of adopting criteria for pollutants that could "reasonably be expected to interfere with those designated uses".(*4)

And finally as noted in our comment 3, the rule did not consider the potential cost for MS4s for either a BMP based program or a program designed to meet WQBELS. The Statewide cost for this latter effort may be as high as $7 billion per year. Further discussions are provided on these issues in the responses to the CTR by the counties of Alameda, Orange and Sacramento and are incorporated herein by reference.

(*4) Federal Register, August 5, 1997, Vol. 62, No. 150, page 42160

Response to: CTR-027-011

With respect to EPA compliance with the RFA see response to CTR-001-008b and the preamble to the final rule. With respect to the commenter's assertion that the rule is in conflict with the Clean Water Act by proposing a single set of criteria for all fresh waters see response to CTR-036-005 (Category C-21; Legal Issues). With respect to costs for stormwater dischargers, EPA disagrees. See response to CTR-013-003 (Category J; Stormwater Economics).

Comment ID: CTR-028-001a
Comment Author: City of Folsom
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-028 incorporates by reference letter CTR-040
Attachments? N
CROSS REFERENCES J

Comment: The City is a small community with a population of less than 50,000. We volunteered to participate in the Sacramento Stormwater Management Program as a co-permittee on the NPDES permit because we understood that it was a BMP-based program aimed at reducing the discharge of pollutants to the maximum extent practicable. We are very concerned with the CTR's Preamble statement that municipal stormwater agencies must comply with effluent limitations based on water quality criteria. As the County has stated in its comments, this will result in enormous costs without producing significant environmental benefits.

We are also concerned that the EPA Administrator has certified that the CTR will have no effect on small entities such as the City. Based on the estimated compliance costs prepared by the County and the statewide estimates prepared by the California Storm Water Quality Task Force, the CTR will have significant economic effects on small communities throughout the State. For example, our proportional share of the countywide costs to comply with effluent limitations, based on the proposed water quality criteria, could be over $10 million per year.

We urge EPA to reconsider its position that municipal stormwater discharges must comply with water quality standards. EPA should remove the Preamble statement or clarify that municipal stormwater discharges are only required to reduce the discharge of pollutants to the maximum extent practicable.

Alternatively, EPA must revise its economic analysis to include the costs to municipal stormwater agencies and the EPA Administrator must withdraw her certification and, pursuant to the requirements of the Regulatory Flexibility Act, assess the economic impacts of the CTR on small entities.

Response to: CTR-028-001a

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-031-006b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES J; E-01c

Comment: b. If the CTR as proposed in the current draft is applied to municipal storm water dischargers so as to require numeric effluent limitations in municipal stormwater permits, the cost to the public will be phenomenal. In the economic analysis of the CTR, EPA failed to consider these costs, and failed to consider the costs to industrial storm water dischargers as well.

The District Is urban storm water drainage system captures through retention 90% of its annual average runoff, and discharges 90% after detention (1% is directly discharged without treatment). The system cost in 1997 dollars is estimated at $500 million.

The only option available to the District to mitigate violations of the proposed criteria would be to expand system storage to capture 100% of average annual runoff. Increasing system storage by 20,000 acre feet (estimated additional storage required for average years), at the current cost of $11,000-$20,00 per acre foot of storage, would result in a capital expenditure of $220,000,000 to $400,000,000.

Even with this exorbitant investment, in approximately half of the rain seasons storage would be exceeded, and 100% of the discharges would be expected to exceed the dissolved metals criteria noted above.

Smaller cities (under 50,000) in California are currently subject to NPDES municipal storm water discharge permits, and many more will be included upon implementation of the Stormwater Phase II program. EPA's failure to assess economic impacts on small cities would appear to be contrary to the requirements of the Federal Regulatory Flexibility Act.

The District includes in its constituency industrial businesses. The District serves these businesses and assists in the oversight of their pollution prevention and storm water permit compliance efforts. Regardless of EPA' s approach to applying the CTR to municipal storm water permits, industrial storm water dischargers are directly and seriously affected by application of the CTR. EPA's failure to assess these economic impacts on our communities is short-sighted and a breach of good public policy.

Response to: CTR-031-006b

With respect to EPA's compliance with the Regulatory Flexibility Act see response to CTR-001-008b. With respect to the commenter's estimate of its stormwater costs see response to CTR-040-004 (Category J; Stormwater Economics).

Comment ID: CTR-031-009
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-031 incorporates by reference CTR-027
Attachments? N
CROSS REFERENCES

Comment: Any continuing ambiguities and inconsistencies among state and federal law, regulation, and official policy will continue to lead to legal challenges and the corresponding drain on public funds. The CTR should not be adopted as proposed. The above comments and concerns are fundamental to accomplishing consistency with the CWA and Regulatory Flexibility Act, and providing for the unique circumstances of regulating municipal storm water dischargers.

Response to: CTR-031-009

See response to CTR-001-008b.

Comment ID: CTR-034-005
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: LEGAL ISSUES -- Executive ORder 12866, Unfunded Mandates Reform Act, Regulatory Flexibility Act

* SCAP disagrees with EPA's determination under the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities. SCAP's membership includes several small entities serving a population of 50,000 or less that may be significantly affected by the CTR. In addition, all, of our members provide sewer services to all or most of the small businesses in their service areas. These businesses potentially will be affected by the proposed rule through increased

regulation of their discharges, increased sewer discharge fees, or both. EPA's conclusion appears to be based on the fact that the one minor municipal discharger that EPA studied had no effluent data for the CTR pollutants, and EPA therefore assumed that no costs would be incurred by any small municipal dischargers in the State. This reasoning is erroneous. We therefore request that EPA revise its Economic Analysis to fully examine the impact of the proposed rule on small entities, to re-analyze significant alternatives to the proposed rule (including those alternatives that would minimize any significant economic impact of the proposed rule on small entities), and to allow for meaningful involvement in the development of the rule by small entities.

Response to: CTR-034-005

EPA did not base its rationale for RFA compliance based on its assessment of the minor discharger in its Economic Analysis for the proposed CTR. With respect to the rationale for EPA's compliance with the Regulatory Flexibility Act see response to CTR-001-008b. The classification of minor and major dischargers is based on flow, not population served. EPA did include additional minor dischargers in its sample for its Final Economic Analysis in order to more accurately assess the potential cost of CTR implementation on minor dischargers throughout California.

Comment ID: CTR-035-041
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42191 - 42192 -- The Regulatory Flexibility Act EPA's position that the Regulatory Flexibility Act (5 U.S.C.A. 601 et seq.) does not apply is incorrect. While EPA takes the position (p. 42192) that "the criteria or standards themselves do not apply to any discharger, including small entities," we believe that these statements are erroneous, since, as noted on p. 42182, "once an appropriate numeric criterion is selected for either aquatic life or human health protection, this facilitates the calculation of water quality-based effluent limits and/or total maximum daily loads (TMDLs) for that chemical." In fact, EPA itself oversees State issuance of these permits. EPA's reliance on the United States Distribution case cited at p. 42192 to demonstrate why the requirements of the Regulatory Flexibility Act do not apply is misplaced; that case involved the issue of whether the FERC needed to prepare a regulatory flexibility analysis ("RFA") when issuing its Order No. 636. The court determined that the RFA requirement did not apply in this case because of the statutory language exempting regulatory rulemaking where the agency determines "that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule. " (88 F.3d 1170) The court went on to note that the FERC did not even have authority to regulate the small entities allegedly affected by the rule. The exemption purportedly established by the United States Distribution case cannot be applied in this instance because the standards in the CTR are required by federal and state law to be implemented directly into NPDES permits, through water quality based effluent limitations calculated directly from the numerical criteria in the rule, as well as through load reductions to comply

with TMDLs derived from the standards. Under the Clean Water Act, every NPDES permit issued in California requires compliance with applicable water quality objectives and this will include those proposed in the CTR. Further, EPA has authority to apply those criteria directly, either by its review and potential veto of state-issued permits or its direct issuance of permits in cases where it has vetoed a state permit under Section 402(a) and (d) of the Clean Water Act. Accordingly, the Regulatory Flexibility Act requires EPA not only to prepare an official RFA, but to comply with the procedural requirements of Section 609(b) of the Act, including the requirement to notify and involve the Chief Counsel for Advocacy of the Small Business Administration.

Response to: CTR-035-041

See response to CTR-001-008b and the preamble to the proposed rule.

Comment ID: CTR-036-004b
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES J

Comment: Finally, EPA has not met its duties under the Regulatory Flexibility Act (the "RFA"). Under the RFA, federal agencies are required to conduct an initial regulatory flexibility analysis ("IRFA") describing the impact of a proposed regulatory action on small entities. Once more relying on the claim that the proposed rule does not establish criteria that are directly applicable to small entities, EPA states that the mandates of RFA do not apply [62 Fed. Reg. 41160, 42191-92].

This position is contrary to both the letter and the spirit of the RFA. The fact that the toxics criteria contained in the proposed rule must be translated into water quality standards and, in turn, NPDES permit effluent limitations, does not negate the fact that the burden of complying and implementing such toxics criteria ultimately will be borne by individual municipalities and business entities. As noted above, the costs to municipalities alone could run into billion of dollars placing a severe strain on their budgets and forcing them to divert funds currently allocated to other important municipal services, inclusing public safety.

Moreover, EPA's statement that "California will have a number of discretionary choices associated with permit writing" is disingenuous and ironic in light of EPA's rationale for issuing the proposed rule. The toxics criteria will necessarily narrow the State's discretion in issuing NPDES permits and in establishing effluent limits for such permits. If EPA had meant for the State to have any serious discretion, it would not be promulgating these criteria in the first place.

Response to: CTR-036-004b

See response to comment CTR-036-004a (Category J; Stormwater Economics).

Comment ID: CTR-038-005b
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES E-01c; S

Comment: A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. The District, for example, is a small community having a population of under 50,000 and, in addition, serves several small towns and communities (Sonoma, Glen Ellen, Boyes Hot Springs and Agua Caliente) that would be greatly impacted by the proposed rule.

Response to: CTR-038-005b

See responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-038-006c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-21; E-01c; S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, and recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use" (See 40 CFR 131.11(a)(2)). Clearly the intent of both the Clean Water Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In

failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, such as the District and the small communities it serves, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-038-006c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-038-008c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-24; E-01c; S; T

Comment: 7. Separate, sites-specific aquatic life criteria for copper and human health criteria for mercury should be adopted for Schell Slough, or alternatively EPA should specify implementation procedures for these criteria that will preclude unreasonable controls such as end-of-pipe treatment. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the assessment of costs and benefits described in "3" above, EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation procedures that would allow the current discharge to continue (e.g., allowable Mixing zones and averaging periods and, for copper, a translator and water-effect ratio). Again, the District is amenable to continuing to address these constituents through pollution prevention measures and to assessing the actual impacts of these constituents in Schell Slough. Without EPA specifying such implementation procedures in the CTR, it is possible that the CTR could impose significant costs on the District (and the other small communities its serves) without providing a commensurate environmental benefit. In that case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-038-008c

See response to CTR-038-008a Category C-24; Site-Specific Criteria. See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S;

Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-038-009c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-28; E-01n; S

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. By taking this approach, however, EPA is unable to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA must not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA must evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits). With respect to the District's discharge and Schell Slough and Second Napa Slough, the criteria in this category include, but are not necessarily limited to, the following : benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chrysene, dibenzo(a,h)anthracene, aldrin, 4,4'-DDD, 4,4'-DDE, dieldrin, endosulfan I, endosulfan II, endosulfan sulfate, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, OCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, and hexachlorobenzene (see Table 3).

Response to: CTR-038-009c

See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-040-009a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES S; E-01c

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* A consequence of the cost/benefit analysis of the Rule are several erroneous conclusions, namely that: (1) this is not a "significant regulatory action" or a major rule (i.e., one which will result in excess of $100 million annual expenditure) subject to the requirements contained in Presidential Executive Order 12866 and the Unfunded Mandates Reform Act; and (2) this is not a rule that will have a significant economic impact on a substantial number of small entities protected under the Regulatory Flexibility Act.

Response to: CTR-040-009a

See responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-040-010b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES J

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

* The cities of Folsom and Galt, co-permittees in our stormwater program, both have populations less than 50,000. Their costs associated with complying with the effluent limitations proposed in the Rule would be significant (on the order of $10 million annually for each city). Therefore, the EPA Administrator's certification that the Rule would have no effect on small entities, pursuant to the requirements of the Regulatory Flexibility Act, is incorrect.

Response to: CTR-040-010b

With respect to EPA's compliance with the Regulatory Flexibility Act see response to CTR-001-008b. With respect to the commenter's estimate of its stormwater costs see response to CTR-040-004 (Category J; Stormwater Economics).

Comment ID: CTR-040-013
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

III. Concern: The proposed Rule violates applicable Federal law and regulations

* In failing to consider the impacts on small entities (e.g., for bringing stormwater into compliance with WQBELs based on the Rule's criteria), the Rule is inconsistent with the Regulatory Flexibility Act (See Attachment B).

Response to: CTR-040-013

See response to CTR-001-008b and the preamble to the rule.

Comment ID: CTR-040-056
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: R RFA/SBREFA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: 3. The California Toxics Rule is inconsistent with the Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA, 5 U.S.C. section 601 et seq.) requires that each federal agency, including EPA, publish in the Federal Register twice a year a regulatory flexibility agenda which contains a brief description of the subject area of any rule which the agency expects to promulgate which is likely to have a significant economic impact on a substantial number of small entities (includes municipalities with a population of less than 50,000). Because EPA contends that the CTR does not significantly or uniquely affect small entities, EPA does not believe it is required under the RFA to describe the impact of the proposed rule, which accomplish the stated objectives and which minimize any significant economic impact of the proposed rule on small entities.

The EPA Administrator has certified that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. However, because the CTR will in fact have a significant economic impact on a substantial number of small entities, the Administrator's certification can be challenged as being arbitrary and capricious under the Administrative Procedures Act. If that challenge were successful, then the CTR could not be re-promulgated until the required final regulatory flexibility analysis has been completed by the Agency.

Furthermore, any small entity that is adversely affected or aggrieved by final CTR is entitled to judicial review of agency compliance with the requirements of the RFA. The judicial relief possible in a challenge made by a small entity is as follows:

- Remand of the rule, and - Deferred enforcement of the rule against small entities unless the courts find that continued enforcement of the rule is in the public interest.

Response to: CTR-040-056

See response to CTR-001-008b and the preamble of the final rule.

Comment ID: CTR-041-013b
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES E-01c; S

Comment: 8. The proposed Rule is Inconsistent with Applicable Federal Law and Regulations

The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set

of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. (See attached Legal Analysis of the Proposed California Toxics Rule) to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id). In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act (Id).

Thank you for the opportunity to provide comments on this important new rule. Please call if you have any questions regarding our letter.

Response to: CTR-041-013b

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-041-017
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES

Comment: 3. The California Toxics Rule is inconsistent with the Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA, 5 U.S.C. section 601 et seq.) requires that each federal agency, including EPA, publish in the Federal Register twice a year a regulatory flexibility agenda which contains a brief description of the subject area of any rule which the agency expects to promulgate which is likely to have a significant economic impact on a substantial number of small entities (includes municipalities with a population less than 50,000) Because EPA contends that the CTR does not significantly or uniquely affect small entities, EPA does not believe it is required under the RFA to describe the impact of the proposed rule on small entities or to describe any significant alternatives to the proposed rule, which accomplish the stated objectives and which minimize any significant economic impact of the proposed rule on small entities.

The EPA Administrator has certified that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. However, because the CTR will in fact have a significant economic impact on a substantial number of small entities, the Administrator's certification can be challenged as being arbitrary and capricious under the Administrative Procedures Act. If that challenge were successful, then the CTR could not be re-promulgated until the required final regulatory flexibility analysis has been completed by the agency.

Furthermore, any small entity that is adversely affected or aggrieved by final CTR is entitled to judicial review of agency compliance with the requirements of the RFA. The judicial relief possible in a challenge made by a small entity is as follows:

- Remand of the rule, and

- Deferred enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

Response to: CTR-041-017

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-043-005c
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-21; E-01c; S

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters,"states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.1 I (a)(2)). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-043-005c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order

12866), CTR-036-xxx (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-044-005f
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES E-01g08; E-01h01; E-01m; E-02c; E-01c02; S

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005f

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-059-018 (all comments in Category E-01; CTR Cost Comments), and CTR-036-003a (Category S; UMRA).

Comment ID: CTR-044-006c
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y

CROSS REFERENCES C-21; E-01c; S

Comment: We have reviewed the proposed CTR and offer the following comments:

5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.11 (a)(2)) (see Exhibit G). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id.). Moreover, in failing to properly consider the impacts on small entities, such as the City, the rule is inconsistent with the Regulatory Flexibility Act (Id.).

Response to: CTR-044-006c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-044-009c
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-28; E-01c; S

Comment: We have reviewed the proposed CTR and offer the following comments:

8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for

these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "... the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Additionally, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria-and-consider alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA should evaluate the costs and benefits of toxic criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-044-009c

See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-044-047
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: 3. The California Toxics Rule is inconsistent with the Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA, 5 U.S.C. section 601 et seq.) requires that each federal agency, including EPA, publish in the Federal Register twice a year a regulatory flexibility agenda which contains a brief description of the subject area of any rule which the agency expects to promulgate which is likely to have a significant economic impact on a substantial number of small entities (includes municipalities with a population less than 50,000). Because EPA contends that the CTR does not significantly or uniquely affect small entities, EPA does not believe it is required under the RFA to describe the impact of the proposed rule on small entities or to describe any significant alternatives to the proposed rule, which accomplish the stated objectives and which minimize any significant economic impact of the proposed rule on small entities.

The EPA Administrator has certified that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. However, because the CTR will in fact have a

significant economic impact on a substantial number of small entities, the Administrator's certification can be challenged as being arbitrary and capricious under the Administrative Procedures Act. If that challenge were successful, then the CTR could not be re-promulgated until the required final regulatory flexibility analysis has been completed by the agency.

Furthermore, any small entity that is adversely affected or aggrieved by final CTR is entitled to judicial review of agency compliance with the requirements of the RFA. The judicial relief possible in a challenge made by a small entity is as follows:

- Remand of the rule, and - Deferred enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

Response to: CTR-044-047

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-047-004b
Comment Author: City of Santa Fe Springs
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-047 incorporates by reference letters CTR-013 and CTR-027.
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our storm water program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittee to MS4 permits. Many of the larger municipalities in California have conducted storm water discharge characterization studies. These studies have shown that there are common pollutants associated with storm-water discharges from urbanized areas that could result in compliance problems with the proposed criteria . Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-047-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-050-007c
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES C-21; E-01c; S

Comment: IV. EPA Has Not Complied With Applicable Regulatory Review Requirements. There are several significant statutes and executive orders that require EPA to undertake analyses of the costs and benefits of its regulations, and to submit the regulations and analyses to other governmental bodies, including the Office of Management and Budget (OMB) and Congress. Those authorities include the Regulatory Flexibility Act, the Small Business Regulatory Enforcement and Fairness Act (SBREFA), the Unfunded Mandates Reform Act, the Congressional Review Act, and Executive Order 12866 (Regulatory Planning and Review). EPA apparently believes that it does not need to comply with any of those requirements for this rulemaking. (62 Fed. Reg. at 42188-42191). API believes that EPA is required to meet those obligations for the proposed criteria, and that the Agency's rationale for avoiding this responsibility has no legal basis.

EPA supports its decision not to comply with the regulatory review statutes by stating that the proposed criteria "by themselves, do not directly impose economic impacts." (62 Fed. Reg. at 42188). EPA admits that when those criteria are combined with the designated uses that have been adopted by the State, and implemented in permit limits, "there may be a cost to some dischargers." (62 Fed. Reg. at 42188) could be substantial; the Agency itself estimates that the compliance cost could be between $15 and $87 million per year.(62 Fed. Reg. at 42189). (That does not include indirect costs to the economy, which would surely put this rule above the $100 million impact threshold specified in several of the regulatory review statutes listed above.) EPA cannot ignore those costs by creating its own interpretation of those statutes in which only "direct" impacts need be considered. There is no support in the statutory language or legislative history for such a reading, and EPA has cited no such support in its Federal Register notice.

There is another problem with EPA's rationale for avoiding regulatory review: if EPA were right that "indirect" impacts do not trigger those reviews, the impacts of this rulemaking are not really "indirect." Those impacts emerge clearly once the proposed criteria are combined with the State's designated uses. Those designations have already been established, so there is nothing uncertain or indefinite about that aspect of the water quality standards. Then, once the standards are completed, the State must implement

those standards through permit limits. While there are some decisions that the State must make in determining the proper permit limits, which can influence the size of the compliance costs, EPA can readily determine a range of possible costs. In fact, the Agency has already done so, resulting in the $15 - $87 million cost range discussed above. While those costs may not be fixed with certainty, they are certainly "direct economic impacts". Therefore, even if the Agency were correct in looking at only "direct" impacts, this rulemaking poses such impacts, and EPA must comply with the statutory requirements to conduct and submit cost and benefit analyses of its proposed criteria.

V. CONCLUSION

As explained above, EPA's proposal to issue water quality criteria for toxicities in the State of California suffers from serious legal flaws. API urges the Agency to reconsider its intended course of action in light of the issues raised in these and other public comments. If you have any questions regarding these comments, or would like any additional information, please call Theresa Pugh at 202/682-8036.

Response to: CTR-050-007c

See responses to CTR-001-008b, CTR-050-007a (Category C-21; Legal Concerns), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-052-021c
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-21; E-01c; S

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should revise the proposed rule and economics analysis such that they are consistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act. Specific citations for these inconsistencies are contained in comments from BADA and CASA/Tri-TAC.

Response to: CTR-052-021c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory

Flexibility Act, see response to CTR-001-008b, CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-054-008d
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? Y
CROSS REFERENCES C-02b; C-24; E-01c; S

Comment: Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Francisco Bay, or alternatively EPA should specify in the Preamble implementation policies for copper that will result in reasonable control measures actions. To comply with the Clean Water Act and EPA regulations, EPA is required to consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act, EPA is required to evaluate regulatory alternatives based on an analysis of costs and benefits. Based on BADA's analysis of costs and benefits, EPA should either adopt copper criteria that are reasonably achievable or alternatively specify implementation policies that will avoid costly end-of-pipe controls. Potential implementation measures that could be specified include use of the following in calculating effluent limitations: actual dilution based on modeling studies; copper translators; probability of compliance less than 99.9%; and water-effect ratios determined for different segments of the Bay. Unless EPA specifies these or similar implementation policies in the rule, it is possible that the CTR could result in significant costs ($12 million per year to $78 million per year) while resulting in minor environmental benefit (a 1% reduction in copper loading to the Bay). In that case, the CTR would violate the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. (see the discussion under Item 11 below.)

Response to: CTR-054-008d

See responses to CTR-054-008a (Category C-02b; Copper Aquatic Life), CTR-035-012a and CTR-036-005 (Category C-24; Legal Issues), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-054-013a (Category E-01g3; Cost-Effectiveness Ratio), CTR-001-008b, CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-054-051
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA

References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: 3. The California Toxics Rule is inconsistent with the Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA, 5 U.S.C. section 601 et seq.) requires that each federal agency, including EPA, publish in the Federal Register twice a year a regulatory flexibility agenda which contains a brief description of the subject area of any rule which the agency expects to promulgate which is likely to have a significant economic impact on a substantial number of small entities (includes municipalities with a population less than 50,000). Because EPA contends that the CTR does not significantly or uniquely affect small entities, EPA does not believe it is required under the RFA to describe the impact of the proposed rule on small entities or to describe any significant alternatives to the proposed rule, which accomplish the stated objectives and which minimize any significant economic impact of the proposed rule on small entities.

The EPA Administrator has certified that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. However, because the CTR will in fact have a significant economic impact on a substantial number of small entities, the Administrator's certification can be challenged as being arbitrary and capricious under the Administrative Procedures Act. If that challenge were successful, then the CTR could not be re-promulgated until the required final regulatory flexibility analysis has been completed by the agency.

Furthermore, any small entity that is adversely affected or aggrieved by final CTR is entitled to judicial review of agency compliance with the requirements of the RFA. The judicial relief possible in a challenge made by a small entity is as follows:

- Remand of the rule, and - Deferred enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

Response to: CTR-054-051

See response to CTR-001-008b and the preamble to the final rule.

Comment ID: CTR-059-002b
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c; S

Comment: The Sanitation Districts disagree with EPA's assertions that the CTR is not a significant regulatory action under Executive Order 12866 or the Unfunded Mandates Reform Act, and that EPA is not required to comply with the Regulatory Flexibility Act because the CTR establishes no requirements

applicable to small entities. We believe the potential costs for POTWs to comply with the CTR criteria would far exceed the $ 100 million threshold, based on the fact that we estimate that the potential costs for seven Sanitation Districts' facilities to comply with the CTR to be nearly $150 million per year. Clearly, many of the 304 other POTWs in the State will also incur costs, as, will other NPDES permittees, indirect dischargers, stormwater dischargers, and nonpoint sources. Thus, EPA's cost figure of $15 - $87 million per year is simply not a credible estimate. Also, it is quite clear that the CTR is likely to adversely affect local governments, including over 40 small communities located in our service area, and that it is significantly different from other federal regulations previously promulgated in California. We believe that EPA has not complied with the mandates of Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. Accordingly, EPA must revise the economic analysis and it must be reviewed by the Office of Management and Budget and then EPA must select the most cost-effective and least burdensome regulatory alternative.

Response to: CTR-059-002b

See responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-059-016
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Regulatory Flexibility Act

Contrary to EPA's finding in the Preamble that the CTR "establishes no requirements applicable to small entities (p. 4219 1)," we believe that the NPDES permit requirements and TMDLs that will be based on the CTR criteria will apply to small and large entities alike, because, under Section 301 (b)(1)(C) of the Clean Water Act, EPA and States must establish effluent limitations necessary to meet water quality standards. Although the State of California is a delegated NPDES state, EPA has authority to apply the criteria directly, either by its review and potential veto of state-issued permits, or though direct issuance of permits in cases where it has disapproved a state permit under Section 402 of the Clean Water Act. As pointed out by EPA on p. 42165, the scope of the CTR is to "re-establish criteria for the remaining priority toxic pollutants to meet the requirements of section 303(c)(2)(B) of the CWA." Section 303(c)(2)(B) of the Act requires the establishment of water quality standards for toxic pollutants. Thus, EPA is establishing water quality standards, and NPDES permits subsequently issued must contain effluent limitations necessary to meet water quality standards. Thus, EPA's finding is erroneous, and the CTR will establish requirements applicable to small entities.

Of the 78 cities whose Mayors comprise the Sanitation Districts' Board of Directors, 41 are "small communities" with a population of less than 50,000 people.(*1) It is likely that some or all of these communities would be significantly affected if any or all of the Sanitation Districts' water reclamation

plants were required to install expensive treatment facilities as a result of the CTR. EPA must to comply with the requirements of the Regulatory Flexibility Act to address the impacts on small communities such as these. Most, if not all, of these communities, would also be subject to CTR compliance requirements as a result of their responsibilities as co-permittees under the Los Angeles County Municipal Storm Water NPDES Permit.

Under the requirements of the Regulatory Flexibility Act, we therefore believe that EPA is required to prepare initial and final regulatory flexibility analyses that describe the impact of the proposed rule on small entities, identify any significant alternatives to the proposed rule that accomplish the stated objectives, and describe any significant alternatives to the proposed rule that minimize any significant economic impact of the proposed rule on small entities.

(*1)These communities include Vernon, Bradbury, Industry, Irwindale, La Habra Heights, El Segundo, Rolling Hills Estates, Signal Hill, Sierra Madre, Commerce, San Marino, Palos Verdes Estates, Hawaiian Gardens, Santa Fe Springs, Artesia, Hermosa Beach, Lakewood, Lomita, La Canada Flintridge, Duarte, South El Monte, Cudahy, South Pasadena, Maywood, Lawndale, Walnut, La Veme, Temple City, Manhattan Beach, San Ditnas, Bell, West Hollywood, Monrovia, San Gabriel, La Puente, Azusa, Rancho Palos Verdes, Bell Gardens, Covina, and La Mirada.

Response to: CTR-059-016

See response to CTR-001-008b.

Comment ID: CTR-062-004b
Comment Author: City of Downey
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-062 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 discharges, including small communities. The small communities will be significantly impacted by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the U.S. EPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the U.S. EPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the U.S. EPA did not need to complete an analysis required under the Act. The U.S. EPA neglected to address small MS4 communities in California that are currently subject to MS4 permits, and those smaller communities that may be impacted through Phase II. The U.S. EPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the U.S. EPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-062-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-067-006a
Comment Author: Ojai Valley Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES E-01d01

Comment: * The EPA should reevaluate their determination under the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities. OVSD would be classified as a small entity, serving a population of 25,000, and would be significantly affected by the CTR. OVSD would have to further treat our effluent with reverse osmosis in order to comply with proposed CTR criteria, specifically for copper, nickel, zinc, lindane, and trihalomethanes; modifications to the existing plant would result in estimated increased annualized costs of $1.98 million. These costs are significantly higher than EPA's estimated costs per plant of $27,000 to $480,000 per year. In addition, EPA must consider that OVSD's contingent of small businesses potentially will be affected by the proposed rule through increased regulation of their discharges, increased sewer discharge fees, or product bans. Thus we strongly believe that the EPA's Economic Analysis significantly underestimates the potential statewide costs associated with adoption of the CTR and should be revised.

Response to: CTR-067-006a

See response to CTR-001-008b and CTR-045-012b (Category E-01c; Executive Order 12866).

Comment ID: CTR-071-004b

Comment Author: City of Rosemead
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-071 incorporates by reference letter CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis requiredunder the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-071-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-072-004b
Comment Author: City of Bell Gardens
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA

References: Letter CTR-072 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwate program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits, Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-072-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-073-004b
Comment Author: City of Paramount
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-073 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program.

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits, Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issue as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for small communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis of the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-073-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-074-004b
Comment Author: City of San Gabriel
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-074 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could

result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicated that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-074-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-075-004b
Comment Author: City of El Monte
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-075 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program;

4. The proposed rule applies to all current and future MS4 dischargers, including small com=nities. The small communities will be significantly affected by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule:, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-075-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-076-004b
Comment Author: City of Cudahy
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-076 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharge from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase

II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexability Act.

Response to: CTR-076-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-078-004b
Comment Author: City of Maywood
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-078 incorporates by reference letter CTR-013
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the Calfironia Toxic Rule (CTR), which are of major impact to our stormwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studied have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge ccharacterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-078-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-079-004b
Comment Author: City of Glendale
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-079 incorporates by reference letters CTR-013 and CTR-027
Attachments? N
CROSS REFERENCES J

Comment: In addition, we would like to emphasize the following key issues on the California Toxic Rule (CTR), which are of major impact to our stomrwater program:

4. The proposed rule applies to all current and future MS4 dischargers, including small communities. The small communities will be significantly by the proposed rule. In California, there are many small communities that are currently co-permittees to MS4 permits. Many of the larger municipalities in California have conducted stormwater discharge characterization studies. These studies have shown that there are common pollutants associated with stormwater discharges from urbanized areas that could result in compliance problems with the proposed criteria. Most small communities have not conducted discharge characterization studies; however, it is reasonable to assume that discharges from small communities would also contain these same pollutants. This would result in a smaller community being faced with the same compliance issues as large and medium municipalities; however, the cost to comply could be more significant and prohibitive for smaller communities.

The Regulatory Flexibility Act requires the USEPA to conduct an analysis on the economic impact the proposed rule may have on small entities, unless the USEPA certifies that the rule will not affect a significant number of small entities. In the preamble to the proposed rule, it indicates that there are no small entities to be impacted by the rule, and, therefore, the USEPA did not need to complete an analysis required under the Act. The USEPA neglected to address small MS4 communities in California that are currently subject to a MS4 permits, and those smaller communities that may be impacted through Phase II. The USEPA should have conducted an analysis on the economic impacts to smaller communities.

Unless the preamble is modified to indicate that MS4s are not required to comply with water quality standards, the proposed rule should not be applied to smaller MS4 communities until the USEPA has complied with the requirements of the Regulatory Flexibility Act.

Response to: CTR-079-004b

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), and CTR-001-008b.

Comment ID: CTR-092-016b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: R RFA/SBREFA
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c; S

Comment: Introductory Comment

EPA states in the Executive Summary (page ES-2) to the Economic Analysis that:

"EPA did not calculate costs for any program for which it does not have enforceable authority ... (nor) for NPDES sources which are not typically subject to numeric WQBELs....."

From a national policy perspective, this narrowing, of the focus of the Economic Analysis may be a justifiable approach to cost benefit analysis. Local government, however, is not able to disregard the potential cost effects of the CTR on urban and agricultural runoff. Those potential costs will have to be defrayed with proceeds from the same pool of local rate payers responsible for paying for point source pollutant removal programs. In California, those ratepayers have made clear both their support for environmental protection and their reluctance to pay more than is necessary for that protection. A narrow definition of those costs included in the CTR Economic Analysis continues the pattern of fragmenting responsibility and authority for the protection of waterways, which in turn hinders creation and implementation of holistic strategies which would best serve the environment at least cost.

Questions for EPA on the Introductory Comment

Q.-1) If not EPA, who has the responsibility to define the aggregated costs of all water quality-related regulations?

Q.-2) San Jose's reading of federal policy initiatives (which include, but are not limited to, the Regulatory Flexibility Act, Executive Order 12866, and the Unfunded Mandates Reform Act) indicates that EPA is empowered to analyze the economic impact of federal regulations in a way that addresses both aggregated cost impacts as well as the fiscal reality of local level government. Why was this not accounted for in the current analysis?

Response to: CTR-092-016b

See responses to CTR-001-008b, CTR-021-005c (Category E-01c; Executive Order 12866), CTR-021-006b (Category E-01c; Executive Order 12866), CTR-036-003a (Category S; Unfunded Mandates Reform Act), and the preamble to the proposed rule.

Comment ID: CTR-096-004b
Comment Author: City of Modesto
Document Type: Local Government

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES G-10

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

4. The environmental consequences of the necessary treatment facilities and changes in operating practices to meet these discharg5 standards is very significant and has not been addressed in promulgating the proposed rule.

Specifically, the City submits the following comments:

F. A comparison of the Water Quality Standards (WQS) used by its City during the Local Limits Study and the proposed WQS is shown in Table 1. There is a little variation in limits for cadmium, copper, nickel, and zinc as these values are dependent on receiving stream hardness. The values shown in Table I for the City were developed using a hardness of 170 mg/l as CaCO3 while the standards from the CTR are based on 100 mg/l as CaCO3. The WQS from the CTR are actually expressed as dissolved fractions. A factor of I has been used to convert from dissolved to total fractions for the comparison to take place.

Table 1

Comparison of Water Quality Standards

	City Report		WQS		1996		1997	
	Chronic	Acute	Chronic	Acute				
Arsenic, ppb	190.0	360.0	150.0	340.0	Cadmium, ppb	1.7	7.1	2.2
4.3	Chromium, ppb	10.0	15.0	11.0	16.0	Copper, ppb	19.0	29.0	9.0
13.0	Nickel, ppb	250.0	2200.0	52.0	470.0	Zinc, ppb	170.0	180.0	
120.0	120.0	Mercury, ppb	N/A	2.1	.77	1.4			

Table 1 indicates that the City's Local Limits for arsenic, cadmium, chromium, and zinc would have little difficulty meeting the CTR. However, limits for copper, nickel and mercury may be drastically impacted. This impact in developing a stricter local limit may result in an economic hardship to many small business enterprises that currently do metal plating. These businesses may be forced to close down due to the implementation of these limits. Modesto experiences a chronic unemployment rate above 12%, and economic development is critical to this community.

Response to: CTR-096-004b

See response to CTR-096-004a (Category G-10; Pretreatment).

Comment ID: CTRE-003-001c
Comment Author: Bay Planning Coalition
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/09/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES B; J

Comment: The Bay Planning Coalition represents approximately 200 maritime industry, shoreline businesses, local governments and Bay users along the S.F. Bay shoreline and is most significantly affected by the proposed California Toxics Rule. One of our primary interests is the economic analysis which under the EPA's model estimates a range of annual costs of $14.9 to $86.6 million.

We believe the annual costs for implementation of the Rule statewide exceed the EPA estimate range. We are particularly concerned because it appears that the economic impact analysis did not include the costs of compliance for the NPDES stormwater permit applicants. In order for us to provide EPA with sufficient detail on our economic analysis and cost projection as well as the impact of the Rule on small business under the Regtory Flexibility Act, we request an extension of time to respond. A 30-day extension from September 26 to October 27, 1997 would be acceptable. Thank you so much for your consideration.

Response to: CTRE-003-001c

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), CTR-001-008b, and CTR-001-001 (Category B; Comment Period).

Comment ID: CTRH-001-005b
Comment Author: Alan Waltner
Document Type: Public Hearing
State of Origin: CA
Represented Org: Almeda Cnty Clean Wtr Pgm
Document Date: 09/17/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES J-2

Comment: If you go beyond best management practices, you're impliedly eliminating those provisions of the 1995 Basin Plan. I think it would clearly violate the Regulatory Flexibility Act, since you haven't considered the costs of controls.

If, again, our dischargers had to do whatever it took, our members had to do whatever it took -- and in fact, several of our dischargers are small entities under the Regulatory Flexibility Act: the City of

Emeryville, the City of Albany, the City of Piedmont.

The NPDES permits small entities and municipalities under 50,000 in number. If they had to do whatever it took to provide the waste allocations without consideration of the economic impact, those entities, because of the practical problems of needing 50 coliseums of storage in the Bay Area and the practical considerations that plague us -- and the only place you could put that is by the bay, where you have a serious problem with requirements under the Endangered Species Act.

To the extent you're standing in the shoes of the state in promulgating these standards, you violate the cost/benefit balances provision of the Porter Cologne Act.

Response to: CTRH-001-005b

With respect to EPA's compliance with the RFA see response to CTR-001-008b. With respect to stormwater costs see response to CTR-013--003 and CTR-04-004 (Category J; Stormwater Economics). With respect to commenters' assertion that EPA violated the cost/benefit provision of the Porter-Cologne Act, see response to CTR-020-002 (Category C-21; Legal Issues).

Comment ID: CTRH-001-008a
Comment Author: Doug Harrison
Document Type: Public Hearing
State of Origin: CA
Represented Org: Fresno Met. Flood Control
Document Date: 09/17/97
Subject Matter Code: R RFA/SBREFA
References:
Attachments? N
CROSS REFERENCES J-2

Comment: Looking at the results of our monitoring and your criteria, we'll have to achieve another 70 to 90 percent reduction in pollutants in order to be in compliance. That means we'd have to increase our storage volume to 20,000 acre feet just to handle average annual runoff we have underway right now.

That's a price tag of $220 million to $400 million to try to stay in compliance with the current criteria if you interpret the rule to apply to us -- 220 million. And then we can't prevent major storm events in our community, storm impacts that cause a discharge, in which case 100 percent of the discharges would exceed -- would be out of compliance, even though we were retaining 100 percent of the average annual rainfall.

We think that raises a problem with the Regulatory Flexibility Act, both in terms of the cost analysis itself and the impact that accrues to small communities, certainly with respect to the executive order. Just in our case alone the $100 million limit is in serious trouble, dealing with compliance with a five-year schedule just in our community with the possibility of $80 million per year of expense. That does not include O & M cost in that system.

Response to: CTRH-001-008a

See responses to CTR-013-003, CTR-040-004, (Category J; Stormwater Economics), CTR-021-005c

(Category E-01c; Executive Order 12866), and CTR-001-008b.

Subject Matter Code: S UMRA

Comment ID: CTR-005-006b
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-21; R

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and also taking into consideration their use and value for navigation (See CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern. For those identified waters, states must adopt criteria for such toxic pollutants applicable to sufficient to protect the designated use"(See 40 CFR 131.1 1 (a)(2)).

Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-005-006b

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Subject R, Regulatory Flexibility Act), CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-019-002b
Comment Author: Richards, Watson & Gershon
Document Type: Local Government
State of Origin: CA
Represented Org: Cities of Barst
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-019 incorporates by reference letters CTR-001, CTR-013, CTR-027 and CTR-036
Attachments? N

Comment: UNFUNDED MANDATED PROGRAMS

One of the express purposes of the Unfunded Mandates Reform Act of 1995 is "to end the imposition, in the absence of full consideration of Congress of Federal mandates on State, local and tribal governments without adequate Federal funding, in a manner that may displace other essential State, local and tribal governmental priorities." 2 U.S.C. section 1501(2). The proposed rule in its current form seems to have been drafted without regard to its fiscal impact on cities. The rule could require treatment of storm water discharges, despite the fact that no funding mechanism, nor any assistance, financial or otherwise, is being provided to the cities by either USEPA or the State of California. If the USEPA wishes to impose these treatment programs, it needs to provide funds to pay for their implementation.

We believe that USEPA's analysis under the Unfunded Mandates Reform Act of 1995 that the CTR will not result in an expenditure in the aggregate of more than $100,000,000.00 a year is wrong. As pointed by other local government entities which have submitted comments, the USEPA appears to assume that a BMP program will lead to compliance with numeric effluent guidelines and that there will be no associated additional costs for the BMP program. However, the economic analysis does not appear to analyze the potential cost of end of pipe treatment controls and analyze in any sort of detail what sort of BMP's would be necessary to achieve numeric effluent guidelines for the toxic pollutants. The economic analysis itself acknowledges that under its existing NPDES stormwater permit, the cities and counties of the Los Angeles area plan to spend $15,000,000 annually on public education in a program to curb illegal dumping. That cost estimate was based upon the analysis by the SWRCB of the 1990 permit. The actual costs of implementing all of the programs under the 1990 permit have been considerably more. For example, the cost estimates prepared by the San Gabriel Valley COG in connection with the LA. County permit, estimated implementation costs at $8.98 per person per year. The City of Long Beach estimated that it was already spending, as of early 1996, $12.4 million a year and that the estimated costs of implementing the programs under the current permit adopted in July 1996 would be another $3.4 million or about $16.1 million total. That number extrapolated to approximately $38.35 per person per year. The comparative cost numbers prepared by the Santa Monica Bay Restoration Project in connection with the existing Los Angeles permit estimated an average cost of dedicated stormwater program funding of $3.34 a month per household or approximately $13.36 per person per year. Using that number as a base, a city with a population of approximately $40,000 people can expect to spend $500,000 a year under its current stormwater programs. Extrapolating those numbers over the State of California, it is quite clear that the costs of implementing the existing stormwater program are in the hundred of millions of dollars a year.

Considering these economic analyses, it is quite clear that the financial impact of requiring end of pipe treatment controls or other means to achieve numeric effluent guidelines would quite easily exceed $100 million a year.

The foregoing numbers, of course, do not include potential increased costs to residents, business and industry complying with the discharge prohibitions and other requirements under the "City's current municipal permits nor does the EPA's economic analysis calculate the potential costs to regulated dischargers, that is, business and industries required to either obtain an individual NPDES stormwater permit or who are covered under a general permit by filing a notice of intent.

Necessarily, the expenditure of such large amounts of money is an important public policy question, particularly in a situation where neither the State of California nor the federal government has been

willing to provide any meaningful source of funds to local agencies to carry out these programs.

Response to: CTR-019-002b

See responses to CTR-013-003 (Category J; Stormwater Economics) and CTR-036-003a (Category S; Unfunded Mandates Reform Act).

Comment ID: CTR-021-005e
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-13; C-28; E-01c; R

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and wtih an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit wand with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not

promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's innovative approaches towards development of the CTR, particularly as regards the toxic metals. Hwoever, we believe that EPA has needlessly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005e

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; Regulatory Flexibility Act), CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

With respect to detection limits see responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). With respect to the selection and economic analysis of risk levels for carcinogens see responses to CTR-021-005a (Category C-13; Risk Level) and CTR-021-005c (Category E-01c; Executive Order 12866).

Comment ID: CTR-021-006d
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES J; E-01c; R; I-01

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments on the CTR and the EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

3. Failure to Address Important Stormwater-Related Issues. In addition to its POTW, Sunnyvale is the owner of a system of storm drains which contribute wet weather flows to the South Bay. We are concerned that the EA entirely neglects the potential impacts of the proposed CTR on the storm drains. The EA entirely omits any meaningful analysis ofthe costs of bringing storm drains into compliance with the proposed CTR, thereby significantly understating the overall costs of the CTR. We believe that this omission is violative of the Agency's legal obligations under the authorities cited in the preceding

paragraph.

In addition, we join in the comments being filed by the various other operators of stormwater collection systems to the effect that EPA has overstated the legal requirements for storm drains to comply with numerical criteria.

Response to: CTR-021-006d

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R, RFA), CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

EPA believes it properly described the potential impact of the implementation of the CTR on storm drains in the preamble to the proposed CTR and in its Economic Analysis. For further discussion see responses to CTR-013-003 and CTR-040-004 (Category J; Stormwater Economics).

Comment ID: CTR-034-004
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: LEGAL ISSUES - Executive Order 12866, Unfunded Mandates Reform Act, Regulatory Flexibility Act

* SCAP believes that EPA has failed in its duties under the Unfunded Mandates Reform Act to consider the cost of the proposed regulation to local governments and the regulated community and to select the most cost-effective and least burdensome regulatory alternative that achieves the objectives of the rule and is consistent with statutory requirements. Although EPA prepared an assessment of the anticipated costs and benefits of the CTR, we believe that the economic analysis failed to consider major factors contributing to potential costs and substantially overstated the anticipated benefits of the rule (see below).

Response to: CTR-034-004

See response to CTR-036-003a.

Comment ID: CTR-035-040
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:

Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42191 -- The Unfunded Mandates Reform Act of 1995 All local governmental agencies, especially "small agencies" within the meaning of the Unfunded Mandates Reform Act (2 U.S.C.A. 1511 et. seq.) deserve the protections afforded by that Act. EPA's claim that the Act does not apply because "Today's proposed rule does not regulate or affect any entity" is unfounded. The claim is that the CTR may not impose costs greater than $100 million a year is without merit (see discussion below). The CTR directly impacts all NPDES holders in the State of California, as stated above. Accordingly, all of its provisions apply to the CTR, including, without limitation, the requirement found in Section 1533(a)(2) that the Agency's required small government agency plan provide for "meaningful and timely input" into the development of the CTR. As stated earlier, the failure of EPA to allow CASA/Tri-TAC members the opportunity to review the State Proposal for any longer than two weeks simply does not meet a common sense interpretation of "meaningful and timely review." EPA must comply with the Act.

Response to: CTR-035-040

See response to CTR-036-003a.

Comment ID: CTR-036-003a
Comment Author: County of Orange
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-036 incorporates by reference letters CTR-013, CTR-018, CTR-031, CTR-034 and CTR-040
Attachments? N
CROSS REFERENCES J

Comment: EPA also has failed to meet its obligations under the Unfunded Mandates Reform Act of 1995 (the "Reform Act"). As with E.O. 12866, the Reform Act requires federal agencies to assess the effects of their regulatory actions on state, local and tribal governments, and on the private sector [U.S.C. section 1531]. Among other things, the Reform Act requires the preparation of a cost-benefit analysis and the examination of a range of alternatives, whenever the proposed action may result in expenditures in excess of $100 million [2 U.S.C. section 1532, 1535]. In addition, the Reform Act contains a number of specific requirements where an action may significantly or uniquely impact small governments [2 U.S.C. section 1533].

EPA asserts again that it does not have to comply with the Reform Act because the proposed rule "imposes no direct enforceable duties on the State or any local government or on the private sector." [62 Fed. Reg 42160, 42191]. For the reasons discussed earlier, this assertion is without merit. As EPA acknowledges, these criteria will serve as the basis for any water quality standards promulgated by the State, which in turn will be binding on. local government and private industry. Unless EPA is prepared

to view these criteria as being optional, it therefore cannot in good conscience state that they do not create an enforceable duty. Given this, EPA must comply with the mandates of the Reform Act

Response to: CTR-036-003a

EPA has determined that the CTR contains no federal mandates (under the regulatory provisions of title II of the Unfunded Mandates Reform Act) for State, local, and tribal governments or the private sector. The CTR imposes no direct enforceable duties on the State or any local government or on the private sector; rather, the CTR promulgates ambient water quality criteria which, when combined with State-adopted uses, will create water quality standards for those water bodies with adopted uses. The State will then use these resulting water quality standards in implementing its existing water quality control programs.

EPA recognizes that it has undertaken an economic analysis pursuant to E.O. 12866 for this rule. This analysis, however, makes numerous assumptions and does not necessarily predict how the state will implement the criteria. Thus, the economic analysis represents EPA's best estimate of the implementation costs of the rule. In any event, even if EPA were to consider the implementation costs rather than the direct costs of the rule for the purposes of UMRA compliance, EPA has determined that this rule will not result in expenditures of $100 million or more for State, local, or tribal governments, in the aggregate, or the private sector in any one year.

Comment ID: CTR-038-005c
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES E-01c; R

Comment: A further consequence of the flawed economic analysis is the conclusion that the CTR is not a major rule (i.e., one which will result in excess of $100 million per year expenditure) subject to Presidential Executive order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Reform Act. The District, for example, is a small community having a population of under 50,000 and, in addition, serves several small towns and communities (Sonoma, Glen Ellen, Boyes Hot Springs and Agua Caliente) that would be greatly impacted by the proposed rule.

Response to: CTR-038-005c

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-038-006d
Comment Author: Sonoma County Water Agency

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-21; E-01c; R

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, and recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use" (See 40 CFR 131.11(a)(2)). Clearly the intent of both the Clean Water Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, such as the District and the small communities it serves, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-038-006d

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-038-008d
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-24; E-01c; R; T

Comment: 7. Separate, sites-specific aquatic life criteria for copper and human health criteria for mercury should be adopted for Schell Slough, or alternatively EPA should specify implementation procedures for these criteria that will preclude unreasonable controls such as end-of-pipe treatment. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To

fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the assessment of costs and benefits described in "3" above, EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation procedures that would allow the current discharge to continue (e.g., allowable Mixing zones and averaging periods and, for copper, a translator and water-effect ratio). Again, the District is amenable to continuing to address these constituents through pollution prevention measures and to assessing the actual impacts of these constituents in Schell Slough. Without EPA specifying such implementation procedures in the CTR, it is possible that the CTR could impose significant costs on the District (and the other small communities its serves) without providing a commensurate environmental benefit. In that case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-038-008d

See response to CTR-038-008a (Category C-24; Site-Specific Criteria). See response to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-038-009d
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-28; E-01n; R

Comment: 8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt numeric criteria only for constituents "...the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this "play-it-safe" approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. By taking this approach, however, EPA is unable to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria and alternative criteria. For these reasons, EPA

must not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA must evaluate the costs and benefits of the criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits). With respect to the District's discharge and Schell Slough and Second Napa Slough, the criteria in this category include, but are not necessarily limited to, the following : benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(k)fluoroanthene, chrysene, dibenzo(a,h)anthracene, aldrin, 4,4'-DDD, 4,4'-DDE, dieldrin, endosulfan I, endosulfan II, endosulfan sulfate, heptachlor, heptachlor epoxide, toxaphene, PCB-1016, OCB-1221, PCB-1232, PCB-1242, PCB-1248, PCB-1254, PCB-1260, and hexachlorobenzene (see Table 3).

Response to: CTR-038-009d

See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits).

For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-040-009b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES R
E-01c

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

II. Concern: The economic analysis upon which the Rule is based is seriously flawed.

* A consequence of the cost/benefit analysis of the Rule are several erroneous conclusions, namely that: (1) this is not a "significant regulatory action" or a major rule (i.e., one which will result in excess of $100 million annual expenditure) subject to the requirements contained in Presidential Executive Order 12866 and the Unfunded Mandates Reform Act; and (2) this is not a rule that will have a significant economic impact on a substantial number of small entities protected under the Regulatory Flexibility Act.

Response to: CTR-040-009b

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order

12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-040-012b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES E-01c

Comment: MAJOR CONCERNS

We do, however, have fundamental concerns with the Rule as it is presently proposed and its supporting economic analysis. We believe the Rule can be modified in a manner that will be responsive to our concerns while at the same time being consistent with applicable Federal law and regulations. Our major concerns are presented here and are followed by our recommended modifications.

III. Concern: The proposed Rule violates applicable Federal law and regulations

* In failing to properly evaluate the Rule's impacts and in failing to adequately consider regulatory alternatives, the Rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (See Attachment B).

Response to: CTR-040-012b

See responses to CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-040-015a
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES C-13

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source

control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

II. Recommendation: Adopt human health criteria for PAHs at a 10 (-4) risk level and human health criteria for other carcinogens at risk levels that are generally achieved by municipal wastewater and stormwater dischargers.

* As previously stated, the Sacramento Stormwater Management Program would have to expend on the order of $260 million per year to treat stormwater, and this may not achieve the proposed criteria for PAHS, which is based on a 10 (-6) cancer risk level.

* Under the Unfunded Mandates Reform Act, EPA must adopt the least cost alternative for complying with the CWA, unless the Administrator explains in the final rule why the least cost alternative is not adopted. As indicated in the Preamble, risk levels of 10 (-5) and 10 (-4) are acceptable under the CWA.

* Therefore, pursuant to the spirit of the Unfunded Mandates Reform Act, EPA should adopt the PAH criteria at a 10 (-4) risk level. The same should be true for other carcinogens that present attainability problems for dischargers. Most carcinogenic constituents are not readily controllable through source control or BMPs and would generally require end-of-pipe controls to achieve significant reduction. The benefits associated with additional reduction of carcinogenic constituents are not expected to be measurable since, as acknowledged in the economic analysis,point sources are relatively minor sources of these constituents.

Response to: CTR-040-015a

See responses to CTR-058-001 (Category C-13; Risk Level), CTR-013-003 (Category J; Stormwater Economics) and CTR-036-003a.

Comment ID: CTR-040-055
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027.
Attachments? Y
CROSS REFERENCES

Comment: b. Unfunded Mandates Reform Act

Under the Unfunded Mandates Reform Act (UMRA, 2 U.S.C. section 1501 et seq.), EPA is required to consider the cost of a proposed regulation to both state and local Governments and the regulated community. EPA is required to prepare a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate and to select the most cost-effective and least burdensome regulatory alternative that achieves the objectives of the rule and is consistent with statutory requirements. EPA has performed an economic analysis, however, EPA contends that the cost of the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year" necessary to trigger the other

requirements of the UMRA.

EPA only makes a limited analysis of alternatives and does not explicitly defend the rule's cost-effectiveness because it contends that does not apply because the $100 million cut off was not met (*3). Based on the cost research performed by the POTWs and other dischargers, EPA's contention that UMRA's requirements do not apply may be challengeable. The regulated community may also be able to demonstrate that the Administrator was abitrary and capricious by alleging the cost of implementing the CTR will not result i expenditures in the aggregate" of $100 million or more in any one year."

EPA should have considered alternatives, such as the adoption of less stringent criteria or different risk levels (e.g., 10E-4 or 10E-5), that could also achieve the objectives of the rule. These alternatives would have met both the UMRA criteria of being more cost-effective and less burdensome while still maintaining consistency with the Clean Water Act.

(*3) "EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The proposed rule imposes no direct enforceable duties on the State or any local government or on the private sector; rather, this rule proposes ambient water quality criteria which, when combined with State adopted designated uses, will create water quality standards for those water bodies with adopted uses. The State may use these resulting water quality standards in implementing its existing water quality control programs. Today's proposed rule does not directly regulate or affect any entity and, therefore, is not subject to the requirement of sections 202 and 205 of the UMRA." 62 Fed. Reg. 41,191.

Response to: CTR-040-055

See response to CTR-036-003a.

Comment ID: CTR-041-013c
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? N
CROSS REFERENCES E-01c; R

Comment: 8. The proposed Rule is Inconsistent with Applicable Federal Law and Regulations

The proposed rule is inconsistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. (See attached Legal Analysis of the Proposed California Toxics Rule) to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id). In failing to properly consider the impacts on small entities, the

rule is inconsistent with the Regulatory Flexibility Act (Id).

Thank you for the opportunity to provide comments on this important new rule. Please call if you have any questions regarding our letter.

Response to: CTR-041-013c

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; UMRA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-041-016
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? N
CROSS REFERENCES

Comment: b. Unfunded Mandates Reform Act

Under the Unfunded Mandates Reform Act (UMRA, 2 U.S.C. section 1501 et seq.), EPA is required to consider the cost of a proposed regulation to both state and local Governments and the regulated community. EPA is required to prepare a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate and to select the most cost-effective and least burdensome regulatory alternative that achieves the objectives of the rule and is consistent with statutory requirements. EPA has performed an economic analysis, however, EPA contends that the cost of the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year" necessary to trigger the other requirements of the UMRA.

EPA only makes a limited analysis of alternatives and does not explicitly defend the rule's cost-effectiveness because it contends that UMRA does not apply because the $100 million cut off was not met.(*4) Based on the cost research performed by the POTWs and other dischargers, EPA's contention that UMRA's requirements do not apply may be challengeable. Specifically, the EPA Administrator's determination that the cost of implementing the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year" could be found to be arbitrary and capricious.

EPA should have considered alternatives, such as the adoption of less stringent criteria or different risk levels (e.g., 10E-4 or 10E-5), that could also achieve the objectives of the rule. These alternatives would have met both the UMRA criteria of being more cost-effective and less burdensome while still maintaining consistency with the Clean Water Act.

(*4) "EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The proposed rule imposes no direct enforceable duties on the State or any local government or on the private sector; rather, this rule proposes ambient water quality criteria which, when combined with State adopted designated uses, will create water quality standards for those water bodies with adopted uses. The State may use these resulting water quality standards in implementing its existing water quality control programs. Today's proposed rule does not directly regulate or affect any entity and, therefore, is not subject to the requirement of sections 202 and 205 of the UMRA." 62 Fed. Reg. 42,191.

Response to: CTR-041-016

See responses to CTR-058-001 (Category C-13; Risk Level) and CTR-036-003a.

Comment ID: CTR-042-007c
Comment Author: Cal. Dept. of Transportation
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-21; E-01c

Comment: 7. The CTR may violate the Administrative Procedures Act, the and Executive Order (E.O.) Unfunded Mandates Reform Act No. 12866.

In the Preamble to the CTR, EPA repeatedly claims that the CTR will not result in expenditures of more than $100 million per year and, therefore, the statutory requirements of the UMRA and E.O. 12866 are not triggered.(*1) Caltrans' annual costs alone and only in Los Angeles will exceed the $100 million annual figure, even assuming the lowest level of treatment. Therefore, EPA's cost assumptions are challengeable as being arbitrary and capricious and in violation of the Administrative Procedures Act.(*2)

Request: Caltrans requests that EPA reconsider its cost estimates based on the comments received during the public comment period.

Caltrans would like to thank EPA for the opportunity to provide comments on this proposed regulation. It is hoped that EPA will consider and address Caltrans' comments in the final version of the CTR. Should you have any questions concerning our comments on the CTR, please feel free to address these questions to Marcia Arrant at (916) 657-5381.

(*1) See CTR, 62 Fed. Reg. at 42,188, and at 42,191 ("EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.")

(*2) See American Iron and Steel Institute v. EPA, 1997 WL 297251 (D.C. Cir., 1497)(the court found that EPA had arbitrarily failed to adequately address cost-justification for its elimination of mixing zones. EPA had estimated the total cost of elimination mixing zones for bioaccumulative chemicals of concern (BCCS) from all dischargers to the Great Lakes at $200,000, without even acknowledging a comment estimating the cost to one town for removal of mercury from its sewage discharge would be approximately $300,000).

Response to: CTR-042-007c

See responses to CTR-036-003a, CTR-021-005c (Category E-01c; Executive Order 12866), and CTR-042-007a (Category C-21; Legal Issues).

Comment ID: CTR-043-005d
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-21; E-01c; R

Comment: 5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters,"states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.1 I (a)(2)). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. Moreover, in failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act.

Response to: CTR-043-005d

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-044-005g
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES E-01g08; E-01h01; E-01m; E-02c; E-01c02; R

Comment: We have reviewed the proposed CTR and offer the following comments:

4. EPA's Economic Analysis is seriously flawed. The major flaws include:

(1) failing to do an appropriate sampling of small dischargers having little or no dilution; (2) assuming in the high-end cost scenario that a 25% reduction could be achieved through source control and an additional 25% achieved through treatment plant optimization without capital improvements; (3) constraining estimates of potential costs through key assumptions, including the assumption that regulatory relief from the rule would be granted if costs were in excess of certain thresholds; and (4) exaggerating estimates of potential benefits by assuming an end (i.e., achievement of the proposed water quality criteria) that will not result from the rule. Additional concerns with the economic analysis are presented in Exhibit F. The result of these flaws is that potential costs are greatly understated and potential benefits are greatly overstated. Moreover, the flawed economic analysis has lead to the erroneous conclusion that the CTR is not a "significant regulatory action" or major rule subject to Presidential Executive Order 12866 and the Unfunded Mandates Reform Act or a rule that affects small entities protected under the Regulatory Flexibility Act. The City, for example, is a small community having a population of under 50,000 and would be greatly impacted by the proposed rule.

Response to: CTR-044-005g

See responses to CTR-054-013a, CTR-021-005c, CTR-032-004, CTR-021-008, CTR-040-029a, CTR-059-018 (all comments in Category E-01; CTR Cost Comments), and CTR-036-003a.

Comment ID: CTR-044-006d
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-21
E-01c
R

Comment: We have reviewed the proposed CTR and offer the following comments:

5. The proposed rule is inconsistent with applicable Federal law and regulations.

In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. The Clean Water Act requires that water quality standards be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes (see CWA section 303(c)(2)(A)). Consistent with this, EPA regulations require that water quality standards be based on identification of "specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern..." For those identified waters, "states must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use"(See 40 CFR 131.11 (a)(2)) (see Exhibit G). Clearly the intent of both the Act and EPA regulations is that water quality standards be tailored to the characteristics of the waters in question. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider regulatory alternatives, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act (Id.). Moreover, in failing to properly consider the impacts on small entities, such as the City, the rule is inconsistent with the Regulatory Flexibility Act (Id.).

Response to: CTR-044-006d

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-044-009d
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-28
E-01c
R

Comment: We have reviewed the proposed CTR and offer the following comments:

8. EPA should not adopt criteria for any pollutant where the method detection limit exceeds the objective and there is insufficient detectable, reliable data to determine if the pollutant could reasonably be expected to interfere with designated uses. The proposed rule includes criteria for a number of constituents where there is insufficient data to determine whether the discharge of such pollutants could reasonably be expected to interfere with the designated uses. EPA has chosen to promulgate criteria for these constituents even though section 303 (c)(2)(B) of the Clean Water Act requires States to adopt

numeric criteria only for constituents "... the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Clearly, this approach goes beyond the requirements of the Clean Water Act and is therefore unnecessary. Additionally, this approach does not allow EPA to fulfill its duty (under Presidential Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act) to assess the costs, benefits, and impacts of the rule on local government and small entities. While this may be the conservative approach for EPA, it places dischargers throughout the State at risk. As analytical detection limits improve, dischargers may find they are unable to achieve the criteria without costly end-of-pipe controls. But, by then, it will be too late for EPA to evaluate the costs and benefits of the criteria-and-consider alternative criteria. For these reasons, EPA should not adopt criteria for those constituents. If EPA does adopt criteria for those constituents, EPA should evaluate the costs and benefits of toxic criteria, as well as alternative criteria, using worst case assumptions (i.e., assume that discharge levels and ambient levels are at the detection limits).

Response to: CTR-044-009d

See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-044-046
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: b. Unfunded Mandates Reform Act

Under the Unfunded Mandates Reform Act (UMRA, 2 U.S.C. section 1501 et seq.), EPA is required to consider the cost of a proposed regulation to both state and local Governments and the regulated community. EPA is required to prepare a qualitative and quantitative assessment of theanticipated costs and benefits of the Federal mandate and to select the most cost-effective and least burdensome regulatory alternative that achieves the objectives of the rule and is consistent with statutory requirements. EPA has performed an economic analysis, however, EPA contends that the cost of the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year" necessary to trigger the other requirements of the UMRA.

EPA only makes a limited analysis of alternatives and does not explicitly defend the rule's cost-effectiveness because it contends that does not apply because the $100 million cut off was not met.(*3) Based on the cost research performed by the POTWs and other dischargers, EPA's contention that UMRA's requirements do not apply may be challengeable. The regulated community may also be able to demonstrate that the Administrator was arbitrary and capricious by alleging the cost of

implementing the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year."

EPA should have considered alternatives, such as the adoption of less stringent criteria or different risk levels (e. g., 10E-4 or 10E-5), that could also achieve the objectives of the rule. These alternatives would have met both the UMRA criteria of being more cost-effective and less burdensome while still maintaining consistency with the Clean Water Act.

(*3) "EPA has determined that this rule does not contain a federal mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The proposed rule imposes no direct enforceable duties on the State or any local government or on the private sector; rather, this rule proposes ambient water quality criteria which, when combined with State adopted designated uses, will create water quality standards for those water bodies with adopted uses. The State may use these resulting water quality standards in implementing its existing water quality control programs. Today's proposed rule does not directly regulate or affect any entity and, therefore, is not subject to the requirement of sections 202 and 205 of the UMRA." 62 Fed. Reg. 42,191.

Response to: CTR-044-046

See responses to CTR-058-001 (Category C-13; Risk Level) and CTR-036-003a.

Comment ID: CTR-050-007d
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? N
CROSS REFERENCES C-21
E-01c
R

Comment: IV. EPA Has Not Complied With Applicable Regulatory Review Requirements. There are several significant statutes and executive orders that require EPA to undertake analyses of the costs and benefits of its regulations, and to submit the regulations and analyses to other governmental bodies, including the Office of Management and Budget (OMB) and Congress. Those authorities include the Regulatory Flexibility Act, the Small Business Regulatory Enforcement and Fairness Act (SBREFA), the Unfunded Mandates Reform Act, the Congressional Review Act, and Executive Order 12866 (Regulatory Planning and Review). EPA apparently believes that it does not need to comply with any of those requirements for this rulemaking. (62 Fed. Reg. at 42188-42191). API believes that EPA is required to meet those obligations for the proposed criteria, and that the Agency's rationale for avoiding this responsibility has no legal basis.

EPA supports its decision not to comply with the regulatory review statutes by stating that the proposed criteria "by themselves, do not directly impose economic impacts." (62 Fed. Reg. at 42188). EPA admits that when those criteria are combined with the designated uses that have been adopted by the State, and implemented in permit limits, "there may be a cost to some dischargers." (62 Fed. Reg. at 42188) could be substantial; the Agency itself estimates that the compliance cost could be between $15 and $87 million per year.(62 Fed. Reg. at 42189). (That does not include indirect costs to the economy, which would surely put this rule above the $100 million impact threshold specified in several of the regulatory review statutes listed above.) EPA cannot ignore those costs by creating its own interpretation of those statutes in which only "direct" impacts need be considered. There is no support in the statutory language or legislative history for such a reading, and EPA has cited no such support in its Federal Register notice.

There is another problem with EPA's rationale for avoiding regulatory review: if EPA were right that "indirect" impacts do not trigger those reviews, the impacts of this rulemaking are not really "indirect." Those impacts emerge clearly once the proposed criteria are combined with the State's designated uses. Those designations have already been established, so there is nothing uncertain or indefinite about that aspect of the water quality standards. Then, once the standards are completed, the State must implement those standards through permit limits. While there are some decisions that the State must make in determining the proper permit limits, which can influence the size of the compliance costs, EPA can readily determine a range of possible costs. In fact, the Agency has already done so, resulting in the $15 - $87 million cost range discussed above. While those costs may not be fixed with certainty, they are certainly "direct economic impacts". Therefore, even if the Agency were correct in looking at only "direct" impacts, this rulemaking poses such impacts, and EPA must comply with the statutory requirements to conduct and submit cost and benefit analyses of its proposed criteria.

V. CONCLUSION

As explained above, EPA's proposal to issue water quality criteria for toxicities in the State of California suffers from serious legal flaws. API urges the Agency to reconsider its intended course of action in light of the issues raised in these and other public comments. If you have any questions regarding these comments, or would like any additional information, please call Theresa Pugh at 202/682-8036.

Response to: CTR-050-007d

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-052-021d
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES C-21
E-01c
R

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

EPA should revise the proposed rule and economics analysis such that they are consistent with applicable Federal law and regulations. In proposing a single set of criteria for all estuaries, the rule is inconsistent with the Clean Water Act and EPA's water quality standards regulations. In failing to properly evaluate the rule's economic impacts and in failing to adequately consider alternative criteria for San Francisco Bay Area waters, the rule is inconsistent with Presidential Executive Order 12866 and the Unfunded Mandates Reform Act. In failing to properly consider the impacts on small entities, the rule is inconsistent with the Regulatory Flexibility Act. Specific citations for these inconsistencies are contained in comments from BADA and CASA/Tri-TAC.

Response to: CTR-052-021d

With respect to EPA's decision to publish a single set of criteria in the rule, see responses to CTR-035-012a and CTR-036-005 (both responses are in Category C-21; Legal issues). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see response to CTR-001-008b (Category R; RFA), CTR-036-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-054-008e
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References:
Attachments? Y
CROSS REFERENCES C-02b
C-24
E-01c
R

Comment: Separate, scientifically defensible, reasonably achievable aquatic life criteria for copper should be adopted for San Francisco Bay, or alternatively EPA should specify in the Preamble implementation policies for copper that will result in reasonable control measures actions. To comply with the Clean Water Act and EPA regulations, EPA is required to consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act, EPA is required to evaluate regulatory alternatives based on an analysis of costs and benefits. Based on BADA's analysis of costs and benefits, EPA should either adopt copper criteria that are reasonably achievable or alternatively specify implementation policies that will avoid costly end-of-pipe controls. Potential implementation measures that could be specified include use of the following in calculating effluent limitations: actual dilution based on modeling studies; copper translators; probability of compliance less than 99.9%; and water-effect ratios determined for different segments of the Bay. Unless EPA specifies these or similar implementation policies in the rule, it is possible that the CTR could result in significant costs ($12 million per year to $78 million per year) while resulting in minor environmental benefit (a 1% reduction in copper loading to the Bay). In that

case, the CTR would violate the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. (see the discussion under Item 11 below.)

Response to: CTR-054-008e

See responses to CTR-054-008a (Category C-02b; Copper Aquatic Life), CTR-035-012a and CTR-036-005 (Category C-24; Legal Issues), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-054-013a (Category E-01g3; Cost-Effectiveness Ratio), CTR-001-008b, CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-054-050
Comment Author: Bay Area Dischargers Associati
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES

Comment: b. Unfunded Mandates Reform Act

Under the Unfunded Mandates Reform Act (UMRA, 2 U.S.C. section 1501 et seq.), EPA is required to consider the cost of a proposed regulation to both state and local Governments and the regulated community. EPA is required to prepare a qualitative and quantitative assessment of theanticipated costs and benefits of the Federal mandate and to select the most cost-effective and least burdensome regulatory alternative that achieves the objectives of the rule and is consistent with statutory requirements. EPA has performed an economic analysis, however, EPA contends that the cost of the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year" necessary to trigger the other requirements of the UMRA.

EPA only makes a limited analysis of alternatives and does not explicitly defend the rule's cost-effectiveness because it contends that does not apply because the $100 million cut off was not met.(*3) Based on the cost research performed by the POTWs and other dischargers, EPA's contention that UMRA's requirements do not apply may be challengeable. The regulated community may also be able to demonstrate that the Administrator was arbitrary and capricious by alleging the cost of implementing the CTR will not result in expenditures in the aggregate "of $100 million or more in any one year."

EPA should have considered alternatives, such as the adoption of less stringent criteria or different risk levels (e. g., 10E-4 or 10E-5), that could also achieve the objectives of the rule. These alternatives would have met both the UMRA criteria of being more cost-effective and less burdensome while still maintaining consistency with the Clean Water Act.

(*3) "EPA has determined that this rule does not contain a federal mandate that may result in

expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The proposed rule imposes no direct enforceable duties on the State or any local government or on the private sector; rather, this rule proposes ambient water quality criteria which, when combined with State adopted designated uses, will create water quality standards for those water bodies with adopted uses. The State may use these resulting water quality standards in implementing its existing water quality control programs. Today's proposed rule does not directly regulate or affect any entity and, therefore, is not subject to the requirement of sections 202 and 205 of the UMRA." 62 Fed. Reg. 42,191.

Response to: CTR-054-050

See responses to CTR-058-001 (Category C-13; Risk Level) and CTR-036-003a.

Comment ID: CTR-056-022b
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: S UMRA
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES E-01E

Comment: EBMUD perceives there to be a significant overall economic impact resulting from CTR, contrary to the conclusions reached by EPA. Because the cost may exceed $100 million annually on the regulated community (the majority of which are publicly owned agencies), it appears that pursuant to Executive Order 12,866 and the Unfunded Mandates Reform Act, the CTR can be considered a significant regulatory action which is likely to adversely affect the economy of many regions of the State, the environment and/or local governments. EBMUD is also of the opinion that EPA failed to make a, "...reasoned determination that the benefits of the intended regulation justify its costs," and is obligated to redo the draft Economic Analysis and submit it for review by the Office of Management and Budget.

Response to: CTR-056-022b

See responses to CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-059-002c
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES E-01c
R

Comment: The Sanitation Districts disagree with EPA's assertions that the CTR is not a significant regulatory action under Executive Order 12866 or the Unfunded Mandates Reform Act, and that EPA is not required to comply with the Regulatory Flexibility Act because the CTR establishes no requirements applicable to small entities. We believe the potential costs for POTWs to comply with the CTR criteria would far exceed the $ 100 million threshold, based on the fact that we estimate that the potential costs for seven Sanitation Districts' facilities to comply with the CTR to be nearly $150 million per year. Clearly, many of the 304 other POTWs in the State will also incur costs, as, will other NPDES permittees, indirect dischargers, stormwater dischargers, and nonpoint sources. Thus, EPA's cost figure of $15 - $87 million per year is simply not a credible estimate. Also, it is quite clear that the CTR is likely to adversely affect local governments, including over 40 small communities located in our service area, and that it is significantly different from other federal regulations previously promulgated in California. We believe that EPA has not complied with the mandates of Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. Accordingly, EPA must revise the economic analysis and it must be reviewed by the Office of Management and Budget and then EPA must select the most cost-effective and least burdensome regulatory alternative.

Response to: CTR-059-002c

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-059-006c
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y
CROSS REFERENCES C-28
E-01c

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we reconunend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attaimnent of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of

water body.

Criteria Below Detection Limits

We believe that there are fundamental problems with EPA's decision to adopt criteria that are below detection limits. This issue relates to EPA's statutory and regulatory obligations in establishing water quality criteria; namely, that EPA is subject to the same policies, procedures, analyses, and public participation requirements as States pursuant to 40 CFR section 131. These regulations require States to "review water quality data and information on discharges to specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use." (40 CFR section 131.11) For criteria where the method detection limit exceeds the objective, there are inadequate data to determine if the pollutant could reasonably be expected to interfere with attainment of designated uses. We believe that because of the inability to detect these substances and the lack of monitoring information indicating water quality use impairment EPA has not been able to fulfill its obligations to conduct a water body-specific analysis of the need to promulgate criteria.(*1)

(*1)U.S. Environmental Protection Agency, Economic Analysis of the Proposed California Water Quality Toxics Rule, Office of Water (EPA-820-B-96-001, July 1997), p. 8-18.

Second, EPA has not fulfilled its obligations under the Unfunded Mandates Reform Act and Executive Order 12866 to analyze the costs and benefits of promulgating proposed criteria which cannot be detected or for which insufficient monitoring data are available.

Given these deficiencies, we recommend that EPA defer the adoption of criteria for constituents which are below detection limits until such time as EPA has demonstrated that the levels of toxic pollutants being discharged are at a level to warrant concern. As an alternative, EPA could defer to the State for promulgation of criteria for such compounds on a water body-specific basis as part of the State's continuous water quality planning process.

Response to: CTR-059-006c

See responses to CTR-034-010b and CTR-060-010 (Category C-28; Detection Limits). For a discussion of how the rule complies with the E.O. 12866, the Unfunded Mandates Reform Act, and Regulatory Flexibility Act, see responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-059-015b
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-059 incorporates by reference letter CTR-035

Attachments? Y

CROSS REFERENCES E-01c

Comment: Executive, Order 12866 and Unfunded Mandates Reform Act

The Sanitation Districts disagree with EPA's assertion that the CTR is not a significant regulatory action under Executive Order 12866 or the Unfunded Mandates Reform Act. We believe that the potential costs for POTWs to comply with the CTR criteria could far exceed the $ 100 million threshold, based on the fact that we estimate that the potential costs of seven Sanitation Districts' facilities to comply with the CTR could be nearly $150 million per year. Clearly, many of the 304 other POTWs in the State will also incur costs, as will other NPDES permittees, indirect dischargers, stormwater dischargers, and nonpoint sources. Thus, EPA's cost figure of $15 - $87 million per year is simply not a credible estimate. Also, it is quite clear that the CTR is likely to adversely affect local governments, and that it is significantly different from other federal regulations previously promulgated in California. Therefore, we believe that EPA has not complied with the mandates of E.O. 12866 and the Unfunded Mandates Reform Act, and that the economic analysis must be revised, and EPA must select the most cost-effective and least burdensome regulatory alternative. In addition, the Office of Management and Budget should review the economic analysis and the rule before it is promulgated, as required by Section 6 of E.O. 12866.

Response to: CTR-059-015b

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-084-002b
Comment Author: City of Redding
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References:
Attachments? N
CROSS REFERENCES E-01c01

Comment: ISSUES OF CONCERN

The Unfunded Mandates Act of 1995, 62 FR 42191. The City of Redding disagrees with the conclusion that the proposed rule does not result in expenditures by state or local governments in aggregate of $100 million or more in any one year. The strict water quality criteria in the proposed rule would directly cause the state to adopt more stringent standards for dischargers, which would then require the local dischargers to implement exorbitant and costly measures against our users.

Regarding unfunded mandates, the City of Redding believes that the state and local governments would have no alternative in implementing this federal rule than to enforce exorbitant and costly measures against our users. Therefore, the proposed rule would directly cause significant burden and costs to state and local governments.

Response to: CTR-084-002b

See responses to CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-090-012b
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: S UMRA
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01c

Comment: The PUC is aware that the Clean Water Act does not require and in fact does not allow for economic considerations in meeting water quality requirements. However, other policies and regulatory mandates (Executive Order 12866 and the Unfunded Mandates Reform Act) require that we disclose to the public the cost of meeting water quality requirements. There is no doubt that there will be costs that California must bear to produce water quality. We must assure the public that the costs will produce benefits. We are not confident that this proposed rule can do that.

Response to: CTR-090-012b

See responses to CTR-021-005c (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Comment ID: CTR-092-016c
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: S UMRA
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES E-01c
R

Comment: Introductory Comment

EPA states in the Executive Summary (page ES-2) to the Economic Analysis that:

"EPA did not calculate costs for any program for which it does not have enforceable authority ... (nor) for NPDES sources which are not typically subject to numeric WQBELs....."

From a national policy perspective, this narrowing, of the focus of the Economic Analysis may be a

justifiable approach to cost benefit analysis. Local government, however, is not able to disregard the potential cost effects of the CTR on urban and agricultural runoff. Those potential costs will have to be defrayed with proceeds from the same pool of local rate payers responsible for paying for point source pollutant removal programs. In California, those ratepayers have made clear both their support for environmental protection and their reluctance to pay more than is necessary for that protection. A narrow definition of those costs included in the CTR Economic Analysis continues the pattern of fragmenting responsibility and authority for the protection of waterways, which in turn hinders creation and implementation of holistic strategies which would best serve the environment at least cost.

Questions for EPA on the Introductory Comment

Q.-1) If not EPA, who has the responsibility to define the aggregated costs of all water quality-related regulations?

Q.-2) San Jose's reading of federal policy initiatives (which include, but are not limited to, the Regulatory Flexibility Act, Executive Order 12866, and the Unfunded Mandates Reform Act) indicates that EPA is empowered to analyze the economic impact of federal regulations in a way that addresses both aggregated cost impacts as well as the fiscal reality of local level government. Why was this not accounted for in the current analysis?

Response to: CTR-092-016c

See responses to CTR-001-008b (Category R; RFA), CTR-021-005c (Category E-01c; Executive Order 12866), CTR-021-006b (Category E-01c; Executive Order 12866), CTR-036-003a, and the preamble to the proposed rule.

Subject Matter Code: T State Implementation Policy

Comment ID: CTR-004-001
Comment Author: South Bayside System Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? N
CROSS REFERENCES

Comment: SBSA is the regional wastewater treatment agency serving over 200,000 residents and businesses in southern San Mateo County. SBSA has a permitted capacity of 29 MGD average dry weather flow utilizing advanced treatment processes including filtration, discharging to the San Francisco Bay. While there are many concerns about various features of this regulation the main issue to SBSA is the inability to determine what the actual impacts will be due to uncertainties of how the California Toxics Rule (CTR) will be it-implemented by the state. Assumptions that the impacts will be small because of regulatory flexibility cannot be made (see Attachment A).

Response to: CTR-004-001

EPA believes that it is possible for a discharger to pursue regulatory relief which would result in a less stringent WQBEL through a TMDL, variance, site-specific criteria, or alternative mixing zone and that it properly included the possibility of these mechanisms in calculating the low-end cost in the Economic Analysis.

With respect to the comments on TMDLs, EPA's proposed rule does not alter the statutory and regulatory language requiring the states to perform TMDLs which are then submitted for EPA approval. The preamble merely acknowledges the reality that past and ongoing TMDL processes are often a collaborative effort by dischargers, the State, EPA , and other stakeholders and that EPA expects that this collaborative approach will be utilized in the future. With respect to the comments on pounds per day, pollutant trading, and interim limits, EPA believes the preamble discussion was appropriate in articulating current EPA policy but should not be put into regulatory language since these issues are related to permit implementation which is the primary responsibility of the State.

EPA disagrees with the comments on variances and site-specific criteria. EPA believes that even though these mechanisms are not specifically authorized as part of the CTR, the rule does not preclude these mechanisms from being pursued and approved by the State and EPA in the future consistent with current regulations. Therefore, for the purposes of crafting a reasonable cost analysis, the economic analysis incorporates the possibility of dischargers obtaining variances and site-specific criteria.

With respect to mixing zones, the preamble merely reiterates EPA's current policy on the proper application of mixing zones and does not restrict mixing zones any more than they were restricted in the past. EPA will review the State's new mixing zone policy for consistency with the Clean Water Act. A federal rulemaking would not have to accompany EPA approval of specific mixing zones in permits since, unlike a variance or site-specific criteria, a change in the mixing zone does not require a change in the underlying water quality standards of a specific waterbody. See also CTR-004-009 (Category G-05;

Mixing Zones and Dilution Credits).

Given the possibility that dischargers may be able to obtain permits with less stringent WQBELs based on the mechanisms discussed above, EPA calculated a low-end cost of the rule that included the costs of a discharger pursuing regulatory relief if the costs exceed a trigger of $200 per toxic-pounds equivalent removed.

EPA acknowledges that regulatory relief which would result in a less stringent WQBEL through a TMDL, variance, site-specific criteria, or alternative mixing zone may not always be available or appropriate. Therefore, in the final Economic Analysis, EPA calculated a high-end cost of the rule that did not contain any assumption of regulatory relief if the costs per toxic-pounds equivalent exceeded a specific "cost-trigger."

Given the uncertainty inherent in predicting how regulatory relief will be granted given that it will be decided by regulatory authorities on a case-by-case basis, EPA believes that its approach in the final Economic Analysis is a reasonable way of expressing the possible range of regulatory outcomes and the costs (and benefits) resulting from those outcomes.

Comment ID: CTR-007-006
Comment Author: Port of San Diego
Document Type: Port Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? N
CROSS REFERENCES

Comment: 5. The District is concerned with the apparent complexity of calculating the various water quality criteria limits. In order to reduce the number of errors likely to occur as a result ofthe calculations, the District recommends that detailed step-by-step forms be created outlining the precise calculation methods for the various priority toxic pollutants.

Thank you for this opportunity to comment on the proposed rule. Sincerely,

STUART A. FARNSWORTH Senior Environmental Planner

Response to: CTR-007-006

EPA agrees that the calculations for various water quality criteria may be complex. To assist regulatory authorities in calculating various water quality criteria, EPA has included in the "General Notes" to the proposed CTR (see 62 CFR 42160 at pp. 42205-42208) and final CTR, a section containing formulas, tables, and additional information necessary for calculating various water quality criteria proposed in the CTR.

Comment ID: CTR-009-001

Comment Author: City of Thousand Oaks
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? Y
CROSS REFERENCES

Comment: Dear Ms, Frankel:

The City of Thousand Oaks has reviewed the 40 CFR Part 131 Water Quality Standards; Establishment of numeric Criteria for Priority Toxic Pollutants for the State of California; Proposed Rule as published in the Federal Register, Vol. 62, No. 150, Tuesday, August 5, 1997, and offers the following comments:

The City applauds the EPA's encouragement and endorsement of maximum flexibility applied by the State to implement these priority pollutant criteria. To that end, the City agrees with EPA that the State of California should develop and promulgate its own comprehensive water quality standards and implementation procedures, in accordance with Section 303 of the federal Clean Water Act as expeditiously as possible. The City understands the agency's lack of resources to complete the entire rulemaking task for the State, but also suggests that the EPA appreciate the lack of resources the regulated community has to comply with partial and inflexible requirements. The same "Public" is the ultimate provider of these resources. It is therefore incumbent on all layers of government to assure the value received is at least commensurate with the cost.

Response to: CTR-009-001

As recognized by the commenter, EPA has chosen to defer to the State with respect to implementation procedures. To facilitate coordination between EPA and the State on issues pertaining to implementation of CTR criteria and regulatory flexibility outlined in the CTR preamble, EPA has provided lengthy formal comment on the State's draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California and Functional Equivalency Document (FED), and draft supplement and draft addendum to the supplement for the FED. EPA will continue to work closely with the State on CTR implementation issues and concerns. Pursuant to Executive Order 12866, EPA did prepare an economic analysis which provides an estimate of potential costs and benefits due to the implementation of the CTR.

Comment ID: CTR-015-003
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? N
CROSS REFERENCES

Comment: Implementation Issues

It is made clear that the State Board will have the responsibility for determining implementation of the water quality criteria in the Rule and not the Agency. However, there are several implementation issues discussed in the Preamble. The relationship of the Agency to the State Board and to the Regional Water Quality Control Boards ("Regional Boards") is unclear and requires more specific explanation. Further, the Agency does not acknowledge some of the State Board's existing authority and policies, but frequently recognizes Regional Board Basin Plans.

The District supports the inclusion of any provisions that allow for state flexibility in implementation of the Rule. The Agency needs to re-examine its discussions, however, as some of them do not seem consistent with the Agency's own guidance. Finally, it is critical that the Agency work closely with the State Board on these issues. From a preliminary review of the State Board's Draft Policy for Implementation of Toxics Standards, which was just released, it is apparent that there has been no coordination on these issues. There are several inconsistencies and contradictions which should be resolved before the Rule is promulgated.

Response to: CTR-015-003

State Water Resources Control Board and Regional Water Quality Control Board authorities and policies are generally outlined and/or incorporated by reference into Basin Plans adopted by the Regional Water Quality Control Boards. To facilitate coordination between EPA and the State on issues pertaining to implementation of CTR criteria and regulatory flexibility outlined in the CTR preamble, EPA has provided lengthy formal comment on the State's draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California and Functional Equivalency Document (FED), and draft supplement and draft addendum to the supplement for the FED. EPA will continue to work closely with the State on CTR implementation issues and concerns.

See also CTR-015-004 (Category G-05; Mixing Zones and Dilution Credits), CTR-004-007 (Category G-07; Variances), and CTR-015-006 (Category G-02; Compliance Schedules).

Comment ID: CTR-027-005b
Comment Author: California SWQTF
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-027 incorporates by reference letters CTR-001, CTR-036 and CTR-040
Attachments? N
CROSS REFERENCES G-03

Comment: 5. The proposed rule restricts the State's regulatory flexibility in permitting by establishing averaging periods and low flow conditions, and directives regarding establishing effluent limits for criteria not being adopted as part of the CTR. USEPA has preempted the State's flexibility by establishing averaging periods for applying acute and chronic aquatic life and human health criteria, and by establishing low flow conditions that must be used in developing limits based on proposed criteria.

These are implementation issues that should remain with the State regulatory authority.

Recommendation: The rule should be revised to delete all provisions that preempt the State's regulatory flexibility.

Response to: CTR-027-005b

EPA has adopted recommendations for averaging periods and low flow values because they are intrinsic to ensuring that the numeric values are protective of the designated use. These factors are part of the ambient condition necessary to protect the designated use, see preamble to the proposed CTR and Technical Support Document for Water Quality Based Toxics Control, U.S. EPA 1991, Section 2.3, and Appendix D. As acknowledged in the preamble, the State may develop and adopt criteria averaging periods and critical low flows that differ from EPA's recommendations, as long as they are scientifically supportable, but when EPA promulgates rules, it is using these averaging periods and flow recommendations as representing the best scientific judgement given all the uncertainties in deriving these factors.

Comment ID: CTR-032-003
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: It is important that the significant efforts and accomplishments of the Task Forces not be ignored in this CTR promulgation process. The District suggests that EPA consider providing more specific guidance to the State on the need for and use of regulatory flexibility beyond its statement that "EPA supports the State's consideration of stakeholder Task Force recommendations to help in dealing with these controversial and complex issues." (CTR p.42185)

Response to: CTR-032-003

See response to CTR-009-001.

Comment ID: CTR-032-005b
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N

CROSS REFERENCES V

Comment: The CTR criteria need to be specifically and directly linked in the regulations to the State's Implementation Policy. Furthermore, the CTR and the Implementation Policy need to be moved to more parallel tracks and reviewed and adopted at the same time, not in series. EPA needs to provide more specific direction to the State on how and under what conditions regulatory relief options will be pursued jointly by the State and/or Regional Boards and impacted dischargers. The concept of numeric triggers should be refined, or an equivalent threshold identified, above which specific regulatory relief options would be pursued and requirements for major treatment plant improvements held in abeyance. Without these types of commitments and the linkage of the two regulatory actions, there is no sound basis for the CTR cost estimates.

Response to: CTR-032-005b

See response to CTR-009-001 and CTR-004-001.

Comment ID: CTR-038-008e
Comment Author: Sonoma County Water Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? Y
CROSS REFERENCES C-24
E-01c
R
S

Comment: 7. Separate, sites-specific aquatic life criteria for copper and human health criteria for mercury should be adopted for Schell Slough, or alternatively EPA should specify implementation procedures for these criteria that will preclude unreasonable controls such as end-of-pipe treatment. To comply with the Clean Water Act and EPA regulations, EPA should consider specific water bodies. To fulfill the spirit of Presidential Executive Order 12866 and the requirements of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act, EPA should evaluate regulatory alternatives based on an analysis of costs and benefits. Based on the assessment of costs and benefits described in "3" above, EPA should either adopt the criteria that is currently achieved, or alternatively specify implementation procedures that would allow the current discharge to continue (e.g., allowable Mixing zones and averaging periods and, for copper, a translator and water-effect ratio). Again, the District is amenable to continuing to address these constituents through pollution prevention measures and to assessing the actual impacts of these constituents in Schell Slough. Without EPA specifying such implementation procedures in the CTR, it is possible that the CTR could impose significant costs on the District (and the other small communities its serves) without providing a commensurate environmental benefit. In that case, the CTR would be inconsistent with the Clean Water Act, EPA regulations, Presidential Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act.

Response to: CTR-038-008e

See response to CTR-038-008a (Category C-24; Site-Specific Criteria).

Comment ID: CTR-052-015
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: C. RECOMMENDATIONS FOR MODIFICATIONS TO THE CTR AND EA

Revise the CTR to address attainability and cost issues. The CTR should be revised such that EPA acknowledges the cost and benefit issues and provides specific regulatory relief where cost-effective compliance cannot be achieved.

Response to: CTR-052-015

See response to CTR-042-007a (Category C-21; Legal Concerns).

Comment ID: CTR-053-005
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES

Comment: Finally, Heal the Bay will review the implementation policy issued by the State to ensure that the policy includes a process to identify: (1) those criteria pollutants that, based on the recommendations of the task force and recent scientific data, should be more stringent than the proposed California Toxics Rule; (2) the process to perform the required CEQA analysis of those criteria; and (3) the time-lines for adopting the more stringent criteria.

Response to: CTR-053-005

No response required by comment.

Comment ID: CTR-055-002b
Comment Author: USS-POSCO Industries
Document Type: Specific Industry
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? Y
CROSS REFERENCES C-21

Comment: Waste Load Allocation (WLA) is a flawed concept and UPI requests the EPA promulgate conditions for exemption as part of the requirement for compliance with such allocations.

The implementation of CWA Section 303(c)(2)(B) as discussed beginning on page 42184 causes numerous obstacles, both financial and technological, to facilities such as UPI. Our facility will be subject to water quality-based effluent limitations (WQBELs). Therefore, total maximum daily loads (TMDL) and WLAs will be utilized as future discharge permit criteria.

State Task Force recommendations also recognize that the TMDL process can be significantly labor and data intensive. UPI concurs that the TMDL process is significantly labor and data intensive. During the five year period from 1989 through 1993 UPI spent close to a million dollars ($1,000,000) on the studies of point source wasteload performance at its facility. The study was initiated to verify the efficacy of our waste water treatment system in removing chemical process constituents that were added to the water from the river (Delta) during use of the water as process water. Chain-of-custody and laboratory results for this study were documented in our required monthly self monitoring reports to the RWQCB.

The above study of efficacy of wastewater treatment prior to discharge is summarized in the following attached tables which show averages for three month periods over five full years.

Table 9. Summary of Discharge 001 Gross Mass Loading, lb/day Table 10. Summary of Discharge 001 Net Mass Loading, lb/day Table 11. Summary of Discharge 001 Net Concentrations, ug/l

Each table is shown in two sections. Section A shows the tabulation of results for cadmium (Cd), total chromium (Cr, total), hexavalent chromium (CrE+6), copper (Cu), total iron (Fe, total), dissolved iron (Fe, dissolved), lead (Pb), nickel (Ni) and zinc (Zn). Section B shows the tabulation of results for arsenic (As), mercury (Hg), selenium (Se), silver (Ag), tin (Sn), cyanide, phenolics, polyaromatic hydrocarbons (PAHs), naphthalene, and tetrachloroethylene. All analyses were done using approved standard procedures to determine the total concentration of each chemical. All results that were reported at minimum detection level (MDL) are included in the averages at one half of the reported MDL.

The attached tables illustrate the following: The gross lb/day discharge loadings (Table 9) show certain trends of improvement, eg, CrE+6, for which the process sources had been controlled. Note that since completion of the study compliance samples for CrE+6 during the most recent two year period have been reported at less than MDL. Other decreases, such as shown for Cd, Hg and Pb, are the result of improved analytical test procedures.

The net discharge lb/day loadings (Table 10) and net discharge ug/l concentrations (Table 11) show

many results that are at or below zero discharge for many constituents. Other net discharge ug/l concentrations are significantly below the applicable MDLs, which also indicates that the net concentration is essentially zero. This indicates that chemical control for most chemicals is essentially 100% complete and that no process constituents are contained in the permitted discharge, except as noted below.

Exceptions to the above are Cr, Sn, and phenolics for which the net results are significantly above zero.

The above study shows the substantial effort and expenditure that was required to verify performance with respect to chemicals of concern (COCs) for a specific source category (and for several additional chemicals that were added to the COC list). The list of COCs is being expanded to 126 in the proposed regulations, more than six times as large a list as was evaluated in our performance study.

While the use of the Waste Load Allocation (WLA) principle may sound good, it is only good if properly administered. Two criterion should be considered to make the use of WLAs practicable and administratively feasible for both the agencies and the dischargers.:

* The COCs applicable to WLA discharge compliance should be identified by the Administrator for each source category, per Title 33, Section 1316(b)(1).

* Each NPDES Permit Applicant shall analyze and report on chemical listed on the standard permit application every five years to verify which if any discharge chemicals are subject to WLA discharge compliances.

For the above reasons, UPI requests the EPA add the following to the end of Section 131.38(e)(1) of part 131 of Title 40:

"New and existing point source dischargers shall be considered to be in compliance with such WQBELs except for (i) any WQBEL constituent that is identified for the source category pursuant to Section 1316(b)(1) of Title 33, or (ii) any WQBEL constituent which may cause an increase in the receiving water due to such discharge as determined from information contained in the standard required permit application."

Response to: CTR-055-002b

The comment regarding wasteload allocations is outside the scope of this rule. The CTR sets criteria for pollutant levels in ambient water but does not address how wasteload reductions are to be allocated to sources of pollutants. Wasteload allocations are already addressed under current regulations and guidance. When developing effluent limitations for a NPDES permit, the permitting authority must consider effluent limitations based on both the technology available to treat the pollutants and limitations that are protective of the designated uses of the receiving water. The intent of technology based effluent limitations is to require a minimum level of treatment for industrial/municipal point sources based on currently available treatment technologies. For industrial sources, national effluent limitations guidelines are developed based on the demonstrated performance of a reasonable level of treatment that is within the economic means of specific categories of industrial facilities. However, effluent limitations guidelines are not always established for every pollutant present in an industrial discharge and, in many instances, the guidelines are established only for those pollutants which are necessary to ensure that industrial facilities will comply with the technology-based requirements of the CWA (i.e., BPT, BCT, BAT, NSPS).

NPDES permitting regulations at 40 CFR 122.44(d) require that if, after technology based effluent limitations are applied, the permitting authority projects that any point source discharger may exceed an applicable water quality criterion, then a water quality based effluent limitation for that pollutant must be imposed. In addition, Section 301(b)(1)(c) of the Clean Water Act requires that effluent limitations be established as necessary to meet water quality standards. Neither EPA nor the states are required to set water quality based effluent limits at any higher level because of technological difficulties in measuring compliance. See NRDC v. EPA, 859 F. 2d 156, 208 (D.C. Cir. 1988). Water quality based effluent limitations are usually calculated from WLAs based on TMDLs, or on WLAs estimated for a single point source using simplified water quality models. These regulations also require that all effluents be characterized by the permitting authority to determine the need for water quality based effluent limitations. (The Technical Support Document for Water Quality-based Toxics Control (1991) provides additional guidance on collecting monitoring data for establishing water quality based effluent limits.) In accordance with these regulations, when determining whether a water quality based effluent limitation is needed in a permit, the permitting authority is required to consider, at minimum: (1) existing controls on point and nonpoint sources of pollution; (2) the variability of the pollutant or pollutant parameter in the effluent; (3) the sensitivity of the species to toxicity testing; and (4) where appropriate, the dilution of the effluent in the receiving water. The permitting authority must also consider whether technology based limits are sufficient to maintain State water quality standards.

Given the requirements outlined above, EPA believes that the requested changes to the end of 40 CFR 131.38(e)(1) are not appropriate within the scope of today's rule.

Comment ID: CTR-057-009
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? N
CROSS REFERENCES

Comment: 1995 Public Advisory Task Force Efforts

Following the State's rescission of the ISWP in 1995, eight Public Advisory Task Forces were established to deal with specific issues and problems that either arose after the plan was adopted in 1991 or were carried over from the pre-adoption public review period. These task forces were comprised of representatives from numerous public groups and agencies, including the EPA, In hindsight, it is important to note that many of the problems that were identified and addressed by the task forces review can be attributed to the similarities between the proposed Rule and the ISWP. In view of the fact that the task forces were able to achieve consensus with respect to their individual recommendations for plan revision, we believe that the EPA should acknowledge these efforts in the CTR as a means of encouraging the development of an EPA-approved State priority-pollutant plan.

Response to: CTR-057-009

See response to CTR-009-001.

Comment ID: CTR-086-005
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: It is important that the significant efforts and accomplishments of the Task Forces not be ignored in this CTR promulgation process. CDA suggests that EPA consider providing more specific guidance to the State on the need for, and use of, regulatory flexibility beyond its statement that "EPA supports the State's consideration of stakeholder Task Force recommendations to help deal with these controversial and complex issues." (p. 42185)

Response to: CTR-086-005

See response to CTR-009-001.

Comment ID: CTR-086-007
Comment Author: EOA, Inc.
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: California Dent
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-086 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: The CTR criteria need to be specifically and directly linked in the regulations to the State's Implementation Policy. Furthermore, the CTR and the Implementation Policy need to be moved to more parallel tracks and reviewed and adopted at the same time, not in series. EPA needs to provide more specific direction to the State on how and under what conditions regulatory relief options will be pursued jointly by the State and/or Regional Boards and impacted dischargers.

CDA appreciates the opportunity to comment on the draft CTR.

Response to: CTR-086-007

See response to CTR-009-001.

Comment ID: CTR-090-009

Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: We recommend that EPA:

1. Incorporate in the rule, not the preamble, the implementation of the regulatory relief such as the tiered mixing zones, the use of translators, the use of the water effects ratio, interim limits and compliance schedules. Without these assurances and inclusion of these in the rule the economic analysis is useless.

Response to: CTR-090-009

EPA believes that it is not necessary to include implementation of regulatory relief such as tiered mixing zones, translators, and interim limits in today's rule since these issues are closely related to the issuance of permits which is properly deferred to the State, the permitting authority. In fact, shortly after the publication of the proposed CTR, the State's Draft Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California proposed the use mixing zones, translators, water effects ratio, interim limits, and compliance schedules as appropriate to develop discharge limits for permits.

The CTR does include a compliance schedule provision and incorporates the water effects ratio into the calculation of the water quality criteria if appropriate.

EPA disagrees with the commenter's assertion that the economic analysis is useless unless the CTR includes the implementation measures stated by the commenter. EPA believes that the economic analysis is useful since it presents a range of possible economic impacts which vary depending upon a number of assumptions about how the State could implement the rule, including the use of regulatory relief.

Comment ID: CTR-092-001
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: T State Implementation Policy
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Relationship Between the CTR and State Implementation

The City of San Jose understands the level of effort that has gone into this rulemaking process. We find much of the preamble to the Rule to encouraging and generally support the road map to implementation of the rule that is laid out in the preamble.

The preamble describes a number of potential regulatory approaches that could be used by the State to implement the criteria proposed in the CTR. Regulatory tools such as translator mechanisms, water effect ratios, site specific objectives, interim limits while performing special studies, mixing zones, compliance schedules and trading programs are all good examples of regulatory approaches that should be used, especially under conditions such as those which exist in South San Francisco Bay, where water quality has improved tremendously in the recent past, yet full attainment of water quality objectives is still not possible.

EPA's Economic Analysis makes it clear that EPA is not only supporting use of these regulatory tools by the State, but is in fact assuming that they will be used. The accuracy of this assumption is questionable at this point in time, in light of the State's historic approach to implementation. Since EPA has the responsibility to approve any of the implementation procedures that the State decides to employ, we believe it is necessary for EPA to play an active role in the implementation phase.

Although we have not had an opportunity to review and comment on the recently issued "Proposed Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays and Estuaries of California", we believe that the implementation policy presents an opportunity to resolve the uncertainly concerning whether the State will adopt reasonable, flexible approaches to implementing the criteria that would be established by the CTR. We are requesting that the uncertainties concerning State implementation be resolved before the CTR is finalized.

Response to: CTR-092-001

See response to CTR-009-001.

Comment ID: CTRH-001-055
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: T State Implementation Policy
References:
Attachments? N
CROSS REFERENCES

Comment: I have one more thing I can hardly read here. I was just referring back to Phil Bobel, who mentioned the state's process.

I would certainly not encourage you to do what the state has tried to do for the last three years, which is a very complicated, totally burdensome task force stakeholder process, which had most of the environmental groups walking away from it for lack of resources to keep up with all of the meetings.

And that had the result of nothing, essentially no -- I guess implementation came on Friday suddenly, but

no criteria came out of that process at all, despite all those meetings. So I certainly don't encourage you to follow that.

I think a reasonably swift process here is warranted. We're already four years late, so I would certainly encourage you to finish this rule as quickly as possible, and hopefully people will be able to make intelligent comments about it.

Response to: CTRH-001-055

No response required by comment.

Subject Matter Code: V Collaborative Approach

Comment ID: CTR-031-002e
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: V Collaborative Approach
References: Letter CTR-031 incorporates by reference letter CTR-027
Attachments? N
CROSS REFERENCES F
C-17a
C-17b
J

Comment: 2. Since the preamble implies that CTR criteria may be applied in NPDES permits for municipal storm water dischargers as numeric effluent limitations, the proposed rule is flawed with regard to: a) setting attainable, scientifically valid criteria in a manner consistent with state and federal regulatory approaches; b) assessing the potential economic impact on the public served by municipal storm water dischargers; c) assessing environmental impacts pursuant to the National Environmental Policy Act and the Endangered Species Act; and d) providing for the coordinated review and evaluation of the proposed CTR in conjunction with the proposed State Implementation Plan.

Response to: CTR-031-002e

EPA has coordinated the CTR schedule to coincide as closely as possible with the State's Implementation Plan. However, EPA wishes to promulgate the CTR as soon as possible. Therefore, EPA could not commit that the proposed CTR would be released at the same time as the proposed State Implementation Policy. For the same reasons, EPA cannot ensure that the final CTR will be released at the same time as the final State implementation policy. EPA and the State have made every effort to ensure that its separate actions will work well together and are consistent with one another.

With respect to ESA, EPA has completed consultation as required by Section 7 of the ESA. With respect to compliance with NEPA, section 511(c) of the Clean Water Act excludes this rulemaking from the requirements of NEPA. The comment also assumes that stormwater discharges subject to numeric effluent limitations will have to be treated by new end-of-pipe facilities. As explained in the response to Storm Water Economics Comments (Category J, Comment # 040-004), EPA believes that implementation of criteria as applied to wet-weather discharges will not require the construction of end-of-pipe facilities.

Comment ID: CTR-031-008b
Comment Author: Fresno Metro. Flood Ctrl Dist.
Document Type: Flood Ctrl. District
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: V Collaborative Approach

References: Letter CTR-031 incorporates by reference CTR-027
Attachments? N
CROSS REFERENCES B

Comment: d. The proposed CTR and the recently released proposed State Implementation Plan must be fully integrated, internally consistent, and their combined effect thoroughly assessed. However, EPA has allowed only one week of overlap between the proposals for stakeholder review.

The EPA concedes within the proposed CTR that the criteria themselves lack substance without the corresponding implementation measures. EPA also acknowledges that the economic impact of the CTR can not be fully evaluated without consideration of the ISWP. However, the EPA can not simply abdicate its responsibility to assess the impact of its proposal, nor can it expect stakeholders to accept the proposed CTR without full understanding of its implementation.

All stakeholders require the opportunity to evaluate the proposed CTR and Implementation Plan together as a comprehensive, cohesive body of regulation.

Response to: CTR-031-008b

EPA has coordinated the CTR schedule to coincide as closely as possible with the State's Implementation Plan. However, EPA must promulgate the CTR as soon as possible to comply with its statutory obligations under the Clean Water Act. Therefore, EPA could not commit that the proposed CTR would be released at the same time as the proposed State Implementation Policy. For the same reasons, EPA cannot ensure that the final CTR will be released at the same time as the final State implementation policy. EPA and the State have made every effort to ensure that its separate actions will work well together and are internally consistent.

EPA agrees that the CTR without the corresponding implementation measures would have no direct effect on permitees. However, EPA disagrees that it has abdicated its responsibility to assess the impact of the proposal. EPA has projected the potential economic impacts of the CTR using reasonable implementation measures which are either already used by the State or are recommended in EPA's Technical Support Document (TSD) EPA believes this methodology is appropriate and reasonable since EPA cannot anticipate the final State implementation measures. EPA's estimates measure the impact of the CTR combined with the implementation procedures EPA believes are reasonable for the State to adopt. If the State adopts implementation procedures that differ from EPA recommended procedures, the change in impact will be reflected in the State's economic analysis.

Comment ID: CTR-032-005a
Comment Author: Las Gallinas Val. Sanitry Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: V Collaborative Approach
References: Letter CTR-032 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES T

Comment: The CTR criteria need to be specifically and directly linked in the regulations to the State's Implementation Policy. Furthermore, the CTR and the Implementation Policy need to be moved to more parallel tracks and reviewed and adopted at the same time, not in series. EPA needs to provide more specific direction to the State on how and under what conditions regulatory relief options will be pursued jointly by the State and/or Regional Boards and impacted dischargers. The concept of numeric triggers should be refined, or an equivalent threshold identified, above which specific regulatory relief options would be pursued and requirements for major treatment plant improvements held in abeyance. Without these types of commitments and the linkage of the two regulatory actions, there is no sound basis for the CTR cost estimates.

Response to: CTR-032-005a

See response to CTR-031-008b. With regard to providing regulatory relief, the State has discretion to what extent it will provide regulatory relief in its water quality standards program and NPDES program. EPA disagrees with the assertion that it has no sound basis for estimating costs if it does not link both regulatory actions. The numeric cost triggers in EPA's economic analysis are used to establish a lower bound of costs since EPA cannot anticipate exactly how the State will implement regulatory relief on a case-by-case basis. To provide a more conservative cost estimate, EPA did not use the numeric cost triggers for its upper bound cost estimate. In effect, the upper bound cost estimate assumes that the State will not provide any regulatory relief.

Comment ID: CTR-034-002
Comment Author: SCAP
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: V Collaborative Approach
References: Letter CTR-034 incorporates by reference letter CTR-035
Attachments? N
CROSS REFERENCES

Comment: Equally important, we also urge EPA to work more closely with the State Water Resource Control Board (SWRCB), including such steps as the use of simultaneous comment periods and joint final promulgation. This heightened level of coordination would truly enhance the effectiveness of both EPA and the State's efforts to comply with Section 303(c)(2)(B) of the Clean Water Act, since, as EPA acknowledges in numerous locations in the Preamble, the impacts of the CTR criteria depend greatly on the State's approach to implementation (see, for instance, pp. 42188 and 42191). Thus, an important reason for EPA to grant our request to reopen the comment period is to allow sufficient time to review the draft CTR in the context of the SWRCB's recently released Statewide Implementation Policy. Thus, we ask that EPA extend the comment period until December 10, 1997, the SWRCB's public comment deadline, or, at a minimum, for 30 days.

Response to: CTR-034-002

See response to CTR-031-002e. Regarding request for extension in the comment period see section on Comment Period (Category B, CTR-001-001).

Comment ID: CTR-054-015
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA should use a collaborative approach to address the major issues raised by BADA and other commenters. The CTR is extremely important to all stakeholders, including the regulated community, the environmental community, and the regulatory agencies. The traditional rule-making approach does not lend itself to resolving the issues raised in a manner that will satisfy the various stakeholders. The State Plan Task Force experience has demonstrated that varying interests can come together and quickly reach consensus on how to address statutory and regulatory requirements in a mutually satisfactory manner. BADA would encourage EPA to use such an approach in preparing a final CTR and would offer to assist EPA is organizing such an approach.

Response to: CTR-054-015

EPA has decided that to promulgate the CTR in a timely manner it is necessary to use the traditional rule-making approach rather than a collaborative approach involving stakeholders or a regulatory negotiation approach. The EPA must promulgate CTR water quality criteria as quickly as possible to fill the gap in California that has existed for five years. In promulgating a final rule EPA has considered all written and verbal comments as well as applicable State Plan Task Force recommendations. After consideration of all comments, EPA must ultimately promulgate criteria that are protective, scientifically defensible, and meet the requirements of the Clean Water Act. EPA believes the traditional notice and comment rule-making approach is the best way of fulfilling its obligations under the Clean Water Act in the most timely manner.

Comment ID: CTRE-001-001b
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 07/21/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES B

Comment: We are writing to you on behalf of Tri-TAC and the California Association of Sanitation Agencies regarding the forthcoming publication of the proposed Water Quality Standards for Toxic Pollutants for California ("California Toxics Rule") and release of draft state implementation policies

and functional equivalent document. As you are aware, Tri-TAC and CASA have supported the decisions of the U.S. Environmental Protection Agency (EPA) and the State Water Resources Control Board (SWRCB) to eliminate duplication in state and federal water quality rulemaking activities through the pursuit of a collaborative approach. Our understanding is that, through this approach, EPA will adopt water quality criteria for toxic pollutants that will apply in California and the SWRCB will adopt implementation policies that will guide the Regional Water Quality Control Boards in the implementation of those criteria. In a later phase, the SWRCB intends to adopt state criteria that will replace the federal criteria.

We have been informed recently by EPA staff that publication of the draft California Toxics Rule is imminent and is expected to take place by the end of July. According to staff, a 50-day public comment period will be provided. We have heard from SWRCB staff that they plan to release the proposed state implementation policies and FED on September 12. We have asked each agency to provide an overlapping comment period for these draft regulations, and have been informed that the current schedule will provide about one week of overlap, assuming that both agencies release their drafts on schedule. We are quite concerned about this situation in several respects. First, we believe that a one-week overlap does not provide sufficient time for a meaningful review and comparison of the regulations (and comparative analysis of the economic impact analyses, which depend heavily on the implementation policies). We believe that a minimum of 30 days is necessary for the overlap review period, and that the slight delay that this would create for EPA is warranted and would have a negligible impact on the timing of the overall rule promulgation process. Second, we are very concerned about whether the SWRCB will meet its projected release schedule. While we believe that sufficient time has been available to prepare the draft policies and FED, it is imperative that the SWRCB do everything possible to meet its commitment to move forward in a timely manner, and that any extension of EPA's comment period not be used to adjust the state's schedule. Third, we understand that both EPA and the SWRCB plan to hold public hearings regarding their respective proposals this fall. We believe that it is important that representatives of both agencies attend and participate in the hearings that each agency holds, and that an explanation be provided regarding both the CTR and the implementation policy.

In short, we request that EPA and the SWRCB carefully review their efforts to coordinate both the development and release of the California Toxics Rule and State implementation Policies, and specifically, we request that EPA provide a comment period sufficient to ensure that a 30-day overlap will occur with the SWRCB's release of the FED for the State Implementation Policies. More generally, we hope that both agencies will offer flexibility in the promulgation process so that the various scheduling and review needs can be met. We hope that your respective agencies will continue to move forward with a collaborative rulemaking process, and are concerned that cooperation not break down due to institutional barriers at this point in the process.

Thank you for your consideration of our comments. We would be happy to discuss these issues further at your convenience.

Response to: CTRE-001-001b

See response to CTR-031-002e. Regarding request for extension in the comment period see section on Comment Period (Category B, CTR-001-001).

Comment ID: CTRE-023-001b
Comment Author: Bay Area Dischargers Assoc.

Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 07/17/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES B

Comment: The Bay Area Dischargers Association (BADA) is comprised of 10 POTWs in the San Francisco Bay Area. Our five largest charter members include the Central Contra Costa Sanitary District, City and County of San Francisco, City of San Jose, East Bay Dischargers Authority, and East Bay Municipal Utility District. Together BADA agencies provide wastewater service to most of the Bay Area.

BADA requests that the U.S. EPA allow at least 90 days for public review of the proposed California Toxics Rule (CTR). We understand the proposed rule will be published in the Federal Register toward the end of this month. The reasons for our request are as follows:

1. The CTR could have a significant economic impact on California municipalities and businesses. In order to properly assess the impacts of the proposed CTR standards, it is necessary to know how the standards are to be implemented. Yet, the proposed implementation provisions being developed by the State Water Resources Control Board will not be available until September 12, 1997. The several days of overlap are insufficient for California municipalities and businesses to assess the economic and environmental impacts of the proposed standards. At least 45 days of overlap is needed.

2. The U.S. EPA has spent more than three years developing the proposed CTR, in part because of its importance. It is therefore, reasonable to provide at least 90 days for the public to review and comment on the rule, especially considering its potential economic impact on the State and the unavailability of the implementation provisions

3. It is recommended that the EPA work closely with the SWRCB during the review period to define the implementation policy and procedures that the EPA would be likely to approve.

For these reasons, BADA urges you to issue a notice extending the review period from 45 days to 90 days.

Response to: CTRE-023-001b

Regarding request for extension in the comment period see section on Comment Period (Category B, CTR-001-001).

EPA did review the State's proposed implementation policy and procedures. EPA provided written comments to the SWRCB on December 9, 1997. These comments and other communications with the SWRCB are likely to facilitate EPA's review of the final SWRCB implementation plan.

Comment ID: CTRH-001-019b

Comment Author: Phil Bobel
Document Type: Public Hearing
State of Origin: CA
Represented Org: Tri-TAC
Document Date: 09/17/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES B

Comment: MR. BOBEL: Thank you, Steve.

I'm Phil Bobel. I represent Tri-TAC, an organization of sewage treatment plants, the POTWs as we call them, made up of three groups: CASA, the California Association of Sanitation Agencies; the League of Cities; and the California Water Environment Association.

And later this afternoon you're going to hear from Bob Reid who represents CASA. And our comments are essentially the same, so I'm going to not repeat and just summarize a couple things.

I was even going to say you guys had done a really good job. But in light of all the previous speakers, I deleted that part of my testimony.

I will try to be positive and constructive. I promised to do that. In describing the nature of my comments on your little form, I put that I would be constructive. So I will do that.

The first point I'd like to make is positive. I think that the coordination you're doing with the state is great. The fact that we're going to have coordination with the feds focusing on the numeric criteria, the state focus on the implementation policy, working to come up with a system that will serve us all, is a good way to use resources of both organizations.

I applaud you for that and hope you will be able to pull that off. This is different than what we've tried to do before, and it will require some creativity.

One specific thing that I think would help if we did, is to allow all of us to see both what the state is proposing and what the feds are proposing, so we need a little more time in this comment period.

We've appealed before and been told no, but I still put that on the table as a good idea for the ultimate goal of a coordinated, consolidated, as much as possible, federal and EPA approach to this thing.

If you don't do that, or even if you do do that, I think it's going to require some other kinds of creativity as we move out of -- away from your hearing and toward a final rule.

And in that period of time, I would ask you and the state to sit down together and see what kind of a process you can use to take the comments that you'll hear from your federal regs and the comments you hear on the state plan, and put those together, hear more back from folks that are interested and come up with a package that makes sense.

You're going to need some way of going back to interested parties over a longer period of time -- communicating, coordinating -- and I would refer you to the process that the state used on their task force

approach and suggest that we need something like that as we move to the future. Creativity is going to be needed.

Response to: CTRH-001-019b

EPA has decided that to promulgate the CTR in a timely manner it is necessary to use the traditional rule-making approach rather than a collaborative approach involving stakeholders or a regulatory negotiation approach. The EPA must promulgate CTR water quality criteria as quickly as possible to fill the gap in California that has existed for five years. In promulgating a final rule EPA has considered all written and verbal comments as well as applicable State Plan Task Force recommendations. After consideration of all comments, EPA must ultimately promulgate criteria that are protective, scientifically defensible, and meet the requirements of the Clean Water Act. EPA believes the traditional notice and comment rule-making approach is the best way of fulfilling its obligations under the Clean Water Act in the most timely manner.

EPA and the State have made every effort to ensure that its separate actions will work well together and are internally consistent.

Comment ID: CTRH-001-025
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES

Comment: I also want to back up the comment that Phil made about CASA. San Francisco is a member through the League of Cities, with Tri-TAC -- San Francisco is a member of Tri-TAC through the League of Cities, and also agree that you need to be creative here.

You may he taking the approach that this is a rulemaking for you, and once you're done making the rule, you're out. But because of the fact that we've come to a different perspective with you adopting numbers and statements looking at implementation, you're going to have to do an awful lot of creative work to -- working outside of models we're used to, in order to get to something that's going to make sense for the waters of the State of California, that's going to make sense for the people fishing and eating the fish.

So I really want to back up Phil and everyone else that makes those comments. That's very critical.

Response to: CTRH-001-025

See response to CTRH-001-019b.

Comment ID: CTRH-001-030
Comment Author: Michelle Pla

Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES

Comment: I think I want to close again with there's some really great things in there. There's also some flaws. And I think we're really missing the boat if we don't try to think outside of just a regular rulemaking here and begin thinking about a watershed approach, how we're going to get to making these waters clean.

And that's got to take a collaboration between EPA and the state that we haven't probably seen before. And I know you're attempting to do that. I want to encourage you to keep working on that.

Thank you.

Response to: CTRH-001-030

See response to CTRH-001-030.

Comment ID: CTRH-001-056
Comment Author: Dave Tucker
Document Type: Public Hearing
State of Origin: CA
Represented Org: San Jose Env. Serv. Dept.
Document Date: 09/17/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES

Comment: MR. TUCKER: My name is Dave Tucker and I will be delivering Lou Garcia's comments today. He stepped away for a few minutes, then reappeared, but I got overcome by this. I'll keep my comments brief.

My comments will be on behalf of the City of San Jose Environmental Services Department. We will keep our comments brief today. We will be following up with extensive written comments by the close of the comment period next week.

I'm going to discuss two topics this afternoon. One is about the things that we support highly, and that is the flexibility and innovation that is included in the program regarding water quality standards.

However, we do recommend that EPA take a more active or proactive approach to employing such flexibility during the interim period between the federal promulgation and that of the completion of the statewide process, and that EPA be an active participant, actually extending into the water quality

planning and implementation process to California as an on-line stakeholder.

Response to: CTRH-001-056

EPA did review the State's proposed implementation policy and procedures. EPA provided written comments to the SWRCB on December 9, 1997. These comments and other communications with the SWRCB are likely to facilitate EPA's review of the final SWRCB implementation plan. EPA plans to continue to be an active participant into the water quality planning and implementation process in California.

Comment ID: CTRH-002-021b
Comment Author: Ing-Yig Cheng
Document Type: Public Hearing
State of Origin: CA
Represented Org: L.A. Bureau of Sanitation
Document Date: 09/18/97
Subject Matter Code: V Collaborative Approach
References:
Attachments? N
CROSS REFERENCES B

Comment: As you are aware, the California Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California, the proposed policy, was issued a few days ago. EPA and State essentially had the same objective to establish water quality criteria that are implementable for the water of California. Therefore, it is necessary for regulators and dischargers alike to fully comprehend the consequences of these rules on similar issues but from perhaps a different perspective.

Consequently, we strongly urge EPA to allow for additional 30 days for you and for us to fully review both documents together. We also urge EPA and State to coordinate these two rule-making process to minimize inconsistencies that might otherwise occur, EPA is the final focal point of this concern because the process of State's obtaining EPA approval of ISWP and EBEP will be greatly enhanced if EPA and State can work together; and without EPA's approval, State's plan will be no good. So I think it will be ideal if CTR and the State's proposed policy can be promulgated simultaneously.

Thank you again for the opportunity to address you.

Response to: CTRH-002-021b

Regarding request for extension in the comment period see section on Comment Period (Category B, CTR-001-001).

EPA did review the State's proposed implementation policy and procedures. EPA provided written comments to the SWRCB on December 9, 1997. These comments and other communications with the SWRCB are likely to facilitate EPA's review of the final SWRCB implementation plan.

EPA has coordinated the CTR schedule to coincide as closely as possible with the State's Implementation

Plan. However, EPA must promulgate the CTR as soon as possible to comply with its statutory obligations under the Clean Water Act. Therefore, EPA could not commit that the proposed CTR would be released at the same time as the proposed State Implementation Policy. For the same reasons, EPA cannot ensure that the final CTR will be released at the same time as the final State implementation policy. EPA and the State have made every effort to ensure that its separate actions will work well together and are internally consistent.

EPA
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Environmental Protection
Agency

Plan EJ 2014

Legal Tools

EJ Legal Tools identifies key legal authorities for EPA policy makers to consider in advancing environmental justice.

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PLAN EJ 2014

Legal Tools

December 2011

Office of General Counsel

U.S. Environmental Protection Agency
Washington, D.C. 20460

This document discusses a number of federal statutory and regulatory provisions, but does not itself have legal effect, and is not a substitute for those provisions and any legally binding requirements that they may impose. It does not expressly or implicitly create, expand, or limit any legal rights, obligations, responsibilities, expectations or benefits to any person. To the extent there is any inconsistency between this document and any statutes, regulations or guidance, the latter take precedence. EPA retains discretion to use or deviate from this document as appropriate.

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FOREWORD

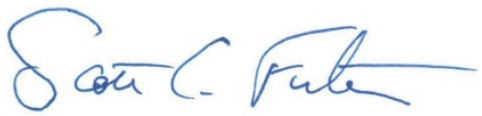
I am pleased to present *EJ Legal Tools*, a review of legal authorities under the environmental statutes administered by the U.S. Environmental Protection Agency that may have contributive application in the effort to advance environmental justice under *Plan EJ 2014* – the Agency's overarching strategy for advancing environmental justice.

Plan EJ 2014 implements one of Administrator Lisa P. Jackson's top priorities: expanding the conversation on environmentalism and working for environmental justice. That priority reflects the recognition that all too often, minority and low-income communities in our country suffer disproportionate pollution burdens and the intensified health risks and environmental quality-based obstacles to economic growth that attend such burdens. *Plan EJ 2014* focuses EPA's efforts to address these conditions by more effectively integrating environmental justice into our programs, policies, and daily work.

Plan EJ 2014 called for the Office of General Counsel to identify legal authorities under the federal environmental statutes that bear meaningfully on the environmental justice challenge. This document responds to that call. It identifies numerous legal tools that EPA may consider using to more fully ensure that its programs, policies, and activities fully protect human health and the environment in minority and low-income communities. Some of the tools we have identified are already in use today; others have not yet been applied in an environmental justice setting.

EJ Legal Tools should be viewed as a starting point, rather than end point, in the examination of legal authorities. It does not purport to consider every possible contributive authority; rather it focuses on those authorities that appear to be most relevant to the environmental justice challenge as we currently understand it. Moreover, consistent with the leading-by-example orientation of *Plan EJ 2014*, *EJ Legal Tools* looks principally through the lens of EPA as implementer, leaving for further examination and discussion the question of how environmental justice-related legal authorities might inform the activities of states and tribes operating EPA-approved programs and EPA's oversight of those activities. Accordingly, *EJ Legal Tools* should be regarded as a living document, subject to future addition and adjustment.

As the Agency moves forward, its course of action will of course be based not only on its legal authority, but also on sound science and public engagement – all stitched together by good policy judgment. *EJ Legal Tools* is thus intended to serve as a part of an enabling environment for policy judgments that can lead toward a future where all people, regardless of ethnicity or income, have clean air, water, and land in the places where they live, work, play, and learn.



Scott C. Fulton
General Counsel
U.S. Environmental Protection Agency

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TABLE OF CONTENTS

INTRODUCTION

This document is designed to identify legal tools to help the U.S. Environmental Protection Agency (EPA) advance its goal of environmental justice in the United States. EPA defines "environmental justice" as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."[1] The goal of environmental justice is to ensure that all communities and persons across the Nation, including minority, low-income, and indigenous populations overburdened by pollution, receive full human health and environmental protection.[2] Environmental justice is a central element of EPA's mission to protect human health and the environment and is one of EPA's top priorities.

This document provides an overview of a number of discretionary legal authorities that are or may be available to EPA to address environmental justice considerations under federal statutes and programs. It grows out of EPA's renewed commitment to environmental justice embodied in *Plan EJ 2014*, which marks the forthcoming 20th anniversary of Executive Order 12898, entitled "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations" (Feb. 11, 1994).[3] *Plan EJ 2014* is a comprehensive framework for advancing EPA's environmental justice priorities. It specifically calls for the Office of General Counsel (OGC) "to identify opportunities to utilize EPA's statutory authorities to advance environmental justice."[4]

In response to *Plan EJ 2014*, this document consolidates, updates, and expands on OGC's past work on the subject of environmental justice. That work began in earnest over 17 years ago in support of EPA's efforts to implement Executive Order 12898 and its accompanying Presidential memorandum.[5] Part of that effort focused on environmental justice opportunities in the context of environmental permitting programs, and led to a memorandum issued by then-General Counsel Gary S. Guzy, entitled "EPA Statutory and Regulatory Authorities Under Which Environmental Justice Issues May Be Addressed in Permitting" (Dec. 1, 2000).[6] *EJ Legal Tools* reaffirms the principles set forth in that memorandum, expands on its permitting discussion, and addresses other EPA authorities. An understanding of the Agency's legal tools for achieving environmental justice is critical because Executive Order 12898 itself is not a source of authority. Instead, Executive Order

[1] *Plan EJ 2014* (Sept. 2011) at p. 3 (discussing how EPA also defines the terms "fair treatment" and "meaningful involvement" for purposes of achieving environmental justice).

[2] Like *Plan EJ 2014*, this document uses the term "overburdened communities" as the way "to describe the minority, low-income, tribal, and indigenous populations or communities in the United States that potentially experience disproportionate environmental harms and risks as a result of greater vulnerability to environmental hazards." *Id*. at p. 1. & n. 1.

[3] 59 Fed. Reg. 7629 (Feb. 16, 1994) (codified at 3 C.F.R. 859).

[4] *Plan EJ 2014* at p. 23.

[5] 30 Weekly Comp. Pres. Doc. 279 (Feb. 11, 1994).

[6] The memorandum is available at: http://www.epa.gov/environmentaljustice/resources/policy/ej_permitting_authorities_memo_120100.pdf.

12898 calls on federal agencies covered by it to implement its provisions on environmental justice to the greatest extent practicable and permitted by existing law.[7]

As highlighted in the Presidential memorandum accompanying Executive Order 12898, existing environmental and civil rights statutes provide many legal authorities that, in appropriate circumstances, may provide opportunities to ensure that federal programs, policies, and activities do not have disproportionately high and adverse human health or environmental effects on minority or low-income communities, including tribal communities. This document analyzes EPA's statutes and their relevant regulatory standards for action to protect public health or welfare and the environment. It also covers EPA's cross-cutting and non-regulatory programs. It identifies instances when EPA may exercise its discretion to advance environmental justice under existing policy, guidance, and regulations.

It is important to emphasize not only what this document is – a review of what may be some of the more significant potential environmental justice opportunities EPA's policy makers have discretion to consider – but also what it is not. Consistent with the theme of *Plan EJ 2014*, *EJ Legal Tools* focuses principally on EPA's opportunities for advancing environmental justice when EPA is the implementing authority. For the most part, *EJ Legal Tools* does not focus on the actions of state, tribal, or local governments when they are the implementing authority. It also does not attempt a discussion of ways that EPA may advance environmental justice through its alternative dispute resolution or enforcement programs.

Significantly, *EJ Legal Tools* is not a document prescribing when and how the Agency should undertake specific actions. While some of the legal authorities are clear, others may involve interpretive issues or legal risk that call for further analysis. Without the context of specific applications, this document does not attempt to fully characterize any such legal risks. Policy decisions about undertaking particular actions are the responsibility of the Agency's program offices, which consider a wide range of questions beyond the issue of a particular action's legal defensibility, such as budgetary or other practical constraints on implementation, or the benefits or risks of using a legal tool in a given circumstance. Moreover, this document is not an exhaustive inventory of every conceivable legal authority; rather, it attempts to identify some of the leading opportunities that may have viability both in terms of legal defensibility and practicality.

This document should be regarded as a living document. As EPA gains experience working to achieve environmental justice and using the available legal tools, this document may be supplemented and adjusted, as appropriate. The desirability and the effectiveness of any particular legal tool ultimately will depend on the answers to questions such as these:

- Is the science regarding an activity or program sufficiently well developed to provide a sound basis for decision making?
- How strong is the factual basis for predicting that EPA's actions will be effective?
- Will the specific action or measure address the environmental or public health impacts on the affected population?

[7] *See* Executive Order 12898, Sections 1-101 and 6-608.

- Will adopting a new policy or approach (or altering an existing one) create, increase or reduce regulatory uncertainty?
- Does the policy or approach involve a function that could be effectively and efficiently carried out at the federal level?
- Are the public participation measures planned appropriate to provide transparency and meaningful participation for the affected population?
- Will the regulated activity have indirect environmental benefits to the community or unintended environmental or socio-economic costs?
- Will the regulated activity relieve, or avoid adding to, cumulative impacts?
- Would use of the discretionary authority promote the community's transition to clean technologies?
- What resources are needed to effectively carry out the activity?

These are primarily policy questions, although their answers may affect how strong the rationale is for EPA's action and, thus, the action's legal defensibility. The questions are included here to illustrate the type of variables relevant to a decision of whether to invoke an authority identified in this document under a particular set of circumstances.

As noted above, Executive Order 12898 calls on federal agencies, including EPA, to make environmental justice part of their mission "[t]o the greatest extent practicable and permitted by law."[8] We hope that, thoughtfully considered and deployed, *EJ Legal Tools* can serve as a meaningful resource for continued EPA efforts to advance its goal of achieving the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development and implementation of environmental laws, regulations, and policies.

[8] *Id*. at Section1-101.

CHAPTER ONE: CLEAN AIR ACT PROGRAMS

INTRODUCTION

EPA has various discretionary authorities that give, or may give, it opportunities to promote environmental justice under programs implementing the Clean Air Act (CAA).[9] The following discussion focuses on addressing and describing opportunities identified to date in permitting and rule development under the CAA and other related environmental statutes. Additional opportunities may be identified as the Agency gains further experience in addressing environmental justice considerations.

The potential for taking environmental justice considerations into account varies greatly across the various CAA programs. A general caveat applies: Because the primary authority and responsibility to select and implement air pollution control measures often rests with the states and with authorized Indian tribes, EPA may have limited authority to influence state or tribal decisions. Nevertheless, the CAA does afford EPA opportunities to consider environmental justice in certain standard-setting and permitting contexts. Because much of this chapter describes opportunities rather than current practice, case law directly addressing consideration of environmental justice under the CAA is limited and many of the opportunities described in this chapter are untested.

This chapter groups the relevant authorities into five broad categories: (1) standard setting, which includes new source performance standards, standards for solid waste incinerators, hazardous air pollutant standards, national ambient air quality standards (NAAQS), and mobile source standards; (2) NAAQS implementation; (3) permitting, which includes the new source review preconstruction permit program and the title V operating permit program; (4) provisions relating to Native American communities and federally recognized Indian tribes; and (5) miscellaneous additional provisions.

STANDARD SETTING

I. NEW SOURCE PERFORMANCE STANDARDS

Section 111 of the CAA contains several provisions that could accommodate the incorporation of environmental justice considerations, such as impacts on or participation in decision-making by minority, low-income, or indigenous populations. First, section 111(b) requires EPA to list categories of stationary sources that "cause[], or contribute[] significantly to, air pollution which may be reasonably anticipated to endanger public health or welfare." In determining priorities for promulgating standards for listed categories of sources, EPA is to consider under section 111(f)(2)(B) "the extent to which each such pollutant may reasonably be anticipated to endanger public health or welfare." Together, these two provisions could facilitate the advancement of environmental justice by giving EPA discretion to consider how or whether certain stationary sources particularly impact minority, low-income, or indigenous populations, and to consider the health impacts of the emissions from those sources. While EPA retains the

[9] 42 U.S.C. §§ 7401- 7671q.

authority to add new source categories to the list and could consider environmental justice factors in deciding what categories to add, there are currently no plans to significantly expand the list. EPA has already promulgated standards for all of the listed source categories and is required by statute to review and, if appropriate, revise those standards at least every eight years.

II. STANDARDS FOR SOLID WASTE INCINERATORS

The CAA provides specific authority to EPA to establish siting requirements for solid waste incinerators that could include environmental justice considerations, such as impacts on or participation in decision-making by minority, low-income, or indigenous populations. Section 129(a)(3) of the CAA provides that standards for new solid waste incinerators include "siting requirements that minimize, on a site specific basis, to the maximum extent practicable, potential risks to public health or the environment." Most of the standards that EPA initially promulgated for each category of solid waste incineration units were remanded to the Agency for further action. EPA recently issued revised standards for commercial and industrial solid waste incinerators, and is currently in the process of issuing revised standards for municipal waste incinerators and other categories of solid waste incinerators. EPA also recently issued standards for sewage sludge incinerators.[10] On May 20, 2011, EPA delayed the effective date of the emissions standards for commercial and industrial solid waste incinerators until the completion of reconsideration proceedings or pending litigation, whichever comes first.

The current standards for large and small municipal waste incinerators require new sources to develop a siting analysis that evaluates how the facility's combustion of municipal waste affects ambient air quality, visibility, soils, vegetation, and other relevant factors. In that analysis, the source must consider the impacts of other industrial facilities near the site. New municipal waste incinerators must also develop a materials separation plan that addresses separation of certain municipal waste components to make such components available for recycling. The siting plans and the materials separation plans must be made available to the public for comment. Similarly, in September 1997, EPA issued emissions standards for medical waste incinerators under section 129 of the CAA. These standards require new sources to develop a siting analysis that considers air pollution control alternatives that minimize, on a site-specific basis and to the maximum extent practicable, potential risks to public health and the environment. EPA issued revisions to the medical waste incinerator standards in October 2009, but did not revise these siting requirements.

The emissions standards issued recently for sewage sludge incinerators and commercial and industrial solid waste incinerators also include siting requirements for new sources. Specifically, owners or operators of new sewage sludge incinerators are required to conduct a siting analysis, which includes submitting a report that evaluates site-specific air pollution control alternatives that minimize potential risks to public health or the environment, considering costs, energy impacts, non-air environmental impacts and any other factors related to the practicability of the alternatives. In conducting an analysis to meet the siting requirements of these recent rules as well as the rules issued earlier for municipal and medical waste incinerators, the owner or operator of the planned new source could consider environmental justice factors as part of the analysis of minimizing potential risks to public health, to the extent a particular

[10] *See* 40 C.F.R. Part 60, Subparts LLLL and MMMM.

demographic category is a population that is more vulnerable to the air pollution produced by the source. The regulatory text of the siting requirements does not currently require such consideration; however, EPA could consider revising the regulations to do so.

III. HAZARDOUS AIR POLLUTANT STANDARDS

A. List of Hazardous Air Pollutants

Section 112(b) of the CAA contains an initial list of hazardous air pollutants (HAPs) and states that EPA shall, "where appropriate," revise the list through rulemaking to add substances that "present, or may present . . . a threat of adverse human health effects . . . or adverse environmental effects."[11] Additions may be made in response to a petition or on the Agency's own initiative. EPA is required to add an air pollutant to the HAPs list if it determines, or if a petitioner shows, that "emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may be reasonably anticipated to cause adverse effects to human health or adverse environmental effects."[12] In reaching such a determination, EPA could take into account environmental justice factors in its consideration of adverse human health effects to the extent a particular demographic category is a population that is more vulnerable to the air pollutant at issue.

B. MACT Standards

Under section 112 of the CAA, EPA is required to establish emissions standards for major sources of HAPs, requiring the maximum achievable degree of reduction in HAPs emissions. These standards are technology-based, and are calculated using the emission control achieved by the best performing sources. Therefore, EPA does not have discretion to consider public health impacts in setting the floor for the maximum achievable control technology (MACT) standards. However, EPA may choose to set a standard beyond the level achieved by the best performing sources (*i.e.*, beyond the floor), and when doing so can take into consideration under section 112(d)(2) any non-air quality health and environmental impacts resulting from such standards.

Section 112(d)(4) of the CAA provides that, for HAPs with an established health threshold, EPA may consider such health threshold when establishing emissions standards under section 112(d). This provision has historically been interpreted as allowing EPA to set emissions standards that are less stringent than the MACT floor, where a less stringent standard would ensure that the health threshold is not exceeded, with an ample margin of safety. The legislative history indicates that a health-based emissions limit under section 112(d)(4) should be set at the level at which no observable effects occur, and provide for an ample margin of safety. EPA has exercised this discretionary authority in the past to effectively exempt from the MACT requirement pollutants for which EPA concluded there was a health threshold.

Recently, EPA explained its interpretation of section 112(d)(4) in its proposed emissions standards for major source commercial, industrial, and institutional boilers and process heaters. In that notice, EPA did not propose a health-based standard for such boilers under section 112(d)(4), but explained that it interpreted this provision to allow the Administrator to consider

[11] CAA section 112(b)(2).

[12] CAA section 112(b)(3)(B).

factors other than the health threshold when establishing a health-based standard. Other factors include the potential for cumulative adverse health effects due to concurrent exposure to other HAPs with similar biological endpoints, from either the same or other source categories, where the concentration of the threshold pollutant emitted from the given source category is below the health threshold; the potential impacts on ecosystems of releases of the pollutant; and reductions in criteria pollutant emissions and other co-benefits that would be achieved via the MACT standard. These factors could be applied to consider impacts on overburdened communities, particularly in urban areas where there may be a large number of industrial sources of HAPs located close together.

C. GACT Standards

EPA has discretion to set emissions standards representing generally available control technology (GACT) for area sources (*i.e.*, sources that are not major sources), instead of MACT standards. The Senate report on the 1990 CAA Amendments describes GACT as "methods, practices, and techniques which are commercially available and appropriate for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems."[13] Like MACT, GACT standards are technology-based and the CAA does not explicitly provide for consideration of public health risk in establishing the GACT standards. However, the CAA does not specify any criteria that EPA must consider when exercising its authority to promulgate GACT standards, as opposed to MACT standards, for an area source category or subcategory. The CAA therefore does not preclude EPA from considering non-technology factors, including impacts on minority, low-income, and indigenous populations, in choosing between MACT or GACT standards for individual area source categories or subcategories.

D. Regulation of Area Sources Based on an "Adverse Effects" Finding

Section 112(c)(3) of the CAA provides that EPA shall list each area source category or subcategory that the Administrator finds presents a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation under section 112. EPA must then issue section 112(d) emission standards for the listed category or subcategory. EPA has previously stated that it "believes that it has discretion to consider a range of health effect endpoints and exposure criteria in making [an adverse effect finding under section 112(c)(3)]" and that it "may consider factors such as the number of sources in a category, the quantity of emissions, the toxicity of the HAPs, the potential for individual and population exposures and risks, the geographical distribution of the sources and the reasonableness of control measures."[14] Although EPA is not aware of any previous section 112(c)(3) adverse effect finding that specifically considered environmental justice factors, the range of factors identified above could include consideration of potential adverse health effects to minority, low-income, and indigenous populations.

E. Residual Risk

Section 112(f) of the CAA requires EPA within eight years after promulgation of each technology-based emission standard for major sources under section 112(d) to review and revise

[13] S. Rep. No. 101-228 (1989).

[14] Proposed Rule: National Emission Standards for Hazardous Air Pollutants (NESHAP) (Secondary Lead Smelters), 59 Fed. Reg. 29750, 29754-29755 (June 9, 1994).

such standards, if necessary to protect public health with an ample margin of safety and to prevent adverse environmental effects, taking into consideration costs, energy, safety, and other relevant factors. In recent rulemakings, EPA has included an environmental justice analysis that provides information on the demographic impacts of proposed rules. If EPA determined that additional controls were necessary to protect public health with an ample margin of safety, EPA would promulgate regulations to provide such protection. In making such determinations, EPA can consider demographics where, for example, it determines that a particular demographic category is a population that is more vulnerable to the pollutants emitted by the source category at issue.

IV. NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS)

Section 109(d) of the CAA provides that EPA periodically review and revise, as appropriate, the NAAQS, which are designed "to protect the public health" and the public welfare. In setting the NAAQS, EPA focuses on the health effects on population groups that are at higher risk of adverse health effects. Thus, the NAAQS inherently take certain environmental justice factors into account as part of the standard-setting process. The legislative history of section 109 indicates that a primary (health-based) standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group."[15] This can include, for example, groups that are more susceptible to harm from a given exposure to a pollutant like ozone, such as persons with asthma or pre-existing respiratory conditions, or groups that are more exposed to the pollution, such as children's or outdoor workers' exposure to ozone, or exposure of children to lead.

Similarly, in establishing a monitoring network to support a NAAQS, EPA may use its discretion to site some monitors in locations to protect susceptible and vulnerable populations. For example, in the final rule on the Primary National Ambient Air Quality Standards for Nitrogen Dioxide, the Administrator required the Regional Administrators to use their discretionary authority to site a specific number (40) of monitors with a primary focus on susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups.[16] EPA determined that it was necessary and appropriate to site monitors in such locations to address the risk of increased exposure to these populations. It is important to recognize, however, that the consideration of at-risk populations is, as it must be, treated as part of EPA's statutory responsibility to protect public health, whether or not environmental justice is at issue.

[15] S. Rep. No. 91-1196, at 10 (1970); *see also Coalition of Battery-Recyclers Ass'n v. EPA*, 604 F.3d 613 (D.C. Cir. 2010) ("this court has held that 'NAAQS must protect not only average healthy individuals, but also "sensitive citizens"' such as children, and '[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.'" (quoting *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998)).

[16] 75 Fed. Reg. 6474, 6509-11 (Feb. 9, 2010).

V. MOBILE SOURCES

A. Fuel Controls or Prohibitions

Section 211(c) of the CAA provides that EPA may control or prohibit the manufacture or sale of any fuel or fuel additive that causes or contributes to air pollution that may reasonably be anticipated to endanger public health or welfare. As with other regulations implementing health-based standards, EPA can take into account impacts on sensitive populations. EPA used the predecessor of current section 211(c) to control the use of lead in gasoline to protect the public health, considering among other factors the impact of ambient lead and related blood-lead levels on children, including urban children and children living in substandard housing.[17] In the 1977 amendments to the CAA, Congress cited this example in support of its revisions to section 211(c) and various other CAA provisions. The current language on endangerment to public health or welfare in section 211(c) and other provisions is designed, among other things, "[t]o assure that the health of susceptible individuals, as well as healthy adults, will be encompassed in the term 'public health,'. . . ."[18]

B. Motor Vehicles and Nonroad Engines and Vehicles

Section 213(a) of the CAA provides for the regulation of emissions from new nonroad engines and vehicles that cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Similar language is found in section 202(a)(1). Again, EPA has the latitude to take into account impacts on sensitive populations.

NAAQS IMPLEMENTATION

I. GENERAL CONFORMITY DETERMINATIONS FOR FEDERAL AGENCY ACTIONS

General conformity requires federal agencies to demonstrate that the emissions from a federal action will conform to the purposes of the appropriate state, tribal or federal implementation plan for attaining clean air and will not otherwise cause or contribute to a violation of or interfere with the ability to attain and maintain the NAAQS. EPA could issue guidance to federal agencies recommending that environmental justice considerations such as impacts on minority, low-income, or indigenous populations be addressed in completing their general conformity determinations, although section 176(c)(1) of the CAA does not provide clear authority to rely specifically upon environmental justice factors to find that an activity does not conform. Such guidance could recommend that federal agencies address environmental justice factors regarding impacts on or participation by overburdened communities both in the process of finalizing those determinations (such as by allowing for extended public comment periods or having specific public meetings with affected communities to discuss the activity under consideration) and in the substance of those determinations (such as considering protection of overburdened communities when evaluating project mitigation options or selecting locations for acquiring offsets).

[17] *Ethyl v. EPA*, 541 F.2d 1, 40, 44, 47-48 (D.C. Cir. 1978).

[18] H.R. Rep. No. 95-294, at 50 (1977).

II. FEDERAL IMPLEMENTATION PLANS AND NEW PLANNING AFTER FAILURE TO ATTAIN THE NAAQS

Under section 110(c) of the CAA, EPA must promulgate a Federal Implementation Plan (FIP) for an area within two years of making a finding that a state has failed to submit a complete State Implementation Plan (SIP) or disapproving a submitted SIP. Where EPA takes such an action with regard to a broad planning SIP, such as an attainment demonstration or reasonable further progress plan, EPA could consider environmental justice factors in determining which sources to regulate in order to meet the goal of attainment or reasonable further progress.

Under section 179(d) of the CAA, if EPA determines that a state failed to attain the NAAQS by the applicable attainment date, EPA must require the state to submit a SIP revision including "such additional measures as the Administrator may reasonably prescribe, including all measures that can be feasibly implemented in the areas in light of technological achievability, costs, and any non-air quality and other air quality-related health and environmental impacts." EPA could consider environmental justice factors in determining whether to require regulation of particular sources of air pollution or require adoption of specific programs due to "non-air quality and other air quality-related health and environmental impacts."

In addition, consistent with the provisions of sections 301(a) and 301(d)(4) of the CAA, EPA promulgates FIP provisions as are necessary or appropriate to protect air quality in Indian country where tribal efforts do not result in adoption and approval of tribal plans or programs.[19] EPA has promulgated FIPs for Indian country at the national, regional, and source-specific levels.[20]

PERMITTING

I. NEW SOURCE REVIEW

New Source Review (NSR) is a preconstruction permitting program. If a new major source or a major modification to an existing major source will increase emissions by an amount large enough to trigger NSR requirements, then the source must obtain a permit before it can begin construction. The NSR provisions are set forth in sections 110(a)(2)(C), 165(a) (PSD permits), 172(c)(5) and 173 (NSR permits) of the Clean Air Act. Under the CAA, states have primary responsibility for issuing permits, and they can customize their NSR programs within the limits of EPA regulations. EPA's primary role is to approve state programs and to review, comment on, and take any other necessary actions on draft and final permits to assure consistency with EPA's rules, the state's implementation plan, and the CAA. Citizens also play a role in the permitting decision and must be afforded an opportunity to comment on each construction permit before it is issued. In addition, EPA directly issues permits in certain situations (*e.g.*, in states that have declined to fully

[19] *See* 63 Fed. Reg. 7254, 7265 (Feb.12, 1998); 40 C.F.R. § 49.11.

[20] *See*, *e.g.*, 76 Fed. Reg. 38748 (July 1, 2011) (New Source Review permitting rule for Indian country); 75 Fed. Reg. 10174 (March 5, 2010) (Source-Specific FIP for Navajo Generating Station, Navajo Nation); 70 Fed. Reg. 18074 (April 8, 2005) (FIPs for Indian Reservations in Idaho, Oregon and Washington).

implement an NSR program, in Indian country, and in Outer Continental Shelf areas) and, through the EPA Environmental Appeals Board, adjudicates appeals of EPA permits and permits issued by states and local districts with delegated federal programs.[21]

The NSR permit program for major sources has two different components – one for areas where the air is dirty or unhealthy, and the other for areas where the air meets health-based standards or is unclassified. Under the CAA, geographic areas (*e.g.*, counties or metropolitan statistical areas) are designated as "attainment" or "nonattainment" with the NAAQS – the air quality standards that are set to protect human health and the environment. Permits for sources located in attainment (or unclassifiable) areas are called Prevention of Significant Deterioration (PSD) permits and those for sources located in nonattainment areas are called nonattainment NSR permits.

The requirements of these permit programs are somewhat distinct. One notable difference in the two programs is that the control technology requirement in nonattainment areas is called the Lowest Achievable Emission Rate (LAER), which is defined as the most stringent emission limitation required under a state implementation plan or achieved in practice for a class of category of sources. In PSD areas, a source must apply Best Available Control Technology (BACT), and the statute allows the consideration of cost and other factors in weighing BACT options. Also, in keeping with the goal of progress toward attaining the NAAQS, sources in nonattainment areas must always provide or purchase "offsets" – decreases in emissions that compensate for the increases from the new source or modification. In PSD areas, offsets are not required, but sources must demonstrate that they will not cause or contribute to a violation of the NAAQS or the PSD increments, the latter of which are margins of "significant" air quality deterioration above a baseline concentration that establish an air quality ceiling, typically below the NAAQS, for each PSD area. Sources can typically make this demonstration based on the BACT level of control or by accepting tighter air quality-based limitations, but permitting authorities have the discretion to require mitigation measures in a PSD permit that are comparable to offsets if such measures are necessary to meet this "cause or contribute" standard.

EPA's opportunities to advance environmental justice in NSR and PSD permitting differ depending on whether EPA or the state is the permitting authority. When EPA is the permitting authority, the Agency controls both the content of the permit and the permit review process. Control over the review process gives EPA opportunities to enhance environmental justice by facilitating increased public participation in the formal permit consideration process (*e.g.*, by granting requests to extend public comment periods or hold multiple public meetings, or by providing translation services at hearings in areas with limited English proficiency). EPA can also take informal steps to enhance participation even earlier in the process, such as inviting community groups to meet with EPA and express their concerns before a draft permit is issued. And when EPA makes permit decisions, the Agency has sufficient legal authority to consider potential disproportionate environmental burdens on a case-by-case basis, with no need to amend existing regulations or guidance documents. In fact, EPA is already following this case-by-case approach in issuing PSD permits consistent with its legal authority.

[21] *See* 40 C.F.R. §§ 52.21(u) and 124.19.

When a state is the permitting authority, EPA's role includes commenting on individual permits during the comment period. This presents an opportunity for EPA to advance environmental justice by focusing the state's consideration on potential disproportionate environmental burdens in determining that the permits comply with applicable requirements. EPA can offer comments to states regarding disproportionate burdens arising from permits (although states would not necessarily need to accept and act on such comments). EPA routinely comments on proposed permits, but has not previously emphasized such issues in comments.

Another EPA role in state permitting is writing the regulations that establish the minimum criteria for PSD and NSR permitting programs implemented by state permitting authorities. EPA has promulgated the minimum requirements for an approvable state PSD permitting program in 40 C.F.R. § 51.166, and similar state program requirements for nonattainment NSR are contained in 40 C.F.R. § 51.165. At present, these rules do not explicitly discuss environmental justice considerations and thus do not directly require state permitting authorities to reflect these considerations in their permitting decisions. If EPA were to interpret the Clean Air Act to provide the Agency with the discretion to require more direct consideration of these factors in permitting decisions by EPA and the states, the Agency could consider revising the criteria applicable to state permitting programs in order to make environmental justice considerations more explicit in one or more aspects of the permitting criteria.

A. Nonattainment NSR Permitting Authority

Section 173(a)(5) of the CAA requires a permitting authority reviewing a nonattainment NSR permit to determine whether "an analysis of alternative sites, sizes, production processes, and environmental control techniques for such proposed source demonstrates that benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification." Thus, this provision calls for consideration of siting issues.

Under the regulations at 40 C.F.R. § 51.161, state implementation plans must require the state or local permitting agency to provide an opportunity for public comment on information submitted by a source owner or operator who is seeking a nonattainment NSR permit. This opportunity must include the following: (1) a 30-day public comment period; (2) public availability of the information provided by the permit applicant (and the permitting authority's analysis of the effects of the proposed source seeking the permit), in at least one location in the affected area; and (3) a prominent advertisement of the availability of the information.

Implementation of the nonattainment NSR programs meeting these core requirements is primarily a state responsibility. In light of some differences in the statutory provisions applicable to the nonattainment NSR program and the PSD program, EPA has assumed responsibility for issuing nonattainment NSR permits less frequently than PSD permits. Given the primacy of state legal authority as the foundation for implementing this program, and the focus of this document principally on circumstances in which EPA is the implementing authority, further analysis of opportunities to incorporate environmental justice considerations into nonattainment NSR permitting decisions by states is beyond the scope of this exercise. However, further analysis of these issues may well be beneficial in the context of future undertakings.

B. PSD Program Permitting Authority and Implementation History

Section 165(a)(2) of the CAA provides that a PSD permit may be issued only after "a public hearing has been held with opportunity for interested persons including representatives of the Administrator to appear and submit written or oral presentations on the air quality impact of [the proposed] source, alternatives thereto, control technology requirements, and other appropriate considerations." Likewise, one purpose of the PSD program is "to assure that any decision to permit increased air pollution in any area to which this section applies is made only after careful evaluation of all the consequences of such a decision and after adequate procedural opportunities for informed public participation in the decisionmaking process."[22] In addition to requiring an opportunity for public participation in permitting decisions, the "alternatives" and "other appropriate considerations" language in section 165(a)(2) can be interpreted to provide the Agency with discretion to incorporate environmental justice considerations when issuing PSD permits. EPA has recognized that this language provides a potential statutory foundation in the Clean Air Act for this discretion.[23] However, EPA has never explicitly based a PSD permit condition solely on such discretion or section 165(a)(2) alone, and the full contours of such discretion have not yet been defined.

Nevertheless, section 165(a)(2) could be construed to provide EPA with discretion (but not a mandatory obligation) to impose permit conditions on the basis of environmental justice considerations raised in public comments regarding the air quality impacts of a proposed source. EPA has argued that this provision authorizes the incorporation of plant siting considerations into PSD permitting decisions. The ability to condition a permit due to environmental justice considerations would further the purpose of part C of title I of the Clean Air Act "to protect public health and welfare from any actual or potential adverse effect . . . from air pollution . . . notwithstanding the attainment and maintenance of all [NAAQS]."[24]

The EPA Environmental Appeals Board (EAB) first addressed environmental justice considerations under the CAA in 1993.[25] In its initial Order Denying Review in Part and Remanding in Part in *Genesee Power*, the EAB stated that the CAA did not allow for consideration of environmental justice and siting issues in air permitting decisions. In response, EPA's Office of General Counsel filed a Motion for Clarification on behalf of the Office of Air and Radiation and Region V. The Motion pointed out, among other things, that the CAA requirement to consider alternatives to the proposed source and the statutory definition of "best available control technology" provided opportunities for consideration of environmental justice in PSD permitting. The Motion also referenced legislative history that suggests Congress intended for the Clean Air Act to provide for examination of the air quality impact of particular site location decisions. In an amended opinion and order issued on October 22, 1993, the EAB deleted the controversial language but did not decide whether

[22] CAA section 160(5).

[23] *See* Memorandum from Gary S. Guzy, EPA General Counsel, entitled "EPA Statutory and Regulatory Authorities Under Which Environmental Justice Issues May Be Addressed in Permitting" (Dec. 1, 2000).

[24] CAA section 160(1).

[25] *In the Matter of Genesee Power Station*, PSD Appeal Nos. 93-1 through 93-7 (EAB Sept. 8, 1993).

it is permissible to address environmental justice considerations under the PSD program.[26] Thus, EPA has asserted arguments that support the authority to condition or deny PSD permits based on environmental justice, siting, or other considerations not explicitly addressed by other provisions in part C of title I of the Clean Air Act, but the Agency has never attempted to establish permit conditions based directly and exclusively on such authority.

Subsequently, based on Executive Order 12898 on environmental justice, the EAB has held that environmental justice considerations must be considered in connection with the issuance of federal PSD permits issued by EPA Regional Offices or states acting under delegations of federal authority.[27] In the *Knauf Fiber Glass* matter, the EAB remanded a PSD permit to the delegated permitting authority for failure to provide EPA's environmental justice analysis in the administrative record in response to comments raising the issue.[28] In these cases, the EAB did not specifically cite section 165(a)(2) or any other provision of the CAA as the basis for EPA discretion to consider environmental justice. But the EAB has recognized that consideration of the need for a facility is within the scope of section 165(a)(2) when a commenter raises the issue.[29]

Based on these EAB decisions, EPA Regional Offices or their delegates in the States routinely conduct an environmental justice analysis in conjunction with the review of PSD permit applications. Indeed, the EAB "has held that environmental justice must be considered in connection with the issuance of PSD permits," and "has . . . encouraged permit issuers to examine any 'superficially plausible' claim that a minority or low-income population may be disproportionately affected by a particular facility."[30] EPA guidance or EAB decisions do not call for integrating environmental justice considerations into any individual component of the PSD permitting review, such as the determination of BACT. Rather, the practice of EPA Regional Offices and delegated states has been to conduct a largely freestanding environmental justice analysis for PSD permits.

EPA has not issued any formal guidelines for the scope and content of an environmental justice analysis on PSD permits, but has developed some general parameters through individual actions. Such an analysis has generally involved an assessment of the impacts a source may have on minority or low-income communities, which is typically informed by the analysis of whether a source will cause or contribute to a violation of the health-based NAAQS in any area. The EAB has often deferred to the judgments of EPA

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[26] 4 E.A.D. 832, 833 n. 1 (EAB 1993).

[27] *In re Prairie State Generating Company*, 13 E.A.D. 1, 123 (EAB 2006) (citing *In re Knauf Fiber Glass, GmbH*, 8 E.A.D. 121, 174-75 (EAB 1999)); *see also In re AES Puerto Rico, L.P.*, 8 E.A.D. 324, 351 (EAB 1999) (order denying review based in part on the thorough environmental justice analysis), *aff'd sub nom Sur Contra La Contaminacion v. EPA*, 202 F.3d 443 (1st Cir. 2000); *In re EcoEléctrica, L.P.*, 7 E.A.D. 56, 67-69 (EAB 1997); *In re Puerto Rico Electric Power Authority*, 6 E.A.D. 253, 254-58 (EAB 1995) (citing *In re Chemical Waste Management of Indiana*, 6 E.A.D. 66 (EAB 1995) (examining for the first time the general policy directive set out in EO 12898 and the EAB's role in implementing it in the context of a RCRA permit)).

[28] *In re Knauf Fiber Glass, GmbH*, 8 E.A.D. at 174-75.

[29] *See In re Prairie State Generating Company*, 13 E.A.D. at 32.

[30] *In re Shell Gulf of Mexico, Inc.*, 15 E.A.D. __, slip op. at 63 and n. 71 (EAB Dec. 30, 2010) (internal citations omitted).

Regional Offices that the NAAQS provide a useful benchmark for assessing potential adverse impacts on the health of members of affected communities.[31]

However, in *In re Shell Gulf of Mexico, Inc.*, the EAB remanded an environmental justice analysis as inadequate when the record contained no document designated as an environmental justice analysis, and no "information or other evidence" that the analysis of environmental justice issues undertaken solely in response to public comments "considered anything beyond compliance with the NAAQS" in effect when the permit was issued.[32] The EAB considered this insufficient under the circumstances because, before the permit was issued, EPA had announced that it was revising the relevant NAAQS effective shortly after the permit was issued because the unrevised NAAQS was not adequately protective of public health.[33] In a later case, *In re Avenal Power Center, LLC,* the Board explained that its remand in the *Shell* case was because of "the region's scant environmental justice analysis, which provided no examination or analysis of [specified environmental justice] impacts *whatsoever*."[34]

In the *Avenal* case, the EAB rejected a challenge to a dedicated environmental justice analysis that "collected and analyzed demographic, health-related, and air quality data" regarding the impacts of emissions from a proposed facility.[35] The EAB noted that the Region made the environmental justice analysis available for public comment. The EAB recognized that "[t]he plain language of the Executive Order" allows agencies "considerable leeway . . . in determining how to comply with the letter and spirit of the Executive Order."[36] Thus, a "substantive environmental justice analysis that endeavors to include and analyze data that is germane to the environmental justice issue raised during the comment period" may comply with the Executive Order even if it does not reach a definitive conclusion if "the permit issuer demonstrates that it exercised its considered judgment when determining that it could not reach a determinative conclusion due to the insufficiency of available valid data."[37] The EAB further noted that petitioners bear a "particularly heavy burden [in] demonstrating that the Agency clearly erred in making its technical judgments" regarding what data to consider in an environmental justice analysis.[38]

Notwithstanding the lack of formal rules or guidance under the PSD program, in the decisions discussed above that postdate issuance of Executive Order 12898, the EAB

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[31] *See generally In re Knauf Fiber Glass, GmbH,* 9 E.A.D 1, 15-17 (EAB 2000) (upholding Agency finding that facility "will not have disproportionately high and adverse human health or environmental effects on a minority or low-income population" based on finding of attainment of relevant NAAQS, citing 40 C.F.R. § 50.2(b) (NAAQS set at level to protect the public health and welfare)); *AES Puerto Rico, L.P.*, 8 E.A.D. at 351 (affirming environmental justice analysis based on reasoning that NAAQS are health-based and protect sensitive populations).

[32] *Shell,* 15 E.A.D. at __, slip op. at 75-76 & n. 83.

[33] *Id.*

[34] *In re Avenal Power Center, LLC,* 15 E.A.D. __, slip op. at 24-25 (EAB Aug. 18, 2011) (emphasis added).

[35] *Id.* at 20.

[36] *Id.* at 24.

[37] *Id.* at 25-26.

[38] *Id.* at 27.

acknowledged that EPA can address environmental justice considerations in PSD permit reviews and evaluated the adequacy of EPA's environmental justice analyses as a matter of compliance with the Executive Order. Notably, the EAB has recognized that EPA has authority to use its discretion under PSD program regulations to establish permit conditions on the basis of environmental justice considerations:

> In support of environmental justice for this community, the Region took steps to require that many elements of the air quality analyses performed during the permit process be reconfirmed after the permit is issued. As conditions of the permit, [the permittee] is required to conduct ambient SO_2 monitoring and to perform a multi-source air quality analysis for SO_2. These permit conditions are a testament to the role of public participation in the permit process. Because of the concerns raised during the public comment period, this permit contains additional conditions that are not mandated by the PSD regulations but are within the Region's discretion to require. The Region incorporated the conditions into the permit as a tangible response to the community's concerns about air quality and to fulfill the goals of the Executive Order.[39]

The additional conditions in this instance involved post-construction monitoring requirements (discussed further below) that are within the discretion of the permitting authority to impose under express authority in EPA regulations.[40]

Under section 165(a)(7) of the CAA, one requirement of a PSD permit review is that a permit applicant "conduct such monitoring as may be necessary to determine the effect which emissions from any such facility may have, or is having, on air quality in any area which may be affected by emissions from such source." This provision and section 165(e)(2) have been applied by permitting authorities to require collection of pre-construction monitoring data on ambient air quality conditions in the area to inform the air quality analysis needed to determine whether the permit may issue. In practice, most permit applicants have not been required to collect new site-specific monitoring data but have been allowed to use previously collected data from another location that is shown to be representative of the area affected by the proposed construction. However, to support an environmental justice analysis, EPA could use this authority to gather site-specific data as appropriate to evaluate potential impacts on particular minority, low-income, and indigenous populations.

Moreover, EPA has interpreted section 165(a)(7) to provide a permitting authority with the discretion to require post-construction monitoring to determine the effect a source is actually having on air quality in any area.[41] Thus, a permitting authority has the discretion to require post-construction monitoring in a PSD permit to provide assurance that there will not be a disproportionate impact on air quality in a minority, low-income, or indigenous community. The EAB has affirmed the discretion of a permitting authority to establish post-construction

[39] *In re AES Puerto Rico, L.P.*, 8 E.A.D. at 351 (internal citations omitted).

[40] 40 C.F.R. § 52.21(m)(2).

[41] 40 C.F.R. §§ 51.166(m)(2) and 52.21(m)(2).

monitoring requirements on the basis of environmental justice considerations.[42] Such monitoring can verify the source's actual impact.

The role of environmental justice considerations in addressing hazardous air pollutant impacts in PSD permitting is not straightforward. In the 1990 CAA Amendments, Congress provided in section 112(b)(6) of the CAA that the PSD provisions do not apply to hazardous air pollutants (HAPs). Due to this provision, BACT limits are not required to be set for HAPs in PSD permits. However, the Administrator ruled prior to the 1990 Amendments that in establishing BACT for criteria pollutants (pollutants directly regulated under PSD), analysis of control technologies for criteria pollutants could also consider their relative ability to control emissions of pollutants *not* directly regulated under PSD.[43] In EPA's view, the 1990 Amendments did not change this limited authority, and it could be viewed as a basis for addressing environmental justice considerations derived from collateral impacts of air toxics emissions. In addition, EPA may have authority to take into account effects of HAPs that are also criteria pollutants, such as volatile organic compounds.

II. TITLE V

All major stationary sources of air pollution and certain other sources are required to apply for CAA title V operating permits that include emission limitations and other conditions as necessary to assure sources' compliance with applicable requirements of the CAA, including the requirements of the applicable implementation plan.[44] Unlike PSD/NSR permitting, the title V operating permit program does not generally impose new substantive air quality control requirements (which are referred to as "applicable requirements"), but does require permits to contain monitoring, recordkeeping, reporting, and other conditions to assure compliance by sources with applicable requirements.[45] One purpose of the title V program is to enable the source, EPA, states, and the public to better understand the applicable requirements to which the source is subject and whether the source is complying with those requirements. Thus, the title V operating permit program is a vehicle for ensuring that existing air quality control requirements are appropriately applied to facility emission units and that the units comply with these requirements.

Section 502(d)(1) of the CAA calls upon each state to develop and submit to EPA an operating permit program intended to meet the requirements of CAA title V. Under section 505(a) of the CAA and the relevant implementing regulations at 40 C.F.R. § 70.8(a), states and other permitting authorities are required to submit each proposed title V permit to EPA for review. Upon receipt of a proposed permit, EPA has 45 days to object to final issuance of the permit if it is determined not to be in compliance with applicable requirements or the requirements of title V.[46] If EPA does not object to a permit on its own initiative, section 505(b)(2) of the CAA provides that any person may petition the Administrator, within 60 days of

[42] *In re AES Puerto Rico, L.P.*, 8 E.A.D. at 351.

[43] *In re North County Resource Recovery Assoc.*, 2 E.A.D. 229, 230 (Adm'r 1986).

[44] CAA sections 502(a), 504(a), and 504(c).

[45] 57 Fed. Reg. 32250, 32251 (July 21, 1992) (EPA final action promulgating Part 70 rules).

[46] 40 C.F.R. § 70.8(c).

the expiration of EPA's 45-day review period, to object to the permit.[47] In response to such a petition, section 505(b)(2) of the CAA requires the Administrator to issue an objection if a petitioner demonstrates that a permit is not in compliance with the requirements of the CAA.

Because title V generally does not authorize the direct imposition of substantive emission control requirements, title V permitting does not appear to be an effective mechanism for establishing new, substantive control requirements to address environmental justice considerations regarding impacts on or participation by minority, low-income, or indigenous populations. The title V process, however, can allow public participation to serve as a motivating factor for applying closer scrutiny to a title V source's compliance with applicable CAA requirements. By providing significant public participation opportunities, title V can serve as a vehicle by which citizens can raise environmental justice considerations that arise under other provisions of the CAA. Communities can use the title V process to help ensure that each title V permit contains all of a source's applicable requirements, and other conditions necessary to assure the source's compliance with those requirements.

Under the 40 C.F.R. Part 70/71 permitting process, EPA has exercised its CAA authority to require extensive opportunities for public participation in permitting actions. For example, 40 C.F.R. § 70.7(h) requires that all permit proceedings (except for modifications qualifying for minor permit modification procedures) "provide adequate procedures for public notice including an opportunity for public comment and a hearing on the draft permit." This provision also specifies steps permitting authorities must take to allow for adequate public participation.

Under section 505(c) of the CAA, title V permits must contain provisions, including monitoring requirements, to assure compliance with permit terms and conditions. EPA has made clear in several recent title V orders responding to citizen petitions that permitting authorities need to evaluate monitoring requirements in title V permits, and must supplement monitoring in title V permits where necessary to assure compliance with permit terms and conditions. In the *CITGO* and *Premcor* Orders,[48] EPA summarized the title V monitoring requirements. EPA explained that the Part 70 monitoring rules[49] are designed to satisfy the statutory requirement in section 504(c) of the CAA that "[e]ach permit issued under [title V] shall set forth . . . monitoring . . . requirements to assure compliance with the permit terms and conditions."

As a general matter, permitting authorities must take three steps to satisfy the monitoring requirements in EPA's Part 70 regulations. First, under 40 C.F.R. § 70.6(a)(3)(i)(A), permitting authorities must ensure that monitoring requirements contained in applicable requirements are properly incorporated into the title V permit. Second, if the applicable requirement contains no periodic monitoring, permitting authorities must add "periodic monitoring sufficient to yield reliable data from the relevant time period that are representative of the source's compliance with the permit."[50] Third, if there is some periodic monitoring in the applicable requirement, but that monitoring is not sufficient to assure compliance with permit terms and conditions, permitting

[47] *See also* 40 C.F.R. § 70.8(d).

[48] *In the Matter of CITGO Refining and Chemicals Company L.P.*, Petition VI-2007-01 (May 28, 2009) (*CITGO* Order); *In the Matter of Premcor Refining Group, Inc.*, Petition VI-2007-2 (May 28, 2009) (*Premcor* Order).

[49] 40 C.F.R. §§ 70.6(a)(3)(i)(A) & (B) and 70.6(c)(1).

[50] 40 C.F.R. § 70.6(a)(3)(i)(B).

authorities must require supplemental monitoring or perform such monitoring itself in order to assure such compliance.[51]

In addition, in all cases, the rationale for the selected monitoring requirements must be clear and documented in the permit record.[52] Further, permitting authorities have a responsibility to respond to significant comments.[53] This principle applies to significant comments on the adequacy of monitoring.[54]

Further, title V and EPA's implementing regulations also contain requirements regarding other types of conditions necessary to ensure compliance, such as reporting requirements. Section 504(c) of the CAA requires that each permit set forth "inspection, entry, monitoring, compliance certification, and reporting requirements to assure compliance with the permit terms and conditions." Further, 40 C.F.R. § 70.6(c)(1) requires that title V permits contain "compliance certification, testing, monitoring, reporting, and recordkeeping requirements sufficient to assure compliance with the permit terms and conditions." There are also several specific provisions in Part 70 addressing these other types of requirements, such as 40 C.F.R. § 70.6(a)(3)(ii) on recordkeeping.[55]

As the *CITGO* and *Premcor* Orders illustrate, EPA can use its role in overseeing and implementing the title V permitting process to help ensure that a title V permit contains all of the source's applicable requirements, and other conditions – including provisions for monitoring and recordkeeping – necessary to assure the source's compliance with those requirements. The process for public petitions to the Administrator on state-issued permits under section 505(b)(2) of the CAA and 40 C.F.R. § 70.8(d) allows an opportunity for the public to raise to EPA concerns regarding particular title V permits. In addition, EPA has authority to comment on whether a title V permit assures compliance with requirements of the CAA. Further, under CAA section 505(b), EPA must object if the Agency determines a permit is not in compliance with the requirements of the CAA.

As stated above, title V requires permitting authorities to submit proposed permits to EPA for a 45-day review period before the title V permits may be issued. EPA Regional Offices review only some of the proposed title V permits that are submitted by the permitting authorities because the resources available for such review and the statutory time frame provided for review of proposed permits are not sufficient to allow review of all proposed title V permits. In some instances, Regional Offices have prioritized title V permit review based on factors related to environmental justice. One way that EPA could address environmental justice considerations under title V more systematically would be for the Agency to direct its resources available for review of proposed title V permits to the review of such permits where they impact overburdened communities. Thorough EPA review would protect public health by potentially

[51] 40 C.F.R. § 70.6(c)(1).

[52] 40 C.F.R. § 70.7(a)(5).

[53] *See, e.g., In the Matter of Onyx Environmental Services*, Petition V-2005-1 (Feb. 1, 2006) ("it is a general principle of administrative law that an inherent component of any meaningful notice and opportunity for comment is a response by the regulatory authority to significant comments").

[54] *See, e.g., Premcor Order* at 7.

[55] *Premcor Order* at 8.

identifying any deficiencies with proposed permits and help ensure that the title V permits affecting these populations include all applicable requirements and adequate monitoring, recordkeeping, and reporting requirements to assure compliance with the applicable requirements.

Where EPA has not approved a state or tribal title V program (*e.g.*, in most of Indian country), EPA directly implements the title V permit program under 40 C.F.R. Part 71. In reviewing and acting on permit applications under Part 71 in Indian country and other areas, EPA can exercise the legal authorities discussed above to promote meaningful public involvement and ensure that title V permits contain adequate provisions to assure compliance with applicable requirements.

NATIVE AMERICAN COMMUNITIES AND FEDERALLY RECOGNIZED INDIAN TRIBES

As discussed in more detail in Chapter Five, Executive Order 12898 on environmental justice specifically addresses Native American communities and federally recognized Indian Tribes by providing that "[e]ach Federal agency responsibility set forth under this order shall apply equally to Native American programs."[56] In addition, the CAA provides opportunities for EPA to work with Indian tribes, and for EPA and tribes to consider and address impacts on Native American communities.

In 1998, EPA promulgated the Tribal Authority Rule (TAR), 40 C.F.R. Part 49, which implements the directive in section 301(d)(2) of the CAA that EPA promulgate regulations identifying the CAA provisions for which eligible tribes may be treated in the same manner as states. Under the TAR, an eligible tribe may be treated in the same manner as a state for all of the core CAA programs, including the establishment of implementation plans, the Prevention of Significant Deterioration program, and title V permitting programs. Many of these programs provide significant opportunities and responsibilities for tribes to work with affected communities in implementing the CAA. Tribes may also apply to EPA under CAA section 105 and the TAR for access to funds to implement tribal clean air programs for their areas. To date, 37 tribes have received treatment-as-a-state (TAS) status for various CAA provisions. Three of those tribes have EPA-approved tribal implementation plans (TIPs) to address air quality issues on their reservations, with several more TIPs under development, and one tribe has been approved to implement on EPA's behalf the federal title V operating permit program under 40 C.F.R. Part 71 for its reservation.

In addition, under section 164 of the CAA, states and Indian tribes have the authority to modify the classifications for their attainment areas, which will determine the level of significant deterioration allowable under the PSD increments. Several tribes have decided to provide their reservations the enhanced protection of air quality provided by Class I status and have obtained EPA approval to redesignate their reservations as Class I.

[56] Executive Order 12898, Section 6-606.

Further, EPA has authority under CAA section 301(d)(4) to directly implement provisions of the CAA in Indian country in the absence of EPA-approved programs.[57] When EPA undertakes direct implementation of the CAA in Indian country, EPA generally consults and works closely with the relevant tribal governments. EPA tribal programs are discussed more fully in Chapter Five.

MISCELLANEOUS

I. ACCIDENT PREVENTION AUTHORITIES

The Chemical Accident Prevention Provisions, 40 C.F.R. Part 68, implement CAA section 112(r)(7)(B). These rules require the preparation of risk management plans (RMPs) that summarize steps stationary sources take to prevent catastrophic toxic airborne releases, fires, and explosions. The RMPs include an assessment and disclosure of potential areas and populations that may be affected by worst-case accidents and other more likely events, as well as an accident history and a summary of accident prevention measures and emergency response programs. Portions of the RMPs could be made available to the public via an on-line database, although by statute EPA may not allow the general public access to certain off-site consequence information (*e.g.,* worst-case scenarios and more likely release scenarios) and rankings of facilities by scenario. During the rule's development, commenters asked for opportunities for local input into source prevention programs, including public meetings with sources during program development and the right to trigger audits or inspections. While the final rule does not provide for local input, EPA could amend its rules to create public input opportunities.

EPA has rulemaking authority under CAA section 112(r)(7)(A) to require additional monitoring and recordkeeping related to accidental release prevention, and to distinguish among sources by location. EPA has not exercised this authority. This authority applies to the same substance list as the rules under CAA section 112(r)(7)(B) discussed above and is similar to other CAA monitoring and recordkeeping authorities summarized in this document, except its focus is on accidental releases. Therefore, EPA has the authority to establish additional release monitoring requirements in overburdened communities if needed to prevent and address accidental releases.

In addition to the regulatory authority in CAA section 112(r)(7), the statute directly establishes a "general duty" to assess hazards, design and maintain a safe facility, and respond to accidents. This authority in CAA section 112(r)(1) is not limited to a set list of chemicals. Instead, it applies to any stationary source handling substances that are extremely hazardous due to use and properties. EPA has the authority to provide guidance on this duty.

II. RADIATION

EPA has examined the potential use of RCRA Subtitle C landfills for the risk-based disposal of radioactive waste containing low concentrations of radionuclides. These efforts are in the preliminary stages. However, environmental justice considerations regarding impacts on or

[57] *See also* 40 C.F.R. Part 49.

participation in decision-making by minority, low-income, and indigenous populations may arise in a manner similar to those under RCRA (siting of disposal facilities, monitoring, closure, land use). See Chapter Three.

III. INDOOR AIR POLLUTION

EPA has authority to do research and disseminate information concerning indoor air pollution pursuant to the Radon Gas and Indoor Air Quality Research Act of 1986.[58] EPA does not have regulatory authority to address indoor air pollution. In the past, EPA has addressed indoor air pollution such as second-hand smoke, otherwise known as "environmental tobacco smoke" (ETS), through means such as issuance of an ETS Risk Assessment and informational programs to advise the public about the risks of exposure to ETS. Such techniques could potentially be brought to bear with other indoor air pollutants that have disproportionate impacts on at-risk populations, potentially including minority, low-income, or indigenous populations.

IV. INFORMATION AUTHORITIES

EPA has a range of information-gathering and dissemination authorities that it can use to promote environmental justice. These authorities relating to research, monitoring and reporting can be implemented to focus attention on, and enhance participation in decision-making by, minority, low-income, and indigenous populations in ways that enable those populations to obtain information they can use to safeguard their health and environment.

As discussed above, EPA and state permitting agencies can impose monitoring requirements in individual permits. In addition, CAA section 114(a) authorizes certain record-keeping and reporting requirements, and section 114(c), in general, requires public availability of the information obtained pursuant to those requirements. EPA also has authority under CAA section 112(*l*)(3) to establish an air toxics clearinghouse to provide technical and other information about air toxics. EPA may also promulgate regulations under CAA section 112(r)(7) to impose monitoring, recordkeeping, reporting and other requirements in connection with the accidental release of regulated substances.

Further, under section 103 of the CAA, EPA has authority to conduct research relating to the causes, effects, extent, prevention, and control of air pollution. Clean Air Act section 112(*l*)(3) directs the Agency to use this authority to examine methods for preventing, measuring, and controlling emissions and evaluating associated health and ecological risks. Finally, CAA section 112(m) requires EPA to monitor the deposition of hazardous air pollutants onto the Great Lakes, the Chesapeake Bay, Lake Champlain, and coastal waters. EPA could focus that authority on collecting information relevant to the communities that depend on these water resources for fishing and other uses.

[58] 42 U.S.C. § 7401 note (1986).

CHAPTER TWO: WATER PROGRAMS

INTRODUCTION

This chapter addresses three statutes: the Clean Water Act,[59] the Safe Drinking Water Act,[60] and the Marine Protection, Research, and Sanctuaries Act.[61] The primary opportunities for advancing environmental justice exist under the Clean Water Act and Safe Drinking Water Act because they regulate a broad range of activities that could potentially affect minority, low-income, and indigenous communities that are or may be disproportionately impacted by environmental pollution. Under both of these statutes, EPA has discretionary authorities that could provide opportunities to advance environmental justice.

CLEAN WATER ACT

I. INTRODUCTION

The Clean Water Act (CWA) was adopted "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[62] To achieve this objective, Congress prohibited the discharge from a point source of any pollutant into a water of the United States unless that discharge complies with specific requirements of the CWA. In addition, Congress directed states to adopt water quality standards for their waters identifying the desired uses and acceptable levels of pollution in their waters. The CWA provides EPA broad authorities to establish regulations to implement the CWA's programs and gives EPA oversight authority of state programs. This chapter discusses the primary statutory and regulatory programs established under the CWA and identifies EPA's discretionary authorities to advance environmental justice under the CWA's various programs. The CWA's grant-related authorities and the oil spill program under section 311 are discussed separately in Chapters Seven and Three, respectively. Because states and authorized tribes[63] have primary responsibility to implement many of the CWA's regulatory programs, EPA may have limited authority to influence state and tribal decisions.

II. WATER QUALITY CRITERIA GUIDANCE AND WATER QUALITY STANDARDS

Water quality standards are the foundation of the water quality-based control programs mandated by the CWA. Water quality standards define the goals for a waterbody by designating

[59] 33 U.S.C. §§ 1251-1387.

[60] 42 U.S.C. §§ 300f -300j-26.

[61] 33 U.S.C. §§ 1401-1445.

[62] CWA section 101(a).

[63] As discussed in Section VII below and in Chapter Five, federally recognized Indian tribes may assume responsibility for administering many CWA programs under CWA section 518(e). However, eligible tribes are not required to do so. Currently, the water quality standards program is the only CWA regulatory program that is administered by some tribes.

its uses, setting criteria to protect those uses and establishing antidegradation protections to maintain existing uses and high water quality. Because water quality standards set the foundation for what level of water quality must be met by other CWA programs, they provide particular opportunities for ensuring protection of water quality in areas used by minority, low-income, and indigenous populations.

A. Water Quality Criteria Guidance

It is the national goal of the CWA that wherever attainable an interim goal of water quality that provides for the protection and propagation of fish, shellfish and wildlife and provides for recreation in and on the water be achieved.[64] Section 304(a)(1) of the CWA provides that EPA shall develop and publish criteria for water quality accurately reflecting the latest scientific knowledge on a variety of factors including "the kind and extent of all identifiable effects on health and welfare" that may be expected from the presence of pollutants in any body of water, including ground water. Pursuant to this authority, EPA has for 30 years developed and published water quality criteria guidance for protection of human health from consumption of fish and drinking water as well as exposure to bacteria through recreation in and on the water. States often adopt regulatory water quality standards pursuant to section 303(c) of the CWA based on EPA's recommended section 304(a) criteria.

(1) *EPA Authorities to Issue Recommended Criteria Guidance for Protection of Populations Consuming High Levels of Fish and Shellfish*

EPA's recommended water quality criteria generally are expressed as ambient numeric pollutant levels that EPA considers to be protective of the intended use of the water (*e.g.*, consumption of fish). EPA currently has recommended water quality criteria for protection of human health for over 100 individual pollutants. An important element of EPA's criteria recommendations for protection of human health is that they reflect EPA's assumptions regarding fish consumption. EPA's current recommended human health criteria reflect an assumption that the general population to be protected at the criteria level will consume 17.5 grams per day of fish (the national average value) and 100% of human exposure will be through surface water exposure pathways.

EPA's use of 17.5 grams per day reflects EPA's current methodology for deriving water quality criteria to protect human health, which EPA revised and published in 2000.[65] In the methodology, EPA "recommends a default fish intake rate of 17.5 grams/day to adequately protect the general population of fish consumers."[66]

For the protection of overburdened communities, EPA's methodology specifically considered "the States' and Tribes' need to provide adequate protection from adverse health effects to highly exposed populations such as recreational and subsistence fishers."[67] EPA recommends default fish consumption rates for recreational fishers and subsistence fishers of

[64] CWA section 101(a)(2).

[65] USEPA, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) (EPA-822-B-00-004 (October 2000)) at 4-25.

[66] *Id.*

[67] *Id.*

17.5 grams/day and 142.4 grams/day, respectively.[68] EPA's broad authorities under CWA sections 304(a)(1) and (2) would support the Agency's issuance of additional guidance to advance environmental justice if EPA determines that such guidance would help to protect populations consuming higher levels of fish and shellfish. Such guidance might provide additional recommended default consumption levels for a broader range of highly exposed populations beyond the current recommendations for recreational and subsistence fishers.

Recognizing that the level of fish intake in highly exposed populations varies by geographical location, EPA's methodology also suggests a four-preference hierarchy for states and authorized tribes to follow when deriving consumption rates. The four-preference hierarchy, which encourages use of the best local, state, and regional data available, consists of: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.[69]

EPA has the opportunity and statutory authority when reviewing new or revised state and tribal water quality standards to ensure that states and tribes are appropriately considering all relevant data in determining if their water quality standards are providing adequate protection for highly exposed populations. For example, when one state adopted revised human health criteria for toxic pollutants in 2011, EPA evaluated the revised criteria to ensure that the state considered all available and relevant local and regional data respecting fish consumption rate. EPA determined that the revised criteria – which were based on a ten-fold increase in fish consumption patterns among tribal populations in the state – were derived in a manner consistent with EPA's recommended methodology for the protection of highly exposed populations. If the Agency determines that states and authorized tribes are not adequately considering available data or implementing EPA's four-preference hierarchy, EPA has broad statutory authority to issue additional guidance clarifying that the Agency expects them to address all fish consumption data in developing their water quality standards and to use default assumptions in the absence of local data. EPA could then use the guidance in its review of state and tribal water quality standards.

(2) *Authorities to Issue Guidance for Protection of Populations Swimming and Recreating in Waters of the United States, Including Urban Waters*

In 1986, EPA issued recommended water quality criteria guidance on the acceptable levels of indicators of fecal contamination in waters designated for primary contact recreation (*e.g.*, swimming). The Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act) amended the CWA to direct EPA to publish revised water quality criteria recommendations for protection of all coastal and Great Lakes waters designated for primary contact recreation.[70] EPA is required to publish its revised criteria recommendations in October 2012 pursuant to a consent decree. EPA has completed a research effort pursuant to CWA section 104(v) and the consent decree to develop the scientific support for the Agency's water quality criteria recommendations. In implementing its clear statutory authority to publish recommended criteria for protection of primary contact recreation uses, EPA will have the

[68] *Id.*

[69] *Id.*

[70] CWA section 304(a)(9).

opportunity to address what EPA believes to be the appropriate level of protection for people that swim in coastal and Great Lakes waters.

Although the BEACH Act amendments do not direct EPA to develop updated water quality criteria recommendations for waters other than coastal and Great Lakes waters, EPA has authority under CWA section 304(a) to update its 1986 recommendations for all inland waters. The knowledge gained through the research developed to support issuance of revised water quality criteria recommendations pursuant to the BEACH Act amendments could be considered in deciding whether to issue revised criteria for inland waters. The new data could help EPA to ensure that its recommendations for those waters are based on the best science available and reflect levels of risk the Agency currently believes appropriate. While updated water quality criteria recommendations could benefit all populations of swimmers, those populations would include communities in urban areas whose primary recreational opportunities may be in urban waters.

B. State or Tribal Water Quality Standards

The CWA requires states and authorized tribes to review their water quality standards every three years and submit the results of their reviews to EPA.[71] EPA must approve or disapprove all new or revised state or tribal water quality standards pursuant to section 303(c)(3). If EPA disapproves a state or tribal standard and the state or tribe does not revise its disapproved standard as necessary, EPA is required to promulgate a revised standard.[72] The Administrator is also required to promulgate a new or revised standard for a state or tribe whenever she determines that such a standard is necessary to meet the requirements of the CWA and the state or tribe does not act to adopt an appropriate standard.[73]

(1) *EPA Authorities for Providing Protection from Adverse Effects from Fish Consumption by Overburdened Populations*

EPA has issued guidance interpreting CWA section 101(a)(2) uses to include, at a minimum, uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish. In other words, EPA views "fishable" to mean not only that fish and shellfish can thrive in a water body, but also that, when caught, fish and shellfish can safely be eaten by humans.[74]

(a) Designated Fishing Uses

EPA regulations currently provide that all waters must be designated for the protection of aquatic life (which would include fishing), unless the state or tribe documents to EPA's satisfaction that such uses are not attainable.[75] Designated fishing uses generally do not specify

[71] CWA section 303(c)(1).

[72] CWA section 303(c)(4)(A).

[73] CWA section 303(c)(4)(B).

[74] Letter from Geoffrey H. Grubbs, Director, EPA Office of Science and Technology, and Robert H. Wayland, III, Director, EPA Office of Wetlands, Oceans and Watersheds (Oct. 24, 2000).

[75] 40 C.F.R. § 131.10(j).

the level of fish consumption to be protected. The level of fish consumption to be protected is generally identified by states and tribes in their adoption of water quality criteria.

(b) Water Quality Criteria to Protect Fishing Uses

As discussed above, EPA's guidance recommends that states and tribes, when adopting designated uses to protect fish consumption, adjust the fish consumption levels or values used to develop criteria to protect the "fishable" use, so that it will protect fish consumption by recreational and subsistence fishers. Protecting recreational and subsistence fishing can be an important element of advancing environmental justice where recreational and/or subsistence fishing is common among minority, low-income, and indigenous populations. Executive Order 12898 on environmental justice, Section 4-4, expressly addresses subsistence consumption of fish.

Under EPA's regulations, in reviewing state or tribal water quality standards, EPA would have the discretionary authority to consider all available information to determine if the state or tribal standards are adequately protecting overburdened communities. EPA Regional Offices could disapprove criteria adopted to protect designated fishing uses if EPA deemed the criteria insufficiently protective of highly exposed populations fishing, or expected to fish, in such waters. In the event EPA disapproves a state or tribal submission, EPA is authorized, and directed, to promulgate a new or revised standard for the state or tribe if the state or tribe does not adopt the necessary standard.

As early as 1995, EPA promulgated water quality criteria regulations for the Great Lakes based on protection of a population more highly exposed than the general population. EPA based its human health criteria on protecting consumption that "represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing populations."[76] While that rulemaking did not address overburdened communities, it is an example of EPA's exercise of its authority to promulgate criteria to protect more highly exposed populations.

(2) *EPA Authorities for Providing Protection for Populations Recreating in Urban Waters*

Ensuring that urban waters are appropriately designated to protect recreational uses could be an important element in advancing environmental justice where recreational uses are common among minority, low-income, and indigenous populations in urban waters. In 2009, EPA exercised its CWA statutory authority to safeguard primary contact recreation uses for the Mississippi River, including segments of the river that flow past St. Louis, Missouri. EPA exercised its authority under CWA section 303(c)(4)(B) in determining that new or revised designated uses were necessary for those segments, because the state had failed to demonstrate that the primary contact recreation uses were not attainable. More recently, in May 2011, EPA exercised its CWA section 303(c)(4)(B) authority with respect to primary contact recreation uses for certain waters within the Chicago Area Waterways in Illinois. EPA could give high priority when reviewing state or tribal standards to ensuring that urban waters (or other waters where it is known that highly exposed populations may recreate) are designated for primary contact recreation unless the state or tribe has demonstrated such use is unattainable.

[76] 60 Fed. Reg. 15374 (Mar. 23, 1995).

(3) *CWA Authorities for Establishing Water Quality Standards in Indian Country*

EPA has considered opportunities for increasing protection of surface waters in Indian country in the context of establishing water quality standards under the CWA. To date, EPA and tribes primarily have used two CWA authorities to establish CWA water quality standards for Indian country surface waters: promulgation by EPA of federal standards for such waters, and approval by EPA of tribal standards submitted by authorized Indian tribes for reservation waters. For federal promulgation, EPA has authority under section 303(c)(4)(B) of the CWA to make a determination that Indian country waters need new or revised standards even in the absence of a tribal submission. EPA used this authority in 1989 to promulgate federal water quality standards for one reservation: the Colville Indian Reservation located in the State of Washington.[77] In 1998 and 2003, EPA considered promulgating federal water quality standards for Indian country surface waters where such waters did not have EPA-approved water quality standards. EPA never finalized such standards for a variety of reasons, including the resource-intensive nature of this type of rulemaking and the many competing perspectives encountered regarding the standards that were being considered. For example, some Indian tribes affirmed their interests in preserving their sovereign prerogatives over their waters.

EPA has continued to consider issues relating to promulgating federal water quality standards for Indian country waters. Based on EPA's experience, however, it has become clear that such efforts can be extremely resource intensive and may not ultimately be successful given significant existing constraints on Agency resources as well as the need to balance the many competing perspectives that are necessarily raised regarding tribal sovereignty as well as significant public policy and technical issues that often accompany rulemaking. Subject to availability of resources, EPA remains open to considering promulgation of federal standards at the request of individual tribes.

EPA believes that more promising opportunities exist to address the issue by enhancing the ability of tribes to seek authorization to establish water quality standards under the CWA for reservation waters. As described below in Section VII.A of this Chapter and also in Section II.B of Chapter Five, section 518(e) of the CWA authorizes EPA to treat eligible Indian tribes in a similar manner as states (TAS) for a variety of CWA programs, including establishing water quality standards. To date, 47 federally recognized tribes have obtained TAS eligibility for water quality standards, and 38 of those tribes have adopted standards that EPA has approved for the tribes' reservation waters. EPA believes that such direct tribal involvement is best suited to implementing tribal sovereign decision-making and most effectively ensures that tribal needs and uses of water are addressed in the CWA water quality standards program. Many tribes have found, however, that the TAS process can be challenging and time-consuming. To address this problem, in Section II.B of Chapter Five, EPA discusses several possible options to streamline the process to enhance the ability of tribes to obtain TAS status for the water quality standards program.

Ultimately, when considering legal tools under the CWA authorities referenced in this document that may affect tribal interests, EPA will first consult with tribal governments before

[77] 40 C.F.R. § 131.35.

any decisions are made, consistent with the *EPA Policy on Consultation and Coordination with Indian Tribes*, which is discussed in Chapter Five.

(4) *EPA Authorities to Promote Greater Public Participation*

Consistent with CWA section 101(e), EPA also has discretionary authority to encourage states to improve public participation processes in the development of state water quality standards through greater outreach, including to minority, low-income, and indigenous populations, and by translating crucial public documents and notices for limited English speaking populations consistent with Section 5-5(b) of Executive Order 12898 on environmental justice.

III. IDENTIFYING IMPAIRED WATERS AND ESTABLISHING TMDLS

Section 303(d) of the CWA requires states to identify waters not expected to meet water quality standards after implementation of existing pollution control requirements, and to establish total maximum daily loads (TMDLs) for such waters on a priority basis. TMDLs calculate the total pollutant load that can be introduced to a water body consistent with attainment of water quality standards, and allocates that load among known pollution sources. NPDES permits issued subsequent to TMDL development must include limitations consistent with the TMDL. EPA must approve or disapprove state lists and TMDLs and, if it disapproves, must establish lists and TMDLs for the states.[78] Some courts have held that EPA has a mandatory duty to establish TMDLs where states fail to act.

EPA has an obligation to ensure that states: (1) identify waters on section 303(d) lists that do not meet water quality standards; and (2) establish TMDLs for those waters. Section 303(d)(1)(A) of the CWA requires states to establish priority rankings that take into account the severity of the pollution and the uses to be made of the waters. States have broad discretion in prioritizing waters. Although EPA reviews state submissions to confirm that states have prioritized waters according to the statutory factors, the Agency does not approve the States' prioritizations.

EPA could examine the need to improve public participation in the section 303(d) process (*e.g.*, through greater outreach, including to minority, low-income, and indigenous populations, and by translating crucial public documents and notices for limited English speaking populations). EPA would have clear authority to carry out these actions when the Agency is providing for public participation.

EPA could also take impacts on minority, low-income, and indigenous populations into account in deciding how to allocate the waste load and load allocations when establishing TMDLs. EPA's long-standing position is that states (and EPA) have broad discretion in deciding how to assign allocations when establishing TMDLs. If pollutant loads would particularly affect overburdened communities, possibly because of significant exposures to other pollutants, it might be reasonable for EPA to exercise its discretion by reducing load allocations to sources that would directly impact those communities. It might also be possible for EPA to amend existing regulations to require consideration of impacts on overburdened communities in

[78] 40 C.F.R. § 130.7; *see* CWA section 303(d).

allocating loads. Because EPA's position has been that states and EPA have broad discretion in setting load allocations, promulgating regulations that would constrain such discretion and require consideration of impacts on overburdened communities would be a new and untested requirement.

IV. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM PERMIT PROGRAM

National Pollutant Discharge Elimination System (NPDES) permits are the primary way discharges of pollutants to waters of the United States are regulated. Currently, 46 states are authorized to issue NPDES permits, while EPA remains the permitting authority in four states, the District of Columbia, and U.S. territories. EPA is also the permitting authority on most tribal lands and for federal facilities in many states.

NPDES permits must contain: (1) technology-based limitations that reflect the pollution reduction achieved through particular equipment or process changes, without reference to the effect on the receiving water; and (2) where necessary, more stringent limitations representing that level of control necessary to ensure that the receiving waters achieve water quality standards. The Clean Water Act does not appear to provide any general authority to impose conditions on permits based on environmental justice considerations that are unconnected to water quality impacts or technology-based limitations. The CWA does, however, authorize the permit writer to impose monitoring, reporting, and recordkeeping requirements in permits as necessary to assure compliance with those permit limitations. Monitoring, reporting, and recordkeeping requirements can be useful tools to promote public understanding of the pollutant loadings discharged by the facility.

Environmental justice considerations could also be taken into account in setting permitting priorities and improving public participation in the permitting process. In addition, in implementing the NPDES statutory and regulatory authorities, EPA would have discretionary authority to take environmental justice considerations into account in the following ways:

- Provide technical assistance to Indian tribes on water pollution prevention programs, where appropriate (CWA section 104(a)).

- Conduct public investigations concerning pollution of any navigable waters and report on the results of such investigations (CWA section 104(a)(3)).

- Consider whether to include additional reporting requirements, such as requiring additional reports to be submitted to EPA where they can be made publicly available, to address environmental justice issues and focus attention on minority, low-income, and indigenous populations, where appropriate (CWA section 402(a)).

- Provide guidance to Regional Offices on how to consider environmental justice when conducting oversight of state NPDES programs. For example, provide guidance on changes to the Memorandums of Agreement between EPA and authorized states to ensure review of permits in overburdened communities.

- Consider cumulative impacts to impaired waters, focusing attention on waters affecting minority, low-income, and indigenous populations when new permits are proposed (CWA section 402(a)).

- Consider impacts on minority, low-income, and indigenous populations when deciding whether to object to a state-issued permit for failure to comply with the CWA (CWA section 402(d)).

- Where EPA issues permits, continually evaluate whether new information regarding human health impacts, especially among populations who are already overburdened, constitutes cause to modify permits.

- Focus attention on minority, low-income, and indigenous populations when determining whether to designate a small municipal separate storm sewer system for coverage under the NPDES storm water discharge program[79] or an animal feeding operation as a "significant contributor of pollution to the waters of the United States" and therefore a concentrated animal feeding operation.[80]

- Under CWA section 302, EPA is authorized to establish effluent limitations for one or more point sources if the applicable technology-based requirements will not assure protection of public health and other concerns. This determination requires findings of a reasonable relationship between costs and benefits. The Agency has never used this authority, but could evaluate whether this authority could be used with respect to pollutants of concern to minority, low-income, and indigenous populations. EPA could use its authority under CWA section 402(a)(1) to incorporate such limitations in specific NPDES permits issued by EPA.

An example of how environmental justice factors could be considered in the NPDES permitting program is the memorandum entitled "Improving EPA Review of Appalachian Surface Coal Mining Operations under the Clean Water Act, National Environmental Policy Act, and the Environmental Justice Executive Order" (Surface Coal Mining Memorandum).[81] That memorandum, which was issued on July 21, 2011, provides guidance regarding how to apply the current regulatory and statutory requirements of the NPDES permitting program to surface coal mining projects in Appalachia, an area of concern for the environmental justice community. The guidance is intended to enhance the consideration of environmental justice factors when EPA Regional Offices are conducting oversight of the authorized state NPDES programs.

V. STORM WATER PROGRAMS AND REQUIREMENTS

Heavy precipitation and wet weather can have a big impact on minority, low-income, and indigenous populations, especially in urban centers. Combined sewer overflows are discharges from combined sewer systems that are designed to collect rainwater runoff, domestic sewage, and industrial wastewater in the same pipe. They are subject to NPDES permit requirements,

[79] 40 C.F.R. § 123.35.

[80] CWA section 402; 40 C.F.R. § 122.23.

[81] The memorandum is available at http://water.epa.gov/lawsregs/guidance/wetlands/mining.cfm#memo20100401.

including both technology-based and water quality-based requirements of the CWA.[82] Sanitary Sewer Overflows (SSO) are discharges from sanitary sewer systems that collect and transport sewage that flows into a publicly owned treatment works (POTW). Sanitary Sewer Systems are part of the CWA definition of publicly owned treatment works and are therefore subject to secondary treatment requirements and more stringent limits as necessary to meet water quality standards.[83] Municipal separate storm sewer systems (MS4), regulated under CWA section 402(p), are conveyances or systems of conveyances that are: owned by a state, city, town, village, or other public entity that discharges to waters of the United States; designed or used to collect or convey storm water (including storm drains, pipes, ditches, etc.); and are neither a combined sewer nor part of a POTW (sewage treatment plant). MS4 permittees are required to reduce pollutants in storm water discharges "to the maximum extent practicable" under CWA section 402(p)(3)(B)(iii), which also provides authority for MS4s permits to require additional pollutant controls. In addition, CWA section 402(p)(6) authorizes EPA to identify additional storm water discharges and to regulate such discharges to protect water quality.

Storm water discharges from point sources are treated differently from other point source discharges under the CWA. In 1987, Congress amended the CWA to add CWA section 402(p). This provision, which is specific to point source storm water discharges, requires implementation of a comprehensive approach to addressing storm water. Among other things, section 402(p)(1) created a temporary moratorium on NPDES permits for point source storm water discharges, except for storm water discharges listed in section 402(p)(2). Section 402(p)(6) instructed EPA to subsequently designate additional point source storm water discharges for regulation under the statute. EPA implemented sections 402(p)(2) and (6) through what are known as the Phase I and Phase II storm water regulations.[84] Once EPA identifies a discharge under those sections as requiring a permit, the discharge can be subject to applicable technology-based and water quality-based effluent limitations.

EPA has authority under the CWA to establish new, more stringent storm water requirements and standards for urban areas, which may result in substantial improvements for minority, low-income, and indigenous populations. Such efforts could include controlling combined sewer overflows, infiltration and inflow into sanitary sewers, discharges from municipal separate storm sewer systems, and EPA's new effort to designate storm water discharges not yet designated for inclusion in the storm water program.

A. Combined Sewer Overflows (CSOs)

During periods of rainfall or snowmelt, wastewater volume in a combined sewer system can exceed the capacity of the sewer system or treatment plant. When this happens, the excess wastewater flows directly into nearby streams, rivers or other water bodies, potentially exceeding applicable water quality standards and exposing populations to raw sewage. CSOs can contain storm water, untreated human and industrial waste, toxic pollutants and debris. CSOs have been a cause of water quality impairment as documented in CWA section 305(b) reports, and may

[82] CWA sections 301(b)(1)(A), 301(b)(2)(A), and 402(p) and (q).

[83] CWA section 301(b)(1)(B).

[84] *See* 40 C.F.R. §§ 122.26 and 122.30-37; *see also* 64 Fed. Reg. 68722 (Dec. 8, 1999); 55 Fed. Reg. 47990 (Nov. 16, 1990).

occur in streams or rivers frequented by the public, thus representing a potential hazard to human health and the environment.

CSOs are subject to permitting under the CWA. EPA's 1994 CSO Control Policy specifies the technology-based and water quality-based effluent limits that should be included in NPDES permits for CSOs.[85] Congress subsequently added section 402(q) to the CWA, which provides in part that "each permit, order or decree issued pursuant to this chapter after December 21, 2000 for a discharge from a municipal combined storm and sanitary sewer shall conform to the Combined Sewer Overflow Policy signed by the Administrator on April 11, 1994." That policy specified that NPDES permitting authorities issue or reissue permits to require compliance with the technology-based and water quality-based requirements of the CWA. Technology-based requirements include implementation of "nine minimum controls." In addition, permittees are required to develop "Long Term Control Plans" in order to meet water quality standards. EPA expects a permittee's long-term control plan to give the highest priority to controlling overflows in sensitive areas. Sensitive areas include outstanding national resource waters, national marine sanctuaries, waters with threatened or endangered species or their habitat, waters with primary contact recreation, public drinking water intakes or their designated protection areas, and shellfish beds.[86] For such areas, the CSO Long Term Control Plan should prohibit new or significantly increased overflows, eliminate or relocate overflows wherever physically possible and economically achievable, and provide for treatment where necessary to meet applicable water quality standards.

There are approximately 836 permits in the United States for combined sewer systems. Affected communities are located in 32 states (including the District of Columbia), primarily concentrated in the Northeast and Midwest, and serve approximately 46 million people. EPA can bring additional focus to CSO-related issues in minority, low-income, and indigenous populations to advance environmental justice. EPA could evaluate existing Long Term Control Plans to see if they adequately address environmental justice considerations and seek modification of those Plans found to be lacking. Specifically, EPA could focus on whether the locations of overflows are causing water quality impairments that pose a particular risk to minority, low-income, and indigenous populations. This could be a significant resource issue for the Regional Offices and states. Further EPA could provide technical assistance where Long Term Control Plans are still being developed, with an eye toward environmental justice. Strengthening the oversight of the implementation of CSO controls could have a beneficial impact in urban population centers.

B. Sanitary Sewer Overflows (SSOs)

In 2010, EPA estimated that there are between 23,000 and 75,000 sanitary sewer overflow events per year. Of these, EPA estimated that 50% are caused by blockages and 25% are caused by wet weather infiltration or inflow into the pipes. EPA estimated that these overflows accounted for a total volume of between three and ten billion gallons of sanitary sewer wastewater discharged per year. They may overflow into areas that the public frequents, such as parks, beaches, backyards, city streets, and playgrounds.

[85] 59 Fed. Reg. 18688 (April 19, 1994).

[86] 59 Fed. Reg. at 18692.

Under the CWA, sanitary sewers are part of the definition of publicly owned treatment works. Therefore, they are subject to secondary treatment requirements and more stringent limits as necessary to meet applicable water quality standards. As such, overflows are generally prohibited. EPA and state NPDES inspectors assess collection systems and treatment plants to evaluate compliance with permit conditions, including proper operation and maintenance practices. These permit conditions are based on 40 C.F.R. § 122.41(e), which provides: "The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit."

Some suburban and exurban systems, called "satellite" systems, connect to urban systems but are generally not covered by the same permit. The unpermitted or separately permitted satellite systems may contribute large flows to urban systems or may be improperly operated or maintained. Yet they may not be co-permittees with the treatment plants and frequently do not bear a proportionate burden of the sewage treatment costs. In January 2005, EPA issued a "Guide for Evaluating Capacity, Management, Operation, and Maintenance (CMOM) Programs at Sanitary Sewer Collection Systems,"[87] which recommends practices for permittees and EPA and state inspectors to consider in assessing permit compliance or in writing settlement agreements. The guidance advises that satellite communities should not be allowed to contribute excessive flow to wastewater treatment plants, which are often located in financially stressed urban areas that may have an impact on minority, low-income, and indigenous urban populations.

In 2001, EPA proposed regulations codifying many of the suggested CMOM practices, including restrictions on satellite flow to sanitary sewer systems, but the rulemaking was never completed. Authority to regulate satellite flows into a sanitary sewer collection system can be predicated on the theory that either the satellite is itself discharging through the treatment works to a water of the United States or that the satellite and the downstream collection systems are both part of the POTW under the definition of "treatment works" in CWA section 212(2)(A) and, as such, certain effluent limitations could be placed on each entity that is part of the POTW. Pursuing a regulation to strengthen the requirements for satellite systems could be an important opportunity to level the playing field between suburban/exurban collections systems and communities and downstream urban communities. The regulation could potentially also address the problem of "basement backups," which may occur often in the homes of minority, low-income, and indigenous populations.

C. Municipal Separate Storm Sewer Systems (MS4s)

Section 402(p)(2)(C) and (D) of the CWA requires EPA to issue NPDES permits for storm water discharges from certain municipal separate storm sewer systems (MS4s). In plain terms, MS4s are discrete conveyances of storm water to waters of the United States. "Municipal separate storm sewer" means, among other things, "a conveyance or system of conveyances (including roads with drainage systems, municipal streets, catch basins, curbs, gutters, ditches, man-made channels, or storm drains) . . . [o]wned or operated by a . . . county. . . or other public

[87] The Guide is available at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30006OW9.txt.

body (created by or pursuant to State law) . . . [and] [d]esigned or used for collecting or conveying storm water . . . ." [88]

EPA or states issue permits to regulated MS4s to control their discharges. Such permits "shall require controls to reduce the discharge of pollutants to the maximum extent practicable, including management practices, control techniques and systems, design and engineering methods, and such other provisions as the Administrator or the State determines appropriate for the control of such pollutants."[89]

Under section 402(p)(3)(B)(iii), EPA can focus attention on minority, low-income, and indigenous populations in establishing more specific requirements for MS4 permits. For example, where an overburdened community uses a particular resource, such as engaging in subsistence fishing in urban waters, the permitting authority could impose requirements tailored to the need of that particular community.

D. Other Storm Water Point Source Discharges Not Yet Regulated

EPA has the legal authority under the CWA to regulate discharges of storm water from impervious surfaces or developed property based on the findings described in CWA section 402(p)(6).

Section 402(p)(6) provides:

> Not later than October 1, 1993, the Administrator, in consultation with State and local officials, shall issue regulations (based on the results of studies conducted under paragraph (5)) which designate stormwater discharges, other than those discharges described in paragraph (2), to be regulated to protect water quality and shall establish a comprehensive program to regulate such designated sources. The program shall, at a minimum, (A) establish priorities, (B) establish requirements for State stormwater management programs, and (C) establish expeditious deadlines. The program may include performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate.

EPA has broad discretion to identify discharges of storm water as requiring regulation under CWA section 402(p)(6). Under this provision, EPA can regulate long-term storm water discharges from development/impervious surfaces by making a finding that discharges from development/impervious surfaces warrant regulation in order "to protect water quality."

EPA also has broad discretion to determine how to control those designated discharges.[90] The last sentence of section 402(p)(6), which states that "[t]he program may include performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate[,]" gives EPA discretion to determine what kinds of program elements to establish. EPA has the authority to issue guidance or a rule that would be directly applicable to point

[88] 40 C.F.R. § 122.26(b)(8).

[89] CWA section 402(p)(3)(B)(iii).

[90] *See Envtl. Defense Ctr. v. EPA*, 344 F.3d 832, 844 (9th Cir. 2003); *see also Conservation Law Found. v. Hannaford Bros. Co.*, 327 F.Supp.2d 325, 330-32 (D. Vt. 2004), *aff'd*, 2005 WL 1712899 (2d Cir. 2005).

source discharges rather than be implemented through NPDES permits. Also, the express reference to "establishing priorities" in section 402(p)(6) gives EPA a basis to decide what discharges are most important to regulate, and it may decide not to address all discharges at one time. EPA could use the broad discretion that section 402(p)(6) provides to advance environmental justice in taking actions under section 402(p)(6).

Under CWA section 402(p)(2)(E), EPA has authority to designate through informal adjudication additional point sources of storm water discharges to be regulated under the NPDES program. EPA has implemented this "residual designation" authority in regulations at 40 C.F.R. §§ 122.26(a)(9)(C) and (D). These regulations provide that the permitting authority or the Regional Administrator may designate and require operators of storm water discharges or a category of discharges to obtain a permit if the authority determines that the discharge or category of discharges contributes to a water quality standards violation or is a significant contributor of pollutants to waters of the United States. Alternatively, a designation may be based on finding that storm water controls are needed for the discharge based on waste load allocations that are part of a TMDL that address the pollutants of concern.

EPA could choose to make greater use of its residual designation authority in affected areas to advance environmental justice. For example, in an overburdened community, EPA could decide that currently unregulated sources of storm water, *e.g.*, parking lots or impervious surfaces over a certain size, would be designated for regulation under the NPDES permit program. This could result in such facilities needing to make changes in order to better control their storm water. These controls could result in healthier urban streams, thereby providing benefits not only to the ecosystem itself, but also to the surrounding communities. Storm water controls yield the additional benefit of transforming gray urban environments into more inviting green spaces, enhancing recreational opportunities and enhancing quality of life.

Like the residual designation authority described in the preceding paragraphs, EPA has authority to designate an animal feeding operation (AFO) as a "concentrated animal feeding operation" (CAFO) requiring an NPDES permit. A CAFO is a "point source" under section 502(14) of the CWA. EPA regulations at 40 C.F.R. § 122.23(c) authorize the State Director or Regional Administrator in some circumstances to designate a CAFO upon a determination that it is a significant contributor of pollutants to waters of the United States. The regulations list factors to be considered in designating CAFOs, including "[o]ther relevant factors."[91] Although EPA has not yet exercised its CAFO designation authority to a significant extent, EPA could increase designations and consider potential impacts on minority, low-income, and indigenous populations as a "relevant factor." Such designation currently requires an onsite inspection and, if the AFO contains fewer than a specified number of animals, a determination that pollutants are discharged to waters of the United States through a manmade ditch, flushing system, or other similar manmade device or that pollutants are discharged directly into waters of the United States that originate outside the facility and pass over, across or through the facility or otherwise come into contact with the animals confined in the operation.[92]

[91] 40 C.F.R. § 122.23(c)(2)(v).

[92] 40 C.F.R. § 122.23(c)(3).

VI. SECTION 404 WETLANDS PROGRAM

Section 404 permits authorize the discharge of "dredged or fill material" to waters of the United States. The types of activities regulated under section 404 include filling of wetlands to create dry land for development, construction of berms or dams to create water impoundments and discharges of material dredged from waterways to maintain or improve navigation. Section 404 permits issued by the U.S. Army Corps of Engineers must satisfy two sets of standards: the Corps' "public interest review" and the CWA section 404(b)(1) guidelines promulgated by EPA. The public interest review is a balancing test that requires the Corps to consider a number of factors, including economics, fish and wildlife values, safety, food and fiber production and, in general, the needs and welfare of the people.[93] The section 404(b)(1) guidelines provide that no permit shall issue if: (1) there are practicable, environmentally less damaging alternatives; (2) the discharge would violate water quality standards or jeopardize threatened or endangered species; (3) the discharge would cause significant degradation to the aquatic ecosystem; or (4) if all reasonable steps have not been taken to avoid or minimize adverse effects of the discharge.[94] The 2011 Surface Coal Mining Memorandum provides the following guidance to the relevant Regional Administrators:

> [W]e recommend that Regions work collaboratively with the Corps to analyze the potential for disproportionately high and adverse human health or environmental effects on low-income and minority populations, including impacts to water supplies and fisheries, from issuance of a permit for surface coal mining activities in waters of the U.S. . . . .[95]

The broadest potential authority to consider environmental justice in the CWA section 404 program rests with the U.S. Army Corps of Engineers, which conducts a broad "public interest review" in determining whether to issue a section 404 permit. In evaluating the "probable impacts of the proposed activity and its intended use on the public interest," the Corps is authorized to consider, among other things, aesthetics, general environmental concerns, safety, and the needs and welfare of the people.[96] This public interest review could include environmental justice considerations. As part of the permit-issuance process, EPA may comment on and encourage the U.S. Army Corps of Engineers to consider cultural, social subsistence, "way of life," historic values and cumulative impacts when conducting public interest review.[97]

EPA has discretionary oversight authority over the Corps' administration of the section 404 program (*i.e.*, EPA comments on permit applications, can elevate regional Corps permit decisions to the Washington, D.C. level, and can "veto" Corps permit decisions under section 404(c) that would have "an unacceptable adverse effect on municipal water supplies, shellfish beds and fishery areas (including spawning and breeding areas), wildlife, or recreational areas."

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[93] 33 C.F.R. § 320.4(a).

[94] 40 C.F.R. § 230.10.

[95] Surface Coal Mining Memorandum at 39. See, *supra*, Section IV of this Chapter.

[96] 33 C.F.R. § 320.4(a).

[97] 33 C.F.R. § 320.4(a)(1).

EPA can use these authorities in response to potential degradation of these public resources (*e.g.*, recreational or fishing areas that are important to at-risk populations) from impacts of surface coal mining in Appalachia that may have an adverse health or environmental effect on a minority, low-income, or indigenous population. Such impacts can be addressed when they result directly from a discharge of dredged or fill material (*e.g.*, the filling of a water body), or are a secondary effect of the permitted activity (*e.g.*, the fill will allow construction of an industrial facility that will cause water pollution due to runoff). EPA can raise these concerns when sending Agency comments during the Corps' public comment period and can include consideration of these issues when exercising the discretion to "veto" under section 404(c). EPA has used this authority to completion 12 times and has discussed environmental justice considerations in some of its final 404(c) determinations.[98]

EPA also may consider environmental justice relating to aquatic ecosystem degradation when determining whether to exercise veto authority or object to state-issued permits under CWA section 404(j).

VII. AUTHORIZATION OF TRIBAL PROGRAMS

A. Treatment in the Same Manner as States

Section 518 of the CWA and its implementing regulations provide that EPA may treat eligible Indian tribes in the same manner as states for purposes of many programs under the Clean Water Act, including for grants, adoption of water quality standards, issuance of water quality certifications and issuance of CWA section 402 and 404 permits. EPA has issued regulations implementing the treatment-as-a-state (TAS) provisions in section 518(e) and has granted applicant tribes TAS status for various programs under the CWA. Notably, a number of tribes have TAS status for purposes of CWA grants under section 106 and for water quality standards and certifications under sections 303(c) and 401 of the CWA. Currently, 47 tribes have TAS status for the water quality standards program and 38 of those tribes have EPA-approved water quality standards for their reservation waters.

EPA's implementation of TAS statutory authority over the past 20 years and its support of the adoption of environmental protections on Indian lands have allowed the Agency to advance environmental justice. As discussed in Chapter Five, EPA is exploring other ways to encourage and support tribal applications for TAS and adoption of tribal water quality standards for reservation waters.

B. Grants to Alaska to Improve Sanitation in Rural and Native Villages

CWA section 113 authorizes EPA to enter into agreements with the State of Alaska to carry out demonstration projects for the provision of safe water and elimination of pollution in native villages in Alaska. EPA tribal programs are discussed more fully in Chapter Five and tribal grants programs are discussed in Chapter Seven.

[98] *See, e.g.*, Final Determination of the Assistant Administrator for Water Pursuant to Section 404(c) of the Clean Water Act Concerning the Proposed Yazoo Backwater Area Pumps Project in Issaquena County, MS, September 19, 2008.

VIII. TOXIC POLLUTANT EFFLUENT STANDARDS AND PROHIBITIONS

Section 307(a)(2) of the CWA authorizes the Administrator to propose and promulgate an effluent standard or prohibition for a toxic pollutant applicable to a class or category of point sources taking into account a number of factors about the pollutant, including its toxicity, persistence, degradability, and potential presence in aquatic organisms. The Agency last used this authority in 1979. Pursuant to CWA section 307(a)(4), EPA promulgated effluent standards and prohibitions following "formal" rulemaking on the record. Promulgated effluent standards and prohibitions exist for six classes of toxic pollutants including pesticides and polychlorinated biphenyls (PCBs).[99] For example, the effluent standards and prohibitions for pesticides generally apply to manufacturers and formulators of the named pesticides and set either stringent allowable effluent discharge standards or prohibitions on discharge.

Section 307(a) of the CWA differs from the Agency's technology-based effluent limitations guidelines because it does not require that the Agency consider technological feasibility, cost or economic impact in setting effluent standards or prohibitions (although the Agency did consider such factors during the 1970's hearings). The onerous requirement that section 307(a) standards and prohibitions be promulgated through "formal" rulemaking (essentially a trial with cross-examination of expert witnesses) led the Agency to abandon the use of section 307(a) and instead simply promulgate effluent limitations guidelines pursuant to CWA sections 301 and 304. The burdens associated with formal rulemaking would continue to exist if the Agency chose to pursue use of section 307(a). The Agency, however, could explore whether the discretionary authorities in section 307(a) might be uniquely appropriate for addressing concerns about environmental protection of minority, low-income, and indigenous populations.

IX. SEWAGE SLUDGE

Section 405 of the CWA establishes the framework for sewage sludge management and disposal. The regulations are found at 40 C.F.R. Part 503. EPA issued standards for sewage sludge in 1993 that apply to ten metals and one pathogen (salmonella) and indicators of fecal contamination. The standards also specify requirements for biosolids land application, incineration and surface disposal.

EPA conducts biennial reviews of the standards as required by the CWA. EPA staff have identified additional work that may be appropriate for biosolids, including working on analytical methods for emerging contaminants found in biosolids, evaluating the risk assessment for biosolids and improving the Agency's understanding of treatment effectiveness. EPA could consider whether the current risk assessment, based on a sensitive child's exposure, is a sufficient surrogate for exposure of the members of overburdened communities.

X. RESEARCH, INVESTIGATIONS, TRAINING AND INFORMATION

The CWA provides broad authority for EPA to gather data, conduct research, and provide technical and grant assistance that could be used to advance environmental justice by focusing attention on, and promoting participation in, environmental decision-making by minority, low-income, and indigenous populations. Among these authorities are: (1) section 104(b) – collect and disseminate information on chemical, physical and biological effects of varying water

[99] *See* 40 C.F.R. Part 129.

quality and other information pertaining to pollution and the prevention, reduction and elimination thereof; (2) section 104(*1*) – collect and disseminate scientific knowledge on effects and control of pesticides in water; (3) section 104(p) – study and research methods of preventing, reducing, or eliminating pollution from agriculture; and (4) section 104(q) – research and investigation of methods of preventing, reducing, storing, collecting, treating or otherwise eliminating pollution from sewage in rural areas

An example of how EPA has used these authorities in recent years is EPA's issuance of fish consumption advisories pursuant to the authorities in section 104(b). Using the authorities in CWA section 104(b), EPA collected information on pollutant levels in both surface water and fish tissue, and issued information regarding risks associated with consumption of certain fish species. EPA has discretionary authority to consider environmental justice when deciding whether and what type of fish consumption advisories to issue in the future.

SAFE DRINKING WATER ACT

The Safe Drinking Water Act (SDWA) includes two separate regulatory programs. The public water supply (PWS) program establishes requirements for the quality of drinking water supplied by public water systems. This program establishes federal requirements that are directly implemented by EPA and approved states or tribes; there is no federal permit requirement. The underground injection control (UIC) program establishes controls on the underground injection of fluids in order to protect underground sources of drinking water. This program is implemented through permits (including permits by rule) issued by EPA or approved states or tribes.[100] The following section analyzes how EPA may address environmental justice considerations under both of these programs.

I. PUBLIC WATER SUPPLY PROGRAM

Under the SDWA PWS program, the Administrator is to establish national primary drinking water regulations that set either maximum levels or treatment requirements for contaminants that may occur in public water systems and have adverse effects on public health. The SDWA applies only to public water systems, defined in the SDWA as systems providing water through constructed conveyances to at least 15 service connections or regularly serving at least 25 individuals. The PWS program does not apply to systems smaller than the criteria above. Upon application of states and eligible tribes, the Administrator may authorize them to administer the PWS program. All but one state have authority (or "primacy") to administer the program. EPA administers the program in that state and in the District of Columbia. In addition, one tribe has primacy. EPA administers the program in all other situations.

[100] Like the CWA, the SDWA allows federally recognized Indian tribes to assume responsibility for administering SDWA regulatory programs. Specifically, under section 300j-11 of the SDWA, eligible tribes may administer both the PWS and UIC programs, as discussed further in Chapter Five.

A. Unregulated Contaminant Monitoring Rules

The Agency issues a new unregulated contaminant rule every five years with a new list of up to 30 contaminants.[101] This rulemaking provides crucial information for EPA's decision whether to regulate new contaminants. EPA can use this authority to gather information that may help to identify possible environmental justice considerations associated with currently unregulated contaminants, including those that may pose a special risk to minority, low-income, or indigenous populations.

B. Public Notification/Consumer Confidence Reports

The Agency is implementing public notification regulations and other right-to-know provisions of the SDWA, which were amended to ensure greater public notice of noncompliance problems and which already require notices in plain English and other relevant languages. EPA could consider updating these rules or provide guidance on these requirements to promote more aggressive outreach to these populations, particularly those with limited English proficiency.

C. Lead Rules

EPA promulgated a stringent rule for controlling lead in drinking water, and has updated this rule multiple times, including amendments made in 2007 to address concerns arising from exposure to lead in drinking water in the District of Columbia. Through continued implementation of this rule, and the next phase of revisions EPA is considering to the rule, EPA can help address the health concerns of minority, low-income, or indigenous populations exposed to high lead levels. In addition, EPA can provide outreach concerning the newly amended definition of "lead-free" in the SDWA to promote lowered levels of lead in consumer plumbing fixtures. [102]

D. Ground Water Rule

In 2006, EPA promulgated the Ground Water Rule to provide for increased protection against microbial pathogens in public water systems that use ground water sources, which are typically smaller and/or more rural water systems.[103] EPA did so in accordance with the SDWA as amended, which requires EPA to promulgate National Primary Drinking Water Regulations requiring disinfection as a treatment technique for all public water systems, including surface water systems and, as necessary, ground water systems. In the Ground Water Rule, EPA established a risk-targeted approach to target ground water systems that are susceptible to fecal contamination to take corrective action to reduce cases of illnesses and deaths due to exposure to microbial pathogens. EPA could evaluate how implementation of the Ground Water Rule has impacted overburdened communities, and consider changes or additional guidance accordingly.

E. Operator Certification and Capacity Development

EPA has authority to revise operator certification guidelines. Such revisions could be designed to enhance the development of better drinking water operator training programs for systems serving overburdened communities. EPA could also review state capacity development

[101] SDWA section 1445(a)(2).

[102] SDWA sections 1412 and 1417.

[103] The rule, which was published at 71 Fed. Reg. 65574 (Nov. 8, 2006) and amended by 71 Fed. Reg. 67427 (Nov. 21, 2006), is codified at 40 C.F.R. Part 141, Subpart S.

strategies to focus additional attention on improving the technical, managerial and financial capacity of small water systems.[104]

II. UNDERGROUND INJECTION CONTROL (UIC) PROGRAM

Under the Underground Injection Control (UIC) program, there may be opportunities to protect drinking water for minority, low-income, and indigenous populations through permit conditions, scrutiny of aquifer exemptions, and revisions to rules and guidance.

Under the UIC program, the Administrator must establish requirements for state UIC programs that will prevent the endangerment of drinking water sources by underground injection. EPA has promulgated a series of such requirements beginning in 1980. The SDWA also provides that states and eligible tribes may apply to EPA for primary enforcement responsibility ("primacy") to administer the UIC program. EPA must establish a UIC program in states that do not seek this responsibility or fail to meet the minimum requirements established by EPA. EPA also generally implements the program in Indian country since only two tribes currently have primacy for the program.

A. Permitting

Underground injection must be authorized by permit or rule. Where EPA issues a permit, it may include conditions to protect drinking water for minority, low-income, and indigenous populations. The SDWA provides that EPA can deny permits or establish permit limits where such injection may "endanger" public health. "Endangerment" is defined to include any injection that may result in the presence of a contaminant in a drinking water supply that "may . . . adversely affect the health of persons."[105] As a result, in those states, territories, and federal lands where EPA issues UIC permits, EPA may establish any necessary permit requirements under 40 C.F.R. § 144.52 when EPA finds that injection activity may result in drinking water supply contamination that may adversely affect the health of persons, including minority, low-income, and indigenous populations. Based on its analysis of the effect of Executive Order 12898, the Environmental Appeals Board (EAB) has considered the scope of EPA's authority to address environmental justice in the UIC permitting program.[106] Notably, in the *Envotech, L.P.* decision, the EAB recognized that under the UIC permitting program EPA may expand public participation and exercise its discretion under the SDWA to "impose on a case-by-case basis, permit conditions 'necessary to prevent the migration of fluids into underground sources of drinking water'" in order to protect underground sources of drinking water "upon which the minority or low-income community may rely."[107]

EPA may impose permit conditions on a case-by-case basis to ensure that proposed injection wells do not threaten the drinking water of minority, low-income, and indigenous populations. EPA's authority applies in all cases, "regardless of the composition of the

[104] SDWA sections 1419 and 1420.

[105] SDWA section 1421(d).

[106] *See generally In re Envotech, L.P.*, 6 E.A.D. 260, 278-82 (EAB 1996) (citing *In re Chemical Waste Management of Indiana*, 6 E.A.D. 66 (EAB 1995) and the similar permitting processes in RCRA and the SDWA).

[107] *Id. at 281* (citing 40 C.F.R. §144.52(a)(9)).

community surrounding the proposed injection site."[108] Nevertheless, in response to an environmental justice concern, the EAB has stated EPA may and "should, as a matter of policy, exercise its discretion under 40 C.F.R. § 144.52(a)(9) to include within its assessment of the proposed well an analysis focusing particularly on the minority or low-income community whose drinking water is alleged to be threatened."[109]

B. Aquifer Exemptions

EPA rules allow states to affirmatively exclude certain aquifers from UIC protection, where the aquifer has no real potential to be used as a drinking water source (*e.g.*, because of the high level of solids content).[110] In evaluating aquifer exemption requests from states (where states have primacy) or permit applicants (where EPA has primacy), EPA may be able to consider environmental justice issues. Public notice must be provided before EPA approves an aquifer exemption request. EPA could consider the importance of promoting meaningful participation in decision-making by minority, low-income, and indigenous populations in determining whether the public notice was adequate to reach them. In addition, EPA could consider implications for minority, low-income, and indigenous populations when determining whether the aquifer exemption request meets the criteria for exempted aquifers in 40 C.F.R. § 146.4, *e.g.*, whether there has been an adequate investigation as to whether the aquifer is currently serving as a source for drinking water for overburdened communities.

C. Regulatory and Guidance Revisions

EPA could revise the current regulations and guidance for all types of UIC wells to ensure focused attention on minority, low-income, and indigenous populations with regard to potential endangerment of drinking water supplies by injection. For example, EPA could review its regulations and guidance to determine whether changes to its regulations are necessary to address mountaintop mining risks to underground sources of drinking water, in response to allegations that such operations result in discharges of mining effluent into injection wells that may be contaminating groundwater.

III. SOURCE WATER PROTECTION PROGRAMS

Section 1424(e) of the SDWA allows EPA to determine that an area has an aquifer which is the sole or principal drinking water source for the area and would create a significant health hazard if contaminated. Once EPA has made this determination and provided notice of it, no commitment for federal financial assistance may be entered into for any project EPA determines might contaminate the designated aquifer through a discharge zone so as to create a significant hazard to public health. Under this authority, EPA could solicit participation in identification, designation, and protection of sole source aquifers. EPA could use this authority to identify and protect aquifers that serve overburdened communities.

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[108] *Id.*

[109] *Id.* at 282.

[110] 40 C.F.R. § 144.1(g).

IV. RESEARCH, REPORTING, INFORMATION GATHERING, TECHNICAL ASSISTANCE

The SDWA gives EPA authority to perform activities in the following areas:

- Research (SDWA section 1442(a)): Research and investigate concerns for minority, low-income, and indigenous populations.

- Research (SDWA section 1458): Conduct a continuing program of studies to identify groups "that may be at greater risk than the general population of adverse health effects from exposure to contaminants in drinking water," focusing attention on minority, low-income, and indigenous populations where they face greater risks.

- Monitoring (SDWA section 1445(g)): Establish and maintain a database of the occurrences of regulated and unregulated contaminants in public water systems in a manner that is widely accessible and easy to use by minority, low-income, and indigenous populations.

- Technical Assistance (SDWA section 1442(a)): Provide technical assistance to public water systems, including those serving minority, low-income, and indigenous populations.

MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT

The Marine Protection, Research, and Sanctuaries Act (MPRSA), commonly known as the Ocean Dumping Act, establishes a permitting program that covers the dumping of material into ocean waters. The ocean disposal of sewage sludge and industrial waste is expressly prohibited.

EPA administers permits for the dumping of all material other than dredged material, which is permitted by the U.S. Army Corps of Engineers subject to EPA review and concurrence. When issuing MPRSA permits, EPA is to determine whether the proposed dumping will "unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities."[111] EPA also is charged with designating sites at which permitted disposal may take place; these sites are to be located wherever feasible beyond the edge of the Outer Continental Shelf.

In considering permit applications and designating ocean dumping sites, EPA is authorized to take into account a variety of factors, including "[t]he effect of such dumping on human health and welfare, including economic . . . values," and, as such, could take into account the potential for disproportionate impacts on minority, low-income, and indigenous populations (particularly those that include subsistence consumers of sea food) from the proposed

[111] MPRSA section 102(a).

dumping.[112] In addition, the MPRSA provides specifically that EPA is to consider land-based alternatives to ocean dumping and the probable impact of requiring use of these alternatives "upon considerations affecting the public interest."[113] EPA could take impacts on these populations into account in evaluating alternative locations and methods of disposal of the material that is proposed to be dumped at sea. Ocean dumping permits also designate and include "such other matters as the Administrator . . . deems appropriate," which may include environmental justice considerations.[114]

[112] MPRSA section 102(a)(B).

[113] MPRSA section 102(a)(G).

[114] MPRSA section 104(a)(6).

CHAPTER THREE: SOLID WASTE AND EMERGENCY RESPONSE PROGRAMS

INTRODUCTION

This chapter discusses the Resource Conservation and Recovery Act,[115] the Emergency Planning and Community Right-to-Know Act,[116] and the Comprehensive Environmental Response, Compensation, and Liability Act,[117] As explained below, these statutes provide EPA various legal authorities to address environmental justice considerations.

RESOURCE CONSERVATION AND RECOVERY ACT

I. GENERAL AUTHORITY FOR ADDRESSING ENVIRONMENTAL JUSTICE – HAZARDOUS WASTE MANAGEMENT

The Resource Conservation and Recovery Act (RCRA) authorizes EPA to regulate the generation, transportation, treatment, storage, and disposal of hazardous wastes. RCRA requires EPA to promulgate regulations establishing such standards, applicable to generators, transporters, and owners and operators of hazardous waste treatment, storage, and disposal facilities "as may be necessary to protect human health and the environment."[118] RCRA section 7004(b) requires EPA to provide for "public participation in the development, revision, implementation, and enforcement of any regulation, guideline, information, or program." EPA may use these authorities to advance the fair treatment and meaningful participation of minority, low-income, and indigenous populations in the development of regulations, standards, and guidelines for hazardous waste management.

II. PERMITTING OF HAZARDOUS WASTE TREATMENT, STORAGE AND DISPOSAL FACILITIES

A. Omnibus Authority – RCRA Section 3005(c)(3)

The primary area of RCRA where environmental justice considerations have surfaced is in the permitting of hazardous waste treatment, storage, and disposal facilities (*e.g.*, incinerators, fuel blenders, and landfills). Pursuant to RCRA section 3005, EPA issues permits to such facilities if they demonstrate compliance with EPA regulations. Upon application by a state, EPA may authorize a state's hazardous waste program to operate in lieu of the federal program,[119] and to issue permits. The "omnibus" authority in RCRA section 3005(c)(3) provides

[115] 42 U.S.C. §§ 6901-6992k.

[116] 42 U.S.C. §§ 11001-11050.

[117] 42 U.S.C. §§ 9601- 9675.

[118] *See* RCRA sections 3002(a) (standards applicable to generators), 3003(a) (standards applicable to transporters), and 3004(a) (standards applicable to owners and operators of hazardous waste treatment, storage and disposal facilities).

[119] The state's program must be equivalent to the federal program to obtain and retain authorization. When EPA adopts more stringent RCRA regulations (including permit requirements), authorized states are required to revise

that "[e]ach permit issued under this section shall contain such terms and conditions as the Administrator (or the State) determines necessary to protect human health and the environment."

The scope of EPA's authority to address environmental justice issues in RCRA hazardous waste permits was directly addressed by the Environmental Appeals Board (EAB) in 1995.[120] In the *Chemical Waste Management* decision, the EAB found that within the RCRA permitting scheme EPA has significant discretion to implement the environmental justice mandates of Executive Order 12898 through public participation mechanisms and the "omnibus" authority.[121] In the area of public participation, the EAB made three relevant findings. First, it recognized that public comments can affect a permitting decision if they relate to issues about compliance with RCRA's statutory or regulatory requirements or otherwise relate to protection of human health and the environment.[122] Second, the EAB reaffirmed that EPA can provide opportunities for public involvement in the permitting process beyond those required by 40 C.F.R. Part 124.[123] Third, it held "that when the Region has a basis to believe that operation of the facility may have a disproportionate impact on a minority or low-income segment of the affected community, the Region should, as a matter of policy, exercise its discretion to assure early and ongoing opportunities for public involvement in the permitting process."[124]

The EAB also examined the breadth of EPA's discretion to promote environmental justice under the "omnibus" authority. As stated by the EAB, the clause authorizes permit conditions or denial as follows:

> Under the omnibus clause, if the operation of a facility would have an adverse impact on the health or environment of the surrounding community, the Agency would be required to include permit terms or conditions that would ensure that such impacts do not occur. Moreover, if the nature of the facility and its proximity to neighboring populations would make it impossible to craft a set of permit terms that would protect the health and environment of such populations, the Agency would have the authority to deny the permit. *See In re Marine Shale Processors, Inc.*, 5 E.A.D. 751, 796 n.64 (EAB 1995) ("[T]he Agency has traditionally read [section 3005(c)(3)] as authorizing denials of permits where the Agency can craft no set of permit conditions or terms that will ensure protection of human health and the environment."). In that event, the facility would have to

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their programs within one year after the change in the federal program or within two years if the change will necessitate a state statutory amendment. 40 C.F.R. § 271.21(e).

Normally, state programs do not apply in Indian country unless a state seeks to have its program apply in Indian country within the state borders and EPA has made a finding that the state has the requisite authority for such program applicability. Therefore, responsibility for ensuring protection of human health and the environment in Indian country under the provisions of RCRA typically falls to EPA.

[120] *See In re Chemical Waste Management of Indiana, Inc.*, 6 E.A.D. 66 (EAB 1995).

[121] *Id*. at 73-74.

[122] *Id*. at 73.

[123] *Id*.

[124] *Id*. at 73-74.

> shut down entirely. Thus, under the omnibus clause, if the operation of a facility truly poses a threat to the health or environment of a low-income or minority community, the omnibus clause would require the Region to include in the permit whatever terms and conditions are necessary to prevent such impacts. This would be true even without a finding of disparate impact.[125]

The EAB also found that RCRA allows the Agency to "tak[e] a more refined look at its health and environmental impacts assessment, in light of allegations that operation of the facility would have a disproportionately adverse effect on the health or environment of low-income or minority populations."[126] The EAB noted that "a broad analysis might mask the effects of the facility on a disparately affected minority or low-income segment of the community" whereas a close evaluation could, in turn, justify permit conditions or denials based on disproportionately high and adverse human health or environmental effects.[127] However, while acknowledging the relevance of disparities in health and environmental impacts, the EAB also cautioned that "'there is no legal basis for rejecting a RCRA permit application based solely upon alleged social or economic impacts upon the community.'"[128]

Thus, the "omnibus" authority of RCRA section 3005(c)(3) may allow EPA to address cumulative risks due to exposure from pollution sources beyond the applicant facility in areas that may be disproportionately burdened. EPA may also use the "omnibus" authority where appropriate to craft permit conditions addressing unique exposure pathways and scenarios (*e.g.*, subsistence fishers or farming communities) or sensitive populations with pre-existing vulnerabilities at a particular hazardous waste management facility. EPA could also consider factors such as cumulative risk, unique exposure pathways, or sensitive populations in establishing priorities for the permit and corrective action programs.[129]

B. Contingency Plans

RCRA-permitted facilities are required under RCRA section 3004(a) to maintain "contingency plans for effective action to minimize unanticipated damage from any treatment, storage or disposal of . . . hazardous waste." Under this provision, EPA has the authority to require facilities to prepare and/or modify their contingency plans to reflect the needs of proximate minority, low-income, or indigenous populations that have limited resources to prepare for or respond to emergency situations. For example, contingency plans may need to account for the cumulative impacts of multiple facilities on local communities or pre-existing vulnerabilities in specific populations.

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[125] *Id*. at 74.

[126] *Id*.

[127] *Id*. at 74-75.

[128] *Id*. at 73 (citation omitted).

[129] The statutory authority for EPA's corrective action programs is found in RCRA sections 3004(u), 3004(v), and 3008(h).

C. Public Participation

RCRA section 7004(b)(2) established public participation requirements for RCRA permitting. In 1995, EPA promulgated the "RCRA Expanded Public Participation" rule.[130] As a part of this rule, certain facilities "must hold at least one meeting with the public in order to solicit questions from the community and inform the community of proposed hazardous waste management activities."[131] RCRA is sufficiently flexible to allow for further exploration of whether the public participation process for RCRA permits could be expanded to allow for more meaningful participation by minority, low-income, and indigenous populations, including at hazardous waste management facilities to be located in or near their communities. In this regard, EPA also would have authority under RCRA to expand the application of those procedures to the permitting of: (a) publicly owned treatment works, which are regulated under the Clean Water Act; (b) underground injection wells, which are regulated under the Safe Drinking Water Act; and (c) ocean disposal barges or vessels, which are regulated under the Marine Protection, Research, and Sanctuaries Act, discussed more fully in Chapter Two. These facilities are subject to RCRA's permit-by-rule regulations[132] and are deemed to have a RCRA permit if they meet certain conditions set out in those regulations.

D. Review of State Permits

EPA's authority to review state-issued RCRA permits may also provide opportunities for consideration of environmental justice factors. EPA could provide comments on these factors (in appropriate cases) during the comment period on the state's proposed permit on a facility-by-facility basis, particularly where state law includes an analog to the RCRA "omnibus" authority.[133] If a state does not have "omnibus" authority analogous to RCRA section 3005(c)(3), EPA may address any necessary additional conditions under the "omnibus" authority in any federal portion of the RCRA permit. These conditions become part of the facility's RCRA permit.

E. Monitoring, Analysis and Testing

EPA may require a permittee or an applicant to submit information in order to establish permit conditions necessary to protect human health and the environment.[134] RCRA section 3013(a) provides that if the Administrator determines that "the presence of any hazardous waste at a facility or site at which hazardous waste is, or has been, stored, treated, or disposed of, or the release of any such waste from such facility or site may present a substantial hazard to human health or the environment," EPA may order a facility owner or operator to conduct reasonable monitoring, testing, analysis, and reporting to ascertain the nature and extent of such hazard. In appropriate circumstances, EPA could use its authority under section 3013 or 40 C.F.R. § 270.10(k) to compel a facility owner or operator to carry out necessary studies or risk assessments, so that, pursuant to the "omnibus" authority, EPA can establish permit terms or conditions as part of the permit application process as necessary to protect human health and the

[130] 60 Fed. Reg. 63417 (Dec. 11, 1995); 40 C.F.R. Part 124, Subpart B.

[131] 40 C.F.R. § 124.31(b).

[132] 40 C.F.R. § 270.60.

[133] 40 C.F.R. § 271.19(a).

[134] 40 C.F.R. § 270.10(k).

environment and reduce the potential for disproportionate impacts on overburdened communities.

RCRA section 3019 provides EPA with authority to require applicants for land disposal permits to provide exposure information and to request that the Agency for Toxic Substances and Disease Registry conduct health assessments at such land disposal facilities. This authority could be used to enhance the availability of information relating to areas with substantial minority, low-income, or indigenous populations.

F. Facility Siting Standards

Another example of where EPA might incorporate environmental justice considerations is under RCRA section 3004(o)(7). This section provides EPA with authority to issue location standards for hazardous waste treatment, storage, and disposal facilities as necessary to protect human health and the environment. Using this authority, EPA could, for example, revise the location standards to establish minimum buffer zones around hazardous waste management facilities to minimize clustering of schools, residential areas, and other community activities around such facilities.[135] Facilities would need to comply with these requirements to receive a permit.

III. HAZARDOUS WASTE REGULATION

RCRA authorizes EPA to promulgate regulations applicable to facilities that manage hazardous waste "as may be necessary to protect human health and the environment."[136] Consistent with the EAB's decision in *Chemical Waste Management*, RCRA's regulatory standard allows EPA to take a "refined look" at the risks posed by the management of hazardous waste to ensure that RCRA regulations are fashioned in a manner that does not "have a disproportionately adverse effect on the health or environment of low-income or minority populations."[137]

This regulatory latitude may have meaning not only with respect to permitting regulations, but also to regulations that determine whether materials are hazardous wastes. For example, in determining whether materials are solid wastes and, therefore, subject to regulation, EPA needs to determine whether materials are "discarded."[138] EPA issued a Definition of Solid Waste rule on October 28, 2008,[139] in which it established a number of conditions under which material would not be considered discarded and, therefore, not a solid waste.

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[135] Local zoning and planning regulations may also be a significant factor in facility siting decisions.

[136] RCRA sections 3002(a), 3003(a), and 3004(a).

[137] *In re Chemical Waste Management of Indiana, Inc.*, 6 E.A.D. at 74.

[138] RCRA defines the term "solid waste" to mean "any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities . . . . " RCRA section 1004(27). Courts have held that under this definition the ordinary plain-English meaning of the term "discard" controls. *See American Mining Congress v. EPA*, 824 F.2d 1177 (D.C. Cir. 1987). The ordinary plain-English meaning of the term "discarded" means "disposed of," "thrown away," or "abandoned."

[139] 73 Fed. Reg. 64668 (Oct. 28, 2008).

On July 22, 2011, in response to an administrative petition to amend or repeal this rule, EPA proposed further revisions to the definition of solid waste.[140] This proposal included an expanded environmental justice analysis, which identified gaps in the 2008 Definition of Solid Waste final rule that could result in risk to human health and the environment from discarded material, including the potential for disproportionate impacts to minority and low-income populations. The July 2011 proposal requested comment on revisions to the 2008 final rule that could increase environmental protection, including in minority and low-income populations, while still appropriately defining when a hazardous secondary material being reclaimed is a solid waste and subject to hazardous waste regulation.

IV. INDIAN COUNTRY

It is long-standing Agency policy that, absent Congressional intent to the contrary, the Nation's environmental laws are meant to apply equally nationwide. The Agency interprets this nationwide consistency to mean that, where there is no EPA-approved program in Indian country, EPA implements the relevant environmental program there. States generally lack authority to implement federal environmental laws in Indian country. Although other environmental statutes provide for Indian tribes to implement their provisions in a manner similar to states, RCRA lacks such a provision.[141] Thus, EPA implements the RCRA Subtitle C and I programs in Indian country.

V. UNDERGROUND STORAGE TANKS

Subtitle I of RCRA provides EPA with authority to regulate underground storage tanks (USTs) containing regulated substances, as defined in RCRA section 9001(2). RCRA section 9003 authorizes UST regulations "necessary to protect human health and the environment." It also allows the use of the Leaking Underground Storage Tank Trust Fund (the LUST Trust Fund) to undertake certain corrective actions with respect to releases of petroleum from USTs. There are three corrective action programs in this area. First, there is a regulatory program (including corrective action) in 40 C.F.R. Part 280 that applies to both petroleum and hazardous substance USTs. States can be authorized to operate a program that is no less stringent than the federal program. Second, the LUST Trust Fund can be used for some cleanups for releases from petroleum USTs.[142] Third, corrective action orders can be issued pursuant to RCRA section 9003(h)(4) covering USTs containing regulated substances. States operating pursuant to a cooperative agreement can utilize the federal authorities for the latter two categories.[143] EPA, and states operating pursuant to cooperative agreements, "shall give priority in undertaking corrective actions . . . and in issuing orders requiring owners or operators to undertake such actions, to releases of petroleum from underground storage tanks which pose the greatest threat to human health and the environment."[144]

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[140] 76 Fed. Reg. 44094 (July 22, 2011).

[141] *Backcountry Against Dumps v. EPA*, 100 F.3d 147 (D.C. Cir. 1996).

[142] RCRA section 9003(h)(2).

[143] RCRA section 9003(h)(7).

[144] RCRA section 9003(h)(3).

In evaluating releases from USTs in disproportionately impacted minority, low-income, or indigenous communities for possible response actions, EPA or the state can take into account such things as unique exposure pathways and scenarios and sensitive populations in determining whether the release in question is among those which pose the greatest threat to human health and the environment.

VI. GENERAL AUTHORITY FOR ADDRESSING ENVIRONMENTAL JUSTICE – STATE SOLID WASTE MANAGEMENT PLANS

Under RCRA Subtitle D,[145] states are the primary implementing authority for managing nonhazardous solid waste. EPA issues guidelines and recommendations to state solid waste permitting programs under RCRA sections 1008(a), 4002, and 4004. RCRA section 1008(a) expressly provides that solid waste management guidelines shall describe levels of performance that provide "protection of public health and welfare" and shall include, where appropriate, consideration of "demographic" factors. Guidelines for state solid waste management plans developed under RCRA section 4002(c) may include consideration of factors such as "population density, distribution, and projected growth" and the "political, economic, organizational, financial, and management problems affecting comprehensive solid waste management." These provisions give EPA the legal authority to address environmental justice considerations in the development of regulations, standards, and guidelines for solid waste management. EPA could, for example, develop guidelines that encourage states to consider demographic and socio-economic factors such as the density and distribution of minority, low-income, and indigenous populations, as well as disproportionate burdens on minority, low-income, or indigenous populations when siting new solid waste management facilities.

RCRA section 7004(b) requires EPA and the States to provide for, encourage and assist in "public participation in the development, revision, implementation, and enforcement of any regulation, guideline, information, or program." EPA promulgated the "RCRA Expanded Public Participation" rule on December 11, 1995.[146] While these regulations describe the public participation process for RCRA permitting, EPA has the authority to promulgate similar regulations or issue guidelines for states to provide meaningful participation by minority, low-income, and indigenous populations in the development of solid waste management guidelines and plans and in the implementation of state solid waste programs.

EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT

Section 303 of the Emergency Planning and Community Right-to-Know Act (EPCRA) requires local emergency planning committees to prepare emergency response plans for facilities that contain certain amounts of designated extremely hazardous substances. The national response team could publish guidance under Section 303(f) on considering environmental justice issues in preparing and implementing emergency plans.

[145] RCRA sections 4001-4010.

[146] 60 Fed. Reg. 63417 (Dec. 11, 1995); 40 C.F.R. Part 124, Subpart B.

For a discussion of EPCRA section 313 and of the role of Indian tribes under EPCRA, see Chapters Four and Five, respectively.

SUPERFUND

I. GENERAL AUTHORITY FOR ADDRESSING ENVIRONMENTAL JUSTICE

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund, authorizes the federal government to respond to releases and threats of releases into the environment of hazardous substances or pollutants or contaminants. EPA does so by taking response measures, generally consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP),[147] deemed "necessary to protect the public health or welfare or the environment."[148] EPA's authority to take actions "necessary to protect the public health or welfare or the environment" authorizes EPA to ensure fair treatment and meaningful participation in environmental decision-making for minority, low-income, and indigenous populations that are disproportionately impacted. For instance, EPA's authority to consider "public health or welfare or the environment" could be the basis for considering cumulative risk in taking response actions. [149] However, all response activities must generally be consistent with the NCP.

Impacts on minority, low-income, and indigenous populations could be considered a factor in setting clean-up priorities among non-National Priorities List (NPL) sites. EPA could implement a policy to prioritize sites where these populations have disproportionate environmental burdens. This can be done at non-NPL sites without rulemaking, as there is currently no defined system of "priorities" for non-NPL sites. EPA may simply choose to study and/or clean up any contaminated non-NPL sites, focusing on environmental justice considerations to the extent it finds appropriate.

Finding this same flexibility would be very difficult for NPL sites. NPL sites are listed mainly by application of the hazard ranking system (HRS), which uses exclusively numerical inputs to rank sites. The challenge is to quantify environmental justice considerations in a manner that is usable under the existing HRS ranking scheme. For example, to date EPA has not been able to quantify tribal considerations so as to use them under the HRS.

However, in assessing remedial alternatives, EPA considers nine factors, many of which (including "overall protectiveness of human health and the environment" and "community acceptance") can accommodate environmental justice considerations relating to impacts on, and participation by minority, low-income, and indigenous populations.[150] Addressing such

[147] 40 C.F.R. Part 300.

[148] CERCLA section 104(a)(1).

[149] See definitions of the terms "response," "removal," and "remedial action" at CERCLA sections 101(25), 101(23), and 101(24), respectively.

[150] *See* 40 C.F.R. § 300.430(e)(9)(iii).

environmental justice considerations through application of the nine factors set out in the NCP could, in turn, influence the final remedy selection decision.

II. PUBLIC PARTICIPATION

CERCLA section 117(a) provides for public participation before EPA's adoption of any plan for remedial action. This is consistent with the environmental justice goal of ensuring meaningful participation by communities in decisions that affect them. CERCLA section 117(e)(1) also provides EPA the discretionary authority to provide technical assistance grants (TAGs) to affected groups or individuals to help them interpret information about Superfund sites.

EPA has the legal ability to revise its guidance on public participation to enhance opportunities for participation of minority, low-income, or indigenous communities in remedy selection. EPA could also examine the regulations governing TAGs to determine whether they can be revised to enhance participation and better address the concerns of underrepresented communities, with appropriate revisions where it appears that improvements could be made. This could be done for public participation, and to some extent also for TAGs, without rulemaking.

III. TRIBES

CERCLA section 126(a) provides for a tribal role in Superfund actions for certain purposes. It specifies that "[t]he governing body of an Indian tribe shall be afforded substantially the same treatment as a State" with respect to various provisions of CERCLA, including provisions relating to notification of releases, consultation on remedial actions, access to information, and roles and responsibilities of states under the NCP.[151]

CERCLA also contains other provisions that provide for a tribal role. CERCLA authorizes tribes to enter into cooperative agreements and receive financial assistance to carry out response actions pursuant to section 104(d). For cleanups on land held by a tribe, land held in trust for Indians, land held by an Indian if subject to a trust restriction on alienation, or land otherwise within an Indian reservation, CERCLA exempts tribes from the requirements that apply to states to pay a share of response costs and to give certain assurances regarding hazardous waste disposal capacity pursuant to section 104(c)(3). Further, CERCLA authorizes tribes to recover costs incurred in carrying out response actions from persons responsible for releases and to act as trustees for tribal natural resources and seek recovery for damages to such resources. Thus, CERCLA provides many mechanisms for tribal participation in the Superfund process. And tribes are eligible for various types of EPA grants to assist in such participation.

Moreover, EPA has adopted regulations that define "State" to generally include tribes under the NCP, which governs most CERCLA response activities.[152] This enables tribes to carry out many of the functions of states and participate meaningfully in the decision-making and clean-up process.[153] Consistent with the NCP, tribal standards are potential "applicable or

[151] CERCLA sections 103(a), 104(c)(2), 104(e), and 105, respectively.

[152] 40 C.F.R. § 300.5 (also defining the term "Indian tribe," which is defined in CERCLA section 101(36)).

[153] 40 C.F.R. § 300.500(a).

relevant and appropriate requirements" (ARARs) for CERCLA response actions taken on tribal lands. Tribal standards can be treated in the same manner as state requirements provided they qualify as ARARs.

Participation of tribes in the Superfund process is generally governed by the text of CERCLA as well as EPA regulations found at 40 C.F.R. Part 35, Subpart O and Part 300, Subparts F and G. Tribes can enter into cooperative agreements with EPA and receive financial assistance to participate in cleanups as the lead or support agency. Tribes also may receive core program cooperative agreements that fund non-site specific activities that support a tribe's involvement in CERCLA responses and help develop tribal infrastructure. Further, like states, CERCLA directs EPA to consult with tribes when they are "affected" by a CERCLA response action.[154]

Additionally, in 2007, EPA amended subpart O to reduce obstacles to tribal involvement in CERCLA and "to fulfill CERCLA's mandate in sections 121 and 126" to provide tribes with substantial and meaningful involvement in Superfund.[155] The amended regulations authorize grants to intertribal consortia, as well as individual tribes, thereby reducing burdens on smaller tribes. The amendments also eliminate potentially burdensome requirements for tribes to show jurisdiction as a prerequisite to receiving financial assistance under core program cooperative agreements and most agreements to participate in response activities as support (rather than lead) agency. Finally, the amendments removed requirements for tribes to provide a cost share for core or support agency agreements, and eliminated requirements for tribes relating to property acquisition.

EPA could examine ways to better promote tribal participation in the Superfund process. EPA could enhance tribal outreach and communication with measures to ensure that tribes have an opportunity to participate in all stages of cleanups carried out on tribal lands. Furthermore, EPA could interpret CERCLA to facilitate broader participation by federally recognized Indian tribes.

IV. COOPERATIVE WORK WITH THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Pursuant to CERCLA section 104(i), the Agency for Toxic Substances and Disease Registry (ATSDR) has responsibility to implement certain health-related authorities of CERCLA in cooperation with EPA and other federal agencies. EPA could explore with ATSDR the idea of giving priority to health concerns in areas where communities may be experiencing disproportionate health impacts. For instance, CERCLA requires ATSDR to consult with EPA on health issues related to exposure to hazardous or toxic substances and to prioritize health assessments in consultation with EPA, taking into consideration NPL schedules and the needs of EPA.[156] Health assessments conducted by ATSDR may be used to determine if a site should be listed on the NPL or to increase a site's priority upon the recommendation of the Administrator

[154] CERCLA sections 104(c)(2) and 126(a).

[155] 72 Fed. Reg. 24496 (May 2, 2007).

[156] CERCLA section 104(i)(6)(c).

of ATSDR.[157] In addition, an ATSDR health advisory that recommends protecting people from a release may be the basis for listing a release on the NPL.[158]

V. GRANTS AND COOPERATIVE AGREEMENTS

Pursuant to section 104(d) of CERCLA, EPA may enter into cooperative agreements or contracts authorizing states, political subdivisions, and Indian tribes to carry out activities authorized under section 104 of CERCLA, and may provide funding to states and tribes for program support and implementation (*e.g.*, core grants). EPA has the legal latitude to impose grant limitations or conditions to address environmental justice considerations relating to fair treatment and meaningful participation in environmental decision-making by minority, low-income, and indigenous populations.

[157] CERCLA section 104(i)(6)(H).

[158] 40 C.F.R. § 300.425(c)(3)(i).

CHAPTER FOUR: PESTICIDES AND TOXICS PROGRAMS

INTRODUCTION

This chapter discusses the Federal Insecticide, Fungicide, and Rodenticide Act,[159] the Federal Food, Drug, and Cosmetic Act,[160] the Toxic Substances Control Act,[161] and Section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA).[162] Section 303 of EPCRA is discussed in Chapter Three. As discussed below, these statutes and their implementing regulations provide various opportunities to address environmental justice considerations by focusing attention on minority, low-income, and indigenous populations (*e.g.*, subpopulations with unique diets). Most of the opportunities described herein are available under current law.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides a broad framework for the regulation of pesticides. Generally, FIFRA requires that all pesticides that are sold or distributed in the United States be "registered" by EPA. EPA may only register a pesticide if, among other things, the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and if, "in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment."[163] In making a determination as to whether a pesticide causes unreasonable adverse effects on the environment, EPA is required to consider the economic, social, and environmental costs and benefits associated with the use of a pesticide. The burden of providing EPA with the necessary information to determine whether the standard for registration is met rests at all times with the registrant or applicant for registration. FIFRA is structured to provide for risk/benefit balancing. In making the risk/benefit determination, EPA relies on the authority under FIFRA and its implementing regulations to mitigate risks through various restrictions on labeling, conditioning registrations, and cancelling or suspending registrations. Additionally, there are regulations to protect workers and prescribe requirements for training and certification.

I. ACTIONS UNDER FIFRA SECTIONS 2, 3, 4 AND 6

The Agency's authority to register pesticides is found in section 3 of FIFRA. The standard for registration under section 3, *i.e.*, that a pesticide will perform its function without causing unreasonable adverse effects on the environment, is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[164] The statute does not restrict the scope of economic,

[159] 7 U.S.C. §§ 136-136y.

[160] 21 U.S.C. §§ 301-399a.

[161] 15 U.S.C. §§ 2601-2695d.

[162] 42 U.S.C. §§ 11001-11050.

[163] FIFRA section 3(c)(5).

[164] FIFRA section 2(bb).

social and environmental factors to be weighed in the cost/benefit analysis beyond the requirement that the cost or benefit be tied to the pesticide use.[165] To make the finding that a pesticide does or does not cause unreasonable adverse effects requires a full consideration of the risks and benefits of its use.[166]

Section 2(bb) of FIFRA provides that *any* unreasonable risk from pesticide use warrants consideration. This has been interpreted broadly to allow EPA to factor economic, social and environmental considerations into the cost/benefit analysis.[167] The Fifth Circuit Court of Appeals has found that "a significant risk of bird kills, *even if birds are actually killed infrequently*, may justify the Administrator's decision to ban or restrict diazinon use."[168]

Given the Congressional mandate to consider a wide range of factors in balancing costs against benefits, it is reasonable for the Agency to consider environmental justice considerations in its decision whether to register, retain, or cancel a pesticide. If there is a particular population that the Agency believes is disproportionately affected by or exposed to the pesticide, the Agency may take this into account in its assessment of social or human health costs associated with a given pesticide. EPA could also consider whether the people bearing the risks from the use of a pesticide are receiving any of the benefits from the use of the pesticide. In the past, EPA has considered similar issues in its risk assessments and regulatory decisions for lindane, endosulfan, soil fumigants, and rodenticides.

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[165] *In re Lethelin Products Co., Inc.*, FIFRA Docket No. 392, 5 (1977); *In re Chapman Chemical Co.*, FIFRA Docket No. 246, 7 (1976).

[166] FIFRA section 3(c)(5); *accord Love v. Thomas*, 858 F.2d 1347 (9th Cir. 1988); *In re Chapman Chemical Co.*, FIFRA Docket No. 246, 7 (1976).

The legislative history of section 3(c)(5) directly supports reading the statute expansively. The Senate Committee on Agriculture and Forestry, in commenting on the amendments to section 2(bb) proposed by the Senate Committee on Commerce, noted that:

> [T]he balancing of benefit against risk is supposed to take every relevant factor that the Administrator can conceive of into account. The question he must decide is "Is it better for man and the environment to register this pesticide or is it better that this pesticide be banned?" He must consider hazards to farm workers, hazards to birds and animals and children yet unborn. He must consider the need for food and clothing and forest products, forest and grassland cover to keep the rain where it falls, prevent floods, provide clear water. He must consider aesthetic values, the beauty and inspiration of nature, the comfort and health of man. All these factors he must consider, giving each its due.

S. Comm. on Agriculture and Forestry, 92d Cong., Supp. Rep. (to accompany H.R. 10724) 10 (1972). The Conference Committee subsequently adopted the Senate's version of section 2(bb) in the final bill. *See* H.R. Rep. No. 92-1540, at 10, 30 (1972).

[167] *E.g.*, *Ciba-Geigy Corp. v. EPA*, 874 F.2d 277 (5th Cir. 1989); *In re Chapman Chemical Co,*, FIFRA Docket No. 246, 7.

[168] 874 F.2d at 279-80 (emphasis added); *accord In re Chapman Chemical Co.*, FIFRA Docket No. 246, 7 (a finding of *any* risk from the use of a particular pesticide, if the risk is "unreasonable" in relation to the benefits of its continued use, is sufficient to warrant cancellation. The standards for canceling and registering a pesticide are mirror images – both depend upon whether the pesticide causes unreasonable adverse effects).

A. Public Notice Prior to Registration of New Active Ingredient

Prior to registration, FIFRA requires public notice of the receipt of applications for registration of pesticides containing a new active ingredient or pesticides that would entail a changed use pattern.[169] The information required to be in the notice is relatively nominal and no risk assessment information is required to be provided.

Starting in October 2009, the Agency initiated an enhanced public participation process to provide information and an opportunity to comment on certain pesticide applications before they are registered. For new active ingredients, first food uses, first residential uses, first outdoor uses and any others that may have significant public interest, the Agency will post a risk assessment and a proposed decision for 30 days of public comment before making a decision on the registration. Generally, the Agency doesn't expect any of the information to be posted to involve claims of confidentiality, but posting will be done in accordance with appropriate confidential business information procedures. Should there be environmental justice considerations regarding a particular pesticide application, the public will have the opportunity to raise them through this process.

B. Regulatory Process After Registration

Once registered, pesticides must continue to meet the standard for registration. If they do not, the Agency may pursue cancellation or suspension under FIFRA section 6; as stated above, those steps would make it unlawful to sell and, possibly, use the pesticide. In 1996, Congress amended FIFRA to add section 3(g), which set forth the goal of periodically reviewing all pesticides on a 15-year cycle. To accomplish this, in 2006, EPA initiated a new program called "registration review." The program's goal is to review each pesticide active ingredient every 15 years to make sure that as the ability to assess risks to human health and the environment evolves and as policies and practices change, all pesticide products in the marketplace can still be used safely. In 2007, Congress again amended FIFRA section 3(g) to mandate the 15-year time period for subsequent pesticide registration review.

The same unreasonable adverse effects standard used for registering pesticides, which allows for consideration of environmental justice considerations, applies to FIFRA section 4 reregistration decisions, section 6 actions, and section 3(g) registration review actions. And, in suspension, cancellation, reregistration, and registration review, the public is provided with opportunities to participate in the process.

C. Information Available to the Public after Registration

Under FIFRA section 3(c)(2)(A), information is to be made available to the public once a pesticide is registered. Because of trade secret and related restrictions in FIFRA section 10, requests for such information must be made in accordance with the FOIA regulations at 40 C.F.R. Part 2.

D. Labeling of Pesticide Products

The Agency currently considers, and in appropriate circumstances imposes, certain locale-specific restrictions on pesticide uses. Such restrictions are often due to a pesticide's expected impacts when used in a particular climate or geographic area or when used in areas where certain endangered species may reside. Risk factors associated with minority, low-

[169] FIFRA section 3(c)(4).

income, and indigenous populations can be considered, where appropriate, in FIFRA section 3, 4, or 6 actions. In fact, in certain actions, EPA takes into consideration major identifiable subpopulations, as discussed more fully below.

FIFRA and its implementing regulations at 40 C.F.R. Part 156 provide EPA authority to require labeling restrictions on pesticide products. Labeling restrictions can be imposed to mitigate risks to specific populations or areas, by requiring that affected populations be made aware of the risks. Text on labels could include communicating risk reduction measures in ways appropriate to the circumstances of minority, low-income, and indigenous populations, including those with low English-language or general literacy rates.[170] The Agency has the authority to require that more extensive information about particular risks be shared with specific groups or communities, including factors that may reduce or increase risk of harm from exposure, and measures people can take to protect themselves.

E. Adverse Effects Reporting

In 1997, EPA promulgated a rule codifying EPA's interpretation regarding FIFRA section 6(a)(2), which requires pesticide registrants to report information concerning unreasonable adverse effects of their products to EPA.[171] The purpose of the rule is to clarify what information to submit and how and when to submit it. In addition, in situations when a pesticide registrant fails to report information or delays in reporting that information, the rule specifies which failures will be regarded by EPA as violations of FIFRA section 6(a)(2), and subject to action under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N). These reports are used in the registration and subsequent periodic review of registrations to determine if further regulatory action is necessary. These reports sometimes include information on specific subpopulations that could inform future regulatory actions to mitigate adverse effects, and could be used to implement other strategies identified in paragraph D above.

F. Requests for Additional Data

The Agency has broad authority to require data generation and submission by registrants after a pesticide is registered. Under FIFRA section 3(c)(2)(B), EPA can require registrants to submit data that it determines are "required to maintain in effect an existing registration." The data could include focused information about the adverse effects on minority, low-income, and indigenous populations. The data could also include more focused information on exposure to pesticides of farm workers and their children; minority, low-income, and indigenous populations; or animals, water, land and other resources that are of special importance to particular populations.

Should the Agency determine that registrants need to develop and submit data relating to exposure of, or adverse effects on, minority, low-income, and indigenous populations in order to maintain an existing pesticide registration, section 3(c)(2)(B) of FIFRA can be used to impose the data requirement. Once the data are obtained, the Agency can use them in its regulatory decision-making.

[170] For example, 40 C.F.R. § 156.206(e) requires certain warning statements be in Spanish, as well as English.

[171] 40 C.F.R. Part 159. *See also* 62 Fed. Reg. 49370 (Sept. 19, 1997).

G. Improvements to Human Health Risk Assessment Procedures

In February 2010, EPA announced its intent to use important risk assessment techniques developed in the implementation of the Food Quality Protection Act of 1996 (FQPA) in all pesticide risk assessments. The FQPA, which rewrote section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (see discussion below), required EPA to aggregate pesticide exposures from all sources – from food, from drinking water, and from use of pesticides in the home – and also mandated that EPA take into account the cumulative effects from exposures to multiple pesticides that have a common mechanism of toxicity. Further, the FQPA amendments directed that an additional safety factor be used to protect infants and children from the risks of pesticides given the lack of complete data on the potentially increased sensitivity to pesticides in the young. Risk assessment techniques developed over the last 13 years in the wake of these mandates have progressed from cutting-edge procedures to well-established scientific practice.

Currently, many risk assessment techniques are now used in assessing risks to agricultural workers from pesticide exposures on the job or to the general public from pesticides that are used in homes but not in growing food. Some techniques will undergo external, scientific peer-review. The revisions to EPA's risk assessment methods ensure that EPA, in assessing risk, treats all pesticide exposures – and all people who are exposed to pesticides – the same.

II. FIFRA WORKER PROTECTION STANDARD IN 40 C.F.R. PART 170

A. Overview

All agricultural employers, owners, and managers, as well as labor contractors, are required to comply with the worker protection standards (WPS) when using pesticides with labeling that refers to the WPS on an agricultural establishment. Most WPS requirements apply to agricultural workers or pesticide handlers, but there are some requirements that apply to all persons and some that apply only to certain persons such as those who handle pesticide application equipment or clean pesticide-contaminated personal protective equipment.

Currently, the regulation includes numerous safeguards ranging from protective clothing and precautionary field reentry limits to requirements for warning and worker training. The safeguards promote environmental justice to the extent they are used to mitigate risks to minority, low-income, and indigenous workers that are disproportionately exposed to risks of harm from the pesticides due to their work. EPA is completing draft revisions to the worker safety regulations. The draft revisions are intended to improve protections for agricultural workers, including workers in minority, low-income, and indigenous populations. Likewise, the Agency is completing draft revisions to the certification regulations.[172] The certification revisions may include, for example, changes to the certification plans in Indian country.

The Agency might also examine other related areas that were not covered in the WPS. One such area is the potential pesticide exposure of farm workers and their families who live near treated fields. Under the current regulations, pesticide labels may contain (and some already do contain) restrictions on applications to avoid potential pesticide exposure from pesticide drift to those who live in or near treated fields.

[172] 40 C.F.R. Part 171 sets forth the requirements for certifying applicators of restricted use pesticides as required by FIFRA section 11.

Pesticide drift is a major concern. Frequently, workers and their families live near the treated fields, and they may be impacted by airborne pesticide residues following application. EPA is considering additional safeguards, which could afford such people greater protection. For example, the Pesticide Programs Dialogue Committee has a subcommittee that has been addressing the issue of pesticide spray drift. As an outcome of this subcommittee's work, EPA issued a draft Pesticide Registration Notice for public comment to address many of the concerns discussed at these meetings. Recommendations in the Pesticide Registration Notice promote environmental justice through recommending language for pesticide labeling to reduce spray drift, and thereby further protecting human health in general and affected minority, low-income, and indigenous populations, in particular, from the adverse effects of the pesticides. EPA is finalizing the Pesticide Registration Notice, taking into account the numerous comments the Agency received during the comment period.

B. Examples of How EPA Implements FIFRA Authorities to Advance Environmental Justice

Over the past decade, OPP has engaged in a number of activities to enhance the protections provided by the worker protection standards. For example, in 2005, a collaborative partnership with the Association of Farmworker Opportunity Programs was formed to improve pesticide safety training for farm workers and their families. EPA works with the association to increase the number of farm workers and families trained in pesticide safety. New pesticide training efforts are being undertaken to prevent take-home exposures to farm worker children.

Between 2002 and 2004, worker protection assessment workshops were held around the country. These workshops included public meetings with worker advocacy groups, agricultural interest groups, regulators, health care providers, and pesticide safety trainers in Texas, California, Florida, and the District of Columbia to evaluate the agricultural worker protection regulation and potential changes to the regulation and the program. Also, focused work group meetings were held to develop more detailed responses and recommendations for potential changes. In Texas, Florida, and California, work group members had field experience with hazard communication, worker and handler training scenarios, and constraints on posting and decontamination recommendations. In addition to these workshops, there have been numerous training courses created that specifically focus on the applicability and practicability of potential regulatory change options. Field tours are standard for such courses.

III. TREATMENT OF TRIBES AND INDIAN COUNTRY UNDER FIFRA

With the notable exception of FIFRA section 23, which is discussed below, FIFRA does not explicitly reference federally recognized Indian tribes or implementation in Indian country. The term "Indian tribe" is not defined in FIFRA, and the current definition of the term "State" in section 2(aa) of FIFRA does not mention tribes or Indian country. Because states generally lack authority to regulate in Indian country, the absence of explicit references to tribes and Indian country in several sections of FIFRA raises issues about implementation of those provisions in Indian country, which may include areas with overburdened communities.

While the pesticide registration program is generally national in scope, section 18 of FIFRA authorizes states to request that EPA grant exemptions from the requirements of FIFRA to allow use of pesticides that would otherwise not be authorized under that statute in order to respond to a pest-related emergency situation in the state. And states have the authority under

section 24(c) of FIFRA to register additional uses of pesticides in order to respond to special local needs. Because tribes are not explicitly referenced in either of these sections, they have not generally had the benefits of these provisions of FIFRA even in situations where they, like their non-tribal neighbors, may have special local pest-related needs or emergencies.

EPA has, however, used other authorities available in FIFRA to help ensure that the statute's benefits are available to communities in Indian country. On November 28, 2008, the Administrator approved a three-year pilot program under the auspices of section 2(ee)(6) of FIFRA that allowed the use of registered pesticides in Indian country consistent with the use allowed under an emergency exemption or special local-needs registration where such exemption or section 24(c) registration is in effect in the same state as the areas of Indian country (or, if the exemption or registration is limited to particular counties within a state, in the same county as the areas of Indian country).[173] This section 2(ee)(6) finding minimized any programmatic gap in the event of special local needs or emergencies in Indian country.

As noted above, FIFRA section 23 contains the only explicit reference to Indian tribes in the statute. It authorizes EPA to enter into cooperative agreements with Indian tribes for specified purposes to carry out FIFRA. Consistent with section 23, EPA enters into cooperative agreements with tribes (often relating to inspections). EPA interprets FIFRA sections 11 and 23 to authorize EPA approval of tribal certification and training programs for applicators of restricted use pesticides.[174] Currently, the Agency is working on revisions to 40 C.F.R. § 171.10 to improve options for certifying applicators in Indian country.

IV. INTEGRATED PEST MANAGEMENT

Under 7 U.S.C. § 136r-1, EPA, in coordination with the U.S. Department of Agriculture, "shall implement research, demonstration, and education programs to support adoption of Integrated Pest Management." Additionally, the two agencies "shall make information on Integrated Pest Management widely available to pesticide users, including Federal agencies. Federal agencies shall use Integrated Pest Management techniques in carrying out pest management activities and shall promote Integrated Pest Management through procurement and regulatory policies, and other activities." Integrated Pest Management (IPM) is an effective and environmentally sensitive approach to pest management that relies on a combination of common-sense practices. IPM programs use current, comprehensive information on the life cycles of pests and their interaction with the environment. This information, in combination with available pest control methods, is used to manage pest damage by the most economical means, and with the least possible hazard to people, property, and the environment.

EPA recommends that schools use IPM to reduce pesticide risk and exposure to children and is advancing national implementation. EPA also supports IPM use in public housing. EPA

[173] Section 2(ee)(6) of FIFRA allows the Administrator to determine that certain uses of a registered pesticide should not be considered violative of FIFRA notwithstanding the fact that the uses are not specifically authorized by the labeling of the registered pesticide. In this particular instance, the Administrator used this authority to determine that use in areas of Indian country that is similar to use authorized under section 18 or 24(c) on neighboring lands is not inconsistent with the purposes of FIFRA and will thus no longer be considered unlawful under FIFRA (unless a tribe declines to be included in the pilot program).

[174] *See* 40 C.F.R. § 171.10.

further encourages growers to use IPM to identify pests before they use pesticides to ensure that the proper control method is used. EPA can consider whether IPM practices constitute necessary labeling restrictions when assessing the risks and benefits of a pesticide.

V. INFORMATION AND TRAINING

FIFRA section 23(c) authorizes EPA, in cooperation with the U.S. Department of Agriculture (USDA), to use the services of cooperative state extension services to inform and educate pesticide users. When registering or reviewing already-registered products, EPA can place training and information requirements on a registration and labeling to help ensure that there are no unreasonable adverse effects on the environment.

VI. PACKAGING STANDARDS

Under FIFRA section 25(c)(3), EPA has the authority to establish standards for package, container, or wrapping in order to protect children and adults from serious injury or illness due to accidental ingestion or contact with the pesticide. For example, under this authority, EPA has required that certain products contain child-resistant packaging to reduce the potential exposure of children to a pesticide.

VII. IDENTIFICATION OF PUBLIC HEALTH PESTS

FIFRA section 28(d) provides EPA with the authority to identify pests of significant public health importance and develop and implement programs to improve and facilitate the safe and necessary use of pesticides to control such pests. Public health pests – such as insects that carry vector-borne diseases, rodents, and microbes – can cause serious risks to public health. Because such pests may be prevalent in overburdened communities, addressing such prevalence would advance environmental justice. EPA provides information to the public about the safe use of such pesticides in homes and schools. Providing the information discussed above to minority, low-income, and indigenous populations will further advance environmental justice.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)

In addition to the general licensing and registration scheme in FIFRA, EPA also exercises statutory authority over pesticides under the FFDCA. The FFDCA contains provisions addressing pesticide residues in foods. EPA is authorized to set tolerances (maximum residue regulations) for pesticides in food under the FFDCA. The Food and Drug Administration and the U.S. Department of Agriculture monitor the food supply to enforce compliance with EPA-established tolerances.

EPA sets tolerances for pesticide residues in food under section 408 of the FFDCA. Its provisions require EPA to determine that the tolerances will be safe. "Safe" means there is a reasonable certainty of no harm. Unlike FIFRA, which balances risks and benefits, this is a risk-only standard. Importantly, the FFDCA's risk-only standard has been written into FIFRA for pesticides used on food.

In implementing the reasonable certainty of no harm standards in the setting of tolerances, as well as in the FIFRA registration process, EPA considers consumption patterns of

major identified subpopulations to determine the degree of risk posed by pesticide residues. If certain groups have a common diet, that factor can be taken into account in ruling on pesticide tolerances and registrations. More specifically, if the data are available, EPA can take into account different exposures or dietary consumption patterns for an identifiable minority, low-income, and indigenous population (*e.g.,* Inuit dietary consumption patterns). EPA's ability to consider the diets of subpopulations is limited by data availability. EPA relies on surveys done every decade or so for consumption information. To further the use of its ability to consider dietary consumption patterns, EPA could seek to ensure that future consumption surveys adequately sample individuals from overburdened communities. Also, EPA could solicit additional information on this subject in notices it publishes in allowing for public comment in FFDCA proceedings.

Under FFDCA section 408(b)(2)(C), EPA must specifically consider the exposure of infants and children when determining if the pesticide residue is safe. Dietary consumption patterns of children and infants are considered in the tolerance setting process.

Under FFDCA sections 408(d) and (e), the public may participate in the establishment, modification, suspension or revocation of a pesticide tolerance. Unlike FIFRA section 3(c)(4), mentioned above, where the notice is nominal (usually the name of the new active ingredient), in general, under the FFDCA the public is provided more information, including risk assessments. However, the rulemaking requirements under FFDCA section 408 are unique, and tolerances may be established, modified, or revoked in response to a petition. Although EPA must publish notice of the petition and make available a summary of the petition, EPA may issue a final rule acting on the petition without issuing a proposed rule or making other information available prior to issuance of the final rule. Final rules are subject to an administrative objection and hearing process.

EPCRA SECTION 313 AND RELATED AUTHORITIES

The Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) was enacted in response to incidents involving major chemical releases, including the 1984 release of methyl isocyanate in Bhopal, India. (See Chapter Three for a discussion of EPCRA section 303.) The statute provides for emergency planning and emergency release notification at the state and local level. The Toxics Release Inventory (TRI) was established pursuant to EPCRA section 313, which provides for reporting requirements for facilities within certain industry groups that manufacture, process or use toxic chemicals. Under EPCRA section 313 and its implementing regulations at 40 C.F.R. Part 372, covered facilities must report releases to all environmental media. The Pollution Prevention Act of 1990 (PPA)[175] significantly expanded the information required to be reported by facilities that are subject to EPCRA section 313 reporting requirements. In addition, Executive Order 12856[176] requires federal agencies to comply with the planning and reporting provisions of EPCRA and the PPA.

[175] 42 U.S.C. §§ 13101-13109.

[176] The Executive Order is entitled "Federal Compliance With Right-to-Know Laws and Pollution Prevention Requirements" and was published at 58 Fed. Reg. 41981 (Aug. 6, 1993).

I. EPCRA

Under section 313 of EPCRA, specified facilities must report annually to EPA and the states on releases of listed toxic chemicals. The reporting requirements apply to owners and operators of facilities that have ten or more full-time employees and that are in a covered Standard Industrial Classification (SIC) Code or North American Industry Classification System (NAICS) Code as listed in 40 C.F.R. § 372.23. These facilities must report if they manufacture, process or otherwise use a listed toxic chemical in quantities that exceed specified thresholds. The required information, typically submitted on EPA "Form R," includes whether the chemical is manufactured, processed or used; the maximum amounts of toxic chemical present at the facility in the preceding year; waste treatment and disposal methods used; and the annual quantity of chemical released to the environment.

Section 313(h) states that the annual release report forms required under EPCRA "are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities." Section 313(j) provides that EPA must make these annual release reports publicly accessible in a computer data base, which EPA has established as the TRI, which can be accessed through web tools such as TRI Explorer.[177] EPA also annually compiles, analyzes, and publishes the data.

The various tools the TRI program uses to communicate TRI data to the public may provide excellent opportunities to communicate valuable information about releases in overburdened communities. Because data can be sorted on a facility-by-facility basis, release information can be organized around socio-economic factors such as race or income. Information about potential exposure to toxic chemicals in overburdened communities may be useful to EPA, other agencies and members of the community. The TRI program could choose to focus education and outreach activities for minority, low-income, and indigenous populations. Future efforts to make data available to communities could consider the particular needs of overburdened communities in decisions regarding how to present the information.[178] Moreover, EPA might bring greater focus to environmental justice considerations as it prioritizes chemicals or industry sectors to be added to TRI. For example if certain chemicals or chemical-intensive industries are disproportionately present in overburdened communities, the Agency may consider adding those chemicals or industries through rulemaking under EPCRA sections 313(d) and 313(b)(1)(B), respectively.

In addition, EPA has discretionary authority under EPCRA section 313(b)(2) to add individual facilities to those that must report their releases of toxic chemicals:

[177] Fulfilling this requirement of EPCRA section 313(j) is consistent with the directive in the Presidential memorandum accompanying Executive Order 12898 that provides for agencies to "ensure that the public, including minority communities and low-income communities, has adequate access to public information relating to human health . . . when required . . . under [EPCRA]." 30 Weekly Comp. Pres. Doc. at 280.

[178] However, data users should also be made aware that the TRI data has several important limitations. For example, it does not provide a comprehensive data set of all toxic chemical releases, nor does it provide actual exposure information.

> The Administrator, on his own motion or at the request of a Governor of a State (with regard to facilities located in that State), may apply the requirements of this section to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under subsection (c) of this section if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.

One potential consideration in identifying additional facilities for reporting could be location in overburdened communities, including those that are minority, low-income, or indigenous. The TRI program has begun a preliminary effort to identify types of facilities that might be good candidates for the use of this tool.

EPA may also set different (lower or higher) thresholds for reporting from certain facilities under EPCRA section 313(f)(2). At the Administrator's discretion, these thresholds may apply to classes of chemicals or to categories of facilities. Presumably, a category of facilities could be characterized based on proximity to overburdened communities.

II. POLLUTION PREVENTION ACT OF 1990

Under section 6607(a) of the PPA, each owner or operator of a facility is required to annually file a toxic chemical release form under EPCRA section 313. They must include with the annual report a toxic chemical source reduction and recycling report for the preceding calendar year. Section 6607(b) of the PPA details the information that is required to be included in the toxic chemical source reduction and recycling report. As a result of these PPA provisions, there are seven additional categories of pollution prevention and recycling data that must be reported annually under EPCRA section 313.

III. EXECUTIVE ORDER 12856

Owing to Executive Order 12856, all federal facilities are now required to adhere to the same planning and reporting provisions of federal right-to-know and pollution prevention laws that cover the private sector. This Executive Order goes beyond EPCRA requirements in an attempt to set a new standard for federal facilities to adhere to right-to-know principles and a pollution prevention ethic. On January 26, 2007, Executive Order 13423[179] superseded EO 12856 regarding federal facility reporting. Instructions on implementing the Executive Order confirm that federal facilities continue to report under EPCRA section 313 and PPA section 6607.

TOXIC SUBSTANCES CONTROL ACT

The Toxic Substances Control Act (TSCA) gives EPA broad authority to gather information about and to regulate any part of the life cycle of chemical substances and mixtures

[179] The Executive Order is entitled "Strengthening Federal Environmental, Energy, and Transportation Management" and was published at 72 Fed. Reg. 3919 (Jan. 26, 2007).

to protect human health and the environment from unreasonable risks of injury. Subchapter I sets out general authorities applicable to the entire universe of chemical substances and mixtures; it also specifies requirements for PCBs and mercury. Subchapter II addresses asbestos in schools and other public and commercial buildings; Subchapter III sets up a program for addressing indoor exposure to radon; Subchapter IV establishes extensive regulation of the hazards of lead in paints and homes; Subchapter V provides authority for EPA to provide grants and issue guidance to promote healthy, high-performance schools; and Subchapter VI establishes formaldehyde standards for composite wood products and requires EPA to promulgate implementing regulations. The core of TSCA is principally designed to regulate through three basic themes: (1) a program of federal scrutiny of new chemicals before they are distributed in commerce; (2) information-gathering authorities (including authority to require testing of chemicals and mixtures); and (3) substantive regulation at any or all stages of a chemical's or mixture's life cycle.

I. FINDINGS AND INTENT

When Congress enacted TSCA, it set out its findings, policy, and intent in section 2. This section expresses a broad concern over potential risks to human health and the environment, and a desire to vest in EPA "adequate authority" to regulate chemical substances and mixtures that present an "unreasonable risk of injury to health or the environment." In addition, section 2(c) clearly states that Congress intended EPA to "consider the environmental, economic, and social impact of any action" taken under TSCA. This explicit statement of intent – particularly the broad reference to "social impact" – could provide the opportunity for EPA to consider and apply environmental justice considerations to all regulatory actions under TSCA. The statute does not provide a definition for "social impact," nor has EPA defined this term in its regulations. However, EPA has specifically considered disproportionately impacted populations during rulemaking under TSCA. For example, EPA removed an "opt-out" provision from its Renovation, Repair and Painting Rule in part because of concerns related to minority and low-income populations.[180]

II. TSCA SUBCHAPTER I

In general, Congress gave EPA broad discretion to select which chemical substances or mixtures to investigate and regulate. This suggests that EPA can consider the interests of minority, low-income, and indigenous populations when setting priorities concerning which chemical substances or mixtures warrant EPA's attention for assessment and possible regulatory action.

Most of EPA's general regulatory authority flows from sections 4, 5, and 6 of TSCA. Each of these sections serves a different regulatory purpose, and therefore each applies the "unreasonable risk" standard in a different way. Section 4 allows EPA to require testing to determine the effects of a chemical substance or mixture on health or the environment where EPA determines that there are insufficient data and experience to determine those effects, and where EPA finds that the substance or mixture "*may present* an unreasonable risk of injury" (emphasis added), or that the substance or mixture is produced in substantial quantities and may enter the environment "in substantial quantities" or pose "significant or substantial human

[180] *See* 75 Fed. Reg. 24802, 24804-05 (May 6, 2010).

exposure." Because this section addresses risks that are uncertain, the threshold for regulatory action is less difficult to meet than the threshold for substantive regulation under section 6 (see below). EPA has generally prioritized chemical substances to investigate for possible section 4 testing based on volume or suspected hazard, but the Agency has substantial discretion to select chemical substances; considering impacts on overburdened communities also would appear to fit within the Congressional intent that EPA consider "social impacts" of regulatory actions. In addition, because the "unreasonable risk" standard entails a balancing of the costs and benefits of regulation, EPA might be able to consider whether a risk is borne disproportionately by minority, low-income, and indigenous populations in evaluating whether it may be "unreasonable."

TSCA section 5, among other things, prevents the commercial manufacture or import of any new chemical substance in the United States until 90 days after EPA is notified of the intended manufacture or import. EPA can also, by rule, require similar notification from manufacturers, importers, and processors of significant new uses of existing chemical substances. During the notification period, EPA reviews information in the notice. As under section 4, EPA can regulate new chemicals or significant new uses pending the development of information based on a lower threshold of certainty; if a substance "may present an unreasonable risk," EPA can impose restrictions on the manufacture, processing, distribution in commerce, use, or disposal of the substance, or requirements to conduct tests on the substance. In addition to the impacts that may be caused by the chemical substance generally, this broad pre-market entry review can take into account the submitting company's circumstances such as a manufacturing plant's location, thus presenting another possible opportunity for considering impacts on minority, low-income, and indigenous populations.

TSCA section 6 gives EPA its broadest authority to regulate any chemical substance or mixture if there is "a reasonable basis to conclude" that the substance or mixture "presents or will present an unreasonable risk of injury to health or the environment." This provision allows EPA to address risks in all environmental media – water, air, land, or any combination of media. Similarly, TSCA section 6 gives EPA the authority to address the unreasonable risk that occurs from a broad range of activities – manufacturing, processing, distribution in commerce, use, or disposal. EPA can establish TSCA section 6 requirements that are limited to specified geographic areas.

Although the standard for acting under section 6, *i.e.*, that a substance "presents or will present" an unreasonable risk, is stricter than the "may present" standard in sections 4 and 5, it does not require factual certainty that a risk is unreasonable, but rather a "reasonable basis" for that conclusion. The legislative history of TSCA makes it clear that EPA may take regulatory action to prevent risk even though there are uncertainties as to the threshold level of risk. In making the unreasonable risk determination, TSCA section 6(c)(1) requires EPA to consider:

A. The effects of the chemical on health and the magnitude of its exposure to humans;

B. The effects of the chemical on the environment and the magnitude of its exposure to the environment;

C. The benefits of the chemical for various uses and the availability of substitutes; and

D. The reasonably ascertainable consequences of regulation, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

In essence, the finding of unreasonable risk involves a balancing of the probability that risk will occur and the magnitude and severity of that risk, against the adverse effects on society of proposed Agency action to reduce the risk. As stated above, EPA could argue that the determination of whether a risk is unreasonable could include consideration of whether it is disproportionately borne by minority, low-income, or indigenous populations, including an examination of potential cumulative exposures of such populations. Further, EPA could base regulation under section 6 on consideration of the most vulnerable or exposed populations.

The broad discretion vested in EPA to administer this standard through regulations means that the Agency could potentially consider the impacts of such regulations on minority, low-income, and indigenous populations. For example, if EPA had information about manufacturing or processing of a chemical presenting an unreasonable risk of injury to health or the environment with respect to a particular area with a significant minority, low-income, or indigenous population, EPA may be able to address the risk through a regulation under TSCA section 6.

As mentioned above, TSCA directly regulates the manufacture, processing, distribution in commerce, use and disposal of PCBs under section 6(e). Because of the specific statutory prohibitions on PCBs, EPA does not have to demonstrate that PCBs "present or will present" an unreasonable risk to impose regulatory conditions. In fact, to allow an ongoing use of PCBs, EPA must find that it will pose "no unreasonable risk" of injury to health or the environment. The implementing regulations[181] for section 6(e) establish disposal requirements for PCBs and regulatory conditions for continuing to use remaining PCB-containing equipment to ensure its safe operation. Under these rules, EPA reviews applications for approval of PCB disposal facilities, applying the "no unreasonable risk" standard. It is possible that EPA could consider the interests of minority, low-income, and indigenous populations in the "no unreasonable risk" analysis for such facility-specific approvals.

III. TSCA SUBCHAPTER II: ASBESTOS

Subchapter II of TSCA, the Asbestos Hazard Emergency Response Act (AHERA),[182] was enacted to establish a uniform program for addressing the presence of asbestos in school buildings. Pursuant to TSCA section 212, EPA has appointed an Asbestos Ombudsman who is tasked with receiving "complaints, grievances, and requests for information submitted by any person with respect to any aspect of [AHERA]" and with rendering "assistance with respect to the complaints, grievances, and requests received." The Asbestos Ombudsman also is responsible for making any recommendations to the Administrator that he or she feels are appropriate. Owing to this defined role, the Asbestos Ombudsman can serve as a useful interface between the Agency and any community dealing with environmental justice considerations that relate to or fall within the scope of AHERA. In addition, the Asbestos Ombudsman is uniquely

[181] 40 C.F.R. Part 761.

[182] 15 U.S.C. §§ 2641-2656.

situated to recommend and promote actions on the part of EPA that might address any such concerns.

IV. TSCA SUBCHAPTER III: INDOOR RADON

Subchapter III of TSCA established various cooperative relationships between EPA, the U.S. Department of Housing and Urban Development, and states to develop and implement programs to assess and reduce indoor exposure to radon. There are two separate provisions concerning federal assistance to state radon programs that explicitly call for application of a criterion that could be implemented to advance environmental justice. First, TSCA section 305 describes technical assistance that EPA must provide to state radon programs. Both sections 305(a)(5) and 305(a)(6) include statements that, to the maximum extent practicable, "homes of low-income persons" should be selected for projects that evaluate homes and demonstrate radon mitigation methods. Second, TSCA section 306(i)(2) establishes a limitation on financial assistance (grants) that a recipient state "should make every effort, consistent with the goals and successful operation of the State radon program, to give a preference to low-income persons."

V. TSCA SUBCHAPTER IV: LEAD-BASED PAINT HAZARDS

Subchapter IV was added to TSCA in October 1992. This Subchapter deals with hazards from lead-based paint. The TSCA Subchapter IV lead-based paint hazard rules are important to advancing environmental justice when the risk reduction to be achieved affects public or inner-city housing. To the extent that lead-based paint hazards disproportionately affect minority, low-income, and indigenous populations, EPA can argue that there is authority under TSCA section 2(c) (discussed above) to factor environmental justice considerations into the implementation of TSCA Subchapter IV authorities.

EPA has, in fact, considered environmental justice factors in a title IV rulemaking. In 2008, EPA promulgated a rule governing renovation activities in pre-1978 housing and child-occupied facilities (mostly pre-schools and day-care centers) pursuant to TSCA section 402(c)(3).[183] Subsequently, in July of 2010, EPA amended the 2008 rule by eliminating the "opt-out" provision that excused contractors from the lead-safe work practice requirements if the homeowner provided the contractor with a signed statement having to do with the presence of children or pregnant women.[184] In extending the rule requirements to all pre-1978 housing and child-occupied facilities regardless of current occupancy, EPA explicitly cited environmental justice considerations as one of the reasons for making the change.

EPA may have additional opportunities to factor in environmental justice considerations. For example, in October 2009, EPA committed to initiate an appropriate proceeding to review whether the current lead hazard standards EPA promulgated in 2001 under TSCA section 403 are sufficiently protective. In so doing, EPA may have the opportunity to account for heightened risk factors such as diet and exposure of vulnerable populations. Under TSCA section 405(d) EPA is to engage in public education and outreach activities to increase public awareness of a variety of health issues related to lead exposure and poison prevention. Specifically, TSCA section 405(d)(2) provides that public education and outreach activities shall be designed to

[183] *See* 73 Fed. Reg. 21692 (April 22, 2008) (codified at 40 C.F.R. Part 745, Subparts E and Q).

[184] *See* 75 Fed. Reg. 24802 (May 6, 2010) (codified at 40 C.F.R. Part 745, Subpart E).

provide educational and information to: health professionals; the general public, with emphasis on parents of young children; homeowners, landlords, and tenants; consumers of home improvement products; the residential real estate industry; and the home renovation industry. There may be opportunities to target such education and outreach to high-risk populations.

VI. TSCA SUBCHAPTER V: HEALTHY HIGH-PERFORMANCE SCHOOLS

Section 2695a of TSCA requires EPA, in consultation with the U.S. Departments of Education and Health and Human Services, to issue voluntary school site selection guidelines that account for, among other things, the special vulnerability of children to hazardous substances or pollution exposures. These guidelines are available on the EPA website and are accompanied by "related links and resources" that provide a variety information on environmental justice.[185]

Section 2695c of TSCA requires EPA, in consultation with the U.S. Departments of Education and Health and Human Services, to issue voluntary guidelines for use by states in developing and implementing environmental health programs for schools. Among other things, the guidelines are to take into account the special vulnerability of children in low-income and minority communities to exposures from contaminants, hazardous substances, and pollution emissions, and the impact of school facility environments on student and staff disabilities and special needs.

Section 2695 of TSCA authorizes EPA, in consultation with the U.S. Department of Education, to provide grants to assist states in, among other things, implementing state school health programs and identifying ongoing school building environmental problems. To the extent health and environmental problems associated with schools disproportionately affect minority, low-income, and indigenous populations, EPA could use this authority to address environmental concerns. Section 2695 has a sunset provision, expiring Dec. 19, 2012.

[185] *See* "School Siting Guidelines" available at: http://www.epa.gov/schools/siting/.

CHAPTER FIVE: TRIBAL PROGRAMS

EPA'S INDIAN POLICY AND TRIBAL CONSULTATION

Protecting Indian tribes and the places where they live is an important aspect of implementing EPA's commitment to environmental justice. Tribal communities often face vulnerabilities due to lack of a health care infrastructure and heightened exposure to certain toxins. In general, EPA's discretionary authority to promote environmental justice, as discussed in other chapters of this document, is available to address human health and environmental conditions in tribal communities, consistent with Executive Order 12898 on environmental justice, which applies to tribal populations, Native American programs, and federally recognized Indian tribes.[186] EPA advances environmental justice in Indian country by, among other things, assisting tribes in developing their own programs to protect the health of tribal members and their environment and by directly implementing federal programs in Indian country. Tribes are sovereign governments that retain important powers over their members and territory. This chapter focuses on ways to enhance the exercise of tribal sovereignty to protect human health and the environment in Indian country under EPA's statutes. For a discussion of EPA's direct implementation of its statutes in Indian country, see Chapters One to Four.

EPA has a long-standing commitment to work directly with federally recognized tribes as partners on a government-to-government basis to protect tribal health and environments, as illustrated by EPA's Indian Policy and related Headquarters and Regional policy statements and guidance documents. In 1984, EPA became the first federal agency to adopt an Indian Policy.[187] In that Policy, which has been reaffirmed by each EPA Administrator since its adoption, EPA recognized the importance of ensuring close involvement of federally recognized tribal governments in making decisions and managing environmental programs affecting their areas and members. Among other things, the Agency committed to look directly to tribal governments to play an important role in setting standards, making environmental policy decisions, and managing programs in their areas. For a number of programs, one aspect of EPA's implementation of this approach is to treat eligible tribes in a similar manner as states for purposes of receiving grants and administering approved environmental regulatory programs and other functions under EPA statutes. This approach enables tribes to perform essentially the same role in their areas that states play outside of Indian country in regulating the environment under EPA statutes.[188] In other cases, EPA can advance environmental justice in Indian country by directly implementing EPA programs there.

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[186] As used in Executive Order 12898, the terms "minority population" and "low-income population" include American Indians and Alaska Natives. *See* Appendix A to the Council on Environmental Quality's publication "Environmental Justice: Guidance Under the National Environmental Policy Act" at pages 25-26 (Dec. 10, 1997) (providing guidance on key terms in Executive Order 12898). Moreover, Section 6-606 of the EO provides that its provisions apply equally to Native American programs and that steps be taken to address federally recognized Indian tribes.

[187] *EPA Policy for the Administration of Environmental Programs on Indian Reservations* (Nov. 8, 1984). The Policy was issued by then-Administrator William D. Ruckelshaus and is available at http://www.epa.gov/tribal/pdf/indian-policy-84.pdf.

[188] The term "Indian country" as defined at 18 U.S.C. § 1151 means:

Consistent with EPA's 1984 Indian Policy and other federal policies, EPA is committed to consulting with tribal governments on matters that affect their communities and environments. Effective tribal consultation continues to be a stated goal of the federal government. In November 2009, President Obama issued a memorandum reiterating a commitment to regular and meaningful consultation and collaboration with tribal governments on federal decisions that affect them.[189] The memorandum also directed federal agencies to develop a detailed plan of actions to implement the policies and directives of Executive Order 13175,[190] which relates to coordination and consultation with tribal governments on federal actions with tribal implications. On May 4, 2011, the Agency released its new *EPA Policy on Consultation and Coordination with Indian Tribes*,[191] to further implement Executive Order 13175 and EPA's 1984 Indian Policy. The new policy sets a broad standard for when EPA should consider consulting on a government-to-government basis with federally recognized tribal governments. Notably, the scope of the new policy is broader than that found in Executive Order 13175. The new policy establishes clear standards for EPA's consultation process, as well as a management oversight and reporting structure to ensure accountability and transparency. When considering legal tools that may affect tribal interests, including those described in this document to enhance tribal governmental involvement in the protection of human health and the environment in Indian country, EPA will first consult with tribal governments before any decisions are made to use the tools, consistent with the *EPA Policy on Consultation and Coordination with Indian Tribes*.

In addition, through its Indian Policy and other Agency-wide efforts, EPA continues to recognize the importance of tribal involvement in Agency decision-making. Several EPA Regions and programs also have developed specific procedures and plans describing EPA's expectations for tribal consultation and providing guidance designed to promote effective and efficient outreach to, and consultation with, tribal governments in appropriate situations. Such

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> (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

Although Indian country is a relevant geographic area for certain purposes and generally describes the area where EPA and authorized tribes, as opposed to states, would administer environmental programs under EPA's statutes, this document is intended to identify a variety of legal tools available to EPA to address environmental justice issues in any overburdened tribal communities, regardless of location, including Alaska Native communities located outside of Indian country.

[189] Presidential Memorandum on Tribal Consultation (Nov. 5, 2009). This memorandum is available at 74 Fed. Reg. 57881 (Nov. 9, 2009) and http://www.epa.gov/tribal/pdf/tribal-consultation-memorandum-09.pdf.

[190] EO 13175, entitled "Consultation and Coordination With Indian Tribal Governments," 65 Fed. Reg. 67249 (Nov. 9, 2000). Importantly, EPA's responsibilities under Executive Order 13175 are separate from the responsibilities under Executive Order 12898. The Agency's consideration of tribal interests and consultation with tribes under Executive Order 13175 stems from the federal government's special relationship with federally recognized tribes. Consistent with the scope of Executive Order 12898, the legal tools identified in this document are intended to address environmental justice issues involving a broader range of tribal communities, including communities of state-recognized and non-recognized tribes, and tribal communities living outside of Indian country, including in Alaska.

[191] The policy is available at http://www.epa.gov/tribal/pdf/cons-and-coord-with-indian-tribes-policy.pdf.

consultation is highly significant in helping to ensure appropriate tribal input in relevant EPA decision-making, and ultimately in the protection of human health and the environment in tribal communities.

TREATMENT IN A MANNER SIMILAR TO A STATE

I. EPA'S TAS PROCESS

As noted in Chapters One and Two, the Clean Air Act (CAA), Clean Water Act (CWA), and Safe Drinking Water Act (SDWA) all expressly provide for Indian tribes to play a role in protecting human health and the environment. These statutes allow, but do not require, tribes to seek to administer EPA environmental programs. Specifically, the statutes authorize EPA to approve tribal applications for eligibility to receive grants and carry out environmental programs. Such treatment enables tribes to protect human health and the environment in tribal areas in generally the same way that states do for areas outside of Indian country. In addition, EPA has interpreted the Toxic Substances Control Act (TSCA) and the Emergency Planning and Community Right-to-Know Act (EPCRA) – both of which are silent as to tribes – to authorize tribal roles within their areas. See Chapter Four. EPA also interprets the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to authorize approval of certain tribal programs for the certification and training of applicators of restricted use pesticides. See Chapter Four. Moreover, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) provides that tribes shall be afforded substantially the same treatment as states for various specified provisions of the statute, including the provisions regarding notification of releases and consultation on remedial actions affecting a tribe or tribes. See Chapter Three.

As a general matter, EPA's statutes and regulations that authorize EPA to treat an Indian tribe as a state (TAS)[192] do so for eligible Indian tribes (*i.e.*, those that are federally recognized, have a governing body carrying out substantial duties and powers over a specific area, and are capable of carrying out the functions in a manner consistent with EPA's statutes and regulations). In addition, the statutes or regulations generally call for a jurisdictional showing for the relevant geographic area over which the tribe seeks to administer an environmental regulatory program.

[192] TAS terminology originates from existing language in the tribal provisions of certain EPA statutes and implementing regulations establishing the authority for EPA to approve tribal applications for eligibility to receive funding and administer environmental programs under federal laws. In 1994, EPA adopted and implemented a policy to discontinue the use of the term "treatment as a state" to the extent possible because the term is disfavored by federally recognized tribes and does not accurately reflect their unique legal status or relationship with the federal government, which is significantly different than that of states. 59 Fed. Reg. 64339 (Dec. 14, 1994) (commonly known as the TAS Simplification Rule). EPA believes that Congress did not intend to alter the unique federal/tribal relationship when it authorized treatment of tribes "as states;" rather, the purpose was to reflect an intent that tribes should assume a role in implementing EPA statues on tribal land comparable to the role states play on state land. *Id*. EPA continues to supports discontinuation of the term "treatment as a state." When its use is needed for clarity and consistency due to the term's statutory origin, EPA prefers to use the more accurate term "treatment in a manner similar to a state," which is also abbreviated "TAS." EPA continues to evaluate this terminology and to seek ways to better reflect the unique status of federally recognized tribes and the federal/tribal relationship by avoiding unnecessary comparisons to states.

There are, however, significant differences among the various TAS authorities. For instance, in some cases, the statutes differ in how they address the geographic extent of potential tribal programs. The CWA authorizes EPA to approve eligible tribal programs over reservation areas. Other statutes allow approval of programs over broader areas, including non-reservation areas of Indian country. EPA also interprets the statutes differently regarding demonstrations of tribal authority to carry out environmental regulatory functions. For example, EPA interprets the CAA TAS provision to constitute a delegation of authority by Congress to eligible tribes to manage air resources throughout their reservations. By contrast, EPA currently interprets the CWA and SDWA TAS provisions to require a demonstration of inherent tribal authority to regulate the relevant activities.

In addition, the statutes include some differences in the scope of available programs that tribes may apply to administer. For instance, the CWA identifies various statutory provisions for which EPA may treat eligible tribes similarly to states. They include: grants under CWA section 106, water quality standards under section 303, clean lakes under section 314, nonpoint source management under section 319, water quality certifications under section 401, the National Pollutant Discharge Elimination System (NPDES) program under section 402, and regulating the discharge of dredged or fill material into waters of the United States under section 404.[193] Similarly, the SDWA authorizes TAS for eligible tribes to exercise "primary enforcement responsibility for public water systems and for underground injection control," and to receive financial assistance to carry out those functions.[194] By contrast, the CAA authorizes TAS more generally and directs EPA to promulgate regulations specifying "those provisions of [the CAA] for which it is appropriate to treat Indian tribes as States."[195] EPA has promulgated such regulations at 40 C.F.R. Part 49; these regulations generally authorize eligible tribes to "be treated in the same manner as States with respect to all provisions of the Clean Air Act" with the exception of a few enumerated provisions largely relating to program submission or other requirements that EPA determined were not appropriate to impose on tribes.[196] See Chapter One.

EPA has promulgated regulations under its various statutes governing the process by which tribes may apply for TAS status as well as the procedures EPA will follow in taking action on tribal applications.[197] These regulations provide substantial detail to interested tribes regarding the information they should submit in their applications and generally call for EPA to process the applications in a timely manner. Generally, as discussed below, EPA may have the

[193] CWA section 518(e).

[194] SDWA section 1451(a)(2)-(3).

[195] CAA section 301(d)(2).

[196] 40 C.F.R. §§ 49.3 and 49.4.

[197] *See, e.g.*, 40 C.F.R. §§ 49.1-49.9 (CAA programs); 40 C.F.R. § 131.8 (CWA water quality standards program); 40 C.F.R. §§ 123.31-123.34 (CWA NPDES permitting program); 40 C.F.R. §§ 233.60-233.62 (CWA wetlands permitting program); 40 C.F.R. §§ 501.22-501.25 (CWA sewage sludge management program); 40 C.F.R. §§ 130.6(d), 35.583, and 35.633 (CWA grants); 40 C.F.R. §§ 142.72, 142.76, and 142.78 (SDWA public drinking water system supervision program); 40 C.F.R. §§ 145.52, 145.56, and 145.58 (SDWA underground injection control program); 40 C.F.R. §§ 35.676 and 35.686 (SDWA grants); 40 C.F.R. § 300.515(b) (CERCLA response actions); 40 C.F.R. § 745.324 (TSCA lead-based paint program); and 40 C.F.R. §§ 35.693, 35.703, and 35.713 (TSCA grants).

capacity to streamline the TAS process for environmental regulatory programs, and efforts to this end are currently under way.

II. STEPS TO ENHANCE TAS

The statutory TAS provisions allow EPA some flexibility in determining how best to implement its authority to authorize tribes to administer federal programs. Thus, since EPA adopted its first TAS regulations, it has taken various steps to try to improve the process, both by simplifying the way it is administered under various programs and by revising its TAS regulations.

A. What EPA has Already Done

EPA has taken several steps to make the TAS process more robust, efficient, and effective. First, EPA has worked continuously to improve the TAS process since issuing its first TAS regulations in 1988. For instance, EPA's experience processing TAS applications led the Agency to issue a regulation revising and simplifying all of its then-existing TAS regulations in 1994. Under the simplified TAS process, EPA streamlined various procedures to eliminate duplicative requirements both in the preparation of tribal applications and also in the processing of those applications by EPA. EPA again refined the TAS process in 1998 and 2008 after convening workgroups to examine the Agency's continuing experience with tribal TAS applications and to identify potential additional efficiencies and areas where additional guidance would be useful. The latter process, which included significant consultation with tribal officials, culminated with the issuance of a formal TAS Strategy[198] designed to promote more efficient and transparent review of tribal TAS applications. The TAS Strategy provides important guidance regarding the information tribes should submit in their applications, describes practical and efficient procedures and timelines EPA intends to use to process the applications, and includes measures to help ensure accountability and appropriate sharing of information with applicant tribes.

In addition, EPA has generally attempted to interpret its statutory authority broadly to allow for tribal involvement in a wide variety of programs. For instance, as noted above, the CAA provided EPA with discretion to determine which provisions of the statute were appropriate for TAS. In implementing the CAA TAS regulations, EPA determined that all provisions of the statute were appropriate for TAS, with certain limited enumerated exceptions largely relating to provisions that would have inappropriately imposed requirements on, rather than affording opportunities to, tribal governments. Similarly, EPA has interpreted TSCA and EPCRA – which include no explicit reference to tribal roles – to authorize TAS for tribes to implement various roles under those statutes in their areas, including managing lead-based paint residential abatement programs under TSCA.[199]

Moreover, in addition to section 126 of CERCLA, which specifies certain provisions of the statute for which tribes shall be afforded TAS, EPA's National Oil and Hazardous

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[198] Memorandum from Marcus Peacock, EPA Deputy Administrator, entitled "Strategy for Reviewing Tribal Eligibility Applications to Administer EPA Regulatory Programs" (Jan. 23, 2008). This memorandum, which refers to the TAS guidance memorandum issued on March 19, 1998, is available at http://www.epa.gov/tribal/pdf/strategy-for-reviewing-applications-for-tas-01-23-08.pdf.

[199] *See, e.g.*, 40 C.F.R. § 745.324.

Substances Pollution Contingency Plan (NCP) regulations under CERCLA define "State" to include Indian tribes "except where specifically noted" to the contrary[200] and establish eligibility criteria for tribes that want to carry out response actions under CERCLA section 104.[201] Further, as discussed in Chapter Four, the only explicit reference to tribes in FIFRA is in section 23 of the statute, which authorizes EPA to enter into agreements with tribes under the statute and to assist tribes with training and certification of applicators of certain pesticides. EPA has interpreted its authorities under FIFRA to allow tribes to submit their own plans to train and certify applicators of restricted use pesticides. Chapter Four also describes how EPA has implemented its authorities under FIFRA to take several steps to ensure that the statute's benefits are available to communities in Indian country. These include steps by EPA to directly implement programs in areas of Indian country to address emergencies and special local needs.

EPA has taken steps to enable tribes to seek TAS and implement approved programs without the need to demonstrate certain criminal enforcement authorities. The only statute that expressly provides that tribes do not need to exercise criminal authority to obtain TAS is SDWA section 1451(b)(2). The other statutes are silent on this issue, and EPA has used its discretion to issue regulations that enable the Agency to approve tribes for TAS notwithstanding limitations on tribal criminal enforcement authority.[202] In these cases, EPA's regulations generally call for the federal government to retain primary criminal enforcement authority and for the tribes to enter into agreements with EPA to provide investigative leads and otherwise assist in the development of criminal enforcement actions.

Further, in an effort to streamline TAS applications in situations where jurisdictional or land status issues may exist for only part of a particular tribe's application, EPA's regulations generally allow the Agency to approve an applicant tribe's TAS status for those areas where the jurisdictional scope of the tribe's application is undisputed.[203] Although the resulting TAS approval may be limited in geographic extent and may not address all areas covered by the tribe's application, this approach enables the tribe to assume a role for the approved area without the delays and uncertainties that may accompany resolution of jurisdictional or land status disputes. In any such situation, EPA would consult with the applicant tribe regarding the scope of the application and any EPA approval.

EPA's ability to approve tribal roles for certain programs faces statutory barriers. Notably, EPA was unsuccessful in defending a regulation authorizing TAS for tribes under the Resource Conservation and Recovery Act (RCRA). Although RCRA does not contain an explicit TAS provision, EPA attempted to exercise its discretion to provide a role for tribes similar to that of states for certain RCRA programs. Following a challenge to EPA's rule, the D.C. Circuit, relying on certain definitional language addressing tribes in RCRA, held that EPA

[200] 40 C.F.R. § 300.5.

[201] 40 C.F.R. § 300.515(b).

[202] *See, e.g.*, 40 C.F.R. §§ 49.7(a)(6) and 49.8 (CAA regulations); 40 C.F.R. §§ 123.34, 233.41(f), and 501.25 (CWA regulations for, respectively, NPDES, section 404, and sewage sludge programs).

[203] *See, e.g.*, 40 C.F.R. § 49.9(e).

lacked authority to treat tribes as states under the current language of that statute.[204] The Court did recognize, however, EPA's authority to regulate under RCRA within Indian country.[205]

B. Further Steps to Enhance TAS

EPA believes that direct tribal involvement through the TAS process is an effective means of ensuring that the needs of tribal communities, and the uses those communities make of their environmental resources, are addressed during implementation of programs under EPA's statutes. Enhancing tribes' ability to obtain eligibility to administer these programs promotes environmental protection in Indian country, with significant emphasis on tribal sovereign decision-making and control of Indian country health and environments by the communities living there. EPA is, therefore, interested in additional steps the Agency may take to streamline the TAS process and thereby promote enhanced tribal involvement. EPA can, for instance, continue to review its TAS procedures on a national level as the Agency gains additional experience processing TAS applications in the context of the goals and expectations of the TAS Strategy described above.

In addition, EPA is considering whether it can reinterpret existing CWA TAS requirements in ways that would eliminate the need for tribes to show inherent authority over non-member activities for purposes of TAS for CWA regulatory programs. That would significantly streamline the TAS application and review processes, and could create an incentive for more tribes to seek TAS for EPA regulatory programs to protect tribal health and environments. Under EPA's current approach, some tribes may defer seeking TAS for CWA programs because of this inherent authority element. To demonstrate inherent authority, tribes sometimes need to present detailed factual showings relating to impacts of the regulated activities on the applicant tribe, including non-member activities on reservation land. Tribes have expressed concern over making these demonstrations, which are functioning for some tribes as a deterrent to seeking TAS status. As EPA recognized in the preamble to its final TAS regulations for the water quality standards (WQS) program, the CWA might be amenable to a different interpretation.[206] For example, EPA interprets the TAS provision in the CAA as a Congressional delegation to eligible tribes of authority over their entire reservations (including activities on non-member-owned fee lands) for CAA purposes. Under that delegation approach, tribes do not need to demonstrate inherent authority in order to obtain TAS status over their entire reservations. One federal district court judge stated, in dicta, that EPA could properly have construed the CWA TAS provision as a delegation of authority,[207] and a majority panel of a federal appeals court cited that statement favorably.[208] Moreover, as EPA acknowledged in the

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[204] *See Backcountry Against Dumps v. EPA*, 100 F.3d 147 (D.C. Cir. 1996), which also is referenced in Chapter Three.

[205] *Id.* at 153.

[206] 56 Fed. Reg. 64876, 64877-80 (Dec. 12, 1991) (discussing whether CWA section 518(e) could be construed to delegate to tribes authority to regulate water quality throughout reservations without further judicial or Congressional guidance).

[207] *Montana v. EPA*, 941 F. Supp. 945, 951 (D. Mont. 1996), *aff'd*, 137 F.3d 1135 (9th Cir.), *cert. denied*, 525 U.S. 921 (1998).

[208] *Arizona Public Service v. EPA*, 211 F.3d 1280, 1292 (D.C. Cir. 2000), *cert. denied sub nom. Michigan v. EPA*, 532 U.S. 970 (2001).

preamble to the final WQS regulations,[209] in a plurality opinion of the Supreme Court, Justice White cited CWA section 518(e) as an example of a Congressional delegation of authority.[210] EPA's interpretation of the CAA, which was upheld in a legal challenge,[211] has significantly streamlined many TAS applications under that statute. EPA is considering whether a similar interpretation is available under the comparable language of the CWA.

EPA is also considering whether for certain CWA programs, such as the WQS program, EPA could approve a tribal program without requiring the tribe to demonstrate that it has civil authority to regulate the environment. For instance, in submitting WQS for EPA review and approval, states must certify that the WQS were duly adopted pursuant to state law.[212] States are not, however, required to make a separate demonstration of regulatory authority over state waters or the activities of persons in their areas. EPA is considering whether it may be possible to reinterpret its existing WQS TAS regulations to reduce burdens on tribes by making the showing for tribal involvement more comparable to that of states. Such an approach, along with other similar efforts to streamline TAS procedures and requirements, may provide important opportunities to enhance tribes' ability to manage their environments through the TAS process.

Similarly, there may be opportunities for EPA to reconsider its prior interpretation of the SDWA TAS provision as it relates to a tribe's jurisdictional showing. Of course, any such approaches under the SDWA or CWA would need to be carefully analyzed in light of the existing statutory language and in the context of EPA's prior interpretations and programmatic needs.

EPA could also clarify its interpretation of some existing regulations to further the role of tribes. For example, CERCLA section 126(a) specifies that "[t]he governing body of an Indian tribe shall be afforded substantially the same treatment as a State" with respect to certain provisions of the statute, including consultation on remedial actions under CERCLA section 104(c)(2). As noted above, in Subpart F of the NCP regulations, EPA established criteria for TAS under CERCLA section 104, including the need for the tribe to have jurisdiction over a site at which a Fund-financed response is contemplated.[213] In view of the language in section 126(a) and the scope of section 300.515(a) of the NCP regulations, EPA could clarify whether this jurisdictional criterion is relevant for purposes of tribal consultation on remedial actions that affect them, as opposed to situations in which the tribe has the lead for conducting the response action. Similarly, EPA could clarify whether the jurisdictional criterion is relevant for purposes of entering into an EPA/State Superfund Memorandum of Agreement under 40 C.F.R. § 300.505 when the tribe is not the lead for the response action.

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[209] 56 Fed. Reg. at 64880.

[210] *Brendale v. Confederated Tribes and Bands of the Yakima Indian Nation*, 492 U.S. 408, 428 (1989).

[211] *Arizona Public Service v. EPA*, 211 F.3d 1280 (D.C. Cir. 2000), *cert. denied sub nom. Michigan v. EPA*, 532 U.S. 970 (2001).

[212] 40 C.F.R. § 131.6(e).

[213] 40 C.F.R. § 300.515(b).

ALTERNATIVES TO TAS

As EPA has gained experience with its tribal programs, it has increasingly recognized that not all tribes are interested in assuming, or are able to assume, TAS. Indeed, EPA recognizes that there are other ways tribes can participate in the protection of their communities and environments. For example, EPA can provide financial assistance to tribes to develop their capacity for environmental management without the need to seek TAS for any particular program. The Tribal General Assistance Grant Program, which is discussed further in Chapter Seven, is one example. But EPA also recognizes that tribes can use program development grants under specific media statutes, like the CWA, to help them manage their environments without seeking TAS status for any regulatory program. Consistent with that approach, EPA developed a guidance document – "Final Guidance on Awards of Grants to Indian Tribes under Section 106 of the Clean Water Act" – that discusses measures tribes can take, using CWA development grant funds, to participate in managing reservation environments separate from the TAS process for regulatory programs.[214] The Guidance discusses both regulatory measures under tribal (rather than federal) law, and measures not involving the exercise of any regulatory authority that nevertheless enhance environmental protection.

Moreover, as an alternative to TAS under the CWA, tribes may seek to manage and protect reservation waters, including water bodies they share in common with states, by working cooperatively with states under CWA section 518(d). That provision authorizes tribes and states to enter into cooperative agreements, subject to EPA review and approval, to jointly plan and administer CWA programs. Its legislative history indicates that it was intended to create an alternative to TAS to protect reservation environments under the CWA.[215] Use of this authority has been very limited; there may be room for expanding use of this authority.

DIRECT IMPLEMENTATION

As discussed in other chapters, EPA can undertake direct implementation of human health and environmental programs in Indian country. In some cases, EPA may undertake implementation activities directly using Agency resources. In other situations, the Agency may work in conjunction with tribes under direct implementation cooperative agreements, which are described more fully in Chapter Seven.

Because very few tribes have as yet sought and been approved to administer environmental regulatory programs under EPA's statutes, the majority of environmental regulatory activity under federal laws in Indian country involves direct implementation by EPA. In most cases, therefore, EPA will be the entity with relevant authority to implement the various legal tools described in this document in Indian country. However, as described elsewhere, Indian tribes are sovereign entities exercising important powers over their members and areas, and those areas may include overburdened communities. In making decisions to advance environmental justice in overburdened tribal communities, EPA will remain respectful of tribal

[214] The guidance is available at http://water.epa.gov/grants_funding/cwsrf/upload/2006_10_20_cwfinance_final-tribal-guidance.pdf

[215] *See* 132 Cong. Rec. 32380, 32403 (1986).

governmental roles by, among other things, consulting with the relevant tribal governments on matters that affect them.

EPA currently implements a wide variety of environmental programs in Indian country. Some programs are specifically targeted to Indian country areas; others are national programs or requirements that apply in Indian country and elsewhere. EPA has used its rulemaking authority to implement environmental protection programs in Indian country. For example, EPA promulgated a Federal Implementation Plan for protection of air quality on the Indian Reservations in the States of Idaho, Oregon, and Washington; at the time of EPA's action, none of the tribes in those states had obtained TAS for CAA regulatory programs or established Tribal Implementation Plans. More broadly, EPA has recently issued regulations governing Review of New Sources and Modifications in Indian Country.[216] This rule for the first time establishes a regulatory framework for important elements of the New Source Review Program of the CAA in Indian country: *i.e.*, permitting for minor sources and for major stationary sources and major modifications in areas that are designated as not attaining the National Ambient Air Quality Standards. EPA continues to explore additional opportunities to implement programs in Indian country, including through rulemaking and other activities.

[216] 76 Fed. Reg. 38748 (July 1, 2011) (to be codified at 49 C.F.R. §§ 49.151-49.161 and 49.166-49.173, and Part 51, Appendix S).

CHAPTER SIX: ENVIRONMENTAL REVIEW PROGRAMS

INTRODUCTION

The National Environmental Policy Act (NEPA)[217] applies broadly to federal actions that may significantly affect the environment, and readily encompasses concerns raised by environmental justice, including impacts on the natural or physical environment and interrelated health, social, cultural, and economic effects.[218] Similarly, EPA has broad authority under section 309 of the Clean Air Act (CAA) to review and comment on other federal agencies' proposed regulations and actions that may significantly affect the environment.[219] Accordingly, the Presidential memorandum accompanying Executive Order 12898 emphasizes the importance of using the NEPA and CAA section 309 review processes to advance environmental justice. It directs federal agencies to "analyze the environmental effects, including human health, economic and social effects, of [their proposed] actions, including effects on minority communities and low-income communities, when . . . required by [NEPA]."[220] The memorandum calls for agencies to address significant adverse environmental effects on these communities in mitigation measures outlined or analyzed in environmental assessments, environmental impact statements, or records of decision.[221] It also directs EPA in its section 309 reviews to ensure that agencies fully analyze under NEPA the environmental effects, including human health, economic and social effects, of their proposed actions on minority communities and low-income communities.[222] NEPA and CAA section 309 are important tools for ensuring consideration and enhancing understanding of the environmental justice implications of federal actions across the entire Executive Branch.

Reflecting the importance EPA assigns to using NEPA as a tool in its efforts to promote environmental justice, EPA issued an April 19, 2011 memorandum entitled "Addressing Environmental Justice Through Reviews Conducted Pursuant to the National Environmental Policy Act and Section 309 of the Clean Air Act." The memorandum urges each EPA Regional Office, as well as Headquarters, to enhance Agency efforts to take environmental justice into account in their NEPA work. This includes fully utilizing EPA's authorities to advance environmental justice in the course of complying with NEPA under its own programs, as well as in connection with its review of other federal agencies' NEPA documents under CAA section 309.

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[217] 42 U.S.C. §§ 4321-4370h.

[218] The Council on Environmental Quality's regulations implementing NEPA define the term "effects" or "impacts" to include "ecological . . ., aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative." 40 C.F.R. § 1508.8.

[219] See CAA sections 309(a) (applying to matters "relating to duties and responsibilities" granted to the Administrator) and 309(b) (directing the Administrator to refer to the Council on Environmental Quality matters determined to be "unsatisfactory from the standpoint of public health or welfare or environmental quality").

[220] 30 Weekly Comp. Pres. Doc. at 280.

[221] *Id*.

[222] *Id*.

NEPA

NEPA and its implementing regulations, including those of the Council of Environmental Quality (CEQ),[223] require federal agencies to consider the environmental effects of their proposed actions that are subject to NEPA. When proposing a major federal action significantly affecting the quality of the human environment, section 102(2)(C) of NEPA requires an agency to prepare an Environmental Impact Statement (EIS). An agency can prepare an environmental assessment (EA) to determine whether the effects are potentially significant, or can move directly to preparing a more detailed EIS. If in an EA an agency determines the proposal's effects will not be significant, the agency may complete its NEPA review with a "[f]inding of no significant impact."[224]

In preparing EISs, NEPA and CEQ's implementing regulations direct federal agencies, including EPA, to establish a pre-EIS scoping process;[225] analyze the environmental effects of the proposed action; discuss all reasonable alternatives (including those outside the agency's jurisdiction) and the alternative of no action; identify practicable mitigation[226] not covered in the alternatives discussion; and provide for meaningful public participation. Because of statutory and judicially created exemptions, NEPA generally applies only to a limited number of EPA program activities, such as when EPA issues new source NPDES permits, conducts certain types of research, or constructs facilities. However, EPA may prepare voluntary EISs or EAs for its NEPA-exempt actions under its "Statement of Policy for Voluntary Preparation of National Environmental Policy Act (NEPA) Documents," and the criteria for doing so include "the potential for using an EA or an EIS to facilitate analysis of environmental justice issues . . . and to expand public involvement . . . ."[227] To help ensure that EPA fully considers environmental justice in its NEPA reviews, in 1998 EPA issued its *Guidance for Incorporating Environmental Justice Concerns in EPA's NEPA Compliance Analyses*.[228] This guidance suggests that the EPA NEPA analyst may approach the analysis of environmental justice from three vantage points: whether there exists a potential for disproportionate risk, whether communities have been

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[223] 40 C.F.R. Parts 1500-1508.

[224] 40 C.F.R. § 1508.13.

[225] CEQ and EPA guidance emphasizes the importance of public participation in the scoping process. *See* CEQ's *Environmental Justice: Guidance Under the National Environmental Policy Act* (Dec. 10, 1997) at 10-13 and EPA's *Guidance for Incorporating Environmental Justice Concerns in EPA's NEPA Compliance Analyses* (April 1998) at 4.0 – 4.1. *See also* 40 C.F.R. §§ 1501.7 and 6.203(a)(2).

[226] Pursuant to 40 C.F.R. § 1508.20, the term "[m]itigation" includes:

> (a) Avoiding the impact altogether by not taking a certain action or parts of an action.
> (b) Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
> (c) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
> (d) Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.
> (e) Compensating for the impact by replacing or providing substitute resources or environments.

[227] *See* 63 Fed. Reg. 58045, 58046 (Oct. 29, 1998), which is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=98-29019-filed.pdf.

[228] The guidance is available at: http://www.epa.gov/environmentaljustice/resources/policy/ej_guidance_nepa_epa0498.pdf.

sufficiently involved in the decision-making process, and whether communities currently suffer, or have historically suffered, from environmental and health risks or hazards.[229] EPA also follows the 1997 guidance on this subject issued by CEQ, entitled *Environmental Justice: Guidance Under the National Environmental Policy Act*.[230]

For purposes of environmental justice, when NEPA applies and the Agency prepares an EA or EIS, EPA's NEPA regulations,[231] policy, and guidance call for EPA to: (1) examine the direct and indirect effects of the EPA action on minority, low-income, and indigenous populations, including health impacts and socio-economic impacts that are interrelated to effects on the physical environment; (2) analyze, from an environmental justice perspective, the cumulative impact of the EPA action when added to other past, present, and reasonably foreseeable future activities (federal and non-federal); (3) analyze reasonable alternatives that address environmental justice impacts; (4) consider mitigation measures to address impacts on minority, low-income, and indigenous populations; and (5) provide for public review and comment on the draft EIS or EA, including the discussion of environmental justice issues.

Under NEPA, EPA may consider in an EA or EIS environmental factors that are not expressly set forth in its organic statutes, regulations, or guidance. Courts have held that NEPA, which is a procedural statute, does not expand the scope of an agency's regulatory jurisdiction. Nonetheless, federal agencies can use the NEPA process to inform how they exercise their discretion. For example, where an agency's organic authority allows for two (or more) possible approaches to an issue, a NEPA environmental justice analysis may be used to inform the choice of which approach to take. Similarly, an environmental justice analysis may help an agency identify an approach under its organic authority that it might not otherwise have considered.

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[229] *Id*. at 2.3.

[230] The CEQ guidance at 8-9 includes the following general principles for considering environmental justice under NEPA:

- Consider the composition of the affected area to determine whether minority, low-income, or tribal populations are present, and if so whether there may be disproportionately high and adverse human health or environmental effects on these populations.
- Consider relevant public health and industry data concerning the potential for multiple exposures or cumulative exposure to human health or environmental hazards in the affected population, as well as historical patterns of exposure to environmental hazards.
- Recognize the interrelated cultural, social, occupational, historical, or economic factors that may amplify the natural and physical environmental effects of the proposed action.
- Develop effective public participation strategies.
- Assure meaningful community representation in the process, beginning at the earliest possible time.
- Seek tribal representation in the process.

The CEQ guidance is available at http://ceq.hss.doe.gov/nepa/regs/ej/justice.pdf.

[231] 40 C.F.R. Part 6.

CLEAN AIR ACT SECTION 309

Under section 309(a) of the CAA, EPA is required to review and comment on the environmental impacts of the actions of other federal agencies, including proposed regulations and projects subject to the EIS requirement in section 102(2)(C) of NEPA. In addition, pursuant to CAA section 309(b), if EPA determines, as a result of its review, that a particular activity is unsatisfactory from the standpoint of public health, welfare, or environmental quality, it must publish the determination and refer the matter to CEQ for resolution.[232] Consistent with the President's memorandum accompanying Executive Order 12898, and because of the clear linkage between environmental justice and the stated criteria for an EPA referral to CEQ, EPA may readily use the CAA section 309 review process to ensure that other federal agencies fully analyze and address, as appropriate, the environmental effects, including human health, social, and economic effects, of their proposed actions on minority, low-income, and indigenous populations.

To help advance environmental justice through this review process, EPA issued its *Guidance for Consideration of Environmental Justice in Clean Air Act Section 309 Reviews* (July 1999).[233] The guidance covers how to consider environmental justice at each stage of the CAA section 309 review process. It addresses pre-environmental-review activities, identifying minority and low-income populations, potential impacts, review of draft EISs, public participation, alternatives, mitigation,[234] ratings, and review of final EISs. Under the CAA section 309 review process, EPA reviews and comments on a wide variety of federal projects with significant environmental impacts. In its comment letters to sister agencies, EPA routinely raises environmental justice issues, including those related to the nature of impacts on minority, low-income, or indigenous communities; the thoroughness of the analysis; and identification of alternatives or mitigation to address the impacts.

In July 2011, EPA issued guidance that is designed to help other federal agencies and states, among other things, to account for environmental justice considerations in the context of mountaintop mining, with a specific discussion on the opportunities afforded by NEPA.[235] The guidance recommends, among other things, that EPA Regional Offices encourage agencies "to make the full range of NEPA notices and documents, including draft EAs, readily available to the public" and "to improve the accessibility of public meetings." This illustrates how EPA can play an important role, consistent with NEPA, to advance environmental justice through

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[232] *See* CEQ's regulations at 40 C.F.R. Part 1504 for the procedures on referrals.

[233] The guidance is available at: http://www.epa.gov/compliance/resources/policies/nepa/enviro_justice_309review.pdf.

[234] *See EPA Guidance for Consideration of Environmental Justice in Clean Air Act Section 309 Reviews* (July 1999) at 2.3.5, which provides that mitigation measures should be developed specifically to address potential disproportionately high and adverse effects to minority and/or low-income communities. Similarly, the action agency, with tribal concurrence, should select mitigation measures that will not diminish tribal resources and that will ensure the protection of such resources from environmental harm.

[235] *See* "Improving EPA Review of Appalachian Surface Coal Mining Operations under the Clean Water Act, National Environmental Policy Act, and the Environmental Justice Executive Order" (July 21, 2011), which is discussed in Chapter Two.

transparency and open government as well as comprehensive consideration of the environmental impacts through an effective environmental justice analysis.

CHAPTER SEVEN: GRANTS AND PROCUREMENT

EPA AUTHORITY TO ADDRESS ENVIRONMENTAL JUSTICE THROUGH ASSISTANCE AGREEMENTS AND OTHER FINANCIAL MECHANISMS

I. GRANTS FOR ENVIRONMENTAL JUSTICE PROJECTS

EPA manages an environmental justice grants program[236] that provides financial assistance to eligible organizations working on or planning to work on projects to address local environmental and/or public health issues in their communities.[237] The program also provides financial assistance to eligible organizations to build collaborative partnerships, to identify the local environmental and/or public health issues, and to envision solutions and empower the community through education, training, and outreach.[238] The Agency's statutes authorize these grants, which provide assistance for demonstrations, research, surveys, and training. Eligible environmental justice activities include:

(1) Demonstrations or analysis of environmental justice conditions and problems (for example, socio-economic impact studies);

(2) Projects to research specific local environmental justice issues; and

(3) Environmental justice training or education for community residents, teachers, or related personnel.

II. RESEARCH, DEVELOPMENT, AND TRAINING GRANTS UNDER ENVIRONMENTAL STATUTES

The Environmental Justice Grant Program implements statutes that give EPA broad authority to support activities including research, development, training, surveys, investigations, and demonstrations related to pollution of particular environmental media.[239] For example, Clean Water Act section 104(b)(3) authorizes EPA to make grants for activities related to water pollution to state agencies, other public or nonprofit private organizations, and individuals. Similarly, consistent with EPA's competition policy, EPA could make a grant under Solid Waste Disposal Act section 8001(a) to a community association for a survey of health and welfare

[236] The term "grants" as used in this chapter includes cooperative agreements as well as grants. Both are assistance agreements; they differ only in the extent of Agency involvement in the project.

[237] *See* Environmental Justice Collaborative Problem-Solving Cooperative Agreement Program at http://www.epa.gov/environmentaljustice/grants/ej-cps-grants.html.

[238] *See* Environmental Justice Small Grants Program at http://www.epa.gov/environmentaljustice/grants/ej-smgrants.html.

[239] The authorities under which these environmental justice grants will be awarded are: Clean Water Act (CWA) section 104(b)(3), Safe Drinking Water Act (SDWA) section 1442(b)(3), Solid Waste Disposal Act (SWDA) section 8001(a), Clean Air Act (CAA) section 103(b)(3), Toxic Substances Control Act (TSCA) section 10(a), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 20(a), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 311(c), and Marine Protection, Research, and Sanctuaries Act (MPRSA) section 203.

effects of a local landfill. The authority to fund these "research and demonstration" activities is well established. Projects funded under these authorities and other EPA authorities have the potential to make a significant impact in identifying issues of environmental justice concern and establishing a foundation for developing corrective actions. The Agency must comply with the Office of Management and Budget (OMB) regulations implementing the Paperwork Reduction Act when funding any information-gathering activities under such a grant.

III. SUPERFUND TECHNICAL ASSISTANCE GRANTS

CERCLA section 117(e) authorizes EPA to make Technical Assistance Grants (TAGs) of up to $50,000 to groups of individuals affected by Superfund sites. TAGs help communities obtain technical assistance from independent experts who can interpret site information to promote better understanding of a site and more meaningful public participation in the clean-up decision-making process. TAGs are subject to most Agency-wide general grant regulations, but often with less formal requirements. TAGs are based on an established legal mechanism for providing assistance to communities impacted by Superfund sites. TAGs awarded to eligible minority, low-income, or indigenous populations advance environmental justice by providing those groups with information that would enable them to participate in the environmental decision-making process.

IV. NATIONAL AND COMMUNITY SERVICE ACT

Under the 1993 amendments to the National and Community Service Act,[240] EPA and other federal agencies may enter into interagency agreements with the Corporation for National and Community Service (the Corporation) for service programs that address established priorities: the environment, public safety, human needs, and education. Agencies may use these funds to implement their own programs or to enter into contracts or cooperative agreements with entities that are carrying out national service programs in the States. EPA can consult with the Corporation about the availability of funding under this authority, and, if available, seek to enter into interagency agreements for projects that advance environmental justice.

V. NATIONAL ENVIRONMENTAL EDUCATION ACT

Section 6 of the National Environmental Education Act[241] authorizes EPA to award grants for projects to design, demonstrate, or disseminate practices, methods, or techniques related to environmental education and training. EPA is authorized to support projects that address environmental issues which, in the judgment of the Administrator, are of high priority; these could include projects that advance environmental justice. EPA annually solicits applications for section 6 grants from local education agencies, colleges and universities, state education and environmental agencies, nonprofit organizations, and noncommercial educational broadcasting entities. Each recipient must meet a 25 percent cost-sharing requirement. No grant awarded under section 6 may exceed $250,000, and 25 percent of the funds awarded under this provision each year must be for grants of not more than $5,000.

[240] 42 U.S.C. § 12571.

[241] 20 U.S.C. § 5505.

VI. ASSISTANCE AGREEMENTS WITH TRIBAL GOVERNMENTS

As discussed in Chapter Five, enhancing tribes' ability to manage their lands and to participate and assist in the implementation of environmental programs typically will advance environmental justice and help them address concerns they may have.

A. Assistance Available to Tribes

Some of EPA's organic statutes that authorize EPA to provide assistance to states also authorize the Agency to award assistance to federally recognized tribal governments. EPA awards environmental program grants to tribes under CAA section 105 (air pollution control), CWA sections 106 and 108 (water pollution control), CWA section 104(b)(3) (water quality cooperative agreements; wetlands development grants), CWA sections 319(h) and 518(f) (nonpoint source management grants), FIFRA section 23(a)(1) and (2) (pesticide cooperative enforcement; pesticide program implementation; and pesticide applicator certification and training), PPA section 6605 (pollution prevention grants), SDWA sections 1433(a), (b) and 1451 (public water system supervision; underground water source protection), TSCA section 404(g) (lead-based paint program), TSCA section 306 (indoor radon grants), TSCA section 28 (toxic substances compliance monitoring), Public Law 105-276 (hazardous waste management program grants; underground storage tank program grants), and CERCLA section 128(a) (tribal response program grants). Regulations governing these assistance agreements may be found in 40 C.F.R. Part 35, Subpart B. In addition to these grant programs, tribes are also eligible for Superfund Cooperative Agreements under CERCLA section 104(d) that are awarded and administered in accordance with 40 C.F.R. Part 35, Subpart O (EPA's Superfund response action grant regulations applicable to state, local, and tribal governments).

B. Indian Environmental General Assistance Program Act

The Indian Environmental General Assistance Program Act of 1992 (IEGAPA)[242] authorizes EPA to make grants to Indian tribes to build capacity to administer environmental protection programs on Indian lands. New General Assistance Program (GAP) grants under the IEGAPA must be for at least $75,000 and the term of an award may not exceed four years. GAP grants are awarded non-competitively.

C. Direct Implementation Tribal Cooperative Agreements

EPA's annual appropriations act typically authorizes EPA to enter into Direct Implementation Tribal Cooperative Agreements (DITCAs) with federally recognized Indian tribes or intertribal consortia to assist EPA in implementing federal environmental programs required or authorized by law in the absence of an acceptable tribal program. EPA works closely with tribes to identify DITCA-eligible activities and to determine those direct implementation activities where there is a joint tribal and EPA priority for program implementation. DITCAs are awarded non-competitively.

D. Indian Self-Determination Act Preference

The Indian Self-Determination Act requires tribal grantees to give preference and opportunities in the award of contracts, subcontracts, and subgrants to Indians.[243]

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[242] 42 U.S.C. § 4368b.

[243] *See* 40 C.F.R. § 31.38.

VII. BROWNFIELDS REVITALIZATION FUNDING

The Brownfields revitalization funding authority under CERCLA section 104(k) authorizes EPA to, among other things, make grants for site characterization, assessment, and cleanup, as well as for the capitalization of revolving loan funds for remediation of Brownfield sites. The statute also authorizes EPA to provide, or support with financial assistance, Brownfields-related research, training, and technical assistance. Eligibility for grants for site characterization, assessment, and capitalization of revolving loan funds is limited to governmental entities or certain types of quasi-governmental organizations that are connected to governments.

In authorizing the Agency to make grants under this authority, CERCLA directs the Administrator to establish a system for ranking grant applications. The statute contains ten ranking criteria, including the extent to which a grant would address or facilitate the identification and reduction of threats to the health or welfare of children, pregnant women, minority or low-income communities, or other sensitive populations; the extent to which a grant would address or facilitate the identification and reduction of threats to human health and the environment, including threats in areas in which there is a greater-than-normal incidence of disease or conditions that may be associated with exposure to hazardous substances, pollutants, or contaminants; and the extent to which a grant would meet the needs of a community that is unable – because of the small population or low income of the community – to draw on other sources of funding for environmental remediation and subsequent redevelopment of the area in which a Brownfield site is located.

VIII. GRANT CONDITIONS

A. Conditions Related to Goals of the Statute

EPA may place conditions on any grant award if the conditions are directly related to the goals of the statute authorizing the award.[244] In *Shanty Town Associates Ltd. Partnership v. EPA*, the court held that EPA acted within its CWA authority in conditioning a Title II grant to a municipality for construction of a sewage collection system. EPA's environmental impact statement found that the new sewage system would induce development and therefore increase nonpoint source pollution from the area served. The Agency inserted in the grant to the city a condition limiting the use of the new system to existing development. A developer challenged the condition on the ground that it was not related to the purpose of the grant, which was sewage treatment works construction, not land use control or nonpoint source management. The court held that, although CWA Title II does not mention use limitations, EPA had authority to impose them as a condition because they were directly related to the goals of the CWA.

EPA may consider including in appropriate grants special conditions aimed at advancing environmental justice. Grants that might be appropriate for such a condition include, but are not limited to, National Estuary Program grants under CWA section 320(g), state/tribal cooperative agreements under CERCLA section 104, and state continuing environmental program grants.[245] However, any condition should be written in terms of implementing a goal of the act authorizing

[244] *Shanty Town Associates Ltd. Partnership v. EPA*, 843 F.2d 782 (4th Cir. 1988).

[245] Continuing environmental program grants are awarded under CWA sections 106 and 319, SDWA section 1443, SWDA section 3011, CAA section 105, TSCA section 28, and FIFRA section 23.

the grant. Indeed, the more closely aligned the grant condition is to the statutory goals the more legally defensible the condition will be. For example, a condition requiring the grantee to consider cumulative impacts, unique exposure scenarios, or sensitive populations would arguably be directly related to a statute's goal of protecting human health.

One avenue EPA could use to ensure that environmental justice considerations are considered in determining the activities to be funded under state and tribal environmental program grants is to include environmental justice in the national goals, objectives, and priorities of each program as expressed through the National Program Guidance. Including environmental justice in the National Program Guidance for each program would provide EPA with a basis for negotiating activities into recipient work plan commitments. National Program Guidance is an appropriate means to provide a framework for addressing environmental justice considerations in each program and each award because work plans should reflect program priorities outlined in the National Program Guidance.[246] And, by signing the grant documents, the grant recipient will have expressly accepted the conditions imposed by the terms of the grant.

If a condition or program priority can be said to implement the underlying statute rather than Title VI of the Civil Rights Act (see discussion of Title VI below), EPA could seek to enforce the condition through the remedies and disputes process under the general grant regulations,[247] rather than under EPA's recipient anti-discrimination regulations.[248] The procedures under the grant regulations, which are described below, are simpler and allow for more informal, faster action than the procedures under Title VI regulations.

B. Environmental Justice in Evaluation Criteria

Each Request for Proposals (RFP) issued in competitive grant programs contains an explanation of the evaluation criteria the Agency uses to evaluate the merits of each applicant's grant proposal. Where appropriate, EPA could incorporate environmental justice considerations into its stated evaluation criteria. Any evaluation criteria included in an RFP should be consistent with the goals of the act authorizing the grant and must be consistent with any evaluation criteria stated in that act.[249] Environmental justice considerations incorporated into evaluation criteria may be reflected in the terms and conditions of the grant award, as appropriate.

C. Conditions for High-Risk Grantees

The general grant regulations at 40 C.F.R. § 31.12 allow EPA to impose certain conditions or restrictions on a "high-risk" recipient during the pre-award stage of the grants process. A recipient or subgrantee may be considered high risk if EPA determines, for example, that it has a history of unsatisfactory performance, has not conformed to terms and conditions of previous awards, or is otherwise not responsible. Special conditions or restrictions may include withholding authority for advance payments, or withholding authority to proceed to the next phase before receipt of evidence of acceptable performance within a given funding period;

[246] 40 C.F.R. §§ 35.107 and 35.507.

[247] 40 C.F.R. Parts 30 and 31.

[248] 40 C.F.R. Part 7.

[249] *See, e.g., Ill. Environmental Protection Agency v. EPA*, 947 F.2d. 283 (7th Cir. 1991).

additional project monitoring; or requiring the recipient or subgrantee to obtain technical or management assistance. As a short-term measure the Agency could consider identifying recipients as high-risk when there is evidence of current or past practices that are inconsistent with environmental justice principles, *e.g.*, those reflected in the Title VI regulations or Executive Order 12898. The Agency would need to make a determination of whether a high-risk designation is appropriate through information gathered in a pre-award review, an audit of the recipient's past performance, or using other available information. In this case, EPA might impose a special condition on subsequent grants establishing special requirements for such recipients.

D. Disadvantaged Business Enterprises

EPA promotes nondiscrimination in the award of contracts under EPA financial assistance agreements through its regulations at 40 C.F.R. Part 33. Financial assistance recipients are required to make good faith efforts to meet negotiated fair share objectives for disadvantaged-business-enterprise participation in procurement under financial assistance agreements. Disadvantaged business enterprises include, but are not limited to, businesses owned or controlled by African-Americans, Hispanic Americans, Native Americans, Indian Tribes, Asian Pacific Americans, Native Hawaiian organizations, women, and Historically Black Colleges and Universities. Each procurement contract signed by an EPA financial assistance agreement recipient must include a term and condition that incorporates the requirements of Part 33.

IX. REMEDIES FOR NON-COMPLIANCE WITH GRANT CONDITIONS

A. Remedies

EPA's regulations establishing administrative requirements for grants to states, local governments, and Indian tribes are found at 40 C.F.R. Part 31. Similar regulations governing grants to all other recipients are found at 40 C.F.R. Part 30. Under both regulations, if a recipient materially fails to comply with any term or condition of a grant agreement, EPA may take one or more of the following actions:[250]

(1) issue a stop-work order;

(2) withhold payments;

(3) suspend or terminate the agreement;

(4) annul the agreement, wholly or partly, and recover all awarded funds (Part 30 or Part 31, as appropriate, sets forth grounds for annulment);

(5) withhold further awards for the program; and

(6) seek other remedies legally available.

[250] *See* 40 C.F.R. §§ 30.63 and 31.43, as applicable.

B. Disputes

Grant recipients and applicants that wish to dispute an Agency action, including a decision to take one of the remedial actions listed above, may pursue the administrative dispute resolution process set forth in the regulations at 40 C.F.R. Part 30, Subpart C, and 40 C.F.R. Part 31, Subpart F.[251] Persons other than a grant applicant or recipient may not bring a dispute challenging a grant action under these regulations, although they may informally petition the Agency. The dispute resolution process seeks to resolve matters through a relatively simple and informal EPA management review. A disputant under these regulations may submit documentary evidence and briefs for inclusion in a written record, is entitled to an informal conference with EPA officials, and is entitled to a written decision from the appropriate EPA Dispute Decision Official (DDO). Upon request for review of a DDO decision, a disputant is entitled to a written decision from the appropriate Regional Administrator (RA) or Assistant Administrator (AA). An RA's decision may be reviewed by the appropriate AA, at the discretion of the AA. If the AA decides not to review the RA's decision, the RA's decision is the final agency action.

NON-DISCRIMINATION IN FEDERAL ASSISTANCE PROGRAMS

I. INTRODUCTION

EPA implements Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, section 13 of the Federal Water Pollution Control Act Amendments of 1972, Title IX of the Education Amendments of 1972, and the Age Discrimination Act of 1975, which prohibit discrimination based on race, color, national origin, disability, sex, and age. Regulations at 40 C.F.R. Part 7, entitled "Nondiscrimination in Programs or Activities Receiving Federal Assistance from EPA," include general and specific prohibitions against intentional and unintentional (*i.e.*, disparate effects) discrimination by EPA's assistance recipients on the basis of race, color, national origin, sex, or handicap.[252] Every EPA grant recipient, including almost every state environmental agency, is subject to the terms of Part 7.[253]

EPA enforcement of these anti-discrimination provisions can be a tool in the Agency's efforts to address discrimination and advance environmental justice. In particular, the Presidential memorandum accompanying Executive Order 12898 identifies Title VI as an important tool to help achieve the goal of environmental justice. The memorandum directs federal agencies to ensure that recipients of federal financial assistance do not discriminate based on race, color, or national origin under Title VI in their programs or activities that affect human

[251] The dispute resolution procedures in Part 31, Subpart F, apply to states, local governments, and Indian tribes. Those in Part 30, Subpart C, apply to all other applicants and recipients. The procedures in the two regulations are virtually the same.

[252] The procedures outlined in Part 7 have been adopted by the Part 5 regulations with respect to complaints of sex discrimination in education programs or activities. *See* 40 C.F.R. § 5.605.

[253] In implementing the *Plan EJ 2014* goal of supporting community-based programs, EPA intends to develop language for environmental justice principles, including Title VI guidance (as appropriate with all Agency grants), for inclusion in the FY2011 National Environmental Performance Partnership System and National Program Manager guidance.

health or the environment. Further, Title VI's prohibition against discrimination applies to all the programs and activities of a recipient of federal assistance, including EPA assistance. Because "program or activity" is defined to include all the operations of recipients of EPA assistance, including state or local departments or agencies, the applicability of the Part 7 regulations is very broad.

EPA's Office of Civil Rights (OCR) is responsible for implementing Part 7.[254] EPA is now focused on investigating and resolving the large number of pending Title VI complaints, some of which have been pending in EPA for a number of years. As those complaint investigations are completed, EPA will expand its foundation of decisions and policies upon which consistent, aggressive Agency enforcement activities, as described below, can be based.

II. PRE-AWARD COMPLIANCE

Before EPA awards assistance (grants or cooperative agreements, in most cases), it is required to determine whether the applicant is in compliance with Part 7.[255] To obtain the information necessary to make that determination, EPA requires applicants to submit notice of any pending lawsuits alleging discrimination, any civil rights compliance reviews regarding the applicant conducted during the two-year period before the application, the name and title of its compliance coordinator, and a copy of the applicant's grievance procedures, if any.[256] In addition, applicants may be required to submit any other information that EPA determines is necessary to make the pre-award compliance determination.[257]

EPA could revise the application form to request additional information that could help identify potential civil rights concerns related to the grant applicant. For example, applicants could be required to provide information regarding the applicant's resources, policies, and practices for addressing discrimination. The process for revising the form would include OMB approval and would entail relatively minor cost and resources. A more significant expansion of the pre-award compliance review process, however, would warrant close coordination (including Standard Operating Procedures) within EPA in order to avoid major disruptions and delays in the grant application review and approval process.

In addition, applicants for EPA assistance must submit an assurance with their applications that, with respect to their programs or activities that receive EPA assistance, they will comply with the non-discrimination provisions in Part 7.

III. POST-AWARD COMPLIANCE

The Agency may periodically conduct reviews of any assistance recipient's programs or activities to ensure compliance with Title VI. These compliance reviews may include information and data requests. They may also include on-site reviews when EPA has reason to believe that discrimination may be occurring in those programs or activities.[258] EPA could

[254] *See* 40 C.F.R. §§ 1.25(b)(5) and 7.20(a).

[255] 40 C.F.R. § 7.110(a).

[256] *See* EPA Form 4700-4.

[257] 40 C.F.R. § 7.110(a).

[258] 40 C.F.R. § 7.115.

expand its compliance review program in a number of ways. Part 7 requires recipients to collect, maintain, and, upon request, provide EPA with a description of any pending lawsuits against the recipient alleging discrimination; racial/ethnic, national origin, sex, and handicap data; a log of discrimination complaints; and reports of any compliance reviews conducted by other agencies.[259]

EPA could increase the frequency and/or regularity with which it requests compliance review information from recipients. That information could be reviewed to determine if a more comprehensive compliance review is necessary. In addition, EPA could establish criteria for selecting targets for compliance reviews that further the Agency's environmental justice goals. EPA could also expand the scope of its compliance reviews beyond the procedural requirements in the regulations to include any recipient activity that the Agency believes may raise Title VI concerns. Currently, the compliance reviews are generally limited to ascertaining whether the recipient is in compliance with the procedural requirements contained in Part 7 (*i.e.*, whether the recipient has a grievance procedure and compliance coordinator). Part 7 requires most recipients to adopt grievance procedures to assure prompt and fair resolution of complaints of discrimination. EPA could more heavily scrutinize recipients' grievance procedures and, where inadequate, assist them in developing such procedures. This would help provide complainants with another avenue of redress, and recipients would be better able to resolve concerns in-house, thereby potentially reducing the number of Title VI complaints filed with EPA.

Expansion of the current compliance review program has the potential to have greater impact than what is accomplished through complaint investigations (where existing resources are principally spent) because the scope of compliance reviews could be broader than that of complaint investigations. EPA's regulations already provide the authority to implement this change. However, a significantly more robust compliance review program would require substantial additional resources.

IV. COMPLAINT INVESTIGATIONS

Any person who believes that he or she or a specific class of persons has been discriminated against in violation of Part 7 may file a complaint with any EPA office within 180 days of the alleged discrimination. For claims of unintentional discrimination under EPA's Title VI regulations, the administrative complaint process is the only available forum for relief because Title VI complaints filed in federal courts are limited to claims of intentional discrimination.

EPA could do more outreach to educate the public on using Title VI to address issues of discrimination in their communities. This outreach could potentially have a significant impact in that it could improve the quality of Title VI complaints and bring additional issues of discrimination to EPA's attention. Such a program could be established internally, relying on Standard Operating Procedures to maintain consistency. Initially, such outreach would require significant effort, in that educational materials would need to be developed. Ongoing educational efforts, however, would require less effort to maintain.

[259] 40 C.F.R. § 7.85.

EPA's regulations at 40 C.F.R. § 7.120 require that the complaint meet the minimum jurisdictional criteria to be accepted. First, the complaint must be in writing. Second, it must be filed within 180 days of the alleged discriminatory act. Third, it must allege discrimination based on race, color, or national origin. Finally, it must identify a recipient of EPA assistance alleged to have committed discriminatory acts. EPA must investigate accepted complaints and will either dismiss complaints where no violation is found, attempt to resolve complaints informally, as described below, or make a finding of violation. Investigations are often resource-intensive and time-consuming. EPA could make more use of alternative dispute resolution (ADR) processes to resolve complaints more efficiently and effectively. The Agency may call on its own trained mediators and environmental experts, as well as external ADR professionals, to facilitate this process and perhaps resolve some Title VI issues more quickly and collaboratively.

The increased and systematic use of ADR to resolve Title VI issues could potentially have a significant impact by addressing potential discrimination issues without EPA using the resources required for a full complaint investigation. Because EPA's regulations already reference the informal resolution of complaints, such a program could be established internally, without the need for additional regulations or guidance. OCR has started to expand the use of ADR and has worked with EPA's Conflict Prevention and Resolution Center (located within the Alternative Dispute Resolution Law Office) to have mediators "on call" to assist with informal resolution of Title VI complaints.

V. ACTIONS AVAILABLE TO OBTAIN COMPLIANCE

If informal resolution efforts fail, EPA will notify the recipient of its preliminary findings and make recommendations for achieving voluntary compliance. Where a preliminary determination of noncompliance does not result in voluntary compliance, EPA must issue a formal determination of noncompliance with a requirement that the recipient come into voluntary compliance within 10 calendar days. If resolution and voluntary compliance are not successful, the Agency may use any means authorized by law to obtain compliance, including referral of the matter for enforcement to the U.S. Department of Justice. If EPA pursues litigation, the objective would likely be to obtain injunctive relief to end or mitigate the discrimination.

EPA may also choose to begin proceedings to annul, terminate, refuse to award, or refuse to continue assistance. The proceedings may, at the request of the applicant or recipient, include a hearing before an administrative law judge (ALJ). The ALJ's determination becomes the Administrator's final decision in the event the applicant or recipient does not file exceptions to the ALJ's determination. In cases of review by the Administrator, all parties may submit written statements. If the Administrator's decision is to deny an application, or annul, suspend or terminate assistance, the decision does not become final until 30 days after she submits a full written report of the circumstances and grounds for the action to the House and Senate committees having legislative jurisdiction over the EPA program involved. The Administrator's decision is not subject to review under the general grant regulations.

PROCUREMENT TOOLS FOR ADDRESSING ENVIRONMENTAL JUSTICE

I. INTRODUCTION

There are various statutory and regulatory procurement authorities that EPA could utilize to advance environmental justice. There are several existing government-wide policies designed to provide "maximum practicable opportunities" in the award of contracts and subcontracts to small business concerns owned by "socially and economically disadvantaged" groups as well as businesses located in areas of high unemployment. These existing government policies are included in the Federal Acquisition Regulation (FAR),[260] which regulates agencies' procurement of supplies and services.

EPA could use these existing policies to help provide economic empowerment to communities that have traditionally had environmental justice issues.

EPA could also seek to advance environmental justice in its procurements through the incorporation of environmental justice tasks in procurement statements of work and environmental justice considerations in evaluation criteria.

II. EXISTING PROCUREMENT MECHANISMS THAT COULD BE USED TO PROMOTE ENVIRONMENTAL JUSTICE

FAR 19.201 expresses the policy that "maximum practicable opportunities" be directed towards small disadvantaged business concerns and small business concerns located in Historically Underutilized Business Zones. See Section II.C below.

A. The "8(a)" Program

Section 8(a) of the Small Business Act authorizes the Small Business Administration (SBA) to enter into contracts with other federal agencies and to perform those contracts by subcontracting to "socially and economically disadvantaged small business concerns."[261] Such entities are small businesses if: (1) they are at least 51 percent owned by one or more socially and economically disadvantaged individuals; and (2) management and daily business operations are controlled by one or more of such individuals.[262]

Participants in the 8(a) program must satisfy both the social and economic disadvantage requirements. For purposes of the 8(a) program, the following definitions apply:

- "Socially disadvantaged individuals" are "those who have been subjected to racial or ethnic prejudice or cultural bias within American society because of their identities as members of groups without regard to their individual qualities."[263]

[260] 48 C.F.R. Parts 1-53.

[261] 15 U.S.C. § 637(a).

[262] 15 U.S.C. § 637(a)(4).

[263] 13 C.F.R. § 124.103(a).

They presumptively include African Americans, Hispanic Americans, Native Americans, Asian Pacific Americans, and Subcontinent Asian Americans.[264]

- "Economically disadvantaged individuals" are "socially disadvantaged individuals whose ability to compete in the free enterprise system has been impaired due to diminished capital and credit opportunities as compared to [non-socially disadvantaged individuals] in the same or similar line of business . . . and such diminished opportunities have precluded or are likely to preclude such individuals from successfully competing in the open market." In determining whether an individual is "economically disadvantaged," SBA specifically considers: (i) the personal financial condition of the individual claiming disadvantaged status; (ii) the financial condition of the business concern itself; and (iii) the individual's ability to obtain access to credit and capital needed to operate a competitive business enterprise.[265]

Under the 8(a) program, SBA assists disadvantaged small businesses in the making and performance of contracts by helping procuring agencies identify potential 8(a) contracts, matching the needs of 8(a) firms with available contracts, and promoting continuity of awards. SBA also establishes the fair market value price the procuring agency would pay for the contracted goods and services. Under the 8(a) program, awards may be made on either a sole source or competitive basis.

B. The Small Disadvantaged Business Participation Program

FAR 19.12 allows agencies to use the participation of small disadvantaged business (SDB) concerns in performance of a contract as an evaluation or subevaluation factor when determining the awardee of a federal contract.[266] In developing these evaluation factors or subfactors, agencies may consider the following:[267]

- The extent to which SDB entities are specifically identified;
- The extent of commitment to use SDB entities;
- The complexity and variety of work SDB entities are to perform;
- The realism of the proposal;
- Past performance of offerors in complying with subcontracting plan goals for SDB entities; and
- The extent the participation of SDB entities in terms of value of the total acquisition.

Thus, the Small Disadvantaged Business Participation Program could be used to promote environmental justice in new EPA procurements by evaluating the deployment of proposed SDB

[264] 13 C.F.R. § 124.103(b).

[265] 13 C.F.R. § 124.104.

[266] *See* FAR 19.1202-1. Because of the multiple uses of the word "concern" in this document, hereafter, we use the phrase "SDB entity" to mean "small disadvantaged business concern."

[267] *See* FAR 19.1202-3; EPAAR 1519.204(c) and 1552.219-74.

entities by each offeror submitting a proposal and theoretically awarding contracts to those entities making the most use of SDB entities.

The policies for assisting small and disadvantaged businesses in government procurements are similar to the tenets underlying environmental justice. Many of the groups defined as "socially and economically disadvantaged" for procurement purposes are those that have been subject to the types of disproportionate environmental burdens that environmental justice is designed to address. In order to promote environmental justice, EPA could more aggressively award contracts under the small and disadvantaged business programs.

C. Policies Favoring Small Business Entities Located in Historically Underutilized Business Zones (HUBZones)

The Historically Underutilized Business Zone (HUBZone) Act of 1997 created the HUBZone program whereby the federal government provides contracting help for qualified small business entities located in historically underutilized business zones "to increase employment opportunities, investment, and economic development in those areas."[268] Under the HUBZone program, there can be a HUBZone set-aside for acquisitions exceeding $100,000 if the contracting officer has a reasonable expectation that offers will be received from two or more HUBZone small business entities and the award will be made at a fair market price. Under these circumstances, procurements over $3,000 but less than $100,000 can be set aside for HUBZone concerns at the contracting officer's sole discretion.[269] Further, a contracting officer may make a sole-source award to a HUBZone entity without considering small business set-asides only if one HUBZone small business entity can satisfy the applicable requirements and if certain dollar thresholds are exceeded.[270]

These policies favoring HUBZone concerns can promote economic empowerment within "urban or rural areas with high proportions of unemployed or low-income individuals."[271]

D. Indian Incentive Program

In addition to the above, FAR 26.100 implements 25 U.S.C. § 1544, which provides an incentive to prime contractors that use Indian organizations and Indian-owned economic enterprises as subcontractors. In short, the Indian Incentive Program allows an incentive payment equal to five percent (5%) of the amount paid to a subcontractor in performing the contract, if the contract so authorizes and the subcontractor is an Indian organization or Indian-owned economic enterprise.[272]

[268] *See* 15 U.S.C. § 631 and FAR Subpart 19.13.

[269] *See* FAR 19.1305.

[270] *See* FAR 19.1306.

[271] *See* 15 U.S.C. § 631(d).

[272] *See* FAR 26.102.

III. OTHER POTENTIAL PROCUREMENT TOOLS TO ADVANCE ENVIRONMENTAL JUSTICE

A. Environmental Justice as Part of Statements of Work and Evaluation Criteria

The Agency could immediately specify environmental justice tasks in its procurement statements of work so long as those tasks state the Agency's minimum needs and further the Agency's mission.[273] Environmental justice considerations could be incorporated into evaluation criteria as long as the criteria represent the key areas of importance and emphasis to be considered in the source selection decision.[274] For example, under the appropriate circumstances, the quality of an offeror's past performance on environmental justice work could be considered by the Agency as a factor in the award selection process.

B. Require Successful Bidders to Incorporate Environmental Justice (By Sub-Contractor or Employment) in Performing the Contract Work

EPA could potentially require its contractors to promote environmental justice in performing EPA contracts through subcontracting to or direct employment of individuals/groups targeted based on environmental justice considerations. Such a requirement would have to be promulgated as an EPA Acquisition Regulation and go through notice and comment rulemaking in accordance with the Office of Federal Procurement Policy Act[275] before it could be utilized by the Agency.

[273] *See* 41 U.S.C. § 253.

[274] FAR 15.304(b).

[275] 41 U.S.C. § 418b.

CHAPTER EIGHT: FREEDOM OF INFORMATION ACT

INTRODUCTION

Access to public information about human health and the environment is a key element of advancing environmental justice under Executive Order 12898 and its accompanying Presidential memorandum. Section 5-5(c) of Executive Order 12898 provides for federal agencies to "work to ensure that public documents, notices, and hearings relating to human health or the environment are concise, understandable, and readily accessible to the public." In addition, the Presidential memorandum specifically directs agencies to "ensure that the public, including minority communities and low-income communities, has adequate access to public information relating to human health or environmental planning, regulations, and enforcement when required under the Freedom of Information Act . . . ."[276]

This chapter discusses well-established legal authorities under the Freedom of Information Act (FOIA).[277] The process identified below has the potential for a high level of impact in advancing environmental justice. In summary, special modifications to advance environmental justice could be incorporated into EPA's upcoming anticipated FOIA rulemaking, followed by introducing new policies and practices implementing FOIA that would achieve maximum results with minimal changes. Thus, a combination of regulatory change, complementary new internal policy and procedures, increased outreach and training for overburdened communities and interested groups, and improved attention to accessibility of information for overburdened communities, can all be used to augment EPA's commitment to environmental justice.

FOIA

I. BACKGROUND REGARDING FOIA PROCESSES

FOIA provides the public with access to information regarding the activities of federal executive agencies. It also contains important exemptions that protect certain classes or types of information. A FOIA request is generally a request to a federal agency for access to records concerning another person (as opposed to the requester), an organization within the agency, or a particular topic of interest. In 2009, the Obama Administration issued two memoranda to the heads of agencies, committing to a new level of openness in government and stressing the importance of FOIA in that pursuit.

Over the past decade, the Agency has moved in the direction of more FOIA accountability and reduction of its FOIA backlog. More recently, proactive disclosure of information as a means of eliminating the need for the public to file a FOIA request provides broader access to environmental information. Proactive disclosure of information facilitates several strategy objectives to promote environmental justice. These include, at a minimum,

[276] 30 Weekly Comp. Pres. Doc. at 280.

[277] 5 U.S.C. § 552.

increased public participation in numerous aspects of EPA's work, improved knowledge base on environmental justice issues, increased information and data collection relating to the health and environment of overburdened communities, and related goals.

II. FOIA PROCESSES—REGULATORY CHANGES AND NEW POLICY/PROCEDURES

EPA's FOIA regulations[278] were last updated in 2002. In 2007, for the first time in over a decade, Congress amended FOIA by passing the OPEN Government Act of 2007. The new law addresses how FOIA is administered and codifies provisions of Executive Order 13392, entitled "Improving Agency Disclosure of Information."[279] EPA's FOIA regulations have not yet been revised to implement the 2007 Act, but EPA expects to do so, informed by guidance from the U.S. Department of Justice.

In the course of revising its FOIA regulations, EPA could consider using the opportunity to advance environmental justice by enhancing access to information by minority, low-income, and indigenous populations. EPA's statutory and regulatory authorities provide a broad, discretionary basis for protecting human health and the environment. Enhancing access to information would recognize the heightened public health concerns often present in overburdened communities.

Improving the effectiveness of FOIA for overburdened communities could likely be done in a number of ways.

First, and not insignificantly, the following approaches are dependent on defining and identifying a given FOIA request as one raising an environmental justice issue. Various authorities emphasize the unique nature of overburdened communities, but as FOIA requests now exist, there is no unique identifier that would identify a given request as sensitive to environmental justice issues. Thus, EPA could develop metrics to clearly and easily identify those requests in the Agency's initial review.

Second, EPA could use discretionary disclosure authority under FOIA to help address the information needs of minority, low-income, and indigenous populations. In March 2009, the U.S. Attorney General encouraged the use of discretionary FOIA disclosures by instituting a series of new principles: (1) an agency should not withhold information simply because it may do so legally; (2) if full disclosure is not possible, an agency should consider partial disclosure; (3) an agency should proactively and promptly handle FOIA requests; and (4) an agency should as a matter of course post information online using modern technology – even in advance of any public request. These principles lend themselves easily to advancing environmental justice and may facilitate the type of information access overburdened communities may need from EPA.

As a general rule, EPA's ability to make a discretionary disclosure depends on whether a discretionary exemption applies. EPA cannot make a discretionary disclosure for non-discretionary exemptions, including Exemption 1 (national security), Exemption 3 (disclosure prohibited by another statute), Exemption 4 (confidential business information), and Exemptions

[278] 40 C.F.R. Part 2.

[279] 70 Fed. Reg. 75373 (Dec. 19, 2005).

6 and 7(C) (both related to personal privacy). Where EPA has information that is covered only by an exemption that allows discretionary disclosure, that information may be released in response to a FOIA request.

Third, a searchable repository of records released under FOIA could be made available on a public website. Such a repository could include an environmental justice "tag" for records and projects that may be of interest to minority, low-income, or indigenous populations. A searchable, public database would aid proactive disclosure of environmental justice data, research, issues, education, and Agency actions. As EPA moves towards proactively identifying and posting FOIA information, it could consider integrating these "tags" into this process. And database design should emphasize accessibility in format, comprehension, ease of use, and cost effectiveness in use.

Fourth, the information needs of overburdened communities may be considered in the way the information is provided or presented. For example, where electronic access may be limited, and the number of responsive records makes it practical to do so, the information can be provided in hard copy. Additionally, where information is of a highly technical nature, explanatory or background information may be included with the response. These opportunities are highlighted further under Section IV below.

III. FOIA ENVIRONMENTAL JUSTICE TRAINING

Training could be provided to EPA offices in order to enhance responsiveness to environmental justice considerations through the FOIA process, consistent with the reforms discussed above. Training could, among other things, alert staff to look for opportunities to make proactive, public disclosures at an earlier stage, even prior to an actual FOIA request. Informed staff may be able to identify environmental data, information, research, and activities of importance to overburdened communities, and these could be provided on EPA's website. Such proactive, pre-request public disclosures could include, for example, EPA-required information from pollution sources, unless prohibited by law.

Similarly, outreach and training efforts could be increased in interested communities. Training could enhance community awareness of FOIA as a tool to advance environmental justice.

IV. FOIA PROCESSES: INFORMATION COMPREHENSIBILITY AND ACCESSIBILITY

Information of value to overburdened communities could be created, formatted, and provided to these communities in a way that advances the goals of comprehensibility and accessibility. Although FOIA does not require the creation of new records, the Agency could choose to put information that is highly technical, scientific, medical, or complex in nature into plain language synopses in order to serve a wide range of educational backgrounds. Second, the Agency may choose to translate documents in circumstances involving limited English proficiency. Financial challenges of low-income populations could be taken into account as well – with an eye toward reducing the costs associated with making FOIA requests by perhaps shifting to pre-request electronic disclosures on EPA's website. Limited income may also be associated with reduced access to the Internet, and this may prevent some communities from

seeking public information. Cooperation, training, and outreach to interested groups and public information entities such as libraries may also help address these concerns.

CONCLUSION

The FOIA process provides a vehicle that could advance environmental justice. Much of what could be accomplished in this area is accessible under current law. Where regulatory change is indicated, it could be accomplished in the course of upcoming, anticipated changes to EPA's FOIA regulations.

GLOSSARY OF SELECTED ABBREVIATIONS AND ACRONYMS

A

AA	Assistant Administrator
ADR	Alternative Dispute Resolution
AFO	Animal Feeding Operation
AHERA	Asbestos Hazard Emergency Response Act
ALJ	Administrative Law Judge
ARARs	Applicable or Relevant and Appropriate Requirements
ATSDR	Agency for Toxic Substances and Disease Registry

B

BACT	Best Available Control Technology
BEACH Act	Beaches Environmental Assessment and Coastal Health Act

C

CAA	Clean Air Act
CAFO	Concentrated Animal Feeding Operation
CEQ	Council on Environmental Quality
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CMOM	Capacity, Maintenance, Operation and Management
CSO	Combined Sewer Overflows
CWA	Clean Water Act

D

DDO	Dispute Decision Official
DITCA	Direct Implementation Tribal Cooperative Agreements

E

EA	Environmental Assessment
EAB	Environmental Appeals Board
EIS	Environmental Impact Statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ETS	Environmental Tobacco Smoke
EPCRA	Emergency Planning and Community Right-to-Know Act

F

FAR	Federal Acquisition Regulation
FFDCA	Federal Food, Drug, and Cosmetic Act

FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOIA	Freedom of Information Act
FQPA	Food Quality Protection Act

G

GACT	Generally Available Control Technology
GAP	General Assistance Program

H

HAP	Hazardous Air Pollutants
HRS	Hazard Ranking System
HUBZone	Historically Underutilized Business Zone

I

IPM	Integrated Pest Management

L

LAER	Lowest Achievable Emission Rate
LUST	Leaking Underground Storage Tank

M

MACT	Maximum Achievable Control Technology
MPRSA	Marine Protection, Research, and Sanctuaries Act
MS4	Municipal Separate Storm Sewer System

N

NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NCP	National [Oil and Hazardous Substances Pollution] Contingency Plan
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NSR	New Source Review

O

OCR	Office of Civil Rights
OMB	Office of Management and Budget

P

PCB	Polychlorinated Biphenyl
POTW	Publicly Owned Treatment Works
PPA	Pollution Prevention Act of 1990

PSD	Prevention of Significant Deterioration
PWS	Public Water Supply

R

RA	Regional Administrator
RCRA	Resource Conservation and Recovery Act
RMPs	Risk Management Plans

S

SBA	Small Business Administration
SDB	Small Disadvantaged Business
SDWA	Safe Drinking Water Act
SIC	Standards Industrial Classification
SSOs	Sanitary Sewer Overflows

T

TAGs	Technical Assistance Grants
TAR	Tribal Authority Rule
TAS	Treatment as a State
TIPs	Tribal Implementation Plans
TMDLs	Total Maximum Daily Loads
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act

U

UIC	Underground Injection Control
UST	Underground Storage Tank

W

WPS	Worker Protection Standards
WQS	Water Quality Standards

RE: 1x10e-6 as a Definition of Acceptable Risk
Niemi, Cheryl (ECY)
to:
Lon Kissinger
01/02/2013 01:44 PM
Hide Details
From: "Niemi, Cheryl (ECY)" <cnie461@ECY.WA.GOV>
To: Lon Kissinger/R10/USEPA/US@EPA,

Thank you!

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
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Olympia WA 98504
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cheryl.niemi@ecy.wa.gov

From: Kissinger.Lon@epamail.epa.gov [mailto:Kissinger.Lon@epamail.epa.gov]
Sent: Wednesday, January 02, 2013 1:42 PM
To: Kapuscinski.Rich@epamail.epa.gov; Bailey.Marcia@epamail.epa.gov; Olsen.Marian@epamail.epa.gov; Stifelman.Marc@epamail.epa.gov; Maddaloni.Mark@epamail.epa.gov; Chung.Angela@epamail.epa.gov; Szelag.Matthew@epamail.epa.gov; Macchio.Lisa@epamail.epa.gov; Bailey.Marcia@epamail.epa.gov; Fleming.Sheila@epamail.epa.gov; Stralka.Daniel@epamail.epa.gov; Mcdonough.Margaret@epamail.epa.gov
Cc: Bradley, Dave (ECY); Niemi, Cheryl (ECY)
Subject: Fw: 1x10e-6 as a Definition of Acceptable Risk

Hi,

The last time I came across Kate Kelly's diatribe discounting development of 1 in a million as a regulatory risk value was when I was working on development of the WA State Dept. of Ecology's version of CERCLA. Washington is now revising its ambient water quality criteria and I've been trying to assist them. Ecology is now facing pressure from the pulp and paper industry on the use of 1 in a million as the lower end of Ecology's risk range for its AWQC.

I was wondering whether any of you had seen any cogent arguments as to why 1 in a million is an appropriate value for the lower end of EPA's risk range? Alternatively, I was wondering if there were others I should circulate this to.

Thanks!

Lon Kissinger
Toxicologist
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Mail Stop: OEA-095
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Seattle, WA 98101

kissinger.lon@epa.gov

206-553-2115 voice
206-553-0119 FAX

----- Forwarded by Lon Kissinger/R10/USEPA/US on 01/02/2013 01:32 PM -----

From: "Niemi, Cheryl (ECY)" <cnie461@ECY.WA.GOV>
To: Lon Kissinger/R10/USEPA/US@EPA
Date: 01/02/2013 01:06 PM
Subject: FW: 1x10e-6 as a Definition of Acceptable Risk

Hi Lon. Here is the paper. Would like to know if the information about the FDA is correct as to the origin of 10-6. Thanks for your help! Cheryl

---

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
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Olympia WA 98504
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cheryl.niemi@ecy.wa.gov

(See attached file: Document.pdf)

Water Quality Standards – Delegates' Table Attendance List

June 24, 2013, 9:30 AM–2:10 PM; Lacey Community Center

Delegates:

- **Hellman, Johan** *(Washington Public Ports Association)*
- **Hope, Bruce** *(Western States Petroleum Association)*
- **Housekeeper, Brandon** *(Association of Washington Business)*
- **Humphreys, Brandy** *(Confederated Tribes of Grand Ronde)*
- **Johnson, Ken** *(Weyerhaeuser)*
- **Judd, Nancy** *(Association of Washington Business)*
- **Kibbey, Heather** *(City of Everett)*
- **Kilroy, Sandra** *(King County)*
- **Myrum, Tom** *(Washington State Water Resources Association)*
- **Rawls, Bruce** *(Spokane County)*
- **Schroeder, Carl** *(Association of Washington Cities)*
- **Steele, David** *(Pacific Coast Shellfish Growers)*
- **Stuhlmiller, John** *(Washington Farm Bureau)*

Audience:

- **Alam, Mahbub** *(Department of Ecology)*
- **Aldrich, Nancy** *(City of Richland)*
- **Bartlett, Karen** *(City of Tacoma)*
- **Barton, Dianne** *(Columbia River Inter-Tribal Fish Commission)*
- **Blair, Lori** *(Boeing Company)*
- **Book, Seth** *(Skokomish Tribe)*
- **Brazil, Brian** *(Trans Alta)*
- **Brouillard, Elaine** *(Roza Sunnyside Board of Joint Control)*
- **Budworth, Chad** *(Boeing Company)*
- **Chung, Angela** *(Environmental Protection Agency - Region 10)*
- **Crane, Stuart** *(Yakama Nation)*
- **Creech, Jane** *(Department of Ecology)*
- **Curry, James** *(Northwest Food Processors Association)*
- **Deutsch, Joanie** *(Strategies360)*
- **Dick, Frank** *(City of Vancouver)*
- **Fuller, Elayne** *(East Columbia Basin Irrigation District)*
- **Gatchalian, Don** *(Yakima County)*
- **Hoff, Gina** *(United States Bureau of Reclamation)*
- **Holm, Kris** *(Water Resources Northwest)*
- **Howard, Sandy** *(Department of Ecology)*
- **Loehr, Lincoln** *(Stoel Rives)*
- **Merkle, Carl** *(Confederated Umatilla Tribes)*
- **Morrow, Jon** *(City of Ellensburg)*
- **Oleson, Mel** *(Boeing Company)*
- **Patora, Kasia** *(Department of Ecology)*
- **Peeler, Dave** *(Self)*
- **Peterson, John** *(Clark Regional Wastewater District)*
- **Rice, Casey** *(Yakima Valley Community College)*
- **Rozmyn, Lisa** *(Washington State University)*
- **Schmidt, Lynn** *(City of Spokane)*
- **Scott, Kevin** *(Port Townsend Paper)*
- **Shopbell, Stephanie** *(South Columbia Basin Irrigation District)*
- **Szelag, Matthew** *(Environmental Protection Agency - Region 10)*
- **Turner, Doris** *(Boeing Company)*
- **Wagner, Theresa** *(City of Seattle)*
- **Wendling, Peg** *(City of Bellingham)*
- **Zhang, Sarah** *(Self)*

Water Quality Standards Public Meeting Attendance List

November 6, 2013; Ecology Headquarters Building

The following individuals attended Ecology's November 6, 2013, Water Quality Standards public meeting:

- **Ahearn, Ashley** *(KUOW National Public Radio)*
- **Anderson, Kym** *(Port of Seattle)*
- **Asher, Chance** *(WA Department of Ecology)*
- **Barton, Dianne** *(Columbia River Inter-Tribal Fish Commission)*
- **Bethel, Heidi** *(U.S. EPA)*
- **Blair, Lori** *(The Boeing Company)*
- **Bolster, Todd** *(Northwest Indian Fisheries Commission)*
- **Bowden, Brent** *(City of Seattle)*
- **Brazil, Brian** *(TransAlta)*
- **Britsch, Steve** *(Snohomish County)*
- **Brouillard, Elaine** *(Roza-Sunnyside Board of Joint Control, RSBOJC)*
- **Chung, Angela** *(US EPA, Region 10)*
- **Cochrane, Brian** *(Yakima County Public Services)*
- **Conner, Leslee** *(Port of Tacoma)*
- **Cooper, Betsy** *(King County)*
- **Cornfield, Jerry** *(The Herald)*
- **Cruickshank, Peter** *(Yakama Nation)*
- **Daly, Brad** *(City of Walla Walla)*
- **Dean, Alison** *(Simpson Tacoma Kraft Co)*
- **Degens, Roxanne** *(EA Engineering, Science, and Technology, Inc.)*
- **Dewey, Bill** *(Taylor Shellfish Farms)*
- **Dickison, Jeff** *(Squaxin Island Tribe)*
- **Duncan, David** *(WA Department of Ecology)*
- **Dunn, Larry** *(Lower Elwha Klallam Tribe)*
- **Dykstra, Peter** *(Plauché & Carr LLP)*
- **Erwin, Tanyalee** *(Washington Stormwater Center at WSU)*
- **Feist, Marlene** *(City of Spokane)*
- **Garber, Andrew** *(Seattle Times)*
- **Gatchalian, Don** *(Yakima County)*
- **Graham, Bryan** *(Schnitzer Steel)*
- **Greenlund, Doug** *(City of Spokane Environmental Programs)*
- **Guthrie, Marilyn** *(Port of Seattle)*
- **Hastings, Tina** *(CH2M HILL)*
- **Hayman, Glenn** *(Hayman Environmental)*

- **Hildebrandt, Peter** *(Alcoa and WSPA)*
- **Holm, Kris** *(Water Resources NW)*
- **Holmes, Frank** *(Western States Petroleum Association)*
- **Houskeeper, Brandon** *(Association of Washington Business)*
- **Humphreys, Brandy** *(Confederated Tribes of Grand Ronde)*
- **Hupp, Marcy** *(Perkins Coie)*
- **Johnson, Ken** *(Weyerhaeuser)*
- **Judd, Nancy** *(Windward for AWB)*
- **Kaetzel, Rhonda** *(Public Health Seattle-King County)*
- **Kibbey, Heather** *(City of Everett)*
- **Kilroy, Sandra** *(King County)*
- **Kissinger, Lon** *(US EPA, Region 10)*
- **Knowles, Alfred** *(URS Corporation)*
- **Knutson, Allison** *(HDR Engineering, Inc.)*
- **Kramer, Becky** *(The Spokesman-Review)*
- **Krapas, Doug** *(Inland Empire Paper Company)*
- **Kukes, Dee** *(Quincy-Columbia Basin Irrigation District)*
- **Loehr, Lincoln** *(Stoel Rives)*
- **Logan, Lee** *(Inside EPA)*
- **Louch, Jeff** *(National Council for Air and Stream Improvement)*
- **Macchio, Lisa** *(US EPA, Region 10)*
- **Matzke, Andrea** *(Oregon Dept. of Environmental Quality)*
- **McBride, Dave** *(WA Dept. of Health)*
- **McCabe, Chris** *(Northwest Pulp & Paper Association)*
- **McCollum, Paul** *(Port Gamble S'Klallam Tribe)*
- **McCrea, Rachel** *(WA Department of Ecology)*
- **McGinnis, Roger** *(Hart Crowser)*
- **McKague, Jeanette** *(Washington REALTORS)*
- **McKay, Amanda** *(Floyd|Snider)*
- **Merrill, Laura** *(WA State Association of Counties)*
- **Moore, Rick** *(CH2M HILL)*
- **Myers, Scott** *(Self)*
- **Myrum, Tom** *(Washington State Water Resources Association)*
- **Naylor, Char** *(Puyallup Tribe)*
- **Nelson, Mary** *Anne (Idaho DEQ)*
- **Nelson, Libby** *(Tulalip Tribes)*
- **Norcross, Neil** *(Tesoro)*
- **O'Connell, Emmett** *(Northwest Indian Fisheries Commission)*
- **Ogier, Sarah** *(King County)*
- **O'Keefe, Gerry** *(Washington Public Ports Association)*
- **O'Neill, Catherine** *(Seattle University)*
- **O'Rourke, Rory** *(Port Gamble S'Klallam Tribe)*
- **Parkinson, Dave** *(Geosyntec Consultants)*
- **Peeler, Dave** *(Deschutes Estuary Restoration Team)*
- **Peterson, John** *(Clark Regional Wastewater District)*
- **Pfeifer, Grant** *(WA Department of Ecology)*

- **Ponzio, Rebecca** *(Washington Environmental Council)*
- **Price, Richard** *(EA Engineering, Science, and Technology)*
- **Pringle, David** *(Strategies 360)*
- **Rants, Mary** *(NW Pulp & Paper Association)*
- **Rapin, Nancy** *(Muckleshoot Tribe)*
- **Rawls, Bruce** *(Spokane County)*
- **Rose, Leslie Ann** *(Citizens for a Healthy Bay)*
- **Rude, Pete** *(City of Seattle)*
- **Saffery, Susan** *(Seattle Public Utilities)*
- **Schmidt, Lynn** *(City of Spokane)*
- **Schroeder, Carl** *(Association of Washington Cities)*
- **Seiter, Ann** *(Northwest Indian Fisheries Commission)*
- **Sheffels, Evan** *(Washington State Farm Bureau)*
- **Shopbell, Stephanie** *(South Columbia Basin Irrigation District)*
- **Steele, David** *(Pacific Coast Shellfish Growers Association)*
- **Steinmann, Linda** *(Office of Financial Management)*
- **Still, Tracy** *(URS Corporation)*
- **Stratton, Steve** *(National Council for Air and Stream Improvement)*
- **Sutton, Dorie** *(City of Vancouver)*
- **Szelag, Matt** *(US EPA, Region 10)*
- **Taylor, Denice** *(Suquamish Tribe - Fisheries)*
- **Thatcher, Erin** *(CH2M HILL)*
- **Tupper, James** *(Tupper Mack Wells PLLC)*
- **Turner, Doris** *(The Boeing Company)*
- **Tuttle, George** *(Washington State Department of Agriculture)*
- **VanNatta, Kathryn** *(Northwest Pulp & Paper Association)*
- **Varner, Phyllis** *(City of Bellevue)*
- **Voyce, Lisa** *(HDR Engineering, Inc.)*
- **Wagner, Theresa** *(City of Seattle)*
- **Wertz, Ingrid** *(Self)*
- **Wilshusen, Fran** *(Northwest Indian Fisheries Commission)*
- **Wilson, David** *(CH2M HILL)*
- **Wishik, Laura** *(City of Seattle)*

Water Quality Standards Update: Next Steps Attendance List

July 22, 2014, 1:30 - 3:30 PM; Ecology Headquarters Building

- **Alam, Mahbub** *(WA Dept. of Ecology)*
- **Aldrich, Nancy** *(City of Richland)*
- **Archer Parsons, Andrea** *(City of Port Orchard)*
- **Baca, Matthew** *(Earthjustice)*
- **Bain, David** *(Cascadia Environmental Science Center)*
- **Balliet, Jamie** *(East Columbia Basin Irrigation District)*
- **Barnes, Abby** *(WA Department of Natural Resources)*
- **Barrette, Margaret** *(Pacific Coast Shellfish Growers Association)*
- **Barton, Dianne** *(Columbia River Inter-Tribal Fish Commission)*
- **Bauman, Jenise** *(Western Washington University)*
- **Benbrook, Rachel** *(Nooksack Salmon Enhancement Association)*
- **Bierlink, Henry** *(Whatcom Farm Friends)*
- **Blair, Lori** *(The Boeing Company)*
- **Boehme, Jonathan** *(City of Port Angeles)*
- **Bolster, Todd** *(Northwest Indian Fisheries Commission)*
- **Book, Seth** *(Skokomish Tribe)*
- **Booth, Kevin** *(Avista Corp)*
- **Borden, Bruce** *(Lowes)*
- **Bravinder, Phyllis** *(Fidalgo Bay Aquatic Reserve Citizen Science Committee)*
- **Brazil, Brian** *(TansAlta)*
- **Bremer, David** *(Representative Denny Heck)*
- **Bridges, Thomas** *(Mukilteo Water & Wastewater Disrict)*
- **Brimmer, Janette** *(Waterkeepers Washington / Pacific Coast Federation of Fishermen's Associations)*
- **Brouillard, Elaine** *(Roza Sunnyside Board of Joint Control)*
- **Brown, Chad** *(WA Dept. of Ecology)*
- **Bryant, Mark** *(Hart Crowser)*
- **Buchalski, Catherine** *(WSU Skagit County Extension)*
- **Budworth, Chad** *(The Boeing Company)*
- **Burdick, Sarah** *(WSDOT)*
- **Burgess, Karen** *(United States Environmental Protection Agency)*
- **Buterbaugh, Galen** *(Lake Spokane Association)*
- **Butkus, Paul** *(PCA /Boise Paper)*
- **Cabbage, Patrick** *(WA Dept. of Ecology)*
- **Castle, Art** *(Building Industry Association of Washington)*
- **Cave, Scott** *(City of Quincy)*
- **Chase, Scott** *(WSU Shore Stewards, Island County)*
- **Chen, Wendy** *(EA Engineering, Science and Technology, Inc)*

- **Chisolm, B** *(WAPG)*
- **Chung, Angela** *(United States Environmental Protection Agency, Region 10)*
- **Collins, Kathleen** *(Washington Water Policy Alliance)*
- **Converse, Brett** *(JUB Engineers)*
- **Cornfield, Jerry** *(The Herald)*
- **Cotelesse, Chris** *(InsideEPA)*
- **Creech, Jane** *(WA Dept. of Ecology)*
- **Crompton, Becky** *(Golder Associates)*
- **Crowley, Allison** *(Seattle City Light)*
- **Cummings, Dano** *(City of Spokane)*
- **Daly, Brad** *(City of Walla Walla)*
- **Davis, Marcia** *(City of Spokane)*
- **Dayao, Donnelle** *(City of Sumner)*
- **Deardorff, Gary** *(City of Kennewick)*
- **Defoe, Seth** *(Kennewick Irrigation District)*
- **Deutsch, Joanie** *(Strategies 360)*
- **DeVaney, Jon** *(Yakima Valley Growers-Shippers Association)*
- **Durance, Kristen** *(Ross Strategic)*
- **Ehlebracht, Mike** *(Hart Crowser)*
- **Espinoza, Joy** *(WA Dept. of Ecology)*
- **Figlar-Barnes, Ron** *(Skokomish Tribe)*
- **Finley, Ande** *(Fisherman Bay Sewer District)*
- **Fleming, Josh** *(Boise Paper)*
- **Froschl, Christine** *(Puget Soundkeeper Alliance)*
- **Gallardo, Angela** *(City of Burien)*
- **Gannett, Craig** *(Davis Wright Tremaine, LLP)*
- **Gatchalian, Don** *(Yakima County)*
- **Gaub, Ty** *(U.S. Oil & Refining Co.)*
- **Gombosky, Melissa** *(Association of Washington)*
- **Gorsuch, Joseph** *(Copper Development Association)*
- **Govednik, Erin** *(WA Dept. of Health)*
- **Graham, Jeremy** *(City of Olympia)*
- **Graves, Nathan** *(Kennedy/Jenks Consultants)*
- **Gray, Donovan** *(WA Dept. of Ecology)*
- **Greenway, Shawnte** *(Urban Wilderness Project)*
- **Gyselinck, Craig** *(Quincy-Columbia Basin Irrigation District)*
- **Halbert, Chip** *(Landau Associates)*
- **Hall, Ryan** *(Self)*
- **Halstrom, Jim** *(Washington State Horticultural Association / WA Water Policy Alliance)*
- **Haslip, Heather** *(Port of Skagit)*
- **Hayman, Glenn** *(Hayman Environmental)*
- **Hedgecock, Jill** *(URS Corporation)*
- **Hegel, Kevin** *(City of Montesano)*
- **Henderson, Mark** *(WA Dept. of Ecology)*
- **Hendrickson, Kris** *(Landau Associates)*

- **Hermanson, Mike** *(Spokane County Water Resources)*
- **Hernandez, Carrie** *(Citizens for a Healthy Bay)*
- **Hildebrandt, Pete** *(Alcoa & Western States Petroleum Association)*
- **Himebaugh, Jan** *(Building Industry Association of Washington)*
- **Himebaugh, Daniel** *(Washington State Senate Majority Coalition Caucus)*
- **Hines, Eleanor** *(Northwest Straits Chapter, Surfrider Foundation)*
- **Hoeft, Bruce** *(Surfrider, South Sound chapter)*
- **Holm, Kris** *(WRNW)*
- **Houskeeper, Brandon** *(Association of Washington Business)*
- **Hughes, Nikkole** *(Washington State House of Representatives)*
- **Hupp, Marcy** *(Perkins Coie)*
- **Hutton-Tine, Alex** *(Recology)*
- **Iams, Karl** *(U.S. Oil & Refining Co.)*
- **Jack, Richard** *(King County Dept Natural Resources and Parks)*
- **Jarnot, Brittany** *(Everett, Fife, Issaquah, Kent, Lake Stevens, Puyallup, Redmond, Renton)*
- **Johnson, Ken** *(Weyerhaeuser)*
- **Johnson Arledge, Rebecca** *(City of Seattle)*
- **Jones, Dan** *(Washington State House of Representatives)*
- **Judd, Nancy** *(Windward Environmental for AWB)*
- **Kibbey, Heather** *(City of Everett)*
- **Kilroy, Sandra** *(King County)*
- **Kook, Shirley** *(Lewis County)*
- **Kounts, John** *(Washington PUD Association)*
- **Krautkramer, Mike** *(Robinson Noble, Inc.)*
- **Krider, Leah** *(The Boeing Company)*
- **Leang, Amy** *(WA Dept. of Health)*
- **leDoux, Beth** *(Snoqualmie Watershed Forum)*
- **Leisenring, Marc** *(Geosyntec Consultants)*
- **Levitt, Eli** *(WA Dept. of Ecology)*
- **Li, Julia** *(Public)*
- **Lipson, Jacob** *(Washington State House of Representatives)*
- **Loehr, Lincoln** *(City of Everett)*
- **Lorenz, Wayne** *(Wright Water Engineers)*
- **Martin, Connie Sue** *(Schwabe Williamson & Wyatt)*
- **Mattax, Brian** *(Golder Associates Inc.)*
- **Mattson, Larry** *(WSDOT - South Central Region Environmental Office)*
- **Mauren, Lorna** *(City of Tacoma)*
- **McBride, Dave** *(WA Dept. of Health)*
- **McGinnis, Roger** *(Hart Crowser)*
- **Meehan, Maureen** *(City of Seattle, Department of Transportation)*
- **Merkle, Carl** *(Confederated Umatilla Tribes)*
- **Merrill, Laura** *(Washington State Association of Counties)*
- **Mitchener, Mary** *(Hart Crowser)*
- **Moore, Cassandra** *(Self)*
- **Morgan, Newton** *(Kitsap Public Health District)*

- **Morgan, Matt** *(Roza Sunnyside Board of Joint Control)*
- **Morton, Neil** *(GeoEngineers)*
- **Mountjoy Venning, Jane** *(Thurston County Environmental Health Education)*
- **Myrum, Tom** *(WA State Water Resources Association)*
- **Norcross, Neil** *(Tesoro Refining & Marketing Co. LLC)*
- **Norton, Ted** *(Golder Associates)*
- **O'Keefe, Gerry** *(WPPA)*
- **Oleson, Mel** *(Citizen)*
- **O'Neill, Catherine** *(Seattle University School of Law)*
- **Ordonez, Jeanette** *(Futurewise)*
- **Page, Chris** *(The William D. Ruckelshaus Center)*
- **Partridge, Holly** *(Confederated Tribes of Grand Ronde)*
- **Penttila, Brian** *(Pacific Northwest Pollution Prevention Resource Center)*
- **Percynski, Beth** *(Procter & Gamble)*
- **Peterson, John** *(Clark Regional Wastewater District)*
- **Phillips, Sandra** *(Spokane Regional Health District)*
- **Plusquellec, Scott** *(City of Seattle, Office of Intergovernmental Relations)*
- **Powell, Mark** *(Washington Environmental Council)*
- **Rader, Kevin** *(Mutch Associates)*
- **Rae, Alyson** *(Snohomish County)*
- **Ramos, C** *(Boise Paper)*
- **Ransavage, Ryan** *(Miles Sand & Gravel Company)*
- **Rhoads, Kate** *(Seattle Public Utilities)*
- **Rhodes, Brian** *(Western States Petroleum Association and Shell)*
- **Rides at the Door, Roylene** *(USDA Natural Resources Conservation Service)*
- **Riggs, Michele** *(Cedar Grove Composting)*
- **Rusk, Dan** *(Washington State House of Representatives)*
- **Sackellares, Robert** *(Georgia Pacific)*
- **Saffery, Susan** *(City of Seattle, Seattle Public Utilities)*
- **Schell, Megan** *(WA Dept. of Health)*
- **Schmidt, Lynn** *(City of Spokane)*
- **Schmidtz, David** *(Phillips 66 Ferndale Refinery)*
- **Schroeder, Carl** *(Association of Washington Cities)*
- **Seiter, Ann** *(Northwest Indian Fisheries Commission)*
- **Sheffels, Evan** *(WA Farm Bureau)*
- **Shopbell, Stephanie** *(South Columbia Basin Irrigation District)*
- **Sklare, Julie** *(City of Everett)*
- **Skrinde, Rolf** *(Twin City Foods)*
- **Slack, Kim** *(Anchor QEA)*
- **Smith, Richard** *(Smith & Lowney, PLLC)*
- **Soldano, Alex** *(Gordon Thomas Honeywell Governmental Affairs)*
- **Spain, Glen** *(Pacific Coast Federation of Fishermen's Associations (PCFFA)*
- **St. Amant , Glen** *(Muckleshoot Indian Tribe)*
- **Stang, John** *(Crosscut.com)*
- **Steding, Doug** *(Graham & Dunn)*

- **Steffensen, Wendy** *(RE Sources North Sound Baykeeper)*
- **Steinmetz, Marcie** *(Chelan PUD)*
- **Taylor, Calvin** *(City of Tacoma)*
- **Taylor, Toni** *(Spokane County Water Resources Division)*
- **Thorpe, Ed** *(Coalition for Clean Water)*
- **Tosch, McClure** *(Yakama Nation)*
- **Trim, Heather** *(Futurewise)*
- **Tupper, James** *(Tupper Mack Wells PLLC)*
- **Turner, Doris** *(The Boeing Company)*
- **Uding, Nancy** *(Washington Toxics Coalition)*
- **Utau, Ryan** *(McBride Public Affairs)*
- **VanderWood, Jerry** *(Associated General Contractors of Washington)*
- **VanNatta, Kathryn** *(Northwest Public Power Association)*
- **Varner, Phyllis** *(City of Bellevue)*
- **Verity, Laura** *(Ponderay Newsprint Co.)*
- **Vincent, Carla** *(Pierce County SWM)*
- **Wagner, Theresa** *(City of Seattle)*
- **Wagner, Lydia** *(WA Dept. of Ecology)*
- **Waldron, Chris** *(PIONEER Technologies Corporation)*
- **Washington, Diana** *(WA Dept. of Ecology)*
- **Webber, Terry** *(American Forest & Paper Association)*
- **Wendling, Peg** *(City of Bellingham)*
- **Wertz, Ingrid** *(Seattle Public Utilities)*
- **Whitaker, Brandon** *(Port of Everett)*
- **White, Jr., Jerry** *(Spokane Riverkeeper - Center for Justice)*
- **Whitman, Kara** *(Ruckelshaus Center)*
- **Wilke, Chris** *(Puget Soundkeeper Alliance)*
- **Wisdom, Charles** *(Geosyntec Consulting)*
- **Wood, Jill** *(Island County Public Health)*
- **Wright, Jeff** *(City of Everett)*
- **Wynkoop, Jennifer** *(Landau Associates Tacoma)*
- **Zlateff, Dana** *(City of Issaquah)*
- **Zorza, Dubber** *(Hood River Sand & Gravel)*

From: Gildersleeve, Melissa (ECY)
Sent: Tuesday, October 01, 2013 3:24 PM
To: Chung, Angela; Matthew Szelag
Subject: Meetings to discuss EPA input on ECY rules

Angela and Matt—Below are a list of items that I suggest we walk through in a series of 3 meetings. Maybe schedule 4 in case we need more. I am thinking I would get Kelly to attend the last one so we could do a summary of where we are with regard to your feedback and how we will message our options that we will present on November 6th.

The following dates look open and we could devote up to 3 hours (or more) toward a meeting. I think the HHC should be ready to happen sooner. We are developing options/outline for variance rule now and I would like to have that in a more final form for when we meet with you.

October 8, 16, 21, 22, 25,30 and Nov 1

Thanks-Melissa

Items to discuss with EPA prior to Nov 6th

Meeting #1 - Human Health Criteria—
Walk through the specific options and get EPA feedback.
Relative Source Contribution Discussion
Risk Level Discussion
Salmon in and Salmon Out discussion
Consumer vs. nonconsumer
Discussion around messages for work being done in Idaho.

Meeting #2 - Implementation Tools
Compliance Schedule (20 year)
Intake Credit
Variances
-Statewide variance
-Waterbody wide variance
-Discharger specific variance
-Use of other pollution control programs to support variance
-Variance program similar to Idaho

Meeting #3 - Role up of HHC & implementation discussions and the options that will be presented on Nov 6th. Clarify Messages for each agency especially where there is potential push on guidance. Possibly just have Kelly and Dan at this meeting once we have completed legwork with the other two meeting.

Melissa Gildersleeve, Section Manager, Water Quality, Department of Ecology 360-407-6461
Please consider the environment before printing this e-mail.

Water Quality Standards Rule Making

Human Health Criteria

Summary

November 6, 2013

	Current	Alternative1	Alternative 2	Alternative 3
Fish Consumption Rate	**6.5** grams/day	**225** grams/day	**175** grams/day	**125** grams/day
Basis	Mean of the per capita national data set.	Mean of highest highly exposed fish consumption study and recreation fish consumption.	Negotiated value used in Oregon's updated Human Health Criteria. Based on 90-95th percentile of Oregon Fish Consuming populations.*	Mean of the fish consumption rate surveys of 3 Puget Sound tribes

From: Opalski, Dan [mailto:Opalski.Dan@epa.gov]
Sent: Tuesday, March 11, 2014 9:42 PM
To: Susewind, Kelly (ECY)
Cc: Bellon, Maia (ECY)
Subject: Re: Listing and EJ Discussion

Thanks for the follow-up. I have my folks following up on the listing methodology question and will get back to you on that.

Regarding the environmental justice concern, you are right that there isn't anything that will/does call out a particular risk level. Dennis' central point is that in the context of the other rules and programs in place in the state and their fairly consistent protection at 10-6, the potential disproportionality enters in when you're looking now at a rule whose protection relates so fundamentally to consumption behavior, with many (though not all) of the high consumers being tribal people and other ethnic groups with subsistence or near subsistence fish consumption levels. So it is not about disparate treatment within the rule or relative to a specific standard, but about going with a potentially different risk target for a particular rule that is especially relevant to the lifestyles and traditional practices of specific subpopulations.

I'm heading out early in the morning for a long day of travel to southern Idaho and back. I'll try to be responsive when I can and then will be back in on Thursday.

DanO.

Washington State Senate

Olympia Address:
PO Box 40442
Olympia, WA 98504-0442

Senator Doug Ericksen
42nd Legislative District

(360) 786-7682
FAX: (360) 786-1323
E-mail: Doug.Ericksen@leg.wa.gov

April 3, 2014

Dennis McLerran, Regional Administrator
U.S. EPA Region 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101

Dear Mr. McLerran,

As you know, Washington's Department of Ecology is revising the human health criteria for the state's surface water quality standards. The new water quality standards will be the basis for a wide range of regulatory decisions that affect all Washington residents. Therefore, I am seeking to assure that the criteria, which will be reviewed by EPA, is supported by sound scientific analysis and that it will not harm the state's economic vitality.

One particular concern is cancer risk. Your review of the state's proposed criteria will include consideration of the appropriate cancer risk for Washington. I understand that your agency's policies establish a generally acceptable cancer risk range, typically falling between 10-6 and 10-4 risk level. EPA guidance also provides that the agency will afford flexibility for states to adopt cancer risk levels that best suit the state's goals for use of its surface waters.

Unfortunately, a recent conversation with officials and stakeholders has revealed some uncertainty surrounding EPA's review of cancer risk. I respectfully seek a response from your agency that outlines the review process that the state's proposed criteria will undergo, and I specifically would like to know what your agency considers to be an appropriate cancer risk level for Washington.

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I also seek your input as to the state's options for setting a cancer risk level -- i.e. whether the criteria may be based on a risk level chosen from a generally acceptable range, whether EPA expects Washington to adopt a risk level of 10-6, or whether other options are available.

Thank you for your attention to this matter.

Sincerely,

Senator Doug Ericksen, Chair
Senate Energy, Environment
and Telecommunications Committee

cc: Senator Rodney Tom
Senator Mark Schoesler
Senator Sharon Brown
Senator Barbara Bailey

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF THE
REGIONAL
ADMINISTRATOR

APR 2 4 2014

The Honorable Doug Ericksen
Energy, Environment and Telecommunications Committee Chair
Washington State Senate
Post Office Box 40442
Olympia, Washington 98504-0442

Dear Senator Ericksen:

Thank you for your letter dated April 3, 2014. I appreciate your taking the time to express your concerns regarding the Department of Ecology's (Ecology's) ongoing process to adopt human health criteria into Washington's water quality standards. As you know, the Environmental Protection Agency supports Ecology's efforts to use scientifically sound regional and local fish consumption data as part of its rulemaking. Your letter specifically asks about the EPA's process for reviewing the State's human health criteria and the EPA's perspective on the cancer risk level that Ecology may use to derive human health criteria for carcinogens.

The EPA intends to comprehensively review Ecology's human health criteria, including how Ecology integrates science in its policy decisions to provide health protection for all citizens of Washington, including high fish consumers. In its review, the EPA must ensure that the human health criteria Washington State adopts are protective of applicable designated uses and based on a sound scientific rationale, consistent with 40 CFR § 131.11(a).

Currently, Washington's water quality standards contain a provision that states, "[r]isk-based criteria for carcinogenic substances shall be selected such that the upper-bound excess cancer risk is less than or equal to one in one million." WAC 173-201A-240(6). If Ecology were to revise this language to allow for a different risk level, the EPA would expect Ecology to provide a rationale that explains how such a policy change would be protective given Ecology's current policy position and available data that indicate a broad spectrum of Washington citizens regularly eat fish. The EPA recommends that Ecology carefully consider the implications of making a potential change to its existing cancer risk level and how it would affect the health protection of all fish consumers in the State, including high fish consumers.

Again, thank you for contacting the EPA. If you have any questions, please feel free to contact me or have your staff contact Dan Opalski, the Director of the Office of Water and Watersheds. You can reach Dan by phone at (206) 553-1855 or by email at opalski.dan@epa.gov.

Sincerely,

Dennis J. McLerran
Regional Administrator

cc: Ms. Maia Bellon, Director, Washington Department of Ecology

03949

Washington State Senate

Olympia Address:
PO Box 40442
Olympia, WA 98504-0442

Senator Doug Ericksen
42nd Legislative District

(360) 786-7682
FAX: (360) 786-1323
E-mail: Doug.Ericksen@leg.wa.gov

May 28, 2014

RECEIVED ON:
JUN 02 2014
EPA Region 10
Office of the Regional Administrator

Dennis McLerran, Regional Administrator
U.S. EPA Region 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101

Dear Regional Administrator McLerran,

Thank you for responding to my April 3 letter regarding the ongoing process to adopt human health criteria into Washington's water quality standards. Unfortunately, your response highlights one of the great shortcomings of current government. I asked a specific question relating to a very important issue that will affect Washington's economy and public health, but you did not provide me with a specific answer. Here is an excerpt from my letter:

I respectfully seek a response from your agency that outlines the review process that the state's proposed criteria will undergo, and I specifically would like to know what your agency considers to be an appropriate cancer risk level for Washington. I also seek your input as to the state's options for setting a cancer risk level—i.e. whether the criteria may be based on a risk level chosen from a generally acceptable range, whether EPA expects Washington to adopt a risk level of 10-6, or whether other options are available.

I am taking this opportunity to rephrase my inquiry for the sake of clarity. Please answer the following questions:

(1) Have you or your staff indicated to the Washington Department of Ecology (Ecology) that there is a threshold cancer risk level that must be proposed for the state's criteria to receive approval?

(2) Have you or your staff indicated to Ecology that a cancer risk level of 10-6 is required or that it is the level you want the state to propose?

(3) Have you or your staff provided any specific directives to Ecology outlining what you will accept for a cancer risk level for Washington?

Thank you for your attention to this matter. I look forward to your prompt response.

Sincerely,

Senator Doug Ericksen, Chair
Senate Energy, Environment
and Telecommunications Committee

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF THE
REGIONAL
ADMINISTRATOR

JUL 1 2014

The Honorable Doug Ericksen
Energy, Environment, and Telecommunications Committee Chair
Washington State Senate
Post Office Box 40442
Olympia, Washington 98504-0442

Dear Senator Ericksen:

Thank you for your letter dated May 28, 2014. I appreciate your taking the time to follow up with me about the Department of Ecology's ongoing rulemaking process to adopt human health criteria into Washington's water quality standards. The U.S. Environmental Protection Agency is very appreciative of the challenging work that Ecology has undertaken thus far to adopt human health water quality criteria, which has included a robust public process and a detailed review of the factors used to derive human health criteria, including scientifically sound regional and local fish consumption data. Your letter asks three related questions about the EPA's communications regarding the cancer risk level that Ecology may use to derive human health criteria for carcinogens. Below is my response to your questions.

As you may be aware, water quality criteria must protect applicable designated uses and be based on sound scientific rationale (see 40 CFR § 131.11(a)). In discussions with Ecology and other interested parties, the EPA has acknowledged the language in its national guidance for deriving ambient water quality criteria to protect human health (EPA's 2000 Human Health Methodology) regarding state adoption of water quality criteria for carcinogens. The Methodology identifies some flexibility in choosing cancer risk levels below Washington's current ten to the minus six (10^{-6}) level of protection. At the same time, the EPA recognizes that the Methodology encourages the consideration of local and regional data when available and that other important principles, such as environmental justice and treaty rights, need to be considered in decisions by the states and the EPA on water quality standards, including risk levels.

When reviewing the State's adopted human health water quality criteria, the EPA will consider Ecology's basis for justifying the input parameters used to calculate the criteria, ensuring that they are consistent with the best available science and a sound scientific rationale. In addition, the EPA has communicated to Ecology that we will need to review the State's entire final water quality standards submittal to better understand Ecology's overall plan to reduce toxic pollutants in the environment before determining what Clean Water Act action we will take. These types of details are important elements implicit in my April 24, 2014 response to you, where I indicated that the EPA must ensure that the human health criteria that Washington adopts are protective of applicable designated uses and based on a sound scientific rationale.

Regarding the specific issue of water quality criteria to limit exposure to cancer-causing pollutants, I have recommended that Ecology retain their current state-wide cancer risk level of 10^{-6}, which is used to

derive the State's human health criteria. There are several reasons why I would like Ecology to maintain their cancer risk level of 10^{-6}.

First, Washington's risk-based criteria for carcinogenic substances were derived by the EPA under the National Toxics Rule using a cancer risk level of 10^{-6}, pursuant to Washington's decision to select that risk level. In the current human health criteria rulemaking process, Ecology has stated a desire to better protect higher fish consumers in Washington. It is not clear why, in developing human health criteria to protect higher fish consumers, it is necessary or appropriate for Washington to reduce the level of cancer risk protection for the entire State – a level that has been in effect for more than twenty years.

Second, if Washington reduces the level of cancer risk protection from the current level of 10^{-6}, tribes, certain low-income, minority communities, and other high fish consuming groups could be provided less protection than they have now. Thus, a reduction in the level of cancer risk protection raises environmental justice concerns, which are a significant consideration in the EPA's review of the State's overall submittal. Consistent with Executive Order 12898 and the EPA's environmental justice policy and guidance documents, such as the EJ Legal Tools document issued in December 2011, the EPA incorporates environmental justice considerations into its decision-making. Notably with respect to many of the tribes, this approach to the cancer risk level would not advance environmental or public health protections consistent with their treaty-reserved right to harvest and eat fish and shellfish.

Third, in order to protect downstream waters consistent with the EPA's regulations at 40 CFR 131.10(b), I support regional consistency among Region 10 states and authorized tribes particularly when there are similarities in pollutants and associated environmental and human health risks. In line with that, I believe this is an opportunity for Washington to join Oregon as a national environmental leader in setting human health criteria that protect the designated uses and reflect the best available regional and local data. Seizing that opportunity will involve thoughtful selection of a cancer risk level that protects not only the State's general population, but its most vulnerable populations.

I firmly believe that there is a way for Ecology to adopt a water quality standards package that retains the State's current 10^{-6} level of protection from cancer-causing pollutants while giving industry time to comply with more stringent water quality criteria through implementation tools, such as compliance schedules and variances. I think this approach could support a thriving economy while protecting higher fish consuming populations.

Again, thank you for your follow-up inquiry. If you have any questions, please feel free to contact me or have your staff contact Dan Opalski, the Director of the Office of Water and Watersheds. You can reach Dan by phone at (206) 553-1855 or by email at opalski.dan@epa.gov.

Sincerely,

Dennis J. McLerran
Regional Administrator

cc: Ms. Maia Bellon, Director, Washington Department of Ecology

United States Environmental Protection Agency
Office of Water
Mail Code 4305T
EPA-820-F-14-001
June 2014

Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions

DISCLAIMER

These Frequently Asked Questions (FAQs) do not impose legally binding requirements on the U.S. Environmental Protection Agency (EPA), states, tribes, or the regulated community, nor do they confer legal rights or impose legal obligations upon any member of the public. The Clean Water Act (CWA) provisions and the EPA regulations described in this document contain legally binding requirements. These FAQs do not constitute a regulation, nor do they change or substitute for any CWA provision or the EPA regulations.

The general description provided here may not apply to a particular situation based upon the circumstances. Interested parties are free to raise questions about the substance of these FAQs and the appropriateness of their application to a particular situation. The EPA retains the discretion to adopt approaches on a case-by-case basis that differ from those described in these FAQs where appropriate. These FAQs are a living document and may be revised periodically without public notice. The EPA welcomes public input on these FAQs at any time.

1. Why is it important that upstream designated uses and water quality criteria ensure the attainment and maintenance of downstream water quality standards?

Pursuant to sections 303 and 101(a) of the Clean Water Act ("CWA" or "the Act"), the federal regulation at 40 CFR 131.10(b) requires that "*In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.*" This provision requires states and authorized tribes (hereinafter "states/tribes") to consider and ensure the attainment and maintenance of downstream[1] water quality standards (WQS) during the establishment of designated uses and water quality criteria in upstream[2] waters. Adopting either narrative or numeric criteria to ensure the attainment and maintenance of downstream WQS (i.e., designated uses, criteria and antidegradation requirements) may likely be the preferred path for states/tribes to ensure consistency with 40 CFR 131.10(b). This is especially important if there

[1] The EPA interprets the term "downstream" to include both intra- and interstate waters, as well as waters that form a boundary between adjacent jurisdictions.

[2] Throughout these FAQs the EPA is using the term "upstream" to include "instream" when referring to the water body(ies) for which states/tribes are developing designated uses/water quality criteria that will ensure the attainment and maintenance of downstream WQS.

are data or information suggesting that upstream designated uses and/or water quality criteria may not provide for the attainment and maintenance of downstream standards.

Designated uses and water quality criteria that ensure attainment and maintenance of downstream WQS may be important because they may help to avoid situations where downstream segments become impaired due, either in part or exclusively, to individual or multiple pollution sources located in upstream segments. Designated uses and water quality criteria that provide for the attainment and maintenance of downstream WQS may help support more equitable use of any assimilative capacity available to upstream and downstream pollution sources and/or jurisdictions and may facilitate restoration of the downstream waters. Ensuring the attainment and maintenance of downstream WQS during development of upstream designated uses and water quality criteria may also help limit and/or avoid resource-intensive water quality problems and/or legal challenges that can occur after adoption of uses and criteria that lack consideration of downstream waters' WQS. Furthermore, downstream protection consideration prevents the shifting of responsibility for pollution reductions from upstream sources and/or jurisdictions to downstream sources and/or jurisdictions. State/tribal uses and criteria that protect downstream waters may, among other things, increase the resiliency of the nation's waters to climate change and may help address environmental justice issues in urban waters. In addition, designated uses and criteria that ensure attainment and maintenance of downstream WQS facilitate consistent and efficient implementation and coordination of water quality-related management actions (e.g., water quality monitoring and assessment, development of Total Maximum Daily Loads (TMDLs) and other watershed-based restoration and protection plans, and National Pollutant Discharge Elimination System (NPDES) permitting and CWA Section 401 certifications).

Consistent with the disclaimer above, the EPA reiterates that these FAQs do not impose any additional requirements on states/tribes with regards to downstream protection beyond those requirements already identified in 40 CFR 131.10(b). States/tribes have discretion in choosing their preferred approach to downstream protection based on their individual circumstances, and these FAQs are not intended to limit a state's or tribe's discretion, provided their selected criteria approach is also consistent with 40 CFR 131.11. Furthermore, the EPA recognizes that states/tribes may not have the available resources to develop numeric criteria to protect downstream waters at this time or in the near future; therefore, these FAQs envision a hybrid approach where a state/tribe may adopt narrative criteria, numeric criteria or a combination of these criteria. In addition to the discussion of possible criteria development approaches discussed in response to Question 3, *"What are possible criteria development approaches for ensuring the attainment and maintenance of downstream WQS?,"* the EPA has developed a set of four customizable templates[3] for narrative downstream protection criteria to assist states/tribes with this effort. These templates may be used to develop a "broad narrative" that provides basic legal coverage under 40 CFR 131.10(b) (e.g., applies to all waters in the state/tribe) as well as a variety of "tailored narratives" that can be developed to address specific water bodies, pollutants, and/or water body types.

[3] http://water.epa.gov/scitech/swguidance/standards/narrative.cfm

2. What should states/tribes consider regarding downstream protection when developing and adopting upstream designated uses and water quality criteria?

- **Use a watershed approach to develop WQS.**
  Early in the process of developing designated uses and/or water quality criteria, it is useful to take a step back and consider water quality at the United States Geological Service (USGS)-defined subwatershed (e.g., HUC 12) or broader geographic scale. Such an analysis could be as general or detailed as a state's or tribe's resources allow. Start by asking questions about what the most sensitive designated uses are within such a watershed, which uses are in place downstream, and what criteria are in place to protect those uses. Developing a designated use inventory and/or map[4] that identifies uses within a watershed may help in defining the scope of potential downstream vulnerabilities. States/tribes may already have developed advanced mapping tools that can be used in this effort. It may also be useful to consider whether the uses and criteria for the downstream receiving waters are adequate or if they need to be developed, revised or refined. In addition, consider other water bodies that may flow to downstream waters and may affect hydrologic flow and/or pollutant concentrations in these locations. Also, if dealing with a subwatershed, consider which upstream subwatershed might have the greatest potential to positively or negatively impact downstream water quality (e.g., based on land characteristics and use, proximity to sensitive downstream waters, water body characteristics, stressor source and distribution). Furthermore, understanding and considering the programmatic (e.g., point and nonpoint source, assessment, listing and TMDL) and jurisdictional issues at play and any solutions in place at the subwatershed or overall watershed levels may provide useful information and help to avoid potential future conflicts.

- **Communicate and coordinate early between jurisdictions, programs, and agencies regarding shared watersheds.**
  When a state/tribe is developing designated uses and water quality criteria that may affect the waters of another state or jurisdiction, early communication with the potentially affected jurisdiction(s) and with the EPA (as appropriate) is key to help define the scope of downstream protection issues and determine protective endpoints. States may also consider the administrative processes and procedures for setting WQS that are outlined in their regulations. Where possible, adjacent states/tribes may find it useful to develop WQS jointly for shared waters. States/tribes may consider creating a formal agreement (e.g., Memorandum of Understanding (MOU), joint powers agreement), developing partnerships (e.g., watershed commission), and/or including third party entities (possibly the EPA) to assist with cross-jurisdictional or cross-program communication and coordination. Also, the EPA/states/tribes may consider developing an electronic communications clearinghouse that can be used to coordinate complex issues with multiple stakeholders, as well as having periodic check-ins to ensure that appropriate actions are being taken and to determine if adjustments are needed.

[4] One tool that can provide a starting point for this type of analysis is the National Atlas' Streamer, which can be used to trace downstream or upstream from any point on a stream or river: http://nationalatlas.gov/streamer/welcome.html

To foster consistency and efficiencies across programs, state/tribal WQS programs may wish to find out how other programs such as their state's NPDES, assessment/listing, and TMDL programs may consider and protect downstream waters, and what information or direction those other programs need to effectively implement WQS—especially narrative criteria—to ensure protection of downstream waters.

- **First focus on downstream protection in priority situations.**
  When considering the development of uses and criteria that ensure the attainment and maintenance of downstream WQS, states/tribes may wish to first focus their efforts on situations where downstream impacts may be greatest to make the best use of available resources. Priority situations will likely vary from state to state or tribe to tribe, and may include those in which:
  - the pollutant accumulates over time in downstream waters (e.g., nitrogen or phosphorus); is persistent (i.e., resists degradation) in the environment (e.g., lead, mercury, arsenic, PCBs, dioxin); is bioaccumulative in aquatic life, wildlife, or humans (e.g., methylmercury); and/or transforms into a more toxic form downstream (e.g., some pesticide metabolites or disinfection byproducts);
  - downstream waters are protected by more stringent or additional criteria;
  - drinking water intakes exist downstream;
  - cumulative impacts are known to occur downstream;
  - environmental justice[5] issues are relevant (e.g., human subpopulations disproportionally at risk exist downstream);
  - sensitive or rare aquatic species (e.g., state- or federally-listed threatened or endangered species) and/or species with particular economic or social importance exist downstream;
  - contentious cross-jurisdictional issues related to downstream water quality exist and coordination may be called for;
  - waters with special use designations and/or protections exist downstream and/or upstream (e.g., headwaters, low order streams);
  - downstream waters are on a state's CWA section 303(d) list of impaired and threatened waters for the relevant pollutants; and/or
  - numeric criteria for the relevant pollutants have been adopted downstream.

- **Choose an approach to develop uses and criteria that ensures the attainment and maintenance of downstream WQS, and document the decision and corresponding analyses.**
  Depending on the situation, it may be appropriate to pursue adoption of a narrative or numeric criterion (or a combination) for downstream protection. In many situations, a narrative downstream protection criterion that provides general coverage could be sufficient. However, in some priority situations (see above for potential examples), states/tribes may wish to consider a more tailored and specific narrative criterion and/or a numeric criterion for specific water bodies or pollutants (for more information, see response to Question 3, *What are possible criteria development approaches for ensuring the attainment and maintenance*

[5] For more information visit the EPA's environmental justice website: http://www.epa.gov/compliance/ej/index.html.

of downstream WQS?). In either case, share with the public a written summary and any related analyses of how attainment and maintenance of downstream WQS was considered during the development of upstream uses and/or criteria, including information supporting how the selected approach demonstrates that such protection is ensured. This summary should be included as supporting documentation for a state's WQS submission, in accordance with 40 CFR 131.5 and 131.6.

Similarly, in designating new or revised upstream uses (e.g., after removing a use consistent with a use attainability analysis, or UAA), the state/tribe should include information on the state's/tribe's consideration of the applicable downstream WQS. Specifically, when designating or revising upstream uses specified in CWA section 101(a)(2), or subcategories of such upstream uses, this information should include how the state's/tribe's new or revised upstream uses (and associated criteria) will continue to demonstrate protection of existing or designated uses of downstream waters. States/tribes must designate any new or revised upstream use taking into consideration the needs in the immediate water (i.e., the upstream water) as well as the WQS of the downstream waters.

However, 40 CFR 131.10(b) does not require a state/tribe to retain a use in an upstream segment that has been demonstrated through a use attainability analysis to be unattainable, solely to satisfy the requirement of 40 CFR 131.10(b). Where an upstream use is demonstrated to be unattainable because the water quality necessary to support the use cannot be achieved, then the attainable water quality and consequently the attainable use in the downstream segment may also be limited by the attainable water quality in the upstream segment, taking into consideration mitigating factors such as flow, dilution, and pollutant degradation. Where an upstream use is shown to be unattainable due to physical conditions, an attainable use may be established instead, but numeric or narrative criteria should also be established that provide for the attainment and maintenance of the (potentially more stringent) water quality standards assigned to downstream waters.

- **Consider the spatial extent of potential impacts on downstream WQS.** Downstream impacts of upstream uses and criteria should be considered as far downstream as adverse impacts are observed or expected to occur from upstream pollution (including hydrologic flow alteration[6]). Just how far downstream a loading of pollutants (or effects from hydrologic flows) could affect the attainment and maintenance of WQS depends on a number of variables, including the nature of the pollutants (e.g., fate and transport properties), upstream and downstream flow volumes, inputs from other sources/tributaries, and the distance/travel time to downstream water bodies with additional or more stringent criteria and/or uses requiring additional protection. Network[7] or fate-and-transport modeling can be useful for delineating the spatial extent of potential impacts. See response to Question

[6] EPA is including impacts from hydrologic flow alteration as states/tribes are increasingly choosing to adopt criteria for the protection of hydrologic flows. Thus, particularly where a state/tribe has approved hydrologic flow criteria in their WQS, EPA considers 40 CFR 131.10(b) to apply.

[7] A network model using the Strahler number is a simple approach (e.g., the point at which the flowing water body segment with a Strahler number n flows into another water body with a Strahler number n+2) that may be useful. (Strahler, A. N. (1957), "Quantitative analysis of watershed geomorphology", Transactions of the American Geophysical Union 38 (6): 913–920)

3, *What are possible criteria development approaches for ensuring the attainment and maintenance of downstream WQS?* for more information regarding numeric and narrative approaches to the development of upstream criteria that are protective of downstream waters.

- **Consider antidegradation requirements of downstream waters during development of upstream designated uses and water quality criteria.**

  When developing or revising designated uses and/or water quality criteria, it is important to consider antidegradation requirements of downstream waters. Consideration of "Tier 1" requirements (i.e., protection of existing uses) in downstream waters is most pertinent when the existing use of a downstream water body is "higher" or "better" than its designated use. (For example, the designated use might be "limited aquatic life" but the existing use could be described as "full aquatic life," a use that might require more stringent criteria.) In such cases, it is important to consider the existing use downstream, in addition to the designated uses and water quality criteria. One way that protection of existing uses can be facilitated is by ensuring that the designated use is revised to reflect any higher or better existing use.

  When states/tribes located upstream are evaluating their own antidegradation requirements for high quality waters, they should also consider the attainment and maintenance of the antidegradation requirements of states/tribes located downstream. Where downstream high quality waters ("Tier 2") and/or "Outstanding National Resource Waters" ("Tier 3") exist, this will likely call for coordination between upstream and downstream states/tribes to ensure that high quality downstream waters are appropriately protected.

3. What are possible criteria development approaches for ensuring the attainment and maintenance of downstream WQS?

Adoption of narrative criteria or numeric criteria (or both) that are protective of downstream waters are viable options under 40 CFR 131.10(b). States/tribes have discretion in choosing their preferred approach. The EPA expects that many states/tribes will consider using a combination of narrative and numeric criteria depending on their circumstances.

In some situations, a broad narrative criterion approach may be advantageous, as such an approach is quickly and easily developed and provides basic legal coverage for a variety of water bodies and pollutants or hydrological flow alteration. Narrative criteria approaches are adaptive, allowing for protection of downstream WQS in a changing environment where loads (either pollutant concentrations or hydrologic flows or both) from different sources may change over time. States/tribes may also wish to consider a more tailored narrative criteria approach that is specific to their unique circumstances (e.g., for certain water body types or certain pollutants). A state/tribe could have several tailored narratives that, for example, include a narrative criterion for streams to protect downstream lakes or a narrative criterion that is specific to recreational criteria where the downstream jurisdiction has adopted more stringent criteria. Tailored narratives may include more details to guide implementation programs, such as including language on whether the state/tribe intends to protect downstream waters through utilizing mass balance or modeling approaches or describing the spatial extent to be covered by the provision.

The EPA's narrative downstream protection criteria templates[8] may be used to assist states/tribes in developing either broad and/or tailored narratives. However, it is important to note that a broad narrative criterion approach (and to a lesser extent, a tailored narrative criteria approach) does not obviate the need to interpret the narrative standard quantitatively in permits or TMDLs, as such an approach does not provide the same degree of specificity regarding specific endpoints as compared to a numeric criteria approach.

Numeric criteria approaches to downstream protection are more straightforward in terms of implementation in permits, assessment of waters, and TMDLs and will likely reduce workload on these programs. However, numeric criteria tend to be more data- and analysis-intensive to develop and would thus likely impose an additional workload on state and tribal WQS programs. Also, numeric approaches may need to be developed on a specific spatial scale (e.g., ecoregional, watershed-specific, site-specific). Additionally, the EPA recognizes that it may be resource intensive for upstream states/tribes to develop numeric criteria to ensure attainment and maintenance of all downstream WQS. As stated above, states/tribes have discretion in how to address 40 CFR 131.10(b), including the option to adopt a broad narrative downstream protection criterion, possibly in combination with one or more tailored narrative and/or numeric criteria that are specific to the unique circumstances of the pollutant and/or water body.

Where feasible, states/tribes are encouraged to adopt numeric criteria to protect downstream waters for accumulative pollutants (e.g., nutrients, bioaccumulative toxics).

Although the criteria approaches described below are not exhaustive, states may consider and use one or more of the following approaches to ensure attainment and maintenance of downstream WQS[9].

a. NARRATIVE APPROACH

- **Adoption of one or more narrative upstream criteria that are protective of downstream waters, pursuant to which assessment can be performed and control actions can be developed to ensure the attainment and maintenance of the WQS applicable to downstream waters**.
  Under this approach, one or more narrative upstream criteria can be written to reflect a quality of water that ensures the attainment and maintenance of downstream WQS. Such criteria(on) should provide a strong basis for implementation via water quality management actions (e.g., in NPDES permitting, Section 401 certification, TMDL programs, and Section 305(b)/303(d) assessment/listing programs). A broad narrative criterion may be a good option for providing basic legal coverage for downstream waters, and/or for situations where states/tribes are planning to embark on development of numeric criteria for downstream protection and need coverage in the interim. Additionally, a more tailored or customized (set of) narrative criterion(a) may be useful when site-specific or site-dependent criteria are in place, or unique water bodies or special circumstances exist downstream. Again, a narrative criterion should facilitate the establishment of effluent limitations, assessment and listing of

[8] http://water.epa.gov/scitech/swguidance/standards/narrative.cfm

[9] As a reminder, regardless of the approach(es) selected by a state/tribe, the EPA notes that to be effective for CWA purposes, criteria must be adopted pursuant to state law and approved by the EPA.

impaired waters, and development of TMDLs, and ensure consideration of the antidegradation requirements of downstream waters. Therefore, states/tribes should consider customizing their narrative downstream protection criteria so that such criteria, and any associated translators or policies, include directions on the following:

- Applicable pollutant parameters, downstream water bodies, and/or conditions (e.g., hydrological, seasonal, or ecological conditions);
- A discussion of what are (or how to identify) the applicable stream segment endpoint(s) for permit writers to use in developing permit limits, or how such endpoints are determined;
- The use of water quality modeling to derive effluent limits in permits that ensure compliance with WQS in downstream waters; and
- Accounting for other pollutant sources when determining effluent limits, e.g., by 1) utilizing watershed models that can account for multiple pollutant sources, including nonpoint sources, and/or 2) retaining assimilative capacity for other sources downstream by using a limited percentage of the receiving water body flow.

States/tribes should also ensure that any mixing zone policy is not inconsistent with such narrative criteria[10].

b. NUMERIC APPROACHES[11]

Some of these numeric approaches are good candidates to pair with a broad narrative downstream protection criterion so that far-field downstream effects can be addressed more directly where appropriate.

- **Consider whether upstream uses are protective of downstream uses, and where appropriate, revise upstream uses and/or put in place numeric criteria to provide for the attainment of downstream uses.**
  This approach would entail identifying sensitive downstream water bodies or water body types protected by more stringent or additional numeric WQS, and considering what upstream use and/or numeric criteria would provide for the attainment and maintenance of that downstream use. There may be situations where this approach to developing numeric criteria is not appropriate, e.g., where different natural aquatic habitats lend themselves to different use designations. Upstream criteria more stringent than the criteria downstream may need to be considered when the pollutants to which they apply are accumulative (e.g., nutrients, bioaccumulative toxics).

[10] The EPA notes that it reads the phrase "In designating uses of a water body and the appropriate criteria for those uses" in 40 CFR 131.10(b) to include mixing zone provisions as such provisions are considered general policies under 40 CFR 131.13 that are reviewed by the EPA for consistency with 40 CFR 131.11, the EPA's water quality standards implementing regulations for water quality criteria.

[11] The EPA notes that where numeric approaches rely on the use of models to establish a numeric downstream protection criterion, it is possible that if a TMDL is ultimately developed for such a water body using different or more complex modeling, there may be a need to reconcile or revisit the numeric downstream protection criterion for that water body based on the updated modeling to ensure that it remains consistent with 40 CFR 131.10(b).

- **Establish downstream protection values at strategic locations (e.g., according to prioritization considerations under Question 2) using water quality modeling applications.**
  Watershed and water quality modeling can be used to determine numeric criteria that the EPA refers to as downstream protection values, or DPVs. DPVs are numeric water quality criteria (with magnitude, duration, and frequency), developed in tandem with upstream criteria and designated uses, which are derived to ensure attainment and maintenance of downstream WQS. States/tribes may choose to establish DPVs at strategic locations, such as the mouths of specific tributaries to estuaries, lakes or rivers, or other locations where numeric water quality criteria may be key to efficiently protecting downstream water quality through effective management decisions upstream (e.g., derivation of effluent limitations, via modeling, to prevent exceedance of the DPV).

  An example of this approach can be found in the DPVs for nutrients that the EPA developed for Florida streams that protect downstream lakes from the associated effects resulting from eutrophication[12]**.** The pour point to a more sensitive downstream water body is a natural choice for a location at which to measure water quality, and all contributions from the stream network above this point in a watershed may affect the water quality at the pour point. DPVs may also be established in upstream locations to represent sub-allocations of the total allowable loading or concentration. Such sub-allocations may be useful where there are differences in hydrological conditions and/or pollutant sources in different parts of the watershed.

- **Use water quality modeling approaches to determine what upstream criteria ensure the attainment and maintenance of the WQS in downstream waters.**
  Numeric water quality criteria that are protective of downstream waters can foster clear and effective cross-program and cross-jurisdictional communication, consistency, and efficiencies. When developing upstream criteria that are protective of more sensitive or at-risk downstream waters, this option would entail first identifying one or more of the following:
    - Downstream water bodies subject to more stringent or additional WQS;
    - Downstream water bodies in which specific pollutants will accumulate or transform; and
    - The relevant standard(s) of those waters in a downstream state, tribe, or territory.

  Once downstream water bodies are identified, watershed and/or water quality modeling (using modeling applications such as WASP[13], AQUATOX[14], BASINS[15] and BATHTUB[16]) can be performed to determine upstream criteria that will provide for the attainment and maintenance of the downstream WQS. When determining whether and how to model the

[12] U.S. EPA 2010, EPA-HQ-OW-2009_0596; FRL-9228-7, Signed Nov. 14, 2010; and 40 CFR 131.43(c)(2)(ii)
[13] http://www.epa.gov/athens/wwqtsc/html/wasp.html
[14] http://water.epa.gov/scitech/datait/models/aquatox/index.cfm
[15] http://water.epa.gov/scitech/datait/models/basins/index.cfm
[16] Walker, W. W. Jr., 1996, Simplified Procedures for Eutrophication Assessment and Prediction: User Manual," Vicksburg, MS: U.S. Army Corps of Engineer Waterways Experiment Station, Instructional Report W-96-2 (updated April 1999).

downstream levels and effects of a pollutant, some technical considerations include: the type of pollutant, chemical/physical/biological effects of the pollutant, fate and transport/in-stream processes, seasonality, sources of dilution, and synergistic or cumulative effects with other sources/tributaries.

If use of a water quality modeling application is infeasible, it can be useful to develop a simple mass balance model by mapping the streams within the watershed being considered. To help determine what upstream criteria will be protective of downstream standards, consider using field data (or data from national databases such as the EPA's Water Quality Portal[17] and NPDAT[18]) or estimates (e.g., from NHDPlus Version 2[19], Manning equation, other applicable equations, etc.) of flow volume and velocities, monitoring data on pollutant concentrations, and available information on fate and transport characteristics (e.g., decay factors or attenuation coefficients).

- **Use other approaches to develop numeric criteria that are protective of downstream uses, where data or resources are insufficient to support water quality modeling.** If sufficient data or resources are not available, approaches that do not require water quality modeling can be used to develop criteria that are protective of downstream uses. These approaches are:
    - Use the criterion of the downstream water body as the criterion applicable at the pour point of the upstream tributary into the downstream water body.
    - Use regression or other statistical methods to relate downstream pollutant concentrations to upstream pollutant concentrations and determine the upstream concentration protective of the downstream WQS.
    - Derive a reference condition-based criterion by using stream loads or concentrations that are spatially linked to and temporally coincident with the downstream water body during periods when that downstream water body is attaining its designated use or water quality goal (e.g., existing water quality).

  An example of the third approach can be found in the Delaware River Basin Commission's (DRBC's) Special Protection Waters Program. In that program, to prevent degradation of existing water quality in the Delaware River Basin, DRBC characterized the existing water quality at 'control points' on select tributaries near their pour points to the Delaware River (called Boundary Control Points, or BCPs) and on the Delaware River itself (Interstate Control Points, or ICPs)[20]. The BCPs represent water quality from tributary watersheds and the ICPs integrate information on the water quality of their cumulative upstream tributary drainage. This design facilitates the calculation of permit limits, via modeling, that protect receiving water quality as well as the quality of downstream sections of the Delaware River. Segmentation of the Delaware River basin into manageable, site-specific control points also aids the design of monitoring plans to evaluate the effectiveness of controls.

[17] http://www.waterqualitydata.us/

[18] http://www2.epa.gov/nutrient-policy-data/nitrogen-and-phosphorus-pollution-data-access-tool

[19] http://www.horizon-systems.com/nhdplus/NHDPlusV2_home.php

[20] http://www.state.nj.us/drbc/library/documents/LDeligibilitySPWfinal-rpt.pdf

4. What other flexibilities, tools, and approaches are available for states/tribes to consider?

- **When protection of downstream WQS results in more stringent upstream criteria values, variances can be one mechanism for attaining protective criteria over time.** The federal WQS regulation at 40 CFR 131.13 authorizes states, at their discretion, to "include in their [s]tate standards, policies generally affecting their application and implementation, such as mixing zones, low flows and *variances*. Such policies are subject to EPA review and approval." (emphasis added). The EPA describes a variance as a time-limited change to designated use and criteria that targets a specific pollutant(s), source(s), and water body(ies) and/or water body segment(s)[21]. Variances are different from revisions to designated uses in that variances are time-limited and intended to provide time for states, dischargers, and/or other stakeholders to implement adaptive management approaches to improve water quality and ultimately attain the designated use[22].

  As discussed in the response to Question 2, 40 CFR 131.10(b) does not require a state/tribe to retain a use in an upstream segment that has been demonstrated through a use attainability analysis to be unattainable, solely to satisfy the requirement of 40 CFR 131.10(b). Where an upstream use is demonstrated to be unattainable because the water quality necessary to support the use cannot be achieved, then the attainable water quality and consequently the attainable use in the downstream segment may also be limited by the attainable water quality in the upstream segment, taking into consideration mitigating factors such as flow, dilution, and pollutant degradation. Where an upstream use is shown to be unattainable due to physical conditions, an attainable use may be established instead, but numeric or narrative criteria should also be established that provide for the attainment and maintenance of the (potentially more stringent) water quality standards assigned to downstream waters.

  By design, a variance reflects the highest attainable uses and associated criteria[23]. The EPA recognizes that the water quality associated with the highest attainable use and criteria may still cause or contribute to an impact downstream during the time period of the variance. However, since a variance establishes a timing mechanism to ensure feasible progress is made to improve water quality towards meeting the underlying designated use and criteria, a variance is expected to only result in improving water quality over time and lessening any adverse impact to downstream water quality standards.

- **Use existing TMDLs on downstream waters to help determine what pollutant concentrations in upstream waters are expected to provide for the attainment and maintenance of downstream WQS.**

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[21] For additional information on WQS variances, also see *Discharger-Specific Variances on a Broader Scale: Developing Credible Rationales for Variances that Apply to Multiple Dischargers* (March 2013, EPA-820-F-13-012, http://water.epa.gov/scitech/swguidance/standards/library/) and the EPA's *Water Quality Standards Handbook* at http://www.epa.gov/wqshandbook as well as the background discussion on variances in the Water Quality Standards Regulatory Clarifications Proposed Rule (78 FR 54518, September 4, 2013) at http://www.gpo.gov/fdsys/pkg/FR-2013-09-04/pdf/2013-21140.pdf (see pp. 54531-54536).

[22] 78 FR 54531 (September 4, 2013).

[23] 78 FR 54533 (September 4, 2013).

Ideally, downstream protection should be addressed in WQS prior to a TMDL being developed. However, if an established TMDL has already identified the pollutant loading rates not to be exceeded in a particular upstream water body segment or tributary in order for a downstream water body to attain WQS, this can provide useful information when considering what uses and criteria in upstream waters will provide for the attainment and maintenance of the WQS of downstream waters. States/tribes may also develop a TMDL-like analysis for an unimpaired segment. Such analyses are not subject to EPA approval or disapproval[24].

- **For current WQS, it may be useful to analyze trends in water quality in order to identify situations where adjustments to uses and/or criteria of upstream waters may be necessary to prevent future impairment of downstream water bodies exhibiting adverse trends in pollutant concentrations or hydrologic flows.**
  If water quality in downstream waters is trending over time towards a level of pollutants (or hydrologic flows) that may lead to exceedance of the applicable pollutant criteria in the future, this information can be used to preemptively identify pollutant sources (or sources of changes in hydrologic flows) and determine if one or more upstream criteria needs to be made more stringent to prevent impairment of the downstream water body(ies).

- **Consider stream order as a basis for protecting downstream WQS.**
  Protecting and restoring headwaters and lower order streams can help maintain and/or improve downstream water quality. Water quality managers may want to consider stream order as one factor in prioritizing their resources and deciding where and when to focus their efforts.

[24] Clean Water Act section 303(d)(3) provides "For the specific purpose of developing information, each State shall identify all waters within its boundaries which it has not identified under paragraph 1(A) and 1(B) of this subsection and estimate for such waters the total maximum daily load with seasonal variations and margins of safety, for those pollutants which the Administrator identifies under section [304(a)(2)] as suitable for such calculation and for thermal discharges, at a level that would assure protection and propagation of a balanced indigenous population of fish, shellfish, and wildlife."

Confederated Tribes and Bands
of the Yakama Nation

Established by the
Treaty of June 9, 1855

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OFFICE OF DIRECTOR

October 3, 2012

Ted Sturdevant
Director
Washington State Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

Dear Mr. Sturdevant,

Thank you for your invitation to the Delegates Table of the Policy Forum on Washington State's Water Quality Standards rulemaking. However, we are disappointed to see Ecology's change in direction on updating the fish consumption rate to wait for a new administration to fix this issue. Yakama Nation will not be participating in the delegates forum for such an important issue. We expect our concerns to be heard and considered at a much higher level than a "Delegates Table".

In the Treaty of 1855 Yakama Nation reserved the right to clean water and healthy fish. Recognizing federal and state governments were ignoring human health risk to tribal members from pollution in the Columbia River Basin we began work to address this issue. In 1991 collaboration with EPA and CRITFC we planned and participated in a fish consumption survey of the Umatilla, Nez Perce, Yakama, and Warm Springs tribes of the Columbia River. In 1994 the results of our study showed that our people eat significantly more fish than Washington's Fish Consumption Rate, putting tribal people at risk. Yet in 2012, eighteen years after publishing the results of our study, Ecology is still putting off correcting the undue risk to our people and resources.

The Yakama Nation wants an outcome, not just a number. The fish consumption rate that is selected must be protective of all Yakama people, not just a percentage of them. We have voiced our concerns to the state of Washington and federal government with no result.

Yakama Nation does not plan on participating in the delegates table on water quality as we are a sovereign nation, not a stakeholder. This fish consumption rate issue is very important to Yakama Nation and we request a government to government consultation.

Please coordinate this consultation with McClure Tosch. Mr. Tosch can be reached at 509-865-5121 ext. 6413 or tosm@yakamafish-nsn.gov

Sincerely,

Harry Smiskin, Chairman
Yakama Nation Tribal Council

cc: Dennis McLerran, EPA Region 10 Administrator

03966

LUMMI INDIAN BUSINESS COUNCIL
2616 KWINA ROAD · BELLINGHAM, WASHINGTON 98226 · (360)384-1489
DEPARTMENT_____DIRECT NO._____

October 8, 2012

Mr. Ted Sturdevant, Director
Washington State Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

SUBJECT: **August 15, 2012 Invitation to Join the Key Delegates Table for the Washington State Water Quality Standards Policy Forum**

Dear Director Sturdevant:

Thank you for your August 15, 2012 letter that provided both an overview of the Department of Ecology's current efforts to improve the Washington Water Quality Standards relating to human health risk exposure, including updating the fish consumption rate, and inviting tribal participation as a member of the "Key Delegates Table" of a newly created Policy Forum. In response to your letter, I have the following comments:

1. Please include the recently completed Lummi Nation Seafood Consumption Study in the Ecology report that documents the most relevant fish consumption rate studies in Washington. Craig McCormack of your staff provided helpful comments following his quick review of a draft version of that study. The final report, which addressed comments received from the Tribal Advisory Committee and the Technical Advisory Committee for the study as well as other comments, is available on line at: http://lnnr.lummi-nsn.gov/LummiWebsite/Website.php?PageID=211. The Tribal Advisory Committee for our study recommended that the Lummi Seafood Consumption rate be no less than the 383 grams/day average rate determined by the study.

2. I agree that it is critical that Ecology receives input from high fish-consuming communities in Washington, particularly tribal governments, as the state fulfills its promise to adopt more realistic and protective fish consumption rates during this triennial review of your water quality standards. However, the Lummi Nation's consultation policy (LIBC Resolution No. 96-156) requires that we forego participation in stakeholder groups unless specifically authorized through a tribal council resolution and participate only in one-on-one, government-to-government forums. Lummi Nation policy representatives are to seek and respond only to a

unified federal position and a unified state position. Once the Policy Forum that you are creating has informed the Washington State position and you have developed the state position, please contact me and we will engage in government-to-government consultation on this matter.

3. We understand that the state has a deliberate rule making process. However, we are concerned that the adoption of more appropriate human health criteria for the Washington State Water Quality Standards is being and will be unduly delayed. Even the most ardent detractors of the need to protect the human health of Washington residents should be able to concede that the current consumption rate used to establish the Washington Water Quality Standards (6.5 grams/day) is neither reasonable nor accurate. The unreasonableness of the current rate is illustrated in Figure 1. A more reasonable and protective rate needs to be adopted in the very near term, not after a multi-year process to find consensus among parties that are unlikely to agree.

   As you know, Oregon convened a Human Health Focus Group as part of their Fish and Shellfish Consumption Rate Project. Three of the six Human Health Focus Group members were either affiliated with the University of Washington or the Washington Department of Health. It seems that Ecology should start with the work conducted already in Oregon, make appropriate adjustments for Washington, and adopt water quality standards that reflect a revised and more protective consumption rate.

I understand that there may be politically difficult decisions to be made. However, I believe that the number of studies conducted to date coupled with the work already performed in Oregon provides a solid foundation for Washington to move forward in an expeditious manner to adopt appropriately protective water quality standards for all Washington citizens.

Sincerely,

Merle Jefferso

Merle Jefferson, Sr., Executive Director
Lummi Natural Resources Department

Cc Dennis McLerran, EPA Region 10 Administrator

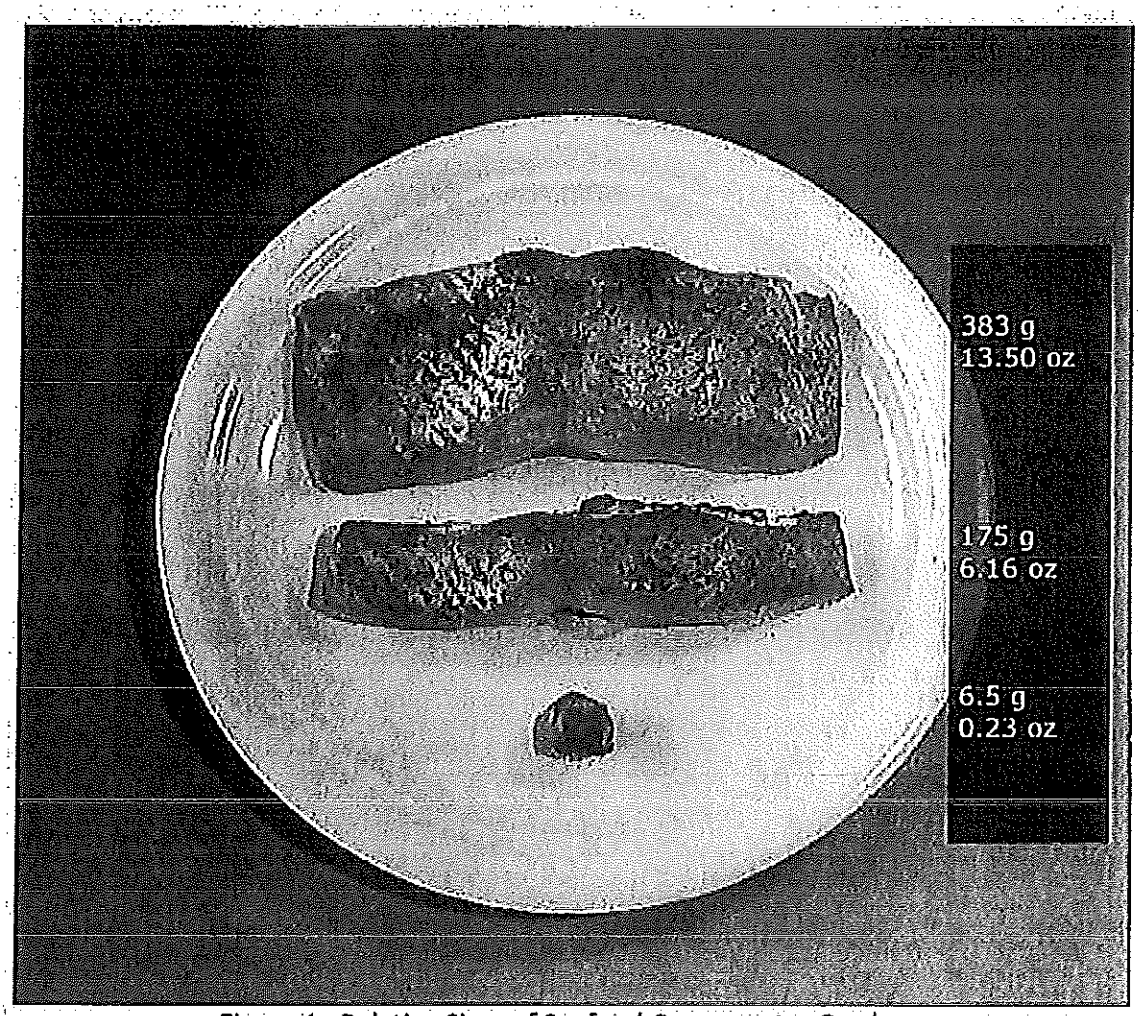

Figure 1. Relative Sizes of Seafood Consumption Portions

SQUAXIN ISLAND TRIBE

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DEPARTMENT OF ECOLOGY
OFFICE OF DIRECTOR

October 11, 2012

Ted Sturdevant, Director
Department of Ecology
POB 47611
Olympia, WA 98504-7611

Dear Director Sturdevant,

I am writing in response to your August 15, 2012 letter to Chairman Lopeman inviting a representative to sit at the Key Delegates Table for a Fish Consumption Rate Policy Forum.

The Squaxin Island Tribal Council has discussed your invitation and respectfully declines to participate. The Clean Water Act requires a fish consumption rate protective of human health and we have sufficient, solid science to move ahead without further delay. We want action, not further discussion.

Thank you for your consideration.

Sincerely,

Andy Whitener
Natural Resources Director

Natural Resources Department / S.E. 2952 Old Olympic Hwy. / Shelton, WA 98584
Fax (360) 426-3971 / Phone (360) 426-9781

03970

Kalispel Tribe of Indians
P.O. Box 39
Usk, WA 99180

(509) 445-1147
(509) 445-1705 *fax*
www.kalispeltribe.com

October 24, 2012

Ted Sturdevant, Director
Washington State Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: August 15, 2012 Invitation to Join the Key Delegates Table

Dear Mr. Sturdevant:

The Kalispel Tribe of Indians respectfully declines your invitation to join the Key Delegates Table for the Washington State Water Quality Standards Policy Forum. As a sovereign nation, we will not participate in a forum that treats the Tribe as a mere stakeholder and does not afford proper respect to the Tribe's sovereign input. We also do not support a political process that condones further delay in adopting water quality standards that protect Kalispel and other people who eat significant amounts of fish.

As you engage in yet another round of dialogue with the regulated community, please be mindful of the practical consequences of the Department of Ecology's inaction. Ecology's current fish consumption rate ("FCR") of 6.5 g/day has never been protective of people who eat large amounts of fish. For some of these fish consumers, the elevated health risk that they have faced for years has turned or will turn into cancers and other actual health problems. While it is unfortunate that 1 in a million people from the general population will develop cancer due to the amount of fish that he or she eats, it is unconscionable when government knowingly subjects Indians and other highly exposed sub-populations to a much higher cancer risk. Ecology has known for almost two decades that its current FCR is underprotective, and further delay is unacceptable. Even as I write these words, Ecology is in the process of reissuing an NPDES permit to a discharger directly upstream of Kalispel waters based on an FCR of 6.5 g/day. Existing regional fish consumption surveys provide Ecology with ample data to support a more protective FCR. Ecology need only develop the political willpower to protect the citizens of Washington.

The Kalispel Tribe is in the process of exerting its sovereignty to protect all tribal members from elevated health risks due to their fish consumption within Kalispel waters and anticipates submitting revised water quality standards to EPA by year's end. The Tribe would welcome the opportunity to share its expertise with Ecology, but only in a forum that respects the Tribe's sovereignty and affords the requisite sense of urgency to adopting a more protective fish consumption rate.

Sincerely,

Glen Nenema

Glen Nenema, Chairman
Kalispel Tribe of Indians

PORT GAMBLE S'KLALLAM TRIBE
31912 Little Boston Rd. NE – Kingston, WA 98346

October 12, 2012

Ted Sturdevant
Director
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Dear Director Sturdevant,

Thank you for your August 15th, 2012, letter and invitation regarding the process for setting more appropriate fish consumption rates (FCR) for Washington's Water Quality Standards. We understand that this process includes convening a Policy Forum to inform rulemaking work for improving Water Quality Standards and that the Key Delegates Table of the Fish Consumption Rate Policy Forum will be considered the core of the Policy Forum.

While I appreciate the invitation for our participation in the Policy Forum via the Key Delegates Table, we are going to respectfully decline our involvement with this group. This is due primarily to our concerns about where this Policy Forum is likely to go and how long it may take for anything to come out of it. The fact is that we, and most other Puget Sound Tribes, are unhappy with the delay in this FCR process, and think Ecology should use the clear and available science in your existing consumption rate report to move forward immediately. So we are hereby requesting a government-to-government consultation and appreciate that you included that invitation as well. We will follow up with Tom Laurie on setting up this G2G consultation meeting.

As you may know, Paul McCollum, our Natural Resources Director, is a member of EPA's Region 10 Tribal Operations Committee (RTOC) representing western Washington Tribes and we have worked closely with other Washington Tribes in recent discussions with Dennis McLaren about this FCR issue. Rory O'Rourke, our Environmental Scientist, has also written an article on the matter, which you may have seen. We are fully engaged in this issue at so many levels.

We are very supportive of the recent Affiliated Tribes of Northwest Indians (ATNI) resolution #12 – 54 which advises EPA to immediately establish a revised minimum rate of no less than 175 grams per day. We will work hard in collaboration with the RTOC and NWIFC and EPA Region 10 to encourage EPA to quickly adopt this new minimum rate. This will then be very useful such that EPA will be able to force this minimum consumption rate for states such as Washington that have unjustifiably low rates, to use EPA's new rate until they can get their rate revisions done for their respective Water Quality Standards.

It is unfortunate that Ecology used the SMS approach for the initial FCR process rather than directly with the WQS, but we appreciate that you are now moving forward with both the SMS and SWQS. We are happy to note that in both your letter of August 15th and your

Phone: (360) 297-2646 Toll Free: (800) 831-9921 Fax: (360) 297-7097

PORT GAMBLE S'KLALLAM TRIBE
31912 Little Boston Rd. NE – Kingston, WA 98346

letter of September 25th, 2012 to Dennis McLerran in response to his letter of September 6th, 2012 that you are accelerating the process and timelines for this important fish consumption rate revision.

The science is in hand already for Ecology to implement these critical FCR revisions for the Water Quality Standards. So rather than go into a long formal stakeholder process that could easily get politicized and have too many involved that are against a FCR revision whatsoever, we would like to see things happen on a much quicker time scale.

It is our recommendation that Ecology immediately implements the fish consumption rate of 212 grams per day, which is the median of the Preliminary Recommendation of 157 to 267 g/day in Ecology's "Fish Consumption Rates Technical Support Document, A Review of Data and Information About Fish Consumption in Washington" Version 1.0 dated September 2011 (Publication no. 11-09-050). The science is solid enough to support this range that was derived after collaboration between Ecology staff, meetings with Tribes, and the use of Tribal consumption studies. Therefore, the median of the range seems like the best approach to get this FCR revised immediately, and then work on a review and update in three to five years.

We are disappointed the version 2.0 of this document was changed so drastically and does not even have a recommended range.

We look forward to a government-to-government meeting and consultation and hope to get an update and provide some more detailed input at that time.

Sincerely,

Jeromy Sullivan, Chairman

Cc
Dennis McLerran, EPA Region 10 Administrator
Kelly Susewind, Ecology Water Quality Program Manager
Melissa Gildersleeve, Manager, Watersheds Management Section
Tom Laurie, Ecology Executive Advisor for Tribal & Environmental Affairs

Phone: (360) 297-2646 Toll Free: (800) 831-9921 Fax: (360) 297-7097

Spokane Tribe of Indians

P.O. Box 100 •Wellpinit, WA 99040 • (509) 458-6500

October 15, 2012

Ted Sturdevant
Director
Washington State Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: Water Quality Standards Policy Forum Invitation

Dear Mr. Sturdevant:

Thank you for your August 15, 2012 letter inviting me or my designee to participate in a Policy Forum being organized by the State of Washington that will address the State's water quality standard revisions. Your letter described a Policy Forum that includes many types of "stakeholders" that have an interest in the State's water quality standards. As a sovereign regulator, the Tribe will not participate in Policy Forum that includes multiple non-sovereign entities and "stakeholders." The Tribe fully expects Ecology to discuss these important changes on a government-to-government level.

Additionally, the Policy Forum appears to be designed to address Ecology's complete change of course from adopting an appropriate and legal fish consumption rate (FCR) as part of its water quality standard changes in the near term to a delayed path of further regulatory uncertainty. This regulatory uncertainty will cause further degradation of the Tribe's waters. Simply put, the Tribe is not a "stakeholder," it is a sovereign regulator and has no interest in discussing these matters in an forum that appears to be designed to perpetuate Ecology's further delay on this important topic as discussed below.

The health and well-being of the waters that flow through the Spokane Tribe's reservation are a paramount interest of the Tribe. The Tribe is concerned not only with the health of the portion of the rivers and creeks within its Reservation, but also with the entirety of these waters as they flow through the Tribe's ancestral lands. The Reservation's southern boundary is set to the south bank of the Spokane River, the Western Boundary is set by the West Bank of the Columbia River and the Eastern Boundary is set to the East Bank of Tshimikain Creek, the borders were set in this manner to protect the Tribe's subsistence and cultural uses of these waters, and the Tribe will do whatever is necessary to protect its fundamental rights in these waters.

For many decades the Tribe's subsistence use of its rivers and creeks have been thwarted by upstream pollution, raised water temperatures, and during certain times of the year portions of its waters are uninhabitable for aquatic life due to depressed oxygen levels and high levels of total dissolved gas ("TDG"). Additionally, PCBs and other toxins make fish consumption potentially dangerous to human health and negatively affect the Tribe's use of its resources. In response to this infringement on the Tribe's fishing, cultural, and agricultural rights in its water bodies, the Tribe applied for and received treatment in the same manner as a state status ("TAS") under the Clean Water Act ("CWA"), 33 U.S.C. § 1377, on July 23, 2002. The Tribe's first water quality standards were approved on April 22, 2003. These first standards included a FCR of 86.3 grams per day, and recently, the Tribe updated its standards to include a more protective FCR which is currently pending EPA review. This new standard recognizes the Tribe's historical and rightful FCR which it is entitled to within its waters. Additionally, this higher FCR will help prepare the Tribe's waters for the return of anadromous fish when passage is achieved at Grand Coulee Dam.

Unfortunately, projects to improve water quality and control water pollution within the Reservation have not been successful in bringing the Tribe's waters back to health due to upstream pollution and hydropower facilities. The Tribe's current approved FCR of 86.3 grams per day is significantly above Washington's 6.5 grams per day and this difference is causing significant trouble in the Tribe's attainment of its WQS. Currently, the Tribe's waters are affected by multiple upstream point sources and stormwater pollution that operate under permits written pursuant to Washington's current FCR. This is done even though EPA regulations require that the permits be written in a manner that ensures downstream standards are met. Unfortunately, these regulations are ignored by Ecology and EPA which indicates to the Tribe that short of litigation what is really needed is for Ecology to quickly adopt an appropriate FCR that protects downstream water quality standards of Tribes and the State of Oregon.

In conclusion, there are multiple valid fish consumption studies for the waters of the State, and federal regulations that require the State to adopt standards that do not degrade downstream waters. Accordingly, the State should stop delaying and adopt a legal FCR as soon as possible. Should you have any questions or wish to arrange a government-to-government meeting, please contact B.J. Kieffer, Director of the Spokane Tribe Natural Resources Department at 509-626-4427.

Sincerely,

for Rudy Peone
Chairman
Spokane Tribal Business Council

Cc: Dennis McLerran, EPA Region 10 Administrator

PHONE (360) 598-3311
Fax (360) 598-6295
http://www.suquamish.nsn.us

THE SUQUAMISH TRIBE

PO Box 498 Suquamish, WA 98392-0498

October 19, 2012

Ted Sturdevant, Director
Washington Department of Ecology
PO Box 47600
Olympia, WA 98504

RE: Response to Delegates Table Invitation – Fish Consumption Rates

Dear Mr. Sturdevant:

The Suquamish Tribe ("Tribe") received your letter, dated August 15, 2012, describing Ecology's revised approach to the adoption of fish consumption rates ("FCR") in state standards for water quality and toxic cleanup, and offering an invitation to participate in a "Key Delegates Table at a Policy Forum." The Tribe remains committed to supporting the development of environmental standards that incorporate fish consumption rates that are protective of tribal people. Ecology's new strategy, however, delays the adoption of a more accurate fish consumption rate and leaves the resolution of this essential step to an undefined stakeholder process and schedule, without the support or the commitment of future State of Washington administrations. More importantly, it fails to address a cohesive process to reduce the risks to tribal members and treaty trust resources associated with current water quality and toxic cleanup standards.

The Department of Ecology has known for years that the current fish consumption rates do not protect Washington residents—and that tribal communities are at particular risk of toxic exposure because of their traditionally high consumption rates. Numerous studies and surveys, including the August 2000 *Fish Consumption Survey of the Suquamish Indian Tribe Of The Port Madison Indian Reservation, Puget Sound Region*, demonstrate that the current consumption rate used to establish Washington Water Quality Standards (6.5 grams/day) is neither accurate nor protective. While the tribes, EPA and Ecology recognize the validity of this information, little substantive progress has been made to address the inadequacies of the current consumption rate and regulatory standards that are intended to be protective of human health. Indeed, the same tribal health issues related to fish consumption were raised a decade ago during the 2002-2003 review of state water quality standards.

To move forward on these issues, tribes have continued to work with the Department of Ecology over the last several years, and were repeatedly assured by Ecology that at a minimum Ecology would move to revise FCRs in guidance and incorporate the revised FCRs in the sediment management standards before the completion of the current state administration's term. In July 2012, and presumably under political pressure from industry, Ecology abruptly reversed its course and decided not to revise the FCR to incorporate a more protective rate into state standards, without consultation with the tribes or

other stakeholders.

Ecology's about face strategy undermines the significant effort and resources that many tribal governments have devoted to working with Ecology for the purpose of documenting the technical basis for revising the fish consumption rate and to develop health protective sediment and water quality standards for the state. Ecology's recent actions do not meet the intent of government-to-government consultation to provide for meaningful participation in the decision-making process. For these reasons, the Suquamish Tribe will not be participating as a stakeholder in the delegates table policy forum.

The Tribe, however, intends to continue to engage with Ecology on a government-to-government level, as the appropriate forum to discuss key issues, as long as tangible progress toward adopting protective standards is being made. The Tribe urges Ecology to proceed, without additional delay, to finalize the technical guidance document recommending a range of protective consumption rates; amend the sediment standards to include a consumption rate at or above the rate (175 grams/day) recently adopted by Oregon and approved by EPA; and adopt human health-based criteria including a revised consumption rate in the state water quality standards.

We look forward to making measurable progress on this issue with the intent to protect the health of tribal and non-tribal people as well as the environment without further bureaucratic delay. If you have any questions, please contact me at (360) 394-8461 at your convenience.

Sincerely,

Leonard Forsman, Chairman
Suquamish Tribe

Phone (360) 466-3163
Fax (360) 466-5309

Swinomish Indian Tribal Community

A Federally Recognized Indian Tribe Organized Pursuant to 25 U.S.C. § 476
11404 Moorage Way
LaConner, Washington 98257-0817

October 29, 2012

Ted Sturdevant, Director
Washington State Department of Ecology
P.O. Box 47600
Olympia, Washington 98504-7600

Re: Invitation to Join the Key Delegates' Table for the Washington State Water
Quality Standards Policy and Technical Forums

Dear Director Sturdevant,

I am writing today to provide additional clarity from the Swinomish Indian Tribal Community ("Swinomish") regarding the State process for revising water quality standards for toxic pollution to protect human health in Washington State.

Swinomish has strong misgivings that the Washington State Department of Ecology ("Ecology"), as well as the Governor's Office, will take strong and effective action to promulgate more accurate (and thus protective) water quality standards and associated human health risk exposure parameters, such as the fish consumption rates, which are much needed and long overdue policy revisions. As stated by myself and many fellow leaders, the "can has been kicked down the road by this Administration," and the State's present decision has once again proven that they cannot uphold its responsibility nor its commitment to provide a healthy and safe Puget Sound. For us, this is a serious concern not only for the human health of our citizens but for the sustainability of our treaty resources and rights.

Although Ecology started out with great strides six (6) years ago to uphold its mission "to protect, preserve, and enhance Washington's environment" as well as Chapter 173-201A WAC: Water Quality Standards for Surface Waters of the State of Washington. The stated purpose of which is to "establish water quality standards for surface waters of the state of Washington consistent with public health and public enjoyment of the waters and the propagation and protection of fish, shellfish, and wildlife…,". Since then, however, we've witnessed that both of the Governor's Ecology Directors, Jay Manning and yourself, have failed on the commitment to update a fish consumption rate and adopt water quality standards that are truly protective of human health.

With these concerns in mind, Swinomish ardently declines Ecology's invitation to participate in both the technical and policy forums. As a federally recognized Native American tribe, we will continue to work with our federal trustee, the United States Environmental Protection Agency ("EPA"), to establish a government-to-government consultation and process for any continued discussions regarding the rule-making revisions.

Under the Centennial Accord, we will strive; to establish a government-to-government relationship with the newly elected Governor's Office and a newly appointed Director of Ecology, to create a new pathway based on the current sound science, and to attempt to advance a fish consumption rate as part of the sediment management standards and water quality standards. The reality is that the Department of Ecology's current planis woefully inadequate to accomplish what the Tribes are seeking unless the Governor adopts an accurate fish consumption rate that protects the health of the United States citizens of no less than 175 gpd, moves the Water Quality Standards into the CR 102 phase and adopts the Sediment Standards with the fish consumption rate and a health criteria.

At the end of the day, the Swinomish Indian Tribal Community will continue to invest our time in building broad support for the passage of water quality and sediment standards that will ensure that the health of not only our citizens, but all Washington State citizens, is not put in jeopardy by the almighty dollar.

Respectfully,

Brian Cladoosby

Brian Cladoosby, Chairman

cc: Dennis McLerran, EPA Region 10, Regional Administrator

From: Niemi, Cheryl (ECY)
Sent: Tuesday, October 11, 2011 10:02 AM
To: Fran Wilshusen
Subject: RE: Tribal Fish Consumption Workgroup Mtg. scheduled for this Thursday, October 13, 10AM - 12:30PM

Hi Fran,

I am not going to be able to attend this meeting but Melissa will be there. I'd looked forward to meeting Ann but guess it will happen at a later time. Hope all goes well.

Cheryl

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
P.O. Box 47600
Olympia WA 98504
360.407.6440
cheryl.niemi@ecy.wa.gov

From: Fran Wilshusen [mailto:fwilshus@nwifc.org]
Sent: Monday, October 10, 2011 12:50 PM
To: Nancy.Rapin@muckleshoot.nsn.us; naomistacy@msn.com; zwelcker@kanjikatzen.com; char.naylor@puyalluptribe.com; aosullivan@suquamish.nsn.us; larry.dunn@elwha.nsn.us; jdonatuto@swinomish.nsn.us; jkonovsky@squaxin.nsn.us; hhals@jamestowntribe.org; dtaylor@suquamish.nsn.us; tosm@yakamafish-nsn.gov; carlmerkle@ctuir.com; gstamant@muckleshoot.nsn.us; mmchugh@tulaliptribes-nsn.gov; Ann Seiter
Cc: (Group) Coordinated Tribal Water Quality Program; kmatson@nwifc.org; Chron; McCormack, Craig (ECY); Niemi, Cheryl (ECY); Gildersleeve, Melissa (ECY); Hankins, Martha (ECY); Darrell Phare; Hooper, Dawn (ECY); Todd Bolster
Subject: Tribal Fish Consumption Workgroup Mtg. scheduled for this Thursday, October 13, 10AM - 12:30PM

Hello, All:

We have a **Fish Consumption Technical Workgroup** meeting scheduled for **Thursday, October 13 from 10:00 to 12:30**. The meeting will be held at the Jamestown S'Klallam Tribal Center, Alderwood Room in Blyn. For those who want to join by phone, teleconferencing will be available, a call-in number and instructions will be forthcoming.

The purpose of the meeting is to:

1. Introduce Ann Seiter as the new coordinator for the FCR Project and review her workplan (attached).
2. Discuss our approach for reviewing the Ecology technical report, available at www.ecy.wa.gov/biblio/1109050.html
3. Review and update our Fish Consumption Workgroup distribution list.
4. Prioritize next steps.
5. Schedule next workgroup meeting

Below is the list for the Tech Work Group as it reads now:

Tribal Fish Consumption Workgroup			
Name	**Email Address**	**Organization**	**Phone Number**
Nancy Rapin	Nancy.Rapin@muckleshoot.nsn.us	Muckleshoot Tribe	(253) 876-3128
Naomi Stacy	naomistacy@msn.com		
Zach Welcker	zwelcker@kanjikatzen.com	Kanji & Katzen, PLLC	(206) 344-8100 ext 105
Char Naylor	char.naylor@puyalluptribe.com	Puyallup Tribe	(253) 841-0382
Fran Wilshusen	fwilshus@nwifc.org	Northwest Indian Fisheries Commission	(360) 438-1180
Alison O'Sullivan	aosullivan@suquamish.nsn.us	Suquamish Tribe	(360) 598-3311
Larry Dunn	larry.dunn@elwha.nsn.us	Lower Elwha Klallam Tribe	
Jamie Donatuto	jdonatuto@swinomish.nsn.us	Swinomish Tribe	
John Konovsky	jkonovsky@squaxin.nsn.us	Squaxin Island Tribe	(360) 432-3804
Hansi Hals	hhals@jamestowntribe.org	Jamestown S'Klallam Tribe	(360) 681-4631
Denise Taylor	dtaylor@suquamish.nsn.us	Suquamish Tribe	

Please call me with any questions or suggestions you may have for our upcoming meeting.

Thank you.

Fran Wilshusen Schroeder
(360)790-2440

From:	Ann seiter <aseiter@nwifc.org>
Sent:	Wednesday, November 16, 2011 1:35 PM
To:	(Group) Tribal Fish Consumption Workgroup
Cc:	gstamant@muckleshoot.nsn.us; Mike McHugh; Oliver Grah; Tom Gibbons; tosm@yakamafish-nsn.gov; Darrell Phare; Todd Bolster; Carl Merkle; BarbaraHarper@ctuir.org; Brian Crossley; McCormack, Craig (ECY); Niemi, Cheryl (ECY); kmerrill@knrd.org
Subject:	Fish Consumption Rate Tech mtg Monday
Attachments:	FCR_Tech_Grp_agenda_for_11-21-11.docx; FCRate Doc Review NWIFC Mtg Seiter (2) Review 20111121.pptx

Tribal Fish Consumption Rate Technical Work Group and
Other Interested Parties

Attached is an agenda for the meeting of the Fish Consumption Rate Technical Work Group on Monday, November 21, 2011 from 10 am to 12:30 pm. The meeting will be an in-person meeting at the NWIFC conference center. We have video link-ups available at the North Sound Office or Forks, but not at the Point No Point Treaty Council offices.

We have also set up a call in number for the meeting at 206-553-1454 for those of you who are unable to attend but would like to listen in. We have had so much trouble with poor connections and background noise that we request those of you who will be calling in to mute your phones as much as possible. I apologize in advance if it is difficult for you to hear. I am also attaching the powerpoint presentation that Craig McCormack from the WA Department of Ecology will be using for those of you who cannot be at the meeting in person.

I will try to stick to the times in the agenda as much as i can. There is another meeting in the facility after we adjourn so we have a tight timeline. Thanks for your cooperation in this.

Several key members of the technical work group have already confirmed that they will attend in person. No one has indicated an interest in going to the video link sites so I have cancelled the one at Point No Point so far. If you will be using a video site, please let me know as soon as possible. Thanks.

I look forward to meeting with you on Monday.

Ann

--
Ann Seiter
aseiter@nwifc.org
Coordinator: Fish Consumption Rate Project
PO Box 2201; Sequim, WA 98382
FCR Project Office/Voice Mail: 360-681-4613
Home Office: 360-683-5725

From: Laurie, Tom (ECY)
Sent: Tuesday, January 03, 2012 3:03 PM
To: Hankins, Martha (ECY); Bradley, Dave (ECY); Gildersleeve, Melissa (ECY); Niemi, Cheryl (ECY)
Subject: FW: FCR meeting January 25th

FYI

- Tom
Tribal & Env. Affairs
360/407-7017 (desk)
360/790-4110 (cell)

From: Ann seiter [mailto:aseiter@nwifc.org]
Sent: Tuesday, January 03, 2012 2:35 PM
To: North, Teri (ECY)
Cc: Laurie, Tom (ECY)
Subject: FCR meeting January 25th

Hi Teri,
Hope you had some happy holidays. I wanted to give you an update on the proposed attendees for the meeting about Fish Consumption Rates with Ted on January 25th at 1:30. We are expecting the following people at this point:

NWIFC: Dave Herrera (Skokomish), Terry Williams (Tulalip), Andy Whitener and John Konovsky (Squaxin Island), and Shawn Yanity (Stillaguamish). Shawn is stepping in for Russ Hepfer from Lower Elwha, who cannot make it.
EPA: Jim Woods and Mike Bussell
Also in attendance will be myself and Fran Wilshusen.

I will send an agenda and the NWIFC comments to Ecology on this issue when they are ready, but this may not occur until after the next NWIFC meeting on January 18th. Please let me know if you have any questions.

Ann

--
Ann Seiter
aseiter@nwifc.org
Coordinator: Fish Consumption Rate Project
PO Box 2201; Sequim, WA 98382
FCR Project Office/Voice Mail: 360-681-4613
Home Office: 360-683-5725

From: Ann seiter <aseiter@nwifc.org>
Sent: Wednesday, February 08, 2012 10:24 AM
To: (Group) Tribal Fish Consumption Workgroup; (Group) Coordinated Tribal Water Quality Program
Cc: (Group) Fish Consumption
Subject: Reminder and powerpoint for tomorrow Feb 9 meeting
Attachments: Feb 9 2012 - Tribes - Context of meeting .pptx; Feb. 9 2012 - Tribes - WQS Implementation Tools .pptx; FCR_CTWQP_drft_agenda_Feb_9.docx

Categories: Red Category

Tribal Fish Consumption Work Group
Coordinated Tribal Water Quality Program

This is a reminder that we will be meeting tomorrow to discuss potential changes to state water quality standards at the NWIFC from 10 am to 3 pm. Lunch will be provided. Please RSVP if you haven't already. Thanks.

Attached is the agenda I sent earlier, along with the powerpoint presentations that Cheryl Niemi from the WA Department of Ecology will be using.

Hope to see you tomorrow in person or via video link.

Ann

--
Ann Seiter
aseiter@nwifc.org
Coordinator: Fish Consumption Rate Project
PO Box 2201; Sequim, WA 98382
FCR Project Office/Voice Mail: 360-681-4613
Home Office: 360-683-5725

From: Gildersleeve, Melissa (ECY)
Sent: Tuesday, February 21, 2012 12:22 PM
To: North, Teri (ECY); Baldi, Josh (ECY); Laurie, Tom (ECY); Niemi, Cheryl (ECY)
Cc: Susewind, Kelly (ECY); Sturdevant, Ted (ECY)
Subject: RE: FCR meeting February 23rd
Attachments: RE: things that should happen soon

Ted needs to be briefed before this meeting with tribes on Thursday. We have spent a lot of time with them over the last couple of weeks and I want to be sure he is ready on Thursday for what he will hear.

..this ties back to the stuff I sent last week attached about getting him briefed on implementation rule and what we are telling stakeholders.

From: North, Teri (ECY)
Sent: Tuesday, February 21, 2012 11:51 AM
To: Gildersleeve, Melissa (ECY); Baldi, Josh (ECY)
Subject: FW: FCR meeting February 23rd

Here's the agenda for Thursday's meeting. Also, I found out last week that Dennis McLerran will be attending in person.

Teri North, Assistant to the Director
Department of Ecology
(360) 407-7009
teno461@ecy.wa.gov

From: North, Teri (ECY)
Sent: Thursday, February 16, 2012 8:04 AM
To: Laurie, Tom (ECY)
Subject: FW: FCR meeting February 23rd

FYI

Teri North, Assistant to the Director
Department of Ecology
(360) 407-7009
teno461@ecy.wa.gov

From: Ann seiter [mailto:aseiter@nwifc.org]
Sent: Wednesday, February 15, 2012 11:03 PM
To: North, Teri (ECY)
Cc: Fran Wilshusen
Subject: FCR meeting February 23rd

Hi Teri,
We are still planning on meeting with Ted on the 23rd and representatives are anxious to do so. Fran and I have been working on a draft agenda and calling around for confirmations. We will be going over the agenda at

the NWIFC Environmental Policy Committee meeting on Tuesday, so it isn't quite ready yet, but here is the general framework:

- Review the purpose of the Leadership Group
- Update on current activities related to the FCR--technical support document, input from stakeholders.
- Tribal perspectives on the comments received on the document, messaging, additional technical work and timelines for preparation of responses.
- Review the status and timelines for the rule making processes: SMS and WQS
- Next steps

We expect about 4 policy representatives, and 4 staff from NWIFC or tribes (including Fran and I). We may not have a better headcount until Tuesday's preparatory meeting. Additionally there may be representatives from EPA and tribal policy representatives may want to bring staff. If there will be several Ecology staff present, then the room may be tight.

Let me know if you have additional questions.

Ann
--

Ann Seiter
aseiter@nwifc.org
Coordinator: Fish Consumption Rate Project
PO Box 2201; Sequim, WA 98382
FCR Project Office/Voice Mail: 360-681-4613
Home Office: 360-683-5725